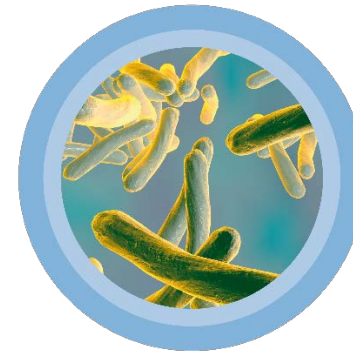


LQS – LIAISON® QuantiFERON® Software

User Manual

EN-US_033-LQS-UME rev. A

11-2019



DiaSorin

The Diagnostic Specialist

DISCLAIMER

The information contained in this manual is based on experience and the best knowledge relating to the subject matter as acquired by DiaSorin S.p.A.

DiaSorin is not liable for any loss or damage, including consequential or special damages resulting from the use and or misuse of the contained information, be it negligence or other fault.

This manual refers to access at the highest authorization level. Accessing the application with lower level authorization may cause a lack of some functionalities.

LQS may only be used by authorized and specially trained personnel.

This manual cannot be considered substitutive of official trainings supported by DiaSorin.

In the event of problems or doubts about using the product, contact your local support representative.

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REVISION INDEX

Revision	Amended chapters/sections	Description of changes

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1 Introduction

This manual was created to assist the laboratory user with the utilization of the **LIAISON QuantiFERON Software** (hereinafter **LQS**).

The information in this manual is strictly intended for authorized personnel trained in the use of **LQS**.

1.1 Description

The product described in this document is an In Vitro Medical-Diagnostic device (IVD) intended for professional use. The personal computer on which the application is installed and other hardware components are not part of the definition of medical device.

1.1.1 Intended use

The **LIAISON QuantiFERON Software (LQS)** is optional software intended to analyze the data generated by the LIAISON® QuantiFERON®-TB Gold Plus assay on the LIAISON® XL analyzer. **LQS** reports assay results as positive, negative or indeterminate by an algorithm that combines the individual results associated with the four QIAGEN QuantiFERON®-TB Gold Plus Blood Collection Tubes into a final result.

LQS assists users in analyzing and interpreting the intermediate results transmitted by the analyzers on the LIS channel in accordance with the guidelines in the instructions for use for the LIAISON QuantiFERON-TB Gold Plus assay.

LQS does not come into contact with humans (either patients, or professional users). The product is not classified as an instrument.

NOTE

Analysis and interpretation of LIAISON QuantiFERON-TB Gold Plus assay results can be determined automatically via the LQS application, or manually by following the Interpretation of Results section in the instructions for use of the LIAISON QuantiFERON-TB Gold Plus assay.

1.2 Customer Support

If you have any questions about **LQS**, please contact your local DiaSorin Customer Support.

1.3 Intellectual property rights

The **LIAISON QuantiFERON Software (LQS)** and system documentation are protected by copyright laws. All rights are reserved. The manual was developed solely for use with **LIAISON QuantiFERON Software** systems.

The information, documents and related graphics published herein (the “Documentation” or “Document”) are the sole property of DiaSorin S.p.A. Permission to use the Information is granted provided that:

- use of the Documentation is for handling DiaSorin products by qualified personnel or for informational purposes only;
- the copyright notice appears on all copies;
- the documentation is not modified in any way;

no graphics are used separately from the accompanying text.

1.4 Authorization and clauses about Documentation

LQS is an in vitro medical-diagnostic device (IVD) intended for professional use in Clinical Analysis Laboratories and must only be used by authorized and specially trained personnel.

This manual of instructions for use provides indications on using the application functionalities; the manual cannot, however, be considered substitutive of training sessions supported by DiaSorin.

The information contained in this manual is based on experience and knowledge relating to the subject matter as acquired by DiaSorin S.p.A.

Should **LQS** be used differently from what is described in this manual, the functionalities provided by the system, its performance and data security may become compromised. DiaSorin is not liable for any damages resulting from the misuse of the contained information be it negligence or other fault.

In no event shall the manufacturer and/or distributor of the application software be held liable for malfunctions or data corruption due to the propagation of computer viruses in the host system.

In the event of problems or doubts about using the product, contact technical service.

1.5 DiaSorin Warranty

DiaSorin S.p.A. makes no representations or warranties of any kind or nature with respect to the documentation.

DiaSorin S.p.A. disclaims all representations and warranties, whether express or implied, created by law, contract or otherwise, including, without limitation, any warranties of merchantability, fitness for a particular purpose, title or non-infringement.

In no event shall DiaSorin S.p.A. be liable for any damages of any kind or nature, including, by way of example, direct, indirect, special (including loss of profit), consequential or incidental damages arising from or in connection with the existence or use of the information, regardless of whether DiaSorin S.p.A. has been advised as to the possibility of such damages.

1.6 Messages, Notes and Symbols

The symbols described hereafter are used in this manual, or on the packaging of the device.

1.6.1 Display of warnings and notes

CAUTION



The word “**Caution**” and the relating symbols describe potential dangers/problems.

Failure to follow the safety instructions can result in defects in the software functionality. Incorrect processing or data corruption cannot be excluded.







CAUTION

The word “**Caution**” describes a potential problem. Failure to follow the instructions given can result in incorrect processing or loss of data.

NOTE

The word “**Note**” describes a potential problem. Failure to follow the note given can lead to incorrect system operation.

1.6.2 Symbols used on the device label

	Manufacturer
	In Vitro Diagnostic Medical Device
	CE mark
	Catalogue number
	Serial number
	Consult instructions for use

1.7 Safety instructions

1.7.1 General safety

The following safety instructions must be observed at all times, both before and during operation of the system.

The Instructions for use are provided for user safety and give important instructions for using the system described.

- Before using **LQS**, read the following explanations for safety carefully, and understand the contents completely. Users must be trained before being allowed to use the system.
- The Instructions for use must always be kept available near the system.
- For maintaining safety, do not modify the **LQS** system, do not replace components or accessories.
- Installation and service of the system or changes in the installation may never be performed by non-authorized persons not approved by DiaSorin S.p.A. Multiple plug sockets different from those installed by DiaSorin or its authorized personnel are not allowed.
- Do not perform any operations or functions not described in the instructions for use. If trouble occurs on the system, contact DiaSorin S.p.A., or an authorized representative.
- The precautions for use indicated on the **LQS** device manual are entered after careful examination; however, it is possible for situations beyond prediction to occur. When using the device, it is imperative to follow the instructions correctly.

The Instructions for use must be accessible to the user at all times.

NOTE

To guarantee the full operational conditions of the **LQS** system, it is mandatory to allow DiaSorin S.p.A. personnel, or authorized service, to perform all necessary scheduled and unscheduled interventions.

CAUTION



Failure to adhere to the information given in the Instructions for use may result in damage to the system or errors in data interpretation.

1.7.2 Liability

The **LQS** device was developed in accordance with the safety requirements for in Vitro medical-diagnostic devices. It is the operator's responsibility to comply with local regulations and laboratory procedures for installation and operation of the device.

The manufacturer has done everything possible to guarantee the safe operation of the device. The system is tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

The information contained herein is based on experience and the best knowledge relating to the subject acquired by DiaSorin S.p.A.

DiaSorin is not liable for any data loss or corruption, including damages resulting from the misuse of the contained information be it negligence or other fault of personnel.

- The device must only be used in accordance with its intended use.
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

CAUTION



Improper use of the system may result in an incorrect interpretation of results, compromise the data in the system or data loss.

1.7.3 Precautions for electromagnetic wave interference

1.7.3.1 Electromagnetic wave interference given by LQS to other devices

LQS is a software device installed on third party hardware components. Refer to documentation provided by the hardware component manufacturer for more information on any electromagnetic waves generated by the components.

1.7.3.2 Electromagnetic wave interference that may be given to the LQS by other devices

If **LQS** is used near devices that generate strong electromagnetic wave interference, noises could cause malfunctions to the hardware system on which it is installed.

Refer to documentation from the hardware supplier for more information on electromagnetic wave interference.

1.8 User safety

The aim of this section is to bring to user's attention the status of residual risks despite the safe design measures, safeguarding and complementary protective measures adopted by the manufacturer to lower the risks to an acceptable level.

The user must carefully read this manual to understand the residual risks and learn how to work safely with the **LQS** device.

If further clarification should be needed, it is recommended to contact the local DiaSorin representative.

1.8.1 Definitions

- (a) "risk" means the probability of damages that can arise in a hazardous situation;
- (b) "user" means the person operating the device;
- (c) "intended use" means the use of the device in accordance with the information provided in the instructions for use;
- (d) "reasonably foreseeable misuse" means the use of the device in a way not intended in the instructions for use, but which may result from readily predictable human behavior.

1.8.2 Inherent safe design and manufacturing process

The device was designed and manufactured applying a risk management process based upon the ISO standard 14971:2007 and EN ISO update 14971:2012. Risk management is set as required by ISO standard 13485:2016 and according to the Quality Policy.

By applying the standards, through an iterative process of risk analysis, the manufacturer has:

- determined the limits of the device, which include the unintended use and any reasonably foreseeable misuse;
- identified the hazards and risk situations associated with using the device;
- estimated the risk for hazardous situations, taking into account the severity of the potential harm and the probability of its occurrence by the application of an appropriate FMEA (Failure Mode Effect Analysis) methodology;
- evaluated the risks, with a view to determining whether risk reduction has been required;
- reduced the risk by the identification, implementation and verification of the effectiveness of appropriate risk control measures.

The process described above will be maintained by the manufacturer until the retirement of the **LQS** device. The manufacturer has established procedures to review post-production information in order to ensure the appropriate safety degree and to maintain the IVD device always adequate to the so called “state of the art” in compliance with the European Community Directive 98/79/EC related to IVD Medical Devices.

Where possible, the device has been designed and developed to prevent abnormal use if such use would create a risk.

The instructions for use must be carefully read, paying attention to all warnings, taking into account the way the device must be operated and which are the uses not allowed.

1.9 Operational precautions and limitations

This section describes the operational requirements, precautions, and limitations to ensure accurate data interpretation.

The user must follow the requirements below to ensure proper functioning of the system.

Not following the requirements and precautions provided can impact the system and the outcome of the results interpretation.

1.9.1 General requirements

- Ensure the system is connected to a power supply system with operational continuity. The lack of power could lead to data loss and interruption in communication with instruments and LIS.
- Do not run any system maintenance that is not specified in the documentation provided by DiaSorin S.p.A.

1.9.2 System operation

1.9.2.1 Precautions and requirements before operation

Before beginning to operate the system, the user must:

- Read this manual thoroughly to fully understand the functionality of the system and associated hazards.
- Check that the connections of all interfaced devices (instruments and LIS) are operational.

- Check that the device is not giving any alarm signals.

1.9.2.2 Precautions during operation

- Do not disconnect any electrical connection during operation.
- Check and take the necessary countermeasures in case of warnings shown by the system.
- Pay the utmost attention during sample labeling operations to avoid mismatches.
- Do not clear the samples on which results are being processed.

1.9.3 Limitations of result interpretation

Any result interpreted by **LQS** should not be used as medical advice or service without approval by authorized medical personnel. Results must be used with the patient's other clinical data, such as symptoms, other test results, patient history, clinical data, information available from clinical evaluation, and other diagnostic procedures.

LQS has been validated for its intended use only. However, problems can occur due to potential operator errors and limitations in the technology of the **LQS** device. If interpretation results are inconsistent with clinical evidence, additional analyses are suggested to confirm the result.

1.10 System requirements

In case LQS is installed with customer-owned hardware components, the minimum requirements listed below must be met:

Personal Computer	<ul style="list-style-type: none"> • Intel processor with Passmark benchmark ≥ 8000 • 8 Gb RAM • 50 Gb of free Disk space • Operating system: Windows 7 Professional, Windows 8 Professional or Windows 10 Professional. • CD reader
Monitor	Resolution: 1920 x 1080 (full HD), 21.5" or higher

Connections	Integrated serial ports or serial device server ethernet; the number of ports must be adapted according to the number of devices to be connected
Barcode printer	<ul style="list-style-type: none"> • USB interface • EPL2 programming language • Resolution: 203 DPI or higher • Maximum printing width: 104 mm or higher • Print speed: 102 mm / sec or higher
Barcode reader	We recommend using a fixed-position laser scanner alternative to the keyboard

NOTE

If the personal computer does not have the required resources, you cannot use the product; **LQS** will show an error message and it will not run.

1.11 System maintenance

The customer is responsible for system maintenance, both for the hardware components and the basic software (security patch application, antivirus installation/update, data backup, account maintenance).

1.12 Installation of the system

CAUTION



Installation

The **LQS** may only be installed by authorized and properly trained service personnel.

LQS may be installed on PC with hardware compliant with system requirements (see chapter 1.10).

Refer to the instructions in the Service Manual for detailed instructions on installing the device.

1.13 Removal of the System

If the System must be shipped or removed, user shall contact the local DiaSorin field service representative for assistance.

Refer to the instructions in the Service Manual for detailed instructions on uninstalling the device.

CAUTION

Uninstallation

The **LQS** must be uninstalled by authorized service personnel.

2 PC security measures

2.1 Introduction

LQS was designed to be used in a controlled environment. Access to the application is allowed only to trained and authorized users. Nevertheless, the system is subject to the risk of unauthorized access, leading to possible data loss, corruption or unauthorized distribution.

Updates to the software provided with the system (e.g. Operating System) must be distributed under a controlled process, to ensure that the software still behaves according to its intended use after the update.

This chapter describes the policies followed by DiaSorin and partners regarding software updates on systems installed at the end-user.

2.2 Unauthorized access

2.2.1 Potential issues

Usage of the device is designed only for trained and authorized users, who are supposed to follow the intended use of the System.

Unauthorized users could access or damage the computer without the owner's knowledge. Consequences may be software damage, data loss, corruption or unauthorized distribution.

2.2.2 Protection measures

Access to the **LQS** is based on the use of identification credentials with different access permissions. This enables usage of the application only to authorized personnel:

- operating the application, including access to any data, is only possible when entering authorized credentials (made of “username” and “password”), that are unique for each user;
- “username” is unique and cannot be re-assigned;
- “username” and “password” must be at least 8 characters long;
- for each “username”, a password expiration can be set; Upon expiration of the password, the System will force the user to change the “password”;
- each user can change his/her own access “password”;
- during installation of the System, a temporary password will be provided that the system forces the user to modify at his/her first login;
- it's possible to set an idle time expiration in which the user is forcibly disconnected.

2.3 Malware

2.3.1 Potential issues

Using the computer on which **LQS** is installed could lead to voluntary or involuntary introduction of malicious software, like viruses, worms, spyware. This malicious software (also called malware) is designed to infiltrate or damage a computer without the computer owner's permission. Consequences may be data loss, corruption or unauthorized distribution.

The introduction of such malicious software may occur:

- via LAN network;
- via removable USB media;
- via CD-Rom.

2.3.2 Protection measures

The state-of-art, worldwide spread approach is to provide a network firewall, a personal firewall and an integrated protection tool, generically called antimalware.

Protection of the computer on which **LQS** is installed is the responsibility of the end user as it is not part of the medical device supplied.

2.4 Unauthorized access via LAN network

2.4.1 Potential issues

A computer on which **LQS** is installed, connected to a LAN network could be accessed by unauthorized persons, causing unpredictable effects on software. Consequences may be software and data loss, corruption or unauthorized distribution of data.

2.4.2 Protection measures

It is good practice to keep the firewall integrated with the operating system active to prevent inbound access from a remote station.

2.5 Privacy

2.5.1 Potential issues

LQS produces interpretation of results that refer to the health condition of patients.

Therefore, a potential risk of distributing patient data may exist in regards to:

- A. DiaSorin personnel (directly or indirectly involved in technical activities on the laboratory systems)
- B. DiaSorin partners personnel (directly or indirectly involved in technical activities on the laboratory systems)
- C. DiaSorin suppliers personnel (directly or indirectly involved in technical activities on the laboratory systems)

2 PC security measures

Patient health data could be available to the above mentioned personnel in the following situations:

1. during a technical intervention on laboratory systems, personnel of type “A” or “B” may need to access the **LQS** software that may contain patient health data, therefore check such data on the screen or print data as hard copy;
2. personnel of type “A”, “B” or “C” could retrieve patient health data as part of data exchanged in electronic or paper format, as part of technical troubleshooting or maintenance activities that involve such personnel.

Furthermore, users different from the above listed types could get in contact with patient health data.

Specific country regulations may require different means to overcome the listed potential issues.

2.5.2 Protection measures

The following measures are adopted in order to make the system compatible with the known regulatory requirements. Measures that are already listed and described in the present chapter are not repeated here.

1. Sample identifier (SID) as well as patient identifier (PID), are an anonymous sequence of alphanumeric characters, that the end-users may use in combination with their laboratory system (LIS), in which all the patient information are maintained, and particularly the patient demographics;
2. The system can perform all the operations without the need to insert the patient personal data;
3. Processed data are stored in a temporary database that resides in the temporary memory of the system. Upon closing the application, these data are erased;
4. System logs are encrypted and only accessible to authorized personnel;

As it regards the responsibilities of end-users, where local regulations require so, the end-user is responsible for the following aspect:

on **LQS** SID and PID must not clearly refer to the patient; such information shall be traced in the laboratory systems.

In regards to the responsibilities of DiaSorin, where local regulations require so, they are configured as follows:

- a. DiaSorin will solicit the respect of privacy regulations, if there should be evidence that **LQS** is used without compliance to the applicable privacy regulations;
- b. DiaSorin is not liable for improper use of data generated through the **LQS** once data is released outside of the system itself, i.e. after data has been written, printed, or sent in electronic format to other laboratory systems.

3 System description

3.1 Overview

LQS is an *in vitro* diagnostic device (IVD) intended for the analysis of data generated by LIAISON® XL analyzer when testing samples using the LIAISON® QuantiFERON®-TB Gold Plus assay. **LQS** acquires the intermediate results of the four QuantiFERON-TB Gold Plus blood collection tubes (Nil, TB1, TB2, Mitogen) and calculates their interpretation.

LQS can be interfaced with the laboratory LIS to automate acquisition of acceptances and the reporting of results.

For all samples where running the LIAISON QuantiFERON-TB Gold Plus assay is not included, **LQS** behaves transparently, acting as a link between LIS and connected instruments.

In summary, the routine operation of **LQS** involves the following steps:

- records LIAISON QuantiFERON-TB Gold Plus assay performance requests from LIS, or those the user enters manually, in its database;
- performance requests are forwarded to the correct devices (analyzers) to be processed following their query;
- **LQS** receives quantitative and/or qualitative results and signals for the requested determinations from the interfaced LIAISON® XL analyzers, and records the information within its temporary database; the analytical results generated by the LIAISON® XL analyzers using LIAISON® QuantiFERON®-TB Gold Plus assay are automatically interpreted by **LQS**;
- **LQS** can also receive results and signals on the Quality Controls performed on the LIAISON® XL analyzers that are forwarded without processing to the laboratory LIS, where present;
- authorized Laboratory personnel may consult the LIAISON QuantiFERON-TB Gold Plus assay results and if necessary print the results;
- for QuantiFERON-TB Gold Plus assay results, **LQS** provides the user with extensive information: performing analyzer, instrument flags, test lot number, calibration ID, and other traceability information.

3 System description

During installation, **LQS** is configured to be adapted to most of the operating modes used in analysis laboratories;

3.1.1 Start-up and access

To start up **LQS** simply use the icon on the PC desktop.

Upon start-up, **LQS** runs the following activities:

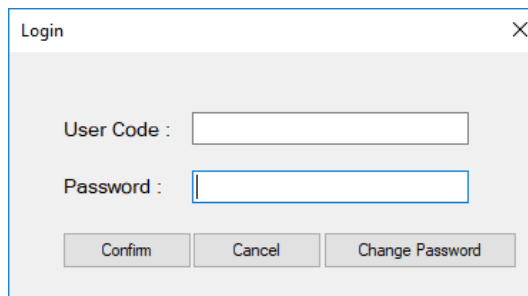
- it checks whether the system has enough available resources. If not, an error message is displayed;
- it loads the configuration into memory;
- it starts communication with connected instruments;
- it starts communication with the LIS, if present (LIS mode).

NOTE

LQS checks the available resources upon start up and regularly during the routine. If they are not enough, LQS cannot keep on working.

To display and process the data present in **LQS**, provide the enabled credentials via the login screen. To access, proceed as follows:

- click on the **Login** key;
- enter the **User Code** and **password** in the appropriate fields;



The screenshot shows a 'Login' dialog box with a close button (X) in the top right corner. It contains two input fields: 'User Code' and 'Password'. Below the fields are three buttons: 'Confirm', 'Cancel', and 'Change Password'.

- click on the **Confirm** key.

NOTE

When a new user first logs in, **LQS** requests the mandatory modification of the password.

LQS manages three access levels for credentials:

- *FSE*, Field Service Engineer, technical user code for access to the advanced configuration environments of **LQS**. The FSE user can add or eliminate other, non FSE level users. Is not visible in the **LQS** user list.
- *LabAdmin*, system administrator, can eliminate or add only LabUser level users. Has no access to the advanced configuration environments. Can manage QuantiFERON samples and accept samples, and runs basic configurations.
- *LabUser*, user. Can access QuantiFERON data and accept samples. Accesses the same environments as the LabAdmin user, but cannot manage users and cannot access configuration options.

NOTE

During installation, the DiaSorin FSE can configure the idle time beyond which **LQS** implements automatic logout. Logout does not entail instrument disconnection. This option can also be configured by a user with LabAdmin credentials.

3.1.2 Closing the application

To properly close the LQS, proceed as follows:

- Access menu **Available Operations**.
- Click on **Exit**.
- A window will warn that, upon closing, all data will be lost. Click on **OK** to continue closing **LQS**.

CAUTION

Data are saved in a temporary database upon closing the application all data are erased.

3 System description

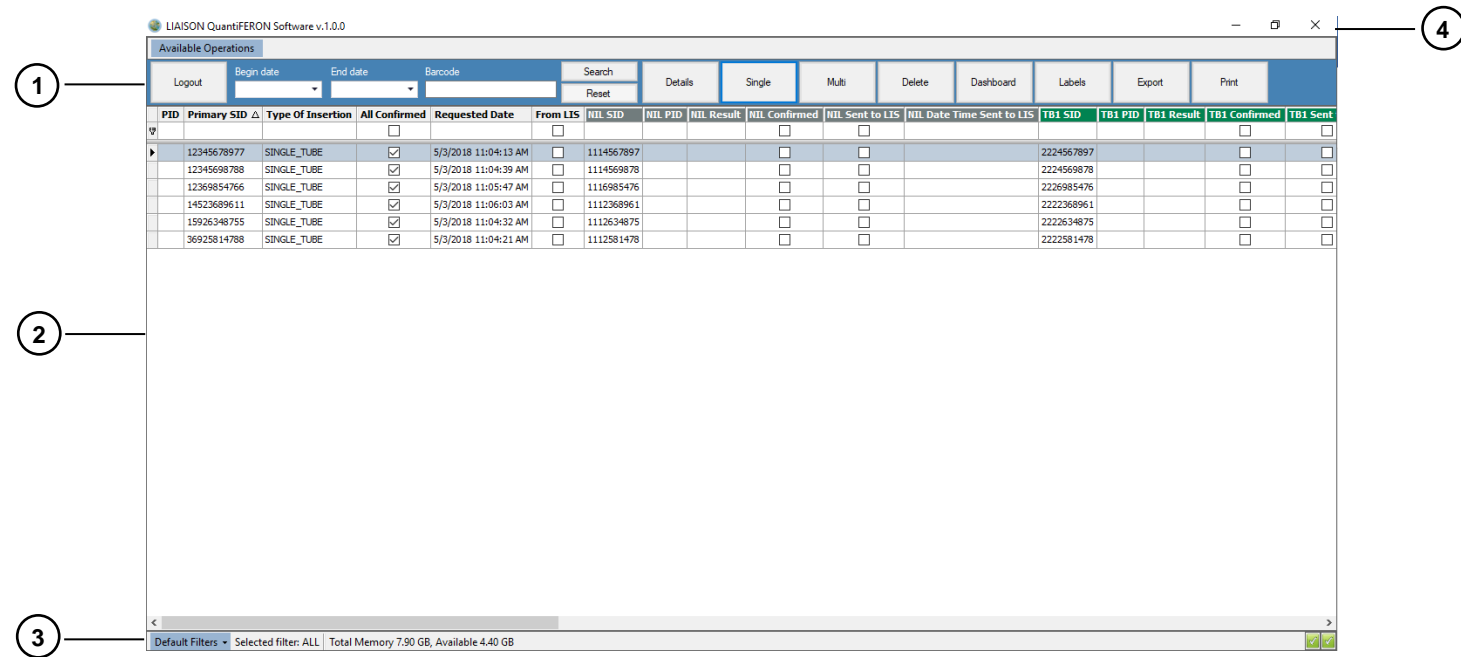
If there are data in the LQS database, a notice will appear on the screen before closing the application asking whether you wish to export the data. To export the data, proceed as follows:

- Click on **OK**.
- Choose the file name and the path where it should be saved.
- Confirm the operation.

NOTE

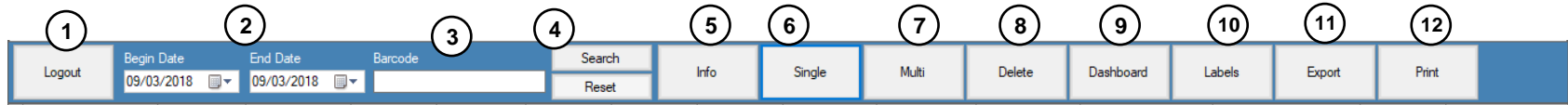
The data are exported to a CSV file; the file cannot be imported later.

3.1.3 User interface



- 1 toolbar to access all application functionalities
- 2 central screen used for displaying and processing QuantiFERON samples
- 3 status bar to access default filters to display the samples, indication of the status of the memory and devices, instruments and LIS connected to **LQS**
- 4 buttons to iconize, reduce window size and close the application.

3 System description



On the upper toolbar, there are the following buttons and functionalities:

- 1 **Login/Logout**, to Login or Logout of the application.
- 2 **Begin Date / End Date**: fields for setting the date ranges of the samples to display.
- 3 **Barcode**, field for searching for a sample using the barcode identifier.
- 4 **Search, Reset** to start the search in WorkList based on the fields set or to clear the fields set.
- 5 **Info**, to display the *result details* for the selected sample.
- 6 **Single**, to manually insert a sample in *Single Tube* mode.
- 7 **Multi**, to manually insert a sample in *Multi Tube* mode.
- 8 **Delete**, to delete the selected sample data.
- 9 **Dashboard**, to access the Dashboard to manage instrument/LIS connections.
- 10 **Labels**, to print the labels of selected sample data.
- 11 **Export**, to export the selected sample data to a CSV file.
- 12 **Print**, to print the selected sample data.

NOTE

This note regards the button 8, Delete. The samples deleted cannot be recovered. Therefore, you have to select accurately the sample data you want to delete.

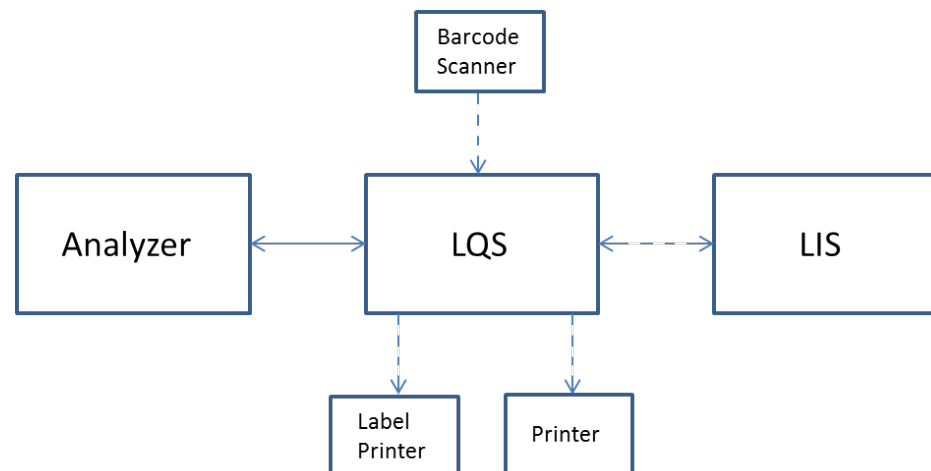
4 Operating Mode

LQS can be used in 2 operating modes:

- LIS mode.
- Stand-alone mode.

The operating mode of **LQS** is configured during installation.

4.1 LIS Mode



*Dashed connections are optional depending on operational mode

In LIS mode, **LQS** is between the LIS and the DiaSorin instruments. In this configuration **LQS** performs the following functions:

- It receives from LIS the programming of all samples to run and forwards it to connected instruments.
- If required, it assists the user in manually inserting and printing the barcode labels for the samples for which QuantiFERON is requested.
- For tests that are not part of the QuantiFERON panel, it forwards to LIS the results received from the instrument with no modifications.
- For the QuantiFERON tests, it acquires the intermediate results Nil, TB1, TB2 and Mitogen and if possible calculates their interpretation and sends the results to LIS.
- It forwards to LIS the results of the quality controls received from the connected instruments.

4.2 Stand-alone Mode

In Stand-alone mode, **LQS** is not connected to an LIS and the QuantiFERON samples must be manually inserted by the user. In this mode **LQS** performs the following functions:

- It assists the user when inserting the samples and enables the creation of their barcode labels (depending on the work mode used).
- It forwards the programming to connected instruments.
- It acquires the intermediate results of the QuantiFERON Nil, TB1, TB2 and Mitogen. If possible, it calculates their interpretation, allowing the user to display it.

CAUTION

It is necessary to pay the utmost care when inserting the acceptances in **LQS** to avoid incorrect assigning.

5 Sample Management

LQS manages the programming of all samples received from the LIS, behaving differently depending on whether the QuantiFERON test or other types of tests are requested.

The following chapters describe in detail the two management modes.

5.1 Sample tube without QuantiFERON assay management

In LIS Mode, for samples that do not involve running QuantiFERON tests, **LQS** behaves transparently between LIS and connected instruments, forwarding queries and results to the LIS and the sample programming to the instruments.

If **LQS** is configured in stand-alone mode, it ignores instrument queries and the results of samples that do not have QuantiFERON ordered, i.e. that were not previously inserted on LQS.

5.2 Sample tube with QuantiFERON assay management

Samples that need the QuantiFERON assay are inserted in **LQS** by receiving the programming from LIS or through manual acceptance in **LQS**.

LQS was developed to adapt to the various management modes used in most analysis laboratories.

It is possible to use and configure the following modes:

- Single tube, sample accepted with unique identifier (single sample tube or 4 single sample tubes with same barcode identifier). This tube will hereafter be called Primary tube.
- Family Loading, sample accepted with unique barcode for each of the 4 sample tubes. Sample tube identifier cannot be automatically associated with type of sample tube (no grouping criteria when assigning the barcode).

5 Sample Management

- Bulk Loading, sample accepted with unique barcode for each of the 4 sample tubes. The barcode identifier has a common part (referred to as “primary SID” below) for the sample but the variable part does not allow identifying the type of sample tube. In this mode, it is not necessary to acquire the samples of a family sequentially, therefore it can be applied when samples from multiple patients are received en bloc.
- Direct Loading, sample accepted with unique barcode for each of the 4 sample tubes. The barcode identifiers on the 4 sample tubes have a common part that identifies the sample and a variable part that uniquely identifies the type of sample tube.

The work modes single tube, family loading and bulk loading require manually inserting the acceptances in **LQS** before loading on the analyzers.

The Direct Loading mode is the only one that allows automatically managing the QuantiFERON samples without manually inserting the acceptances in **LQS**. The tubes can be directly loaded on the analyzer.

CAUTION

It is necessary to pay the utmost care when inserting the acceptances in **LQS** to avoid incorrect assigning.

NOTE

Configuring the common part of the barcode and the prefixes/suffixes associated with the type of sample tube must be done during installation by the DiaSorin FSE. Configuration must be agreed upon with the laboratory and signed by the latter.

NOTE

Any alphabetic characters used in barcode identifier must be uppercase in order to maintain the correspondence between how **LQS** and Analyzer acquire the same barcodes. **LQS** does not perform the upper - conversion as Analyzer does.

LQS calculates the interpretation of the intermediate results if they are performed within a time interval defined during the configuration. If this time interval is exceeded, **LQS** logs a warning signal and does not calculate the interpretation.

5.2.1 Single tube

Sample accepted with unique identifier (single sample tube or 4 single sample tubes with same barcode identifier).

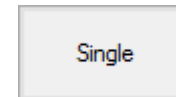
If *Single Tubes* mode is enabled, the user must manually insert the sample in **LQS** and generate the 4 barcodes to affix each on the sample tube corresponding to the sample type.

The work mode varies depending on the presence or otherwise of the LIS connection to **LQS**. The paragraphs below explain the 2 modes in detail.

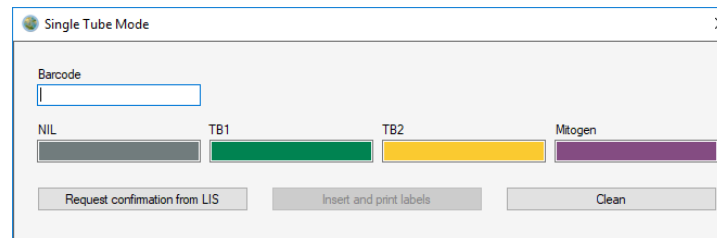
5.2.1.1 Single tube with LIS connection

To process a sample that must run the QuantiFERON assay with connection to the laboratory LIS, proceed as follows:

1. Access the *Single Tube mode* functionality from the main screen by clicking on **Single**.



2. Enter, or read using the optical reader, the sample identifier in the **Barcode** field and confirm.



3. **LQS** generates an identifier associated with each of the 4 types of sample required for running the QuantiFERON assay. Click on **Request Confirmation from LIS** to enable printing the barcode labels after positive confirmation from the LIS.

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NOTE

If there is no response from LIS within a set time, an alert message will appear for the user. Entry into the WorkList will be nonetheless enabled, so it is recommended to check that the identifier entered is correct.

NOTE

The request for confirmation from LIS is optional and can be configured during installation.

4. Confirm inserting the sample and print the labels by clicking on **Insert and print labels**.
 5. To cancel inserting the sample, click on **Clean**.
 6. Place the labels on the respective sample tubes, taking the utmost care in checking the type of sample tube.
-

CAUTION

When labeling the sample tubes with the barcode generated by **LQS** take the utmost care in ensuring the barcode corresponds to the type of sample tube. Incorrectly labeling the sample tubes compromises the interpretation of the results.

Requesting confirmation of the sample and sending the results to LIS can take place using various modes configured during installation. The modes that can be used are listed below:

- QuantIFERON to primary:
 - **LQS** sends the request for confirmation to LIS only for the primary tube, whose identifier can be viewed in the **Primary SID** field of the Worklist.
 - **LQS** sends to LIS only the interpretation of the QuantIFERON, associated with the identifier of the primary tube.
 - QuantIFERON to primary and intermediates:
 - **LQS** requests confirmation for each of the 4 sample tubes and the primary tube, sending a total of 5 queries.
 - **LQS** sends the interpretation of the QuantIFERON associated with the identifier of the primary tube.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.
-

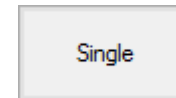
NOTE

The request modes confirm and send results to LIS, they must be configured during installation by the DiaSorin FSE.

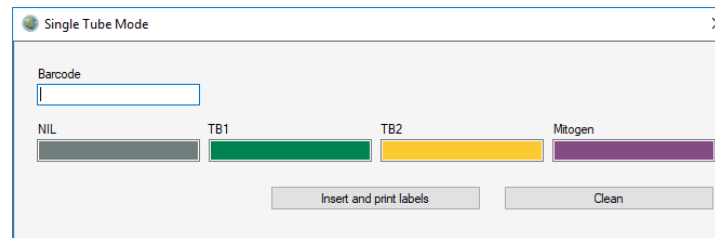
5.2.1.2 Single tube without LIS connection

To process a sample that must run the QuantiFERON assay without connection to the laboratory LIS, proceed as follows:

1. Access the Single Tube mode functionality from the main screen by clicking on **Single**.



2. Enter, or read using the optical reader, the sample identifier in the **Barcode** field and confirm.



3. **LQS** generates an identifier associated with each of the 4 types of sample required for running the QuantiFERON assay.
4. Confirm inserting the sample and print the labels by clicking on **Insert and print labels**.
5. To cancel inserting the sample, click on **Clean**.
6. Place the labels on the sample tubes you just inserted and load them on the connected instruments.

CAUTION

When labeling the sample tubes with the barcode generated by **LQS** take the utmost care in ensuring the barcode corresponds to the type of sample tube. Incorrectly labeling the sample tubes compromises the interpretation of the results.

5.2.2 Family Loading

Sample accepted with unique barcode for each of the 4 sample tubes. Sample tube identifier cannot be automatically associated with type of sample tube (no grouping criteria when assigning the barcode).

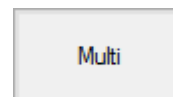
If using the *Family Loading* mode for running samples with QuantiFERON assay, it is necessary to manually insert the samples in LQS before processing them on the instruments.

The work mode varies depending on the presence or otherwise of the LIS connection. The paragraphs below explain the 2 modes in detail.

5.2.2.1 Family Loading with LIS connection

Using the Family loading mode with LIS connection, to insert and process a QuantiFERON sample, proceed as follows:

1. Access the Family loading functionality from the main screen by clicking on **Multi**.



2. Enter, or read using the optical reader, the identifier of each sample type following the order shown on the screen:

- NIL
- TB1
- TB2
- Mitogen

A screenshot of the "Family Loading" software window. The window title is "Family Loading" with a close button (X) in the top right corner. Below the title bar, there are four input fields corresponding to sample types: "NIL" (with a text input field), "TB1" (with a green bar), "TB2" (with a yellow bar), and "Mitogen" (with a purple bar). At the bottom of the window, there are three buttons: "Request confirmation from LIS", "Insert in archive", and "Clean".

NOTE

Confirm each barcode entered with **Enter** if manually typed. Take the utmost care in ensuring the barcode corresponds to the right type of sample tube. An incorrect attribution can compromise the interpretation of the results.

3. Click on **Request confirmation from LIS**, to check the samples have been inserted correctly. In case the sample is not confirmed by LIS **LQS** shows an error message.

NOTE

The request for confirmation from LIS is optional and configured during installation. If not enabled, **Request confirmation from LIS** is not enabled. Therefore, you can proceed directly with inserting in the archive.

NOTE

If there is no response from LIS within a set time, an alert message will appear for the user. Entry into the Worklist will be nonetheless enabled, so it is recommended to check that the identifier entered is correct.

4. Confirm inserting the sample by clicking on **Insert in archive**.
5. To cancel inserting the sample, click on **Clean**.
6. Load the sample tubes you just inserted on the connected instruments.

Requesting confirmation of the sample and sending the results to LIS can take place using various modes configured during installation. The modes that can be used are listed below:

- QuantiFERON to 4 barcodes:
 - **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
- QuantiFERON to 4 barcodes and intermediates:
 - **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.

- QuantiFERON to Master:
 - **LQS** sends the request for confirmation to LIS only for the intermediate sample tube defined as Master tube during the initial configuration.
 - **LQS** sends to LIS only the interpretation of the QuantiFERON, associated with the identifier of the Master sample tube.
- QuantiFERON to Master and intermediates:
 - **LQS** sends the request for confirmation to LIS for all 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON, associated with the identifier of the Master sample tube.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.

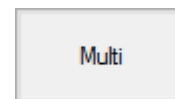
NOTE

The request modes confirm and send results to LIS, they are configured during installation by the DiaSorin FSE.

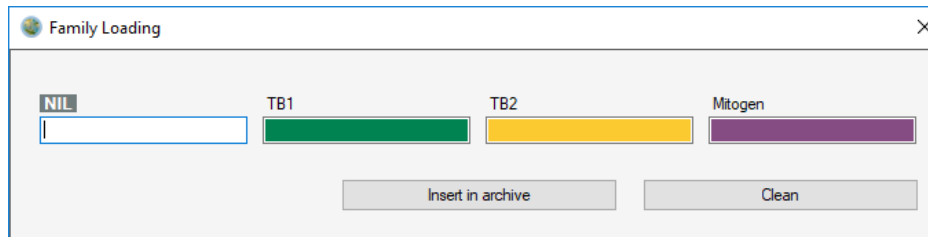
5.2.2.2 Family Loading without LIS connection

If the Family Loading mode is enabled without LIS connection, to insert and process a QuantiFERON sample, proceed as follows:

1. Access the *Family loading* functionality from the main screen by clicking on **Multi**.



2. Enter, or read using the optical reader, the identifier of each sample type following the order shown on the screen:
 - NIL
 - TB1
 - TB2
 - Mitogen



The screenshot shows a software window titled "Family Loading" with a close button (X) in the top right corner. Inside the window, there are four input fields arranged horizontally, each with a label above it: "NIL" (white background), "TB1" (green background), "TB2" (yellow background), and "Mitogen" (purple background). Below these fields are two buttons: "Insert in archive" and "Clean".

NOTE

Confirm each barcode entered with **Enter** if manually typed. Take the utmost care in ensuring the barcode corresponds to the right type of sample tube. An incorrect attribution can compromise the interpretation of the results.

3. Confirm inserting the sample by clicking on **Insert in archive**.
4. To cancel inserting the sample, click on **Clean**.
5. Load the sample tubes you just inserted on the connected instruments.

NOTE

Once a sample has been inserted, **LQS** is ready for the next one.

5.2.3 Bulk Loading

Sample accepted with unique barcode for each of the 4 sample tubes. The barcode identifier has a common part for the sample but the variable part does not allow identifying the type of sample tube. In this mode, it is not necessary to acquire the samples of a family sequentially therefore it can be applied when samples from multiple patients are received en bloc.

If using the *Bulk Loading* mode for running samples with QuantiFERON assay, it is necessary to manually insert the samples in LQS before processing them on the instruments.

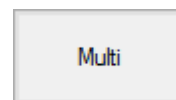
The work mode varies depending on the presence or otherwise of the LIS connection. The paragraphs below explain the 2 modes in detail.

In both modes, once new samples have been inserted, LQS checks whether there are samples for which sample tubes to complete the family are missing and displays an error message.

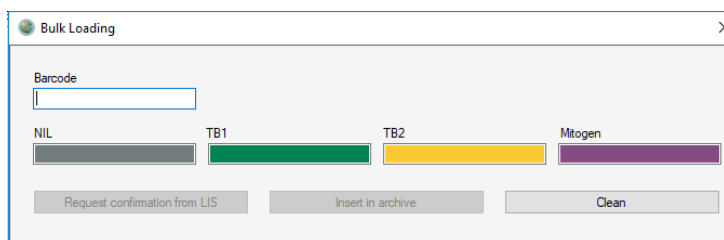
5.2.3.1 Bulk Loading with LIS connection

Using the Bulk loading mode with LIS connection, to insert and process a QuantiFERON sample, proceed as follows:

1. Access the *Bulk Loading* functionality from the main screen by clicking on **Multi**.



2. Enter, or read using the optical reader, one sample identifier at a time, selecting the corresponding sample type before reading the next one.



NOTE

Confirm each barcode entered with **Enter** if manually typed.

NOTE

If in the archive there are already barcodes belonging to the sample done, **LQS** will display them in the box for the corresponding sample tube type.

3. Click on **Request confirmation from LIS**, to check the samples have been inserted correctly. In case the sample is not confirmed by LIS **LQS** shows an error message.

NOTE

If there is no response from LIS within a set time, an alert message will appear for the user. Entry into the Worklist will be nonetheless enabled, so it is recommended to check that the identifier entered is correct.

NOTE

The request for LIS confirmation is optional and can be configured during installation.

4. Confirm inserting the sample by clicking on **Insert in archive**.
5. To cancel inserting the sample, click on **Clean**.
6. Load the sample tubes you just inserted on the connected instruments.

NOTE

Once a sample has been inserted, **LQS** is ready for the next one. If, when closing the insert form, there are still samples without all the associated sample tubes, **LQS** shows an alert notice.

Requesting confirmation of the sample and sending the results to LIS take place according to the modes listed below:

- *QuantiFERON to 4 barcodes:*

- **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
- **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
- *QuantiFERON to 4 barcodes and intermediates:*
 - **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.
- *QuantiFERON to Master:*
 - **LQS** sends the request for confirmation to LIS only for the intermediate sample tube defined as *Master tube* during the initial configuration.
 - **LQS** sends to LIS only the interpretation of the QuantiFERON, associated with the identifier of the Master sample tube.
- *QuantiFERON to Master and intermediates:*
 - **LQS** sends the request for confirmation to LIS for all 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON, associated with the identifier of the Master sample tube.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.
- *QuantiFERON to common part:*
 - **LQS** sends the request for confirmation to LIS only for the *primary SID*.
 - **LQS** sends to LIS only the interpretation of the QuantiFERON, associated with the primary SID.
- *QuantiFERON to common part and intermediates:*
 - **LQS** sends the request for confirmation to LIS for both the *primary SID* and each of the 4 sample tubes, for a total of 5 queries.
 - **LQS** sends to LIS the interpretation of the QuantiFERON, associated with the *primary SID*.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.

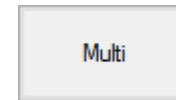
NOTE

The request modes confirm and send results to LIS, they must be configured during installation by the DiaSorin FSE.

5.2.3.2 Bulk Loading without LIS connection

If the Bulk Loading mode is enabled without LIS connection, to insert and process a QuantiFERON sample, proceed as follows:

1. Access the *Bulk Loading* functionality from the main screen by clicking on **Multi**.



2. Enter, or read using the optical reader, one sample identifier at a time, selecting the corresponding sample type before reading the next one.

A screenshot of a software dialog box titled "Bulk Loading". It features a "Barcode" input field at the top. Below it are four sample type buttons: "NIL" (grey), "TB1" (green), "TB2" (yellow), and "Mitogen" (purple). At the bottom of the dialog are two buttons: "Insert in archive" and "Clean".

NOTE

Confirm each barcode entered with **Enter** if manually typed.

NOTE

If in the archive there are already barcodes belonging to the sample done, **LQS** will display them in the box for the corresponding sample tube type.

3. Confirm inserting the sample by clicking on **Insert in archive**.
4. To cancel inserting the sample, click on **Clean**.
5. Load the sample tubes you just inserted on the connected instruments.

NOTE

Once a sample has been inserted, **LQS** is ready for the next one. If, when closing the insert form, there are still

samples without all the associated sample tubes, LQS shows an alert notice.

5.2.4 Direct Loading

Sample accepted with unique barcode for each of the 4 sample tubes. The barcode identifiers on the 4 sample tubes have a common part that identifies the sample and a variable part that uniquely identifies the type of sample tube.

If Direct Loading mode is enabled, **LQS** automatically recognizes the type of sample tube. There is no need for the user to intervene for processing the sample, other than loading the sample tubes on the connected instruments.

LQS nonetheless allows manually inserting the samples, but only in *Single Loading* mode (disabled **Multi** button).

Confirming the sample and sending the results to LIS take place according to the modes listed below:

- *QuantiFERON to 4 barcodes:*
 - **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
- *QuantiFERON to 4 barcodes and intermediates:*
 - **LQS** sends the request for confirmation to LIS for each of the 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON for each of the 4 sample tubes.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.
- *QuantiFERON to Master and intermediates:*
 - **LQS** sends the request for confirmation to LIS for all 4 sample tubes.
 - **LQS** sends to LIS the interpretation of the QuantiFERON, associated with the identifier of the Master sample tube.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.
- *QuantiFERON to common part and intermediates:*
 - **LQS** sends the request for confirmation to LIS for both the *primary SID* and each of the 4 sample tubes, for a total of 5 queries.
 - **LQS** sends to LIS the interpretation of the QuantiFERON, associated with the *primary SID*.
 - **LQS** sends to LIS the intermediate results, each associated with the barcode of the corresponding sample tube.



NOTE

The request modes confirm and send results to LIS, they must be configured during installation by the DiaSorin FSE.

6 General functionalities

LQS regardless of the operating mode configured, provides a series of functionalities to facilitate managing the QuantiFERON samples, discussed in the following paragraphs.

6.1 WorkList

After login, the Worklist of only the samples for which the QuantiFERON interpretation has been requested is immediately presented.

PID	Primary SID	Type Of Insertion	All Confirmed	Requested Date	From LIS	NIL SID	NIL PID	NIL Result	NIL Confirmed	NIL Sent to LIS	NIL Date Time Sent to LIS	TB1 SID	TB1 PID	TB1 Result	TB1 Confirmed	TB1 Sent
1234567897		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:04:13 AM	<input type="checkbox"/>	1114567897			<input type="checkbox"/>	<input type="checkbox"/>		2224567897			<input type="checkbox"/>	<input type="checkbox"/>
1234569878		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:04:39 AM	<input type="checkbox"/>	1114569878			<input type="checkbox"/>	<input type="checkbox"/>		2224569878			<input type="checkbox"/>	<input type="checkbox"/>
1236985476		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:05:47 AM	<input type="checkbox"/>	1116985476			<input type="checkbox"/>	<input type="checkbox"/>		2226985476			<input type="checkbox"/>	<input type="checkbox"/>
1452368961		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:06:03 AM	<input type="checkbox"/>	1112368961			<input type="checkbox"/>	<input type="checkbox"/>		2222368961			<input type="checkbox"/>	<input type="checkbox"/>
1592634875		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:04:32 AM	<input type="checkbox"/>	1112634875			<input type="checkbox"/>	<input type="checkbox"/>		2222634875			<input type="checkbox"/>	<input type="checkbox"/>
3692581478		SINGLE_TUBE	<input checked="" type="checkbox"/>	5/3/2018 11:04:21 AM	<input type="checkbox"/>	1112581478			<input type="checkbox"/>	<input type="checkbox"/>		2222581478			<input type="checkbox"/>	<input type="checkbox"/>

Default Filters Selected filter: ALL Total Memory 7.90 GB, Available 4.40 GB

In this environment, the following fields are displayed by default, for each sample:

Field	Description
Type of Insertion	Indicates the type of insertion used (Single mode, family loading, bulk loading or direct loading)
All Confirmed	Indicates whether the sample was confirmed by LIS
Requested Date	Date QuantiFERON request was received
PID	Patient identifier code
Primary SID	Primary sample identifier
From LIS	Indicates whether the sample was manually inserted or received from LIS
Nil SID	Nil sample tube identifier
Nil Result	Result received for the Nil sample tube
NIL Confirmed	Indicates whether the Nil sample tube was confirmed by LIS
Nil Date Time	Date and time of the test
Nil Unit Measure	Nil test unit of measurement
TB1 SID	TB1 sample tube identifier
TB1 Result	Result received for the TB1 sample tube
TB1 Confirmed	Indicates whether the TB1 test was confirmed by LIS
TB1 Date Time	Date and time of the test
TB1 Unit Measure	TB1 test unit of measurement
TB2 SID	TB2 sample tube identifier
TB2 Result	Result received for the TB2 sample tube
TB2 Confirmed	Indicates whether the TB2 test was confirmed by LIS

TB2 Date Time	Date and time of the test
TB2 Unit Measure	TB2 test unit of measurement
Mitogen SID	Mitogen sample tube identifier
Mitogen Result	Result received for the Mitogen sample tube
Mitogen Confirmed	Indicates whether the Mitogen test was confirmed by LIS
Mitogen Date Time	Date and time of the test
Mitogen Unit Measure	Mitogen test unit of measurement
QuantiFERON Result	Result of interpretation calculated by LQS of the intermediate results
QuantiFERON Date Time Calculation	Date and time of the QuantiFERON calculation

The WorkList display can be customized, and it is possible to add or hide information depending on the user's needs. In addition to the default display fields described above, it is possible to display the fields below:

Field	Description
Nil PID	Patient identifier associated with the Nil sample tube
Nil Sent to LIS	Indicates whether the result of the Nil sample tube was sent to LIS
Nil Flags Instrumental	Flags received from the instrument associated with the Nil result
Nil Status	Result status flags (F Final Result, S Partial Result, X Work not executable, R result retransmitted, C Correct result, Q Result sent upon request)
Nil Date Time Sent to LIS	Indicates the date and time the result was sent to LIS
Nil Analyzer	Instrument on which the Nil test was run
Nil Kit No.	Kit number that ran the Nil test
Nil Lot No.	Lot number of the Nil reagent

6 General functionalities

Nil Integral Expiration Date	Expiration date of the Nil reagent
Nil Calibration ID	Nil calibrator identifier
Nil Sample Lane Number	Lane number on which the Nil sample tube rack was loaded
Nil Sample Tube Position	Nil sample tube position in the rack
TB1 PID	Patient identifier associated with the TB1 sample tube
TB1 Sent to LIS	Indicates whether the TB1 test result was sent to LIS
TB1 Flags Instrumental	flags received from the instrument associated with the TB1 result
TB1 Status	Result status flags (F Final Result, S Partial Result, X Work not executable, R result retransmitted, C Correct result, Q Result sent upon request)
TB1 Date Time Sent to LIS	Indicates the date and time the result was sent to LIS
TB1 Analyzer	Instrument on which the TB1 test was run
TB1 Kit No.	Kit number that ran the TB1 test
TB1 Lot No.	Lot number of the TB1 reagent
TB1 Integral Expiration Date	Expiration date of the TB1 reagent
TB1 Calibration ID	TB1 calibrator identifier
TB1 Sample Lane Number	Lane number on which the TB1 sample tube rack was loaded
TB1 Sample Tube Position	TB1 sample tube position in the rack
TB2 PID	Patient identifier associated with the TB2 sample tube

TB2 Sent to LIS	Indicates whether the TB2 test result was sent to LIS
TB2 Flags Instrumental	Flags received from the instrument associated with the TB2 result
TB2_Status	Result status flags (F Final Result, S Partial Result, X Work not executable, R result retransmitted, C Correct result, Q Result sent upon request)
TB2 Date Time Sent to LIS	Indicates the date and time the result was sent to LIS
TB2 Analyzer	Instrument on which the TB2 test was run
TB2 Kit No.	Kit number that ran the TB2 test
TB2 Lot. No.	Lot number of the TB2 reagent
TB2 Integral Expiration Date	Expiration date of the TB2 reagent
TB2 Calibration ID	TB2 calibrator identifier
TB2 Sample Lane Number	Lane number on which the TB2 sample tube rack was loaded
TB2 Sample Tube Position	TB2 sample tube position in the rack
Mitogen PID	Patient identifier associated with the Mitogen sample tube
Mitogen Sent to LIS	Indicates whether the result of the Mitogen sample tube was sent to LIS
Mitogen Flags Instrumental	Flags received from the instrument associated with the Mitogen result
Mitogen Status	Result status flags (F Final Result, S Partial Result, X Work not executable, R result retransmitted, C Correct result, Q Result sent upon request)
Mitogen Date Time Sent to LIS	Indicates the date and time the result was sent to LIS
Mitogen Analyzer	Instrument on which the Mitogen test was run

6 General functionalities

Mitogen Kit No.	Kit number that ran the Mitogen test
Mitogen Lot. No.	Lot number of the Mitogen reagent
Mitogen Integral Expiration Date	Expiration date of the Mitogen reagent
Mitogen Calibration ID	Mitogen calibrator identifier
Mitogen Sample Lane Number	Lane number on which the Mitogen sample tube rack was loaded
Mitogen Sample Tube Position	Mitogen sample tube position in the rack
QuantiFERON Result Received	Interpretation result of the 4 intermediate components
QuantiFERON Time Between Result	Time elapsed since receipt of first intermediate result until receipt of the last
QuantiFERON Date Time Sent to LIS	Date and time the QuantiFERON was sent to LIS
QuantiFERON Sent to LIS	Indicates whether the result of the QuantiFERON was sent to LIS
QuantiFERON Error	Signal for any errors in the calculation of the interpretation of the intermediate results

For each of the fields displayed in the Worklist, it is possible to apply the sort function, by clicking on the headline of the field itself.

NOTE

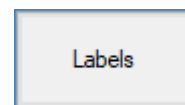
Configuring the fields displayed in the Worklist can only be done by the DiaSorin FSE.

6.2 Barcode label printing

In the main toolbar of **LQS**, there is a button to print the barcode labels for the samples present in the Worklist.

To print the barcode labels, proceed as follows:

- Select in the Worklist the sample(s) for which you wish to print the labels.
- Click on **Labels**, in the toolbar at the top.



- **LQS** will send the print command to the barcode printer connected during installation.

6.3 Managing results

In the event the user decides to reload the sample tubes for which there are already intermediate results on the instrument or these are not valid for the calculation of the QuantiFERON, **LQS** can manage the instrument query and update the user interface with the new results.

NOTE

The criteria to manage repeats can be configured and enabled only by the DiaSorin FSE, during installation of the **LQS**.

6.3.1 Managing Reload

If you wish to reload a sample on the analyzer for the QuantiFERON test, simply proceed as follows:

- Reload the sample tubes for which you wish to repeat the test on the instrument.
- After reading the barcode, the instrument triggers the query to **LQS**.
- In LIS Mode, **LQS** forwards the query to LIS and waits to receive the programming.
- **LQS** sends the programming to the instrument and waits to receive the results.

6.3.2 Managing Query all

If in LIS Mode, the operator requests via the analyzer the test order to LIS via function “Query all”, LQS will proceed as follows:

- Forwards queries to LIS.
- LQS receives the orders from LIS and forwards to the analyzer only the test orders that differ from the QuantiFERON.

6.3.3 Managing repeated tests

If the management of repeated results is enabled, LQS will behave in the following way:

- If LQS receives the results within a set time, these will overwrite the previous ones and used to recalculate the QuantiFERON. Otherwise, LQS rejects the results just received.
- In LIS Mode, the new results are forwarded to LIS.

6.3.4 Managing failed tests

When the intermediate results are not all valid for calculating the QuantiFERON, the latter will have a value of ‘FAILED’.

To repeat the samples, it is necessary to reload the sample tubes on the instrument. If the management of failed results is enabled, LQS will behave in the following way:

- If LQS receives a valid result for each failed result within the set time, these will overwrite the previous ones and be used to recalculate the interpretation of the QuantiFERON. If not, LQS rejects the results just received and sets the value of the QuantiFERON as ‘FAILED’.
- In LIS Mode, the new results are forwarded to LIS.

6.4 Filters and search

LQS provides various features for filtering and searching within the WorkList, to enable checking the status of the routine.

To apply one of the LQS default filters, proceed as follows:

1. Click on **Default Filters**, in the status bar at the bottom of the WorkList.

Default Filters ▾



2. Choose which filter to apply from the following list:

- *Samples with missing sample tubes;*
- *Samples with sample tubes awaiting confirmation from LIS;*
- *Complete samples (with all sample tubes present and confirmed);*
- *Complete samples with at least one result;*
- *Complete samples with QuantiFERON calculated;*
- *Complete samples with QuantiFERON not calculated due to the presence of errors;*
- *Complete samples with at least one result sent to LIS;*
- *Complete samples with QuantiFERON calculated and sent to LIS;*
- *All.*

The default filter applied to the list is *All*.

To search for a sample within a set period, proceed as follows:

1. In the upper toolbar of **LQS**, enter the dates of interest in the appropriate calendar fields **Begin Date** and **End Date**.

Begin Date	End Date
09/03/2018 	09/03/2018 

2. Click on **Search**.

Search

3. The list of samples searched will appear.

4. To cancel the operation, click on **Reset**, all the samples of the current date will be displayed again.

If you wish to search for a specific barcode within the WorkList, proceed as follows.

1. Enter the barcode for the sample to search in the WorkList, in the field **Barcode**.



2. Click on **Search**.
3. The list of samples searched will appear.
4. To cancel the operation, click on **Reset**.

There is also a filter function for each of the columns in the WorkList. To use it, proceed as follows:

1. Enter the data to search in the search field, located under the headline of the column you are interested in. **LQS** filters the WorkList dynamically depending on the search key entered.
2. To cancel the operation, simply delete the data entered in the search field.

NOTE

When logging out of the application, all filters applied are reset.

Once the samples of interest are filtered, **LQS** allows sorting them in ascending/descending order:


1. Click on the title of the desired field.
2. An arrow pointing upwards will appear, next to the title of the field selected. By clicking a second time, the arrow will point in the opposite direction.

LQS will sort the samples as shown in the table below:



Arrow pointing upwards

All entries are sorted from 0 to 9 or A to Z

 Arrow pointing downwards All entries are sorted from 9 to 0 or A to Z

6.5 Export and print data

LQS enables exporting to a CSV file the list of samples in the WorkList. The export is subject to the filters applied to the Worklist.

To run the export, proceed as follows:

1. Filter the WorkList in order to display the desired samples.
2. Select the sample data to export.
3. Click on **Export**, in the toolbar at the top.

A rectangular button with a light gray background and a thin border, containing the word "Export" in a dark gray sans-serif font.

4. When asked to confirm the export, click on **OK**.
5. Specify the path in which to save the export file and rename the file, if necessary. Confirm the operation.

LQS also provides a button to print the Worklist. To print the Worklist, proceed as follows:

1. Filter the Worklist to display the desired samples.
2. Select the filtered samples.
3. Click on **Print**, in the toolbar at the top. Click on **OK** when asked to confirm.

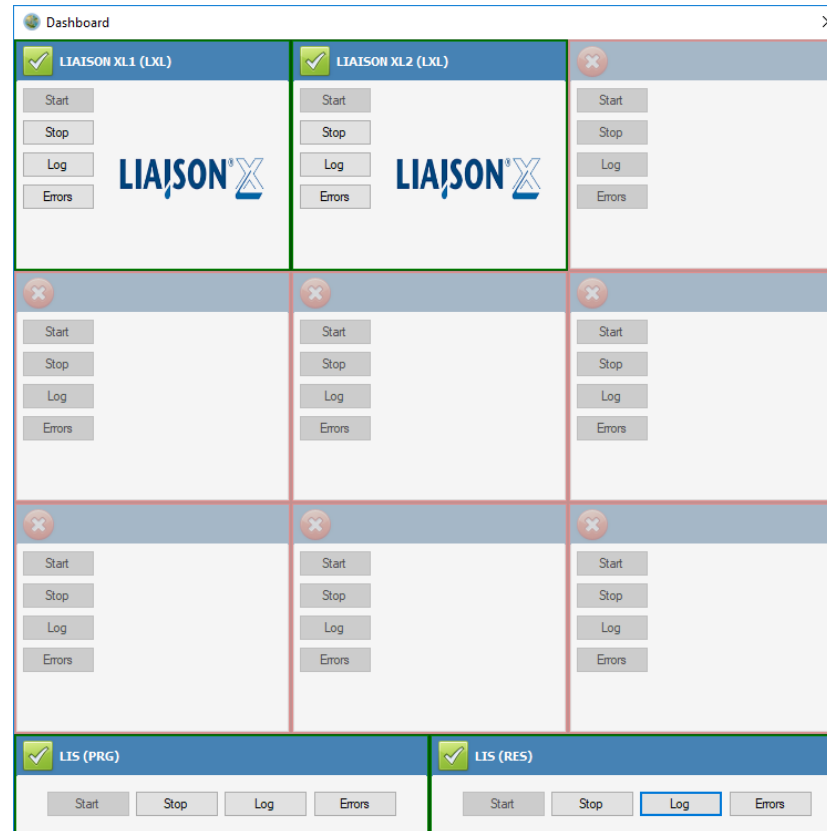
A rectangular button with a light gray background and a thin border, containing the word "Print" in a dark gray sans-serif font.

NOTE


Only the authorized DiaSorin FSE is allowed to configure the export and print format.

6.6 Dashboard



LQS offers the possibility of displaying the status of connected devices through a graphic interface, as shown in the figure, accessible from the **Dashboard** button in the top toolbar:



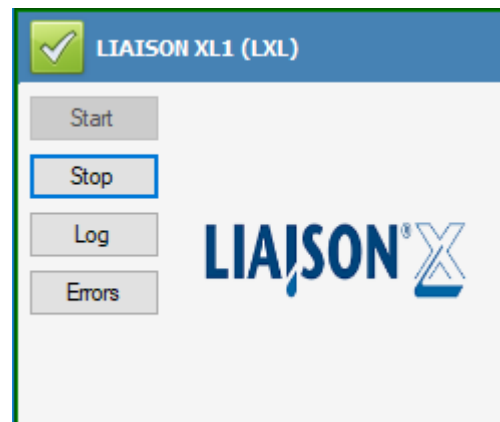
For each of the interfaced instruments, the type and status of the connection is displayed. The latter is marked with the symbols listed in the table below:

Symbol	Description
	Connected instrument

6 General functionalities

	Disconnected instrument
	Presence of instrument error

To operate on the instrument connections, use the buttons on the side toolbar of each instrument:



Function	Description
Start	activates communication with the selected instrument
Stop	disconnects the selected instrument
Log	opens the window displaying the communication logs with the selected instrument
Errors	opens a window with the list of communication errors

LQS permanently stores both logs and instrument errors. By filtering the data from the appropriate calendar fields, located in the toolbar of the display window, and clicking on the **Search** button, you can select those for the period of interest alone.

In The following tables the List of error Code.

Error Code	Description
CON001	Error in LIS or Instrument communication (e.g., Timeout, NAK).
CON002	Error in QuantiFERON calculation (e.g., Failed result timeout expired, Failed results management disabled, Repetition timeout expired, Repetition management disabled, Error occurred during the receiving of the results).
CON003	The instrument has required a not confirmed sample.

NOTE

Only authorized users can view the log files with non-encrypted sensitive data.

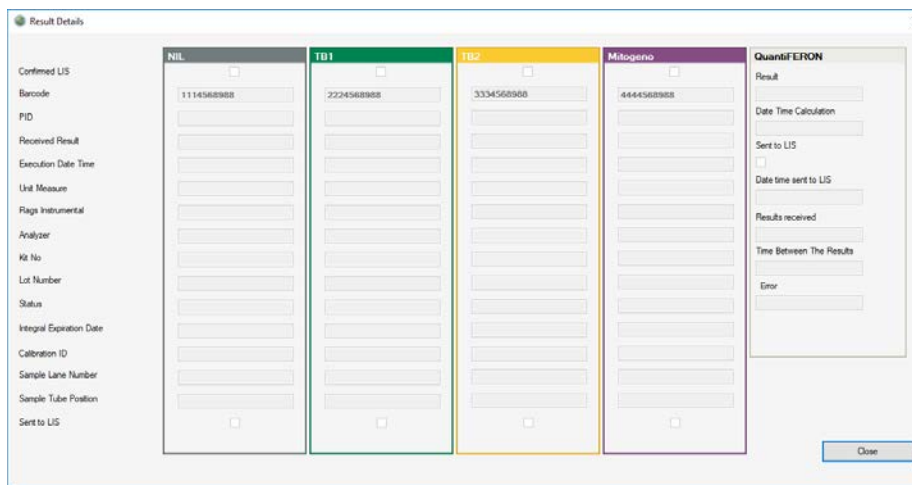
NOTE

After opening the window displaying the instrument errors, **LQS** resets these errors and returns the instrument to connected status (green checkbox).

6.7 Information and traceability

LQS enables displaying the traceability information for samples for which the QuantiFERON was requested.

To access this, after selecting the sample in the Worklist, click on **Details** in the upper toolbar of **LQS**. The following screen will open:



The information that can be accessed from the traceability environment, for each type of sample tube associated with a certain sample, are the following;

Field	Description
Confirmed LIS	Reports receipt of confirmation from LIS with a flag
SID	Sample tube identifier
PID	Patient identifier
Received Result	Sample tube result
Execution Date Time	Date and time of the test
Unit Measure	Unit of measurement assigned
Flags Instrumental	Error flags received from the instrument
Analyzer	Instrument that made the measurement
Kit No.	Kit number for the reagent

Lot. No.	Lot number
Status	Result status flags (F Final Result, S Partial Result, X Work not executable, R result retransmitted, C Correct result, Q Result sent upon request)
Integral Expiration Date	Expiration of each reagent lot
Calibration ID	Calibrator ID
Sample Lane Number	Rack number on which the sample tubes were loaded
Sample Tube Position	Position in the rack for each sample tube
Sent to LIS	Reports sending the intermediate results to LIS
Result	Result of interpretation calculated by LQS of the intermediate results
Date Time calculation	Date and time of the QuantiFERON result calculation
Date Time Sent To LIS	Date and time the QuantiFERON result was sent to LIS
Results Received	Results of the intermediate components received
Time between the results	Time elapsed between receipt of the first and last result of the intermediate components
Error	Calculation errors

LQS logs all system events, such as entering/deleting samples and changes made to the general configuration. Each event is associated with the identifier of the user that triggered it. Additionally, **LQS** traces login and logout events for each user.

To access *System Log* or *Access Log*, proceed as follows:

1. Click on **Available Operations** on top left.

Available Operations

2. From the drop-down menu, select **System Log** or **Access Log**. A window will open with a list of the events logged by **LQS**.

Date/Time	User Code	Operation	Description
4/19/2018 11:47:52 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000007 [NLI: 1118000007 TB1: TB2: Mitogen:
4/19/2018 11:47:44 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000006 [NLI: 1118000006 TB1: 2228000006 TB2: 3338000006 Mitogen: 4448000006
4/19/2018 11:47:40 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000006 [NLI: 1118000006 TB1: 2228000006 TB2: 3338000006 Mitogen:
4/19/2018 11:47:36 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000006 [NLI: 1118000006 TB1: 2228000006 TB2: Mitogen:
4/19/2018 11:47:32 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000006 [NLI: 1118000006 TB1: TB2: Mitogen:
4/19/2018 11:47:24 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000005 [NLI: 1118000005 TB1: 2228000005 TB2: 3338000005 Mitogen: 4448000005
4/19/2018 11:47:20 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000005 [NLI: 1118000005 TB1: 2228000005 TB2: 3338000005 Mitogen:
4/19/2018 11:47:15 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000005 [NLI: 1118000005 TB1: 2228000005 TB2: Mitogen:
4/19/2018 11:47:11 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000005 [NLI: 1118000005 TB1: TB2: Mitogen:
4/19/2018 11:47:02 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000004 [NLI: 1118000004 TB1: 2228000004 TB2: 3338000004 Mitogen: 4448000004
4/19/2018 11:46:58 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000004 [NLI: 1118000004 TB1: 2228000004 TB2: 3338000004 Mitogen:
4/19/2018 11:46:53 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000004 [NLI: 1118000004 TB1: 2228000004 TB2: Mitogen:
4/19/2018 11:46:49 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000004 [NLI: 1118000004 TB1: TB2: Mitogen:
4/19/2018 11:46:38 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000003 [NLI: 1118000003 TB1: 2228000003 TB2: 3338000003 Mitogen: 4448000003
4/19/2018 11:46:34 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000003 [NLI: 1118000003 TB1: 2228000003 TB2: 3338000003 Mitogen:
4/19/2018 11:46:31 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000003 [NLI: 1118000003 TB1: 2228000003 TB2: Mitogen:
4/19/2018 11:46:27 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000003 [NLI: 1118000003 TB1: TB2: Mitogen:
4/19/2018 11:46:19 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000002 [NLI: 1118000002 TB1: 2228000002 TB2: 3338000002 Mitogen: 4448000002
4/19/2018 11:45:54 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000002 [NLI: 1118000002 TB1: 2228000002 TB2: 3338000002 Mitogen:
4/19/2018 11:45:50 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000002 [NLI: 1118000002 TB1: 2228000002 TB2: Mitogen:
4/19/2018 11:45:45 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000002 [NLI: 1118000002 TB1: TB2: Mitogen:
4/19/2018 11:45:37 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000001 [NLI: 1118000001 TB1: 2228000001 TB2: 3338000001 Mitogen: 4448000001
4/19/2018 11:45:31 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000001 [NLI: 1118000001 TB1: 2228000001 TB2: 3338000001 Mitogen:
4/19/2018 11:45:26 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000001 [NLI: 1118000001 TB1: 2228000001 TB2: Mitogen:
4/19/2018 11:45:07 PM	diasorinRD	Insertion of samples: Bulk Loading	Barcode: 8000001 [NLI: 1118000001 TB1: TB2: Mitogen:
4/19/2018 11:44:30 PM	diasorinRD	Save General Configuration	Updating general configuration
4/19/2018 11:44:30 PM	diasorinRD	Save General Configuration	Multitubes old value: Family>Loading new value: Bulk>Loading

- Use the calendar fields to select the period of interest and click on **Search**. A list with just the events from the period of interest will appear, with respective user.

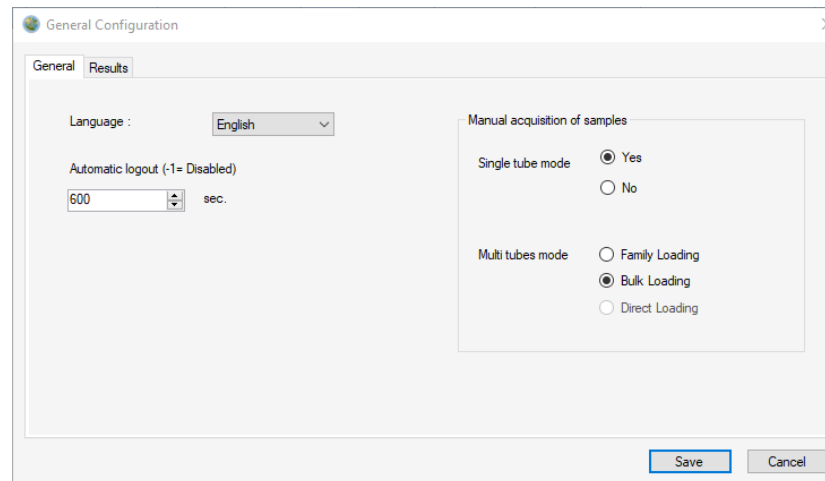
NOTE

The time in which the logs will remain in memory can only be configured by the DiaSorin FSE during installation.

7 Configuration

The user with administrative privileges (LabAdmin) can access a part of the configuration of some features in [LQS](#).

7.1 General Configuration



To access general configuration, proceed as follows:

1. Click on [Available Operations](#).

2. From the menu, select **General Configuration**.

7.1.1 Display language

From **General Configuration** in **LQS** it is possible to change the display language. Proceed as follows:

1. From the drop-down menu **Language**, select the desired language.
2. Click on **Save** to make the update effective.

NOTE

Changing the display language can be done without restarting the application.

7.1.2 Manual sample acquisition

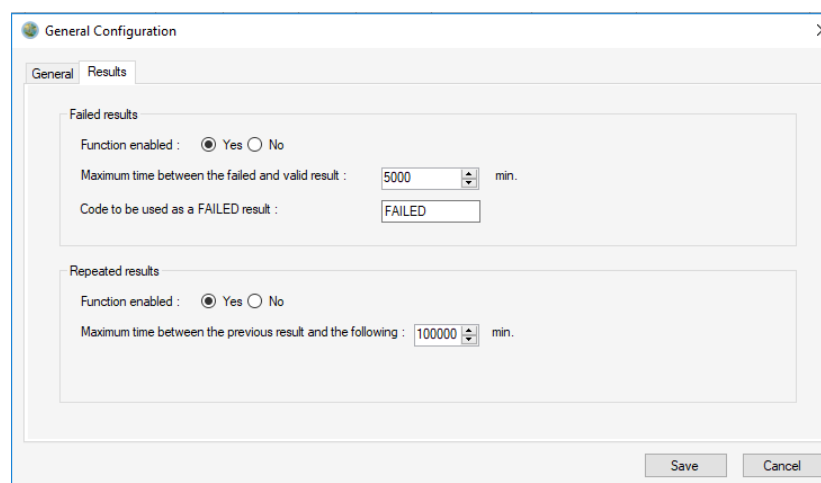
From **General Configuration** in **LQS** it is possible to change the manual acquisition mode of QuantiFERON samples. Proceed as follows:

1. In Single tube mode, select if enable or disable the option selecting:
 - **Yes**
 - **No**
2. In Multi tubes Mode, select the management to use from among:
 - **Family Loading**
 - **Bulk Loading**
 - **Direct Loading**
3. Click on **Save** to make the update effective.

NOTE

The Direct Loading mode is only available with an LIS connection.

7.1.3 Result



The Results configuration tab is divided into 2 sub-categories:

- **Failed results**, settings that concern the management of failed results.
- **Repeated results**, settings that concern the management of repeated results.

7.1.3.1 Failed Results

LQS can be configured to manage the instrument's failed results or not.

If the **LQS** management is enabled, it behaves as follows:

1. When the failed result is received, it enters the code configured in the *Code to be used as a FAILED result* field as the result.
2. It awaits a valid result for the number of seconds configured in the *Maximum time between the failed and valid result* field.
3. When the valid result is received, it acquires it if the set time out has not expired. Otherwise it is discarded and the QuantiFERON result is not calculated.

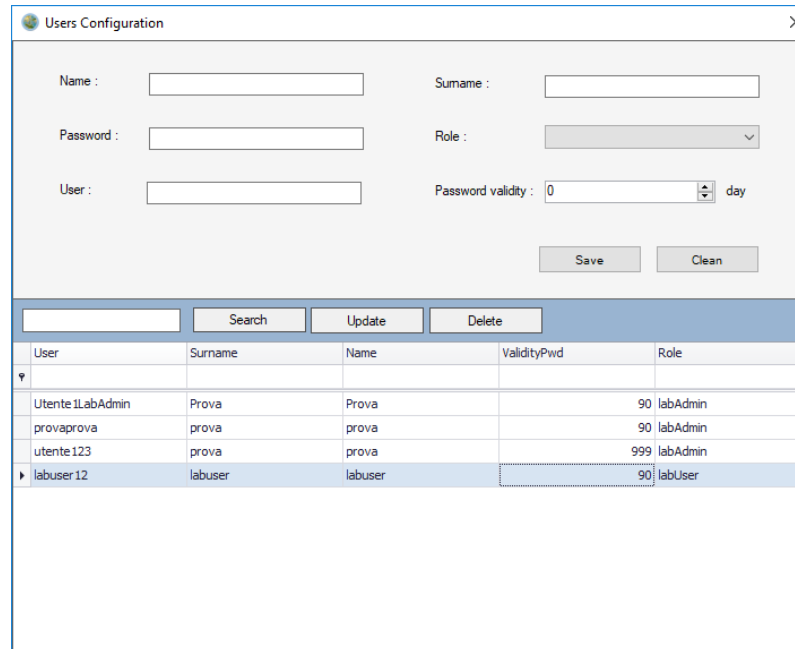
7.1.3.2 Repeated Results

LQS can be configured to manage the instrument's repeated results or not.

If the LQS management is enabled, it behaves as follows:

1. It receives the first result.
2. When the repeated result is received, it acquires it and overwrites the previous one, if the set *Maximum time between the previous result and the following* has not expired. Otherwise the result is discarded.

7.2 User Configuration



User	Surname	Name	ValidityPw	Role
Utente1LabAdmin	Prova	Prova	90	labAdmin
provaprova	prova	prova	90	labAdmin
utente123	prova	prova	999	labAdmin
labuser12	labuser	labuser	90	labUser

To access user configuration, proceed as follows:

1. Click on **Available Operations**.
2. Click on **User Configuration**.

Field	Description
Name	Name of user.

Surname	Surname of user.
Password	Password of user. Must be at least 8 characters long.
Role	Privileges to associate with the user: <ul style="list-style-type: none"> • LabUser, user without access permission to user configuration.
User	Username to use at login.
Password Validity	Number of days password is valid.
Search	Button to begin search in user list.
Update	Button to access editing for the user selected from the user list.
Delete	Button to delete the user selected from the user list.

7.2.1 Enter new user

To enter a new user, proceed as follows:

1. In the **name** and **surname** fields, enter the details for the user to be created.
2. In the **password** field, enter the temporary password required for the first login.

NOTE

At the first login, **LQS** will ask the user to change the temporary password entered when creating the user.

3. In **Role**, choose the privileges to assign to the user.
4. In **User**, enter the username to use at login.
5. In **Password validity**, choose the days the password is valid.

NOTE

Once the valid days set have elapsed, **LQS** will propose changing the password at the user's login.

6. Click on **Save** to create the user.

7.2.2 Edit User

It is possible to edit some of the settings for a user already in **LQS**.

Editable fields are:

- **name**
- **surname**
- **Password validity**

To edit a user, proceed as follows:

1. Select the user from the user list.
2. Click on **Update**.
3. Make the necessary modifications.
4. Click on **Save**.

7.2.3 Delete a user





To delete a user, proceed as follows:


1. Select the user from the user list.
2. Click on **Delete**.
3. Confirm the deletion by clicking on **OK**.
4. Click on **Save**.

8 Country notes

8.1 USA

Table in chapter 1.6.2 is replaced by the following:

Symbol	Title	Standard	Reference Number	Description
	Manufacturer	ISO 15223-1: Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	In Vitro Diagnostic Medical Device	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.5.1	Indicates a medical device that is intended to be used as in vitro diagnostic medical device.
	Catalogue number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified

	<p>Consult instructions for use</p>	<p>ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied</p>	<p>5.4.3</p>	<p>Indicates the need for the user to consult the instructions for use</p>
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8.2 Portugal

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