cobas® 4800 archive viewer

Operator's Manual

Document information

Manual version	Software version	Main change
1.0	1.0	First publication

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

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.

Description The **cobas® 4800** archive viewer is intended to allow users to search for, view and print specific archived data generated on the **cobas® 4800** System. The archive viewer is stand-alone software that runs on a separate Windows PC, and is not part of the **cobas® 4800** System. The **cobas® 4800** archive viewer is not intended to generate or report diagnostic results.

Copyright © 2013 Roche Diagnostics International Ltd. All rights reserved.

Trademarks The following trademarks are acknowledged:

COBAS, COBAS Z, COBAS X, 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 fulfills its 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.

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

Symbol	Meaning
(icon)	Cross-reference
(icon)	Procedure start
(icon)	Procedure end
•	List item
(icon)	Tip

Table 1   Information symbols

Contact addresses

◣	Roche Molecular Systems, Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA Made in Switzerland

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Table of contents

System description

About the archive viewer

The **cobas® 4800** archive viewer software allows you to access archived data generated on the **cobas® 4800** System. Without the archive viewer, you cannot directly access archived data.

Key features   Import, search, view, print, and export archived data.

Key benefits   You can produce data in printed and/or electronic form.

To ensure that your system is functioning normally, you can compare current data to historical data.

Process overview
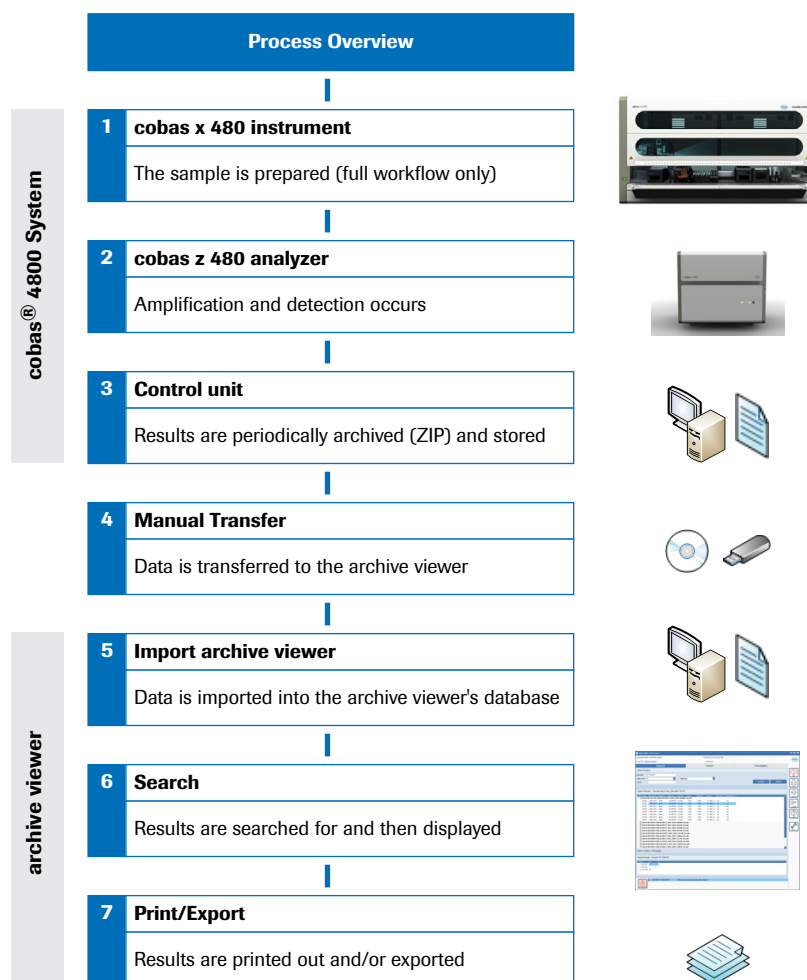

Figure 1   The archive viewer process

Use case   Results from a particular day or date range are requested. You enter parameters to search the archived data. The archive viewer displays the results and you print them out.

About archived data

Archived data is generated on the **cobas® 4800** System and contains the following information:

- Result
- Flags
- Run ID and file name
- Run date and time
- Instrument name
- Operator who performed the test
- Sample ID
- Sample details e.g. Ct values for some tests
- Lot number of the reagents
- Test and subtest

To search, view, print, and export archived data, you must manually transfer the archived data from the control unit to the archive viewer.

You can import archived data that was generated on software versions 1.0, 1.1, 2.0 and 2.1.

Archived data is read-only and cannot be modified in any way.

Capacity The amount of archived data that you can import is limited only by the available disk space on the archive viewer PC.

Multiple systems You can import archived data from multiple **cobas® 4800** Systems. You can view which system the archived data was generated on.

About user roles and tasks

The archive viewer has three predefined user roles:

- Administrator
- Operator
- Super administrator

The following table shows the tasks that each user role can perform.

Tasks	Administrator	Operator	Super administrator
Import archived data	❍	❍	
Search	❍	❍	
View	❍	❍	
Export/print	❍	❍	
Get help (PDF)	❍	❍	❍
View/print the audit trail	❍	❍	❍
Confirm and/or delete messages	❍	❍	❍
Change the operator's password	❍		

Table 2   User roles and tasks

Tasks	Administrator	Operator	Super administrator
Change the administrator's password	❍		
Configure the auto log off time	❍		
Reset the passwords to the default setting			❍

Table 2   User roles and tasks

Each user role has a default password. Users log on using:

- The user role.
- Their name (exception: super administrator).
- The password assigned to the user role.

For accountability reasons, all user actions are logged.

Installation

List of installation requirements

To install the archive viewer, you need:

Requirement type	Requirement	Checklist
Software	Windows 7	☐
	If you want to display a generated PDF file (e.g. for a report), a PDF viewer is needed	☐
Hardware	PC (the archive viewer cannot be installed on cobas® 4800 control unit)	☐
	≥ 1 GB RAM	☐
	≥ 2 GB of free disk space	☐

Table 3   Installation requirements

NOTICE

Security

To prevent misuse of the archive viewer (e.g. unauthorized access, viruses), you are responsible for maintaining the PC's infrastructure. Follow these guidelines:

- Install and manage virus protection software
- Manage Windows updates
- Keep user passwords secure
- Block remote access control
- If Adobe Reader is installed, install patches and disable JavaScript

Installing the archive viewer

A setup wizard guides you through the installation process.

Considerations If Windows 7 service pack 1 or service .NET Framework 4 are not already installed, installation forces a reboot after installing the software.

> ▶ **To install the archive viewer**

1 From the installation DVD, double-click **cobas® 4800 archive viewer Setup.exe**.
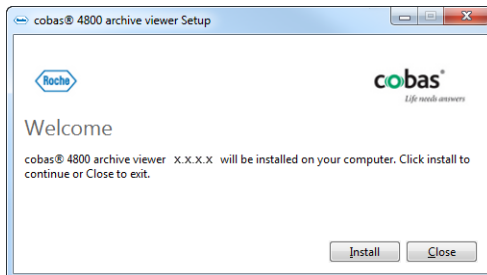
2 Choose the **Install** button.

Figure 2   Welcome screen

3 If the **User Account Control** dialog box is displayed, choose the **Yes** button.

The setup wizard is displayed:

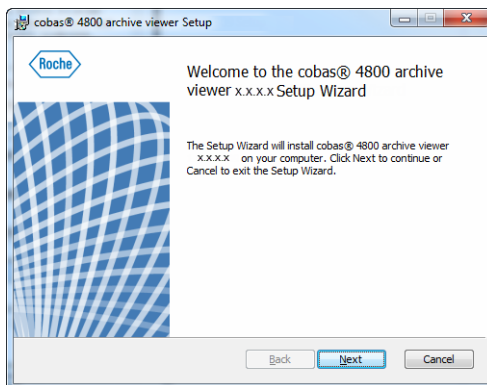**Figure 3**   Setup wizard guides you through the installation process

4 To step through the setup wizard, choose the **Next** button.
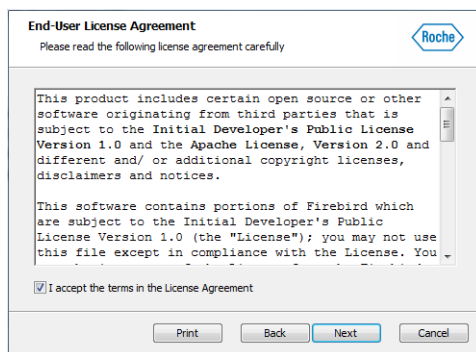
5 Read and accept the terms of the license agreement.

Figure 4   License terms and conditions

6 Define the installation path.

7 Choose the **Install** button.

8   Choose the **Finish** button and close the dialog box.

To help you quickly access the archive viewer, a shortcut is created on the desktop.

(■)

(⊞) **Related topics**

• *List of installation requirements* (p. 8)

Configuration

The administrator configures the archive viewer.

Defining the auto log off time

To ensure that information is secure when the PC is unattended, set the archive viewer to log the user off after a set period of inactivity.

▶ **To define the Auto Log off time**

🔅 By default, the user will be logged off after 2 minutes of inactivity. The archive viewer will not log off a user during an import.

1   Log on as administrator.

2   Choose the **Options** button.

3   Enter the time in minutes between 1-999 (default = 2 minutes).

4   Choose the **OK** button.

■

Related topics

• *Logging on* (p. 15)

About password management

To ensure that information is secure, you can manage user passwords. Each user role has a default password.

Password rules • The administrator can change the administrator's and operator's password.

• The super administrator can reset the administrator's and operator's password.

• To change a password, you must enter the current password.

• The administrator's and operator's password must be different.

• A password must be at least 6 characters long and include 1 number and 1 letter.

Related topics

• *Changing the password* (p. 11)

• *To reset the operator's or administrator's password* (p. 27)

Changing the password

To ensure that information is secure, you can change the operator's and administrator's password.

(▶) **To change the password**

1   Log on as administrator.

2   Choose the **Options** button.

3   Choose one of the following:

   • To change the operator's password, choose the **Change Operator Password** button
     or,

   • To change the administrator's password, choose the C**hange Administrator Password** button

4   Enter the old and new password.

5   Choose the **OK** button.

   (■)

(▸▤) **Related topics**

• *About password management* (p. 11)

Setting screen scaling settings

If the scaling settings are not set to 100%, it is possible that some information may not be readable on the screen. To ensure that all information is displayed on the screen, you can change the scaling settings.
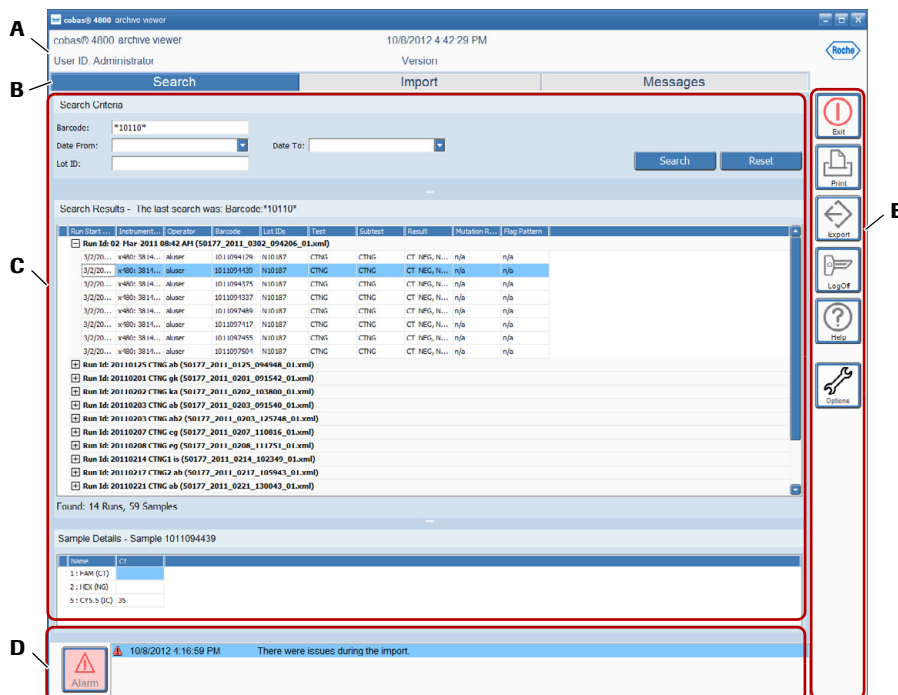
(▶) **To set screen scaling settings**

1   Go to the Display dialog box of the Control Panel.

2   Set the scaling to 100%.

   (■)

Operation

Overview of the user interface

After you log on, the **Search** tab is displayed. To make it easy to understand and use, the user interface is divided into areas.

A Status area

B Tab navigation bar

C Main work area

D Alarm area

E Global action bar

Figure 5	Overview of the user interface

Status area	Displays the version of the archive viewer, the user currently logged on, and the date/time.
Tab navigation bar	Displays the tabs. Choose a tab to open it. In the first row the tabs of the main work areas are displayed. In the second row the subtabs belonging to the currently selected work area are displayed.
Main work area	Displays the content of the currently selected tab.
Alarm area	Displays the most recent unconfirmed alarms. To get more details about the selected alarm, choose the **Alarm** button. The alarm area is only displayed if there is an alarm.
Global action bar	Contains buttons used for general software functions. These buttons are always available.

Related topics

- *List of the global action bar buttons* (p. 14)

List of the global action bar buttons

Button	Button name	Meaning
	Options	Define settings (e.g. user passwords).
	Exit	Log off and shut down the archive viewer.
	Alarm	The alarm area contains at least one error message.
	Export	Export data.
	Help	Open the Operator's Manual (PDF).
	Log off	Log off. The user is logged off but the archive viewer remains open.
	Print	Print results, messages, and user activities. To allow you to configure the print settings, a preview window is displayed.

Table 4   Global action bar buttons

Overview of the operator's workflow

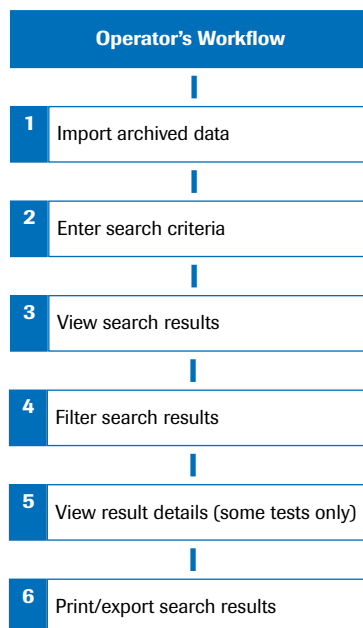| Operator's Workflow |
| :---: |
| **1** Import archived data |
| **2** Enter search criteria |
| **3** View search results |
| **4** Filter search results |
| **5** View result details (some tests only) |
| **6** Print/export search results |

Figure 6   Operator's workflow

Logging on

Log on to use the archive viewer.

💡 You cannot start two instances of the archive viewer. When starting two instances of the archive viewer, the software application crashes

▶ **To log on**

1   From the desktop of the PC, double-click (**cobas® 4800** archive viewer).

2   From the logon dialog box, do the following:

- **Account**: Choose the user role from the drop-down list.
- **Operator**: For administrator and operator, enter your name. You do not have to enter a name when logging on as the super administrator.
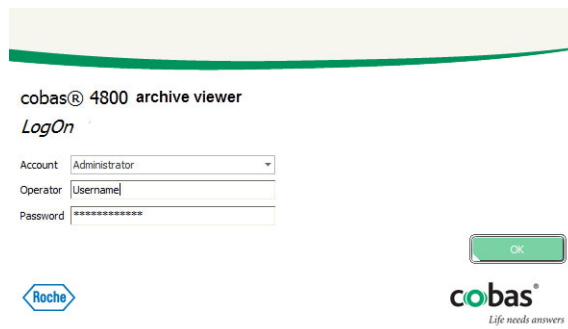- **Password**: Enter the password for the selected user role.

Figure 7   Log on

3   Choose the **OK** button.

■

Importing archived data

Import archived data to search, view, print, and export archived data.

Considerations   When importing too many files in one batch (e.g. more than 200,000 samples), the import fails. When importing, split the run data files into multiple batches.

▶ **To import archived data**

1   Use a storage device (e.g. a USB memory stick) to copy the archived data from the control unit.

2   Insert the storage device into the archive viewer PC.

3   On the **Import** tab, choose the **Add Archive Files** button.

4   Browse to the archived data and select the folder.

You can import only one archived folder at a time.
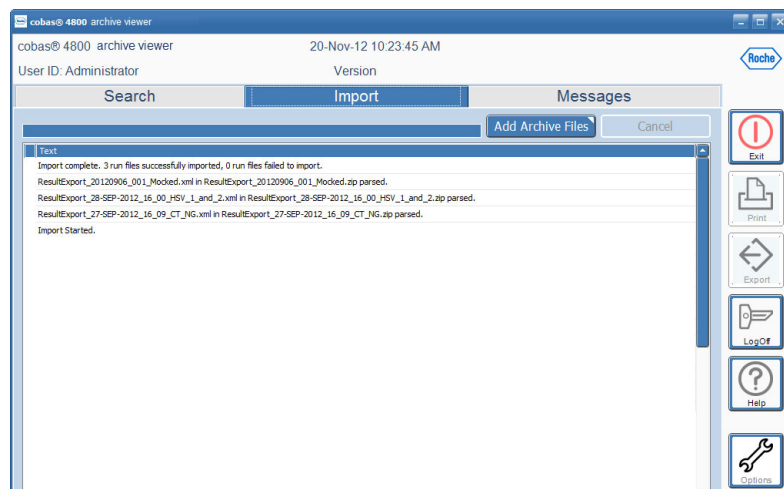
5   Choose the **Select Folder** button.

Figure 8   **Import** tab

The archived data is imported.

⬛

📖 **Related topics**

- *About archived data* (p. 6)
- *Searching archived data* (p. 18)
- *List of error messages* (p. 25)

About search results

After you search, all results matching your search criteria are displayed:

A	Displays the **Search Criteria**.
B	Displays the **Search Results**. If required, choose (+) to expand grouped search results.
C	An example of a highlighted result.
D	Displays the **Sample Details** if available for the test (e.g. Ct values).
E	Start a search.
F	Clear the search criteria.
G	Print the selected result or results.

Figure 9	Viewing search results
Run Start Date	Displays the date and time of the run including the file name (n_n.xml).
Instrument Name	Displays the unique serial number of the instrument.
Operator	Displays the name of the person who performed the test.
Barcode	Displays the ID of the sample.

Lot IDs	Displays the reagent lot number.
Mutation Result	Displays information about the test mutation result (only for some tests).
Flag Pattern	Displays flags that were generated on the **cobas® 4800** System. Each flag is identified by its unique ID (e.g. R1). For a list of flags, check the Operator's Manual.

Searching archived data

Save time by quickly searching through all the data stored in the archive viewer.

Hints • Use * to refine your search criteria. For example:

- ◦ **11A** displays results that include 11A.
- ◦ *11A** displays results that begin with 11A.
- ◦ **11A* displays results that end with 11A.

• If there are more than 9 results to display, results are grouped by run ID. To expand and collapse the group, use the plus and minus (+/-) symbols.

• To disable a specific search criteria, leave the field empty. When the search criteria is disabled, all results are displayed.

• No progress bar is displayed during searching.

• You cannot cancel a search.

▶ To search archived data

1 On the **Search** tab, define the **Search Criteria**:

- **Barcode**: To search by the Sample ID, enter an alphanumerical character.
- **Date From/Date To**: From the drop-down list, define the time frame.
- **Lot ID**: To search by reagent lot number, enter an alphanumerical character.

2 Choose the **Search** button.

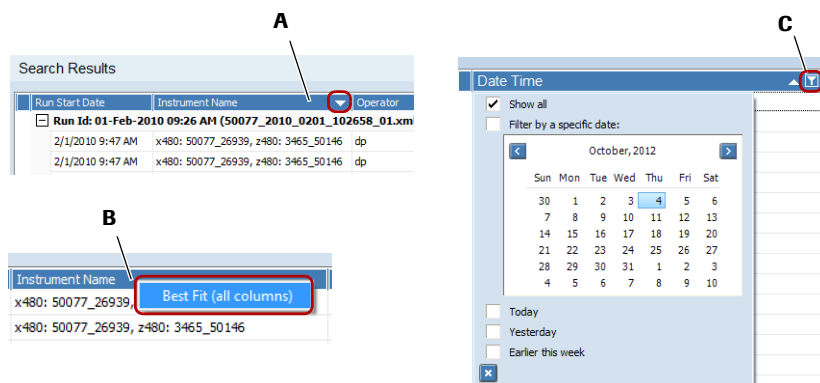All results matching your search criteria are displayed.

■

Related topics

About organizing lists

Condense lengthy lists to quickly access items of interest.

A   To sort the list in ascending or descending order, choose the column header. The sort order is indicated by an arrow. Search results can only be filtered using this option.

B   To fit all columns across the screen, right-click the column header and choose **Best Fit (all columns)**.

C   To display a list with appropriate filter options for this column, choose the filter symbol.

Figure 10   Organizing lists

Viewing test-specific sample details

For some tests, you can view details of the sample (e.g. the Ct value).

▶ **To view test-specific sample details**

1   On the **Search** tab, perform a search.

2   From the **Search Results** list, choose a search result.

If sample details are available for the test, they are displayed at the bottom of the screen:
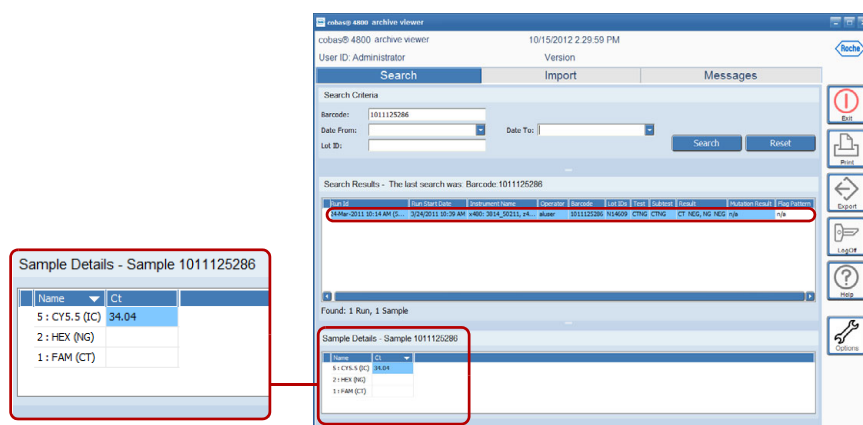

Figure 11   Viewing test-specific sample details

Ct   Displays the Ct value. The amplification/detection cycle where the growth curve crosses a specific fluorescence level and the growth rate can be observed.

■

🗐 **Related topics**

- *Searching archived data* (p. 18)

About printing and exporting results

To save time when printing or exporting results, follow these hints:

Hints
- If no specific results are selected, all results are printed out or exported.
- If one or more results are selected, the selected results are printed out or exported.
- If one or more grouped results are selected, all the results of the selected groups are printed out or exported.
- To choose several nonadjacent results, use the Ctrl key.
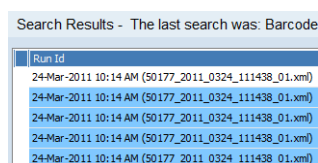- To choose a range of adjacent results, use the Shift key.

Figure 12   Choosing a range of adjacent results for printing or exporting

Related topics

- *Searching archived data* (p. 18)
- *Printing out results* (p. 20)
- *Exporting results* (p. 22)

Printing out results

To share results, you can print out the results or generate an electronic copy.

You can also print error messages and a list of user activities.

Print preconditions
- To print results, PDF software must be installed on the archive viewer PC.
- To print results on paper, a printer must be connected and configured to the archive viewer PC.

Considerations

Issue	Details	Considerations/actions
Wrong sample type in KRAS report for controls and calibrators.	In the KRAS report, Mutant Controls and Calibrators are displayed as samples instead of calibrators and controls.	Use fix plate layout positions to identify controls and calibrators.
Wrong amplification position text on KRAS report.	In the KRAS report, the amplification position text contains the wrong order (e.g. A02-A01 instead of A01-A02).	For information only. Results are correctly listed.
Wrong sample type in PIK3CA report for controls.	In the PIK3CA report, Mutant Controls are shown as samples instead of calibrators and controls.	Use fix plate layout positions to identify controls.

Table 5   Report considerations

Issue	Details	Considerations/actions
Wrong amplification position text on PIK3CA report.	In the PIK3CA report, the amplification position text contains the wrong order (e.g. D01-D03-D02 instead of D01-D02-D03).	For information only. Results are correctly listed.
Wrong sample type in BRAF report for controls.	In the BRAF report, Mutant Controls and Wildtype Controls show as samples instead of calibrators and controls.	Use fix plate layout positions to identify controls.
Wrong amplification position text on EGFR report.	In the EGFR report, the amplification position text contains the wrong order (e.g. D01-D03-D02 instead of D01-D02-D03).	For information only. Results are correctly listed.
Wrong sample type in EGFR report for controls.	In the EGFR report, Mutant Controls show as samples instead of calibrators and controls.	Use fix plate layout positions to identify controls

Table 5   Report considerations

▶ **To print results**

1 On the **Search** tab, choose one or more search results.

2 Choose the **Print** button.

The report is displayed in PDF:

Figure 13   Report displayed in PDF

Barcode	Displays the ID of the sample.
Sample Type	Displays the type of sample: Sample (S) Positive control (PC) Negative control (NC)
Operator	Displays the name of the user who generated the report.
Mutation Result	Displays information about the test mutation result (only for some tests).
Flag Pattern	Displays flags that were generated on the **cobas® 4800** System. Each flag is identified by its unique ID (e.g. R1). For a list of flags, check the Operator's Manual.

Table 6   Viewing a report.

3 Save and/or print the PDF using the functionality of the PDF software.

▪

Related topics

- *Searching archived data* (p. 18)
- *Exporting results* (p. 22)
- *About printing and exporting results* (p. 20)

Exporting results

To create custom reports, graphs and charts, export results to the default spreadsheet software installed on the PC.

▶ **To export results**

1 On the **Search** tab, choose one or more search results.

2 Choose the **Export** button.

The results are exported as a comma separated value file (*.csv) to the default spreadsheet software (e.g. Microsoft Excel):

Figure 14 Sample of exported results

▪

Related topics

- *Searching archived data* (p. 18)
- *Printing out results* (p. 20)
- *About printing and exporting results* (p. 20)

Logging off

Log off to change the user or to ensure that information is secure when the PC is unattended. The archive viewer remains open.

▶ **To log off**

1 From the global action bar, choose the **LogOff** button.

▪

Exiting the archive viewer

Log off and shut down the archive viewer.

▶ To exit the archive viewer

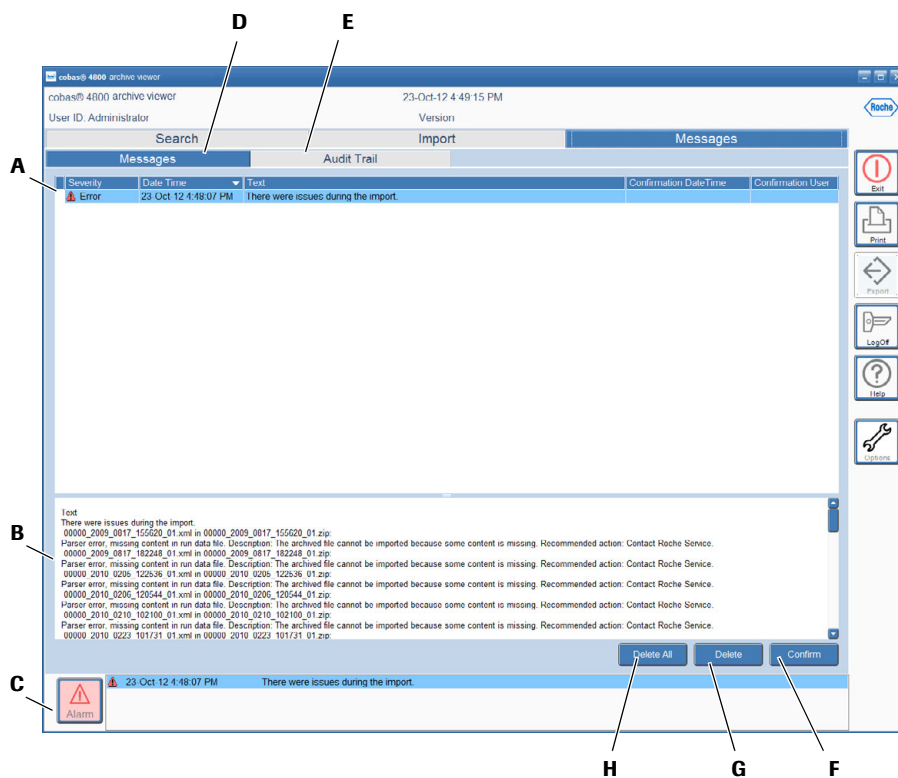1   From the global action bar, choose the **Exit** button.

■

Troubleshooting

About messages

Under the **Messages** tab, there are two tabs.

Tab	Description
Messages	Contains error messages.
Audit Trail	Contains a time-stamped record of user activities.

Table 7　　　　　Tabs in **Messages** work area

A　Displays all unconfirmed messages.

B　Displays a description of the error and recommended action for the selected message.

C　Displays alarms.

D　**Messages** tab.

E　**Audit Trail** tab.

F　Confirm a selected message.

G　Delete the selected message.

H　Delete all messages.

Figure 15　　　　　Messages tab

Severity	Contains an icon and text to indicate an error message.

Table 8　　　　　Viewing **Messages**.

Messages are kept until they are deleted manually. To free up space, periodically delete confirmed messages.

List of error messages

If one or more errors occur when importing archived data, the error message **There were issues during the import** is displayed. In the **Messages** tab, you can view a description of the error and a recommended action. This table gives you an overview of all error messages:

| Description	Explanation	Recommended action
Unable to find archive file on directory	You have selected a folder which does not contain any archived file.	Select a folder that contains a valid archived file.
Archive file is empty	The contents of the archived file are empty and cannot be imported.	Contact Roche Service.
Archive file is corrupt	The archived file is corrupt and cannot be imported.	Import the archived file again from the original source. If this does not solve the problem, contact Roche Service.
No hash file found	The archived file does not contain any valid hash file and cannot be imported.	Contact Roche Service.
No XML file found	The archived file does not contain any valid XML file and cannot be imported.	Contact Roche Service.
Parser error, missing content in run data file	The archived file cannot be imported because some content is missing.	Contact Roche Service.

Table 9   Error messages

⊞ **Related topics**

- *About messages* (p. 24)

Viewing the audit trail

The audit trail provides a secure, computer-generated, time-stamped record of user activities.

▶ **To view the audit trail**

1 Choose **Messages > Audit Trail.**

2 If necessary, choose the column header to organize the list (e.g. by **User**).
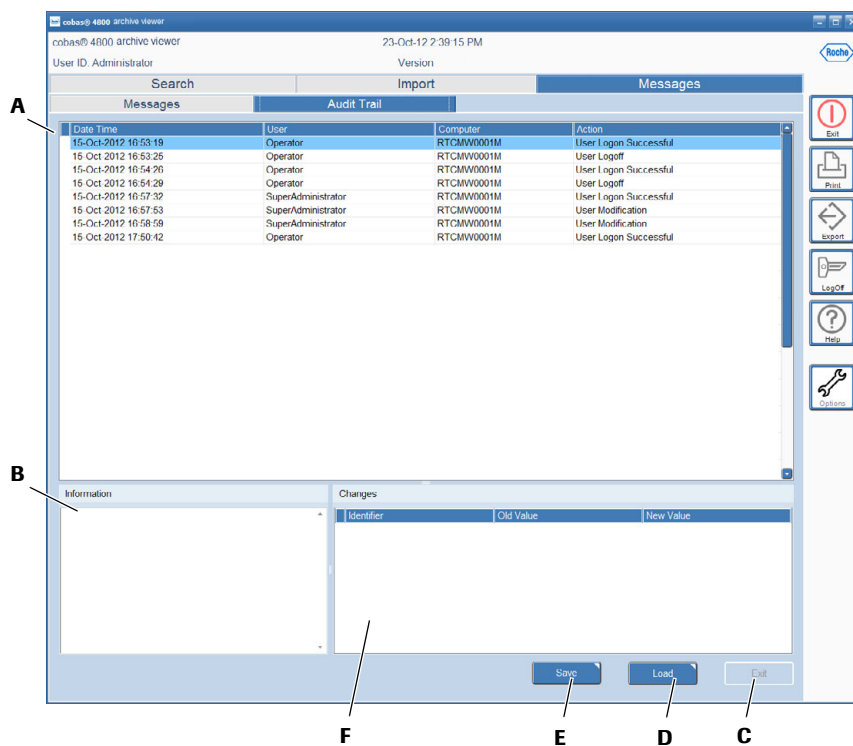
A Displays all user activities.

B Displays more information.

C Return to the current audit trail (after you loaded a saved audit trail)

D Open a saved audit trail.

E Save the entire audit trail.

F Displays changes.

Figure 16	Viewing the **audit trail**.
Computer	Displays the name of the archive viewer PC. This is defined by the operating system.
Action	Displays a list of actions performed by the user. For example **Delete** if they deleted an alarm, or **User Modification** if they changed a password, or **Export** if they exported results.

So long as disk space is available on the archive viewer PC, user activities are recorded.

■

Related topics

- *Printing out results* (p. 20)
- *About organizing lists* (p. 18)

Resetting the password

If a password is forgotten, the super administrator can reset the administrator's and operator's passwords.

▶ **To reset the operator's or administrator's password**

1   Log on as super administrator.

2   Choose the **Options** button.

3   Choose one of the following options:

   • To reset the operators's password, choose the **Reset Operator Password** button
     or,

   • To reset the administrator's password, choose the **Reset Administrator Password** button

4   Choose the **Yes** button and then the **OK** button.

5   Close the **SuperAdministrator Settings** dialog box.

   ▪

📖 **Related topics**

• *About password management* (p. 11)