



Laboratory Quality Control

User's Guide

LQC v2.0

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Welcome to Laboratory Quality Control

Laboratory Quality Control (LQC) is Data Innovations' quality control product that operates solely in conjunction with the Instrument Manager software (minimum version 8.15).

LQC consists of two applications, **Configure QC** and **Review QC**.

- From **Configure QC**, define analyzers, controls, measures, and other parameters you can use to customize LQC to meet your QC needs.
- From **Review QC**, view and validate QC results sent from the Instrument Manager software to LQC.

Prerequisites

Instrument Manager, minimum version 8.15, is *required* to install, configure, and operate the LQC software. This will include Cache 2016 database.

LQC User Documentation

The [Installation Guide](#) provides instructions on:

- Installing LQC, which comprises **LQC** and **Configure LQC**.
- Connecting LQC software to Instrument Manager.
- Writing Instrument Manager rules to identify QC samples on your analyzers.

The [User Guide](#) provides instruction on performing day-to-day QC tasks in **LQC**, including:

- Recording control material.
- Viewing Control Data.
- Accepting or rejecting control results.
- Printing QC Data.
- Westgard Rules.

The [Configuration Guide](#) details instructions users should follow before running daily QC tasks. This section provides instruction on using **Configure QC** to:

- Define analyzers, controls, measures.
- Define organizations, users, workstations.
- Define units.

System Requirements

Intersystems Caché 2016 or later installed

Instrument Manager 8.15 or later installed

Intel Quad Core or higher (more than one processor may be required depending on activity)

1024 x 768 definition monitor screen or higher, 32-bit color

Mouse or other pointing device

Any TCP/IP network, 100 Mbits/sec between server and clients

Microsoft Windows Server 2012 R2

Microsoft Windows 8.1 - 64 Bits

Microsoft Windows Server 2008 R2 - 64 Bits

Microsoft Windows 7 - 64 Bits (32 Bits supported for thin client)

4GB of RAM, or higher for 32 bits

8GB of RAM or higher for 64 bits

What's New LQC 2.0.0 - Release Notes

System level changes

Database change

Starting with version 2.0, LQC no longer supports the Caché 2013 database server. It now requires Caché 2016 which is installed with IM 8.15 or later. You must upgrade Instrument Manager to version 8.15 or higher prior to installing LQC 2.0.

Major improvements

Export data 1.10.2. 1.3 Turi kokybės kontrolės duomenų eksportavimo funkcija.

LQC now incorporates an interface for exporting QC data to .csv files and other formats. Target, cumulative, and date range statistics are exported. The data can be filtered by measure, analyzer, control material, and analysis date range. Columns can be hidden or reorganized as required.

Improved reports

The QC report has been improved. It now prints the date range statistics in addition to the target and cumulative statistics. A filter allows the user to print all results, the ones in error, or none at all.

Reagent lot change tracking

Reagent lot changes are now displayed on the measures tab screen, and indicators flag when the changes were made on the Levey-Jennings chart screen.

Group by Measure

The QC review tree on the left can now be structured by measures (analyzer). The QC review tree allows the user to select the analyzer and measure for the QC to be reviewed. Grouping by measures allows the QC reviewer to easily verify that a measure is in control for a group of interchangeable analyzers. Moreover, a filter allows the user

Visual indicators now flag instruments with errors and warnings on

to see only the branches with either reviewed or not yet reviewed analytical processes that are out of control.

Visual indicators now flag instruments with errors and warnings on the QC review tree

The QC review tree now highlights the branches of un-reviewed analytical processes that are out of control and which trigger warnings which are shown in orange or errors which are shown in red.

Westgard rules can now be applied selectively

The user can now define additional Westgard multi-rules by selecting or deselecting individual rules, and use these on a measure by measure basis.

Reviewer user status with read-only ability now available

A new Read-Only role allows people to inspect the QC data without having the right to perform any change.

LQC can now be integrated with Instrument Manager Mirroring

From Instrument Manager version 8.15 onwards, Mirroring has replaced Hot Backup as the standard Caché-based failover system that ensures full system availability in the case of a computer failure or a physical destruction event. LQC can now be integrated with the IM mirror set so that the software and databases will be instantly available in the case of a failure event.

Known Issues

Report preview fixed

The QC report now correctly previews and prints when asked to print exactly one measure for one control level. Prior to 2.0, LQC would display nothing under these conditions.

Report saving fixed

Saving a redesigned report no longer generates a spurious error.

Assigned

“Assigned Values Then Study” incorrectly behaved like “Assigned values”. It now correctly uses the target from the study when the study is complete.

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Instrument Manager was written and designed at Data Innovations LLC, 120 Kimball Avenue, South Burlington, VT 05403 USA. Portions of Instrument Manager were created using the TList 8 OCX component.

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Chapter 1

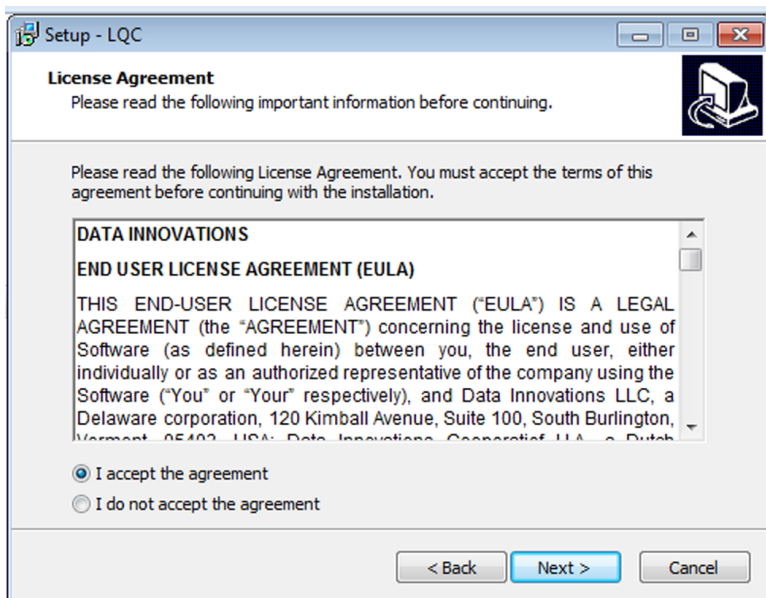
LQC Installer's Guide

Installing the LQC Software

NOTE: LQC must be listed as your Quality Control provider in your Instrument Manager license to ensure IM can send data to LQC.

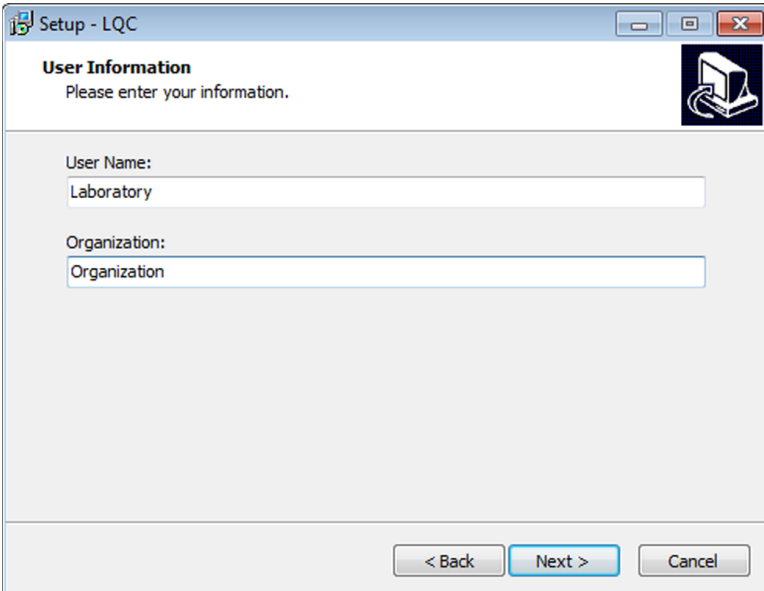
To install LQC software, use the following procedure:

1. Insert the installation CD and navigate to the root directory.
Alternatively, you can install the software from a shared directory on a local disk or a remote directory
2. Double-click on the **Setup** icon to launch the installation. The Setup wizard windows appears.
3. Click **Next**.
4. From the License Agreement window, use the scroll bar to review the terms of the End User License Agreement.



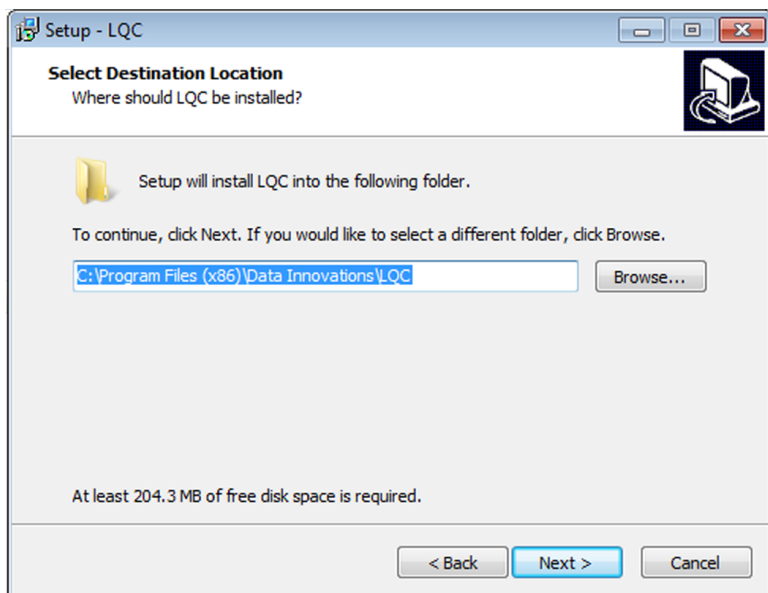
5. Select the **I accept the agreement** radio button and click **Next** to confirm your agreement.
6. Review the Release Notes and click **Next**.
7. Enter user information. The default values are retrieved from your Windows user information. Update these as needed. The

Organization you enter here will be used as a default name within LQC. Click **Next**.

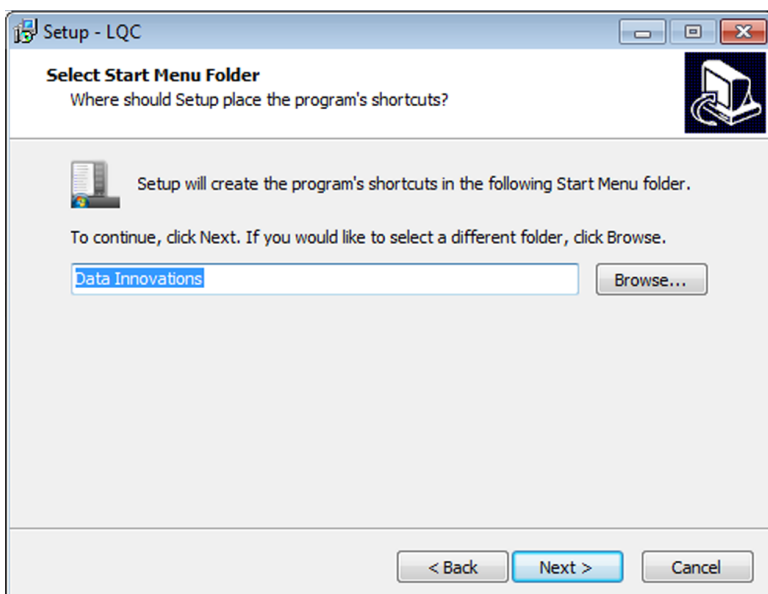


The screenshot shows a Windows-style window titled "Setup - LQC". Inside, the "User Information" section is active, with the instruction "Please enter your information." and a small icon of a computer monitor with a circular arrow. There are two text input fields: "User Name:" with the text "Laboratory" entered, and "Organization:" with the text "Organization" entered. At the bottom of the window, there are three buttons: "< Back", "Next >" (which is highlighted with a blue border), and "Cancel".

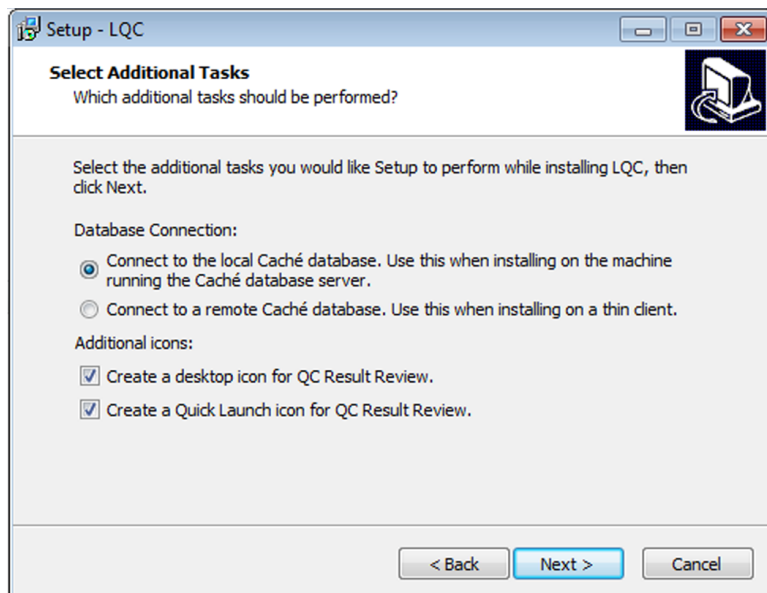
8. From the **Select Destination Location** window, click **Next** to accept the default installation path (recommended). If you need to select a different destination location, use the **Browse** button to specify that location.



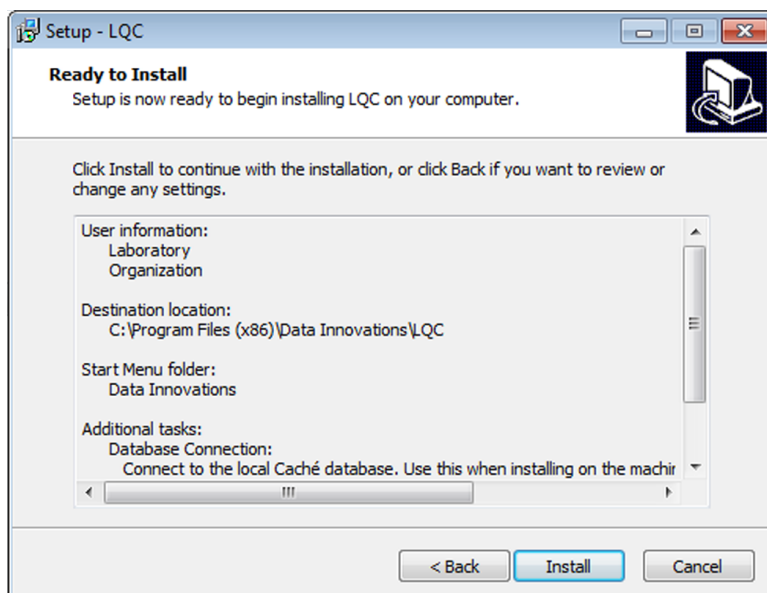
9. From the **Select Start Menu Folder** window, click **Next** to accept the default folder of Data Innovations(recommended).



10. Click **Next** to accept the default tasks to be performed (recommended).



11. Review the settings. Click **Back** to make changes. Click **Install** to proceed to the installation.



12. Click **Finish** once the install is complete.

Install LQC as a Thin Client

A thin client is uses the resources of the base Instrument Manager/LQC computer system to run.

Prerequisites

- LQC is installed and working on the base (server) machine, where the Instrument Manager software is installed.
- An IM thin client is installed on the client computer where you want to install the LQC thin client.
- The IM thin client is correctly accessing the Caché database.
- You have one or more thin client connections (one for each user accessing LQC via a thin client) licensed in your Instrument Manager license.
- The Windows operating system on the prospective thin client computer is supported by LQC.
- The Windows account on the thin client system (client) has administrative rights for the duration of the installation.

Set up LQC as a Thin Client

1. Obtain the IP address of the base machine (i.e. the computer where Instrument Manager and LQC are installed).
2. On the client computer, run the LQC installation wizard from the installation DVD.
3. With the exception of the Setup - LQC window, accept the defaults in the Install Wizard. On the Setup - LQC window, select Connect to a remote Caché database. Use this when installing on a thin client.
4. After the installation is complete, launch LQC to access the Connect to Caché window.
5. Enter the IP address for the base (server) machine into the Server address field.

6. Click Save, then OK.

LQC is now installed as a thin client. Launching LQC from the thin client connects you to the LQC instance installed on the base machine.

Troubleshooting Tips

If you cannot connect to LQC via thin client, check for the following issues:

- Firewall
- IP address is incorrect
- Port number changed

NOTE: To change the port number, check Show advanced connection options from the Connect to Caché window, and edit the port number.

- Licensing issues.

NOTE: Running LQC and Instrument Manager on the same thin client machine requires one Thin Client license in your Instrument Manager license file.

- IM_ADMIN password is changed
- Caché is stopped

Connecting IM to LQC

Follow the steps below to define the Instrument Manager Connections that you want to send data to LQC.

NOTE: LQC must be listed as your Quality Control provider in your Instrument Manager license to ensure IM can send data to LQC.

1. Start Instrument Manager (IM).
2. Using **Configuration > Load Drivers**, load the Data Innovations LLC Laboratory Quality Control driver.
3. From the **Configuration** menu, open the **Configuration Editor**.
4. Create a configuration for LQC.
5. Click **Driver Properties** to define connection, instrument ID, and Instrument Alias.

NOTE: The Instrument Alias defined in the driver configuration must match the QC Client Alias assigned in Configure LQC.

NOTE: Instrument Manager first evaluates on the Connection Name/Instrument ID combination defined in the driver to determine the Instrument Alias for the connection. If the Instrument ID field is blank, only the Connection Name is used to determine the Instrument Alias.

Data Innovations LLC Laboratory Quality Control Configuration

Alias Configuration		
Connection Name	Instrument ID	Instrument Alias
Analyzer	12321	Analyzer

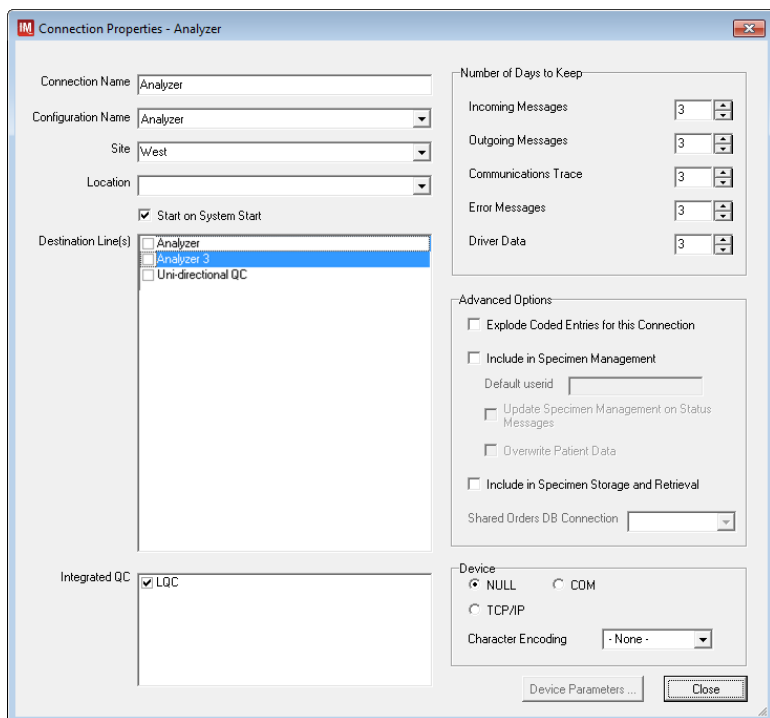
QC Type

☒ Uni-Directional ☐ Integrated

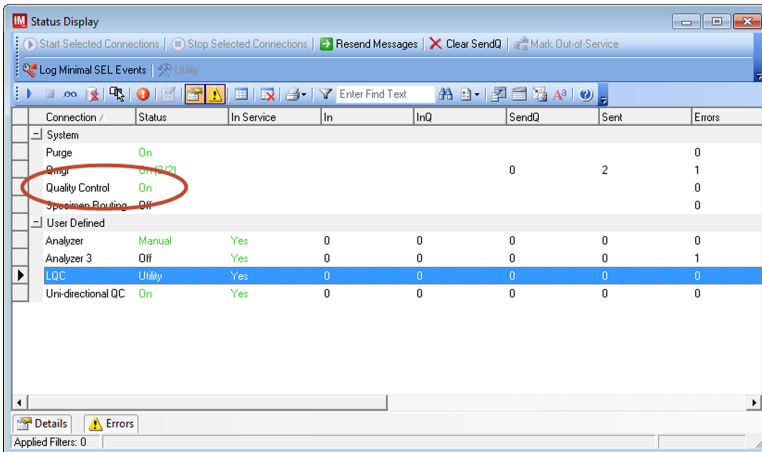
Close

NOTE: QC Type is set as Integrated and cannot be changed to uni-directional. Integrated QC does not require purchased connections. Integrated QC does need to be licensed as part of your Instrument Manager licensing.

6. Click **Close**.
7. Click **Yes** when prompted to save the configuration.
8. Open **Connection Assignment** from Instrument Manager's Configuration menu.
9. Create a connection for the LQC configuration.
10. Uncheck the **Start on System Start** check box for the LQC connection.
11. Click **Close** on the Connection Properties screen and save your changes.
12. Open the Connection Properties screen for each analyzer connection configured to send data to LQC and ensure the LQC connection is checked as an Integrated QC destination line.



13. From IM's System menu, select **Status**.
14. Start your LQC connection using the Quality Control System connection.
15. Select the System Quality Control connection and click the **Start Selected Connections** button, or select the **System Quality Control** connection, right-click, and select **Start Selected Connections**.



NOTE: The System Quality Control Connection reflects the status of all integrated QC connections. You can stop and start all integrated QC connections from the Status Display screen.

NOTE: Your Integrated LQC connection will be listed with other user defined connections as a utility connection. QC connections listed as User Defined cannot be individually stopped or started.

In LQC

To define analyzers and your QC setup in LQC, refer to the instructions on configuring LQC.

QC Rules

Instrument connections using LQC must be defined in both LQC and Instrument Manager.

In Instrument Manager

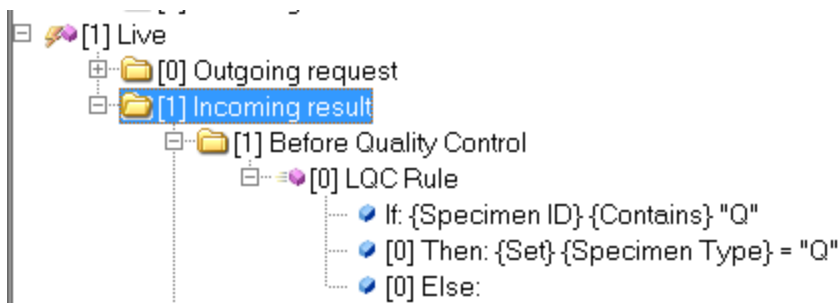
Using Rules Processing, write an Instrument Manager rule on the analyzer to identify the QC sample and set the specimen type:

- The rule must be written in the Before Quality Control location for incoming results.
- The rule must identify the QC specimen using a known pattern and then set ({SET}) the {Specimen Type} to "Q".

NOTE: Only specimen with a Specimen Type of "Q" are sent to LQC.

Below is an example rule that identifies the QC specimen ID using the {Contains} operator. When a QC specimen is sent from the analyzer, this rule sets specimen type to "Q", which ensures the QC result is sent to LQC:

```
If: {Specimen ID}{Contains} "Q"  
Then: {Set}{Specimen Type} = "Q"
```



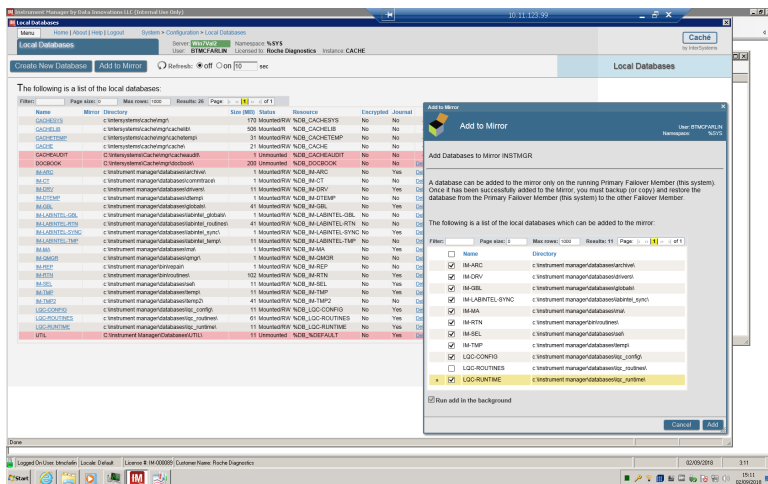
Please refer to the Instrument Manager documentation for more information about Rules Processing.

Configure LQC with IM Mirror Set

From Instrument Manager version 8.15 onwards, Mirroring has replaced Hot Backup as the standard Caché-based failover system that ensures full system availability in the case of a computer failure or a physical destruction event. LQC can now be integrated with the IM mirror set so that the software and databases will be instantly available in the case of a failure event.

To add LQC and its databases to a High Availability or Disaster Recovery Mirror Set, or a Read/Write Reporting Mirror Set, first read the Mirroring set up instructions in the IM Help User Guide. See the following section in the IM Help User Guide: Productivity>Mirroring>Mirroring Setup>Primary Mirror Member Setup.

You will need to have LQC installed on all members of the mirror set. Then you must ensure that the LQC databases are included and synchronized as part of the mirror set.



Refer to the IM Help (Productivity>Mirroring>Mirroring Setup>Primary Mirror Member Setup) where databases are added to the mirroring set through the Caché data management window.

Configure LQC with IM Mirror Set

Access this window from Instrument Manager's **Configuration>Manage Mirror Members**.

Navigate to the Caché Home page. Browse to **System Administration>Configuration>System Configuration>Local Databases** page.

If a mirror set is already set up, then click the **Add to Mirror** button to see a list of all the databases that are included in the Caché mirror set. The LQC databases should appear in this list. Click the checkboxes to include the two databases LQC_CONFIG and LQC_RUNTIME. Do not include LQC Routines.

You should re-synch the databases after adding these if they are being added to an existing mirror set.

If a mirror set is not already set up, then follow the IM Mirroring setup procedure and ensure that the two LQC databases are included during the setup process. These databases are stored in the **Instrument Manager>Databases** folder along with the other IM databases.

Chapter 2

LQC User's Guide

Purpose and Methodology

The purpose of Quality Control (QC) within a laboratory is to ensure that all instruments consistently report reliable sample results. QC assures results are reported correctly (accuracy) and that subsequent results do not change significantly (precision) *unless* the patient's condition has changed.

QC can be implemented by using an assayed control material on each instrument and comparing control results against the assay (i.e. known) value to identify discrepancies, the analyzer's level of accuracy, and the analyzer's level of precision.


Laboratory Quality Control (LQC) uses a combination of decision criteria (i.e. the Westgard multi-rule logic) assigned by the user to:

- assess and calculate statistics in figures or in Levey-Jennings charts.
- assist the user in judging the acceptability of analytical runs.
- assist the user in determining whether an analyzer is *in-control* or *out-of-control*.

Launch LQC

Launch LQC in one of the following ways:

- Double-click the **LQC** shortcut on the desktop.
- From the Start menu, open **All Programs>Data Innovations>Review QC Results**.

- From the Windows tray, click the gold key icon .

You will be asked to log in to Laboratory Quality Control. You must log in using the username and password set up for you in Instrument Manager's User Security feature.

Authentication

All **LQC** and **Configure LQC** users are authenticated using the username and password set up in Instrument Manager's User Security feature. Once you are configured as a user in Instrument Manager User Security, you will be able to log on to LQC and Configure QC using your Instrument Manager credentials.

By default, Instrument Manager's pre-configured administrative user (username: IM_ADMIN, no password) has system administrator rights to Configure QC.

- All other users created in Instrument Manager User Security will, by default, have ordinary user (Lab Technician) level access in Configure QC .
- Upon first installing LQC, the IM_ADMIN user will be the only user with system administrator access.
- The IM_ADMIN user can assign system administrator rights to other IM users from Configure QC.

Control Material

Basic Principles

Upon first launching Laboratory Quality Control, start by recording control material. Both recording and updating control material is done in Laboratory Quality Control.

Control products are usually sold in batches or lots. When recording a new lot in LQC, you will be prompted to enter specific control information, including the lot ID, expiration date, and expected values quoted by the manufacturer. This information can be found on the package insert provided by the manufacturer. Analyzers can now also flag when new reagent lots are used with a control lot. This information is shown on the Measures table and a green bottle icon now appears at the bottom of the Levey Jennings chart to show when the reagent lot was switched out (see the end of this section).

Record Control Material

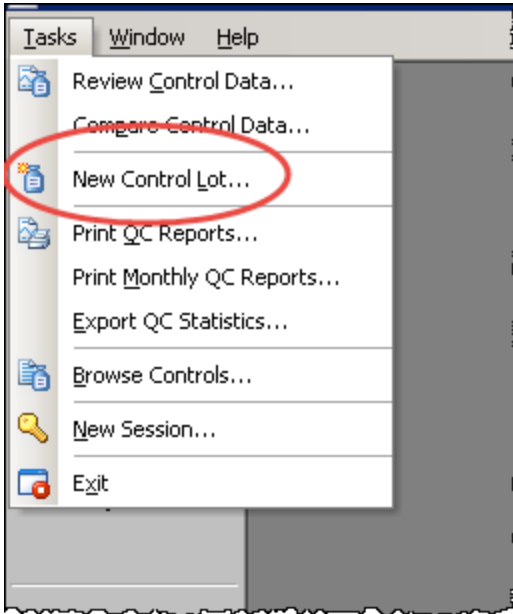
A creation Wizard in LQC guides you through the recording process.

To record Control Material:

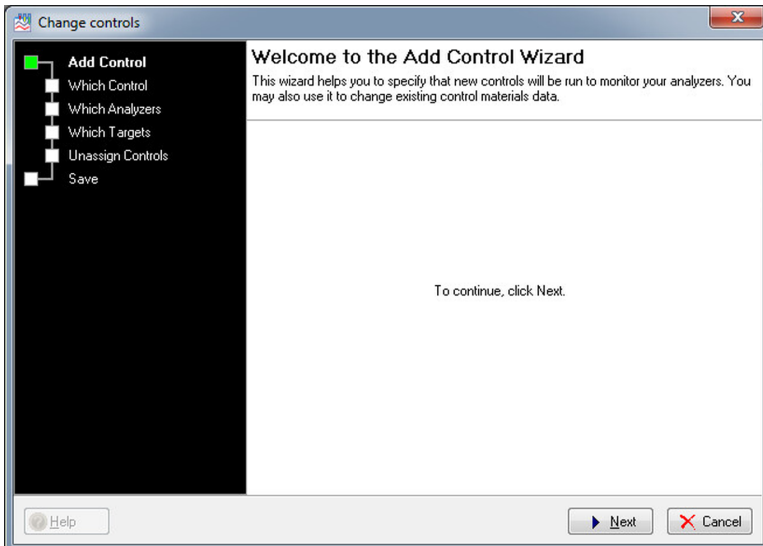
Click the New QC Lot button



Or select **Tasks > New Control Lot...**



The Add Control Wizard



Which Control

Click **Next** to enter a control using the Change control Wizard.

Which Control

Change control - CD High 7E1070

Which Control

What are the characteristics of the new control material ?

Click in the list below to select the type of the new control.

- CD High
- CD Low
- CD Normal
- Multiq U 1
- Multiq U 3
- Uri L1
- Uri L2

Your Controls / All Controls

Enter the lot number and expiration date of the new control. You may want to enter an existing lot number in order to retrieve and change the corresponding control data.

Lot : 7E1070

Expiration Date : 08/16/2019

Help Next Cancel

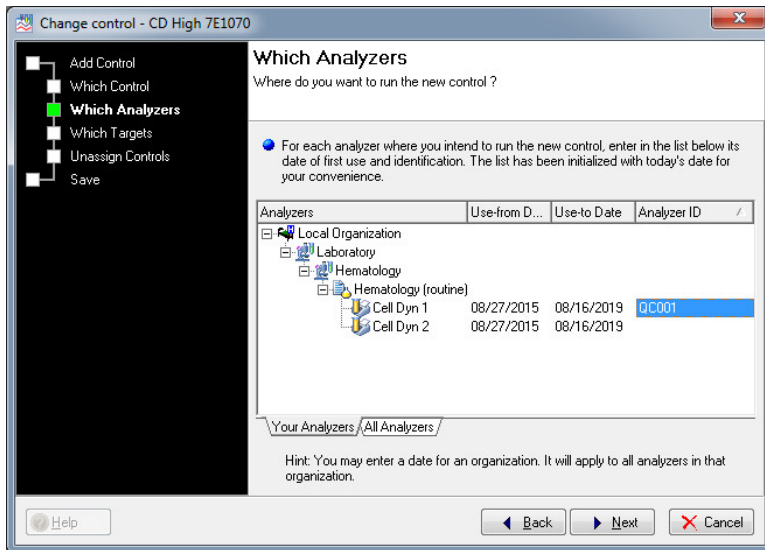
Select the type of new control to be analyzed with the product by clicking on the appropriate control type in the central box.

Complete the **Lot** box with the lot number mentioned in the package insert.

Use the calendar icon to enter the **Expiration Date** box. This information is found in the package insert.

Click **Next** to proceed to the next section.

Which Analyzers



Click the name of the analyzer on which the controls will be performed.

Specify the start and end date of the control period required for the analyzer.

(If the new control material is to be used in a preliminary study (see info box on next page), don't forget to include the study period in the Use-from Date.)

In the **Analyzer ID** column, enter an identification code for the control on the analyzer. The Analyzer ID identifies the specimen ID of the QC result.

NOTE: The Analyzer ID is used by Instrument Manager to identify the specimen ID for the QC result. If left blank, LQC will not recognize the QC result.

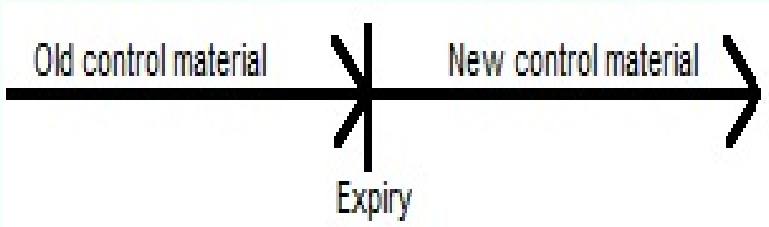
Click **Next** to proceed to the next Wizard section.

QC practices vary from one laboratory to another. In certain cases, new control material is automatically used to replace expired assays, and analyses are conducted

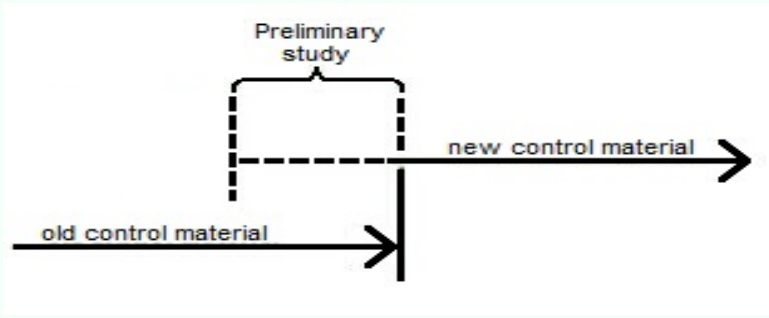
Which Analyzers

immediately with the new material on the specified machines.

Case 1: No study.



In other cases, the new control material is first evaluated during a study period to ensure adequate performance and then it is included in the actual QC process and replaces the old material used on the corresponding analyzers.



Which Targets

Change control - CD High 7E1070

Which Targets

What are the expected values assayed by the control manufacturer ?

☐ Enter below the expected values assayed by the manufacturer.

Tests	Low Li...	High Li...	Target	Sd	CV
Cell Dyn					
White Blood Cells	3	4	3.500	0.170	4.8
Red Blood Cells					
Platelets					

Hint: You may enter either the lower and upper limits, or the target and standard deviation or coefficient of variation.

Import...

Help Back Next Cancel

Use the information in the package insert provided by the lot manufacturer to complete the **Which targets** section. You have the option to enter the Control Limits, the Target or Standard Deviation.

NOTE: If multiple analyzers of the same type are defined, click the **[+]** next to the test name to expand a list of analyzers and enter different target values for those analyzers. To define different analytical units, click the **[+]** next to the analyzer name.

When you define control limits, LQC will automatically compute the target value, standard deviation (SD) and coefficient of variation (CV).

Conversely, if you define a target and standard deviation or coefficient of variation, the system will compute the corresponding limits. In both cases, the computation will be such that the control limits correspond to the target \pm three standard deviations (SD).

For certain analyzers, LQC can import control limits automatically from a CD provided by the manufacturer. Click the **Import** button to import control limits from a CD. See [Importing Control Material](#).

Users can choose to define:

Unassign Controls

- Control limits
- Mean and SD (CV will be calculated)
- Mean and CV (SD will be calculate)

Control limits can also be saved as default in Configure QC. The saved assayed values will then be automatically suggested for every new lot that you define.

Click **Next** to proceed to the next Wizard section.

Unassign Controls

Unassign	Lot	on Analyzers	the
<input checked="" type="checkbox"/>	6E1060	Cell Dyn 2, Cell Dyn 1	08/28/2015

The **Unassign Controls** section of the Wizard lists all control lots currently in use in the laboratory.

Check the **Unassign** check box before a lot number to indicate that it must be replaced by the new control material as of the indicated date. The default value of the date field is computed by LQC using the current date plus the duration of the study period, as defined in the **Add Control Wizard** in Configure QC. Additionally, you can define the study period in the **Min Days** column, accessible from the **QC** tab for the Analyzer in Configure QC.

Click **Next**.

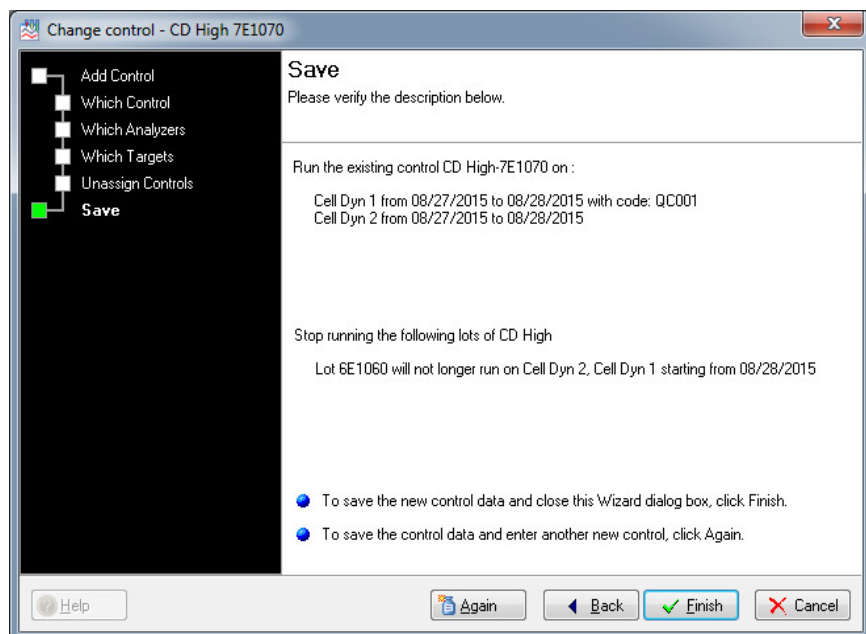
Save

LQC displays a summary of the information that you have entered about the new lot.

If the information is complete and correct, click **Finish** to confirm and save.

If it is not, click **Back** to modify.

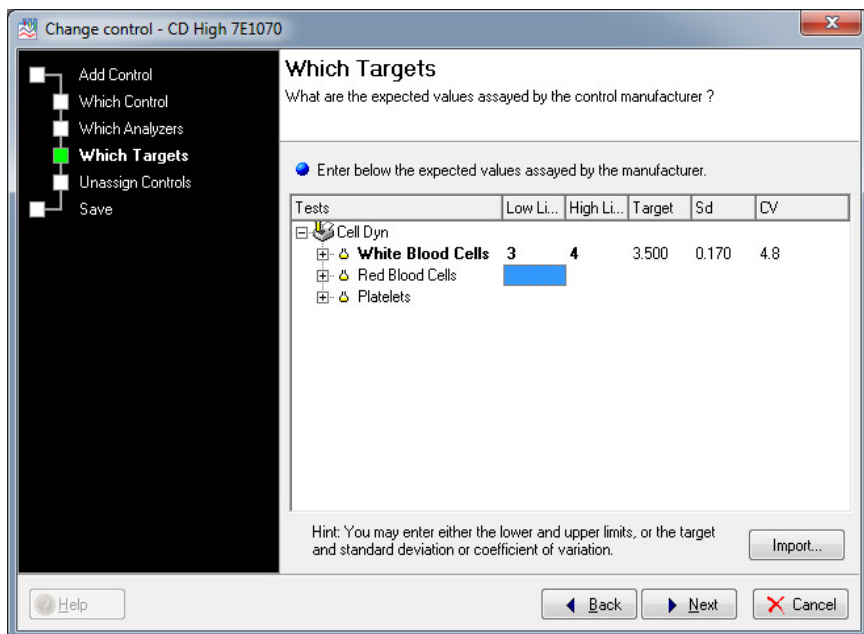
If you wish to record another lot, click **Again**.



The control material is now ready to be used in the quality control process.

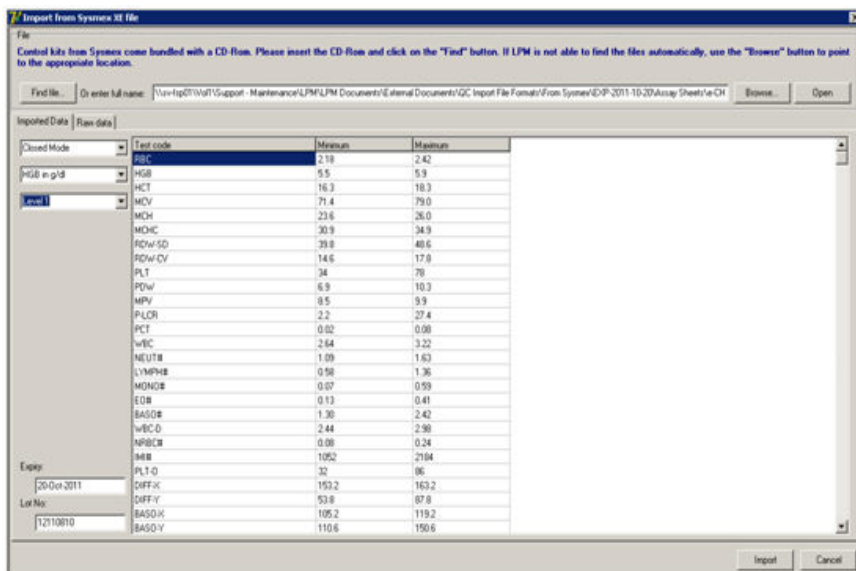
Import Control Material

For certain analyzers, LQC can import control material ranges from a file or CD provided by the manufacturer. The import procedure varies slightly depending on the analyzer. Click the **New control lot** button or select **Tasks > New control lot...** to launch the add control wizard. Follow the usual procedure for adding a new control lot until you reach the **Which Targets** screen.



Click the **Import...** button. LQC will typically try to open the file from the most logical location. If LQC cannot find the file, it will prompt you to locate the applicable file. Review the data and click the **Import** button.

NOTE: Some import files will allow you to select the format of the data. For instance, in the XE importer, you can select whether you want HGB expressed in grams or moles as illustrated below.



Updating Control Material

The information about the control material available in the laboratory must be kept up-to-date in LQC. Any changed or incorrect data must be immediately reflected in the software.

The following information can be updated in LQC:

Generic control data, including intended period of use in the laboratory and identification of the analyzer on which the control material has to be tested.

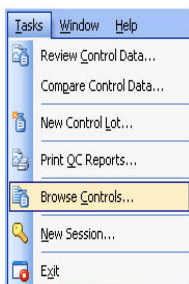
Specific control data, including targets/limits set for the control material and identification of the replaced material.

Information such as lot number and control type cannot be modified manually. In case of a mistake, just mark the product as no longer in use, and record a new one with the correct values.

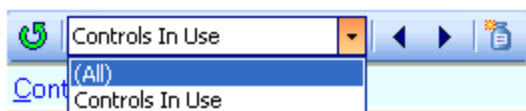
Modify generic control data (period of use, analyzer)

In the LQC main menu bar, select **Tasks>Browse Controls...**

Modify generic control data (period of use, analyzer)



In the **Browse Controls** window, select the control material that you want to modify in the left panel. (If the material is no longer in use, first select **All** in the selection box above the list.)

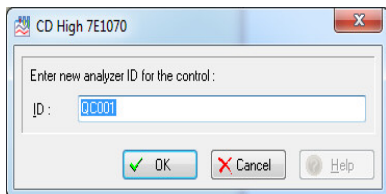


The **Browse Controls** window is displayed.

Controls :		Control : BioChem 1		BC1-23145		03/28/2021	
Type	Lot	Analizers	In use	Use-from Date	Use-to Date	Analyzer ID	
BioChem 1	BC1-23145	Laboratory	<input checked="" type="checkbox"/>				
BioChem 2	BC2-23145	Biochemistry	<input checked="" type="checkbox"/>				
		Chemistry (routine)	<input checked="" type="checkbox"/>				
		RUG Chemistry	<input checked="" type="checkbox"/>	03/01/2018	03/28/2021	BC1	

To quickly modify the period of use of the selected material, double-click the **Use-from** or **Use-to Date**, change the date, and click **OK**.

To specify receipt of a different control barcode from the analyzer, double-click the analyzer ID, enter another ID, and click **OK**.



To review the full details about the selected control material, click **Control > Details**.

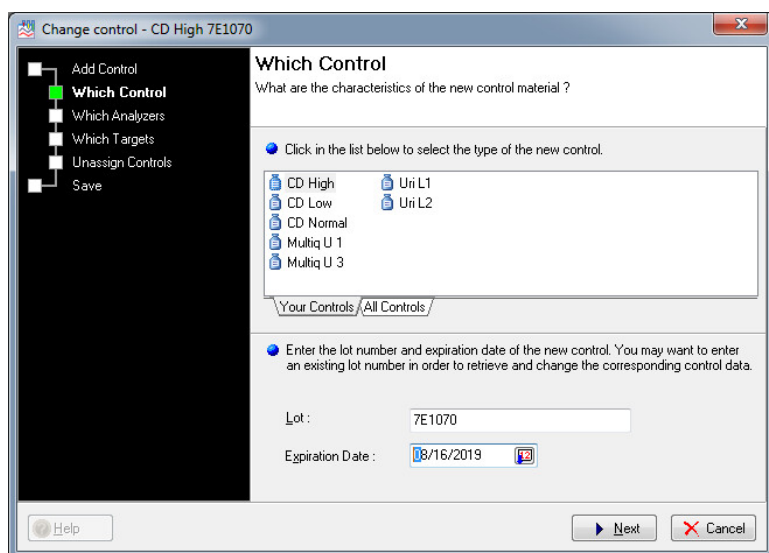
The Control Details are displayed:

Modify specific control data (limits/target, replaced material)

Click the New QC Lot button or select **Tasks > New Control Lot...**



In the Browse controls window below, select the control type defined for the material that you want to modify, then type the exact lot number in the Lot box. If the lot in question is present in LQC, its expiration date is automatically displayed in the **Expiration Date** box.

A screenshot of a software dialog box titled "Change control - CD High 7E1070". The dialog has a left sidebar with a tree view containing: "Add Control", "Which Control" (highlighted with a green square), "Which Analyzers", "Which Targets", "Unassign Controls", and "Save". The main area is titled "Which Control" and contains the text "What are the characteristics of the new control material?". Below this is a list box with the instruction "Click in the list below to select the type of the new control." The list contains: "CD High", "CD Low", "CD Normal", "Multiq U 1", "Multiq U 3", "Uri L1", and "Uri L2". Below the list is a tabbed interface with "Your Controls" selected and "All Controls" as an alternative. Below the tabs is a text area with the instruction "Enter the lot number and expiration date of the new control. You may want to enter an existing lot number in order to retrieve and change the corresponding control data." Below this are two input fields: "Lot:" with the value "7E1070" and "Expiration Date:" with the value "8/16/2019" and a calendar icon. At the bottom are buttons for "Help", "Next", and "Cancel".

To modify limit or target values currently defined for the selected material, check the **Which Analyzers** box in the left panel to jump directly to the appropriate section, modify the current values as appropriate and click **Next**.

To modify the replaced control, check the **Unassign Controls** box, modify as appropriate.

New Reagent Lots

Click **Next** to move to the last section of the Wizard, then click **Finish** to save the change.

New Reagent Lots

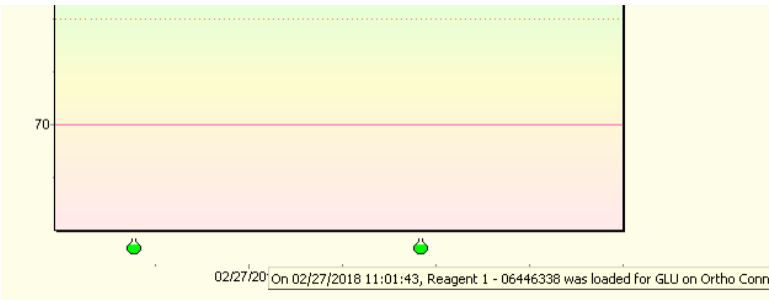
Changes of reagent lots used with a control lot are now flagged on the Levey Jennings chart for the measure. The changes are sent from the instrument, and up to four reagent lot changes can be made during the period of use for each control lot. This information is sent in the results messages from the analyzer where up to four reagent lot numbers can be included, in a comma separated string.

The lot numbers for up to four changes of reagent lot are also displayed in columns in the measures tab table.

NOTE: You must have the Format: Detailed radio button checked to see the reagent lot columns. It is below the table on the Measures tab and to the right of the screen.

GLU										Ortho Conn			
			Measure	Target	% dev	% max	Comment		Control Lot	Reagent Lot 1	Reagent Lot 2	Reagent Lot 3	Reagent Lot 4
02/20/2018	14:55:41	CCCHEM2	85.5	85.00	0.6	5.9	CS		100				
02/20/2018	16:03:00	CCCHEM2	86.5	85.00	1.8	5.9			100				
02/20/2018	16:41:19	CCCHEM2	86.5	85.00	1.8	5.9			100				
02/26/2018	16:41:04	CCCHEM2	85.5	85.00	0.6	5.9			100	06446337			
02/27/2018	11:01:43	CCCHEM2	85.5	85.00	0.6	5.9			100	06446338			

Green bottle icons are displayed below the Levey Jennings chart where the switch to the new reagent lot used with the control lot took place. Hovering the mouse cursor over the bottle below the chart brings up details of the new lot including the date and time when it was switched out.



Finally, the lot numbers can also be reviewed in the **Result** Details of **QC Results** form selected from the main menu bar. The lot numbers of reagent lots used are shown in the **Reagents** field at the bottom of the form. If multiple reagent lots were used their numbers are separated by commas.

Details of QC Result

Result | Audit Trail

Control

Type : Technopath Urine 2

Lot number : 22905162

Aspiration

Analyzer : Wansbeck AU680-2

At : 09/03/2018 09:32:16

Result

Analysis : Urine Creatinine

11.682

Comments :

Comment	Author	Date
4-1s	Ganesh	09/03/2018 09:32:18
4-1s		

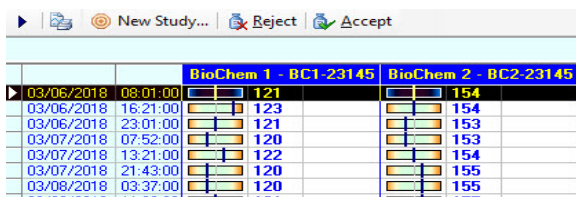
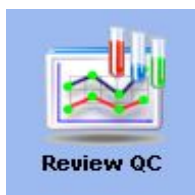
Reagents

12345678, 87654321

Status

OK Cancel Help

To accept or reject control results, select a result and click the **Reject** or **Accept** buttons from the Levey-Jennings chart. Alternatively, you can select a result, right-click, and select **Reject** or **Accept** from the right-click menu.



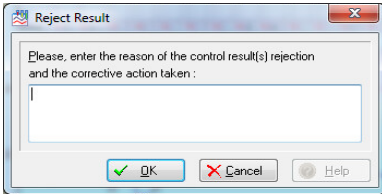
Reject Control Results

If you have not yet done so, open the **Review QC** screen and select the **Measures** tab

Select the result(s) you wish to reject.

Click the **Reject** button in the tool bar.

The Reject Result dialog box appears.



Type an explanation into the text box.

Click **OK**.

Reviewing Control Data



All results, whether rejected or accepted, are displayed on a Levey-Jennings chart.

Viewing Graphs and Statistics

Click the Review QC button.



1.10.2. 1.2 Generuoja pasirinkto laikotarpio Levey-Jennings grafikus.


Select the appropriate analyzer  and analyte/measure  in the tree view on the left. The system displays the Levey-Jennings chart on the right by default. Charts for each control level are displayed.



See [Reviewing the Levey-Jennings Chart](#)

There are two tabs below the tree pane on the left labeled **Group by Analyzer** and **Group by Measure**. Group by

Analyzer is equivalent to the default option in previous versions of LQC. Group by measure (analyte) is the new option for LQC 2.0. In the previous version, each individual analyzer instrument was listed first, and then all the measures/analytes run on that machine were listed below that. In the new version,

Measures data can be organized by Analyzer type.  All analyzers are listed of the same type, and these all run the same measures, so using the analyzer type in the tree means that results from comparable analyzers for the same measures/analytes are grouped together. Instruments/analyzers can also be filtered by lab "**My Workplace**" or lab group "**My Laboratory**".

My Workplace: The lowest-level workplace which contains the current workstation (the workstation users are currently running on)

My Laboratory: The lowest-level laboratory which contains the current workstation.

Depending on your needs, you may choose between the following display options (tabs) below the charts:

- **Raw/cumulative** – Display 1 QC point for each measure (**Raw**) or 1 QC point per day, representing the mean of all measures for that day (**Cumulative**).
- **EWMA** – Display the EWMA (Exponentially Weighted Moving Average) for improved bias detection.
- **In Use/All** – Display only controls which are currently in use (**In Use**) or all controls defined for the laboratory (**All**).
- **Grid** – Show/hide the grid on the chart.

Use the appropriate option in the shortcut menu that pops up when you click the right mouse button to:

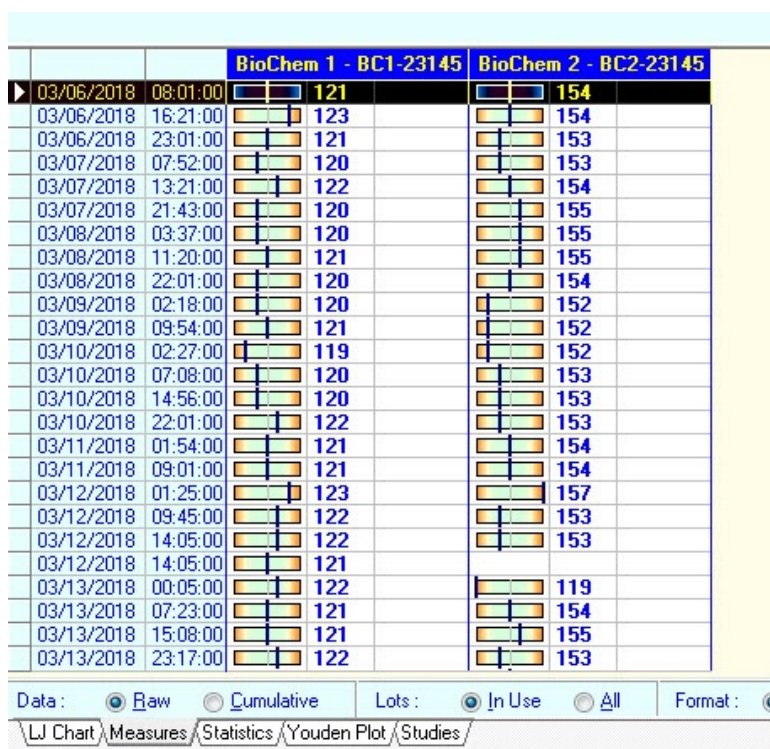
- Accept, Reject, or Comment a point.
- Print Levey-Jennings reports.

Viewing Graphs and Statistics

- **Modify the study/control period.**
- Create a new study (see next section for detailed instructions).

To view the corresponding Z-bar charts, select the **Measures** tab.

- The z-score bar indicates how many standard deviations a control result is from the mean value expected for that material.
- You can quickly see if any result exceeds a single control limit, or spot systematic changes or trends occurring across different control materials.
- When applicable, the **Alarms** field also indicates changes of target values.
- A black horizontal line as illustrated in the figure below indicates a change in target values.



- The z-score bar uses the target values at the time of the QC.
- These target values are displayed in a hint box that appears when you hover over a result field:

12.000 $\mu\text{mol/l}$
16/01/2003 15:32:23

Target: 8.000
Std dev.: 0.400
CV: 5.0%
Assigned Target: 7.000
Assigned Std dev.: 1.000
Assigned CV: 14.3%

The target at the time of measure differs from the current one.

To view the corresponding statistics, select the **Statistics** tab.

- **Assigned statistics:** Statistics defined by the user.
- **Statistics of control study:** Statistics obtained during the study period.
- **Statistics of all measures:** Global statistics.
- **Control** (using assigned or study values): Values effectively used in the QC.

Na	
BioChem 1 - BC1-23145	BioChem 2 - BC2-23145
<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Assigned statistics</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text" value="121"/></div> <div>Low: <input type="text" value="118"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text" value="1"/></div> <div>High: <input type="text" value="124"/></div> </div> <div>Cv: <input type="text" value="0.8"/></div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Statistics of control study</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text"/></div> <div>Cv: <input type="text"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text"/></div> <div>N: <input type="text" value="0"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>From: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>To: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Statistics of all measures</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text" value="121"/></div> <div>Cv: <input type="text" value="0.8%"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text" value="1"/></div> <div>N: <input type="text" value="68"/></div> </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Control (with assigned values)</div> <div style="display: flex; justify-content: space-between;"> <div>From: <input type="text" value="03/29/2018 09:06"/></div> <div><input type="button" value="P3"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>To: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Assigned statistics</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text" value="154"/></div> <div>Low: <input type="text" value="151"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text" value="1"/></div> <div>High: <input type="text" value="157"/></div> </div> <div>Cv: <input type="text" value="0.6"/></div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Statistics of control study</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text"/></div> <div>Cv: <input type="text"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text"/></div> <div>N: <input type="text" value="0"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>From: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>To: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Statistics of all measures</div> <div style="display: flex; justify-content: space-between;"> <div>X: <input type="text" value="153"/></div> <div>Cv: <input type="text" value="4.0%"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Sd: <input type="text" value="6"/></div> <div>N: <input type="text" value="66"/></div> </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Control (with assigned values)</div> <div style="display: flex; justify-content: space-between;"> <div>From: <input type="text" value="03/29/2018 09:06"/></div> <div><input type="button" value="P3"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div>To: <input type="text"/></div> <div><input type="button" value="P3"/></div> </div>

Creating a New Study

Legend:

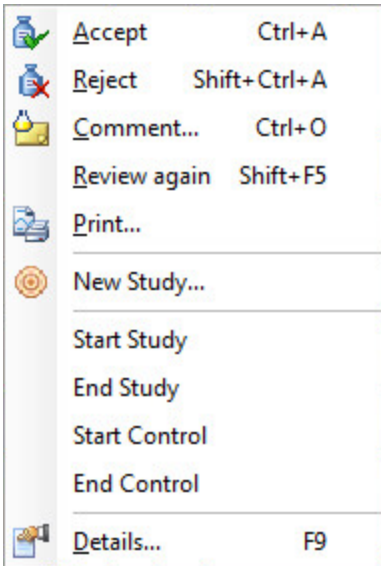
X	Mean calculated for the N points	High	Higher control limit
Sd	Standard deviation	Cv	Coefficient of variation (= $\frac{s}{\text{Mean}}$)
Low	Lower control limit	N	Total number of control measurements available for use in assessing the quality of the run

Creating a New Study

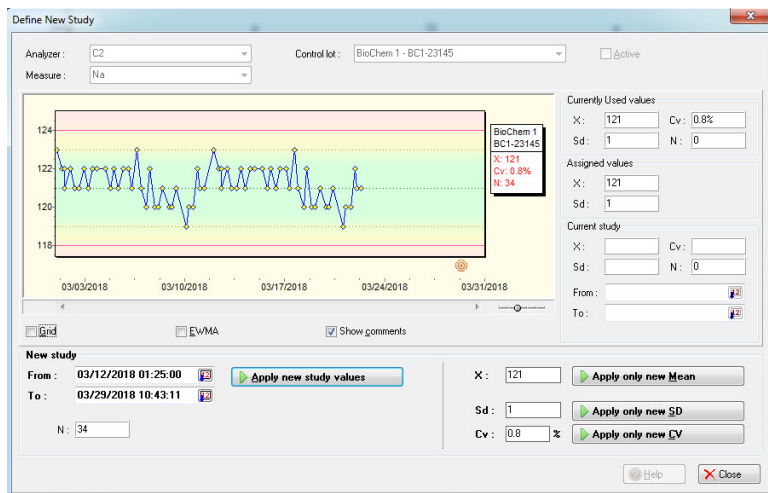
Click the **Review QC** button.

Select the appropriate analyzer and measure in the tree view on the left.

Create a new study by clicking **New Study** button on the toolbar above the Levey-Jennings chart. Alternatively, you can select **New Study** from the right-click menu accessible when hovering over the Levey-Jennings chart, Measures tab, or Youden Plot.



The definition screen is displayed:



This screen allows the user to:

Define a new control study period by :

- Selecting a start and end period with a right click directly on the chart.
- Define a start and end period in the **From** and **To** field in the **New study** pane at the bottom left of the screen and clicking the **Apply new study values** button.

Note that the study period defined on screen when the window opens goes from the aspiration time of the selected result to the current date.

Compute statistics for the defined period.

Manually record a new Mean, new SD, or new CV by entering values directly in the **X**, **Sd**, and **Cv** fields in the **New study** pane at the bottom right of the screen.

- If you wish to apply all the newly defined study values, click the **Apply new study values** button
- If you wish to apply the newly specified Mean, click the **Apply only new Mean** button
- If you wish to apply the newly specified Sd, click the **Apply only new SD** button.

Compare QC Data

- If you wish to apply the newly specified CV, click the **Apply only new CV** button.

NOTE: The new values (modified from this form or from the Statistics tab) will become effective at the time of the modification onward and only upcoming data will use the newly defined values. There will be no retroactive computation of previous QC data.

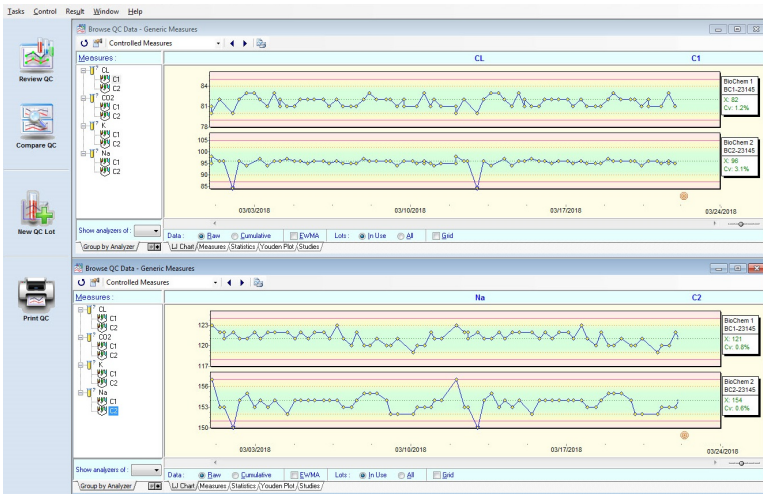
Compare QC Data

Click the **Compare QC** button.



For each section of the screen, select the appropriate analyzer, lot, and analyte in the corresponding tree view.

LQC displays the control charts for the two controls.



View the Change History

The change history contains all the changes to control data within the control period. Data used to control includes target values, the start

and end dates of the control period, the source of limits used for Westgard rules, etc.

To view the history:

Click the **Review QC** button.

Select the appropriate analyzer and analyte in the tree view on the left. The system displays the control charts for your selection

Click the **Studies** tab. The change history appears:

CL										C2										
Control /																				
Validity start	Reference population	Low	High	Target	Sd	Cv	Study me	Study Sd	Study cv	Control start	Control end	Mean	Count							
Control : BioChem 1, BC1-23145																				
Assigned values				82	1					0	03/29/2018		82	68						
Control : BioChem 2, BC2-23145																				
Assigned values				96	3					0	03/29/2018		96	66						

Control target for : BioChem 2, BC2-23145										From : to :									
Assigned statistics					Statistics of control study					Statistics of all measures									
Target : 96	Cv :				X : 96	Cv : 3.8%				X : 96	Cv : 3.8%								
Sd : 3					Sd : 4	N : 66				Sd : 4	N : 66								
Low :	High :				From :	To :				From :	To :								
Control										Modification									
Reference : Assigned values										By : Ganesh On: CHANGEWIN7VLM									
From : 03/29/2018 09:06:36 To :										At : 03/29/2018 09:06:36									
Lots : <input checked="" type="radio"/> In Use <input type="radio"/> All																			
LJ Chart / Measures / Statistics / Youden Plot / Studies																			

Reading the Change History

The top of the screen contains a list of changes. Each line shows the control data that are in use starting from the **Validity Start** date. That date is shown in the first column.

Changes that are audited and lead to the creation of a new line in the history are:

- A change in the fixed data (mean, SD, lower limit, upper limit), assigned for example using the **New Control Lot** wizard or the **New Study** wizard.
- A change in the start or end date of study.
- A change in the start or end date of control.
- A change in the reference statistics used for Westgard rules. For example, when changing from Study to Assigned values when the user specifies a new standard deviation to be used after an initial automatic study.




















The bottom of the screen contains the data for the current row of the list.

Reading the Change History

- The **Assigned** statistics group shows the statistics that have been entered by the user, either via the setting, through the **New Control Lot** wizard, or any other method.
- The **Statistics of control** study group shows the statistical data measured during a phase of automatic study.
- The **Statistics of all measures** group contains the statistics of all measures collected during the validity period (from the validity start to the next modification).
- The last line of the history always contains the values currently in use.

Reviewing the Levey-Jennings Chart

Use the visual cues on the chart to interpret it as described below. Note that the result status is displayed as a hint if you hover your mouse pointer over it (it displays previous target values manufacturer target value, Sd and Cv, etc.).

	Statistical control limits (Mean \pm 3S)		Measure included in a preliminary study, not in the actual QC
	Mean \pm 2S		Value too low or too high to display on the chart
	Target line		
	Target value	 	Measure recorded outside the 'In-use from' and 'In-use to' dates defined for the control
	Coefficient of variation (= $\frac{s}{\text{Mean}}$)		
	Accepted measure. Hover over the point with the mouse pointer to read the exact value and date		QC error with a short description. Here, for example, a violation against the '2 of 3-2S' rule has been detected (2 out of 3 measurements exceed the same mean plus or minus 2S control limit). For more detailed information about the Westgard multi-rule logic, please refer to the relevant sections of this userguide
	The measure has not been accepted nor rejected yet (unreviewed).		
	The measure has been rejected (In EWMA view, this symbol indicates an accepted value!)		
	Comments available. To read the comment, drag the mouse pointer over the symbol.		
	The target value has been changed		
			This symbol marks a switch to a new reagent lot
			A black vertical line indicates a change in target values (Low, high, Sd and CV)
	A green vertical line (optional) indicates the beginning and end of a control or study		

Reviewing the Levey-Jennings Chart

The Levey-Jennings chart plots the results observed for a stable control material versus time:

- Each point is situated against the high and low control limits.
- A result that falls outside the high/low limits is called an outlier.
- A shift occurs when there is a sudden change in control results from one day to the next.
- A trend occurs when 5 or more values show a gradual increase or decrease.

Slide the bar to increase or decrease the display period.

Print QC Data

With LQC, you can print detailed graphical color reports about the QC data from controls performed on specific analyzers or over a specific period. These reports are readily available for printing.


To print a QC report

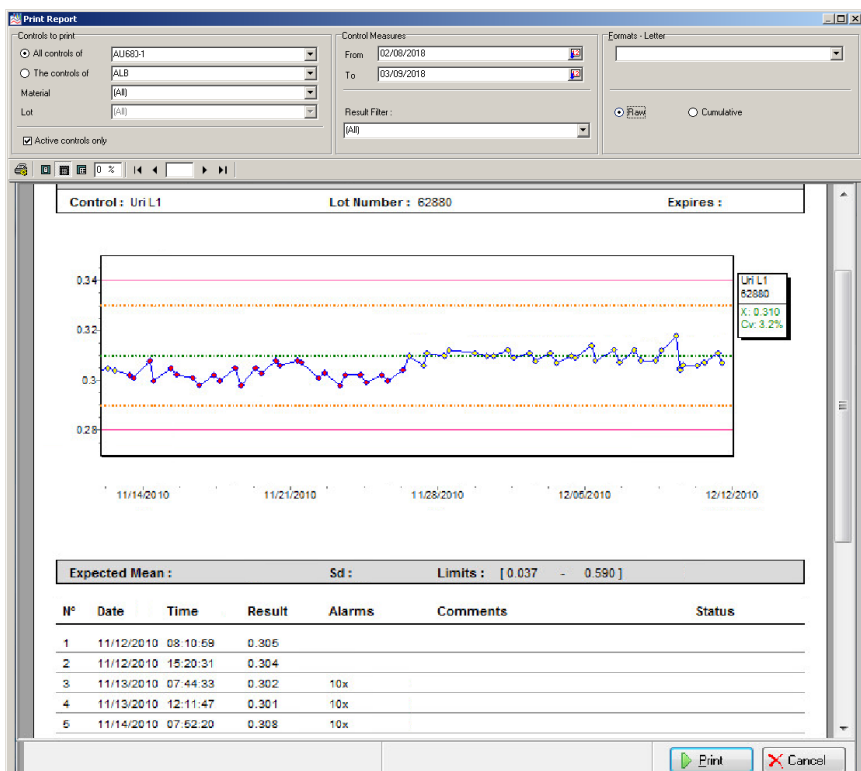
1. Click the **Print QC** button, or select **Tasks > Print QC Reports...**



Or



Click  in the menu bar from the **Review QC** screen. The Print Report dialog box is displayed:

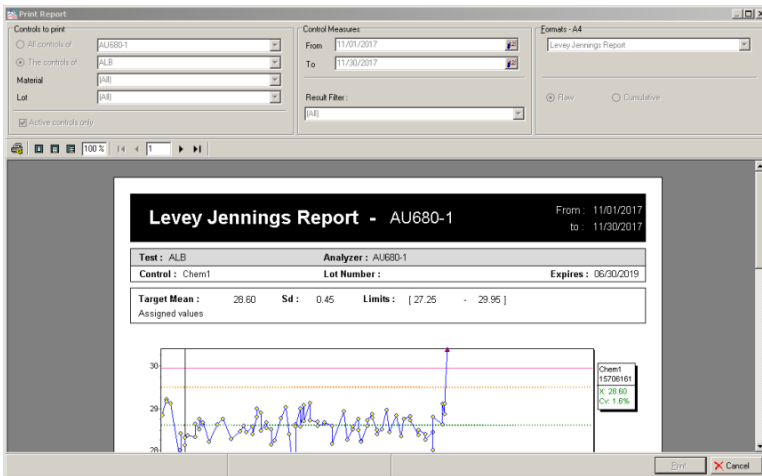


2. Select the appropriate print options under the **Controls to print**, **Control Measures to print**, and **Formats** sections to further customize the report before printing.
3. Materials and specific reagent lots can also now be selected in order to reduce the number of results reported.
4. Users can now print the date range statistics in addition to the target and cumulative ones.
5. Results can be filtered to print all results, the ones in error, or none at all.
6. Click **Print** at the bottom of the screen to print the displayed report.

Print Monthly Report

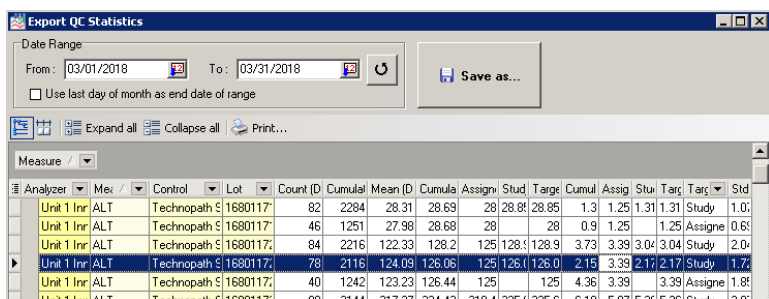
Reports can now be printed for the most recent full month by selecting **Tasks>Print Monthly QC Reports**.

The print form will open automatically with the dates set to the previous full calendar month. Select the required controls, materials, and lots to filter the data down to the required pages. Set the paper format in the printer dialogue (usually A4 or Letter format) so that the dialog box **Formats** will populate with the appropriate report options.



Export QC Statistics


QC statistics for a specified date range can now be exported to a .csv file, an .htm file, an .xml file, an Excel file, or a text file. Set the date range and click the **Refresh** button to update data displayed in the **Export QC Statistics** window. You can additionally use the down arrows at the top of each column to further filter the data displayed. These columns initially display all instances of the variables defined in the column headers. Specific instances of the variables in each column can be chosen to filter.



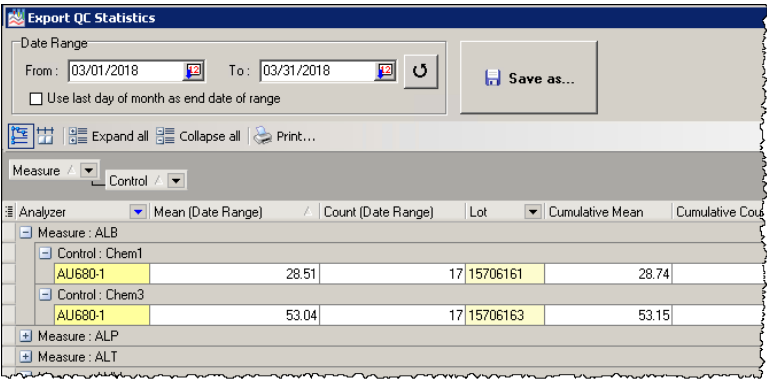
Grouping Bar

Reports and statistics can also be organized using the **Grouping Bar** functionality.

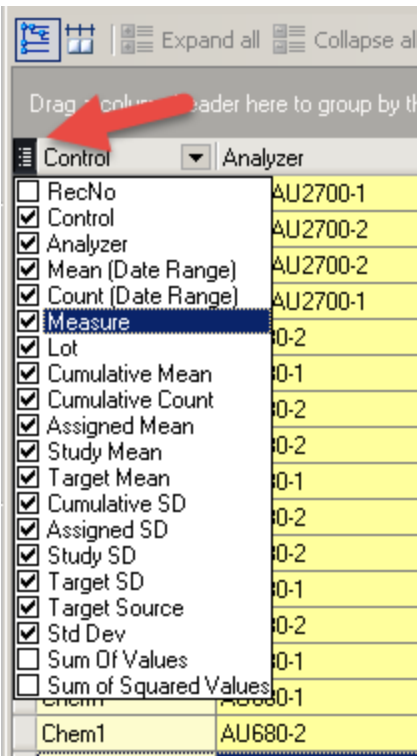


Click on the  icon to open the grouping bar space, and then drag and drop the relevant header onto the bar. Other headers can be dragged onto the bar and the groups will automatically re-arrange. A hierarchy tree will be formed and the statistics in the table will be re-arranged according to the defined structure. Individual rows of statistics arranged in the table can then be opened and closed and relevant data viewed side-by-side. All of the results will be included in the exported .csv, Excel or .txt file once **Save as** is clicked and a storage location defined. The grouping structure will be retained when the **Export QC Results** form is closed so that it can be used again. If filters or groups are applied then the filtered data or groupings will

appear in the .htm file, and .xml output files, and in the printed PDF/XPS file.



The choice of columns displayed on the table can be selected using the drop down menu that appears when the icon at the left of the header row in the table is clicked (see below). Use the check boxes that appear to select which columns and headers will be displayed.

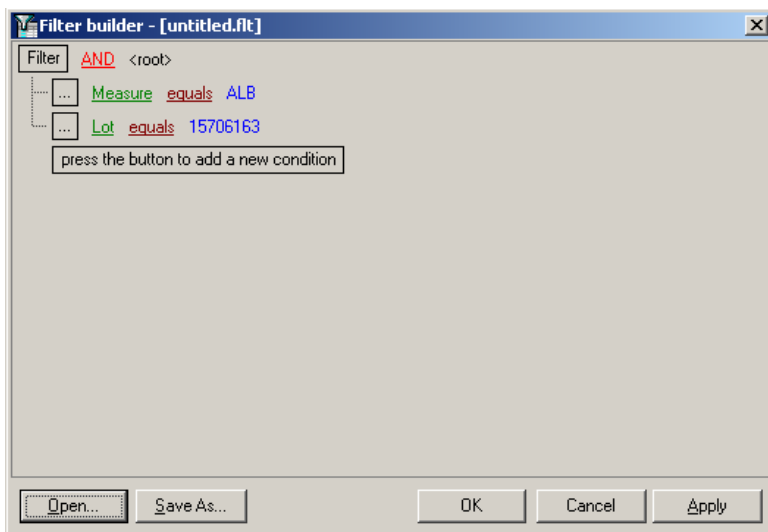


Grouping Bar

When a filter is applied by selecting specific instances of the variables at the top of each column, the filter logic is then shown at the bottom of the screen. The filter can be switched on or off by clicking the check box on this display bar. If more than one variable is filtered, a down arrow will appear that gives the option of switching between the individual filtered variables. Note the filter will not be saved when the form is closed.

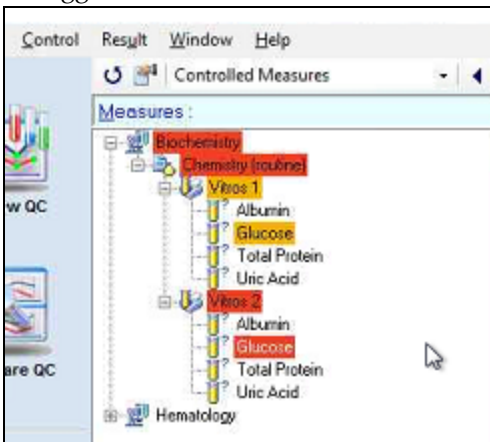


More complex filter building can be accomplished by clicking the **Customize** button at the right of the bar. This will open a window where detailed filter logic can be designed using Logical Operators, and values and limits can be defined for individual variables. Once the logic is defined it can be saved, and applied, and when the window is closed the full query will be displayed on the filter logic bar.



Westgard rules and multi-rules

LQC applies Westgard rules and multi-rules logic to QC data to decide whether an analytical run is in-control or out-of-control. If a run violates a Westgard rule or rules in LQC, then visual cues signal violations - red for errors and orange for warnings - in the LQC Review QC tree pane, beside the analyzer/measure in question. In the case of a warning and an error occurring at the same time, the red error flag will take priority over the orange warning on the tree. If any one control is flagged, the parent instrument for that control method is flagged too.



Note that values are flagged on the Levey Jennings charts using a different alert/review symbol/color system.

Warnings on the tree show in **ORANGE** for these rules:

- 1-2s • 10x • 12x • 7T

Errors on the tree show in **RED** for these rules:

- 1-2.5s • 1-3s • 1-3.5s • 2-2s • R-4s • 4-1s • 2of3-2s • 3-1s

NOTE: Once errors or warnings are reviewed and accepted or rejected in the Levey Jennings chart they will no longer be color flagged on the measures/analyzers tree. Note also that historic data will not trigger a colored flag. Only new results which violated a rule under the upgraded system will trigger a colored flag.

Examples of rule failure for each group of rules

NOTE: Colors are only flagged while control lots are valid. If the control lot goes out of date the flat will no longer be shown.

To configure the Westgard rules for analyzers and measures see the following pages:

[Configuring Analyzers](#)

[Configuring Measures](#)

Examples of rule failure for each group of rules

Depending on the level of error detection and the level of false rejections, applying a combination of the Westgard rules creates a powerful and effective tool for evaluating the quality of the control measurements in your laboratory.

Westgard Rule Selection

During setup of analytical processes, LQC presents for selection a number of rules. If more than one rule is selected, rules are applied one after the other and the run is considered out of control as soon as one rule fails.

Standard protocol 1-3S/2of3-2S/R-4S/3-1S/12x is usually used for three-level controls, while the protocol 1-3S/2-2S/R-4S/4-1S/10x is usually used for one or two-level controls.

The Westgard rules trigger the occurrence of alarms, which can be selected to warn or prevent validation of the relevant control results. Results which are not rejected by the user are incorporated into the statistics and taken into account by further application of Westgard rules. Results which are rejected by the user are neither added to the statistics nor considered for Westgard rules, but appear on the various QC charts.

Westgard Rule Application

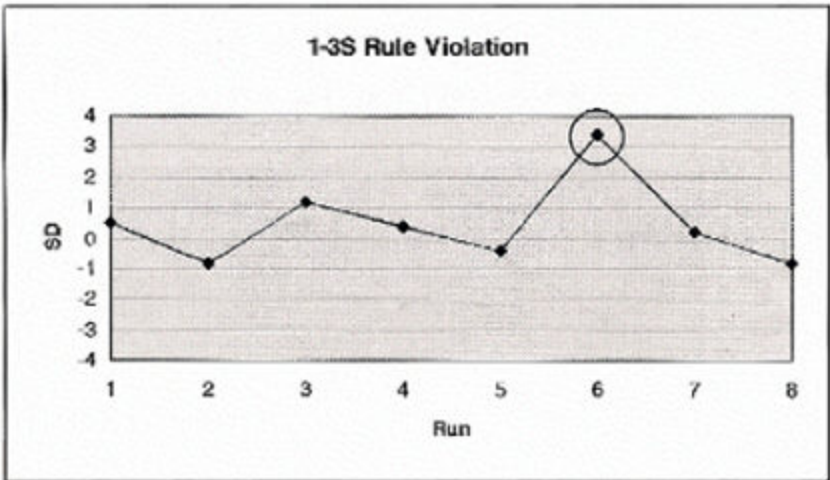
LQC applies the Westgard rules when receiving new control results. LQC reapplies Westgard rules on results after a control result is changed (for example, modified, commented, accepted, or rejected).

However, the Westgard rule is *not* reapplied on the control results received after the changed result(s), but before the new control results. To reapply Westgard rules to already received results, you must manually modify the result individually.

Group A: 1-2S, 1-2.5S, 1-3S, and 1-3.5S Rules

Group A rules are primarily sensitive to random error, but also respond to large systematic errors. LQC applies these rules within level only. The rules are broken when the data entered is outside of the mean + the appropriate standard deviation.

For example, when the 1-3S rule is applied, a data point will fail if it exceeds the +3SD or -3SD limits. In the example below, Run 6 has failed the 1-3S rule.



Group B: 2-2S and 2 of 3-2S Rules

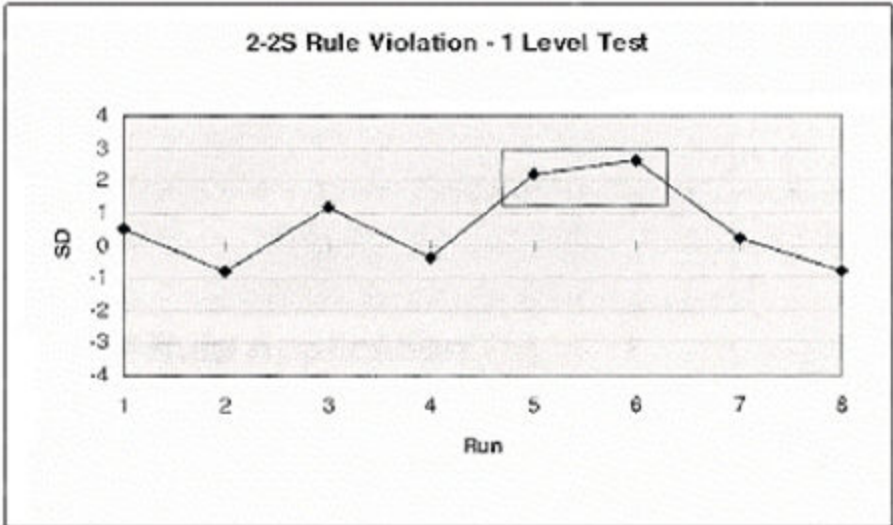
LQC uses the 2-2S rule in the standard protocol for one or two-control levels, and the 2 of 3-2S rule in the standard protocol for three-control levels.

The 2-2S Rule

The 2-2S rule is applied both within and across levels. This rule is sensitive to systematic errors.

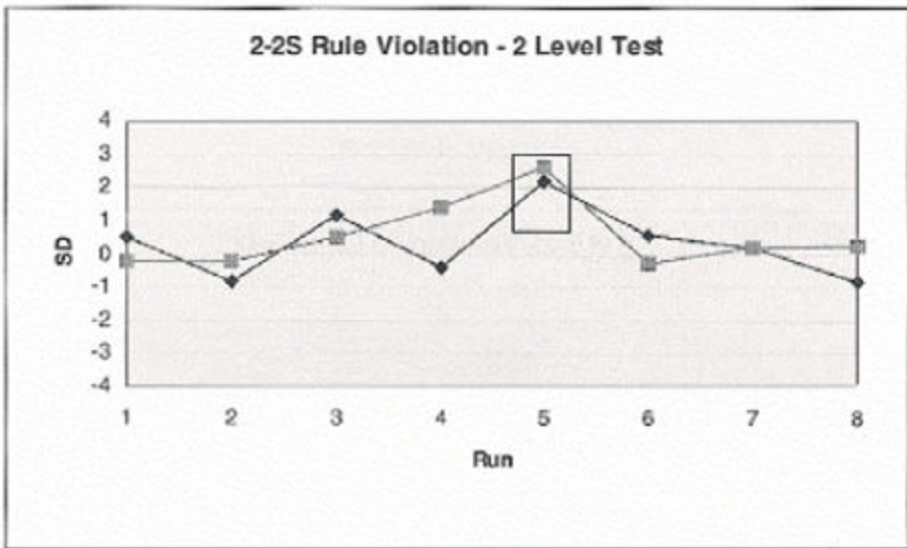
The 2-2S Rule

For a one-level test, or when only one level is entered for a two or three-level test, the rule is applied within level only. When the current data point and the previous in-control data point each exceed the same $+2SD$ limits or the same $-2SD$ limit, the current data point fails this rule. The following example illustrates this rule for a one-level test. Run 6 will be marked as a failure because Run 5 and Run 6 exceed the same $+2SD$ limits.



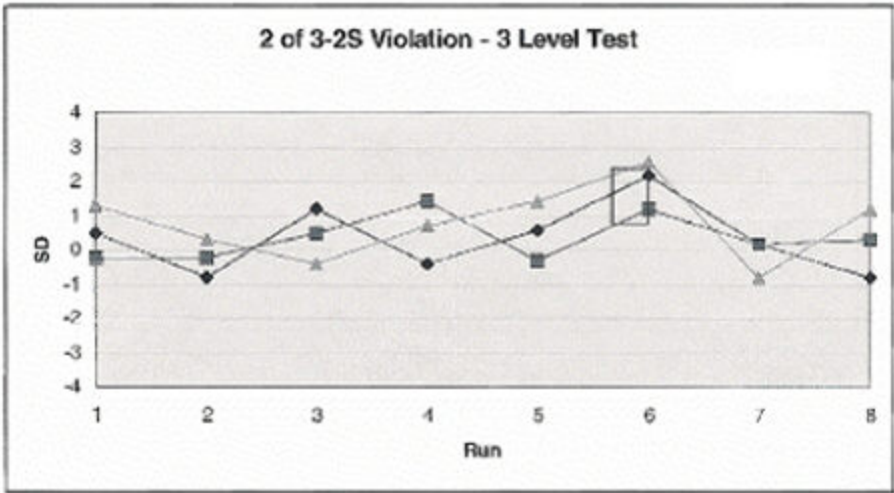
For a two-level test, or when only two levels are entered for a three-level test, the rule is applied both within and across levels. For within-level evaluation, LQC evaluates the data as discussed above for a one-level test.

For across-level evaluation, the run fails this rule when both points entered for the run each exceed their respective $+2SD$ limits or $-2SD$ limits. In the example below, Run 5 has failed the 2-2S rule because both of the points have exceeded their respective $+2SD$ limits.



The 2 of 3-2S Rule

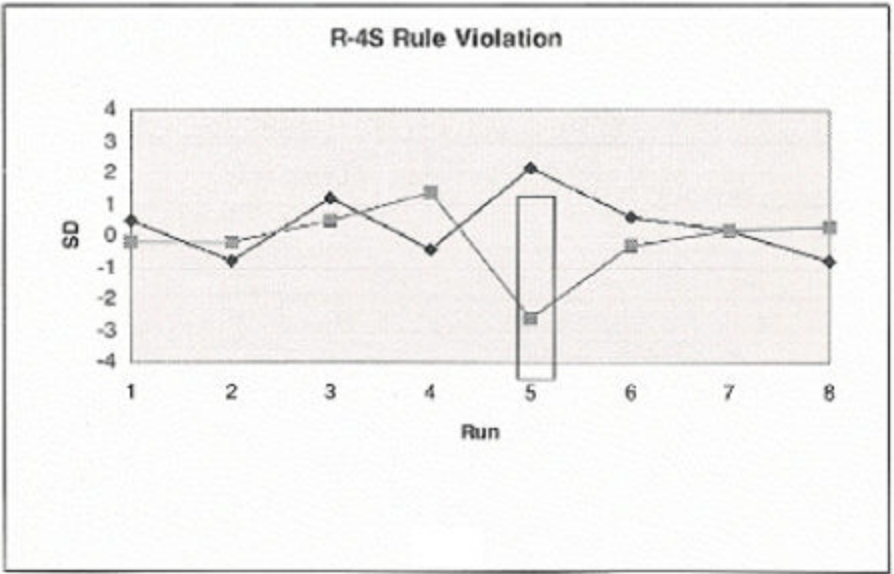
For a three-level test, Westgard multi-rule logic dictates that the 2-2S rule becomes the 2 of 3-2S rule. Similar to the 2-2S rule, the 2 of 3-2S rule is sensitive to systematic error. This rule is applied across levels only to a three-level test when all three levels are entered in the current run. If data is entered for one or two levels only, then the 2 of 3-2S rule acts like the 2-2S rule. The run fails this rule when 2 of the 3 points entered each exceed their respective +2SD limits or -2SD limits. For within-level evaluation on a three-level test, the 2-2S rule is used and the data is evaluated as discussed above for a one-level test. So in fact, for a three-level test, both the 2-2S and the 2 of 3-2S rules are used. In the illustration below, Run 6 is an example of a 2 of 3-2S rule failure because both of the points have exceeded their respective +2SD limits.



Group C: R-4S Rule

Sensitive to random error, the R-4S rule is often called the "range rule." The run is rejected when the range between two measurements exceeds 4 SDs when being evaluated against their respective evaluation means. This rule is applied across levels only, and will not be applied if only one data point is entered for a run.

The current run will fail the R-4S rule if the difference between any two points entered in the run exceeds 4 SD when being evaluated against their respective evaluation means. Run 5 in the example below illustrates a run that has failed the R-4S rule.



Group D: 4-1S and 3-1S Rules

The 4-1S rule is usually applied to a one or two-level test, while the 3-1S rule is used when you are using a three level control.

The 4-1S Rule

The 4-1S rule is sensitive to systematic error. For a one-level test, the 4-1S rule is applied within level only. The rule is broken when the current data point and all three of the previous in-control data points all exceed the same +1 SD limit or the same -1SD limit.

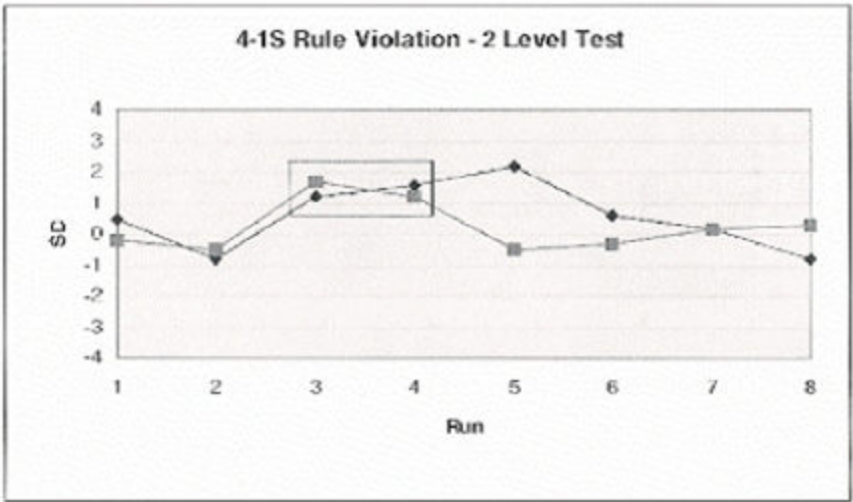
In the example below, Run 7 violates the 4-1S rule because it and all three of the previous data points exceed the same +1 SD limit.

The 4-1S Rule



For a two-level test, the 4-1S rule is applied both within level, as described above, and across levels. By applying this rule across levels, you reduce the number of runs necessary to accumulate four measurements. LQC will apply this rule only if data was entered for both levels in the current run and in the previous in-control run. The current run will fail if all four data points exceed their respective +1 SD limits or their -1 SD limits.

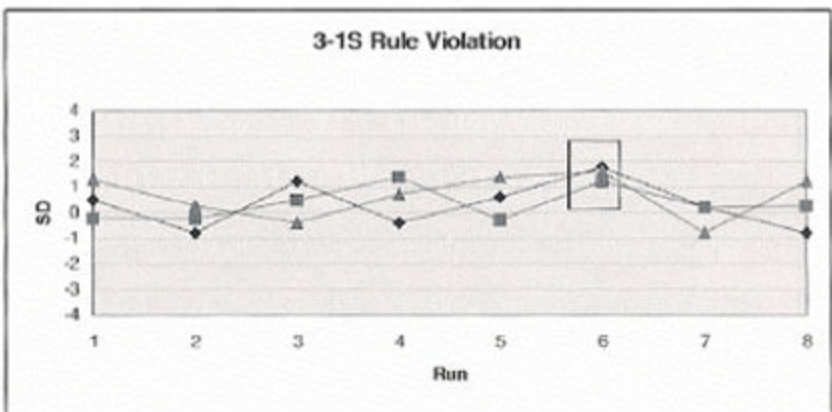
In the illustration below, Run 4 will fail the 4-1S rule because both of the data points in the run, along with both of the data points from the previous run, have all exceeded their respective +1 SD limits.



The 3-1S Rule

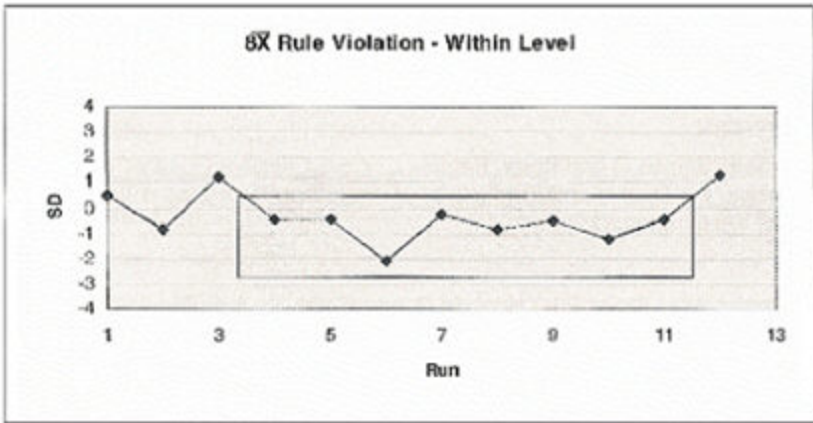
LQC applies the 3-1S rule only to a test utilizing three levels of control. This rule is also sensitive to systematic error. This rule is applied across levels only if data is entered for all three levels in the current run. The 3-1S rule is not applied within levels. The current run will fail if data for all three levels exceed their respective +1 SD limits or their -1 SD limits.

In the example below, Run 6 fails the 3-1S rule because all three of the data points in the run have exceeded their respective +1 SD limits.

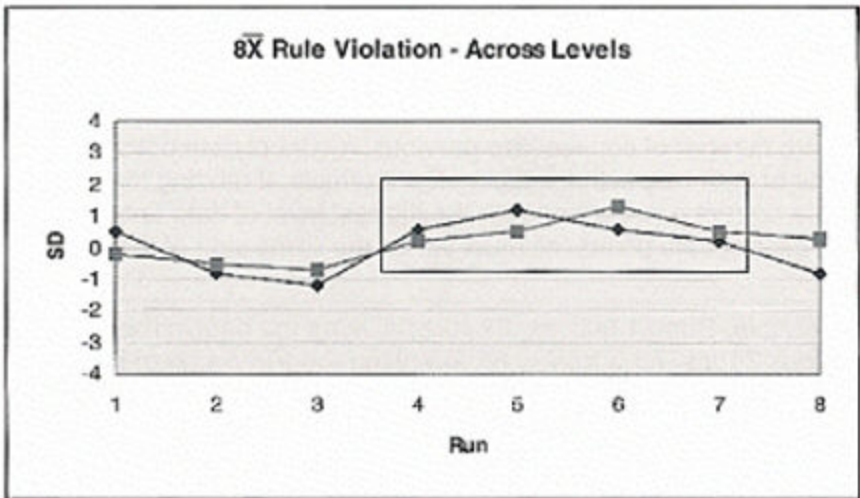


Group E: The Mean Rules

LQC uses, by default, the 10X rule for a one or two-level test and the 12X rules for a three-level test. The X rules are sensitive to systematic error. These rules are applied both within and across control levels. Any of the above rules will fail when the data in the current run, and the appropriate number of consecutive previous in-control data points, all fall on the same side of their respective means. For example, if utilizing the 8X rule, the data in the current run, starting with the highest level of data entered, and the last nine in-control data points, all must fall on the same side of their respective means. In this example, Run 11 fails the 8X rule because the data in this run, along with the previous 7 runs (for a total of 8), are all on the same side of the mean.



In the example below, Run 7 fails the 8X rule because the data in the current run along with the last 6 data points from previous runs (for a total of 8) are all on the same side of the mean.



References

James O. Westgard, Elsa Quam, Trish Barry. *Basic QC Practices, Training in Statistical Quality Control for Healthcare Laboratories*. Madison: Westgard Quality Corporation, 1998.

I. Cavill. *Quality Control*. Edinburgh: Churchill Livingstone, 1982.

Aljoscha Steffen Neubauer. "The EWMA control chart: properties and comparison with other quality-control procedures by computer simulation". *Clinical Chemistry* Vol. 43 No. 4 (1997): 594-601.

James O. Westgard, Patricia L. Barry, Marian R. Hunt. "A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry". *Clinical Chemistry*, Vol. 27 No. 3 (1981): 493-501.

Montgomery DC. *Introduction to statistical quality control*, 4th edition. New York: John Wiley and Sons, 2001.

T. P. Whitehead. *Quality Control in Clinical Chemistry*. New York: John Wiley & Sons, 1977.

Chapter 3

LQC Configuration Guide

Configure QC Overview

The Configure QC module enables you to configure the Laboratory Quality Control software (LQC) to meet the QC requirements of your laboratory.

From Configure QC you can:

- Define analyzers, controls, measures.
- Define organizations, users, workstations.
- Define units.

The Laboratory Quality Control Configuration Module is part of the Laboratory Quality Control suite. The purpose of the *Configuration Guide* is to help you understand the basic principles governing the way parameters are defined within Laboratory Quality Control.

Information is divided into two sections:

- [Configuration Module terminology, interface, and main functions.](#)
- [An overview of the most common configuration steps for customizing LQC to your laboratory's requirements.](#)

NOTE: This manual is not intended as an exhaustive description of every possible screen and function that you may encounter while using Laboratory Quality Control configuration tools. Additional information may also be found in the other manuals and procedures accompanying the Laboratory Quality Control suite.

Prerequisites

Instrument Manager, minimum version 8.15, is *required* to install, configure, and operate the LQC software.

Restrictions

Because configuring Laboratory Quality Control via the Configure QC module can impact the way your system and laboratory operate, it is best to restrict access to users with IT knowledge and an understanding of your laboratory's procedures and workflow.

Connecting IM to LQC

Follow the steps below to define the Instrument Manager Connections that you want to send data to LQC.

NOTE: LQC must be listed as your Quality Control provider in your Instrument Manager license to ensure IM can send data to LQC.

1. Start Instrument Manager (IM).
2. Using **Configuration > Load Drivers**, load the Data Innovations LLC Laboratory Quality Control driver.
3. From the **Configuration** menu, open the **Configuration Editor**.
4. Create a configuration for LQC.
5. Click **Driver Properties** to define connection, instrument ID, and Instrument Alias.

NOTE: The Instrument Alias defined in the driver configuration must match the QC Client Alias assigned in Configure LQC.

NOTE: Instrument Manager first evaluates on the Connection Name/Instrument ID combination defined in the driver to determine the Instrument Alias for the connection. If the Instrument ID field is blank, only the Connection Name is used to determine the Instrument Alias.

Data Innovations LLC Laboratory Quality Control Configuration

Alias Configuration		
Connection Name	Instrument ID	Instrument Alias
Analyzer	12321	Analyzer

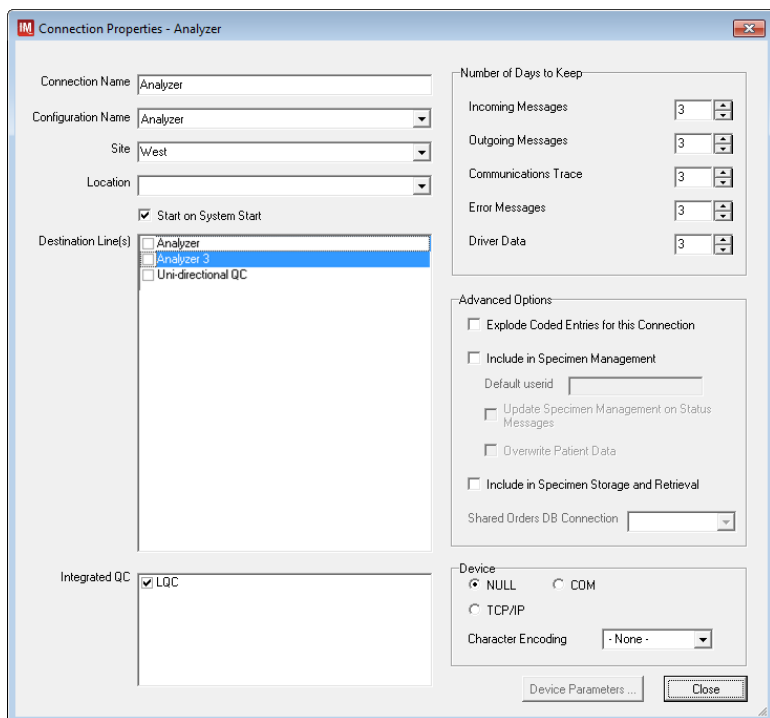
QC Type

☒ Uni-Directional ☐ Integrated

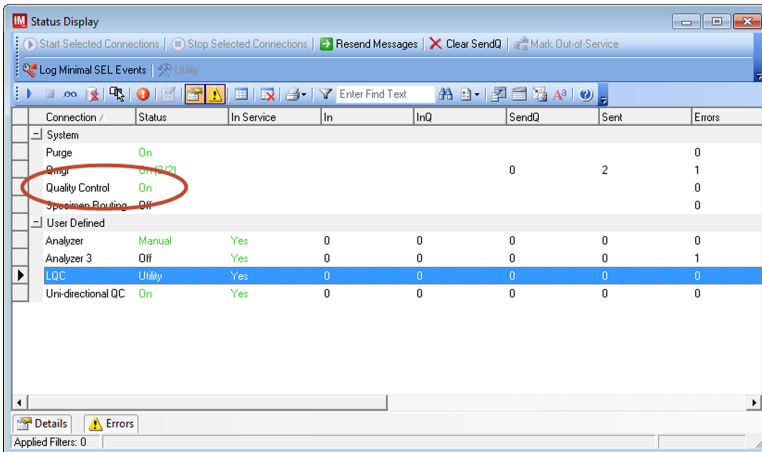
Close

NOTE: QC Type is set as Integrated and cannot be changed to uni-directional. Integrated QC does not require purchased connections. Integrated QC does need to be licensed as part of your Instrument Manager licensing.

6. Click **Close**.
7. Click **Yes** when prompted to save the configuration.
8. Open **Connection Assignment** from Instrument Manager's Configuration menu.
9. Create a connection for the LQC configuration.
10. Uncheck the **Start on System Start** check box for the LQC connection.
11. Click **Close** on the Connection Properties screen and save your changes.
12. Open the Connection Properties screen for each analyzer connection configured to send data to LQC and ensure the LQC connection is checked as an Integrated QC destination line.



13. From IM's System menu, select **Status**.
14. Start your LQC connection using the Quality Control System connection.
15. Select the System Quality Control connection and click the **Start Selected Connections** button, or select the **System Quality Control** connection, right-click, and select **Start Selected Connections**.



NOTE: The System Quality Control Connection reflects the status of all integrated QC connections. You can stop and start all integrated QC connections from the Status Display screen.

NOTE: Your Integrated LQC connection will be listed with other user defined connections as a utility connection. QC connections listed as User Defined cannot be individually stopped or started.

In LQC

To define analyzers and your QC setup in LQC, refer to the instructions on configuring LQC.

Authentication in LQC

All LQC and **Configure LQC** users are authenticated using the username and password set up in Instrument Manager's User Security feature. Once you are configured as a user in Instrument Manager User Security, you will be able to log on to LQC and Configure QC using your Instrument Manager credentials.

By default, Instrument Manager's preconfigured administrative user (username: IM_ADMIN, no password) has system administrator rights to Configure QC.

- All other users created in Instrument Manager User Security will, by default, have ordinary user (Lab Technician) level access in Configure QC by default.
- Upon first installing LQC, the IM-ADMIN user will be the only user with system administrator Access.
- The IM_ADMIN user can assign system administrator rights to other IM users from Configure QC.

From **QC Management>Users**, you can create new and edit existing users.

NOTE: Users must log into Configure QC using the username and password defined in Instrument Manager User Security.

Basic Concepts

Parameters and Tables

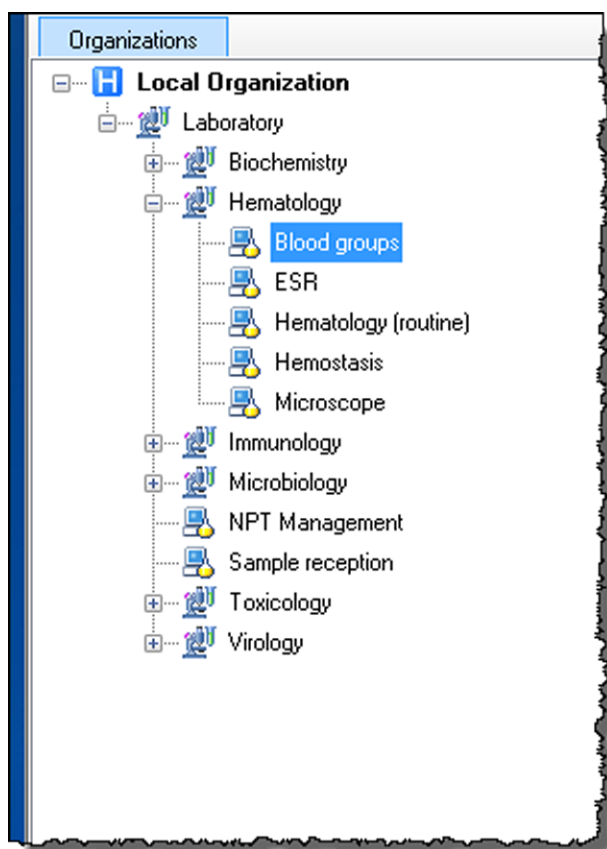
In LQC, a parameter is a set of properties used to define an element (or object) used in LQC. These elements can be operational components (e.g. a control definition) or interface components (e.g. workstations).

In the case of a control definition, the parameter defines all control properties: the supplier-provided name, test list, error conditions, and alarm properties.

Every parameter is part of a wider entity, called a parameter table.

Separate tables are available to define Analyzers, Measures, Controls, Organizations, Users, Workstations, and Units.

FIGURE 1: THE BLOOD GROUPS PARAMETER SELECTED IN THE ORGANIZATIONS TABLE



Properties, Attributes

Within LQC, each type of parameter is defined by a series of specific criteria (properties) and their respective values (attributes). The combination of these criteria and values identify each parameter uniquely. A property refers to a single characteristic of a parameter. For example, each parameter in the **Measures** table identifies, among other things, a short name, a standard name, etc.

Each of the above-mentioned properties can be assigned different values (attributes).

SODIUM PARAMETER: THE ATTRIBUTE FOR THE SHORT NAME PROPERTY IS NA

The screenshot displays the 'LQC Configuration - [QC Management > Measures]' window. On the left, a tree view shows the hierarchy of measures, with 'Sodium' selected under the 'Vitros' category. The main area on the right is divided into tabs: 'General', 'Notes', 'Properties', and 'Audit'. The 'General' tab is active, showing various configuration fields. The 'Names' section includes 'Keyboard Code', 'Short name' (set to 'NA'), 'Standard name' (set to 'Sodium'), and 'Long name'. The 'Handling' section shows 'Analyzer Type' set to 'Vitros' and 'Analyzer Code' set to 'NA', with a red warning message 'The Analyzer type may not' next to the code field. The 'Result' section includes 'Units' and 'Decimal places' (set to 2). The 'Usage' section has a checkbox 'This definition is in use in the lab' which is checked. On the right side of the window, there are buttons for 'OK', 'Save', 'Reload', 'Cancel', 'New', 'Clone', 'Wizard...', and 'Help'. The bottom right corner of the window shows the user 'Administrator'.

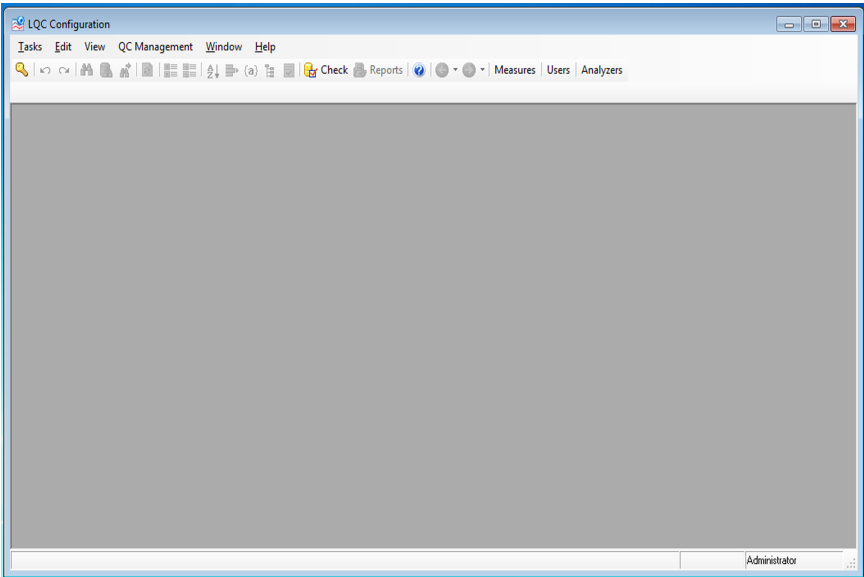
Log In and Log Out of LQC Configuration

Log into LQC Configuration Tools

To launch LQC Configuration Tools:

1. In the Windows Start menu, select **All Programs**.
2. From All Programs, open the **Data Innovations** folder, then the **Quality Control** folder.
3. Click **Configure QC**.
4. In the **Log-in required** dialog box, enter the user name and password configured for you in Instrument Manager.
5. Click the **Connect** button.

The main LQC Configuration window opens.




Additional Menu Options Available

Error Log	Opens a text file record of any system errors related to LQC. This log is primarily used by Support for troubleshooting.
-----------	--

Exception Log	Opens a text file record of any exceptions logged in LQC. This log is primarily used by Support for troubleshooting.
Log-in	Log into LQC Configuration under a different user-name and password.
Online Documentation	Opens the online help in a browser.
Release Notes	Opens a copy of LQC release notes.

Switching Between Multiple User Accounts

If you have several user accounts with different access levels and would like to switch from one to the other, follow the steps detailed below:

1. Double-click the gold key icon  in the Windows System Tray or select **New Session** from the **Tasks** menu.
2. In the **Log-in required** dialog box, enter the username and password for another account and click the **Connect** button.

The Configuration Module is now running and the main window is displayed.

Quitting LQC Configuration Tools


The Laboratory Quality Control server normally operates 24 hours a day. Generally, the only thing you have to do at the end of your working session is to shut down the Configuration module and log off as system administrator .

For security reasons, never forget to log off as system administrator. This will prevent other users from accessing LQC Configuration and implementing configuration changes under your name.

- In the Configuration Module main window, select **Tasks > Exit** or click the [close] icon on the upper right corner of the LQC Configuration window.

Additional Menu Options Available

To make sure that no one can log back on with your login inform-

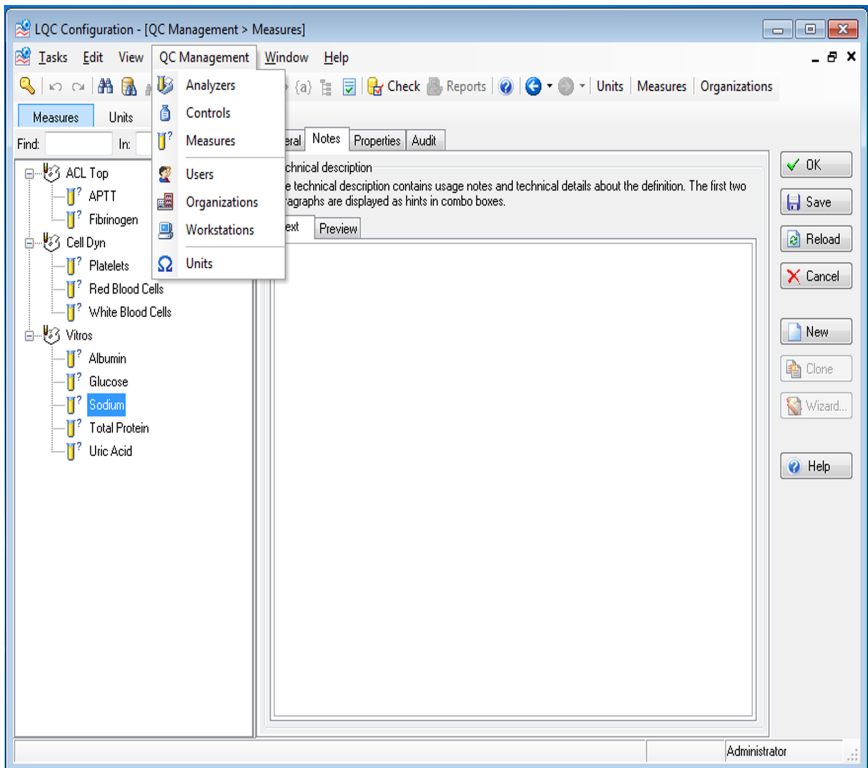
ation, double-click the gold key icon  in the Windows System Tray and make sure you leave the login dialog box empty by removing your username. At this point, any person wishing to access one of the modules from the LQC suite on your PC will be required to enter his/her username and password in the dialog box. Certain tasks (such as QC integration from Instrument Manager) will continue to run in the background even if no user is connected.

Opening a Parameter Table

Parameter tables are organized in generic categories corresponding to specific menus in the main screen.

To access a particular table, you need to select the appropriate option in the menu bar:

In the main window menu bar select the **QC Management** menu, then select the menu option corresponding to the desired table.



The selected table is displayed. The parameters belonging to that table are listed in the left panel.

Table Layout

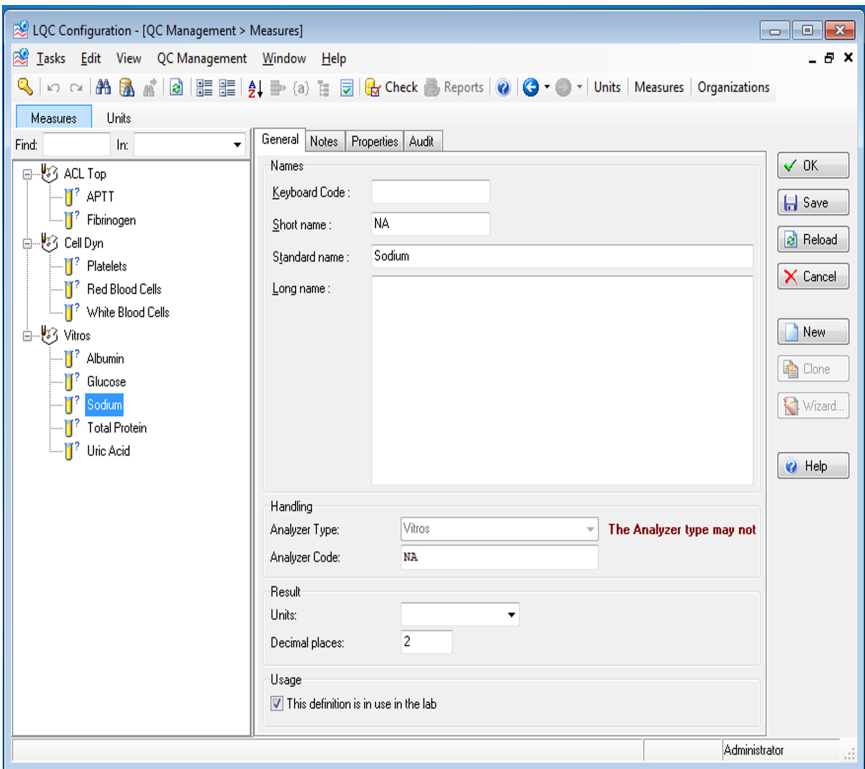
Information in a table is organized in two panels: one highlighting the active parameter, the other allowing you to view or edit the

Table Layout

parameter's properties.

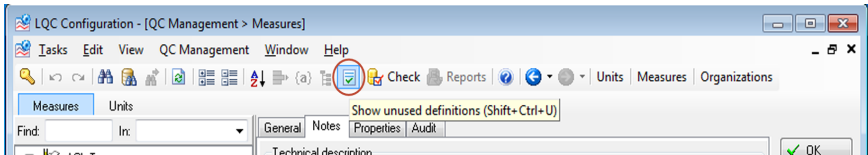
- The title bar displays the name and path to access the selected table appearing between square brackets
- The left panel provides an overview of all parameters in the table. Parameters may be listed hierarchically or in a flat structure, depending on the display mode that you have selected. See [Choosing a Display Mode](#) for further details on available display modes.
- The right panel is a tabbed card containing the various properties provided for the parameter selected in the left panel.
- The button-area on the right-hand side displays all commands available for the selected item and allows you to perform such common functions as parameter creation, modification, and consultation within the active table.

TYPICAL TABLE LAYOUT IN LABORATORY QUALITY CONTROL CONFIGURATION TOOLS



The left panel does not always display the full list of parameters defined in the active table. With the **Show unused definitions** button you can restrict the list to active parameters only or expand it to all parameters defined in the system. Depending on the option that you specify, inactive parameters may be invisible when you open a table. Some of the screens also allow for a text-based filter, where only the definitions containing a given text in their name are shown.

SHOW UNUSED DEFINITION



Common Parameter Tabs

Most tables have vastly different tab structures, but there are a few tabs that are common to many different tables. This paragraph is a brief introduction to these tabs.

General Tab

The General tab contains primary identification information about the active parameter, including its label, status, and specific position in the corresponding table (if the table is hierarchical).

The only required field here is the Standard Name that is used to indicate the name of the parameter in the system.

If provided, the Short Name is used for display in the LQC software.

If the Short Name attribute is left blank, the Standard Name is used for display in LQC. For parameters with particularly long Standard Names, entering a short name may have a positive impact on the display of results in LQC.

- Standard name: The complete parameter name, as it will be displayed in all long fields of the application. This name is used everywhere in the laboratory (mandatory). Maximum 32 characters.
- Short name: One or more characters used to identify the parameter in short fields. Among others this name is displayed in measures. Maximum 8 characters.
- Long name: A longer or more detailed description used for communications with people outside the organization/laboratory and displayed on reports. Maximum 256 characters.
- In Use or This definition is in use in the lab: if the box is checked it means that the parameter is active.

Notes Tab

This tab contains a text box to add notes related to the parameter.

Properties Tab

The Properties tab lists all properties available for the selected parameter.

NOTE: The information in the Properties tab relates to the internal status of the LQC software and is used primarily for troubleshooting, not for configuration.

Properties in the tab are ordered alphabetically and per system category. The list displays the name of the properties and attributes (e.g., name and keyboard code) that you have defined, as well as a quantity of system data and system objects used mainly for programming purposes.

Audit Tab

The Audit tab contains audit and history information about the parameter. This information is updated automatically by the system and indicates the date of creation or last modification of a parameter, as well as the name of the person who performed the action.

Choosing a Display Mode

Several display modes are available in Laboratory Quality Control Configuration, enabling you to easily manage and access data.

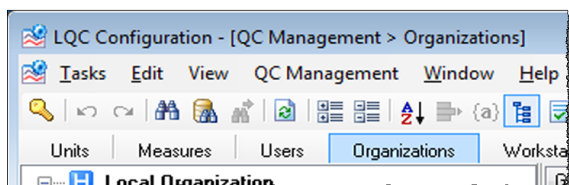
Typically, most tables in Laboratory Quality Control Configuration are hierarchical, which means that parameters are linked by parent-child relationships. In other words, certain parameters are comprised of sub-groups within a main table. A user, for example, usually belongs to a specific analysis department and the analysis department is itself part of a larger unit within the laboratory. Each parameter will then represent a different level within the table structure (in this case, the

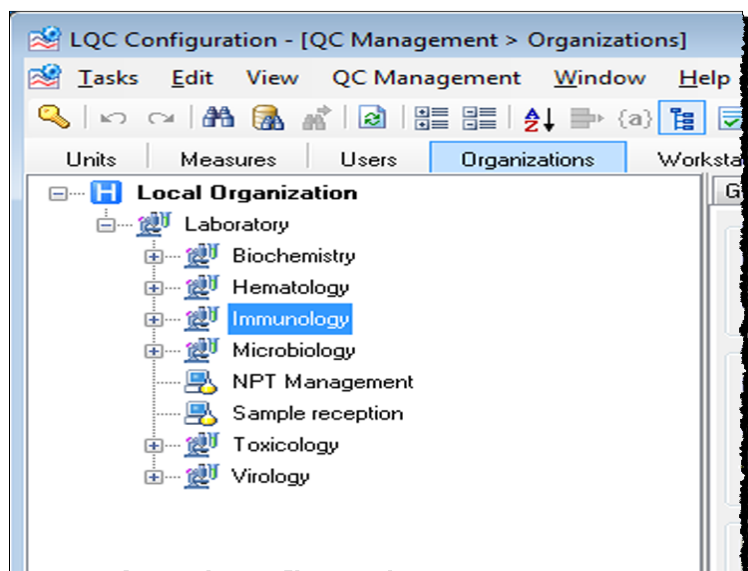
Organizations table).

You can choose one of two views when you open a table: the *Hierarchical View*, where all parent-child relationships are displayed in a tree structure, and the *Flat View*, where all parameters are displayed alphabetically on a single level.

The **Hierarchical** button in the toolbar allows you to toggle between hierarchical and flat views. You are free to select the display mode that best suits your needs when opening a table:

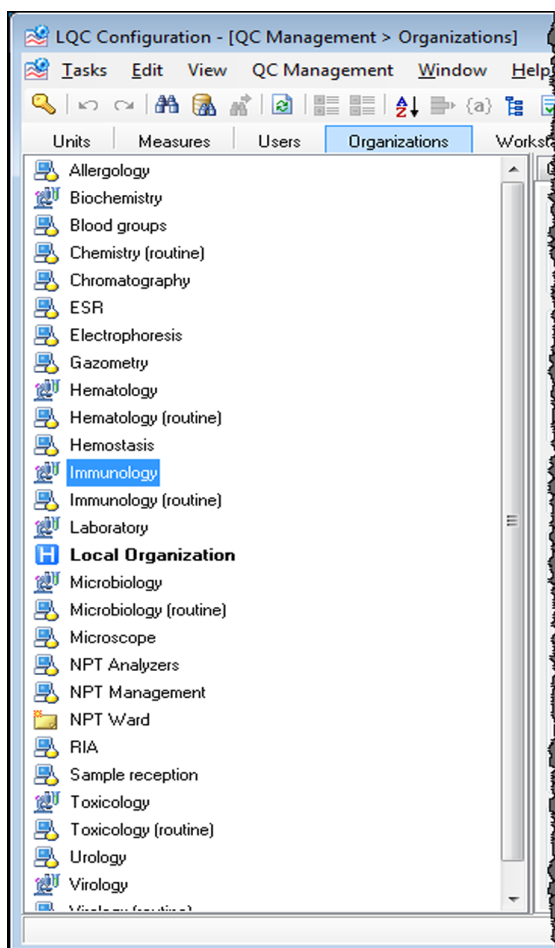
Hierarchical View





Flat View

All parameters are displayed alphabetically on a single level as shown on the image below.




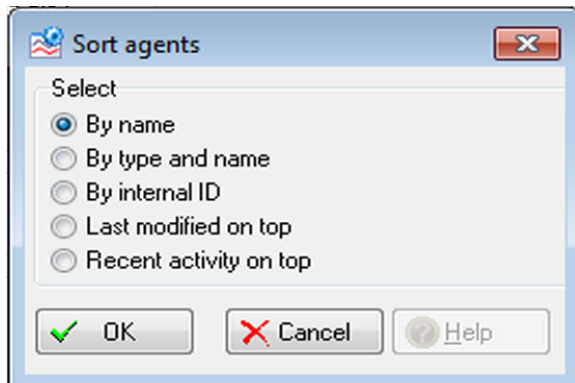
You can specify which display mode must be used as default each time a table is opened in the Configuration module:

- Select **View** and check the **Hierarchical** option to work in hierarchical view mode;
- Uncheck this option to return to flat view mode.

Sorting Mode

Parameters can be sorted based on their Standard name or Short name as well as be displayed based on their last modification date.

1. To use that option click the  button:
2. Select the applicable option from the Sort order dialog box:



Parameters will now be displayed based on the selected sorting criterion.

Navigating within Configuration Tools

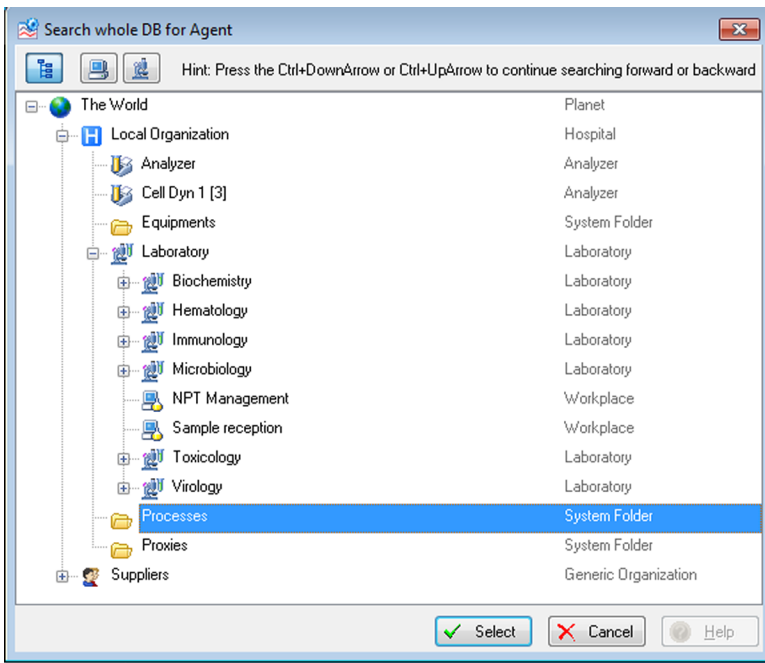
Navigating within a Table

There are multiple ways to navigate within a table.

Hover your mouse pointer over fields and buttons to display hints about their specific purpose.

In addition, combo boxes offer the auto-complete feature. When you type text in a field, the dropdown list opens with all available options. If the information already exists, the cursor will automatically select it and complete the field.

Note that for agent tables such as **Organizations** or **Workstations**, placing the cursor in the combo box and clicking the dropdown arrow will automatically open the applicable search window, as illustrated below:



To select a parameter

- Click on the desired parameter or on its name in the left panel of the active table. If you are in hierarchical view mode, first

locate the branch containing the parameter, and then click the [+] sign to open it. The attributes applying to the selected parameter appear in the tabbed screen on the right panel.

To view the content of another parameter in the same table

- Click directly on the appropriate item in the tree structure or use the up and down arrow keys on your keyboard.

Navigating between Tables

Navigation arrows

To navigate between all tables that were accessed during the active session click the left and right navigation buttons in the toolbar. This will enable you to access the previous or next table/parameter. A hint will indicate which table you are about to access:



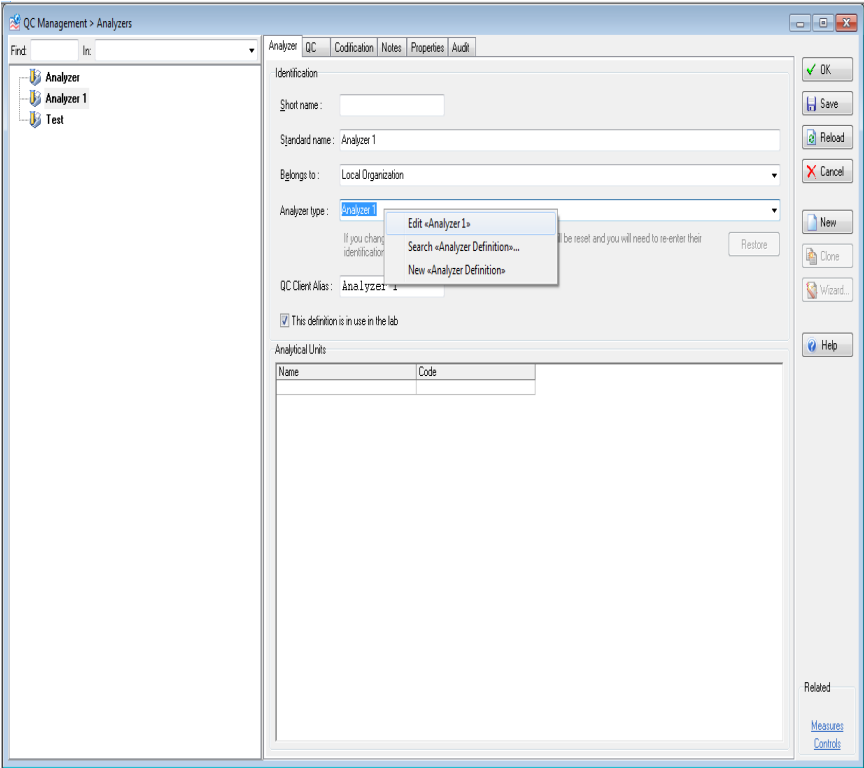
By clicking the down arrows on each side of the navigation buttons, you will access the list of all parameters that were previously opened in the active session.

Right-click navigation ('Edit' option)

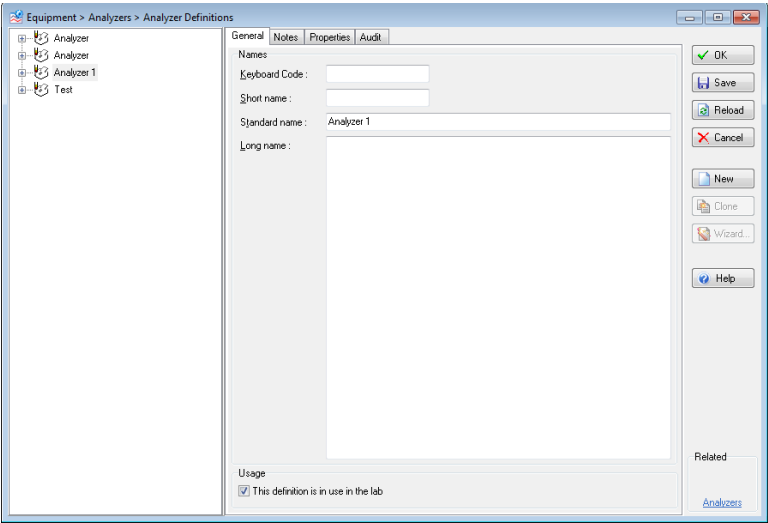
When you are on a parameter's page you can easily access another parameter referenced on that page by right-clicking the Edit '...' option from the attributes field. This takes you directly to the referenced parameter's page.

- On the parameter page, right-click in the field of the attribute that you wish to access. In our example, we are on the Analyzer parameter page for the Analyzer 1 and we would like to navigate to the Analyzer Definition for the Analyzer Type Analyzer 1.

Right-click navigation ('Edit' option)



The Analyzer 1 definition is displayed:



Finding Specific Information

Basic Search Option

The Find function helps you locate parameters very quickly, whatever their hierarchical level in the table.

Note that the basic search operation is performed based on the *Standard* name of the parameter; it excludes Short or Long names. To search parameters based on these properties, use the Advanced Search Option.

To perform a basic search:



From the toolbar, click on the **Find** button or use the standard **Ctrl+F** key combination.

In the **Find** dialog box, enter the name (or a fragment of the name) of the searched parameter and click **Find Next** to reach the parameter that most resembles the entered information.



The searched parameter is automatically selected in the left panel, while its properties and attributes appear on the different tabs in the right panel.

To find additional occurrences you must repeat the operation by clicking the **Find Next** button in the Find dialog box, pressing the F3 key,




or clicking the Find next button in the toolbar.

Advanced Search Option

The advanced search feature allows you to find data used in the database. Unlike the basic search option, advanced search can search data based on all names (short, standard, long), on one of these three names, and on additional search criteria such as Codes to host, Keyboard codes, etc.

This functionality is very useful when you do not know the Standard name. For instance if the searched parameter is NA (Short name for Sodium), it will not be found using the basic search option as the system will identify all parameters whose Standard names contain NA (for example, Anti-DNAseB).

To perform an advanced search:

1. Click the Find in database...  button from the toolbar menu or use the **Shift + Ctrl-F** key combination.
2. From the **Search whole DB** search table, type in the parameter in the **Search for** field. :

Search whole DB for QC Management > Organizations

Search for :

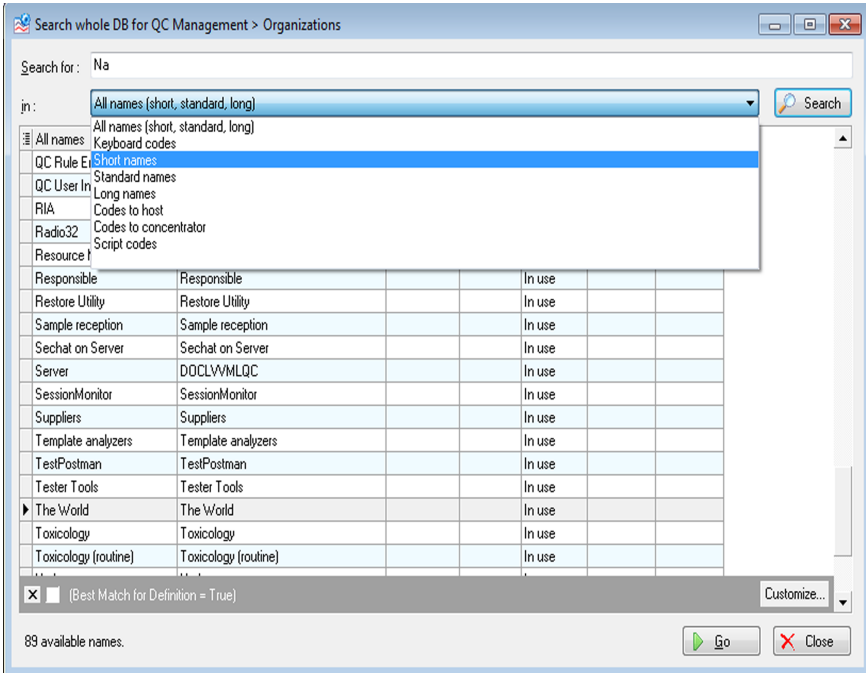
in : All names (short, standard, long) Search

All names	Name	Short	Filter	In use	Class	Best Mat
QC Rule Engine	QC Rule Engine			In use		
QC User Interface	QC User Interface			In use		
RIA	RIA			In use		
Radio32	Radio32			In use		
Resource Manager	Resource Manager			In use		
Responsible	Responsible			In use		
Restore Utility	Restore Utility			In use		
Sample reception	Sample reception			In use		
Sechat on Server	Sechat on Server			In use		
Server	DOCLV/MLQC			In use		
SessionMonitor	SessionMonitor			In use		
Suppliers	Suppliers			In use		
Template analyzers	Template analyzers			In use		
TestPostman	TestPostman			In use		
Tester Tools	Tester Tools			In use		
▶ The World	The World			In use		
Toxicology	Toxicology			In use		
Toxicology (routine)	Toxicology (routine)			In use		

☒ (Best Match for Definition = True) Customize...

89 available names. Go Close

3. Select the search criterion you wish to apply from the in drop-down menu and click **Search**.



4. Once the results are displayed, select the desired result and click the **Go** button to access the parameter page where you can view/edit properties and attributes. The searched for parameter will be highlighted in the parameters list.

Modifying Parameters

Depending on the privileges that you have been granted, Laboratory Quality Control may allow you to edit existing parameters. Every piece of information relating to a parameter can be modified, including its standard name, but also its detailed attributes, its location within a hierarchical structure, and its status (active/inactive). For traceability purposes, it is not possible to delete existing parameters. Outdated parameters that should no longer be displayed can be deactivated, usually by unchecking the **In Use** or **This definition is in use in the lab** checkbox, and choosing to hide inactive items. This operation can always be reverted by clicking the **Show unused** button.

Note that applied changes are automatically saved and thus taken into account by all Laboratory Quality Control applications when you click the **Save** button *or* when you navigate away from a table by selecting another one. Therefore, make sure that the changes you make are accurate before saving or navigating away from the parameter. In case of doubt or if you would like to discard the changes you've made, click **Cancel** in the right panel and confirm that you would like to either save changes, discard changes, or continue editing.

NOTE: Changes to certain critical parameters may result in a user seeing the same attribute referred to by both the old name and the new name within LQC. For this reason, it is best to wait until all stations are idle to edit parameters (see also [Frequently Asked Questions](#) section).

Changing a Parameter location

To change a parameter location:

Open the table containing the parameter that you wish to modify in hierarchical view and select the parameter name in the left panel.

Activating/Deactivating a Parameter

Replace the content of the **Belongs to** box on the main parameter tab with the name of the new parent.

Click **Save** in the right-panel button area to save the changes or **OK** to save the information and close the window.

If you changed the parent branch, click **Refresh** to update the table structure.

Activating/Deactivating a Parameter

To activate/deactivate a parameter:

Open the table containing the parameter that you wish to modify and select the parameter's name in the left panel.

Select/deselect the **In use** or **This definition is in use in the lab** checkbox in the first tab.

Click **Save** in the right-panel area to save the changes or **OK** to save the information and close the window.

Renaming a Parameter

To rename a parameter:

Open the table containing the parameter that you wish to modify and select the parameter's name in the left panel.

Replace the content of the Standard attribute.

Click **Save** in the right-panel area to save the changes or **OK** to save the information and close the window.

Names are not identifying elements for a definition. Renaming a definition can therefore be performed at any time. The new name will automatically be substituted everywhere in the module. Although nothing theoretically prevents you from giving the same name to two different definitions within the same table, you should avoid doing so.

Editing a specific attribute of a Parameter

To edit a specific attribute of a parameter:

Open the table containing the parameter that you wish to modify and select the parameter name in the left panel.

Review the different tabs and apply the desired modifications directly where appropriate.

Click **Save** in the right-panel area to save the changes or **OK** to save the information and close the window.

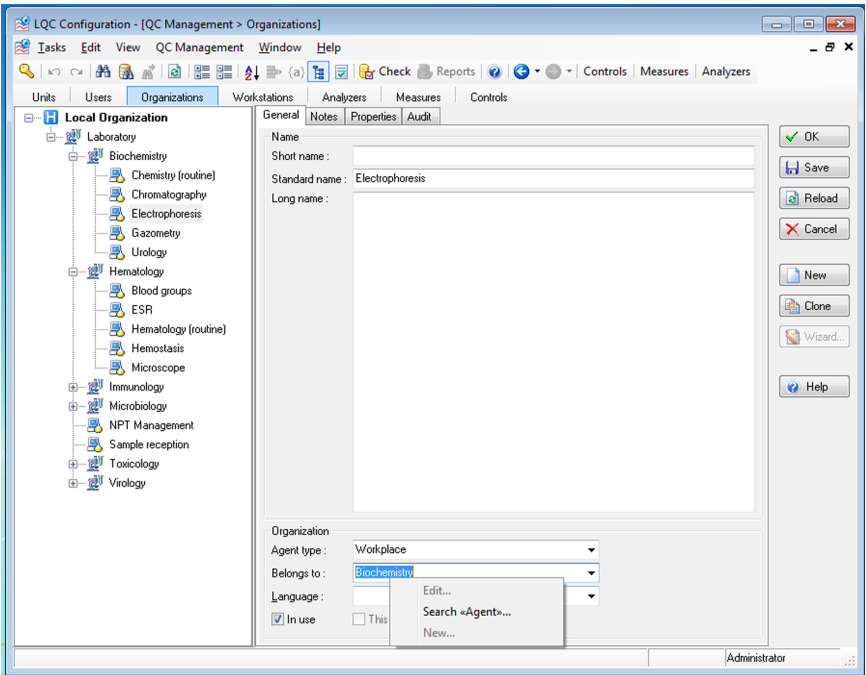
Right-Click 'Search' Option

The right-click search feature allows you to replace a property attribute directly from a parameter page by searching the entire database for a new entry.

Editing a specific attribute of a Parameter

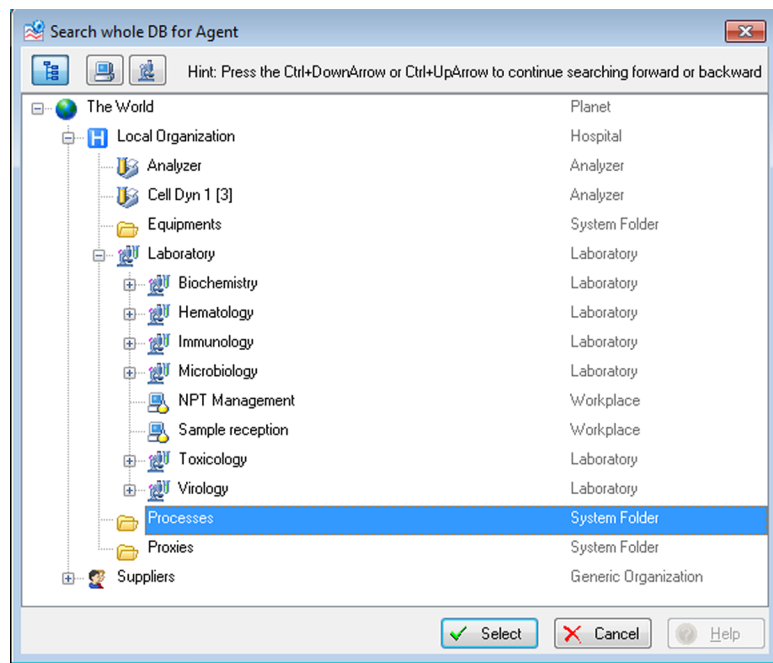
Right-click in the applicable field. Select the **Search** option from the combo box displayed on your screen:

MODIFYING A PARAMETER



You will access a window that will allow you to search the entire database for a possible entry for that field.

SEARCH WHOLE DB FOR AGENT (HIERARCHICAL AGENT)



Saving Parameters

Search whole DB for Agent (dropdown)

Name
Department
Generic Organization
Hospital
Laboratory
Service
Workplace

Once you have selected an entry, click the **Select** button. The initial field attribute will automatically be replaced by the selected value.

Saving Parameters

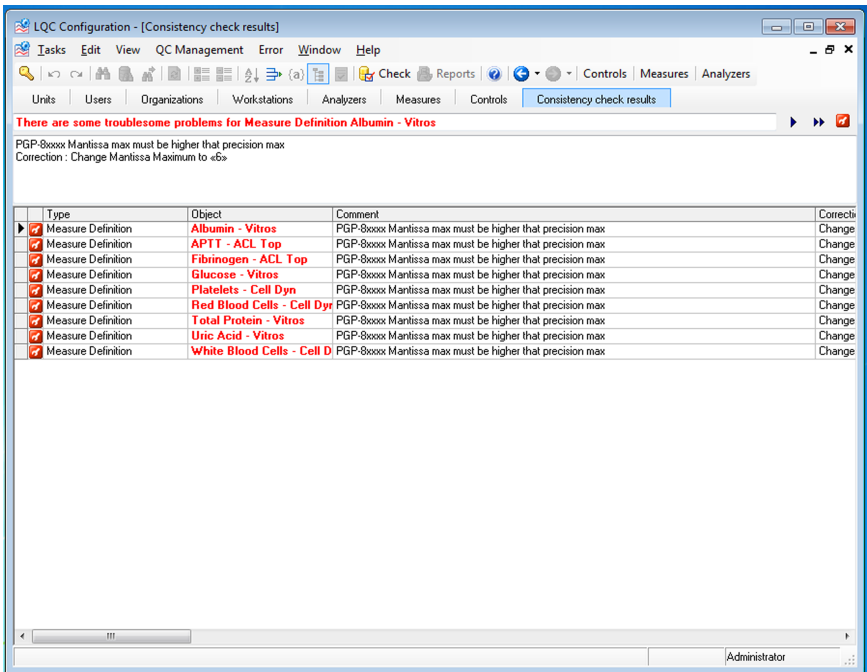
During navigation, changes are automatically saved and thus taken into account by all programs/modules once you click the **Save** button or when you navigate away from a table/parameter page by selecting another one.

Therefore, make sure that the changes you make are accurate before you navigate away from the parameter page. In case of doubt or if you would like to discard the changes you've made, click the **Cancel** button in the right-panel area and confirm that you would like to either save changes, discard changes, or continue editing.

When you have edited one or several parameters within a table, always check that the entered information is consistent. Laboratory Quality Control Configuration contains an automatic validation/correction option to check that all mandatory information has

been completed and is logically correct. This feature is called **Check Consistency**.


If you have entered data that Laboratory Quality Control does not recognize or considers inconsistent, and you click **OK**, the Consistency Check Warning window will automatically be displayed. You can either choose to correct the value or confirm your choice by clicking the **Save** button.



Note that once you have confirmed your choice, changes will be applied even if they are inconsistent.

You can also perform a consistency check after you have saved your changes or at any given time by clicking **Tasks > Check Consistency** in the main menu bar.

From the Consistency Check Window, select the applicable error type

and click  to correct the error as defined in the Correction column.

See [Checking Parameter Consistency](#)


Parameter Input

Various methods for entering data into a parameter are available within LQC Configuration . The input method depends on the type of attributes that are entered for parameter properties. Certain attributes are entered on the keyboard, others can only be selected from pre-defined lists, whereas others may require a selection list.

Each type of input area on a parameter card corresponds a different input method. This section deals with the various methods for data entry.

Entering Information in Text Fields

Text fields are used to enter single or multiple alphanumeric values using the keyboard. A large majority of input boxes are of this type.

Text fields are sometimes followed by an input-facilitating button  for multiple selections based on standard coded values.

- The hyphen is used in multiple selection fields to specify a range of values.
- The comma is used to separate individual values or ranges.

TEXT FIELDS

Analyzer	QC	Codification	Notes	Properties	Audit
----------	----	--------------	-------	------------	-------

Identification

Short name :

Standard name :

Belongs to :

Analyzer type :

If you change the analyzer type, the list of performed measures will be reset and you will need to re-enter their identification codes in the [Codification] tab.

QC Client Alias :

☒ This definition is in use in the lab

Restore

Using Selection Lists

To ensure consistency in the type of information included in a table, certain properties accept only certain predefined values. These may be values (parameters) that you have defined in a table or these may be standard values provided by the system. In either case, selection lists are available in the form of standard selection boxes or as contextual lists that pop up when the mouse hovers over a hot area.

To complete a selection box, select the appropriate value (parameter) by browsing through the list, or type the corresponding keyboard code (+ Enter) directly, if such a code is available for the value that you need.

Using Selection Panels

SELECTING A VALUE FROM A SELECTION LIST

Organization

Agent type: Workplace

Belongs to: Analytical Unit
Analyzer
Database
Department
Equipment

Works for: Genetic Organization
Hospital
Laboratory
Person
Planet
Process
QC Client
QC Importer
Service
Workplace
Workstation

☒ In use

Using Selection Panels

Selection panels are available when a property requires values to be selected from a list of possibilities. A selection panel is comprised of two sections.

- The left section lists the different possibilities;
- The right section contains the values that you have selected from the left.
- Two buttons in the middle are used to move items from one section to the other.

Selecting multiple items and moving a whole group of items to the right is possible using standard Windows manipulation .

SELECTION PANEL

General Control Notes Properties Audit

Control

The control material is designed by : (This property is not used in LQC)

to be similar to : (This property is not used in LQC)

and has the following stable properties :

Unknown stability

- Analyzer - Potassium
- Analyzer - Sodium
- Analyzer - Sodium
- Analyzer 1 - Potassium
- Analyzer 1 - Sodium
- Test - Potassium
- Test - Test

Stable properties

- Test - Glucose

Add...

Completing Grids

Grids provide tables of values to enter attributes for properties of a certain type. Values are entered on the last empty row down the grid. You click in the desired part of the row to enter a value. In some cases, a selection list will be available to let you select a pre-defined value. New empty lines can also be inserted between existing lines and existing lines can be deleted using the popup menu associated with the right mouse button.

Completing Grids

SAMPLE GRID WITH TABLE OF VALUES



To complete a grid, proceed as follows:

TABLE: MANIPULATING ITEMS IN A TABLE OF VALUES GRID

TO DO THIS	PROCEED AS FOLLOWS
Place a new value in the grid	Click at the desired location and enter the value or select it from the selection list.
Insert a new line in the grid	Click where you want the new line to be inserted, right-click, and select Insert from the right-click menu.
Remove a line from the grid	Click on the line you want to remove, right-click, and select Remove from the right-click menu.

Tasks Menu

Browse Change Log...

This feature allows users to consult a detailed history of all changes made to a parameter. This table provides the following information:

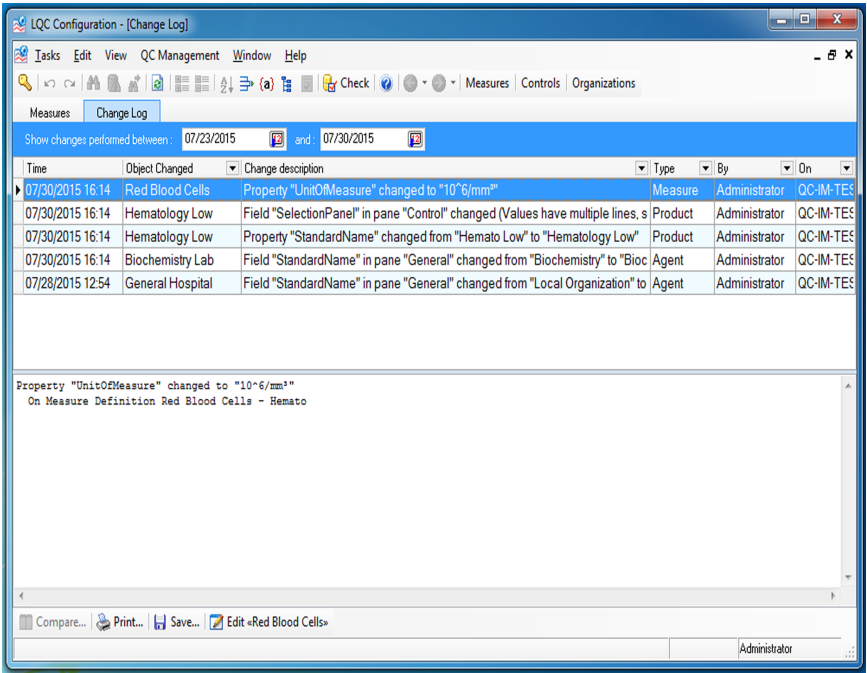
- The exact date and time when the change was performed.
- The name of the changed object.
- A brief description of the change.
- The name of the person who performed the change.
- Which station the change was implemented on.
- A more detailed view of the change in the lower panel.

Available options allow you to print the Change Log report, export the grid in various file formats, and access the parameter screens corresponding to the object you have selected in the list.

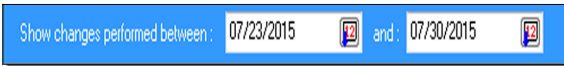
Access the change log from **Tasks>Browse Change Log...**

From the Change Log screen, you can

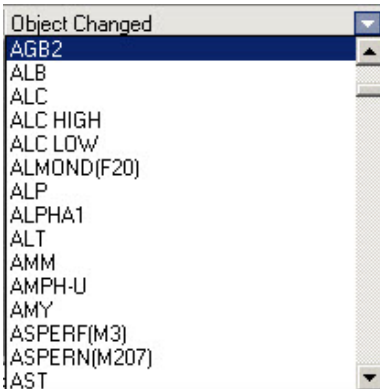
- View the Change Log. Select an item in the log to view its description in the lower panel.



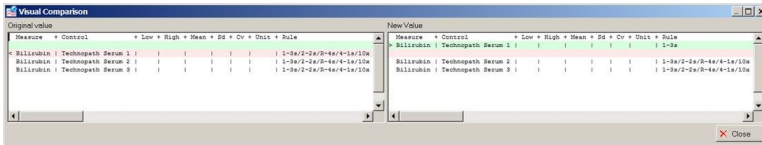
- If the list of changes is extensive, you can filter the list by specifying the period that you wish to view.



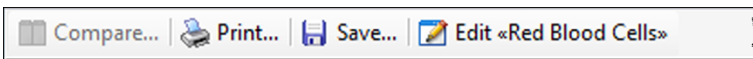
- Filter by the **Object**, **Change description**, **By** and **On** columns using the arrow located on the right of each column.



- In case you or another user made changes to a parameter, you can compare the original value with the new value. That feature is usually available (i.e. not grayed out) when you have edited some text. To access the visual comparison window, click the **Compare...** button at the bottom left of the window. The **Visual Comparison** window appears, highlighting the changes made.



- Print the Change Log report by clicking **Print** on the bottom left of the window. Next, select your printer and printing options and click **Print**.
- Export the grid by clicking **Save** at the bottom left of the window, specifying the location you wish to export the grid, and providing a file name.
- To open the configuration screen of any of the parameters listed in the Change Log table, select the desired parameter and click the **Edit** button at the bottom of the window. The name of the button indicates which table you are about to open.



Check Consistency

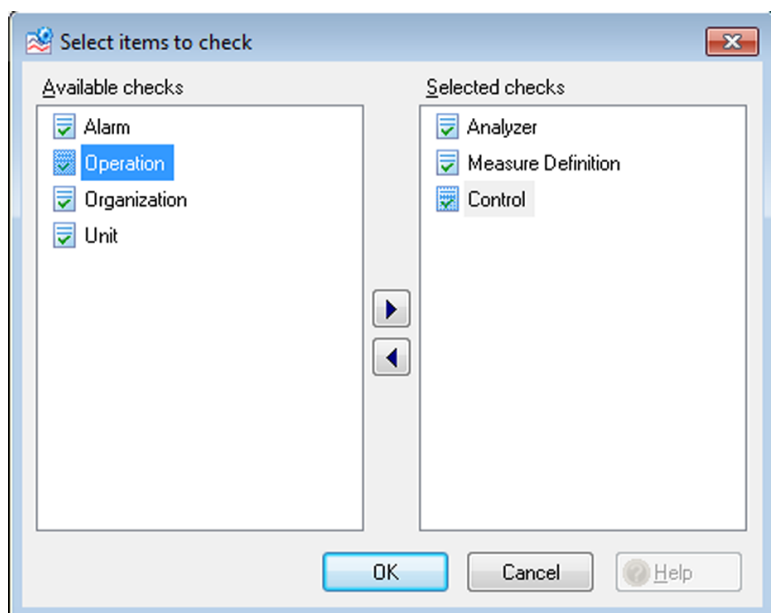
When you have edited one or several parameters within a table, you can perform a check to ensure that the entered information is consistent. LQC Configuration contains an automatic validation function that checks to ensure all mandatory information has been entered and is logically consistent. At the end of the process a detailed Consistency check results report is generated for online consultation. In some cases the consistency check tool is automatically launched by

Check Consistency

Configure QC when inconsistent data is entered. However you can perform a check manually from the **Tasks** menu.

To check data consistency, follow the steps detailed below:

1. In the main window menu bar, select **Tasks > Check Consistency**. LQC Configuration Tools opens the **Select items to check** dialog box.
2. Specify which table you wish you validate.



3. Click **OK**. The validation process is launched.

A Consistency check results report is displayed at the end of the process with the following information:

- **Type column:** Indication of the related parameter type
- **Object column:** Identification of the related parameter (Standard Name)
- **Comment column:** Code and short error description
- **Correction :** Suggested correction

CONSISTENCY CHECK RESULTS REPORT

There are some troublesome problems for Measure Definition Albumin - Vitros

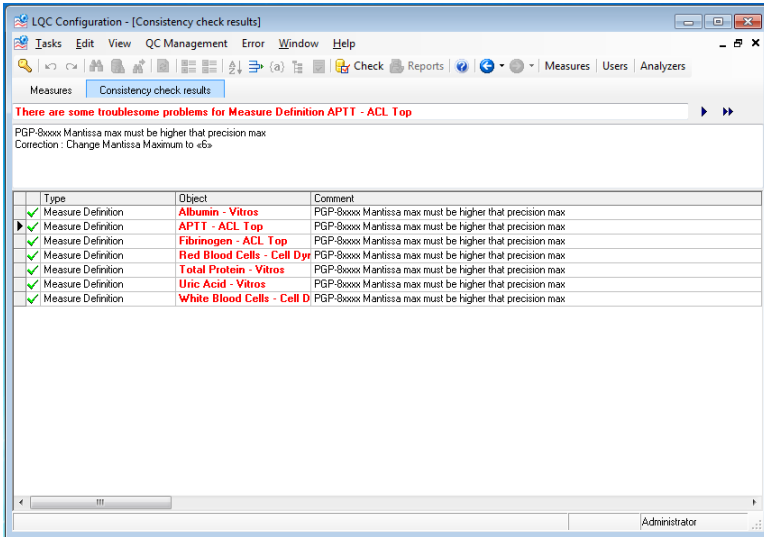
PGP-8000x Mantissa max must be higher than precision max
Correction : Change Mantissa Maximum to «6»

Type	Object	Comment	Correct
Measure Definition	Albumin - Vitros	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	APTT - ACL Top	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Fibrinogen - ACL Top	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Glucose - Vitros	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Platelets - Cell Dyn	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Red Blood Cells - Cell Dyn	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Total Protein - Vitros	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	Uric Acid - Vitros	PGP-8000x Mantissa max must be higher than precision max	Change
Measure Definition	White Blood Cells - Cell Dyn	PGP-8000x Mantissa max must be higher than precision max	Change

Administrator

Use the automated correction tool if you wish to apply the suggested correction for the selected error by clicking the red **Correct the Selected Problem** icon on the right upper corner of your screen. A green check mark on the far left column of the grid will indicate that the cor-

rection has been implemented.



Maintenance

Rebuilding Dependencies

LQC uses some internal tables for speed, which are computed from the tables that you change with LQC Configuration Tools. These internal tables are usually recomputed automatically. However, you may need to re-compute them explicitly in two cases:

- If LQC Configuration Tools is abruptly stopped for some reason, such as a power outage.
- When you change the content of one or more profiles.

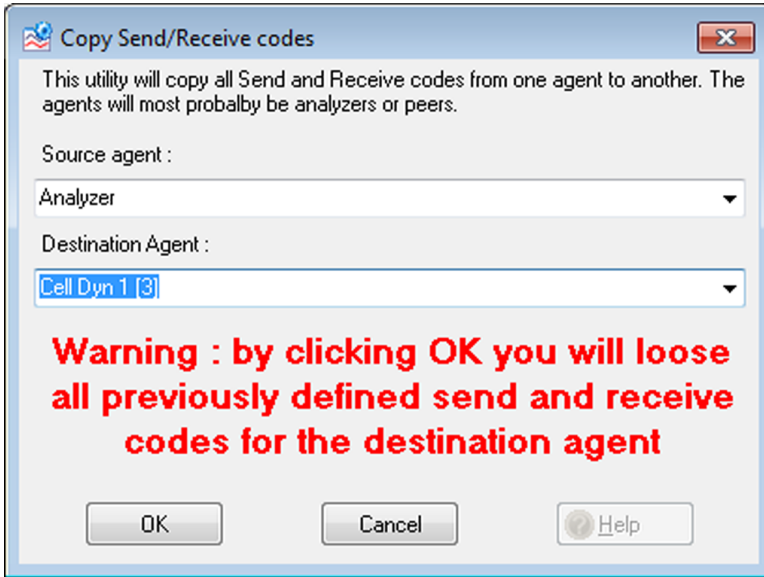
To rebuild the dependency tables:

- In the main menu bar, select **Tasks > Maintenance > Rebuild Dependencies**

Utilities

Copy Send/Receive Codes...

Select this option to copy all send and receives codes from one agent to another.



Support

This menu contains tools that allow field technicians to access information about system performance (running applications, DLLs processes, handles, etc). You should use them only under supervision of the Data Innovations technical service.

New session

This option is an alternative method to switch users by ending the current session and starting a new one. The new user will have to type in his/her user name and password in order to log on to the system. See [Starting and Stopping LQC Configuration Tools](#) for more details.

Exit

Exit Configure QC.

Configuring Users

Users are agents that are allowed to use Laboratory Quality Control interactively. Roles and Organizations are the base for security and rights management.

Accessing the User Configuration Screen

To open the Users Configuration Screen, use the **QC Management > Users** menu item from the main menu.

Users are created automatically in LQC Configuration upon log in. Log in is authenticated against the credentials already defined in Instrument Manager User Security. Although you can create a user in Configure QC, new users cannot log into LQC until their credentials are configured in Instrument Manager.

Creating a new user

The creation of a new user should be done in Instrument Manager.

- In IM, create a new user. Set up the User ID, Password and Full Name.
- Log in to LQC with the User ID / Password just created in IM. The user profile is then imported automatically into the LQC database.
- **Lab Technician** role is assigned by default to a new user.
- In LQC Configuration, go to QC Management> Users, select the given user.
- The first/last name can be updated here, and the roles and organizational dependencies defined.
- The User ID and Password cannot be changed in LQC. Passwords are managed in Instrument Manager User Security.
- Click the **Save** button to register any changes.

Attributing User Rights

To attribute rights to a user:

1. Select the user in the tree on the left.
2. Select the **General** tab and enter an organization in the **Belongs To** field.
3. Enter the organization in the **Works for** field to define the user's permissions. The user will be allowed to interact with analyzers and measures in LQC based on the permissions of the organization defined in the **Works for** field.
4. Use the **Roles** checkboxes to attribute the rights associated with that role to the user. The available roles for users are **Reviewer**, **Lab Technician** or **QC Manager**.
5. Click the **Save** button.

All Laboratory Quality Control users have access to Configure QC.

There are three levels of access that are defined from the Users table in Configure LQC:

	LQC Main User Interface	LQC Configuration
Reviewer	Read	Read
Lab Technician	Read/Write	Read
QC Manager	Read/Write	Read/Write

Reviewer (view only)

A new **Reviewer** user status has been added to LQC 2. In LQC Configuration the reviewer role can be assigned to a user. In the main LQC user interface the reviewer will be able to view QC data only, but not change it, nor accept or reject any errors or warnings that may be flagged. In addition the Reviewer will not be able to change the LQC configuration settings.

Lab Technician (ordinary user)

Users designated as Lab Technician can edit QC data in the main LQC interface, and can see LQC configuration settings but cannot edit configuration settings.

QC Manager (system administrator)

This level of access is read/write. Users designated as QC Manager can edit QC data in the main LQC user interface, and alter LQC configuration settings.

Although Laboratory Quality Control Configure QC can be started on its own, it will most likely always run while you are already logged on to Laboratory Quality Control, either as an ordinary user (Lab Technician) or as system administrator (QC Manager).

Because changes to the Laboratory Quality Control configuration are only authorized for QC Manager users, you may be required to log off and log back on if you are connected to Laboratory Quality Control as an ordinary user.

Modifications are saved in the Caché database and can be performed from anywhere on the network.

Automated logout

The User table allows you to specify an automatic logout timeout for workstations:

- The QC Manager user can define a global auto logout timeout.
- The QC Manager user can define an auto logout timeout that is specific to some users (which can be higher than the global timeout).

Configuring Organizations

Organizations represent the conceptual structure of the whole lab, with its subdivisions in specialized work places. Organizations help you divide the lab in smaller structures that are easier to manage.

Users and analyzers are assigned to a given organization, so that users can only interact with the analyzers in their own organization.

Accessing the Organization Configuration Screen

To open the Organization Configuration Screen, select the **QC Management > Organizations** menu item from the main menu.

Creating a new Organization

To create a new organization in the tree:

1. In the tree on the left, select the parent organization where you want to add a new subdivision.
2. Click on the **New** button.
3. In the **General** tab, enter a meaningful name.
4. In the Organizations pane, select the most appropriate agent type from the dropdown. The agent type helps you organize the tree by displaying a different icon.
5. Click the **Save** button.

Changing the organization tree structure

To change an organization from one place to another:

1. In the left-hand tree, select the organization you want to move.
2. Select the **General** tab.
3. In the **Organization** pane, click on the arrow of the **Belongs To** box. A list of possible parents is displayed.
4. Click the new parent organization
5. Click the **Save** button.

Notes:

Notes:

- When you move an organization in the tree, all sub-organizations automatically follow.
- The configuration screen prevents you from making cycles in the organization tree. In some cases, especially when you want to swap the positions of two organizations, you may need to move the organizations in multiple steps, first moving to a common parent, then moving them back to their intended position.
- It is not possible to create a tree structure larger than 8 levels deep.

Configuring Workstations

Workstations represent all the workstations on which LQC can run. Workstations are created automatically when LQC is installed. Workstations cannot be manually created in Configure QC, though you can edit workstation parameters.

NOTE: You cannot manually add a workstation using Configure QC.

One workstation is always defined (corresponding to the server) and additional ones will appear when a client workstation with LQC installed is connected to the server.

Accessing the Workstation Configuration Screen

To open the Users Configuration Screen, use the **QC Management > Workstations** menu item from the main menu.

Configuring Analyzers

Analyzers

An analyzer is an analytic instrument which is able to perform measures from a predefined panel on samples. Each measure yields one or more results which correspond to the characteristics of the patient. Analyzers are grouped by their *Analyzer Definition*. Analyzers with the same definition share the same measures, while analyzers with different definitions use different measures to perform the same test. For example, an analyzer of type "A" and an analyzer of type "B" will each have measures (e.g. "White Blood Cells") with different characteristics, even though these different measures correspond to the same test.

Access the Analyzer configuration screen

To open the analyzers configuration screen, select **QC Management > Analyzers** from the main menu.

Adding a new analyzer

To add a new analyzer, perform the following steps:

1. Click on the **New** button.
2. The **Create New Analyzer** wizard appears:

Create New Analyzer

Models

To reuse the setup of an existing analyzer, select it.
Otherwise select "-- New Analyzer --" at the end of the list.

Name	Type
-- New Analyzer --	

Identification

Analyzer Name :

Belongs to :

QC Client Alias :

3. In the **Models** pane, select an appropriate existing analyzer with a test configuration you want to reuse. Select – **New Analyzer** – if you want to create a new one, without any existing test and measure codes. (You will need to add them later).
4. In the **Identification** pane, enter a valid **Analyzer Name**. The name must consist of at least 1 character, and no more than 32 characters. If the name is too long, the field is displayed as italic characters and the **OK** button is disabled.
5. In the **Belongs To** field, enter the organization in which the analyzer is to be created. The organization helps you manage user rights.
6. In the **QC Client Alias field**, enter the alias that is defined in the Data Innovations LLC Laboratory Quality Control driver in Instrument Manager for the connection.

Data Innovations LLC Laboratory Quality Control Configuration

Alias Configuration			
	Connection Name	Instrument ID	Instrument Alias
	Analyzer	Analyzer 1	Analyzer

QC Type

☐ Uni-Directional ☒ Integrated

Close

7. Click **OK** to create the analyzer and close the wizard. The newly created analyzer will be displayed in the list.
8. Next, go to the **Codification** tab, and enter receive codes for the measures.

NOTE: If you just created a new analyzer definition, the list of performed measures will be empty. You must proceed to [Configuring Measures](#) in order to add measures to the analyzer.

QC Management > Analyzers

Find: In: **Analyzers**

Analyzers

Codification | Measure Definition | Notes | Properties | Audit

Measure Definition	Send	Receive	Receive	Receive
Potassium	K	K		
Sodium	Na	Na		

☐ Allow changes ☐ Only definitions where send and receive differ

Clear Import Export

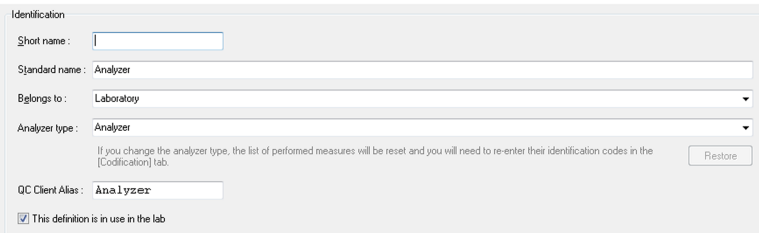
OK Send Reload Cancel New Clone Wizard Help

Related Measures Controls

NOTE: The Receive code defined in this tab must match the Instrument Manager test code received from the analyzer or defined for the test in IM Test Code Mapping.

Specifying the QC Client Alias

You must set up an alias in Instrument Manager for each instrument connection that will use QC. The same alias must be entered in the **QC Client Alias** field for the connection in the **Identification** pane:



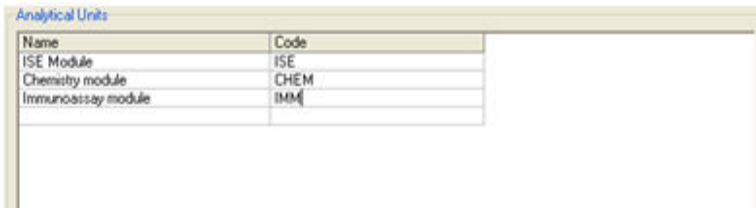
The screenshot shows the 'Identification' pane with the following fields and values:

- Short name: (empty text box)
- Standard name: Analyzer
- Belongs to: Laboratory (dropdown menu)
- Analyzer type: Analyzer (dropdown menu)
- QC Client Alias: Analyzer
- ☒ This definition is in use in the lab

A note below the 'Analyzer type' dropdown states: 'If you change the analyzer type, the list of performed measures will be reset and you will need to re-enter their identification codes in the [Codification] tab.' A 'Restore' button is also visible.

Two analyzers may not have the same alias.

Moreover, if the analyzer has multiple modules or analytical units that you want to track, you must list them in the Analytical Units pane:



Name	Code
ISE Module	ISE
Chemistry module	CHEM
Immunosassay module	IMM

Two modules of the same analyzer may not have the same alias, but modules from different analyzers may. For example, you may have two different analyzers each with a module having alias ISE.

Specifying the controls to be run

Access the controls to run on a given analyzer:

Select the analyzer to configure in the list on the left.

Select the QC tab. The list of defined controls for this analyzer is displayed.

Controls - Common Parameters panel

NOTE: Controls must be defined from QC Management>Controls before they will appear on the QC tab for a defined analyzer. See [Configuring Controls](#) for instructions.

Analyzer: QC | Codification | Notes | Properties | Audit |

Controls - Common parameters

The following controls are run on the analyzer:

Control	Westgard rule	Target used by rule	Min Measures	Min Days	Max Measures
Chem1	1-3s/2of3-2s/R-4s/3-1s/12x	Assigned values			
UTLCH2	1-3s/2of3-2s/R-4s/3-1s/12x	Assigned values			
CT20	1-3s/2of3-2s/R-4s/3-1s/12x	Assigned values			
CHROM1	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
CHROM2	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
Sweat1	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
Sweat2	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
Sweat3	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
IMM51	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
IMM52	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
CAPP	1-3s/2-2s/R-4s/4-1s/7Dx	Assigned values			
SCHEB01	1-2s	Assigned values			

Westgard rules

☐ 1-3.5s ☒ 1-3s ☐ 2-2s ☒ 2of3-2s ☒ R-4s ☐ 4-1s ☐ 10x ☐ 1-2.5s ☐ 1-2s ☐ 7T

☒ 3-1s ☒ 12x

Controlled measures

Measure	Cv	Unit	BUHL2						CAPP						Chem1					
			Low	High	Mean	Sd	Cv	Unit	Low	High	Mean	Sd	Cv	Unit	Low	High	Mean	Sd	Cv	Unit
CYC																				
ELE																				
FCAL																				
FELA																				
MET																				
NORMET																				
OSM																				
SWCL																				
SWCON																				
TAC																				
UCIT																				

Buttons: Add Control, Remove Control, Edit Controls, Copy QC to, OK, Save, Reload, Close, New, Clone, Wizard, Help, Related Measures Controls

Controls - Common Parameters panel

The **Controls – Common parameters** panel displays a list of all controls defined for the given analyzer and their common parameter values. The parameters are common for the measures the control is defined on.

Parameter Values

- **Westgard rule** - a rule for evaluating the quality of the control measurements.
- **Target used by rule** – how the target value will be obtained:
 - **Assigned values:** The assigned target and Sd values are used to control measures.

- **Study:** The target and Sd values will be provided after a control study. All three appropriate parameters should be defined.
- **Assigned values >Study:** The target and Sd values will be provided after a control study, but the assigned values will be used during the study period. The number of measures while studying should be defined only.

Control study values:

- **Min Measures:** the study will provide a useable target after X measures.
- **Min Days:** the study should normally last for X days.
- **Max Measures:** the study will be completed after X measures.

Westgard Rules panel

Westgard rules can be selected from the drop-down menu in the **Controls - Common Parameters** panel or by using the check boxes in the Westgard rules panel.

There are two Westgard multi-rule sets incorporated with LQC that appear by default in the drop-down rule menu and on the panel:

- The standard multi-rule protocol **1-3s/2of3-2s/R-4s/3-1s/12x** is usually used for three-level controls.
- The **1-3s/2-2s/R-4s/4-1s/10x** multi-rule is usually used for one or two-level controls.

Westgard rules and multi-rule combinations can now also be selected and grouped individually for each analyzer/measure being monitored. Check boxes under the **Controls - Common Parameters** table lists the different rules.

The ones on the top line of the middle section of the panel are for 2 levels controls, the ones on the bottom of the middle section are for 3 levels controls, and the two in the middle (1-3s and R-4s) can be used with 2 and 3 levels controls.

<input checked="" type="checkbox"/> 1-3s	<input checked="" type="checkbox"/> 2-2s	<input checked="" type="checkbox"/> R-4s	<input checked="" type="checkbox"/> 4-1s	<input checked="" type="checkbox"/> 10x
<input type="checkbox"/> 2of3-2s	<input type="checkbox"/> 3-1s	<input type="checkbox"/> 12x		

Controlled measures panel

Controlled measures panel

The **Controlled measures** panel displays a list of analyzer measures controlled or controllable and their proper control parameter values.

- Low – Low limit
- High – High limit
- Mean – Target value
- Sd – Standard deviation
- CV – Coefficient of Variation
- Unit – Unit the value of controlled measure is expressed in.

1.10.2. 1.1 Skaičiuoja kokybės parametrų statistines vertes (vidurkį, standartinį nuokrypį, variacijos koeficientą).

Understanding the Controlled measures panel

- The colored cells indicate that the corresponding control is applied on the measure. The **Low** and **High** limits as well as the values of the **Mean**, **Sd**, **CV** and **Unit** parameters are displayed, if defined.
- The measure is controllable if the control has a proper stable property or if this property can be added.
- These parameter values are editable.
- When cells are grayed out it means that the corresponding measure can't be controlled by the control because the control doesn't have a proper stable property and this property cannot be added automatically.
- Measures that are not controlled or controllable by any controls used in an analyzer are not shown in the **Controlled measures** panel.
- If a measure was controlled and that the proper stable property of the control was later removed, the measure and control parameters would then appear grayed out.

To add a new control:

1. Click the **Add Control** button or right-click a control in the **Controls - Common parameters** pane and select **Insert**. The New Control wizard appears.

2. Click **Next**, and select the control you want to run from the **Defined Controls** tab (controls having stable properties to be applied to the analyzer) or the **All Possible Controls** tab (if the control is selected from this group, the wizard will set up a stable property automatically).
3. Click **Next**
4. Select the Westgard rule to be applied, the source for target values, and the study period.
5. Click **Next**.
6. Select the tests to control by selecting them in the **Available** field and clicking the right-facing arrow to move them into the **Selected** field.
7. Click **Next**.
8. Optionally enter default values for assigned values.
9. Click **Next** then **Finish** to complete the wizard.
10. Navigate through the defined controls and, optionally, modify the control rules. The **Controlled measures** pane allows you to review and change the default target values.
11. Click the **Save** button.

To add a control to a measure:

1. Select a control in **Controls - Common parameters**.
2. Right-click a controlled measure in the **Controlled measures** pane.
3. Select **Add Control**.

To edit a control:

1. Click the **Edit Controls** button.
2. Edit the control's properties from **QC Management > Controls**.

If the control is added to a measure, you can also edit it by right-clicking the measure and selecting **Edit Control**.

You can also edit controls by right-clicking in the **Controls - Common parameters** pane and clicking **Edit**.

See [Configuring Control Definitions](#)

To remove a control from the analyzer

1. Right-click a control in the **Controls - Common parameters** pane.
2. Select **Remove** .
3. Click **Yes** from the informational message; removing the control removes it from all controlled measures.

To remove a control from a measure

1. Select a measure in the **Controlled measures** panel.
2. Right-click the Control in the **Controlled measures** panel.
3. Select **Remove Control** to remove the control from the measure.

To copy a QC Configuration to another analyzer

1. From **QC Management>Analyzers**, select an analyzer in the left pane.
2. Click the **QC** tab.
3. Click the **Copy QC to** button.

NOTE: If the button is not activated, ensure an analyzer with the same analyzer definition is available.

4. From the **Choose analyzer to copy QC to** dialog, select an analyzer from the list of available analyzers.
5. Click **OK**.
6. Click **OK** to the dialog, "The current QC parameters have been copied to the analyzer successfully."

Configuring Control Definitions

Controls define each of the control fluids you use to control the analyzers. Each control type, and within a type each level, is represented by a control definition.

Controls are manufactured in lots. The measured characteristics are normally stable within a lot and may vary from one lot to another. After creating controls, you can assign them to an analyzer definition from the Analyzer QC tab.

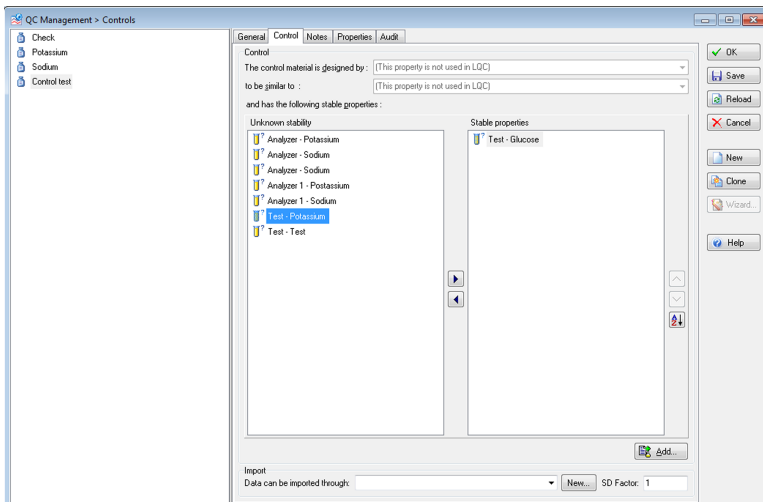
Accessing the Control Configuration Screen

To open the Control Configuration Screen, use the **QC Management > Controls** menu item from the main menu.

Adding a new Control Definition

To add a new control definition:

1. Click the **New** button.
2. Go to the **General** tab and enter a valid standard name that matches the name given by the manufacturer. Optionally enter additional names.
3. Go to the **Control** tab and select the Stable properties.



Adding a new Control Definition

NOTE: The analyzer and measure for control must be defined before they will appear for selection from the Control tab.

4. Click the Save button.

Configuring Measures

Measure Definitions

Measure Definitions are used to describe the tests the analyzer performs. Measure definitions are not dependent on fluid type (the same measure may be used to analyze serum or urine) or patient state (the same measure can be used to analyze normal (i.e. fasting patient) samples or dynamic tests).

Accessing the Measure Configuration Screen

To open the Measure Configuration Screen, use the **QC Management > Measures** menu item from the main menu.

Adding a new measure definition

Before creating a measure, you must have defined an analyzer.

To create a new measure definition:

In the tree on the left, select the analyzer definition, or an existing measure for the analyzer definition.

Click the **New** button.

Select the **General** tab.

Enter a valid standard name and optionally other names.



The screenshot shows a 'Names' section with four input fields. The 'Standard name' field is pre-filled with 'Red Blood Cells'. The other fields are empty.

Names	
Keyboard Code :	<input type="text"/>
Short name :	<input type="text"/>
Standard name :	<input type="text" value="Red Blood Cells"/>
Long name :	<input type="text"/>

In the **Handling** pane, make sure the **Analyzer Type** is set to the appropriate analyzer definition.

To select the list of controls and Westgard rules to be run for the

Handling

Analyzer Type: Analyzer

Analyzer Code:

Click the Save button.

NOTE: This Analyzer Type field is automatically populated with the analyzer type you select. Although you can select another analyzer type from the dropdown before saving the measure, once you have saved the measure you will not be able to change the Analyzer Type.

To select the list of controls and Westgard rules to be run for the select measure on the selected analyzer:

General QC Notes Properties Audit

Controls

The following controls are run on the analyzer :

Analyzer	Control	Westgard rule	Target used by rule	Min Measured	Min Days	Max Measure
AU680-1	Chem1	1-3s/2-2s/R-4s/4-1s/10x	Assigned values			
AU680-1	Chem3	1-3s/2-2s/R-4s/4-1s/10x	Assigned values			
AU680-2	Chem1	1-3s/2-2s/R-4s/4-1s/10x	Assigned values			
AU680-2	Chem3	1-3s/2-2s/R-4s/4-1s/10x	Assigned values			

Westgard rules

☐ 1-3.5s ☒ 1-3s ☒ 2-2s ☐ 2of3-2s ☒ R-4s ☐ 4-1s ☐ 3-1s ☒ 10x ☐ 12x ☐ 1-2.5s ☐ 1-2s ☐ 7T

Select the measure to configure in the list on the left which is shown on the tree under the analyzer class.

Select the QC tab to display all the instruments in this class that run the selected measure/analyte. The list of defined controls for this analyzer is displayed.

Select the Westgard rule to be applied for this measure.

Westgard rules can be selected from the drop-down menu or configured using the check box panel below this table.

There are two Westgard multi-rule sets incorporated with LQC that appear by default in the drop-down rule menu:

The standard multi-rule protocol **1-3S/2of3-2S/R-4S/3-1S/12x** is usually used for three-level controls.

To select the list of controls and Westgard rules to be run for the

The **1-3S/2-2S/R-4S/4-1S/10x** multi-rule is usually used for one or two-level controls.

Westgard rules and multi-rule combinations can now also be selected and grouped individually for each analyzer/measure being monitored. Check boxes under the controls table in the LQC Configuration; Measures; QC tab lists the different rules.

The ones on the top line are for 2 levels controls, the ones on the bottom line are for 3 levels controls, and the one in the middle (1-3s) can be used with 2 and 3 levels controls.

When the rules are set, Click **Close** and save the changes.

Configuring Units

Configure QC provides a predefined list of units and allows you to configure additional units.

Accessing the Organization Configuration Screen

To open the Units table, select the **QC Management > Organizations** menu item from the main menu.

Creating a new Organization

To create a new unit in the table:

1. In the tree on the left, select the parent unit where you want to add a new unit.
2. Click on the **New** button.
3. In the **General** tab, enter a meaningful name.
4. In the **Unit** pane, select a conversion factor.
5. Click the **Save** button.

Frequently Asked Questions

This section identifies some of the most frequent issues you may encounter while using Laboratory Quality Control Configuration Tools.

- [Is it possible to move a parameter in the hierarchy?](#)
- [Is it possible to create new levels \(branches\) in the hierarchy?](#)
- [I cannot find certain parameters in a table. Have they been deleted?](#)
- [Should all validation stations be disconnected when I edit LQC Configuration Tools?](#)

Is it possible to move a parameter in the hierarchy?

The new parameter that you have just defined has been inserted at a wrong position in the hierarchy. This can happen if the parameter was created by cloning and automatically inserted immediately under the source parameter. To change the current location of a parameter in the hierarchy, simply re-define the parent branch by selecting the appropriate item in the **Belongs to** selection list from the General tab of the parameter.

Don't forget to click the 'Refresh' button afterward to apply the changes and re-build the hierarchy.

Is it possible to create new levels (branches) in the hierarchy?

As a hierarchy may contain up to 10 levels, and "The World" is the only agent possible at level 0, you can create a maximum of 9 sub-levels in the Agent table hierarchy. Laboratory Quality Control Configuration considers and handles a level just as any parameter. The only difference is that a level contains only identification and relational information of the type **Belongs to**. To create a new branch in the hierarchy, simply create a new parameter in the appropriate table and specify where it must be inserted using the Belongs to selection list in the General tab.

I cannot find certain parameters in a table. Have they been deleted?

You cannot create level 1 branches of the type 'system folders'. The message 'Always use wizard to create such agents' will warn you that you are trying to create a system-reserved item.

I cannot find certain parameters in a table. Have they been deleted?

You know for certain that you have defined or encountered certain parameters in a table but can't find them in the table structure. One thing you can always be assured of is that, for traceability reasons, no parameter is ever deleted from the database and old results will continue to refer to the definition in question. (This is why you should never try to re-use outdated definitions for other purposes.) What could happen, however, is that another administrator responsible for LQCConfiguration considered that the parameter was no longer relevant to the laboratory and deactivated it by unchecking the **In use** or **This definition is in use in the lab** check box in the General tab. The check box may also have been unchecked by error. Laboratory Quality ControlConfiguration provides an option to filter the information and display active parameters only. If the parameter is deactivated, you will not be able to see it unless you use the **Show unused items** button.

You may also check the following:

- You may have misspelled the parameter. The Find function can be applied to any fragment of a name in a table. If you are not sure of the spelling, type only the part of the name that you are certain of.
- The parameter may have been inserted in another table. Check its location.

Should all validation stations be disconnected when I edit LQC Configuration ?

In a client-server configuration, any modification in Laboratory Quality Control Configuration Tools is immediately applied to the core database underlying the whole system. Depending on their type,

Should all validation stations be disconnected when I edit LQC

certain modifications may be included immediately in the validation stations that they relate to, without requiring any user interaction.

In all cases, however, you should avoid editing parameters during the busiest times in the laboratory, when a high-volume of messages are moving through the system.

Glossary

A

Accept

Indicate that a value or a set of values are marked as technically correct.

Accuracy

The closeness of a result to the value which is accepted either as a conventional true value or an accepted reference value.

Alarm

A warning sent by an analyzer when an abnormal value is detected in view of the tolerance levels for reference values and standard deviations.

Analyte

The specific substance, compound, property or constituent to be determined in an assay or analysis.

Assayed control material

A substance used to monitor the performance of a process or an instrument. By comparing control results against the essay (known) value, you can determine the instrument's accuracy and precision.

B

Bias

A systematic difference between an observed value and some measure of the truth. Generally used to describe the inaccuracy of a method relative to a comparative method in method evaluation or to a comparative group in proficiency testing.

C

Coefficient of variation (CV)

The relative standard deviation, i.e. the standard deviation expressed as a percentage of the mean
[$CV = 100(s/X)$].

Control limits

The defined limits or ranges of results expected due to the random error of the QC method, and beyond which some course of action should be taken.

E

EWMA (Exponentially Weighted Moving Average)

A statistic for monitoring the analytical process that averages the data in a way that gives less and less weight to data as they are further removed in time from the current measurement.

L

Levey-Jennings control chart

A commonly used control chart in which individual control measurements are plotted directly on a control chart with limit lines drawn either as $\text{mean} \pm 2s$ or $\text{mean} \pm 3s$. Time is displayed on the x-axis usually in terms of days or runs.

Lot

A batch of samples introduced to the analytical process to allow evaluation of the performance of the measurement system.

M

Mean

A measure of central tendency of the distribution of a set of replicate results.

Measures

Also known as analytes

O

Outlier

A result that falls outside the low/high limits for any parameter.

P

Precision

A measure of how close an instrument comes to repeatedly duplicating the same result on the same sample. The precision of an analytical device is usually expressed as the variance, standard deviation or coefficient of variation of a series of measurements.

R

Reject

Indicate that a value should not be sent to the central system because it is not technically correct, in cases such as failure of the analyzer.

Role

Every user in DI QC is allocated particular user roles. A user role describes the specific actions that a user is allowed to perform within the application. Depending on the role that a user has received, he/she will have access to certain functions only and be entitled to intervene at specific steps in the request processing flow.

S

Standard deviation (Sd)

A statistic that describes the dispersion or spread of a set of measurements about the mean value of a

Gaussian or normal distribution.

Statistical control limits

The lines drawn on control charts to define the range of results expected due to the random error of the QC method. The limits are often obtained from a group of 20 or more measurements on a particular control material by calculating the mean and standard deviation, then using multiples such as the mean plus/minus 3s, 2s, or 1s to establish rejection limits for different control rules.

T

Trend

A trend occurs when five or more control values show a graphical increase or decrease.

W

Westgard rules

A control procedure that uses a series of control rules to test the control measurements. A 1-2S rule is used as a warning, followed by use of 1-3S, 2-2S, R-4S, 4-1S, and 10-X as rejection rules.

Z

Z-score

A calculated value that tells how many standard deviations a control result is from the mean value expected for that material. It is calculated by taking the difference between the control result and the expected mean, then dividing by the standard deviation observed for that control material. For example, if a control result of 112 is observed on a control material having a mean of 100 and a standard deviation of 5, the z-score is 2.4 $[(112 - 100)/5]$. A z-score of 2.4 means that the observed control value is 2.4 standard deviations from its expected mean, therefore this result exceeds a 2s control limit but not a 3s control limit.

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