cobas® IT middleware

User Manual version 7
Software version 1.05.01

Roche

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Life needs answers

Document information

Manual version	Software version	Revision dates	Main change
1.00.00 (revision 1)	1.00.00	January 2012	First version of the manual.
1.01.00 (revision1)	1.01.00	August 2012	Software and manual updates.
1.02.00 (revision1)	1.02.00	June 2013	Software and manual updates.
Version 4	1.03.00	February 2014	Software and manual updates.
Version 5	1.04.00	July 2014	Software and manual updates.
Version 6	1.05.00	January 2015	Software and manual updates.
Version 7	1.05.01	May 2015	Software and manual updates.

Table 1 Revision history

Editor's note Every effort has been made to ensure that the information contained in this manual is accurate at the time of printing. Not all functionality described in this manual may be available to all users. Roche Diagnostics International Ltd reserves the right to make any further required changes to software without prior notice. Such changes may not immediately be reflected in this document.

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Feedback Every effort has been made to ensure that this manual fulfils its intended purpose as mentioned above. All feedback on any aspect of this manual is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Intended use

This document is intended for Roche Service representatives installing and configuring the software **cobas® IT** middleware system, version 1.05.01.

Description

The **cobas® IT** middleware is a middleware solution (MWS) for the diagnostic laboratory. Laboratories are located in hospitals or run in private ownership. The **cobas® IT** middleware can be connected to one or several of the following systems:

- Roche and non-Roche pre-analytic instruments
- Roche and non-Roche post-analytic instruments
- Roche analytical instruments (biochemistry, immunology, urine analysis, coagulation)
- Roche Live View (customer dashboard displaying operational KPIs based on data generated by **cobas® IT** middleware)
- Non-Roche analytical instruments (biochemistry, immunology, urine analysis, coagulation, hematology, and molecular and tissue diagnostics)
- Laboratory information systems
- Hospital information systems
- Electronic health record systems
- Non-Roche work area management solutions for hematology, clinical chemistry, or urine-analysis.

The **cobas® IT** middleware solution supports the exchange of data with the instruments or systems mentioned above via a uni- or bidirectional interface. Uni- and bidirectionally transmitted data contain patient information, order data, and result data. The solution manages the data in a central database.

Features and Functionalities

The **cobas® IT** middleware solution provides the following functionalities to the customers.

Connectivity management

- Connectivity to analytical instruments

  The solution is able to connect to analytical instruments provided by Roche or other manufacturers, in the following specialties: biochemistry, immunology, urine analysis, coagulation, hematology and molecular diagnostics.

  The solution is able to transfer test requests to the instruments and receive test results.

- Connectivity to pre-analytics

  The solution is able to control sample routing, sample sorting, aliquoting, and distribution on pre-analytics automation systems and connected instruments

- Connectivity to post-analytics

  The solution is able to connect to post analytics instruments and supports archiving and manual retrieval of samples.

- Connectivity to Laboratory, Hospital Information Systems and Electronic Health Record
  - The Laboratory Information System (LIS), Hospital Information System (HIS) and Electronic Health Record System (EHR) send patient and order information via standard messages. The message can result in the automatic creation of an order and the related sample registration in the solution.
  - Patient results are sent electronically to the LIS, HIS and EHR to complete the requested order. Connectivity to one or multiple LIS, HIS and EHR is possible.
  - Quality control results coming from the instruments can be forwarded to the LIS
  - Sample information about current position and workflow status can be sent to the LIS for the purpose of traceability
- Connectivity to Work area solutions

  The solution provides connectivity to other middleware solutions (e.g. hematology work area solutions or urine analysis work area solutions).
- The solution does not influence any validation of data performed by the connected systems.

  The solution is able to manage the distribution and routing of primary samples and aliquots for pre-analytical devices, connected instruments and offline workplaces.
- Workflow Management

  Connectivity to Clinical Decision Support Systems (CDSS) is provided through standard interfaces to send patient results to the CDSS and to integrate the result of the CDSS (the result can be a recommendation or a calculated risk score).

Data Management

- Sample Registration

  The solution provides functionality to create samples manually and to edit and delete existing samples. This functionality is used in particular if the LIS is momentarily not working.
- Technical Validation

  The solution provides support for the technical validation of patient results with a set of tools including: reference range checking, delta checks, serum indices, rule engine.

  The parameters of the tools are set up in advance by the customers to allow automatic release of the results to the other systems (e.g. LIS, HIS) or to trigger additional actions (e.g. rerun, reflex, repeat). Results which are not automatically released will require a manual validation.
- Result Entry

  The solution provides support to enter results obtained from offline work areas as well as send results to analytic instruments

- Quality Control

  The management of Quality Control supports the technical validation by handling QC data obtained from instruments. The solution administrates active and in-active control materials, manages Roche- and Non-Roche- control materials, enables the analysis of QC results with support of graphics and allows exporting quality control results to commercial benchmarking tools.

  Quality Control functionality enables the solution to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results and improve the quality of the results reported by the laboratory. Quality control is a measure of how well the measurement system reproduces the same result over time and under varying operating conditions. Laboratory quality control material is usually run at the beginning of each shift; after an instrument is serviced; when reagent lots are changed; after calibration; and when patient results seem inappropriate.

- Sample archiving

  After processing the sample, archiving is a structured option to retain samples for an assigned period. The duration of the archiving period is subject to customers' configuration. The **cobas® IT** middleware solution is able to support manual and automatic archiving of samples.

  The sample storage and retrieval options allow the user to locate samples at any moment, e.g. if an additional test is requested whether the sample is being processed or stored in the archive.

Information Management

- Rule Engine

  The rule engine enables the user to define algorithms supporting the technical validation.

  The rules use the results provided by the instrument(s) and order or patient related information. Rules trigger standard validation actions including rerun of test with dilution, request of additional test, comment, release.

  No pre-defined rules are loaded by default. The implementation, modification and validation of the rules are under the customer's responsibility.

- System Overview

  Notifications are shown on the screen of the solution if any action is required on samples, results, QC or instruments or if a sample is missing means order for a sample has been received in the system, but sample has not been identified in the lab yet. The notifications display a message whenever a predefined event occurs. Definition of events that shall trigger the display of a notification is under the customer's responsibility.

- Turn Around Time management

  The production monitor allows tracking the timespans between each step of the workflow which can be displayed in real-time and trigger alerts in case of delays

- Live View (Production statistics)

  Statistics generated by the **cobas® IT** middleware solution can be extracted and displayed on monitors, wallboards and mobile devices (accessible only within the intranet). The statistics is calculated on production performance data, like Late sample tracking, Turn-Around-Time, throughput, system efficiency and connectivity status.

Indication for Use

The **cobas**® **IT** middleware solution is intended for Clinical Laboratories and Blood Donation Testing Labs.

Connectivity Management

Features and Functionalities	Clinical Laboratories	Blood Donation Testing Labs
Connectivity to analytical instrument	✓	✓
Connectivity to pre-analytics	✓	✓
Connectivity to post-analytics	✓	-
Connectivity to Laboratory, Hospital Information Systems and Electronic Health Record	✓	✓
Connectivity to Work area solutions	✓	✓
The solution does not influence any validation of data performed by the connected systems	✓	✓
Workflow Management	✓	-

Table 2 Indication for use - connectivity management

Data Management

Features and Functionalities	Clinical Laboratories	Blood Donation Testing Labs
Sample Registration	✓	✓
Technical Validation	✓	✓
Result Entry	✓	-
Quality Control	✓	Pass-through QC for c6800/8800 (see chapter 3.5.1)
Sample archiving	✓	The **cobas**® **IT** middleware solution is able to support manual archiving of samples

Table 3 Indication for use - data management

Information Management

Features and Functionalities	Clinical Laboratories	Blood Donation Testing Labs
Rule Engine	✓	✓
System Overview	✓	✓
Turn Around Time management	✓	✓
Live View (Production statistics)	✓	✓

Table 4 Indication for use - information management

Contact addresses

Manufacturer

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany
Made in Switzerland

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Using this manual

Ensure the following:

- Keep this manual in a place where it will not be damaged.
- Ensure that this document is available at all times.

Conventions used in this manual

You can find detailed information on each task in this User Manual or by choosing the **Assistance** button in the global information area.

The following symbols and conventions are used in this manual.

Symbols The following symbols may be used to draw your attention to important information:

Symbol	Meaning
	Cross-reference
	Procedure start
	Procedure end
•	List item
	Tip
	Safety alert

Table 5 Information symbols

Abbreviations The following abbreviations are used:

Abbreviations	Definitions
H	
HIS	hospital information system
L	
LIS	laboratory information system
M	
MPA	MODULAR PRE- ANALYTICS
Q	
QC	quality control
S	
SD	standard deviation
STAT	short turnaround time

Table 6 Abbreviations

What is new in software version <1.05>

live view module removed The description of the live view module has been removed. This feature is now described in separate user documentation.

About closed samples New section. Description of closed samples, which can lead to failed host messages.

About closed samples (p. 79)

Ordering a repeat test New section. You order a repeat test to perform the same processing parameters on a sample.

Ordering a repeat test (p. 85)

Filtering QC Updated. New filtering criteria for QC results.

Filtering QC (p. 20)

Unlocking QC results for a test-instrument combination New section. You can define a test-instrument combination when manually releasing a QC lock.

Unlocking QC results for a test-instrument combination (p. 127)

Filtering cumulative QC statistics New section. New filtering criteria are available for filtering cumulative QC statistic.

Filtering cumulative QC statistics (p. 130)

Applying the calculated mean and SD to cumulative QC statistics across instruments New section. You can now apply the calculated mean and SD to QC statistics over multiple instruments.

Applying the calculated mean and SD to cumulative QC statistics across instruments (p. 131)

Viewing time-based rules profiles Updated. Description of terms used in the **Time-based rule** panel.

Viewing time-based rules profiles (p. 132)

Creating time-based rules profiles New section. This function allows you to assign a new time-based rules profile.

Creating time-based rules profiles (p. 132)

Editing time-based rules profiles New section. This function allows you to change an existing time-based rules profile.

Editing time-based rules profiles (p. 133)

Safety classifications

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The following safety information applies to the system and is listed in accordance with ANSI Z535.6-2011. The Danger safety classification to indicate a situation that will result in injury or death is not applicable to this system and is therefore not listed.

Safety alert symbol

- The safety alert symbol alone promotes awareness to hazards that are generic or direct the reader to safety information provided elsewhere in the document.

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 which, if not avoided, may result in damage to the system.

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

Tip

Indicates additional information on correct use or useful tips.

System safety information

Failure to observe the following safety information may result in incorrect results, data corruption, and data losses.

NOTICE

Incorrect operation or the use of wrong components

The data in the system can be incorrect or corrupt.

- Use only computers, monitors, printers, and accessories recommended by the manufacturer.

  Service your computer regularly (defragment the hard disk; install, run, and update antivirus software; check the event log for system error entries).

NOTICE

Corrupt data due to viruses

Software viruses can corrupt system data.

- Install a firewall, maintain up to date antivirus software, and keep your operating system up to date.

CAUTION

Incorrect or corrupt data due to unauthorized access

Data security is breached if unauthorized users have access to your user ID and password.

- Always enter your password unobserved.
- Do not write down your password.
- Never write down the password in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone.
- Roche will never ask you for your password.
- If you ever disclose your password to anyone, change it immediately after.
- If you think anyone else might have access to your account, then contact your local Roche affiliate.

NOTICE

The host interface does not support secure data transmission

When using host communication, your infrastructure must ensure that transported data is protected appropriately. It is your responsibility that access to the network is restricted only to authorized entities and/or the communication protocol is secured.

- This can be achieved by using system level tunneling protocols like TLS or other means of network encryption.

NOTICE

Internet Explorer

Ensure that you use the 32 bit Internet Explorer.

- 64-bit Internet Explorer is not supported.

NOTICE

Data is not encrypted

Unauthorized access to data.

- Your infrastructure must ensure that access to the data storage and backup files is permitted only to authorized entities.

NOTICE

Disaster recovery

Unexpected disasters, such as hard disk failures, system software failures or natural disasters such as fires or floods can occur.

- Your IT department must assemble a disaster recovery kit to protect your entire system.

CAUTION

Sample quality measurement is only indicative

The sample quality measurement in the condition is taken by camera. This is only indicative. It is not enough to ensure the patient results are reliable.

The decision to use sample quality measurements, and the consequences of using them, are solely the responsibility of the laboratory administrator.

- To get a reliable measurement of sample quality, use serum indices tests.

See *Defining serum indices tests* (p. 169)

Introduction

System overview

In this chapter you can find information about accessing the system, filtering options, column configuration, and the opened tasks and actions that you need to address.

In this chapter

Chapter **1**

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About cobas® IT middleware

This system is a middleware solution for central laboratories, which provides the following functionality:

- Sample entry
- Sample distribution
- Sample validation
- Sample archiving and retrieval
- QC administration
- Patient management
- Test management

The functionality available is dependent on the level of access granted to each user account.

The **cobas® IT middleware** can connect to an LIS (laboratory information system) or HIS (hospital information system), and one or several Roche pre-analytic, analytic, and Roche post-analytic instruments.

Logging into the system

You log into **cobas® IT middleware** to start using the system.

To log into the system

1 In the global information area, choose the **Log on** button.

The **Log on** dialog box is displayed.

2 Enter your user name, password, select a language, and choose the **Log on** button.

You are logged into the system.

Changing the password

You change your password when the current one expires or is no longer safe to use.

Password format

Here, you cannot enter a password that starts with a number or special characters.

For details of password security, see *Incorrect or corrupt data due to unauthorized access* (p. 13).

To change your password

1 In the global information area, choose the **Log on** button.

The **Log on** dialog box is displayed.

2 Choose the **Change password** button.

The **Log on** dialog box expands to display the **Change password** options.

3 Enter the old password, the new password twice, and then choose the **Save** button.

The new password is saved in the system.

Filtering options

There are several workplaces where you can filter the data which is displayed. You can predefine filters to help you use preferred filtering options. Depending on the panel you are in, the filtering criteria can display different selections.

You can group and sort the data that you filtered for to facilitate information search.

You can sort data in ascending or descending order by clicking the column headers.

When no date is defined in the filtering criteria, a range of ten days is used by default. Therefore samples older than ten days are not shown in the filtered list.

By default, the filters only show results that are 10 days old or less. This value is configurable. If necessary, talk to your Roche Service Representative.

Filtering samples

To filter samples

1 Choose **Routine** >**Release tests by sample**.

The **Samples: {0}**panel is displayed containing the list of samples.

2 Choose the  button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

Filtering QC

To aid in searching for specific QC results, the following options allow you to search by multiple criteria in the **Filter by** drop-down list:

- QC lot
- QC material
- Result status
- Sample type

To filter QC

1 Choose **Routine** >**Review QC results**.

The **QC results: {0}**panel is displayed containing the list of QC results.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

Filtering multi-rules

To filter multi-rules

1 Choose **Monitoring** > **Rules**.

The **Rules: {0}** panel is displayed containing list of all defined rules.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

Filtering profiles

To filter profiles

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

Filtering patients

To filter patients

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}**panel is displayed containing a list of patients.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

■

Filtering test results

To filter tests results

1 Choose **Routine** > **View test results**.

The **Tests: {0}**panel is displayed containing the list of tests.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

■

Filtering the list of racks

To filter the list of racks

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed containing a list of racks that fit the default filter criteria.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

■

Filtering the error log list

To filter the error log list

1 Choose **Administration** > **View error log files**.

The **Error log files: {0}** panel is displayed, containing a list of error that fit the default filter criteria.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

■

Filtering the list of consumption reports

To filter the list of consumption reports

1 Choose **Monitoring** > **Consumption report**.

The **Consumption report** panel is displayed containing a list of consumption reports that fit the default filter criteria.

2 Choose the  button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to filter by, and then choose the **Apply** button.

The matching data is displayed.

Filtering the late samples list

To filter the list of late samples

1 Choose **Monitoring > Late sample monitor**.

The **Late samples** list is displayed containing a list of all samples which have violated a late sample rule.

2 Choose the  button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria by which you want to filter, and then choose the **Apply** button.

The matching data is displayed.

Creating/deleting filters

You can create custom filters but you can only have one default filter which applies every time you open a panel with a filter. The ADMIN user can change the filters globally, but the Routine users can only modify their personal filters. If you delete your default filter, the ADMIN default filter applies on your next logon.

The filtering criteria are available in the following panels:

- **Samples: {0}**
- **Retrieve samples**
- **QC results: {0}**
- **View cumulative QC statistics**
- **Patients: {0}**
- **Tests: {0}**
- **Rules: {0}**
- **Profiles: {0}**
- **QC instrument assignment: {0}**
- **Test/instrument assignments: {0}**
- **Rack management: {0}**
- **Error log files: {0}**

Filtering criteria which support multi-selection filtering is available for:

Panel	Filter
Samples: {0}	**Instrument**
	Orderer
	Orderer group
Tests: {0}	**Instrument**
	Orderer
	Orderer group
	Test
QC results: {0}	**QC**
	QC lot
	Instrument
	Test
View cumulative QC statistics	**QC**
	QC lot
	Instrument
	Test
Test/instrument assignments: {0}	**Instrument**
Retrieve samples	**Test**

Table 1-1 Panels with multi-selection filtering.

To create a custom filter

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}**panel is displayed containing the list of samples.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to add to your custom filter, and then choose the **Save** button.

The **Save view as** dialog box is displayed.

4 Add a title to your custom filter, and then choose the **Save** button.

The title for the created profile is displayed in the filtering drop-down list.

To create a default filter

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}**panel is displayed containing the list of samples.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down lists, choose the criteria you want to add to your custom filter, and then choose the **Save** button.

The **Save view as** dialog box is displayed.

4 Add the title "Default" to your custom filter, and then choose the **Save** button.

The **Default** filter is displayed in the filtering drop-down list.

To delete a custom filter

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}**panel is displayed containing the list of samples.

2 Choose the button.

The filtering panel is displayed.

3 From the filtering drop-down list, choose the custom filter you want to delete, and then choose the **Delete** button.

A callout is displayed, asking you to confirm.

4 Choose the **Confirm** button.

The custom filter is deleted.

Configuring the columns

You configure the columns to choose the type of information to be displayed in the tables. You can change the order in which the columns display by choosing the  buttons in the callout.

To save the configuration of the columns, you must save it with the filter view.

To configure the columns

1. Choose **Routine** > **Create and update samples**.

   The **Samples: {0}**panel is displayed containing the list of samples.

2. Choose the  button.

   The filtering panel is displayed.

3. Choose the **Configure columns** button.

   The **Configure columns** callout is displayed.

4. From the **Available columns** field, choose the columns you want to see in the tables, and then choose the button.

   The columns display in the **Visible columns** field.

5. Choose the **Confirm** button.

   The configuration of the columns is set.

Reviewing the error log files

You mark the error log files as reviewed for general troubleshooting.

To review the error log files

1 Choose **Administration** > **View error log files**.

The **Error log files: {0}** panel is displayed, containing a list of errors that fit the default filter criteria.

To filter the error log list, see *Filtering the error log list* (p. 22)

2 Choose the error or errors you want to review.

The **Error log details** panel is displayed.

3 Choose the **Review** button.

The error is reviewed and it is no longer displayed in the error log table.

Viewing the details of an error log

You want to view the details of an error log to know the source and the type of that error.

To view the details of an error log

1 Choose **Administration** > **View error log files**.

The **Error log files: {0}** panel is displayed, containing a list of errors that fit the default filter criteria.

To filter the error log list, see *Filtering the error log list* (p. 22)

2 Choose the error or errors for which you want to view details.

The **Error log details** panel is displayed.

Task overview

In the **Overview**, you can view a list of all pending tasks, instrument connection status, and samples in each work area.

A task has three different urgency levels: normal, warning, and critical. The ranges of the levels are defined using two thresholds (one between normal and warning and another one between warning and critical). Every task has its own not editable refresh time and navigation point.

A task can have different attributes (for example, warnings and errors) and combine the results in one single task. Four different attributes can be configured:

- Activation/Deactivation of a specific task
- Threshold definition
- Display level (defines the lowest task level which must be displayed; for example, normal level means that all levels are displayed, but critical means that the task is only displayed if the critical threshold is exceeded)
- Sorting priority (defines the sorting of the task on the overview)

To configure the attributes, see *Configuring system messages for the Overview* (p. 186).

Tasks which can be handled from the **Overview**:

- **Tests pending release (ROUTINE)**
- **Tests pending release (STAT)**
- **Samples pending release (ROUTINE)**
- **Samples pending release (STAT)**
- **QC violations**
- **Masked tests**
- **Rack disposal**
- **Open samples**
- **Processing samples**
- **Samples pending release**
- **Released samples**
- **Samples in manual output**
- **QC interval info**
- **Missing samples (ROUTINE)**
- **Missing samples (STAT)**
- **Log files not seen**
- **System error**
- **Pending consumption reports**

Connection status Displays the instruments connected to the system status. Green means the instrument is connected and information flows between the two, red means the connection stopped.

Sample monitoring **Samples in my location** is a graphical display of samples and their current status. By choosing a status bar or the corresponding legend item, for example, **Processing samples**, the samples in that status are displayed.

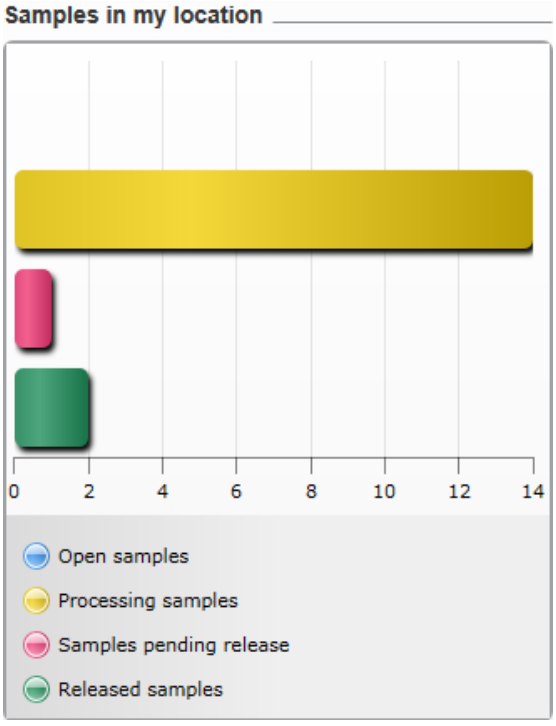

Figure 1-1 Sample monitoring graphical display

Displaying pending tasks

You want to view the list of tasks to have an overview of the pending tasks that must be addressed.

By default, the **Overview** area only shows data that are 10 days old or less. This value is configurable. If necessary, talk to your Roche Service Representative.

Configuring missing sample results

It is possible to configure which results and how many results are shown as missing samples.

It is possible to configure the tasks shown in the **Missing samples (ROUTINE)** task and the **Missing samples (STAT)** task.

To configure the Missing samples (ROUTINE) task

1. In the **Overview** area, select **Missing samples (ROUTINE)**.

   The **Samples: {0}** panel is displayed.

2. In the drop-down box, select **Missing (Routine)**.
3. Open the filter, and set the filter so that it displays the data you want in the **Overview** area for **Missing samples (ROUTINE)**.
4. Save the filter under the name "[FILTER_SLIS_SampleBasedTestValidation_MISSING_ROUTINE]", (not including the inverted commas).

5 Log out, and log back in.

In the **Overview** area, select **Missing samples (ROUTINE)**. The samples are displayed according to the filter you configured.

■

To configure the Missing samples (STAT) task

1 Configure the same as the **Missing samples (ROUTINE)** task, except select **Missing samples (STAT)**, and **Missing (STAT)**.

2 As a filter name, enter "[FILTER_SLIS_SampleBasedTestValidation_MISSING_STAT]", (not including the inverted commas.)

3 Log out, and log back in.

In the **Overview** area, select **Missing samples (STAT)**. The samples are displayed according to the filter you configured.

■

Task overview

Understanding the user interface

In this chapter you can find information about the user interface description and usage.

In this chapter *Chapter* 2

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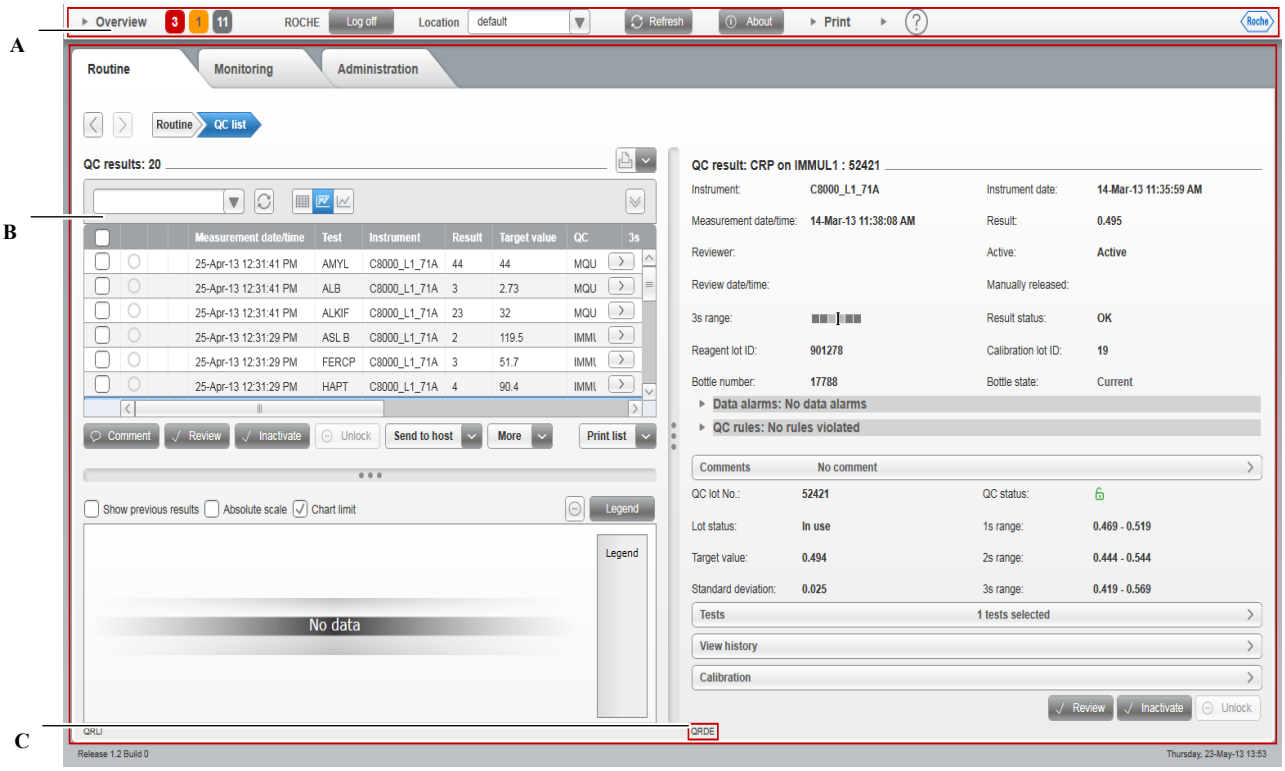
Main screen structure

The **cobas IT** middleware screen has the following main structure:

- Screen
  - Global information area
  - Work area



A Global information area
B Work area
C Panel ID

Figure 2-1 Main screen structure

Screen

The main screen contains the global information area and the work area. The global information area is always accessible. The work area contains the tabs **Routine**, **Monitoring**, and **Administration**.

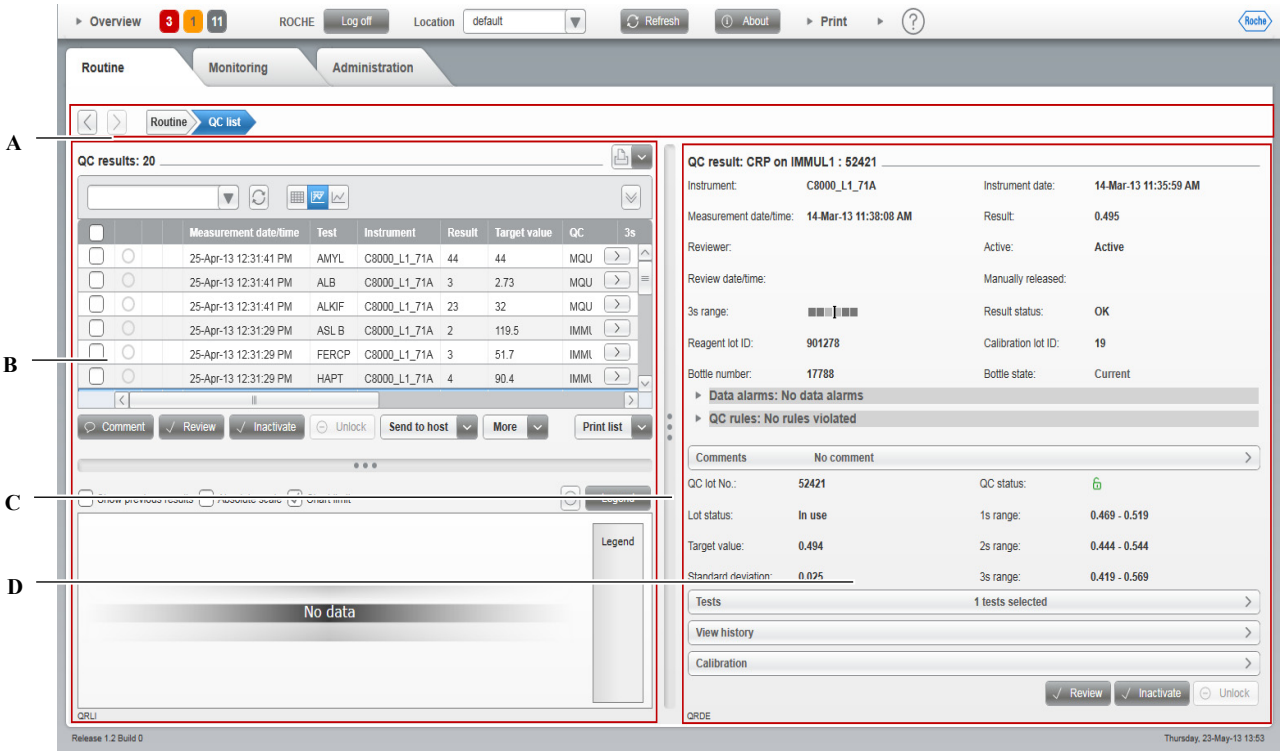
Global information area

The global information area contains permanently available information. It provides access to:

- The **Overview** area
- The task indicators
- The **Log on/ Log off** button
- The laboratory **Location**, for more information, see *Laboratory configuration* (p. 135)
- The **Refresh** button
- The **About** button
- The **Assistance** button

Work area

The work area contains the **Routine**, **Monitoring**, and **Administration** tabs. Each tab has a navigation bar above one or two panels, depending on the screen mode in use.



A Navigation bar with back and forward buttons and navigation path

B Main panel

C Panel splitter

D Detail panel

Figure 2-2 Split screen mode with main panel on the left and detail panel on the right

Exporting the table to CSV

You can export the grid from all panels which contain a table.

To export a table to CSV

1 In the panel for which you want to export the table to CSV, choose the button, and then from the drop-down list choose the **Export to CSV** option.

2 In the **Are you sure you want to export the report to CSV format?** callout, choose the **Save** button.

Printing the table

The system prints what is selected in the table.

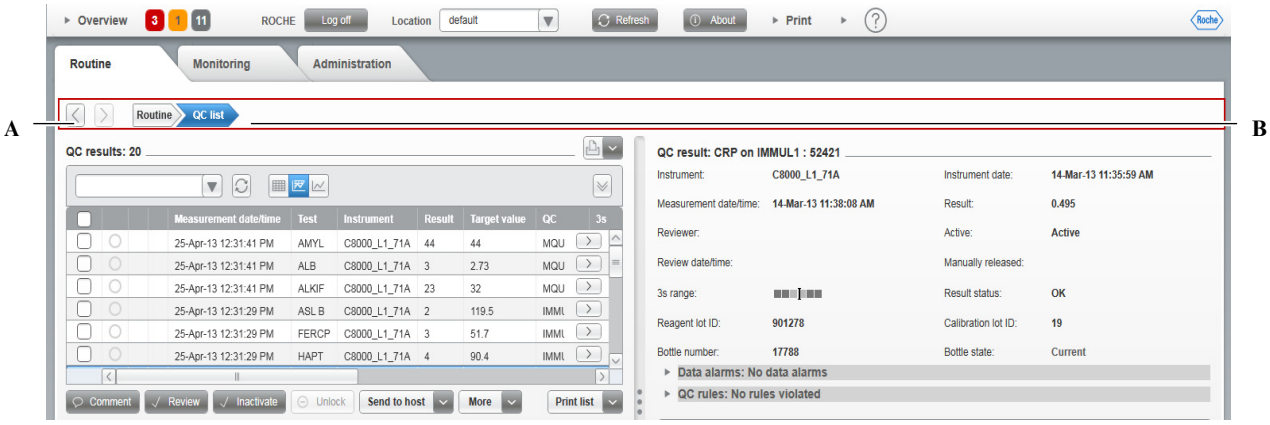
To print the table

1 In the panel for which you want to print the panel, choose the button, and then from the drop-down list choose the **Print** option.

Navigation bar

The navigation bar is at the top of the work area above the panels. It contains navigation aids:

- Back and forward buttons to navigate your browse history.
- Navigation path that shows the path back to the home panel of the current tab.



A **Back** and **Forward** buttons **B** Navigation path

Figure 2-3 Navigation bar

Back and forward buttons

While you navigate through the work area performing tasks and managing your work, each location is automatically stored in a browse history. Use the back and forward buttons on the navigation bar to browse the history.

Navigation path

The path from the home panel of the tab to the current location is shown as a navigation path in the navigation bar. Choose a path element to go back to the selected location.

Shortcut menu

Enables you to navigate to the corresponding panels where you can perform the specified tasks.

Tabs and panels

Information on a tab is contained on panels. Two view modes are available:

- Split-screen mode
- Full-screen mode

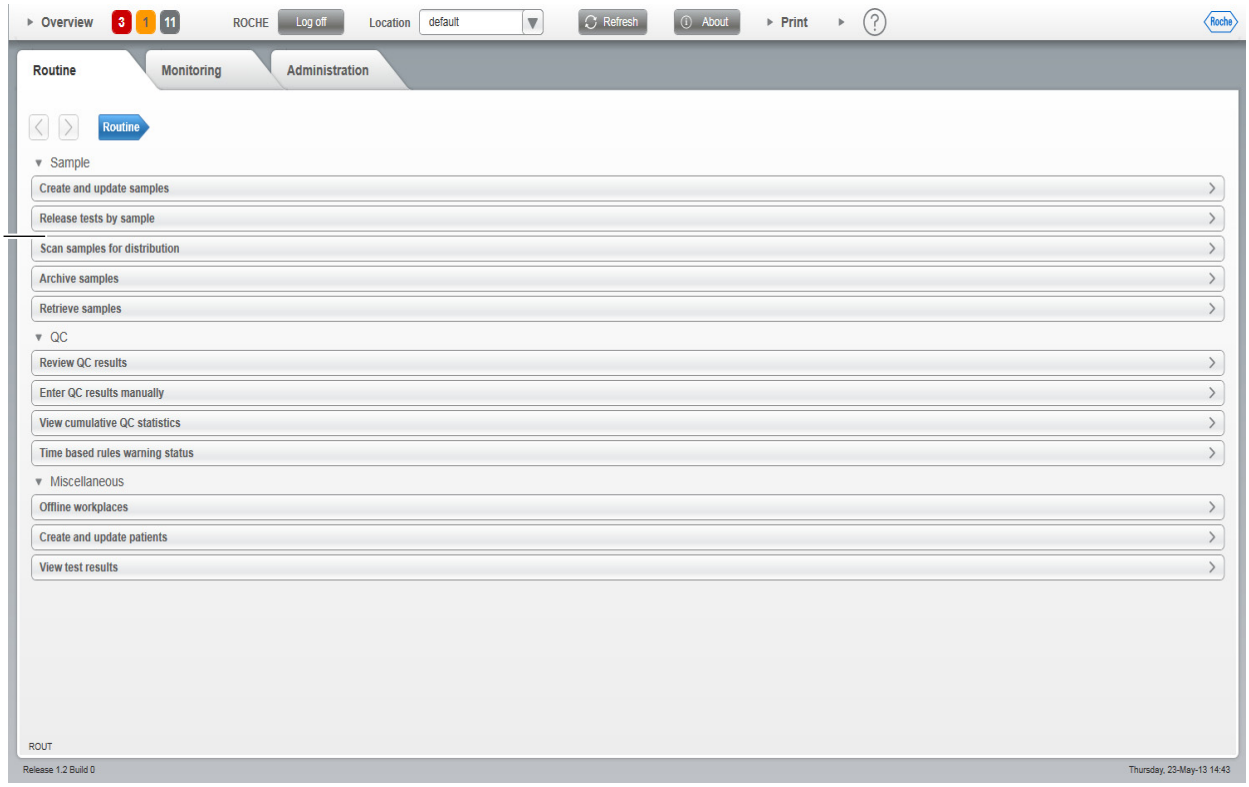
Use the panel splitter to enlarge visibility on the left or right panel.

Split-screen mode Two panels are displayed side by side in split-screen mode. The left panel is the main panel and the right panel the detail panel where details of the selected element from the main panel are displayed. Use the panel splitter to change from split-screen to full-screen mode and vice versa.

Full-screen mode In full-screen mode, only one panel is displayed.

Home panel

The home panel is the first panel of a tab. It contains the task buttons that are related to the tab. Choose a task button to see the details.



A Task button.

Figure 2-4 Routine tab home panel containing the main task buttons

Panels

A panel is an organizational unit within a tab and can have different sizes.

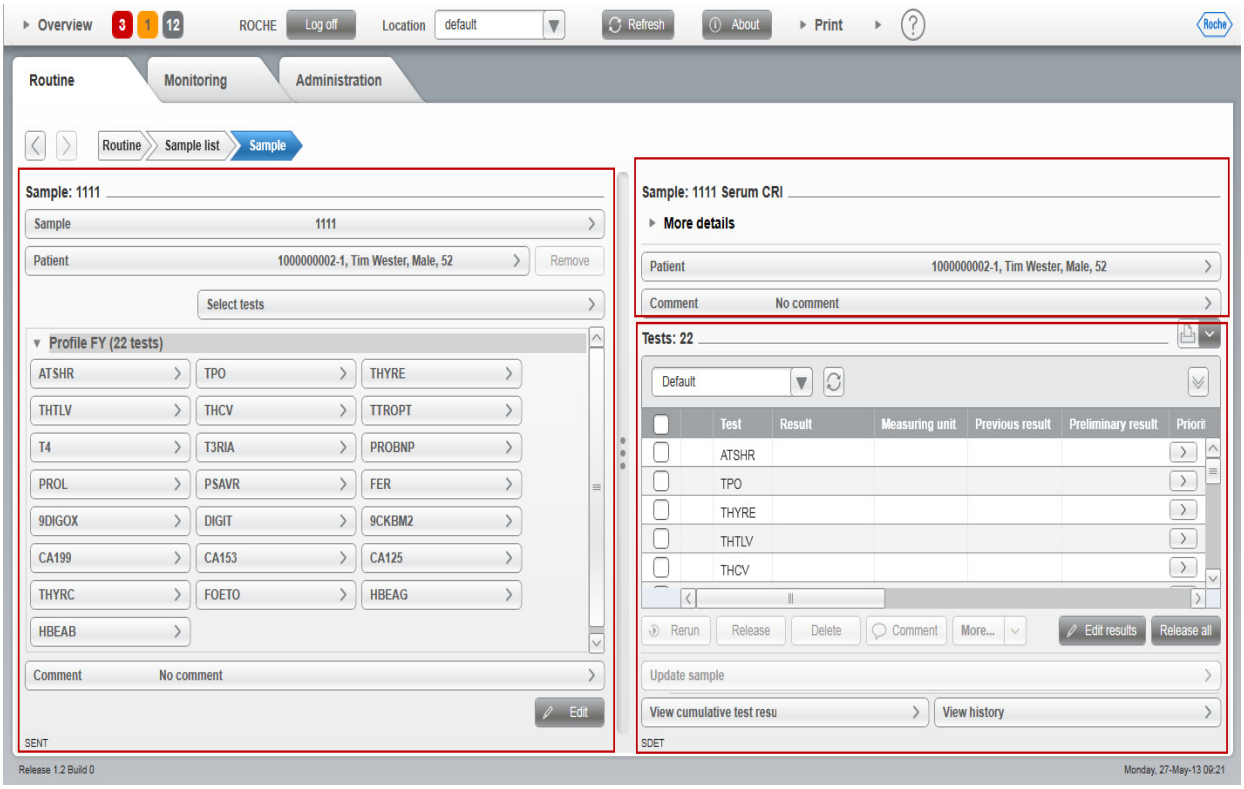
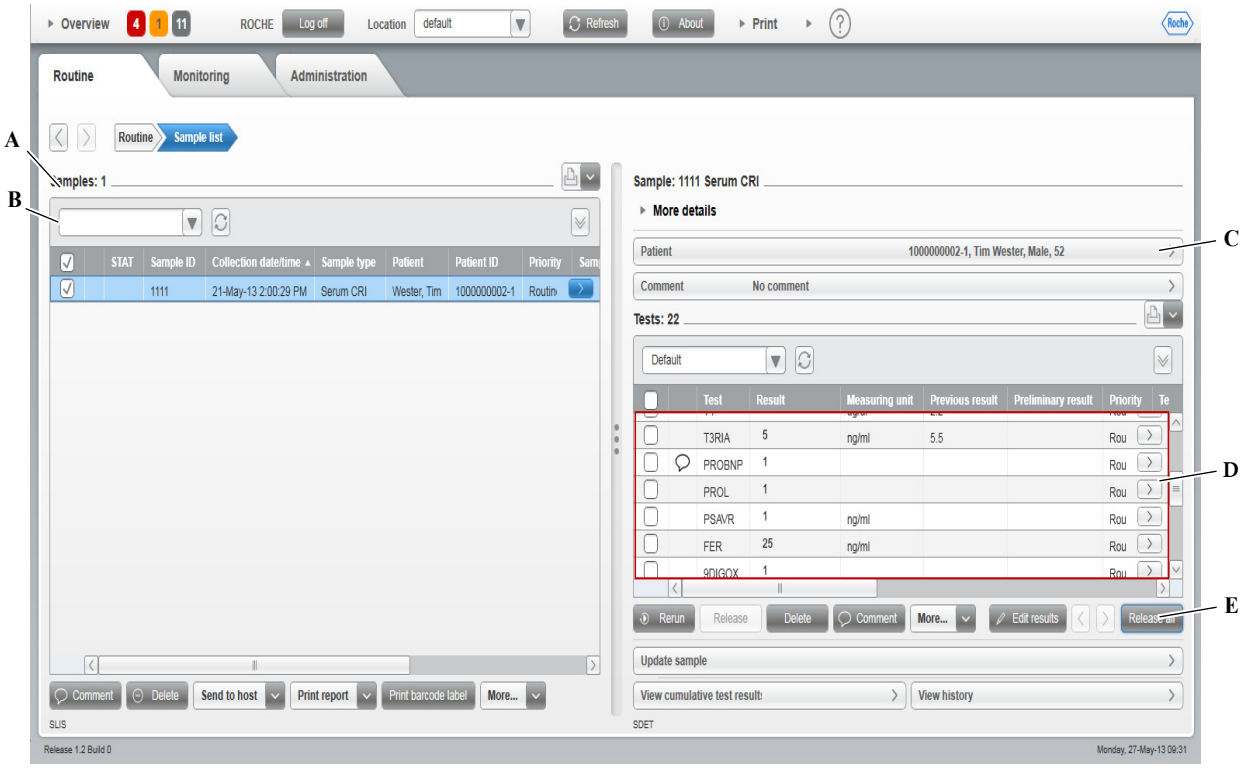


Figure 2-5 Panels of different sizes

Panels can have different elements:

- Panel title
- Tables
- Lists
- Filters
- Task buttons
- Buttons



A Panel title
B Filter
C Task button
D Table
E Button

Figure 2-6 Elements in panels

Generic user interface elements

Generic user interface elements are:

- Icons
- Callouts

Icons

Icons on the user interface:

Icon	**Meaning**
	STAT samples.
	Comment attached.
	QC material is displayed in the Levey-Jennings chart.
	Data alarm.
	Rerun.
	QC is expired.
	Closed sample.

Callouts

A callout is a context-specific interaction element. It shows detailed information, offers context-specific tasks, or it allows operator actions confirmation.

A callout always points to the user interface element it belongs to and has a close button.

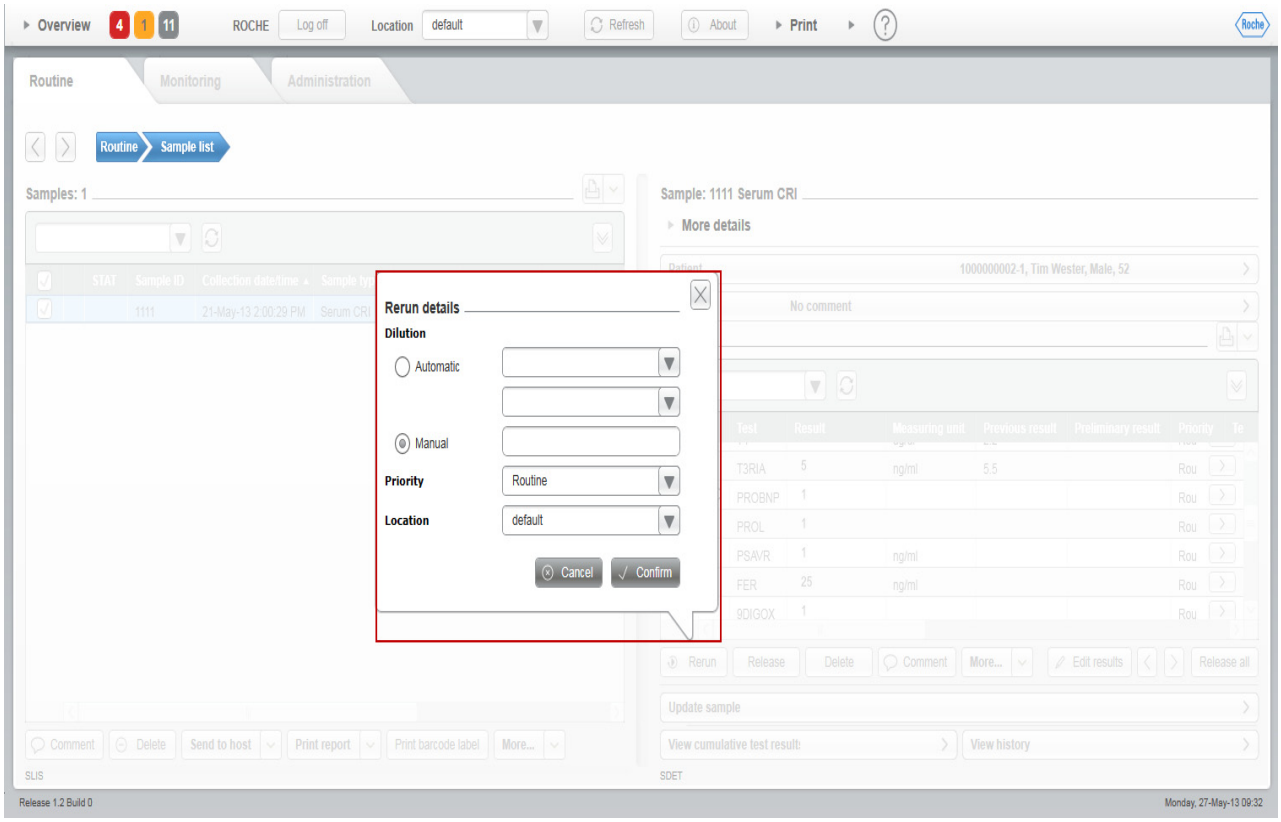


Figure 2-7 Callout

About

Choose this button to get information about the system version, modules, and session.

Assistance

If you need assistance in performing a task or in troubleshooting, open the assistance center by choosing the button.

Routine

Sample distribution and sample management

In this chapter you can find information about sample scanning, printing barcode labels, searching for samples, creating new samples, updating existing samples, adding more tests to a sample, removing unwanted tests from a sample, adding sample comments, sample archiving, sample retrieval, and sample disposal.

In this chapter

Chapter **3**

Sample activities before distribution

Before samples are distributed to the required workplaces and/or instruments, ensure that the following applies to all samples you want to test:

- They are available and entered in the system.
- They have barcode labels on.
- There are no tests that have to be removed.
- There are no additional test orders.

Samples have different statuses in the system, depending on the testing stage they are in.

The following sample statuses are displayed in the system:

Sample status	Meaning
Open	The sample has at least one test with the status requested.
Processing	The sample has at least one test which has been sent to the instrument, but the result has not yet been returned.
Evaluated	The sample has at least one test result which has passed the validation process but has been blocked from automatic release.
Released	All sample assigned tests have passed the validation process and have been sent to the LIS/HIS.

Table 3-1 Sample statuses

Viewing a list of samples

You view the list of samples to sort through and look for particular samples that must be distributed.

To view a list of samples

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of samples that fit the default filter criteria.

To filter the list of samples, see *Filtering samples* (p. 20)

Sending samples to the host

It enables you to force the sending of result messages, for those tests that are released, to the host to report the current sample location and the last action done on the sample.

To send samples to the host

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of samples that fit the default filter criteria.

To filter the list of samples, see *To filter samples* (p. 20)

2 Choose the **Send to host** button, and then do one of the following:

- To send only the selected samples which have not been sent to the host, choose the **Send unsent** option,
  or,
- To send the selected samples regardless of their sent to host status, choose the **Send all** option.

The samples are sent to the host.

Searching for a sample

You search for a sample to view its status and ensure that all assigned tests are done.

To see a list of sample statuses and their description, see *Sample statuses* (p. 49).

To search for a sample

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 From the filtering drop-down list, choose the appropriate custom filters, and then choose the **Apply** button.

The **Samples: {0}** panel is displayed containing the list of matching samples.

To create a predefined filter profile, see *Filtering samples* (p. 20)

3 Look through the list to find the sample you searched for.

Printing barcode labels

You print barcode labels for unlabeled samples that come to the laboratory with a testing request, and for aliquoted samples.

To print barcode labels

1 From the global information area, choose **Overview**.

The **Overview** area is displayed.

2 Choose **Open samples** task button.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

To filter the list of samples, see *To filter samples* (p. 20)

3 Change the filter to display **All** samples.

The sample details are displayed.

4 Choose one or more sample tasks, and then choose the **Print barcode label** button.

The labels are printed.

Changing the priority of a sample

You change the priority of a sample when the level of importance of the associated tests changes between routine and STAT. You can change the priority of a sample only when the sample is in status *requested*.

To change the priority of a sample

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Choose the details arrow of the sample for which you want to change the priority.

The sample information is displayed in view mode.

3 Choose the **Edit** button, and then choose the **Sample** task button.

The **Sample information** panel is displayed in edit mode.

4 From the **Priority** drop-down list, choose the priority of the sample and choose the **Next** button.

The priority of the sample is changed.

Creating a sample

You create a new sample when:

- A new sample is sent to the laboratory without being entered in the LIS /HIS system.
- **cobas IT** middleware is in LIS backup mode.

To create a sample

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Choose the **Create** button.

The **Sample information** panel is displayed.

3 Enter the appropriate sample information in the required fields, and then choose the **Next** button.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

To filter the patients list, see *Filtering patients* (p. 21).

4 Do one of the following:

- To assign the sample to an existing patient, choose a patient from the list, and then choose the **Assign patient** button.
  or,
- To create a new patient, choose the **Create patient** button.

To create a new patient, see *To create a new patient* (p. 89)

The **Test groups** panel is displayed.

5 Choose one of the tests groups, choose the tests to be performed on the sample, and then do one of the following.

- To save the current sample, choose the **Save** button,
  or,
- To save the current sample entry and to create more samples, choose the **Save and create new** button.

The sample is created.

Updating sample information

You update a sample when the sample details have changed or the system is in LIS backup mode.

To update sample information

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Choose the details arrow > of the sample you want to update.

The **Samples: {0}** panel is displayed.

3 Choose the **Edit** button, and then do one of the following:

- Choose the **Sample** task button, and then update sample information.
  or,
- Choose the **Patient** task button, and then update patient information.
  or,
- Choose the **Select tests** task button, and then update sample test information.

4 Choose the **Save** button.

The sample is updated.

Requesting additional tests

You add tests manually to a sample with tests already assigned when you receive new test requests for it.

To request additional tests

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Choose the details arrow of the sample to which you want to add tests.

The sample information is displayed.

3 Choose the **Select tests** task button.

The **Test groups** panel is displayed.

4 Choose the **Edit** button, choose a test group, choose the additional tests to be assigned to the sample, and then choose the **Save** button.

The tests are added to the sample.

Removing unwanted tests

You remove tests assigned to a sample when they are no longer needed.

Only tests without results can be removed.

To remove unwanted tests

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Choose the details arrow of the sample to which you want to remove tests.

The sample information is displayed.

3 Choose the **Edit** button, choose the test you want to remove, right-click on the test, and then choose the **Remove test** from the shortcut menu.

The test is removed.

4 Choose the **Save** button.

The changes made are saved.

Adding a comment to a sample

You add a comment to a sample in order to attach significant information to that sample. Comments can be made visible only to laboratory staff (internal comments) or to everyone who has access to the sample information.

To add a comment to a sample

1 Choose **Routine** > **Create and update samples**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

2 Click the details arrow of the sample to which you want to add a comment.

The details of the sample are displayed.

3 Choose the **Comment** task button.

The **Comments** panel is displayed.

4 To hide the comment in results reports, choose the **Internal comment** check box.

5 Do one of the following:

- Enter a comment in the **Comment** field.
  or,
- Choose a predefined comment from the **Predefined comments** drop-down list.

6 Choose the **Save** button.

The comment you have entered is saved.

Changing the dilution of an added test

CAUTION

Incorrect results due to manual predilution.

If a sample was manually prediluted and the dilution factor was entered into **cobas® IT** middleware, the first result that comes from instrument is multiplied by the factor.

If the instrument then performs an automatic rerun of the test, the manual predilution factor is not applied to the second result, leading to an incorrect result.

- If you allow an instrument to perform automatic reruns, ensure that the workflow does not permit a sample with a manual predilution to run on the instrument.
- To be safe, it is recommended to not allow manual predilutions in the laboratory. Instead, set automatic dilutions, either on the instruments, or using rules. This is good laboratory practice.

You want to change the dilution of an added test to correct the previous dilution when necessary.

To change the dilution of an added test

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing the list of all tests that fit the default filter criteria.

To filter the list of samples, see *To filter samples* (p. 20).

2 Choose the test for which you want to change the dilution, and then choose the **Rerun** button.

The **Rerun details** callout is displayed.

3 Change the dilution of the test, and then choose the **Confirm** button.

The dilution of the test is changed.

Sample distribution

Sample distribution means placing the sample to be tested in the appropriate instrument and/or workplace for analyses. You can distribute samples using a barcode reader or by entering the sample ID in the system.

Scanning a sample

You scan a sample in order to retrieve it from the system, print barcode labels, and send it to the appropriate instruments for testing or archiving.

Only barcode readers behaving like a keyboard are supported.

When scanning a sample you must wait for the beep and then scan the next sample.

Samples can be archived directly from the mask when the manual scan action "archive" is configured.

To scan a sample

1 Choose **Routine** > **Scan samples for distribution**.

The **Scan samples for distribution** panel is displayed.

2 Choose the sample workflow, choose the **Sample ID** field, and then scan the barcode label of the sample using a barcode reader.

The sample information is displayed.

Viewing a list of pending samples

You want to view a list of pending samples to ensure that all tests belonging to those samples are processed within the assigned time frame.

To see sample statuses and their descriptions, see *Sample statuses* (p. 49)

To view a list of pending samples

1 From the global information area, choose **Overview**.

The **Overview** area is displayed.

2 To view a list of test results pending validation, do one of the following:

- To view routine samples with tests pending validation, choose the **Samples pending release (ROUTINE)** task button.
  or,
- To view STAT samples with tests pending validation, choose the **Samples pending release (STAT)** task button.

The **Samples: {0}** panel is displayed containing a list of samples with tests to be released.

To filter the list of samples, see *To filter samples* (p. 20)

Viewing missing samples

You want to view missing samples to ensure all samples registered in the system are being processed.

To view missing samples

1. From the global information area, choose **Overview**.

   The **Overview** area is displayed.

2. To view a list of missing samples, do one of the following:

   - To view routine missing samples, choose the **Missing samples (ROUTINE)** task button.
     or,
   - To view STAT missing samples, choose the **Missing samples (STAT)** task button.

   The **Samples: {0}** panel is displayed containing a list of missing samples.

Distributing samples without a barcode reader

You distribute samples by entering the sample ID manually if you do not have a barcode reader.

To distribute samples without a barcode reader

1. Choose **Routine** > **Scan samples for distribution**.

   The **Scan samples for distribution** panel is displayed.

2. Do one of the following:

   - Scan the sample with the barcode reader
     or,
   - Enter the **Sample ID**, the **Sample type** is required if non-unique sample IDs are used, and the **Sample workflow**, and then choose the **Find** button.

   The tasks for the sample are displayed. You can distribute that sample as suggested by the system.

Resetting the distribution status of a sample

You reset the distribution status of a sample when the sample must be reprocessed on a previous target or instrument. This is the case when the next target or instrument stopped working and therefore the sample must be redirected to the next available one.

You can only reset one target at a time.

To see sample statuses and their descriptions, see *Sample statuses* (p. 49).

To reset the distribution status of a sample

1. Choose **Routine** >**Scan samples for distribution**.

   The **Scan samples for distribution** panel is displayed.

2. Do one of the following:

   - Scan the sample with the barcode reader
     or,
   - Enter the **Sample ID**, the **Sample type** is required if non-unique sample IDs are used, and the **Sample workflow**, for the sample whose distribution status you want to reset.

   The tasks for the sample are displayed.

3. Choose the target you want to reset, and then choose the **Reset target** button.

   The distribution status is reset.

Viewing sample history

You view sample history to have an overview of all the actions performed on that sample.

To view sample history

1. Choose **Routine** > **Release tests by sample**.

   The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

   To filter the list of samples, see *To filter samples* (p. 20).

2. Choose the sample for which you want to view the history.

   The sample details are displayed.

3. Choose the **View history** task button.

   The **History** panel is displayed containing all sample events.

Viewing sample history details

You view sample history details to have more in from at ion about a particular event or action performed on that sample.

To view sample history details

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

To filter the list of samples, see *To filter samples* (p. 20).

2 Choose the sample for which you want to view the history.

The sample details are displayed.

3 Choose the **View history** task button.

The **History** panel is displayed containing all sample events.

4 Choose the sample event for which you want to view details.

The details of that event are displayed.

Masking a test, a test profile, or an instrument

You mask a test or a test profile when the reagent level is low. In this case the sample is redirected to the next available instrument containing that test or test profile.

Depending on the masking profile configuration the tests which are in the profile are masked for query, for sort or block release.

You mask an instrument when it becomes unavailable for testing.

To mask a test profile

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Test profile** drop-down list, choose the profile you want to mask, and then choose the **Mask** button.

The profile is masked.

To mask an instrument

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose the instrument you want to mask, and then choose the **Mask** button.

The instrument is masked.

To mask a test

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to mask a test.

3 From the **Test** drop-down list, choose the test you want to mask, and then choose the **Mask** button.

The test is masked.

Unmasking a test profile, or an instrument, or a test

You unmask a test or a test profile when the reagent level of that test or test profile is high enough to run tests.

You unmask an instrument when the instrument becomes available for testing.

To unmask a test profile

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 Choose the test profile you want to unmask, and then choose the **Unmask** button.

The profile is unmasked.

To unmask an instrument

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose the instrument you want to unmask, and then choose the **Unmask** button.

The instrument is unmasked.

To unmask a test

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to unmask a test.

3 From the **Test** drop-down list, choose the test you want to unmask, and then choose the **Unmask** button.

The test is unmasked.

Masking a test for a query

When an analytic instrument sends a test request query to get the tests which must be performed, the masked test is not sent to the instrument as requested.

To mask a test for a query

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to mask a test.

3 From the **Test** drop-down list, choose the test you want to mask, then choose the **Mask** button, and then from the **Mask** drop-down list choose the **Query** option.

The test is masked for a query.

Unmasking test for a query

To unmask a test for a query

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to unmask a test.

3 From the **Test** drop-down list, choose the test you want to unmask, then choose the **Unmask** button, and then from the **Unmask** drop-down list choose the **Query** option.

The test is unmasked for a query.

Masking a test for sorting

If a test is masked for sorting, when the system is sorting and aliquoting, the system pretends the sample does not have the test.

To mask a test for sorting

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to mask a test.

3 From the **Test** drop-down list, choose the test you want to mask, then choose the **Mask** button, and then from the **Mask** drop-down list choose the **Sort** option.

The test is masked for sorting.

Unmasking a test for sorting

To unmask a test for sorting

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to unmask a test.

3 From the **Test** drop-down list, choose the test you want to unmask, then choose the **Unmask** button, and then from the **Unmask** drop-down list choose the **Sort** option.

The test is unmasked for sorting.

Blocking result release

You want to block a test result release when the test is masked.

To block result release

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to block a result release.

3 From the **Test** drop-down list, choose the test you want to block a result release, then choose the **Mask** button, and then from the **Mask** drop-down list choose the **Block release** option.

The results release is blocked.

Unblocking result release

It turns-off the test results release blocking.

To unblock result release

1 Choose **Monitoring** > **Mask tests**.

The **Mask tests** panel is displayed.

2 From the **Instrument** drop-down list, choose an instrument for which you want to unblock a result release.

3 From the **Test** drop-down list, choose the test you want to unblock a result release, then choose the **Unmask** button, and then from the **Unmask** drop-down list choose the **Unblock release** option.

The results release is unblocked.

Offline workplaces

Enables you to manage samples and tests which must be run on instruments and/or workplaces not connected to the system, or instruments which do not support sending sample queries to the system.

Creating a work list for an offline instrument

You create a work list for offline instruments to run samples on instruments which are not connected to the system or do not support sending sample queries to the system.

To create a work list for an offline instrument

1. Choose **Routine** >**Offline workplaces**.

   The **Manage offline workplaces** panel is displayed.

2. Choose the **Target** for which you want to create the work list, and then choose the **Create work list** button.

   The **Assign samples to the work list** callout is displayed.

3. Enter the required information, and then choose the **Create work list** button.

   The work list is created.

Sending the work list to the instrument

To send the work list to the instrument

1. Choose **Routine** >**Offline workplaces**.

   The **Manage offline workplaces** panel is displayed.

2. Choose the **Target** to which you want to send the work list, and then choose the **Send to instrument** button.

   The work list is sent.

Editing a result for a test in the work list

You edit the work list in order to enter the results for the tests which were processed in the offline workplaces.

To edit a result for a test in the work list

1. Choose **Routine** >**Offline workplaces**.

   The **Manage offline workplaces** panel is displayed.

2. Choose the **Target** to which you want to edit the work list.

   The work list for that target instrument is displayed.

3 Choose a work list you want to edit, and then choose the **Edit** button

The **Result** field becomes editable.

4 Enter the result, and then choose the **Save** button.

The result is added to the test and the test is removed from the work list.

Deleting tests from a work list

You delete tests from the work list when those tests do not must be run on the offline instrument and/or workplace.

To delete tests from a work list

1 Choose **Routine** >**Offline workplaces**.

The **Manage offline workplaces** panel is displayed.

2 Choose the **Target** to which you want to send the work list.

The work list for that target instrument is displayed.

3 Choose the test or tests you want to delete, and then choose the **Delete** button.

The **Delete entries** callout is displayed.

4 Choose the **Confirm** button.

The test is deleted.

Printing a task list

It enables you to print the list of tasks to be sent to the offline instrument and/or workplace.

You can preview the report by choosing the **Print sample list** button > > **Preview report** option.

To print a task list

1 Choose **Routine** >**Offline workplaces**.

The **Manage offline workplaces** panel is displayed.

2 Choose the **Target** to which you want to send the work list, and then choose the **Print sample list** button >> **Print report** option.

The task list is sent to the printer.

Printing a sample batch report for an instrument

You print a sample batch report to summarize all tasks for all samples ran on an instrument which is used as help for manual steps in the laboratory.

You can preview the report by choosing the **Print list** button >> **Preview report** option

To print the sample batch for an instrument

1 Choose **Routine** >**Offline workplaces**.

The **Manage offline workplaces** panel is displayed.

2 Choose the **Target** for which you want to print the sample batch report, and then choose the **Print list** button >> **Print report** option.

The sample batch report is sent to the printer.

Sample archiving

Archiving permits storage of samples and racks. For a defined storage period, you can track the samples in the system and obtain the location of all archived samples. The storage period of the sample depends on numerous parameters:

- Intrinsic stability of the tests in the sample (for example, bilirubin degrades faster than iron)
- The type of sample tube associated with the sample type
- The preanalytical conditions (type of sample tube, time to bring the sample into the laboratory, time to process)

Creating a new archive rack

Create a new archive rack when there are no racks available in the archive.

Risk of sample information loss.

Creating an archive rack from a rack that is still in use on the instrument can lead to loss of information. Creating the archive rack changes the rack location in the database from the instrument to the worklist. When the instrument adds the next sample to this rack, the location is changed again to the instrument. The rack is then emptied on the database.

- Do not create an archive rack from a rack that is still in use on the system.

To create a new archive rack

1 Choose **Routine** > **Archive samples**.

The **Archive samples** panel is displayed.

2 Do one of the following:

- To assign a rack ID, in the **Rack ID** field, enter a new rack ID, and then choose the **Assign/create rack** button.
  or,
- To get a rack ID assigned automatically, choose the **Assign/create rack** button.

The **Create new rack** callout is displayed.

3 To print a rack barcode label, choose the **Print barcode label** check box.

4 Choose the rack type, and then choose the **Create** button.

The rack is displayed in the rack list.

Reactivating an online rack

You reactivate an online rack in order to reuse it back on the instrument for a predefined period of time. This option is used for aliquot racks that must to be online for a limited time.

To reactivate an online rack

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed containing the list of all racks that fit the default filter criteria.

2 From the **Filter by** drop-down lists, choose **Online rack**, **equals to**, **True**, **Active**, **equal to**, **False**, and then choose the **Apply** button.

The list of racks that can be reactivated online is displayed.

3 Choose the rack you want to reactivate, and then choose the **Reactivate online rack** button.

The **Reactivate online rack** callout is displayed.

4 Choose the **Confirm** button.

The rack is reactivated.

Assigning an existing rack to the rack list

You assign an existing rack to the rack list to be able to reuse existing racks for archiving.

To assign an existing rack to the rack list

1 Choose **Routine** > **Archive samples**.

The **Archive samples** panel is displayed.

2 To assign an existing rack to the rack list using a barcode reader, scan the rack.

The rack is assigned to the rack list.

3 To assign an existing rack to the rack list without a barcode reader, choose the **Assign** button.

The **Rack management: {0}** panel is displayed containing a list of racks that fit the default filter criteria.

4 Choose the rack you want to assign, and then choose the **Assign** button.

The existing rack is assigned to the rack list.

Archiving a sample

You archive a sample to store it for later add-on tests. The way the system archives samples to a rack is influenced by several options:

- The rack filling mode which determines the next free position of a rack to be filled.
- The automatic rack selection options which are used if the selected rack is full or does not match the sample type of the selected sample.

When archiving a sample you can select one or more of the following options:

Rack scan options	Sample scan options
Print barcode labels automatically	**Create unregistered samples automatically**
	Archive samples with pending tests
	Archive already archived samples
	Refill gaps
	Select rack automatically
	Auto create rack

Table 3-2 Rack and sample scan options

To archive a sample

1 Choose **Routine** > **Archive samples**.

The **Archive samples** panel is displayed containing a list of racks.

2 Select a rack, and then do one of the following:

- Scan the barcode label of the sample you want to archive using a barcode reader.
  or,
- Enter the sample ID and the sample type, if there are multiple samples with the same ID, of the sample you want to archive, and then choose the **Archive** button.

When there are open tests for the sample to be archived, the **Open tests for sample** callout is displayed. Choose the **Archive** button to archive or the **Cancel** button to cancel.

The **Rack: {0} '{1}'** panel is displayed containing the sample and its archiving position in the rack.

Archiving samples automatically

If the system is configured to support this workflow, you can automatically archive samples.

To archive samples automatically

1

Removing archive racks

You remove archive racks to clear the rack work list. The rack list reflects the racks used at the archiving workplace which contain the samples scanned for archiving.

To remove archive racks

1 Choose **Routine** > **Archive samples**.

The **Archive samples** panel is displayed containing a list of racks.

2 Choose a rack you want to remove, and then choose the **Remove rack** button.

The rack is removed.

Clearing the list of archive racks

You clear the list of archive racks to start a new list of racks in the archive.

To clear the list of archive racks

1 Choose **Routine** > **Archive samples**.

The **Archive samples** panel is displayed containing a list of racks.

2 Choose the **Clear list** button.

The racks are removed from the work list.

Reverting sample archiving

You want to revert sample archiving in order to correct errors which happened during the archiving process.

To revert sample archiving

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed.

2 Choose the rack which contains the sample you want to revert, and then choose the **Remove** button.

The sample is reverted.

Viewing available positions in an archive rack

You view rack positions of the sample when you must retrieve a sample manually from the archive.

Marker	Definition
Empty	Open position
Blue	Filled, sample in place
Green	Last filled position
Red stripes	Sample in this position and archived in another position (container type option: "Keep sample")

Table 3-3 Visualization scheme of rack position markers

Marker	Definition
Red stripes with blue or green background	"Ghost sample": position has been filled with another sample
⊗	Position empty but reserved (container type option: "Reserve position")
⚠	Storage duration elapsed: based on workflow configuration

Table 3-3 Visualization scheme of rack position markers

To view available positions in an archive rack

1 Choose **Routine** >**Archive samples**.

The **Archive samples** panel is displayed containing a list of racks.

2 Choose the rack for which you want to view the positions available.

The **Rack: {0} '{1}'** panel is displayed, containing a graphic view, a table view, or both views of the positions in the rack and their availability.

Sample retrieval

Manual sample retrieval uses a retrieval report with the current retrieval orders. First you assign the samples to the retrieval report. For manually archived samples, sample location and status are reset.

To create a new retrieval report you can clear the complete list regardless of the current sample status.

Retrieving samples manually

You retrieve samples from the archive manually when tests are added to that archived sample and there is no automatic retrieval available.

To retrieve samples manually

1 Choose **Routine** > **Retrieve samples**.

The **Retrieve samples** and **Samples: {0}** panels are displayed.

2 Choose the sample or samples you want to retrieve, and then choose the **Assign** button.

The sample or samples are displayed in the retrieve samples table.

3 Choose the **Retrieve** button.

The sample or samples appear as retrieved in the system.

Printing a list of samples to be retrieved from the archive

You print a sample retrieval list to manually retrieve samples from an archive.

To print a list of samples to be retrieved from the archive

1 Choose **Routine** > **Retrieve samples**.

The **Retrieve samples** and **Samples: {0}** panels are displayed.

2 From the **Samples: {0}** panel, choose the sample or samples you want to retrieve, and then choose the **Assign** button.

The sample or samples are displayed in the **Retrieve samples** panel.

3 Choose **Print list** button, and then **Print** from the shortcut menu.

The sample list is sent to the printer.

Sample disposal

Disposing means emptying a list of racks and wasting their samples (or to dispose for single use racks). The sample disposal is performed on rack level, consequently whole racks are disposed. The archive rack expiry date is used to identify archive racks for disposal. You select the racks to be disposed of, request the disposal and the system removes all archived samples from the rack, resets the archive position, sample location, and sample status of the sample. If the archive rack is no longer used you can delete it.

The same list used for disposing samples and/or deleting racks can also be used to search for archive racks and print a general rack list which can be used to document the current sample archive content or to prepare a disposal report to support the manual disposal of samples.

The physical disposal of the archived samples has to be notified in the system. Once disposed the rack can be reused later for the storage of other samples.

Printing a list of racks with samples for disposal

You print a list of racks with samples for disposal to manually retrieve the samples from the archive and dispose of them.

To print a list of racks with samples for disposal

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed containing a list of racks that fit the default filter criteria.

To filter the list of racks, see *Filtering the list of racks* (p. 22)

2 Choose the rack or racks for which you want to dispose of the samples, choose the **Print list** button, and then choose **Print** from the shortcut menu.

The list of racks is sent to the printer.

Disposing of the archived samples

You dispose of the archived samples because their storage time has ended.

To dispose of the archived samples

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed.

2 Choose the rack whose samples you want to dispose of, and then choose the **Dispose of samples** button.

The **Dispose of racks** callout is displayed asking you to confirm.

3 Choose the **Confirm** button.

The samples from the rack are disposed of.

Deleting a disposed rack

You delete disposed racks because it does not make sense to leave empty single-use racks in the system.

To delete a disposed rack

1 Choose **Monitoring** > **Manage racks and dispose of samples**.

The **Rack management: {0}** panel is displayed.

2 Choose the rack you want to delete, and then choose the **Delete rack** button.

The **Delete racks** callout is displayed asking you to confirm.

3 Choose the **Confirm** button.

The rack is deleted.

Late sample tracking

Late sample tracking enables you to ensure that a sample has been handled correctly in the laboratory workflow. You are notified when a sample exceeds a configured time limit within the workflow, enabling you to review late samples and identify the causes for delay.

Late sample tracking is on the **Monitoring** tab in **Sample monitoring** panel. The **Late sample rules** task button enables you to manage the rules. The **Late sample monitor** task button enables you to view late samples.

A late sample rule tracks a sample between two events in the workflow. For example, between *sample registration* and *result released*. If a sample takes too long, it is marked with a *warning* or an *error*, and displayed in the **Late sample monitor** panel. It is also added to the summary on the **Late samples** task button in the **Overview** area.

In the **Late sample rules** panel, configure the rule's start and end events, starting conditions, and the warning and error time limits.

You can limit a rule's scope. You can limit the rule to apply only:

- To samples that have specific tests.
- To a specific sample type, orderer group, or priority.
- To specific days of the week or time of day.
- If certain conditions are true at the time of the start event.

Configuring a late sample rule

You can limit the application of a late sample rule, according to the following parameters.

- Selection criteria (priority, sample type, orderer group, and location).
- Tests performed.
- The start and end events between which the sample is tracked. (Required.)
- Further conditions which must apply at the time of the start event.
- Whether tracking stops when only one of the specified tests in the sample has passed the end event, or when all of them have passed it. (Required)
- Rule schedule. The times or days of the weeks when the rule applies. (Required.)
- The time limits after which a warning and error are raised. (Required.)

To configure a late sample rule

1 Choose **Monitoring > Late sample rule list**.

The **Late sample rules** panel is displayed

2 Choose the **Create** button.

The **Late sample rule** panel is displayed.

3 Give the rule a name and description.

If you want the rule to be active, select the **Enabled** check box. If you are not using the rule, clear the check box.

4 To limit the rule to samples of a specific priority, sample type, orderer group, or location, optionally select values in the drop-down lists in the **Criteria** group box.

5 To limit the rule to samples with specific tests, optionally select the tests in the **Test performed** group box.

- Choose the **Assign tests** button. From the **Assign tests** callout select the tests. or,
- Choose the **Assign tests by profile** button. From the **Assign tests by profile** callout select the appropriate test profiles.

6 To set the event that starts the sample tracking, in the **Tracking period group box**, under **From**, choose the **Assign** button.

The **Assign events** callout is displayed.

7 Select the starting event. To set the tracking to start only under certain conditions, optionally select the conditions in the **Conditions** dropdown list. When ready, choose the **Assign** button to close the callout.

8 To set the event that ends the sample tracking, in the **Tracking period group box**, under **To**, choose the **Assign** button.

9 In the **Assign events** callout, select the end event. When ready, choose the **Assign** button to close the callout.

10 By default, tracking stops when only one of the selected tests has passed the end event. If no tests are selected, tracking stops when one test in the sample has passed the end event. If you want this behavior, clear the **Wait for all tests to complete** check box.

If you want to continue to track the sample until all the selected tests have passed the end event, select the **Wait for all tests to complete** check box. If no tests are selected, tracking continues until all tests in the sample have passed the end event.

Wait for all tests to complete

The option **Wait for all tests to complete** only applies to the following events.

- **REQUESTSENT** (test order sent to analyzer).
- **RESULT** (result measured).
- **RESULT_RELEASED** (result released).

11 In the **Schedules** group box, choose the **Add** button.

The **Create schedule** callout is displayed.

12 Select the days and enter the time period to which you want the rule to apply.

13 In the **Warning after (mins)** field enter the time limit for a warning. If the sample has not reached the end event after this number of minutes, the sample is displayed in the **Late sample monitor** list with a warning.

14 In the **Error after (mins)** field enter the time limit for an error. If the sample has not reached the end event after this number of minutes, the sample is displayed in the **Late sample monitor** list with an error.

15 When ready, choose the **Assign** button.

The callout closes, and the schedule is created.

Rule schedules

To set different time periods on different days, create more schedules.

16 When finished, choose the **Save** button.

The rule is created and added to the list of late sample rules.

Editing a late sample rule

You edit a late sample rule to change any of its parameters. For example, you may have created a rule but did not want to enable it straight away. You would edit the rule in order to activate it.

To edit a late sample rule

1 Choose **Monitoring > Late sample rules**.

The **Late sample rules** panel is displayed.

2 Choose the button of the rule that you want to edit.

The **Late sample rule** panel for the selected rule is displayed.

3 Choose the **Edit** button and make the appropriate changes.

To edit a schedule, choose the button. The **Edit schedule** callout is displayed, in which you can make changes.

4 Choose the **Save** button.

The changes that you have made to the rule are applied.

Reviewing a list of late samples

You review late samples in the **Late samples** panel. Information about a late sample includes:

- The late sample rule applied.
- Color-coded delay time (minutes) where yellow = warning and red = error.
- The initial event.
- The date and time when tracking commenced.

You can temporarily exclude a late sample from the **Late samples** table. You use the **Snooze** button to specify the period of time that the late sample is excluded. After this period has elapsed the late sample is included in the table again.

The **Stop tracking** button stops a late sample from being tracked and removes it from the **Late samples** table.

To review a list of late samples

1 Choose **Monitoring > Late sample monitor**.

The **Late sample monitor** panel is displayed.

To filter the list of late samples, see *Filtering the late samples list* (p. 23).

2 You can select one or more late samples and then do one of the following:

- Choose the button to display the **Sample** panel containing details about the sample selected.
  or,
- Choose the **Snooze** button to select the time period for which the late sample will be excluded from the **Late sample monitor** table.
  or,
- Choose the **Stop tracking** button to stop the late sample from being tracked and remove it from the **Late sample monitor** table.

To view a summary of late samples

1 From the global information area, choose **Overview**.

The **Overview** area is displayed in which the **Late samples** task button displays the total of late sample errors and warnings.

2 Choose the **Late samples** task button to display the **Late samples** panel which provides a list of all of the late samples.

About closed samples

The host configuration can lead to situations where samples become closed. If the system receives a query or other message for a closed sample, the sample is marked in the Routine client with a red lock symbol (). Closed samples can result in failed host messages.

A sample becomes closed in the following ways:

- The sample closes after a configurable number of hours in the system, with the default being never.
- Some configurations use the collection date to help identify samples, in addition to the sample ID. In this case, if the host sends a new sample with the same sample ID but a different collection date, then the original sample is closed.

If problems arise due to the sample closing, contact your system engineer.

Test result processing

In this chapter you can find information about test result processing, evaluation and release activities.

In this chapter

Chapter **4**

Table of contents

About result evaluation and release

Result evaluation is an action of checking test results against a series of rules in order to assess their accuracy, precision, sensitivity, and specificity.

A result value can either be numeric or alphanumeric. The evaluation process is slightly different for numeric and alphanumeric result values.

Automatic evaluation and release enables automatic processing of all results within the reference range and minimizes the workload of the manual review.

The system can apply different rules to the results which are visible as results data alarms or result status changes. The system can handle and apply:

- Instrument data alarms
- Reference ranges data alarms
- Delta-check data alarms
- Serum indices data alarms
- Rule engine data alarms
- QC violations

The post-validation activities are executed after a measurement was run through the evaluation and release process.

After the results are evaluated they are investigated for further actions (for example, rerun, additional test) and then released.

Releasing results is an action performed by the system or by you. It consists of letting the results go to the next step of the workflow, assuming the measurement is accurate.

The laboratory IT administrator can set up an automatic release for each evaluated test. When a test result does not have a data alarm after the evaluation screening (for example: reference range, delta-check, QC, rules), it are automatically released by the system.

Tests have different statuses in the system, depending on their testing stage.

The following test statuses are displayed in the system:

Test status	Meaning
Requested	The test is requested by the LIS/HIS and no further activities were started by the system.
Measured	The test has been measured but cannot be evaluated yet, for example, due to pending results of serum indices.
Evaluated	The test result has passed the validation process but has been blocked from automatic release.
Result evaluated	The evaluation process stops because of a QC bracketing error.
Released	The test has passed the validation process.

Table 4-1 Test statuses.

Viewing a list of pending tests

You can view a list of pending tests to ensure that all the tests assigned to samples sent to the laboratory have been processed within the established turnaround time.

For a list of test statuses and their descriptions, see *Test statuses.* (p. 83).

To view a list of pending tests

1. Choose **Routine** > **View test results**.

   The **Tests: {0}** panel is displayed.

2. Choose the button.

   The filtering panel is displayed.

3. From the filtering drop-down lists, choose the **Sample status**, **is equal to**, **Any test open**, and then choose the **Apply** button.

   The list of pending tests is displayed.

Editing test results

You edit a test result when the test was performed on an offline workplace. You cannot edit test results that have been released.

To edit test results

1. Choose **Routine** > **Release tests by sample**.

   The **Samples: {0}** panel is displayed, containing a list of sample that fit the default filter criteria.

   To filter the list of tests, see *Filtering test results* (p. 22).

2. Choose the sample for which you want to edit test results.

   The sample details are displayed.

3. Choose the **Edit results** button.

   The test results become editable.

4. Edit the test results, and then choose the **Save** button.

   The test results are edited.

Entering a test result and its instrument assignment manually

You enter a test result with its instrument assignment when the instrument malfunctioned or for offline instruments and/or manual workplaces.

To enter a test result and its instrument assignment manually

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed, containing a list of sample that fit the default filter criteria.

To filter the list of tests, see *Filtering test results* (p. 22).

2 Choose the sample for which you want to edit test results.

The sample details are displayed.

3 Choose the result you want to edit, and then choose **More...** button >> **Edit** option.

The **Enter result for...** callout is displayed.

4 Enter the results, choose the instrument where the test was run, and then choose the **Save** button.

The result and the instrument were saved.

Ordering a repeat test

You order a repeat test to perform the same processing parameters on a sample when the first test result gives reason to do so.

To order a repeat test

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed.

2 Choose the test you want repeated, and then choose the **Repeat** button.

- A test repeat icon appears next to the test to be repeated.
- The test will be automatically repeated.

Requesting a manual test rerun with or without dilution

You request a manual test rerun to retest for a substance that cannot be measured without being diluted. The result from the rerun becomes the active one and the old one is kept in the test history.

NOTICE

Triggering formulas for rerun tests

Self referencing formulas do not get triggered for rerun tests.

- In the **Enter result for {0}** dialog box, select the **Calculate formula** check box

To request a rerun for one or more tests

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed.

To filter the list of tests, see *Filtering test results* (p. 22)

2 Choose the test you want to rerun, and then choose the **Rerun** button.

The **Rerun details** callout is displayed.

3 Choose the **Priority** and the **Location** of the rerun.

4 To add a dilution to the test rerun, do one of the following:

- From the **Automatic** drop-down list, choose a dilution option if needed, and then choose the **Confirm** button.
  or,
- In the **Manual** field, enter the dilution, and then choose the **Confirm** button.
  or,
- In the **Manual** field, enter number 1 to rerun the test without a dilution, and then choose the **Confirm** button.

The test is rerun.

Reverting to a previous test result

You can choose to revert the actual result of a test to any previous result measured on the same sample (when necessary). For example, a pathological result was confirmed and you want to send the first result because it was measured on the 'fresher' sample material.

To revert to a previous result

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing a list of samples.

2 Choose the details arrow > of the sample for which you want to revert a test to a previous result.

The **Sample: {0} {1}** panel is displayed.

3 Choose the test you want to revert to a previous result.

The **Test** panel is displayed containing test details.

4 Choose the test result option that you want to revert to, and then choose the **Activate** button.

The result becomes active.

Adding a comment to a test

You add a comment to a test in order to attach significant information to that test. For tests with added comments, a comment icon is displayed. If you click the comment icon, it shows its content.

To add a comment to a test

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed.

To filter tests, see *Filtering test results* (p. 22)

2 Choose the test to which you want to add a comment, and then choose the **Comment** button.

The **Add comment** callout is displayed.

3 Do one of the following:

- Enter a comment.
  or,
- Choose a predefined comment, from the drop-down list.

4 Choose the **Save** button.

The comment is added to the test.

Adding a comment to a test result

You add a comment to a test result in order to attach significant information to that result. For results with added comments, a comment icon is displayed. If you click the comment icon, it shows its content.

To add a comment to a test result

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed.

2 Choose the test result to which you want to add a comment.

The test details are displayed.

3 From the **Test runs: {0}** list, choose the rerun for which you want to enter a comment.

The rerun details are displayed.

4 At the bottom of the rerun details choose the **Comment** task button.

The **Comments** panel is displayed.

5 To not display the comment in results reports, choose the **Internal comment** check box.

6 Do one of the following:

- Enter a comment in the **Comment** field.
  or,
- Choose a predefined comment, **Predefined comments** from the drop-down list.

7 Choose the **Save** button.

The comment is added to the test result.

Entering a test result manually

You enter a result manually to override a previous result, or for offline instruments. The previous result is always kept in the system and can be viewed. If a test is associated with a defined set of results, you can select only a result from the list.

Manually entered results are processed with the rule engine, when applicable, similar to results sent by instruments.

If you enter a test result manually without assigning an instrument, the consumption report assigns the result to the "unknown" instrument.

To enter a test result manually

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed.

2 Choose the test to which you want to add a result manually, and then choose the **Edit results** button.

The result for that test becomes editable.

3 Enter the result value or choose the predefined value if the result is qualitative, choose the **Calculate formula** check box if it is a calculated test, and then choose the **Save results** button.

The result is saved.

Displaying a list of test results pending release

You display a list of results pending release in order to review them and take all necessary actions for their manual release.

To display the list of test results pending release

1 From the global information area, choose **Overview**.

The **Overview** area is displayed.

2 To view a list of test results pending release, do one of the following:

- To view routine samples with tests pending release, choose the **Tests pending release (ROUTINE)** task button.
  or,
- To view STAT samples with tests pending release, choose the **Tests pending release (STAT)** task button.

The **Tests: {0}** panel is displayed containing a list of tests to be released.

Releasing test results by sample

You release test results to confirm their accuracy and to make them available for patient diagnosis. This step is required for tests which were not automatically released by the system. You can release one, more than one, or all test results at once.

To release test results of a sample

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing a list of all samples that fit the default filter criteria.

2 Choose the details arrow of the sample containing the tests you want to release.

The details of the sample and its tests are displayed.

3 To release, do one of the following:

- To release one or more tests, choose the test or tests you want to release, and then choose the **Release** button.
  or,
- To release all tests, choose the **Release all** button.

The test results are released, and the next sample pending release is highlighted.

Releasing test results by instrument

You evaluate test results by instrument to investigate, execute further evaluation actions and release results sorted by instruments.

To release test results by instrument

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing a list of all the tests that fit the default filter criteria.

2 Choose the button.

The filtering panel is displayed.

3 From the **Filter by** drop-down lists, choose **Instrument**, **is equal to**, the instrument for which you want to release test results, **Test status**, **is equal to, pending release** and then choose the **Apply** button.

A list of test results for that instrument, pending release, is displayed.

4 Choose the test or tests you want to release, and then choose the **Release** button.

The test results are released.

Releasing all results for a specific test

You evaluate all results for a specific test when you verify their results and decide that all can be released at once.

For a list of test statuses and their descriptions, see *Test statuses.* (p. 83).

To release all results for a specific test

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing a list of all the tests that fit the default filter criteria.

2 Choose the button.

The filtering panel is displayed.

3 From the **Filter by** drop-down lists, choose **Test**, **is equal to**, the name of the test for which you want to release all results, **Test status**, **is equal to, pending release** and then choose the **Apply** button.

A list of results for that test, pending release, is displayed.

4 Choose all the tests, and then choose the **Release** button.

The test results are released.

Viewing the result history

You view the result history to track changes on unreleased results.

To view result history

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing the list of all tests that fit the default filter criteria.

To filter the list of test results, see *Filtering test results* (p. 22)

2 Choose the details arrow of the test for which you want to view the history.

The test details are displayed.

3 Choose the **View history** task button.

The result history is displayed.

Viewing the result history details

You view result history details to have more information about a particular event or action performed on that test.

To view result history

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing the list of all tests that fit the default filter criteria.

To filter the list of test results, see *Filtering test results* (p. 22)

2 Choose the details arrow of the test for which you want to view the history.

The test details are displayed.

3 Choose the **View history** task button.

The result history is displayed.

4 To view result history details, double-click the result history event for which you want to view details.

■

Sending results to the host

The system sends results to the host automatically upon release. If for a technical reason the host has not received them, you must send the results again.

▶ To send results to the host

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing the list of tests that fit the default filter criteria.

To filter the list of tests, see *Filtering test results* (p. 22)

2 Choose the test result or test results you want to send to the host, then choose the **Send to host** button, and then do one of the following:

- To send only the selected tests, choose the **Send unsent** option,
  or,
- To send all tests, choose the **Send all** option.

The samples are sent to the host.

■

Resetting the state of a test request

When a test has been sent to the instrument, it is given a status of *sent state*. If the instrument stopped working, samples that were not fully processed must be processed again, on another instrument, or the same instrument when repaired.

In this case the status of the open tests must be reset so that the system re-sends the test request. You use the **Reset sent state** option to re-send the test request to the instrument.

▶ To reset the state of a test request

1 Choose **Routine** > **View test results**.

The **Tests: {0}** panel is displayed containing the list of tests that fit the default filter criteria.

To filter the list of tests, see *Filtering test results* (p. 22)

2 Choose the test result or test results for which you want to reset the state, then choose the **More...** button >> **Reset sent state** option.

The test request state is reset.

■

Printing single patient result reports

You print a patient single result report to summarize data in a specific context that is used as help for manual steps in a laboratory (for example, retrieval list).

You can preview the reports before printing it by choosing the **Print report** button >> **Preview** option.

To print patient single result reports

1 From the global information area, choose **Overview**.

The **Overview** area is displayed.

2 Choose the **Released samples** task button:

The **Samples: {0}** panel is displayed.

3 Choose the sample for which you want to print a patient single result report, choose the **Print report** button >> **Print** option.

The patient single result report is sent to the printer.

Patient management

In this chapter you can find information about creating, deleting, editing, adding comments, viewing patient demographics, searching, and printing result reports for patients.

In this chapter

Chapter **5**

About patient management

Handling patients in **cobas IT** middleware includes assessment of patient demographics and data related to a patient 's stay in the hospital. The system enables the storage, organization, and tracking of patient data.

Patient management allows you to search for patients, add new patients, delete, or edit existing patients.

Creating a patient

You create a patient when there is a sample with assigned tests belonging to a patient who has not been entered in the system.


CAUTION

Patient demographic data

Patient demographic data can impact the reference ranges used in result validation.

- Enter patient demographic data with caution.
- Patient demographics can be updated via host interface.

To create a new patient

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

2 Choose the **Create patient** button.

The **New patient** panel is displayed.

3 Enter the required information, and then choose the **Save** button.

The patient is created.

Deleting a patient

You delete a patient when that patient was created by mistake. You need the appropriate user rights in order to delete patients.

To delete a patient

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

To filter patients data, see *Filtering patients* (p. 21).

2 Choose the patient you want to delete, and then choose the **Delete patient** button.

The **Delete patient** callout is displayed asking if you want to delete the patient.

3 Choose the **Confirm** button.

The patient is deleted.

Searching for a patient

You search for existing patients to edit patient information or to view the samples associated with that patient.

To search for a patient

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

2 Choose the button.

The filtering options are displayed.

3 Do one of the following:

- From the filtering drop-down lists, choose the criteria you want filter by, and then choose the **Apply** button.
  or,
- From the filters drop-down list, choose the appropriate custom filter.

The matching patients are displayed.

To create a custom filter, see *To create a custom filter* (p. 24).

Viewing patient demographics

It enables you to view and check the correctness of a patient's related information.

To view patient demographics

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

2 Choose the details arrow of the patient whose demographics you want to view.

Patient demographics are displayed.

Editing patient information

You edit patient information when patient data has changed.

To edit patient information

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

2 Choose the details arrow of the patient you want to edit.

Patient details are displayed.

3 Choose the **Edit** button.

Patient details become editable.

4 Edit patient information and choose the **Save** button.

The patient information is edited and saved.

Adding a comment to a patient

You add a comment to a patient when you want to attach significant information to that patient.

Comments can be made visible only to the laboratory staff (internal comments) or to everyone who has access to the sample information.

To add a comment to a patient

1 Choose **Routine** > **Create and update patients**.

The **Patients: {0}** panel is displayed containing a list of patients that fit the default filter criteria.

2 Choose the details arrow of the patient to which you want to add a comment.

Patient: {0} panel is displayed.

3 Choose the **Comment** task button.

The **Comments** panel is displayed.

4 Enter a comment in the **Comment** field, and then choose the **Save** button.

The comment you have entered is saved.

View patient cumulative test results

You want to view a cumulative result report to summarize result data in a specific context in order to communicate and document them.

To view patient cumulative test results

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

To filter the list of test results, see *Filtering test results* (p. 22)

2 Choose the details arrow > of the sample for which you want to view the cumulative results report.

The sample details are displayed.

3 Choose the **View cumulative test results** task button.

The **Cumulative test results** panel is displayed.

Printing the cumulative test results report

You print a cumulative result report to view and to summarize result data in a specific context in order to communicate and document them.

You can preview the report before printing by choosing the **Print report** button >> **Preview report** option.

To print the patient cumulative results report

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing the list of all samples that fit the default filter criteria.

To filter the list of test results, see *Filtering test results* (p. 22)

2 Choose the details arrow > of the sample for which you want to print the cumulative results report.

The sample details are displayed.

3 Choose the **View cumulative test results** task button.

The **Cumulative test results** panel is displayed.

4 Choose the **Print report** button >> **Print report** option.

The report is sent to the printer.

QC

QC configuration and routine QC

QC samples are widely used in clinical chemistry laboratories to assess the quality and stability of routine analytical methods. In this chapter you can find information about configuring a QC, reviewing QC results, error analysis, comments, activating QC, inactivating QC, and cumulative statistics.

In this chapter

Chapter **6**

About QC configuration

Each QC material covers one or several tests. In a laboratory, tests are configured on different instruments. A laboratory may use different QC lots for the same tests and/or different QC lots on individual instruments. Therefore, the test does not only refer to a distinct QC lot, but additionally to the instrument that has the corresponding tests configured.

cobas IT middleware tracks changes of the used QC lots and monitors the validity of the lot currently in use by documenting the lot number and the expiry date. For each QC lot, you can configure whether the lock of a QC result leads to the lock of the associated patient data, so that they cannot be released automatically.

NOTICE

Manual and automated QC results

The combination of manual and automated QC results for the same QC materials may interfere with the management of stand-by bottles, causing unwanted release of patient results to the host.

- Manually entered patient results may be assigned and released using the wrong QC material.

Creating a QC lot

CAUTION

QC Validation lock

Invalid results are released automatically when **Validation lock** is disabled.

- Do not disable the QC **Validation lock** option.

A QC material is a sample type (it simulates a relevant human sample) with known target values used to carry out the assigned QC tests on an instrument. It checks if the given result is within the QC reference ranges and therefore the instrument works correctly.

An active QC lot is in use after all information has been entered. Inactive means the QC is not being used. This feature is useful when you define a QC lot which will be used in the future.

To create a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC: {0}** panel is displayed containing all QCs that fit the default filter criteria.

2 Choose the **Create** button.

The **QC lot: {0}** panel is displayed.

3 Enter the required QC lot information, and then choose the **Add tests** button.

The **Test selection: {0}** panel is displayed.

4 Choose the tests to be assigned to the QC lot, and then choose the **Assign** button.

The test or tests are assigned to the QC material.

If you want to use location specific, instrument type specific, or instrument-specific target values, choose the **Location**, the **Instrument type** and/or the **Instrument** for the assigned tests, enter the **Target value** and the **Standard deviation**, and then choose the **Save** button.

The new QC lot is created.

5 To create a connection between patient results and corresponding QC results in order to lock those patient results when that QC result has failed, choose the **Validation lock** check box from the **Profiles: {0}** panel.

For more information see *About profiles* (p. 113)

Assigning tests to a QC lot

You assign tests to a QC lot when you want them to be evaluated against that QC lot.

To assign tests to a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to assign a test or tests, and then choose the **Edit** button.

The details of the selected QC lot are displayed.

3 Choose the **Add tests** button.

The **Test selection: {0}** panel is displayed.

4 Choose the tests to be assigned to the QC lot, and then choose the **Assign** button.

The test or tests are assigned to the QC material.

If you want to use location specific, instrument type specific, or instrument-specific target values, choose the **Location**, the **Instrument type** and/or the **Instrument** for the assigned tests, enter the **Target value** and the **Standard deviation**, and then choose the **Save** button.

The new tests are assigned to the QC lot.

Duplicating a test assigned to a QC lot

You duplicate a test when you must assign it with a different standard deviation or target value to another instrument.

To duplicate a test assigned to the QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to duplicate a test or tests, and then choose the **Edit** button.

The details of the selected QC lot are displayed.

3 To add more tests to the QC lot, see *Assigning tests to a QC lot* (p. 104).

4 To duplicate an assigned test choose the test or tests you want to duplicate, and then choose the **Copy test** button.

The test or tests are duplicated.

Deleting tests assigned to a QC lot

To delete tests assigned to a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to delete a test or tests, and then choose the **Edit** button.

The details of the selected QC are displayed.

3 Choose the test or tests you want to delete, and then choose the **Delete** button.

The test or tests are deleted.

4 Choose the **Save** button.

The test deletion is saved.

Assigning tests to a category

A category enables you to assign multiple tests to the same site, instrument type, and instrument at the same time.

To assign tests to a category

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to assign tests to a category, and then choose the **Edit** button.

The details of the selected QC are displayed.

3 To add more tests to the QC lot, choose the **Add tests** button.

The **Test selection: {0}** panel is displayed.

4 Choose the tests to be assigned to a category, and then choose the **Assign category** button.

The **Assign category** callout is displayed.

5 Enter the required information, and then choose the **Assign** button.

The tests are assigned to a category.

Assigning a QC lot and target sets to an instrument

When an instrument sends a QC result, the following information has to be identified within the system: on which instrument, for which QC material and QC lot the result was measured.

A QC code must be entered, as this is a value sent by the instrument in the QC message. For the instruments that do not work in QC mode the sample ID is used as a QC code. The mapped instrument assignment is identified by this code and the results then are attributed to the correct QC lot.

You assign a QC lot to an instrument to map the instrument and its tests to the QC lot defined in the system. If a QC lot is not assigned to an instrument, the results from that particular instrument do not get sent to the system.

To assign a QC lot and target sets to an instrument

1 Choose **Monitoring** > **QC instrument assignment**.

The **QC instrument assignment: {0}** panel is displayed containing a list of instruments that fit the default filter criteria.

2 Choose an instrument to which you want to assign a QC lot and target sets, then choose the **Edit** button, and then choose the **Assign QC lots and target sets** task button.

The **QC: {0}** panel is displayed.

3 Choose the QC you want to assign to the instrument, and then choose the **Assign** button.

4 Enter the **QC code** or choose the **Sample ID** check box, then choose the **Usage**, and then choose the **Save** button.

The QC lot and target sets are assigned to the instrument.

Editing a QC lot

You edit an existing QC lot when its information changed.

Use the filters at the top of the work area to select the QC lot you want to edit. The more filter criteria you set, the more precise the result are. Note as soon as you switch to another component the filter setting is cleared except the setting of the status.

To edit a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QCs that fit the default filter criteria.

2 Choose the QC lot you want to edit, and then choose the **Edit** button.

The details of the selected QC lot are displayed in edit mode.

3 To add more tests to the QC lot, choose the **Add tests** button.

The **Test selection: {0}** panel is displayed.

4 Choose the tests to be assigned to the QC lot, and then choose the **Assign** button.

The test or tests are assigned to the QC lot.

5 Edit QC lot details, and then choose the **Save** button.

The changes are saved.

Copying a QC lot

You copy a QC lot to reuse its configuration information onto another site, instrument type, and/or instrument which uses the same QC lot.

You can choose to copy a QC lot with or without the target information.

You can copy the following information:

- The QC material name (mandatory)
- The sample type
- The manufacturer
- The purchase number
- The tests assigned to the QC lot
- The instrument information of the assigned tests
- The target information

You must enter the following information:

- The QC lot number
- Expiry date and time

To copy a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot you want to copy, and then choose the **Copy QC lot** button.

The **Copy QC lot {0}**callout is displayed.

3 To copy the target information of the QC lot, choose the **With target values:** check box.

4 Enter the required information, and then choose the **Confirm** button.

The **QC lot: {0}** panel is displayed.

5 To add more tests to the QC lot, choose the **Add tests** button.

The **Test selection: {0}** panel is displayed.

6 Choose the tests to be assigned to the QC lot, and then choose the **Assign** button.

The test or tests are assigned to the QC lot.

7 To assign a site, an instrument type, and/or an instrument, choose the assigned test or tests, and then choose the **Assign category** button.

The **Assign category** callout is displayed.

8 Choose a site, an instrument type, and/or an instrument, and then choose the **Assign** button.

9 To duplicate an assigned test, choose the **Copy test** button.

10 Choose the **Save** button.

The QC material is copied and saved in the system.

Deleting a QC lot

If an existing QC lot is replaced by a new one (for example, because regulatory requirements changed), the corresponding QC lot must be deleted.

Linked QC results are deleted together with the QC lot

To delete a QC lot

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot you want to delete, and then choose the **Delete** button.

The **Remove QC lot?** callout is displayed.

3 Choose the **Confirm** button.

The QC lot is deleted.

Viewing QC lot history

You want to view the QC lot history in order to monitor the lot configuration changes, for example the target values changes.

To view the QC lot history

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to view the history, and then choose the **Lot history** task button.

The history of the selected QC lot is displayed.

Viewing QC lot history details

You want to view the lot history details to have more information about a particular event or action performed on that lot.

To view the QC lot history details

1 Choose **Monitoring** > **QC configuration**.

The **QC lot: {0}** panel is displayed containing all QC lots that fit the default filter criteria.

2 Choose the QC lot for which you want to view the history, and then choose the **Lot history** task button.

The history of the selected QC lot is displayed.

3 Double-click a history for which you want to view details.

Configuring QC settings

You configure the QC settings to make a comment mandatory when changing the deviation and the target information of a test/instrument assignment, and to set the period of time after which QC results are ignored.

To configure QC settings

1 Choose **Monitoring** > **QC settings**.

The **QC settings** panel is displayed.

2 Choose the **Edit** button.

The information becomes editable.

3 Enter the necessary information, and then choose the **Save** button.

The settings are saved.

About multi-rules QC

To assess the quality and stability of routine analytical methods, QC samples are used. To judge their quality and stability, multi-rules QC are defined as criteria for judging whether the observed QC measurements represent typical or atypical performance of the analytical method. For instance, such multi-rules QC may detect systematic shifts in the mean response of a process, monotonic increases in the random error of a process, or linear drift effects in the mean response of a process over a time frame.

All multi-rules attempt to signal when the QC measurements no longer represent the expected or previously observed error distribution. The performance of QC procedure can improve when several QC rules are simultaneously used. This is also called multi-rule QC.

Multi-rule QC types compare different QC measurements and refer to the relative scale of QC results.

Supported multi-rule QC types:

1. Standard deviation (MxNs):

   Matches a series of M consecutive values, each having a deviation of more than N-times the standard deviation (N*s) above or below the mean value. The rule matches only if the deviation of all values is on the same side of the mean (either all above or all below). Example:2*2s - Two consecutive values with a deviation of more than 2*s either both above or both below the mean value.

2. Distance (RxNs). The distance R (difference) between two consecutive values is greater than N-times the standard deviation (N*s).

   Example: Rx4s - Two consecutive values that are more than 4s apart.

3. Proportion (Fraction) (MofNxPs). Matches a series of M consecutive values with at least N of them having a deviation of more than P-times the standard deviation (P*s). All deviations must be on the same side of the mean value (either all above or all below).

   Example:

   2of3x2s - At least two values out of three values are more than 2s below/above the mean value.

4. Unilateral trend (Mxbar). Matches a series of M consecutive values that are all on the same side of the mean (all above or all below the mean value).

   Example:

   10xbar - 10 consecutive values are all above the mean value or all below the mean value.

5. Monotonic trend (Mmono). M consecutive values that are strictly monotonically increasing or decreasing.

   Example: 10mono - 10 consecutive values each higher than the immediately preceding value or each lower than the immediately preceding value.

When defining multi-rules QC based on the multi-rule types, the user specifies the multi-rule parameters (M, N, P), thus creating distinct QC rules.

Each multi-rule QC can be specified to be across QC.

- Across QC means that the rule applies to other QC lots for that test. For example, if you have both a Precinorm and Precipath QC defined for a test, the results for each of them are evaluated together. If, for example, you have a 2 x 2s rule defined, the rule will be triggered if one Precinorm QC value and a consecutive Precipath result are both 2 standard deviations from the mean.

Abbreviation for rule method	Meaning of rule
Stand. dev.	n x ks. A warning or error is raised if a certain number of consecutive results n are more than a certain number of standard deviations k from the mean. From the drop-down lists, select the values of n and k.
Distance	R x Ks A warning or error is raised if two consecutive results are separated by more than K standard deviations. From the drop-down list, select the value of K.
Proportion	p out of n x ks A warning or error is raised if a certain subset p out of a number of consecutive results n are more than a certain number of standard deviations k from the mean. For example, if 2 out 3 consecutive results are more than 2 standard deviations from the mean. From the drop-down lists, select the values of p, n, and k.
Mxbar	A warning or error is raised if a certain number of consecutive QC value results m are all the same side of the mean. From the drop-down list, select the value of m.
Mmono	A warning or error is raised if a certain number of consecutive QC value results m show a consistent rising or falling trend. For example, if each of 4 consecutive QC results are higher than the previous ones. From the drop-down list, select the value of m.

Creating a QC rule

Different types of QC rules monitor different kinds of statistical errors, for example: systematic shifts in the mean response of a process, monotonic increases in the random error of a process, or linear drift effects in the mean response of a process over a time frame. When different QC rule types are combined, the sensitivity to detect systematic errors that are not due to random processes and have to be handled by the laboratory staff is increased.

You create QC rules to add user-defined rules which help to better assess the quality and stability of routine analytical methods, using QC samples.

To create a QC rule

1 Choose **Monitoring** > **Rules**.

The **Rules: {0}** panel is displayed containing list of all defined rules.

2 Choose the **Add** button.

The **Rule: {0}** panel is displayed.

3 Enter the **Name**, the **Type**, the **Rule** and the **Description** for the new rule, and then do one of the following:

If no description is inserted the system adds “missing”.

- To compare the QC results returned by all QC lots select the **Across QCs** check box.
  or,
- To compare the QC results returned by a single QC lot deselect the **Across QCs** check box.

4 Choose the **Save** button.

The new rule is saved.

Editing QC rules

You edit a QC rule to change its corresponding information. You can only edit the user created rules. The pre-configured rules cannot be edited.

To edit QC rules

1 Choose **Monitoring** > **Rules**.

The **Rules: {0}** panel is displayed containing a list of all defined rules.

2 Choose the rule you want to edit.

The **Rule: {0}** panel is displayed.

3 Choose the **Edit** button.

The rule details become editable.

4 Edit the rule information, and then choose the **Save** button.

The rule is edited and the changes are saved.

Deleting QC rules

A QC rule can only be deleted if it has not been assigned and used. The pre-configured rules cannot be deleted.

To delete a QC rule

1 Choose **Monitoring** > **Rules**.

The **Rules: {0}** panel is displayed containing list of all defined rules.

2 Choose the rule you want to delete, and then choose the **Delete** button.

The **Delete QC rule?** callout is displayed asking you to confirm the deletion.

3 Choose the **Confirm** button.

The rule is deleted.

About profiles

Profiles group a set of QC rules which are applied to one or more combinations of tests and instruments. A default profile is pre-defined and it contains all test-instrument combinations which are not assigned to user-defined profiles and two QC rules: 1x2s and 1x3s. The default profile can be adapted to reflect the laboratory needs.

Creating a profile

You create a profile in order to assign a set of rules to certain tests/ instruments combinations via this profile.

Term	Definition
Validation lock	Enables you to block patient results from automatic release if there are invalid QC results, except the QC material used as study. Do not disable the QC **Validation lock** option.
Automatic release	Enables QC results within the defined ranges to be released automatically.
QC bracketing	Enables you to release a patient result only after both the previous and the next QC results are available and valid.

Table 6-1 Terms used in the **Profile: {0}** panel.

To overrule the QC bracketing, in the **Tests: {0}** panel when editing a test choose the **More...** button>> **Overrule QC bracketing**.

To create a profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose the **Add** button.

The **Profile: {0}** panel is displayed.

3 Enter the **Name**, and optionally, the **Validation lock**, **Automatic release**, and the **QC bracketing** check boxes.

4 To assign QC rules to the profile, choose the **Assign QC rules** task button.

The **Rules: {0}** panel is displayed containing a list of all the QC rules.

5 Do one of the following:

- To assign only certain rules, choose one or more the rules, and then choose the **Assign** button.
  or,
- To assign all the rules at once, choose the **Assign all** button.

6 To assign test-instrument combinations to the profile, choose the **Assign test/instrument** task button.

The **Test/instrument assignments: {0}** panel is displayed containing a list of instruments that fit the default filter criteria.

7 Do one of the following:

- To assign only certain instruments, choose one or more rules, and then choose the **Assign** button.
  or,
- To assign all the instruments at once, choose the **Assign all** button.

8 Choose the **Save** button.

The profile is created.

Enabling QC bracketing mode

Enables you to release a patient result only after both the previous and the next QC results are available and valid.

To enable QC bracketing mode

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose the profile for which you want to enable **QC bracketing**.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button, then choose the **QC bracketing** check box, and then choose the **Save** button.

The **QC bracketing** mode is enabled

Overruling QC bracketing mode

It enables you to overrule the missing QC results and to remove the evaluation block from patient results which depend on those QC results.

Overruling QC bracketing

You must have the necessary user rights to overrule QC bracketing.

You can overrule the QC bracketing in the **Tests: {0}** panel when editing a test choose the **More...** button>> **Overrule QC bracketing** option.

To overrule QC bracketing mode

1 Choose **Routine** > **Release tests by sample**.

The **Samples: {0}** panel is displayed containing a list of all samples that fit the default filter criteria.

2 Choose the details arrow > of the sample containing the test you want to overrule the QC bracketing mode.

The details of the sample and its tests are displayed.

3 Choose the test or tests for which you want to overrule the QC bracketing mode, and then choose the **More...** button>> **Overrule QC bracketing** option.

The **Overrule QC bracketing** callout is displayed.

4 Choose the **Confirm** button.

The QC bracketing mode is overruled.

Assigning QC rules to an existing profile

You want to assign QC rules to an existing profile in order to determine which QC rule monitors which test/instrument combination.

For every assigned rule you must select either the **Error** or **Warning** status in the **Alert level** column, which determines the consequences for the open requests in case the rule is not fulfilled.

The **Warning** error status indicates the violation of a rule, but does not affect the release of results. The status indicates that the measured result triggered a 'rules' error and should be monitored. The **Error** status indicates the violation of a rule (as configured to an error) is triggered and the system locks the test. The status indicates that action is required.

To assign QC rules to an existing profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile you want to assign.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 Choose the **Assign QC rules** task button.

The **Rules: {0}** panel is displayed containing a list of all the QC rules.

5 Do one of the following:

- To assign one or more rules, choose the rule or rules, and then choose the **Assign** button.
  or,
- To assign all the rules at once, choose the **Assign all** button.

6 Choose the **Save** button.

The QC rules are added to the profile.

Deleting QC rule assigned to a profile

You delete the rules assigned to a profile, including the DEFAULT profile when they are not used by the profile.

To delete QC rule assigned to a profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile for which you want to delete assigned QC rules.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 Choose the rule or rules you want to delete, and then choose the **Delete rule assignment** button.

The rule or rules are deleted from the profile.

Assigning test/instrument combinations to an existing profile

You want to assign test/instrument combinations to an existing profile in order to apply the QC rules, time-based configuration, and other QC settings (the Validation lock, Automatic release, and QC bracketing) defined for that particular profile, to those test/instrument combinations.

Every new test/instrument combination is assigned by the system to the DEFAULT profile.

To assign test/instrument combinations to an existing profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile you want to assign.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 Choose the **Assign test/instrument** task button.

The **Test/instrument assignments: {0}** panel is displayed containing a list of all the instrument/test combinations.

5 Do one of the following:

- To assign only certain test/instrument combinations, choose one or more test/instrument combinations, and then choose the **Assign** button.
  or,
- To assign all the test/instrument combinations at once, choose the **Assign all** button.

6 Choose the **Save** button.

The test/instrument combinations are assigned to the profile.

Deleting assigned test/instrument combinations from an existing profile

You cannot delete test/instrument combinations from the DEFAULT profile. These test/instrument combinations are removed from the DEFAULT profile when assigned to other profiles.

To delete assigned test/instrument combinations from an existing profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile for which you want to delete assigned test/instrument combinations.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 Choose the test/instrument combination you want to delete, and then choose the **Delete test/instrument assignment** button.

The test/instrument combination is deleted.

Editing a profile

You edit a profile when its information changed, you want to assign or delete test/instrument combination, or you want to assign or delete QC rules to the profile.

To edit a profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile you want to edit.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 Enter the necessary information, and then choose the **Save** button.

The profile is edited.

Deleting a profile

You delete a profile when you no longer use it. The **Default** profile cannot be deleted.

To delete a profile

1 Choose **Monitoring** > **Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile you want to delete, and then choose the **Delete** button.

The **Delete QC profiles?** callout is displayed

3 Choose the **Confirm** button.

The profile is deleted.

About QC for standby reagent

Some analytical instruments support loading more than one reagent cassette for the same test. Loading multiple cassettes allows faster switching during operation and maintains high throughput (for example, cobas® 8000 modular analyzer series). Even when not in use, the inactive reagent cassette, called standby reagent, is calibrated and regularly checked against QC. The results are sent to the host in the same way as the QC results from the active reagent cassette, with specific information in the message. The host handles standby reagent QC results differently than active reagent QC results. Otherwise, standby reagent QC results interfere with QC evaluation (QC rules, QC bracketing). The interference can lead to the automatic release of patient results although the corresponding QC results for the active reagent were not valid.

QC results from the standby reagents have to be stored in the system. QC results from standby reagents must not be used for patient result evaluation as long as the reagent cassette is not active. When the standby reagent sends an erroneous QC result, it is not necessary to lock the QC processes on the running system. You must review the QC results from a standby reagent and trigger adequate actions in case of error. When the reagent cassette is activated, the previously sent QC results are used for patient result evaluation. To avoid interference with patient result processing, handle QC results from standby reagent separately from the active reagent QC result.

To identify the reagent cassette, each QC or patient result message sent by the instrument includes information about the reagent cassette sequence number of.

Assigning a rule to a standby reagent

To assign a rule to a standby reagent

1 Choose **Monitoring > Profiles**.

The **Profiles: {0}** panel is displayed containing all profiles that fit the default filter criteria.

2 Choose a profile you want to edit.

The **Profile: {0}** panel is displayed.

3 Choose the **Edit** button.

The profile information becomes editable.

4 From the **Rule for standby evaluation** drop-down list, choose a rule, and then choose the **Save** button.

The rule is assigned to the standby reagent.

About QC study lots

A QC study lot is used to test a new QC lot before using it on an instrument. Test results are not compared against it and it is not included in cumulative QC statistics.

Changing an active QC lot into a QC study lot

To change an active QC lot into a QC study lot

1. Choose **Monitoring** > **QC instrument assignment**.

   The **QC instrument assignment: {0}** panel is displayed containing a list of instruments that fit the default filter criteria.

2. Choose an instrument for which you want to change the QC lot to study, then choose the **Edit** button, and then from the **Usage** drop-down list choose the **Study** option.

3. Choose the **Save** button.

   The active QC lot is changed into QC study lot.

Removing instrument QC lot connection

To remove instrument QC lot connection

1. Choose **Monitoring** > **QC instrument assignment**.

   The **QC instrument assignment: {0}** panel is displayed containing a list of instruments that fit the default filter criteria.

2. Choose an instrument for which you want to remove the QC study lot, then choose the **Edit** button, and then from the **Remove** button.

3. In the **Remove instrument lot connections** callout, choose the **Confirm** button.

   The instrument lot connection is removed.

About QC

QC samples are widely used in laboratories to assess the quality and stability of routine analytical methods. A QC is described by:

- QC material
- QC lot information
- Test information
- QC reference ranges of the test.

The QC material is a sample that is produced and used especially for the purpose of QC. Each QC material has a distinct sample type and a defined purpose for which it is used. This includes the test, its QC reference ranges, and the instruments that are covered with a distinct QC material. A certain amount of a QC material that was produced in a single coherent process is referred to as QC lot. As a QC lot is always related to a distinct QC material, it refers to a distinct sample type.

The purpose of a QC run is to evaluate whether the settings of the laboratory workflow are still valid to run patient samples. For that purpose a defined QC material is measured under predefined conditions that do not vary.

To judge whether a QC run is valid, the QC reference range of the test for a distinct QC material-QC lot combination has to be known. The QC reference range is defined by the target value and the standard deviation and is either provided by the manufacturer of the QC material or calculated from laboratory internal results. The measured QC has a validity time frame within which it can be used as reference for patient samples. Each test measured with a QC material has reference values which can change when different QC lots of a QC material are used, or when the manufacturer sends an update for the reference ranges or internal reference values are calculated by the laboratory.

Viewing QC results in a Levey-Jennings chart

When you view QC results in a Levey-Jennings chart, you have a graphical overview of QC results, you can view failed QC results, and you can compare QC results. This view enables identification of measurement trends and deviations.

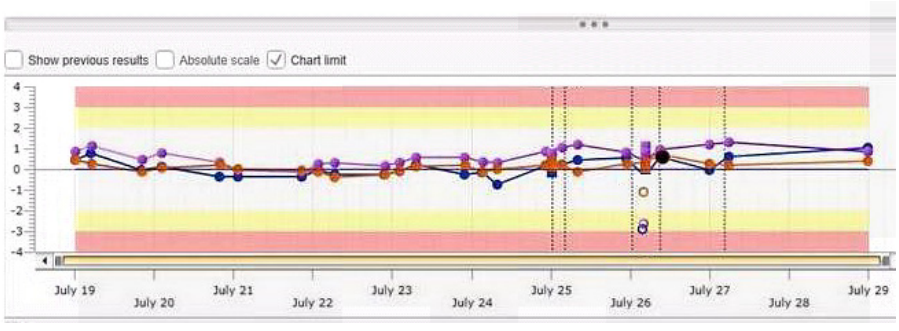


Figure 6-1 Levey-Jennings chart

The yellow area of the chart represents the range of 2 to 3 standard deviations. The red area of the chart represents the range of greater than 3 standard deviations.

The symbols used in the chart represent the following:

- Full circle: active current result.
- Empty circle: inactive current result.
- Full square: active standby result.
- Empty square: inactive standby result.
- Vertical broken line: bottle change.

To zoom into parts of the chart drag the mouse across it.

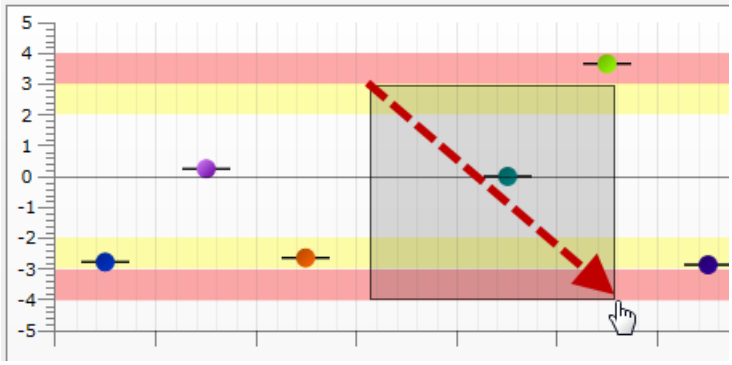


Figure 6-2 Zooming chart.

The QC results displayed in the Levey-Jennings chart are dependent on the filtering criteria used.

Standardized calculated SD = Calculated SD/Target SD.

Term	Abbreviation	Formula	Definition
Target mean (target value)	x_0		Target value of a control.
Target standard deviation	target SD		Standard deviation of the target value of a control.
Calculated arithmetic mean	$\bar{x}$	= AVERAGE of the relevant QC results.	Mean of cumulative QC results.
Calculated standard deviation	SD	$\sqrt{\frac{1}{N-1}\sum_{i=1}^{N}(x_i-\bar{x})^2}$	Standard deviation of cumulative QC results. X_i equals singular QC result.
Standard deviation index	SDI	$\frac{(x-x_0)}{SD_{x_0}}$	$x = \bar{x}$ x_o = target value SD_{x_0} = standard deviation of target value
Bias		$\frac{(\bar{x}-x_0)}{x_0}$	x_0 = target value
Coefficient of variation	CV	$\frac{SD \times 100}{\bar{x}}$	Percentage (%)
Number of values	N	= number of all QC results that are included in the statistics for a distinct control	A QC is a unique combination of control material, QC lot, instrument, and analyte.

Table 6-2 Cumulative QC statistics - formulas.

To view QC results in a Levey-Jennings chart

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter QC data, see *Filtering QC* (p. 20)

2 Choose the icon, of the QC result you want to view in a Levey-Jennings chart.

All results of the same QC / lot / instrument/ test are displayed in the Levey-Jennings chart.

Viewing QC results details

It enables you to get more specific details about the QC result. The following QC result details are displayed:

- QC result and QC result status
- Information whether this QC result is included into further processing (cumulative QC statistics, patient result locking)
- Information whether and by whom the QC result was reviewed
- QC material and QC lot information
- Instrument and test
- QC rules that were applied on the QC result and their status
- Cumulative QC statistics
- Comments regarding the QC result
- Data alarms

To view QC result details

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter QC data, see *Filtering QC* (p. 20)

2 Choose the QC result for which you want to view details.

The **QC result: {0} on {1} : {2}** panel is displayed containing detailed information about the QC result.

Viewing patient results associated with a QC result

When a QC result with patient results associated to it is excluded from further processing, the previous QC result included in further processing determines the lock of patient result validation according to the QC rule states.

To view patient results associated with a QC result

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter QC data, see *Filtering QC* (p. 20)

2 Choose the QC result for which you want to view details.

The **QC result: {0} on {1} : {2}** panel is displayed containing detailed information about the QC result.

3 Choose the **Tests** task button.

The **Tests: {0}** panel is displayed containing the patient results associated with that QC result.

Viewing the history of a QC result

You want to view the history of a QC result to have an overview of the events associated with that QC result.

To view the history of a QC result

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter QC data, see *Filtering QC* (p. 20)

2 Choose the QC result for which you want to view details.

The **QC result: {0} on {1} : {2}** panel is displayed containing detailed information about the QC result.

3 Choose the **View history** task button.

The **History** panel is displayed containing the events associated with that QC result.

Reviewing QC results

You review QC results to check them prior validation.

To review QC results

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Choose the QC result you want to review, then choose the **Review** button.

The QC result is reviewed.

Analyzing QC violations

You analyze QC violations in order to troubleshoot, based on the information provided by the system.

To analyze QC violations

1 From the global information area, choose **Overview**.

The list of tasks is displayed.

2 Choose the **QC violations** task button.

The **QC results: {0}** panel is displayed containing the newest, reviewed, and unreviewed, result for each QC where a QC error has produced a QC lock.

3 Click the details arrow of the failed QC result you want to analyze.

The **QC result: {0} on {1} : {2}** panel is displayed containing QC result details.

Adding a comment to a QC result

You add a comment to a QC result in order to attach significant information to that result.

For QC results with added comments, a comment icon is displayed in the **Sample list**. If you choose the comment icon, it shows its content.

To add a comment to a QC result

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Choose a QC result, and then choose the **Comment** button.

The **Add comment** callout is displayed.

3 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The comment is added.

Inactivating QC results

You inactivate a QC result when it is not used in test validation and must be excluded from cumulative QC statistics.

To inactivate QC results and exclude them from statistics

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Choose a QC result that you want to inactivate, and then choose the **Inactivate** button.

The **Add comment** callout is displayed.

3 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The QC result is deactivated.

Activating QC results

You activate a QC result to use it for test result validation and to include it in cumulative QC statistics.

To activate QC results

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter the QC results, see *Filtering QC* (p. 20)

2 Choose a QC result that you want to activate, and then choose the **Activate** button.

The **Add comment** callout is displayed QC result is activated.

3 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The QC result is activated.

Unlocking QC results

QCs can be locked:

- When the QC result status of the most recent QC is “error”,
- Due to a violation of the time-based rules, or
- By data alarms sent by the instrument which have been configured to lock QCs ('block QC').

If configured, the QC result status “error” also locks the validation of the patient results that are associated with that particular QC result.

On the table on the **QC results: {0}** panel (**Routine > Review QC results**), the QC status of a locked QC shows a red locked symbol ( ). The QC status of an unlocked QC shows a green unlocked symbol ( ). A manually unlocked QC has a green check mark ( ) in the "Manually released" column.

You unlock QC results to manually release its QC lock. You can only unlock the most recent QC. The manual release of the QC lock releases the patient result validation lock, and it enables patient results validation again. Manual release requires a comment to justify the action.

To unlock QC results

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Select the QC material or materials that you want to unlock, and then choose the **Unlock** button.

The **Add comment** callout is displayed.

3 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The QC result or QC results are unlocked.

Unlocking QC results for a test-instrument combination

To unlock QC results for a test-instrument combination

1 Choose **Routine > Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Filter for the QC results available for the configured QC lot and test-instrument combination.

3 Select the QC material or materials that you want to unlock, and then choose the **Unlock** button.

The **Add comment** callout is displayed.

4 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The QC result or QC results are unlocked.

Entering QC results manually

You enter a QC result manually when there is no communication between an instrument and the system, for example, offline instruments and workplaces. Manually entered results that are within the reference range and do not violate any QC rules, are released automatically by the system and can be used to release test results.

To enter a QC result manually

1. Choose **Routine** > **Enter QC results manually**.

   The **Enter QC results manually** panel is displayed.

2. From the **Instrument** drop-down list, choose an instrument.

   Instrument-specific QC material information is displayed.

3. Choose the QC lot to which you want to add a result manually.

   The **Result** field becomes editable.

4. In the **Measurement date/time** choose the date and time for the QC result, in the **Result** field, enter the QC result, and then choose the **Save** button.

If no date and time is chosen, the current date and time of the system is used.

The QC result is saved.

Sending manually entered QC results to the host

To prevent potential errors by blocked results being sent to the host system, manually entered QC results have to be sent to the host manually.

To send manually entered QC results to the host

1. Choose **Routine > Review QC results**

   The **QC results:** panel is displayed.

2. On the **QC results:** panel, from the list of QC results, select the QC results to be manually sent to the host.

   The buttons beneath the list of QC results become active.

3. From the **Send to host** drop-down list, choose the **Send unsent** option or the **Send all** option.

   The QC result is sent to the host.

Rejecting manually entered QC results

When you reject manually entered QC results, you disable their use in result validation and exclude them from cumulative QC statistics.

To reject manually entered QC results

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Choose the QC material containing manually entered test results that you want to reject, and then choose the **Inactivate** button.

The **Add comment** callout is displayed.

3 To add a comment, do one of the following:

- Enter a comment, and then choose the **Save** button.
  or,
- Choose a predefined comment, and then choose the **Save** button.

The QC result is rejected.

Printing a QC result report

You can print a QC result report to obtain an overview of the QC results, sorted by different filtering criteria, which you can use for regulatory purposes, inventory, or further analysis and troubleshooting.

The PDF plug-in on Internet Explorer can interfere with the correct printing of the grid-view. To prevent this interference, deactivate the plug-in.

To print a QC result report

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

To filter QC data, see *Filtering QC* (p. 20)

2 To print a QC result report, do one of the following:

- Choose the **Print list** button >> **Print list** option.
  or,
- Choose the **Print list** >> **Print graph** option.

The report is sent to the printer.

Viewing cumulative QC statistics

You view cumulative QC statistics results to compare them with the configured target value and QC reference ranges, and for record keeping.

To view cumulative QC statistics

1 Choose **Routine** > **View cumulative QC statistics**.

The **Cumulative QC statistics overview** panel is displayed.

2 Choose the QC for which you want to view cumulative statistics.

The cumulative QC statistics for that QC is displayed.

Filtering cumulative QC statistics

You can filter the cumulative QC statistics using the following criteria:

- Date range
- From
- Instrument
- Instrument group
- QC
- QC lot
- Test
- To

To filter cumulative QC statistics

1 Choose **Routine** > **Cumulative QC statistics overview**.

The **Cumulative QC statistics overview** panel is displayed.

2 To open the cumulative QC statistics filter, at the top of the **Cumulative QC statistics overview** panel, choose the ⩔ button.

3 Define the filtering criteria and choose the **Apply** button.

The list of QC statistics is filtered.

Applying the calculated mean to cumulative QC statistics

You apply the calculated mean and/or the SD (standard deviation) to cumulative QC statistics when you want to define a laboratory' s own target value and QC reference ranges as these are more restrictive than the ones provided by the manufacturer.

To apply the calculated mean and / or SD to cumulative QC statistics

1 Choose **Routine > View cumulative QC statistics**.

The **Cumulative QC statistics overview** panel is displayed.

2 From the list of results on the **Cumulative QC statistics overview** panel, choose the statistics to be evaluated and then choose the **Calculate mean and SD** button.

The **View cumulative QC statistics** panel is displayed.

3 Choose the cumulative QC statistics of a QC lot to which you want to apply the calculated mean, and then choose the **Apply calculated mean** button.

The **Apply calculated mean** dialog box is displayed.

4 Do the following:

- To apply the target value and the standard deviation, choose the **Apply calculated mean and SD** button.
  or,
- To apply only the standard deviation, choose the **Apply SD only** button.

The calculated mean and/or standard deviation is applied.

Applying the calculated mean and SD to cumulative QC statistics across instruments

To apply the calculated mean and SD to cumulative QC statistics across instruments

1 Choose **Routine > View cumulative QC statistics**.

The **Cumulative QC statistics overview** panel is displayed.

2 From the list of results on the **Cumulative QC statistics overview** panel, choose the statistics to be evaluated and then choose the **Calculate mean and SD across instruments** button.

You can only choose statistics from the same QC lot.

The **Cumulative QC statistics across instruments** panel is displayed.

3 On the **Cumulative QC statistics across instruments** panel, choose the cumulative QC statistics of a QC lot and do one of the following:

- Choose the options for the **Location** drop-down list, the **Instrument type** drop-down list, and the **Instrument** drop-down list.
  or,
- Choose the **Assign category** button, and fill in the options using the **Assign category** dialog box.

4 Choose the **Apply calculated mean and standard deviation.** button.

Viewing time-based rules warning status

For more information about the Time based rules, see *Viewing time-based rules profiles* (p. 132).

To view time-based rules warning status

1 Choose **Routine** > **Time based rules warning status**.

The **Time based rules warnings: {0}** panel is displayed containing a list of QC lots and their corresponding warning that fit the default filter criteria.

Viewing time-based rules profiles

Use time-based rules profiles to define the time-based rules for QC tests. Only non-overlapping QC intervals can be used.

Term	Definition
Min. daily measurements	The minimum required QC test runs in a 24-hour time frame.
Warning time (h)	A warning is displayed this number of hours before the next QC test run is due.
Start time	Time when the QC test must begin.
End time	Time by which the QC test must be completed.
QC Interval (h)	The maximum period of time between two QC test runs. When this time period has elapsed and no QC test was run, the QC lot is locked.
Warning time (h)	A warning is displayed this number of hours before the next QC test run is due.
Grace period	Time after the end time by which the QC lot is locked if no QC test was run.

Table 6-3 Terms used in the **Time-based rule** panel.

To view time-based rules profiles

1 Choose **Monitoring** > **Time-based rule profile**

The **Time-based rule profiles: {0}** panel is displayed containing a list of profiles.

2 Select the profile and choose the forward > button

The **Time-based rule profile** panel is displayed.

Creating time-based rules profiles

Use this function to assign a new time-based rules profile.

For more information about the terms used in the **Time-based rule** panel, see *Viewing time-based rules profiles* (p. 132).

To create time-based rules profiles

1 Choose **Monitoring** > **Time based rule profile**

The **Time-based rule profiles: {0}** panel is displayed containing a list of profiles.

2 At the bottom of the **Time based rule profiles: {0}** panel, choose the **Create** button.

The **Time based rule profile** panel is displayed.

3 In the **Time based rule profile** group box, fill in the **Profile name**: field and the **Enabled**: check box.

4 In the **Interval type** group box, select one of the following options:

- **Daily measurement** option: If you choose the **Daily measurement** option, the **Min. daily measurements** field and the **Warning time (h)** field are displayed.
  or,
- **Interval** option: If you choose the **Interval** option, the **Delete** button and the **Create** button are displayed.

5 If you want to define the profile using the **Daily measurement** option, fill in the **Min. daily measurements** field and the **Warning time (h)** field.

6 If you want to define the profile using the **Interval** option, choose the **Create** button and fill in the **Interval** dialog box. When complete, choose the **Assign** button.

7 Below the **Control material/instrument/test assignment** group box, choose the **Assign** button.

The **Assignment** dialog box is displayed.

8 Fill in the **Assignment** dialog box and choose either the **Assign and create** button or the **Assign** button.

9 Choose the **Save** button.

Editing time-based rules profiles

Use this function to change an existing time-based rules profile.

For more information about the terms used in the **Time-based rule** panel, see *Viewing time-based rules profiles* (p. 132).

To edit time-based rules profiles

1 Choose **Monitoring > Time-based rule profile**

The **Time-based rule profiles: {0}** panel is displayed containing a list of profiles.

2 Select the profile and choose the forward > button

The **Time-based rule profile** panel displays

3 At the bottom of the **Time-based rule profile** panel, choose the **Edit** button.

4 To change the profile name or enabled status, in the **Time-based rule profile** group box, fill in the **Profile name**: field and the **Enabled**: check box.

5 To change the interval type, in the **Interval type** group box, select one of the following options:

- **Daily measurement** option: If you select the **Daily measurement** option, the **Min. daily measurements** field and the **Warning time (h):** field display.
  or,
- **Interval** option: If you select the **Interval** option, the **Delete** button and the **Create** button display.

6 If you want to change the profile using the **Daily measurement** option, fill in the **Min. daily measurements:** field and the **Warning time (h)** field.

7 If you want to change the profile using the **Interval** option, choose the **Create** button and fill in the **Interval** dialog box. When complete, choose the **Assign** button.

8 Below the **Control material/instrument/test assignment** group box, choose the **Assign** button.

The **Assignment** dialog box displays.

9 Fill in the **Assignment** dialog box and choose either the **Assign and create** button or the **Assign** button.

10 Choose the **Save** button.

About calibration

Some Roche instruments can send reagent and calibrator data additionally to the patient and QC results, for example **Elecsys**® 1010 analyzer, **Elecsys**® 2010 analyzer, **cobas** e 411 analyzer, in the manufacturer messages, and **cobas**® 8000 modular analyzer series.

For the other instruments, data cannot be extracted directly.

For calibration data, instruments send the following: calibrator ID, lot number, expiry date, used reagents, instrument/module ID, user ID.

Patient or QC result are sent with corresponding calibration ID. This ID enables the system to find the corresponding calibration data and display it with the result.

Viewing QC calibration information

To view QC calibration information

1 Choose **Routine** > **Review QC results**.

The **QC results: {0}** panel is displayed containing a list of all QC results that fit the default filter criteria.

2 Double-click a QC result for which you want to see calibration information.

The **QC result: {0} on {1} : {2}** panel is displayed containing detailed information about the QC result.

3 Choose the **Calibration** task button.

The **Calibration** panel si displayed.

Consumption report

This chapter describes the electronic consumption report which is a statistic of test results, which have been processed by the system and reported to a connected host system.

In this chapter

Chapter **7**

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About the consumption report

This report enables you to trace the consumption of instruments in order to:

- Ensure the collection of the data coming from the connected instruments,
- Provide a secure storage on which consumption statistics can be reliably (100%) reported,
- Report or export statistics for the users,
- Report statistics for the electronic cost per reportable invoicing model,
- Improve the quality management with information like calibration, QCs, rerun.

Report information

If system performs a patient test, a rerun test or test results are resent, the system stores the following information:

- Type of event (patient result, rerun, re-send)
- Test result (mandatory)
- Test name (as in customer-specific test configuration, mandatory)
- Sample ID (mandatory)
- Date time of pipetting/measurement (optional)
- System date-time when message is received (mandatory, different time is assigned for rerun and resent messages)
- Test application code / ACN (instrument reference for the reagent, configured in instrument configuration, mandatory)
- Instrument name (main instrument and module, mandatory)
- Instrument type (mandatory)
- Instrument serial number (if available, optional)
- Collector ID (sample source location, mandatory)
- Orderer group (optional)
- Orderer (mandatory)

If the system performs a QC test or calibration, the system stores the following information:

- Type of event (QC result, calibration)
- Test result (mandatory)
- Test name (as in customer-specific test configuration, mandatory)
- Date time of pipetting/measurement (optional)
- System date-time when message is received (mandatory, different time is assigned for rerun and resent messages)
- Test application code / ACN (Instrument reference for the reagent, configured in instrument configuration, mandatory)
- Instrument name (Main instrument and module, mandatory)
- Instrument type (mandatory)
- Instrument serial number (if available, optional)

Viewing the list of consumption report

You can view the list of consumption reports which were created during the last 13 months.

To view the list of consumption report

1 Choose **Monitoring** > **Consumption report**.

The **Consumption reports** panel is displayed containing all reports that fit the default filter criteria.

Releasing a consumption report manually

You release a consumption report manually when you want to inspect it before sending or saving it.

The consumption report can be released automatically. Roche Service representative can configure the automatic release of the consumption report.

To release a consumption report manually

1 Choose **Monitoring** > **Consumption report**.

The **Consumption reports** panel is displayed containing all reports that fit the default filter criteria.

2 Choose the report you want to release manually, and then choose the **Release** button.

The report is released.

Duplicate report found

After upgrading a system to version 1.03.03, a duplicate report might appear. This is nothing to worry about. Ignore the second report.

Duplicate report found after upgrading to version 1.03.03

After upgrading a system to version 1.03.03, a duplicate report might appear. The two reports are identical, except that the release date is different, if automatic release was enabled.

1 Ignore the second report.

This is nothing to worry about. It does not occur in other versions.

Configuration

Configuration

In this chapter you can find information about laboratory configuration, test configuration, reference ranges configuration, validation status configuration, serum indices, instrument configuration, sample configuration, routine configuration, user administration rights, system configuration, forms, and reports.

In this chapter

Chapter **8**

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Laboratory configuration

Locations are configured to assign instruments, tests, and sample types to the laboratory location to which they belong. Users and workplaces are also assigned to a location.

Time synchronization

Keep time synchronized between all systems. Manually ensure the time settings of the **cobas IT** middleware, the instruments, and LIS are closely synced.

The system lists the following location types by default:

- Laboratories
- Instrument groups

Locations cannot be changed

Once a new location is entered and saved, the location name cannot be edited.

Inserting a laboratory location

Enables you to insert and define all laboratory locations.

To insert a laboratory location

1 Choose **Lab configuration** > **Locations** > **Lab**.

The **Locations** work area is displayed.

2 Right-click in the work area, and then choose **Insert new location** from the shortcut menu.

The **Location** dialog box is displayed.

3 Enter the required information, then choose the **OK** button.

Once you enter and save the **Location** and the **Type**, you cannot change them.

The data is saved and the new laboratory location is displayed in the **Locations** work area.

Inserting an instrument group

Enables you to insert and define all instrument groups.

To insert an instrument group

1 Choose **Lab configuration** > **Locations** > **Instrument Groups**.

The **Instrument groups** work area is displayed.

2 Right-click in the work area, and then choose **Insert new instrument group** from the shortcut menu.

The **Edit instrument group** dialog box is displayed.

3 Enter the required information, then choose the **OK** button.

The data is saved and the new instrument group is displayed in the **Instrument groups** work area.

Creating an organization

It enables you to insert and define an organization.

To create an organization

1 Choose **Lab configuration** > **Organization**.

The **Organization** work area is displayed.

2 Right-click in the work area, and then choose **Insert new organization** from the shortcut menu.

The **Organization** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The data is saved and the new organization is displayed in the **Organization** work area.

Editing an organization

It enables you to edit an organization for a specific location type. You cannot change the organization name or type.

To edit an organization

1 Choose **Lab configuration** > **Organization**.

The **Organization** work area is displayed.

2 Right-click in the work area, and then choose **Edit organization** from the shortcut menu.

The **Organization** dialog box is displayed.

3 Enter the new information, and then choose the **OK** button.

The new information is saved in the system.

Deleting an organization

It enables you to delete an organization for a specific location type.

To delete an organization

1 Choose **Lab configuration** > **Organization**.

The **Organization** work area is displayed.

2 Right-click in the work area, and then choose **Delete organization** from the shortcut menu.

The organization is deleted.

Creating orderer groups

You create orderer groups to distinguish orderers into logical groups for statistical evaluations and result reports.

To create orderer groups

1 Choose **Lab configuration** > **Orderer groups**.

The **Orderer group** work area is displayed.

2 Right-click in the work area, and then choose **Insert new orderer group** from the shortcut menu.

The **Orderer group** dialog box is displayed.

3 Enter the **Orderer group no.**, the group **Name**, and then close the dialog box.

The **cobas IT** middleware dialog box is displayed.

4 Choose the **Yes** button.

The data is saved and the new orderer group is displayed in the **Orderer groups** work area.

Creating a new orderer

You can insert a new orderer and enter the relevant details of the orderer for requesting certain tests. Orderers include, but are not limited to, doctors and external orderers.

To create a new orderer

1 Choose **Lab configuration** > **Orderer**.

The **Orderer** work area is displayed.

2 Right-click in the work area, and then choose **Insert new orderer** from the shortcut menu.

The **Orderer** dialog box is displayed.

3 Enter the required information, and then:

- To save the data and enter a new orderer, choose the **Apply** button.
  or,
- To save the data and close the dialog box, choose the **OK** button.

Configuring clinical data code

Enables you to insert new clinical data codes. You can edit an existing clinical data code by following the procedure below and choosing **Edit description for code** from the shortcut menu. To delete an existing clinical data code, choose **Delete code** from the shortcut menu.

To configure a clinical data code

1. Choose **Lab configuration** > **Clinical data**.

   The **Clinical data** work area is displayed.

2. Choose a clinical data type.

   The **Clinical data type** work area is displayed.

3. Right-click in the work area, and then choose **Insert new code** from the shortcut menu.

   The **Insert clinical data codes** dialog box is displayed.

4. Enter the **Code** and the **Name**, and then choose the **Insert** button.

   The **cobas IT** middleware dialog box is displayed.

5. Choose the **Yes** button.

   The data is saved and the new clinical data code is displayed in the **Clinical data type** work area.

Assigning an orderer to an orderer group

It enables you to assign an orderer to an existing orderer group.

Creating orderer groups (p. 149)

To assign an orderer to an orderer group

1. Choose **Lab configuration** > **Orderer**.

   The **Orderer** work area is displayed.

2. Choose an orderer.

   The **Orderer** dialog box is displayed.

3. From the **Group** drop-down list, choose an orderer group to which you want to assign the orderer, and then choose the **OK** button.

   The orderer is assigned to the orderer group.

Configuring patient gender

You configure patient gender if the default setting does not support the exchange of data with the host system. To edit an existing gender, follow the procedure below and choose **Edit gender** from the shortcut menu.

To configure patient gender

1 Choose **Lab configuration** > **Gender**.

The **Gender** work area is displayed.

2 Right-click in the work area, and then choose **Insert new gender** from the shortcut menu.

The **Gender** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The patient gender is configured.

Entering a new doctor, manufacturer, or supplier

You can enter, modify or delete a doctor, manufacturer or supplier. All these entries are assigned to a patient. A filter allows you to display all entries or just the active entries. Please note all inactive entries (doctor, manufacturer, and supplier) cannot be used and must first be set to active again.

Host code and Host name fields

The host code is a unique key assigned to every doctor, supplier, or manufacturer. When you do not enter a code, the system generates one. The **Host name** is the name of the doctor, supplier, or manufacturer in the host system. In most cases it is an acronym. The host name is also unique.

This information applies only when the system is connected to a LIS (laboratory information system) or HIS (hospital information system).

To edit a doctor, follow the procedure below and choose **Edit Ordering doctor** from the shortcut menu. To delete a doctor, choose **Delete Ordering doctor** from the shortcut menu.

To edit a manufacturer, follow the procedure below and choose **Edit Manufacturer** from the shortcut menu. To delete a manufacturer, choose **Delete Manufacturer** from the shortcut menu.

To edit a supplier, follow the procedure below and choose **Edit Supplier** from the shortcut menu. To delete a supplier, choose **Delete Supplier** from the shortcut menu.

To enter a new doctor

1 Choose **Lab configuration** > **Person management > Ordering doctor**.

The **Person management** work area is displayed.

2 Right-click in the work area, and then choose **New Ordering doctor** from the shortcut menu.

The **New Ordering doctor** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new doctor information is saved.

To enter a new manufacturer

1 Choose **Lab configuration** > **Person management > Manufacturer**.

The **Person management** work area is displayed.

2 Right-click in the work area, and then choose **New Manufacturer** from the shortcut menu.

The **New Manufacturer** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new manufacturer information is saved.

To enter a new supplier

1 Choose **Lab configuration** > **Person management > Supplier**.

The **Person management** work area is displayed.

2 Right-click in the work area, and then choose **New Supplier** from the shortcut menu.

The **New Supplier** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new supplier information is saved.

Entering a new priority

You can enter and define new priorities to be selected for test requests. New priorities are activated by default, but you can deactivate a priority in the system by using the shortcut menu.

To edit a priority, follow the procedure below and choose **Edit priority** from the shortcut menu. To deactivate a priority, choose **Deactivate priority** from the shortcut menu. To activate a priority, choose **Activate priority** from the shortcut menu.

Once a priority is entered and saved, you cannot delete it! The priority must be numeric. 0 (zero) is the highest priority.

New priorities are active by default.

To deactivate a priority in the system, right-click on a profile and choose **Deactivate priority** on the shortcut menu. The Active column is deselected for the priority.

To enter a new priority

1 Choose **Lab configuration** > **Priorities**.

The **Priorities** work area is displayed.

2 Right-click in the work area, and choose **Insert new priority** on the shortcut menu.

The **Priority** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new priority is saved.

Activating/deactivating or editing historical actions

You can activate or deactivate historical settings in the system to unlock or lock the logging of actions in the history.

To activate/deactivate or edit historical actions

1 Choose **Lab configuration** > **Order history**.

The **Overview history** work area is displayed.

2 Right-click a historical action, and then do one of the following:

- To activate a historical action, choose **Activate selected records** from the shortcut menu.
  or,
- To deactivate a historical action, choose **Deactivate selected records** from the shortcut menu.
  or,
- To edit a historical action, choose **Edit** from the shortcut menu.

Test configuration

It enables you to administer and maintain test groups, tests, reference ranges, profiles, comments, validation status, process status, rules, and serum indices.

In the **Tests / reference ranges configuration**, you can:

- Define/edit a test.
- Define / edit the reference ranges.
- Define / edit rules.
- Maintain comment texts.

Creating a test group

You can group tests into categories which enable a large number of tests to be displayed at the same time by the system.

To edit a test group, follow the procedure below and choose **Edit test group** from the shortcut menu. To delete a test group, choose **Delete test group** from the shortcut menu.

To create a test group

1 Choose **Test configuration** > **Test groups**.

The **Test groups** work area is displayed.

2 Right-click in the work area, and then choose **Insert new test group** from the shortcut menu.

The **Edit test group** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new test group is created.

Defining a test

In the **Test definition** dialog box, you can define a new test, edit or delete an existing test, define and edit reference ranges, and assign formulas / rules to the test.

To define a test

1 Choose **Test configuration** > **Tests / reference ranges**.

The **Test / reference ranges** work area is displayed.

2 Right-click in the work area, and then choose **Insert new test** on the shortcut menu.

The **Test / reference ranges** dialog box is displayed.

3 In the **Test No.** field, enter a unique test number.

4 In the **Abbreviation** field, enter an appropriate test abbreviation.

The abbreviation will be displayed in the **Rule engine**. Ensure the abbreviation identifies the test.

5 In the **Host code** field, enter the code for this test used by the host system to which the data is sent.

6 From the **Module** drop-down list, select the appropriate module.

7 In the **Test** field, enter a name for the test.

8 From the **Test group** drop-down list, select a group to which the selected test belongs.

9 From the **Sample type** drop-down list, select a sample type to which the selected test belongs.

You can use the (**...**) button to edit or add a new **Test group** or **Sample type** without closing the **Test / reference ranges** dialog box.

10 From the **Main test** drop-down list, select a main test.

The main test is used in QC. When there is a QC error in the main test, all assigned sub-tests will be blocked.

11 In the **Method/manufacturer** field, enter a manufacturer name.

12 From the **Decimal places** drop-down list, select the number of decimal places from 0...3.

13 Select the **Is confidential** check box if you do not want to include the defined test information and results in statistics.

14 In the **Units** field, enter the unit for the results.

15 From the **Is Serum Index** drop-down list, choose the serum index applicable to your test, and then do one of the following:

- To save the data and keep the dialog box open, choose the **Apply** button.
  or,
- To save the data and close the dialog box open, choose the **OK** button.
  or,
- To add a new test and keep the dialog box open, choose the **Add New** button

The new test is defined.

Defining automatic result processing

On the **Workflow** tab (**Tests / reference ranges**), you configure the automatic result release. Results within the defined ranges will be released automatically.

The following criteria must be fulfilled for automatic release:

Automatic release	Positive precondition must be fulfilled	Negative precondition must be fulfilled
Automatic release feature must be enabled	X	-
Validation range was used and NOT violated	X	-

Table 8-1 Precondition for an automatic release

Automatic release	Positive precondition must be fulfilled	Negative precondition must be fulfilled
Result is a repetition	-	X
Instrument data alarm (has to be defined accordingly)	-	X
QC error	-	X
Hemolysed (serum index)	-	X
Icteric (Serum index)	-	**X**
Lipemic (Serum index)	-	**X**
Manual result entry	-	**X**
Result is not in status 'In calculation'	-	**X**
Result is not 'SI needed' (SI= Serum index)	-	**X**
Automatic validation in pass-through mode		
QC error	-	**X**
Manual result entry	-	**X**
Validation status is not in status 'In calculation'	-	**X**
Validation status is not 'SI needed' (SI= Serum index)	-	**X**

Table 8-1 Precondition for an automatic release

To enable automatic release for manually entered results, set the following option: **Advanced configuration > Options > MODUL> AUTO_RELEASE_MANUAL_RESULTS**) to Y.

This setting applies to all manually entered results in the system.

To define automatic result processing

1 Choose **Test configuration** > **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Choose a test for which you want to define automatic release.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Workflow** tab.

The content of the tab is displayed.

4 In the **Validation of results** group box, select the **Automatic release** check box. All results will be automatically released if the following criteria are fulfilled:

- **Release repetitions**: Results from repeated tests will be automatically released.
- **Ignore result validation range**: This overrules the request of the result being compared to a validation range (without violation). All other release criteria must be met. This option is mostly used when results will be released on an external system.
- **Delta check blocks automatic result release**: Results with violated delta check settings will not be automatically released.

5 Choose the **OK** button.

The result is set to be processed automatically.

Defining and editing result texts

It enables you to define numeric or alphanumeric strings which can be inserted manually as results.

To define a result text

1 Choose **Test configuration** > **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Choose on a test for which you want to define result texts.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Result texts** tab.

The content of the tab is displayed.

4 Right-click the result texts table, and then choose **Insert new value** from the shortcut menu.

The **Text input** dialog box is displayed.

5 In the **Text** field, enter the alphanumeric test result, in the **Position** field, enter a number for the order in which the result texts appear in the **Result entry** dialog box, and then do the following:

- To save the data and add additional result texts, choose the **Apply** button.
  or,
- To save the data and return to the **Tests / reference ranges** dialog box, choose the **OK** button.

The result text is defined.

To edit result texts

1 Choose **Test configuration** > **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Double-click on a test for which you want to define result texts.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Result texts** tab.

The content of the tab is displayed.

4 Right-click the result texts table, and then choose **Edit value** from the shortcut menu.

The **Text input** dialog box is displayed.

5 Edit the **Text** and **Position** fields, and then do the following:

- To save the data and add additional result texts, choose the **Apply** button
  or,
- To save the data and return to the **Tests / reference ranges** dialog box, choose the **OK** button.

The result text is edited and the information is saved.

6 To delete a result text, right-click the result text in the table, and then choose **Delete value** on the shortcut menu. The result text is deleted without any prompt for confirmation.

Configuring a test profile

Test profiles enable you to group commonly requested tests such that you can order them at the same time rather than having to order each test individually.

To edit a test profile, follow the procedure below and choose **Edit profile** from the shortcut menu. To delete a test profile, choose **Delete profile** from the shortcut menu.

To configure a test profile

1 Choose **Test configuration** > **Profiles**.

The **Profiles** work area is displayed.

2 Right-click in the work area, and then choose **Insert new profile** from the shortcut menu.

The **Profiles** dialog box is displayed.

3 Enter the required information, and then do the following:

- To save the profile and enter another one, choose the **Apply** button.
  or,
- To save the data and return to the **Profiles** dialog box, choose the **OK** button.

The profile is created.

Creating a comment group

You can insert and define comment groups. To edit a comment group, follow the procedure below and choose **Edit group** from the shortcut menu. You cannot edit default comment groups. To delete a comment group, choose **Delete group** from the shortcut menu.

The 3 default comment groups are:

- All comments - all predefined comments independent of the group.
- Not assigned - all comments not related to a group.
- QC - comments for QC results.

To create a comment group

1 Choose **Test configuration** > **Comment texts**.

The **Comment groups** work area is displayed.

2 Right-click in the **Assigned comment groups** table, and then choose **Insert/Assign new group** from the shortcut menu.

The **Comment group** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The comment group is created.

Adding predefined comment texts to a comment group

It enables you to add predefined comments to a specific comment group.

To add predefined comment texts to a comment group

1 Choose **Test configuration** > **Comment texts**.

The **Comment groups** work area is displayed.

2 Double-click a comment group.

The **Comment texts** dialog box is displayed.

3 Choose **Insert new comment text** on the shortcut menu.

The **Comment texts** dialog box is displayed. The **Group** is pre-selected.

4 Enter the **Text code** and **Comment text**, and then choose the **OK** button.

The comment displays in the **Comment tex**t dialog box.

Assigning a group of predefined comments to a comment context

You assign a group of predefined comments to a comment context to enhance the efficiency of entering comments during routine laboratory workflows for those comment contexts.

To assign a comment group to a comment context

1 From the **Test configuration**, choose **Comment texts**.

The **Comment groups** work area is displayed.

2 Double-click a comment context.

The **Comment group assignment** dialog box containing the predefined comment context is displayed.

3 In the **Not assigned comment groups** table, select a comment group, and then choose the >> button.

The comment group displays in the **Assigned comment groups** table.

4 Close the dialog box.

The system saves the comment group assignment.

Reference ranges configuration

Reference ranges are defined as the limits for a normal result established for the healthy population to compare the test results with these defined reference ranges. A violation of a reference range sets a data alarm and the result will be blocked. The reference ranges are used to automate the validation of test results.

Definable reference ranges:

- **User-defined range**: The range according to your laboratory's specifications.
- **Normal range**: The normal range for a healthy patient.
- **Validation range**: The range within which the system can release the result if the automatic release is active.
- **Critical range**: The range which, when violated, causes a data alarm to be set. A result outside of this range is critical in a medical sense.

The table below displays the behavior of the ranges when violated. Violated means that the value lies outside the entered reference range.

Range, validation status	Data alarm set when range violated	Result blocked when range violated	Remarks, validation status
User-defined range	**X**	-	-
Normal range	**X**	-	-
Validation range	**X**	**X**	If violated, the result is not automatically released.
Critical range	**X**	-	-

Table 8-2 Violation behavior for reference ranges

A test result can be displayed (for example, in reports) together with an indicator/ graph showing whether the result has violated a normal / critical range. The following indicators are available:

Numeric results	Within critical range	Below critical range	Above critical range	No critical range defined
Within normal range	**N** _(*)_	**LL** *(_)_	**HH** _(_)*	**N** _(*)_
Below normal range	**L** *(_)_	**LL** *(_)_	**HH** _(_)*	**L** *(_)_
Above normal range	**H** _(_)*	**LL** *(_)_	**HH** _(_)*	**H** _(_)*
No normal range used	-	**LL** *(_)_	**HH** _(_)*	-

Table 8-3 Numeric results indicators

Alphanumeric results	Within critical range	Outside critical range	No critical range defined
Within normal range	**N**	**AA**	**N**
Outside normal range	**A**	**AA**	**A**
No normal range used	-	**AA**	-

Table 8-4 Alphanumeric results indicators / graphs

Creating a new reference range

Before you can define reference ranges, a test must be defined.

When you define the age range from 35...50 years, for example, and your patient is 60 years old, the system will not use any of the defined ranges and flags the result as not released.

For patients 35 to 50 years old, the system uses the defined reference ranges.

Whenever the parameter you enter in these optional group boxes does not fit with the patient properties, the system flags the results as 'no reference range defined'.

For example, if you select **Male** from the **Gender** drop-down list and the test is used for a female, the system will not process the result. This applies to any parameter in the three group boxes **Mandatory fields**, **Optional fields**, and **Clinical information**. The drop-down lists of the **Clinical information** group box are only active when they have been activated on the **Various** tab in **Test / reference ranges**.

You cannot mix numeric and alphanumeric ranges within one set of ranges. To use numeric and alphanumeric ranges for one test, you must define two separate sets of ranges for this test.

When a result is entered manually or sent by the instrument, the system queries the reference ranges according to the priority until it finds matching parameters (for example, mandatory and optional field entries, clinical data, etc.). Therefore we highly recommend defining the parameters (mandatory, optional fields and clinical information) as detailed as possible and set the highest available priority. Less detailed reference ranges should have a lower priority. Alphanumeric and numeric ranges are queried separately. I**ncrease priority / Decrease priority** only applies if you have defined more than one reference range. If you defined more than one range with the same range limits, the system uses the range with the lower priority number first. You can also edit, delete, or copy an existing reference range.

You can define up to five ranges which have different meanings. A range is expressed using:

- An upper limit and a lower limit.
- Relative to a value: Less than (<), Less than or equal to (<=), Greater than or equal to (>=), and Greater than (>).
- As a comma-separated list of alphanumeric values.

To create a new reference range

1 From the **Test configuration**, choose **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Choose a test for which you want to define reference ranges.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Reference ranges** tab, right-click **Insert new reference range** from the shortcut menu.

The **Reference range for...** dialog box is displayed.

4 In the **Name** field, enter a name for the reference range.

5 In the **Mandatory fields** group box, enter the age range / unit for the reference range.

6 To restrict the ranges to a specific group of patients, edit the optional **Optional fields** and **Clinical information** group boxes.

7 In the **Range** group boxes define the reference ranges and then choose the **OK** button.

The reference ranges are created.

Enabling reference ranges that take into account clinical information

To create reference ranges that take into account clinical information, such as the week of pregnancy or any medication a patient might be taking, you must first select the relevant check box.

Creating a new reference range (p. 161)

To enable reference ranges that take into account clinical information

1 From the **Test configuration**, choose **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Choose a test for which you want to enable reference ranges that take into account clinical information.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Various** tab.

The content of the tab is displayed.

4 From the **Used for reference ranges** group box, choose the check boxes that apply, and then do one of the following:

- Choose the **Apply** button to save the profile and enter another one.
  or,
- Choose the **OK** button to save the data and return to the **Profiles** dialog box.

The reference ranges that take into account clinical information are enabled.

Defining actions for a reference range

For each reference range that you create, you can assign one or more actions to be performed. The actions are listed in the **Reference range actions** and **After evaluation rules** tab table of the **Reference range** dialog box.

It is possible to stop actions from being performed after a particular action has been executed. When defining an action, you can select the **Stop when executed** check box. Doing so will stop any further actions from being performed after the current action has been executed.

After a result is evaluated, all corresponding after evaluation actions will be executed. Corresponding means that the result meets the condition for the defined action. Existing actions can be edited or removed. Example: If the result sent from the instrument is '65', all the pre-defined range checks in the example below are violated and all defined actions are performed.

Available **Actions**:

Action	Description
Add profile	Adds a predefined test profile and the priority.
Block	Blocks automatic release.
No action	Nothing happens.
Sample comment	Adds a predefined comment to a sample.
Reflex	Adds a predefined reflex test.
Replace result	Replaces the original, generated result with a manually entered result. Does not apply to results after they were released.
Rerun	Performs a rerun of the selected test with optional dilution settings. You can either set an automatic dilution factor or a manual one.
Result comment	Adds a comment to the result.
Release	Performs result release.
Test comment	Adds a predefined comment to a test.

Table 8-5 List of actions

Example:
- User-defined range: 15...35 (Lower limit / Upper limit)
- Normal range: <40 (Less than)
- Validation range: 25...45 (Lower limit / Upper limit)
- Critical range: 46...60 (Lower limit / Upper limit)

An action will only be executed after the selected condition is fulfilled and if the action is not suppressed.

To define actions for a reference range

1. From the **Test configuration** workplace, choose **Tests / reference ranges**.
2. Choose a test for which you want to define actions for a reference range.

   The **Test / reference ranges** dialog box is displayed.
3. Choose the **Reference ranges** tab, and then double-click the reference range to which you want to add an action.

   The **Reference range for...** dialog box is displayed.
4. Choose **Add action** from the shortcut menu.

5 From the **Condition** drop-down list, choose a condition (validation status).

6 Choose the **Stop when executed** check box if you want no further actions to be performed after the defined action is executed (if the selected condition is fulfilled).

7 From the **Action** drop-down list, choose an action to be assigned to the condition, and then choose the **OK** button.

The **Insert Action** dialog box closes and the action is added to the **Reference range actions** and **After evaluation rules** table.

Validation status configuration

The available validation statuses are pre-configured and the configuration cannot be edited. You can edit the displayed validation status text color, the name, description, and the display priority. You can create your own validation status combination by adding a predefined validation status to a validation status combination.

Every status in a validation status combination can be excluded (inverted), which means if you use, for example, the status **Below critical range (Result is outside and below the critical range)** in your validation status combination and set it to **Exclude status**, the status changes to **(No result is outside and below the critical range)**.

Defining a validation status combination

It enables you to define individual configurations for the validation statuses displayed.

To edit a validation status, choose **Edit validation status** from the shortcut menu. To remove a validation status, choose **Remove validation status** from the shortcut menu.

To define a validation status combination

1. Choose **Test configuration** > **Validation status**.

   The **Validation** work area is displayed.

2. Right-click in the work area, and then choose **New validation status** from the shortcut menu.

   The **Validation status** dialog box is displayed.

3. In the **Name** field, enter the name for the validation status combination.
4. In the **Description** field, enter a short description of the validation status combination.
5. To change the display color for the validation status combination, choose the **Color** button.
6. Choose the **Display with result** check box.

   The validation status is displayed in the relevant table with the result.

7. From the left table, select a predefined validation status.

   You can only select predefined validation statuses with a base status.

8. Use >> and << to add and/or remove a base status to and from a status combination.
9. Select a validation status in the right table, and then set the status either to **Exclude status** or **Include status**.

   The description text changes to inverse. Example:

   - **Include status: Below critical range,** means the status is fulfilled when the result is below the critical range.
   - **Exclude status: Below critical range,** means the status is fulfilled when the result is **NOT** below the critical range.

A validation status or validation status combination can only be defined once.

10 Choose the **OK** button.

The dialog box is closed and the new validation status combination is displayed at the bottom of the table.

11 Right-click the **Validation status** that was just defined and choose **Increase / Decrease priority** from the shortcut menu.

The validation status with the highest priority is displayed together with the result.

Defining delta check

It enables you to compare the current and previous result of the same test for a patient. If the deviation defined in this tab is violated, a delta check data alarm is displayed. You can define the allowed deviation according to the package inserts supplied with the tests.

To define a delta check

1 Choose **Test configuration** > **Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Double-click a test for which you want to define a delta check.

The **Test / reference ranges** dialog box is displayed.

3 Choose the **Delta check** tab.

The content of the tab is displayed.

4 Do the following:

- Choose **Symmetric** when upper / lower deviation is the same.
  or,
- Choose **Asymmetric** when upper/lower deviation is different.

5 Enter the deviation as a percentage and / or as an absolute value.

A violation is reported when the defined settings are violated.

6 Type the **Validity** as the number of days (0...N) within which the previous result must be compared.

Entering no value means the system uses the value defined in workplace **Advanced configuration > Options > MODUL > GUELTIGKEITSDAUER_VORWERT**. Normally this value is set to 0 by default.

Entering 0 means unlimited validity.

7 When the last result is an alphanumeric result (for example, POS or NEG), select the **Alphanumeric check** check box. In this case it is not necessary to enter a numerical deviation.

8 Choose the **OK** button.

The delta check is defined.

Rule engine

The rule engine configuration covers all actions necessary to manage rules and formulas including creation, duplication, removal, activation, and deactivation of rules.

For more information about the rule engine and rule management, see chapter *Rule management* (p. 201).

Serum indices

Serum indices are used when tests are tested that are influenced by the quality of the sample (hemolysis, lipaemia and icterus).

This chapter describes how to set up the serum index parameters.

You can enable one or more sample types for the serum index. The serum index can be allocated to any type of sample type but it is mainly used for serum samples.

All settings that must be configured for serum indices are:

- **Sample type.**
- **Tests for serum indices.**
- **Actions for serum indices sensitive tests when serum indices are above interference values.**
- **Instrument.**
- **Interference table defining interference limits for each test for a given instrument**.

Defining serum indices sensitive sample types

You need to define a serum index sensitive sample type in order to set up a serum index sensitive test.

To define serum indices sample types

1 Choose **Sample configuration** > **Sample type**.

The **Sample type** work area is displayed.

2 Right-click a sample type, and choose **Edit sample type** on the shortcut menu or create a new sample type if you have not configured the appropriate sample type yet.

The **Edit sample type** dialog box is displayed**.**

3 Select the **Serum index sensitive** check box, and then do one of the following:

- To save the data and keep the dialog box open, choose the **Apply** button or,
- To save the data and close the dialog box, choose the **OK** button.

The serum indices sensitive sample type is defined.

Defining serum indices settings for an instrument

To define serum indices settings for an instrument

1 Choose **Instruments configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Right-click on an instrument, and then choose **Edit instrument** from the shortcut menu.

The **Edit <instrument name>** dialog box is displayed**.**

3 Choose the **Serum Indices** tab.

The content of the tab is displayed.

4 Select one of the following options:

- **No serum index**: the instrument does not measure serum indices and the tests measured on this instrument are not affected by the serum indices.
- **Serum index as result flags**: the instrument measures serum indices and flags the result if at least one of the serum indices is above the interference limit. In this case no further configuration for serum indices is required at all.
- **Serum index as results**: the instrument measures the serum indices and sends the results as quantitative numbers (for example 453, 23, -1, etc.).

5 If **Serum index as results** is selected, then from the **Interference table** drop-down list, choose an interference table to be assigned to the instrument if the serum indices are handled as quantitative results.

6 Choose the **OK** button.

The settings are saved and the dialog box closes.

Defining serum indices tests

It is always requested if a serum index sensitive test is requested. It is handled as a regular test and it is displayed in the list of requested tests.

The serum index tests will be released together with the serum index sensitive test except for data alarms that are defined as **considered for validation**.

To define serum indices sensitive tests, see *Defining a test* (p. 154).

To define serum indices tests

1 Choose **Test configuration** > **Test / reference ranges**.

The **Test / reference ranges** work area is displayed.

2 Right-click in the work area, and then choose **Insert new test** from the shortcut menu.

The **Test / reference ranges** dialog box is displayed.

3 Enter the required information.

4 In the **Sample type** field, select a sample type that has been defined previously as serum index sensitive. If you do not select a serum sensitive sample type, you cannot define the other serum index settings for the test.

5 From the **Is Serum Index** drop-down list, select the relevant serum index.

6 Choose the **OK** button.

The serum indices test is defined.

Defining an interference table

The serum index **Interference table** is used to define the allowed limits for hemolysis, icterus and lipaemia that influence the test measurement. Each test has its own limits for hemolysis, icterus and lipaemia which are provided by the manufacturer.

Depending on the instrument type, the serum indices are measured differently. Therefore, more than one interference table has to be defined.

Other instruments do not measure serum indices at all, but the **cobas IT** middleware system allows the use of normalized serum indices results from another instrument.

To define interference table

1 Choose **Test configuration** > **Serum index** > **Interference tables**.

The **Serum index interference tables** work area is displayed.

2 Right-click in the work area, and then choose **Insert interference table** from the shortcut menu.

The I**nterference table** dialog box is displayed.

3 Enter a name for the interference table, and then choose the **OK** button.

The **Serum index interferences** dialog box is displayed containing three tables:

- **Interference list:** Consists of all assigned serum index tests with the relevant quantitative values.
- **Instruments:** Displays all available instruments. You can filter them in order to display only the serum index assigned instruments.
- **Assigned instruments:** Displays the instrument assigned to the selected test. Instruments can be assigned / unassigned manually with >> and <<.

4 Right-click in the **Interference list** table and choose **New entry** from the shortcut menu.

The **Edit interference limits** dialog box is displayed**.**

5 From the **Test** drop-down list, select a test, enter all required information and then choose the **OK** button.

The parameters will be stored and the dialog box closes.

6 In the **Instruments** group box, choose the **Include instruments with wrong settings** check box.

All instruments without an allocated interference table will be listed. The **Include assigned instruments** displays all instruments already assigned to an interference table.

An instrument can only have one assigned interference table. However, an interference table can be assigned to more than one instrument.

7 Choose >> to assign the table to an instrument or << to un-assign, and then choose the **Close** button.

The dialog box closes and the table is listed in the **Serum index interference tables** work area.

Instrument configuration

You can insert, define, and assign all actions for that instrument. The system enables you to assign tests, sample type, dilution factors, and activate or deactivate data alarms for the relevant instrument for analysis.

When configuring an instrument in the **Edit <instrument>** work area the **Default rack type** must be selected.

Configuring instruments

You can configure three types of instruments:

- Pre-Analytic
- Analytic
- Post-Analytic

Once the **Instrument No**. and **Container type** is entered and saved, you cannot change it.

To configure an instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Right-click in the work area, and then choose **Insert new instrument** > **Insert Analytic Instrument** or **Insert Pre-Analytic Instrument** or Insert Post-Analytic Instrument from the shortcut menu.

The **Add instrument** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

Modular instrument No.

If you enter an instrument number for a modular instrument type, e.g. 100, the next 20 numbers will be reserved for the modular instruments, e.g. 100-120.

The instrument is configured in the system.

Copying sample types from another instrument

You can copy selected sample type from another instrument to the selected one.

To copy a sample type from another instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument.

The **Edit <instrument name>** dialog box is displayed.

3 Choose the **Sample type** tab.

The content of the tab is displayed.

4 Right-click in the table, and then choose **Copy sample type from** from the shortcut menu.

The menu expands to display a list of instruments.

5 Choose an instrument from which you want to copy the sample types.

The **Copy sample type from <instrument name>** dialog box is displayed.

6 Select the sample type you want to copy from the instrument, and then choose the **Copy selection** button.

The copied sample type is displayed in the tab.

Copying instrument details to a new instrument

You can copy a configuration (assigned tests, instrument data alarms, sample type, etc.) from an instrument to another.

To copy instrument details to a new instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Right-click an instrument, and then choose **Copy instrument** from the shortcut menu.

The **Copy instrument** dialog box is displayed.

3 Enter the unique instrument **ID**, enter the name of the instrument to which you want to copy instrument details, and then choose the **OK** button.

The new instrument is displayed in the table with the copied instrument details.

Configuring the connection to the instrument

Connection from the **cobas IT** middleware to the instrument is either through the COM port or through a network.

To configure the connection to the instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument for which you want to configure the connection.

The **Edit <instrument name>** dialog box is displayed.

3 Choose the **Interface** tab, enter the required information, and then choose the **Apply** button.

The connection to the instrument is configured.

4 To start the instrument, choose the **Start** button.

The status of the instrument changes to **Running**.

5 Close the dialog box.

The instrument displays in the **Instrument** work area with status **Running**.

Activating or deactivating instrument data alarms

You can activate or deactivate instrument data alarms to make them display or not with the results.

In the **Edit instrument** dialog box > **Data alarms** tab, you can activate or deactivate the following options, depending on how you want the system to react to incoming instrument data alarms:

Option	Description
Active	If selected it activates the data alarm.
Valid	If selected the release is blocked.
Comment	If selected it adds the message of the data alarm as comment to the test.
Display in information work area	If selected the data alarm displays in the **Overview**.
Mask instrument	If selected the instrument which caused the data alarm is masked.
Masks test	If selected the test which caused the data alarm is masked.
Block QC	If selected it blocks the QC release.
Result is preliminary	If selected together with the **Rerun preliminary result** check box from **Tests** tab, it requests an automatic rerun of the test that generated a data alarm.

Table 8-6 Data alarms check boxes

CAUTION

Disabling instrument data alarms

Invalid results are released automatically when instrument data alarms are disabled.

- Do not disable the instrument data alarms block options.

To activate or deactivate instrument data alarms

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument for which you want to activate or deactivate data alarms.

The **Edit instrument** dialog box is displayed.

3 Choose the **Data alarms** tab.

The content of the tab is displayed.

4 Right-click an instrument data alarm, and then choose **Data alarms** from the shortcut menu.

The shortcut menu extends.

5 Do the following:

- To activate a data alarm, choose **Activate** from the shortcut menu.
  or,
- To deactivate a data alarm, choose **Deactivate** from the shortcut menu.

6 Choose the **OK** button.

The configuration is saved.

Activating test or instrument masks in case of raised instrument data alarms

You can activate masks for a test or all tests assigned to the instrument after an instrument data alarm is raised. Module assignments are not copied.

To activate test or instrument masks in case of raised instrument data alarm

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument for which you want to activate test masks in case of raised instrument data alarms.

The **Edit instrument** dialog box is displayed.

3 Choose the **Data alarms** tab.

The content of the tab is displayed.

4 Right-click an instrument data alarm, and then choose **Test masks** on the shortcut menu.

The shortcut menu extends.

5 Do one of the following:

- Choose **Mask test** to mask the test from the instrument after the instrument data alarm is raised.
  or,
- Choose **Mask instrument** to mask all tests from the instrument after the instrument data alarm is raised.

The **Mask test** column indicates if the test will be masked from the instrument (selected).

The **Mask instrument** column indicates if all tests will be masked from the instrument (selected).

6 Choose the **OK** button.

The configuration is saved.

Adding an instrument group

You can add instrument groups and assign individual instruments to the groups. Instrument groups are formed for fast selection of specific instruments.

To add an instrument group

1 **Instrument configuration** > **Instrument groups**.

The **Instrument groups** work area is displayed.

2 Right-click in the work area, and then choose **Insert new instrument group** from the shortcut menu.

The **Edit instrument group** dialog box is displayed.

3 Enter required information, and then choose the **OK** button.

The instrument group is added to the **Instrument groups** work area.

Assigning instruments to instrument groups

You can assign individual instruments to instrument groups in order to quickly select specific instruments.

To assign instruments to instrument groups

1 Choose **Instrument configuration** > **Instrument groups**.

The **Instrument groups** work area is displayed.

2 Double-click an instrument group to which you want to assign an instrument.

The **Edit instrument group** dialog box is displayed.

3 Right-click in the table, and then choose **Insert new instrument** from the shortcut menu.

The **Assignment instrument group** - **instrument** dialog box is displayed.

4 Select an **Instrument**, and then choose the **OK** button.

The selected instrument is displayed in the instrument group list.

Assigning tests to an instrument

The system enables you to assign tests to the opened instrument for analysis.

QC errors are only active in this dialog if the test can be masked.

To assign tests to an instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument to which you want to assign tests.

The **Edit <instrument name>** dialog box is displayed.

3 In the **Tests** tab, choose **New assignment test** from the shortcut menu.

The **Test assignment** dialog box is displayed.

4 Select a **test**, enter the required information, and then do one of the following:

- To save the test details and assign more tests, choose the **Apply** button.
  or,
- To save the test details and close the dialog box, choose the **OK** button.

The tests are assigned to the instrument.

Copying tests from another instrument

You can copy selected tests from another instrument to the selected one.

To copy tests from another instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument to which you want to copy tests.

The **Edit <instrument name>** dialog box is displayed.

3 In the **Tests** tab, choose **Copy tests from...** from the shortcut menu.

The menu expands to display a list of instruments.

4 Choose an instrument from which you want to copy the tests.

The **Copy tests from instrument <name>** dialog box is displayed.

5 Select the tests you want to copy from the instrument, and then choose the **Copy selection** button.

The copied tests are displayed in the **Tests** tab.

Creating mask profiles

In additional to single test masking, you can create mask profiles for different shifts.

You can mask a profile in the Routine client > Routine tab >Miscellaneous task list >Mask tests task button.

To create mask profiles

1 Choose **Instrument configuration** > **Mask profiles**.

The **Mask profiles** work area is displayed.

2 Right-click in the work area, and then choose **Insert new profile** from the shortcut menu.

The **Mask profile** dialog box is displayed.

3 Enter the **Profile ID** and **Profile name**.

4 Choose the **Apply** button.

The **Tests not assigned** table displays all assigned tests for instruments with **test masks** selected in the instrument properties.

5 In the **Tests not assigned** table, select the test(s) for the instrument(s) you want to assign to the mask profile, and then choose the << button.

The tests display in the **Assigned tests** table.

6 Choose the **OK** button.

The mask profile is displayed in the **Mask profiles** work area.

Configuring messages to the instrument

You can define message properties to be sent from **cobas IT** middleware to the instrument.

To configure messages to the instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument for which you want to configure messages.

The **Edit <instrument name>** dialog box is displayed.

3 Choose the **Properties/Misc.** tab.

The content of the tab is displayed.

4 Choose the functions you want to activate for the instrument, and then choose the **OK** button.

The configuration of the messages is saved.

Adding automatic dilution factors to an instrument

You can add a list of dilution factors for the instrument. This list is available for selection when adding a dilution factor to a test. The availability of the automatic dilution factors configuration, depends on the instrument type.

To add automatic dilution factors to the instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument to which you want to add dilution factors.

The **Edit instrument** dialog box is displayed.

3 Choose the **Automatic dilution factor** tab.

The content of the tab is displayed.

4 Right-click in the table, and then choose **Add dilution factor** from the shortcut menu.

The **Automatic dilution factor** dialog box is displayed.

5 Enter the required information, and then choose the **OK** button.

The dilution factor displays on the **Automatic dilution factor** tab.

Copying automatic dilution factors from another instrument

You can copy selected automatic dilution factors from another instrument to the selected one.

To copy an automatic dilution factor from another instrument

1 Choose **Instrument configuration** > **Instrument**.

The **Instrument** work area is displayed.

2 Double-click an instrument to which you want to copy dilution factors.

The **Edit instrument** dialog box is displayed.

3 Choose the **Automatic dilution factor** tab.

The content of the tab is displayed.

4 Right-click in the table, and then choose **Copy dilution factors from** from the shortcut menu.

The menu expands to display a list of instruments.

5 Select an instrument from which you want to copy the dilution factors from.

The **Copy dilution from instrument <name>** dialog box is displayed.

6 Select the dilution factors you want to copy from the instrument, and then choose the **Copy selection** button.

The copied dilution factor is displayed in the tab.

Assigning a sample type to an instrument

You can add a list of sample types to be analyzed by the instrument.

To edit the sample type, follow the procedure below and choose **Edit sample type** from the shortcut menu. To delete the sample type, choose **Delete sample type** from the shortcut menu.

To copy the sample type from another instrument, see *To copy a sample type from another instrument* (p. 171).

To assign all instrument tests for a sample type, follow the procedure below and choose **Assign all instrument tests for a sample type** from the shortcut menu. To remove all instrument tests for a sample type, follow the procedure below and choose **Remove all instrument tests for a sample type** from the shortcut menu.

To assign a sample type to an instrument

1. Choose **Instrument configuration** > **Instrument**.

   The **Instrument** work area is displayed.

2. Double-click an instrument to which you want to assign a sample type.

   The **Edit instrument** dialog box is displayed.

3. Choose the **Sample type** tab.

   The content of the tab is displayed.

4. Right-click in the table, and then choose **Insert new sample type** from the shortcut menu.

   The **Instrument sample type** dialog box is displayed.

5. Enter the required information, and then choose the **OK** button.

   The assigned sample type displays in the **Sample type** tab.

Host Administration

The Host Administration enables you to establish connections to the host system according to the host system demands.

For more information regarding this functionality see the Host Interface Manual.

Sample configuration

In this workplace you can administer container types which specify the storage media, define specific sample types, and create sample workflows.

Creating a new sample type

You can add a sample type to the system and later assign tests to the new sample type.

To edit the sample type, follow the procedure below and choose **Edit sample type** from the shortcut menu. To delete the sample type, choose **Delete sample type** from the shortcut menu.

To create a new sample type

1. Choose **Sample configuration** > **Sample type**.

   The **Sample type** work area is displayed.

2. Right-click in the work area, and then choose **Insert new sample type** from the shortcut menu.

   The **Edit sample type** dialog box is displayed.

3. Enter the required information, and then choose the **OK** button.

   The sample type is created.

Configuring sample tube types

You configure sample tube types for pre-analytic instruments to map external sample tube types to internal ones which can then be used in the workflow configuration.

To edit a sample tube type, follow the procedure below and then choose **Edit tube type** from the shortcut menu. To remove a sample tube type, choose **Remove tube type** from the shortcut menu.

To configure sample tube types

1. Choose **Sample configuration** > **Tube Type**.

   The **Tube Types** work area is displayed.

2. Right-click in the work area, and then choose **Add tube type** from the shortcut menu.

   The **Tube type** dialog box is displayed.

3. Enter the required information, and then choose the **OK** button.

   The new sample tube type is added to the system.

Adding sample classes

You can define different sample classes and their lifetime, and delete options in the system sample cleanup. These sample classes are used on the instrument side for unsolicited samples and on the host interface. They have different lifetimes and cleanup options, depending on the instrument or the host they come from.

To edit a sample class, follow the procedure below, and then choose **Edit sample class** from the shortcut menu. To remove a sample class, choose **Remove sample class** from the shortcut menu.

To configure sample classes

1 Choose **Sample configuration** > **Sample class**.

The **Sample classes** work area is displayed.

2 Right-click in the work area, and then choose **Add sample class** from the shortcut menu.

The **Sample class** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new sample class is added to the system.

Creating a container type or rack type

To distribute the samples, you can create and assign a container type along with the rack and fixed position for sample archiving.

The following default container types are available:

- RD 5 positions rack
- Integra 15 positions rack

If **Only one sample type** is not selected, various sample types may be inserted into the same rack. To create a rack for one sample type, select **Only one sample type** and the sample type material.

WARNING

Multiple MODULAR *PRE-ANALYTICS* must have different rack ID ranges

The software identifies a tube from a **MODULAR** *PRE-ANALYTICS* by the rack ID and default rack type. If two tubes have the same rack ID and default rack type, the software will mix up patients and results.

- Make sure that each **MODULAR** *PRE-ANALYTICS* uses rack IDs in a different range, or a different default rack type.

To create a container type or rack type

1 Choose **Sample configuration** > **Container types**.

The **Container types** work area is displayed.

2 Right-click in the work area, and then choose **Insert new container type** from the shortcut menu.

The **Insert container type** dialog box is displayed.

3 Select a **Container type**.

This activates the other fields according to the container type.

4 Enter the **Container type name** and other required information, and then choose the **OK** button.

Editing a container type

Once **Container type** and the **Properties** group box, except **Keep samples**, are entered and saved, you cannot change them.

The new container type displays in the table.

Adding a new container to a container type

To add a new container to a container type

1 Choose **Sample configuration** > **Container types**.

The **Container types** work area is displayed.

2 Choose a container type for which you want to add a container.

The **Container** work area is displayed.

3 Right-click in the work area, and then choose **Insert new container** from the shortcut menu.

The **Insert new container** dialog box is displayed.

4 Enter the required information, and then do one of the following:

- To save the container and exit the dialog box, choose the **OK** button.
  or,
- To save the container and add more containers, choose the **Apply** button.

The container is added into the system.

Deleting a container type

You delete a container type when you no longer need it.

Container types with negative ID (for example: Instrument (-1)) must not be deleted.

To delete a container type

1 Choose **Sample configuration** > **Container types**.

The **Container types** work area is displayed.

2 Choose the container type you want to delete, and then choose **Delete container type** from the shortcut menu.

The container type is deleted.

Deleting multiple containers

1 Choose **Sample configuration** > **Container types**.

The **Container types** work area is displayed.

2 Choose a container type for which you want to delete multiple containers.

The **Container** work area is displayed.

3 Choose the containers you want to delete, and then choose **Delete container** from the shortcut menu.

The **cobas IT middleware** dialog box is displayed asking you for the deletion confirmation.

4 Choose the **Yes** button.

The containers are deleted.

Transferring content to a container

Scanning a sample automatically assigns the sample to a container and position. Additionally, you can manually transfer the contents of one container to another.

To transfer content to a container

1 Choose **Sample configuration** > **Container types**.

The **Container types** work area is displayed.

2 Double-click a container type.

The **Container** work area is displayed.

3 In the **List of container types:** table, right-click a container you want to transfer the content to and choose **Insert/delete content** on the shortcut menu.

The **Insert content into/ remove from test** dialog box is displayed.

4 In the **Insertable objects** table, select the content you want to transfer to the selected container and choose the >> button.

The content transfers to the **Content of test** table, depending on whether the sample is the correct sample type.

5 Close the dialog box.

The sample displays in the **Content of:...** table with the name of the original content container.

Creating and defining a sample workflow

You can create and define a sample distribution workflow set for a specific location, sample type, workflow type, instrument, or priority.

To copy a workflow, follow the procedure below and choose **Copy workflow** from the shortcut menu. To delete a workflow, choose **Delete workflow** from the shortcut menu

To create and define a sample workflow

1 Choose **Sample configuration** > **Workflows**.

The **Overview locations** work area is displayed.

2 Double-click a laboratory location.

The **Overview workflow** work area is displayed containing the workflows created for that location.

3 Right-click in the work area, and then choose **New workflow** from the shortcut menu.

The **Workflow** dialog box is displayed with the laboratory **Location** selected by default.

4 Enter the **Name** of the workflow and the description, and then choose the **OK** button.

Creating a workflow

Once you enter and save a **Location**, you cannot change it.

The new workflow is created and it is displayed in the **Overview workflow** work area.

5 Double-click the newly created workflow.

The **Edit workflow** work area is displayed.

6 Right-click in the table on the right, and then choose **New Rule assignment** from the shortcut menu.

The **Test assignment** dialog box is displayed.

7 Enter the required information, and then choose the **OK** button.

The system saves the data and the sample workflow rule created is displayed in table on the right.

Configuring rack ranges

It enables you to define laboratory-specific rack ranges for different instrument groups to use the same rack IDs.

To edit already configured rack ranges, follow the procedure below, and then choose **Edit rack range** from the shortcut menu. To remove a rack range configuration, choose **Remove rack range** from the shortcut menu.

WARNING

Multiple MODULAR *PRE-ANALYTICS* must have different rack ID ranges

The software identifies a tube from a **MODULAR** *PRE-ANALYTICS* by the rack ID and default rack type. If two tubes have the same rack ID and default rack type, the software will mix up patients and results.

- Make sure that each **MODULAR** *PRE-ANALYTICS* uses rack IDs in a different range, or a different default rack type.

To configure a rack range

1 Choose **Sample configuration** > **Rack ranges**.

The **Rack ranges** work area is displayed.

2 Right-click in the work area, and then choose **New rack range** from the shortcut menu.

The **Rack range** dialog box is displayed.

3 Enter the required information, and then choose the **OK** button.

The new rack range is configured.

Configuring a barcode label printer

The system enables you to add and manage barcode label printers for sample sorting.

To edit the barcode label printer configuration, follow the procedure below and choose **Edit configuration** from the shortcut menu. To delete a configuration, choose **Delete configuration** from the shortcut menu.

To configure a barcode label printer

1 Choose **Sample configuration** > **Barcode printing**.

The **Client scripts** work area is displayed.

2 Right-click in the **Printer assignment** table, and then choose **Insert configuration** from the shortcut menu.

The **Insert new printer configuration** dialog box is displayed.

3 Enter the required information, and then choose the **Save** button.

The new barcode label printer is configured.

Configuring a label type

It enables you to create label templates which you can use when printing barcode labels for unlabeled samples and racks.

To edit a label type, follow the procedure below and choose **Edit label** from the shortcut menu. To delete a label type, choose **Delete label** from the shortcut menu.

To configure a label type

1 Choose **Sample configuration** > **Barcode printing**.

The **Client scripts** work area is displayed.

2 Right-click in the **Label configuration** table, and then choose **Insert new label** from the shortcut menu.

The menu expands.

3 Do one of the following:

- To insert a sample label, choose **Insert sample label** from the shortcut menu.
  or,
- To insert a rack label, choose **Insert rack label** from the shortcut menu.

The **Enter new sample label** or **Enter new rack label** dialog box is displayed.

4 Enter the required information, and then choose the **Save** button.

The new label type is saved and it is displayed in the **Label configuration** table.

Handling a task

You can start, stop, or restart a task.

To start a task

1 Choose **Sample configuration** > **Barcode printing**.

The **Client scripts** work area is displayed.

2 Right-click a task, and then choose **Start task** from the shortcut menu.

The task is started and it is displayed in green with the status **Running**.

To stop a task

1 Choose **Sample configuration** > **Barcode printing**.

The **Client scripts** work area is displayed.

2 Right-click a task, and then choose **Stop task** from the shortcut menu.

The task is stopped and it is displayed in red with the status **Stopped.**

To restart a task

1 Choose **Sample configuration** > **Barcode printing**.

The **Client scripts** work area is displayed.

2 Right-click a task, and then choose **Restart task** from the shortcut menu.

The task is restarted and it is displayed in green with the status **Running**.

Test delegation configuration

It enables you to configure the system to delegate a test from one laboratory to another.

To edit a test location, follow the procedure below, and then choose **Edit location** from the shortcut menu. To delete a test location, choose the **Delete location** from the shortcut menu.

To add a new test location

1 Choose **Sample configuration** > **Test delegation**.

The **Test delegation** work area is displayed.

2 Right-click in the work area, and then choose **Insert new location** from the shortcut menu.

The **Test delegation** dialog box is displayed.

3 Enter the required information, and then choose the **Apply** button.

The new test location is added to the system.

Configuring volume profiles

It enable the system to calculate the necessary volumes for an aliquot.

To edit a volume profile choose **Edit volume profile** from the shortcut menu. To delete a volume profile choose **Delete volume profile** from the shortcut menu.

To configure volume profiles

1 Choose **Sample configuration** > **Volume profiles**.

The Sample configuration- work area is displayed.

2 Right-click in the work area, and then choose **Insert new volume profile** from the shortcut menu.

The **Edit volume profile** dialog box is displayed.

3 Enter the required information, and then choose **Apply**.

The volume profile is saved.

User administration configuration

There are three default users that can be defined:

- QCCONFIG with access rights to all routine and QC configuration functions. Deprecated user: Use ADMIN instead.
- ADMIN with access rights to all routine and all configuration functions except **Advanced configuration**.
- Routine user with access rights to all routine functions.

The routine actions are controlled by user right assignment based on work areas and rights for routine actions. The work areas are either laboratories or instrument groups. The administrator can assign rights for routine actions specific to each work area. When you log on, you must choose a work area for which the sample and tests are displayed according to your assigned rights.

Creating a user

You can create all users for the central laboratory and the database.

Here you manage their system rights and their access to workplaces as a separate location, if installed for the user.

To edit user details but not the name, follow the procedure below, and then choose **Edit user** from the shortcut menu. To copy a user, choose the **Copy user** from the shortcut menu.

Deleting a user

You can only delete a user in the **cobas IT** middleware, not in the database. Therefore you cannot create a second user of the same name in the **cobas IT** middleware.

To delete a user, choose the **Delete user** from the shortcut menu.

To create a user

NOTICE

User names

Oracle key words and e-mail addresses are not permitted as a user name. User names must satisfy the rules for Oracle non-quoted identifiers.

- Do not use Oracle keywords as a user name (e.g. ALL, ALTER, AND, AUDIT, BY, CHECK, DEFAULT, ELSE, EXCLUSIVE, FOR, FROM,…). Please refer to the *V$RESERVED_WORDS* table for a complete list of keywords.
- E-mail addresses cannot be used as a user name.
- User names cannot begin with a numeric character.

1 Choose **User administration** > **User**.

The **User name** work area is displayed.

2 Right-click in the work area, and then choose **Insert new user** from the shortcut menu.

The **User ID** dialog box is displayed.

3 Enter the required information, and then choose the **Save** button.

After you enter and save a user name, you cannot edit it.

Timeout

In this field, you can enter a value between 1 and 86,400 seconds (24 hours).
If you do not enter a value the default time of 500 seconds. will apply.

Password format

To enter a password starting with a number or special character, enclose the password string in double quotes. The double quotes do not form part of the password.

All fields are mandatory.

The new user is displayed in the User name work area.

Assigning/revoking system rights to users

The system displays all system rights for a user by location type and location. After selecting a location, you can assign or un-assign a system right for the user. User rights give access to specific locations, authorizations, and system functions.

To assign/revoke rights to users

1 Choose **User administration** > **User**.

The **User name** work area is displayed.

2 In the **User administration** menu tree, double-click a user, and then double-click **Rights**.

The **Rights** submenu expands.

3 Double-click a location type.

The **list of locations** expands.

4 Select a location.

The **Overview user system rights** work area is displayed containing the system rights for the location and the user.

5 Right-click a system right, and then choose **Assign** from the shortcut menu.

The **Assigned** column is checked indicating that the right is assigned to the user.

Revoke a system right

Right-click a system right with the **Assigned** column selected. Choose **Revoke** from the shortcut menu. The **Assigned** column is deselected.

Copying user rights to another user

You can use the original user configuration as a template for copying all system rights to new or existing users. When copying a user, you must enter the details of the new user.

To copy user rights to another user

1 Choose **User administration** > **User**.

The **User name** work area is displayed.

2 In the **User administration** menu tree, double-click a user, and then double-click **Rights**.

The **Rights** submenu expands.

3 Double-click a location type.

The **list of locations** expands.

4 Select a location.

The **Overview user system rights** work area is displayed containing the system rights for the location and the user.

5 Right-click a user, and then choose **Copy** from the shortcut menu.

The **Copy authorization** dialog box is displayed.

6 Enter the required information, and then choose the **OK** button.

The user rights are copied to the other user.

Giving a user the right to see confidential tests and results

In the **User** component (**User administration** workplace), you can assign rights to a user to enable them to see confidential tests and results. A test can be either **confidential** or **non-confidential**. The table below shows the access rights that can be applied to a user. There are two access rights (one for the test and the other for the result handling) and consequently three access levels.

	Tests (CONF_TEST)	Results (CONF_RESU)
User (standard)	-	-
User (confidential test user)	**X**	-
User (confidential test and result user)	**X**	**X**

Table 8-7 Confidential results access level

Standard user rights A standard user cannot see any tests and their results when they are defined as confidential (see table above). If an order consists of confidential tests only, only the empty order is visible to the standard user. However, a user with no rights can request a confidential test.

When you delete an order, ensure it does not contain confidential tests which are not visible to you.

A standard user who has no rights cannot perform the following (the list applies only to confidential tests):

- Validation.
- Rerun a confidential test.
- Show previous results.
- Enter comment on confidential tests.
- View sample, order, and test history.
- Show and/or print result report.
- Show test details.
- Change dilution factor.
- Overrule required serum index.

Confidential tests user rights Apply to a user who has rights to see confidential tests but not the rights to see their results (see table above). As a confidential test user, you can only see a placeholder such as ***** (default) or a predefined text string (for example, Confidential) instead of the results. Printed reports also do not contain the confidential results.

Confidential tests and results user rights Apply to a user who has the rights to see confidential tests and their results. The user has unlimited rights to change results, edit the test, etc.

If you set a confidential test to non-confidential, you can view all current results of this test as well as the results from the past including the entire history, etc.

The following procedure describes how to set up a user and assign the rights to see confidential tests and their results. Please note since the names for the workplace and components can be changed by the user, the names may not be the same in your system.

To give a user the right to see confidential tests and results

1. **User administration** > **User**.

   The **User name** work area is displayed.

2. In the **User administration** menu tree, double-click a user, and then double-click **Rights**.

   The **Rights** submenu expands.

3. Double-click a location type.

   The **list of locations** expands.

4. Select a location.

   The **Overview user system rights** work area is displayed containing the system rights for the location and the user.

5. Right-click the **CONF_RESU** right, and then choose **Assign** from the shortcut menu.

   The **Assigned** column is checked indicating that the right is assigned to the user.

6 Right-click the **CONF_TEST** right, and then choose **Assign** from the shortcut menu.

The **Assigned** column is checked indicating that the right is assigned to the user.

The defined rights apply only to the selected client (location). If you work in another location, you must define the rights accordingly.

Editing the password profile

You edit the password profile in order to change the lifetime of passwords, the maximum failed logon attempts, and the reuse of passwords.

Parameter	Description
'Password life time	Number of days after which a user is requested to change the password.
Password extension time	Number of days after notification of the "password life time". If exceeded, without the user changing the password, the system locks the user account.
Failed login attempts	The number of incorrect logon attempts permitted after which the system locks the user account.
Password reuse time	The number of days within which a password cannot be reused.
Password reuse max	The number of password changes required before the current password can be reused.

Table 8-8 Password profile parameters

Password reuse time and **Password reuse max** must be set in conjunction with each other.

If you specify a value for both parameters, then you cannot reuse a password until it has been changed as many times as specified by the Password reuse max, during the number of days specified for Password reuse time. For example, if you set Password reuse time to 30 and Password reuse max to 3, then you can reuse the password after 30 days if it has been changed 3 times.

If you do not specify a value for either parameter, the default value (-1), meaning unlimited, is applied. Therefore you can always reuse your password without any restrictions.

If you specify a value for one of these parameters and specify unlimited (-1) for the other, then you can never reuse a password.

To edit the password profile

1 **User administration** > **Password profiles**.

The **Password profiles** work area is displayed.

2 Right-click profile name, and then choose **Edit profile** from the shortcut menu.

The **Password profiles** dialog box is displayed

3 Edit the parameters, and then choose the **Save** button.

The parameters are saved.

Forms

The system provides single and cumulative form types and the sample entry form. Forms have an ID, a name, and an abbreviation.

Adding forms

You can manage all forms for the sorted output of results.

To add forms

1. Choose **Report configuration** > **Forms**.

   The **Form Types** work area is displayed.

2. In the upper table, select a form type.

   The lower table displays the forms assigned to the selected form type.

3. Right-click in the lower table, and then choose **Insert new form** on the shortcut menu.

   The **Form items** dialog box is displayed.

4. Enter the required information and close the dialog box.

   The **cobas IT** middleware dialog box is displayed asking you to save.

5. Choose the **Yes** button.

   The new form is added.

Adding test groups to a form

Test groups are assigned to forms in order to sort the sequence and output of results.

To add test groups to a form

1. Choose **Report configuration** > **Forms**.

   The **Form Types** work area is displayed.

2. Right-click in the lower table, and then choose **Insert new form** from the shortcut menu.

   The **Form items** dialog box is displayed.

3. In the upper table, select a form type.

   The lower table displays the forms assigned to the selected form type.

4. In the lower table, double-click a form.

   The **Form items** dialog box is displayed.

5. Right-click in the left table, and then choose **Insert new test group** from the shortcut menu.

   The **Form test group** dialog box is displayed.

6 Choose a test group which you want to assign to the form, and then choose the **Insert** button.

The selected test group is displayed in the left table along with the tests belonging to the group in the right table.

Adding form groups

The system enables you to insert and define form groups for quick selection of specific forms.

To add a form group

1 Choose **Report configuration** > **Form groups**.

The **Form groups** work area is displayed.

2 Right-click in the work area, and then choose **Insert new form group** from the shortcut menu.

The **Form groups** dialog box is displayed.

3 Enter the required information, and then close the dialog box.

The **cobas IT** middleware dialog box is displayed asking you to save.

4 Choose the **Yes** button.

The new form group is added.

Assigning forms to form groups

You assign forms to form groups for quick selection of these specific forms.

To assign forms to form groups

1 Choose **Report configuration** > **Form groups**.

The **Form groups** work area is displayed.

2 Double-click a form you want to assign to a form group.

The **Form groups** dialog box is displayed.

3 Right-click in the table, and then choose **Insert new form** from the shortcut menu.

The **Forms** dialog box opens.

4 From the **Form** drop-down list, select a form, and then choose the **Insert** button.

5 Select another form or close the dialog box.

The assigned form is displayed in the table.

Editing result reports

You edit the result report configuration to change the contents and layout of results.

To edit a result report configuration

1. Choose **Report configuration** > **Result report configuration**.

   The **Result report configuration** work area is displayed.

2. Right-click in the work area, and then choose **Edit configuration** from the shortcut menu.

   The **Result report configuration** dialog box is displayed.

3. Enter the required information, and then choose the **OK** button.

   The result report configuration is edited and saved.

System configuration

It enables you to configure predefined tasks. A task has three different urgency levels: normal, warning, and critical. The ranges of the levels are defined using two thresholds (one between normal and warning and another one between warning and critical). Every task has its own, not editable refresh time (to avoid performance issues) and in some cases a navigation point (clicking the task navigates to the place where the task can be executed). A task can count different attributes (for example, warnings and errors) and aggregate the results in one single task. This feature is not configurable but predefined for every task.

Configuring system messages for the Overview

The system enables you to configure the display of system messages for the **Overview**.

To configure system messages for the Overview

1 Choose **System configuration** > **Information window > System messages**.

The **System messages overview** work area is displayed.

2 Right-click a system message and choose either:

- **Activate message** to display the message in the **Overview**. The **Active** column is selected.
  or,
- **Deactivate message** to hide the message in the **Overview**. The **Active** column is cleared.

3 Choose **Active level edit** from the shortcut menu.

The **Active level** dialog box is displayed.

4 Select an **Active level** condition, and then enter a **Sort** position number.

Active level conditions

- **Red:** to display error messages in the Information work area.
- **Yellow**: to display both warning level (yellow) and error level (red) system messages in the Information work area.
- **Green**: to display normal level (green), warning level (yellow), and error level (red) system messages in the Information work area.
- **All:** to display all system messages, that is, with and without active level conditions, in the Information work area.

5 Choose the **OK** button.

The configuration is saved into the system.

Reviewing log files

Log system errors information can be viewed in the **Routine client > Utilities** tab component.

To review log files

1 Choose **System configuration** > **Log files**.

The **Log information** work area is displayed.

2 From the filter criteria in the upper work area, filter the system and log information type that you want to view.

The table displays the log information list according to the filter selections.

3 Right-click in the work area, and then choose **Display log info** on the shortcut menu.

The **Log information** dialog box is displayed for viewing only.

4 Close the work area.

5 Right-click on the same system ID and choose **Set reviewed** from the shortcut menu.

The system marks the log file as **Reviewed**. The **Seen** check box is selected in the **Log information** dialog box.

Rule management

This chapter describes the different types of rules that you can use in the **cobas® IT middleware** for automated results processing and release.

In this chapter

Chapter **9**

Table of contents

About rules

Rules enable you to automate processes on the **cobas® IT middleware**.

CAUTION

Testing rules

Rules that have not been tested beforehand may not behave as expected in routine operation. This could lead to incorrect or inaccurate results.

- All configured rules must be tested before routine operation.

Types of rules

There are two classes of rules available on the **cobas® IT middleware**:

- Test configuration rules
- Rule engine rules

Rule engine rules can be divided into:

- Rules
- Formulas

Formulas are a specific type of rule engine rule and are used to calculate a new test result based on results from other tests. Formulas are also referred to as *calculated tests*.

All rules are created and managed in the **Test Configuration** workplace. Test configuration rules are created and managed in the **Tests / reference ranges** component. Rules and formulas are created and managed in the **Rule engine** component.

Rule event triggers

All rules are triggered by events.

- Test configuration rules are triggered by test-specific events (after order, result conversion, after evaluation).
- Rule engine rules are triggered by order-related, test-related before order or sample-related events (for example, after test request, result change).

Which type of rule to use

The matrices below indicates the most appropriate rule type you should use where:

x = recommended, (x) = possible but not appropriate, '-' = not applicable

Actions performed by the rule	Test configuration rule	Rule	Formula
Reflex test (for example, add test if Creatinine Kinase CK is > 150)	x	(x)	-
Rerun test	x	x	-
Comment	x	x	-
Conversion /result replacement	x	(x)	-
Orderer /patient-related actions	-	x	-
Actions based on previous results (do not order additional tests if the test was already done the day before)	-	x	-
Mathematical calculation (for example, Creatinine-clearance, cPSA, Indirect Bilirubin)	-	-	x

Table 9-1 Rule decision matrix (by rule actions)

Actions performed by the rule	Test configuration rule	Rule	Formula
Actions on multiple tests	-	x	x
Rounding up/down	-	x	x
Actions on multiple conditions	-	x	x
String manipulation	-	x	-
Dilution setting for reruns	x	x	-
Complex rules based on java code	-	-	-
Sample related actions (priority setting, insurance)	-	x	-

Table 9-1 Rule decision matrix (by rule actions)

When is the rule triggered?	Test configuration rule	Rule	Formula
After a request	x	x	-
Result conversion before validation	x	-	-
After evaluation	x	x	-
After release	x	x	x
After evaluation with a specified validation status	x	x	-
After a result value change	-	x	-

Table 9-2 Rule decision matrix (by rule trigger event)

Test configuration rules

You create and manage test configuration rules in the **Tests / reference ranges** component of the **Test Configuration** workplace. The rules are created as part of the test creation / editing process.

There are three test configuration rules, each based on a specific event that triggers the rule:

- After request rule
- Result conversion rule
- After evaluation rule

After request rules enable you to define rules that will be executed after a test has been requested. *Result conversion rules* enable you to define rules that convert existing results into your own proprietary results. *After evaluation rules* enable you to define rules that will be executed after the result passed the evaluation process.

Test configuration also provides you with an entry point to formula definition. You create the (calculated) test in the **Tests / reference ranges** component and then, via a direct link, define the formula in the **Rule engine** component.

Creating an after request rule

You define an after request rule when that rule is executed after a test has been requested.

When there are two or more after request rules, you can increase or decrease the priority of a rule by right-clicking it and selecting **Increase priority / Decrease priority** from the shortcut menu.

To define a rule after a test was requested

1. Choose **Test Configuration > Tests / reference ranges.**

   The **Tests / reference ranges** work area is displayed.

2. Right-click on the test to which you want to add a rule, and then select **Edit test** from the shortcut menu.

   The **Test / reference ranges** dialog box is displayed.

3. Choose the **After request rules** tab, right-click in the **Action** table and then choose **Add action** from the shortcut menu.

   The **Add action** dialog box is displayed.

4. From the **Action** drop-down list, select:

   - **Add test**
     or,
   - **Add profile**.

5. Depending on the selection, select a test or profile from the **Test No. / Profile code** drop-down list.

   When you select **Add test**, a **Test no**. drop-down list and a **Priority** drop-down list are displayed. When you select **Add profile**, a **Profile code** drop-down list and a **Priority** drop-down list are displayed.

6 From the **Priority** drop-down list, optionally select a priority type.

7 Choose the **OK** button.

The dialog box closes and the new action is added to the **Action** table.

Creating a result conversion rule

You define result conversion rules to convert existing results into your own proprietary results. The test result conversion takes place prior to the validation. Validation is performed on the converted test result.

When there are two or more conversion rules, you can increase or decrease the priority of a rule by right-clicking it and selecting **Increase priority / Decrease priority** from the shortcut menu.

For numerical results you can select the following conditions:

Sign	Description
<	Less than (for example, <5, all results smaller than 5 will be converted).
≤	Less than or equal to (for example, <=5, all results smaller than 5 and including 5 will be converted).
=	equal to (for example, all results which are 5 will be converted).
≥	Greater than or equal to (for example, >=5, all results bigger than 5 and including 5 will be converted).
>	Greater than (for example, >5, all results bigger than 5 will be converted).
≠	Not equal (that is, all results other than 5 will be converted).
[...]	Lower (including) and upper limit (including) (for example, all results between 5 (including 5) and 10 (including 10) will be converted.
[...[	Lower (including) and upper limit (excluding) (for example, all results between 5 (including 5) and 10 (excluding 10) will be converted.
]...]	Lower (excluding) and upper limit (including) (for example, all results between 5 (excluding 5) and 10 (including 10) will be converted.
]...[	Lower (excluding) and upper limit (excluding) (for example, all results between 5 (excluding 5) and 10 (excluding 10) will be converted.
always	Unconditional conversion.

Table 9-3 Numeric result conversion conditions

For alphanumerical results you can select the following:

Sign	Description
equals	Result must be completely equal (which means also case sensitive) in order to get converted (for example, POS = POS).
is like	Results can be similar. The use of wildcards (%) and placeholders(_) is allowed (for example, P_OS means a four letter result with a user definable second letter, POS% means a result with at least three given letters and an unlimited suffix.
is in	Result is one of the values in a comma-separated list (for example, POS is OK when the given list is POS, POSITIVE, PLUS).
always	No restriction; all given alphanumeric results will be converted.

Table 9-4 Alphanumeric result conversion conditions

To create a result conversion rule

1 Choose **Test Configuration > Tests / reference ranges**.

The **Tests / reference ranges** work area is displayed.

2 Right-click the test to which you want to add a result conversion rule, and then select **Edit test** from the shortcut menu.

The **Test / reference ranges** dialog box is displayed.

3 Select the **Result conversion rules** tab, and then choose one of the following:

- **Numeric results**
  or,
- **Alphanumeric results**.

4 From the **If result** drop-down list, select one condition, and then enter the numeric or alphanumeric value that will be converted into the adjacent field.

5 In the **Set result to** field, type the value to which the set result will be converted when the condition is fulfilled.

6 Choose the **Add** button.

The result conversion rule is added to that test.

Creating after evaluation rules

You define after evaluation rules for those rules which are executed after a test result has been evaluated.

When there are two or more after evaluation rules, you can increase or decrease the priority of a rule by right-clicking it and selecting **Increase priority / Decrease priority** from the shortcut menu.

After evaluation rules are executed, when the corresponding conditions are fulfilled in order of priority. If a rule has the **Stop when executed** check box selected, no further rules will be run after the condition has been fulfilled.

Actions, which will be assigned to the selected condition, will be executed after the selected condition is fulfilled. The following actions are available:

Action	Description
Add profile	Adds a predefined test profile and the priority.
Block	Test result is blocked from automatic validation.
No action	Nothing happens.
Reflex	Performs a predefined reflex test.
Replace result	Replaces the original result with a manually entered result. This can only be done if the result is not released.
Rerun	Performs a rerun of the selected test with optional dilution settings. You can either set an automatic dilution factor or a manual one. This action will not work if a test had been released.
Result comment	Adds a predefined comment to the result.

Table 9-5 List of actions

Action	Description
Sample comment	Adds a predefined comment to a sample.
Validation	Performs a validation.
Test comment	Adds a predefined comment to a test.

Table 9-5 List of actions

To create after evaluation rules

1. Choose **Test Configuration > Tests / reference ranges.**

   The **Tests / reference ranges** work area is displayed.

2. Right-click the test to which you want to add a rule, and then choose **Edit test** from the shortcut menu.

   The **Test / reference ranges** dialog box is displayed.

3. Choose the **After evaluation rules** tab, right-click in the **After evaluation rules** table and then choose **Add action** from the shortcut menu.

   The **Add action** dialog box is displayed.

4. From the **Condition** drop-down list, select the condition (status) that will trigger the action.

5. From the **Action** drop-down list, select an action.

   Depending on the selected action, you have to select/enter additional, related parameters.

6. Choose the **OK** button.

   The **Insert action** dialog box closes and the rule is added in the **After evaluation rules** table.

Editing and removing test configuration rules

You can edit or delete After order rules and After evaluation rules as necessary. Result conversion rules can be deleted.

To edit After request rules and After evaluation rules

1. Choose **Test Configuration > Tests / reference ranges.**

   The **Tests / reference ranges** work area is displayed.

2. Right-click the test for which you want to edit or delete a rule, and then choose **Edit test** from the shortcut menu.

   The **Test / reference ranges** dialog box is displayed.

3. Choose one of the following:

   - **After request rules** tab
     or,
   - **After evaluation rules** tab.

4. Right-click the rule that you want to edit or delete, and then select **Edit action** from the shortcut menu

   The **Edit action** dialog box is displayed.

5 Make the appropriate changes and choose the **OK** button.

The **Edit action** dialog box closes and the rule is amended.

■

To delete After request rules, Result conversion rules, and After evaluation rules

1 Choose **Test Configuration > Tests / reference ranges.**

The **Tests / reference ranges** work area is displayed.

2 Right-click the test for which you want to edit or delete a rule, and then choose **Edit test** from the shortcut menu.

The **Test / reference ranges** dialog box is displayed.

3 Choose one the following:

- **After request rules** tab
  or,
- **Result conversion rules** tab.
  or,
- **After evaluation rules** tab

4 Right-click the rule that you want to delete, and from the shortcut menu choose one of the following:

- **Remove action**
  or,
- **Delete conversion**

The rule is removed.

■

Rule engine rules

Rule engine rules are created and managed in the **Rule engine** component of the **Test Configuration** workplace.

There are two types of Rule engine rules:

- Rules
- Formulas

Rules and formulas are triggered by events. A rule is triggered by one or more events, the types of which are determined by the object on which the rule is based (test, order, before order, sample).

A formula is triggered by one event only, the input of one or more numeric test results.

Rules are created in **Test Configuration > Rule engine > List**. Formulas are also created there. However, since a formula must be defined for a calculated test, it is more likely that the calculated test will first be created in **Test Configuration > Tests / reference ranges.**. The formula creation will then be initiated from the **Formula** tab of the calculated test.

You use the remaining **Test Configuration > Rule engine** sub-components to manage rules and formulas:

- **Rule assignments** enables you to view event assignment to rules and formulas' calculated tests and input tests.
- **Log** is where you can view the log entries of rules and formulas.
- **History** enables you to monitor the change history and revision records of rules and formulas.
- **Test suite** is where you can select a rule or formula that will be tested by running it in draft status.
- **Settings** enables you to define the appearance of the graphical elements used in the **Rule definition** editor, define the test suite location, enable logging, and apply other rule settings.

Rule engine rules creation

Rules and formulas are defined in the same way using the **Rule definition** dialog box (editor). However, there are small differences in their definition which reflect the event assignment.

You determine whether you are defining a rule or a formula in the **Rule definition** dialog box, and the consequence of its layout reflects your choice.

Both layouts are similar and reflect the main stages in its use.

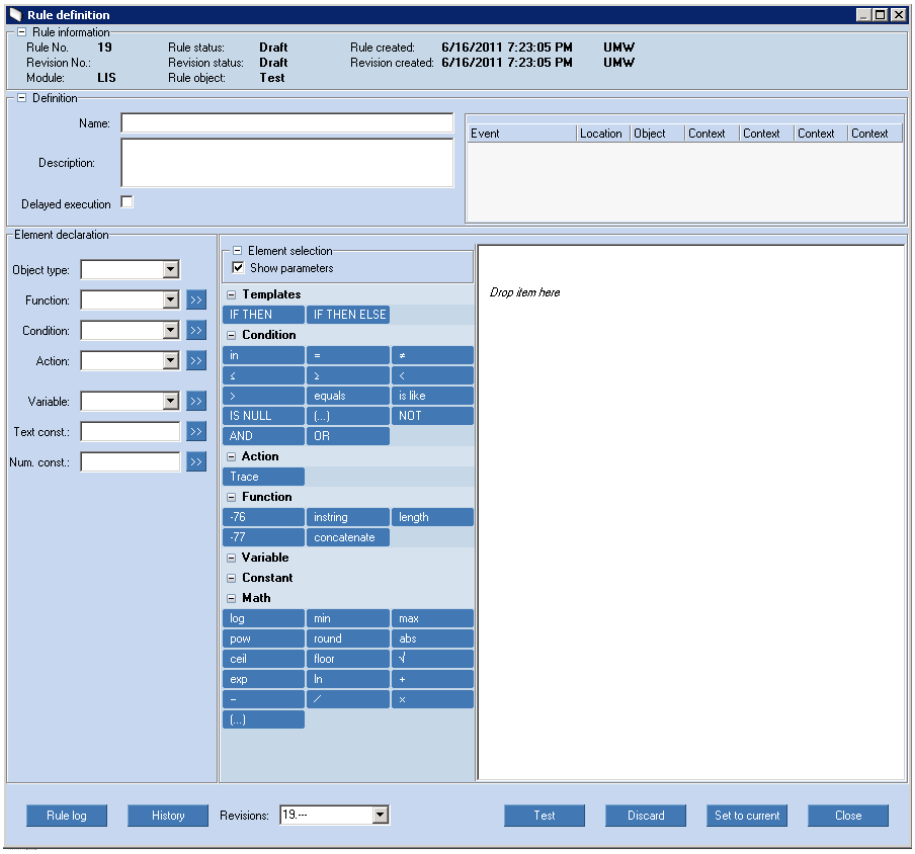

Figure 9-1 Rule definition dialog box

Creating a rule

The main stages in rule creation are:

- Rule definition.
- Event assignment.
- Element declaration.
- Element selection and rule creation.

The **Rule information** group box contains information about the rule (for example, number, revision, status, dates).

Rule definition and event assignment

The **Rule definition** group box is where you provide a name and a description to the rule, and where you assign the event(s) that will trigger the rule. Events are assigned using the **Assignment for rule No. xx** dialog box.

Element declaration

You use the **Element declaration** group box to select elements that you will use to define the rule. As you select the elements, they move to the corresponding area in the **Element selection** group box from where they will be used to define the rule.

When you select an element, in most cases a **Parameters** dialog box is displayed in which you must define parameters (mandatory and optional) for the element before it can be moved to the **Element selection** group box.

The **Object type** element filters the associated actions, functions, and conditions. The **Function** element enables you to select values (in terms of patient age, numeric result, numeric previous result, etc.) that can be used to define the rule.

Condition elements are used in "IF" elements of the IF THEN and IF THEN ELSE templates (for example, 'Has flag', 'Is numeric', 'Test status is').

Action elements are used to perform a task (for example, 'Add test comment', 'Block result', 'Release result').

Variable elements (for example, 'Date', 'Number', 'String') when selected, create a corresponding **Action** element to which a value can be assigned.

Text const. and **Num. const**. Elements enable you to define text or numerical constants which will be used in the rule definition.

Element selection The **Element selection** group box contains the elements that you use to define a rule. They are grouped logically, and also correspond to element types in the **Element declaration** group box.

There are 'default' elements (for example, Math elements, Templates elements, Condition elements) and those that you selected in the **Element declaration** group box.

Show parameters

Choose **Show parameters** to view action and variable element names in full. For example, a date variable element displays as 'var1=' when **Show parameters** is not selected, but displays as 'var1(Date)=' when **Show parameters** is selected.

Rule creation You create the rule by dragging the appropriate elements from the **Element selection** group box and dropping them on the pane to its right. Although the action of dragging and dropping elements is straightforward, there are certain constraints.

If you try to drop an element in an invalid location, a 'no entry' sign is displayed alerting you to this, and the element cannot be 'dropped'. When you position an element over a valid location, a 'rectangle' appears, indicating that you can drop the element at this location.

A rule can be started with a **Templates** element or an **Action** element.

Conditions can only go into an 'if' element. Actions can go into an empty pane or be dropped on an element line of the arrow.

You use functions:

- To assign a value to a variable.
- In 'if' statements.
- For calculations.
- For text creation.

You use variables in a similar way to functions; a value should be assigned first (action).

When you have created your rule, you can test it by choosing the **Test** button. A message box informs you if there are any errors or not.

To create a rule

1. Choose **Test Configuration > Rule engine > Rule list**.

   The **Rules and formulas** work area is displayed.

2. Right-click the rule list table, and then choose **New rule / formula** from the shortcut menu.

   The **Rule definition** dialog box is displayed

3 From the **Rule type** drop-down list, select **Rule**.

4 From the **Module** drop-down list, select the relevant module.

5 From the **Object** drop-down list, select one of the following objects:

- **Order** (rule is order-based).
  or,
- **Test** (rule is test-based).
  or,
- **Before order** (rule is before-order-based).
  or,
- **Sample** (rule is sample-based)

6 Choose the **Apply** button.

The **Rule definition** dialog box is displayed.

7 In the **Name** field, enter a rule name.

8 In the **Description** field, type a rule description.

9 Optionally select the **Delayed execution** check box, then enter the amount of time for the delay of the rule execution.

10 Right-click the **Event** list table, and then choose **Open assignments** from the shortcut menu.

The **Assignment for rule No. xx** dialog box is displayed.

11 From the **Event** drop-down list, select an event.

Depending on the selection, more drop-down lists appear and you have to select more parameters.

12 Choose the **Apply** button.

The defined event moves to the **Assignments** table.

13 Assign additional events as required.

14 Choose the **Close** button.

The **Assignment for rule No. XX** dialog box closes and the defined events appear in the **Event** table of the **Rule definition** dialog box.

15 From the **Element selection**, drag and drop the following on the **Drop item here** text:

- The **IF THEN** element.
  or,
- The **IF THEN ELSE** element.

16 From the **Element** selection, drag and drop more elements on the **Drop item here** text, as needed to create the rule.

17 Click the **Test** button.

The system checks if the rule syntax is defined correctly.

If the rule is correct, the message text **Rule compiles without errors** is displayed. If the rule is incorrect, an error message is displayed.

18 Choose the **Set to current** button.

The **Rule status** changes to **Active**.

19 Choose the **Close** button.

The rule definition dialog box closes.

Creating a formula

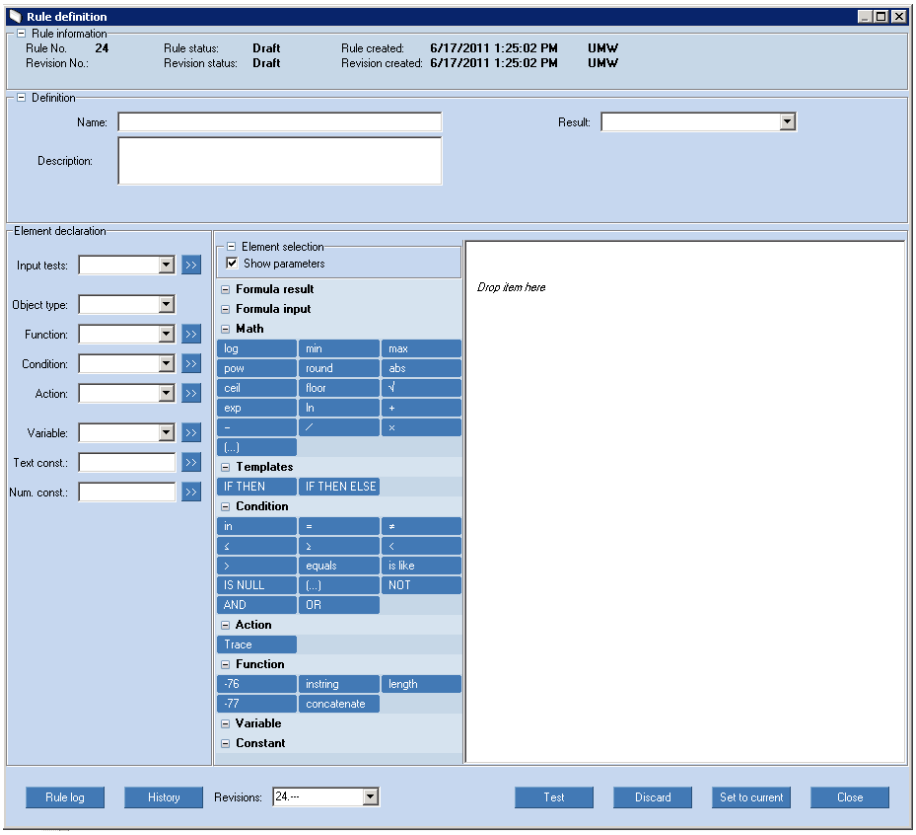

Figure 9-2 Formula definition

You use the **Rule definition** dialog box to create formulas. Its layout and functionality is very similar to the editor used to define rules. However, it contains the following differences.

In the **Definition** group box, there is no event assignment. From the **Result** drop-down list, you select the calculated test for which you are defining the formula. Note that if you have come to the editor from the **Formula** tab of the calculated test in test configuration, the test is automatically selected.

In the **Element declaration** group box, the first declaration element is **Input tests** with which you select the tests, the results of which will be used as the input values to the calculated test.

The **Element selection** group box contains two additional groups. **Formula result** contains the calculated test selected from the **Result** drop-down list in the **Definition** group box as an element. **Formula input** contains the elements corresponding to the selections made from the **Input tests** in the **Element declaration** group box.

Some actions and or conditions can be applied to profiles also.

The process otherwise is the same as for creating a rule.

The following procedure outlines the creation of a formula starting from the **Tests / reference ranges** component.

To create a formula from the Tests / reference ranges component.

1. C**hoose Test Configuration workplace > Tests / reference ranges**.
2. Choose the test to which you want to add a formula.

   The **Test / reference ranges** dialog box is displayed.
3. Choose the **Formula** tab, and then choose the **Formula** button.

   The **Formula for xx** dialog box is displayed.

The **Formula for xx** dialog box is exactly the same as the **Rule definition** dialog box used to create a formula from the **List** sub-component.

4. In the **Name** field, enter a name for the formula (optional).
5. In the **Description** field, enter a description (optional).
6. In the **Element declaration** group box, select an element, for each element to be used in the formula, select an element and then do one of the following:
   - Choose the >> button
     or,
   - Press [**Enter**].

   The element moves to the corresponding **Element selection** area. When you select a **Condition** element, an **Action** element, or certain **Function** elements, the **Parameters** dialog box is displayed depending on the selection. When you choose the **OK** button, the element moves to the corresponding **Element** selection area.

You can remove elements from the **Formula creation** pane by right-clicking the element and then choosing **Delete**.

7. Drag the **Formula result** and drop it on the **Drop item here** text in the **Formula creation** pane.

   A result = icon is displayed in the **Formula creation** pane.

Do not drop it anywhere else in the **Formula creation** pane because it will display a 'No entry' icon on the cursor, indicating that it cannot be dropped.

8. To build the formula, drag one or more of the necessary elements from:
   - **Input tests** from the **Formula input** area.
     or,
   - Numbers or text from the **Constant** area.
     or,
   - Appropriate numerical functions from the **Math** area.
9. Drop and arrange them inside the parenthesis of the result = icon.
10. When the formula is complete, choose the **Set to current** button.

    The formula status changes to **Active** (default status) and the **Revision status** changes to **Current**.
11. Choose the **Close** button.

    The **Formula for XX** dialog box is closed.

Editing Rule engine rules

You modify a rule or formula when you need to change one or more of its components.

A rule or formula can have many revisions, only one of which is current and applied.

The draft copy of the rule or formula is saved in the rules table.

The modifications that you make to a rule or formula are made to a draft version after which you can do one of the following:

- Change the draft (modified) version of the rule or formula to the current version, which will then be used in calculations.
- Save the draft (modified) version of the rule or formula for further modification at another time, and continue using the original version.
- Discard the draft version of the rule or formula, and continue using the original version.

You can track the **Revision No.**, **Revision status**, and **Formula status** of rules and formulas using the **List** sub-component.

When you open the draft again to work on it, the **Rule definition** dialog box is displayed in edit mode.

To edit a rule or formula

1 Choose **Test Configuration > Rule engine > Rule list.**

The **Rule list** dialog box is displayed.

2 Select the appropriate **Rule type** (rule or formula) and any other search criteria as appropriate, and then choose the **Search** button.

The rules or formulas matching your search criteria are displayed.

3 Right-click the rule or formula that you want to edit, and then choose **Open rule / formula** from the shortcut menu.

The **Rule definition** dialog box is displayed containing the rule you want to modify.

4 Choose **Edit rule**.

The **Revision status** of the rule or formula changes from **Current** to **Draft** and you can edit it. Additionally, the **Discard** and **Test** buttons are displayed.

5 Edit the rule, and then choose the **Set to current** button.

The **Revision status** of the rule changes from **Draft** to **Current**. The **Revision No.** increases by one. The changes you have made to the rule are saved.

6 Choose the **Close** button.

The **Rule definition** dialog box closes.

Removing Rule engine rules

You can remove a rule when it is no longer used.

When you remove a rule, all of its revisions remain in the rule list. Each revision of the rule has a **Rule status** of **Removed** and a **Revision status** of **Outdated**. No version of the rule can be used again.

You can discard a rule revision by choosing the **Discard** button.

Removed rule revisions are displayed when the **Show removed rules** and **Show outdated revisions** selection parameters are selected.

To remove a rule

1 Choose **Test Configuration > Rule engine > Rule list.**

The **Rule list** dialog box is displayed.

2 Select the appropriate **Rule type** (rule or formula) and any other search criteria which enable you to locate the rule or formula that you want to remove, and then choose the **Search** button.

The rules or formulas matching your search criteria are displayed.

3 Right-click a revision of the rule that you want to remove, and then choose **Remove rule / formula** from the shortcut menu.

A message box is displayed asking if you want to remove the rule.

4 Choose the **OK** button.

The rule is removed and all of its revisions have a **Rule status** of **Removed** and a **Revision status** of **Outdated**, and the corresponding bars are black.

Rule engine rules management

Managing rules and formulas includes:

- Rule / Formula life cycle.
- Monitoring rules and formulas.
- Activating rules or formulas.
- Defining rule and formula settings.

Rule / formula life cycle

A rule and a formula are identified by a number which is automatically allocated when you create it, and is appended by a revision (version) number which enables you to track changes that you make to it. For example, 5.3 means rule / formula five is in its third revision.

A rule / formula and its revision(s) each have a status reflecting the position of the formula in its life cycle.

The possible statuses are:

- **Draft** (rule/formula is being created).
- **Active** (rule/formula is being used in calculations).
- **Inactive** (rule/formula is currently not being used).
- **Removed** (rule/formula can no longer be used).

Revisions:

- **Draft** (revision is being created/revised).
- **Current** (revision is being used in calculations).
- **Outdated** (revision is no longer current).

A formula is either **Active** or **Inactive**. When a formula is active, it is used in test calculations. When a formula is inactive, it will not be used in test calculations.

Monitoring Rule engine rules

The **List**, **Log**, and **History** sub-components enable you to monitor the use of rules and formulas in terms of their status changes, runs and life cycle.

In addition to allowing you to manage formulas, the **List** sub-component provides you with the means of monitoring rules and formulas.

The **List** sub-component comprises selection parameters and the formulas table containing the formulas matching the selection criteria.

Color-coding provides you with a visual indication of the **Rule status** and the **Revision status** as follows:

Rule status:

- **Draft** = **gray**.
- **Active** = **green**.
- **Inactive** = **red**.
- **Removed** = **black**.

Revision status:

- **Draft** = **gray**.
- **Current** = **green**.
- **Outdated** = **black**.

To view rules and formulas

1 Choose **Test Configuration > Rule engine > Rule list.**

The **Rule list** dialog box is displayed.

2 Select the appropriate rule or formula and revision filters to display the rules and formulas that you want to view, and then choose **Select**.

Tip

If the filters in the **Selection parameters** group box are not visible, click the '+' to display them.

The rules and formulas matching your selection criteria are listed in the table.

Viewing Rule engine rule logs

Each time an event is triggered, the system allocates an incremental **Run No**. and a log is generated. The **Log** sub-component enables you to view the logs of rules or formulas.

Basic logs are only recorded if the option **Enable basic logging** is enabled in the **Rule engine** > **Settings**. This option is disabled by default. However, errors are always logged.

The selection filters enable you to view the logs by time period, rule or formula, run number, or by any combination of these.

You also have access to rule or formula definitions and the rule or formula history from the **Log** sub-component.

You can access the logs of a rule or formula from the **Rule definition** dialog box through the **Log** button.

You can view logs for a specific rule or formula by entering the **Rule No.** and choosing **Search**.

To view rule or formula logs

1 Choose **Test Configuration > Rule engine > Rule log**

The **Rule log** dialog box is displayed.

2 In the **Selection** group box, choose the appropriate search criteria to display the logs that you want to view, and then choose the **Search** button.

The logs matching your search criteria are listed in the logs table.

To view the logs for a specific rule or formula

1 Choose **Test Configuration > Rule engine > Rule log**

The **Rule log** dialog box is displayed.

2 Right-click the log of the rule or formula that you want to view, and then choose **Show rule log** on the shortcut menu.

The logs for the specified rule or formula are listed in the logs table.

To view a rule or formula definition from the logs table

1 Choose **Test Configuration > Rule engine > Rule log**

The **Rule log** dialog box is displayed.

2 Right-click the log of the rule or formula whose definition you want to view, and then choose **Show rule definition** in the shortcut menu.

The **Rule definition** dialog box is displayed containing rule or formula definition.

Viewing Rule engine rule histories

You can monitor the change history and revision records of a rule or formula by viewing its history.

The history of a rule or formula records each status change of a rule or formula and its revisions as an entry in the history table, indicating when the status change occurred, and which user made the change.

Some history entries (for example, 'activation') are only rule-specific and not revision-specific. Consequently, no revision number is displayed, and the shortcut menu option **Show rule** is unavailable.

To view the history of a formula and a specific revision

1 Choose **Test Configuration > Rule engine > Rule history**

The **Rule history** dialog box is displayed.

2 Right-click the rule or formula whose history you want to view, and then choose **Show rule history** on the shortcut menu.

The **History of rule no xx** dialog box is displayed containing all history entries of the rule or formula selected.

3 To view a revision of the rule or formula, right-click the revision you want to view, and then click **Show rule** on the shortcut menu.

The **Rule definition** dialog box is displayed containing details of the revision of the rule or formula selected.

De-activating and activating Rule engine rules

You deactivate a rule or formula when it is no longer applied to result processing. You activate a rule or formula when you need to apply it in result processing.

A rule or formula can have any number of revisions. You activate the one that you want to be applied.

When a rule or formula is active, the **Rule status** of all revisions of the formula is **Active**. This is indicated by the corresponding **Rule status** bars in the **Rule list** displaying green. The rule or formula revision that is applied in the test result processing has a **Revision status** of **Current**. This is indicated by the corresponding **Rule status** bar displaying green.

When a rule or formula has been deactivated the **Rule status** of all of its revisions is **Inactive**. This is indicated by the corresponding bars in the **Rule list** displaying red. The formula will not be applied in the processing of the test result.

To view the active and/or inactive rules or formulas in the rule table, the **Show active rules** and **Show inactive rules** check boxes in the **Selection parameter** group box must be selected.

To de-activate a rule or formula

1 Choose **Test Configuration > Rule engine > Rule list**

The **Rule list** dialog box is displayed.

2 Right-click the revision of the rule or formula you want to de-activate (green **Rule status**), and then choose **Deactivate rule / formula** option in the shortcut menu.

The rule or formula is de-activated, the revision of the formula changes to **Inactive,** and the corresponding bars turns red.

To activate a rule or formula

1 Choose **Test Configuration > Rule engine > Rule list**

The **Rule list** dialog box is displayed.

2 Right-click a revision of the rule or formula you want to activate (red **Rule status**), and then choose **Activate rule/formula** in the shortcut menu.

The rule or formula revision is activated and the **Rule status** of all revisions of the rule or formula changes to **Active,** and the corresponding bars change to green. The revision of the rule or formula that is applied has a **Revision status** of **Current,** and the corresponding bar is green.

Rule engine settings

The **Settings** sub-component of the **Rule engine** component enables you to apply general settings to rules or formulas, and to define the appearance of the mathematical notation elements used in the **Rule definition** dialog box.

General settings

Add formula inputs when result is requested means if you request a calculated test, the system checks whether the test is defined as a formula result. If yes, the system automatically requests the formula input tests, which are needed for the calculated test.

For example, if you request Bilirubin indirect, Bili indirect is calculated out of Bili total and Bili direct. When Bili indirect is requested, the tests Bili total and Bili direct are automatically added to the sample when this check box is chosen.

Add formula result when inputs are ready means if released result(s) of all test(s) defined as formula inputs of a formula are available, the test that is defined as a formula result is requested and calculated.

New rules are by default enables you to determine whether a new rule or formula is active or inactive by default.

You use **Test client** to select the location which is used by the **Test suite**.

You can enable or disable basic logging using the **Enable basic logging** drop-down list.

Mathematical notation appearance

You define the shape, color, and the background color of the frame of the mathematical notation elements to enhance the appearance of the formulas created.

If you want to reset the frame and background colors to no color, select **Reset frame color** or **Reset background color** on the shortcut menu.

To define the appearance of a mathematical notation element

1 Choose **Test Configuration > Rule engine > Rule settings.**

The **Settings** dialog box is displayed.

2 Right-click the mathematical notation whose appearance you want to define, and on the shortcut menu choose the following:

- **Set background color**: the **Color** dialog box opens, in which you can select a color and choose the **OK** button.
  or,
- **Set frame color**: the **Color** dialog box opens in which you can select a color and choose the **OK** button.
  or,
- **Select shape**: a sub-menu opens from which you select one of the following: Ellipse - Octagon - Rhombus - Rectangle.

The corresponding definition is applied to the mathematical notation.

Working examples

The following examples illustrate rule and formula definitions that can be created.

Rule and formula examples

Using the rule or formula examples from this section, without adapting them to the requirements of your organization, may return incorrect or inaccurate results.

- These are only examples. You must adjust the rules and formulas according to the requirements of your organization.

Cockcroft-Gault Creatinine Clearance formula

You can calculate a creatinine clearance using the Cockcroft-Gault formula.

The formula that you create should include nested *IF THEN ELSE* templates, which are used to differentiate between three gender types;

- Female (F)
- Male (M)
- Unknown (U)

The formula calculates the result according to the gender type. If the gender is unknown, the *Calculated result* is set to **0** in this example.

The formula that you create is based upon the Cockcroft-Gault Creatinine Clearance equation:

CCrea in ml/min = {(140-age in years) x (body weight) x (0.85 if female)} / (72 x $Crea_{Serum}$)

Required input elements:

- **Input tests**:
  - Crea-Serum (mg/dl)
  - Body weight (kg)

You must create a “virtual” test with which the body weight value will be input.

- **Variable** = “Number”:
  - “1” for Male
  - “0.85” for Female
  - “0” for Unknown
- **Num. const** = “140”
- **Num. const.** = “72”
- **Object type** = “Patient”, **Function** = “Gender” (“M”, “W”, “U”)
- **Object type** = “Patient”, **Function** = “Age” (years).

If the patient is unknown, then the age is unknown as well. The formula is still calculated, but the result is empty.

The final formula looks like this:

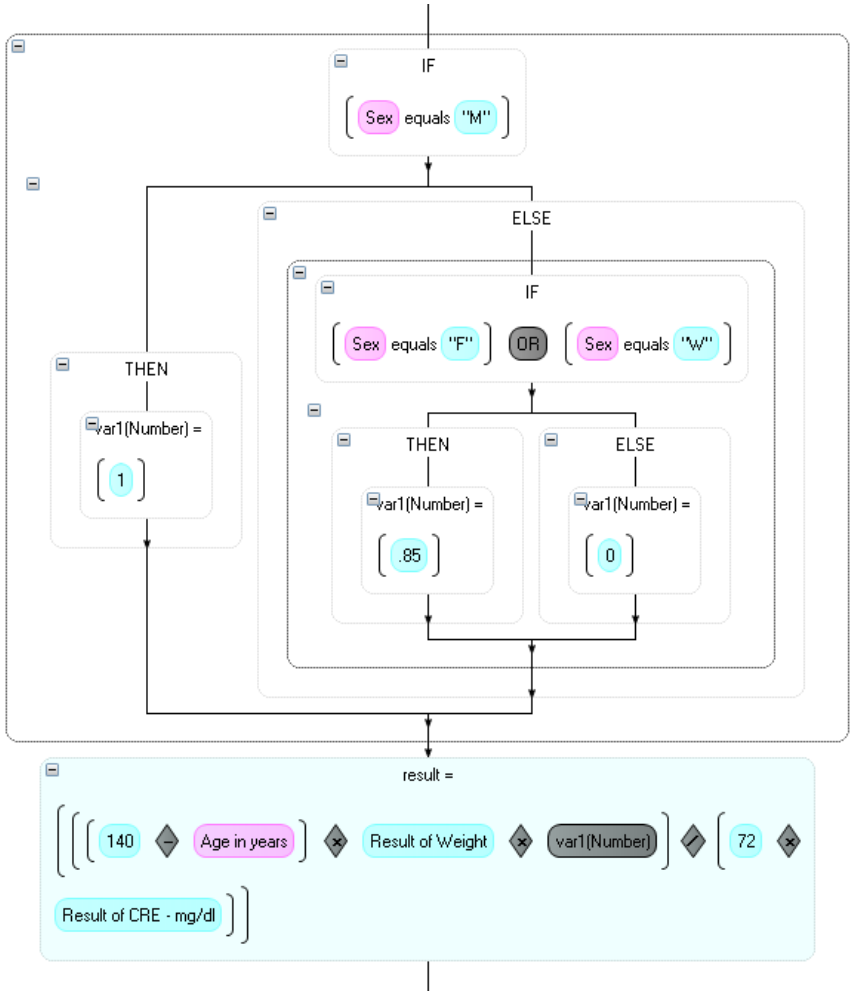

Figure 9-3 Cockcroft-Gault Creatinine Clearance formula

TSH (Thyroid Stimulating Hormone) test rule

The following example shows a rule definition that adds the hormones fT3 and fT4 when a TSH result is high (>= 4.2).

To test the rule, create several orders with TSH requests, and then enter a result less or greater than 4.2.

An exception to this rule would be an order coming from the Hormone treatment ward and the previous TSH result was tested within the last 60 days.

Required inputs:

- Assign the **Before evaluation** event.
- Input tests:
  - TSH (rule assignment)
  - fT3 (“Request test” **Action**)
  - fT4 (“Request test” **Action**)

- **Function** =
  - “Numeric result”
  - “Orderer code”
  - “Previous result age(Days)”
- **Action** = “Add result comment”
- **Condition**= “Has previous result”
- **Num. const.** =
  - “4.2”
  - “60”
- **Text const.** = “HORMONE%”

The final formula will look like this:

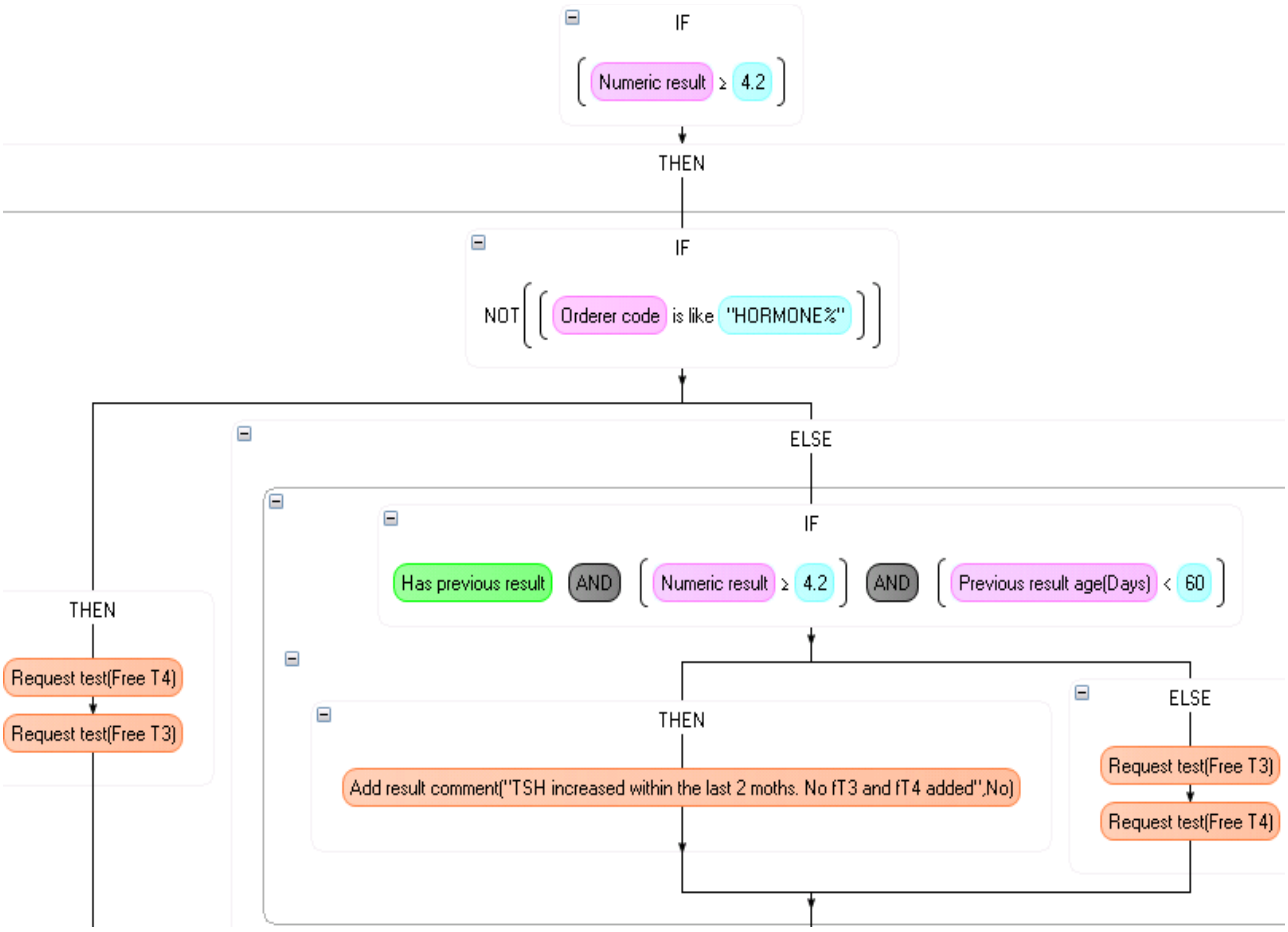

Figure 9-4 TSH formula

Appendix

Glossary

This glossary is a compendium of technical terms used in conjunction with the **cobas IT** middleware.

aliquot Part of a primary sample that is transferred after collection into a different container as the one used for collection. It can be used for parallel testing or for archiving.

archive rack Rack used for archiving samples.

assistance User support area.

bias Estimates how much the mean of the measured QC results deviates from the target mean. It is calculated according to the following formula: bias = (mean of the measured QC results - target mean)/ target mean.

calculated test Test for which the result is calculated on the basis of other measured test results, with the help of algorithms and formulas.

calibration The process that establishes the relation between measured signals (e.g. from a photometer, photomultiplier, or ion-selective electrodes) and corresponding concentration values of a calibrator.

coefficient of variation (CV) The statistical calculation that measures the dispersion of a probability distribution.

consumption report Report which gives information about the number of tests, QC tests and calibrations performed by an instrument as well as the information about the number of resent results.

cumulative QC statistics The statistics of a QC for a defined time frame. It comprise the following statistical parameters:

- arithmetic mean ($\bar{x}$)
- standard deviation (SD)
- standard deviation index (SDI) = (arithmetic mean - target value) / target SD
- bias = (arithmetic mean - target value) / target value
- relative coefficient of variation (CV, in %)
- number of QC results used for calculation (N).

data alarm Alarm associated with a test result or calibration. It is caused by the abnormal condition of measurement.

delta check Comparison of the current result with a previous result of the same test performed on the same patient. Used in medical validation for plausibility and/or for detection of a potentially critical condition of the patient.

demographics Patient-related data such as name, date of birth, and gender.

dilution factor Ratio of final volume of sample/aliquot volume. Final volume = aliquot + diluent.

evaluation A step in the validation workflow. Automatic comparison of a test result against a set of rules which provides information on whether test results can be released or not.

expiry date The time period for which the performance characteristics of a material, stored under optimal conditions, can be assured.

history Record of all events that occurred to an object.

host An external information system of higher level which provides services or a connection to a wider network, for example LIS or HIS.

instrument data alarm Data alarms sent from an instrument.

Levey-Jennings chart Chart which provides a visual method of monitoring trends in QC results. It shows QC results in relation to the expected mean and standard deviation.

location The highest logical unit of an organization within an information solution system, which identifies a laboratory.

log file File that contains records of specific events that have occurred on a system.

lot number The unique identification of a lot

masking Temporarily preventing the system from performing activities on, or accessing a selected item, for example module, instrument, test.

multi-rule QC Multiple QC rules that are combined to monitor one or multiple QC results.

pass-through mode A mode that enables the system to send results to another system without any assessment, modification, or validation. Note that the instrument factor is applied.

QC bracketing Setting in which a test result must be preceded by, and followed by, a successful QC result before it is released.

QC data alarm Data alarms associated with the validation of QC results.

QC failure A situation in which measured values or results of a QC run are in any way unusual or unexpected

QC lot A portion of a lump production of QC material produced by a single supplier. It has a unique identification and a defined shelf life during which the material is guaranteed to yield stable results.

QC lot number The unique identification of a QC lot of a distinct QC material.

QC material Material used to assess the performance of an analytical procedure or part of an analytical procedure. Also called the QC sample.

QC reference range It represents the range of expected QC results that are measured under standardized conditions. It is either expressed as a multiple of the target standard deviation or as the minimum and maximum value.

QC result The result of a QC measurement, that is, the result of a test measured on an instrument for a distinct QC material-QC lot combination.

QC result status Indicates whether the QC result complies to the applied QC rules. It is based on the QC rule status of the applied QC rules.

QC rule A rule which judges the acceptability of an analytical run.

QC study lot QC lot which is used to test a new QC lot before that QC lot is used on an instrument. This means that test results are not compared against it and it is not included in cumulative QC statistics.

reflex test Test that is carried out in addition to the tests that were requested originally. Reflex tests are triggered by the results of the original tests.

release The final step in the validation workflow in which the evaluated test results are sent to the host.

report Filtered data, structured and presented in a specified layout, electronic or printed.

rerun test Repeating a test on a sample under the same or changed conditions.

sample sorting A steps in the pre-analytical phase which involves separating samples into groups that require a different action.

serum index Calculations of absorbance measurements that provide a semi-quantitative representation of levels of lipemia, hemolysis, and icterus that are present in a sample. Lipemic Index: estimate of sample turbidity. Hemolysis Index: estimate of the hemoglobin concentration. Icteric Index: estimate of the bilirubin concentration

serum index data alarm Data alarms associated with the validation of test results with respect to serum indices.

systematic error Deviation between an observed value from the expected value. For QC, it is calculated as arithmetic mean of QC results for a defined time frame of a QC minus the target value for that QC.

target value In QC, the expected value of a specific test.

test masking Temporarily preventing the system from performing a test. This includes QC runs and calibrations.

test profile Named group of tests which are processed together.

turnaround time (TAT) The period of time from the start to the end of the test, for an analyzer in the operating mode.

validation data alarm Data alarms associated with the validation of test results with respect to reference range, rule engine, delta check, QC, and Serum index.

work area The intermediate logical unit of organization within an information solution system below a location. It may consist of several workplaces.

workplace The lowest logical unit of organization within an information solution system below a work area.

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