

cobas[®] 4800 system

Operator's Manual (for the US) Software Version 2.0 for **cobas**[®] 4800 BRAF V600 Mutation Test

Document information

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	Every effort has be manual is correct a the right to make a development.	en made to ensure th at the time of printing any changes necessary	at all the information g. However, Roche Dia v without notice as par	contained in this agnostics Ltd. reserves rt of ongoing product
	Any customer mod agreement null and	dification to the equip d void.	oment will render the	warranty or service
	Software updates a	are done by Roche Sei	rvice representatives.	
Intended use	The cobas [®] 4800 sy used as an in-vitro targets from huma which this test is in	vstem including dedic diagnostic device pro n samples for selectin ndicated.	cated software for IVE widing amplification a g patients for treatme	O use is intended to be and detection of specific nt with therapeutics for
	It is important that	t the operator read th	is manual thoroughly	before using the system.
	The cobas [°] 4800 sy techniques and by	vstem is to be used by instruction on the us	laboratory profession: e of the system.	als trained in laboratory
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Preface

This manual covers all topics related to the **cobas**[°] 4800 software and describes the test-specific workflow for the **cobas**[°] 4800 BRAF V600 Mutation Test. The **cobas z** 480 analyzer which is also part of the **cobas**[°] 4800 system is described in the Instrument Manual for the **cobas z** 480 analyzer.

How to use this manual

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- Keep this manual in a safe place to ensure that it is not damaged and remains available for use.
- This manual and all other relevant manuals should be easily accessible at all times.

To help you find information quickly, there is a table of contents at the beginning of the manual and each chapter. In addition, a complete index can be found at the end of the manual.

Where to find information

In addition to the Operator's Manual, the following documents are also provided to assist in finding desired information quickly: Instrument Manual for the The Instrument Manual for the cobas z 480 analyzer provides information about the cobas z 480 analyzer hardware, maintenance and specifications of the **cobas z** 480 analyzer, as well as intended use and safety information. The test-specific package insert provides information on preparation and handling of Test-specific package insert the reagent and DNA isolation kit as well as on manual PCR setup of the microwell plate. For each test, there is a specific Operator's Manual similar to this one. This Other test-specific Operator's Manuals Operator's Manual is only for use of cobas 4800 software version 2.0 in conjunction with the cobas 4800 BRAF V600 Mutation Test.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

Symbols	The following symbols are used:
<i>Symbols</i>	The following symbols are used.

Symbol	Used for
•	Start of procedure
	End of procedure
•	List item
۲	Cross-reference
<u>-ð</u> -	Tip
	Safety alert
X	Electrical and electronic equipment marked with this symbol are covered by the European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).
	The symbol denotes that the equipment must not be disposed of in the municipal waste system.

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BRAF V600 Mutation Test

Abbreviations

ns The following abbreviations are used:

Abbreviation	Definition
A	
ANSI	American National Standards Institute
С	
сс	cubic centimeter
CSA	Canadian Standards Association
D	
DIL	Diluent
DNA	Deoxyribonucleic Acid
E	
EC	European community
EN	European standard
I	
IVD	In Vitro Diagnostic
L	
LED	Light Emitting Diode
LIS	Laboratory Information System
м	
MWP	Microwell Plate
N	
n/a	not applicable
Р	
PCR	Polymerase Chain Reaction
R	
RNA	Ribonucleic Acid
Q	
QC	Quality Control
S	
SD	Standard Deviation
U	
UL	Underwriters Laboratories Inc.
UPS	Uninterruptible Power Supply
w	
WEEE	Waste Electrical and Electronic Equipment

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A

System description

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General safety information

In this chapter, you will find information on the safe operation of the **cobas** 4800 system.

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Safety classifications

This section explains how precautionary information is presented in this manual.

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

The safety alert symbol by itself without a signal word is used to promote awareness to hazards which are generic or to direct the reader to safety information provided elsewhere in the document.

These symbols and signal words are used for specific hazards:



NOTICE

CAUTION

injury.

WARNING

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

Indicates a hazardous situation which, if not avoided, could result in death or serious

NOTICE

Indicates a hazardous situation which, if not avoided, could result in damage to equipment.

For more information about product safety labels, refer to the Instrument Manual for the cobas z 480 analyzer.

Important information which is not safety relevant is indicated by the following symbol:



Tip

Indicates additional information on correct use of the system or useful tips.

Safety precautions



Particular attention must be paid to the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury. Each precaution is important.

Operator qualification

Operators are required to have a sound knowledge of relevant guidelines and standards as well as the information and procedures contained in all relevant manuals.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Carefully follow the procedures specified in all relevant manuals for operation and maintenance.
- Leave maintenance, installation, or service that is not described in the manuals to trained Roche Service personnel.
- Follow standard laboratory practices, especially when working with biohazardous material.

Safe and proper use of the system

Personal protective equipment	• Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
	• Wear a face shield if there is a chance of splash or splatter.
Accuracy/precision of measured results	• Do not use reagents that have exceeded their expiration date, otherwise inaccurate data may be obtained.
	• For diagnostic purposes always assess the results in conjunction with the patient's medical history, clinical examination, and other findings.
	• Each laboratory must verify that reagent performance meets the published specifications.
Installation	• Installation must be performed by trained Roche Service personnel only.
Third-party software	Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior of the cobas 4800 system or the cobas 4800 software. Do not install any non-approved software.

Miscellaneous safety precautions

Power interruption	A power failure or momentary drop in voltage may lead to data loss. Operation with an uninterruptible power supply (UPS) is strongly recommended. Check the UPS regularly to make sure it functions properly.
Data backup	There is an automatic backup process that stores the data on the D drive. It is the customers responsibility to perform regular backups of all measurement results.

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Safety summary

Safety summary

This safety summary contains the most important and general warning and caution messages. Additionally, you will find specific safety information at the beginning of Part *Operation* and Part *Maintenance*, as well as in the Instrument Manual for the **cobas z** 480 analyzer.

 For more information about the safe use of the cobas 4800 system, refer to the Instrument Manual for the cobas z 480 analyzer and to the test-specific package insert.

Warning messages

Biohazardous materials



Infection by samples and associated materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous. Therefore, universal precautions should be taken when handling and processing samples.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
- Wear a face shield if there is a chance of splash or splatter.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or waste solution comes into contact with your skin, wash it off immediately with soap and water, and apply a disinfectant. Consult a physician.

Waste



Infection by biohazardous waste

Contact with waste solution or used pipetting tips may result in infection. All materials and mechanical components that come into contact with waste are potentially biohazardous. Therefore, universal precautions should be taken when handling waste.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with soap and water, and apply a disinfectant. Consult a physician immediately.

Contamination of the environment by liquid waste and solid waste

The waste generated during the procedure is potentially biohazardous.

 When disposing of any liquid or solid waste, do so according to the appropriate local regulations. Safety summary

Explosion and fire risk



Explosion through sparks

Hazard of explosion through sparks.

• Keep all potentially flammable or explosive material (e.g. anesthetic gas) away from the analyzer.

Fire risk through usage of sprays

Spraying liquid on the power supply parts can cause a short circuit and result in a fire.

During fire-fighting operations disconnect the equipment from the main power supply.

Caution messages



List of caution messages

Before operating the system, read the caution messages contained in this summary and in all relevant manuals carefully. Failure to observe them may result in minor or moderate injury.

Reagents



Skin inflammation or injury caused by reagents

Direct contact with reagents, detergents, or cleaning solutions may cause skin irritation, inflammation, or burns.

- When handling reagents, exercise the precautions required for handling laboratory reagents. Be sure to wear protective equipment (such as goggles, gloves).
- Observe the cautions given in the package insert and observe the information given in the Material Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.
- If a reagent or detergent comes into contact with your skin, wash it off immediately with soap and water, and apply a disinfectant. Consult a physician immediately.

Invalid results due to incorrect reagent volume

Incorrect reagent handling may cause an undetectable loss of reagent.

- Store reagents always according to specified storage conditions.
- Do not leave opened sample containers on the system for any considerable length of time to avoid evaporation.
- Partially used reagents should not be used on other cobas 4800 systems.

Invalid results due to expired reagents and consumables

Data obtained using expired reagents and consumables are not reliable. Reagents are supplied in a kit package with a label that indicates the expiration date. The expiration date of microwell plate and sealing film is printed on their package label.

 Do not use reagents and consumables that have exceeded their expiration dates. Replace expired reagents and consumables with unexpired reagents and consumables before sample processing.

Safety summary

Choosing the wrong test kit

• Make sure to choose the correct test kit for the required test. Choosing a wrong test kit will not let you proceed with the test.

Interfering substances in samples



Invalid results due to interfering substances

Interfering substances in samples, for example clots or foam, may cause clogging and lead to incorrect results.

Incorrect results due to two barcode labels or mixing up specimen barcodes



Incorrect results due to two barcodes on the same tube or mixing up specimen barcodes

- · Take adequate measures to avoid mixing up specimen barcodes.
- Make sure that there is only one barcode on each specimen tube.

Incorrect results due to wrongly typed sample IDs



Incorrect results due to wrongly typed sample IDs

If the sample IDs are entered manually, there is the risk of making spelling mistakes or entering wrong sample IDs.

- After printing the microwell plate layout, compare the sample IDs on the sample tubes with the sample IDs on the microwell plate layout.
- If you notice a mistake, correct the mistake in the sample ID column. Then save the work order file and use the new printout for setting up the microwell plate.

Cross contamination



Incorrect results due to carryover

Traces of analytes or reagents may be carried over from one test to the next.

- Take adequate measures to prevent cross contamination and to avoid potentially false results.
- When any indication of potential sources of contamination is seen (e.g. punctured sealing film, spilled reagents or samples, etc.), or if manual sample preparation was not performed according to good laboratory practice, proper decontamination services must be performed.

Safety summary

Data security



Unauthorized access and data loss due to malicious software and hacker attacks

Portable storage media can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The cobas 4800 system is not protected against malicious software and hacker attacks.

The customers are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the **cobas** 4800 system unusable.

Roche recommends the following precautions:

- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment. cobas IT firewall must be used when the **cobas** 4800 system is integrated into a network.
- Do not copy or install any software on the **cobas** 4800 software control unit unless it is part of the system software or you are instructed to do so by a Roche Service representative.
- If additional software is required, contact your Roche Service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche Service representative.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers while connecting to the **cobas** 4800 system.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.
- Do not enter any confidential patient-relevant information into the work order file. There is the risk of unauthorized access to patient data.

Disposal

Disposal



Disposal of control unit components

Components of your control unit (such as the computer, monitor, keyboard) which are marked with this symbol are covered by the European Directive on *Waste Electrical and Electronic Equipment* (WEEE, 2002/96/EC).

These items must be disposed of via designated collection facilities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your Roche representative.

Constraint: It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat them in the same way as the analyzer. For more information, refer to the analyzer's instrument manual.

For information about disposal of the analyzer, refer to the Instrument Manual for the cobas z 480 analyzer.

1 General safety information

Disposal

cobas[®] 4800 system

Overview

Table of contents

In this chapter, you will get a basic overview of the **cobas** 4800 system.

In this chapter	Chapter	2
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System overview

The **cobas**[•] 4800 system provides a platform to perform qualitative in vitro nucleic acid amplification tests from human specimens.

The **cobas**[•] 4800 system combines the following components:



Figure A-1 cobas 4800 software version 2.0 system overview

2 Overview

System overview

Software

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In this chapter the software basics and database are explained.

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Basic software elements

Basic software elements

The screen of the **cobas** 4800 software is divided into the following dedicated areas making the software easy to understand and intuitive to use:

- Status area
- Tab navigation bar
- Main work area
- Global action bar
- Alarm area



The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid data.



- A The *status area* displays the currently logged **D** in user as well as and date and time.
- B The *tab navigation bar* displays the tabs.
 Choose a tab to open it. In the first row of the navigation bar, the tabs of the main work areas are displayed. In the second row, the subtabs belonging to the currently selected work area are displayed.
- **C** This is the main work area. It displays the content of the currently selected tab.

The *global action bar* contains buttons used for general software functions. These buttons are always available.

The alarm area displays the most recent alarms that are not yet confirmed by the operator. Select an alarm in the list and click the Alarm button on the left to get more details about the selected alarm.

Figure A-2

Software screen

3 Software

Colors

Color	Meaning			
Green	Normal condition. The status is OK.			
Yellow	Warning condition. Status is not OK, but immediate intervention is not required.			
Red	Alarm condition. Immediate intervention is required. Operation may have stopped.			
Blue	The item is selected or active.			
Table A-1	Color concept			

The cobas 4800 software uses the familiar traffic light color scheme.

Tabs

Tabs are used to group information and software functions into units that can be displayed on one screen. The second row of tabs represent subgroups of the tab selected in the first row. The tab in the third row is a subtab of the **Instruments** tab in the second row and becomes visible once the **Instruments** tab is selected.

Navigating within the software needs only one or two clicks.

- 1. Choose a main tab in the first tab row. Here you have access to the five main work areas **Overview**, **Workplace**, **Results**, **Messages**, and **Utilities**.
- 2. Choose a subtab in the second row. Here you have access to all tabs of the selected work area.



The Workplace tab is displayed only if a run is active.



- A Main tabs. Overview is selected. The first row of tabs give access to the main work areas.
- **B** Subtabs. **Instruments** is selected. The second row of tabs show all tabs of the selected work area.

C Subtab belonging to Instruments tab. It is only visible if the Instruments tab is selected.

Figure A-3 Main tabs and subtabs

Buttons

Text buttons Choose a button to start the associated function. Some text buttons have a triangular marking in a corner. This triangle tells you what exactly happens on screen if you choose the button.

Button	Behavior		
Cancel	Performs a specified action in the current window		
	A triangle in the top right corner of a button tells you that a new dialog box will be displayed when you choose the button.		
	A triangle in the bottom left corner of a button tells you that the current window or dialog box will be closed when you choose the button.		

Table A-2	Triangular markings	s in text but	tons
	mangalar manange	o in toxt but	10110

Global action buttons

On the right side of the screen, the global action buttons are available. They are always visible and perform the following functions:

Button	Name	Use for		
	New Run	Starting a new run		
New Run		A wizard will guide you through the whole run.		
	Abort	Aborting a run		
Abort		The Abort Run dialog box is displayed when several runs are active. Select the run you want to abort.		
Exit	Exit	Exiting the cobas 4800 software.		
	Editor	Opening the sample editor		
Editor		Opens the window for creating a new work order file for microwell plate preparation.		
Export	Export	Exporting results		
	Print	Printing results, messages, and alarms		
Print		A preview window is displayed allowing to configure printing options.		
	Log on, Log off	Logging on and off.		
LogOff		The button label will change depending on whether the user is logged in or logged off.		
(j) Info	Info	Accessing the manuals and displaying the installed software versions		
Table A-3	Global action	buttons		

Basic software elements

The software provides powerful sorting and filtering tools for information displayed in tables. These allow a lengthy list to be condensed in ways that provide fast access to items of interest. It is also possible to hide certain columns, display additional columns, and change their left-to-right order.

This section just gives a general overview. Some functions are not available in some of the work areas, or less options are available, e.g. in a context menu.

Organizing lists

The sorting and filtering tools are accessed by right- or left-clicking the respective column headings.



- A Click the column header to sort the table in ascending or descending order. The sort order is indicated by an arrow.
- **B** Right-click the column header to display context menu for sorting and grouping information items.
- **C** Click the filter symbol (funnel icon) to display a list with appropriate filter options for this column.



Displaying the filter options

Sort by column

Click a column header to sort the table by the entries of this column. Successive clicks switch between ascending and descending sort order, the order is indicated by the arrow that appears in the header.



Not every column is sortable. If a column is sortable, an arrow indicating the sorting direction will appear in the column header after clicking the column header.

Basic software elements

Column header context menu

Right-click any column header to display a context menu with further sorting and grouping options.



Displaying and hiding columns

Right-click any column header and select Column Chooser.



Figure A-6 Column Chooser dialog box

The **Column Chooser** dialog box contains all available information items that are not included in the table. Which items are available depends on the table from which you started the **Column Chooser**.

To add a column (information item) to the table, select the item in the **Column Chooser** and drag it to the appropriate place in the table header.

To remove a column from the table, select its header and drag it into the **Column Chooser**.

Filter drop-down menu

A filter symbol (funnel icon) is displayed in the column header of all columns that can be filtered. Right-click the filter symbol and a drop-down menu appears.



- A Click the filter symbol (funnel icon) to display the filter context menu.
- B Select Custom to display the Custom AutoFilter dialog box for refining the filter criterion.
- **C** Select the item that should serve as a filter criterion.

Figure A-7	Filter context menu
------------	---------------------

When a filter criterion is applied, its details are displayed in a bar at the bottom of the list (A).

Severity 🔻	Date Time	T
A Warning	12.04.2010	11:40:
📕 🚹 Warning	12.04.2010	19:16:
Error	12.04.2010	11:54:
Error	12.04.2010	14:17:
🚺 📥 Error	12.04.2010	11:54:
📕 🔔 Error	12.04.2010	14:17:
🕂 🗹 (Date Time		



To return to the full view at any time (no filtering), click the close button in the filter details bar. Previously used filter settings remain accessible from the filter history.

• For more information, see *Managing filters and advanced filtering* on page A-25.

Custom AutoFilter

The **Custom AutoFilter** option is available only in those columns that have a filter symbol (funnel icon) in their column header.

With the help of the **Custom AutoFilter** you can apply one or two filter conditions, logically linked by AND or OR.

Click the filter icon in a column heading and select (**Custom**) to display the **Custom AutoFilter** dialog box.



Managing filters and advanced filtering

When a filter criterion is applied, its details are displayed in a bar at the bottom of the list. This bar allows convenient selection of previously selected filter conditions (filter history) as well as disabling and enabling the criteria respectively.



For information about filtering in the **Results** work area, see *Creating result filters* on page B-29.

Tool tips

Tool tips provide brief functional descriptions when the mouse is paused over a tool or application button. They mainly occur in the sample editor and give information to the user when there is a mistake in editing.

◆ For a list of tool tips in the sample editor, see *List of messages and tool tips within the sample editor* on page D-12.

Test Information	
Creation 27.01.2011 15:53:50 Microwell Plate ID	A
Barcode is mandatory.	— B
Box where an error occurred	B Tool tip informing about the nature of the error



_							
A	A Box where an error occurred			B Tool tip informing about the nature error			
	DNA Isolation Kit #4				0		
	DNA Isolation Kit #3				0		
	DNA Isolation Kit #2	The reagent is expired.			8	В	
	DNA Isolation Kit #1	ad1]1234568a1234-	SA10 220	16102345	6	— A	
	DNA Isolation Kit-ID		Reagent K	it-ID	Specimens		


Wizard

Performing a **cobas** 4800 system run requires the coordination of operator, instrument, and software interactions. A wizard guides the operator through all processing steps and helps keep track of all necessary operator actions. The wizard is started by clicking the **New Run** button and ends with the display of the final PCR results. The run wizard is accessible through the **Workplace** tab.

A run goes through a series of steps. The next step can only be accessed if the current step has been successfully finished. Any step that has been finished is displayed as a green box. The step that is currently in progress is displayed as a blue box. Any steps that have not been started are displayed as grey boxes.

A PCR Only run includes the following steps:



NOTICE

It is not possible to go back to a previous step in a run. Follow the guidelines outlined in this manual to avoid losing reagents, samples, or disposables.



Figure A-14 Working with the wizard

Database

Database

All data of the **cobas** 4800 system are stored in an Oracle database. The database has a storage capacity of 100 000 results. The purge and archive function is used to archive results and purge them from the database to free up space in the database for new results. Purge and archive should be done much earlier before the database limit is reached.

• For information about the purge and archive function, see *Archiving* on page B-39.

NOTICE

No run can be started when the database has reached the maximal size. Use the purge and archive function to clean up the database.



The purge and archive function only covers run data and results. Messages are kept in the **cobas** 4800 software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.

The actual size of the database is displayed in the Instrument Overview tab.

Overview	Results	Messages	Utilities
Instrument Overview	Instruments		
	Cobas Z 480	d 44 9 CB free d 122 9 CB free 38 CB of 00 0 CB free 38 CB of 00 0 CB free	

A Database size

Figure A-15 Database size in Instrument Overview tab

Audit trail

The software provides a secure, computer-generated, time-stamped audit trail to record user activities that include the following:

- Operator log on and log off
- Result acceptance, purging, and archiving
- Configuration changes, including changes in user accounts

The audit trail of the **cobas** 4800 software is designed based on guidelines in FDA Title 21 CFR, Part 11, Electronic Records: Electronic Signatures.

To access the audit trail, choose Messages > Audit Trail.

	Results		Messages	Utilities
Alarms	Message	es 📗	Audit Trail	
and the second se	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
03-Aug-2010 10 30 59	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:30:59	TROM/VCOE5440	UserAccess	admin	User Logon Failed
03-Aug-2010 10:31:00	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:31:00	TROM/VCOE5440	UserAccess	admin	User Logon Failed
03-Aug-2010 10:31:09	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:31:09	TROM/VCOE5440	UserAccess	admin	User Logon Failed
03-Aug-2010 10:31:19	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:31:19 Admin	TROM/VCOE5440	UserAccess	Admin	User Logon Successful
03-Aug-2010 10:32:35 Admin	TROM/VCOE5440	Application	cobas 4800	Application Closed
03-Aug-2010 10:39:45	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:39:45	TROM/VCOE5440	UserAccess	admin	User Logon Failed
03-Aug-2010 10:39:49	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:39:49	TROM/VCOE5440	UserAccess	admin	User Logon Failed
03-Aug-2010 10:39:53	TROM/VCOE5440	UserAccess	Admin	User Modification
03-Aug-2010 10:39:53 Admin	TROM/VCOE5440	UserAccess	Admin	User Logon Successful
B—				
3-				Archive Refeat
B-List of user activities		C	Changes area	Archwe Reflesh

Figure A-16 Audit trail

3 Software

Database

BRAF V600 Mutation Test

Hardware

Table of contents

In this chapter, you will find information on the control unit and the handheld barcode scanner.

In this chapter	Chapter 4
Hardware	
Control unit	
Handheld barcode scanner	
Technical specifications	

Hardware

	T sı a	his chapter include canner. Apart from nalyzer which is de	es information about the control unit and handheld barcode these two components, the system also includes the cobas z 480 scribed in the Instrument Manual for the cobas z 480 analyzer.
NOTICE	N to s	lote that the type and o change without no pecification provided	d specification of the control unit and the barcode scanner is subject tice. The specifications listed below apply to the type and d at the time of publishing of this manual.
Control unit			
	A	dedicated control	unit runs the cobas 4800 software.
	•	Use only manufac system, and the o	cturer's original installation CD-ROM or DVD sets for the operating riginal cobas 4800 software.
CAUTION	•	Any manipulation affecting cobas 4 failure.	of cobas 4800 system data files or other information determining or 800 system functions can result in erroneous results or equipment
	•	Only use the cont	rol unit that is supplied with the cobas 4800 system.
	Software C	perating system	Windows XP Professional SP3
	Г	atabase	Oracle Database Enterprise Edition

Handheld barcode scanner

	A handheld barcode scanner is connected to the control unit. It is used to scan reagent and specimen barcodes during creation of the work order file for microwell plate preparation.
Supported barcode types	The following barcode types are supported:
	• Codabar
	• Code 39
	• Code 128, subset B and C
	Data matrix (Roche-manufactured reagents only)
Usage	The barcode label is read by holding the head of the barcode scanner in close proximity to the barcode label and then pressing the button on the barcode scanner. The barcode ID is then automatically read and displayed on the screen.
NOTICE	Be sure to hold the head of the handheld barcode scanner over the correct barcode label. It is recommended to visually verify the displayed scanned characters with the human readable characters on the barcode label.



Figure A-17 Handheld barcode scanner

Technical specifications

Туре	IT4600
Interface	The handheld barcode scanner is connected to the control unit through the USB interface.
Skew angle	±40 degrees
Pitch angle	±40 degrees
Motion tolerance	10 cm (4 in) per second
Scan contrast	45% minimum for Matrix codes
	37.5% minimum for all others
Temperature	Operating: 0-50°C (32-122°F)
	Storage: -40 to +70°C (-40 to +158°F)
Humidity	0-95% non-condensing

This is the last page of Part A.

Operation B

5	Workflow short guide	<i>B</i> –3
6	Operation	B-9
7	Configuration	<i>B</i> – <i>33</i>

Table of contents

Workflow short guide

This chapter provides a short instruction on the workflow.

In this chapter	Chapter	5
PCR Only run		B-5
PCR Only run short guide		B–6

PCR Only run

The workflow for a PCR Only run is shown below.

For the PCR Only workflow, the test reagents and prepared patient specimens are manually pipetted into the microwell plate (AD plate 0.3 ml).

• For information on handling and preparing reagents and specimens, and how to pipette them into the microwell plate, refer to the test-specific package insert.



Figure B-1 Workflow for a PCR Only run



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

PCR Only run

PCR Only run short guide

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

• For a complete and detailed description of the workflow, see Chapter 6 *Operation*.

Ste	p		Us	ser action
1	Manually prepare the reagents and specimens.		1. 2.	Remove the reagents and specimens from storage. Manually prepare the reagents and specimens according to the test-specific package insert.
2	Start a new run.	Outcome Reading Names Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent Intervent	1. 2. • 3.	Choose New Run . Do one of the following: Select a test from the list. Choose Load Workorder File . Load the required work order file and proceed to step 3, action 8 (paragraph below). Choose OK .
3	Create a work order file for microwell plate setup.		 1. 2. 3. 4. 5. 6. 7. 8. 	Scan the microwell plate barcode into the Microwell Plate ID box. Scan the DNA sample preparation kit barcode into the first DNA Isolation Kit-ID box. Scan the barcode of the BRAF V600 Mutation Test kit into the first Reagent Kit-ID box. Type the number of specimens into the first Specimens box. If you use more than one test kit, enter a maximum number of 22 specimens into the first Specimens box. The other boxes may contain up to 24 specimens each. Scan the sample ID barcodes into the Sample ID column in the lower part of the screen. If you use more than one test kit, repeat steps 2 to 5 for each test kit in the order described above. Choose Save . Save the file with the default file name assigned by the software. Choose [b] to print the work order file for microwell plate setup.
4	Set up the microwell plate.		1. 2. 3. 4.	Pipette the reagents and prepared specimens into the microwell plate in accordance with the printout of the work order file and the description in the test-specific package insert. Seal the microwell plate. If necessary, log back into the software. In the software, choose Next .



cobas[®] 4800 system

BRAF V600 Mutation Test

5 Workflow short guide

PCR Only run

Ste	p		Us	er action
5	Load the microwell plate into the analyzer.	12Image: Second	1. 2. 3.	Press load button on the analyzer. Place the sealed microwell plate onto the extended loader. Press load button again. The amplification and detection run starts automatically.
6	Review and accept results.	Oppositive Basults Messages Utility The more state of the state	1. 2. 3.	After the run has finished, click Show Results . Review and accept results in Results work area. Select results and click to print the results report.
7	Unload the microwell plate from the analyzer.		1. 2. 3.	Unload the microwell plate from the analyzer as soon as is practical after the run has finished. Check the microwell plate for indications of leakage or evaporation. Discard the microwell plate according to the appropriate local regulations.
Tab	PCR Only run short g	guide (continued)		

5 Workflow short guide

PCR Only run

BRAF V600 Mutation Test

Operation

Table of contents

This chapter describes how to prepare and to perform a run, and how to handle results.

6 Chapter In this chapter Safety informationB-11 Preparations for a runB-12 Perform startup proceduresB-12 Performing a runB-14 Set up the microwell plateB-16 Sealing the microwell plateB-18 Starting amplification and detection runB-19 Using the sample editor to create a work order fileB-21 Unload the microwell plate from the cobas z 480 analyzerB-22 Searching resultsB-25 Filtering and sorting runs and resultsB-25 Accepting resultsB-26 Exporting resultsB-28

Safety information



Make sure that you have read and understood the chapter *General safety information*. In particular, please note the following safety messages:

Warning messages:

- Infection by samples and associated materials on page A-7
- Infection by biohazardous waste on page A-7
- Contamination of the environment by liquid waste and solid waste on page A-7
- Explosion through sparks on page A-8
- Fire risk through usage of sprays on page A-8

Caution messages:

- Skin inflammation or injury caused by reagents on page A-8
- Invalid results due to incorrect reagent volume on page A-8
- Invalid results due to expired reagents and consumables on page A-8
- Invalid results due to interfering substances on page A-9
- Incorrect results due to carryover on page A-9
- Incorrect results due to two barcodes on the same tube or mixing up specimen barcodes on page A-9
- Incorrect results due to wrongly typed sample IDs on page A-9
- Data security on page A-10

Safety precautions:

• Operator qualification on page A-6

Observe the system safety labels illustrated and described in the Instrument Manual for the **cobas z** 480 analyzer.

Preparations for a run

Preparations for a run

Perform the following procedures before starting a run.

Perform startup procedures

To start up the **cobas** 4800 system, you need to perform the following steps:

- 1. Switch on the analyzer.
- 2. Start the **cobas** 4800 software.

NOTICE

To prevent hardware damage, follow the steps in the exact order outlined when starting up the **cobas** 4800 system.

To switch on the cobas z 480 analyzer

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

The analyzer is powered on and initializes automatically upon startup. During initialization, the analyzer performs several function tests to ensure proper function.



A Main switch of the analyzer

Figure B-2 Switching on the analyzer

For information about the meaning of the colors of the status LEDs on the analyzer's front, refer to the Instrument Manual for the cobas z 480 analyzer.

Preparations for a run

► To start the cobas 4800 software

- **1** Power on the monitor and control unit.
- **2** To start the software, do one of the following:
 - Double-click the **cobas** 4800 software icon on the desktop.
 - Open the **Start** menu and choose the **cobas** 4800 software icon.
- **3** Enter your assigned user ID and password.
- 4 Choose Logon.



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

► To manually prepare the reagents and specimens

- **1** Remove the reagents and specimens from storage.
 - For information on handling and preparing reagents and specimens, refer to the test-specific package insert.
- **2** Manually prepare the reagents and specimens according to the instructions in the test-specific package insert.

Performing a run

	to amplification and detection on the analyzer.
NOTICE	Do not disconnect the network cable during a run.
	 It is not possible to go back to a previous step in a run. Follow the guidelines outlined in this manual to avoid losing reagents, specimens, or disposables.
<u>کر</u>	The software will outomatically log off the user after a partain period of inactivity if the bay
-Å-	Log off user on inactivity is checked in the user settings. Only users with the Supervisor role can change these settings for their own user level and for the Operator user level.
	For information on how to change the settings of a user account, refer to <i>Changing user accounts</i> on page B-44.
-`Ċ́-	You can use the sample editor to prepare one or more work order files before starting a
Ę	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 as described below.
	• For information about the sample editor, see <i>Using the sample editor to create a work order file</i> on page B-21.
-ð.	If you use more than one DNA sample preparation kit, make sure to first enter the specimens prepared with the first kit into the Sample ID column, then the specimens prepared with the second kit and so on. For tracking purposes, specimens should be separated according to the kits with which they were prepared.

A wizard guides you through the entire run, from preparation of the microwell plate

Roche Diagnostics

Performing a run

► To start a new run

1 Choose New Run.

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

	A	
	Select Test	
	⊙ Test Selection	
	Select Test Test A PCR only	
B—	C Load Workorder File	Browse C
		OK Cancel
A	Select a test type	C Browse for a work order file
B	Load a work order file	
Figu	ure B-3 Select Test dialog box	

2 Do one of the following:

- Select a test from the list.
- Choose Load Workorder File and load an existing work order file.
- 3 Choose OK.

The **Workplace** area is displayed.

Performing a run

Set up the microwell plate

NOTICE

- Use only Roche consumables designed for use on the **cobas** 4800 system. Use of non-Roche consumables may damage the analyzer or lead to incorrect results.
- The microwell plate is barcoded and designed to be used only once. The **cobas** 4800 software tracks the use of the plate and rejects previously used microwell plates.

A B C D	E Colspan="2">Colspan="2"Colspan=""2"Cols	F G C
A B C D	Information about test type and run date Boxes for DNA isolation kit ID (DNA sample preparation kit) Box for barcode of microwell plate Boxes for barcodes of specimens	00

Figure B-4 Creating a work order file for setting up the microwell plate

If an error happens while creating a work order file, the color of the box will change to red. If the boxes for microwell plate ID, DNA isolation kit ID (DNA sample preparation kit), reagent kit ID (BRAF V600 Mutation Test kit), and number of specimens are concerned, a tool tip is displayed. Move the mouse pointer over the red box to display the tool tip that gives information about the nature of the error.

If the error happens in the sample ID area, an error message will be displayed above the sample ID area, and no tool tip is displayed.

• For more information, see *List of messages and tool tips within the sample editor* on page D-12.



- Make sure to enter the barcode of the BRAF V600 Mutation Test kit into the box next to the barcode of the DNA sample preparation kit which was used to prepare the same set of specimens.
- Make sure to enter the kit barcodes into their relevant boxes. Entering a barcode into a wrong box will lead to an error.
- If no handheld barcode scanner is available, enter the barcodes manually and press the Enter key after entering each barcode. When entering the barcodes, follow the order described below.

- 1 Scan the microwell plate barcode into the Microwell Plate ID box.
- 2 Scan the barcode of the DNA sample preparation kit into the first box of the DNA Isolation Kit-ID area.
- **3** Scan the barcode of the BRAF V600 Mutation Test kit into the first box of the **Reagent Kit-ID** area.
- 4 Type the number of specimens into the first box in the Specimens area. If you use more than one test kit, enter a maximum number of 22 specimens into the first Specimens box. The other boxes may contain up to 24 specimens each.
- **5** Scan the sample ID barcodes into the **Sample ID** column in the lower part of the screen.
 - For information about the pipetting order, refer to the test-specific package insert.
- **6** If you use more than one test kit, repeat steps 2 to 5 for each test kit in the order described above.
- 7 After entering all sample IDs, choose Save.

Save the file with the default file name assigned by the software.

8 Choose 🕒.

A printable work order file that shows the microwell plate layout is displayed. Use this printout for pipetting the reagents and prepared specimens into the microwell plate.

• To pipette the reagents and prepared specimens into the microwell plate

- 1 Pipette the reagents and specimens into the microwell plate in accordance with the printout of the work order file and the description in the test-specific package insert.
 - For information on handling and preparing reagents and specimens, and how to pipette them into the microwell plate, refer to the test-specific package insert.



Microwell plate layout

The work order file describes the layout of the microwell plate and shows which specimens and reagents are to be pipetted into which well.

Sealing the microwell plate



-Ò́-

After pipetting all reagents and prepared specimens into the microwell plate, the microwell plate must be sealed properly with a sealing film. Sealing the microwell plate is crucial to eliminate evaporation at high temperatures.

Incorrect results due to evaporation or contamination of specimens 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, evaporation or contamination of specimens and controls. 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.

Make sure not to touch the film neither on the adhesive side nor on the non-adhesive side. Only touch the film at the removable edges.

- 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 film.





Sealing the microwell plate

Starting amplification and detection run

-`೧´-

The sealed microwell plate has to be inserted into the analyzer for amplification and detection.

- The prepared specimens added to working master mix have limited stability. Make sure not to wait too long before starting the amplification and detection run.
- ${}_{\textcircled{\mbox{\scriptsize O}}}$ For information about the exact timing window, refer to the test-specific package insert.
- Before starting a run, check if the Xenon lamp needs replacement in the **Instruments** tab in the **Overview** work area. Replace the Xenon lamp, if required.
- For details about Xenon lamp replacement, refer to the Instrument Manual for the cobas z 480 analyzer.
- ► To load the microwell plate into the cobas z 480 analyzer
 - 1 If necessary, log back into the software.
 - 2 In the **cobas** 4800 software, choose **Next**. The screen for loading the microwell plate onto the analyzer is displayed.
 - **3** Press the load button on the analyzer.



Figure B-6 Loading prepared microwell plate

The microwell plate loader opens.

- 4 Place the sealed microwell plate onto the loading frame of the loader.
- **5** Press the load button again to close the loader.

The loader is retracted.

NOTICE

Do not turn off the analyzer power during a run.

6 Check the timer in the wizard.

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

Performing a run

Reviewing and accepting results

Test results are displayed in the **Results** work area.

To review and accept results

1 In the Workplace work area, choose Show Results.

Overview	/ W	orkplace	Results	Messages	Utilities
6-OCT-2010	17:41 BRAF		NR 007 7	10 17-11 0045	
	Run "06-OCT-2010 17:4"	I BRAF* has finished.		10 1741 Brow	- MAX HEX - MAX
tart of run	complete	08-Oct-20 0 min	10 05:43 PM		
Elapsed time		3 min	3 2 1 0 1 3 5 2 4 6	9 11 13 15 17 1923 22 85 27 99 13 35 85 37 39 8 10 12 14 16 18 20 22 14 36 28 29 39 Cycles	4.434-0749.5153
Start	Define	Work Order	Load MVIP in cobas z 480	Amplification and Detection	End Show Result

- A Fluorescence growth curves
- B Show Results button

The **Results** work area is displayed.

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

• For more information, see *Accepting results* on page B-26.

- **3** Select results and choose b rint the results report.
 - For more information, see *Printing results* on page B-26.

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 access the sample editor

1 Choose 📰 in the global action bar.

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

Select Test	
Select Test Test A PCR only Test B PCR only	
O Load Workorder File	
	Browse
	OK Cancel

- **2** Select the test type.
- 3 Choose OK.
- 4 Create the work order file as described above.
- For information on how to create a work order file, see Set up the microwell plate on page B-16.

Performing a run

Unload the microwell plate from the cobas z 480 analyzer

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



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 microwell plate from the analyzer

- **1** When the run has finished, open the plate loader to remove the microwell plate.
- **2** Examine the microwell plate after amplification and detection.



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 microwell plate according to the appropriate local regulations.

Results

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

Overview		Res	ults			Message	5	Utilitie	s	
T	oday	This Week						Search	D or comment	Group by
Group b	by Ru	n Name							1	Edd Edus
Filter	Fit	tering Off							V	Contrates
Sangle ID		▼ Test Result	Start of Run	Test Type	Operator	Position	Plags	Conmert	Sample Type Sam	ple Matrix Accept
🛨 Run Na	me: 03-AUG-28	010 11:09 BRAF								
+ Run Na	me: 03-AUG-21	010 11:37 BRAF								_
+ Run Na	me: 03-AUG-21	010 18:35 BRAF								_
+ Run Na	ime: 04-AUG-21	010 13:32 BRAF								_
E Run Na	me: 06-0C1-20	10 17:41 BRAP	AL 10 2010 12 41-22		1 shows and the	Lafet			factors.	1 about
Patient	0	Mutation Not Detected	06.10.2010 17:41:37	DR.AP	Labrianager	901			specmen	Labriar
Patient i	4	Invalid	06.10.2010 17:41:37	10.45	Labranager	804	8 202 8 203		Spectreen	Labora
Patrent	3	Invald	06.10.2010 17:41:37	19 AF	Laboration	F01	8202.8203	-	Spectreen	Labora
Patient	2	troakt	06.10.2010 17:41:37	10.45	Laboranager	001	8202 8203		Southern	Labora
Patient	1	Invalid	06.10.2010 17:41:37	IRAF	Labranager	C01	8202.8203		Specimen	Labrar
941/999	6763C2345	Valid	06.10.2010 17:41:37	18 AF	Labranacer	401			Matart Control	Labora
941099	0763(22345	Valid	06.10.2010 17:41:37	ID AF	Labranager	801			Withow Control	Labrar
Flags Flags R202		Description Mutant Ct not detected.								0
Flags Flags R202 R203	ds	Cesorgion Mutari Ci net detected. Wildhype Ci net detected.							pload Results to LIS	Accept =
Flags Flags Race Race Race Race Race Filter Run h	4 buttor neader	Merrosoften Marce C net desendet wikkype Q net deneted				D	Det a Resu	ails are	Post Prests a UK Pa Hing buttons	C Accept =

Figure B-7 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 column orders and hiding selected columns.
- For more information, see *Lists* on page A-22.



- Customization of the result view in the **Results** work area does not influence result printouts and result export. The details per result that are included in reports and export files 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 Click the plus sign next to the run header to display the individual results of that run.
- **2** To display more information about a particular result, select the result you want to review.
- 3 Choose Details.

The **Details** area is displayed. Flags of the selected result are displayed.

- 4 Review the results data.
 - For information about flags, see Chapter 10 *Result flags*.

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 Group by.
- **2** Select a grouping criterion from the list.

All results are grouped by the selected criterion.

Grouping results

Group by					
	Grouping Off				
	Run Name				
	Start of Run				
	Test Type				

Figure B-8

3 To display the runs in an ungrouped order, choose **Group by** and select **Grouping off** 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.

Search ID or comment 🛛 🗙

Figure B-9 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** box.
- **2** Type the search term into the box.

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

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

- For more information, see *Lists* on page A-22.
- **3** To remove the search term, click \times next to the **Search** box.

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 more information about sorting, see *Lists* on page A-22.
- For more information about filtering, see *Creating result filters* on page B-29.

Accepting results

More details about particular results can be viewed in the **Details** area, for example result flags.

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.
 - Use the Ctrl key to select several nonadjacent results.
 - Use the Shift key to select a range of adjacent results.
- 3 Choose Accept.

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

- For information about adding columns, see *Displaying and hiding columns* on page A-23.

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 the result report.

cobas BRAF V	8 4800 600 Mutation	n Analysis	Report			Roche	
Diart of Run	× 1	06.10.2010 17	41.37 [DRA last	lation \$2 D #1:	AD112345	MBA3234	
	Name:	coban z 480	Response	Reagent Kit ID #1: 543		899876102345	
returnent	Serial No:	NU_TEST_123	45 Reagent	Lot / Exp Cole:	100017677	96-2012	
BRAF AP 1	iersion.	1.0.0.1028	- in the		-	e	
EUN STAT	28	VALID					
RUN NAME	66-OCT-2010	17.41 BRAF					
- one of the second	Control Toron		Control Birthow			Annual and Party	
	Control Type		Control Blatters	They		Accepted D	
A01	Mutant Control	1	Vald			Labmanager	
801	Wettype Control	1	Valid			Labrearager	
Specimens							
Position	Sample D		Test Result	Flag		Accepted D	
C01	Patient 1	1	invalid	R202.R	203	Laboranasee	
001	Patient 2	1	invalid	#202.#	203	Labmanaper	
801	Patient 3	1	invalid	#202.#	203	Labranaper	
F01	Patient 4	1	invalid	R202.R	203	Labmanager	
001	Patient 5	1	inulid	R202,R	203	Labmanager	
H01	Patient 6	1	Mutation Not Detected			Labrearage	
Comments							
Operator:							
		•	als.		Sign	dure .	
Raviewer:			ata .	Signature			
ontanii 48	0 software 2.0	0.1028				Page 1 of	





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.
 - Use the Ctrl key to select several nonadjacent results.
 - Use the Shift key to select a range of adjacent results.
- **3** Choose in the global action bar.

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.
 - Use the Ctrl key to select several nonadjacent results.
 - Use the Shift key to select a range of adjacent results.
- **3** Choose **Print** in the global action bar.

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.

PDF Export Options	×
Page range:	
 Compressed 	
Don't embed these fonts:	
Images quality:	Highest 🔽
Application:	
Author:	
Keywords:	
Subject:	
Title:	
	OK Cancel

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

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

- **6** Define the file name and path for storage.
- 7 Choose OK.

Exporting results

<u>َ</u>ڀ

After reviewing, test results can be exported and saved as a file.

When exporting results as a file, all results of a run are exported. It is not possible to export individual results of a run.

Make sure not to select the run header of the run you wish to export. Only select one of the results of the run.

► To export results as a file

- 1 Select one of the of the results of the run you want to export.
- **2** Choose **Export** in the global action bar.

A dialog box for selecting or creating a folder for storage is displayed.

- **3** Select the folder where you want the export file to be stored.
- 4 Choose OK.
- .
Creating result filters

A maximum of three 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.

Today Group by Fiter Run Date Sample Type Test Type Operator	This Week Run Name Filtering Off Off Torlaz Yesterday This Week Select a Date Select a]					Search D or	comment ×	Group by Edt Filter
Group by Filter Run Date Test Type Operator	Run Name Filtering Off Off Tortex O Yesterday O This Week O Last Week O Select a Date Select a Date								Edit Filter
Run Date	Off Toriau Vesterday This Week Last Week Select a Date Select a Date								
Test Type Operator	Yesterday This Week Last Week Select a Date Select a Date								
	O Select a Date								
	O belett a bate Hange								
							Save	Save As	Delete Filter
Sanple ID	Test Result	Start of Run	Test Type	Operator	Position	Flagi	Conment	Sample Type	Sample Matrix Accept
Run Name: 03-A	IG-2010 11:09 Test								
Patient 6	Mutation Not Detected	03.08.2010 11:09:34	Test	Admin	H01			Specimen	Admin
Patient 5	Invalid	03.08.2010 11:09:34	Test	Admin	601	R202,R203		Specimen	Admin
Patient 9	Driviald	03.08.2010 11:09:34	Test	Admin	POL	R202,R203		Specimen	Admin
Patient 2	Invald	03.00.2010 11:09:34	Sect	Atrin	001	8202,8203		Specimen	Admin
Patient 1	Invald	03.08.2010 11:09:34	Test	Admin	C01	R202,R203		Specimen	Admin
0									0
	Service 12 Patient 6 Patient 5 Patient 5 Patient 3 Patient 3	Desker ▼ Text Back Parts 5 MAXING 201511007 best Parts 5 Jonad Parts 5 Jonad Parts 6 Jonad Parts 7 Jonad Parts 7 Jonad Parts 1 Jonad Parts 1 Jonad	Device D Test Res. Part of Rev Parts Asses DAA Sector DA	Desk Test Basa Set of Basa Test Trans Parts Asses Bash Namet B3 AUX 2019 1109 120 Test Trans Test Trans Parts 6 MAADON NG Criedid 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans Parts 7 Bread 610.02 2010 1109 24 Test Trans	Desk V Test Resk Part of Res Test Type Contrary Parts 6 MAXement 03:A42C-2018 01100 Test Bits Advec Test Advec Advec Parts 6 MAXement 03:A42C-2018 01100 Test Bits Advec Test Advec Advec Parts 7 Binsdad 030.2001 100:514 Test Advec Advec Advec Parts 7 Binsdad 030.2001 100:514 Test Advec Advec Parts 1 Binsdad 030.2001 100:514 Test Advec Advec	Deside D: Test Result Start of April Test Type: Operator Paulton Parts 6 Multicon Mic Oriented 0.00.2010 1109:34 Netl Advan Netl Parts 6 Multicon Mic Oriented 0.00.2010 1109:34 Netl Advan Netl Parts 7 Dived 0.00.2010 1109:34 Netl Advan Part Parts 7 Dived 0.00.2010 1109:34 Netl Advan Path Parts 7 Dived 0.00.2010 1109:34 Netl Advan Col Parts 7 Dived 0.00.2010 1109:34 Netl Advan Col	Desk Test Read Start of Ran Feet Type Operative Feeton Feeton	Date Test Read Part of Run Test Type Test Run Parts Parts<	Store Store <th< td=""></th<>

Figure B-11 Filter definition area in the Results work area

To create a new result filter

1 Choose Edit Filter.

The filter definition area is displayed.

2 Choose Run Date and select a run date or range.

Today	This Week			Search ID or o	comment X	Group by
Group by Filter	Run Name Run Date 27.04 2010-27.04 2010				V	Edit Filter
Run Date Sample Type Test Type Operator	Off Today Yesterday This Week Last Week Select a Date Select a Date Select a Date	4 April 4 2000 b M D M D F 5 17 20 20 1 2 3 4 15 6 7 0 3 4 15 6 7 0 3 4 15 16 11 15 16 10 10 20 21 22 20 24 25 12 24 5 6 7 0 9 12 24 5 6 7 0 9 12 4 5 6 7 0 9	Appl I C 2010 J M D M D P S S 10 20 20 21 1 2 3 4 10 12 13 14 15 16 17 16 11 12 13 14 15 16 17 16 12 13 14 15 16 17 16 12 13 14 15 16 17 16 12 13 14 15 16 17 16 14 20 12 22 20 10 12 13 24 22 20 10 12 13 16 16 17 16 14 15 16 17 16 16 17 16 16 17 16 16 16 17 16 16 16 16<			
				Save	Save As	Delete Filter

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

3 Choose **Sample Type** and select one or more sample types.

To include only controls into the filter, select Non Specimen.

- 4 Choose **Test Type** and select one or more test types.
- **5** Choose **Operator**. Click the arrow next to the box and select an operator from the list.

Group by	Run Name	
Filter	Operator Labmanager	
Run Date	Operator	
Sample Type	Labmanager	
Test Time	Off I	
rest type	Admin1	
Operator	FSE	
	FSE1	
	Labmanager	1
	Labmanager1	

6 Choose Save as.

A dialog box for defining the filter name is displayed.

- 7 Type a name for the filter into the box.
- 8 Choose Save in the dialog box.

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:
 - Choose **Save** to save the changes.
 - Choose **Save as** to save the filter under a new name.

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 Delete Filter.

A confirmation dialog box is displayed.

3 Choose **Yes** to delete the filter.

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 **Edit Filter**. The filter definition area will be closed.



Grouping of filtered results

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

• For more information, see *Grouping results* on page B-24.

To disable result filtering

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

In the filter information area, **Filtering Off** is displayed next to **Filter**. All results are displayed in the runs area once again.

D Edit Filter

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

6 Operation

Results

7 Configuration *Table of contents*

Configuration

In this chapter the configuration of the system and the export of support data is described.

7 Chapter In this chapter ConfigurationB-35 System SettingsB-35 ReportingB-37 TestsB-38 User managementB-41 Password managementB-41 Changing a passwordB-41 User account managementB-42 RulesB-45 Account rulesB-45 Password rulesB-46

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Configuration

Configuration



The accessible configuration settings are dependent on the user group of the logged in operator.

- Users assigned to the **Supervisor** group can access all configuration settings described below.
- Users assigned to the **Operator** group can only export support data (data for Roche Service) and change their password.

The configuration tasks are divided into the following areas:

- System configuration
- User management

System Settings

→ Utilities > Configuration > System Settings

• Use the **System Settings** group to define the parameters found in Table B-2.

bas 4800		23.04.2010 15	26			Roche
er ID: Labmanager		Version 2.0.0.1	014			_
Overview	Result	s	Messages	R	Utilities	
Configuration	Use	HIS	Export Support I	Data		
Groups	Settings					New Pun
System Settings Reporting Tests Archiving	Plannter Enable such tog on dialog Deftauft vorliderer direct. US configured LB Timeout	Value C:Documents and Sett	Comment Setto the to show the log of Default directory that will be Configure where rul SKAM Configure the LIS timeout in	n dakog on applicati used för stävng and is present or not seconds	on start loading workorder files.	
					Cancel Save	
▲ 22.04 2010 18:27 ▲ 16.04 2010 18:34 ▲ 15.04 2010 09:54	The connection to the The connection to the Optimal monitor resol	instrument z480 has bee instrument z480 has bee ition is 1280×1024. The o	n lost. In lost. configured resolution is 1440x91	00		(j)

Figure B-12 System Settings group

7 Configuration

Configuration

BRAF V600 Mutation Test

Parameter	Values	Comment
Enable auto log on dialog		Select the check box to ensure that the log on dialog box is displayed after starting the software.
Default workorder directory	Path name	Location where the system looks for and saves work order files. Type the full path and use Windows naming conventions (e.g. C:\Temp\Workorders). Alternatively, choose and browse for the path.
LIS configured		Make sure that the check box is not selected. LIS connection is not supported.
LIS Timeout		LIS connection is not supported.

Table B-2

System Settings parameters

Reporting

Use the **Reporting** group to specify the laboratory name, enable or disable the header of the result report, and to define the maximum number of entries in a report.



Figure B-13 Reporting group

Parameter	Values	Comment
Lab name	Name	The name of the laboratory that will be included in the header of the reports.
Show Lab Header on Reports		Select the checkbox if you want the specified header to be displayed on the reports.
Maximum Entries	Number (1 to 1000)	Defines the maximum number of result entries in a report.
Table B-3 Reporting p	arameters	

Configuration

Tests

→ Utilities > Configuration > Tests

Use the **Tests** group to enable or disable tests on the **cobas** 4800 system. Disabled tests cannot be run on the system.

eobas 4800					<u> </u>
cobas 4800		23.04.2010 16:0	01		Rusha
User ID: Labmanager		Version 2.0.0.10	14		
Overview	Results		Messages	Utilities	
Configuration	User		Export Support Data		
Groups	Settings				New Run
System Seeings Reporting Tests Archving	Planeter Test PCR Only Test BCR Only Test C PCR Only	Viue	Convert		
				Cancel Save	
Auron 15 04 2010 18 34 15 04 2010 19 34 15 04 2010 09 54 16 04 2010 19 50	The connection to the instru The connection to the instru Optimal monitor resolution is	ment 2480 has been ment 2480 has been s 1280x1024. The co	liost. Iost. Infigured resolution is 1440x900		

Figure B-14 Tests group

Parameter	Values	Comment
Test A PCR Only workflow		Select a check box to enable a test for use on the
Test B PCR Only workflow		cobas 4800 system. Clear the check box to prevent
Test C PCR Only workflow		a test from being used.
Table B-4 Tests para	meters	

Ò.

Archiving

→ Utilities > Configuration > Archiving

Use the Archiving group to define the settings for purging and archiving results.

The purge and archive function is used to archive results and purge them from the results database. This will free up space for new results in the database. Results are archived at regular intervals in a password protected ZIP-file at a predefined location. Each run is archived in a separate ZIP-file.

- No manual intervention is necessary. The cobas 4800 system performs purging and archiving of results automatically based on the settings in Utilities > Configuration > Archiving.
- Ensure that the archive directory is included in the backup plans.
- Contact Roche Service if result archives need to be viewed or restored.
- The purge and archive function only covers run data and results. Messages are kept in the **cobas** 4800 software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.
- For information on how to delete confirmed messages, refer to *Messages work area* on page D-7.

Construction L3 bit 2010 10.002 Version 2.0.0 10.14 Version 2.0.0 10.14 Overview Results Messages Utilities Configuration Users Export Support Data Groups Settings Premeter Value Premeter Value Comment Maximum age of audit trail evel 0.000 The number of days after that an audit trail will be deleted Purge & Archive 0.000 The number of days after that an audit trail will be stored Archiving Purge & Archive Structury Diverting Maximum age of Pesutis 385 Results, older than the defined number of days, will be archived	shas 4900		22.04.2010 10.0	2		10.001
Oversion 2001014 Version 2001014 Oversiew Results Messages Utilities Configuration Users Export Support Data Image: Configuration Image: Configuration <thimage: configuration<="" th=""> Image: Configu</thimage:>	00854600		23.04.2010 16.0.	2		Roche
Overview Results Messages Utilities Configuration Users Export Support Data Image: Support Data	Iser ID: Labmanager		Version 2.0.0.101	4		_
Configuration Users Export Support Data Groups Settings System Settings Parameters Reporting Parameters Pure & Arche 1000 Tests Pure & Arche Archiveing Active: Discription are of audit train record. Mainrum age of Results 395	Overview	Results		Messages	Utilities	_
Groups Settings System Settings Page-interior Vide Concentration Image: Concen	Configuration	Users		Export Support Data		
System Settings Reporting	Groups	Settings				New Run
Tests Purge & Archive Directory Diversity and Activities Deactivates the submarked Purge & Archive Introton Archiveng Deace Subsection and the strengt of th	System Settings Reporting	Parameter Maximum age of audit trail recor.	Value 10000	Comment The number of days after that an au	dit trail will be deleted	
Atchining Puge & Archive Unicitity Duricitity Duricitity Dennes per detecting viente archive results will be stored Wasimum age of Results 305 Results, adder than the defined number of days, will be archived	Tosts	Purge & Archive	Ditation	Activates/Deactivates the automated	Purge & Archive function	Abort
	Archving	Maximum age of Pesuits	385	Results, older than the defined numb	er of days, wil be archived	
					Cancel Save	LayOff
Cancel Sover	A 22.04.2010 16.27	The connection to the instrum	nent z480 has been	lost.		
Cancel Save		The connection to the instrum Optimal monitor resolution is	tent z480 has been	lost. Informed resolution is 1440x900		

Figure B-15 Archiving group

7 Configuration

Configuration

cobas[®] 4800 system

Parameter	Values	Comment
Maximum age of audit trail records	Number (10 to 10000)	Number of days after which the audit trail records will be deleted.
Purge & Archive		Select the check box to enable the purge & archive function.
		Deselect the check box to disable the purge & archive function.
Purge & Archive Directory	Directory path	Location where the results are archived. The archive directory can be located on a server.
		Type the full path to the archive directory and use Windows naming conventions. (e.g. D:\Archive). Alternatively, choose and browse for the path.
Maximum age of Results	Number (10 to 10000)	Number of days after which the results will be be archived and purged from the database. All results that are older then the specified days will be archived and purged.

User management

→ Utilities > Users

There are three groups of functions available for managing users:

- Changing passwords
- Managing user accounts
- Setting up rules for passwords and user accounts
- Only users that are assigned as Supervisor can manage users and can set up rules for passwords and user accounts.
 - Users assigned as **Operator** can change their password only.
 - Keep user access information on a secure place and do not make it public to prevent unauthorized access to the system.

Password management

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The initial password is defined during set up of a user account.

• For more information, see *To define a new user account* on page B-43.

Changing a password

Any user can change his/her password. Supervisors can change the passwords of all users. The password must follow the password rules that are defined in the **cobas** 4800 software.

• For more information, see *Password rules* on page B-46.

To change the password

1 Choose Utilities > Users > choose Change Password.

The Change Password dialog box is displayed.

- 2 In the Old Password box, type the current password.
- **3** In the **New Password** box, type the new password.
- 4 In the **Confirm new Password** box, type the new password again.
- **5** Choose **Apply**.

User management

BRAF V600 Mutation Test

► To change the password of another user

- 1 Choose Utilities > Users.
- **2** Select a user in the list.
- **3** Choose **Reset Password**.
- 4 In the **Password** box, type the new password.
- 5 In the Confirm Password box, type the new password again.
- 6 Choose Apply.

User account management

The following functions are available:

- Creating new user accounts
- Changing and deleting existing user accounts
- Unlocking user accounts

😅 cobas 4800			च व
cobas 4800	23.04.2	010 17:28	Rube
User ID: Labmanager	Version	2.0.0.1014	Contraction
Overview	Results	Messages	Utilities
Configuration	Users	Export Support Data	
User Access Users	User A	ccount	Hg New Ru
Change Passoord Uters Rules	e Use	D • Salmansger Nome Lakwansger Group:	In case no user is logged in et, e.g. managra users for the Operator role
A 22.04 2010 18.27	Delete P	g of user on hack-by unge Password on med logon court & enable sesword never expires Resct Password Edit Uhlock has been loot	Apply Discard

Figure B-16 Users area

User rights A user assigned to the **Operator** group has the following user rights:

- Starting and aborting runs
- Viewing result details and accepting, exporting, and printing results
- Performing maintenance
- Confirming messages

User management

A user assigned to the **Supervisor** group has the same user rights as the **Operator** group plus:

- Editing configuration settings
- Managing user accounts and editing account rules
- Deleting messages

Creating user accounts

User name and password must be unique.

To define a new user account

1 Choose Utilities > Users > choose New.

cobs 4800 23.04 2010 17.58 User D. Labranager Version 2.0.01014 Overview Results Messages User Access User S User Access User S User S User Accourt User Access User Name: Labsprater User Name: Labsprater User Name: Labsprater User Name: Labsprater User Orope: I Monte Topper Table Access User Orope: I Monte Topper Labsprater Vser Orope: I Monte Topper Access to maked I Access I Monte Topper	😑 cobas 4800					
User Disk Messages Utilities Overview Results Messages Utilities Overview Results Messages Utilities Overview Users Export Support Data User Accourt User Accourt User ID User Image and a set of s	cobas 4800			23.04.2010 17.58	8	
Overview Results Messages Utilities Configuration Users Export Support Data User Access User Support Data User Account Charge Password Labersgreit Labersgreit Labersgreit Labersgreit User Count Users Labersgreit Labersgreit Rules Verform Password User Group: Verform Password User Group: Verform Password User Count: User Group: Verform Password Verform Password User Group: Verform Password Verform Password Verform Password Verform Password Veringer Password Verform Password <t< td=""><td colspan="2">User ID: Labmanager</td><td></td><td>Version 2.0.0.101</td><td>4</td><td></td></t<>	User ID: Labmanager			Version 2.0.0.101	4	
Configuration Users Export Support Data User Account User Account Charge Password Istancaget Eatlenance Users User Account User Account User Account Users User Account User Account User Account User Account User Account User Coroups Image Password Supervise Extended right = nanaget users Supervise Cordern Password User Oroups Image Password on ent logon > Accounts mailed Password Password East New Date	Oven	viêw	Results		Messages	Utilities
User Accost User S Charge Plassord Uers Uers Roles Password Confirm Password User Concest Password Pas	Config	uration	Users		Export Support Data	
Charge Password Uers Roles Uers Roles Uers Lamon start Lamon start Lamon start Uers Roles Uers Uers Lamon start Lamon start Lamon start Lamon start Uers Name: Lamon start Description Roles Password Uer Oroup: Ver Description Supervise:	User Access	Users		User Account		
Log off user on nactivity Change Password on next logon Account is enabled Password newr expires Reset Password New Dates Est Unlock Apply Cocard	Charge Password Users Rules	The United Laboratory Laboratori Laborettori Laborettori		User ID: User Name: Language: Password Confirm Passw User Groups:	English English Viting Viting Viting Supervisor Supervisor Supervisor Operator Permission	s in case no user is logged in frst, e.g. managing users s for the Operator role
		New	Delete	 Log off user Change Pas Account is e Password ne Res Edt 	on inactivity sword on next logon nabled where repires et Password Unlock	Apply Discard

Figure B-17 Defining a new user account

2 Type the User ID.

The user ID must be unique on the system.

- **3** Type the User Name.
- 4 Select the user language.
- **5** Type the password and confirm it.

The password must follow the password rules that are defined on the system.

6 Assign the User Group.

To each group, a set of user rights is assigned.

- 7 Select Log off user on inactivity to make sure that the user will be automatically logged off after a certain period of inactivity on the system.
 - For more information, see *Account rules* on page B-45.
- 8 Select Change Password on next logon to ensure that the user changes his or her password during the next log on.

Roche Diagnostics

User management

BRAF V600 Mutation Test

- **9** Clear **Account is enabled** if you are preparing a new user account to be ready for a later date.
- **10** Clear **Password never expires** if the user should change the password periodically.
 - For more information, see *Account rules* on page B-45.

11 Choose Apply.

This button is only active if all necessary definitions have been made.

Changing user accounts

► To change a user account

- 1 Choose Utilities > Users.
- **2** Select a user from the list.
- 3 Choose Edit.
- 4 Make the necessary changes in the User Account area.
- 5 Choose Apply.

Deleting user accounts

• To delete a user account

- 1 Choose Utilities > Users.
- **2** Select a user from the list.
- 3 Choose Delete.

A confirmation dialog box is displayed.

- 4 Choose **Yes** to confirm the action.

Unlocking user accounts

By default, user accounts become locked after five unsuccessful login attempts. Locked users are indicated in the **Users** list.

To unlock a locked user account

- 1 Choose Utilities > Users.
- **2** Select the locked user from the list.
- 3 Choose Unlock.

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BRAF V600 Mutation Test

Rules

User management

→ Utilities > Users > choose Rules.

There are two sets of rules, one for user accounts and one for passwords.



Enter zero to switch off a rule.

Account rules

Password expires after (days) 60 Auto log off user after (min) 15	Account Rules	
Auto log off user after [min] 15	Password expires after [days]	60 📑
Licer looked offer wrong loging	Auto log off user after [min]	15 🚔
Oser locked alter wibing logins	User locked after wrong logins	3 🖨

Figure B-18 User account rules

ltem	Values	Comment
Password expires after [days]	Number (0 to 999)	Select or type the number of days after which the user must change the password.
Auto log off user after [min]	Number (0 to 999)	Select or type the number of minutes of inactivity on the system after which the user is automatically logged off.
User locked after wrong logins	Number (0 to 999)	Select or type the number of failed login attempts before the system automatically locks the account.
Table B-6	User account settings	

User management

Password rules

Password Rules	
A valid password shall	
have a minimum length of	0 🚔
contain at least uppercase characters (A through Z)	0 🍧
contain at least lowercase characters (a through z)	0 🚍
contain at least digits (0 through 9)	0 🖨
contain at least nonalphanumeric characters (e.g. !, \$, #, %)	0 🗧

rassword rules setting	Figure B-19	Password rules settings
------------------------	-------------	-------------------------

ltem	Values	Comment
have a minimum length of	Number	Select or type the minimum number of characters a password must consist of. The minimal required value is automatically set by the system based on the values of the other password rules.
contain at least uppercase characters (A through Z)	Number	Select or type the minimum number of uppercase characters a password must contain.
contain at least lowercase characters (a through z)	Number	Select or type the minimum number of lowercase characters a password must contain.
contain at least digits (0 through 9)	Number	Select or type the minimum number of digits a password must contain.
contain at least non- alphanumeric characters (e.g. !, \$, #, %)	Number	Select or type the minimum number of non- alphanumeric characters a password must contain.

Table B-7

Password rules settings

Exporting support data

If necessary, support data for individual runs or a batch of runs can be exported to an external storage device. The support data will help Roche Service to support you optimally.

Overview	Results	Messages	Utilities
Configuration	Users	Export Support Data	
Run Name	Run Date	Ordered by	
03-AUG-2010 11:09	03.08.2010 11:18.48	Admin	
3-AUG-2010 11:37	03.08.2010 11:43.30	Admin	
3-AUG-2010 18:35	03.08.2010 18:39.51	Laboperator	
34-AUG-2010 13:32	04.08.2010 14.00.36	Laboperator	

Figure B-20 Export data for Roche Service

► To export support data

- 1 Choose Utilities > Export Support Data.
- 2 Select the runs that were affected by the problem.
- 3 Choose Extract Support Data.

A dialog box for entering the folder for storage is displayed.

- 4 In the dialog box, select the folder where you want the exported data to be saved.
- **5** Follow the instructions of Roche Service how to send the data to them.

This is the last page of Part B.

7 Configuration

Exporting support data

Maintenance **C**

8 Maintenance C-3

Maintenance

Table of contents

In this chapter the required maintenance procedures are described.

In this chapter	Chapter	8
Safety information		C-5
Maintenance		С-6

Safety information



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

Warning messages:

- Infection by samples and associated materials on page A-7
- Infection by biohazardous waste on page A-7
- Contamination of the environment by liquid waste and solid waste on page A-7
- Explosion through sparks on page A-8
- Fire risk through usage of sprays on page A-8

Caution messages:

Skin inflammation or injury caused by reagents on page A-8

Safety precautions:

• Operator qualification on page A-6

Observe the system safety labels illustrated and described in the Instrument Manual for the **cobas z** 480 analyzer.

Before performing any maintenance, read the safety messages carefully. If you ignore safety messages, you may suffer serious or fatal injury.

Maintenance

Maintenance

In the **cobas** 4800 software, the **Instrument Overview** and the **Instrument** tab show the actual maintenance status of the **cobas z** 480 analyzer.

For information about exchanging xenon lamp, ventilation dust filters and fuses, and about general cleaning of the analyzer, refer to the Instrument Manual for the cobas z 480 analyzer.

This is the last page of Part C.

D

Troubleshootir	ıg
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9	Troubleshooting and error messages	D-3
10	Result flags	D-17

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Troubleshooting and error messages

In this chapter, you will find information about troubleshooting and error messages that help to deal with exceptional situations.

In this chapterChapter9OverviewD-5Messages work areaD-7Reviewing and confirming new alarmsD-9TroubleshootingD-10Problem reportsD-10Remote supportD-11List of messages and tool tips within the sample editorD-12List of error messagesD-14

Overview

Overview

The **cobas** 4800 system records all problems originating from the **cobas** 4800 software and **cobas z** 480 analyzer. The error records can be viewed in the alarm area at the bottom of the screen and in the **Alarms** and **Messages** work areas.



A The *alarm area* displays the most recent alarms that are not yet confirmed by the operator. Select an alarm in the list and click the **Alarm** button on the left to get more details about the selected alarm.

Figure D-1 Alarm area

Alarm area

ea The color of the alarm button changes depending on the severity of the alarms listed in the alarm area.

Icon	Purpose
Alarm	Red icon: the alarm area contains at least one error.
Alarm	Yellow icon: the alarm area only contains warnings but no errors.
Alarm	White icon: the alarm area is empty.

Table D-1

Alarm button

Overview

Message and alarm icons The severity of the alarms and messages is indicated by the following icons:

lcon	Purpose
Δ	Designates an error message (red icon). The error must be resolved before additional samples can be run. A problem report is generated automatically.
	• For details about problem reports, see <i>Problem reports</i> on page D-10.
⚠	Designates a warning (yellow icon) indicating an error was detected but the system can still be run.
Â	Designates an informational message.

Table D-2

Message and alarm icons

Messages work area

Tab	Description				
Alarms	Contains all alarms from the cobas z 480 analyzer or the cobas 4800 software that have not yet been confirmed by the operator.				
Messages	Contains all information, error, and warning messages.				
Audit Trail	Shows recorded user activities, e.g. operator log on and log off.				
	For more information on the audit trail, see Audit trail on page A-29.				
Table D-3	Tabs in Messages work area				

There are three tabs in the Messages work area.



The purge and archive function only covers run data and results. Messages are kept in the software until they are deleted manually. Therefore, it is recommended to manually delete confirmed messages from time to time to free up additional space in the database.

obas 4800			03.05.201	0 12 56	
Iser ID: Labrana	ger		Version 2.0	0.1014	
Overview Alarms		Results Messages		Messages	Utilities
				Audit Trail	
Severity	T Date Time	T Code	Text		4
Warning	03.05.2010 11:37:39	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
Frror	03 05 2010 11 33 56	6 2 5 20 35	The following	error Simulator Error ReadAcquisation failed Ac	quisition Buffer overflow, 93>89 oc
Error	03.05.2010 11:33.55	6.2.3.1.0	Restart instru	ment, inform Roche service	
A Error	03.05.2010 11:33.55	6.2.3.1.0	Restart instru	ment, inform Roche service	
A Error	03.05.2010 11:33.55	6.2.3.1.0	Restart instru	ment, inform Roche service	
Warning	30.04.2010 16:41:17	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
UWarning	27.04.2010 18:46:47	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
Varning	26.04.2010 18:36:11	8.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
Warning	23.04.2010 18:14:42	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
Warning	22.04.2010 16:27:28	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
UWarning	16.04.2010 18:34:36	8.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
A Warning	15.04.2010 09:54.38	6.2.5.10.10	Optimal mon	tor resolution is 1280x1024. The configured reso	olution is 1440x900
UWarning	14.04.2010 13:36:55	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
A Warning	13.04.2010 19:03:18	6.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
A Error	13.04.2010 14:14:54	6.2.5.30.44	The Roche D	P.CalcPack Algorithms Kinetic Adapters ATF co	uld not be loaded. Please contact
A Error	13.04.2010 14:14:54	6.2.5.30.48	An unknown	error occurred. The run was aborted. If the proble	em persists, restart the application.
4 Warning	13.04.2010 14:10:22	8.2.5.20.34	The connecti	on to the instrument z480 has been lost.	
Warning	13.04.2010 14:01:27	6.2.5.20.34	The connection to the instrument z480 has been lost.		
A Warning	12.04.2010 19:16:46	6.2.5.20.34	The connection to the instrument z480 has been lost.		
Error	12.04.2010 14:17:31	6.2.5.30.24	The Roche DP.CalcPack Algorithms Kinetic Adapters ATF could not be loaded. Please contact		uld not be loaded. Please contact
Error	12.04.2010 14:17:31	6.2.5.30.28	An unknown	error occurred. The run was aborted. If the proble	em persists, restart the application.
Text Restart instrument Help Text Instrument Softwa	I, inform Roche senice re Exception: The instrument h	as been stopped and must be re-	stated.		
Report	03 05 2010 11:37 03 05 2010 11:33	The connection to the inst The following error Simula	rument z480 has	: been lost. cavisation Bulfer overflow 183>	Delete Confirm

- **A** All unconfirmed alarms are listed in the **Alarms** tab. Alarms are moved to the **Messages** tab after confirmation.
- **B** Alarm details. Select an alarm in the list to see the alarm details.
- C Choose Report to manually generate a problem report.

Alarms tab

D Choose Delete to delete the selected alarm or Confirm to confirm the selected alarm.
 Confirmed alarms are deleted from the Alarms tab, but are still listed in the Messages tab.

Figure D-2

Messages work area

		03.05.20	10 12:05			
ser ID: Labrna	nager	Version 2	2.0.0.1014			
Overview Alarms		Results	Messages		Utilities	
		Messages	Audit Tr	ail D		
Seventy 1	Date Time 💌 T Code	T Test		Confirm	stion Date Y Confirmati Y	
Marning	03.05.2010 11:37 6.2.5.20.34	The connection to the instru	ment z480 has been lost.			
A Warning	30.04.2010 16:41: 6.2.5.20.34	The connection to the instrument z480 has been lost.				
A Warning	27.04.2010 18:46 6.2.5.20.34	The connection to the instru	The connection to the instrument z480 has been lost.			
🛯 🥼 Warning	26.04.2010 18:36 6.2.5.20.34	The connection to the instru	The connection to the instrument z480 has been lost.			
📕 🥼 Warning	23.04.2010 18:14: 6.2.5.20.34	The connection to the instru	The connection to the instrument z480 has been lost.			
📕 🦺 Warning	22.04.2010 16:27 6.2.5.20.34	The connection to the instru	ment z480 has been lost.			
🛛 🚹 Warning	16.04.2010 18:34 6.2.5.20.34	The connection to the instru	ment z480 has been lost.			
Warning	15.04.2010.09.54 6.2.5.10.10	Optimal monitor resolution in	s 1280x1024. The configured resolut	tion is 144		
Marning	14.04.2010 13:36: 6.2.5.20.34	The connection to the instru	ment z480 has been lost.			
Varning	13.04.2010 19:03 6.2.5.20.34	The connection to the instru	ment z480 has been lost.			
d vvarning	13.04.2010 14:10 6.2.5.20.34	The connection to the instru	ment 2480 has been lost.			
A Warning	13.04.2010 14.01 0.2.5.20.34	The connection to the instru The connection to the instru	ment 2480 has been lost.			
A Marning	12.04.2010 18.10	The connection to the instru	ment a 400 has been lost.			
🗶 🖌 (Seventy	f = 'Warning'					
Text The connection) = 'Warning' to the instrument z480 has been lost.					
Text The connection Help Text) = 'Warning' to the instrument z480 has been lost.				·	
Text The connection Help Text) = Warning/ to the instrument 2480 has been lost.				•	
Text The connection Help Text) = Warning' to the instrument 2480 has been lost.					
Text The connection Help Text) = "Warning" to the instrument 2480 has been lost.				Í	
x ♥ [Sevenby] Text The connection Help Text	J = Warming' to the instrument z480 has been lost.					
x ♥ (Seventy) Text The connection Help Text	1 = Warming				Dekte Confirm	
x ♥ [Seventy] Text The connection Help Text	Stanning to the instrument 2400 has been lost. Bases 2010 11:07 The second s	e connection to the instrument +400	uas been loot.	l	Deter	
E Several Text The connection Help Text	Stanmoy to the instrument 2400 has been lost. Color 2010 11:27 The Color 2010 11:27 The Color 2010 11:37	e connection to the instrument 2400	as been lost. Acquission failed Acquisition Buffe	overflow (33-93 occ	Detet Corfm	
Ext Text The connection Help Text	Starmey to the instrument 2400 has been lost. do	e connection to the instrument 2400 f following error Smulator Error Rea tatir instrument, inform Rocks erecurs	as been lost. Arcquistion failed Acquistion Buffer	overflow: 93>99 occ	Celete Corform	

- A Use the sort, filter, and group functions in the column headers to customize the list of messages.
- **B** Choose **Delete** to delete the selected message.
- **C** Choose **Confirm** to confirm the selected message.

Figure D-3	Messages tab
Field	Description
Severity	Contains an icon to indicate whether the message is an error, warning, or information message.
Date/Time	Displays the date and time when the message was generated.
Code	Displays the message code.
Text	Displays an abbreviated description of the error or situation that occurred.
Confirmation date	Displays date and time of confirmation.
Confirmation user	Displays the operator who confirmed the message.
Table D-4	Fields in Messages tab

Messages work area

Reviewing and confirming new alarms

All alarms should be confirmed.

The selected alarm(s) are removed from the **Alarms** tab, but are still listed in the **Messages** tab.



Choose the 🕒 button to print the contents of the Alarms or Messages tab.

To confirm a new alarm

- 1 Choose **Messages** > **Alarms** or double-click the alarm in the alarm area at the bottom of the screen.
- **2** Select the alarm to be confirmed.
 - Use the Ctrl key to select several nonadjacent alarms.
 - Use the Shift key to select a range of adjacent alarms.
- 3 Choose Confirm.

Troubleshooting

Troubleshooting

Problem reports

Each time a new error message is generated, a problem report is created by the **cobas** 4800 system. If necessary, a problem report can also be created manually.

Problem reports are used by Roche Service to assist in troubleshooting cases. Problem reports are stored as ZIP-files in a predefined folder where they can be retrieved and sent to Roche Service when required.

When there are already 500 problem reports in the folder and another problem report is added, the oldest problem report will automatically be deleted from the folder.

To retrieve a problem report

- 1 Open Windows File Explorer and go to "C:\Documents and Settings\All Users\Application Data\Roche DiagnosticsAG\ cobas4800SR{RELEASE_VERSION}\ProblemReport".
- **2** Copy the requested problem report to a portable storage device.
- **3** Send the problem report to Roche Service together with a detailed problem description.

To manually create a problem report

- 1 In the cobas 4800 software, choose Messages > Alarms.
- 2 Choose Report.
- **3** Retrieve the problem report as described above.
Remote support

In a remote support session, the **cobas** 4800 software is remotely operated by Roche Service. Call Roche Service to initiate a remote support session.

NOTICE

Do not operate the **cobas** 4800 software during a remote support session.

To initiate a remote support session

1 Request a remote support session at Roche Service.

Roche Service initiates a remote session. A message is displayed on screen asking to allow remote access on this computer.

2 Confirm the displayed message.

The remote support session starts. The session is terminated by Roche Service.

List of messages and tool tips within the sample editor

List of messages and tool tips within the sample editor

If an error happens while creating a work order file, the color of the box will change to red. If the boxes for microwell plate ID, DNA isolation kit ID (DNA sample preparation kit), reagent kit ID (BRAF V600 Mutation Test kit), and number of specimens are concerned, a tool tip is displayed. Move the mouse pointer over the red box to display the tool tip that gives information about the nature of the error.

If the error happens in the sample ID area, an error message will be displayed above the sample ID area, and no tool tip is displayed.



Figure D-4 Errors within the sample editor

The following table shows the messages and tool tips with an explanation or solution:

Error message	Solution / Comment	
The barcode cannot be read.	Scan the barcode once again.	
	• For information on handling the barcode scanner, see <i>Handheld barcode scanner</i> on page A-34.	
	If the error persists, type the barcode manually into the box. Contact Roche Service if you suspect that there is a problem with the handheld barcode scanner.	
Barcode is mandatory.	Scan the correct barcode or type it into the box.	
The reagent kit does not match the selected test.	Make sure to scan the barcode of the reagent kit (BRAF V600 Mutation Test kit) that belongs to the test you are about to run.	
At least one sample is required if a reagent barcode is entered.	Enter the correct number of specimens into the Specimens box.	
The DNA isolation kit does not match the selected test.	Make sure to choose the DNA sample preparation kit that belongs to the test you are about to run.	
All reagents must be from the same lot.	If you use more than one reagent kit (BRAF V600 Mutation Test kit), make sure that the reagent kits all belong to the same lot.	

List of messages and tool tips within the sample editor

Error message	Solution / Comment	
The reagent type is incorrect.	Make sure to enter the barcode of the correct DNA sample preparation kit into the DNA Isolation Kit-ID box. Enter the barcode of the correct reagent kit (BRAF V600 Mutation Test kit) into the correct Reagent Kit-ID box.	
Sample ID for <i>xy</i> is identical to <i>xz</i> . Enter unique Sample IDs.	You have entered a sample ID twice or more times into the Sample ID column. Make sure to enter the correct barcode for each sample.	
The MWP was previously used and cannot be used again.	The microwell plate was used in a previous run. Make sure to use a new microwell plate.	
Sample ID of <i>xy</i> exceeds 20 character maximum.	Make sure that the sample ID entered into the Sample ID column does not have more than 20 characters.	
Sample ID of <i>xy</i> must be at least two characters.	Make sure that the sample ID entered into the Sample ID column has at least two characters.	
No specimens were defined.	The Sample ID column must contain at least one sample ID. Enter the correct sample IDs.	
The reagent is expired.	Make sure to use only reagents that are not expired.	
Table D-5 Messages and tool tips in the sample editor		

List of error messages

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

Message code	Message source	Example
2.5. 10 .xx	Messages created by the cobas 4800 system.	2.5.10.22
2.5. 20 .xx	Messages created by the cobas z 480 analyzer.	2.5.20.13
2.5. 30 .xx	Messages created by the calculation module.	2.5.30.19
Table D-6	Message source	

The following table lists the user-relevant messages displayed in the **cobas** 4800 software.

<u>`</u>0́-

• If there is no user action stated in the message table, call Roche Service.

<u>2</u>-

Placeholders in the message table are printed in italics (e.g. xy).

ID	Severity	Message	Solution / Comment
2.5.10.10	Warning	Suboptimal monitor resolution detected. Optimal monitor resolution is 1280 x 1024.	Change the monitor resolution to 1280 x 1024.
2.5.10.12	Warning	Run could not be recovered.	Check the flags in the Results work area for more information. If unclear, contact Roche Service.
2.5.10.13	Warning	Run was successfully recovered.	The run was successfully recovered and samples are flagged.
2.5.10.17	Warning	Purge and archive aborted due to insufficient hard disk space.	Clean up hard disc D:\ manually by deleting files that are no longer needed. If unclear, contact Roche Service.
2.5.10.18	Warning	Purge and archive could not be completed.	Contact Roche Service.
2.5.10.19	Warning	Purge and archive could not create directory.	Define the Purge and Archive directory in the Configuration area. If the error persists, contact Roche Service.
2.5.10.21	Warning	On <i>HardDisk</i> is $x \text{ kB}$ of $y \text{ kB}$ free ($z\%$ full).	Archive and delete old data.
2.5.10.22	Error	On <i>HardDisk</i> is $x \text{ kB}$ of $y \text{ kB}$ free ($z\%$ full).	Archive and delete old data.
2.5.10.23	Warning	No analysis package installed.	Contact Roche Service.
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.
2.5.20.30	Error	Current optical filters are not supported on instrument <i>xy</i> .	Contact Roche Service.
2.5.20.31	Error	Wrong instrument block: <i>xy</i> .	Contact Roche Service.
2.5.20.32	Error	Instrument error has occurred.	Restart the analyzer. If the problem persists, contact Roche Service.
2.5.20.33	Error	The instrument software version <i>xy</i> is not supported.	Contact Roche Service.

 Table D-7
 Error messages

cobas[®] 4800 system

BRAF V600 Mutation Test

9 Troubleshooting and error messages

List of error messages

ID	Severity	Message	Solution / Comment
2.5.20.34	Warning	Connection to the following instrument has been lost: <i>xy</i> .	The analyzer is not switched on, not connected, or defective.
			Check connections between analyzer and control unit or switch on the analyzer. Then choose Refresh .
2.5.20.35	Error	Instrument error has occurred.	Instrument error. The run was aborted. Restart the analyzer. If the error persists, contact Roche Service.
2.5.30.40	Warning	Incorrect microwell plate loaded in instrument: <i>xy</i> . Expected microwell plate: <i>yz</i> .	The barcode of the loaded microwell plate does not match. Exchange the microwell plate for the one stated in the work order file.
2.5.30.41	Warning	MWP was used in a previous run. Please exchange MWP.	Microwell plate was used in a previous run. Exchange the microwell plate for an unused one.
2.5.30.42	Error	Microwell plate barcode could not be read.	Contact Roche Service.
2.5.30.43	Error	Algorithm definition file cannot be loaded.	Problem with algorithm definition file. Contact Roche Service.
2.5.30.44	Error	Algorithm definition file does not exist.	Contact Roche Service.
2.5.30.45	Warning	Wrong algorithm version.	The version of the algorithm file does not match the required version.
			Contact Roche Service.
2.5.30.46	Error	Run template data file is corrupted.	Contact Roche Service.
2.5.30.47	Error	Calculation parameter file cannot be loaded.	Contact Roche Service.
2.5.30.48	Error	An unknown error occurred. The run was aborted.	Restart the software. If the error persists, contact Roche Service.
2.5.30.49	Error	Calculation parameter file does not exist.	Contact Roche Service.

 Table D-7
 Error messages (continued)

List of error messages

BRAF V600 Mutation Test

Result flags

In this chapter the result flags are explained.

In this chapter	Chapter 10
About result flags	D-18
List of result flags	

About result flags

Flags are automatically generated with results if during processing certain technical checks were not passed, the result exceeds or does not reach predefined limits, or if technical or mechanical problems occurred during a run.

Results that do not have flags associated with them can be considered valid. However, not all results that have flags associated with them are incorrect. Some flags are warnings rather than error messages and do not necessarily invalidate the result(s).

The flags may originate from either the **cobas z** 480 analyzer, the **cobas** 4800 software, or the result interpretation.

► To display result flag information

- 1 Choose Results.
- 2 Select a result that has a flag entry in the Flags column.
- **3** Choose **Details**.

The details area is displayed. All flags that were generated for this result are displayed.



Figure D-5 How to display flag information

Each flag is identified by its flag code, and information on the nature of the reason for each flag is displayed.

List of result flags

Flag code starts with	Flag source	Example
М	Multiple or other reasons	M6
R	Result interpretation	R200
Z	cobas z 480 analyzer	Z1
Table D-8	Flag source	

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

The following table lists all result flags of the **cobas** 4800 system that are user relevant.

Flag code	Severity	Description	Recommended action
M1	Error	Software error. Additional information can be found in the alarm messages and the trace log files.	Check the alarm messages in the Messages area for more information. If unclear, contact Roche Service.
M2	Error	Aborted by the user.	
M3	Information	Privileged user performed a run without checks. The results cannot be used for patient diagnostics.	None. Flag is for information only.
M4	Information	Privileged user performed a run. The results cannot be used for patient diagnostics.	None. Flag is for information only.
M6	Warning	The run was recovered. Run results were retrieved by data recovery process. Use results with caution.	None. Flag is for information only.
M7	Information	The run was imported by a privileged user without checks.	None. Flag is for information only.
M8	Information	Privileged user performed a recalculation of the results.	None. Flag is for information only.
R200	Error	Mutant control invalid.	Repeat the run. Refer to the test-specific package insert.
R201	Error	Wild type control invalid.	Repeat the run. Refer to the test-specific package insert.
R202	Error	Mutant Ct not detected.	Repeat the specimen. Refer to the test-specific package insert.
R203	Error	Wild type Ct not detected.	Repeat the specimen. Refer to the test-specific package insert.
R204	Error	Mutant Ct out of range.	Repeat the specimen. Refer to the test-specific package insert.
R205	Error	Wild type Ct out of range.	Repeat the specimen. Refer to the test-specific package insert.
Z1	Error	Hardware or software error from the instrument. The run was aborted.	Contact Roche Service.

Table D-9 List of flags

This is the last page of Part D.

10 Result flags

List of result flags

BRAF V600 Mutation Test

Glossary E

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Glossary

A

AD plate Abbreviation for amplification and detection plate; synonymous with microwell plate.

Amplification The process of producing many DNA copies from one original DNA or RNA target region. PCR is a nucleic acid amplification technique.

Anneal The biochemical process of hybridizing or binding two segments of complementary nucleic acid.

С

Controls Reagent formulated to produce known results that are processed like samples. The **cobas** 4800 software monitors control results. Each run requires a wildtype and a mutant control.

Control unit A personal computer that runs the Microsoft Windows XP Professional operating system and the **cobas** 4800 software.

D

Denaturation The process of separating double stranded DNA into single strands by breaking the hydrogen bonds.

Detection Obtaining measurements to determine whether a sample is reactive for the target analyte. Fluorescence measurements are made at selected temperatures and times during the amplification process. When the run is complete data are analyzed to determine the presence of the amplified products from the target and internal control nucleic acid sequences.

DNA Deoxyribonucleic Acid (DNA) is the genetic material that is passed from parent to progeny and propagates the characteristics of the species in the form of genes it contains and the proteins for which it codes. DNA contains the following four nucleotides: dATP, dCTP, dTTP, and dGTP.

Μ

Microwell plate Plate used for amplification and detection. The 96-well plate is barcoded and has to be sealed with a special sealing film before inserting into the **cobas z** 480 analyzer. On the packaging label, the microwell plate is specified as AD plate.

MWP Abbreviation for microwell plate.

Roche Diagnostics

Р

PCR Polymerase Chain Reaction. The in vitro process used to amplify short specific target nucleic acid sequences. PCR is performed by cycling the temperature of the amplification mixture according to a set profile. The profile generally consists of denaturation and annealing.

Τ

Target The DNA or RNA target region that is detected and amplified during PCR.

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Revisions

This chapter contains the new contact addresses and the changed copyright information.

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