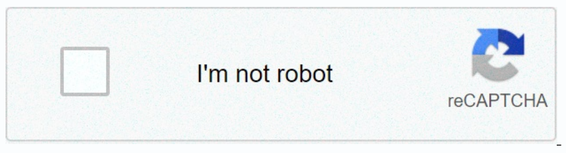

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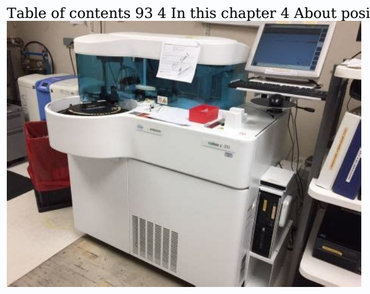

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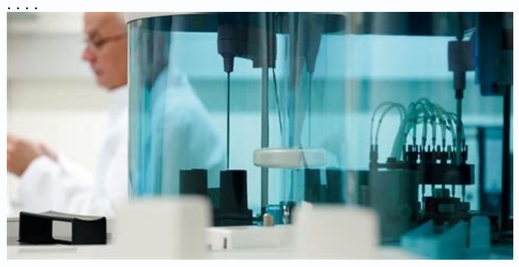

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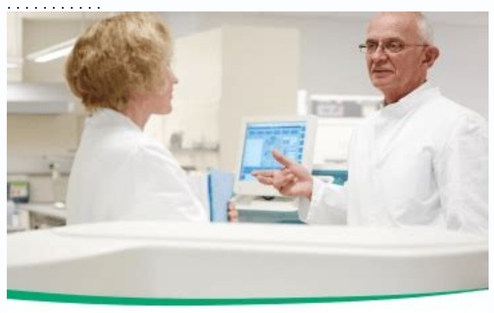

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Reagents in reagent packs A Gate for reagent packs B Reagent pack A B Reagents in reagent packs are used for photometric measurement, for special washing, and for maintenance.
They are located in the temperature-controlled reagent disk. You must load/unload reagent packs via the gate. Reagents in reagent packs are: • All photometric test reagents • Diluents (NaCl, A1CD2) • Detergents (NAOHD, SMS) • EcoTergent (mandatory reagent) Ecotergent is indicated as BathDet (water bath detergent) in the instrument software ISE reagents A B C ISE reagents are used for ISE measurement.
They are located in bottles between the reagent disk and the reaction disk. Reagents used for ISE measurement are: • ISE Internal Standard Gen.2 (ISE IS) • ISE Reference Electrolyte (ISE REF) • ISE Diluent Gen.2 (ISE DIL) A ISE DIL B ISE IS C ISE REF Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 96 About positions of reagents Evaporation of internal standard Downward drift in controls and patient sample results can occur due to increased evaporation of the internal standard. Evaporation of the internal standard can occur due to an unfavorable combination of: • Low humidity • High altitude • Air movement in the laboratory depending on the use of: - Air conditioning - Fans • Filling level of the internal standard In case of internal standard evaporation the use of a bottle insert for the internal standard is recommended.
For ordering the bottle inserts and information on the correct usage of the bottle inserts, please contact your Roche service representative. Calibrators A Sample container B CFAS A C ISE Standard (Low/High) B C Calibrators are prepared in sample containers and then placed on the sample disk. Calibrators used for photometric measurement are, for example: • CFAS • H 2 O Calibrators used for ISE measurement are: Long name Short name ISE Standard Low (S1) ISE Low (S1) ISE Standard High (S2) ISE High (S2) ISE Standard High (S3) ISE High (S3) y ISE calibrators Software ISELOW Std (1) Low ISEHIGH Std (2) High ISECOMP Std (3) Compensator Code 502 503 763 Controls A Sample container A B PCCC 1, PCCC 2 B Controls are prepared in sample containers and then placed on the sample disk. Controls used for photometric and ISE measurement are, for example: • PreciControl ClinChem 1 (PCCC 1) • PreciControl ClinChem 2 (PCCC 2) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 97 ISE washing reagents A A Sample container B Activator C SysClean Sample probe detergents B C The ISE washing reagents are placed on defined positions in the sample disk. The Reagent used for cleaning the ISE flow path is: • ISE cleaning solution (SysClean) SysClean is placed on position W1. The Reagent used for conditioning the ISE electrodes is: • ISE Activator (Activator) Activator is placed on position W2. A B Sample probe detergents are located in bottles next to the sample disk. Detergents used for washing sample probes are: • Sample Cleaner 1 (SmpCln 1) (Multiclean) • Sample Cleaner 2 (SmpCln 2) (SMS) A SmpCln 1 B SmpCln 2 Cell detergents A A CellCln 1 B B CellCln 2 Cell detergents are located in bottles behind the front door of the analyzer. Detergents used for washing cells are: • Cell Wash Solution I / NAOHD (CellCln 1) • Cell Wash Solution II / Acid Wash (CellCln 2) u Related topics • Loading reagent packs (101) • Unloading reagent packs (104) • Replacing ISE reagents (106) • Changing sample probe detergents (112) • Changing cell detergents (113) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 98 About statuses of reagents About statuses of reagents To ensure measurement, the required reagents must be on board and their fill level must be high enough.
Additionally, the reagent packs and the ISE reagents must have a valid calibration and QC.
The Reagent Preparing button and the Reagent Overview button indicate if a reagent is empty, missing, or below a set volume level by changing its color. u Defining reagent level alarms (116) From the System Overview menu, you can choose the Reagent Overview button. q To view the Reagent Overview button in the System Overview menu, you must choose AU or ISE in the Overview group box. The Reagent Overview dialog box displays the statuses of all reagents on board. You can check the remaining amounts, the calibration statuses, and the QC statuses. Reagent packs The Reagent group box displays the reagent disk with the 42 reagent packs and their statuses. In the center of the reagent disk, you can view detailed information on the selected reagent pack. If you want to view more detailed information, you can choose the Detail button. A B C A Reagent pack B Detailed information C Color legend A C A Reagent pack status C QC status B Calibration status Each reagent pack is divided into three sections displaying the following statuses: • Reagent pack status • Calibration status • QC status Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 99 Section Status Cas Reagent status Cal QC Calibration status Quality control status Color The color of each section displays the current status. Description Active Reagent currently in use. Warning Reagent remaining tests below yellow alarm level. Zero tests Reagent empty. Reagent available in another reagent pack. Caution Standby Reagent empty.
Reagent not currently in use. Free Pos. Reagent position empty. Expired Valid Expiration date exceeded. Calibration valid. Requested Calibration requested. Failed Calibration failed. Valid Quality control valid.
Requested Quality control requested. Violated Quality control failed. N.A. Quality control not applicable (no values available). y ISE reagents The ISE group box displays the fill level and the statuses of the ISE reagents ISE IS, ISE DIL, and ISE REF. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 100 About statuses of reagents A B C D Each ISE reagent is divided into four sections displaying the following statuses: • Fill level (remaining volume) as graphic display • Fill level (remaining volume) as amount (mL) • Calibration status • QC status A Fill level display C Calibration status B Fill level amount (mL) D QC status Section Status Cal Calibration status Color The colors of the calibration and QC sections display the actual statuses. Description Valid Calibration valid. QC Quality control status Requested Calibration requested. Failed Calibration failed. Valid Quality control valid. Requested Quality control requested. Violated N.A. Quality control failed. Quality control not applicable (no values available). y Detergents The Inventory group box displays the fill level of the detergents. A Fill level display A B B Fill level amount (mL) Each detergent is divided into two sections displaying the following statuses: • Fill level (remaining volume) as graphic display • Fill level (remaining volume) as amount (mL) Roche Diagnostics cobas c 311 analyzer

· Software version 01-10 · Operator's Manual · 3.1 Reagents 101 Loading reagent packs If the remaining volume of a reagent pack is low, or the expiration date has expired, you must replace it. To ensure measurement, you must scan and insert a new reagent pack, or a reagent pack that has been used on this analyzer before. ! WARNING Incorrect results due to the incorrect placement of a reagent pack If you insert a reagent pack the wrong way around, the reagent is pipetted in the wrong order, leading to incorrect results or system damage. r Always load the reagent packs in the direction shown on the label near the loading port. ! WARNING Incorrect results due to insufficient reagent volume When using a cobas c pack MULTI, it must be filled with the exact filling volume specified in the package insert. If this is not the case, measurement accuracy may deteriorate. Additionally, an alarm (reagent short) may occur if the analyzer detects that the reagent volume is low. r Ensure that the cobas c pack MULTI contains the correct filling volume. Refer to the package insert. The analyzer monitors the remaining volumes by counting down. When loading new reagent packs, the analyzer starts counting at the initial number of available tests. When loading reagent packs that have already been used, the analyzer continues counting at the last monitored number of available tests. If a reagent is empty, missing or below a set volume level, the Reagent Preparing button and the Reagent Overview button change their color to red, yellow, or purple. u Defining reagent level alarms (116) You can print a Reagent Load/Unload List report that shows the reagent packs to be loaded. u Preparing the reagents (79) j The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 102 Loading reagent packs 3 2 1 r To load reagent packs 1 Choose Reagent > Setting . 2 Press Ctrl and choose the reagents you want to load from the list. 3 Choose the Loading button. 4 5 4 Choose the Execute button. 5 Wait 1–2 minutes for the gate cover of the reagent disk to unlock. f You can see and hear the locking bar retract. 6 6 Open the gate cover. 8 7 7 With the reagent barcode label facing the barcode reader, put the reagent pack on the guide rail in front of the barcode reader. 8 To scan the reagent pack, slide the reagent pack along the guide rail to the rear stop. f The analyzer scans the barcode label on the reagent pack. f The analyzer checks if the corresponding test application is available.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 103 10 q The following data are encoded in this barcode: o System ID o Lot number o Cassette number o Expiration date o Bottle configuration information (reagent packs) 9 Wait for the reagent pack to be accepted. 10 With the barcode on the right side, load the reagent pack into the slot. 11 11 Close the gate cover. f The gate cover is locked automatically. 12 Wait up to 1 minute for the reagent pack to be registered.

If the reagent pack has not been on the analyzer before, the following actions are taken: • The analyzer registers the initial capacity. • The bottles of the reagent pack are pierced. f When the cassette is registered, you can see the cassette information in the Cassette Loading dialog box.

13 To finish loading, choose the End button. u Related topics • Defining reagent level alarms (116) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 104 Unloading reagent packs Unloading reagent packs If you need an empty position on the reagent disk for loading a new reagent pack, or if the reagent is empty or below a set volume level, you must unload a reagent pack. In Reagent > Setting , in the Remaining Tests column, you can check for empty reagent packs. You can print a Reagent Load/Unload List report that shows the reagent packs to be unloaded. u Preparing the reagents (79) j The analyzer is in Standby status. 1 r To unload reagent packs 1 Choose Reagent > Setting .

2 Press Ctrl and choose the reagent packs you want to unload from the list. 3 Choose the Unloading button. 2 3 4 5 4 Choose the Execute button. 5 Wait up to 1 minute for the gate cover of the reagent disk to unlock. f You can see and hear the locking bar retract. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 7 Reagents 105 6 6 Open the gate cover.

7 Unload the reagent pack. 8 8 Close the gate cover. f The gate cover is locked automatically. 9 Wait for the reagent pack to be deleted. f In Reagent > Setting the reagent pack information is deleted from the list.

10 10 To finish unloading, choose the End button. 11 Store the reagent packs in a refrigerated place or dispose them according to local regulations. I You can reload a used reagent pack onto the same analyzer at a later time.

However, after deleting a test, you cannot reload used reagent packs for this test. Note: You must delete the test and download it again to, for example, change the unit of measure.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 106 Changing ISE reagents Changing ISE reagents ISE IS Changing ISE reagents ISE REF ISE DIL If the remaining volume of an ISE reagent is low or the expiration date has expired, you must replace it. When replacing the ISE reagent ISE IS or ISE REF, you must perform a reagent prime. Before starting operation, you must calibrate the ISE measuring system for all replaced ISE reagents. 1 Replace bottle 2 Prime 3 Calibrate In this section Replacing ISE reagents (106) Performing a reagent prime (108) Performing an ISE calibration (109) Replacing ISE reagents If the remaining volume of the ISE reagent ISE IS, ISE REF, or ISE DIL is low, or the expiration date has expired, you must replace it with a new and full ISE reagent bottle to ensure measurement. After replacing the ISE reagent ISE IS, ISE REF, or ISE DIL, you must reset the reagent volume. If you replace ISE IS or ISE DIL, the liquid level is detected automatically before the first measurement. If you replace ISE REF, the reagent volume is monitored by countdown. ! WARNING Incorrect results due to ISE measurement failure r Perform ISE prime after resetting the ISE reagent volume. In the Reagent Overview dialog box, you can check the remaining volume of ISE reagents. You can print a Reagent Load/Unload List report that shows the ISE reagents to be replaced. u About statuses of reagents (98) Preparing the reagents (79) j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 107 1 r To replace ISE reagents 1 If necessary, insert the bottle insert into the new internal standard bottle. A B C 2 2 CAUTION! Incorrect result due to incorrect placement of reagents. Make sure to place the reagent bottles according to their correct positions. 2 Replace the corresponding bottle of ISE reagent with a new and full bottle.

A ISE DIL B ISE IS C ISE REF A B A Aspiration filter B ISE REF 3 3 If you replace the ISE REF bottle, clean the aspiration filter A in the tubing: • Take out the tubing from the bottle. • Unscrew the filter from the tube end. • Wash the filter with deionized water. • Then rinse the filter with deionized water. • Shake off the water. • Place the tubing in the new bottle, so that the end of the tube touches the bottom of the bottle. 4 Terminate Maintenance mode. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 108 Changing ISE reagents 6 5 5 Choose Reagent > Status . 6 On the Status tab, choose the changed ISE reagents. 7 Choose the ISE Volume Reset button. 7 8 8 To reset the fill volume to the level of a full bottle, choose the YES button. f The volume of ISE REF is displayed immediately. The volumes of ISE DIL and ISE IS are displayed with the next measurement. u Related topics • Cleaning the ISE REF aspiration filter (284) • Defining reagent level alarms (116) • Terminating the Maintenance mode (237) Performing a reagent prime When the tubing is disconnected from the ISE REF bottle, air may enter the electrodes. If the ISE IS bottle or the ISE REF bottle is replaced, the flow path must be filled with new liquid. In both cases, you must perform a reagent prime. n • IS+REF: approximately 10 minutes • REF: approximately 2 minutes d m IS+REF: ISE IS 9230 µ L, ISE REF 1690 µ L m REF: ISE REF 3120 µ L j The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 109 2 1 r To perform an ISE reagent prime 1 Choose Utility > Maintenance .

2 Select the (7) Reagent Prime option. 3 Choose the Select button. 3 4 5 7 4 Choose the Parameter button. 5 Select one of the following options: • To prime both the ISE measuring tubing and the ISE reference tubing, select the IS+REF option. • To prime the ISE reference tubing, select the REF option. 6 Choose the OK button. 7 Choose the Execute button. f The reagent prime is completed when the analyzer returns to Standby status. Performing an ISE calibration If you replace ISE IS, ISE REF, or ISE DIL, you must calibrate the ISE.

According to your specific working requirements, you can define two different ISE calibration curves (e. g., type A for urine and type B for plasma). The ISE calibrators can be used with or without barcode. During ISE calibration, the ISE internal standard (ISE IS) is measured additionally. d m Calibrators ISE Low (S1), ISE High (S2), and ISE High (S3) j ISE IS and ISE REF have been primed. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 110 Changing ISE reagents 2 3 1 r To perform an ISE calibration 1 Choose Calibration > Status . 2 From the Test column, choose ISE-A or ISE-B to select the calibration curve. 3 In the Method group box, choose the Full button. f The selected calibration method Full is displayed on the Calib. Method tab and highlighted green. f The Save button turns yellow. 4 4 Choose the Save button. f All tests with a highlighted green entry in the Calib. Method tab are requested for calibration.

5 6 5 To print the Calibration Load List report, choose the Print button. 6 Load the ISE calibrators onto the sample disk as indicated in the Calibration Load List report. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 7 7 Start the measurement. Reagents 111 8 8 Check the calibration results: • If the calibration is valid, unload the calibrators. • If the calibration fails, check the alarms and troubleshoot. Repeat the calibration for these tests. u Related topics • About manual calibration (126) • Assigning non-barcoded calibrators to sample disk positions (133) • Measuring calibrators and controls (84) • Measuring patient samples (88) • Checking calibration (132) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 112 Changing sample probe detergents A B Changing sample probe detergents If the remaining volume of a detergent bottle is low, or the expiration date has expired, you must replace it with a new and full detergent bottle to ensure measurement. The analyzer monitors the remaining volumes by counting down. After changing sample probe detergents, you must reset the initial reagent volume.

j The analyzer is in Standby status. 2 1 r To change sample probe detergents 1 In the sampling area, take out the corresponding sample probe detergent bottle. 2 Replace with a new and full sample detergent bottle. I Improper aspiration may occur due to foam or bubbles. Do not shake the detergent bottle.

A SMS B Multiclean 3 3 Choose Reagent > Status . 4 Choose the new sample probe detergent bottle. 5 Choose the Reagent Volume Reset button. f The Confirmation dialog box is displayed. 4 5 6 6 Choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 113 Changing cell detergents If the remaining volume of a detergent bottle is low, or the expiration date has expired, you must replace it with a new and full detergent bottle to ensure measurement. After changing cell detergents, you must reset the reagent volume. j The analyzer is in Standby status. r To change cell detergents 1 Take out the empty cell detergent bottle. 1 2 2 Clean the filter in the tubing: • Remove the tubing from the cell detergent bottle. • Unscrew the filter from the tube end. • Wash the filter with deionized water. • Then rinse the filter with deionized water. • Screw the filter back on to the tube end. 3 3 Take a new and full cell detergent bottle. 4 Insert the tubing into the cell detergent bottle so that it touches the bottom of the bottle. 4 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 114 Changing cell detergents 5 5 Position the new cell detergent bottle. 8 7 9 6 6 Choose Reagent > Status . 7 Choose the new cell detergent bottle. 8 Choose the Reagent Volume Reset button. f The Confirmation dialog box is displayed. 9 Choose the OK button. 10 Perform a cell detergent prime. u Related topics • Cleaning the detergent aspiration filters (286) • Performing a cell detergent prime (115) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 115 Performing a cell detergent prime When the tubing is disconnected from the cell detergent bottles, air may enter the tubing. Therefore, you must perform a detergent prime. j The analyzer is in Standby status.

1 r To perform a cell detergent prime 1 Choose Utility > Maintenance . 2 Select the (8) Cell Detergent Prime option. 3 Choose the Select button. 2 3 5 4 4 Select the detergent to be primed. • Detergent 1 = CellCln 1 • Detergent 2 = CellCln 2 5 Choose the Execute button. f The detergent prime is completed when the analyzer returns to Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 116 Defining reagent level alarms Defining reagent level alarms To ensure that there is sufficient reagent on board for measuring, you can define reagent levels at which an alarm is issued. Color of alarm Meaning A reagent is empty. The remaining tests of a reagent are below the defined reagent caution level. The remaining tests of a reagent are below the reagent level defined for a purple alarm. y Reagent level alarms If an alarm is issued, in the System Overview menu, the Reagent Preparing button and the Reagent Overview button change the color. q To view the Reagent Overview button in the System Overview menu, you must choose AU or ISE in the Overview group box.

Yellow alarm Purple alarm The red alarm is issued automatically. For yellow and purple alarms, you can define the alarm level for each reagent separately. • For test reagents, the alarm level refers to the remaining number of tests. • For ISE reagents, wash solutions, and diluents the alarm level refers to the remaining volume in mL. A yellow alarm is only issued if the reagent level alarm is defined for this test reagent, wash solution, or diluent.

A purple alarm is only issued under the following conditions: • The reagent level alarm has been defined for this test. • On the System Overview menu, the Preventive Action check box has been selected. It is recommended, that the purple alarm corresponds to the volume of reagents used in one day.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 3 Reagents 117 1 r To define a yellow reagent level alarm 1 Choose Utility > System 2 Choose the Page button until Page 2/5 is displayed on the button. 3 Choose the Reagent Level Check button. 2 4 6 8 4 In the Yellow Alarm group box, you can filter by reagent type: • The Assay option displays only test reagents. • The Without Assay option displays only wash solutions and diluents. 5 Choose the reagent for which you want to define a reagent level alarm. f The current alarm values are displayed in the Count column. 6 To activate the reagent level alarm for this test, select the Activate Alarm option. f The Yellow Check Update button turns yellow.

7 To change the alarm value of this test, enter the new value in the Activate Alarm group box. • For the reagent packs, the level alarm lies between 10-500 tests. • For ISE reagents, wash solutions, and diluents, the level alarm lies between 5-9999 mL. 8 To save the changes, choose the Yellow Check Update button. 9 To confirm, choose the OK button.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 118 Defining reagent level alarms 3 1 r To define a purple reagent level alarm 1 Choose Utility > System 2 Choose the Page button until Page 2/5 is displayed on the button. 3 Choose the Reagent Level Check button.

2 4 6 8 4 In the Purple Alarm group box, you can filter by reagent type: • The Assay option displays only test reagents.

• The Without Assay option displays only wash solutions and diluents.

5 Choose the reagent for which you want to define a reagent level alarm. f The current alarm values are displayed in the Count column. 6 To activate the reagent level alarm for this test, select the Activate Alarm option. f The Purple Check Update button turns yellow. 7 To change the alarm value of this test, enter the new value in the Activate Alarm group box. • For the reagent packs, the level alarm lies between 10-500 tests. • For ISE reagents, wash solutions, and diluents, the level alarm lies between 5-9999 mL. 8 To save the changes, choose the Purple Check Update button. 9 To confirm, choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 2 Publication information Publication version 1.0 1.1 2.0 3.0 3.0.1 3.0.2 3.1 y Revision history Software version Revision date 01-01 01-04 01-06 01-09 2007-11 2009-11 2010-12 2014-10 01-09 2016-07 01-09 01-10 2016-10 2016-12 Change description First version Addendum 3.0 implemented in Online help General update Documentation redesigned according to the new Roche documentation concept. Description of new software features added. Replacement pages with minor additions: o UltraVNC licence agreement o Electromagnetic compatibility statement o RoHS and Content symbol explanation Replacement pages with minor additions: o Fluorinated greenhouse gas o Safety message for incomplete display of test results in case the column is too narrow Description of new software features added (LCP3). License information and regulatory information updated. u What is new in publication version 3.1? (11) Edition notice Where to find information This publication is intended for operators of the cobas c 311 analyzer. Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication. The Online Help contains all information about the product, including the following: • Routine operation • Maintenance • Safety • Troubleshooting information • A software reference • Configuration information • Background information The Safety Guide contains important safety information.

You must read the Safety Guide before operating the instrument. The Operator’s Manual focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Training Images Warranty ! General attention To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system. r Pay particular attention to all safety precautions. r Always follow the instructions in this publication. r Do not use the instrument in a way that is not described in this publication. r Store all publications in a safe and easily retrievable place. Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives. The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes. Any customer modification to the system renders the warranty or service agreement null and void. For conditions of warranty, contact your local sales representative or refer to your warranty contract partner. Always leave software updates to a Roche Service representative or perform such updates with their assistance. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 3 4 Open Source and Commercial Software Trademarks Feedback Approvals The software is distributed without warranty. There is no implied warranty of merchantability or fitness for a particular purpose. For more information, see the GNU General Public License at .

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Contact your Roche representative, should you have any such feedback. The cobas c 311 analyzer meets the requirements laid down in: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity. The following marks demonstrate compliance: Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 For in vitro diagnostic use. Complies with the provisions of the applicable EU directives.

C ® US Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US. Fluorinated greenhouse gas The cobas c 311 analyzer complies with the emission and immunity requirements described in the standard IEC 61326-2-6 / EN 61326-2-6. The product contains a fluorinated greenhouse gas in the hermetically sealed refrigeration.

Type Charge weight (kg) R-134a 0.102 CO_2 equivalent (tonne) 0.14 y Fluorinated greenhouse gas detail Global warming potential 1430 5 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 6 Contact addresses Inside the European Union and EFTA member states Manufacturer of cobas c 311 instrument Authorized representative Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku Tokyo 105-8717 Japan Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany Outside the European Union and EFTA member states Manufactured by: Manufactured for: Hitachi High-Technologies Corporation Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Table of contents 7 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 8 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Intended use The cobas c 311 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in-vitro quantitative and qualitative determination of analytes in body fluids. The cobas c 311 analyzer is intended to be used by trained laboratory technicians. The operational environment for the cobas c 311 analyzer are clinical laboratories, hospital laboratories and commercial hospitals, as well as private laboratories. Symbols and abbreviations Product names Symbols used in the publication Except where the context clearly indicated otherwise, the following product names and descriptors are used. Product name cobas c 311 analyzer cobas c pack y Product names Descriptor analyzer reagent pack n d j u r I f c p w o u Symbol q y z Explanation List item Related topics containing further information Tip.

Extra information on correct use or useful hints. Start of a task Extra information within a task Result of a user action within a task Frequency of a task Duration of a task Materials that are required for a task Prerequisites of a task Topic. Used in cross-references to topics. Task. Used in cross-references to tasks. Figure. Used in figure titles and crossreferences to figures. Table. Used in table titles and cross-references to tables. Equation. Used in cross-references to equations. y Symbols used in the publication Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 9 10 Symbols used on products Symbol Explanation Global Trade Item Number Quantity contained in the package Quantity contained in the package Orientation of the package during transportation Abbreviations Complies with the directive 2011/65/EU on RoHS CSV EC EFTA EN IEC IVD LIS n/a QC SBS SD WEEE y Symbols used on products The following abbreviations are used. Abbreviation ANSI COBI Definition American National Standards Institute Compendium of Background Information comma separated values European Community European Free Trade Association European standard International Electrical Commission In vitro diagnostic Laboratory information system not applicable Quality control scan before sample stop Standard deviation Waste Electrical and Electronic Equipment y Abbreviations Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 What is new in publication version 3.1? Filter function for Reagent Level Check Improved Review By Exception data alarm setting Data alarms for serum index checks Improved handling of invalid reagent packs Chapter structure From software version 01-10 on, you can filter the reagents by type on the Reagent Level Check window. The filter function allows you to only display diluents and wash solutions. This function simplifies setting the reagent level check values for the yellow and purple alarm. In addition, separate reagent level check values are now available for each diluent and wash solution. u Defining reagent level alarms (116) On Utility > System > Page 4/5 > Review By Exception , you define which data alarms prevent a test result from being sent to the Host computer. In version 01-10, the software has been improved so that all data alarms are now available on the Review By Exception window. Seven new data alarms have been implemented in software version 01-10. These data alarms provide more detailed information about a possibly problematic serum condition: lipemic, hemolytic, or icteric samples, or a combination thereof. Former software versions attached only the generic >Index data alarm to results generated from a lipemic, hemolytic, or icteric sample. In some cases, you must delete an application and download it again, for example, to change the unit of measure. You can no longer use reagent packs for this application that were already in use on the system before deleting the application.

u Unloading reagent packs (104) The chapter structure was slightly adapted to be consistent with other Roche publications. For example, the chapter Specifications was moved to Part Appendix . u Specifications (355) 11 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 12 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Operation Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument Table of contents 15 1 Read this chapter to get familiar with the hardware of the instrument. In this chapter 1 About the c 311 analyzer.
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 16 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument 17 About the c 311 analyzer The cobas c 311 analyzer is an automated system for qualitative and quantitative in vitro diagnostics. The ionselective electrode (ISE) and the photometric measurement unit provide a wide variety of tests.

The cobas c 311 analyzer consists of the following units: • Analytical unit • Control unit A Analytical unit A B Control unit B Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 18 Overview of the hardware Overview of the hardware The cobas c 311 analyzer is a standalone device. For a smooth operation, it is important to have access to all parts of the analyzer. In this section Top view (18) Front view (20) Front view with open front door (21) Rear view (23) Top view You can access most of the components of the analytical unit from the top when opening the top cover. A B Sampling area Reaction area A B C ISE area D Reagent area C D Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument 19 Sampling area Reaction area ISE area Reagent area Samples are manually loaded to the sample disk. They are scanned or placed to a manually assigned position. That way, they are identifiable and easy to follow. From the sampling area, samples are pipetted to the reaction or ISE area. A photometric measuring system measures the absorbance of the reaction mixture in reaction cells on the reaction disk. An ion-selective electrode measuring system measures the electromotive force (EMF) in millivolts between the electrode in the diluted sample solution and the electrode in the reference solution. The electrodes are selective for CL - , K + , and Na + . Reagent packs are manually loaded to the reagent disk. They are scanned and stored in a refrigerated compartment. From the reagent area, reagents are pipetted to the reaction area. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 20 Overview of the hardware Front view You can access most of the components of the control unit from the front.

A B C D E A Touchscreen monitor B Keyboard/mouse C Height adjusting lever Touchscreen monitor Keyboard/mouse Height adjusting lever Personal computer F D Personal computer E Front door F Cooling unit The touchscreen monitor displays information.

You can navigate through the software and start the analyzer functions. With the keyboard or the mouse, you can navigate through the software and select or enter information. If you lift the height adjusting lever, you can adjust the height of the touchscreen monitor. The personal computer monitors the functions and operational modes of the analyzer. The installed software has a graphical user interface (GUI) that allows you to control all analyzer functions. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument 21 Printer (optional) Front door Cooling unit If a printer is connected, you can print the results. Some components of the analytical unit are located behind the front door. The cooling unit cools the reagent packs in the refrigeration compartment. Front view with open front door You have to open the front door to access some components of the analytical unit. F A B C G H D E A Reagent syringe B Sample syringe C ISE sipper syringe D Cell cleaner I Reagent syringe E Cell cleaner II F Alarm volume knob G Water tank H Drain tube of the vacuum tank The reagent syringe controls the pipetting of reagent to the reaction cells. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 22 Overview of the hardware Sample syringe ISE sipper syringe Cell cleaner I Cell cleaner II Alarm volume knob Water tank Drain tube of the vacuum tank The sample syringe controls the pipetting of sample to the reaction cells. The ISE sipper syringe controls the pipetting of diluted samples from the reaction cells and the pipetting of ISE reagents to the ISE unit. Cell cleaner I (CellCln I) contains alkaline detergent (NaOH-D) for the cell rinse process. Cell cleaner II (CellCln II) contains acid detergent (acid wash) for the cell rinse process. You can adjust the sound volume of the alarm buzzer with the alarm volume knob. Deionized water supplies the cell rinse unit, the rinse stations, and the incubator bath. The reaction cells are emptied with vacuum: • The reaction mixture is aspirated and emptied into the highly concentrated waste container. • The reaction cell rinse water is aspirated and drained through the diluted waste line. With the drain tube, you drain remaining liquid from the vacuum tank. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument 23 Rear view Some components are located at the rear side of the analyzer. A B C D E A Cooling fan B Power supply outlets (US only, behind cover) C Ethernet connector D Mains connection E Main circuit breaker Cooling fan Power supply outlets (US only) Ethernet connector Mains connection Main circuit breaker F Water supply tube G ISE drain port H Waste line I Waste container J Condensation water tray The cooling fan cools down the analytical unit. The power supply outlets energize the control unit in case the power cable is too short to reach an external power source.

They are located behind a cover. There are two power supply outlets for the control unit. One is for the PC, and the other is for the monitor. The Ethernet connection allows communication between the analytical and the control unit. The mains connection energizes the analytical unit. The main circuit breaker powers the analyzer on and off. You should keep it switched on to cool the reagents. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 J I F G H 24 Overview of the hardware Water supply tube ISE drain port Waste line Waste container Condensation water tray The water supply tube supplies deionized water for diluting samples and for washing. This ISE drain port discharges highly concentrated waste. The waste line collects diluted liquid waste, for example, reaction bath liquid and detergents. The waste container collects highly concentrated liquid waste from the ISE unit.

A liquid level sensor controls the level of the liquid waste and issues an alarm if the container gets full. The condensation water tray collects water condensing at the cooling unit. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of the instrument 25 Overview of the power switches You can switch on and off the entire analyzer or parts of the analyzer. In this section Main circuit breaker (25) Power and maintenance switches (26) Main circuit breaker With the main circuit breaker, you switch on and off the entire analyzer, including the reagent cooling unit. A A Main circuit breaker Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 26 Overview of the power switches Power and maintenance switches With the power and maintenance switches, you switch on and off special areas of the analyzer. A B C A Power switch for the analytical unit B Maintenance switch Power switch for the analytical unit Maintenance switch Power switch for the control unit C Power switch for the control unit With the power switch for the analytical unit, you switch on and off the analytical unit except for the reagent cooling unit. With the maintenance switch, you switch on and off the low voltage of the pipetters, the sample disk, and the reaction disk. With the power switch for the control unit, you switch on and off the personal computer. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation Table of contents 27 2 In this chapter 2 Overview of the user interface . . . . .
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 28 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 29 Overview of the user interface To operate the analyzer, you must be familiar with the user interface. In this section About screen sections (29) About the System Overview menu (32) About the main menus (34) About status colors (37) About buttons (38) List of analyzer statuses (39) List of keyboard shortcuts (40) About screen sections A D B A B C Status line Menu area C Help line D Global buttons Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 30 Overview of the user interface Menu area – System Overview The user interface is divided into four sections: • Menu area • Status line • Help line • Global buttons The menu area displays the System Overview menu or one of the five main menus.

To operate the user interface, use the touchscreen, mouse, or keyboard. The System Overview menu is the root menu of the user interface. You start daily work from this menu. u About the System Overview menu (32) Menu area – main menu In the five main menus you enter, update, and evaluate data. u About the main menus (34) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 31 Status line The status line contains the following information: • Status of host, core unit, and analytical unit • Analyzer status • Logon name • Date and time When performing a maintenance task, the status line also displays the remaining time. Help line The color-coded buttons in the status line are only displayed with the main menus. The color of each button indicates the status of the respective module.

Host Core AU Indicates communication status between the analyzer and the LIS. Indicates status of the core unit of the analyzer.
Indicates status of the analytical unit. The Host button is displayed only if an LIS is connected. u About status colors (37) List of analyzer statuses (39) The help line contains the Help button and a hint. To display the online help, choose the Help button. The online help is context-sensitive and contains the full Operator’s Manual and the Software Description . Hints depend on the location of the cursor and suggest actions or types of information to enter.
u Using the online help (42) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 32 Overview of the user interface Global buttons Global buttons provide quick access to key functions of the analyzer. Stop Shutdown S.Stop Alarm Media Eject Print Pause/Scan Start To stop operation in case of emergency. To log off, start Sleep mode, or shut down the analyzer. To stop sampling. The analyzer completes measuring already pipetted samples. To display the list of current alarms. If an alarm was issued, the Alarm button flashes yellow or red. To disconnect a USB flash drive. To print predefined lists and reports. To pause sampling, for example, to insert a STAT sample. To scan the sample containers on the sample disk. To start sampling. u Related topics • About the System Overview menu (32) • About the main menus (34) • About status colors (37) • List of analyzer statuses (39) • Using the online help (42) About the System Overview menu The System Overview menu is the root menu of the user interface. You start daily work from this menu. System Overview You use the System Overview menu to prepare the analyzer for daily operation. The menu also displays information about the modules of the analyzer and provides access to the five main menus. u About the main menus (34) Quick start guide (58) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 33 Work Flow Guide The Work Flow Guide group box supports daily routine tasks. From left to right, six buttons represent tasks required during daily operation. If a button turns yellow or red, you must act. To display the dialog box for the required action, choose the respective button. u About status colors (37) Overview group box The Overview group box contains color-coded status information on each module of the analyzer. To display status information, choose one of the following buttons: Host To display the status of the LIS (if connected). Core Control Unit AU To display the status of the core unit. To display the status of the control unit. To display the status of the analytical unit. ISE Alarm To display the status of the ISE unit. To display the Alarm dialog box. Reagent Overview To display the Reagent Overview dialog box. Main menu buttons To display a main menu, choose one of the following buttons: Workplace Reagent Calibration QC Utility To display the Workplace menu. To display the Reagent menu. To display the Calibration menu. To display the QC menu. To display the Utility menu.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 34 Overview of the user interface u Related topics • About screen sections (29) • About the main menus (34) • About status colors (37) • Quick start guide (58) About the main menus Main menu buttons In the five main menus, you enter, update, and evaluate data. To display one of the five main menus, choose one of the following buttons in the System Overview menu: • Workplace • Reagent • Calibration • QC • Utility Workplace menu The Workplace menu has the following submenus: Test Selection To order tests for samples.
Data Review To review and manage test results. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 35 Reagent menu The Reagent menu has the following submenus: Setting Status To load and unload reagents. To check the number of available tests and to reset the volumes of sample cleaners, cell cleaners, and ISE reagent. Calibration menu The Calibration menu has the following submenus: Status Calibrator Install To review calibration status. To assign a non-barcoded calibrator to a position on the sample disk. To add a calibrator. To update calibrator data. QC menu The QC menu has the following submenus: Status Run Status Individual Cumulative Control Install To view QC statuses. To view recent QC measurements. To view the individual QC chart. To view the cumulative QC chart. To assign a non-barcoded control to a position on the sample disk. To add a control and to update QC data. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 36 Overview of the user interface Utility menu Return to System Overview The Utility menu has the following submenus: System To configure the basic settings of the analyzer, for example, the use of sample disk positions. To page through the five pages of the submenu, choose the Page 1/5 button. Maintenance To select and monitor maintenance tasks. Application To download test applications from cobas link. Calc. Test To define formulas for calculated tests. Special Wash To program special wash instructions for the sample probe, reagent probe, and the reaction cells. Report Format To define the patient report form. Module Set To assign tests to the analyzer.
If you have an operator level password only, you cannot edit all the settings. To return to the System Overview menu, choose one of the buttons in the status line. u Related topics • About screen sections (29) • About the System Overview menu (32) • About Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 37 About status colors Status colors in System Overview To assure smooth operation of the analyzer, you must pay attention to the status colors. Status colors alert you to take timely action.
Status colors are used in the Work Flow Guide group box and the Overview group box of the System Overview menu. Status colors in status line Status colors are also used in the status line above the main menus. Color coding The general meaning of the colors is as follows: Module in operation or maintenance mode. Module in standby mode. Action needed today (only for reagent preparing). Action needed soon. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 38 Overview of the user interface Action needed immediately. Examples The communication with the host is operational. The analytical unit is in standby mode.
A test reagent volume, diluent volume, or detergent volume is below the daily requirement. A calibration or quality control is needed soon. The core unit reports an alarm at stop level. About buttons Button shapes Buttons have different shapes.
Each shape represents a specific function. The following shapes are used for buttons. Global button. Provides quick access to key functions of the analyzer. Executes the function indicated on the button. Executes the function indicated on the button and closes the dialog box. Displays the dialog box or menu indicated on the button. Workflow button on the System Overview menu. Displays the dialog box or menu related to the specific workflow step. Button in the status line. Displays the System Overview menu. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 39 Sort button in the column header. Sorts list by the column. Not all columns have this button. Examples Global button. Displays the Alarm dialog box. Red indicates that immediate action is needed. Saves changes in a dialog box or menu. Yellow indicates that you changed some settings and must now save those. Confirms a selection and closes the dialog box. Displays the Reagent Overview dialog box. Red indicates that immediate action is needed. Workflow button on the System Overview menu. Displays the Sample Tracking dialog box. Button in the status line. Displays the System Overview menu. Sort button in the header of the reagent, calibrator, and control status lists. Sorts these lists by test name.
A white sort button marks the column that the list is sorted by. u Global buttons (32) List of analyzer statuses The analyzer status (mode) is displayed in the status line. The following list describes the analyzer statuses: Power Up The analyzer is loading programs, performing self-checks, etc. Initialize Standby After power-up, the analyzer initializes itself. The analyzer is ready for operation, but is not pipetting, measuring, or performing an automatic maintenance task. Preparation The analyzer is preparing for operation, for example, washing cuvettes. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 40 Overview of the user interface Operation Sample Reception Mode The analyzer is pipetting and measuring. After tests are completed, the analyzer is waiting for more samples. Sampling Pause Sampling Stop Stop The analyzer pauses sampling. You may load more samples on the sample disk. The analyzer has finished pipetting and is still measuring the samples. Standby (yellow background) The maintenance switch is on. The analyzer is in maintenance mode. You may open the top cover as all components on top are switched off.
Shutdown The analyzer has performed an emergency stop due to hardware failure, or because any of the safety devices requested an emergency stop. The analyzer requires either a complete power-off or a reset (Utility > Maintenance) to resume operation. The analytical unit and the control unit are disconnected from the power supply. However, power for cooling the reagents is supplied.
u Related topics • Status line (31) • About Maintenance mode (236) List of keyboard shortcuts F6 F7 F4 F5 F1 F2 F3 F8 F9 F10 F11 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 For quick access to frequently used menus and dialog boxes, use the following keyboard shortcuts: To display the online help. To display the Start Conditions dialog box. To display the Sample Stop dialog box. To display the Stop dialog box. To display the Workplace menu. To display the Reagent menu. To display the Calibration menu. To display the QC menu.
To display the Utility menu. To display the Sample Tracking dialog box.
To display the Alarm dialog box. Overview of operation 41 F12 To display the System Overview menu. Print Screen To display the Print dialog box. To take a screenshot, press Shift + Print Screen. Scroll Lock To display the Cancel Print dialog box. Pause/Break To display the Shutdown dialog box. Esc To exit a dialog box. u Related topics • Global buttons (32) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 42 Using the online help Using the online help To find information quickly, use the online help. The online help comprises the full Operator’s Manual and the Software Description . In this section Displaying the online help (42) Searching the online help (42) Using favorites in the online help (45) Displaying the online help 1 The online help is context-sensitive. It contains detailed information about the current menu or dialog box. r To display the online help 1 Navigate to a menu or dialog box you need information about, for example, choose Calibration > Status . 2 Choose the Help button or press F1. 2 Searching the online help To find information in the online help, pick one of the following search methods. In this section Searching via table of contents (43) Searching via index (43) Searching the full text (44) Full-text search options (44) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 43 Searching via table of contents 1 To find a topic you know about, search via the table of contents. r To search via table of contents 1 In the online help, choose the Contents tab. 2 On the navigation pane, choose the desired chapter and topic. 2 Searching via index 3 2 1 To find a key word presumably included in the index, search via the index. r To search via index 1 In the online help, choose the Index tab. 2 In the text box, type a key word. f A list of matching index entries is displayed. 3 Choose the desired index entry. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 44 Using the online help Searching the full text 2 1 To find any word or phrase, search the full text. r To search the full text 1 In the online help, choose the Search tab. 2 In the text box, type the word or phrase you are looking for. 3 4 Full-text search options 3 Choose the List Topics button. f A list of matching topics is displayed. 4 Choose the desired topic. For an advanced full-text search, use the following logical operators and search options: AND OR NEAR NOT To search for more than one word or phrase in a topic, use this operator. To search for any of two words or phrases in a topic, use this operator. To find words within ten words of each other, use this operator. To exclude topics with a particular word from the search, use this operator. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 45 Search previous results Match similar words To limit your search to the previous result list, select this check box. To find similar words and phrases, for example, plural forms, select this check box. Search titles only To search in titles only, select this check box. Using favorites in the online help To revisit topics easily, use favorites.
In this section Adding a favorite (45) Displaying a favorite (46) Adding a favorite To create a list of favorites, add your favorite topics to the list. 1 r To add a favorite 1 In the online help, navigate to the topic you want to revisit later. 2 2 Choose the Favorites tab. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 46 Using the online help 3 3 If you want to rename the topic for the list of favorites, enter a new topic title in the text box.
I To organize the list of favorites, use a prefix for topic titles (e.g., 1_Workplace topic X , 2_Reagent topic Y). 4 Choose the Add button. f A new favorite is added to the list of favorites. Displaying a favorite 1 r To display a favorite 1 In the online help, choose the Favorites tab. f The list of favorites is displayed. 2 Choose the desired favorite. 2 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 47 Overview of cobas link cobas link facilitates your work in several ways: • Automatic downloads of current applications, calibrators, and controls from the Roche remote service platform to your cobas instrument • Quick access to instructions for use, value sheets for calibrators and controls, etc. in cobas e-library • Electronic archiving of e-library package inserts and instrument settings • Automatic backup of instrument data to the cobas link data station • Upload of statistical data from the cobas instruments for performance monitoring and QC management • Screen sharing with a Roche Service representative for troubleshooting and support In this section About cobas link (48) About the cobas link information flow (50) About cobas e-library (52) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 48 Overview of cobas link About cobas link To access the Roche remote service platform, your cobas instruments must be connected to a cobas link. Remote service platform Remote service platform Internet cobas link c311 The Roche remote service platform provides information services for you and your cobas instruments via a secure Internet connection. The following applications are available: cobas e-library cobas e-support Automatic download of the most recent information on applications, calibrators, and controls. Screen sharing with a Roche Service representative for troubleshooting and support. cobas e-LabPerformance Upload of statistical data from the cobas instruments for performance monitoring and QC management.
These applications are referred to as cobas e -services.
cobas link Remote service platform Internet cobas link cobas link is a software package running on a dedicated computer in the laboratory, the cobas link data station. The data station and the software are together referred to as a cobas link. A cobas link connects one or more cobas instruments to the remote service platform. cobas links are set up and configured by a Roche Service representative.
The cobas link is connected to the control unit of the cobas c 311 instrument. c311 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 49 Remote service platform Offline mode cobas link In offline mode, the cobas link has no connection to the Internet. The cobas link cannot download information from the remote service platform or upload information. Software patches for cobas link are implemented via update DVDs. cobas e-library is updated via update CDs. The cobas link releases electronic barcodes to the instruments. The cobas link stores backups of the instrument data.
c311 Remote service platform Online mode Internet cobas link In online mode, the cobas link has a stable connection to the Internet and connects the instruments in the laboratory to the remote service platform. The cobas link downloads information from the remote service platform and releases it to the instruments. The cobas link collects information from the instruments and uploads it to the remote service platform. u Related topics • About the cobas link information flow (50) • About cobas e-library (52) c311 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 50 Overview of cobas link About the cobas link information flow The information flow between the Roche remote service platform and the cobas link, and between the cobas link and the cobas instruments is bidirectional. Downloads from remote service platform Remote service platform Remote service platform Downloads from the remote service platform include the following: • cobas e-library packages: contain e-library package inserts and e-barcodes. • cobas link software updates Internet cobas link e-library package inserts e-barcodes The following documents come as e-library package inserts: • Instructions for use • Value sheets for calibrators and controls • Important notes, for example, about reassigned control values • Announcements from the local technical support You can read e-library package inserts in the cobas e-library application on the cobas link data station. u About cobas e-library (52) e-barcodes contain machine-readable information for cobas instruments: • Test-specific instrument settings • Lot-specific instrument settings • Values of calibrators and controls e-barcodes are stored on the cobas link data station. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 51 Parameter downloads from cobas link cobas link The instrument software indicates whether you must download new e-barcodes from the cobas link to the control unit of the instrument. c311 You must download e-barcodes if the Parameter Download button of the System Overview menu is red.
u Downloading parameters from cobas link (86) Uploads to cobas link cobas link c311 A daily backup of the instrument data must be uploaded to the cobas link. • The backup is performed automatically if the cobas link Essential Information Upload maintenance item is included in the daily maintenance pipe. • cobas link stores the last five backups. • The backups are used to restore the control unit of the instrument, for example, in case of a hard disk crash.
u List of maintenance items (251) u Related topics • About cobas link (48) • About cobas e-library (52) • Downloading parameters from cobas link (86) • List of maintenance items (251) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 52 Overview of cobas link About cobas e-library The cobas e-library application is an electronic archive running on the cobas link data station. You must check daily the list of new entries for the latest cobas e-library inserts. w cobas e-library user interface Access to cobas e-library Content of cobas e-library e-library packages You can access cobas e-library on the cobas link data station. For each application, calibrator, and control, cobas e-library contains the latest version of the respective e-library package and the preceding version. Any older e-library packages are deleted from the cobas e-library. cobas e-library is updated daily via an automatic download from the Roche remote service platform. e-library packages contain e-library package inserts and e-barcodes: • e-library package inserts are for your information. • e-barcodes contain machine-readable parameters and are downloaded to the cobas instruments. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of operation 53 e-library package inserts The following documents come as e-library package inserts: • Instructions for use • Value sheets for calibrators and controls • Important notes, for example, about reassigned control values • Announcements from the local technical support List of new entries In the New Entries menu, the list of new entries is limited to 200 entries. Entries are not older than 30 days. You can filter the list, for example, for unread documents related to your cobas instrument. To find entries older than 30 days, you must search the cobas e-library archive. Other features of cobas e-library Other features of cobas e-library include the following: Comment Search Preferences You can comment on documents, for example, with your initials, to mark a document you have read. You can search for documents, for example, via the catalogue number on a reagent cassette. You can define preferences about documents that you want to see displayed in the New Entries menu.
Online help To display the online help, choose the Help button on the bottom left of the cobas e-library screen.
The online help is context-sensitive and contains the Operator’s Manual on cobas e-library. u Related topics • About cobas link (48) • About the cobas link information flow (50) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 54 Overview of cobas link Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation Table of contents 55 3 In this chapter 3
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 56 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 57 Overview of the main workflow The following chart summarizes the quick start guide. 22 19 Top (Standby mode) Measure patient samples Load/unload reagents Software FREDVFPDLQZRUNÁRZ Top (Maintenance mode) Back Front/side 1 Enter logon data 2 Check photometer report 3 Check syringes and tubing system 5 Check for water splashes 4 Switch to maintenance mode 21 Perform recommended calibration and QC 20 Download parameters from cobas link 6 Clean analyzer surface 7 Check reaction cell covers 13 Perform other due maintenance 8 Clean cell rinse nozzles 12 Empty liquid waste container 18 Clear sample database 17 Perform softwarecontrolled maintenance tasks 16 &KHFNZRUNÁRZ buttons 15 Check system alarms 9 Clean shield pipe 10 Clean probes and ISE sipper 11 Clean ISE drain port 14 Terminate maintenance mode u Related topics • Quick start guide (58) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 58 Quick start guide Quick start guide Step 1 Enter your logon data. Assumption To prepare the analyzer for daily operation, you must perform the following steps.
The system has performed software-controlled maintenance in form of a wake-up pipe or power-up pipe. User action 2 3 4 5 Check photometer report. Check syringes and tubing system. Switch to maintenance mode. Check for water splashes. y Quick start guide Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 The photometer report may indicate a problem with the reaction cells, the photometric window, or the photometer lamp. 1. Choose Print > Utility > Photometer Check > View . 2. Make sure that absorbance values do not exceed 14 000. 3. Make sure that current values do not differ significantly from previous results.
If the values do not match, please refer to the corresponding maintenance procedures. Syringe problems cause inaccurate pipetting. 1. Open the front door. 2. Make sure that no syringe is leaking. 3. Make sure that there are no air bubbles in any of the syringes. 4. Make sure that there is no leakage in the tubing system. Before opening the top cover, you must switch to maintenance mode. 1. Make sure that the analyzer is in standby mode. 2. Switch the maintenance switch to Maintenance mode. The status line turns yellow. Water splashes after the wake-up pipe indicate a clogged probe. 1. Open the top cover. 2. Make sure that there are no splashes around the rinse station of the sample probe. 3. Make sure that there are no splashes around the rinse station of the reagent probe. Step 6 Clean analyzer surface.
7 Check reaction cell covers. 8 Clean cell rinse nozzles. 9 Clean shield pipe. 10 Clean probes and ISE sipper. 11 Clean ISE drain port. y Quick start guide Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 59 User action Clean the analyzer surface using a cloth or paper towel moistened with disinfectant. Make sure that the reaction cell covers are clean. Wipe all cell rinse nozzles towards the tip with a gauze pad moistened with deionized water. Wipe the shield pipe with a gauze pad moistened with alcohol. Clean the sample probe, reagent probe, and sipper nozzle with gauze pads moistened with alcohol. Rinse the outlet of the ISE drain port with deionized water. 60 Quick start guide Step 12 Empty liquid waste container. 13 14 15 Perform other due maintenance. Terminate maintenance mode. Check system alarms. 16 Check workflow buttons.
17 Perform software-controlled maintenance tasks. y Quick start guide Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 User action Make sure that the liquid waste container is empty, clean, and properly installed. Perform any weekly, monthly, etc., maintenance tasks that are due and operator-controlled.
1. Close the top cover. 2.
Switch the maintenance switch to Operation mode. 3. Choose Utility > Maintenance > Reset . 1. Choose the Alarm button. 2.
Perform the recommended remedies until all alarms are removed. On the System Overview menu, check which workflow buttons are displayed in yellow or red. The purple reagent alert is displayed only if the Preventive Action check box is selected. The following steps depend on the status color of the workflow buttons. If the Daily Maintenance button is yellow or red, perform the following: 1. Choose the Daily Maintenance button. 2. Perform all required maintenance tasks. Step 18 Clear sample database. 19 Load/unload reagents. 20 Perform recommended calibration and QC. 21 Download parameters from cobas link. y Quick start guide Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 61 User action For fast database access, you must clear the sample database at the beginning of your shift. 1. Choose the Sample Data Clear button. 2. Select the appropriate clear option depending on your data policy. If the Reagent Preparing button is purple, yellow, or red, perform the following: 1. Choose the Reagent Preparing button. 2. Print the Reagent Load/Unload List . 3. Unload/load the reagents according to the report. If the Calibration and QC Select button is yellow: 1. Choose Calibration and QC Select > Recommended .
2. If a start-up group is defined, choose the Start Up button to request calibration for this group as well. 3. If the last shift started less than 24 hours ago, request the ISE calibration manually. 4. Choose the Routine QC button. 5. Choose the Stand By Bottle QC button. 6. Print the load lists for the recommended calibrators and controls. 7. Place the calibrators and controls on the sample disk.
Use only fresh calibrators and controls. 8. Start the calibration and QC measuring process. 9. Check the calibration results. If the Parameter Download button is red, perform the following: 1. Choose the Parameter Download button. 2. Download the required parameters. 3. Repeat the calibration and QC measurements for the corresponding tests. 62 Quick start guide Step 22 Measure patient samples. y Quick start guide User action The following procedure assumes that test orders are sent from an LIS. 1.
Deselect the Preventive Action check box. 2. Check that the green ACCESS SAMPLE DISK lamp is on. 3. Place the sample containers into the appropriate sample disk positions. 4.
Start the measuring process. 5. To track sample processing, choose System Overview > Sample Tracking .
6. To review results, choose Workplace > Data Review > Test Review . u Related topics • Starting from Sleep mode (63) • Starting from power-off (70) • Preparing the analyzer for operation (76) • Replacing reaction cells and cleaning incubator bath (278) • Replacing the photometer lamp (313) • Measuring patient samples (88) • About Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 63 Starting from Sleep mode 1 Start analyzer from Sleep mode Automatic Automatic wake-up at set time and execution of daily pipe Manual 1 Wake-up analyzer manually 2 Monitor execution of daily pipe Typically the analyzer is in Sleep mode overnight. A wakeup time is set. In this case, the analyzer wakes up automatically and executes the daily pipe. After the daily pipe is completed, you must check the analyzer and perform the required manual maintenance tasks. However, you can also perform the manual maintenance tasks at the end of each work shift. If you wake up the analyzer manually before the set wake-up time, you additionally monitor the correct execution of the daily pipe. 2 Check analyzer and perform manual maintenance 3 Check analyzer and perform manual maintenance What is the daily pipe? The daily pipe is a maintenance pipe. A maintenance pipe executes a set of software-controlled maintenance items. The daily pipe includes all maintenance items required for instrument start. Typically the analyzer is set up to perform the daily pipe automatically at wake-up or power-up of the analyzer.
If you do not use a daily pipe, you must manually execute the maintenance items included in the daily pipe. u Daily pipe (244) In this section Waking up the analyzer automatically (64) Waking up the analyzer manually (65) Monitoring the execution of the daily pipe (66) Checking the analyzer and performing maintenance (66) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 64 Starting from Sleep mode Waking up the analyzer automatically Typically the analyzer wakes up from Sleep mode automatically at the set wake-up time. To save time for routine operation, we recommend setting the wake-up time two hours before the work shift begins.
Then the analyzer automatically performs all necessary maintenance items and is ready for operation when you arrive. j m The wake-up time is set. m The top cover is closed. 1 r To wake up the analyzer automatically 1 At the set wake-up time—while you are absent—the control unit PC performs a shutdown. f The shutdown deletes all temporary Windows files and the print buffer for reports. f The restart takes about 6 minutes.
f After initialization, the daily pipe is executed. 2 2 When you arrive at the analyzer, enter your logon data and choose the Logon button. f The System Overview menu is displayed. 3 3 Wait until Standby status is displayed. This status indicates that the daily pipe is complete. 4 Check the analyzer. u Related topics • Checking the analyzer (72) • About Shutdown status and Sleep mode (223) • List of recommended maintenance pipes (244) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 65 Waking up the analyzer manually If you want to start before the set time, you wake up the analyzer manually.
c When you start before the set wake-up time j m The analyzer is in Sleep mode. m The top cover is closed. 1 r To wake up the analyzer manually 1 During Sleep mode, the Logon dialog box is displayed. Enter your logon data and choose the Logon button.
2 2 Select the With Wake Up Pipe check box. f The control unit PC performs a shutdown. The shutdown deletes all temporary Windows files and the print buffer for reports. f The restart takes about 6 minutes. f After initialization, the daily pipe is executed. 3 3 When the Logon dialog box is displayed again, enter your logon data and choose the Logon button.
f The System Overview menu is displayed. 4 Monitor the execution of the daily pipe. u Related topics • About Shutdown status and Sleep mode (223) • List of recommended maintenance pipes (244) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 66 Starting from Sleep mode Monitoring the execution of the daily pipe If you start the instrument manually, you must monitor the execution of the daily pipe. r To monitor the execution of the daily pipe 1 Choose Utility > Maintenance . 1 2 2 Choose the Monitor button. 3 In the Maintenance Monitor dialog box, observe the execution of the maintenance items until (5) Air Purge is started. 4 Check the analyzer and perform manual maintenance. Checking the analyzer and performing maintenance After the daily pipe has been completed, you must check the functional integrity of the photometric components. You also check the analyzer surfaces and perform the daily maintenance tasks if this has not been done at the end of each work shift. d m Disposable cloth or paper towels m Laboratory disinfectant (no bleach) j The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 2 Before operation 67 3 1 r To check the analyzer and perform manual maintenance 1 Choose Utility > Maintenance . 2 From the left list, choose the maintenance pipe programmed for wake-up or power-on (daily pipe). 3 To ensure that the daily pipe was executed on this day, check the displayed date. 4 4 Choose the Print button. 5 5 Choose the View button. I The (2) Photometer Check automatically generates a report. Therefore, you do not need to select the Photometer Check option. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 68 Starting from Sleep mode 6 7 6 In the Photometer Check report, check the current absorbance values. If the current results exceed 14 000 absorbance units at any wavelength, check the following points: • Make sure that the reaction cells, the incubator bath, and the photometric windows are free of contamination or bubbles. • Make sure that the reaction cells are not scratched or cracked. • Make sure that the reaction cells are at least half filled with water. • Then repeat the maintenance item (2) Photometer Check.
If the results do not improve, replace the photometer lamp.
7 Open the front door. A A A Syringe connections B Syringe B 8 8 WARNING! Incorrect results due to inaccurate pipetting. Leaking syringe connection or air bubbles in a syringe may lead to incorrect results. 8 Check all syringes for leakages and air bubbles. • If a syringe connection is leaking, fasten it fingertight.
• If there are air bubbles in the syringe, tap your finger lightly against the syringe while the liquid is flowing. • If you cannot remove the leakage or air bubbles, contact your Roche Service representative. 9 Make sure that no other tube connections or containers are leaking. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 69 10 10 Turn the maintenance switch to Maintenance mode. A A Maintenance switch A Rinse station of sample probe A B B Rinse station of reagent probe 11 13 11 Check the areas around the rinse stations A and B for water splashes. Water splashes may occur during the maintenance item (5) Air Purge. Splashes indicate that a probe is slightly clogged or worn. • If you detect splashes, ensure the analyzer is in Maintenance mode.
• Wipe up any splashes with a paper towel moistened with disinfectant. • Eliminate clogging from the probe.
• If you cannot eliminate the clogging, contact your Roche Service representative. 12 If the manual maintenance tasks were not already performed at the end of the last work shift, perform all daily and other required maintenance tasks. 13 After all maintenance tasks are completed, perform the following: • Turn the Maintenance switch to Operation mode. • Wait until Standby status is displayed with white background. • Choose Utility > Maintenance and perform a reset. u Related topics • Switching the analyzer to Maintenance mode (236) • Eliminating clogging of the sample probe (338) • Eliminating clogging of the reagent probe (346) • Replacing the photometer lamp (313) • List of maintenance tasks (259) • Daily maintenance (261) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 70 Starting from power-off Starting from power-off Start analyzer from power off 1 Perform maintenance and switch on analyzer 2 Monitor execution of daily pipe 3 Check analyzer after completion of daily pipe If the analyzer is switched off at the beginning of your work shift, you must perform the manual maintenance tasks before you switch on the instrument. Identical to the start from Sleep mode, you monitor the execution of the daily pipe and check the functional integrity of the analyzer afterwards. In this section Performing maintenance and switching on the analyzer (70) Checking the analyzer (72) Performing maintenance and switching on the analyzer To ensure that the instrument surfaces are clean, you must perform the manual maintenance tasks. When switching on the analyzer, you must maintain the correct order of steps. If you perform manual maintenance as long as the analyzer is off, you do not need to switch to Maintenance mode. u Daily maintenance (261) j The analyzer is switched off. r To perform maintenance and switch on the analyzer 1 Perform all manual daily and other required maintenance tasks. 2 Make sure that the valve for the water supply is open. 2 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 3 3 Switch on the analyzer unit.
Before operation 71 4 4 Switch on the computer of the control unit. f The analyzer starts initialization. 5 5 Switch on the monitor and the printer. f After six minutes, the Logon dialog box is displayed. 6 6 Enter your logon data and choose the Logon button. f After initialization, the analyzer starts the daily pipe by the Power Up Pipe function.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 72 Starting from power-off 7 7 Wait until Standby status is displayed. This status indicates that the daily pipe is complete. 8 Check the analyzer. u Related topics • Checking the analyzer (72) • List of maintenance tasks (259) • Daily maintenance (261) • Using the Power Up Pipe function (242) Checking the analyzer After the daily pipe has been completed, you must check the functional integrity of the photometric components with the Photometer Check report.
You must also check the analyzer surfaces for water splashes. d m Disposable cloth or paper towels m Laboratory disinfectant (no bleach) r To check the analyzer 1 Choose the Print button. 1 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 73 2 2 Choose the View button. I The photometer check automatically generates a report. Therefore, you do not need to select the Photometer Check option. 3 4 3 In the Photometer Check report, check the current absorbance values. If the current results exceed 14 000 absorbance units at any wavelength, check the following points: f Make sure that the reaction cells, the incubator bath, and the photometric windows are free of contamination or bubbles.
f Make sure that the reaction cells are not scratched or cracked. f Make sure that the reaction cells are at least half filled with water. f Then repeat the maintenance item (2) Photometer Check. If the results have not improved, replace the photometer lamp.
4 Open the front door. A A B 5 5 WARNING! Incorrect results due to inaccurate pipetting.
Leaking syringe connection or air bubbles in a syringe may lead to incorrect results. 5 Check all syringes for leakages and air bubbles. • If a syringe connection is leaking, fasten it fingertight.
• If there are air bubbles in the syringe, tap your finger lightly against the syringe while the liquid is flowing. • If you cannot remove leakage or air bubbles, contact your Roche Service representative. A Syringe connections B Syringe Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 74 Starting from power-off A Rinse station of sample probe A B B Rinse station of reagent probe 7 6 Ensure that no other tube connections or containers are leaking. 7 Check the areas around the rinse stations A and B for water splashes. Such splashes may occur during the maintenance item (5) Air Purge. Splashes indicate that a probe is slightly clogged or worn: f If you detect splashes, switch the analyzer to Maintenance mode. f Wipe up splashes with a paper towel moistened with disinfectant. f Eliminate clogging from the probe.
f If you cannot remove the clogging, contact your Roche Service representative. u Related topics • Switching the analyzer to Maintenance mode (236) • Eliminating clogging of the sample probe (338) • Eliminating clogging of the reagent probe (346) • Replacing the photometer lamp (313) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 75 Troubleshooting system alarms If the Alarm button flashes yellow or red, you must check the cause of the alarm and remove it. The color indicates the alarm level: • Red: Stop level. Operation cannot be continued. • Yellow: Caution level. Operation can be continued. 3 1 2 r To troubleshoot system alarms 1 Choose the Alarm button. f The alarm list contains all current alarms. 2 Choose an alarm.
3 To remove the cause of the alarm, perform the recommended remedy. 4 To delete the alarm from the list, choose the Delete button. 5 Repeat the steps 2 to 4 for all alarms. 4 6 6 Choose the Close button. f The Alarm button turns to normal. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 76 Preparing the analyzer for operation Preparing the analyzer for operation To prepare the analyzer for sample measurement, you must perform some pre-routine actions. The workflow on the System Overview menu guides you through the pre-routine actions. Perform at least the actions indicated in yellow or red: Yellow: This action is due soon. Red: This action is required immediately. In this section Performing daily maintenance (76) Clearing the sample database (78) Preparing the reagents (79) Performing recommended calibration and QC (81) Downloading parameters from cobas link (86) Performing daily maintenance If the Daily Maintenance button is displayed in yellow or red, you must perform software-controlled maintenance items. The color of the button indicates whether you must perform at least one maintenance item: • Yellow: A warning level is exceeded.
• Red: A maintenance interval is exceeded. A warning level is defined in percent. A maintenance interval is defined in hours, days, or months. j m The analyzer is in Standby status. m The Daily Maintenance button is yellow or red. r To perform required maintenance 1 Choose the Daily Maintenance button. 1 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 77 2 2 From the left list, choose a maintenance type that is displayed in yellow or red. 4 3 5 7 3 From the right list, choose a maintenance item or pipe that is displayed in yellow or red. I The right list contains the maintenance items and pipes and their last execution date. If the date is yellow or red, the set warning level or interval is exceeded.
4 Choose the Select button. f The dialog box for the selected maintenance item opens. 5 Define any parameters required and choose the Execute button. 6 Repeat steps 2 to 5 for all required maintenance items. 7 To return to the System Overview menu, choose the status icon in the top left corner. q We recommend that you perform the daily manual maintenance tasks now. Consider the workflows of your lab. u Daily maintenance (261) u Related topics • Maintenance definitions (235) • List of maintenance items (251) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 78 Preparing the analyzer for operation Clearing the sample database Precautions with USB flash drives For faster data access, we recommend that you clear the sample database at the beginning of each work shift. If the Sample Data Clear button is yellow, you must clear the sample database because it is almost full. If the Sample Data Clear button turns red, the sample database is full and the analyzer will not process any further samples. The software provides two options: • The Clear option deletes the database without saving the test results. Use this option if the data are sent to an LIS and you do not require a another backup from the analyzer. • The Backup and Clear option saves the test results on a USB flash drive (recommended) or on a DVD. The test results are deleted afterwards. Wrong handling of USB flash drives may result in data loss or malfunction of the instrument.
• Use only USB flash drives that are tested by your local Roche Service representative. • Insert or remove a USB flash drive only in Standby status. • Use only one USB flash drive at a time. • Before removing a USB flash drive, choose the Media Eject button. • To prevent a virus from infecting the software, use the USB flash drive exclusively on the analyzer. Do not store any other data on this USB flash drive. 1 r To back up the database before clearing 1 Choose the Sample Data Clear button. 2 Connect a USB flash drive to one of the USB ports or insert a DVD. I If a DVD and a USB flash drive are available, the data is stored on the USB flash drive. On a DVD, only 2 000 data sets can be stored. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 79 3 3 Select the Backup and Clear option and choose the OK button. Preparing the reagents 4 6 4 To save the data on a DVD or a USB flash drive, select the Mass Storage option. • Select a file name, for example, the current date. • To review the results on a separate PC, for example, in a spreadsheet program, select the ASCII option. • To review the results on the control unit, select the Binary option. 5 Choose the OK button. f After the backup, all measurement results are deleted from the hard disk of the control unit. 6 To remove the USB flash drive, do the following: • Choose the Media Eject button. • Disconnect the USB flash drive from the USB port. When the Reagent Preparing button is purple, yellow, or red, some reagents on board are running short or are empty. You must load the required reagents according to the Reagent Load/Unload List.
The color of the Reagent Preparing button indicates the number of available tests or the remaining volume: Reagent below the defined daily requirement Reagent below the defined warning level Reagent empty or missing Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 80 Preparing the analyzer for operation 1 2 r To create a Reagent Load/Unload List 1 During pre-routine operation, select the Preventive Action check box. I The purple reagent alarm is only displayed while the Preventive Action check box is selected. 2 Choose the Reagent Preparing button. 3 4 5 3 Choose the Reagent Load/Unload List button and confirm printing. f The report is sent to the print buffer and printed directly. 4 To view the report on screen, choose the Print button. 5 Choose the View button. 6 6 In the Unload List, check which reagents must be unloaded from the analyzer. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 81 8 7 7 To see the Load List, scroll up. 8 In the Load List, check the number of available tests or the remaining reagent volume in mL. I The number in brackets indicates the level that is set as daily requirement (purple alarm). 9 Unload and load the reagents according to the report.
u Related topics • Loading reagent packs (101) • Unloading reagent packs (104) • Replacing ISE reagents (106) • Changing sample probe detergents (112) • Changing cell detergents (113) Performing recommended calibration and QC Performing recommended calibration and QC 1 Request calibration and QC 2 Print load lists 3 Measure calibrations and QCs 4 Check results The analyzer software automatically recommends calibration for all tests that require calibration. Typically, you also perform QC measurements for all tests before operation. In that case you probably do not need to perform a QC measurement during operation. • To activate the recommendation, you must request the calibration and the QC measurement. • You can print load lists, which indicate the required calibrators and controls and their positions on the sample disk. • To start the measurement, you load the calibrators and controls onto the sample disk. • You make sure that all calibrations are valid and all QC results are within the reference range. In this section Requesting recommended calibration and QC (82) Printing load lists for calibrators and controls (83) Measuring calibrators and controls (84) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 82 Preparing the analyzer for operation Requesting recommended calibration and QC QC after calibration The analyzer software recommends calibrations according to the intervals set in the application. However, you must activate the recommended calibrations. To ensure measurement accuracy, you must also perform a QC measurement for all tests. The yellow Calibration And QC Select button indicates that calibration and/or QC are recommended. QC after calibration is a fully automatic function which causes a QC measurement for all newly calibrated tests. If you require QC measurements only for newly calibrated tests, you do not need to choose the Routine QC button and Standby Bottle QC button. When you load the required controls on the sample disk, the QC will automatically be measured after calibration. c Before measuring patient samples j m The analyzer is in Standby status. r To request recommended calibration and QC 1 Choose the Calibration And QC Select button. 1 2 2 In the Calibration group box, choose the Recommended button. f The recommended calibrations are now requested on an internal worklist and will be performed at the beginning of the next analysis run. 3 Check whether the following steps are necessary: • If a start-up group is defined for this work shift, choose the Start Up button to request the calibration for this group in addition to the recommended tests. • If your work shift starts within less than 24 hours since the last work shift, request an ISE calibration manually. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 83 5 4 4 In the QC group box, choose the Routine QC button. 5 Choose the Stand By Bottle QC button (optional). f Control measurements are now requested for all reagents on board (in use and standby reagents). u Related topics • About recommended calibration (124) • Performing an ISE calibration (109) Printing load lists for calibrators and controls To see the required calibrators and controls, you can print a Calibrator Load List and QC Load List report. The load lists also show positions on the sample disk assigned to specific calibrators or controls. 1 r To print load lists for calibrators and controls 1 In the Load List group box, select the Calibration option. 2 Choose the Print button. f The Calibration Load List report is printed on paper and sent to the print buffer. It shows all calibrators required on the sample disk. 2 4 5 3 3 In the Load List group box, select the QC option.
4 Choose the Print button. f The QC Load List report is printed on paper and sent to the print buffer. It shows all controls required on the sample disk. 5 Choose the Close button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 84 Preparing the analyzer for operation 6 6 On the print-out, check the required calibrators and controls with their assigned sample disk positions.

I To check the required calibrators and controls on the screen, choose the global Print button and then the View button. Measuring calibrators and controls Load the calibrators and controls onto the sample disk and start the measurement. d m Calibrators and QC materials m Sample containers r To measure calibrators and controls 1 Make sure that the ACCESS SAMPLE DISK lamp is on. 1 3 2 2 WARNING! Incorrect results due to expired or evaporated calibrators or controls. The concentration increases due to evaporation. Only use fresh calibrators and controls. 2 Prepare the calibrators and controls in suitable sample containers.

• Do not use Hitachi micro cups for calibrators or controls. • Make sure that there are no bubbles on the surface of the calibrator or QC material. 3 If you use barcoded containers, place the calibrators and controls on the sample disk in any vacant position. • Align the containers so the barcode readers can scan the barcode: On the outer ring, turn the barcode to the outside. On the inner ring, turn the barcode to the inside. • Do not place the containers in positions assigned for non-barcoded calibrators or controls. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 85 5 4 If you use non-barcoded containers, place the calibrators and controls on the sample disk according to the manually assigned positions printed in the load lists. 5 Choose the Start button. 6 6 To start the calibration and QC measurement, choose the Start button. 7 7 Check the calibration results: • If the calibration is valid, unload the calibrators. • If the calibration has failed, check the alarms and troubleshoot. Repeat the calibration for these tests. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 86 Preparing the analyzer for operation 8 8 Check the QC results: • If one QC result is out of range, you must check the control, the analyzer, and the reagent. • If most of the QC results are out of range, you must troubleshoot the cause before measuring patient samples. u Related topics • List of sample containers (365) • Checking calibration (132) • Checking QC results (149) Downloading parameters from cobas link To assure accurate measurements, you must keep all parameters up-to-date.

The red Parameter Download button indicates that new parameters for applications, calibrators, or controls are available for download from cobas link. Lot numbers are encoded in barcode labels of the reagents, calibrators, and controls. The Parameter Download button turns red if the used lot numbers do not match the installed lot numbers or if the target values have been adjusted by Roche. q You must ensure that the correct parameters for the reagents, calibrators, and controls in use are installed. Check cobas link regularly for parameter updates. 1 r To download parameters 1 Choose the Parameter Download button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 87 3 2 2 Check the three tabs for available parameters. 3 Select the desired parameter and choose the Download button. f The Download dialog box is displayed corresponding to the selected parameter. 4 On the Download dialog box, choose the Download button and start the download. 5 Once you have downloaded parameters, repeat the calibration and the QC measurement for the corresponding tests. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 88 Measuring patient samples Measuring patient samples When all indicated pre-routine steps have been completed, you can start routine operation and measure patient samples. The Sample Tracking button provides access to the Sample Tracking dialog box. There you can observe the progress of sample processing. The described procedure implies that the test orders have been sent from a LIS (host). u For manual requests or non-barcoded samples, see: Ordering tests (165).

d m Sample containers m Barcode labels j The analyzer is in Standby status. 1 r To measure barcoded samples 1 Deselect the Preventive Action check box. f If the Preventive Action check box is deselected, no purple reagent alarm will occur during routine operation. 2 Make sure that the ACCESS SAMPLE DISK lamp is on. 2 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 89 3 3 To place samples onto the sample disk, do the following: • Prepare samples in suitable containers. • Place the containers into positions assigned for barcoded samples. • Turn the containers so that the barcode readers can scan the barcode labels: On the outer ring, turn the barcode to the outside. On the inner ring, turn the barcode to the inside.

4 4 Choose the Start button. 5 5 In the Start Conditions dialog box, check the settings and choose the Start button. f After a preparation routine, the sample processing begins.

f The analyzer scans the barcodes of the loaded samples and requests the corresponding test selection from the LIS. 6 6 To track the progress of sample processing, choose System Overview > Sample Tracking . Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 90 Measuring patient samples 7 7 To display details about a sample, select the sample. Example: The remaining time indicates when all results for a sample will be available. 9 8 8 Choose Workplace > Data Review . 9 Choose a sample. 10 To review the results, choose the Test Review button. 10 11 12 11 If a test result is flagged with a data alarm, look up the alarm description and perform the remedies. f After all tests are measured and calculated, the analyzer returns to Standby status. If the Sample Reception Mode is activated on Utility > System , the analyzer remains in Sample Reception status for a set period to process further samples. f To terminate the Sample Reception status, choose the Change button in the Start conditions dialog box. f After the set period, the instrument returns to Standby status automatically. f In both statuses, you can access the sample disk again. 12 While the ACCESS SAMPLE DISK lamp is on, unload the measured samples and load new samples.

13 To start the next run, choose the Start button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Before operation 91 u Related topics • List of sample containers (365) • Ordering tests (165) • Placing barcode labels on sample tubes (213) • Loading samples (170) • Tracking samples on the analyzer (178) • Processing reruns (194) • Working with sample results (183) • Processing open test requests (199) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 92 Measuring patient samples Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents Table of contents 93 4 In this chapter 4 About positions of reagents . . . .
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 94 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 95 About positions of reagents You get an overview of all reagents used on the cobas c 311 analyzer and where to find them. Reagents in reagent packs A Gate for reagent packs B Reagent pack A B Reagents in reagent packs are used for photometric measurement, for special washing, and for maintenance. They are located in the temperature-controlled reagent disk.

You must load/unload reagent packs via the gate. Reagents in reagent packs are: • All photometric test reagents • Diluents (NaCl, A1CD2) • Detergents (NAOHD, SMS) • EcoTergent (mandatory reagent) Ecotergent is indicated as BathDet (water bath detergent) in the instrument software ISE reagents A B C ISE reagents are used for ISE measurement. They are located in bottles between the reagent disk and the reaction disk. Reagents used for ISE measurement are: • ISE Internal Standard Gen.2 (ISE IS) • ISE Reference Electrolyte (ISE REF) • ISE Diluent Gen.2 (ISE DIL) A ISE DIL B ISE IS C ISE REF Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 96 About positions of reagents Evaporation of internal standard Downward drift in controls and patient sample results can occur due to increased evaporation of the internal standard. Evaporation of the internal standard can occur due to an unfavorable combination of: • Low humidity • High altitude • Air movement in the laboratory depending on the use of: - Air conditioning - Fans • Filling level of the internal standard In case of internal standard evaporation the use of a bottle insert for the internal standard is recommended.

For ordering the bottle inserts and information on the correct usage of the bottle inserts, please contact your Roche service representative. Calibrators A Sample container B CFAS A C ISE Standard (Low/High) B C Calibrators are prepared in sample containers and then placed on the sample disk. Calibrators used for photometric measurement are, for example: • CFAS • H 2 O Calibrators used for ISE measurement are: Long name Short name ISE Standard Low (S1) ISE Low (S1) ISE Standard High (S2) ISE High (S2) ISE Standard High (S3) ISE High (S3) y ISE calibrators Software ISELOW Std (1) Low ISEHIGH Std (2) High ISECOMP Std (3) Compensator Code 502 503 763 Controls A Sample container A B PCCC 1, PCCC 2 B Controls are prepared in sample containers and then placed on the sample disk. Controls used for photometric and ISE measurement are, for example: • PreciControl ClinChem 1 (PCCC 1) • PreciControl ClinChem 2 (PCCC 2) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 97 ISE washing reagents A A Sample container B Activator C SysClean Sample probe detergents B C The ISE washing reagents are placed on defined positions in the sample disk. The Reagent used for cleaning the ISE flow path is: • ISE cleaning solution (SysClean) SysClean is placed on position W1. The Reagent used for conditioning the ISE electrodes is: • ISE Activator (Activator) Activator is placed on position W2. A B Sample probe detergents are located in bottles next to the sample disk. Detergents used for washing sample probes are: • Sample Cleaner 1 (SmpCln 1) (Multiclean) • Sample Cleaner 2 (SmpCln 2) (SMS) A SmpCln 1 B SmpCln 2 Cell detergents A A CellCln 1 B B CellCln 2 Cell detergents are located in bottles behind the front door of the analyzer. Detergents used for washing cells are: • Cell Wash Solution I / NAOHD (CellCln 1) • Cell Wash Solution II / Acid Wash (CellCln 2) u Related topics • Loading reagent packs (101) • Unloading reagent packs (104) • Replacing ISE reagents (106) • Changing sample probe detergents (112) • Changing cell detergents (113) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 98 About statuses of reagents About statuses of reagents To ensure measurement, the required reagents must be on board and their fill level must be high enough. Additionally, the reagent packs and the ISE reagents must have a valid calibration and QC. The Reagent Preparing button and the Reagent Overview button indicate if a reagent is empty, missing, or below a set volume level by changing its color. u Defining reagent level alarms (116) From the System Overview menu, you can choose the Reagent Overview button.

q To view the Reagent Overview button in the System Overview menu, you must choose AU or ISE in the Overview group box. The Reagent Overview dialog box displays the statuses of all reagents on board.

You can check the remaining amounts, the calibration statuses, and the QC statuses. Reagent packs The Reagent group box displays the reagent disk with the 42 reagent packs and their statuses. In the center of the reagent disk, you can view detailed information on the selected reagent pack. If you want to view more detailed information, you can choose the Detail button. A B C A Reagent pack B Detailed information C Color legend A C A Reagent pack status C QC status B Calibration status Each reagent pack is divided into three sections displaying the following statuses: • Reagent pack status • Calibration status • QC status Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 99 Section Status Cas Reagent status Cal QC Calibration status Quality control status Color The color of each section displays the current status. Description Active Reagent currently in use. Warning Reagent remaining tests below yellow alarm level. Zero tests Reagent empty. Reagent available in another reagent pack. Caution Standby Reagent empty. Reagent not currently in use. Free Pos. Reagent position empty. Expired Valid Expiration date exceeded. Calibration valid. Requested Calibration requested. Failed Calibration failed. Valid Quality control valid. Requested Quality control requested. Violated Quality control failed. N.A. Quality control not applicable (no values available). y ISE reagents The ISE group box displays the fill level and the statuses of the ISE reagents ISE IS, ISE DIL, and ISE REF. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 100 About statuses of reagents A B C D Each ISE reagent is divided into four sections displaying the following statuses: • Fill level (remaining volume) as graphic display • Fill level (remaining volume) as amount (mL) • Calibration status • QC status A Fill level display C Calibration status B Fill level amount (mL) D QC status Section Status Cal Calibration status Color The colors of the calibration and QC sections display the actual statuses. Description Valid Calibration valid. QC Quality control status Requested Calibration requested. Failed Calibration failed.

Valid Quality control valid. Requested Quality control requested. Violated N.A. Quality control failed. Quality control not applicable (no values available). y Detergents The Inventory group box displays the fill level of the detergents. A Fill level display A B B Fill level amount (mL) Each detergent is divided into two sections displaying the following statuses: • Fill level (remaining volume) as graphic display • Fill level (remaining volume) as amount (mL) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 101 Loading reagent packs If the remaining volume of a reagent pack is low, or the expiration date has expired, you must replace it. To ensure measurement, you must scan and insert a new reagent pack, or a reagent pack that has been used on this analyzer before. ! WARNING Incorrect results due to the incorrect placement of a reagent pack If you insert a reagent pack the wrong way around, the reagent is pipetted in the wrong order, leading to incorrect results or system damage. r Always load the reagent packs in the direction shown on the label near the loading port. ! WARNING Incorrect results due to insufficient reagent volume When using a cobas c pack MULTI, it must be filled with the exact filling volume specified in the package insert.

If this is not the case, measurement accuracy may deteriorate. Additionally, an alarm (reagent short) may occur if the analyzer detects that the reagent volume is low. r Ensure that the cobas c pack MULTI contains the correct filling volume.

Refer to the package insert. The analyzer monitors the remaining volumes by counting down. When loading new reagent packs, the analyzer starts counting at the initial number of available tests. When loading reagent packs that have already been used, the analyzer continues counting at the last monitored number of available tests. If a reagent is empty, missing or below a set volume level, the Reagent Preparing button and the Reagent Overview button change their color to red, yellow, or purple. u Defining reagent level alarms (116) You can print a Reagent Load/Unload List report that shows the reagent packs to be loaded. u Preparing the reagents (79) j The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 102 Loading reagent packs 3 2 1 r To load reagent packs 1 Choose Reagent > Setting .

2 Press Ctrl and choose the reagents you want to load from the list. 3 Choose the Loading button. 4 5 4 Choose the Execute button. 5 Wait 1–2 minutes for the gate cover of the reagent disk to unlock. f You can see and hear the locking bar retract. 6 6 Open the gate cover. 8 7 7 With the reagent barcode label facing the barcode reader, put the reagent pack on the guide rail in front of the barcode reader. 8 To scan the reagent pack, slide the reagent pack along the guide rail to the rear stop. f The analyzer scans the barcode label on the reagent pack.

f The analyzer checks if the corresponding test application is available. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 103 10 q The following data are encoded in this barcode: o System ID o Lot number o Cassette number o Expiration date o Bottle configuration information (reagent packs) 9 Wait for the reagent pack to be accepted. 10 With the barcode on the right side, load the reagent pack into the slot. 11 11 Close the gate cover. f The gate cover is locked automatically. 12 Wait up to 1 minute for the reagent pack to be registered. If the reagent pack has not been on the analyzer before, the following actions are taken: • The analyzer registers the initial capacity. • The bottles of the reagent pack are pierced. f When the cassette is registered, you can see the cassette information in the Cassette Loading dialog box. 13 To finish loading, choose the End button. u Related topics • Defining reagent level alarms (116) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 104 Unloading reagent packs Unloading reagent packs If you need an empty position on the reagent disk for loading a new reagent pack, or if the reagent is empty or below a set volume level, you must unload a reagent pack. In Reagent > Setting , in the Remaining Tests column, you can check for empty reagent packs. You can print a Reagent Load/Unload List report that shows the reagent packs to be unloaded. u Preparing the reagents (79) j The analyzer is in Standby status.

1 r To unload reagent packs 1 Choose Reagent > Setting . 2 Press Ctrl and choose the reagent packs you want to unload from the list. 3 Choose the Unloading button. 2 3 4 5 4 Choose the Execute button. 5 Wait up to 1 minute for the gate cover of the reagent disk to unlock. f You can see and hear the locking bar retract. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 7 Reagents 105 6 6 Open the gate cover. 7 Unload the reagent pack. 8 8 Close the gate cover.

f The gate cover is locked automatically. 9 Wait for the reagent pack to be deleted. f In Reagent > Setting the reagent pack information is deleted from the list. 10 10 To finish unloading, choose the End button.

11 Store the reagent packs in a refrigerated place or dispose them according to local regulations.

I You can reload a used reagent pack onto the same analyzer at a later time. However, after deleting a test, you cannot reload used reagent packs for this test. Note: You must delete the test and download it again to, for example, change the unit of measure. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 106 Changing ISE reagents Changing ISE reagents ISE IS Changing ISE reagents ISE REF ISE DIL If the remaining volume of an ISE reagent is low or the expiration date has expired, you must replace it. When replacing the ISE reagent ISE IS or ISE REF, you must perform a reagent prime. Before starting operation, you must calibrate the ISE measuring system for all replaced ISE reagents. 1 Replace bottle 2 Prime 3 Calibrate In this section Replacing ISE reagents (106) Performing a reagent prime (108) Performing an ISE calibration (109) Replacing ISE reagents If the remaining volume of the ISE reagent ISE IS, ISE REF, or ISE DIL is low, or the expiration date has expired, you must replace it with a new and full ISE reagent bottle to ensure measurement. After replacing the ISE reagent ISE IS, ISE REF, or ISE DIL, you must reset the reagent volume.

If you replace ISE IS or ISE DIL, the liquid level is detected automatically before the first measurement.

If you replace ISE REF, the reagent volume is monitored by countdown. ! WARNING Incorrect results due to ISE measurement failure r Perform ISE prime after resetting the ISE reagent volume. In the Reagent Overview dialog box, you can check the remaining volume of ISE reagents. You can print a Reagent Load/Unload List report that shows the ISE reagents to be replaced. u About statuses of reagents (98) Preparing the reagents (79) j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 107 1 r To replace ISE reagents 1 If necessary, insert the bottle insert into the new internal standard bottle. A B C 2 2 CAUTION! Incorrect result due to incorrect placement of reagents. Make sure to place the reagent bottles according to their correct positions. 2 Replace the corresponding bottle of ISE reagent with a new and full bottle. A ISE DIL B ISE IS C ISE REF A B A Aspiration filter B ISE REF 3 3 If you replace the ISE REF bottle, clean the aspiration filter A in the tubing: • Take out the tubing from the bottle. • Unscrew the filter from the tube end. • Wash the filter with deionized water.

• Then rinse the filter with deionized water. • Shake off the water.

• Place the tubing in the new bottle, so that the end of the tube touches the bottom of the bottle. 4 Terminate Maintenance mode. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 108 Changing ISE reagents 6 5 5 Choose Reagent > Status . 6 On the Status tab, choose the changed ISE reagents. 7 Choose the ISE Volume Reset button. 7 8 8 To reset the fill volume to the level of a full bottle, choose the YES button. f The volume of ISE REF is displayed immediately. The volumes of ISE DIL and ISE IS are displayed with the next measurement. u Related topics • Cleaning the ISE REF aspiration filter (284) • Defining reagent level alarms (116) • Terminating the Maintenance mode (237) Performing a reagent prime When the tubing is disconnected from the ISE REF bottle, air may enter the electrodes. If the ISE IS bottle or the ISE REF bottle is replaced, the flow path must be filled with new liquid. In both cases, you must perform a reagent prime.

n • IS+REF: approximately 10 minutes • REF: approximately 2 minutes d m IS+REF: ISE IS 9230 µ L, ISE REF 1690 µ L m REF: ISE REF 3120 µ L j The analyzer is in Standby status.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 109 2 1 r To perform an ISE reagent prime 1 Choose Utility > Maintenance . 2 Select the (7) Reagent Prime option. 3 Choose the Select button. 3 4 5 7 4 Choose the Parameter button. 5 Select one of the following options: • To prime both the ISE measuring tubing and the ISE reference tubing, select the IS+REF option. • To prime the ISE reference tubing, select the REF option. 6 Choose the OK button. 7 Choose the Execute button. f The reagent prime is completed when the analyzer returns to Standby status. Performing an ISE calibration If you replace ISE IS, ISE REF, or ISE DIL, you must calibrate the ISE. According to your specific working requirements, you can define two different ISE calibration curves (e. g., type A for urine and type B for plasma). The ISE calibrators can be used with or without barcode. During ISE calibration, the ISE internal standard (ISE IS) is measured additionally. d m Calibrators ISE Low (S1), ISE High (S2), and ISE High (S3) j ISE IS and ISE REF have been primed. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 110 Changing ISE reagents 2 3 1 r To perform an ISE calibration 1 Choose Calibration > Status . 2 From the Test column, choose ISE-A or ISE-B to select the calibration curve. 3 In the Method group box, choose the Full button. f The selected calibration method Full is displayed on the Calib. Method tab and highlighted green. f The Save button turns yellow. 4 4 Choose the Save button.

f All tests with a highlighted green entry in the Calib. Method tab are requested for calibration. 5 6 5 To print the Calibration Load List report, choose the Print button. 6 Load the ISE calibrators onto the sample disk as indicated in the Calibration Load List report. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 7 7 Start the measurement.

Reagents 111 8 8 Check the calibration results: • If the calibration is valid, unload the calibrators. • If the calibration fails, check the alarms and troubleshoot. Repeat the calibration for these tests. u Related topics • About manual calibration (126) • Assigning non-barcoded calibrators to sample disk positions (133) • Measuring calibrators and controls (84) • Measuring patient samples (88) • Checking calibration (132) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 112 Changing sample probe detergents A B Changing sample probe detergents If the remaining volume of a detergent bottle is low, or the expiration date has expired, you must replace it with a new and full detergent bottle to ensure measurement. The analyzer monitors the remaining volumes by counting down. After changing sample probe detergents, you must reset the initial reagent volume. j The analyzer is in Standby status.

2 1 r To change sample probe detergents 1 In the sampling area, take out the corresponding sample probe detergent bottle.

2 Replace with a new and full sample detergent bottle. I Improper aspiration may occur due to foam or bubbles. Do not shake the detergent bottle.

A SMS B Multiclean 3 3 Choose Reagent > Status . 4 Choose the new sample probe detergent bottle. 5 Choose the Reagent Volume Reset button. f The Confirmation dialog box is displayed. 4 5 6 6 Choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 113 Changing cell detergents If the remaining volume of a detergent bottle is low, or the expiration date has expired, you must replace it with a new and full detergent bottle to ensure measurement. After changing cell detergents, you must reset the reagent volume. j The analyzer is in Standby status. r To change cell detergents 1 Take out the empty cell detergent bottle. 1 2 2 Clean the filter in the tubing: • Remove the tubing from the cell detergent bottle. • Unscrew the filter from the tube end. • Wash the filter with deionized water. • Then rinse the filter with deionized water. • Screw the filter back on to the tube end.

3 3 Take a new and full cell detergent bottle. 4 Insert the tubing into the cell detergent bottle so that it touches the bottom of the bottle.

4 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 114 Changing cell detergents 5 5 Position the new cell detergent bottle. 8 7 9 6 6 Choose Reagent > Status . 7 Choose the new cell detergent bottle. 8 Choose the Reagent Volume Reset button. f The Confirmation dialog box is displayed. 9 Choose the OK button. 10 Perform a cell detergent prime. u Related topics • Cleaning the detergent aspiration filters (286) • Performing a cell detergent prime (115) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Reagents 115 Performing a cell detergent prime When the tubing is disconnected from the cell detergent bottles, air may enter the tubing.

Therefore, you must perform a detergent prime. j The analyzer is in Standby status.

1 r To perform a cell detergent prime 1 Choose Utility > Maintenance . 2 Select the (8) Cell Detergent Prime option. 3 Choose the Select button. 2 3 5 4 4 Select the detergent to be primed.

• Detergent 1 = CellCln 1 • Detergent 2 = CellCln 2 5 Choose the Execute button. f The detergent prime is completed when the analyzer returns to Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 116 Defining reagent level alarms Defining reagent level alarms To ensure that there is sufficient reagent on board for measuring, you can define reagent levels at which an alarm is issued.

Color of alarm Meaning A reagent is empty. The remaining tests of a reagent are below the defined reagent caution level. The remaining tests of a reagent are below the reagent level defined for a purple alarm. y Reagent level alarms If an alarm is issued, in the System Overview menu, the Reagent Preparing button and the Reagent Overview button change the color. q To view the Reagent Overview button in the System Overview menu, you must choose AU or ISE in the Overview group box.

Yellow alarm Purple alarm The red alarm is issued automatically. For yellow and purple alarms, you can define the alarm level for each reagent separately. • For test reagents, the alarm level refers to the remaining number of tests. • For ISE reagents, wash solutions, and diluents the alarm level refers to the remaining volume in mL. A yellow alarm is only issued if the reagent level alarm is defined for this test reagent, wash solution, or diluent. A purple alarm is only issued under the following conditions: • The reagent level alarm has been defined for this test.

• On the System Overview menu, the Preventive Action check box has been selected. It is recommended, that the purple alarm corresponds to the volume of reagents used in one day. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 3 Reagents 117 1 r To define a yellow reagent level alarm 1 Choose Utility > System 2 Choose the Page button until Page 2/5 is displayed on the button. 3 Choose the Reagent Level Check button. 2 4 6 8 4 In the Yellow Alarm group box, you can filter by reagent type: • The Assay option displays only test reagents. • The Without Assay option displays only wash solutions and diluents. 5 Choose the reagent for which you want to define a reagent level alarm. f The current alarm values are displayed in the Count column. 6 To activate the reagent level alarm for this test, select the Activate Alarm option.

f The Yellow Check Update button turns yellow. 7 To change the alarm value of this test, enter the new value in the Activate Alarm group box. • For the reagent packs, the level alarm lies between 10-500 tests.

• For ISE reagents, wash solutions, and diluents, the level alarm lies between 5-9999 mL. 8 To save the changes, choose the Yellow Check Update button. 9 To confirm, choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 118 Defining reagent level alarms 3 1 r To define a purple reagent level alarm 1 Choose Utility > System 2 Choose the Page button until Page 2/5 is displayed on the button. 3 Choose the Reagent Level Check button. 2 4 6 8 4 In the Purple Alarm group box, you can filter by reagent type: • The Assay option displays only test reagents. • The Without Assay option displays only wash solutions and diluents. 5 Choose the reagent for which you want to define a reagent level alarm. f The current alarm values are displayed in the Count column.

6 To activate the reagent level alarm for this test, select the Activate Alarm option. f The Purple Check Update button turns yellow. 7 To change the alarm value of this test, enter the new value in the Activate Alarm group box. • For the reagent packs, the level alarm lies between 10-500 tests. • For ISE reagents, wash solutions, and diluents, the level alarm lies between 5-9999 mL. 8 To save the changes, choose the Purple Check Update button. 9 To confirm, choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration Table of contents 119 5 In this chapter 5 About calibration . . . .
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 120 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 121 About calibration Recommended Calibration The purpose of calibration is to ensure accurate measuring for all tests. Each test is calibrated to determine a valid calibration factor for all test parameters. The measured values depend on the measuring system and the reagents, and they may deviate over time. Therefore it is necessary to repeat calibrations regularly. The analyzer automatically recommends tests that need to be calibrated. You must perform this recommended calibration before starting operation to avoid interruption of operation. Additionally, you can choose individual tests for manual calibration. Manual Recommended calibration Manual calibration QC after calibration Checking calibration results Calibration masking If a test requires calibration, the analyzer automatically recommends calibrating this test. Before starting operation, you must request all recommended tests for calibration. Depending on the specified calibration intervals, you may also need to calibrate tests that are recommended during operation. A request for calibration that is not recommended by the analyzer, is a manual calibration. If you decide to perform a manual calibration, you must individually select the tests to be calibrated and the calibration method. QC measurements are performed for all tests that are newly calibrated if the controls are activated and on board. You do not have to request this QC. The analyzer checks each calibration automatically. If the calibration has been successful, the calibrated parameters are valid and the analyzer continues operation.

If the analyzer detects an irregular condition or result, an alarm is issued, and the calibration is classified as failed and recommended to be repeated. If no valid calibration is available for a test, calibration masking ensures that this test is not measured.

If calibration masking is not activated, this test is measured and a data alarm is attached to the results. u Related topics • About recommended calibration (124) • About manual calibration (126) • About calibration methods (122) • Checking calibration (132) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 122 About calibration methods About calibration methods Tests can be calibrated with up to four different calibration methods, differing in the calibration curve and the number of calibrators used: blank, 2 point, full and span calibration. For recommended calibration, the analyzer determines the calibration method automatically. When calibrating tests manually, you must select a calibration method. Blank Concentration The calibrator of the lowest analyte concentration is used for calibration: • For photometric calibration, standard 1 (e.

g., H 2 O) is used. The calibration curve is adjusted proportionally. The Kfactor is not changed. u For more information, refer to the COBI, Calibration > Photometric calibration > Calibration overview > K factor 2 Point Concentration Two calibrators are used for this calibration: • For photometric calibration, standard 1 (e. g., H and a second standard (e. g., CFAS) are used. 2 O) The calibration curve is adapted by recalculating the Kfactor. u For more information, refer to the COBI, Calibration > Photometric calibration > Calibration overview > K factor Full Concentration All calibrators are used for this nonlinear calibration: • For photometric calibration, all standards defined for this test are used.

• For ISE calibration, standard 1 (ISE Low (S1)), standard 2 (ISE High (S2)), and standard 3 (ISE High (S3)) are used.

The calibration curve is adapted by recalculating all Kfactors. u For more information, refer to the COBI, Calibration > Photometric calibration > Calibration overview > K factor Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 123 Span Concentration Two calibrators are used for this calibration: •

For photometric calibration, standard 1 (e. g., H 2 O) and standard x (x=2-6) are used. The calibration curve is adapted by recalculating the Kfactor.

q This calibration method can only be applied to defined tests. u For more information, refer to the COBI, Calibration > Photometric calibration > Calibration overview > K factor u Related topics • About manual calibration (126) • Performing manual calibration (129) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 124 About recommended calibration About recommended calibration The analyzer automatically recommends all tests that require calibration. The tests recommended by the analyzer must be calibrated to ensure that the analytical unit measures accurately. This recommended calibration is performed before operation starts, and whenever tests require calibration during operation. If the Calibration And QC Select button turns yellow, calibration of one or more tests is recommended. You must request these tests for calibration before starting operation or as soon as it fits into your operation workflow. Calibration is performed for these tests with a preset calibration method. Calibration and QC must be completed successfully before operation. In Calibration > Status , the reason of calibration is displayed in the Cause column. The analyzer recommends calibration in the following cases: • Changeover • Calib Now • Failed • Timeout • QC Violation q If the exclamation point is yellow, you must choose it to update the calibration status. Changeover Calibration must be performed when a new reagent pack is loaded with no valid calibration. The calibration can be valid for all reagent packs of one lot (lot calibration) or for one particular reagent pack (cassette calibration). A lot calibration saves time and reagents, but is only possible if the cassette is calibrated within 24 hours after loading. Calib Now Calibration must be performed if the calibration is due within the time set in Calibration > Status in the Remaining Time field. This ensures, that you do not have to interrupt the operation for calibrating due tests. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 125 The Preventive Action check box must be selected. Failed Timeout QC Violation A recalibration must be performed when the calibration has failed one or more quality criteria. Calibration must be performed at regular intervals to compensate for changes in the reagents and/or in the measuring system due to the course of time. Calibration must be performed when the quality control results are outside the limits. u Related topics • Performing recommended calibration (127) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 126 About manual calibration About manual calibration You can request a manual calibration by choosing individual tests to be calibrated. These individual selected tests can be based on laboratory regulations or objective decisions. For example, your laboratory regulations may require to calibrate every reagent pack after loading, even if it has a valid calibration. Although a recommended calibration has been performed, you can additionally perform manual calibration of any test. To perform a manual calibration, you have to interrupt the routine operation of the analyzer. For each manually requested calibration, you must determine the calibration method. In Calibration > Status , Manual is displayed in the Cause column. The selected calibration method is displayed in the Calib. Method column. u Related topics • Performing manual calibration (129) • About calibration methods (122) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 127 Performing recommended calibration The analyzer automatically recommends all tests that need to be calibrated. To ensure the accuracy of the measured results, you must request all recommended tests. The yellow Calibration And QC Select button indicates that calibration and/or QC are recommended. c Before starting operation. If necessary, during operation: when a reagent pack with no valid calibration is requested, at set time intervals, or when a calibration has failed. d m Calibrators m Controls j The analyzer is in Standby status. r To perform recommended calibration 1 Choose the Calibration And QC Select button. 1 2 2 In the Calibration group box, choose the Recommended button to request recommended calibration. f The required calibration tests are now requested on an internal worklist and will be performed at the beginning of the next analysis run. 3 If you request recommended calibration at the beginning of your work shift, you must also perform one of the following steps: • If a start-up group is defined for this work shift, you must manually request this start up group for calibration. • If your work shift starts within less than 24 hours since the last work shift, you must manually request the ISE calibration. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 128 Performing recommended calibration 4 4 Print the Calibration Load List report. 5 5 WARNING! Incorrect results due to expired or evaporated calibrators or controls.

The concentration increases due to evaporation. Only use fresh calibrators and controls. 5 Load the calibrators onto the sample disk as indicated in the Calibration Load List report. 6 6 Start the measurement. 7 7 Check the calibration results: • If the calibration is valid, unload the calibrators. • If the calibration has failed, check the alarms and troubleshoot. Repeat the calibration for these tests. u Related topics • About recommended calibration (124) • Preparing the reagents (79) • Measuring calibrators and controls (84) • Assigning non-barcoded calibrators to sample disk positions (133) • Measuring patient samples (88) • Checking calibration (132) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 129 Performing manual calibration Independent of the calibration recommended automatically by the analyzer, you can request manual calibration for individual tests. For manually calibrated tests, you have to select the calibration methods. A full calibration of all ISE measurements is required every 24 hours.

When starting operation within 24 hours after the last ISE calibration, you manually request ISE calibration. That way, you do not have to interrupt operation. c Individual time interval. ISE calibration: when restarting operation within 24 hours. d m Calibrators m Controls j The analyzer is in Standby status. 2 1 r To perform manual calibration 1 Choose Calibration > Status . 2 From the Test column, select the test to be calibrated.

3 3 In the Method group box, choose the test-specific calibration method. I For ISE-calibration, you must choose the Full button.

f The selected calibration method is displayed in the Calib.

Method tab and highlighted green. f The Save button turns yellow. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 130 Performing manual calibration 4 4 If you have to cancel a calibration request, go on as follows: • Select the requested test to be canceled. • Deselect the highlighted calibration method in the Method group box. f In the Calib.Method tab and in the Cause tab, the entries for this test disappear. 5 5 Choose the Save button. f All tests with a green highlighted entry in the Calib. Method tab are requested for calibration. 6 6 Print the Calibration Load List report. 7 7 WARNING! Incorrect results due to expired calibrators or QC materials. Do not use expired calibrators or QC materials. 7 Load the calibrators onto the sample disk as indicated in the Calibration Load List report. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 8 8 Start the measurement. Calibration 131 9 9 Check the calibration results: • If the calibration is valid, unload the calibrators. • If the calibration has failed, check the alarms and troubleshoot. Repeat the calibration for these tests. u Related topics • About manual calibration (126) • Preparing the reagents (79) • Measuring calibrators and controls (84) • Assigning non-barcoded calibrators to sample disk positions (133) • Printing load lists for calibrators and controls (83) • Measuring patient samples (88) • Checking calibration (132) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 132 Checking calibration results Checking calibration results After calibration has been performed, you must check if the calibration has been performed successfully. You can also view detailed information on the current calibration data, on the measured values, and on the latest calibrations. The current calibration data is printed automatically.

On the printout or in the Print View dialog box on the calibration monitor report, you can view the calibration results and check for calibration alarms. In this section Checking calibration (132) Checking calibration 2 1 After calibration has been performed, you must check if the calibration has been performed successfully.

The analyzer only uses tests with a valid calibration. If the calibration of a new reagent pack (changeover) fails, the operator can reject the calibration. In this case, the analyzer uses the last valid calibration of this test and recommends the test for calibration again. r To check calibration 1 Choose Calibration > Status . 2 In the Cause column, check if the calibration has been performed successfully. 3 If the column is blank, the calibration has been successful. 4 If Failed is displayed in the column, the calibration result of the corresponding test is not valid. This test is recommended for calibration again. • Check the alarms. • Troubleshoot. • Repeat the calibration for this test. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Calibration 133 Assigning non-barcoded calibrators to sample disk positions You can calibrate with barcoded and non-barcoded calibrators at the same time. If you work with a nonbarcoded calibrator, or if the barcode cannot be read, you must assign the calibrator to a disk position. q Calibration or QC failure due to wrongly placed containers You can work with barcoded and non-barcoded containers at the same time.

Putting a barcoded container in a manually assigned position blocks the measurement. o If you must assign a calibration or QC container manually (for example, due to an unreadable barcode), do not place any container with a barcode in a manually assigned position. o Do not assign a position for a barcoded container. o Assign a position for a non-barcoded container only. You can view the current calibrator position assignments in Calibration > Calibrator . 1 r To assign non-barcoded calibrators to disk positions 1 Choose Calibration > Calibrator . 2 Choose the Position Assignment button. 2 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 134 Assigning non-barcoded calibrators to sample disk positions 4 3 3 Choose a non-barcoded calibrator in the left list. 4 Choose a free position in the right list. 5 5 Choose the Assign button. 7 6 6 If you want to cancel an existing assignment, perform the following steps: • Select the assigned disk position from the right list. • Choose the Remove button. 7 To save the changes, choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Quality control Table of contents 135 6 In this chapter 6 About quality control (QC) . .

The analyzer goes back to the Operation status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 178 Processing samples Tracking samples on the analyzer In the Sample Tracking dialog box, you can track the analytical status of each sample in the sample disk.
Additionally you can search for routine or STAT samples which have been registered by the system. The Track Sample area on the right side of the dialog box displays detailed information about each sample in the sample disk as well as the waiting time until the sample is completed. A B Position Status A Positions for STAT samples C Positions for routine samples B Positions for controls D Positions for calibrators C D You can view the analytical status of each sample in the sample disk. Different symbols and colors indicate the different statuses of the samples in the positions. Empty The selected sample position is empty. Cup Present A cup is present in this position but no request has been made or no process has been started Processing The sample is being processed. Completed Sample is complete without any flags. Wrong A sample whose ID is duplicated in barcode mode.
Failed Measurement is completed, and one or more results have a data alarm.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 179 Sample Error Sampling could not be performed for this sample due to one of the following reasons: o Sample volume is too low o Sample clot If an alarm sample short or sample clot occurs, all subsequently ordered tests for this particular sample and automatic rerun are canceled. A manual rerun is required. Barcode Error The barcode was not read, is unreadable, or is incorrect (displayed only in barcode mode). 1 2 r To find a sample on the analyzer 1 On the Overview menu, choose the Sample Tracking button. 2 Choose the Sample Search button. 4 5 3 3 Choose the Stat or Routine tab, depending on the kind of sample you are searching for. 4 Select the required search option: • Sample Type • Sample ID (barcode mode only) • Sequence No. (non-barcode mode only) • Disk position (non-barcode mode and STAT only) • Comment 5 Choose the OK button. f The samples that match the search criteria are marked in the sample disk. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 180 Processing samples About adding additional samples Test selections for additional samples are downloaded from the host in real-time. You also have the possibility to manually select tests for additional routine and STAT samples. If you want to add additional samples, you have two options before you load the samples onto the sample disk: • You wait until all tests are completed and sampling stops. In this case you can load the additional samples like routine samples. • If you do not want to wait until sampling stops, you can pause the sampling. In this case you must wait until the analyzer is in the Sampling Pause status and the ACCESS SAMPLE DISK lamp lights up in green. u Related topics • Loading routine samples (170) • Loading STAT/additional samples during a run (171) Ordering additional tests Without SBS mode With SBS mode During a run, you can manually request additional tests for samples on the sample disk or they can be requested via the host.

The workflow of requesting additional tests differs depending on whether SBS mode (SBS = scan before sample stop) is used or not. During a run, additional requests should not be sent from the host. Additional tests can be requested during: • Standby , • Sampling Stop , or • Sampling Pause . Additional tests are processed in the next run. Additional tests are processed automatically. Additional tests can be requested during: • Operation or • Sampling Pause . You can request additional tests during Operation only, if the sample is already completed.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 2 Orders and results 181 If the 6th and final SBS database check has been performed before additional tests are ordered, you must restart the measurement to perform the tests during the next run. u Starting a measurement from Standby status (175) j m Analyzer status: Operation or Sampling Pause . 1 r To order additional tests in SBS mode 1 Choose Workplace > Data Review . 2 Select a sample that has already been measured. 5 4 3 3 Choose Workplace > Test Selection . 4 Select the desired additional tests. 5 Choose the Save button. f On the Data Review submenu, the status of the sample changes to Ordered (O). f The SBS internal database check is performed. f The analyzer processes all open test requests identified in the SBS database check. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 182 Processing samples About cancelling and continuing a run Cancelling a run Continuing a run A current run can be cancelled. Either a red alarm stops the analyzer or you stop the analyzer. Both actions have consequences for the results. If a red alarm stops the analyzer, no results will be calculated for already pipetted samples. The sample status change to Ordered (O). In case of an alarm, you must eliminate the cause and restart the measurement.

If you press the Stop button to stop the operation of sampling and sample processing, also no results will be calculated for already pipetted samples. Instead of stopping the whole operation, you can perform a sample stop by choosing the S.Stop button. During a sample stop, the sampling of new samples stops. All other functions related to sample processing continue until results are available. If you want to cancel a run and then to start a new run, for example, with STAT samples, you can pause the sampling by choosing the Pause/Scan button. u About adding additional samples (180) u Loading STAT/additional samples during a run (171) If a run has been cancelled, you must restart the measurement for all samples which have the (O) or Incomplete (I) status. If you have chosen the Pause/Scan button, you can load additional samples or STAT samples. After you have loaded the samples you can continue the run. u Related topics • Processing samples (175) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 183 Working with sample results You can view the sample results in the Workplace > Data Review submenu.

The results generated on the analyzer are saved on the hard disk of the control unit computer. After all the test results requested for a particular sample are available, the analyzer sends them to the host where they can be validated. In this section About the display of results (183) Reviewing sample results (185) Editing sample results (186) Deleting sample results (187) Archiving and displaying archived sample results (189) About the display of results Results are displayed in two lists: • The Sample selection list. • The Test result list. Sample selection list The list on the left side of the Data Review submenu displays the samples registered by the analyzer. Its content varies depending on whether barcode or nonbarcode mode is selected on Utility > System . I P The St. column displays the status of each sample. No symbol O H Complete: Sample successfully processed (no alarm present). Ordered: Sample has been registered and has an open test request. Processing: Sample is being processed. Incomplete: Sample is measured, but a data alarm is present. Sent to host: Sample results have been sent to the host. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 184 Working with sample results Test result list The Disk column displays the disk position number (001- 108) of the current sample in combination with the kind of sample (routine, STAT, or QC). • N 001: Normal (routine sample) - disk position 1 • E 103: Emergency (STAT sample) - disk position 103 • C 086: Control (QC sample) - disk position 86 The list on the right side of the Data Review submenu displays the results of the tests that are performed on the sample currently selected in the sample selection list. In the Test column all registered tests and calculated tests are displayed in alphabetical order or in numerical order of test numbers (set on Utility > System). The symbol for the volumes to be used is displayed to the left of the test name.
These volumes are defined on Utility > Application > Analyze .
A test is marked to be run with normal sample volume. A test is marked to be run with an increased sample volume.
This applies to photometric tests only. A test is marked to be run with a decreased volume. This applies to photometric and ISE tests. A test is marked to be run with a dilution.
The available dilutions are 1:3, 1:5, 1:10, 1:20, and 1:50. The Alarm column displays any data alarm associated with the test result for the selected sample. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 185 Reviewing sample results 2 3 To review the sample results during a run or after a run, you can use the Workplace > Data Review submenu. All sample results in the database are displayed here. Some samples require extra-action before you can remove them from the sample disk. If you want to know which samples require extra-action, you must review the sample results, and you must know the meaning of the symbols in the Data Review submenu. u About the display of results (183) ! CAUTION Incomplete test result displayed due to a too narrow column width Characters in the Result column can be hidden if the column width is set too small. As a consequence, the test results can be misinterpreted. r Check that all characters in the Result column are displayed. r Adjust the column width by selecting the column dividers in the list head and dragging them to the left or right. 4 1 r To review sample results 1 Choose Workplace > Data Review . 2 From the Data drop-down list, choose the Routine View option. 3 From the left list of the submenu, select a sample. f The results, 1st and Rerun, of the tests performed on this sample are displayed in the right list of the submenu. 4 Check the sample results. u Related topics • Checking for open test requests (199) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 186 Working with sample results Editing sample results 2 3 4 1 5 In the Test Review dialog box, you can edit a sample result.
After you have edited a sample result, the result is flagged with E . r To edit sample data 1 Choose Workplace > Data Review . 2 From the Data drop-down list, choose one of the following options: • Routine View • Backup Media 3 From the left list of the submenu, select a sample. f The results, 1st and Rerun, of the tests performed on this sample are displayed in the right list of the submenu. 4 To get more information about the test results, choose the Test Review button.
5 In the Data column, select the test result to be edited. f The test is highlighted in white. The test result is activated, indicated by a blue background. 6 Enter the new result and press Enter. f The old result is overwritten and the Update button turns yellow. 7 7 Perform one of the following: • To save the changes, choose the Update button. • To reset the entry to the original value, choose the Cancel button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 187 Deleting sample results On the Data Review submenu, you can delete a sample result. You can either delete a single test result of a sample or you can delete all results of a sample (the sample record). In this section Deleting a single test result (187) Deleting all test results of a sample (188) Deleting a single test result 2 3 4 1 5 In the Test Review dialog box, you can delete a test result of a sample. r To delete a single test result of a sample 1 Choose Workplace > Data Review . 2 From the Data drop-down list, choose one of the following options: • Routine View • Backup Media 3 From the left list of the submenu, select a sample. f The results, 1st and Rerun, of the tests performed on this sample are displayed in the right list of the submenu.
4 To get more information about the test results, choose the Test Review button. 5 Select the test to be deleted. f The test is highlighted white. 6 To delete the test result, choose the Delete Test button and confirm deleting. 6 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 188 Working with sample results Deleting all test results of a sample On the Data Review submenu, you can delete all results of a sample (the sample record). After you have deleted all test results of a sample, the Sample Count is unchanged. To reset the Sample Count to 0, you must delete all test results of all samples using the Delete All button. 2 2 3 1 r To delete all test results of a sample 1 Choose Workplace > Data Review . 2 To delete all test results of individual samples, perform the following: • Select the samples from the left list of the submenu. • Choose the Delete Record button and confirm deleting. 3 To delete all test results of all samples, choose the Delete All button and confirm deleting. f The Sample Count field is reset to 0. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 189 Archiving and displaying archived sample results Backup on USB flash drives or DVDs Sending data to the host You must backup all sample results regularly. If your analyzer operates without a host, you can backup the sample results either on a USB flash drive or a DVD. If your analyzer operates with a host, the backup is done from the host. You perform a backup on a USB flash drive or a DVD only in case an additional backup is required. USB flash drives and DVDs are both defined as Mass Storage in the software. • If a USB flash drive is connected, the instrument uses the USB as mass storage. • If no USB flash drive is connected, the instrument uses a DVD disk as mass storage. If results have been edited or if automatic host communication is deactivated, you must always choose the Send To Host button on the Workplace > Data Review submenu. You can select multiple test results and transmit them collectively. If an automatic rerun is performed, the results for the original test and the rerun are reported separately to the host. To check whether the automatic host communication is activated or not, choose the Start Conditions dialog box. In this section Using a USB flash drive (190) Archiving sample results (191) Displaying archived sample results (193) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 190 Working with sample results Using a USB flash drive Data management You can use USB flash drives to backup and restore different types of data. Wrong handling of USB flash drives may result in data loss or malfunction of the instrument. • Insert or remove a USB flash drive only in Standby status. • Use only one USB flash drive at a time. • Before removing a USB flash drive, choose the Media Eject button.
• To prevent a virus from infecting the software, use the USB flash drive exclusively on the analyzer. Do not store any other data on this USB flash drive. • Use only USB flash drives that are tested by your local Roche Service representative. Although you may only use one USB flash drive at a time, you can use different USB devices to backup different data: • USB device 1 for patient results and QC results (Workplace > Data Review > Backup Data) • USB device 2 for system parameters (Utility > Maintenance > (14) Parameter Read/Write) • USB device 3 for temporary use (e.g., for reports via Print > View > Backup Disk Write) u Archiving sample results (191) j m The analyzer is in Standby status. 1 r To plug in a USB flash drive 1 Ensure that no other USB device is plugged into the control unit computer. 2 Plug the USB flash drive into any USB port of the control unit computer. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 191 2 r To remove a USB flash drive 1 Ensure that the analyzer is in Standby status. 2 Choose the Media Eject button. 3 Disconnect the USB flash drive from the USB port. Archiving sample results You can backup patient results and QC results, for example, on a USB flash drive. q To prevent a virus from infecting the software, use the USB flash drive exclusively on the analyzer.
Do not store other data on this USB flash drive. u Precautions with USB flash drives (78) j m The analyzer is in Standby status.
1 r To archive sample results 1 Choose Workplace > Data Review . 2 From the left list of the submenu, select the samples for which the data is to be backed up. 3 Choose the Backup Data button. 2 3 4 4 To backup the data on a USB flash drive or a DVD, select the Mass Storage option. I If the control unit is still equipped with a 3 1/2 inch floppy disk drive, you can use the Floppy Disk option alternatively. 5 Insert the chosen medium into the corresponding disk drive.
f If both, a USB flash drive and DVD are available, the data are stored on the USB flash drive.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 192 Working with sample results 7 6 8 9 10 11 6 In the File Name field, enter the name of the backup file (maximum 8 characters).
7 In the File Format group box, select the ASCII option or the Binary option.
• To write the results in ASCII format, choose the ASCII option. This format can be read by other PC systems, but cannot be reloaded into the analyzer.
• To write the results in binary format, choose the Binary option. This format can be reloaded into the analyzer, but cannot be read by other PC systems. After you have chosen the Binary option, go to step 10 . 8 If you have chosen the ASCII option, select one of the following options: • To save the measurement results and the data alarms, choose the Base Data option. • To save the base data with the units of measurements and the sample volume/dilution ratio, choose the All Data option. 9 If you have chosen the All Data option, you can select the following check boxes: • To use double quotation marks as separators, in the generated ASCII file select the With double quotation mark check box. • To use vertical lines as separators, select the Separator "|" check box. • To add information about the pipetting time and date, select the Additional Date/Time check box. 10 Choose the OK button and confirm archiving. f The Save Data dialog box is displayed. The dialog box closes after the data has been backed up. f If a Confirmation dialog box with the message “Mass storage is full” or “Floppy disk is full” is displayed during backup, no data has been transferred to the medium. Insert an empty storage medium and repeat the backup process. 11 To remove the USB flash drive, do the following: • Choose the Media Eject button. • Disconnect the USB flash drive from the USB port. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 193 Displaying archived sample results You can reload the data of sample results onto the control unit only if the data have been saved in binary format. On the Workplace > Data Review submenu, you can view the reloaded data. q No backward compatibility of analyzer system software! Data written in a newer version cannot be read by an analyzer with an older version of the system software. 2 1 r To display archived sample results 1 Choose Workplace > Data Review . 2 From the Data drop-down list, choose the Backup Media option. 3 Insert the corresponding storage medium into the disk drive. 6 4 5 4 In the Media group box, select one of the following options: • To display the data from a USB flash drive or a DVD, choose the Mass Storage option.
• To display the data from a floppy disk, choose the Floppy Disk option 5 In the File Name field, enter the name of the backup file.
6 Choose the OK button. f The saved data is displayed on Workplace > Data Review . Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 194 Processing reruns Processing reruns If a test result has a data alarm flag, this test must be measured again. Depending on your analyzer configuration, this test will be automatically measured again (automatic rerun) or you must manually measure (manual rerun) this test again. In this section About automatic reruns (194) About manual reruns (195) About reruns with changed samples volumes (196) Performing manual reruns (196) About automatic reruns If a test result is flagged with a data alarm and the automatic rerun function is activated, this test will automatically be measured again. Automatic reruns can be performed for most of the data alarms (for example the result is outside the technical limit or repeat limit, >Test, Rept, The following table shows in which cases an automatic rerun will be performed for a specific test if the result of this test has a data alarm flag.
System-wide rerun setting yes yes no no Application-specific rerun setting yes no yes no Rerun is requested l l (1) l (1) l (1) y Correlation between the system-wide and the application-specific rerun setting (1) The sample status changes to Ordered (O). A rerun can be performed by restarting the measurement. Automatic rerun is performed l - - - Automatic reruns are performed whenever a result is flagged with a specific data alarm and the applicationspecific rerun setting for this test and the system-wide rerun setting are activated. Otherwise you must manually restart the measurement. u Starting a measurement from Standby status (175) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 195 About manual reruns Manual reruns in barcode mode If a test result is flagged with a data alarm and if the automatic rerun is set to No in the Automatic Rerun group box on the Start Conditions dialog box, you must manually perform all reruns regardless of applicationspecific settings. In barcode mode, there are several ways to perform a manual rerun. Case 1 2 3 Automatic rerun setting on the Start Conditions dialog box No No Yes Analyzer status Description Sampling Pause or S.Stop Standby Request a manual rerun in the Rerun Assignment dialog box (Test Selection submenu). Request a manual rerun like a normal test request using the Test Selection submenu. Advantages: o You can change the positions of barcoded samples for rerun. o You can measure new samples at the same time if already completed samples are removed from the sample disk. o You can change the sample volume or request a dilution for rerun. If the 3rd Results Acceptance option is selected on the Utility > System submenu, a manual rerun can be performed to receive a third result. This is only possible with an established host connection. You must send the first and second (auto rerun) result to the host before you request a rerun for the 3rd result.
You can use one of the methods described in case 1 or 2 to request a manual rerun. y Possibilities of manual rerun in barcode mode Manual reruns in non-barcode mode In non-barcode mode, there are two ways to perform a manual rerun.
Case 1 2 Automatic rerun setting on the Start Conditions dialog box No No Analyzer status Description Sampling Pause or S.Stop Standby Request a manual rerun in the Rerun Assignment dialog box (Test Selection submenu). Request a manual rerun like a normal test request using the Test Selection submenu. Write down the first sequence number with which the rerun is to be started. Enter this number into the Start Conditions dialog box. Advantage: o You can change the sample volume or request a dilution for the rerun. y Possibilities of manual rerun in non-barcode mode Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 196 Processing reruns About reruns with changed samples volumes Manually requested dilutions Request from host If a test must be measured again, it can be measured with normal, decreased, or increased sample volumes or with diluted samples.
On the ISE unit you can perform a manual rerun with decreased sample volumes only for urine samples. The dilutions for the rerun, performed by the analyzer, are given by one of the following options: • programmed to be performed automatically, • requested manually by the operator, • requested by the host. You can request dilutions manually on the Workplace > Test Selection submenu. In the Sample Volume / Dilution drop-down list, you can choose the Decrease or Increase option, or a dilution ratio (1:3 - 1:50). In the Sample Volume / Dilution drop-down list, not all dilution ratios are available for all tests. Application-specific dilutions are performed automatically by the analyzer. But if you choose a dilution ratio in the Sample Volume / Dilution drop-down list, this selection overwrites the pre-programmed dilution ratio. u Ordering tests (165) Dilutions can be requested by a host. In this case, the samples must be in the sample disk and are processed again. Performing manual reruns You can manually select samples for rerun if a single test result is flagged with a data alarm. Even if a result is not flagged with a data alarm, it may sometimes be desirable to verify a result by a rerun, for example, for a third result. d m Sufficient diluent must be loaded on the analyzer to dilute samples. j m Analyzer status: Sampling Pause or S.Stop . m Samples are placed onto the sample disk. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 197 1 r To perform a manual rerun using the Rerun Assignment dialog box 1 Choose Workplace > Data Review . 2 Select the sample that requires a manual rerun. 2 4 3 3 Choose Workplace > Test Selection . 4 To request a manual rerun for this sample, choose the Rerun Assignment button. 5 5 To add this sample to the list of manual reruns in the bottom of this dialog box, choose the Add button. 6 6 Choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 198 Processing reruns 8 7 10 7 On the Test Selection submenu, select the tests that require a manual rerun. f The color of a selected test key turns from yellow to white (manual rerun). f If your analyzer operates with a host, the color of a selected test key turns from gray to white (third result). f Tests may also be added that have not been measured before. 8 Choose the Save button. 9 Repeat the previous procedure for all samples that require a rerun. f The selected samples are listed in the Rerun List report. 10 Start the measurement. f If a sample listed in the Rerun List report is not placed on the sample disk, this request will be deleted. f When pipetting of a rerun sample begins, the sample will be deleted from the Rerun List report. u Related topics • Starting a measurement from Standby status (175) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 199 Processing open test requests Checking for open test requests With SBS mode Without SBS mode After a run has been completed, it is possible that some of the requested tests could not be performed. These open test requests can occur, for example, if you request additional tests for a sample, or if a data alarm occurs while automatic rerun is inactive. The behavior differs depending on whether SBS mode (SBS = scan before sample stop) is activated or not. If the SBS mode is activated, the analyzer scans the sample database after a run to check for open test requests. This allows the analyzer to process open test requests automatically in most cases. In some exceptional cases, your intervention is still required. If the SBS is not activated, open test requests require your intervention.
You must check each open test request and eliminate the cause before you can process the open test request. Therefore we strongly recommend using the SBS mode. In this section Checking for open test requests (199) Processing open test requests with SBS mode (201) Processing open test requests without SBS mode (205) Checking for open test requests Open test requests can occur in some exceptional cases even though SBS mode is activated. Therefore, it is important that you check for open requests after each run. After a run, the Confirmation dialog box can appear. This dialog box does not appear if the SBS mode is active or if additional tests were requested via the host, for example, reruns or 3rd results. Whether the Confirmation dialog box was displayed or not, you must always check for open test requests. You must not remove samples from the sample disk which have open or additional test requests. First, you must identify and eliminate the cause.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 200 Processing open test requests Cause of open test requests With SBS mode Checks A A rerun was ordered but could not be performed automatically (automatic rerun is inactive or the specific data alarm does not invoke an automatic rerun). Check the Data Review submenu for samples with status Ordered (O). B An incorrect sample ID or Application Code No. (ACN) was sent via host, or no tests were requested for a sample. Check the Sample Tracking dialog box for samples with status Cup Present. Without SBS mode but with confirmation dialog box C Additional samples were requested via the analyzer. Check the Data Review submenu for samples with status Ordered (O). D E F Sample Short (Samp.S) or Sample Clot (Samp.C) occurred; or another data alarm occurred (for example, System > Page 2/5 > Calib Mask setting . For each test: Check Utility > Application > Calib . Check Sample Tracking dialog box for Cup Present indicated in blue. Check for yellow alarms: o Host receiving Text error o Host communication Error Check Data Review submenu if tests are listed. y Causes of open test requests Remedies u Processing open test requests for rerun orders without automatic rerun (202) u Processing samples not measured yet (203) u Processing open test requests without SBS mode (205) Check alarm description. Unmask the test.
Perform a new calibration or reject the failed calibration. o Correct the sample ID or ACN. o Enter test selection or send it via batch manually from host. 1 r To check for open test requests 1 Whether a Confirmation dialog box was displayed or not, always check for open test requests. • If the Confirmation dialog box appear, choose the OK button to close the dialog box.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 201 2 2 Choose the Workplace > Data Review submenu. • Check for samples that have the status Ordered (O) in the St. column. This status would indicate open test requests. • Check these samples if any data alarms are displayed.
3 3 Choose the System Overview > Sample Tracking dialog box.
• Check for samples which have the status Cup Present (light blue) in the St column. • Check for samples with status Failed, Sample Error, or Barcode Error. 4 Identify and eliminate the cause of the open test request using table above. 5 After performing the remedy, process the open test requests. u Related topics • Processing open test requests with SBS mode (201) • Processing open test requests without SBS mode (205) Processing open test requests with SBS mode In some exceptional cases even though SBS mode is activated, open test requests are not performed automatically.
Therefore, it is important that you check for open requests after each run. You must check for the cause and process the exceptions manually. In this section Processing open test requests for rerun orders without automatic rerun (202) Processing samples not measured yet (203) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 202 Processing open test requests Processing open test requests for rerun orders without automatic rerun If a rerun was ordered but could not be performed automatically (automatic rerun is inactive or the specific data alarm does not invoke an automatic rerun), you must process the open test requests manually. d m Sufficient diluent must be loaded on the analyzer to dilute samples.
j m Analyzer status: Sampling Pause or S.Stop . m Samples are placed onto the sample disk. 1 r To process open test requests that could not be processed automatically 1 If there are samples with the status Ordered and without results, perform the following: • Check the Workplace > Data Review submenu for data alarms which do not invoke an automatic rerun (Cal.E, ClcT.E, Mix.E, Reag.S, Samp.C, Samp.S, >I.H, >I.HI, >I.I, >I.L, >I.LH, >I.LHI, >I.LI). • Perform the remedies described in chapter Data alarms. 3 2 2 When the cause of the open test request has been eliminated, choose the Workplace > Test Selection submenu and perform one of the following: • Perform a manual rerun (non-barcode mode only).
• Enter the test selection on the Test Selection submenu and move the affected sample to another position on the sample disk. 3 Start the measurement. f The analyzer scans the sample disk and processes the samples entered in the manual rerun list. Ordered tests are measured as in normal operation. u Related topics • Performing manual reruns (196) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 203 Processing samples not measured yet If an incorrect sample ID or Application Code No. (ACN) was sent via the host or no tests were requested for a sample, you must process the open test requests manually. d m Sufficient diluent must be loaded on the analyzer to dilute samples. j m Samples are placed onto the sample disk. 1 2 r To process samples not measured yet 1 Choose the Sample Tracking button on the Overview menu. 2 In the St column, check for samples which have the status Cup Present (light blue). 3 3 Check and correct the sample ID or the Application Code Number (ACN) that was sent from the host. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 204 Processing open test requests 4 4 Choose the Alarm button. 5 5 Check for yellow alarms. I If a Host Receiving Text error or Host Communication error occurred, check the entered test requests made in the host program or the host connection, respectively.
6 6 Check the Data Review submenu, and perform one of the following: • If tests are listed for this sample, perform the next step. • If no tests are listed, manually enter the test selections in the Test Selection submenu. 7 7 Remove the affected sample from the sample disk and place it in a new position on the disk. f By changing the disk position, the test selection will be requested again from the host after reading the barcode label.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 205 8 8 Restart the measurement.
f All samples with open test requests are processed. No further action is required. u Related topics • Unloading samples (210) • Loading samples (170) • Processing samples (175) Processing open test requests without SBS mode Barcode mode Non-barcode mode Open test requests can be processed either from Standby , Sampling Stop , or Sampling Pause status. For barcoded samples, you have the following options: • You can move the sample to another position and restart the measurement. • You can perform a manual rerun.
Depending on the status, you have the following options: • In the Standby status, you must enter the sequence number before you can restart the measurement.
• In the Sampling Stop status or the Sampling Pause status, you can perform a manual rerun using the Rerun Assignment dialog box. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 206 Processing open test requests Restarting a measurement in barcode mode If you must process open test requests without SBS mode and your system is in barcode mode, you have different options. You can perform the open tests request like a manual rerun or you can restart the measurement.
If the analyzer is in the Standby status, open or additional requests are performed automatically when you restart measurement. You must not change the position of the affected samples. All samples with test requests will be processed, not only those samples that were not measured during the previous run. If the analyzer is in the Sampling Stop status or the Sampling Pause status, you must change the position of the affected samples before you restart the measurement. Repositioned samples will be measured after all other samples are processed. j m Analyzer status: Standby , Sampling Stop , or Sampling Pause r To restart measurement in barcode mode 1 Make sure the cause of the open test request is eliminated. 2 Remove (unload) the affected sample from the sample disk. 3 Check the sample container visually for sample clot or sample short. 4 Load the sample into a new position on the disk. 4 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 207 5 5 Restart the measurement.
f All samples with open test requests are processed. No further action is required. u Related topics • Unloading samples (210) • Loading samples (170) • Processing samples (175) Restarting a measurement in non-barcode mode If you must process open test requests without SBS mode and your system is in non-barcode mode, you must change the sequence number in the Start Conditions dialog box before you can restart the measurement. ! WARNING Incorrect results due to a sample mismatch Putting a sample container on a wrong position may lead to incorrect results. r When operating in non-barcode mode, make sure that you register the samples according to the loaded positions. r Take care when you work in non-barcode mode because of the risk of sample mismatch. r Do not exchange or remove samples. j m Analyzer is in the Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 208 Processing open test requests 2 r To restart measurement (non-barcode mode) 1 Make sure the cause of the open test request is eliminated. 2 On the Data Review submenu, note the lowest sequence number of the affected samples. 3 3 If required, change the test selection on the Test Selection submenu. • To save the changes, choose the Save button. 4 4 Choose the Start button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 6 Orders and results 209 5 5 In the Start Sample No. field, enter the lowest sequence number. 6 Choose the Start button. f All samples beginning from the entered sequence number with open test requests are processed. No further action is required. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 210 Unloading samples Unloading samples After all test requests are completed, sampling stops. After the last result is calculated, the analyzer goes into Standby status or remains in Sample Reception status for a set period of time. In both statuses, you can access the sample disk. The period of time for the Sample Reception status is set in the Sample Reception Setting group box on the Utility > System submenu. You must select the Sample Reception Mode check box and choose a time from the drop-down list. After the Sample Reception status, the analyzer goes into Standby status. If in the Start Conditions dialog box the Sample Reception Mode check box is disabled, the system goes into Standby immediately after the last result is calculated. The advantage of the Sample Reception status is a shorter preparation time for the cuvettes. Therefore you can start the next measurement faster. c After all test requests are completed and calculated. j m Analyzer status: Standby or Sample Reception m ACCESS SAMPLE DISK lamp lights up in green 1 r To unload samples 1 Wait until the ACCESS SAMPLE DISK lamp lights up in green. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 211 2 2 Unload the samples from the sample disk. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 212 About barcodes About barcodes In this section About barcoded and non-barcoded samples (212) Placing barcode labels on sample tubes (213) Managing barcode read errors (213) About barcoded and non-barcoded samples Non-barcoded samples in barcode mode Switching from barcode mode to non-barcode mode and vice versa Typically, the analyzer operates in connection with a host and is set to process samples in barcode mode. We strongly recommend to operate the analyzer in barcode mode and to use barcodes for samples, calibrators, and controls. When the analyzer operates in non-barcode mode, you must ensure throughout the entire processing workflow that the test results are assigned to the correct patient samples. Therefore you must register the samples according to the loaded positions. You can check the registered tests and sequence numbers on the Requisition list. Even if barcode mode is activated on the analyzer, it is possible to process single samples without barcodes. In this case, use the Barcode Read Error dialog box for samples on the Workplace > Test Selection submenu. You can also use calibrators and controls without barcodes, even if barcode mode is activated. In this case, you must assign the position number on the sample disk. The sample ID (barcode number) is used to identify each sample in the sample databases of the analyzer. Therefore, do not switch easily between barcode and non-barcode mode. q If you switch between barcode and non-barcode mode, you must delete all results on the Workplace > Data Review submenu. u Deleting sample results (187) Multiple determinations in non-barcode mode In non-barcode mode, do not order multiple determinations of the same test for a sample when the system is in Operation status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 213 Placing barcode labels on sample tubes It can happen that you manually have to place a barcode label on a sample tube, for example if a barcode is not readable. To prevent a barcode read error, you must ensure the correct position and orientation of the barcode label on the sample tube. •PP •PP •PP PP •PP PP r To place a barcode label on a sample tube 1 To prevent scanning errors, place the label in exact alignment with the center line of the sample tube. 2 Check the distance from the top of the sample tube to the barcode label: • For 100 mm sample tubes: ≥ 12 mm • For 75 mm sample tubes: ≥ 5 mm 3 Check the distance from the bottom of the sample tube to the barcode label: • For 100 mm sample tubes: ≥ 17 mm • For 75 mm sample tubes: ≥ 17 mm Managing barcode read errors If a barcode label could not be read, the sample with the barcode read error is marked in the Sample Tracking dialog box. You must identify and eliminate the cause for the barcode read error. Following causes are possible: 1. The barcode label could not be scanned through the openings in the sample disk for the following reasons: - The sample tube is not loaded correctly onto the sample disk.
- The barcode label is not placed correctly on the sample tube. 2. The barcode label is damaged and therefore unreadable. After you have eliminate the causes for the barcode read error, you must restart the measurement. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 214 About barcodes Barcode label could not be scanned Unreadable barcode You must check if the barcode label is placed correctly on the sample tubes. Additionally you must check if the sample tubes are loaded correctly onto the sample disk. The barcode label on a sample tube must be loaded in such a way that the barcode label is visible through the openings in the sample disk. u Placing barcode labels on sample tubes (213) u Loading samples (170) If a sample has no barcode or if the barcode is not readable, you must enter the barcode manually. After the sample with a manually entered barcode has been measured, the disk position assignment is deleted. If you want to manually rerun this sample, you must reassign the position of this sample in the Barcode Read Error dialog box. Then you can enter this sample in the Manual Rerun list in the Rerun Assignment dialog box. ! WARNING Incorrect results due to a sample mismatch Putting a sample container on a wrong position may lead to incorrect results. r When operating in non-barcode mode, make sure that you register the samples according to the loaded positions. r Take care when you work in non-barcode mode because of the risk of sample mismatch. r Do not exchange or remove samples. c After a barcode read error occurs.
j m Analyzer status: Standby or Sampling Pause . Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 2 Orders and results 215 1 r To enter an unreadable sample barcode 1 Choose the Workplace > Test Selection submenu. 2 Choose the Barcode Read Error button.
3 3 In the Sample group box, choose the Stat option or the Routine option. 4 4 From the Type drop-down list, choose the sample material. 5 5 In the Disk Pos field, enter the position. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 216 About barcodes 7 9 6 6 In the Sample ID field, enter the sample ID.
7 Choose the Add button. f The sample type, position, and sample ID are displayed in the sample list. 8 To add more samples with a barcode read error to the sample list, repeat the steps 3 to 7 . 9 Choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Orders and results 217 Preparing a DVD disk Supported disk types Unsupported disk types Recordable and rewritable disks The control unit computer is optionally equipped with a DVD drive. You can use the DVD drive for installing software updates and backing up and restoring data.
Before you can back up data on a disk, you must format the disk and make the disk compatible. You can use the following disk types for backing up data. Disk type DVD-R DVD+R DVD-RW DVD+RW y Supported disk types Recordable/rewritable Recordable Recordable Rewritable Rewritable Disks that are not listed in Supported disk types cannot be used for backing up data, for example, the following disk types: • CD-R • CD-RW • DVD-R DL • DVD+R DL • DVD-RW DL • DVD+RW DL • DVD-RAM • All types of Blu-ray disks If you perform backups repeatedly without removing the disk from the control unit computer, you can use a recordable disk (DVD-R, DVD+R). • On recordable disks each burn is permanent. • You cannot delete data.
• You cannot reformat and rewrite a recordable disk. • You cannot add data after the disk has made compatible. If you want to use a disk in other computers or to add more backups at the control unit computer, you must use a rewritable disk (DVD-RW, DVD+RW). • You can delete data. • You can reformat the disk. • You can add data after the disk has made compatible. • You can make the disk compatible for several times. In this section Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 218 Preparing a DVD disk Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation Table of contents 219 8 In this chapter 8 Preparing the analyzer for switching off .
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 220 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation 221 Preparing the analyzer for switching off To ensure proper performance of the analyzer and to minimize the risk of data loss, you must prepare the analyzer for power off. j m The analyzer is in Standby status.
1 r To prepare the analyzer for switching off 1 If samples are still placed on the sample disk, unload the samples while the ACCESS SAMPLE DISK lamp is on. 2 2 If the USB flash drive is still connected to one of the USB ports, remove the USB flash drive: • Choose the Media Eject button. • Disconnect the USB flash drive from the USB port.
3 Transfer the QC results. 4 Do the following tasks if they are due: • If you are working without an LIS connection, accumulate QC results and delete QC results. • If you are working with an LIS connection, delete QC results. 5 If you have not performed daily maintenance at the beginning of the work shift, perform daily maintenance now. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 222 Preparing the analyzer for switching off 6 6 If you have defined a maintenance pipe for the next day, make sure that you load sufficient amounts of auxiliary reagents and cleaning solutions. u Related topics • Transferring QC results (154) • Accumulating QC results (155) • Deleting QC results - without LIS (156) • Deleting QC results - with LIS (157) • Performing daily maintenance (76) • Loading reagent packs (101) • Unloading reagent packs (104) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation 223 Switching off the analyzer In this section About Shutdown status and Sleep mode (223) Starting the sleep pipe (224) Putting the analyzer into Sleep mode manually (226) Shutting down the analyzer (227) About Shutdown status and Sleep mode Shutdown Sleep mode Wake-up after Sleep mode After routine operation is finished and all required maintenance has been performed, you can either shut down the analyzer or put it into Sleep mode. In Shutdown status, the analytical unit and the control unit are powered off. Only the power for keeping reagents cooled is supplied. During Sleep mode, most of the parts are powered off. Only the control unit, cooling compartment and control board are powered on. The monitor is automatically powered off to reduce power consumption when it is not used for a fixed time. Move the mouse to wake up the monitor. Sleep mode can be entered manually or automatically after a maintenance pipe. If in Sleep mode, you can wake up the analyzer manually at any time. With the Power Up Pipe function, the analyzer can automatically wake up at a defined time and day and perform a maintenance pipe. This way, the system can perform initialization and maintenance items in the absence of an operator before the beginning of a working session. When the operator arrives, the analyzer is ready for operation. q To wake up the analyzer at a defined time using the Power Up Pipe function, the analyzer must have been in Sleep mode for at least 15 minutes. Otherwise the analyzer will wake up at the defined time 24 hours later. When the analyzer wakes up from sleep mode, the control unit performs a shutdown to reset the PC operation software (Windows). Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 224 Switching off the analyzer Starting the sleep pipe To clean the inside of the sample probe and the ISE flow path, you must perform the maintenance item (10) ISE Wash. We recommend including this maintenance item in a maintenance pipe with sleep function selected. This saves time at the end of the day because the analyzer will automatically enter Sleep mode after completion of the maintenance pipe. u Defining maintenance pipes (240) u List of recommended maintenance pipes (244) The inside of the sample probe and the ISE flow path are washed and the ISE electrodes are conditioned during the maintenance item (10) ISE Wash.
q Even if you are not using the ISE unit, you must wash the inside of the sample probe after daily operation. For this, use the maintenance item (11) Sample Probe Wash. c At the end of a work shift n Approximately 30 minutes d m Sample Cleaner 1 (SmpCln 1, 230 µ L) m ISE cleaning solution (SysClean, 400 µ L) (300 µ L plus 100 µ L dead volume) m ISE Activator (400 µ L) (300 µ L plus 100 µ L dead volume) j m The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation 225 1 r To start the sleep pipe 1 Pipette suitable amounts of ISE cleaning solution and ISE Activator into two Hitachi standard cups. 2 2 Place the ISE cleaning solution into position W1 and the ISE Activator into position W2. A B A ISE cleaning solution B ISE Activator 4 5 3 6 3 Choose Utility > Maintenance . 4 Select the sleep pipe. I The sleep pipe must contain the maintenance item (10) ISE Wash. If you measure high amounts of latex-based tests (e.g., TDM: Therapeutic Drugs Monitoring or DAT: Drugs of Abuse Testing), additionally include the maintenance item (6) Wash Reaction Parts in the sleep pipe. 5 Choose the Select button. 6 Choose the Execute button. f After the ISE Wash, the analyzer goes into Sleep mode. f Ensure that you calibrate the ISE unit when you start the analyzer again. u Related topics • Performing an ISE calibration (109) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 226 Switching off the analyzer Putting the analyzer into Sleep mode manually To power off the analyzer without shutting it down completely, you can put the analyzer into Sleep mode.
During Sleep mode, most of the parts are powered off. Only the control unit, cooling compartment and control board are powered on. r To put the analyzer into Sleep mode manually 1 Choose the Shut down button. 1 3 2 2 Select the Sleep option. 3 Choose the OK button. f The analyzer goes into sleep mode until the specified wake-up time. The wake-up time is displayed. 4 4 Make sure that the monitor is powered off. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation 227 5 5 If you use a liquid waste container, make sure that it is empty, clean, and properly installed. Shutting down the analyzer To put the analyzer in a powerless state, you can shut down the analyzer. When the analyzer is shut down, only the power for keeping reagents cooled is supplied. c At least once a week r To shut down the analyzer 1 Choose the Shut down button. 1 3 2 2 Select the Shutdown option. 3 Choose the OK button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 228 Switching off the analyzer 4 4 Wait until the screen goes black. f The computer has shut down. 5 5 Switch off the power switches of the monitor and printer. 6 6 Switch off the power switch of the analytical unit. I Improper start-up of the analyzer. If power to the analyzer is switched off before the complete shutdown of the computer, the instrument may not start up properly when power is supplied again. 7 7 Turn off the water supply. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 After operation 229 8 8 If you use a liquid waste container, make sure that it is empty, clean, and properly installed.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 230 Switching off the analyzer Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance Table of contents 233 9 In this chapter Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 234 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 235 Maintenance definitions Operator-controlled

maintenance Software-controlled maintenance Maintenance tasks are divided into software-controlled maintenance and operator-controlled maintenance. Software-controlled maintenance is done by executing various maintenance items. Single maintenance items can be grouped using maintenance types. Softwarecontrolled maintenance can be automated using maintenance pipes. Maintenance tasks that require operator interaction (for example, cleaning the sample probe). Maintenance tasks that are performed by the analyzer without operator interaction.

In the analyzer software, these maintenance tasks are called maintenance items. Maintenance item A single software-controlled maintenance task.

Maintenance items can be performed manually by selecting them in the analyzer software.

Maintenance items can be also part of a maintenance pipe.

A A Maintenance type B B Maintenance item Maintenance type Maintenance pipe Maintenance pipe function A set of maintenance items and maintenance pipes grouped according to certain functions (for example, daily maintenance). u Checking maintenance due time (247) A group of maintenance items that can be performed by the analyzer automatically without operator intervention. u Defining maintenance pipes (240) The ability of the analyzer to start a maintenance pipe at a particular time. u Using the Power Up Pipe function (242) u Using the Start Up Pipe function (243) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 236 About Maintenance mode About Maintenance mode Switching the analyzer to Maintenance mode To perform maintenance tasks that require the top cover to be open, you must switch the analyzer to Maintenance mode. In Maintenance mode, the motors driving the pipetter probes, the sample disk, and the reaction disk are turned off while the analyzer remains powered on. The pipetter probes can then be moved by hand to accessible positions. NOTICE Interruption of measurement due to improper use If you use the maintenance switch to change to Maintenance mode while the analyzer is in Operation status or Sampling Stop status, the analyzer stops operation and measurement may be interrupted. r Make sure that the analyzer is in Standby before you activate the maintenance switch. j m The analyzer is in Standby status.

r To switch the analyzer to Maintenance mode 1 Turn the maintenance switch to Maintenance mode. 1 A A Maintenance switch Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 237 2 2 Wait until the Standby status is displayed with a yellow background. I The yellow background indicates that the analyzer is in Maintenance mode. 3 3 Unlock and open the top cover of the analyzer.

u Related topics • Terminating the Maintenance mode (237) Terminating the Maintenance mode To continue operating the analyzer, you must terminate the Maintenance mode properly. r To terminate the Maintenance mode 1 Close and lock the top cover of the analyzer. 1 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 238 About Maintenance mode 2 2 Turn the Maintenance switch to Operation mode. A A Maintenance switch 3 3 Wait until the Standby status is displayed with a white background. 5 4 4 Choose Utility > Maintenance . 5 Select the Reset option. 6 Choose the Select button. 6 7 7 Choose the Execute button. f All mechanical parts return to their home positions. u Related topics • Switching the analyzer to Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 239 About maintenance pipes and maintenance pipe functions You can group maintenance items into maintenance pipes. The analyzer can then perform all items in the pipe automatically without operator intervention. By default, there are no predefined pipes on the instrument. However, Roche recommends using maintenance pipes for automating instrument care. Maintenance pipes can be executed in two different ways: • Manually by the user • Automatically with maintenance pipe functions To perform a maintenance pipe manually, the pipe must have been grouped into a maintenance type first. You can let the analyzer enter Sleep mode automatically after completion of a maintenance pipe. However, if the pipe is executed with a maintenance pipe function, the analyzer will not enter Sleep mode. A A Maintenance type B B Maintenance pipe Maintenance pipe function The analyzer is able to start a maintenance pipe at a particular time using maintenance pipe functions. There are two maintenance pipe functions: • Power Up Pipe function: Starts the maintenance pipe at power-up or wake-up • Start Up Pipe function: Starts the maintenance pipe before start of analysis q Make sure to differentiate between maintenance pipes and maintenance pipe functions, particularly since names of maintenance pipes are freely definable.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 240 About maintenance pipes and maintenance pipe functions Example: pipes and pipe functions Maintenance pipe Power On Pipe • (4) Incubation Water Exchange • (5) Air Purge • (7) Reagent Prime • (2) Photometer Check Automatic Power Up Pipe function Manual You have defined a maintenance pipe that contains several maintenance items. You have named the maintenance pipe Power On Pipe . This maintenance pipe can be executed manually or automatically with a maintenance pipe function.

To execute the pipe automatically, you can either use the maintenance pipe function called Start Up Pipe or the maintenance pipe function called Power Up Pipe . These names are fixed. In this section Defining maintenance pipes (240) Using the Power Up Pipe function (242) Using the Start Up Pipe function (243) List of recommended maintenance pipes (244) Start Up Pipe function Defining maintenance pipes To let the analyzer automatically perform a group of maintenance items, you can program maintenance items into a maintenance pipe.

You can define up to 20 pipes. Each pipe can have up to ten maintenance items including parameters belonging to them. The name of a pipe is freely definable. Maintenance items within a pipe are performed in the order in which they are listed in the maintenance pipe. 1 r To define a maintenance pipe 1 Choose Utility > System (Page 2/5) > Pipe Setting . Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 3 Overview of maintenance 241 2 2 Select the first blank line. 3 Choose the Edit button. 5 6 9 5 4 8 4 Enter an unused name for the new pipe. 5 To edit the maintenance pipe, do the following: • To add a maintenance item to the pipe, select the maintenance item and choose the Add button. • To delete a maintenance item from the pipe, select the maintenance item and choose the Remove button. • To change the position of the maintenance item in the pipe, select the maintenance item and choose the appropriate Order button. 6 If you want to define parameters for the maintenance item, choose the Parameter button. 7 Repeat steps 5 to 6 for all maintenance items you want to include in the pipe. 8 If you want the analyzer to enter Sleep mode automatically after completion of the maintenance pipe, select the Sleep check box. I If the pipe is executed with a maintenance pipe function, the analyzer will not enter Sleep mode. 9 Choose the OK button. f The maintenance pipe is displayed in the Pipe Name list. u Related topics • List of maintenance items (251) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 242 About maintenance pipes and maintenance pipe functions Using the Power Up Pipe function To let the analyzer automatically perform a maintenance pipe at power-up or wake-up, you can use the Power Up Pipe function. You can define a different maintenance pipe for each day of the week. Thus, when powering on the analyzer, you can choose to perform the maintenance pipe for the corresponding day. You can also define a wake-up time for each day. In this case, the analyzer will automatically wake up and perform the maintenance pipe at the defined time and day. However, this only takes effect if the analyzer is in Sleep mode. If the analyzer is in Shutdown status, the maintenance pipe is only performed if you manually power up the analyzer. 1 r To use the Power Up Pipe function 1 Choose Utility > System (Page 2/5) > Power Up Pipe . 2 2 For each day of the week, choose a maintenance pipe to be performed at power-up. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 243 4 3 3 If you want to define a wake-up time, do the following: • Select the check box beside a weekday. • Enter a wake-up time. 4 Choose the OK button. f If you have defined a wake-up time, the analyzer is restarted and initialized 10 minutes before the defined time. Thereafter the maintenance pipe is performed.

f The wake-up time is displayed in the Logon screen during Sleep mode.

Using the Start Up Pipe function To let the analyzer automatically perform a maintenance pipe before the start of analysis, you can use the Start Up Pipe function. r To use the Start Up Pipe function 1 Choose the Start button. 1 2 2 Choose the Change button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 244 About maintenance pipes and maintenance pipe functions 4 3 3 Choose the maintenance pipe to be performed before the start of analysis. 4 Choose the OK button. f The chosen maintenance pipe is displayed in the Start Up Pipe Setting group box. If no maintenance pipe is selected, None is displayed.

5 5 Choose the Start button. f The chosen maintenance pipe is performed.

Thereafter analysis starts automatically. f Once the maintenance pipe begins, None is displayed in the Start Up Pipe Setting group box again. List of recommended maintenance pipes Daily pipe Roche recommends using several maintenance pipes for proper instrument care. However, there are no predefined pipes on the analyzer by default. For the pipe to be performed correctly, you must program the maintenance items in the order listed below. Roche also recommends using maintenance pipe functions to perform maintenance pipes automatically.

This ensures a maximum of instrument care with minimal operator intervention. u Using the Power Up Pipe function (242) u Using the Start Up Pipe function (243) Roche recommends performing this maintenance pipe with the Power Up Pipe function—either at power-up or wake-up of the analyzer. Maintenance item (4) Incubation Water Exchange (251) (5) Air Purge (251) (7) Reagent Prime (252) with the REF option cobas link Essential Information Upload (252) (2) Photometer Check (251) y Recommended maintenance pipes—daily pipe Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 245 Sleep pipe Weekly pipe It can take up to 30 minutes after an (4) Incubation Water Exchange for the incubator to reach the correct temperature (37 ± 0.1ºC). Therefore perform the (2) Photometer Check in a separate pipe if your wake-up pipe does not include a cobas link Essential Information Upload. Even though a maintenance pipe can be executed automatically, some maintenance items require visual checks by the operator. u Waking up the analyzer manually (65) Roche recommends performing this maintenance pipe daily. By selecting the sleep function when defining this maintenance pipe, the analyzer will automatically turn to Sleep mode after the pipe is completed. Ensure that you calibrate the ISE unit when you start the analyzer again. If you measure high amounts of latex-based tests (e.g., TDM: Therapeutic Drugs Monitoring or DAT: Drugs of Abuse Testing), additionally include the maintenance item (6) Wash Reaction Parts in the sleep pipe.

Maintenance item (10) ISE Wash (252) y Recommended maintenance pipes— sleep pipe Roche recommends performing this maintenance pipe every week before shutdown or start-up. q Before you shut down the analyzer, check the cell blank measurement report (Print > Utility > Cell Blank Measurement). The cell blank values will be lost after shutdown. u Washing the reaction parts (275) Maintenance item (6) Wash Reaction Parts (251) (3) Cell Blank Measurement (251) y Recommended maintenance pipes—weekly pipe Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 246 About maintenance pipes and maintenance pipe functions Photometer exchange pipe This pipe is used to let the analyzer display when the photometer lamp must be replaced. Therefore, you must group the pipe into a maintenance type with the following settings: • Period: 750 hours • Timer: Power On • Warning Level: 99 % Maintenance item (6) Wash Reaction Parts (251) (2) Photometer Check (251) (3) Cell Blank Measurement (251) y Recommended maintenance pipes—photometer exchange pipe Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 247 Checking maintenance due time A B A Predefined maintenance types B Custom maintenance types The instrument can display the due time for a maintenance item or pipe within a maintenance type. The due time is not displayed for predefined maintenance types. Two maintenance types are predefined: • Maintenance: Contains all available maintenance items except maintenance checks and service routines • Check: Contains all maintenance checks The analyzer displays the due time for maintenance types, maintenance items, and pipes with the following colors: Maintenance Type Maintenance item/pipe Color Meaning A maintenance item or pipe of this maintenance type exceeded its warning level. A maintenance item or pipe of this maintenance type exceeded its maintenance interval. This maintenance item or pipe exceeded its warning level. This maintenance item or pipe exceeded its maintenance interval. y Colors for maintenance due time 2 4 1 r To check maintenance due time 1 Choose Utility > Maintenance . 2 In the Maintenance Type list, check if any maintenance types are highlighted in yellow or red. 3 Select a maintenance type. 4 In the Maintenance Items list, check if any maintenance items are highlighted in yellow or red: • The Date column displays when the maintenance item or pipe was last performed. • If the maintenance item or pipe is due, the date is highlighted in yellow or red. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 248 Checking maintenance status Checking maintenance status To check the status of the maintenance item currently being performed, you can use the Maintenance Monitor window.

The Maintenance Monitor window displays the status of the unit on which the maintenance item is being performed. The window also displays the remaining time for the maintenance item.

2 3 1 r To check the maintenance status 1 Choose Utility > Maintenance . 2 Select a maintenance type. 3 Select a maintenance item or pipe.

4 Choose the Monitor button. f The status of the selected maintenance item or pipe is displayed. 4 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 249 Requesting the Maintenance Report To view the execution record of all maintenance items or a selected maintenance item, you can request the Maintenance Report. The Maintenance Report lists the date, time, operator ID, and comments of the selected maintenance items. When a maintenance item is performed as a part of a pipe, an asterisk (*) appears on the left side of the date in the Maintenance Report. 2 3 4 1 r To request the Maintenance Report 1 Choose Utility > Maintenance . 2 Select the maintenance type that contains the desired maintenance item or items.

3 If you want to request the Maintenance Report for specific maintenance items, select the respective maintenance items. 4 Choose Print . 6 7 5 5 Choose Utility > Maintenance Report . 6 In the Maintenance group box, do the following: • To print the Maintenance Report for all maintenance items of the selected maintenance type, select the All option. • To print the Maintenance Report for only the selected maintenance items, select the Selected option. 7 To print the Maintenance Report for either the analyzer unit, the control unit, or both, select the respective check boxes. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 250 Requesting the Maintenance Report 8 9 8 In the Date Range group box, do the following: • To print the Maintenance Report for all maintenance items performed, select the All option. • To print the Maintenance Report for only the last maintenance items performed, select the Last option. • To print the Maintenance Report for a range of dates, select the Range option. In the Start field and End field, type the first and last date and time of the date range. I You can define the date format in the Date dropdown list (Utility > System). 9 To print or view the Maintenance report, do the following: • To print the Maintenance Report, choose the Print button. • To display a preview of the Maintenance Report, choose the Preview button and then choose the View button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 251 List of maintenance items Maintenance items are single software-controlled maintenance tasks. Some maintenance items only apply to either the photometric unit or the ISE unit. Some maintenance items apply to both. P: Denotes that a function only applies to the photometric unit. In the maintenance windows, the abbreviation AU is used to refer to the photometric unit. ISE: Denotes that a function only applies to the ISE unit. P+ISE: Denotes that a function applies to both units. The time period in brackets denotes the approximate system time of the maintenance item in (min:s). A A Maintenance type: Maintenance B B All maintenance items (1) Reset (2) Photometer Check (3) Cell Blank Measurement (4) Incubation Water Exchange (5) Air Purge (6) Wash Reaction Parts All mechanical parts return to their home positions (P+ISE) (0:30). Photometer output is checked by measuring a water blank of cell no. 1. You can check the values in the Photometer Check report (P) (2:40). Water blanks of all cells are measured. If there is a difference greater than 0.1 absorbance units in the results for one cell compared to the cell no. 1, that cell number is written to the Abnormal Cell List on the Cell Blank Measurement report. If more than about five reaction cells are affected, you must replace all cells by new ones (P) (16:50). Incubator bath water is exchanged and Ecotergent (4.3 mL) is added (P) (5:30). Any air is purged that may have become trapped in the sample and reagent syringes. Water as well as air are discharged at the rinse stations (P) (1:45). All cells and probes are washed.

The sample probe is washed with Sample Cleaner 1 (approx. 300 µ L). The reagent probe and reaction cells are washed with detergent from a NAOHD reagent pack (approx. 26 mL) (P) (29:30). Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 252 List of maintenance items (7) Reagent Prime (8) Cell Detergent Prime (9) Incubator Bath Cleaning (10) ISE Wash (11) Sample Probe Wash (12) Flow Path Wash (13) Floppy Disk Utility (14) Parameter Read/Write (15) Test Count Write (16) QC Timer Reset cobas link Essential Information Upload Reagents are primed according to the option chosen (IS+REF or REF).

Options System time Description IS+REF 9:30 REF 1:50 Both ISE IS and ISE REF are primed. ISE REF is aspirated through the reference cartridge to prime the reference electrode. y Reagent prime options Reagent consumption ISE IS: 9230 µ L ISE REF: 1690 µ L ISE IS: 0 µ L ISE REF: 3120 µ L Reagent lines for Cell Wash Solution I (CellCln 1) and II (CellCln 2) are primed. Reagent lines are purged of air and cells are filled up and emptied by vacuum. You can select which detergents need to be primed (Detergent 1, Detergent 2, or both) (P) (8:55). The photometer lamp is switched off and the incubator bath water is automatically drained. Then the analyzer performs a complete system shutdown (P). The sample probe and the flow path of the ISE unit are washed. The sample probe is washed with Sample Cleaner 1. The ISE flow path is washed with SysClean from position W1 on sample disk. The ISE electrodes are conditioned with Activator from position W2 (P+ISE) (28:15). The sample probe is washed with Sample Cleaner 1 (approx. 300 µ L) (P) (6:10 for five cycles). The flow path, the drain port, and the drainage tube for concentrated waste solution are cleaned with CellCln 2 (approx. 30 mL) (P) (20:30). A floppy disk inserted into the floppy disk drive will be formatted after confirmation. Parameter settings are read from or written to a floppy disk. Test count is written to a floppy disk. Resets the control interval timer. If, for example, the control interval timer is set to 10 hours, after 5 hours the user can reset the timer to 10 hours (P). Important data such as calibrator and control data is uploaded and stored on the cobas link data station. The last five backups are stored and the oldest backup is overwritten with the newest backup. Hence the last five backups are available to restore to the analyzer if necessary. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 253 List of maintenance checks With maintenance checks, you can test the functionality of several hardware components. Some maintenance checks only apply to either the photometric unit or the ISE unit. Some maintenance checks apply to both. P: Denotes that a function only applies to the photometric unit. In the maintenance windows, the abbreviation AU is used to refer to the photometric unit. ISE: Denotes that a function only applies to the ISE unit. P+ISE: Denotes that a function applies to both units. The time period in brackets denotes the approximate system time of the maintenance check in (min:s). A A Maintenance type: Check B B All maintenance checks (1) Disk Check (2) ISE Check (3) Mechanisms Check Files are checked on the hard disk, floppy disk, USB flash drive, or DVD. A directory listing is printed to the print buffer afterwards. If a malfunction occurs, the system issues an alarm. The hard disk check can also be used to determine the software version. The electrode output of ISE cartridges (Cl, K, Na, and reference cartridges) is measured with ISE IS and a listing of EMF values is printed.

If an EMF value is abnormal, you must retry ISE check (P) (18:00 for ten cycles). Performs a functional check of the mechanical parts of the entire sample line of the analyzer (according to the number of cycles) (P+ISE) (9:30 for 30 cycles). (4) Barcode Reader Check (5) Probe Check The barcode on a sample tube or reagent pack is scanned to check the sample barcode reader or the reagent barcode reader (P). Allows you to move the sample probe or the reagent probe to designated positions with the S. Stop button (P+ISE). (6) Cuvette Mixing Performs a functional check on the ultrasonic mixer. The reagent probe pipettes deionized water into the corresponding reaction cell. The reaction cell is moved to the mixing position and ultrasonic mixing is executed (P+ISE) (5:05 for ten cycles). Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 254 List of tools, materials, and solutions List of tools, materials, and solutions To perform maintenance actions, use the tools, materials, and cleaning solutions below. Tools Tool Function 50 mL syringe with tubing (or wash bottle) Waste solution receptacle (collection tray) Clean the rinse stations Collect water from the water tank Beaker or container, 500 mL Collect water or waste solution Vacuum cleaner Clean the radiator filter and cooling fan Cleaning wire 0.2 mm Clean clogged sample probe Cleaning wire 0.5 mm Radio pliers Tweezers Clean clogged reagent probe and cell rinse nozzles Replace nozzle tips y Required tools for maintenance Materials Material Lint-free gauze pads Paper towels Cotton swabs y Required materials for maintenance Cleaning solutions Cleaning solution Alcohol (e.g., isopropyl alcohol or ethanol) 2% EcoTergent solution Sample Cleaner 1 (SmpCln 1) ISE cleaning solution (SysClean) ISE Activator 0.5% sodium hypochlorite solution Laboratory disinfectant (no alcohol or bleach) Deionized water y Required cleaning solutions for maintenance q If you are not allowed to use one of the recommended cleaning solutions due to local regulations, use a comparable cleaning solution that meets your local regulations. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Overview of maintenance 255 List of spare parts and replacement intervals Some parts require periodic replacement for preventive maintenance. Replacement is either based on given intervals, on test count, or operating time. Replace the listed parts regularly and in accordance with your workload and the recommendations given in this document. For purchase order, inform your Roche representative of the part number. q For proper instrument care, use only original spare parts provided by Roche. o The necessary spare parts are listed in the description of the corresponding maintenance task. o To order spare parts, contact your Roche representative.

ISE unit Photometric unit Item ISE measuring cartridges (Cl, K, Na) ISE pinch valve tubing ISE sipper tubing ISE reference cartridge Replacement interval o 2 months o after measuring 9000 samples o 3 months o 3 months o 6 months y Replacement intervals of parts for the ISE unit Item Reaction cells Replacement interval o monthly Photometer lamp o 6 months o if photometer check value exceeds 14 000 absorbance units at any wavelength o when used for more than 750 hours of power-on time (1) Sample and reagent probe o as required: if the sample probe is bent or otherwise damaged Nozzle tips of the cell rinse unit o as required: if the corner or bottom of a nozzle tip is worn so that water remains in the reaction cell y Replacement intervals of parts for the photometric unit (1) You can let the analyzer display when the photometer lamp must be replaced using the photometer exchange pipe. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 256 List of spare parts and replacement intervals u Related topics • List of recommended maintenance pipes (244) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance Table of contents 257 10 In this chapter 10

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 258 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 259 List of maintenance tasks Maintenance is required to ensure that the analyzer works properly and to keep the risk of contamination low. You must observe the maintenance intervals listed in the table. The listed maintenance intervals are independent of the operating time unless otherwise noted. That is, a few maintenance intervals for the replacement of spare parts are based on test count or operating time. The initial status column lists the required analyzer status at the beginning of the maintenance task. That is, the required analyzer status can change throughout a maintenance task. u List of spare parts and replacement intervals (255) Daily maintenance Weekly maintenance Monthly maintenance Task Washing the ISE flow path (261) Cleaning all pipetter probes and rinse nozzles (263) Cleaning the ISE drain port (266) Initial status Standby status Maintenance mode Checking and draining the vacuum tank (329) Maintenance mode Emptying the liquid waste container (267) Maintenance mode Cleaning the analyzer surface (268) Maintenance mode Maintenance mode Cleaning the cell covers (270) Cleaning the rinse stations (272) Washing the reaction parts (275) Replacing reaction cells and cleaning incubator bath (278) Cleaning the ISE REF aspiration filter (284) Cleaning the detergent aspiration filters (286) Cleaning the radiator filter (288) Maintenance mode Maintenance mode Standby status Standby status Maintenance mode Standby Standby status status Standby status Washing the flow path of concentrated waste solution (289) Every three months maintenance Cleaning the water tank (290) Every two months maintenance Replacing ISE measuring electrodes (Cl, K, Na) (295) Cleaning the ultrasonic mixer (301) Replacing the ISE pinch valve tubing and sipper tubing (305) Shutdown status Maintenance mode Standby status Maintenance mode y Overview of maintenance tasks Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 260 List of maintenance tasks Task Every six months maintenance Cleaning the inlet water filter (309) Cleaning the cooling fan (312) Replacing the photometer lamp (313) As needed maintenance Replacing the ISE reference electrode (320) Checking and draining the vacuum tank (329) Replacing the sample probe (331) Eliminating clogging of the sample probe (338) Replacing the reagent probe (340) Eliminating clogging of the reagent probe (346) Replacing nozzle tips on cell rinse nozzles (348) Eliminating clogging of the cell rinse nozzles (351) y Overview of maintenance tasks Initial status Shutdown status Shutdown status Shutdown status Maintenance mode Standby status Shutdown status Standby status Shutdown status Shutdown status Maintenance mode Maintenance mode u Related topics • List of analyzer statuses (39) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 261 Daily maintenance We recommend performing daily maintenance at the beginning of each work shift. It is also possible to perform daily maintenance after or in between a shift. In this section Washing the ISE flow path (261) Cleaning all pipetter probes and rinse nozzles (263) Cleaning the ISE drain port (266) Emptying the liquid waste container (267) Cleaning the analyzer surface (268) Washing the ISE flow path To clean the inside of the sample probe and the ISE flow path, you must perform the maintenance item (10) ISE Wash. The inside of the sample probe and the ISE flow path are washed and the ISE electrodes are conditioned. We recommend including this maintenance item in a Sleep pipe. This saves time because then you do not have to perform this maintenance item at the beginning of each work shift. u Starting the sleep pipe (224) u Defining maintenance pipes (240) q Even if you are not using the ISE unit, you must wash the inside of the sample probe after daily operation. For this, use the maintenance item (11) Sample Probe Wash. n Approximately 30 minutes d m Sample Cleaner 1 (SmpCln 1, 230 µ L) m ISE cleaning solution (SysClean, 400 µ L) (300 µ L plus 100 µ L dead volume) m ISE Activator (400 µ L) (300 µ L plus 100 µ L dead volume) j m The analyzer is in Standby status.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 262 Daily maintenance 1 r To wash the ISE flow path 1 Pipette suitable amounts of ISE cleaning solution and ISE Activator into two Hitachi standard cups. 2 2 Place the ISE cleaning solution into position W1 and the ISE Activator into position W2. A B A ISE cleaning solution B ISE Activator 3 3 Choose Utility > Maintenance . 4 Select the (10) ISE Wash option.

5 Choose the Select button. 4 5 6 6 Choose the Execute button. 7 If you measure high amounts of latex-based tests (e.g., TDM: Therapeutic Drugs Monitoring or DAT: Drugs of Abuse Testing), additionally perform the maintenance item (6) Wash Reaction Parts. 8 Perform an ISE calibration. u Related topics • Performing an ISE calibration (109) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 263 Cleaning all pipetter probes and rinse nozzles To ensure optimal condition of all probes and measurement accuracy of the analyzer, you must clean the outside of the pipetter probes, the ISE sipper probe, and the cell rinse nozzles. n Approximately 10 minutes d m Lint-free gauze pads m Paper towels m Alcohol (e.g., isopropyl alcohol or ethanol) m Cleaning wire (stainless steel, diameter 0.5 mm) m Deionized water m Tweezers j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) r To clean all pipetter probes and rinse nozzles 1 To remove the sipper cover, loosen the screws. 1 A A Screws B B Sipper cover A Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 264 Daily maintenance A B 2 2 CAUTION! Risk of infection! A probe tip can easily pierce a protective glove. 2 Clean the probes with gauze pads moistened with alcohol: • Use several layers of gauze pads. • Always wipe from top to bottom. • Clean the sample probe using tweezers. • Hold the pipetter arm with one hand and gently wipe with the other hand. • To prevent cross contamination, use new gauze pads for each probe. 5 C A Sample probe B Reagent probe C ISE Sipper probe 3 3 Reattach the sipper cover. 4 4 Wipe the shield pipe with a gauze pad moistened with alcohol. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 265 5 5 To lift off the cell rinse unit, loosen the retaining screw. A A Retaining screw 6 6 Wipe all tips of the cell rinse nozzles with a gauze pad moistened with deionized water from top to bottom. A Cell rinse nozzles A 7 7 Return the cell rinse unit to its original position. u Related topics • Terminating the Maintenance mode (237) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 266 Daily maintenance Cleaning the ISE drain port To prevent accumulation of crystals and clogging of the drain port, you must clean the outlet of the ISE drain port.

n Approximately 3 minutes d m Lint-free gauze pads m Deionized water j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To clean the ISE drain port 1 To remove crystals, rinse the outlet of the ISE drain port with deionized water. A A ISE drain port B Deionized water B 2 2 Wipe up spilled water with gauze pads. u Related topics • Terminating the Maintenance mode (237) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 267 Emptying the liquid waste container Before the liquid waste container gets full, you must empty it. If the analyzer is connected to a drainage system, no action is required. n Approximately 1 minute d m Paper towels m Laboratory disinfectant (no bleach) j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To empty the liquid waste container 1 Lift the liquid level sensor from the waste container and place it on paper towels.

A A Liquid level sensor 2 2 Remove the hose from the waste container and put paper towels under the hose. 3 Dispose of the contents of the concentrated waste container according to local regulations for biohazardous waste. 4 Rinse the waste container thoroughly with water. Dispose of the rinse water according to local regulations for biohazardous waste. 5 Prepare the disinfectant according to the manufacturer’s instructions. Pour it into the waste container. A Hose A Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 268 Daily maintenance 8 7 6 After a suitable time provided by the disinfectant manufacturer’s product description dispose of the disinfectant according to local regulations for biohazardous waste. 7 Place the waste container back into its original position. 8 Return the liquid level sensor and the hose into the waste container. 9 Dispose of the paper towels according to local regulations for biohazardous waste. 10 Disinfect the work area. u Related topics • Terminating the Maintenance mode (237) Cleaning the analyzer surface Spills on the analyzer surface can be biohazardous. Clean up all spills immediately. Additionally, clean the analyzer surface at the end of each day. q Do not use alcohol or bleach to clean the analyzer surfaces.

Alcohol or bleach can damage the finish of the analyzer surfaces. n Approximately 5 minutes d m Disposable cloth or paper towels m Laboratory disinfectant (no alcohol or bleach) j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 269 1 r To clean the analyzer surface 1 Remove all samples from the analyzer. 2 2 Clean all analyzer surfaces using a cloth or paper towel moistened with disinfectant. 3 3 If necessary, clean the cell covers using a gauze pad moistened with disinfectant. u Related topics • Terminating the Maintenance mode (237) • Cleaning the cell covers (270) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 270 Weekly maintenance Weekly maintenance Perform these maintenance tasks at least once a week. In this section Cleaning the cell covers (270) Cleaning the rinse stations (272) Washing the reaction parts (275) Cleaning the cell covers To prevent contamination by samples and reagents, you must clean the cell covers. c • Each day at the end of analysis, check the cell covers for contamination. • Clean the cell covers at least once a week. n Approximately 5 minutes d m Cotton swabs m Lint-free gauze pads m Alcohol (e.g., isopropyl alcohol or ethanol) m Deionized water j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 271 1 r To clean the cell covers 1 To remove the cell covers, loosen the screws. A Screw A A 2 2 Wipe the front and rear faces of the cell covers using a gauze pad moistened with alcohol. 3 3 To pull the U-cover off the cell cover, pinch the sides of it. 4 4 Wipe off the openings of the cell covers using a cotton swab moistened with alcohol. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 272 Weekly maintenance 6 7 5 5 Wash the U-cover with deionized water. 6 If dust and dirt do not come off, wipe the U-cover using a cotton swab moistened with alcohol. 7 Attach the dried U-cover and put the cell covers back in place. u Related topics • Terminating the Maintenance mode (237) Cleaning the rinse stations To prevent bacterial growth and clogging, you must clean the rinse stations of the sample probe and the reagent probe. n Approximately 7 minutes d m 50 mL syringe with tubing or wash bottle m 2% EcoTergent solution m Deionized water m Alcohol (e.g., isopropyl alcohol or ethanol) m Cotton swabs j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To clean the rinse stations 1 Clean the inside of the sample probe rinse station using a cotton swab moistened with 2% EcoTergent solution. A A Rinse station of sample probe Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 A A Drying cylinder Periodic maintenance 273 2 2 Inject about 10 mL of 2% EcoTergent solution into the sample probe rinse station. I Do not inject liquid (water or EcoTergent) into the drying cylinder.

3 3 Inject about 100 mL of deionized water into the rinse station. 4 4 Wipe the drying cylinder with a cotton swab moistened with alcohol. Make sure that no cotton swab fibers block the drying cylinder. A A Drying cylinder Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 274 Weekly maintenance A A Rinse station of reagent probe B B Drying cylinder 5 5 To clean the reagent probe rinse station and the drying cylinder, repeat the steps 1 to 4 .

u Related topics • Terminating the Maintenance mode (237) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 275 Washing the reaction parts To ensure correct measurement results, you must wash the reagent probe and reaction cells. This task contains the following procedures: u To wash the reaction parts p (275) u To perform a cell blank measurement p (276) c • Weekly • Daily if you measure high amounts of latex-based tests (e.g., TDM: Therapeutic Drugs Monitoring or DAT: Drugs of Abuse Testing) n Approximately 48 minutes (30 minutes for the maintenance item (6) Wash Reaction Parts and 17 minutes for the maintenance item (3) Cell Blank Measurement) d m NAOHD reagent pack (approx. 26 mL) m Sample Cleaner 1 (SmpCln 1, approx. 300 µ L) j m The analyzer is in Standby status. 1 r To wash the reaction parts 1 Choose Utility > Maintenance . 2 Select the (6) Wash Reaction Parts option. 3 Choose the Select button. 2 3 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 276 Weekly maintenance 4 4 Choose the Execute button. f The maintenance item is finished when the analyzer returns to Standby status. 2 1 r To perform a cell blank measurement 1 Choose Utility > Maintenance . 2 Select the (3) Cell Blank Measurement option. 3 Choose the Select button.

3 4 4 Choose the Execute button. 5 5 To print or view the Cell Blank Measurement report, do the following: • Choose Print > Utility > Cell Blank Measurement . • To print the report, choose the Print button. • To view the report on screen, choose the Preview button. Then choose the View button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 277 6 6 Check if any cells are listed in the Abnormal Cell List at the top of the report: • If only one to five cells are listed in the Abnormal Cell List, you can continue without any further action. These cells are excluded from measurements. • If more than about five reaction cells are affected, replace all cells by new ones. u Related topics • Replacing reaction cells and cleaning incubator bath (278) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 278 Monthly maintenance Monthly maintenance Perform these maintenance tasks at least once a month. In this section Replacing reaction cells and cleaning incubator bath (278) Cleaning the ISE REF aspiration filter (284) Cleaning the detergent aspiration filters (286) Cleaning the radiator filter (288) Washing the flow path of concentrated waste solution (289) Cleaning the water tank (290) Replacing reaction cells and cleaning incubator bath Reaction cells deteriorate over time. To ensure reproducibility of measurement results, you must replace the reaction cells and clean the incubator bath. This task contains the following procedures: u To remove reaction cells and to clean the incubator bath p (279) u To clean the drain filter of the incubator bath p (281) u To reinstall reaction parts and to terminate the incubator bath cleaning p (282) u To check the intensity of the ultrasonic output p (284) n • Operator time: approximately 10 minutes • System time: 52 minutes (5 minutes for the maintenance check (6) Cuvette Mixing, 30 minutes for the maintenance item (6) Wash Reaction Parts, and17 minutes for (3) Cell Blank Measurement) d m Reaction cells m EcoTergent reagent pack (surfactant for the incubator, approx. 4.3 mL) m Lint-free gauze pads m Cotton swabs m Deionized water m NAOHD reagent pack (approx. 26 mL) m Sample Cleaner 1 (SmpCln 1, approx. 300 µ L) j m The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 279 3 2 1 r To remove reaction cells and to clean the incubator bath 1 Choose Utility > Maintenance . 2 Select the (9) Incubator Bath Cleaning option. 3 Choose the Select button. 4 4 Choose the Execute button. f The water is drained from the incubator bath and the control unit is powered off (shutdown). 5 5 After the computer power supply has been powered off, switch off the power of the analytical unit.

I Do not open the top cover until the analyzer is in shutdown.

6 6 To lift off the cell rinse unit, loosen the retaining screw.

A A Retaining screw Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 280 Monthly maintenance 7 7 To remove the sipper cover, loosen the screws. A A Screws B B Sipper cover A 8 8 To remove the cell covers, loosen the screws. A Screw A A 9 9 To remove each segment of the reaction cells from the reaction disk, remove the respective screws. 10 10 Wipe the inside surfaces of the incubator bath with a clean lint-free gauze pad. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 281 11 11 Wipe the photometer windows carefully. • Do not scratch the photometer windows when cleaning. • Use only gauze pads moistened with deionized water. A Photometer windows A 12 12 Wipe the surfaces of the ultrasonic mixer with a cotton swab moistened with deionized water. A Ultrasonic mixer A 1 r To clean the drain filter of the incubator bath 1 To remove the incubator bath drain filter, grasp the filter by its handle and pull out the filter. 2 Wash the incubator bath drain filter with deionized water and rinse it afterwards with deionized water. A A Incubator bath drain filter Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 282 Monthly maintenance 3 3 Return the incubator bath drain filter to its place. I If you are performing every six month maintenance, we recommend replacing the photometer lamp before reinstalling the reaction parts. 1 r To reinstall reaction parts and to terminate the incubator bath cleaning 1 Place segments of new reaction cells onto the reaction disk. 2 2 Reinstall the cell covers. 3 3 Reattach the sipper cover. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 283 4 4 Return the cell rinse unit to its original position. 5 5 Close the top cover of the analyzer and lock it. 6 6 Switch on the analytical unit and then switch on the control unit. f The incubator bath is filled with some water. A yellow alarm is issued, indicating that the level of incubation water is below the lower limit. 9 8 7 7 Choose Utility > Maintenance . 8 Select the (4) Incubation Water Exchange option. 9 Choose the Select button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 284 Monthly maintenance 10 10 Choose the Execute button. f The incubator bath water is exchanged and EcoTergent (4.3 mL) is added. 11 Wash the reaction parts. 12 Perform a cell blank measurement. 2 3 1 r To check the intensity of the ultrasonic output 1 Choose Utility > Maintenance .

2 Select the (2) Check option. 3 Select the (6) Cuvette Mixing option. 4 Choose the Select button. 4 6 5 5 Enter “10” cycles. 6 Choose the Execute button. 7 If an alarm occurs, follow the remedies described in the alarm message. u Related topics • Replacing the photometer lamp (313) • Washing the reaction parts (275) Cleaning the ISE REF aspiration filter To prevent clogging of the ISE REF aspiration filter and to ensure accuracy of ISE REF aspiration, you must clean the ISE REF aspiration filter. When the filter was disconnected from the ISE REF bottle, air may have entered the ISE electrode. Therefore you must perform a reagent prime for the ISE REF tubing. n Approximately 7 minutes Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 285 d m Paper towels m Deionized water m ISE REF (approx. 3120 µ L) j m The analyzer is in Maintenance mode.

u Switching the analyzer to Maintenance mode (236) 1 r To clean the ISE REF aspiration filter 1 Remove the tubing from the ISE REF bottle. 2 Unscrew the filter from the tube end. 3 3 Wash the filter with deionized water.

4 Then rinse the filters with deionized water. 5 5 Screw the filter on the tube end and place the tube back into the bottle, so that the end of the tube touches the bottom of the bottle. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 286 Monthly maintenance 6 6 Close the top cover of the analyzer and lock it. 7 Terminate the Maintenance mode.

8 Perform a reagent prime with the REF option. u Related topics • Terminating the Maintenance mode (237) • Performing a reagent prime (108) Cleaning the detergent aspiration filters To ensure the accuracy of detergent aspiration and sufficient cell cleaning, you must clean the aspiration filters of the cell detergent bottles CellCln 1 (NaOH-D) and

CellCln 2 (Acid Wash). When the filters were disconnected from the cell detergent bottles, air may have entered the tubing. Therefore, you must perform a cell detergent prime after the cleaning. c • Monthly • Each time you replace a cell detergent bottle n Approximately 5 minutes d m Paper towel m Deionized water j m The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 287 1 r To clean the detergent aspiration filters 1 Open the left front door. 2 2 Take out the two detergent bottles. 3 3 Remove the tubing from each detergent bottle. I CellCln 1 has a filter with a square end. CellCln 2 has a filter with a round end.

5 6 4 4 Unscrew the filter from each tube end. 5 Wash the filters with deionized water. 6 Then rinse the filters with deionized water. 7 Screw the filter on each tube end. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 288 Monthly maintenance 9 8 Insert the tubing back into each bottle: • Insert each aspiration tube so that the end of the tube touches the bottom of the bottle. • Do not bend the aspiration tubes. I Incorrect results due to incorrect insertion of aspiration tube. If the aspiration tubes are not inserted correctly, the detergent may not be dispensed properly. This may lead to incorrect results. 9 Close the left front door. 10 Perform a cell detergent prime. u Related topics • Performing a cell detergent prime (115) Cleaning the radiator filter To prevent overheating of the analyzer, you must clean the radiator filter of the cooling unit. n Approximately 5 minutes d m Vacuum cleaner m Paper towels m Water for rinsing j m The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 289 1 r To clean the radiator filter 1 Open the front doors. 2 Vacuum the radiator filter. 3 3 If there is much particulate matter (i.e. dust), clean the filter as follows: • Remove the filter by pulling it forward from the retaining brackets. • Rinse the filter with tap water. • Dry the filter completely with paper towels. • Reinstall the filter. 4 4 Close the front doors. Washing the flow path of concentrated waste solution To prevent clogging of the concentrated waste solution in the flow path, you must wash the flow path. The flow path, the concentrated waste reservoir, and the drainage tube are cleaned during the maintenance item (12) Flow Path Wash. n • Operator time: approximately 1 minute • System time: approximately 21 minutes Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 290 Monthly maintenance d m CellCln 2 (Acid Wash, approximately 30 mL) j m The analyzer is in Standby status. 1 r To wash the flow path 1 Choose Utility > Maintenance . 2 Select the (12) Flow Path Wash option. 3 Choose the Select button. 3 2 4 4 Choose the Execute button. Cleaning the water tank To prevent contamination of the entire flow path, you must clean the water tank. This task contains the following procedures: u To disconnect the water tank p (291) u To clean the water tank p (292) u To reconnect the water tank p (293) n Approximately 12 minutes Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 291 d m Lint-free gauze pads m Paper towels m Waste solution receptacle m 0.5% sodium hypochlorite solution m Deionized water j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) 1 r To disconnect the water tank 1 WARNING! Electrical shock by electronic equipment. Cleaning the water tank without turning off the power allows the deionized water supply unit to supply water during cleaning. 1 Shut down the analyzer.

Do not reach into the analyzer without switching off power first. 2 2 Turn off the external water supply. 3 3 Open the left front door. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 292 Monthly maintenance 5 4 4 Close the tap at the outlet of the water tank. 5 To absorb spilled water, place a waste solution receptacle (or paper towels) under the hose unit. 6 6 Separate the joint that connects the water tank and the water hose. 7 7 Remove the float assembly from the tank while pulling out the tank and place the float assembly on a paper towel. 1 r To clean the water tank 1 Visually check the water in the tank. 2 If the water is clear, clean the water tank as follows: • Empty the water from the tank and rinse it with deionized water three times. • Fill up at least 1/3 of the tank of deionized water. • Reconnect the water tank. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 2 Periodic maintenance 293 1 3 If the water is not clear, perform a thorough cleaning: • Empty the water from the tank and rinse it thoroughly with 0.5% sodium hypochlorite solution. • Use a brush to clean the interior surface. • Wash with deionized water to eliminate the sodium hypochlorite solution. • Fill up at least 1/3 of the tank of deionized water. • Reconnect the water tank. r To reconnect the water tank 1 Wipe the float assembly with gauze pads moistened with deionized water. 2 Return the float assembly and put the tank back in place. 3 3 Reconnect the water hose to the water tank and open the tap. Ensure that all joints are connected properly. I If the joints of the water tank are not connected properly, water may leak and damage circuit boards. 4 4 Close the left front door. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 294 Monthly maintenance 5 5 Turn on the external water supply. 6 6 Ensure that the top cover is locked before you switch on the analyzer again. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 295 Every two months maintenance Perform this maintenance tasks at least every two months. In this section Replacing ISE measuring electrodes (Cl, K, Na) (295) Replacing ISE measuring electrodes (Cl, K, Na) To ensure the measurement accuracy of the ISE unit, you must replace the ISE measuring electrodes. The electrical response level and the slope value (sensitivity) of each measuring electrode slightly decrease with time and use. This task contains the following procedures: u To replace the ISE measuring electrodes p (296) u To perform an ISE check p (299) c You must replace an ISE measuring electrode in the following cases: • The electrode has been in use more than two months.

• The test count has reached 9000 tests. • The slope value of the electrode falls outside of the normal range. This is indicated by the data alarms Prep.E or Slop.E. n • Operator time: approximately 10 minutes • System time: approximately 56 minutes (10 minutes for (7) Reagent Prime (IS+REF), 2x 18 minutes for (2) ISE Check, plus 10 minutes in between) d m Sodium (Na +) electrode m Potassium (K +) electrode m Chloride (Cl -) electrode m Lint-free gauze pads m Tweezers m Reference solution ISE REF (approx. 1690 µ L) m Internal standard ISE IS (approx. 9230 µ L) m Calibrators ISE Low (S1), ISE High (S2), and ISE High (S3) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 296 Every two months maintenance j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To replace the ISE measuring electrodes 1 To remove the sipper cover and the cover of the ISE measuring compartment, loosen the screws. 2 2 Disconnect the three electrode wires (Cl, K, and Na). 3 3 To loosen the electrodes from the mounting block, pull the release lever toward the Release position. I Injury to your fingers. The release lever is equipped with a spring. Take care of your fingers. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 297 4 4 Remove the electrodes from the mounting block using tweezers. 5 5 To ensure measurement precision, thoroughly wipe up any spilled liquid or liquid adhering to connecting parts. 6 If an O-ring from the electrodes remains inside the ISE measuring compartment, use tweezers to remove it. 7 7 Remove the black rubber protectors from the electrodes. A Rubber protectors A 8 8 Verify that the connecting part and the new electrodes are provided with O-rings. A A O-ring Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 298 Every two months maintenance 9 9 Insert the new electrodes in the right color-coded position into the ISE measuring compartment while holding the lever in the Release position. 10 10 To fasten the electrodes, set the release lever into the Lock position. 11 11 Reconnect the four color-coded electrode cords with their respective electrodes. 12 12 WARNING! Missing covers of the ISE unit may lead to incorrect results. Always reinstall the covers of the ISE unit after performing maintenance. 12 Reattach the sipper cover and the cover of the ISE measuring compartment. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 299 13 13 Close the top cover of the analyzer and lock it. 14 Terminate the Maintenance mode. 15 Perform a reagent prime with the IS+REF option. 2 3 1 r To perform an ISE check 1 Choose Utility > Maintenance . 2 Select the (2) Check option.

3 Select the (2) ISE Check option. 4 Choose the Select button.

4 6 5 5 Enter “10” cycles. 6 Choose the Execute button. f The electromotive force (EMF) values of the internal standard solution are printed ten times for each electrode. At this point, the results can be ignored. 7 Wait 10 minutes and then repeat the steps 3 to 6 . 8 8 Check if any EMF values of the internal standard solution are abnormal: • The difference in successive values for the same electrode should be stable within ± 0.2 mV. • Normal IS EMF values lie between NA: -10 to -90 mV, K -10 to -90 mV and Cl 80–160 mV, Ref -7 to 7 mV. • The maximum deviation for Ref EMF over all values should be no more than ± 2 mV. f If an EMF value is abnormal (level error or noise error for example), the corresponding alarm name is printed.

9 If an EMF value is abnormal, retry ISE check. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 300 Every two months maintenance 10 Perform an ISE calibration before you resume routine operation.

u Related topics • Terminating the Maintenance mode (237) • Performing a reagent prime (108) • Performing an ISE calibration (109) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 301 Every three months maintenance Perform this maintenance tasks at least every three months. In this section Cleaning the ultrasonic mixer (301) Replacing the ISE pinch valve tubing and sipper tubing (305) Cleaning the ultrasonic mixer To prevent inadequate mixing and inaccurate results, you must clean the surfaces of the ultrasonic mixer. If you have already cleaned the ultrasonic mixer during monthly maintenance, you do not need to perform this maintenance task separately. u Replacing reaction cells and cleaning incubator bath (278) This task contains the following procedures: u To clean the surfaces of the ultrasonic mixer p (302) u To check the intensity of the ultrasonic output p (305) n Approximately 15 minutes d m Cotton swabs m Paper towels m EcoTergent reagent pack (surfactant for the incubator, consumption 4.3 mL) m Deionized water j m The analyzer is in Standby status. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 302 Every three months maintenance 3 2 1 r To clean the surfaces of the ultrasonic mixer 1 Choose Utility > Maintenance . 2 Select the (9) Incubator Bath Cleaning option. 3 Choose the Select button. 4 4 Choose the Execute button. f The water is drained from the incubator bath and the control unit is powered off (shutdown). 5 5 After the computer power supply has been powered off, switch off the power of the analytical unit. I Do not open the top cover until the analyzer is in shutdown. 6 6 To remove the cell cover attached to the ultrasonic mixer, loosen the screws. A A Screw Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 303 7 7 To remove the segment of the reaction cells near the ultrasonic mixer, remove the respective screws. I Do not touch the surfaces of the reaction cells. 8 8 Wipe the polished surfaces of the ultrasonic mixer with a cotton swab moistened with deionized water. A Ultrasonic mixer A 9 9 Put the removed segment of reaction cells back in its previous place. 10 10 Reinstall the cell cover. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 304 Every three months maintenance 11 11 Close the top cover of the analyzer and lock it. 12 12 Switch on the analytical unit, and then switch on the control unit.

f The incubator bath is filled with some water. A yellow alarm is issued, indicating that the level of incubation water is below the lower limit. 14 13 13 Choose Utility > Maintenance . 14 Select the (4) Incubation Water Exchange option. 15 Choose the Select button.

15 16 16 Choose the Execute button. f The incubator is exchanged and EcoTergent (4.3 mL) is added. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 305 2 3 1 r To check the intensity of the ultrasonic output 1 Choose Utility > Maintenance . 2 Select the (2) Check option. 3 Select the (6) Cuvette Mixing option. 4 Choose the Select button. 4 6 5 5 Enter “10” cycles. 6 Choose the Execute button. 7 If an alarm occurs, follow the remedies described in the alarm message. u Related topics • Replacing reaction cells and cleaning incubator bath (278) Replacing the ISE pinch valve tubing and sipper tubing After long use, the ISE pinch valve tubing and the sipper tubing will gradually wear out. To ensure the accuracy of sample aspiration, you must replace both tubings. This task contains the following procedures: u To replace the ISE pinch valve tubing and the sipper tubing p (306) u To perform an ISE check p (308) n • Operator time: approximately 9 minutes • System time: approximately 46 minutes (2x 18 minutes for (2) ISE Check, plus 10 minutes in between) d m ISE pinch valve tubing m ISE sipper tubing m Calibrators ISE Low (S1), ISE High (S2), and ISE High (S3) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 306 Every three months maintenance j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To replace the ISE pinch valve tubing and the sipper tubing 1 To remove the sipper cover and the cover of the ISE measuring compartment, loosen the screws. 2 2 Carefully remove both ends of the ISE pinch valve tubing from their tube connectors and pull the tubing through the pinch valve. A ISE pinch valve tubing A 3 3 Insert the new pinch valve tubing through the pinch valve and attach both ends of the tubing to the connectors. I Make sure that there is no slack in the tubing. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 307 4 4 Carefully remove both ends of the ISE sipper tubing from the tube connectors. A ISE sipper tubing A 5 5 Attach both ends of the new sipper tubing to the tube connectors. 6 6 WARNING! Missing covers of the ISE unit may lead to incorrect results. Always reinstall the covers of the ISE unit after performing maintenance. 6 Reattach the sipper cover and the cover of the ISE measuring compartment.

7 7 Close the top cover of the analyzer and lock it. 8 Terminate the Maintenance mode.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 308 Every three months maintenance 2 3 1 r To perform an ISE check 1 Choose Utility > Maintenance .

2 Select the (2) Check option. 3 Select the (2) ISE Check option. 4 Choose the Select button.

4 6 5 8 5 Enter “10” cycles. 6 Choose the Execute button. f The electromotive force (EMF) values of the internal standard solution are printed ten times for each electrode. At this point, the results can be ignored.

7 Wait 10 minutes and then repeat the steps 3 to 6 . 8 Check if any EMF values of the internal standard solution are abnormal: • The difference in successive values for the same electrode should be stable within ± 0.2 mV. • Normal IS EMF values lie between NA: -10 to -90 mV, K -10 to -90 mV and Cl 80–160 mV, Ref -7 to 7 mV. • The maximum deviation for Ref EMF over all values should be no more than ± 2 mV. f If an EMF value is abnormal (level error or noise error for example), the corresponding alarm name is printed. 9 If an EMF value is abnormal, retry ISE check. 10 Perform an ISE calibration before you resume routine operation. u Related topics • Terminating the Maintenance mode (237) • Performing an ISE calibration (109) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 309 Every six months maintenance Perform this maintenance tasks at least every six months. In this section Cleaning the inlet water filter (309) Cleaning the cooling fan (312) Replacing the photometer lamp (313) Replacing the ISE reference electrode (320) Cleaning the inlet water filter To prevent clogging of the water system, you must clean the inlet water filter. n Approximately 5 minutes d m Water pump filter (in case replacement is required) m Paper towels m Beaker or container, 500 mL m Deionized water j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) r To clean the inlet water filter 1 Turn off the external water supply. 1 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 310 Every six months maintenance 3 2 2 Place a beaker (500 mL) beneath the inlet water manifold.

3 Turn the ring on the water filter cap counterclockwise and disconnect the inlet water hose. 4 4 Remove the water filter and insert the hose into the container. 5 5 Clean the filter thoroughly with deionized water. 6 6 Reinstall the filter. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 311 7 7 CAUTION! Incorrect results due to loose water filter cap. If the inlet water hose is not reconnected to the inlet water manifold correctly, it may cause instrument malfunction. This can lead to incorrect measurement results. 7 Reconnect the inlet water hose to the inlet water manifold. 8 8 Turn on the external water supply. 9 9 Ensure that the top cover is locked before you switch on the analyzer again. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 312 Every six months maintenance Cleaning the cooling fan To remove dust and dirt, you must clean the cooling fan at the rear of the analyzer. ! CAUTION Personal injury through touching the fan

There is a grill to protect the operator from coming into contact with the moving fan.

If the fan is cleaned when the analyzer is not in Shutdown status, there is a danger of injury. r Shut down the analyzer before cleaning. r Do not insert your fingers in the openings of the ventilation grill. n Approximately 5 minutes d m Vacuum cleaner j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) 1 r To clean the cooling fan 1 Vacuum dust, dirt, and other debris from the cooling fan at the back of the analyzer. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 313 Replacing the photometer lamp To ensure the reproducibility of measurement, you must replace the photometer lamp. After installing a new photometer lamp, you must wait 30 minutes for the lamp to stabilize. Then you must perform a cell blank measurement.

This is necessary to compensate for a potential change in light intensity. q We recommend combining this maintenance task with the monthly cleaning of the incubator bath and with the cleaning of the ultrasonic mixer every three months. You must check the light intensity of the photometer lamp daily to maintain reproducibility of measurement. The photometer check is included in the daily wake-up pipe. u Checking the analyzer and performing maintenance (66) u List of recommended maintenance pipes (244) If the photometer check value exceeds 14 000 absorbance units at any wavelength, check the following points before replacing the photometer lamp: • Make sure that the reaction cells, the incubator bath, and the photometric windows are free of contamination or bubbles. • Make sure that the reaction cells are not scratched or cracked. • Make sure that reaction cell no. 1 is at least half filled with water. If the photometer check value still exceeds 14 000 absorbance units at any wavelength after replacing the lamp, contact your Roche Service representative. This task contains the following procedures: u To remove the photometer lamp p (314) u To install a new photometer lamp p (317) u To perform a cell blank measurement p (319) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 314 Every six months maintenance c • If the photometer check value exceeds 14 000 absorbance units at any wavelength. • If the lamp has been used for more than six months (corresponding to 5 h of power-on time per day or 750 hours of power-on time in total). If the analyzer is powered on for more than five hours per day, you may need to replace the lamp more frequently. You can let the analyzer display when the photometer lamp must be replaced using the photometer exchange pipe. n • Operator time: approx. 10 minutes • System time: approx. 15 minutes d m Lint-free gauze pads m Photometer lamp j m The analyzer is in Shutdown status. u List of recommended maintenance pipes (244) 1 r To remove the photometer lamp 1 CAUTION! Burns due to the hot surface of the photometer lamp unit. Wait about 30 minutes for the lamp and lamp housing to cool down. 1 Make sure that the photometer lamp unit has cooled down before replacing the lamp.

2 2 To lift off the cell rinse unit, loosen the retaining screw.

A A Retaining screw Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 315 3 3 To remove the sipper cover, loosen the screws. A A Screws B B Sipper cover A 4 4 To remove the cell covers, loosen the screws. A Screw A A 5 5 To remove each segment of the reaction cells from the reaction disk, remove the respective screws.

Do not touch the surfaces of the reaction cells. I If the reaction disk is detached with the reaction cells left in place, water drops adhering to the outside of the reaction cells can drip onto the space surrounding the photometer lamp. This can cause an alarm. 6 6 To remove the reaction disk from the analyzer, loosen the three retaining screws. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 316 Every six months maintenance 7 7 Rotate the connector cover counterclockwise and disconnect the lamp wire from the connector. A A Connector B B Connector cover 8 8 Loosen the two lamp retaining screws and take out the photometer lamp. 9 9 Carefully remove the retaining screws from the lamp base. I The screws are needed to install the new lamp. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 317 1 r To install a new photometer lamp 1 Insert the retaining screws in the new lamp. 2 2 Insert the new photometer lamp. • Align the pin hole in the lamp base with the guide pin of the lamp housing. • Tighten the two lamp retaining screws. I Be careful not to touch the glass part of the new photometer lamp.

If you do touch the glass, wipe it with a gauze pad. 3 3 Connect the connectors of the lamp wires. Secure the lamp wires by wrapping them around the plastic retaining hook. A A Retaining hook B B Connector 4 4 Reinstall the reaction disk. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 318 Every six months maintenance 5 5 Reinstall the reaction cells. 6 6 Reinstall the cell covers. 7 7 Reattach the sipper cover. 8 8 Return the cell rinse unit to its original position. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 319 9 9 Close the top cover of the analyzer and lock it. 10 10 Switch on the analytical unit and then switch on the control unit. 11 Wait 30 minutes for the photometer lamp to stabilize. 2 1 r To perform a cell blank measurement 1 Choose Utility > Maintenance . 2 Select the (3) Cell Blank Measurement option.

3 Choose the Select button. 3 4 4 Choose the Execute button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 320 Every six months maintenance 5 5 To print or view the Cell Blank Measurement report, do the following: • Choose Print > Utility > Cell Blank Measurement . • To print the report, choose the Print button. • To view the report on screen, choose the Preview button. Then choose the View button. 6 6 Check if any cells are listed in the Abnormal Cell List at the top of the report: • If only a few cells are listed in the Abnormal Cell List, you can continue without any further action.

These cells are excluded from measurements. • If more than about five reaction cells are affected, replace all cells by new ones. u Related topics • Replacing reaction cells and cleaning incubator bath (278) • Cleaning the ultrasonic mixer (301) • Shutting down the analyzer (227) Replacing the ISE reference electrode The ISE reference electrode slowly deteriorates with use over time. To ensure the measurement accuracy of the ISE unit, you must replace the ISE reference electrode. This task contains the following procedures: u To replace the ISE reference electrode p (321) u To perform an ISE check p (324) n • Operator time: approx. 5 minutes • System time: approximately 48 minutes (2 minutes for (7) Reagent Prime (REF), 2x 18 minutes for (2) ISE Check, plus 10 minutes in between) d m ISE reference electrode m Lint-free gauze pads m Cotton swabs m Tweezers m Calibrators ISE Low (S1), ISE High (S2), and ISE High (S3) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 321 j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To replace the ISE reference electrode 1 To remove the sipper cover and the cover of the ISE measuring compartment, loosen the screws. 2 2 Disconnect the electrode wire of the ISE reference electrode. 3 3 To loosen the electrodes from the mounting block, pull the release lever toward the Release position. I Injury to your fingers. The release lever is equipped with a spring.

Take care of your fingers. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 322 Every six months maintenance 4 4 Remove the electrode from the mounting block using tweezers.

5 5 To ensure measurement precision, thoroughly wipe up any spilled liquid or liquid adhering to connecting parts. 6 If an O-ring from the electrode remains inside the ISE measuring compartment, use tweezers to remove it.

7 7 Remove the black rubber protectors from the electrode. A Rubber protectors A 8 8 Verify that the connecting part and the new electrode are provided with O-rings. A A O-ring Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 323 9 9 Insert a new ISE reference electrode into the ISE measuring compartment while holding the lever in the Release position. 10 10 To fasten the electrode, set the release lever into the Lock position. 11 11 Reconnect the electrode wire to the ISE reference electrode. 12 12 WARNING! Missing covers of the ISE unit may lead to incorrect results. Always reinstall the covers of the ISE unit after performing maintenance. 12 Reattach the sipper cover and the cover of the ISE measuring compartment. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 324 Every six months maintenance 13 13 Close the top cover of the analyzer and lock it. 14 Terminate the Maintenance mode. 15 Perform a reagent prime with the REF option. 2 3 1 r To perform an ISE check 1 Choose Utility > Maintenance . 2 Select the (2) Check option. 3 Select the (2) ISE Check option. 4 Choose the Select button. 4 6 5 5 Enter “10” cycles. 6 Choose the Execute button. f The electromotive force (EMF) values of the internal standard solution are printed ten times for each electrode. At this point, the results can be ignored. 7 Wait 10 minutes and then repeat the steps 3 to 6 . 8 8 Check if any EMF values of the internal standard solution are abnormal: • The difference in successive values for the same electrode should be stable within ± 0.2 mV. • Normal IS EMF values lie between NA: -10 to -90 mV, K -10 to -90 mV and Cl 80–160 mV, Ref -7 to 7 mV. • The maximum deviation for Ref EMF over all values should be no more than ± 2 mV. f If an EMF value is abnormal (level error or noise error for example), the corresponding alarm name is printed. 9 If an EMF value is abnormal, retry ISE check. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Periodic maintenance 325 10 Perform an ISE calibration before you resume routine operation. u Related topics • Terminating the Maintenance mode (237) • Performing a reagent prime (108) • Performing an ISE calibration (109) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 326 Every six months maintenance Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required Table of contents 327 11 Perform these maintenance tasks as needed. In this chapter 11 Checking and draining the vacuum tank . . . . . .

 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 328 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 329 Checking and draining the vacuum tank If an alarm is issued (“Liquid in vacuum tank”), you must drain the water or waste solution from the vacuum tank. If this alarm occurs frequently, contact your Roche Service representative. c We recommend checking every day whether the drain tube of the vacuum tank is empty. n Approximately 5 minutes d m Beaker j m The analyzer is in Standby status. 1 r To drain the vacuum tank 1 Open the left front door of the analyzer and locate the vacuum tank. 2 2 Check whether the drain tube of the vacuum tank is empty. • If there is liquid in the drain tube, proceed with step 3 . • If there is no liquid in the drain tube, close the left front door. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 330 Checking and draining the vacuum tank 3 3 Remove the cap holding the drain tube from the vacuum tank. 4 4 Drain the waste solution into a beaker. 5 5 Reattach the cap and secure the drain tube. 6 6 Close the left front door. 7 Dispose of the contents of the beaker according to local regulations for biohazardous waste. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 331 Replacing the sample probe If the sample probe is bent or otherwise damaged, you must replace it. In this section Removing the sample probe (331) Installing the sample probe (332) Checking the sample probe (334) Removing the sample probe To replace the sample probe or to eliminate clogging, you must remove the probe first.

n Approximately 1 minute j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) 1 r To remove the sample probe 1 Remove the pipetter arm cover by pressing the arm cover releases and lifting the cover. 2 2 Disconnect the wire of the liquid level sensor. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 332 Replacing the sample probe 3 3 Loosen the tubing from the probe by unscrewing it. Take care not to drop the probe seal. A Probe seal A 4 4 Lift the probe from the probe arm. Installing the sample probe If you replace the sample probe, you must install a new probe. If you have eliminated clogging, you must reinstall the sample probe afterwards.

n Approximately 1 minute d m Sample probe m Sample probe seal j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 333 1 r To install the sample probe 1 Place the sample probe into the pipetter arm. • To ensure proper alignment, the tab must slide into the holding slot on the pipetter arm.

• Make sure that the tubing is inserted and held in the slit of the foam cushion. A Foam cushion A B B Tab for aligning the pipetter 2 2 Reattach the probe to the tubing by screwing it: • Make sure that the probe seal is in place.

• Do not reuse the old probe seal. 3 3 Connect the wire of the liquid level sensor. Do not replace the pipetter arm cover yet. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 334 Replacing the sample probe Checking the sample probe To ensure proper operation of the sample probe, you must check the probe after installation. This task contains the following procedures: u To check the tubing system for leakage p (334) u To perform an air purge and check the operation of the probe p (335) u To perform a Mechanisms Check p (336) n • Operator time: approx. 3 minutes • System time: approx. 12 minutes (2 minutes for (5) Air Purge, 10 minutes for (3) Mechanisms Check) r To check the tubing system for leakage 1 Close the top cover of the analyzer and lock it. 1 2 2 Switch on the analytical unit and then switch on the control unit. 3 After initialization, switch the analyzer to Maintenance mode. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 335 4 4 Open the top cover of the analyzer. 5 7 5 Visually check for any water leakage from the connecting parts of the sample probe. 6 If there is a leak, perform the following: • Close the top cover and turn the maintenance switch back to Operation mode. • Shut down the analyzer temporarily. • Wipe up the leaked water. • Check for the cause and eliminate any leaks. • To check for leakages again, repeat the steps 1 to 5 . 7 If there are no leaks, perform the following: • Replace the pipetter arm cover: first the rear part, then the front part. • Close the top cover of the analyzer. 8 Terminate the Maintenance mode. 2 1 r To perform an air purge and check the operation of the probe 1 Choose Utility > Maintenance . 2 Select the (5) Air Purge option. 3 Choose the Select button. 3 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 336 Replacing the sample probe 5 4 4 Select the Sample syringe option. 5 Choose the Execute button. f The sample pipetter operates. At the rinse station, water and any air which may have been trapped are discharged. 6 6 Close the top cover of the analyzer and lock it. 7 7 Visually check whether the tip of the probe dispenses water in a straight flow. If not, eliminate clogging of the probe. 2 4 3 1 r To perform a Mechanisms Check 1 Choose Utility > Maintenance . 2 Select the (2) Check option. 3 Select the (3) Mechanisms Check option. 4 Choose the Select button. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 337 6 5 5 Enter “30” cycles. 6 Choose the Execute button. f All mechanisms of the analyzer operate. If an error is detected, an alarm is issued. u Related topics • Shutting down the analyzer (227) • Performing maintenance and switching on the analyzer (70) • Switching the analyzer to Maintenance mode (236) • Terminating the Maintenance mode (237) • Eliminating clogging of the sample probe (338) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 338 Eliminating clogging of the sample probe Eliminating clogging of the sample probe If you detect inaccurate pipetting, you must eliminate clogging inside the sample probe. You can first try to wash the sample probe with the maintenance item (11) Sample Probe Wash. If the sample probe is still clogged, you must eliminate clogging with the cleaning wire. This task contains the following procedures: u To wash the sample probe p (338) u To eliminate clogging p (339) n • Operator time: approx. 7 minutes • System time: approx. 18 minutes (6 minutes for (11) Sample Probe Wash, 2 minutes for (5) Air Purge, 10 minutes for (3) Mechanisms Check) d m Sample Cleaner 1 (SmpCln 1, approx. 300 µ L) m Cleaning wire (stainless steel, diameter 0.2 mm) j m The analyzer is in Standby status.

1 r To wash the sample probe 1 Choose Utility > Maintenance . 2 Select the (11) Sample Probe Wash option. 3 Choose the Select button. 3 2 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 339 5 4 4 Enter “5” cycles. 5 Choose the Execute button. f The inside of the sample probe is cleaned with Sample Cleaner 1. 1 r To eliminate clogging 1 Remove the sample probe. 2 2 Insert the probe cleaning wire into the probe tip and run it through the probe. 3 3 Install the sample probe. 4 Check the sample probe. u Related topics • Removing the sample probe (331) • Installing the sample probe (332) • Checking the sample probe (334) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 340 Replacing the reagent probe Replacing the reagent probe If the reagent probe is bent or otherwise damaged, you must replace it. In this section Removing the reagent probe (340) Installing the reagent probe (341) Checking the reagent probe (342) Removing the reagent probe To replace the reagent probe or to eliminate clogging, you must remove the probe first. n Approximately 1 minute j m The analyzer is in Shutdown status.

u Shutting down the analyzer (227) r To remove the reagent probe 1 Disconnect the tube connector of the reagent tubing. 1 2 2 Loosen the probe retaining nut by turning it counterclockwise. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 341 3 3 Lift the probe from the probe arm. Installing the reagent probe If you replace the reagent probe, you must install a new probe. If you have eliminated clogging, you must reinstall the reagent probe afterwards. n Approximately 1 minute d m Reagent probe j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) r To install the reagent probe 1 Place the reagent probe into the probe arm. 1 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 342 Replacing the reagent probe 2 2 Reattach the probe retaining nut by turning it clockwise. 3 3 Connect the tube connector of the reagent tubing. Checking the reagent probe To ensure proper operation of the reagent probe, you must check the probe after installation. This task contains the following procedures: u To check the tubing system for leakage p (343) u To perform an air purge and check the operation of the probe p (344) u To perform a Mechanisms Check p (345) n • Operator time: approx. 3 minutes • System time: approx. 12 minutes (2 minutes for (5) Air Purge, 10 minutes for (3) Mechanisms Check) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 343 1 r To check the tubing system for leakage 1 Close the top cover of the analyzer and lock it. 2 2 Switch on the analytical unit and then switch on the control unit. 3 After initialization, switch the analyzer in Maintenance mode. 4 4 Open the top cover of the analyzer. 5 5 Visually check for any water leakage from the connecting parts of the reagent probe. 6 If there is a leak, perform the following: • Close the top cover and turn the maintenance switch back to Operation mode. • Shut down the analyzer temporarily. • Wipe up the leaked water. • Check for the cause and eliminate any leaks. • To check for leakages again, repeat the steps 1 to 5 . Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 344 Replacing the reagent probe 7 7 If there are no leaks, close the top cover of the analyzer.

8 Terminate the Maintenance mode.

2 1 r To perform an air purge and check the operation of the probe 1 Choose Utility > Maintenance . 2 Select the (5) Air Purge option.

3 Choose the Select button. 3 5 4 4 Select the Reagent syringe option. 5 Choose the Execute button. f The reagent pipetter operates. At the rinse station, water and any air which may have become trapped are discharged. 6 6 Close the top cover of the analyzer and lock it. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 345 7 7 Visually check whether water is dispensed from the tip of the probe in a straight flow. If water is not dispensed in a straight flow, eliminate clogging of the probe. 2 3 1 r To perform a Mechanisms Check 1 Choose Utility > Maintenance . 2 Select the (2) Check option. 3 Select the (3) Mechanisms Check option. 4 Choose the Select button. 4 6 5 5 Enter “30” cycles. 6 Choose the Execute button. f All mechanisms of the analyzer operate. If an error is detected, an alarm is issued. u Related topics • Shutting down the analyzer (227) • Performing maintenance and switching on the analyzer (70) • Switching the analyzer to Maintenance mode (236) • Terminating the Maintenance mode (237) • Eliminating clogging of the reagent probe (346) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 346 Eliminating clogging of the reagent probe Eliminating clogging of the reagent probe If you detect inaccurate pipetting, you must eliminate clogging inside the reagent probe. n • Operator time: approx. 7 minutes • System time: approx.

12 minutes (2 minutes for (5) Air Purge, 10 minutes for (3) Mechanisms Check) d m Cleaning wire (stainless steel, diameter 0.5 mm) j m The analyzer is in Shutdown status. u Shutting down the analyzer (227) r To eliminate clogging 1 Remove the reagent probe. 1 2 2 Insert the probe cleaning wire into the probe tip and run it through the probe. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 347 3 3 Install the reagent probe. 4 Check the reagent probe. u Related topics • Removing the reagent probe (340) • Installing the reagent probe (341) • Checking the reagent probe (342) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 348 Replacing nozzle tips on cell rinse nozzles Replacing nozzle tips on cell rinse nozzles If the corner or bottom of a nozzle tip is worn so that water remains in the reaction cell, you must replace the nozzle tip. The replacement cycle is typically one to two years depending on conditions of use. This task contains the following procedures: u To replace the cell rinse nozzle tips p (348) u To perform a Mechanisms Check p (350) n • Operator time: approx. 6 minutes • System time: approx. 10 minutes d m Nozzle tips m Radio pliers j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To replace the cell rinse nozzle tips 1 To lift off the cell rinse unit, loosen the retaining screw. A A Retaining screw Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 349 2 2 Grip the nozzle tip with radio pliers and pull it off. 3 3 Attach a new nozzle tip by hand and align it with the guide bars. A Guide bar A 4 4 Return the cell rinse unit to its original position. 5 5 Make sure that the new nozzle tip is correctly aligned with the reaction cell.

A B A Correct alignment B Incorrect alignment Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 350 Replacing nozzle tips on cell rinse nozzles 6 6 Close the top cover of the analyzer and lock it. 7 Terminate the Maintenance mode. 2 3 1 r To perform a Mechanisms Check 1 Choose Utility > Maintenance . 2 Select the (2) Check option. 3 Select the (3) Mechanisms Check option. 4 Choose the Select button. 4 6 5 5 Enter “30” cycles. 6 Choose the Execute button. f All mechanisms of the analyzer operate. If an error is detected, an alarm is issued. u Related topics • Terminating the Maintenance mode (237) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Maintenance as required 351 Eliminating clogging of the cell rinse nozzles If you detect salt crystals at a cell rinse nozzle, this may indicate clogging. If a hose of the cell rinse unit does not transport any fluids, a nozzle may also be clogged. n Approximately 5 minutes d m Cleaning wire (stainless steel, diameter 0.5 mm) j m The analyzer is in Maintenance mode. u Switching the analyzer to Maintenance mode (236) 1 r To eliminate clogging of the cell rinse nozzles 1 To lift off the cell rinse unit, loosen the retaining screw. A A Retaining screw 2 2 Insert the probe cleaning wire into the nozzle and eliminate clogging. A A Probe cleaning wire Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 352 Eliminating clogging of the cell rinse nozzles 3 3 Return the cell rinse unit to its original position. u Related topics • Terminating the Maintenance mode (237) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Appendix 12 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1

Specifications Table of contents 355 12 In this chapter 12 System specifications. . . . . .
 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 356 Table of contents Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 357 System specifications List of general specifications General specifications define various characteristics of the analyzer. Throughput Applications Data storage DVD drive System interface Noise emission System start-up time Photometric tests/h ISE tests/h ISE samples/h No. of samples No. of tests Individual QC cobas c 311 analyzer up to 300 up to 450 up to 150 100 applications in total: o 86 photometric tests o 3 ISE tests o 3 serum indices o 8 calculated tests up to 10 000 (routine, STAT and QC samples) up to 10 000 (routine, STAT and QC samples) 2 500 samples, 100 tests/sample Cumulative QC 100 tests, 500 points/test 4.7 GB capacity Applicable DVD types: DVD-R, DVD+R, DVD-RW, DVD+RW RS-232C serial interface < 65 dB(A) 6 min (power on to standby) (1) y General specifications (1) If no Power Up Pipe function has been programmed to occur.

q All data processing equipment connected to the system must comply with the relevant standards (IEC 950, UL 1950, CSA 22.2 No. 950). u Host Interface Manual List of operating conditions The power supply and the water supply must fulfill the following requirements. Never operate the system if one of the operating conditions is not fulfilled. International (Rest of world) Power rating Power supply fluctuation y Electric power supply Single phase Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 US / Canada 230 V AC, 50 Hz 208 V AC, 60 Hz No significant fluctuation, maximum change 10% 358 System specifications Overvoltage category Power consumption Installation y Electric power supply Bacteria-free, deionized water Conductivity Water pressure Water consumption Required water supply y Water requirements Analytical unit Control unit Required earthing Bounding impedance Insulation resistance International (Rest of world) II 1.5 kVA 0.5 kVA < 10 < 0.1 at 30 A > 10 M at 500 V US / Canada Characteristics < 10 cfu/mL 1.0 S/cm or less (1.5 M resistance) 50–340 kPa (0.5–3.4 kg/cm 2) 12 L/h during operation 40 L/h List of environmental conditions The location must comply with the following conditions. Never operate the system if one of the environmental conditions is not fulfilled. Ambient temperature Ambient humidity During operation Temperature changes during operation During transportation and storage During operation During transportation and storage Altitude above sea level Pollution degree (IEC 61010-1) y Environmental conditions Other environmental conditions International (Rest of world) 15–32 °C < ± 2 °C -20 to 75 °C US / Canada 59.0–89.6 °F < 3.6 °F 30–85% (non-condensing) 5–95% up to 2000 m 2 -4 to 167 °F • Indoor use only • Horizontal installation space • Dust-free environment with adequate ventilation • No direct sunlight • No perceptible vibration • No equipment generating electromagnetic waves in the near vicinity • No machines discharging ultrahigh frequencies (e.g., electric discharger) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 359 List of dimensions and weights Height H1 H2 W1 D1 y Dimensions and weights Width Depth Weight Height, width, and depth define the spatial dimensions of the analyzer. US / Canada H1 (analytical unit) H2 (monitor, height adjustable) W1 D1 Analytical unit, approx. Control unit, approx. International (Rest of world) 1260 mm 1380–1570 mm 1325 mm 859 mm 250 kg 20 kg 49.6 in 54.3–61.8 in 52.2 in 33.8 in 551 lb 44 lb Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 360 Analytical specifications Analytical specifications List of reaction system specifications Reaction volume Reaction temperature Reaction disk Reaction cells Reaction times Pipetting cycle Mixing method y Reaction system The reaction system is located around the reaction disk. This system performs all steps related to mixing samples and reagents, incubating and measuring. These specifications apply to the photometric and ISE unit. Characteristics 100–250 µ L 37 ± 0.1 °C circulating incubator bath Turntable system with 66 reaction cells 6 segments of 11 reaction cells each (semi-disposable cuvettes for photometry) 3–10 min, in 1-minute steps 12 s Non-contact ultrasonic mixing (15 levels) q Processing capacity varies depending on measuring conditions, test selection, and system configuration.

Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 361 List of sampling system specifications Sample types Sample pipetting volume (photometric tests) Sample pipetting volume (ISE tests) Detection of sample clogging Liquid level sensor y Sampling system The sampling system is located around the sample disk. This system performs all steps related to identifying and pipetting samples. These specifications apply to the photometric and ISE unit. Characteristics o Serum/plasma o urine o CSF o supernatant o other 1.0–35 µ L, in 0.1 µ L increments 1.0–1.9 µ L water extrusion (15 µ L) 2.0–35 µ L 20.1–35 µ L sample dummy (10 µ L) two cycles used (24 s) 9.7 µ L (6.5 µ L for urine manual rerun only) Pressure sensitive clot detection system Capacitance sensing technology u Related topics • List of sample containers (365) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 362 Analytical specifications List of photometric unit specifications General characteristics The photometric unit is integrated with the reaction system. It measures the absorbance by the content of the reaction cells on the reaction disk. The reagent system is shared with the ISE unit. The characteristics of the reagent system for the photometric unit are given in this topic. The photometric system has the following general characteristics. Light source Photometer Wavelengths Characteristic Tungsten halogen lamp, 12 V / 50 W Multiple wavelength spectrophotometer 12 wavelengths available (± 2 nm): o 340 nm o 376 nm o 415 nm o 450 nm o 480 nm o 505 nm o 546 nm o 570 nm o 600 nm o 660 nm o 700 nm o 800 nm 5.6 mm 0.0000–3.0000 absorbance Up to 2.5 absorbance Monochromatic and bichromatic Optical path length Optical range Linearity Optical mode y Photometric unit Reagent system The reagent system has the following characteristics for the photometric unit. Reagent identification Reagent pipetting volume Reagent pipetting timing Characteristic Barcode identification, manual placement 5–

180 µ L, in 1 µ L increments (5–19 µ L: + 20 µ L water) 3 timings possible R1 R2 0 min 1.5 min R3 Up to 42 3.5 min Number of cobas c packs on board Reagent storage Remaining reagent volume control 5–15 °C Automatic test countdown with each pipetting y Reagent system of the photometric unit Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 363 List of ISE unit specifications General characteristics The ISE unit is located next to the reaction disk. It measures electrolytes with an ion-selective electrode. The reagent system is shared with the photometric unit. The characteristics of the reagent system for the ISE unit are given in this topic. The ISE unit has the following general characteristics. Applications Detection system Measuring range (serum) Measuring range (urine) Measuring range (urine rerun with reduced sample volume) Characteristic Cl - Na + K + Cl - K + Cl - Na + K + Na + , K + , Cl - in serum and urine Ion-selective electrode system Na + 80–180 mmol/L 1.5-10.0 mmol/L 60-140 mmol/L 10-250 mmol/L 1-100 mmol/L 10-250 mmol/L 250-375 mmol/L 100-150 mmol/L 250-375 mmol/L 37 °C ± 2 °C (during operation ± 0.5 °C) 24 s Capacitance sensing technology Measuring temperature Cycle time Liquid level sensor y ISE unit Reagent consumption Bottle volume Reagent system The reagent system has the following characteristics for the ISE unit. Characteristic ISE DIL ISE IS ISE IS ISE DIL ISE IS ISE IS 355 µ L/sample (dilution to 1/31) Measurements in succession Single measurement Measurements in succession Single measurement 600 mL 300 mL 300 mL 710 µ L/sample 1420 µ L/sample 130 µ L/sample 195 µ L/sample y Reagent system of the ISE unit Volume Aspirated from reagent bottle Discharged to reaction cell (1) Aspirated by the ISE sipper ISE IS 710 µ L 450 µ L ISE DIL 355 µ L 291 µ L 400 µ L 250 µ L (2) y Reagent pipetting volumes during analysis (1) The discharged volumes are lower because of the required dummy volume of the reagent pipetter. ISE REF – – 65 µ L Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 364 Analytical specifications (2) Diluted sample. Dilution ratio 1:31 Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 365 List of sample containers The sample containers hold the undiluted or manually prediluted samples as well as calibrators and controls on the sample disk. Standard cups and micro cups are both called cups . Cups can be inserted into sample tubes with 16 mm diameter, which is called cup on tube . Cups can also be used without tubes. A A Sample tube B Micro cup B C D C Standard cup D False bottom tube Container Primary sample tube Diameter x length 16 mm x 100 mm 16 mm x 75 mm 13 mm x 100 mm 13 mm x 75 mm Dead volume 1000 µ L 1000 µ L 500 µ L 500 µ L 100 µ L Hitachi standard cup or cobas sample cup, 2.5 mL Hitachi micro cup (1) , 1.5 mL Roche Diagnostics Standard False Bottom Tube (FBT) (3) Freely definable type of false bottom tube / non-standard tube (3) 13 mm x 75 mm 12–16 mm x 73–102 mm 50 µ 100 L µ (2) L y Accepted sample containers (1) Not applicable to calibrators and controls (2) A dead volume of 50 µ L is available if the Hitachi micro cup is directly loaded on the sample disk (not as a cup on tube) and the sample cup size is set to Micro on the Workplace > Test Selection screen. (3) Only one type of false bottom / non-standard tube can be used on the analyzer at the same time. q Avoid overfilling sample tubes and cups.
Leave approx.
10 mm clearance between the liquid and the top of the tube or cup. Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 366 List of barcode specifications List of barcode specifications Sample IDs or Patient IDs are encoded in barcodes. Barcodes are placed on sample containers and read by barcode readers next to the inner and outer ring of the sample disk. Barcodes used with the cobas c 311 analyzer must be in compliance with one of the following standards: • NW7 (Codabar) • Code 39 • ITF • Code 128 Sample barcodes The following specifications apply to the various barcode types: Reading method Used barcode symbol Check digit Number of ID digits Characters usable for ID Check digit Specification Scanning with CCD sensor o NW7 (Codabar) o Code 39 o ITF o Code 128 Must be used to prevent scanning errors. NW7 Code 39 ITF Code 128 NW7 Code 39 ITF Code 128 2–22 digits + 1 digit (with check digit) 2–22 digits + 1 digit (with check digit) 3–21 digits + 1 digit (with check digit) 3–22 digits + 2 digit (with check digit) 0 to 9 (without check digit) 0 to 9, -, /, ., , $, :, + (with check digit) 0 to 9, A to Z, -, ., [ ], /, +, $, % 0 to 9 Alphanumerics (excluding those alphanumerics assigned to functions and communications) NW7 Code 39 ITF Code 128 Modulus 16 Modulus 11 Modulus 10/2 weight Modulus 10/3 weight 7 check DR weighted Modulus 11 Modulus 43 Modulus 10/3 weight Modulus 103 y Sample barcode specifications Specifications of barcode labels The barcode labels must comply with the following specifications: Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Specifications 367 Secure a margin of 5 mm or more on each edge of barcode label. •PP •PP IRUPPVDPSOHWXEHV •PP IRUPPVDPSOHWXEHV •PP •PP •PP Bar and space Reflectance and PCS value Colors Other y Specifications of barcode labels Specification Minimum bar (space) width Ratio of narrow bar (space) to wide bar (space) Space reflectance PCS value Bar Space Bar print must not be blurred. Label indications must not be contaminated. 0.19 up to 0.20 mm 1:2.5 to 3 ≥ 75% ≥ 0.7 Black White u Related topics • Placing barcode labels on sample tubes (213) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 368 List of accessories and consumables List of accessories and consumables Image of product This is a list of globally available accessories and consumables.
For ordering information, contact your local sales representative. Product name Reaction cells ISE cleaning solution (SysClean) ECO-D solution (EcoTergent) Concentrated liquid waste container y List of consumables u Related topics • About positions of reagents (95) • List of tools, materials, and solutions (254) • List of spare parts and replacement intervals (255) • List of sample containers (365) Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 Glossary 369 Alarm button - maintenance mode Glossary This glossary explains technical terms used in this manual. Alarm button Global button used to display the list of current alarms. If an alarm was issued, the button flashes yellow or red. automatic rerun The repetition, without operator intervention, of tests that have results with data alarms.
auxiliary reagent A non-test-specific reagent for washing and rinsing reaction cells, sample probes, and reagent probes. calibration masking A function that masks a reagent when no valid calibration is available. cobas e-LabPerformance Application that uploads statistical data from the instruments via cobas link to the remote service platform for performance monitoring and QC management. cobas e-library An electronic archive on the cobas link data station containing e-library package inserts and e-barcodes.
For each application, calibrator, and control, the archive contains the latest version of the respective e-library package and the preceding version.
cobas e-services A set of cobas link applications. The set includes: cobas e-library, cobas e-support, and cobas e-LabPerformance. cobas e-support Screen sharing via cobas link with a Roche Service representative for troubleshooting and support. cobas link Software package running on a dedicated computer in the laboratory, the cobas link data station. The data station and the software are together referred to as a cobas link. A cobas link connects one or more cobas instruments to the remote service platform.
cobas link certificate A 16-digit PIN code issued for a specific cobas link. The certificate is valid for 14 days, i.e., you must install the certificate within 14 days from the time you requested it. cobas link Configurator A component of the cobas link software. Used by Roche Service representatives and the administrator to set up and to administrate a cobas link, e.g., to download patches manually. 13 cobas link Essential Information Upload Maintenance item that must be included in the daily wake-up pipe. Performs a backup of the instrument master data to the cobas link data station. cobas link stores the last five backups. current reagent Reagent packs that are currently in use, also called active reagent packs. e-barcode Contains machine-readable information for cobas instruments: test-specific instrument settings, lot-specific instrument settings, and values of calibrators and controls. e-library package Information unit downloaded from the remote service platform to a cobas link. Contains e-library package inserts and e-barcodes. e-library package inserts are for the operator. e-barcodes contain machine-readable parameters that are passed on to the instruments.
e-library package insert The following documents come as e-library package inserts: instructions for use, value sheets for calibrators and controls, important notes, and announcements from the local technical support. E.Stop Analyzer status displayed in the status line. The analyzer performed an emergency stop due to hardware failure or because any of the safety devices requested an emergency stop. The analyzer requires either a complete power-off or a reset to resume operation. global button Feature of the user interface. Global buttons are displayed with all menus and provide quick access to key functions of the analyzer. HHT driver Hitachi driver. A component of the cobas link software. Manages the information flow between the cobas link and the cobas instruments, e.g., the release of e-barcodes to the instruments. HRD viewer Human-Readable Data viewer. A component of the cobas link software. Provides the user interface of the cobas e-library application. LIS Laboratory Information System. Passes orders to the instruments and receives test results. maintenance mode Analyzer mode activated for doing maintenance work. The maintenance switch is on. You may open the top cover as all components on top are switched off.
The status line is yellow and displays the Standby status.
Roche Diagnostics cobas c 311 analyzer · Software version 01-10 · Operator's Manual · 3.1 370 Glossary online help - System Overview menu online help Provides context-sensitive access via F1 to the Operator's Manual and the Software Description . Pause/Scan button Global button used to pause sampling, e.g., to insert a STAT sample, or to scan the sample containers on the sample disk. Photometer Check report Report generated by the Photometer check maintenance item. The photometer report displays the current and previous absorbance values for all wavelengths. The report may indicate a problem with the reaction cells, the photometric window, or the photometer lamp. Make sure that absorbance values do not exceed 14 000 and the current values do not differ significantly from previous results. RCL Roche Connectivity Layer. A component of the cobas link software. Manages the information flow between the cobas link and the remote service platform. Remote service platform Provides information services for operators and instruments via a secure Internet connection. Services include the following: • Downloads of the most recent information on applications, calibrators, and controls • Support and troubleshooting via screen sharing • Advanced performance monitoring by evaluating uploads of statistical data from the instruments S.Stop button Global button used to stop sampling. The analyzer completes measuring already pipetted samples. Then, the analyzer switches to Standby status. Shutdown button Global button used to log off, start Sleep mode, or shut down the analyzer.
standby reagent Reagent packs that are already on board but not yet in use. status line Feature of the user interface. Displays the analyzer status, logon name, date/time, and time remaining to finish the current maintenance task. System Overview menu Root menu of the user interface. Used to prepare the analyzer for daily operation. Displays information about the modules of the analyzer and provides access to the five main menus. 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