cobas® 4800 System

Operator's Manual
Software Version 2.1 for ***cobas®*** *4800*
CT/NG Test

Document information

Manual version	Revision dates	Main changes
1.1	May 2014	Change to error messages and reagent loading positions.

Table 1 Revision history

Edition notice 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 reserves the right to make any further required changes to software without prior notice. Such changes may not immediately be reflected in this document.

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

Intended use This manual is for users of the **cobas**® 4800 CT/NG Test on the **cobas**® 4800 System.

Before using the test, it is important that the operator reads the **cobas**® 4800 System System Manual and this manual thoroughly.

For additional information, refer to the test-specific package insert.

Trademarks The following trademarks are acknowledged:

COBAS, COBAS X, COBAS Z, and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

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

Instrument approvals This manual meets the European Standard EN ISO 18113-3.

Compliance is demonstrated by the following marks:

CE — Complies with the IVD directive 98/79/EC.

c UL us — Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Abbreviations The following abbreviations are used:

Abbreviation	Definition
PC	PreservCyt®

Table 2 Abbreviations

Contact addresses

	Roche Molecular Systems, Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA Made in Switzerland
EC REP	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

What is new in version 2.1

Workflow Recovery workflow run can be generated from a previously performed run within 24 hours. The PCR Only workflow has been renamed and improved to recovery workflow.

For details, see *About workflows* (p. 10)

Result view notifications Icons help you identify if a result failed, is invalid, or has a flag. The result view also highlights cells with positive results.

For details, see *Results* (p. 55)

Work orders The work order editor is now integrated into the software (sample editor). Barcodes are automatically scanned during loading and used to generate a work order.

For details, see *Sample editor* (p. 51)

LIS You can see the LIS availability status and the transfer status. There is a status displayed of results sent to the LIS.

For details, refer to the cobas® 4800 System System Manual.

Reports Reports have been improved. For example, better formatting, positive results are highlighted.

Reagent use optimization Allows multiples (up to 3) of 24 reagent kits for master mix reagent and Mn reagent to be loaded into the system.

For details, see *To load the reagent carrier* (p. 33)

Unloading samples You have the option to automatically unload the samples after they are pipetted and before the run is over.

For details, see *To load samples* (p. 23)

Tracking of used tip racks. To reduce tip waste, partially used tip racks can be used in next run on the same system. You can reuse partially used tip racks as long as enough tips are loaded. The software estimates how many tips are required for a run.

For details, see *Loading the consumables* (p. 27)

Usability Improved test selection dialog and filtering options.

For details, see *To start a new run* (p. 22)
For details, see *Filtering and sorting runs and results* (p. 58)

Test types CT/NG cytology and CT/NG non-cytology workflows can both be run by selecting the CT/NG test.

Table of contents

Overview

General safety information

Test-specific safety information is contained in this manual. For general safety information (e.g. safety classifications, safety precautions), read the **cobas**® 4800 System System Manual.

Overview of the test

The **cobas**® 4800 CT/NG Test is an *in vitro* nucleic acid amplification test for the qualitative detection of *Chlamydia trachomatis (CT)* and/or *Neisseria gonorrhoeae (NG)* in patient specimens.

The following sample carrier can be used for CT/NG testing:

- PreservCyt® carrier with PreservCyt® primary containers
- 24-position sample carrier with primary cobas® PCR Media tubes or secondary tubes

For more information about the test (e.g. minimum sample volumes), refer to the test-specific package insert.

About specimen types

The following specimen types are supported:

Test type	Specimen type	Abbreviation	Carrier used
CT/NG	Swab	-	24-position sample carrier
	Urine	-	24-position sample carrier
	PreservCyt®	PC	• PreservCyt® carrier (primary tubes) • 24-position sample carrier (secondary tubes)

Table 3 Specimen types

WARNING

Incorrect results due to use of non-approved specimen types

Supported specimen types may vary by region. Refer to the test-specific package insert for your region for supported specimen types.

▶ Use only specimen types that are approved by Roche.

For details about the types of secondary tubes you can use, refer to the test-specific package insert.

About workflow types

Two workflow types are supported. The workflow type has to be selected at the start of a new run.

Full workflow The full workflow covers sample preparation on the **cobas x** 480 instrument and amplification and detection on the **cobas z** 480 analyzer.

Recovery workflow The recovery workflow allows you to recover aborted runs which were pipetted correctly into the deepwell plate or microwell plate. For example, you drop the microwell plate while transferring it to the analyzer.

You manually pipette residual eluate from the deepwell plate into the new microwell plate and add new master mix reagent and Mn reagent.

To recover a run, the following criteria must be fulfilled:

- Instrument and analyzer are turned on and maintenance has been performed.
- A full workflow run has been performed and the samples successfully prepared.
- A full workflow run has been performed in the last 24 hours.
- A full workflow run has been aborted by a user (M2 flag) or the analyzer (Z1 flag).

The recovery workflow run is only validated to work with extract from an instrument.

For stability of eluates, refer to the test-specific package insert.

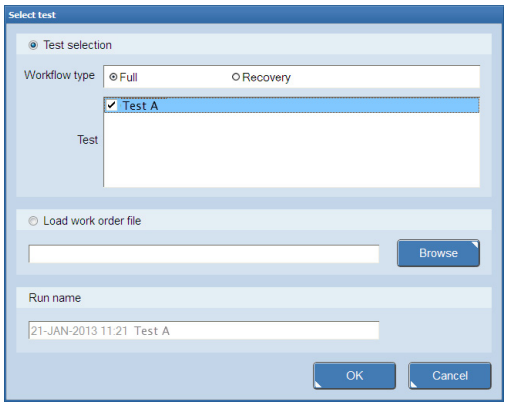


Figure 1 Workflow and test type selection at the start of a new run

About the test concept

Tests are run in batches.

For more details about batch sizes, throughput, or mixed batch runs, refer to the test-specific package insert.

About subtests

The analyzer can simultaneously detect signal from one or more detection channels, which makes it possible to obtain more information from a single reaction. This provides multiple subtests for each test type.

Subtests can be ordered for each sample individually using the sample editor.

For information about the sample editor, see *Sample editor* (p. 51)

The following subtests are available:

Main test type	Subtests	Results
CT/NG	CT and NG in combination	CT/NG
	CT only	CT
	NG only	NG

Table 4 Subtests

About reagents

Reagent kit sizes Individual reagent kits are available for the following run sizes:

- 10 runs with 24 samples (up to 22 patient specimens plus 2 controls)
- 10 runs with 96 samples (up to 94 patient specimens plus 2 controls)

NOTICE

Kit size

- Make sure that the kit size corresponds to the intended run size. Although not an optimal use of reagents, a 96 kit size can be used for a 24 run.
- For the most efficient reagent utilization, it is advisable to maximize the number of patient specimens processed within a run. Remaining reagents cannot be used later for another run.

Reagent handling Some reagents are poured into reagent reservoirs and then placed onto their dedicated positions on the reagent reservoir carriers.

Other reagents are ready to use. They are decapped and then placed onto their dedicated positions on the reagent carrier.

CAUTION

Reagent expiry time zone offset

The reagent expiry date is based on the Coordinated Universal Time (UTC). The local time for reagent expiry could be offset by plus or minus 12 hours, depending on the local time zone relative to UTC.

▶ Check the reagent expiry date and consider that it is based on UTC.

For instructions on handling and storage of reagents, refer to the test-specific package insert.

Controls Two external controls (positive control and negative control) are provided in a control kit. Controls are always processed on position A1 and B1 respectively of the deepwell and microwell plates.

All controls are homogeneous and do not require vortexing or shaking prior to loading on the instrument.

For instructions on handling and storage of controls, refer to the test-specific package insert.

Controls are loaded on the reagent carrier not the sample carrier.

Workflow

In this chapter the different workflows are described.

About workflows

The following workflow types are available.

Workflow	Description	Ordering
Full workflow (with or without LIS)	Sample preparation and amplification and detection	LIS or work order file
Recovery workflow (with or without LIS)	Manual PCR setup and amplification and detection	-

Table 5 Workflow types

Overview of full workflow

The full workflow with and without LIS is shown below.

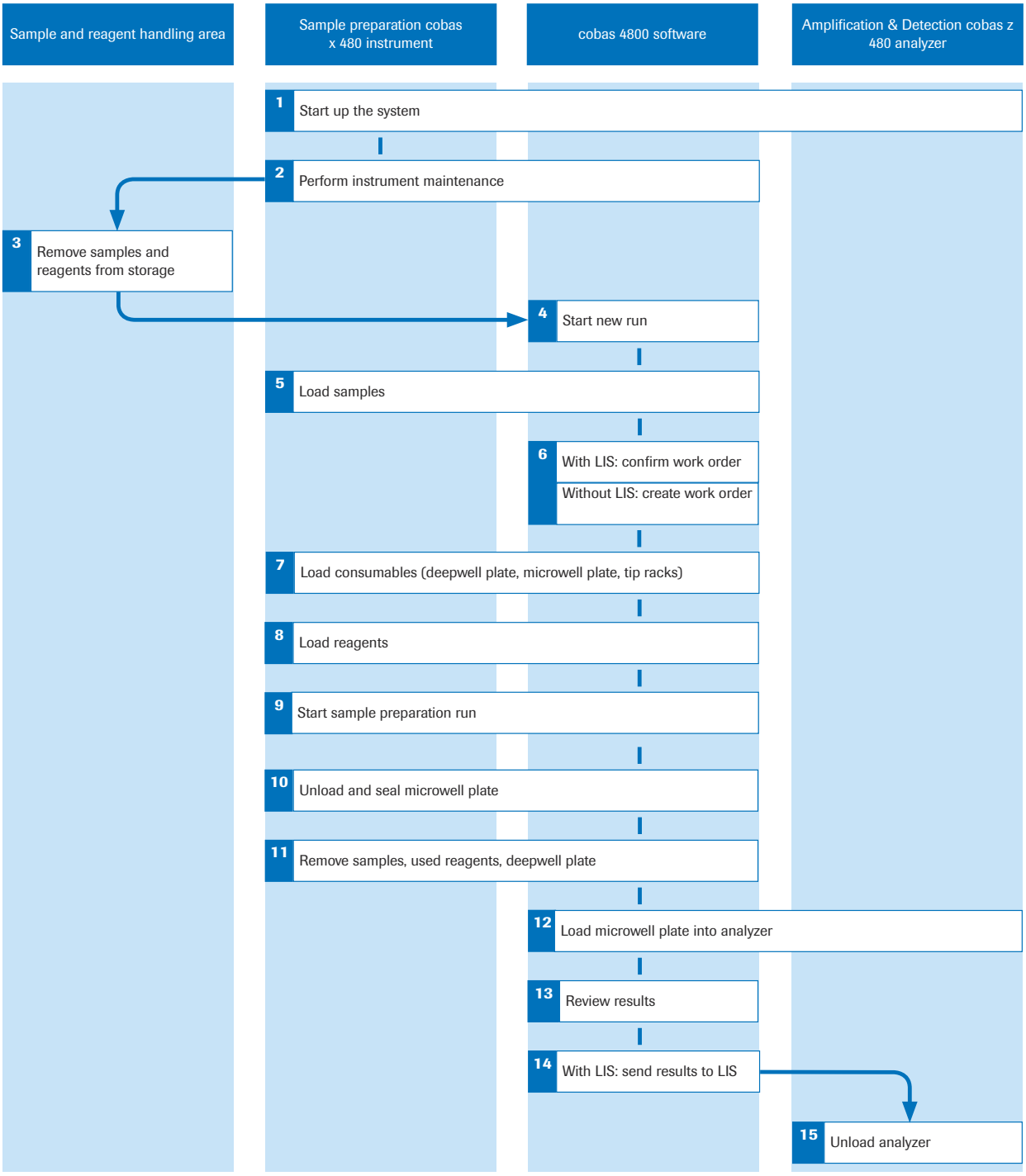


Figure 2 Full workflow (with and without LIS)

WARNING

Infection by samples and associated materials due to inappropriate laboratory practices

Follow Good Laboratory Practices, especially when working with biohazardous material. If Good Laboratory Practices are not followed, contact with biohazardous material may occur, resulting in infection.

- Do not eat, drink, or smoke in laboratory work areas.
- Wear lab gloves and lab coats whenever preparing consumables, reagents, samples, or when cleaning.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.

Full workflow short guide

The following short guide is a summary of the workflow without details.

For a complete and detailed description of the workflow, see *Performing a full workflow run* (p. 18)

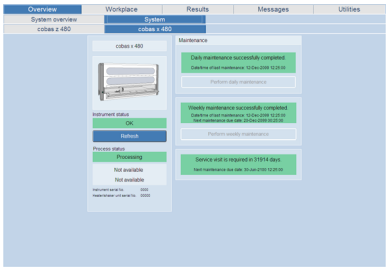
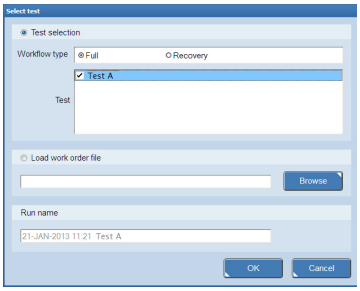
Step		User action
1	Start up the system.	Switch on the analyzer, heater/shaker unit, and instrument 1. Switch on the analyzer. 2. Switch on heater/shaker unit. 3. Switch on the instrument. Start up and log on to the software 1. Switch on the monitor and control unit. 2. Log on to the software.
2	Perform instrument maintenance.	 1. Choose **Overview > System > cobas x 480** tab and check maintenance status of the instrument. • If weekly maintenance is due, choose the **Perform weekly maintenance** button. • If daily maintenance is due, choose the **Perform daily maintenance** button. Follow the instructions displayed on the monitor.
3	Remove samples and reagents from storage.	For instructions on storage and handling of reagents, samples and controls, refer to test-specific package insert.
4	Start new run.	 1. Choose (**New run**). 2. Select the **Full** option. 3. Select the **CT/NG** check box. 4. Optionally, type a run name. 5. Choose the **OK** button.

Table 6 Full workflow short guide (with or without LIS)

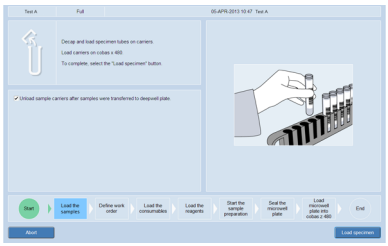
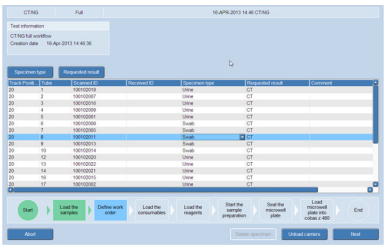
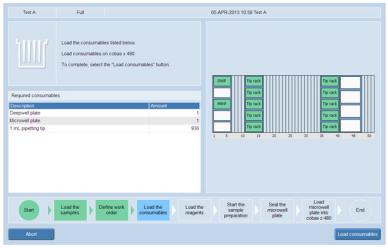
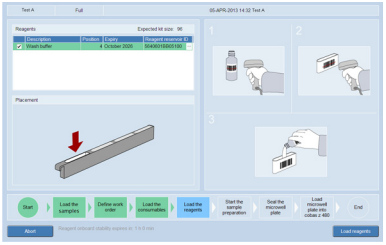
Step		User action
5 Load samples.		1. Decap samples. 2. Place samples on corresponding carrier. 3. Insert sample carriers on autoload tray. 4. Choose the **Load specimen** button.
6 With LIS, confirm the work order or Without LIS, create the work order.		With LIS: 1. Confirm the work order and choose the **Next** button. or Without LIS: 1. Define the type of specimen. 2. Define the requested result. 3. Choose the **Next** button.
7 Load consumables.		1. Place listed consumables on appropriate carriers. 2. Insert carriers on autoload tray. 3. Choose the **Load consumables** button.
8 Load reagents.		*200 mL reagent reservoir carrier* 1. Load wash buffer reagent 200 mL on reagent reservoir carrier as indicated in the wizard (scan-scan-pour-place principle). 2. Insert carrier on autoload tray. 3. Choose the **Load reagents** button. *50 mL reagent reservoir carrier* 1. Load reagents on 50 mL reagent reservoir carrier as indicated in the wizard (scan-scan-pour-place principle). 2. Insert carrier on autoload tray. 3. Choose the **Load reagents** button. *Reagent carrier* 1. Open reagent vials and load them on reagent carrier as indicated in the wizard. 2. Insert carrier on autoload tray. 3. Choose the **Load reagents** button.
9 Start sample preparation run.		1. Choose the **Start run** button. The sample preparation starts. 2. Check the timer in the wizard.

Table 6 Full workflow short guide (with or without LIS)

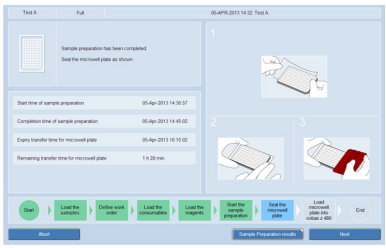
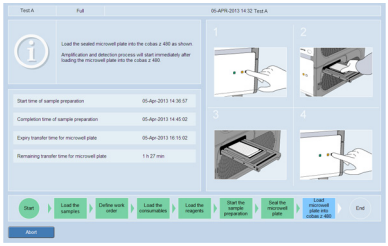
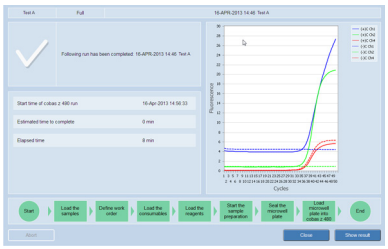
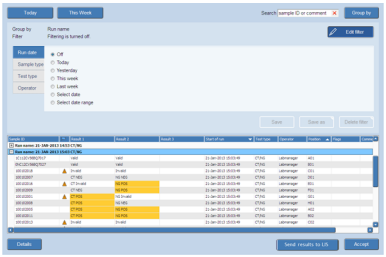
Step		User action
10 Unload and seal microwell plate.		1. To review the results of the sample preparation, choose the **Sample Preparation results** button. 2. Choose the **Unload** button. 3. Seal the microwell plate as indicated on screen. 4. Choose the **Next** button.
11 Remove used reagents, samples, and deepwell plate.		1. Remove used reagents, samples, and deepwell plate from the instrument.
12 Load microwell plate on to the analyzer.		1. Press the load button on the analyzer. 2. Place the sealed microwell plate into the microwell plate loader. 3. Press the load button again. The amplification and detection run starts automatically. 4. Check the timer in the wizard.
13 Review result and accept results.		1. Choose the **Show result** button. 2. Review and accept results in **Results** work area. 3. Select results and choose (**Print**) to print the results report, if required.
14 With LIS, send the results to LIS.		Consider that depending on the configuration, all results are transferred to LIS or only accepted results are transferred to LIS. Control results are always uploaded to LIS. 1. Select a result or group of results and choose the **Send results to LIS** button.
15 Unload the microwell plate from the analyzer.		1. Unload the microwell plate from the analyzer as soon as is practical after the run has finished. 2. Discard the microwell plate according to the appropriate local regulations.

Table 6 Full workflow short guide (with or without LIS)

Overview of recovery workflow

The recovery workflow allows you to recover failed runs where the sample has been successfully prepared. A run can only be recovered one time.

The recovery workflow is shown below.

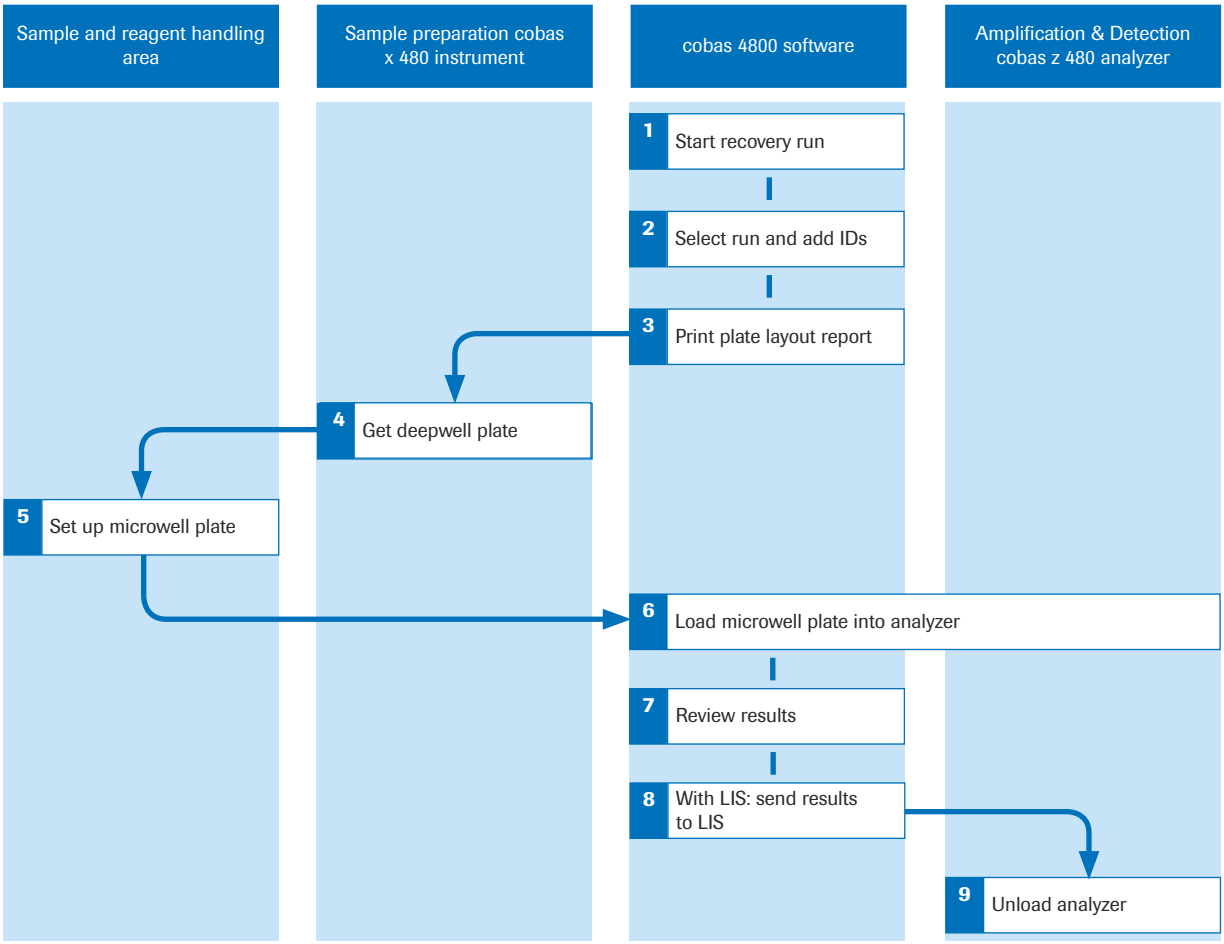


Figure 3 Recovery workflow

CAUTION

Infection by samples and associated materials due to inappropriate laboratory practices

Follow Good Laboratory Practices, especially when working with biohazardous material. If Good Laboratory Practices are not followed, contact with biohazardous material may occur, resulting in infection.

- Do not eat, drink, or smoke in laboratory work areas.
- Wear lab gloves and lab coats whenever preparing consumables, reagents, samples, or when cleaning.
- Wear eye protection when handling samples. Wash hands thoroughly afterwards.

Recovery workflow short guide

The following short guide is a summary of the workflow without details.

For a complete and detailed description of the workflow, see *Performing a recovery workflow run* (p. 42)

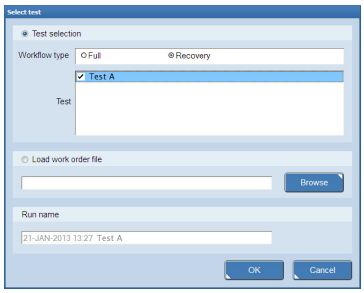
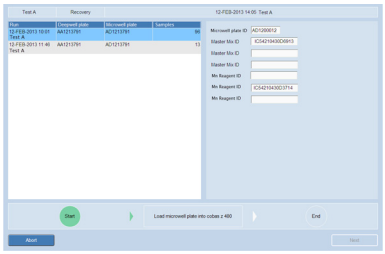
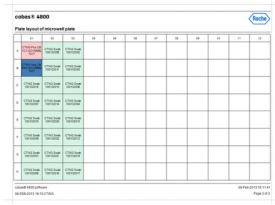
Step		User action
1 Start a recovery workflow run.		1. Choose (**New run**). 2. Select the **Recovery** option. 3. Select the **CT/NG** check box. 4. Optionally, type a run name. 5. Choose the **OK** button.
2 Select the run to recover and add new IDs		1. Choose the run to recover. 2. In the **Microwell plate ID** field, scan the microwell plate barcode. 3. In the **Master Mix ID** field, scan the master mix reagent barcode. 4. In the **Mn Reagent ID** field, scan the Mn reagent barcode.
3 Print the microwell plate layout.		1. To print the work order file for microwell plate setup, choose (**Print**) from the global navigation bar. 2. In the software, choose the **Next** button.
4 Get the deepwell plate.		1. Do one of the following: • If the deepwell plate has been unloaded by the instrument, remove it from the plate carrier, or • If the deepwell plate has been stored, get it from storage, or • If the deepwell plate has not been unloaded by the instrument, unload the deepwell plate manually. For details how to unload the instrument manually, refer to the **cobas®** 4800 System System Manual.
5 Set up the new microwell plate.		1. Pipette the reagents and prepared specimens into the microwell plate in accordance with the microwell plate layout and the description in the test-specific package insert. 2. Seal the microwell plate. 3. If necessary, log back on to the software. 4. In the software, choose the **Next** button.
6 Load microwell plate into the analyzer.		1. Press the load button on the analyzer. 2. Place the sealed microwell plate into the microwell plate loader. 3. Press the load button again. The amplification and detection run starts automatically. 4. Check the timer in the wizard.

Table 7 Recovery workflow short guide

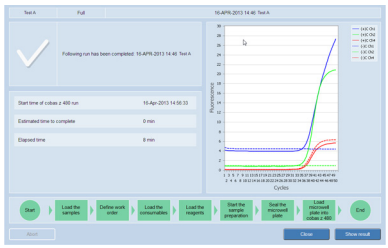
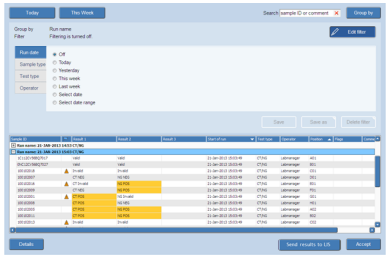
Step		User action
7 Review and accept results.		1. Choose the **Show result** button. 2. Review and accept results in **Results** work area. 3. Select results and choose (**Print**) to print the results report, if required.
8 With LIS, send the results to LIS.		Consider that depending on the configuration, all results are transferred to LIS or only accepted results are transferred to LIS. Control results are always uploaded to LIS. 1. Select a result or group of results and choose the **Send results to LIS** button.
9 Unload the microwell plate from the analyzer.		1. Unload the microwell plate from the analyzer as soon as is practical after the run has finished. 2. Discard the microwell plate according to the appropriate local regulations.

Table 7 Recovery workflow short guide

Operation

In this chapter the operation of the system is described.

Safety information

Considerations before operation

Make sure that you have read and understood the chapter *General safety information* in the **cobas**® 4800 System System Manual. The following safety messages in particular are relevant:

- Warning messages:
  - Loss of sight due to staring into the laser beam
  - Infection by samples and associated materials
  - Infection and injury due to sharp objects
  - Infection by biohazardous waste
  - Contamination of the environment by liquid waste and solid waste
- Caution messages:
  - Personal injury due to contact with moving parts
  - Skin inflammation or injury caused by reagents
  - Personal injury due to hot surface
- Safety precautions:
  - Operator qualification
- Observe the illustrated system safety labels from the **cobas**® 4800 System System Manual

Performing a full workflow run

The following procedures guide you through all required steps to perform a full workflow run with sample preparation on the instrument and amplification and detection on the analyzer. The procedures cover both working modes: with and without LIS. Steps that only apply to one working mode are indicated accordingly.

Performing startup procedures

NOTICE

Instrument damage due to improper handling

To prevent hardware damage, follow the steps in the exact order outlined when starting up the system.

To start up the system, it is important that you perform the following steps in this exact order:

1. Switch on the analyzer.
2. Switch on the heater/shaker unit.
3. Switch on the instrument.
4. Start up the software.

To switch on the analyzer

1 Switch on the analyzer. The power switch is located at the back of the analyzer.

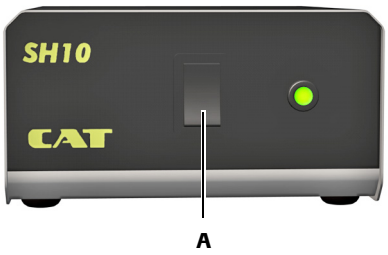
The analyzer is powered on and initializes.

A Power switch of the analyzer

Figure 4 Switching on the analyzer

To switch on the heater/shaker unit

1 Switch on the heater/shaker unit. The switch is located at the front of the heater/shaker controller box.



A Power switch of heater/shaker controller box

Figure 5 Switching on the heater/shaker unit

To switch on the instrument

1 Switch on the instrument. The power switch is located at the front of the instrument.

The instrument is powered on and initializes.

A Power switch of the instrument

Figure 6 Switching on the instrument

WARNING

Delay of results due to improper handling

Turning the power of the instrument off during a run can lead to a sample rerun.

- Do not turn off the instrument power during a run.

To start up and log on to the software

1 Switch on the monitor and control unit.

After the Windows operating system starts, double-click the **cobas 4800 v2.1** desktop icon to open the software.

The software displays the **System overview** tab.

2 Choose (**Log on**) to log on and enter your assigned user ID and password.

3 Choose the **OK** button.

- The user ID is not case-sensitive.
- The password is case-sensitive. The password displays as asterisks when typed to maintain security.

Performing maintenance

Periodic maintenance needs to be performed in order to ensure safe and reliable operation of the instrument.

NOTICE

Periodic maintenance

- Performing daily and weekly maintenance is mandatory. A sample preparation run can only be started when maintenance is done.
- If any parts of the instrument or carriers have become contaminated, the weekly maintenance procedure must be performed.
- Counters are reset to twenty-four hours when daily maintenance is performed. If weekly maintenance is being performed, daily maintenance is not required on that day.

To perform daily or weekly maintenance on the instrument

1 To check the maintenance status, choose **Overview > System > cobas x 480** tab.

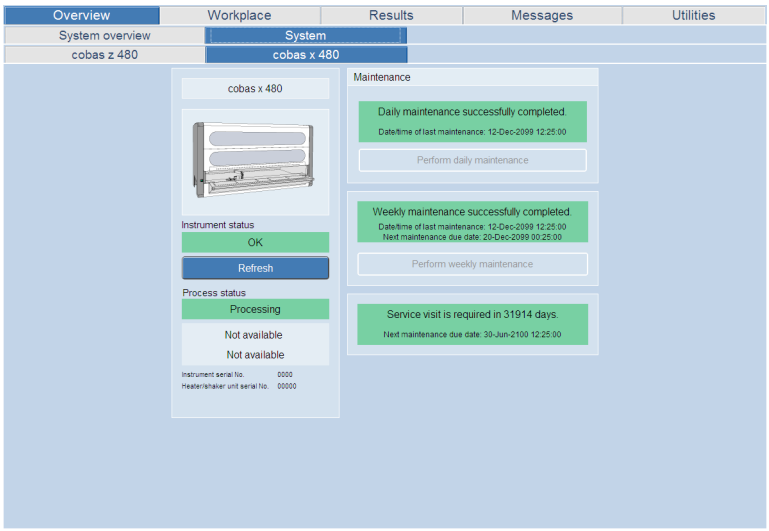


Figure 7 Checking the maintenance status

2 Do one of the following:

- If the weekly maintenance is due, choose the **Perform weekly maintenance** button and follow the instructions displayed on the monitor.

For more details about weekly maintenance, refer to the **cobas**® 4800 System System Manual.

- If the daily maintenance is due, choose the **Perform daily maintenance** button and follow the instructions displayed on the monitor.

For more details about daily maintenance, refer to the **cobas**® 4800 System System Manual.

Removing the samples and reagents from storage

The reagents that you need to perform the run depends on the run size.

For instructions on storage and handling of reagents, samples and controls, refer to test-specific package insert.

Starting a new run

A wizard guides you through the entire run, from sample preparation on the instrument to amplification and detection on the analyzer.

Loss of reagents, samples, or consumables

Inappropriate user actions can cause loss of reagents, samples, or consumables.

- Do not disconnect the USB cable during a run. The run will be aborted immediately
- It is not possible to go back to a previous step in a run. To avoid losing reagents, samples, or consumables, follow the guidelines outlined in this manual.
- If the instrument is installed on a bench top, a small solid waste bag is used. This solid waste bag has a capacity for tips up to one full workflow run. Exchange the small solid waste bag each time before starting a new run to avoid overfilling of the tip waste.
- You can use the sample editor to prepare one or more work order files before starting a run, or to prepare a work order file for the next run while a run is still in progress.

For details about replacing the small solid waste bag, refer to the **cobas**® 4800 System System Manual.

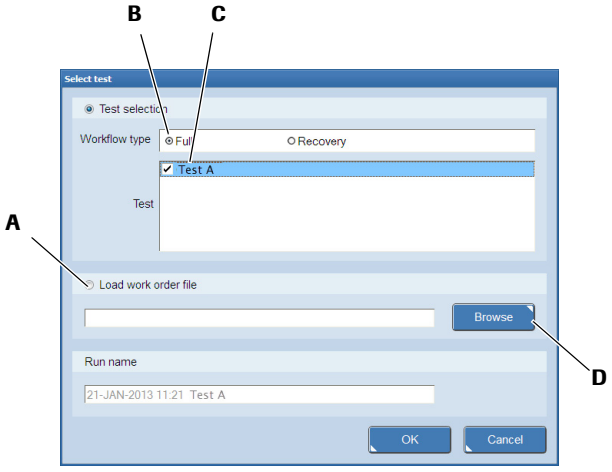
Before starting a run, check the **Overview > System > cobas z 480** tab if the Xenon lamp needs replacement. Replace the Xenon lamp, if required.

For details about Xenon lamp replacement, refer to the **cobas**® 4800 System System Manual.

To start a new run

1 Choose (**New run**).

The **Select test** dialog box is displayed.



A Load a work order file.
B Choose a **Full** workflow.
C Choose a test.
D Browse for a work order file.

Figure 8 **Select test** dialog box

2 Select the **Full** option.

3 Select the **CT/NG** check box.

4 Optionally, enter a name for the run in the **Run name** field.

If you leave the field empty, the system generates a generic run name with the date, time, and test name (e.g. "28-May-2013 11:57 AM Test A"). If you enter a name for the run, the system adds a time stamp to the name.

5 Choose the **OK** button.

The **Workplace** tab is displayed showing the wizard for the new run. The instrument initializes. This can take some time.

■

Loading samples

Samples can be loaded in barcoded primary or secondary tubes.

Up to 94 patient specimens can be loaded for a single test run. Two positions on the plates are reserved for controls. Controls are not loaded together with samples. They are loaded onto the reagent carrier during reagent loading.

For a list of sample types, refer to the test-specific package insert.

For more details about sample carriers, see *About specimen types* (p. 7)

- The sample editor and work order files are only used when the system is not connected to an LIS or if the LIS is not working.
- If an LIS is used, order information is loaded automatically from the LIS after samples are loaded onto the instrument.
- If more specimens are loaded than requested in the work order file, you can define the ordering for these samples in the sample editor.
- If a work order file and the loaded samples do not match, both the work order file and the samples must be reloaded. It is not possible to choose another work order file and leave the samples loaded.
- Samples can be loaded in any order as long as they match the set of samples listed in the work order file.
- If you unload samples to correct a work order mismatch error, all carriers are unloaded. If you unload samples to correct another type of error (e.g. barcode reading), only the carrier with the error is unloaded.
- Do not load empty or capped sample tubes. If a hardware error occurs, manually remove all carriers, and then restart the system.
- You cannot mix specimen type PreservCyt® with specimen types Urine and/or Swab in the same run.

For more information about barcodes and barcode character lengths, refer to the **cobas®** 4800 System System Manual.

WARNING

Spillage and contamination due to overfilling sample tubes

Do not overfill sample tubes to avoid spillage and contamination during loading.

- The maximum sample volume in the secondary tubes is 10 mL.

To load samples

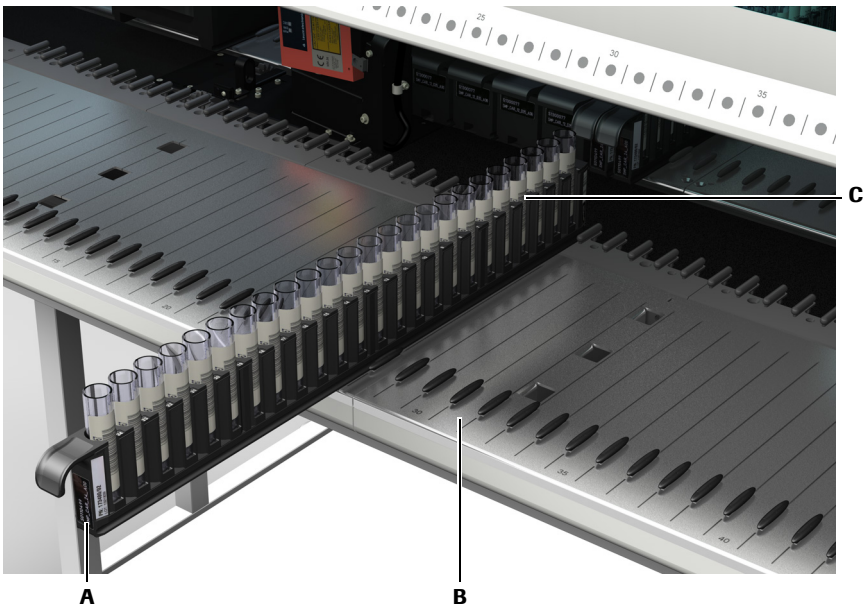
1 Decap the sample tubes or containers and place the samples on the appropriate carrier. The sample barcodes must face to the right of the carrier.

Make sure that the sample tubes or containers are seated correctly in the sample carrier.

For details about sample placement, refer to the **cobas®** 4800 System System Manual.

2 Insert all sample carriers into their designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

For details about carrier loading, refer to the **cobas**® 4800 System System Manual.



A Sample carrier

B Tracks 17 through 34 are reserved for sample carriers

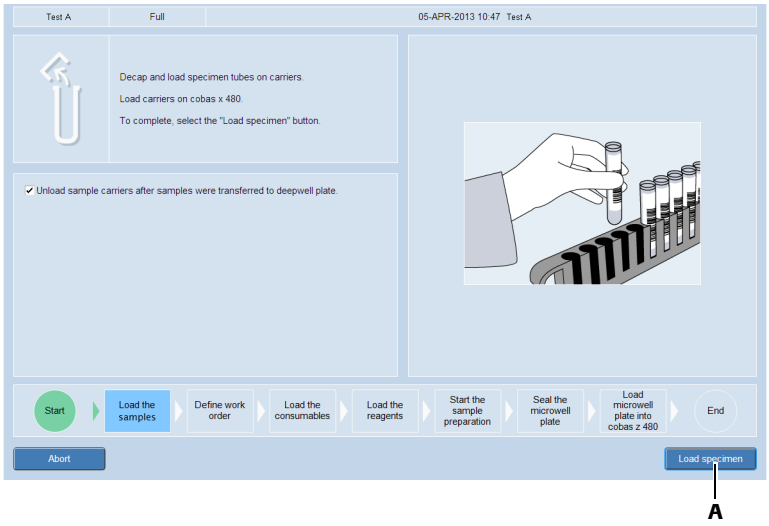
C Sample barcodes facing to the right

Figure 9 Loading samples

3 When you have placed all sample carriers on the indicated track positions on the autoload tray, choose the **Load specimen** button.

Check that all sample carriers are placed correctly before loading the samples.

Sample carriers i.e. samples, are automatically unloaded when pipetting is finished. If you do not want this, clear the **Unload sample carriers after samples were transferred to deepwell plate** check box.



A When sample carriers are ready for loading, choose the **Load specimen** button.

Figure 10 Wizard > **Load the samples**

The sample carriers are loaded automatically onto the instrument. During loading, the barcode reader scans the carrier barcode and the sample barcodes. The scanned sample barcodes are displayed in the **Sample ID** column.

If the instrument is connected to an LIS, the orders are downloaded automatically from the LIS after the samples are loaded.

4 Follow the instructions displayed on the monitor in case a sample barcode cannot be read.

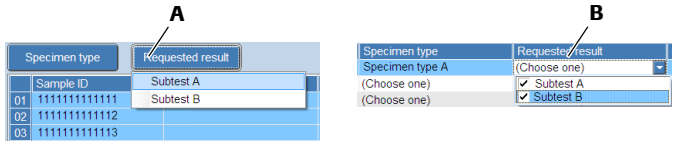
For details about barcode error handling, refer to **cobas**® 4800 System System Manual.

Confirming or creating a work order file

Tips In the same run, you can select specimen types Swab and Urine. You cannot mix samples of specimen type PreservCyt® with samples of a different specimen type.

To select a range of adjacent samples, use the Shift key.

To select several nonadjacent samples, use the Ctrl key.



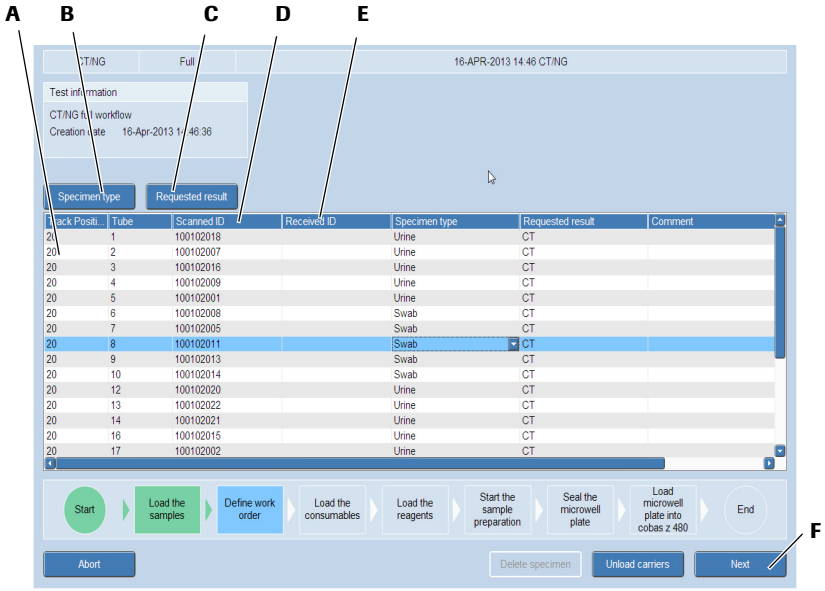
A Defining multiple samples **B** Defining individual samples

Figure 11 Defining multiple or individual samples

To confirm or define the work order file

1 Do one of the following:

- If the instrument receives work orders from an LIS, check that the work order is correct
  or,
- If the instrument does not receive work orders from an LIS, define the type of specimen and the requested result.



A Select one or more samples.

B Defining the type of specimen.

C Defining the result.

D Displays the ID of the scanned sample.

E If you are using LIS or you have loaded a work order file, the sample IDs are displayed under **Received ID**.

F Confirm the work order.

Figure 12 Confirming or creating a work order file

2 Choose the **Next** button.

The work order file information is cross-checked against the loaded samples. Run and test types, number of samples, sample types, and barcode IDs must match.

3 In case the work order file and the loaded samples do not match, follow the instructions displayed on the monitor.

Loading the consumables

One deepwell plate (1.6 mL), one microwell plate, and two tip rack carriers are used for each run.

Delay of results due to insufficient pipetting tips/tip rack carriers

The total number of pipetting tips per run varies and depends on several criteria (test type, specimen type, run size, etc.) The instrument tracks tip usage from run to run. The instrument checks if enough pipetting tips have been loaded to perform the run. If there are not enough, a message is displayed. Partially used tip racks can be used in next run.

- To perform a run, you must load all the required tip rack carriers with enough tips into the instrument. If you unload samples to correct a work order mismatch error, all carriers are unloaded. If you unload samples to correct another type of error (e.g. barcode reading), only the carrier with the error is unloaded.

Incorrect results due to improper loading of the microwell plate or deepwell plate

If the microwell plate or deepwell plate are sealed when placed on the instrument, the seal could be pierced during the run resulting in carryover.

- Do not seal the microwell plate or deepwell plate before loading the plate into the instrument.

All consumables are barcoded and designed to be used only once. The software tracks the use of the consumables and rejects already used consumables.

To load the consumables

1. Place the listed consumables (e.g. 1 mL pipetting tips) on the appropriate carrier. The barcodes must face to the right of the carrier.

   For details about carrier loading, refer to the **cobas**® 4800 System System Manual.

2. Load all carriers into their designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

   Use the following tracks:

   - Plate carrier: tracks 1 through 6
   - Left tip rack carrier: tracks 11 through 16
   - Right tip rack carrier: tracks 35 through 40

3 When you have placed all carriers on the indicated track positions on the autoload tray, choose the **Load consumables** button.

Check that all carriers are placed correctly before loading the consumables.

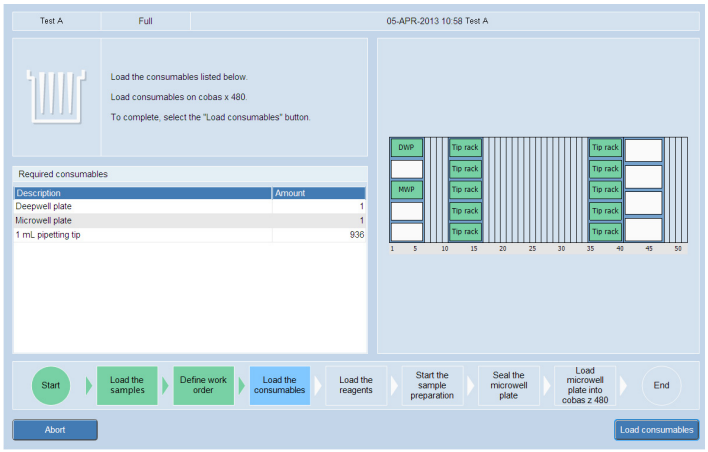


Figure 13 Loading consumables

The carriers are loaded automatically onto the instrument. During and after loading, the barcode reader scans the carrier barcodes and the consumable barcodes.

4 In case a consumables barcode cannot be read or a consumable is recognized as already used, follow the instructions.

For details about barcode handling and inventory errors, refer to the **cobas**® 4800 System System Manual.

After successful loading of consumables, the wizard asks for loading the reagents.

Loading the reagents

The reagent reservoirs are barcoded and need to be filled manually by the operator (scan-scan-pour-place principle) for each run.

The reagent carrier holds the test-specific reagents for sample processing and PCR setup.

The required reagents and controls are manually decapped and then placed onto their dedicated positions on the reagent carrier. The reagent barcodes must face to the right of the carrier.

Scan-scan-pour-place principle

To minimize handling errors the reagent reservoirs are filled and placed using the scan-scan-pour-place principle:

1. Scan the barcode of the required reagent using the hand-held barcode reader.
2. Scan the barcode of an unused reagent reservoir using the hand-held barcode reader.
3. Pour the reagent in the scanned reagent reservoir.
4. Place the filled reagent reservoir onto the required position of the reagent reservoir carrier as indicated in the wizard.

The reagent reservoirs are available in two sizes: 200 mL and 50 mL. The reagent reservoir barcodes must face to the right of the carrier.

WARNING

Incorrect results or delay of results due to wrong placement of reagents

Each reagent has a specific position assigned to it on the carriers. Even though each reagent is uniquely identified by barcodes, it must be placed at the correct location, otherwise an error message will be generated, and loading will not proceed.

There is a limited time (60 minutes) between scanning the reagents and initiating the instrument run. The timer starts when the wash buffer reagent vial is scanned. The system checks if the reagent onboard stability time is elapsed when the run is started.

All controls are homogeneous and do not require vortexing or shaking prior to loading on the instrument.

- Always place the reagent reservoirs and the reagent vials in the indicated positions on the carriers before starting a run.

For instructions on handling and storage of reagents and controls, refer to test-specific package insert.

Considerations before loading the reagents

- Consider the following:
  - All reagents and reagent reservoirs are barcoded and designed to be used only once. The software tracks the use of the reagents and reagent reservoirs and rejects partially used reagents or previously used reagent reservoirs.
  - An acoustic signal is issued and an error message is displayed in the alarm area when the system does not accept a scanned reagent barcode.
  - To minimize the risk of contamination, it is highly recommended to change lab gloves between handling patient samples and loading reagents onto instrument.
  - Make sure that the reagent kit size corresponds to the intended run size. Although not an optimal use of reagents, a 96 kit size can be used for a run size of 72 or less.
  - For the most efficient reagent utilization it is advisable to maximize the number of patient specimens processed within a run. Remaining reagents cannot be used later on in another run.
  - The reagent inventory marks a reagent as used as soon as it is assigned to a reservoir. From this time point on the reagent is dedicated to this run and cannot be used later on another run even if the reagent is not used during the run.

For instructions on storage and handling of reagents and controls, refer to the test-specific package insert.

The following table shows an example of the reagent positions on the different carriers. For the exact placement of reagents, refer to the color coded picture displayed in the software.

Example of reagent loading for Swab and Urine

Carrier type	Position	Reagents
200 mL reagent reservoir carrier	1 through 3	Not used
	4	Wash buffer
50 mL reagent reservoir carrier	1 through 3	Not used
	4	MGP
	5	Elution buffer
Reagent carrier	1 through 14	Not used
	15	Internal control
	16	Positive control

Table 8 Placement of reagents (example for 24/96 batch size)

Carrier type	Position	Reagents
	17	Negative control
	18	Control diluent
	19 through 21	Not used
	22	Master mix reagent (for 96-sample runs only)
	23	Master mix reagent
	24	Mn reagent

Table 8 Placement of reagents (example for 24/96 batch size)

Example of reagent loading for PC

Carrier type	Position	Reagents
200 mL reagent reservoir carrier	1 through 3	Not used
	4	Wash buffer
50 mL reagent reservoir carrier	1	Not used
	2	SDS reagent
	3	Lysis buffer
	4	MGP
	5	Elution buffer
Reagent carrier	1 through 12	Not used
	13	Proteinase K reagent (for 96-sample runs only)
	14	Proteinase K reagent
	15	Internal control
	16	Positive control
	17	Negative control
	18 through 21	Not used
	22	Master mix reagent (for 96-sample runs only)
	23	Master mix reagent
	24	Mn reagent

Table 9 Placement of reagents (example for 24/96 batch size)

To load the reagents on the 200 mL reagent reservoir carrier

1 Scan the barcode of the wash buffer using the hand-held barcode reader.

The reagent in the list is highlighted in light green.

Scanning the barcode of the wash buffer starts the reagent onboard stability timer in the software. The run must be started within 60 minutes.

2 Scan the barcode of an unused 200 mL reagent reservoir using the hand-held barcode reader.

The reagent in the list is checked and highlighted in dark green.

3 Pour the entire reagent vial in the scanned reagent reservoir.

- It is advisable to pour the reagent into the reservoir in a lengthwise movement to minimize the risk of splashing and resulting reagent loss.
- Do not pour reagents into reservoirs that are already placed onto a reagent rack. Always follow the scan-scan-pour-place principle.
- Do not fill reagent reservoirs above the maximal fill height. A line within the reagent reservoir indicates the maximal fill height.
- Handle filled reservoirs with particular care to avoid splashes and tipping over.

4 Place the filled reagent reservoir onto position 4 of the 200 mL reagent reservoir carrier as indicated.

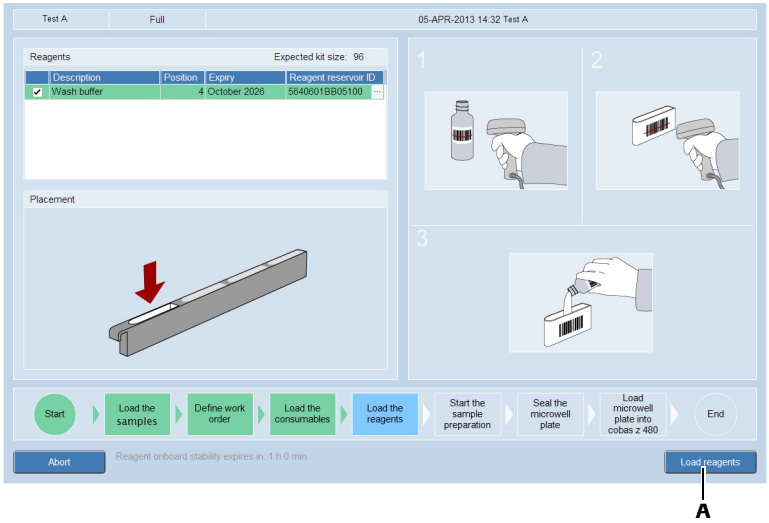
5 Insert the 200 mL reagent reservoir carrier into its designated track positions on the autoload tray. The correct loading position is indicated by blinking LEDs on the LED bar above the autoload tray.

Use the following tracks:

- 200 mL reagent reservoir carrier: tracks 48 through 49

6 When you have placed the 200 mL reagent reservoir carrier on the indicated track positions on the autoload tray, choose the **Load reagents** button.

Check that the 200 mL reagent reservoir carrier is placed correctly before loading it.



A When the carrier is ready for loading, choose the **Load reagents** button.

Figure 14 Load reagents

The 200 mL reagent reservoir carrier is loaded automatically onto the instrument. During loading, the barcode reader scans the carrier barcode and the reagent reservoir barcode.

7 In case a barcode cannot be read or a reagent is recognized as already used, follow the instructions displayed on the monitor.

For details about barcode handling and inventory errors, refer to the **cobas**® 4800 System System Manual.

After successful loading, the wizard asks for loading the reagents for the 50 mL reagent reservoirs.

To load the reagents on the 50 mL reagent reservoir carrier

1 Scan the barcode of one of the reagents in the list using the hand-held barcode reader.

The reagent in the list is highlighted in light green.

2 Scan the barcode of an unused 50 mL reagent reservoir using the hand-held barcode reader.

The reagent in the list is checked and highlighted in dark green.

3 Pour the entire reagent vial in the scanned reagent reservoir.

- It is advisable to pour the reagent into the reservoir in a lengthwise movement to minimize the risk of splashing and resulting reagent loss.
- Do not pour reagents into reservoirs that are already placed onto a reagent rack. Always follow the scan-scan-pour-place principle.
- Do not fill reagent reservoirs above the maximal fill height. A line within the reagent reservoir indicates the maximal fill height.
- Handle filled reservoirs with particular care to avoid splashes and tipping over.

4 Place the filled reagent reservoir into the indicated position of the 50 mL reagent reservoir carrier.

5 Repeat step **1** to **4** for all reagents in the list.

6 Insert the 50 mL reagent reservoir carrier into its designated track position on the autoload tray. The correct loading position is indicated by a blinking LED on the LED bar above the autoload tray.

Use the following track:

- 50 mL reagent reservoir carrier: track 50

7 When you have placed the 50 mL reagent reservoir carrier on the indicated track position on the autoload tray, choose the **Load reagents** button.

Check that the 50 mL reagent reservoir carrier is placed correctly before loading it.

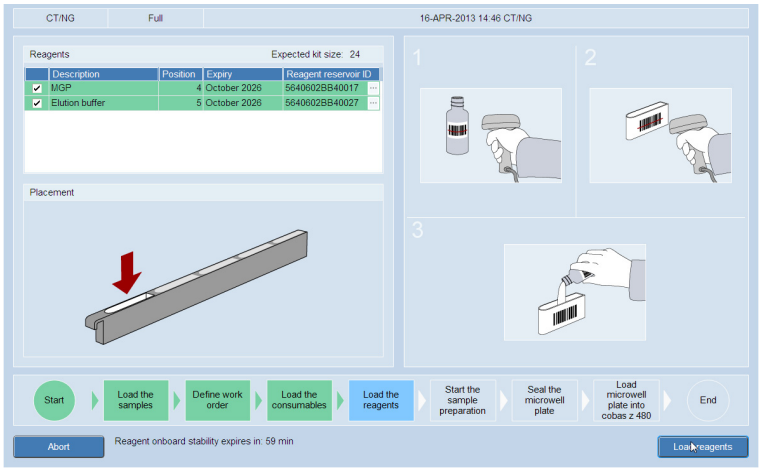


Figure 15 Loading reagents on the 50 mL reagent reservoir carrier

The 50 mL reagent reservoir carrier is loaded automatically onto the instrument. During loading, the barcode reader scans the carrier barcode and the reagent reservoir barcodes.

8 Follow the instructions in case a barcode cannot be read or a reagent is recognized as already used.

For details about barcode handling and inventory errors, refer to the **cobas**® 4800 System System Manual.

After successful loading, the wizard asks for loading the reagents for the reagent carrier.

■

To load the reagent carrier

1 Open the listed reagent vials and place them onto the indicated positions on the reagent carrier.

To minimize reagent waste, the software displays the optimal reagent kit size usage for the run. If the suggested kit size is not available, you can use the **Change kit size for** function. Consider that using a larger kit size than required is not an optimal use of reagents.

The reagent barcode must face to the right of the carrier.

Open the reagent vials before placing them onto the reagent carrier to minimize the risk of contamination.

2 Insert the reagent carrier into its designated track on the autoload tray. The correct track is indicated by a blinking LED on the LED bar above the autoload tray.

Use the following track:

- reagent carrier: track 51

3 When you have placed the reagent carrier on the indicated track on the autoload tray, choose the **Load reagents** button.

Check that the reagent carrier is placed correctly before loading it.

The colors on reagent vials match the colors displayed on the software.

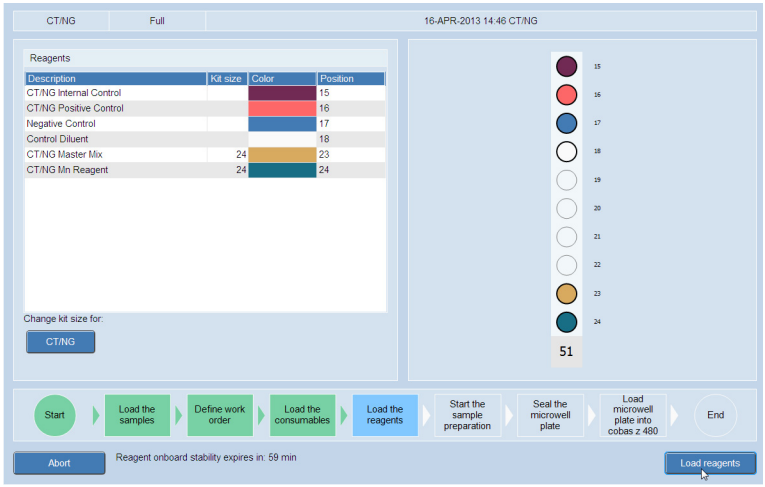


Figure 16 Loading reagents on the reagent carrier

The reagent carrier is loaded automatically onto the instrument. During loading, the barcode reader scans the carrier barcode and the reagent vial barcodes.

4 In case a barcode cannot be read or a reagent is recognized as already used, follow the instructions displayed on the monitor.

For details about barcode handling and inventory errors, refer to the **cobas**® 4800 System System Manual.

After successful loading, the wizard shows the instrument deck. Loaded samples, reagents and consumables are highlighted in green. The sample preparation process is now ready to be started.

Starting the sample preparation run

The loading is now complete and the sample preparation is ready to be started. The loaded instrument deck is shown with all loaded samples, reagents, and consumables highlighted in green.

- The loaded reagents have limited onboard stability. Sample preparation should be started as soon as practical. This is especially important when maximum system throughput is desired. The reagent onboard stability time is indicated on screen.
- Do not touch any carrier or remove a carrier after a run has started.

Moving parts

- Never attempt to start and/or operate the instrument with the front cover open. Keep hands away from all moving parts while the instrument is in use.

To start the sample preparation run

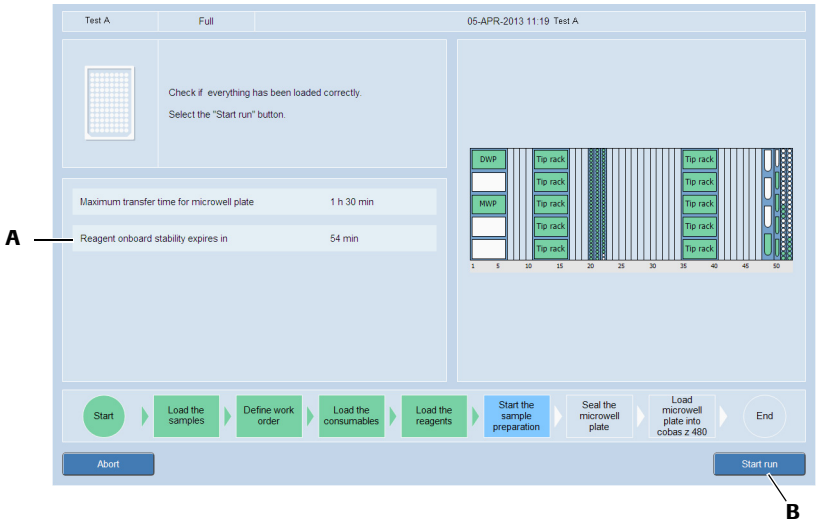
1 Choose the **Start run** button.

The sample preparation is started. After starting the run, the estimated completion time is indicated on the screen.

2 Check the timer in the wizard.

If the **Unload sample carriers after samples were transferred to deepwell plate** check box was selected, the specimens will be unloaded after being pipetted into the deepwell plate.

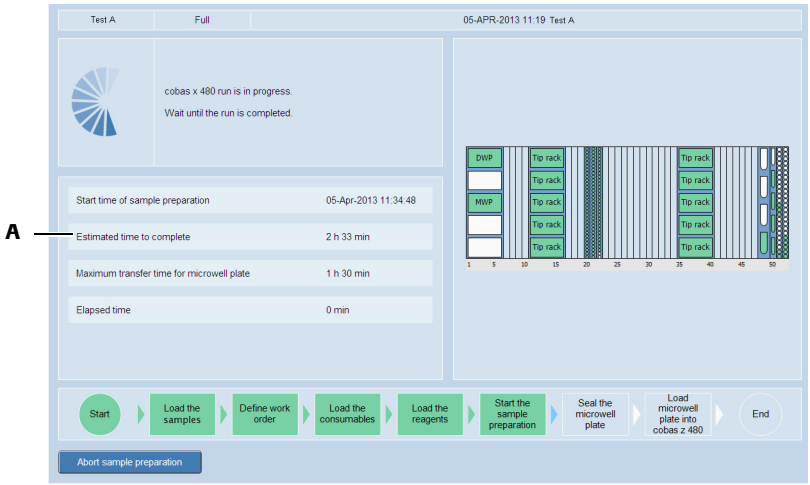
- The indicated completion time is only an estimate.
- After sample preparation is completed, there is a limited time (90 minutes) before the amplification and detection process must be started. A timer is displayed in the **Workplace** tab.



A Onboard reagent expiry time **B** Start the run

Figure 17 Ready to start the run

After you start the run, an estimated time to complete the run is displayed.



A Estimated completion time

Figure 18 Run in progress

Unloading the microwell plate

After a successful sample preparation run, the **Sample Preparation results** button and the **Unload** button become available.

After completion of the sample preparation the microwell plate is transported back to the plate carrier. After unloading, the microwell plate must be sealed and then manually transferred to the analyzer for amplification and detection.

The results of the prepared samples can be reviewed in the **Sample preparation results** dialog box.

NOTICE

Failed sample due to pipetting error

If there is an error during pipetting, a sample can be skipped. This sample will be marked as failed.

- Rerun the failed sample.

To review the sample preparation results

1 To review the results of the sample preparation, choose the **Sample Preparation results** button.

The **Sample preparation results** dialog box is displayed.

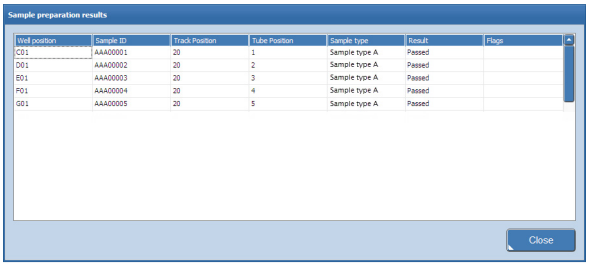


Figure 19 Viewing the sample preparation results

Sample preparation results are printable intermediate results. They cannot be saved or transmitted to the LIS.

For flagged sample preparation results, see *List of result flags* (p. 67)

2 To close the **Sample preparation results** dialog box, choose the **Close** button.

3 To print the results, close the **Sample preparation results** dialog box and choose (**Print**).

4 To unload the plate carrier, choose the **Unload** button.

- Allow the instrument to unload all the carriers. Do not pull them out manually. This would interrupt the unload process and crash the instrument.
- If the instrument encounters a problem during unloading an error message is displayed. Confirm the error message.
- In some cases the instrument must be unloaded manually. After unloading, seal the microwell plate and start the amplification and detection run on the analyzer. The results will be flagged (X9 flag).

The prepared samples with working master mix reagent have a limited stability. You have 90 minutes between completion of the sample preparation and the start of the amplification and detection run. The expiry time is indicated on the screen.

Sealing the microwell plate

On the plate carrier seal the microwell plate properly with a sealing film. Sealing the microwell plate is crucial to eliminate evaporation at high temperatures.

CAUTION

Incorrect results due to evaporation or contamination of samples and controls

- Make sure that microwell plate and sealing film are not expired.
- Follow the outlined procedure to seal the microwell plate to prevent leakage of the sealing film or contamination of samples. Plate leakage can contaminate the analyzer. If contamination is suspected, contact Roche Service.
- Examine the microwell plate after amplification and detection to ensure that no leakage has occurred.

To seal the microwell plate

1 Remove the protection layer from the sealing film.

Do not touch the film on the adhesive side and handle the film only at the sides.

2 Cover the microwell plate with the adhesive side of the sealing film.

3 Firmly press the sealing film to the plate surface using the sealing film applicator.

To ensure a strong seal, use the provided sealing film applicator.

4 Remove both ends of the sealing film alongside the perforation.

Do not lift the sealing film from the plate while tearing off the ends of the foil.

Figure 20 Sealing the microwell plate

5 In the software, choose the **Next** button.

The screen for loading the microwell plate onto the analyzer is displayed.

■

Removing used reagents, samples, and deepwell plate

To optimize throughput used reagents, samples and the deepwell plate can be removed and the instrument can be prepared for the next run as soon as the amplification and detection run on the analyzer has been started.

Starting amplification and detection run

The sealed microwell plate has to be manually transferred to the analyzer for amplification and detection.

The amplification and detection will start immediately after loading.

- The prepared samples with working master mix reagent have a limited stability. Therefore, be sure not to wait too long before starting the amplification and detection run. You have 90 minutes between completion of the sample preparation and the start of the amplification and detection run. The expiry time is indicated on the screen.
- After starting amplification and detection on the analyzer the instrument is ready for the next sample preparation run.

To load the prepared microwell plate into the analyzer

1 Press the load button on the analyzer.

A Load button **B** Microwell plate loader

Figure 21 Loading prepared microwell plate

The microwell plate loader opens.

2 Place the sealed microwell plate into the loading frame of the microwell plate loader.

3 Press the load button again to close the microwell plate loader.

The microwell plate loader is retracted. The run starts immediately.

WARNING

Delay of results due to improper handling

Turning the power of the analyzer off during a run can lead to a sample rerun.

- Do not turn off the analyzer power during a run.

4 Check the timer in the wizard.

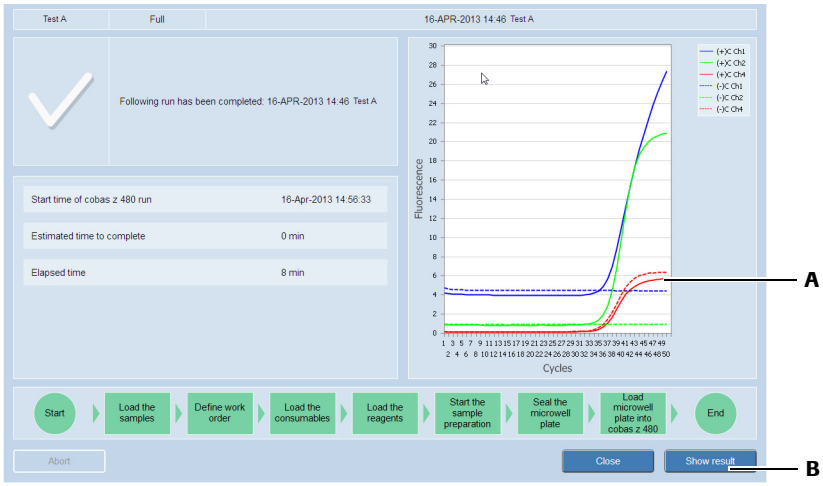
When the run is finished, in the software, the **Show result** button becomes available.

Reviewing and accepting results

Test results are displayed in the **Results** work area as soon as the analyzer has finished amplification and detection.

To review and accept results

1 In the **Workplace** work area, choose the **Show result** button.



A Fluorescence growth curves of the positive (+) and negative (-) controls of all channels **B** **Show result** button

Figure 22 Displaying results

The **Results** work area is displayed.

2 Review and accept results in the **Results** work area.

For details, see *Accepting results* (p. 58)

3 To print the results report, select results and choose (**Print**).

For details, see *Printing results* (p. 58)

■

Sending results to LIS

After review, test results can be sent to the LIS.

- This step can be skipped if working without LIS.
- Depending on the configuration, all results are transferred to LIS or only accepted results are transferred to LIS. Control results are always uploaded to LIS.
- Unless the system is configured to send only accepted results to LIS, all results of the run will be sent even if you only select one result in the run.
- If necessary, the displayed runs can be filtered and sorted.
- To select several nonadjacent results, use the Ctrl key. To select a range of adjacent results, use the Shift key.

To send results to the LIS

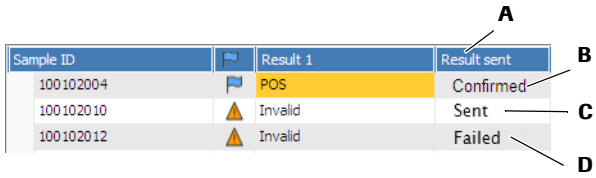
1 Choose the **Results** tab to display the **Results** work area.

2 If required, accept the results you want to send.

3 To send a complete run, select the run header of the run.

4 Choose the **Send results to LIS** button.

After successfully sending results to the LIS, a status is displayed in the **Result sent** column.



A **Result sent** column (must be selected in the **Column Chooser**).

B **Confirmed** means that run was successfully sent to LIS and LIS confirmed the result. This will only be displayed if a certain protocol is used by LIS.

C **Sent** means that LIS has not acknowledged the results.

D **Failed** that the sending of results to LIS failed.

Figure 23 Confirmation from LIS

- Results sent to LIS are kept in the **Results** work area. They are not deleted from the results database.

Unloading the analyzer

Unload the microwell plate as soon as practical after the run has finished to prevent plate leakage and contamination of the analyzer.

CAUTION

Risk of burns due to hot surfaces

- Before removing the microwell plate from the plate loader, wait for an appropriate time to allow the plate loader and microwell plate to cool down. Be aware that the microwell plate may have a temperature of 60 °C to 80 °C even if you have allowed the analyzer to cool down after the run. Otherwise, there is a risk of burns when touching the plate loader or microwell plate.

To unload the analyzer

1 When the run has finished, open the microwell plate loader to remove the microwell plate.

2 Examine the microwell plate after amplification and detection.

CAUTION

Incorrect results due to evaporation of samples or sample contamination

Plate leakage can lead to incorrect results or can contaminate the analyzer. If contamination is suspected, contact Roche Service.

- Unload the microwell plate as soon as practical after the run has finished and check the microwell plate for indications of leakage.

3 Discard the plate according to the appropriate local regulations.

Performing shutdown procedure

To shut down the system, the following steps need to be performed.

To shut down the system

1 Check that there are no remaining pipetting tips or teaching needles on the pipetting head of the instrument. If there are pipetting tips or teaching needles on the pipetting head, perform daily maintenance.

For details on daily maintenance, refer to the **cobas**® 4800 System System Manual.

2 Shut down the system in the following order:

- Log off the software and switch off the control unit.
- Switch off the heater/shaker unit.
- Switch off the instrument.
- Switch off the analyzer.

Performing a recovery workflow run

The following procedures guide you through all required steps to perform a recovery workflow run with amplification and detection on the analyzer.

The recovery workflow is intended for repeat amplification from the remaining eluate in the deepwell plate.

For the recovery workflow, the microwell plate is manually prepared with working master mix reagent, Mn reagent, and residual eluate from the deepwell plate.

Only specimens successfully processed on the instrument can be amplified/detected using the recovery workflow.

The recovery workflow is valid for all specimen types.

Pre-conditions

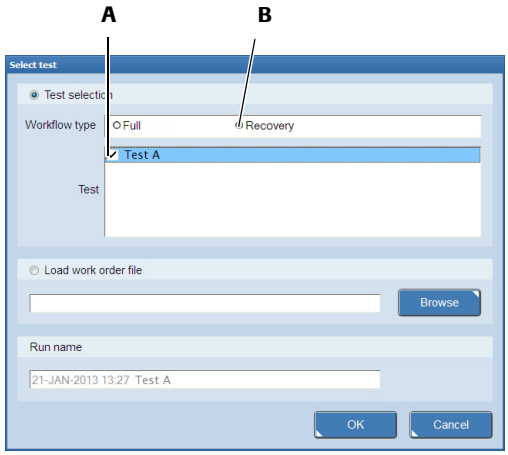
- Instrument and analyzer are turned on and maintenance has been performed.
- A full workflow run has been performed and the samples successfully prepared.
- A full workflow run has been performed in the last 24 hours.
- A full workflow run has been aborted by a user (M2 flag) or the analyzer (Z1 flag).

Starting a recovery workflow run

To start a recovery workflow run

1 Choose (**New run**).

The **Select test** dialog box is displayed.



A Select the test. **B** Select the recovery workflow.

Figure 24 **Select test** dialog box

2 Select the **Recovery** option.

3 Select the **CT/NG** check box.

4 Optionally, type a run name.

5 Choose the **OK** button.

Selecting the run to recover and adding new IDs

The software displays all failed runs that were aborted by the user or analyzer within the last 24 hours.

Select the run to recover and then add the ID of the new microwell plate, master mix reagent, and Mn reagent.

If no hand-held barcode reader is available, you can enter the barcodes manually and press the Enter key after entering each barcode.

To select a run to recover and add new IDs

1 From the list, select a run to recover.

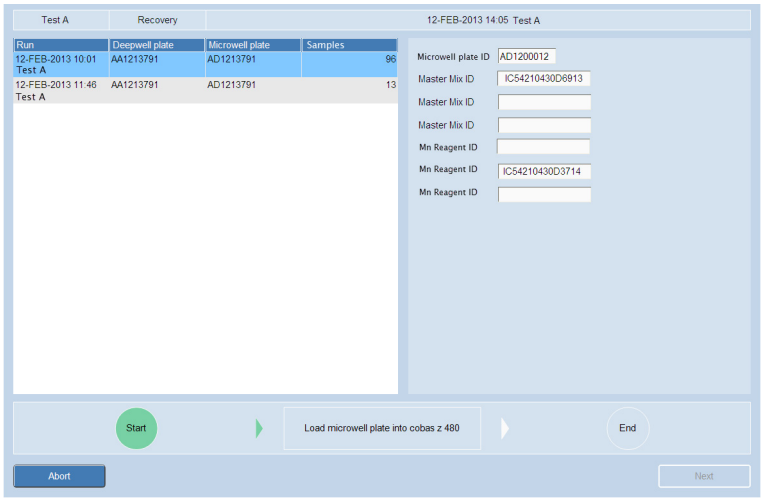


Figure 25 Selecting a run to recover and entering new IDs

2 In the **MWP ID** field, scan the microwell plate barcode.

3 In the **Master Mix ID** field, scan the master mix reagent barcode. You may have to scan more than one barcode.

4 In the **Mn Reagent ID** field, scan the Mn reagent barcode. You may have to scan more than one barcode.

■

Printing the microwell plate layout

A printable report shows the microwell plate layout is displayed. Use this printout for pipetting the reagents and prepared specimens into the microwell plate in the correct way.

To print the microwell plate layout

1 From the global action bar, choose (**Print**).

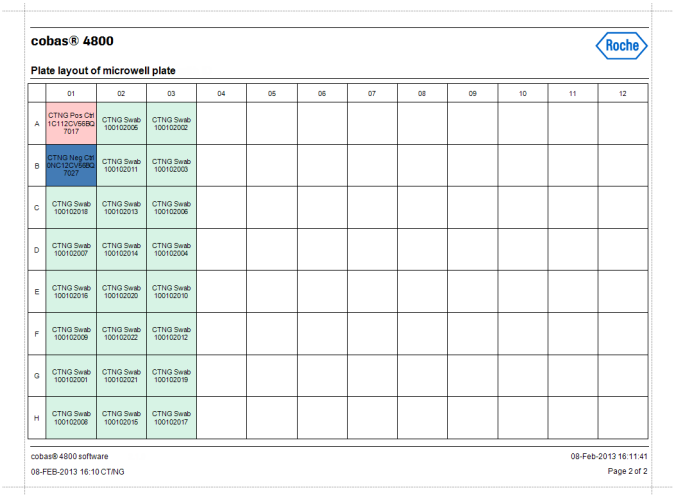


Figure 26 Recovery microwell plate layout

2 In the software, choose the **Next** button.

■

Removing the deepwell plate

The deepwell plate has already been unloaded by the instrument at the end of a run or must be manually unloaded.

To remove the deepwell plate

1 Do one of the following:

- If the deepwell plate has been unloaded by the instrument, remove it from the plate carrier
  or,
- If the deepwell plate has been stored, get it from storage
  or,
- If the deepwell plate has not been unloaded by the instrument, unload the deepwell plate manually

For details how to unload the instrument manually, refer to the **cobas**® 4800 System System Manual.

■

Setting up microwell plate

Set up the microwell plate for the recovery workflow run in the following way:

1. Perform manual PCR setup according to the test-specific package insert.
2. Seal microwell plate.
3. Centrifuge microwell plate.

NOTICE

Analyzer damage due to use of non-Roche consumables

Use of non-Roche consumables may damage the analyzer or lead to incorrect results.

- Use only Roche consumables designed for use on the system. Use of non-Roche consumables may damage the analyzer or lead to incorrect results.
- Only specimens successfully processed on the instrument can be amplified/detected using the recovery workflow. Do not use extract from any other source.

The microwell plate is barcoded and designed to be used only once. The software tracks the use of the plate and rejects previously used microwell plates.

Performing manual PCR setup

- The prepared samples added to working master mix reagent have limited stability. Amplification and detection should be started as soon as practical. Refer to the appropriate test-specific package insert for exact timing window.

WARNING

Incorrect results due to transferring the wrong sample volume

- Make sure to transfer the correct sample volume from the deepwell plate to the microwell plate as described in the test-specific package insert.

WARNING

Incorrect results due to incorrect transfer of eluate

There is no system surveillance for sample tracking between the deepwell plate and the microwell plate. You can print the microwell plate layout which includes the test name and the barcode of the ordered sample.

- Ensure that the eluate is transferred correctly from the deepwell plate to the microwell plate and that the work order file correctly reflects the plate layout.

To perform a manual PCR setup

1 Perform manual PCR setup as described in the test-specific package insert.

Sealing the microwell plate

Seal the microwell plate properly with a sealing film. Sealing the microwell plate is crucial to eliminate evaporation at high temperatures.

CAUTION

Incorrect results due to evaporation of samples or sample contamination

- Make sure that microwell plate and sealing film are not expired.
- Follow the outlined procedure to seal the microwell plate to prevent leakage of the sealing film or contamination of samples. Plate leakage can contaminate the analyzer. If contamination is suspected, contact Roche Service.
- Examine the microwell plate after amplification and detection. An indication of a leak is if the sealing film is bent into the wells of the plate.

To seal the microwell plate

1 Remove the protection layer from the sealing film.

Do not touch the film on the adhesive side and handle the film only at the sides.

2 Cover the microwell plate with the adhesive side of the sealing film.

3 Firmly press the sealing film to the plate surface using the sealing film applicator.

To ensure a strong seal, use the provided sealing film applicator.

4 Remove both ends of the sealing film alongside the perforation.

Do not lift the sealing film from the plate while tearing off the ends of the foil.

Figure 27 Sealing the microwell plate

5 In the software, choose the **Next** button.

The screen for loading the microwell plate onto the analyzer is displayed.

■

Centrifuging the microwell plate

After sealing, centrifuge the sealed microwell plate in a swing bucket centrifuge for at least 5 seconds at 3000 rpm.

Starting amplification and detection run

The sealed microwell plate has to be manually transferred to the analyzer for amplification and detection.

The amplification and detection will start immediately after loading.

- The prepared samples with working master mix reagent have a limited stability. Therefore, be sure not to wait too long before starting the amplification and detection run. You have 90 minutes between completion of the sample preparation and the start of the amplification and detection run. The expiry time is indicated on the screen.
- After starting amplification and detection on the analyzer the instrument is ready for the next sample preparation run.
- Before starting a run, check the **Overview > System > cobas z 480** tab if the Xenon lamp needs replacement. Replace the Xenon lamp, if required.

For details about Xenon lamp replacement, refer to the **cobas**® 4800 System System Manual.

To load the prepared microwell plate into the analyzer

1 Press the load button on the analyzer.

A Load button **B** Microwell plate loader

Figure 28 Loading prepared microwell plate

The microwell plate loader opens.

2 Place the sealed microwell plate into the loading frame of the microwell plate loader.

3 Press the load button again to close the microwell plate loader.

The microwell plate loader is retracted. The run starts immediately.

WARNING

Delay of results due to improper handling

Turning the power of the analyzer off during a run can lead to a sample rerun.

- Do not turn off the analyzer power during a run.

4 Check the timer in the wizard.

When the run is finished, in the software, the **Show result** button becomes available.

Reviewing and accepting results

Test results are displayed in the **Results** work area as soon as the analyzer has finished amplification and detection.

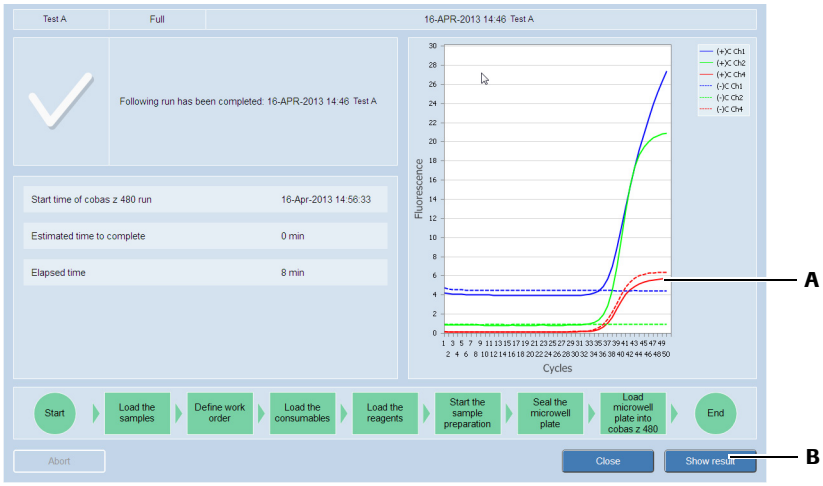
NOTICE

Failed specimens in the recovery results

- Before starting a recovery run, check the sample preparation results for failed specimens. Consider that failed specimens will show up as invalid in the recovery results.

To review and accept results

1 In the **Workplace** work area, choose the **Show result** button.



A Fluorescence growth curves of the positive (+) and negative (-) controls of all channels.

B **Show result** button.

Figure 29 Displaying results

The **Results** work area is displayed.

2 Review and accept results in the **Results** work area.

For details, see *Accepting results* (p. 58)

3 To print the results report, select results and choose (**Print**).

For details, see *Printing results* (p. 58)

■

Sending results to LIS

After review, test results can be sent to the LIS.

- This step can be skipped if working without LIS.
- Depending on the configuration, all results are transferred to LIS or only accepted results are transferred to LIS. Control results are always uploaded to LIS.
- Unless the system is configured to send only accepted results to LIS, all results of the run will be sent even if you only select one result in the run.
- If necessary, the displayed runs can be filtered and sorted.
- To select several nonadjacent results, use the Ctrl key. To select a range of adjacent results, use the Shift key.

To send results to the LIS

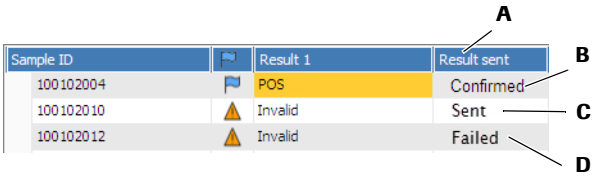
1 Choose the **Results** tab to display the **Results** work area.

2 If required, accept the results you want to send.

3 To send a complete run, select the run header of the run.

4 Choose the **Send results to LIS** button.

After successfully sending results to the LIS, a status is displayed in the **Result sent** column.



A **Result sent** column (must be selected in the **Column Chooser**).

B **Confirmed** means that run was successfully sent to LIS and LIS confirmed the result. This will only be displayed if a certain protocol is used by LIS.

C **Sent** means that LIS has not acknowledged the results.

D **Failed** that the sending of results to LIS failed.

Figure 30 Confirmation from LIS

- Results sent to LIS are kept in the **Results** work area. They are not deleted from the results database.

Unloading the analyzer

Unload the microwell plate as soon as practical after the run has finished to prevent plate leakage and contamination of the analyzer.

CAUTION

Risk of burns due to hot surfaces

- Before removing the microwell plate from the plate loader, wait for an appropriate time to allow the plate loader and microwell plate to cool down. Be aware that the microwell plate may have a temperature of 60 °C to 80 °C even if you have allowed the analyzer to cool down after the run. Otherwise, there is a risk of burns when touching the plate loader or microwell plate.

To unload the analyzer

1 When the run has finished, open the microwell plate loader to remove the microwell plate.

2 Examine the microwell plate after amplification and detection.

CAUTION

Incorrect results due to evaporation of samples or sample contamination

Plate leakage can lead to incorrect results or can contaminate the analyzer. If contamination is suspected, contact Roche Service.

- Unload the microwell plate as soon as practical after the run has finished and check the microwell plate for indications of leakage.

3 Discard the plate according to the appropriate local regulations.

Performing shutdown procedure

To shut down the system, the following steps need to be performed.

To shut down the system

1 Check that there are no remaining pipetting tips or teaching needles on the pipetting head of the instrument. If there are pipetting tips or teaching needles on the pipetting head, perform daily maintenance.

For details on daily maintenance, refer to the **cobas**® 4800 System System Manual.

2 Shut down the system in the following order:

- Log off the software and switch off the control unit.
- Switch off the heater/shaker unit.
- Switch off the instrument.
- Switch off the analyzer.

Sample editor

You can use the sample editor to prepare one or more work order files before starting a run, or to prepare a work order file for the next run while a run is still in progress. A work order file can be selected in the **Select test** dialog box.

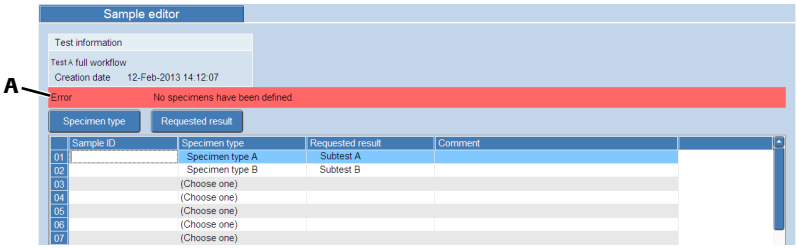
The work order file is an XML-file that contains all orders for a single run on the system. The work order file is loaded into the software at the beginning of a run. For each run, the information in the work order file must match the loaded samples on the system.

- If a work order file and the loaded samples do not match, you can unload the samples and replace them and reload. If you want to choose another work order file, you have to abort and start a new run. It is not possible to choose another work order file and leave the samples loaded.
- Samples can be loaded in any order as long as they match the set of samples listed in the work order file. You can also load more samples than those defined in the work order file and then define them in the sample editor.
- You can edit each order individually or edit multiple orders at the same time using the Shift and/or Ctrl keys.
- You can edit a work order during a full workflow run in the wizard or before a full workflow run in the sample editor.

About messages in the sample editor

If an error happens while creating a work order file, an error message is displayed.

As only one message can be displayed, the error message with the highest priority is shown.



A Message originating from an error in the **Sample ID** column

Figure 31 Errors within the sample editor

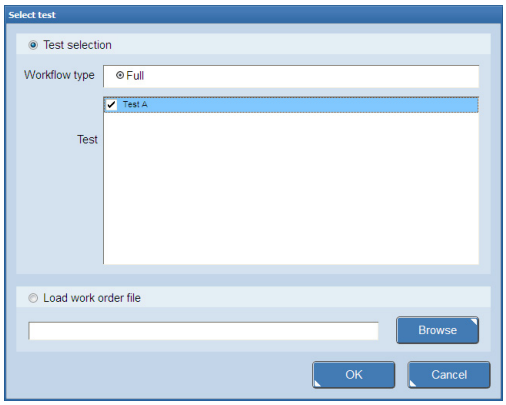
Using the sample editor to create a work order file

Use the sample editor to create a work order file for the next run while a run is still in progress. You can also use the sample editor to create one or more work order files before starting a run.

To create a work order file with the sample editor

1 In the global action bar, choose (**Editor**).

The **Select test** dialog box is displayed.

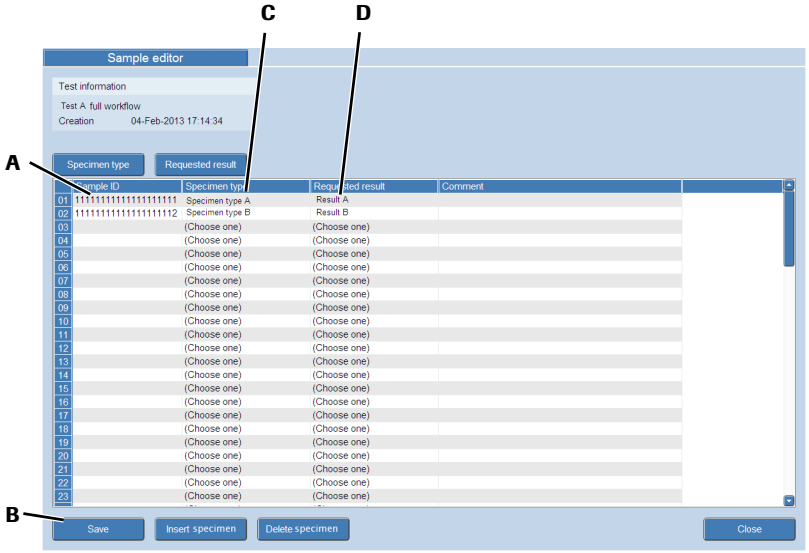


2 Select the **Full** option.

3 Select the **CT/NG** check box.

4 Choose the **OK** button.

5 From the sample editor, scan or enter the sample ID barcodes into the **Sample ID** column.



A Select and scan the sample ID.
B Save the work order file.
C Select a type of specimen.
D Select a requested result.

Figure 32 Using the sample editor to create a work order file

6 Define the type of specimen and the requested result.

7 Choose the **Save** button and save the work order file.

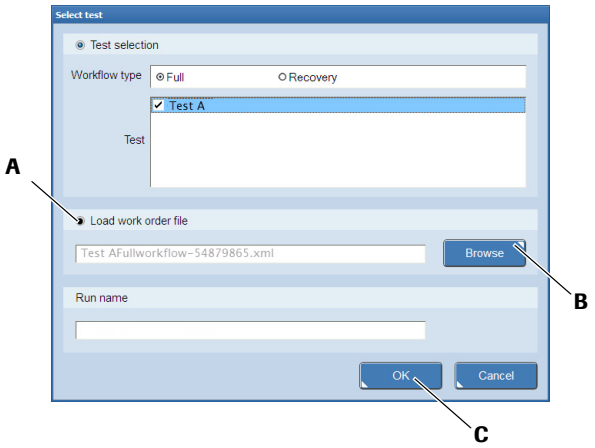
The **Save as** dialog box is displayed. The default location is the one that is defined in the **Configuration** tab (**Utilities** > **Configuration** > **System settings**).

Editing an existing work order file

To edit a work order file

1 In the global action bar, choose (**Editor**).

The **Select test** dialog box is displayed.



A Load a work order file.

B Browse for a work order file.

C Open the work order file in the sample editor.

Figure 33 Loading a work order file

2 Select the **Load work order file** option and then choose the **Browse** button.

3 From the **Open** dialog box, select and open a work order file.

4 From the **Select test** dialog box, choose the **OK** button.

5 From the sample editor, edit the work order file as required.

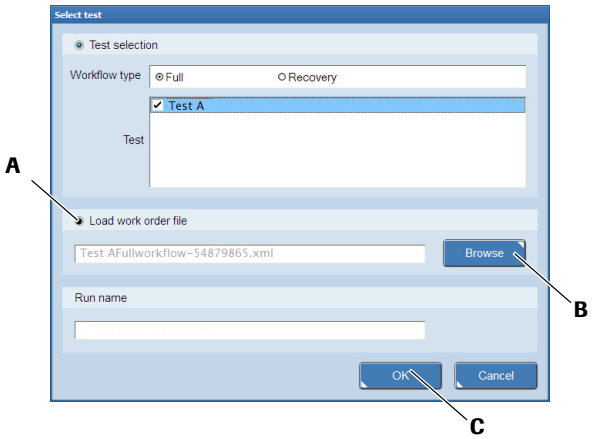
6 Save the work order file.

Loading a work order file

To load a work order file

1 Choose (**New run**).

The **Select test** dialog box is displayed.



A Load a work order file.

B Browse for a work order file.

C Open the work order file in the sample editor.

Figure 34 Loading a work order file

2 Select the **Load work order file** option and then choose the **Browse** button.

3 From the **Open** dialog box, select and open a work order file. Optionally, after loading the work order file, you can change the run name.

4 From the **Select test** dialog box, choose the **OK** button.

The work order is opened in the sample editor and you can perform a full workflow run.

For more information about performing a full workflow run, see *Performing a full workflow run* (p. 18)

Results

The **Results** work area gives access to all runs and test results. Use the **Results** work area to review, accept, print, and send results to LIS.

WARNING

Delay of results due to reading the wrong result

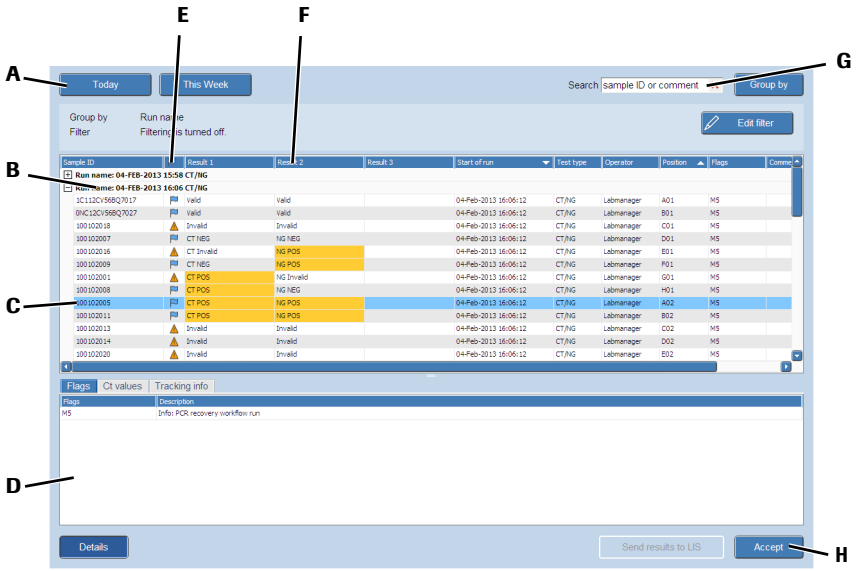
If you do not read the result correctly and rerun the sample, the rerun could cause a delay.

- In the **Results** work area, icons help you identify if a result failed, is invalid, or has a flag.

Icon	Comment
	Result is invalid with one or more flags or failed.
	Result is valid and has one or more flags.
(blank)	Result is valid or has no flags

Table 10 Result icons

To help you easily identify a positive result, the result is highlighted.



A Filter buttons.
B Run header.
C Test results of the selected run.
D **Details** area.
E Result icons.
F Results. Depending on the test, more than one result can be displayed.
G **Search** field.
H Result handling buttons.

Figure 35 **Results** work area

Reviewing results

The layout of the **Results** work area can be customized. Customization includes:

- Creating various filters.
- Sorting and grouping of runs and results.
- Changing the order of the columns and hiding selected columns.

- Customization of the result view in the **Results** work area does not influence result printouts. The details per result that are included in reports are independent of what is displayed on screen.
- When a user customizes the view of the **Results** work area, the new view will be saved for all users.

To display results of selected runs and to review result details

1 To display the individual results of that run, choose the plus sign next to the run header.

2 To display more information about a particular result, select the result you want to review.

3 Choose the **Details** button.

The **Details** area is displayed.

4 Choose the **Flags** tab. Flags of the selected sample are displayed.

For information about flags, see *List of result flags* (p. 67).

5 Choose the **Ct values** tab. Review the results data.

For information about result interpretation, refer to the test-specific package insert.

6 Choose the **Tracking info** tab. Information about the selected sample is displayed (e.g. if processes were successful, what instrument was used, start/end time).

Grouping results

The results can be grouped by the following criteria:

- Run name
- Start time of the run
- Test type

To group the results

1 Choose the **Group by** button.

2 From the list, select a grouping criterion.

All results are grouped by the selected criterion.

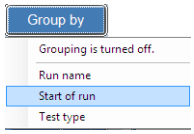


Figure 36 Grouping results

3 To display the runs in an ungrouped order, choose the **Group by** button and then choose the **Grouping is turned off** button from the list.

Searching results

Use the search function to search for sample IDs or comments within the results. The search function searches the whole result database, not only the results that are currently displayed.

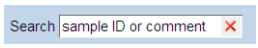


Figure 37 **Search** function on the **Results** work area

The use of the following wildcards is possible:

- Use the question mark (?) as placeholder for a single character.
- Use the asterisk (*) as placeholder for a range of characters (e.g. searching for a sample ID “AD2*” will find all sample IDs starting with “AD2”).

To search for patient IDs or comments

1 Click into the **Search** field.

2 Type the search term into the field.

The result of the search is displayed automatically in the runs area.

If necessary, the displayed results can be filtered and sorted.

3 To remove the search term, choose next to the **Search** field.

All runs are displayed in the runs area once again, not only the results of the search.

Filtering and sorting runs and results

Runs and results that are displayed in the **Results** work area can be filtered and sorted.

For information about organizing and filtering lists, refer to the **cobas**® 4800 System System Manual.

Accepting results

To accept results

1 To accept a complete run, select all results of the run you want to accept.

2 To accept only certain results, select the results you want to accept.

- To select several nonadjacent results, use the Ctrl key.
- To select a range of adjacent results, use the Shift key.

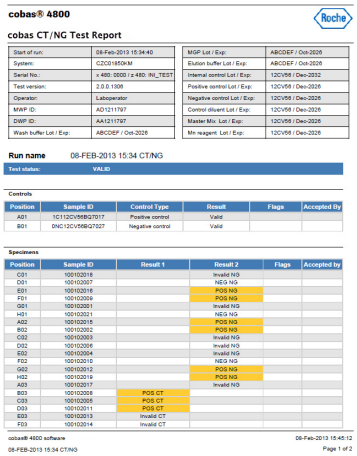
3 Choose the **Accept** button.

In the **Accepted by** column, the user who accepted the results is displayed, for example the laboratory manager.

For information about adding columns, refer to the **cobas**® 4800 System System Manual.

Printing results

Before printing, a print preview is displayed. Use the **File** menu to specify the print and export options and to print or export (PDF) the result report.


cobas® 4800

Roche

cobas CT/NG Test Report

Start of run:	08-Feb-2013 15:34:40	MGP Lot / Exp:	ABCDEF / Oct-2026
System:	CZC01850KM	Elution buffer Lot / Exp:	ABCDEF / Oct-2026
Serial No.:	x 480: 0000 / z 480: INI_TEST	Internal control Lot / Exp:	12CV56 / Dec-2032
Test version:	2.0.0.1306	Positive control Lot / Exp:	12CV56 / Dec-2026
Operator:	Laboperator	Negative control Lot / Exp:	12CV56 / Dec-2026
MWP ID:	AD1211797	Control diluent Lot / Exp:	12CV56 / Dec-2026
DWP ID:	AA1211797	Master Mix Lot / Exp:	12CV56 / Dec-2026
Wash buffer Lot / Exp:	ABCDEF / Oct-2026	Mn reagent Lot / Exp:	12CV56 / Dec-2026

Run name 08-FEB-2013 15:34 CT/NG

Test status: VALID

Controls

Position	Sample ID	Control Type	Result	Flags	Accepted By
A01	1C112CV56BQ7017	Positive control	Valid		
B01	DNC12CV56BQ7027	Negative control	Valid		

Specimens

Position	Sample ID	Result 1	Result 2	Flags	Accepted by
C01	100102018		Invalid NG		
D01	100102007		NEG NG		
E01	100102016		POS NG		
F01	100102009		POS NG		
G01	100102001		Invalid NG		
H01	100102021		NEG NG		
A02	100102015		POS NG		
B02	100102002		POS NG		
C02	100102003		Invalid NG		
D02	100102006		Invalid NG		
E02	100102004		Invalid NG		
F02	100102010		NEG NG		
G02	100102012		POS NG		
H02	100102019		POS NG		
A03	100102017		Invalid NG		
B03	100102008	POS CT			
C03	100102005	POS CT			
D03	100102011	POS CT			
E03	100102013	Invalid CT			
F03	100102014	Invalid CT			

cobas® 4800 software 08-Feb-2013 15:45:12

08-FEB-2013 15:34 CT/NG Page 1 of 2

Figure 38 Print preview

The details per result that are included in the report are independent of what is displayed on screen. Structure and layout of reports cannot be changed by the user.

To print the result report

1 To print complete runs, select the runs you want to print.

2 To print only certain results, select the results you want to print.

- To select several nonadjacent results, use the Ctrl key.
- To select a range of adjacent results, use the Shift key.

3 In the global action bar, choose (**Print**).

A print preview is displayed for each run that was selected.

4 In the **File** menu, define the printing options.

5 To print the result report, choose **File** > **Print**.

To export the result report as a PDF file

1 To export a complete run, select the run you want to export.

2 To export only certain results, select the results you want to export.

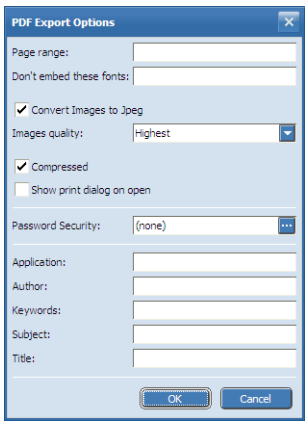
- To select several nonadjacent results, use the Ctrl key.
- To select a range of adjacent results, use the Shift key.

3 In the global action bar, choose (**Print**).

A print preview is displayed for each run that was selected.

4 Choose **File** > **Export Document**.

A dialog box for defining the export options is displayed.



5 After specifying the export options, choose the **OK** button.

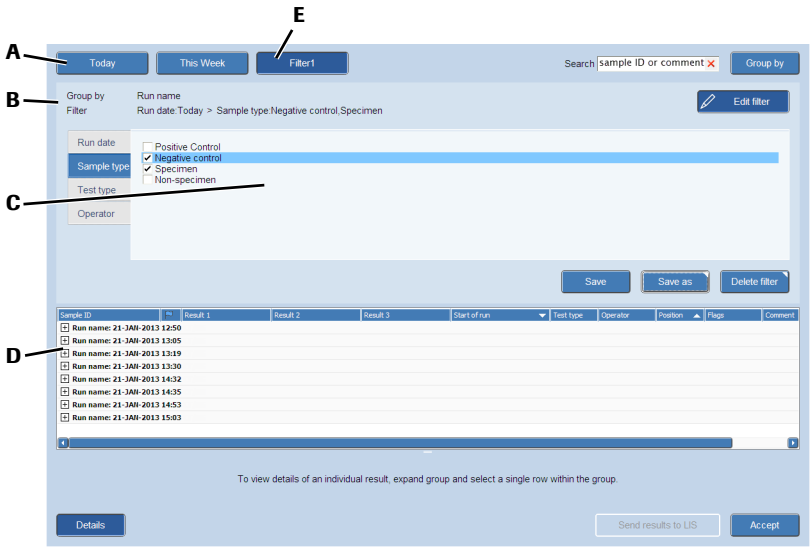
A dialog box for defining file name and path for storage is displayed.

6 Define the file name and path for storage.

7 Choose the **Save** button and confirm with the **Yes** button.

Creating result filters

A maximum of three additional result filters can be defined and saved. The filters will appear as separate buttons above the filter information area. Per default, the filters **Today** and **This Week** are available. The default filters cannot be changed nor deleted. However, they can be used as a basis for a new filter, which has to be saved with another name.



A Filter buttons.
B Filter information area.
C Filter definition area.
D Runs area.
E Example of a customized filter.

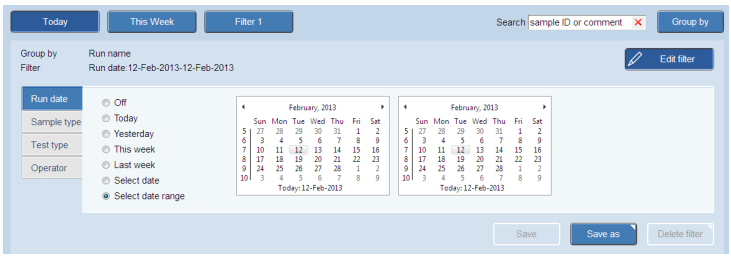
Figure 39 Filter definition area in the **Results** work area

To create a new result filter

1 Choose the **Edit filter** button.

The filter definition area is displayed.

2 Choose the **Run date** button and select a run date or range.



To define a date range, select the start and end date in the calendar boxes.

3 Choose the **Sample type** button and select one or more sample types.

To include only positive controls into the filter, select the **Positive control** option.

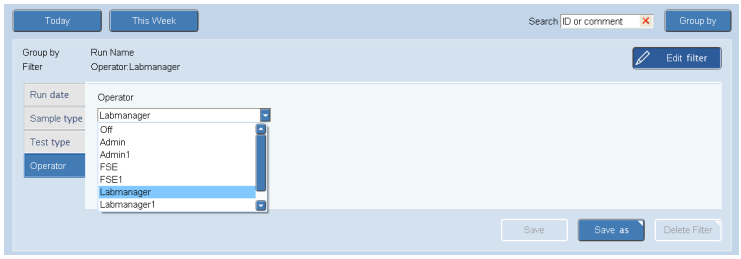
To include only negative controls into the filter, select the **Negative control** option.

To include only specimens into the filter, select the **Specimen** option.

To include only controls into the filter, select the **Non-specimen** option.

4 Choose the **Test type** button and select one or more test types.

5 Choose the **Operator** button. From the **Operator** drop-down list, choose a user.



6 Choose the **Save as** button.

A dialog box for defining the filter name is displayed.

7 Type a name for the filter into the box.

8 From the dialog box, choose the **Save** button.

The filter is displayed as a separate button above the filter information area. The filter and grouping criteria of the new filter are displayed in the filter information area.

■

To change a result filter

1 Choose the filter button of the filter you want to change.

The selected filter button will change to a darker blue shade.

2 Change the filter criteria as described above.

3 Do one of the following:

- To save the changes, choose the **Save** button.
  or,
- To save the filter under a new name, choose the **Save as** button.

■

To delete a result filter

1 Choose the filter button of the filter you want to delete.

The selected filter button will change to a darker blue shade.

2 Choose the **Delete filter** button.

A confirmation dialog box is displayed.

3 To delete the filter, choose the **Yes** button.

The filter button will disappear from the filter area.

■

To apply a filter to the results

1 Choose the filter button you want to apply.

The selected filter button will change to a darker blue shade. Only the results that correspond to the selected filter will appear in the runs area.

2 If the filter definition area is still displayed, choose the **Edit filter** button. The filter definition area will be closed.

Grouping of filtered results

The grouping of the filtered results can be changed anytime by choosing the **Group by** button.

For more information, see *Grouping results* (p. 57).

To disable result filtering

1 Choose the filter button that is currently active. The filter button ceases to be highlighted.

In the filter information area, a message is displayed to indicate that the filtering is turned off. All results are displayed in the runs area once again.

2 If the filter definition area is still displayed, choose the **Edit filter** button. The filter definition area will be closed.

Aborting a run

To abort a run

1 In the global action bar, choose the **Abort** button.

2 If more than one run is active, select the run you want to abort.

A confirmation dialog box is displayed.

3 Confirm the message.

4 In the wizard, choose the **Unload** button.

Configuration

The initial password is defined during the setup of a user account.

Changing your password

Any user can change their password. Laboratory managers can change the passwords of all users. The password must follow the password rules that are defined in the software.

To change your password

1. Choose **Utilities** > **Users** > choose **Change Password**.

   The **Change password** dialog box is displayed.
2. In the **Old password** field, type the current password.
3. In the **New password** field, type the new password.
4. In the **Repeat new password** field, type the new password again.
5. Choose the **OK** button.

Troubleshooting

List of error messages

Error messages are displayed under **Messages** > **Messages**.

The source of a message is indicated in the message code as outlined in the following table.

Message code	Message source	Example
6.2.5.**10**.xx	Messages created by the system.	6.2.5.10.22
6.2.5.**20**.xx	Messages created by the instrument or the analyzer.	6.2.5.20.13
6.2.5.**30**.xx	Messages created by the test.	6.2.5.30.19

Table 11 Message source

The following table lists the messages as they are displayed in the software.

- If there is no user action stated in the message table or you need more information about a solution, call Roche Service.
- Placeholders are printed in {} (e.g. {0}, {1}).

ID	Severity	Message	Solution / Comment
6.2.5.20.21	Error	Processing on **cobas x** 480 instrument was aborted by the instrument.	Check the messages for further details.
6.2.5.20.22	Error	An error occurred on **cobas x** 480 instrument.	Check the messages for further details.
6.2.5.20.23	Error	An error occurred on **cobas x** 480 instrument.	The instrument is either not switched on, not connected, or defective. Check connections between instrument and control unit or switch on the instrument. Then choose the **Refresh** button.
6.2.5.20.24	Warning	No connection to **cobas x** 480 instrument. Connection to **cobas x** 480 instrument was lost during the loading of maintenance information.	The instrument is either not switched on, not connected, or defective. Check connections between instrument and control unit or switch on the instrument. Then choose the **Refresh** button.
6.2.5.20.25	Warning	**cobas x** 480 instrument is not available.	The instrument is either not switched on, not connected, or defective. Check connections between instrument and control unit or switch on the instrument. Then choose the **Refresh** button.
6.2.5.20.27	Error	Specimens have been transferred to the deepwell plate, but an error occurred during unloading.	Unload the instrument manually after sample preparation and transfer the microwell plate to the analyzer. For details how to unload the instrument manually, refer to the **cobas**® 4800 System System Manual.

Table 12 System messages

ID	Severity	Message	Solution / Comment
6.2.5.20.28	Error	Error occurred during the unloading of sample carriers. Unload sample carriers manually. Microwell plate can be transferred to cobas z 480.	During the unloading of sample carriers, an error occurred. Unload sample carriers manually and transfer the microwell plate to the **cobas z** 480 analyzer.
6.2.5.10.10	Warning	Suboptimal monitor resolution has been detected. Optimal resolution is 1280 x 1024.	Current screen resolution is not the recommended one. Change screen resolution to 1280 x 1024.
6.2.5.10.11	Error	Raw data file is corrupted.	Contact Roche Service.
6.2.5.10.12	Warning	Run cannot be recovered.	There are many reasons, why a run cannot be recovered. A run can be recovered only one time. If the run is older than 24 hours, the run cannot be recovered.
6.2.5.10.17	Warning	Purge and archive of data was aborted due to insufficient space on backup drive.	Archive and delete old data from backup drive.
6.2.5.10.18	Warning	Purging and archiving data cannot be completed.	Contact Roche Service.
6.2.5.10.19	Warning	Purge and archive could not create folder.	Contact Roche Service.
6.2.5.10.21	Warning	On hard disk {0}, {1} of {2} are free (hard disk {3}% full).	Archive and delete old data.
6.2.5.10.22	Error	On hard disk {0}, {1} of {2} are free (hard disk {3}% full).	Archive and delete old data.
6.2.5.10.23	Warning	No analysis package installed.	Contact Roche Service.
6.2.5.10.26	Error	Not enough free space on hard disk or database available to start a new run.	Clean up hard disc D:\ manually by deleting files that are no longer needed. If unclear, contact Roche Service.
6.2.5.10.27	Error	Sending test results to LIS failed.	Check communication to LIS. If the connection to the LIS does not work, contact the local IT support to find out if there is a problem with the LIS. If the problem cannot be solved, contact Roche Service.
6.2.5.10.28	Error	The last database backup has failed. Job Name: {0} Run date: {1}Additional Information: {2}	Contact system administrator.
6.2.5.10.29	Error	No database backup has been run.	Contact system administrator.
6.2.5.10.30	Warning	The connection to LIS has been lost.	Check communication to LIS. If the connection to the LIS does not work, contact the local IT support to find out if there is a problem with the LIS. If the problem cannot be solved, contact Roche Service.
6.2.5.10.31	Warning	The connection to LIS has been lost. Therefore no run can be started.	Check communication to LIS. If the connection to the LIS does not work, contact the local IT support to find out if there is a problem with the LIS. If the problem cannot be solved, contact Roche Service.
6.2.5.10.32	Warning	Cannot start a new run while maintenance is required for the {0}.	Before starting a new run, go to the **Overview** tab and perform all the required maintenance actions.
6.2.5.10.33	Warning	Cannot start a new run when the {0} instrument is not available.	Go to the **Overview** tab and check the status of the **cobas z** 480 analyzer and **cobas x** 480 instrument.
6.2.5.10.34	Warning	Results could not be fully loaded	To load the results again, change the current filter by choosing another filter or edit the current filter.

Table 12 System messages

ID	Severity	Message	Solution / Comment
6.2.5.20.30	Error	Current optical filters are not supported on analyzer: {0}.	Optical filters need to be exchanged. Contact Roche Service.
6.2.5.20.31	Error	Analyzer {0} block is not supported.	The analyzer needs to be updated. Contact Roche Service.
6.2.5.20.32	Error	An error occurred on the analyzer.	Unexpected error occurred during processing. Restarting the analyzer may solve the problem. If the error persists, contact Roche Service.
6.2.5.20.33	Error	cobas 4800 software does not support IC software version {1} on the "{0}.	The analyzer needs to be updated. Contact Roche Service.
6.2.5.20.34	Warning	Connection to the following analyzer has been lost: {0}.	The analyzer is not switched on, not connected, or defective. Check connections between analyzer and control unit or switch on the analyzer. Then choose the **Refresh** button.
6.2.5.20.35	Error	An error occurred on the analyzer.	The following analyzer error occurred: {0}. The run was aborted. Restart the analyzer. If the error persists, contact Roche Service.
6.2.5.20.36	Warning	The maintenance for the cobas z 480 is required in order to perform new runs	Exchange the Xenon lamp and check the **cobas z** 480 analyzer before continuing.
6.2.5.30.80	Warning	Wrong MWP loaded in instrument: {0}. Expected MWP: {1}.	Mismatch occurred between loaded and expected microwell plate. Load the microwell plate {1} into the analyzer.
6.2.5.30.81	Warning	MWP was used in a previous run. Please exchange MWP.	The microwell plate was previously used. A microwell plate may only be used once.
6.2.5.30.82	Error	MWP barcode could not be read.	The barcode could not be read. Contact Roche Service.
6.2.5.30.83	Error	Algorithm definition file cannot be loaded.	The following algorithm definition file failed data consistency check: {0}. Contact Roche Service.
6.2.5.30.84	Error	Algorithm definition file is missing.	The following algorithm definition file is missing: {0}. Contact Roche Service.
6.2.5.30.85	Error	Wrong algorithm version.	Algorithm file {0} has version {1}. This version does not match the required version {2}. Contact Roche Service.
6.2.5.30.86	Error	Run template data file is corrupted.	The following run template data file failed data consistency check: {0}. Contact Roche Service.
6.2.5.30.87	Error	Calculation parameter file cannot be loaded.	The following calculation parameter file failed data consistency check: {0}. Contact Roche Service.
6.2.5.30.88	Error	An unknown error occurred. The run was aborted.	An unknown error occurred during processing. The run was aborted and all results flagged. The error was: '{0}: {1}'. Restart the software. If the problem persists, contact Roche Service.
6.2.5.30.89	Error	Calculation parameter file is missing.	The following calculation parameter file is missing: {0}. Contact Roche Service.
6.2.5.30.97	Warning	The specimens were transferred to the DWP, but an error occurred during the unloading.	Unload the instrument manually after sample preparation and transfer the microwell plate to the analyzer. For details how to unload the instrument manually, refer to the **cobas**® 4800 System System Manual.

Table 12 System messages

ID	Severity	Message	Solution / Comment
6.2.5.30.98	Error	The transfer time for the MWP has expired.	Repeat the run.
6.2.5.30.99	Error	Onboard expiration time has been reached.	Repeat the run.
6.2.5.90.01	Warning	Barcode {0} is invalid.	Please use a valid reagent or consumable.
6.2.5.90.02	Warning	Reagent kit size does not match.	Expected kit size is 96. Using reagents from a 24 kit is not sufficient for this run. Use reagents from a 96 kit.
6.2.5.90.03	Warning	Barcode {0} identifies an object not requested here.	Scanned barcode does not match. The barcode of samples, reagents, reservoirs, or consumables required in this step. Check to ensure that the correct ones are used.
6.2.5.90.04	Warning	Barcode {0} is already used before.	The scanned barcode has already been used in this or in a previous run. Use new reagents, reservoirs, and consumables.
6.2.5.90.05	Warning	The reagent {0} has been expired at {1}.	It is not allowed to use expired reagents. Use reagents that are not expired.
6.2.5.90.06	Warning	Barcode {0} is already used in this run.	The scanned barcode has already been used in this or in a previous run. Use new reagents, reservoirs, and consumables.
6.2.5.90.07	Warning	The specimen with the barcode '{0}' was rejected by LIS. Please unload and remove the specimen from the carrier.	Unload the sample carrier, remove the specimen, and reload the sample carrier.
6.2.5.90.08	Warning	Connection to the Com Server while requesting the barcode '{0}' failed.	Check the LIS configuration settings and the message details.

Table 12 System messages

List of result flags

You can find result flags under the **Results** tab. The source of a flag is indicated in the flag code as outlined in the following table.

Flag code starts with	Flag source	Example
M	Multiple or other reasons	M6
R	Result interpretation	R20
X	Instrument	X2
Z	Analyzer	Z1

Table 13 Flag source

The following table lists all result flags of the system that are user relevant.

Flag code	Severity	Description	Recommended action
M1	Error	Error: Software error occurred. For more information refer to alarm messages and log files.	Refer to alarm messages and log files. If this does not help, contact Roche Service.
M2	Information	Information: Run was aborted by the user.	None. Flag is for information only
M5	Information	Information: Results come from a recovery workflow.	None. Flag is information only.

Table 14 List of system flags

Flag code	Severity	Description	Recommended action
M6	Information	Information: Communication with cobas z 480 was lost. Run was recovered after the communication was re-established.	None. Flag is information only. For details, refer to the **cobas**® 4800 System System Manual.
M10	Information	Information: Run was rescued by the software after cobas x 480 processing was completed.	None. Flag is information only.
R20	Warning	Positive control is invalid.	Positive control values were out of range. 1. Repeat entire run with fresh reagents. 2. If the problem persists, contact Roche Service.
R21	Warning	Negative control is invalid.	Negative control values were out of range. To avoid carryover, use good laboratory practice. 1. Repeat entire run with fresh reagents. 2. If the problem persists, contact Roche Service.
X1	Error	Error: Error occurred on cobas x 480. Sample or test was not processed.	An error occurred on the instrument. 1. Check if instrument deck is contaminated or if there are lost tips on the instrument deck. For details how to unload the instrument manually, refer to the **cobas**® 4800 System System Manual. 2. Contact Roche Service.
X2	Information	Information: Specimen barcode was entered manually.	None. Flag is for information only.
X3	Error	Error: Clot was detected. Sample was not processed.	Make sure the samples were handled according to the instructions in the test-specific package insert. 1. Check the sample for clots. 2. If a collection device is present, remove it from the sample tube. 3. Rerun the sample.
X4	Error	Error: Pipetting error occurred. Sample was not processed.	Insufficient sample volume or mechanical error during pipetting is the most likely reason. 1. Make sure that there is enough sample volume. 2. If a collection device is present, remove it from the sample vial. 3. Check whether the tip eject plate is placed correctly. 4. Rerun the sample.
X5	Error	Error: Reagent onboard stability expired. Run was aborted.	Repeat the entire run with fresh reagents.
X6	Error	Error: Microwell plate was not transferred in time. Run was aborted.	1. If the pre-conditions can be met, you could use the recovery workflow. 2. Repeat the entire run with fresh reagents.
X7	Error	Error: Pipetting error occurred. Test was aborted.	Controls could not be processed due to pipetting error in the reagents. Repeat the test with fresh reagents.
X8	Error	Error: Mechanical error in pipetting channel occurred. Sample was not processed.	1. Perform daily maintenance. 2. Rerun the sample. 3. If the problem persists, contact Roche Service.
X9	Warning	Warning: An error occurred during unloading the cobas x 480.	1. Manually unload the instrument. 2. Check the instrument for damages and restart the instrument. 3. Continue the run on the analyzer.
X10	Error	Error: Insufficient number of tips was loaded. Run was aborted.	Repeat entire run with fresh reagents.

Table 14 List of system flags

Flag code	Severity	Description	Recommended action
X11	Error	Error: Cover of cobas x 480 was opened or a carrier was manually removed during a run. Run was aborted.	Repeat entire run with fresh reagents.
X12	Information	Information: Reagent vial barcode or reservoir barcode was entered manually.	None. Flag is for information only.
Z1	Error	Error: Error occurred on cobas z 480. Run was aborted.	Contact Roche Service.

Table 14 List of system flags

Revisions