eQAP℠ User's Guide

Real-time QC data for operational efficiency
Version 10

cobas b 123 POC system

cobas b 221 blood gas system

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Revision History

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04348346009	October 2012	Added **cobas b** 123 POC system and updated screenshots throughout
04348346010	April 2014	Removed Roche OMNI Modular System and updated navigation to Roche Diagnostics USA.

On-Line Quality Assurance Program

Notes

Introduction

Welcome to eQAP real-time peer review. This inter-laboratory statistical service, available through the Roche Diagnostics USA website, offers our customers access to a peer analysis program by providing secure web-based access to customer data and reports.

Enjoy the benefits of:
- instantaneous reporting - receive up to the minute, live, quality control information the moment you log on

- error checking for data entry - the centralized database manages and error-checks all data entries, flagging any results outside established parameters

- extra data entry - simply provide data in summary format, submit via daily entry, or download files saved from the **cobas b** 123 POC system and **cobas b** 221 blood gas system

- customized reports - receive a detailed custom report, highlighting inter-laboratory and peer group statistics.

Overview

Our On-Line Peer Analysis program is an internet-based system for review of Quality Control and Linearity information.

Contact Information

For questions regarding data entry in the eQAP real-time peer review group reporting, contact the Roche Diagnostics Customer Support Center at 1-800-526-2272.

Accessing Roche Diagnostics USA

eQAP peer group reporting program is available through the Roche Diagnostics USA website.

If you are not currently registered, instructions can be found at: *usdiagnostics.roche.com/en/document/Login_Registration_instructions.pdf.*

Accessing eQAP
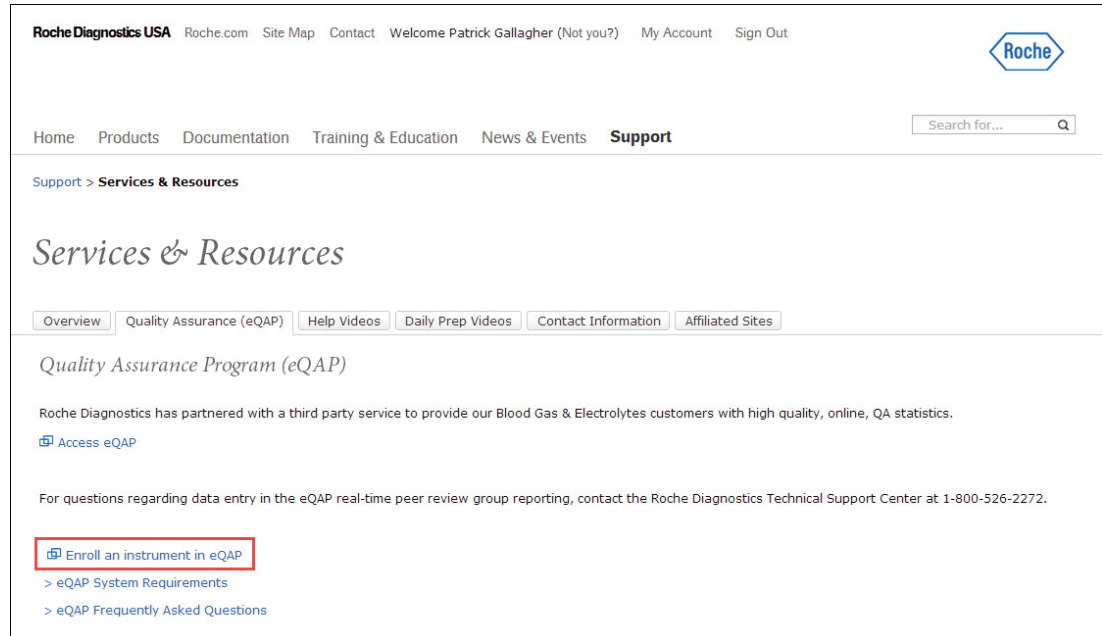
Enroll an instrument in eQAP

1.   Log in to Roche Diagnostics USA.

2.   Click **Quality Assurance Program (eQAP)** from the Support menu.

3.　　　Click the **Enroll an Instrument in eQAP** link. For questions regarding instrument enrollment, contact Roche Technical Support at 1-800-526-2272 ext. 13555, for assistance.

4.　　　Enter the instrument model number. Click **Next**.

5. Enter the information in the appropriate fields of the Enrollment form.

6. Complete the Enrollment form contact information. Click **Done** once the form is completed.

7. Click the **Close Window** link to return to the eQAP main menu.

Log in to eQAP and enter data

1.   Click **Quality Assurance Program (eQAP)** from the Support menu.

2.   Click **Access eQAP** from the eQAP screen.

i NOTE	*If a new or additional analyzer needs to be added, refer to the previous section.*

Selecting the Header Information

Prior to entering your monthly data you must first select the appropriate instrument, data entry month and QC Product criteria.

Selecting the Instrument

The first thing that must be selected is the instrument Model. This pull-down lists all instrument models that are registered for your hospital account.

Once you select your instrument model you must select the specific Instrument ID for that model. This pull-down list displays the instrument's name, serial number or other unique identifier.

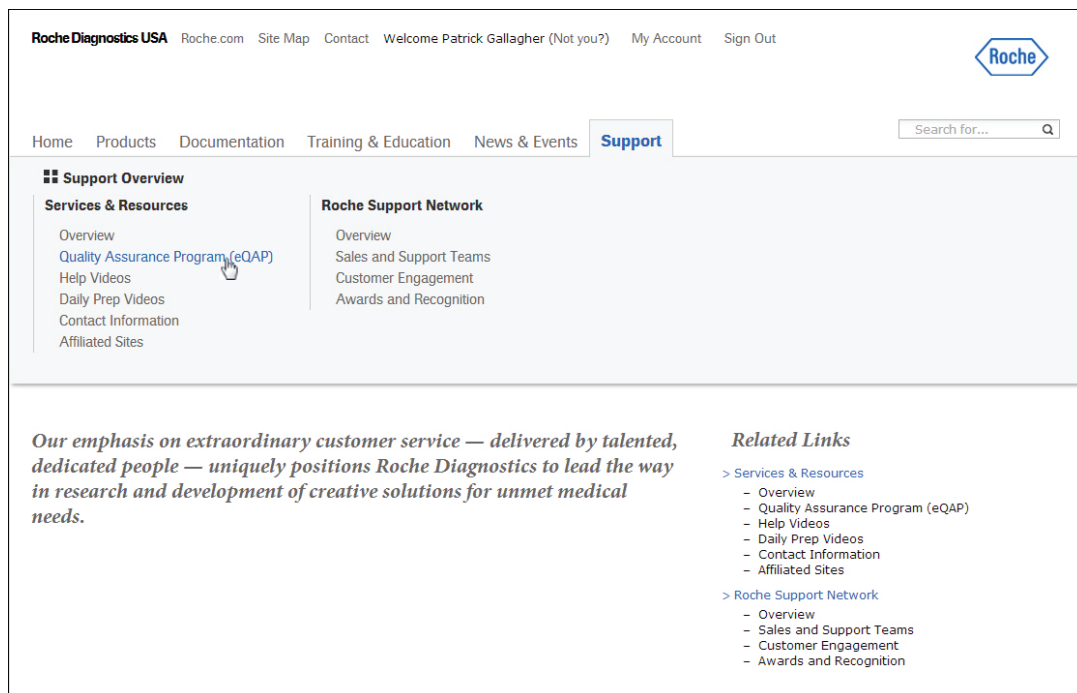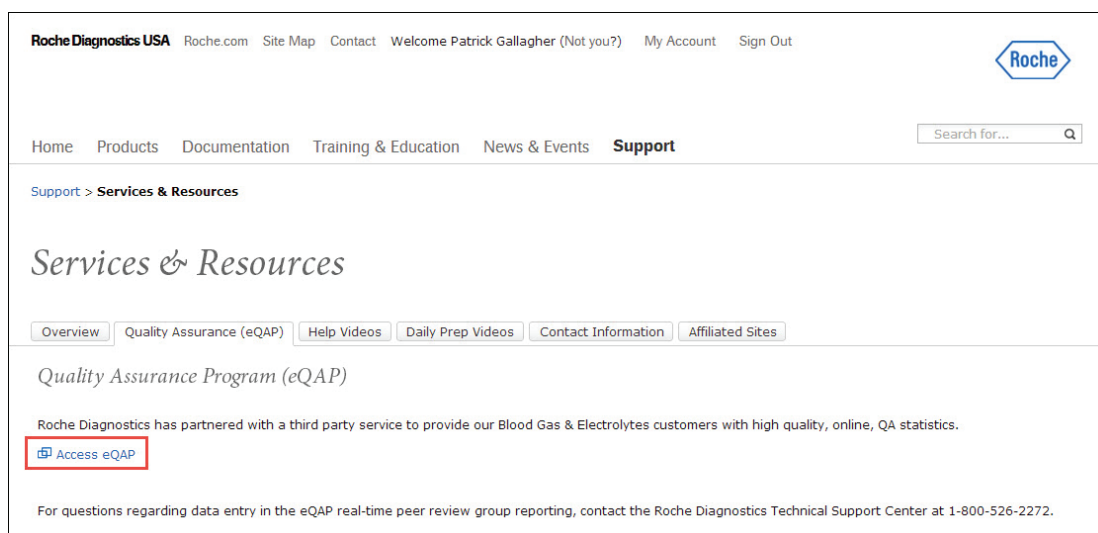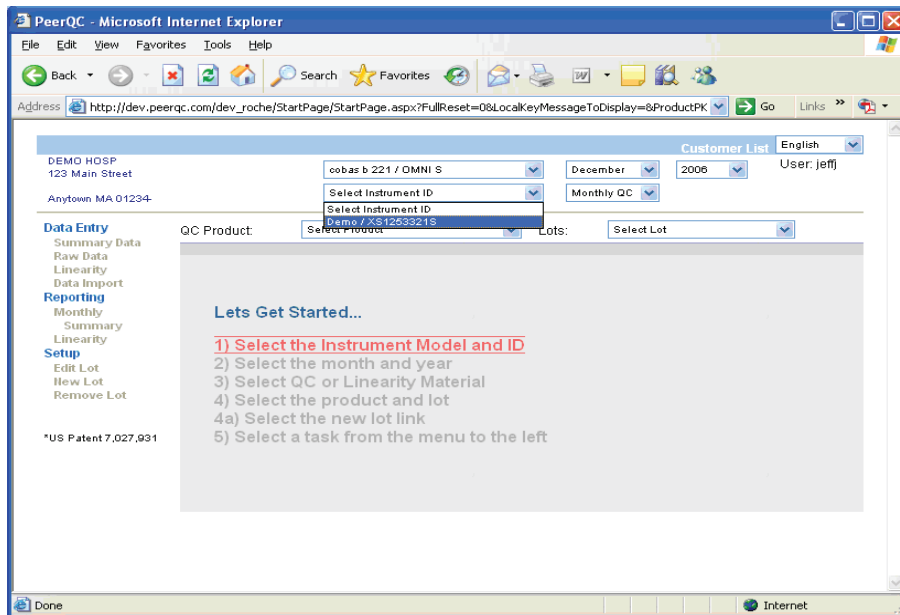### Selecting the Month and Year

Next select the Month and Year for which you are entering data. The system allows you to go back and enter, edit or view historical data.

Select Monthly QC from the Select Function pull-down menu if you are entering QC information. To enter Linearity material, select Linearity and refer to the "Entering Linearity Data" section.

> **i**
> **NOTE**
>
> *The header information must be filled out completely and in order before QC Product and Lot are selectable.*

Selecting the Product and Lot

Once you complete all of the instrument parameters you need to set the QC or Linearity Product and Lot filter criteria. The product pull-down list contains all of the individual QC or Linearity products that you are currently using. The Lot pull down menu displays the lot numbers that you are currently using for the selected product.

The level is displayed at the end of the lot number for easy distinction between the levels.

QC Data

Data Entry Methods

Now you may select your preferred method of data entry by clicking the link on the left side of the site. You may choose:

- Data Import

- Summary Data

- Raw Data.

Data Import

Data Import is available for customers who prefer to utilize the data management capabilities of their instrument. This method requires saving the monthly QC data to a USB device or diskette and then uploading the file from a PC with web access.

How to Import Monthly Data

1. Make the appropriate instrument and reporting period selections in the header area, and select the QC product with lot information. Select **Data Import** from the left menu.

2. Select the type of file to import. The system supports files that were exported from the **cobas b** 221 blood gas system and the **cobas b** 123 POC system.

3.　　Select the **Browse** button. This opens a window allowing you to browse to the location on your PC where the file is stored.

4.　　Select the file and click **Open**.
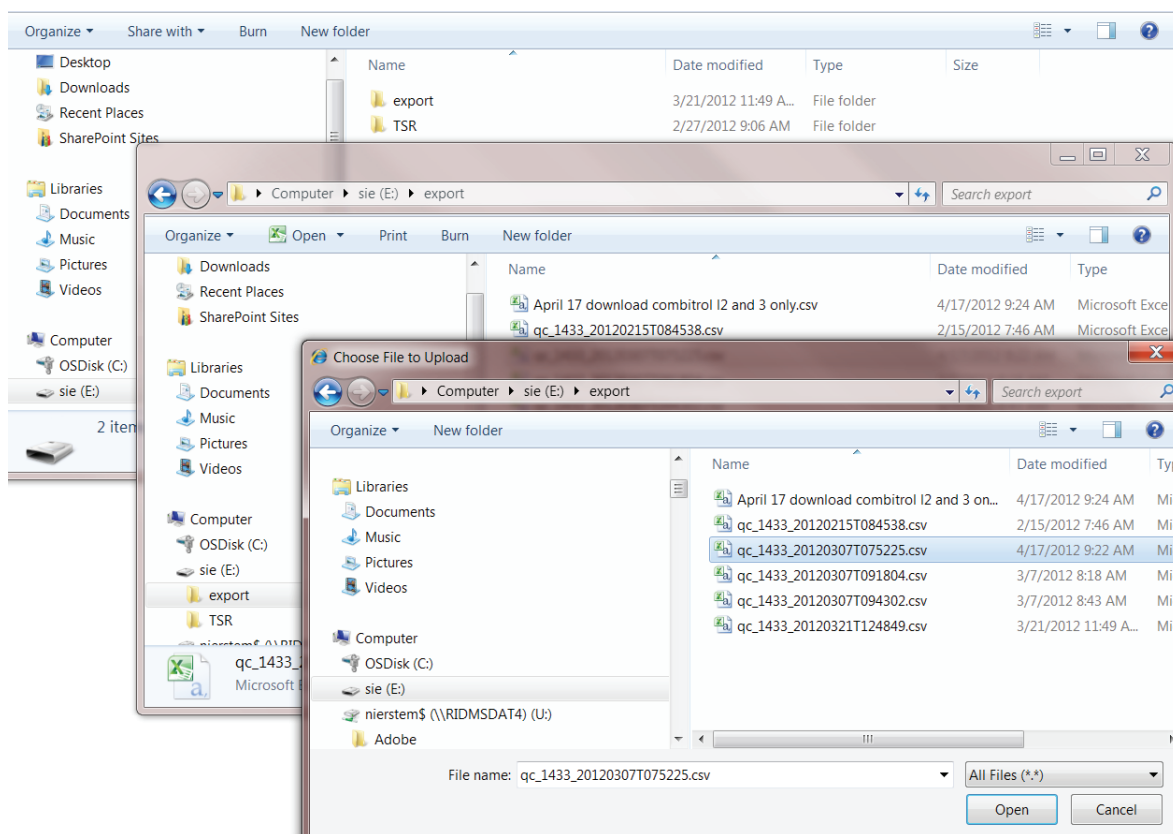
5.　　After selecting the appropriate QC file from the Browse menu, click **Submit File**.
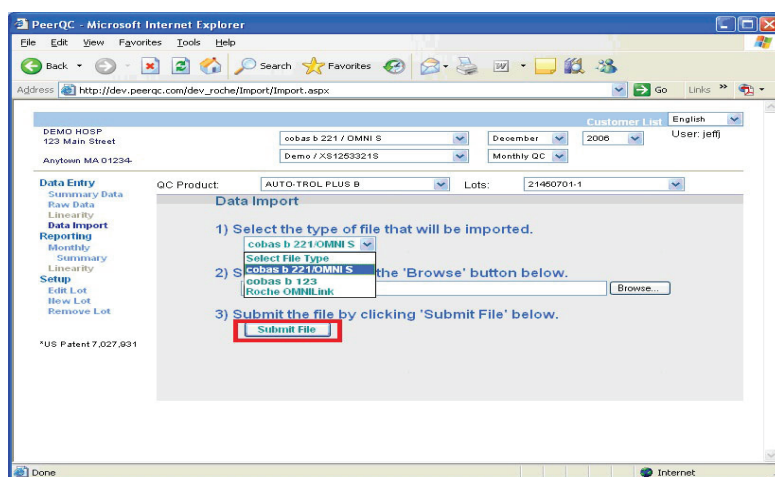
6. The following information screen appears, summarizing the data that was found to import:
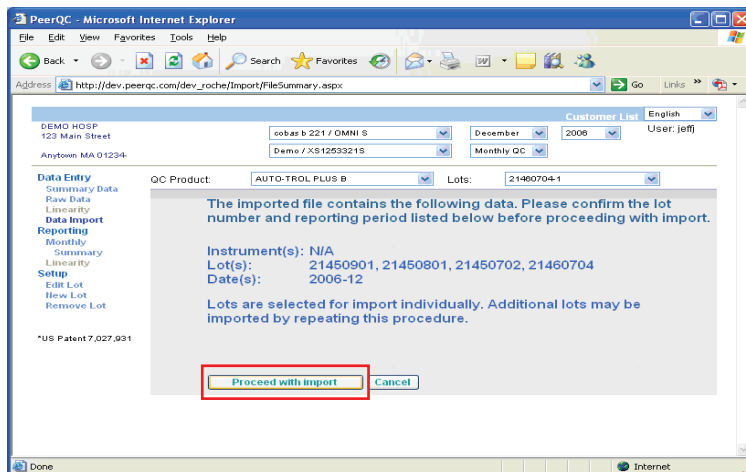
Click the **Proceed with import** button to proceed, or **Cancel** to return to the main screen. Only the lot currently selected at QC Product and Lot is imported.

If there is no matching lot contained within the data file to that selected at QC Product and Lot, the message, "the file contains no relevant data" is displayed.

The following screen displays if data fails to import:
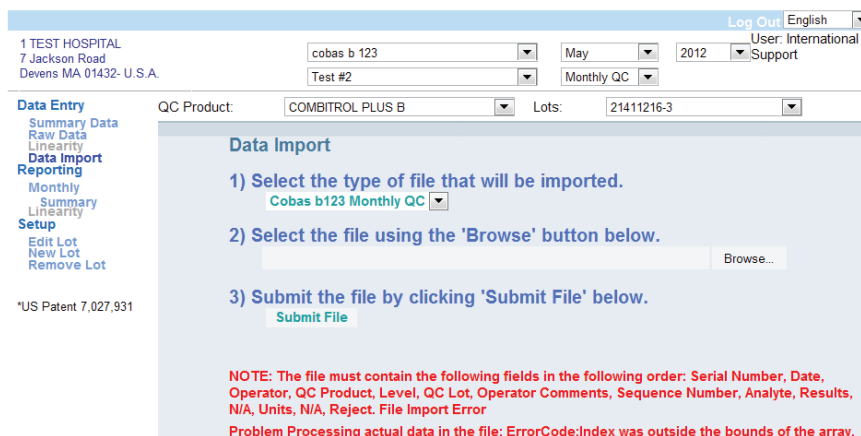
7. Click the **Submit** button to save the imported data into the database. A pop-up window appears confirming the successful download of data.

> ℹ️ NOTE
>
> *You may view the actual raw data imported by selecting Raw Data under Data Entry options. Data may be edited in the Raw Data screen.*

8. Click **OK** to confirm.

9. Click **Next Lot**, at the lower right of the screen, after completing data entry for each lot number (Next Lot button becomes inactive after last lot is selected).

10. After all data is imported, click **Summary** to run a monthly report.

> ℹ️ NOTE
>
> *If the pop-up blocker is ON, you may need to temporarily allow pop-ups. Click on the pop-up message at the top of the screen and select "temporarily allow pop-ups."*

> ℹ️ NOTE
>
> *For information on how to generate a monthly report, refer to the Printing Reports section.*

Summary Data

Summary data entry is the entry method for those customers who have used the instrument or calculated their own Mean and Standard Deviations using a data manager or manual method.

Entering Summary Data

The data entry screen is where you enter all of your QC data for that particular instrument.

How to Enter Summary Data

1. In the Data Entry section on the left side of the screen, click **Summary Data**, then click **Edit** located at the bottom of the data entry grid.
2. For each analyte, click in the Points field. Enter the total number of QC samples run during the month for the respective analyte.
3. Press the **TAB** key to advance to the Mean field.
4. Enter your calculated mean for the month.
5. Press the **TAB** key to advance to the SD field.
6. Enter your calculated 1 SD.
7. Continue entering your data for all analytes of the selected lot number.
8. Click **Submit** located at the bottom of the data entry grid and click **OK**.
9. Click **Next Lot** after completing data entry for each lot number. Repeat steps 1-9 until data for all lots is entered (Next Lot button becomes inactive after last lot is selected).

> **ℹ**
> *NOTE*
>
> ***For information on how to generate a monthly report, refer to the Printing Reports section.***

Raw Data

Raw Data entry is for those customers who do not have the capabilities to process summary statistics. This system is meant to replace the "old" method of plotting daily QC results on a Levy-Jennings chart. With this method customers can log on after they run their controls and enter the data into our system, where it will be stored in our database.

Entering Raw Data

The Raw Data Entry Screen is where all of your individual QC values are calculated into mean and SD values.

How to Enter Raw Data

1. In the "Data Entry" section at the left side of the screen, click **Raw Data,** then select your analyte.
2. Click **Edit** located at the bottom of the data entry grid, then click in the first field of the Value column.
3. Enter your individual value and press the **TAB** key on your keyboard to advance to the next field.
4. Continue entering your data.
5. Click **Submit** when you finish entering values for all analytes or pick the next analyte.
6. Repeat steps 2 through 5 for all remaining analytes.
7. Click **Next Lot** after completing data entry for each lot. Repeat steps 1-9 until data for all lots is entered. (Next Lot Button becomes inactive after last lot is selected).

> **i** *The Raw Data screen is designed to display data points, mean and SD only*
> **NOTE** *when that particular analyte is selected. To view an update of the calculations for each parameter added in the Raw Data screen, click the Summary Data link under the data entry header.*

Data Entry

Validation Message

As you enter data, the system automatically checks each entry to ensure that values entered are correct. If a value falls outside of the range a message appears in the column on the far right of the data entry grid. This is to provide you with a means of correcting possible transcription errors before saving your data. If a message does appear, verify that the value entered is correct and make any necessary changes or continue entering data.

Error Detection

To help ensure quality, our system uses the manufacturer's insert ranges to check for errors. Any value that falls outside of this range are excluded from the peer group calculations. This protects the integrity of the peer group by preventing erroneous data from corrupting the group.

Example: If the insert ranges are 7.150 - 7.210 any value above or below the range is excluded from the peer group.

> **NOTE**
>
> *When using the Data Import feature, you must scroll to each parameter to see the warnings on screen for values that are out of range.*
>
> *All excluded values are periodically reviewed for possible trends in QC degradation. This involves looking at each entry that was excluded and searching for possible errors in the insert ranges.*
>
> *Example: If, out of a possible 20 analyzers reporting Ca values on Lot # A, 15 were reporting outside of the insert ranges, Bionostics would notify the manufacturer of changes recommended for insert ranges to accurately reflect the lot performance. After investigation, if values are verified as needing a change, customers will be notified.*

Printing Reports

You may run your monthly report at any time during the month to compare values against the peer group. All reports are calculated **live** so that your peer group is up to date at the time that you print it.

To run a monthly report click the **Monthly Summary** link on the left side of the web page. Note that the report may take several minutes to generate.

> **Be sure to save a copy of the report.**
>
> NOTE

To print, click **Summary** to run a monthly report.

Linearity Data

Entering Linearity Data

1.　Select **Linearity** from the Select Function menu.
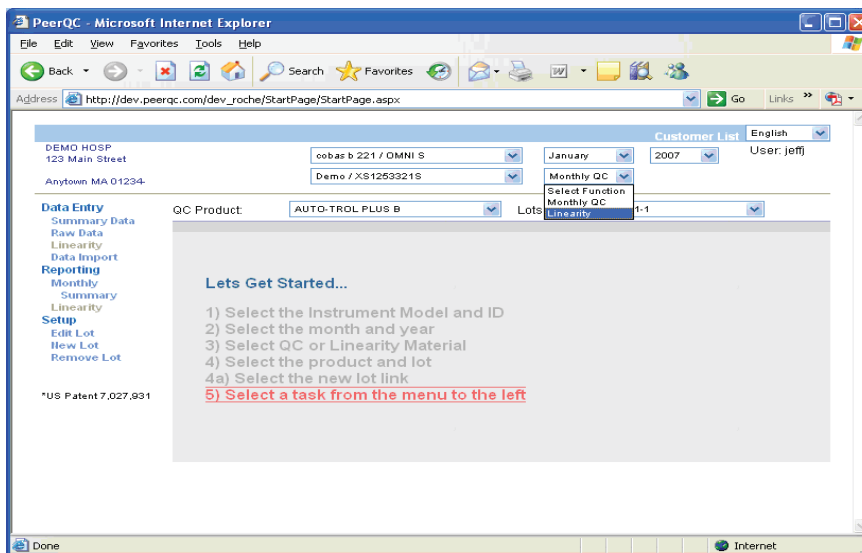
2.　Select the Linearity Product, Kit lot and Lot number from the QC Product and Lot menu listings.
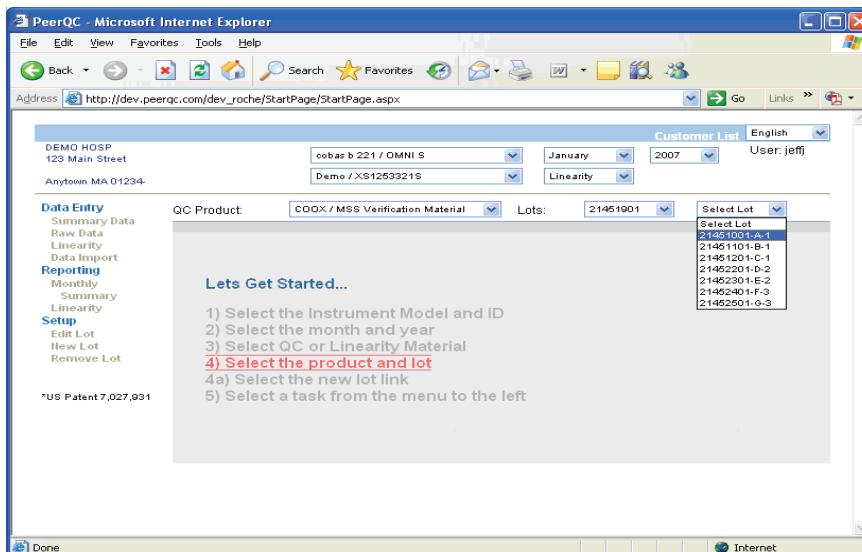
3.   Select the **Linearity** link located under Data Entry in the left column.

4.   Click **Edit**.
5.   Select the analyte to enter data (e.g., pH).
6.   Click in the first field of the **Value** column.
7.   Enter individual Linearity data values.

> **i**
> *NOTE*   ***Press <Tab> to advance to each additional value.***

8. If you enter a value that is outside of the expected range, a Validation Message may appear. You may accept the value, if correct or edit the entry.

Submitting Linearity Data

1. Click **Submit** after entering all Linearity values.
2. A message appears verifying you wish to save. Click **OK**.
3. A message appears verifying the data was saved correctly. Click **OK**.

> ⓘ *Pushing the cancel button prompts you to save the data. If the data has been saved using the submit button, click OK to leave the screen.*
> NOTE
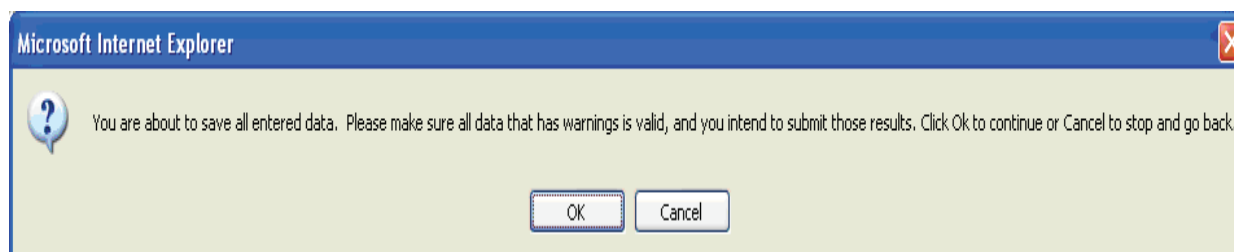
Creating a Linearity Data Report

1. Click the **Linearity** link under Reporting on the left side of the page.
2. The Linearity report displays as a PDF in a separate window.

Roche Diagnostics

Date Printed : 2/27/2012

Calibration Verification - Linearity Report

ROCHE TECHNICAL SUPPORT
9115 Hague Road
Indianapolis, IN 46250-0457

Report Period : January 2012

Instrument   :ROCHE / OMNI 1
Instrument ID :Respiratory

Kit Lot Number : 012318   Expiration Date : July 2013   Product : CVC123

Analyte : pH   Units   :

Your Statistics
Slope: .9764
Intercept: .1726

Peer Statistics
Slope: .9825
Intercept: .1286

Level	Expected Mean	Recorded Values	Mean	SD	CV %	Exp Vs. Recorded		Points	Mean	SD	CV %
1	6.880	6.91, 6.9, 6.91	6.907	.005	1.08	0.027	0.391%	92	6.891	0.011	2.57
2	7.160	7.145, 7.146, 7.147	7.146	.001	0.18	-0.014	-0.196%	89	7.155	0.009	1.94
3	7.390	7.375, 7.377, 7.379	7.377	.002	0.37	-0.013	-0.176%	86	7.395	0.009	2.07
4	7.570	7.555, 7.566, 7.577	7.566	.009	2.05	-0.004	-0.053%	84	7.565	0.006	1.35
5	7.770	7.77, 7.77, 7.769	7.770	.001	0.12	0.000	0.000%	87	7.762	0.008	1.80

Comments
Signature :   Date :

> ℹ️ **NOTE**
>
> *If the pop-up blocker is ON, you may need to temporarily allow pop-ups. Click on the pop-up message at the top of the screen and select "temporarily allow pop-ups."*

Printing Reports

You may run your monthly report at any time during the month to compare values against the peer group. All reports are calculated **live** so that your peer group is up to date at the time that you print it.

To run a monthly report click the **Monthly Summary** link on the left side of the web page. Note that the report may take several minutes to generate. Be sure to save a copy of the report.

Roche Diagnostics

Roche Diagnostics Quality Assurance Report
Report Period : December 2011
Data Submitted : Summary Data

Instrument ID: sn 5443 ICU
Instrument Model: AVL OMNI 3
Serial Number: 5443
QC Lot #   QC Product
1134   AUTO-TROL COMBI
9132   AUTO-TROL COMBI
9230   AUTO-TROL COMBI

Attn :Cardiopulmonary Services

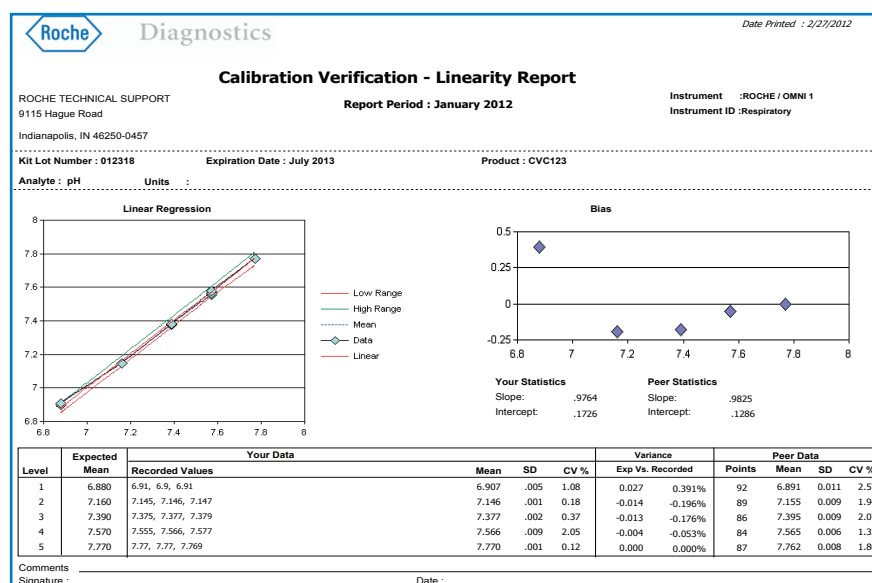|			December 2011 STATISTICS							CUMULATIVE STATISTICS						PEER GROUP STATISTICS All AVL Omni Models				
			N																	
	Level	Lot #	Acc	Rej	Mean	SD	2 SD Range	CV %	SDI	N	Mean	SD	2 SD Range	CV %	SDI	N	Mean	SD	CV %	CVI
pH	1	9132	35		7.155	0.005	7.145 - 7.165	1.14	-1.20	383	7.159	0.005	7.149 - 7.169	1.11	-0.76	12669	7.166	0.009	2.02	87
	1	1134	35		7.155	0.005	7.145 - 7.165	1.14	-0.97	98	7.157	0.004	7.148 - 7.165	1.01	-0.83	1148	7.166	0.012	2.62	44
	2	9230	32		7.392	0.004	7.384 - 7.400	0.92	-1.01	446	7.395	0.005	7.385 - 7.404	1.05	-0.71	28546	7.401	0.008	1.93	47
pCO2	1	9132	35		72.66	0.49	71.69 - 73.63	0.67	2.02	383	72.06	0.72	70.62 - 73.50	1.00	1.55	12601	70.08	1.28	1.82	37
	1	1134	35		73.17	0.49	72.20 - 74.14	0.66	1.76	98	72.67	0.38	70.71 - 74.63	1.35	1.41	1146	70.67	1.42	2.02	33
	2	9230	32		45.57	0.33	44.91 - 46.23	0.73	1.35	446	45.34	0.43	44.48 - 46.19	0.95	1.03	28734	44.59	0.73	1.63	45
pO2	1	9132	35		58.47	2.66	53.15 - 63.80	4.55	-0.20	383	60.16	3.04	52.48 - 67.84	6.38	0.17	12625	59.40	4.56	7.68	59
	1	1134	35		58.47	2.66	53.15 - 63.80	4.55	-0.10	98	59.10	2.31	54.49 - 63.71	3.90	0.09	1179	58.00	3.41	5.79	29
	2	9230	32		97.76	2.01	93.75 - 101.78	2.05	0.45	446	98.14	2.38	93.37 - 102.90	2.43	0.55	28696	96.08	3.71	3.86	53
THb	1	9132	35		18.68	0.22	18.24 - 19.12	1.17	1.09	383	18.45	0.26	17.93 - 18.97	1.41	0.50	0388	18.25	0.39	2.15	84
	1	1134	35		18.68	0.22	18.24 - 19.12	1.17	0.63	98	18.70	0.23	18.25 - 19.16	1.20	0.60	813	18.37	0.50	2.71	43
	2	9230	32		13.23	0.20	12.83 - 13.64	1.52	0.52	445	13.28	0.18	12.92 - 13.64	1.35	0.67	20389	13.07	0.31	2.39	64
O2Hb	1	9132	35		-11.33	0.24	-11.82 - -10.84	-2.15	-0.10	383	-11.73	0.41	-12.54 - -10.91	-3.49	-0.57	9160	-11.24	0.84	-7.48	29
	1	1134	35		-11.33	0.24	-11.82 - -10.84	-2.15	-0.36	98	-11.45	0.38	-12.21 - -10.69	-3.33	-0.52	772	-11.05	0.77	-6.97	31
	2	9230	32		-11.71	0.26	-12.24 - -11.19	-2.23	0.36	445	-12.14	0.20	-12.74 - -11.53	-2.51	-0.13	22095	-12.02	0.88	-7.28	31
COHb	1	9132	35		96.65	0.32	96.01 - 97.30	0.33	0.69	383	96.99	0.69	95.62 - 98.36	0.71	0.96	9786	95.80	1.25	1.30	26
	1	1134	35		96.65	0.32	96.01 - 97.30	0.33	1.09	98	96.54	0.54	95.47 - 97.62	0.56	1.00	815	95.22	1.32	1.38	24
	2	9230	32		102.93	0.32	102.28 - 103.58	0.31	0.55	445	103.11	0.24	102.42 - 103.79	0.23	0.77	23021	102.47	0.84	.82	29

Notes :
1. "Rej." are test values in excess of +/-3 SD from the instrument mean. "Rej." data has been excluded from the current month and all cumulative statistics.
2. Only those lots for which the current month data has been submitted are included in the summaries.
3. Highlighted data indicates that either the Mean or SD value is outside of the assigned package insert range or system acceptance values (for unassayed controls). The data has been excluded from the peergroup. You may resubmit all corrected data within 30 days to receive an updated report.
4. CV% for pH has been calculated on the basis of H+ ion concentration (nmol/L).
5. Unless otherwise indicated, all units for pCO2 and pO2 are reported in mmHg and all electrolyte values are reported in mmol/L.

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Adding or Removing Lot Numbers

Adding New Lot Numbers

To add new lot numbers you must select the new lot number as well as the analytes that you are reporting.

Only lot numbers that are still within their expiration dates are displayed. Only QC material can be added. Linearity material is preloaded for all customers.

How to Add New Lot Numbers

1. Click the **New Lot** link under Setup on the left side of the page.
2. Select the QC Product from the pull-down menu of available QC Products.
    This filters the list of lot numbers.
3. Select the Lot Number from the pull-down list of available lots.
4. Once you have selected your lots a grid appears displaying the list of available analytes.
5. Click **Edit** at the bottom of the grid to activate the analyte grid.
6. Click the checkbox that corresponds to the analytes that you wish to add.
    Use the scroll bar to the right of the screen to view the full list of analytes.
7. You may also select the appropriate units of measure for the selected analyte.

> ⓘ *Method and Reagent are also displayed, but are not applicable for blood gas*
> NOTE *instruments.*

8. Click **Submit** located at the bottom of the grid.
9. You may now click the **Data Entry** link to begin entering data for your new lot.

Removing Lot Numbers

How to Remove Lot Numbers

1.   After selecting the Product and Lots from the QC Product and Lot filter selections, click **Remove Lot Link** located under setup on the left side of the screen.
2.   Click **OK** at the prompt if you are sure you want to remove the selected lot

> **i**
> **NOTE**
>
> *Removing a lot from the drop-down menu does not affect any historical data or reports.*

eQAP export cobas b 221 blood gas system

Setting the Data Export Format cobas b 221 blood gas system

To check or change the order of the data fields for the QC database export press **Setup** > **Displays and Reports** > **QC Measurement** > **QC Database Export**.

> **i** *The QC Database Export "Selected Items" list should typically be set in the same order that they appear on the left side of the set up screen on the "Items" list. Select items using the right pointing arrow key between the "Items" list and the "Selected Items" list the field highlighted on the left side moves under the line where the cursor exists on the "Selected Items" list.*
> NOTE

1. Date
2. Time
3. Material
4. Level
5. Lot number
6. Exp Date
7. Base
8. Equilibration Temp (Temp AQC)
9. Remark field
10. Analytes start here (e.g., pH, CO_2)

The order of the analytes (e.g., pH, pO_2, Na) in the "Selected Items" list can be in any order as long as they begin at item #10. List all analytes needed for import for the program. The additional fields do not effect the import to the eQAP program.

After setting the order of the "Selected items" for export, selected QC records may be exported for evaluation. The export is performed using **Data Manager** > **QC Measurements** > **More** > **Export**. The files must be imported as .txt files to the program. Typically a month's data is exported for evaluation. Use a tab delimited file type.

Exporting files from the cobas b 221 blood gas system to a USB stick or floppy disk

See section B of the **cobas b** *221 blood gas system Instructions for Use* of the analyzer for reference material. It shows a list of icons and the screen that must be accessed to down load the files.

> ***You should clean up your data first by reviewing for outliers and removing bad data points that should have been rejected.***

1. Open the Data Manager file folder using the Data Manager icon in the top right corner of the screen.

2. Pick "QC data" to display a screen similar to the one below.

QC measurements

Date	Time	Material	Level	PCO₂	PO₂	
02.9.2002	16:17	AUTO-TROL TS +	3	22.5	133.5	7
02.9.2002	16:12	AUTO-TROL TS +	2	41.3	90.2	7
02.9.2002	08:10	AUTO-TROL TS +	1	57.9	54.7	7
01.9.2002	21:10	AUTO-TROL TS +	3	22.2	132.4	7
01.9.2002	21:05	AUTO-TROL TS +	2	41.5	89.0	7
01.9.2002	21:01	AUTO-TROL TS +	1	57.8	69.7	7
31.8.2002	21:10	AUTO-TROL TS +	3	22.2	132.6	7
31.8.2002	21:05	AUTO-TROL TS +	2	41.1	87.6	7

Mat change 14:10   System cal 15:02

3. The icon for mark range at the bottom of the screen is used to select the date range (Typically a month's data is exported for evaluation).

4. After picking that icon, set the date range that is needed (One month's data e.g., 3/01/2014 to 3/31/2014). The selected lines are now highlighted in yellow.

5. Export is performed using **Data Manager** > **QC Data** > **More** (the right pointing arrow key) >**Export** to show the Data Export icon on the next screen.

6. Pick the Data Export icon .

7. Setup the file for export:
   a. The files must be imported as .txt files to the program (i.e., text file with field delimiters).
   b. Name the file in a manner that it is unique when imported (e.g., July2013).
   c. Do not use compression. Turn it off so that a red dot is by the 0.
   d. Use a "tab delimited" file type. You may have to select this delimiter using the right left arrow keys near that field.
   e. Use a format style of decimal point (i.e., not a comma).

When data is selected:

8. Press the **Start** button and insert the USB Stick (or for old SNs the floppy disk). This captures all lots of material run during that time frame.

9. Remove the storage medium.
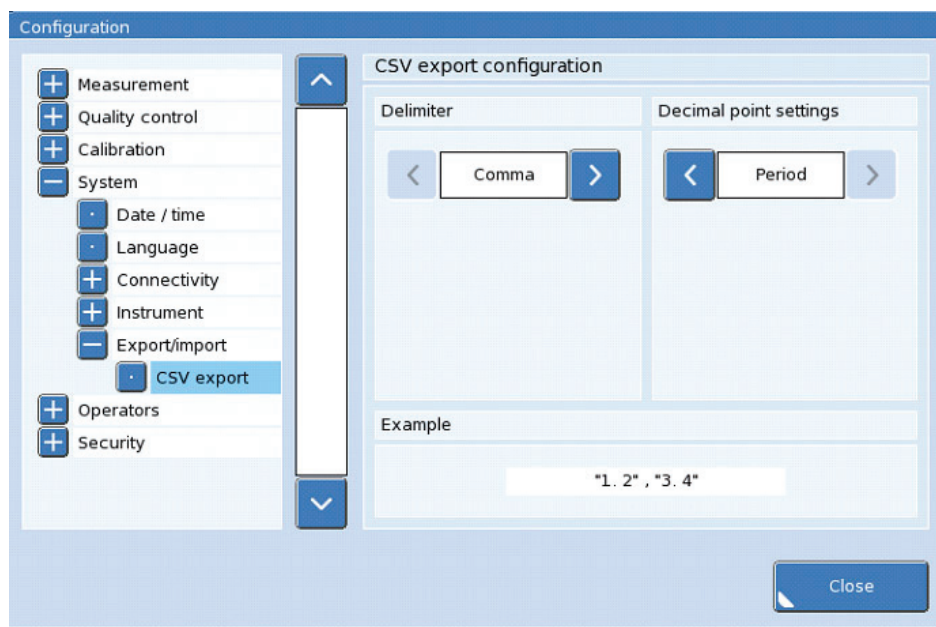
eQAP export cobas b 123 POC system

See Chapter 9, Quality Control of the ***cobas b*** *123 POC system Instructions for Use*, for more detailed information. The following are abbreviated specific steps.

Setting the Data Export Format cobas b 123 POC system

1.   Specify date format as (MM/dd/yyyy), m/dd/yy, mm/dd/yy, m/dd/yyyy, or mm/dd/yyyy for U.S. customers. For International Customers: dd/mm/yy. Include time format to 12 hour or 24 hour clock with format (e.g., 07/17/13 13:52).
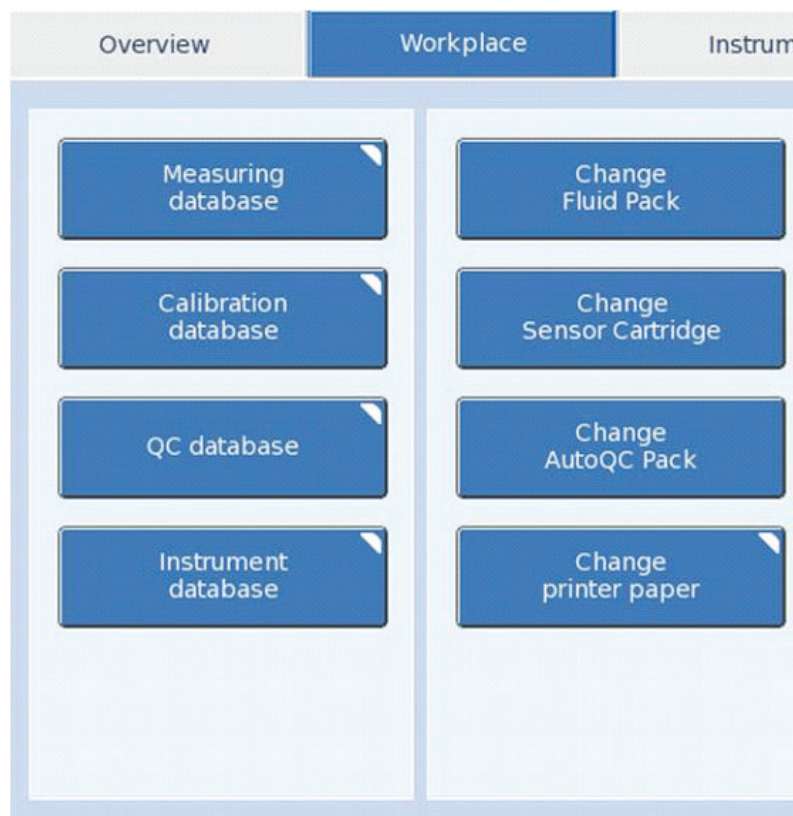To set press **Utilities** > **Configuration** > **System** > **Date/time**
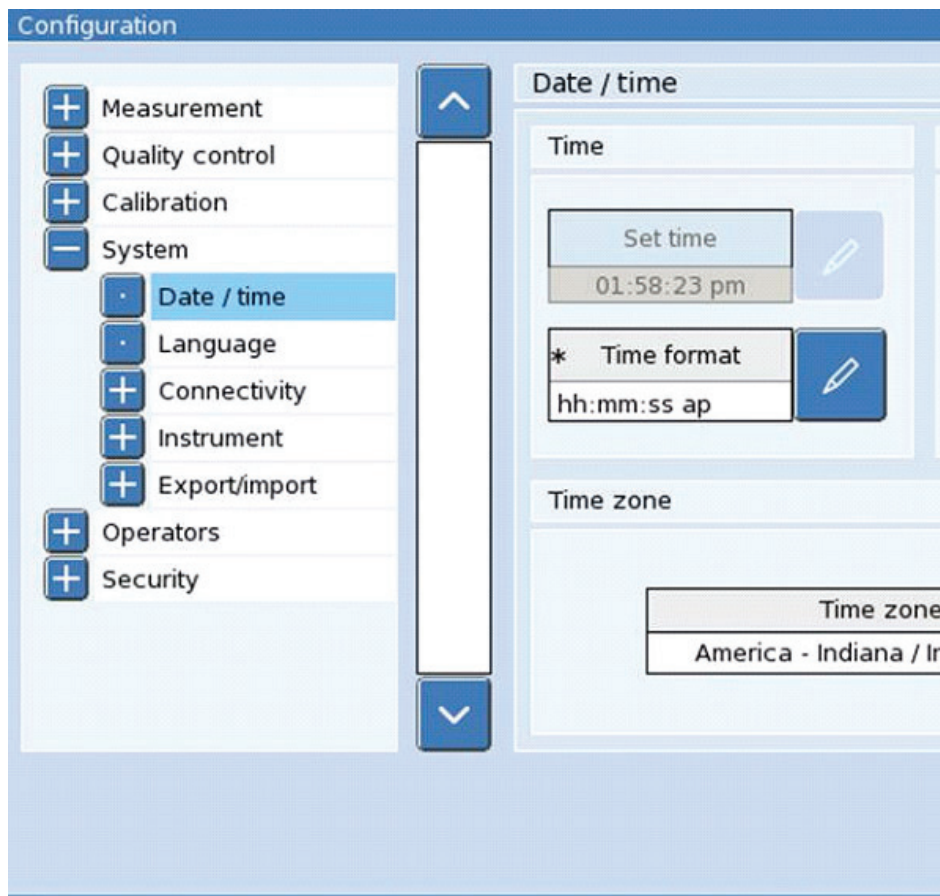
2. Set export to use comma delimited file.
   To set press **Utilities** > **Configuration** > **System** > **Export/import** and select the delimiter to **comma**. Set the decimal point format to **period**.
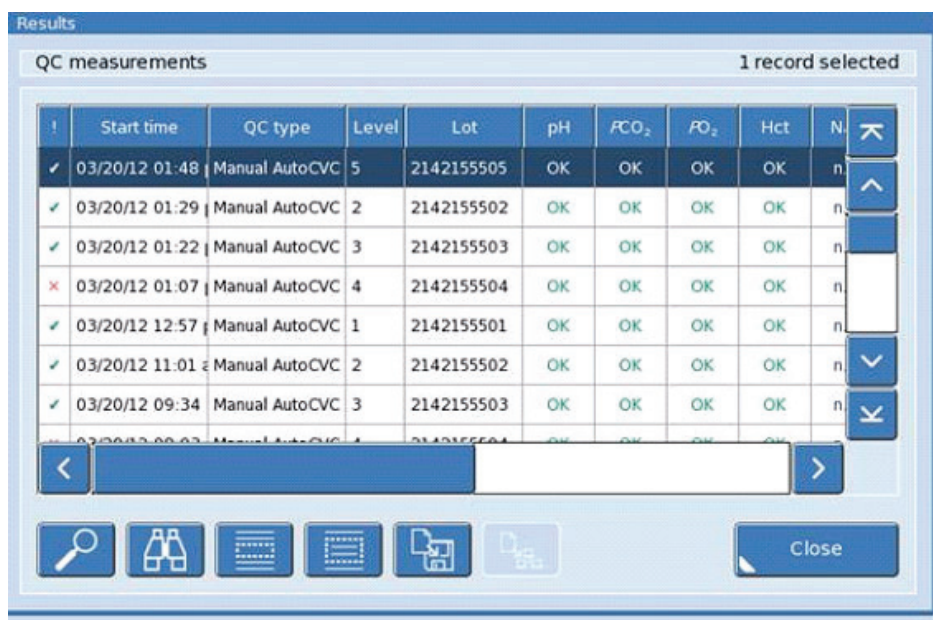

**Exporting files from the cobas b 123 POC system to a USB**

1. To open the database press **Workplace** > **QC Database** >

2.   Designate which records to import from the database.

After selecting the QC database, a list of records appears that can be sorted. Use the search icon that appears at the bottom of the screen to filter for the appropriate record. (This icon looks like binoculars.) After opening the search feature filter by date and QC record type to select the appropriate records as seen in the picture below. Any record type, date or other selection criteria desired may be selected to obtain a specific set of records.
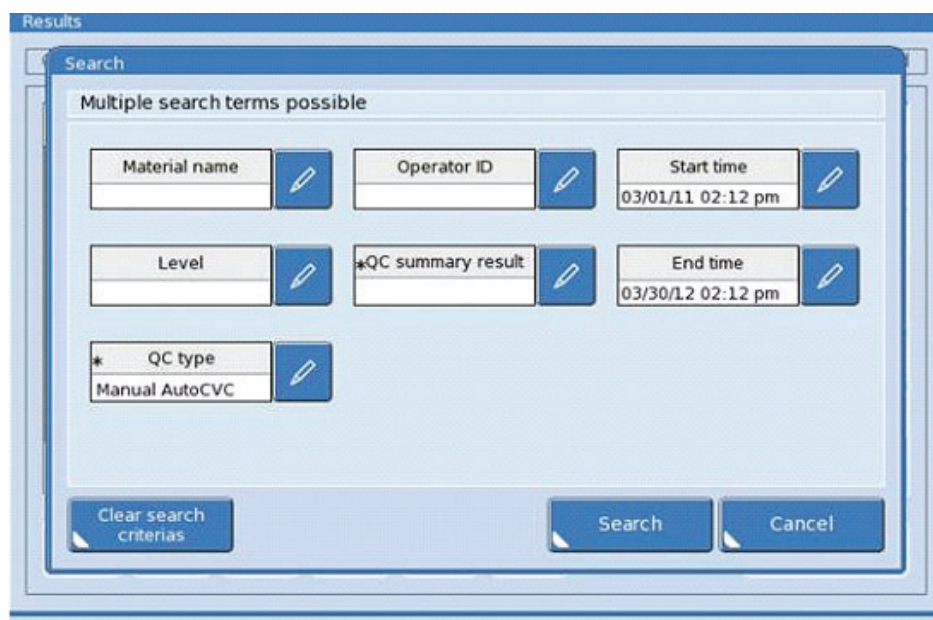
3. Select records for export. Use the icons to select required records. The records are highlighted after selection.
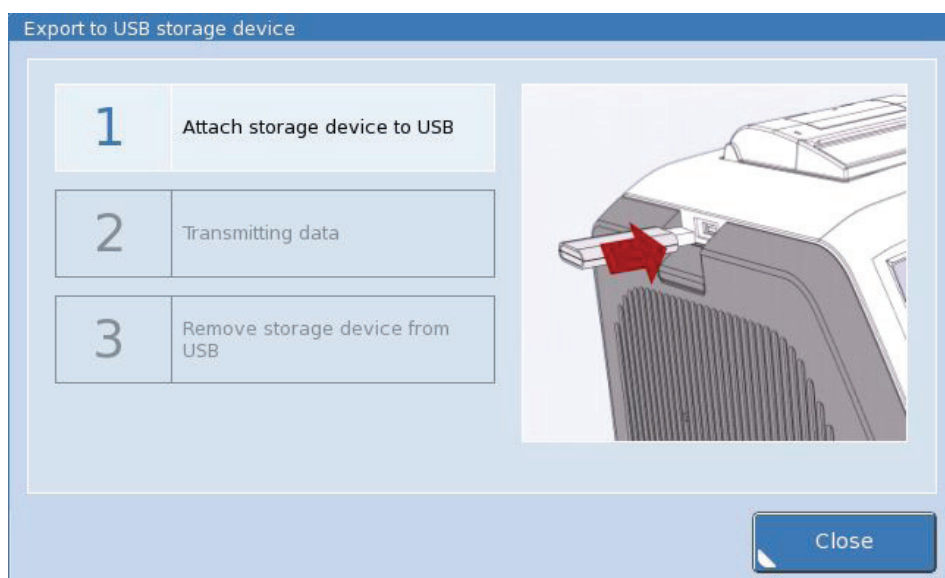

 marks a single record in a file; select each record and press this button to highlight
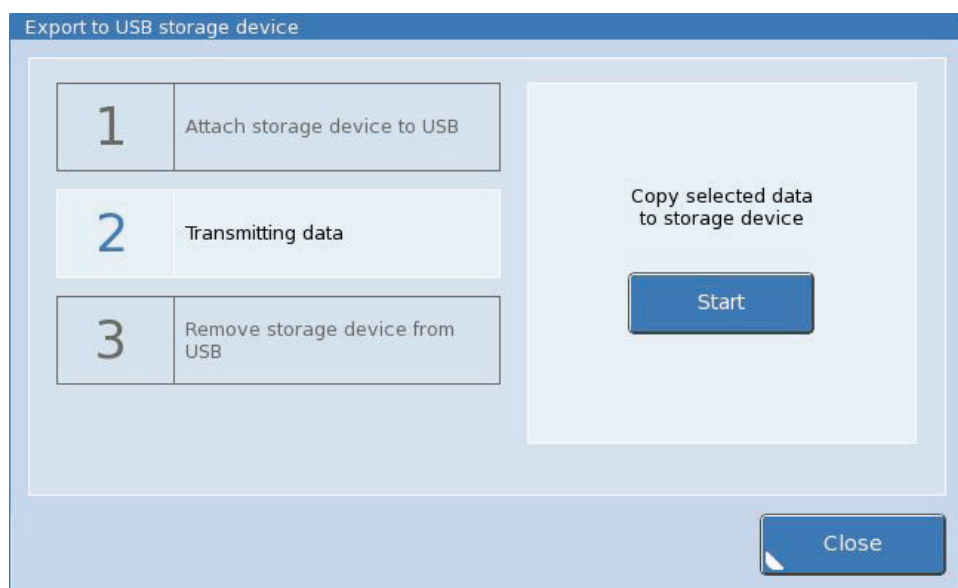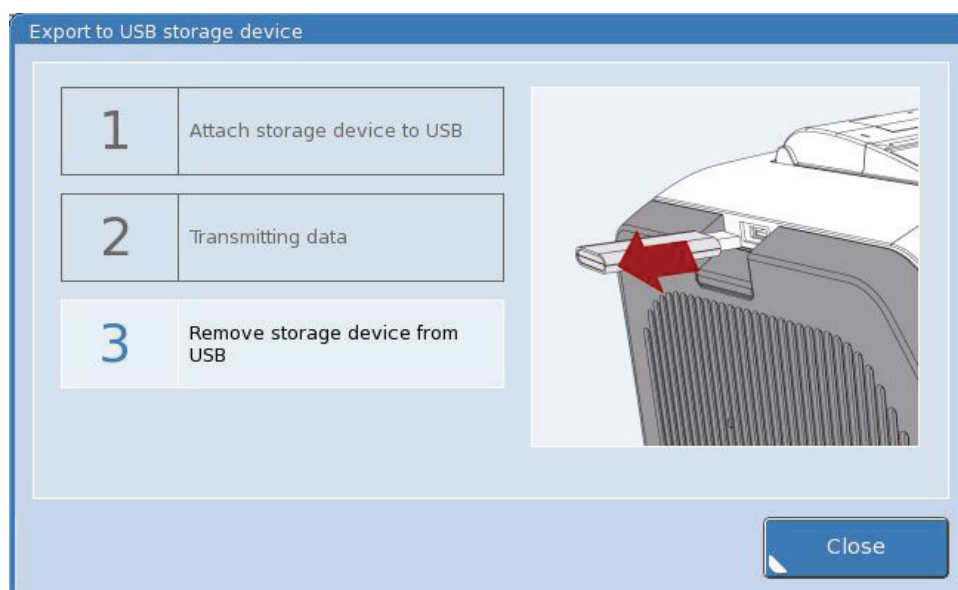
 marks all records

4. Export the records to USB stick.
    Use the export icon to start the export process. The analyzer prompts through three steps including:

•   Add the USB storage device to the instrument's USB port:

- Start the export of data.

- Remove the USB storage device and close the window.

Notes