cobas® t 511 coagulation analyzer

Quick Reference Guide version 6.0
Software version 2.3

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	March 2017	• Initial version
1.1	1.0	July 2017	• Updated safety messages
2.0	2.0	August 2018	• Revised for software 2.0 • Update safety labels on the sample area and on the fluid tray
2.1	2.0.2	March 2019	• Update for maintenance action "Cleaning probe assembly" • Update for **cobas**® t development channel cassette handling
3.0	2.1	August 2019	• New work area implemented - Sample and results • New QC initial run type settings • New illustration concept • New safety message

Revision history

Publication version	Software version	Revision date	Change description
4.0	2.1.1	September 2020	• IVDR Compliance to the Regulation (EU) 2017/746 • Backup system procedure • New safety messages • Handling tubes • Maintenance videos
5.0	2.2	August 2021	• Data alarm detail information • New data alarm • New data upload options • New backup options • Update **E-library** workflows • Update e-barcode handling • Update for LIS security • Encryption at rest - the usage of an encrypted external storage device is recommended. • Specifications for open tube handling implemented • Cleaning the conductive 5-position rack • Update for cuvette transport troubleshooting
6.0	2.3	March 2023	• Update illustrations that showed wrong information • Update the cleaning of the conductive 5-position rack task • Update list of maintenance actions • New interactive help for replacing a syringe and syringe plunger • New import for a copied CSV file into MS Excel • Update rack release time for QC racks • Open orders cancellation • Syringe for reagent reconstitution • Workflow priority for automated reagent cassette reconstitution • Mandatory Roche special wash rule updates • About the HIL-dependent test result comment • Improved weekly maintenance workflow • QC measurements for calculated tests • QC initial run type • Second measurement unit definition • Correct data alarm information • Configurable data alarm for sample clot or probe blocked For more details, see the section: ▸ What is new in publication version 6.0 (19)

Revision history

Edition notice

This publication is intended for operators of the **cobas**® t 511 coagulation analyzer.

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

Where to find information

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

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

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

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

The **Quick Reference Guide** focuses on routine operation. The **Quick Reference Guide** is organized according to the normal operation workflow. It provides information in a concentrated version. For more detailed information, refer to the **User Guide** or the **User Assistance**.

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Preface

Use this publication together with the **cobas**® t 511 coagulation analyzer User Guide or User Assistance.

Operation and maintenance actions are described in the User Guide and User Assistance.

Intended use

The **cobas**® t 511 coagulation analyzer is a fully automated, discrete coagulation analyzer intended for the *in-vitro* qualitative and quantitative determination of coagulation analytes in human citrated plasma, the results of which aid in the diagnosis of coagulation abnormalities and in monitoring anticoagulant therapy.

The **cobas**® t 511 coagulation analyzer is a standalone instrument.

Intended use for IVD accessories

The Intended use of accessories might be not always limited to the **cobas**® t 511 coagulation analyzer.

Insert Sarstedt 8 mm Tube	Rack insert to handle small volume sample tubes on the **cobas**® t 511 coagulation analyzer.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following product names and abbreviations are used:

Product name	Descriptor
System software for **cobas**® t 511 coagulation analyzer	software
cobas® t 511 coagulation analyzer	analyzer
System Cleaner **cobas**	System Cleaner
cobas® Waste Bag	solid waste bag
Cuvette COBAS INTEGRA®	cuvette
cobas® t development channel	development channel
cobas® t development channel cassettes & labels	development channel cassettes and labels
cobas® t development channel vials	development channel reagent bottles
HIL Test	HIL test

Product names

Symbols used in the publication

Symbol	Explanation
•	List item.
	Search: Used on the search tab.
	Table of contents. Used on the table of contents tab.
	History. Used on the history tab to show previously viewed topics.
	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.
	Settings. Button used to open the settings dialog.
	Contact. Used in the User Assistance. Functionality currently unavailable.

Symbols used in the publication

Symbols used on product

Symbol	Explanation
IVD	For *in vitro* diagnostic use.
GTIN	Global Trade Item Number
REF	Catalog number
UDI	Unique device identifier.
CONTENT	Quantity contained in the package.

Symbols used on product

Symbol	Explanation
	Serial number
	Lot number
	Complies with the provisions of the applicable EU regulations.
	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
	Manufacturer
	Date of manufacture
	Caution
	Air pressure
	Humidity range
	Temperature limits
	This side up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Do not stack
	Do not use blades to open.

Symbols used on product

Symbol	Explanation
	Read the operating instructions before handling.
	Do not reuse
	Use by date

Symbols used on product

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CISPR	*Comité International Spécial des Perturbations Radioélectriques* (International Special Committee on Radio Interference)
CSA	Canadian Standards Association
EC	European Community
EMC	Electromagnetic compatibility
EN	European standard
EU	European Union
FCC	Federal Communications Commission
ID	Identification
IEC	International Electrotechnical Commission
IfU	*Instructions for Use*
ISO	International Organization for Standardization
IVD	*In vitro* diagnostic
IVDR	*In vitro* diagnostics regulation
LIS	Laboratory information system
n/a	Not applicable
QC	Quality control
RVC	Reagent volume check
STAT	Short turnaround time
SD	Standard deviation
SOP	Standard Operating Procedure
UI	User interface
UL	Underwriters Laboratories Inc.
UPS	Uninterruptible power supply
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Overview of the main workflow

The main workflow includes procedures for managing and loading supplies and samples, and for handling results.

The order of the main workflow can be adapted based on specific workflow needs.

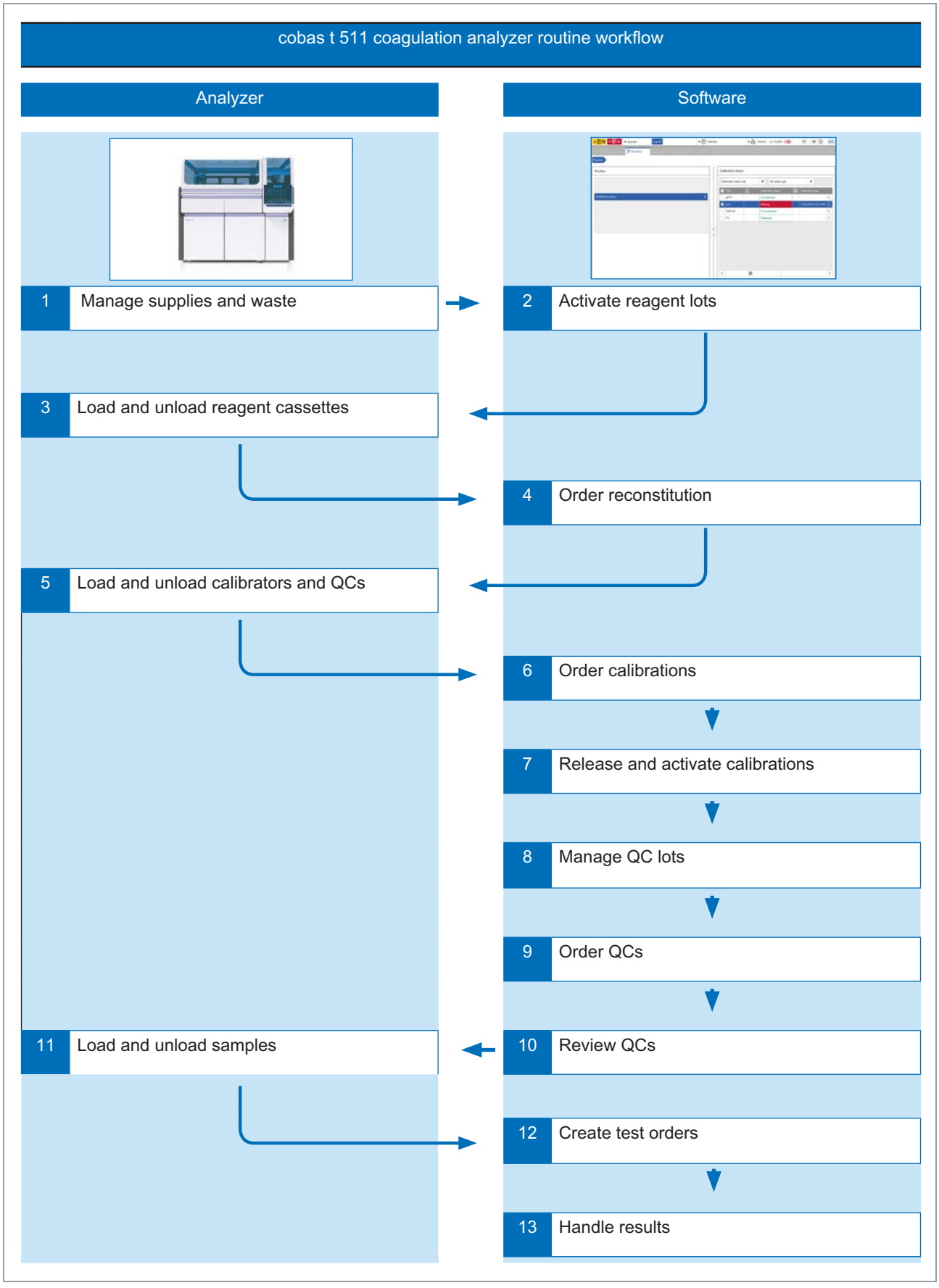
Be sure to follow laboratory best practices and change your lab gloves following any handling of liquid or solid waste.

⚠ WARNING

Delayed results

Limited computational resources may lead to delayed results.

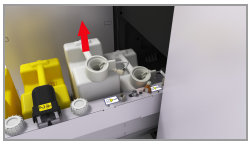
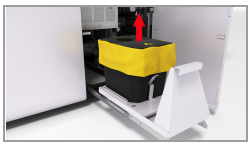
- Ensure that archives are performed regularly and obsolete results are purged.
- Delete obsolete data, for example, problem reports, pdf-files, and screenshots.



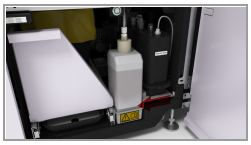
cobas® t 511 routine workflow

Quick reference: Managing supplies and waste

Regularly perform supplies and waste management tasks to ensure continuous operation.

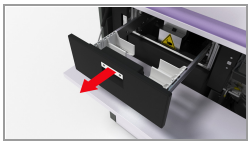
Steps		User action
1 Check supplies and waste on the system		1. Choose **Routine > Other resources**. 2. On the **Other resources** panel, ensure that the **Water** tab, **Liquid waste** tab, **Cleaner** tab, and **Cuvette** tab display **OK** status. 3. To check the status of specific supplies or waste, choose the corresponding tab.
2 Fill water		1. Open the fluids door and pull out the water/liquid waste drawer. 2. Disconnect the water container elbow connector and remove the tubing adapter. 3. Remove the water container and rinse it out with deionized water. 4. Fill the water container with deionized water. 5. Place the water container in the water/liquid waste drawer, reattach the tubing adapter, and reconnect the water container elbow connector. Ensure that the water tubing is not stretched or kinked. 6. Close the water/liquid waste drawer and the fluids door.
3 Empty liquid waste		1. Open the fluids door and pull out the water/liquid waste drawer. 2. Open the waste dispense cap and attach the waste container cap. 3. Lift out the liquid waste container and dispose of the liquid waste according to appropriate local regulations (apply disinfectant to the outside of the liquid waste container before removing it). 4. Pour disinfectant into the liquid waste container (according to local requirements and the specifications of the manufacturer). 5. Place the liquid waste container in the water/liquid waste drawer, remove the liquid waste cap, and close the waste dispense cap. 6. Close the water/liquid waste drawer and the fluids door.
4 Empty solid waste		1. Open the solid waste door and pull out the solid waste drawer. 2. Pull the pull strings at the top of the solid waste bag and lift it out of the solid waste container. 3. Tie the pull strings together and dispose of the solid waste bag according to appropriate local regulations. 4. Insert the replacement bag into the solid waste container. 5. Insert the cover at the top of the solid waste container. 6. Close the solid waste drawer. 7. Pull out the waste tray and dispose of any solid waste. Clean and then reinsert the waste tray. 8. Press the cuvette counter reset button. 9. Close the solid waste door.

Quick reference: Managing supplies and waste

Steps		User action
5 Replace System Cleaner bottle		Ensure that the system is in **Standby** status, **Paused** status, or **Warning** status before performing this action. 1. Open the solid waste door. 2. Remove the System Cleaner bottle tubing from the tubing slot. 3. Lift the System Cleaner bottle together with the System Cleaner bottle tubing adapter out of the System Cleaner bottle tray. 4. Lower the System Cleaner bottle away from the System Cleaner bottle tubing adapter and out of the instrument. 5. Insert the System Cleaner bottle tubing adapter into the replacement System Cleaner bottle. 6. Place the System Cleaner bottle and tubing adapter into the System Cleaner bottle tray. 7. Reinsert the System Cleaner bottle tubing into the tubing slot and close the solid waste door.
6 Load cuvettes		1. Open the front panel. 2. Remove the cuvette drawer and turn it upside down. 3. Fill the cuvette drawer with cuvettes. 4. Insert the cuvette drawer and remove the cuvette drawer panel from the bottom. 5. Insert the cuvette drawer panel at the top of the cuvette drawer. 6. Close the front panel.

Quick reference: Managing supplies and waste

Quick reference: Reagents

Steps		User action
1 Activate reagents		1. To activate a reagent lot, do the following: • Choose **Administration > Reagent lot activation**. • Next to the reagent to be activated, choose the button. • On the **Activate lot: {0}.** panel, select the reagent lot to be activated, choose the **Activate** button, and confirm.
2 Load and unload reagent cassettes on the analyzer		1. Open the front panel. 2. When the status indicator is off, open the reagent cassette drawer. 3. Load reagent cassettes into the loading positions on the left-hand side of the reagent cassette drawer. Remove any reagent cassettes from the unloading positions on the right-hand side of the reagent cassette drawer. 4. Close the reagent cassette drawer. 5. Close the front panel.
3 Order/cancel a reconstitution		You can order a reconstitution from either the **Reagent details** panel or from the **Reconstitution orders** panel: 1. Choose **Routine > Reagent status > Reagent overview**. 2. Select the reagent to be reconstituted. 3. On the **Reagent details** panel, select the check box next to the reagent bottle position. 4. At the bottom of the panel, choose the **Reconstitute** button. From the **Reconstitution orders** panel: 1. Choose **Routine > Reagent status > Reconstitution orders**. 2. On the **Reconstitution orders** panel, select the reagent cassette to be reconstituted and enter the number of tests to be performed. 3. To order a reconstitution immediately, at the bottom of the panel, choose the **Now** option, and then choose the **Order** button. To cancel a reconstitution order, on the **Reconstitution orders** panel, select the pending order to be canceled and choose the **Cancel order** button.
4 Define reagent lower limit volumes for reconstitution		You can configure the trigger volume for reconstitution or for the **Missing reagent** task. 1. Choose **Routine > Reagent status > Reagent overview**. 2. At the bottom-right of the **Reagent overview** panel, choose the **Edit lower limits** button. 3. Enter the **Tests =** field or **mL** field to define the volumes and choose the **Save** button.
5 Mask/unmask or discard a reagent		1. Choose **Routine > Reagent status > Reagent details**. 2. To mask a reagent, select the reagent bottle positions and choose the **Mask** button. 3. To unmask a reagent, select the masked reagent bottle positions and choose the **Unmask** button. 4. To discard a reagent cassette or reagent bottle, select the reagent cassette or reagent bottles and choose the **Discard** button (cannot be reversed).

Quick reference: Reagents

Quick reference: Calibration

Steps		User action
1 Load calibrators		1. Place the tubes containing the calibrator into the appropriate racks. 2. Insert the rack into a rack slot at the right-hand side of the analyzer. 3. Wait while the analyzer loads the rack and reads the barcode. 4. To view the racks which have been loaded onto the system, choose **Routine > Racks**. 5. To unload a calibrator rack, select the check box next to the rack and choose the **Unload** button.
2 Order calibration		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test requiring a calibration and choose the **Order calibration** button.
3 Cancel calibration		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the > button. On the **List of calibrations** panel, select the calibration order to be canceled and choose the **Cancel calibration** button.
4 Delete calibration		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the > button. 3. On the **List of calibrations** panel, select the calibration and choose the **Delete** button.
5 Review and release a calibration		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the > button. 3. On the **List of calibrations** panel, select the calibration and choose the > button. 4. At the bottom of the **Calibration curve** tab, choose the **Release** button.
6 Undo a calibration release		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the > button. 3. On the **List of calibrations** panel, choose either the **Calibration view** tab or the **Cassette view** tab. Select the calibration or cassette and choose the > button. 4. On the **Calibration details {0} {1}** panel, beneath the **Calibration curve** tab, choose the **Undo release** button.
7 Perform update calibration		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the > button. 3. On the **Cassette view** tab or the **Calibration view** tab of the **List of calibrations** panel, choose the cassette or reagent lot to be calibrated and choose the **Update calibration** button.

Quick reference: Calibrations

Steps	User action
8 Perform cassette calibration	1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the button. 3. On the **Cassette view** tab of the **List of calibrations** panel, choose the LCTL exceeded cassette and choose the **Full calibration** button, or if available, choose the **Update calibration** button. 4. On the **Lot calibration time limit exceeded** callout, choose the **Cassette calibration** button. 5. A new line with the cassette calibration appears in the list. 6. To review the calibration, wait until the calibration result changes to **Valid** status. Then select the cassette and choose the button. 7. On the **Calibration details {0} {1}** panel, control the calibration on the **Calibration curve** tab and the **Calibration result details** tab. If the calibration result appears to be usable, choose the **Release** button.
9 Reset a calibration to **Released** status	1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the button. 3. On the **List of calibrations** panel, select the calibration which has expired. If the most recent QC indicates that the calibration is still usable, choose the button. 4. On the **Calibration details {0} {1}** panel, beneath the **Calibration curve** tab, choose the **Reset to released** button. 5. Confirm the **Reset to released** callout.
10 Perform a repeat point for a calibration	1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the button. 3. On the **List of calibrations** panel, select the calibration and choose the button. 4. On the **Calibration details {0} {1}** panel, select the calibration point in question from the list. 5. On the **Calibration curve** tab and the **Calibration result details** tab, review the results of the calibration point. 6. Choose the **Repeat point** button.
11 Ignore a timeout	1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test and choose the button. 3. On the **List of calibrations** panel, choose the **Cassette view** tab. Select the cassette with the exceeded timeout and choose the button. 4. On the **Calibration details {0} {1}** panel, review the calibration. If you decide that the calibration can still be used, beneath the **Calibration curve** tab, choose the **Ignore timeout** button.
12 Review a calibrator	1. Choose **Routine > Calibration status**. 2. At the bottom of the **Calibration status** panel, choose the **Review calibrators** task button. 3. At the top of the **Review calibrators** panel, enter the filtering parameter.

Quick reference: Calibrations

Steps	User action
13 Perform a standby calibration	1. To control which reagent lots are loaded on the analyzer, choose **Routine > Reagent status** and then select the reagent from the list. 2. Choose **Routine > Calibration status** then select the reagent for which you want to perform a standby calibration and choose the > button. 3. Filter for results belonging to the specific reagent lot. 4. Select the check box next to the reagent lot to be calibrated. 5. At the bottom of the **List of calibrations** panel, choose the **Full calibration** button. 6. If the calibration is successful, a calibration result with **Valid** status is displayed. The calibration result can now be released. 7. To order a QC, select the check box next to a non-active calibration and choose the **Order QC** button. 8. If the QC is successful, the QC status changes to **Valid** status.
14 Release a standby calibration	1. Choose **Routine > Calibration status** and then choose the test for the standby calibration to be released. 2. On the **List of calibrations** panel, select the calibration and choose the > button. 3. If the standby calibration has not yet been released, at the bottom of the **Calibration curve** tab, choose the **Release** button.

Quick reference: Calibrations

Quick reference: QC

Steps		User action
1 Load QC materials		1. Place the tubes containing the QC material into the appropriate racks. 2. Insert the rack into a rack slot in the rack loading area at the right-hand side of the analyzer. 3. Wait while the analyzer loads the rack and reads the barcode. 4. To view the racks which have been loaded onto the system, choose **Routine > Racks**. 5. To unload a QC rack, select the check box next to the rack and choose the **Unload** button.
2 Manage QC lots		1. Choose **Routine > QC status > Manage QC lots**. 2. To activate a QC lot, at the bottom of the **Manage QC lots** panel, choose the **Activate** button. 3. To set the QC lot to **Study** status, at the bottom of the **Manage QC lots** panel, choose the **Set to study QC** button. 4. To deactivate a QC lot, at the bottom of the **Manage QC lots** panel, choose the **Deactivate** button.
3 Order routine QC		1. Choose **Routine > QC status**. 2. On the **QC status** panel, select the check box next to the test requiring a QC (or the check box next to the QC material) and choose the **Order QC** button.
4 Order preparation QC		1. Choose **Routine > Calibration status**. 2. On the **Calibration status** panel, select the test for which you want to perform a preparation QC and choose the button. 3. On the **List of calibrations** panel, either select an inactive calibration on the **Calibration view** tab or a loaded but not yet used reagent cassette on the **Cassette view** tab and choose the **Order QC** button.
5 Order study QC		1. Choose **Routine > QC status**. 2. On the **QC status** panel, select the check box next to the QC material. 3. At the bottom of the **QC status** panel, choose the **Order study QC** button.
6 Cancel QC order		1. Choose **Routine > QC status**. 2. On the **QC status** panel, select the check box next to the QC material. 3. To cancel a routine QC or preparation QC, at the bottom of the **QC status** panel, choose the **Cancel QC** button. 4. To cancel a study QC, at the bottom of the **QC status** panel, choose the **Cancel study QC** button.
7 Review QC		1. Choose **Routine > QC status**. 2. On the QC Status work area, select the check box next to the test and choose the button. 3. On the **QC result detail:** panel, control the results and details. 4. On the **QC result detail:** panel, control the results and details to ensure that they are within expected limits. 5. From the **Levey-Jennings chart** panel, you can perform the following actions: • Exclude a result from the statistics. • Send a QC result to the LIS • Set QC level status of the QC material to **Expired** status.

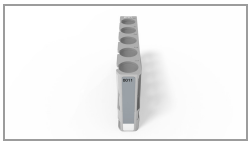
Quick reference: QCs

Steps	User action
8 Set QC target ranges	1. Choose **Routine > QC status**. 2. On the **QC status** panel, select the check box next to the test and choose the button. 3. On the **Levey-Jennings chart** panel, select the QC material and choose the **Set target range** button. 4. On the **Set target range** dialog box, select the range option and choose the **Save** button.

Quick reference: QCs

Quick reference: Test orders and rack handling

To measure a sample, the sample must be loaded onto the analyzer and test orders for this sample are required.

Steps		User action
1 Order a test		1. Choose the **Samples and results** tab. 2. On the **Samples and results** panel, select the check box next to the sample to be tested. 3. To change a routine sample to a STAT, on the **Samples and results** panel or **Sample details '{0}'** panel, choose the **STAT** button. 4. To order a test, at the bottom of the **Samples and results** panel, choose the **Manual order** button. 5. On the **Manual order entry for sample '{0}'** panel, choose the buttons of the available tests and choose the **Order** button.
2 Create a non-barcoded sample		1. Choose **Routine > Racks**. 2. At the bottom of the **Racks overview** panel, choose the **Create non-barcoded sample** button. 3. On the **Create non-barcoded sample** panel, enter the **Rack ID:** field and the **Sample ID:** field at the positions where the non-barcoded samples are located. 4. Choose the **Save** button and confirm in the dialog box that the sample IDs are correctly positioned.
3 Load and unload sample racks	 	1. Place the sample tubes into the sample racks. 2. Put the sample rack into one of the rack slots on the rack loading area. 3. To view the status of the sample racks, choose **Routine > Racks**. 4. To view the status of individual sample tubes on the rack, on the **Racks** panel, select the check box next to the sample rack and choose the button. 5. To unload a sample rack, choose the **Unload** button on one of the following panels: • **Racks overview** • **Rack details** • **Samples and results** 6. To delete a sample rack, at the bottom of the **Racks** panel, choose the **Delete** button.

Quick reference: Test orders

Related topics

- Ordering a test (373)
- Loading and unloading a sample rack (380)

Quick reference: Handling results

Use the result management tools to view results, validate, order repeat tests, and create reports.

Steps	User action
1 Handle results	1. To view sample results, choose the **Samples and results** tab. 2. To view sample details, on the **Samples and results** panel, select the check box next to the sample and choose the button. 3. To view details of a specific test, on the **Sample details '{0}'** panel, select the check box next to the test and choose the button. 4. To validate the test results manually, on the **Sample details '{0}'** panel, select the check box next to the test and choose the **Validate** button. 5. To order a repeat test, on the **Sample details:** panel, select the check box next to the test and choose the **Repeat** button. 6. To send the result to the LIS, select the check box next to the test and choose the **Send** button. 7. To delete the result, select the check box next to the test and choose the **Delete** button. 8. To validate all the test results, choose the **Validate all** button. 9. To create another test order, choose the **Manual order** button.
2 Create and print a report	1. To create a grid report, at the top of the panel, choose the drop-down list. • From the drop-down list, choose whether you want to print or export to a CSV file. 2. To create a defined report, at the bottom of the panel (if applicable) choose the **Print report** button. • Choose the print options and if you want to export to a PDF. 3. To manage reports stored on the system, choose **Administration > Screenshots and file management**.
3 Print cumulative QC report	1. Choose **Routine > QC status**. 2. At the top of the **QC status** panel, choose the drop-down list and choose the **Print cumulative QC report** button. 3. On the **Select time** callout, define the time period for the report and choose the **Print** button.

Quick reference: Handling results