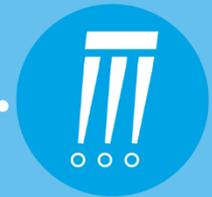


Lonza

WinKQCL[®] 6

Endotoxin Detection and
Analysis Software



Automation

Software User Guide

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Software Manual

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Introduction

The WinKQCL[®] Software is client-server software that is designed and developed specifically for the purpose of endotoxin testing. The WinKQCL[®] Software guides the user through the process of setting up a microplate template and running an assay to determine the amount of endotoxin in a sample solution. WinKQCL[®] Software associates the following information with this template:

- Lonza endotoxin assay reagent information.
- Standard endotoxin solutions at known concentrations.
- Product or sample solutions to be tested and the associated positive product control.
- Identifying metadata for accessory items used to prepare the test, such as microplates, pipette tips, pipettes, reagent reservoirs, etc.

Once the above information is associated with a template, the WinKQCL[®] Software can be used with a compatible microplate reader to run the template and perform these common endotoxin tests:

- An initial qualification test
- A routine test
- An inhibition/enhancement test
- An RSE/CSE test

The WinKQCL[®] Software will use the resulting data to calculate the results for the sample solutions and their associated positive product controls. All results and related information will be displayed in an easy to read and print report. Resulting data can be electronically reviewed and signed.

Since WinKQCL[®] Software stores all template and test information in a single Microsoft[®] SQL Server[®] database, all resulting sample data, including linked standard, accessory, reader, and user information, can be trended and recalled for review from any WinKQCL[®] Software client. See "The WinKQCL[®] Software" on page 8 for more information about what is stored in the database.

In addition to endotoxin tests, WinKQCL[®] Software allows microplate reader-specific validation tests to be performed to ensure the instrument is operating properly.

For more information regarding the endotoxin detection assays supported by the WinKQCL[®] Software, see "Principles of Quantitative Endotoxin Assays" on page 7.

NOTE: The WinKQCL[®] 6 Software is compliant with the technical requirements of the *Code of Federal Regulations Title 21 Part 11* (21 CFR Part 11 technical requirements). Please refer to the WinKQCL[®] Software Validation Package for a point-by-point analysis of how the WinKQCL[®] 6 Software satisfies these technical requirements.

Principles of Quantitative Endotoxin Assays

Use the WinKQCL[®] Software for the quantitation of gram-negative bacterial endotoxin with the following Lonza assay products:

- Kinetic-QCL® Kinetic Chromogenic LAL assay
- PYROGENT® 5000 Kinetic Turbidimetric LAL assay
- PyroGene® Recombinant Factor C (rFC) Assay

The LAL-based assays use the endotoxin-sensitive characteristic of *Limulus* amoebocyte lysate (LAL) to generate an active proteolytic enzyme.

The Kinetic-QCL® and PYROGENT® 5000 Assays

In the Kinetic-QCL® Assay, the activated enzyme catalyzes a degradation reaction. The reaction splits p-nitroaniline (pNA) from the colorless substrate Ac-Ile-Glu-Ala-Arg-pNA. The pNA release is measured photometrically at 405 nm continuously (kinetically) throughout the incubation period.

In the PYROGENT® 5000 Assay, the activated enzyme catalyzes the conversion of soluble coagulogen to insoluble coagulin (coagulogen is the clotting protein). When coagulin is generated, turbidity is caused. Turbidity is measured photometrically at 340 nm continuously (kinetically) throughout the incubation period.

For the Kinetic-QCL® and PYROGENT® 5000 Assays, a correlation exists between the time required for color or turbidity to appear and the endotoxin concentration. The amount of time before color or turbidity appears is the reaction time. To calculate the concentration of endotoxin in a sample, reaction time is compared to the reaction time of endotoxin solutions that contain known amounts of a standard endotoxin.

To minimize the time required for each assay, the software can utilize Kinetic SmartStop™ to use the lowest standard in the assay as a reference. The calculation of endotoxin concentrations in samples is valid only within the range between the lowest and highest standards. Therefore, when all replicates of the lowest standard have reacted, the assay is deemed “finished”.

Principles of the PyroGene® Recombinant Factor C (rFC) Assay

Recombinant factor C (rFC) is activated by endotoxin binding. The active moiety that is created cleaves a synthetic substrate, which results in the generation of a fluorogenic compound.

The assay is carried out in a standard 96-well plate.

Fluorescence is measured at time zero and again after one-hour of incubation at 37°C in a fluorescence microplate reader. When using the PyroWave® XM Reader, excitation wavelengths of 380 nm and emission wavelengths of 440 nm are used to measure fluorescence. The emitted light is measured as relative fluorescence units or RFUs.

The difference between the one-hour reading and the time zero reading (delta RFU) is corrected for blank fluorescence (net delta RFU). The log net fluorescence is proportional to the log endotoxin concentration. The log net fluorescence is linear according to the PyroGene™ Assay package insert. The endotoxin in a sample is calculated relative to a standard curve made up of endotoxin solutions that contain known amounts of a standard endotoxin.

The WinKQCL® Software

The WinKQCL® Software stores and maintains all records in a Microsoft® SQL Server® database. The database is designed for efficient search and retrieval and can be compared to an electronic filing cabinet or repository. The WinKQCL® Software database stores and maintains the following information:

- **Test Results:** These results include endotoxin tests, reader validation tests, and quick read test results. Test results can be retrieved at any time for further analysis, review, export, and for the application of secure electronic signatures.
- **Accessories:** Each accessory that is used in endotoxin testing can include a lot number, manufacturer name, calibration due date, and expiration due date. Each analyst can create a unique default list of accessories from the master accessories list. After the list is created, the user template default list of accessories is attached to any new template the user creates.
- **Products:** This information includes user-defined product names, their units of measure (mL, µg, mg, unit, mEq, device, or user defined), release limits, and non-inhibitory dilutions.
- **Templates:** A template is a user-defined configuration of the 96 well microplate that indicates well positioning for standards and samples, as well as accessory and sample information.
- **Users:** Information relating to users of the WinKQCL® Software, including user ID, password, user status, and user role (Supervisor, Analyst or Reviewer).
- **Configuration:** This information relates to the configuration of the WinKQCL® Software, including global options and laboratory information management system (LIMS) export defaults.
- **Audit Logs:** A record audit log tracks electronic record creation, deletion and edits. A security audit log tracks when accounts are locked and unlocked and when consecutive failed login attempts occur.

The WinKQCL® Software has a powerful trending feature, which gives users many options for retrieval and review of past information. Additionally, the data can be organized into workgroups if more than one functional lab group or more than one lab location will be sharing the database.

As the data stored in the WinKQCL® Software database is usually considered critical data, the WinKQCL® Software database should be stored on a secured server on the company network. Servers are normally placed in a secure and environmentally controlled server room. Most servers have redundancy built into the server hardware. Putting this data on a server removes the risk of losing data due to theft, system damage, or failure. Making the database available over the company network allows the data to be accessed from any computer on the network that is running the WinKQCL® Software.

In addition to storing the database on a secured server, a licensed version of SQL Server® should be installed on the server used to host the database. See "About Microsoft® SQL Server® Editions" on page 18 for more information on using SQL Server® Express Edition vs. licensed editions of Microsoft® SQL Server®.

WinKQCL[®] 6 Software Deployment Preparation

Before deployment, review all instructions in this guide. All procedures must be performed in the correct order.

Deployment Environment Selection

Lonza suggests deploying a client-server environment. This permits multiple clients connecting to a single server.

Client: The WinKQCL[®] Software is installed on all computers that need to run the software. The software connects to the database over the network. This application may be hosted on application sharing systems such as Citrix[®], but this is only recommended for data review purposes.

Database Server: A database server is a server in which the WinKQCL[®] Software database is installed. The database is installed using the WinKQCL[®] Software database deployment tool. This allows customers to utilize existing database servers with minimal impact to other hosted environments. Servers with existing SQL Server[®] instances can be used or a new database server can be set up. The client application may be installed on the database server, but is not necessary.

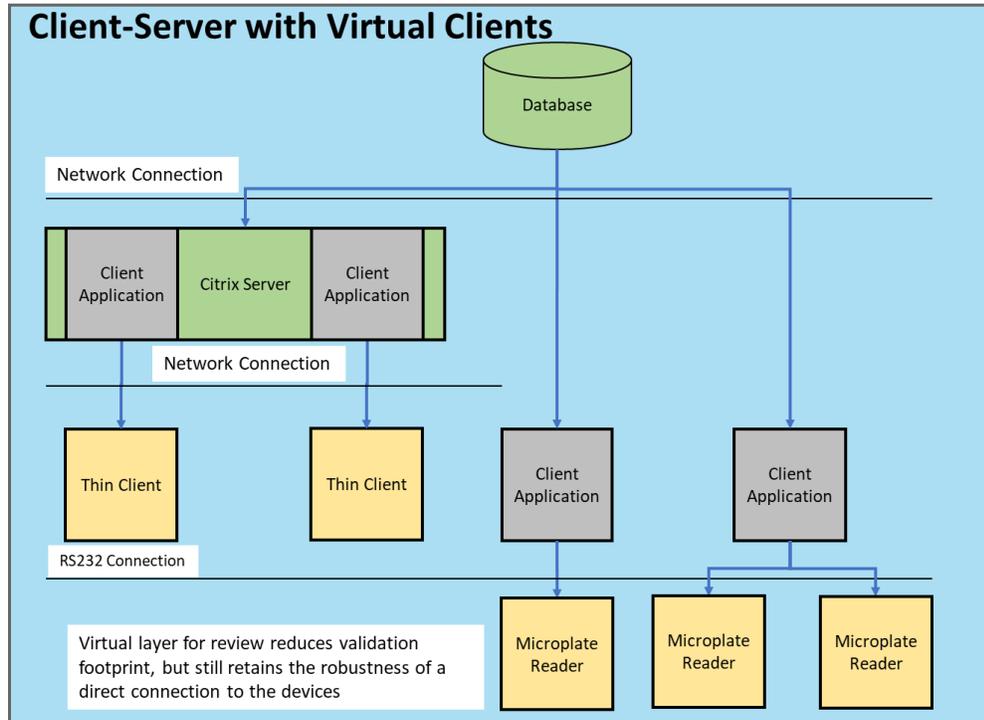
If only a single lab computer is available, WinKQCL[®] Software can be installed as a standalone type of Server.

Standalone: A standalone installation is often used in a lab setting where a single reader and computer are dedicated to endotoxin testing. Both SQL Server[®] and the WinKQCL[®] Software are installed on this system. This configuration is discouraged for a clinical or GxP environment as it provides a less secure system with the data residing on the local laboratory computer.

Client-Server Installation

In a client-server environment, multiple computers are used. One computer is designated as the server. The WinKQCL[®] Software database is installed on this server. The server can be set up as a database-only server or as a full server. The WinKQCL[®] Software client application can be installed on any computer and connect to the database over the company wide area network. Clients connect to the server and share a common database.

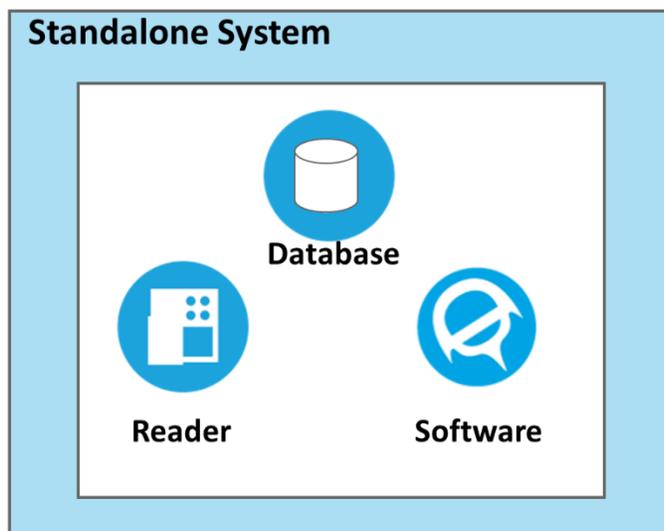
Test results, accessories, products, templates, users, configuration settings, and the audit logs are configured only once for the entire networked system. Authorized users can access the WinKQCL[®] Software database from any WinKQCL[®] Software client on the network.



For information about the system requirements for a client-server environment, see "Requirements for a Networked Client-Server System" on page 12.

Standalone Installation

In a standalone environment, only a single computer is used. The WinKQCL[®] Software and the database are installed on that computer. The database is associated only with that computer. Test results, accessories, products, templates, users, configuration settings, and the audit logs are configured separately for each standalone installation.



For information about the system requirements for a standalone environment, see "Requirements for a Standalone System" on page 15.

WARNING: Standalone installations are not recommended for environments where data security and data integrity are important and in laboratories which may be inspected by regulatory agencies.

Requirements for a Networked Client-Server System

As a networked system, the WinKQCL[®] Software supports client-server operation. The computer that is the WinKQCL[®] Software server contains and runs the central WinKQCL[®] Software database. Client installations do not include a database, because they access and use the database on the server across the network.

To ensure optimal and reliable performance of the WinKQCL[®] Software as a networked client-server system, follow these minimum system requirements. When verifying the operating system, ensure that the most up-to-date service packs are installed.

Minimum Requirements for a Client System

Component	Requirement
Operating System	<p>One of the following:</p> <ul style="list-style-type: none"> ▪ Windows[®] 7 Enterprise, Professional, or Ultimate. ▪ Windows[®] 10 Pro, or Enterprise. ▪ Windows[®] 11 Pro, or Enterprise. <p>64-bit and 32-bit operating systems supported.</p> <hr/> <p>NOTE: Before installing the WinKQCL[®] Software, ensure that the most recent Windows[®] service packs and updates are applied.</p> <p>LTSB and LTSC editions are supported.</p> <p>NOTE: When using the PyroTec[®] PRO System the client operating system must be 64-bit Windows 10 and 11.</p> <hr/>
CPU	Intel [®] Core™ i3 equivalent processor or greater
Memory	<p>2 GB of RAM</p> <p>8 GB of RAM when running the PyroTec[®] PRO System.</p>
Network	A "local area connection" to the company network. The TCP/IP protocol, File and Print Sharing for Microsoft [®] Networks, and Client for Microsoft [®] Networks are installed for the local area connection.

Component	Requirement
	<p>NOTE: A connection to the Internet will allow remote support in the event there are problems.</p>
Graphics	1024 x 768 minimum. 1280 x 1024 or larger recommended (required when running the PyroTec® PRO System).
Hard Drive	2 GB available space. 5 GB available space when running the PyroTec® PRO System.
Serial	One free serial port for each reader. If a serial port is not available USB to serial port adapters (P/N 25-361) can be purchased from Lonza.
Virtualized Client	Hosted services based on standard supported Windows® operating systems will work for data review purposes. For questions on whether a solution should work with the WinKQCL® Software, please contact Lonza Scientific Support.

Minimum Requirements for a Server System

Component	Requirement
Server Type	Physical and virtual servers are supported
Operating System	<p>One of the following:</p> <ul style="list-style-type: none"> ▪ Windows Server® 2012 ▪ Windows Server® 2012 R2 ▪ Windows Server® 2016 ▪ Windows Server® 2019 <p>64-bit and 32-bit operating systems supported.</p> <p>NOTE: Before installing the WinKQCL® Software, ensure that the most recent Windows® service packs and updates are applied.</p>

SQL Server®	<p>Licenses for Microsoft® SQL Server® Workgroup, Standard or Enterprise Edition and associated client access licenses.</p> <p>The following versions of SQL Server® are supported:</p> <ul style="list-style-type: none"> ▪ SQL Server® 2012 ▪ SQL Server® 2014 ▪ SQL Server® 2016 ▪ SQL Server® 2017 ▪ SQL Server® 2019 <p>64-bit and 32-bit SQL Server® supported.</p> <p>The SQL Server® Agent service is required for built-in scheduled database maintenance and backup features. The Browser service is required when TCP Dynamic Ports is enabled. Set the startup type for both of these services to automatic.</p>
SQL Instance	<p>A default instance or any named instance can be used without needing to set up a SQL alias on each of the clients. To dedicate a SQL instance to the WinKQCL® Software database or for a server dedicated to the WinKQCL® Software where the client application is going to be installed on the server, name the instance "WINKQCL".</p> <hr/> <p>NOTE: The WinKQCL® Software does not support case sensitive collations. The preferred collation type is:</p> <p>"SQL_Latin1_General_CP1_CI_AS".</p>
SQL Database	<p>When the database is created, it will be named "winkqclpdb". Do not create the database in advance.</p> <p>Use the WinKQCL® Software database tool to create the database.</p> <hr/> <p>NOTE: After installing SQL Server®, but before creating the database, verify the following items are enabled in the SQL Server Configuration Manager: Shared Memory, Named Pipes, and TCP/IP.</p>
Database Authentication	<p>Mixed (native SQL and Windows®) authentication must be enabled in SQL Server®. In order to send SQL back up files and XML files to a network location, the SQL Server® service logon account must have permission to read and write to the destination folder.</p>

CPU	Intel® Core™ i3 equivalent processor or greater
Memory	4 GB of RAM
Network	<p>A local area connection to the company network. The TCP/IP protocol, File and Print Sharing for Microsoft® Networks, and Client for Microsoft® Networks are installed for the local area connection.</p> <p>A fixed IP address is recommended.</p> <hr/> <p>NOTE: Ensure proper configuration of all local area connections on the server. If on the same subnet and active, ensure the connections are set up in a "link aggregation" in the operating system and in the network switch, so that the traffic to and from SQL Server® routes properly.</p> <p>NOTE: To allow the WinKQCL® Software to communicate with SQL Server® across a firewall, it may be necessary to follow the instructions in the following MSDN articles:</p> <ul style="list-style-type: none"> • MS175043: How to: Configure a Windows Firewall for Database Engine Access. • MS177440: How to: Configure a Server to Listen on a Specific TCP Port (SQL Server Configuration Manager). <p>NOTE: A connection to the Internet will allow remote support in the event there are problems.</p> <hr/>
Hard Drive	<p>20 GB available space for the WinKQCL® Software database.</p> <hr/> <p>NOTE: SQL Server® can be configured to install the data files, the log files and the database engine on different disk partitions. If this is desired, set up these partitions before installing SQL Server®.</p> <hr/>

Requirements for a Standalone System

A standalone system is an installation where the server option is selected during the installation and both the database and the client application are set up on the computer connected to the reader. A WinKQCL® Software instance of Microsoft® SQL Server® Express Edition can be installed from the **WinKQCL Menu** to provide local database services. It is possible to use a licensed version of SQL Server® with a standalone setup to allow automated backups, database checks and defragmentation jobs to run. See "About Microsoft® SQL Server® Editions" on page 18 for more information on using SQL Server® Express Edition vs. licensed editions of SQL Server®.

To ensure optimal and reliable performance of the WinKQCL[®] Software as a standalone system, follow these minimum system requirements. When verifying the operating system, ensure that the most up-to-date service packs are installed.

NOTE: SQL Server[®] checks the hardware and operating systems requirements during installation. If the requirements are not met, the installer may fail.

Minimum Requirements for a Standalone System

Component	Requirement
Operating System	<p>One of the following:</p> <ul style="list-style-type: none"> ▪ Windows[®] 7 Enterprise, Professional or Ultimate. ▪ Windows[®] 10 Pro, or Enterprise. ▪ Windows[®] 11 Pro, or Enterprise. <p>64-bit and 32-bit operating systems and LTSC and LTSC editions are supported.</p> <hr/> <p>NOTE: Before installing the WinKQCL[®] Software, ensure that the most recent Windows[®] service packs and updates are applied.</p> <p>NOTE: When using the PyroTec[®] PRO System Software module the client operating system must be 64-bit Windows[®] 10 and 11.</p> <hr/>
CPU	Intel [®] Core™ i3 equivalent processor or greater
Memory	<p>4 GB of RAM</p> <p>8 GB of RAM when using PyroTec[®] PRO System</p>
Network	A local area network connection is recommended to install Windows [®] updates, storing backups, and for remote support.
Graphics	1024 x 768 minimum. 1280 x 1024 or larger recommended (required for running the PyroTec [®] PRO System Software module).
Hard Drive	20 GB available space.
Serial	One free serial port for each reader. If a serial port is not available, an approved expansion card (P/N 00196005) or USB to serial port adapter (P/N 25-361) can be purchased from Lonza.

Supported devices

The following readers are validated to work appropriately with Lonza's assays:

- BioTek™ ELx808™ IU Absorbance Plate Reader (P/N 25-315S);
- BioTek™ FLx800™ TBIE Fluorescence Plate Reader (P/N 25-344S);
- Tecan® Sunrise™ reader
- Lonza PyroWave® XM Fluorescence Reader (P/N 25-345S)
- Lonza Nebula® Multimode Reader (P/N 25-375S)

The following readers can interface with the WinKQCL® Software, but the user may need to re-optimize the operating parameters for optimal performance.

- BioTek™ Synergy™ 2 multimode reader.
- Molecular Devices® SpectraMax™ multimode series readers: M2, M2e, M3, M4, M5, M5e, and FlexStation®; SpectraMax™ absorbance only readers: VersaMax™, 340PC, 190PC, 340PC384, and 384plus; and SpectraMax™ fluorescence only readers: Gemini™ EM, Gemini™ XPS and Gemini™ XS.

Lonza also offers a liquid handling solution for endotoxin testing:

- PyroTec® PRO Automated Robotic System (P/N 25-A10, 25-A11, 25-A20, or 25-A21)
- PyroTec® HT Automated Liquid Handling System

Deployment Procedures

The following sections provide instructions for new and upgraded WinKQCL® 6 Software deployments.

Licensed SQL Server® Installation

The following section will review the different options for setting up Microsoft® SQL Server® for WinKQCL® version 6 Software.

About Microsoft® SQL Server® Editions

Lonza recommends using a licensed version of Microsoft® SQL Server®, such as Workgroup, Standard or Enterprise Edition when using the WinKQCL® Software in a clinical or GxP laboratory. WinKQCL® Software can utilize existing Microsoft® SQL Server® servers located anywhere on the corporate network and can communicate across a wide area network. As many companies already have these types of database servers in place, please check with the company IT department as to the availability of an existing server. WinKQCL® 6 Software is compatible with Microsoft® SQL Server® 2012, 2014, 2016, 2017 and 2019.

Microsoft® SQL Server® Express Edition is distributed with the WinKQCL® Software in the event a licensed edition of SQL Server® is not available. For 64-bit operating systems, this will be Microsoft® SQL Server® 2019 Express, and for 32-bit operating system, it will install Microsoft® SQL Server® 2014 Express. Express Edition is not a full-featured product. The following limitations exist:

- The Microsoft® SQL Server® Agent Service is not available, therefore automated backups, database checks and defragmentation jobs cannot be run. Backups can be created manually from the server via the WinKQCL® Software application.
- Microsoft® SQL Server® Express Edition limits the size of the database to 10 GB. When using Microsoft® SQL Server® 2019 Express Edition and the database size reaches 95% of the 10 GB size limit, a warning message is displayed during the WinKQCL® Software startup process. As 100% capacity is reached, the WinKQCL® Software may crash as it is unable to write to the database.
- Microsoft® limits the CPU and memory usage to 1 CPU and 1 GB of memory. As a result, the performance of the WinKQCL® Software will be slower when running against SQL Server® Express Edition.

What do I need to execute?

Here are the two configuration options for the WinKQCL® Software system and installation requirements for each:

Standalone – When performing a standalone installation, the following will need to be installed on the system: “Installing SQL Server® Express”, “Creating a New WinKQCL® Software Database”, and “Installing a WinKQCL® Software Client”.

Client/Server – On the client system, the “Installing a WinKQCL® Software Client” is the only portion that needs to be executed. On the server, SQL Server® will need to be installed or configured and the “Creating a New WinKQCL® Software Database” will need to be executed.

Before Installing SQL Server®

Before installing SQL Server®, gather the following information or resolve the following issues:

- It is recommended to back up the SQL Server® database to a network location to ensure the safety of the data. Typically, it is recommended to follow corporate policies for data management. When no such policies exist, please see the Database Maintenance topic "Job Types" on page 135 for setting up scheduled backups.
- Systems such as this typically deliver crucial information into larger LIMS, LIS or Environmental Monitoring systems such as the Lonza MODA® Solution. Direct communication may be made with the MODA® Solution for seamless tamper resistant data transfer, or the system integration can be configured via a file export into a secure location. If using the file export, determine the target directory on the company network for XML or CSV export files. Use the directory path when setting up the export (see "LIMS Options" on page 147).
- A non-expiring domain account is recommended for the SQL Server® service. This account requires access to read and write to the above network locations.
- A standard installation installs the SQL Server® program and the WinKQCL® Software database files on the operating system partition. If the SQL Server® application, shared files, database engine, database files and the database log files need to be stored in different drive partitions or folder locations, set up the folders and drive partition locations in the desired storage location for these items before installing SQL Server®. The default location will be the C:\Program Files\ or the C:\Program Files(x86)\ directory. These custom install locations will be configured during the installation process.

Installing SQL Server® Express

If no WINKQCL instance of SQL Server® is present, the user must first install Microsoft® SQL Server® from the **WinKQCL Menu**. This can be done by:

- First running the **WinKQCL Menu.exe** file
- Then clicking **Install Prerequisites**.
- Followed by clicking on the **Install SQL Server** link.

Creating a New WinKQCL® Software Database

Follow these steps to deploy a new WinKQCL® Software database on an existing SQL Server® running the required version and edition of SQL Server®.

NOTE: The logged on Windows® user account used to set up the WinKQCL® Software database requires specific privileges on the server. Check the following to make sure there will not be problems setting up the WinKQCL® Software database:

- 1) Make sure the domain account is a member of the server's "Administrators" group.
 - 2) Run the Microsoft® SQL Server® Management Studio, browse to Security>Logins in the Object Explorer, and verify that the domain user account or group exists and has the "sysadmin" checkbox selected under Login properties > Server Roles.
-

1. Log on to the system with a domain account that meets the security requirements described in the above note. The server must have a version of SQL Server® installed that meets the minimum WinKQCL® Software server requirements.
2. Close all programs and insert the WinKQCL® Software installation disc into the drive. If a zip file is provided, extract or decompress the zip file before proceeding.
3. When the installation disc is detected, a window is displayed listing the contents on the disc. If the contents window is not displayed, double click the **WinKQCL Menu.exe** file. If this file cannot be launched, follow the manual steps below.

Skip to step 4 if this is being run on a system that already has the Microsoft® SQL Server® prerequisites installed. Under the heading **Database management**, click the link **Install Prerequisites**. If the prerequisites fail to install go to the **Deployment Tools** folder and install the SQL prerequisites manually. The prerequisites include the SQL 2012 Native Client, the SQL 2014 CLR Types, and the SQL 2014 Shared Management Objects. If on a 64-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX64 folder. If on a 32-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX86 folder. Install the prerequisites in the following order:

- sqlncli.msi
 - SQLSysClrTypes.msi
 - SharedManagementObjects.msi
4. Under the heading Database management, click the link Manage databases to launch the WinKQCL® Software Database Tool. If the WinKQCL® Software Database Tool fails to launch, open it manually. Go to the Deployment Tools folder and double-click the file WinKQCDatabaseTool.exe.
 5. On the Database Tool window, select the SQL Server® host name and instance name where the WinKQCL® 6 Software database will be created, and choose the method for connecting to this SQL Server® instance.

6. Click the **Connect** button. When the connection to the database is made, the status bar at the bottom of the window will indicate that the tool is connected to the SQL instance.

7. Click the **Create WinKQCL DB** button to begin the process of creating the new WinKQCL® Software database.
8. A window will be displayed to enter a workgroup name. Enter the workgroup name and click the **OK** button. See Manage Workgroup on page 139 for guidance on naming.
9. A series of SQL scripts will begin creating the database. The progress will be shown in the status bar at the bottom of the window. When the database creation is complete, a message in the status bar will be displayed indicating the database was successfully created.
10. **[Optional]** Click the **Create WinKQCL LIMS DB** button. Users can import data from another system directly into the WinKQCL® Software Template Manager through an intermediate "LIMS Database". A user name and password must be entered to allow the WinKQCL® Software to create this database. Any username can be entered and any strong password can be entered. Ask the company IT department to enter a user name and password. Click the **OK** button to create the LIMS import database.
11. Close the WinKQCL® Software Database Tool. The Server can now be used.

Installing a WinKQCL® Software Client

The following procedure is for an installation of a WinKQCL® 6 Software client. Before starting, the SQL Server® computer name, the SQL Server® instance name, and an administrator account will be required. To find the server's computer name and how to check the connection between the server and client computers, see "Testing the WinKQCL® Software Network Connectivity" on page 156.

1. Log in to the computer as a user with Administrator privileges.
2. Execute the **WinKQCL Menu.exe** file and choose the **Install WinKQCL Client** option. If the menu window cannot be displayed, double click the **setup.exe** file.
3. The WinKQCL® Software installer wizard will detect which prerequisites are needed on the client system before running the WinKQCL® Software installer. The installer may require a restart of the operating system while installing the prerequisites. When Windows® restarts, log back in with the same administrator account. Click the **Install** button on the window displaying the prerequisites that need to be installed.

If the prerequisites fail to install go to the **Deployment Tools** folder and install the SQL prerequisites manually. The prerequisites include the SQL 2012 Native Client, the SQL 2014 CLR Types, and the SQL 2014 Shared Management Objects. If on a 64-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX64 folder. If on a 32-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX86 folder. Install the prerequisites in the following order:

- sqlncli.msi
 - SQLSysClrTypes.msi
 - SharedManagementObjects.msi
4. On the welcome screen for the installer, click the **Next** button. The Destination Folder window is displayed.
 5. On the Destination Folder window, the folder where the WinKQCL® Software program files are installed can be configured. Accept the default, or to change the destination folder, click

Change and select a different folder. Click **Next** to proceed to the Database Server Location Setup Type window.

6. In the **MSSQL Server Computer Name** field, enter the computer name for the WinKQCL® Software server or the fixed IP address of the server if the server is separated from the clients by a firewall. In the **MSSQL Server Instance Name** field, type in the name of the SQL Server instance where the WinKQCL® Software database is located. If the database is located in the default SQL instance, check the checkbox labeled **Use Default MSSQL Server Instance**.
7. Click **Next**. The Ready to Install the Program window is displayed.
8. Click **Install**. The InstallShield® Wizard Completed window is displayed.
9. Click **Finish**.

Upgrading from previous WinKQCL® Software versions

Since WinKQCL® Software versions 2.0 and above store their data in a database, the database can be upgraded and retained. Data from older versions of WinKQCL® Software, versions 1.2 and earlier, cannot be migrated to WinKQCL® 6 Software. Due to deprecated operating systems, it is recommended to migrate to new computers when upgrading from WinKQCL® Software version 5 or earlier.

NOTE: Backups from Microsoft® SQL Server® 2000 cannot be merged directly into Microsoft® SQL Server® 2012 or newer. Furthermore, backups from versions prior to WinKQCL® Software 4.0.2 will require additional steps for migration. Please refer to the supplement *Migrating Legacy Database Procedure* and contact Scientific Support for assistance in this procedure.

WinKQCL® Software Client Application Upgrade

When upgrading from the WinKQCL® Software versions earlier than version 6, it is recommended to uninstall the existing client, then follow the Installing a WinKQCL® Software Client procedure. If using an operating system older than Windows® 7, a new computer will be required for WinKQCL® 6 Software. Please note that the WinKQCL® Software strictly requires the same client and database server version. If the client and the server have different versions of WinKQCL® Software, they are unable to communicate.

WinKQCL® Software Database Upgrade

This procedure can be run from the server or a client to upgrade the WinKQCL® Software database with any WinKQCL® Software version that is hosted on a database server supported by version 6. Do not attempt to connect to the database until the database and all clients are upgraded to the latest version of WinKQCL® Software. Client and servers with different versions of WinKQCL® Software are unable to communicate.

NOTE: The logged on Windows® user account used to set up the WinKQCL® Software database requires specific privileges on the server. Check the following to make sure there will not be problems setting up the WinKQCL® Software database:

- 1) Make sure the domain account is a member of the local “Administrators” group.
-

2) Run the Microsoft® SQL Server® Management Studio, browse to Security>Logins in the Object Explorer, and verify that the domain user account or group exists and has the “sysadmin” checkbox selected under Login properties > Server Roles.

1. As a precautionary measure, back up the existing database to a secure location.
2. Close all programs and navigate to the WinKQCL® Software installation files.
3. Execute the **WinKQCL Menu.exe** file. If this file cannot be launched, follow the manual steps below.
4. Under the heading **Database management**, click the link **Install Prerequisites**. If the prerequisites fail to install go to the **Deployment Tools** folder and install the SQL prerequisites manually. The prerequisites include the SQL 2012 Native Client, the SQL 2014 CLR Types, and the SQL 2014 Shared Management Objects. If on a 64-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX64 folder. If on a 32-bit installation of Microsoft® Windows® or Windows Server®, go to the SqlPrereqX86 folder. Install the prerequisites in the following order:
 - sqlncli.msi
 - SQLSysClrTypes.msi
 - SharedManagementObjects.msi
5. Under the heading **Database management**, click the link **Manage Databases** to launch the WinKQCL® Software Database Tool. If the WinKQCL® Software Database Tool fails to launch, open it manually. Go to the **Deployment Tools** folder and double-click the file **WinKQCLDatabaseTool.exe**.
6. On the Database Tool window select the SQL Server® host name and instance name where the WinKQCL® Software database is located and choose the method for connecting to this SQL Server® instance.

7. Click the **Connect** button. When the connection to the database is made, the status bar at the bottom of the window will indicate that the tool is connected to the SQL Server® instance and the database name, version and type will be shown.

8. Click the **Upgrade** button to begin the process of upgrading the winkqcldb to the latest version.
9. As the database is upgraded, the progress will show in the status bar at the bottom of the window. When the upgrade is complete, a message in the status bar will be displayed indicating the upgrade succeeded.
10. [Optional] Click the **Create WinKQCL LIMS DB** button. Users can import data from another system directly into the WinKQCL® Software Template Manager through an intermediate "LIMS Database". A user name and password must be entered to allow the WinKQCL® Software to create this database. Any username can be entered and any strong password can be entered. Ask the company IT department to enter a user name and password. Click the **OK** button to create the LIMS import database.
11. Close the WinKQCL® Software Database Tool. The Server can now be used.

WinKQCL® Software Registration and Evaluation

The WinKQCL® Software can be evaluated for 30 days from the date it is installed. If the system is not registered, it will be unusable after the evaluation expires.

During the evaluation period, the WinKQCL® Software Registration Information window is displayed at startup. This window provides registration and evaluation options. Click **Evaluate** to open the WinKQCL® Software during the evaluation period.

NOTE: The registration code is stored in the database and the entire WinKQCL® Software network is activated once the registration code is entered on any client. Once the 30-day evaluation period expires, all clients connected to the database will stop working.

To register the WinKQCL® Software, contact Lonza Scientific Support, Field Service, or Sales Representative with the following information:

- Company name
- Company address
- The contact information for two individuals. Please include the following information for each contact:
 - Name
 - Title or Department (examples: "QC Manager" or "Quality Control Department")
 - Phone number
 - Email address
- The number of WinKQCL® Software reader licenses and workgroup licenses purchased.
- WinKQCL® Software installation code (displayed on the WinKQCL® Software Registration Information window)
- The WinKQCL® Software version number (for example, 6.3.0)
- Whether or not Lonza may reach out to users with product updates

NOTE: For email registration requests, include all the required information in the text of the email.

Lonza may reach out to contacts with product update information unless the user specified otherwise.

Lonza Scientific Support can be reached by contacting offices in North America or Europe.

North America / International:

- Phone: 800 521 0390 / +1 301 898 7025
- E-mail: scientific.support@lonza.com

Europe:

- Phone: +32 87 321 611
- E-mail: scientific.support.eu@lonza.com

Upon obtaining the registration code, enter it into the WinKQCL® Software Registration Information window and then click **Register**. Once the registration code is entered on the server or any client, the software will be registered for the entire WinKQCL® Software network.

Uninstalling the WinKQCL[®] Software

Always remove the WinKQCL[®] Software from the computer using the Windows[®] Add or Remove Programs control panel. This section describes how to remove the WinKQCL[®] Software and any related programs. Read these instructions before beginning, some steps may differ depending upon the operating system and whether re-installing the WinKQCL[®] Software on the computer is likely in the future.

NOTE: SQL Server[®] may be a shared service with other applications. When uninstalling the WinKQCL[®] 6 Software, SQL Server[®] must be removed as a separate action, but only do so if there is not conflict.

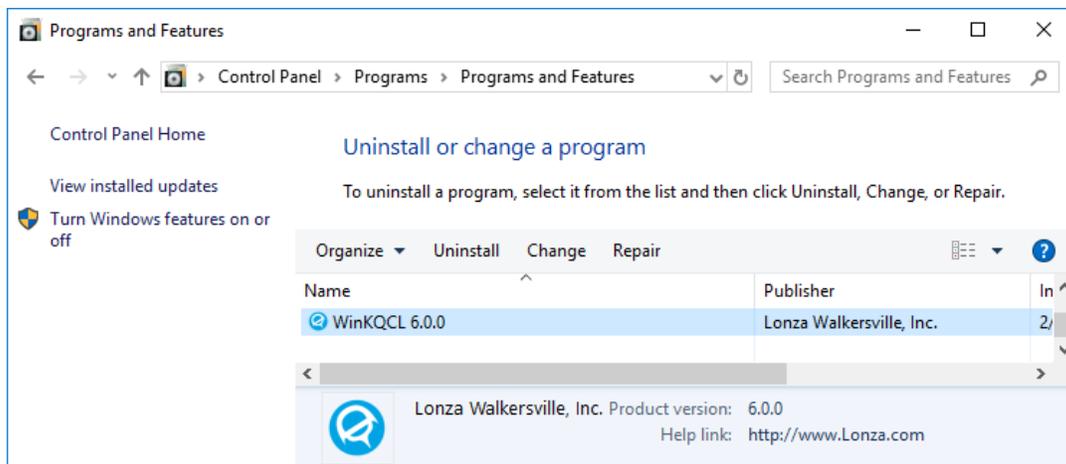
NOTE: It is recommended to uninstall previous versions of the WinKQCL[®] Software first when upgrading to the WinKQCL[®] 6 Software. If using SQL Server[®] 2008 or earlier, please backup the database and refer to the supplemental *Migrating Legacy Database Procedure* and contact Scientific Support for assistance.

WARNING Back up the primary WinKQCL[®] Software database and any archive databases before uninstalling the software (see "Backup the Database" on page 129).

Uninstall Procedure

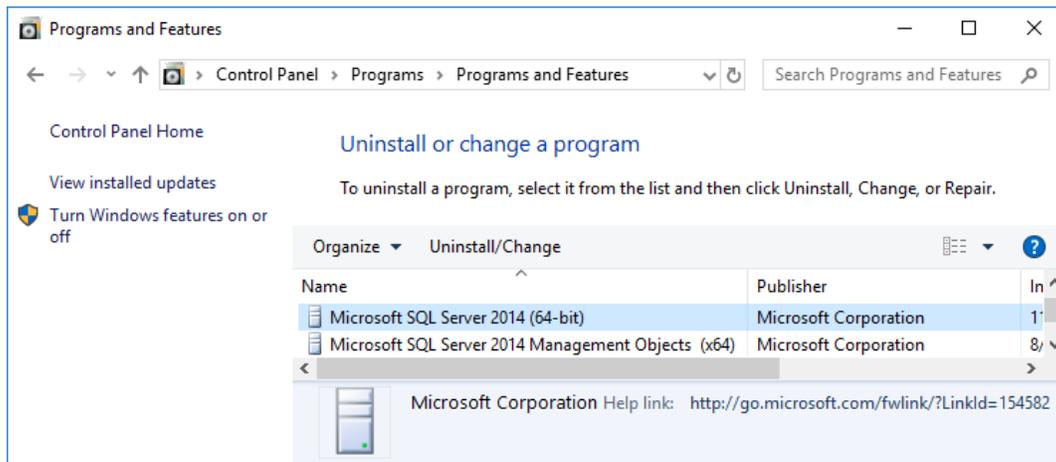
To uninstall the WinKQCL[®] Software, follow these steps:

1. From the **Windows Control Panel**, open the **Programs and Features** window. A shortcut is to click the **Start** button and type in "Uninstall a program".
2. Find and click the installed version of the **WinKQCL[®] Software**.



3. Click the **Uninstall** button and click through the prompts to uninstall the WinKQCL[®] Software application.
4. After the WinKQCL[®] Software is uninstalled; the SQL Server[®] instance and database files remain. To remove SQL Server[®], find and click all of the **Microsoft[®] SQL Server[®]** entries

in the programs list and uninstall each item. Start with the first Microsoft® SQL Server® item in the list.



5. When removing SQL Server®, make sure to select the option that also removes the WINKQCL instance of SQL Server®.
6. If no other SQL instance is present, uninstall the remaining Microsoft® SQL Server® items in the programs list.
7. Reboot the computer.
8. Following an uninstall SQL Server® may leave behind artifacts. If these exist, delete these WinkQCL® Software database files from the SQL Server® data directory.
 - winkqcldb_4_data.mdf
 - winkqcldb_4_log.ldf

WinKQCL[®] Software Initial Configuration

Use this section as a guide for the initial configuration of the WinKQCL[®] Software. More in-depth information about configuration options and functionality is presented elsewhere in this guide.

First Time Login

When the WinKQCL[®] Software is run for the first time, it has one active supervisor account that is used only for initial access to the system.

The installation default user account has the user ID "SUPERVISOR" and the password "PASSWORD1". Passwords are case-sensitive, so enter the default password in all uppercase characters. User IDs are entered in uppercase letters by default. Lower case letters are automatically changed to uppercase in the User ID field.

To start the WinKQCL[®] Software for the first time, follow these steps:

1. Double-click the desktop icon, or click **WinKQCL** from the Windows[®] **Start** menu. If the WinKQCL[®] Software Registration Information window is displayed, either click the **Evaluate > >** button, or contact Lonza Scientific Support to register the software (see "WinKQCL[®] Software Registration and Evaluation" on page 24).
2. In the **Log In** window, enter the default supervisor user ID and password as shown here:
 - User ID: **SUPERVISOR**
 - Password: **PASSWORD1**
3. Click **OK**.

Supervisor password must be changed on the first login (see "Changing the Default Password of the Installation Supervisor Account" on page 28).

Changing the Default Password of the Installation Supervisor Account

When the WinKQCL[®] Software is run for the first time the supervisor password must be changed.

To change the supervisor password, follow these steps:

1. Enter a new password in the **New Password** and **Confirmation** fields. Passwords must be at least 7 characters long and contain a combination of letters and numbers.
2. Click **Save**. The password is changed and the default supervisor account is activated.

WARNING An account with the Manage Workgroups permission must exist to manage the WinKQCL[®] Software. Contact Lonza Scientific Support for assistance if no account with these permissions is available.

After the installation supervisor account is activated, create another supervisor account. This new account is used to maintain the WinKQCL[®] Software. For data integrity purposes, it is not recommended to use the installation supervisor account to maintain and configure the software for traceability on who performed the actions.

Creating a New Supervisor Account

The default supervisor account should not be used for configuration and maintenance activities. Set up a second supervisor account for the lab supervisor or an IT administrator. Use this supervisor account to perform general WinKQCL[®] Software maintenance activities such as database backups, setting up user accounts, and general software configuration and setup.

The procedure below can be used to set up a new account.

To create the new supervisor account, follow these steps:

1. On the main toolbar, choose **Tools > User Maintenance**.
2. On the **Log In** window, enter the password for the installation supervisor account, and click **OK**. The **User List** window is displayed, which lists only the installation default supervisor.
3. Click **New**. The User Details window is displayed.
4. In the **User ID** field, enter a user ID for the new user account (up to 128 number, letter or symbol characters). The user account may be linked to the corresponding domain account by entering the same user ID used to log in to Windows[®].
5. In the **Name** field, enter the user's full name (up to 128 characters).
6. In the **Signature Text** field, enter the user's name to appear at the bottom of a report when they electronically sign a test report. An image of the user's actual signature may be uploaded in the place of the text. See "User Controls and Functionality" on page 142 for information on the signature image file type and image dimensions.
7. Go to the Password tab. For the password set up, the user account may link directly to active directory or let the WinKQCL[®] Software manage the password. If linking to active directory, check the **Uses Active Directory Authentication** checkbox, enter the domain name in the **Domain Name** field, and click the **Check Name** button to verify the account exists. When allowing the WinKQCL[®] Software to manage the password, go to the Password tab and configure the password and password settings. See "User Controls and Functionality" on page 142 for more information on password configuration.
8. Go to the Permissions tab. In the **Primary Role(s)** area of the Permissions tab, check the **Supervisor** checkbox and click the **Apply Defaults** button to apply the default permissions for a supervisor. To grant other roles and permissions to this account, check all checkboxes that apply. For example, a lab supervisor who is experienced in running the endotoxin test may need to have the Analyst, Reviewer, and Supervisor checkboxes selected.
9. Go to the Status tab and if the user is properly trained on the endotoxin assay and software, check the **validated** checkbox.
10. Ensure that all values are correct, and click **Save**.
11. Repeat this process for any additional users that need to be configured.

Logging In with the New Supervisor Account

To log in with the new account, follow these steps:

1. On the main toolbar, click the **Switch User** icon:



Alternatively, if the software is closed, double-click the **WinKQCL 6** icon on the desktop.

2. In the Log In window, enter the user ID and password of the new account. If the account is that of the person logged in to Windows®, check the **Use Current Windows User** checkbox and then enter the corresponding Windows® password.
3. If prompted, change the password.

For compliance and security reasons, deactivate the installation default supervisor account.

1. On the main toolbar, click **Tools > User Maintenance**.
2. In the **User List** window, click the installation supervisor and click **Edit**.
3. In the **User** window, click the **Status tab** and change the state to **Inactive**.
4. Click **Save**.

The installation default supervisor account is deactivated. Access to the WinKQCL® Software is available only to the accounts that are active.

Use the maintenance supervisor account to establish new analyst, reviewer, and additional supervisor user accounts. Assign a second individual as a supervisor for times when the primary supervisor is not available. To establish new user accounts, see "User Details" on page 142.

General Configuration

To properly configure the WinKQCL® Software when installed (and following merging and restoring of any databases), go to each of the following areas of the software.

- **Global Options:** First, configure the options that will affect all client installations on the WinKQCL® Software network. These options include the login inactivity timer, report header, report watermark, and setting whether or not users need to enter their Windows® password when logging on. Configuring the global options first can save time with subsequent configuration steps. See "Global Options" on page 136 for information about the individual options.
- **Manage Workgroups:** Workgroups are used for logical grouping of data typically by site or group utilizing the WinKQCL® Software database. When the WinKQCL® Software server is installed, the initial workgroup is configured. If the merge procedure was executed, additional workgroups may have been created. Use this feature to add any additional workgroups or to modify existing workgroups (see "Manage Workgroups" on page 139).
- **User Maintenance:** Use this feature to add, modify, or inactivate the WinKQCL® Software user accounts (see "User Maintenance" on page 139). Existing users from an upgraded database can be linked to their active directory account. To set up all users in one-step, have the IT administrator follow the instructions for "Active Directory Group Import" on page 145.
- **AER Parameters:** Use this feature to configure the assay evaluation report (AER) default settings (see "AER Parameters" on page 116). When AER parameters are enabled, the

endotoxin test report shows the limits and ranges of the parameters defined in this feature. These options also indicate if the data conforms to the defined specifications.

- **Template Defaults:** Use this feature to configure the default template settings for Kinetic-QCL[®], PYROGENT[®] 5000 and PyroGene[®] Assays (see "Template Defaults" on page 119). The settings are applied when new templates are created and new tests are run. Template default settings control when kinetic tests stop running.
- **Accessories:** Record all accessories used to set up the endotoxin test. Accessories can include but are not limited to pipettes, reagent reservoirs, pipette tips, timers, and refrigerators. Configuring accessories before running tests ensures they are named consistently and a performance baseline is established. If a performance problem occurs later, it is possible to use the trending feature to determine if an accessory is responsible for the problem. See "Accessories" on page 68 for information on configuring this feature.
- **Products:** Record all known products, samples, and medical devices that will be tested. Recording the information here ensures records are named consistently so the data can be properly trended. If products are not named consistently, the trending feature cannot be used to evaluate product performance. See "Products" on page 63 for information on configuring this feature.

NOTE: It is very important to configure the AER Parameters, Template Defaults, Accessories and Products features before running any tests.

- **Reader Setup:** Use this feature to discover, modify, and delete readers connected to the computer (see "Reader Setup" on page 122).
- **LIMS Options:** Use this feature to configure the rules used by the WinKQCL[®] Software when exporting test results to an external database, such as a Lonza MODA[®] Solution database or a laboratory information management system (LIMS) database (see "LIMS Options" on page 147).
- **Schedule Database Maintenance:** Use this feature to schedule the following database maintenance jobs: backups, database checks, and index defragmentation (see "Schedule Database Maintenance" on page 135). This feature is only available when a licensed version of SQL Server[®] is installed (see "About Microsoft[®] SQL Server[®] Editions" on page 18). It is not necessary to use this WinKQCL[®] Software feature to set up database maintenance if a database administrator will be configuring database maintenance directly in Microsoft[®] SQL Server[®].

Security

The WinKQCL® 6 Software uses audit logs to monitor system actions. Administrators can create user accounts and reset passwords, but cannot view passwords.

Audit Logs

Actions that create or modify electronic records are captured in the Record Audit Log (see "Record Audit Log Report" on page 126).

Security issues and system access, including both authorized and unauthorized access attempts, are captured in the Security Audit Log (see "Security Audit Log Report" on page 127).

The audit logs cannot be edited or deleted. Access to audit logs is restricted to users with the View Audit Reports permission.

User ID and Password

Unique user IDs and passwords restrict access to the WinKQCL® Software. When the WinKQCL® Software is implemented in a networked environment, the user ID and password can be used to access the system from any computer on the WinKQCL® Software network.

The WinKQCL® Software recognizes four distinct user roles. For more information about these, see "User Roles" on page 144:

- Supervisors
- Reviewers
- Analysts
- User

There are also numerous permissions that can be granted to a user for more refined rights, see "User Permissions" on page 145 for more information.

For more information about user IDs and passwords, see "User Maintenance" on page 139.

Switch User

To activate the Switch User feature, click the **Switch User** icon on the main toolbar.



Enter the user ID and password and click **OK**. After a successful authentication, the WinKQCL® Software changes the current logged in user of the application to the user that just logged in.

Click **Exit** to cancel the Switch User action and close the WinKQCL® Software.

When Switch User is executed:

- All windows that the previous user opened are closed automatically.
- All tests in progress must be stopped successfully before the WinKQCL® Software allows the Switch User action to continue.

Password Lockout

For this section, a Supervisor is defined as a user with the **Manage Users** permission. When an incorrect password is entered, this error is displayed: "Incorrect password - Remember that passwords are case-sensitive."

When an incorrect password is entered five times in a row, the account is locked and the following error is displayed: "[ERROR WK0034]: This account is locked-out because there are too many failed login attempts. See your supervisor to remove the security lockout."

Supervisors of the program are alerted to this security issue. A "Security Alert" message is displayed in the WinKQCL® Software status bar at the bottom of the screen.



Supervisors can review the User List window to discover the cause of the Security Alert (see "User List" on page 140).

To clear the lockout and the security alert, supervisors select the user account and then click the **Clear Alert** button on the User List window. The supervisor is prompted to enter a comment into the security audit log (see "Security Audit Log Report" on page 127). After the alert is cleared, the password remains the same, but it must be changed the next time this unlocked account is used.

A valid supervisor account must be active at all times. Therefore, a supervisor cannot be locked out of the program because of failed login attempts. Failed attempts are noted in the security audit log, and the supervisor is informed of the failed attempts at the next successful login.

All computers connected to the same WinKQCL® Software database, share the same user accounts.

WARNING An account with the Manage Workgroups permission must exist to manage the WinKQCL® Software. Contact Lonza Scientific Support for assistance if no account with these permissions is available.

Templates

The templates feature allows lab users to set up their 96-well microplate layouts with standards, products, and positive product controls. Once a template is created, it can be edited and re-run as needed. Each time a template is run, the contents of the template will be saved to a results record. Editing a template does not affect previously created results records. The template contents at the time the test was run are copied to the final test record.

To display the templates window, click **Templates** on the main toolbar.

The templates window permits these tasks:

- Search for a specific template, or filter the list to show a subset of templates.
- Create a new template.
- Modify, delete, and copy existing templates.
- Run a test based on a template already in the list. Users can run a template that he or she owns when another analyst is logged in.

For instructions on using the buttons on the right side of the templates window, see "Template Button Controls" on page 35.

For instructions on using the search/filter features, see "Search and Filter Controls" on page 159.

Name	Test	Assay	Analyst ID	Workgroup	Modified	Expired
12 pt standards	Routine	Kinetic-QCL	CLANE	Demo	2/27/2019	
1q - c lane fl	Initial Qualification	PyroGene	CLANE	Demo	2/27/2019	
inh 12 pts	Inhibition/Enhancement	Kinetic-QCL	CLANE	Demo	2/27/2019	
inh/en - c lane	Inhibition/Enhancement	Kinetic-QCL	CLANE	Demo	2/27/2019	
inh/en - c lane fl	Inhibition/Enhancement	PyroGene	CLANE	Demo	2/27/2019	
inh/en - c lane turb	Inhibition/Enhancement	PYROGENT-5000	CLANE	Demo	2/27/2019	
inh/en - j smith	Inhibition/Enhancement	Kinetic-QCL	JSMITH	Demo		X
inh/en - j smith tur	Inhibition/Enhancement	PYROGENT-5000	JSMITH	Demo		X
inh/en - jsmith fl	Inhibition/Enhancement	PyroGene	JSMITH	Demo		X
inh/en - p jones	Inhibition/Enhancement	Kinetic-QCL	PJONES	Demo		X
inh/en - p jones fl	Inhibition/Enhancement	PyroGene	PJONES	Demo		X
inh/en - p jones tur	Inhibition/Enhancement	PYROGENT-5000	PJONES	Demo		X
iq - c lane	Initial Qualification	Kinetic-QCL	CLANE	Demo		X
iq - c lane turb	Initial Qualification	PYROGENT-5000	CLANE	Demo		X
iq - j smith turb	Initial Qualification	PYROGENT-5000	JSMITH	Demo		X

Template List

The following information is displayed in the table for each template:

- **Name:** The name of the template.
- **Test:** The test type, purpose, or objective. For example, routine, initial qualification, RSE/CSE, and inhibition/enhancement.
- **Assay:** The type of chemistry used. Assay types are Kinetic-QCL®, PyroGene®, and PYROGENT® 5000 Assays.
- **Analyst ID:** ID of the analyst who ran the assay.
- **Workgroup:** Lab group and/or location where the template was created.

- **Modified:** Date the template was last modified.
- **Expired:** Indicates whether the reagents and accessories on the template are expired or in need of calibration. An 'X' indicates the template is unable to be run.

Template Button Controls

The buttons on the right side of the Template window have the following functions:

- **Search/Filter:** Click to display or hide the Search and Filter controls at the top of the window. For details about these controls, see "Search and Filter Controls" on page 159.
- **New:** Click to open the Template Manager to create a new template (see "Template Manager" on page 36).
- **Edit:** Click to open the Template Manager and edit the current selection in the list (see "Template Manager" on page 36).
- **View Only:** Click to display details about the current selection in the list (read-only) (see "Template Manager" on page 36).
- **Delete:** Click to delete the selected templates. A template can be deleted only by the analyst that created it and has Delete own Template permission, or by a user with the Delete any Template permission.
- **Run:** Click to display the Configure Assay Plate For Run window. Choose a template created by the logged in user. An analyst can run a test while another user is logged into the software (see "Selecting and Running a Template" on page 54).
- **Run as:** Click the arrow next to Run then select this option to display the Configure Assay Plate For Run window. Choose a template, this will run the template as the currently logged in user rather than template owner (see "Selecting and Running a Template" on page 54).
- **Edit Copy and Run:** Click the arrow next to Run then select this option to open the Template Manager and edit a copy of the current selection in the list. This copy is not saved, but can be used to run a test (see "Selecting and Running a Template" on page 54).
- **Copy:** Click to create a new template that is a partial copy of the selected template. Only information that is not related to products is copied from the selected template to the new template.
- **Copy All:** Click to create a new template that is an exact copy of the selected template. Information that is related to products is included. Only the template name is different. The new template is displayed in the list with the name of the analyst who created it.
 1. For Copy and Copy All functions, click **Copy** and enter a unique name for the new template.
 2. Click **OK**. All information that is not related to products is copied to the new template. (If the original template is changed later, those changes do not appear in the copy.)

The new template is displayed in the list with the name of the analyst who created it. The WinKQCL[®] Software associates the new template with the analyst who created it, rather than the creator of the original copy. This enables multiple analysts to run the same template.
- **Refresh:** Click to repopulate the list with the most current information from the WinKQCL[®] Software database.
- **Close:** Click to close the window.

Template Manager

Use the Template Manager to create, edit, and view templates. This interface is utilized for both master templates and assay templates. All WinKQCL® Software users can view templates. However, only the analyst who created a template can edit it.

The screenshot shows the Template Manager interface. The main window is titled "Template Manager - Example Plate". It contains a 96-well plate layout grid on the left, a properties panel on the right, and a products table at the bottom. Red circles with numbers 1 through 6 highlight specific features:

- 1: Points to a well in the plate grid.
- 2: Points to the "Test Type" dropdown in the properties panel.
- 3: Points to the "Replicates" spinner in the properties panel.
- 4: Points to an error message at the bottom: "The LAL Lot number/Expiration Date combination is not valid".
- 5: Points to the "Run" button in the bottom right.
- 6: Points to the "Products" table.

The properties panel on the right includes tabs for Setup, Standards, Lot / Exp, Accessories, Parameters, and Tags. The Setup tab is active, showing fields for Name (Example Plate), Assay Type (PYROAGENT-5000), Test Type (Routine), Product Layout (Automatic Layout), Replicates (3), Replicate Direction (Horizontal), Sample Fill Direction (Vertical), and CPC Fill Direction (Vertical).

The Products table at the bottom has columns: Num. Smpls, Name, Lot No., ID, Rel. Lim., Alert Limit, ET per, Dil./Conc., PPC Conc., and Note. It lists several products including Dextrose (5%-70%), Polymegacillin, and WFI.

Pane Description

1

Plate layout: The plate layout area always displays an up-to-date view of the location of items on the 96-well microplate.

2

Properties tabs: The tabbed area provides access to the properties of the template that is viewed or edited.

- **Setup:** Primary attributes of the template.
- **Standards:** Definition of the standard curve.
- **Lot / Exp:** Recording or scanning in the lot numbers and expiration dates of reagents that will be used with the template.
- **Accessories:** Association of accessories with the template.
- **Parameters:** Definition of reader parameters that will be used when the template runs. See "Template Defaults" on page 119 for more information about the parameters that can be defined here.

Pane	Description
3	<p>Products / CSE: The products (for Routine and Inhibition/Enhancement templates) or Control Standard Endotoxin (CSE) (for RSE/CSE templates) settings are accessible from this area. The products listed on the left side of the screen are the Template Products and are stored with this template. The product lists on the right side of the screen are generated from the master product list and the LIMS import database.</p> <p>See "Product Setup Area" on page 44 for more information.</p>
4	<p>Messages: The messages area displays information about any issues that must be resolved before the template is valid for saving. Only the most recent message is visible at the bottom of the Template Manager. (In the preceding example, "You must enter a Name for the template" is displayed.) Click the message area to display a list of all issues.</p>
5	<p>Operations buttons: The following operations are available:</p> <ul style="list-style-type: none"> ▪ Cancel: Click to discard any changes made and close the template. ▪ Print: Click to print the plate layout (large or actual microplate size) or the template report. ▪ Save: Click to save the new or changed template to the database. ▪ Run: Click to run immediately or to merge the template with another template before running the test.

Setup Tab

To name the template and specify other information about it, click the **Setup** tab on the template manager window.

- **Name:** Enter a unique description of the template, up to 60 characters in length.
- **Assay Type:** Choose the type of chemistry used. Click **KQCL**, **PYROGENT 5000**, or **PyroGene**. The assay type of new templates defaults to that of the most recently saved template. When a new assay type is chosen, its default preset standard curve is loaded automatically. For details of preset standard curves, see "Standards Tab" on page 39.
- **Test Type:** Choose the type of test that will be performed with the template. Click **Routine**, **Inhibition/Enhancement**, **RSE/CSE**, or **Initial Qualification**.
- **Automatic and Custom Layout:** Choose whether the WinKQCL® Software arranges the standards and products automatically or to grant manual control for the locations and replicate counts on the plate. In custom layout mode, items must be manually placed on the plate. In automatic layout, items are automatically placed according to the number of replicates, replicate direction, and fill direction settings.

NOTE: When a template is configured in automatic layout mode, the WinKQCL® Software will apply a correction factor to the calculated reaction time for kinetic tests. This correction factor assumes reagent is added one column at a time from left to right and compensates

Vertical Replicates

		Horizontal Fill						Vertical Fill					
		1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK		STD1 0.005	STD2 0.050	STD3 0.500	STD4 5.00	STD5 50.0						
B	BLNK		STD1 0.005	STD2 0.050	STD3 0.500	STD4 5.00	STD5 50.0						
C													
D													
E													
F													
G													
H													

Standards Tab

To specify the standards for the template, click the **Standards** tab on the Template Manager window.

- Standard List:** A list of the standards for the template can be defined. Enter the concentration of the standards in the right column. The number of decimal places entered is stored and is reproduced on assay reports. The allowed range is 1.0e-9 to 1.0e+9, inclusive. The blank is always assumed as a value of zero. Right click functions can be used to adjust the order of the standards when using the automatic layout feature. Right click on any of the standard concentration rows and a list of available commands will be displayed to the right of the standard concentration (as shown in the image below).

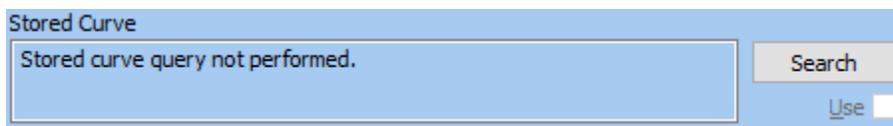
BLNK	0	
STD1	0.00500	Standards Increasing
STD2	0.05000	Standards Decreasing
STD3	0.50000	Duplicate
STD4	5.00000	Insert Blank Above
		Insert Blank Below
		Insert Empty Above
		Insert Empty Below
		Remove

- Standards Increasing / Standards Decreasing:** Clicking **Standards Increasing** will reorder the list with the highest concentration at the top of the list. Clicking **Standards Decreasing** will reorder the list with the lowest concentration at the top of the list. This will only affect standards. Blanks and empty rows will not change in their order.
- Duplicate:** Clicking **Duplicate** will create a duplicate set of replicates of whatever is clicked adjacent to the row selected. This feature is most often used when a user wants to run an extra set of replicates of the lowest standard.

- o **Insert Blank Above / Insert Blank Below:** Can be used to place the blank (negative control) replicates in a different location in the standard curve or to add an additional set of blanks (negative controls).
- o **Insert Empty Above / Insert Empty Below:** Can be used to separate standards and/or blanks with a set of empty wells.
- **Number of Standards:** Controls the number of standards. Clicking the spin wheel up will automatically determine the pattern and continue that pattern. For example, if 1, 2, 4, 8 are the current standards and a 5th standard is added, the new value will be 16.
- **Units:** Choose the unit of measure of the template standards. Click one of the defaults, EU, IU, or ng, or manually enter a label for the units. Type in up to 30 characters.
- **Enable Separate Layout Controls:** Defines the automatic layout for the standards to be different from the automatic layout of the products and positive product controls.
 - o **Replicates:** When enabled, choose the number of replicates for each standard, blank and empty well defined in the standards list.
 - o **Replicate Direction:** In Automatic layout, choose the direction that the standard replicates are placed next to each other. Click **Horizontal** or **Vertical**.
 - o **Sample Fill Direction:** In Automatic layout, choose the direction that the standard items are placed in succession. Click **Horizontal** or **Vertical**.
- **Preset Curve:** Choose from the preset standard curves stored in the database. Click a preset standard curve to load it into the concentration list. The defined curve can be saved as a new preset curve. Enter a unique name up to 20 characters long.
 - o **Save:** Click to save the new or changed preset curve.
 - o **Delete:** Click to delete the loaded preset curve. Default preset curves for assays cannot be deleted.
- **Stored Curve:** For information about this feature, see "Stored Curve" on page 40.

Stored Curve

On the Template Manager window, a Kinetic-QCL® or PYROGENT® 5000 template can be linked to the standard curve of a previously run assay. This action replaces the existing template with the standard curve of another assay. The Stored Curve area looks like this:



Click **Search** to find a standard curve from an assay that matches the reagent lot numbers and reader parameters of the current template. If more than one match is found, the curve from the most recently run assay is automatically selected.

The standard curve from a previous assay can be used if the previous assay meets the following conditions:

- Matches reagent lot numbers, reader parameters, and type of assay.
- Does not have unreacted or masked standards.

- Standards and blank have reacted in order (such as, blank must have reacted after the lowest standard and lowest after the second lowest).
- Did not use a stored curve itself.
- Is signed electronically by the analyst and a reviewer.
- Is one of the following tests:
 - Kinetic-QCL[®] Assay Routine, Inhibition Enhancement, or RSE/CSE Test
 - PYROGENT[®] 5000 Assay Routine, Inhibition Enhancement, or RSE/CSE Test

If a valid curve is not found, the Stored Curve area displays this message: “A signed test with matching parameters was not found”.

The Stored Curve feature is not available for PyroGene[®] Assay or Initial Qualification tests. When editing a PyroGene[®] Assay or IQ template, the Stored Curve area displays this message: “Stored curve not applicable”.

If a stored curve is found, the stored curve area displays information about the source. To use that curve, check the **Use** checkbox.



Once checked, the WinKQCL[®] Software automatically calculates the value of a standard control equal to the midpoint (on a log basis) of the stored curve. STD1 is set to this value. The standard control value may be changed to any concentration within the range of the curve in the source assay. When using a stored curve additional standards cannot be added.

Lot Number / Expiration Date Tab

To specify the lot numbers and expiration dates for the template, click the **Lot / Exp** tab on the Template Manager window.

NOTE: Lonza endotoxin reagent labels include 2D barcodes. ("2D" stands for two-dimensional.) The software supports scanning in lot number information with a 2D barcode scanner. The barcode encodes the part number, lot number and expiration date information. As long as a field in the lot number tab is selected, when the barcode is scanned, the WinKQCL[®] Software automatically determines which lot number field and expiration date field to update.

Kinetic-QCL® Assays:

Setup	Standards	Lot / Exp	Accessories	Parameters
		Lot Number		Expiration
LAL		<input type="text" value="LAL"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾
<u>W</u> ater		<input type="text" value="Water"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾
Endotoxin		<input type="text" value="Endotoxin"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾

PYROGENT® 5000 Assays:

Setup	Standards	Lot / Exp	Accessories	Parameters
		Lot Number		Expiration
LAL		<input type="text" value="LAL"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾
<u>W</u> ater		<input type="text" value="Water"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾
Endotoxin		<input type="text" value="Endotoxin"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾
<u>B</u> uffer		<input type="text" value="Buffer"/>		<input checked="" type="checkbox"/> 2/ 2/2023 ▾

PyroGene® Assays:

Setup	Standards	Lot / Exp	Accessories	Parameters
		Lot Number		Expiration
		rFC Enzyme	<input type="checkbox"/>	2/ 2/2023
		Water	<input type="checkbox"/>	2/ 2/2023
		Endotoxin	<input type="checkbox"/>	2/ 2/2023
		Buffer	<input type="checkbox"/>	2/ 2/2023
		Substrate	<input type="checkbox"/>	2/ 2/2023

- **LAL:** This field is only used with the Kinetic-QCL® and PYROGENT® 5000 Assays. Enter the Lonza Limulus amoebocyte lysate (LAL) lot number exactly as it appears on the Certificate of Analysis and reagent vial. A valid Lonza lot number is needed to save the template and run the assay.
- **rFC Enzyme:** This field is only used with the PyroGene® Assay. Enter the Lonza rFC Enzyme lot number exactly as it appears on the Certificate of Analysis and reagent vial. A valid Lonza lot number is needed to save the template and run the assay.
- **Water:** Enter the LAL reagent water (also known as Water for BET) lot number. This lot of water is used to reconstitute Kinetic-QCL® LAL reagent and endotoxin. This water is used as a diluent for standards and samples and as the blank.
- **Endotoxin:** Enter the endotoxin lot number. This endotoxin is used to construct the standard curve and create positive product controls (PPCs).
- **Buffer:** This field is only used with the PYROGENT® 5000 and PyroGene® Assays. Enter the buffer lot number.
- **Substrate:** This field is only used with the PyroGene® Assay. Enter the fluorogenic substrate lot number.
- **Expiration:** A checked box indicates that an expiration date is associated with the particular reagent. Once checked the box, the expiration date can be edited. An unchecked box indicates that particular reagent has no expiration date. Expiration dates are required for the LAL and rFC Enzyme reagents.

Accessories Tab

To specify accessories for the template, click the **Accessories** tab on the Template Manager window.

Template Accessories

Upon creating a new template, the Template Accessory list is filled with the user's default accessories. To configure default accessories, click **Accessories** on the main toolbar.

- **New:** Click to add an accessory directly to the template. This button is available only when analysts edit their own master template.
- **Edit:** Click to modify the selected template accessory. This button is available only to the analyst who created the template.
- **View:** Click to view the selected template accessory.
- **Delete:** Click to remove the selected template accessories from the list. This button is available only when analysts edit their own master template.

Master Accessories

For more information about the Accessories function of the WinKQCL[®] Software, see "Accessories" on page 68.

- **Copy:** Click to copy the selected master accessories into the template accessories list. This button is available only when analysts edit their own master template.
- **New:** Click to create a new master accessory. This button is available only when analysts edit their own master template.
- **Edit:** Click to modify the selected master accessory. This button is available only when analysts edit their own master template.
- **View:** Click to view the selected master accessory.
- **Delete:** Click to delete the selected master accessories. This button is available only when analysts edit their own master template.

Product Setup Area

On the Template Manager window, the Product area allows users to enter product information for samples to be tested.

Product Setup Functions

- **Product grid:** This grid lists the products of the template. Product attributes can be edited on the grid (see "Editing Template Products" on page 45).
- **Master products list:** This list contains the master WinKQCL[®] Software products. To copy master products into the template, double-click or drag them. To copy multiple master products simultaneously, hold the Ctrl key and click each of the desired master products. Then drag the selected products onto the template products table. To edit master products, click **Products** on the main toolbar.
- **LIMS products list:** This list provides access to worklists imported from LIMS, LIS, or Environmental Monitoring databases. To copy product information from this list into the template, double-click or drag them. To copy multiple LIMS products simultaneously, hold the Ctrl key and click each desired LIMS products. Then drag the selected items onto the

template products table. See "LIMS Product Import" on page 50 for information on importing product data from another system. LIMS products are sorted by Worklist, then Ordinal, and then Lot Number, ascending. When a LIMS product is already included in another template, it is colored blue in the list. Once a test is completed for a given LIMS product, it is no longer available for inclusion in future templates. To re-test a LIMS product, it must be re-imported.

- **New:** Click to add an empty row to the bottom of the list.
- **Remove:** Select a row and click to delete the row from the list.
- **SpeedFill™:** Check box to activate SpeedFill™ mode for rapid product entry using a keyboard or barcode scanner (see "SpeedFill™" on page 48).
- **<<Copy:** Selecting a row from the Products or LIMS list and clicking will copy that item to the bottom of the list.
- **<<Insert:** Selecting a row from the Products or LIMS list and clicking will insert the item above the row selected in the Template Products list.
- **<<Replace:** Selecting a row from the Products or LIMS list and clicking will replace the Template Product on the left with the Product selected on the right.

Editing Template Products

New product can be added to the list in two ways: click **Add** or **Copy** from the Master Product list. When a product is in the list, invalid and missing required attributes are highlighted. These issues must be resolved before saving the template.

All decimal numbers can be entered in scientific notation in this form:

<integer part>.<decimal part>e[+/-]<power>

For instance, 0.005 may be represented as 5e-3.

Template Product Attributes

Attribute	Description	Limits	Required?
Number of Samples / Sample Count	Number of samples of the product that will be tested. Use this field if multiple samples of the same product lot will be used. If a PPC (positive product control) is used with multiple samples, only one PPC will be placed for this group.	Integer from 1 to 94 inclusive.	Yes
Product Name	Name of the product.	Up to 60 characters.	Yes
Lot Number	Lot number of the product.	Up to 40 characters.	Yes

Attribute	Description	Limits	Required?
Product Id	Additional attribute to identify the product. May be useful to categorize products for future testing. Often used to define WFI loop location information or the beginning, middle or end of a lot-manufacturing run.	Up to 40 characters.	No
Release Limit	Release limit of the product. The release limit can be qualified with < or ≤.	Number from 1.0e-9 to 1.0e+9 inclusive.	No
Alert Limit	Alert limit of the product. The alert limit can be qualified with < or ≤.	Number from 1.0e-9 to 1.0e+9 inclusive. If defined then must be less than the release limit.	No
Endotoxin Concentration per	Denominator of unit of measure of endotoxin.	Selection of predefined unit or manual entry of up to 30 characters.	Yes
Dil./Conc. (Routine and Inhibition / Enhancement)	<p>Dilution or concentration (depending on unit) of the product.</p> <p>Units of mL or device result in dilution, all others result in concentration.</p> <p>Dilution entries indicate the denominator of the fraction. For example, a 10-fold (or 1/10) dilution is entered as 10. An undiluted sample is entered as 1.</p> <p>Selecting the Allow multiple dilutions/concentrations checkbox in the Products feature will allow multiple dilutions/concentrations to be stored, separated by a semicolon. If a product with multiple dilutions/concentrations is</p>	<p>Dilution: 1.0 to 1.0e+9 inclusive.</p> <p>Concentration: 1.0e-9 to 1.0e+9 inclusive.</p>	Yes

Attribute	Description	Limits	Required?
	added to a Routine type of template, this will create one template product for each dilution/concentration. If a product with multiple dilutions/concentrations is added to an Inhibition / Enhancement type of template, this will create one template product with all dilutions separated by semicolons.		
PPC	If selected, the PPC concentration field becomes active and a PPC can be associated with the product.	Checked or unchecked.	Yes
PPC Concentration	The concentration of endotoxin that is added to the product.	Within the range of the standard curve.	When PPC selected.
Number of Devices	Defines how many devices the Analyst used when preparing the device rinse that will be tested.	Integer from 1 to 20 inclusive.	For device only.
Extraction Volume	The volume in milliliters of rinse used to extract endotoxin from a set of medical devices.	Number from 1.0 to 1.0e+9 inclusive.	For device only.
Comment/Note	A comment associated with the product.	Up to 60 characters.	No

SpeedFill™

Use the SpeedFill™ mode to define template products quickly. SpeedFill™ mode automatically copies values from previously entered products into the next product added.

Products										
	Num. Smpls	Name	Lot No.	ID	Rel. Lim.	Alert Limit	ET per	Dil./Conc.	PPC Conc.	Note
Copy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
	2	WFI	L100	Drop1	≤ 1	≤ 0.5	mL	1	<input checked="" type="checkbox"/> 0.500	Room 100
*	2	WFI			≤ 1	≤ 0.5	mL	1	<input checked="" type="checkbox"/> 0.500	Room 100

When SpeedFill™ mode is active; a row of checkboxes appears at the top of the product grid. An entry row that is marked with a "*" appears at the bottom of the list. Checking a box in the **Copy** row will automatically copy the value in that column from the previous product into the * row when unchecked fields are filled in either manually or with a barcode scanner. Required items are shaded light red. When all required items are entered in the * row, the row is automatically saved. A new * row is added at the bottom, and the Copy cells are filled automatically.

In this example, the Lot Number and ID are not checked. When the Lot Number in the * row is entered, a new row is added, and all checked columns are copied.

Template Manager CSE Controls

Selecting the RSE/CSE assay type displays the Control Standard Endotoxin (CSE) controls in the lower product area of the Template Manager window.

1. In the Sets box, select the number of sets to test, up to six.
2. In the Units box, select **mL** or **ng** or type a unit name of up to 30 characters. If "mL" (milliliters) is selected, column header will change to "Dilutions". If "ng" (nanograms) is selected or a custom entry is made (up to 30 characters), the column header will change to "Concentrations".
3. In the Lot Number box, enter a number of up to 20 characters.
4. Click the **Add** button to configure a new CSE dilution or concentration. Enter the value for the dilution or concentration in the list. For mL units, values from 1.0 to 1.0e+09 range are accepted. If ng or a value other than mL is entered for the CSE units, values from 0.0001 to 100.0 are accepted.

5. Click the up or down arrow to select the number of sets of the configured dilutions or concentrations to set up on the template. At least 1 but no more than 6 dilution or concentration sets must be configured.
6. Click the **Remove** button to delete a selected dilution or concentration from the list.

Assay Plate Layout

The assay plate layout is always visible in the upper-left area of the Template Manager window.

In Automatic layout mode, the plate layout is automatically adjusted in real time to reflect changes.

In Custom layout mode, the plate layout is defined when replicates are placed and moved on the plate.

	1	2	3	4	5	6	7	8
A	BLNK	BLNK	S3+ WFI L100	S3+ WFI L100	S11 WFI L400	S11 WFI L400		
B	STD1 0.00500	STD1 0.00500	S4 WFI L200	S4 WFI L200	S12+ WFI L400	S12+ WFI L400		
C	STD2 0.0500	STD2 0.0500	S5 WFI L200	S5 WFI L200				
D	STD3 0.500	STD3 0.500	S6+ WFI L200	S6+ WFI L200				
E	STD4 5.00	STD4 5.00	S7 WFI L300	S7 WFI L300				
F	STD5 50.0	STD5 50.0	S8 WFI L300	S8 WFI L300				
G	S1 WFI L100	S1 WFI L100	S9+ WFI L300	S9+ WFI L300				
H	S2 WFI L100	S2 WFI L100	S10 WFI L400	S10 WFI L400				

Well Display

Standard	Red (shaded by relative concentration)	STD <Standard number> <Concentration>
Routine Product	Normal: blue, PPC: yellow	S <Sample number> [+ if PPC] <Sample name> <Lot number>
Inhibition / Enhancement Product	Normal: blue, PPC: yellow	S <Sample number> [+ if PPC] <Sample name> < Dilution > - <Lot number>
CSE	Green	C <Set number> <Dilution identifier> <Dilution>

Custom Layout

Custom layout allows random-access placement of items on the assay plate. Clicking the **Custom** radio button disables the Fill Direction control and displays the radio buttons for Edit and Place.

In Custom layout mode, the Replicates and Replicate Direction controls are used to specify how to place products dragged onto the plate.

In **Edit** mode, the product grid operates as usual, and products can be defined for the template.

In **Place** mode, the product grid changes to display each item that can be placed.

The following actions are possible in Place mode:

Place replicates on the plate

Select the item on the Product, CSE, or Standards list and then:

1. Click an empty well to place a single replicate.
2. Select multiple empty wells to place multiple replicates.
3. Drag the item onto a well to place replicates according to the Replicates and Replicate Direction controls.

Select next or previous product

Press **Ctrl+PageDown** or **Ctrl+PageUp** on the keyboard. Use these key combinations so that the mouse can stay in the plate area while selecting the next product for placement.

Remove an item from the plate

Select an item on the plate, right-click that selected item, and then click **Clear placements**.

Move items to a new location on the plate

Select and drag item to the new plate locations.

LIMS Product Import

The WinKQCL[®] Software provides a mechanism for importing product definitions from a Laboratory Information Management System (LIMS). Products imported from a LIMS are available in the Template Manager for inclusion in a template (see "Product Setup Functions" on page 44).

LIMS Products are stored in a database named **winkqclLims** on the WinKQCL[®] Software database server. When the WinKQCL[®] Software is installed, an empty **winkqclLims** database is created with a SQL Server[®] user who is granted access to import LIMS products. The username and password are selected as part of the WinKQCL[®] Software installation process (see "Creating a New WinKQCL[®] Software Database" on page 19).

To import a LIMS product and make it available for use in a template, connect to the **winkqclLims** database with the username and password configured during the WinKQCL[®] Software installation, and call the **LIMSClient.InsertProduct** stored procedure in the **winkqclLims** database. For all decimal parameters, the maximum total number of digits is 21, with a maximum of 11 digits after the decimal. The companion Precision field indicates the number of digits after

the decimal that are displayed in the software user interface and reports. The stored procedure accepts the following parameters:

Parameter	Type	Description
BatchId	nvarchar(60)	Indicates grouping of the product. Displayed in the "Worklist" column of the Template Manager LIMS Product list.
Name	nvarchar(60)	Name of the product.
LotNumber	nvarchar(40)	Lot Number of the product.
ProductId	nvarchar(40)	Secondary identifier of the product, useful for categorization.
Ordinal	Int	Number used to sort the product in the correct order within its batch.
UnitLabel	nvarchar(30)	Unit of measure of the product. Note for non-English systems: for a product to be interpreted as a device, the UnitLabel parameter must be "device" in English.
SampleCount	Tinyint	Number of samples of the product to test.
ReleaseLimitQualifier	Bit	Indicates whether samples with endotoxin concentrations equal to the release limit are considered passing. Value of 0 indicates samples must read less than release limit; value of 1 indicates samples must read less than or equal to the release limit.
ReleaseLimit	Decimal(21,11)	Release limit of the product.
ReleaseLimitPrecision	Tinyint	Number of digits after the decimal to display for the release limit.
AlertLimitQualifier	Bit	Indicates whether samples with endotoxin concentrations equal to the alert limit are considered passing. Value of 0 indicates samples must read less than alert limit; value of 1 indicates samples must read less than or equal to the alert limit.
AlertLimit	Decimal(21,11)	Alert limit of the product.
AlertLimitPrecision	Tinyint	Number of digits after the decimal to display for the alert limit.
ConcDil	Decimal(21,11)	Concentration or Dilution of the product.
ConcDilPrecision	Tinyint	Number of digits after the decimal to display for the Concentration or Dilution.
DeviceCount	Tinyint	Number of devices tested.
TotalExtractionVolume	Decimal(21,11)	Extraction Volume for a device product.

Parameter	Type	Description
TotalExtractionVolumePrecision	Tinyint	Number of digits after the decimal to display for the Total Extraction Volume.
HasPPC	Bit	Indicates whether the sample includes a PPC. Value of 1 indicates PPC included; value of 0 indicates PPC not included.
PPCConc	Decimal(21,11)	Concentration of the PPC.
PPCConcPrecision	Tinyint	Number of digits after the decimal to display for the PPC Concentration.
Comment	nvarchar(60)	Note or comment related to the product.
Workgroup	nvarchar(60)	The workgroup that the product belongs.

LIMSCient.InsertProduct stored procedure parameters

The parameters of the stored procedure are validated before the product is accepted for input. One of the following values is returned from the stored procedure indicating success or reason for failure:

Return value	Reason
0	Success
1	UnitLabel is device but DeviceCount is null
2	UnitLabel is device but TotalExtractionVolume is null
3	UnitLabel is not device but DeviceCount specified
4	UnitLabel is not device but TotalExtractionVolume specified
5	HasPPC = 1 but PPCConc is null
6	Ordinal must be greater than zero
7	Concentration outside allowed range 1.e-004 to 1.e+009 inclusive
8	Dilution outside allowed range 1 to 1.e+009 inclusive
9	Total Extraction Volume outside allowed range 1 to 1.e+009 inclusive
10	Device Count outside allowed range 1 to 20 inclusive
11	PPC Concentration outside allowed range 1.e-004 to 1.e+009 inclusive
12	Release Limit outside allowed range 1.e-009 to 1.e+009 inclusive
13	SampleCount outside allowed range 1 to 94 inclusive
14	ReleaseLimit is set but ReleaseLimitPrecision is null
15	TotalExtractionVolume is set but TotalExtractionVolumePrecision is null
16	PPCConc is set but PPCConcPrecision is null
17	ReleaseLimitPrecision outside allowed range 0 to 15 inclusive

Return value	Reason
18	ConDilPrecision outside allowed range 0 to 15 inclusive
19	TotalExtractionVolumePrecision outside allowed range 0 to 15 inclusive
20	PPCConcPrecision outside allowed range 0 to 15 inclusive
21	Workgroup is not present in the primary database
22	Alert limit outside allowed range 1.e-009 to 1.e+009 inclusive
23	Alert limit is set but AlertLimitPrecision is null

LIMSCient.InsertProduct stored procedure return values

With the exception of **BatchId** and **Ordinal**, the above parameters correspond to the Template Product fields. See "Editing Template Products" on page 45 for details on these fields. The **BatchId** and **Ordinal** fields are used to sort available LIMS products in the Template Manager. They are sorted by BatchId, then Ordinal, then LotNumber, ascending.

Running an Endotoxin Test

This section covers the steps necessary for using prepared templates to run endotoxin tests. The following topics are covered in this section:

- Opening the configure assay for run window (see "Selecting and Running a Template" on page 54).
- Merging templates in the configure assay for run window (see "Merging Templates" on page 54).
- Running a kinetic absorbance endotoxin test (see "Kinetic-QCL[®] and PYROGENT[®] 5000 Assays Test Procedure" on page 57).
- Running an endpoint fluorescence endotoxin test (see "PyroGene[®] Assay Test Procedure" on page 59).
- The completion of the test (see "The Endotoxin Test is Complete" on page 61).

NOTE: An analyst can run a test in the WinKQCL[®] Software if another user is already logged in and running a test. The WinKQCL[®] Software will keep track of which analyst is linked to which test. Multiple readers will need to be connected to the computer and one of the readers must be available when performing multiple tests in a single WinKQCL[®] Software session.

Selecting and Running a Template

A template can be run from two different locations in the software.

- In the **Templates** window, select a template that the current user created from the table and click **Run**. This will launch the **Configure Assay Plate For Run** window that allows users to add multiple templates to the same 96-well microplate.
- There are two options for running a test while editing or viewing a template in the **Template Manager**:
 - Click **Run > Run Merged Plate** to launch the **Configure Assay Plate For Run** window.
 - Click **Run** to immediately run the open template.

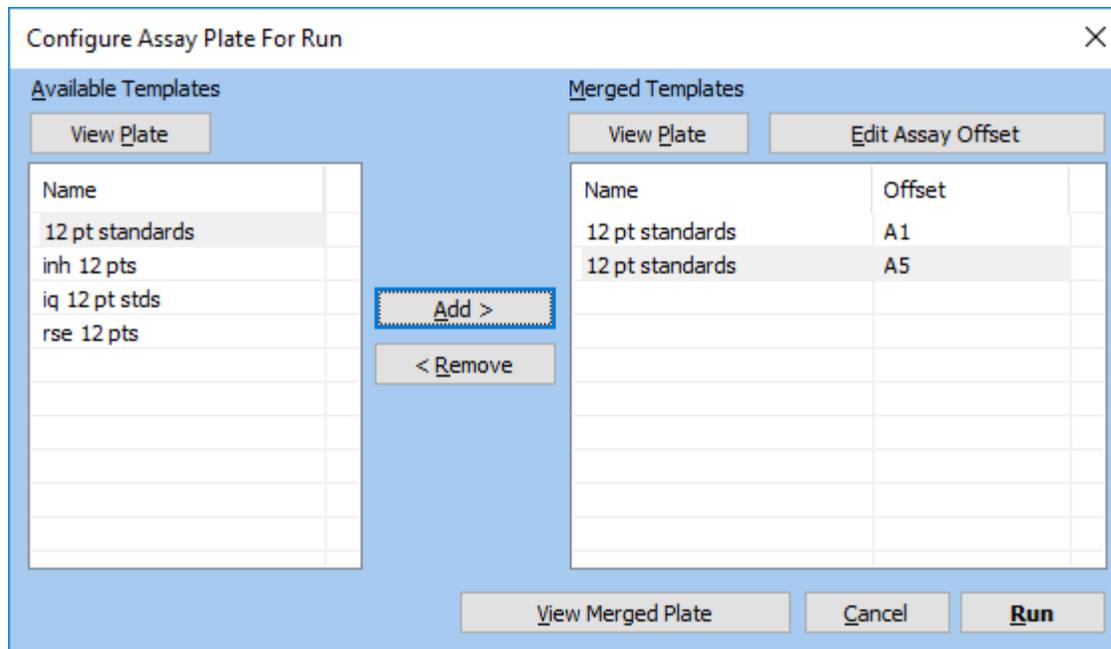
For instructions on how to merge templates using the **Configure Assay Plate For Run** window, see "Merging Templates" on page 54.

Click **Cancel** to close the **Configure Assay Plate For Run** window.

Merging Templates

This topic illustrates how to merge multiple templates onto a single 96-well microplate.

Open the **Configure Assay Plate for Run** window as previously instructed.



The template that is selected to run is called the primary template. The primary template must be positioned to start in the A1 well, regardless of where other assays are positioned on the microplate. Other assays added to the plate are referred to as secondary templates.

- The list of available templates are all templates that share the same values on the parameters tab as the template selected.
- To add a secondary template to the assay plate, select the template and click **Add>**. The selected template is positioned automatically.
- To remove a secondary template from the assay plate, select the template and click **<Remove**.
- To change the position of a secondary template on the assay plate, select the template and click **Edit Assay Offset**. Click the well at the upper-left corner of the new location of the plate.

NOTE: Secondary templates that have an automatic layout and a vertical fill direction must start in row A. Secondary templates that have a horizontal fill direction must start in column 1. Custom templates can be positioned anywhere on the plate, as long as space permits.

- To view the available templates and merged templates, select a template from the list, and then click **View Plate**. The template layout is printable from that window.

12 pt standards

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	STD8 1000	STD8 1000								
B	STD1 0.000:	STD1 0.000:	STD9 10000	STD9 10000								
C	STD2 0.001	STD2 0.001	STD10 10000	STD10 10000								
D	STD3 0.01	STD3 0.01	STD11 10000	STD11 10000								
E	STD4 0.1	STD4 0.1	STD12 10000	STD12 10000								
F	STD5 1	STD5 1	S1 pro 5675	S1 pro 5675								
G	STD6 10	STD6 10	S2 pro 5675	S2 pro 5675								
H	STD7 100	STD7 100	S3+ pr 5675	S3+ pr 5675								

Print Actual Print Close

- To view a merged assay plate, click **View Merged Plate**. The merged layout is printable from the Merged Plate window.

Merged Plate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	STD8 1000	STD8 1000	BLNK	BLNK	STD8 1000	STD8 1000				
B	STD1 0.000:	STD1 0.000:	STD9 10000	STD9 10000	STD1 0.000:	STD1 0.000:	STD9 10000	STD9 10000				
C	STD2 0.001	STD2 0.001	STD10 10000	STD10 10000	STD2 0.001	STD2 0.001	STD10 10000	STD10 10000				
D	STD3 0.01	STD3 0.01	STD11 10000	STD11 10000	STD3 0.01	STD3 0.01	STD11 10000	STD11 10000				
E	STD4 0.1	STD4 0.1	STD12 10000	STD12 10000	STD4 0.1	STD4 0.1	STD12 10000	STD12 10000				
F	STD5 1	STD5 1	S1 pro 5675	S1 pro 5675	STD5 1	STD5 1	S1 pro 5675	S1 pro 5675				
G	STD6 10	STD6 10	S2 pro 5675	S2 pro 5675	STD6 10	STD6 10	S2 pro 5675	S2 pro 5675				
H	STD7 100	STD7 100	S3+ pr 5675	S3+ pr 5675	STD7 100	STD7 100	S3+ pr 5675	S3+ pr 5675				

Print Actual Print Close

- When configuration is complete, click **Run**.

Kinetic-QCL® and PYROGENT® 5000 Assays Test Procedure

To run the Kinetic-QCL® and PYROGENT® 5000 Assay absorbance tests, follow these steps:

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.
2. Log in as an analyst. When launched, the WinKQCL® Software enables the incubator for all attached readers. If another user is already logged in, the test can run with a separate user account without logging the current user out of the software.
3. In the **Templates** window, select a template in the table, and click **Run**. The **Configure Assay Plate for Run** window is displayed (see "Selecting and Running a Template" on page 54). If editing a template, click **Run** to run the template immediately, or click **Run Merged Plate** to go to the **Configure Assay Plate for Run** window. For more information about the Templates window, see "Templates" on page 34.
4. On the **Configure Assay Plate for Run** window, two or more templates can be merged onto a single physical plate (see "Merging Templates" on page 54).

NOTE: The plate layout can be printed in color to the actual size of the microplate from the Template Manager or the Configure Assay Plate for Run window. The microplate can be placed on top of the printed layout graphic to guide the user when adding blanks/negative controls, standards, products and positive product controls to the plate.

5. Click **Next**. The Reader Selection window is displayed.
6. On the reader selection window, select the workgroup for this test and select an available absorbance or multimode reader. Click **OK** to start the test. The WinKQCL® Software tests the connection with the selected reader and then monitors the reader temperature until it reaches $37 \pm 0.5^\circ\text{C}$. When the temperature reaches $37 \pm 0.5^\circ\text{C}$, a prompt appears to place the plate on the carriage.

WARNING In order to allow the WinKQCL® Software to control the BioTek™ ELx808™ Reader, the Main Menu on the reader must be displayed and cannot be changed while the test is in progress. The Main Menu looks like this:

READY	(local time)	(temp)
READ	DEFINE	REPORT
		UTIL

7. [On a reader that cannot be manually opened, click **Plate out**]. Place the 96-well plate containing blanks, standards, and samples on the reader carriage. [If required, click **Plate in**.] Click **OK**.

WARNING Do not leave the carrier door open any longer than is necessary. The incubation chamber and the plate will begin dropping in temperature as soon as the carrier door is opened.

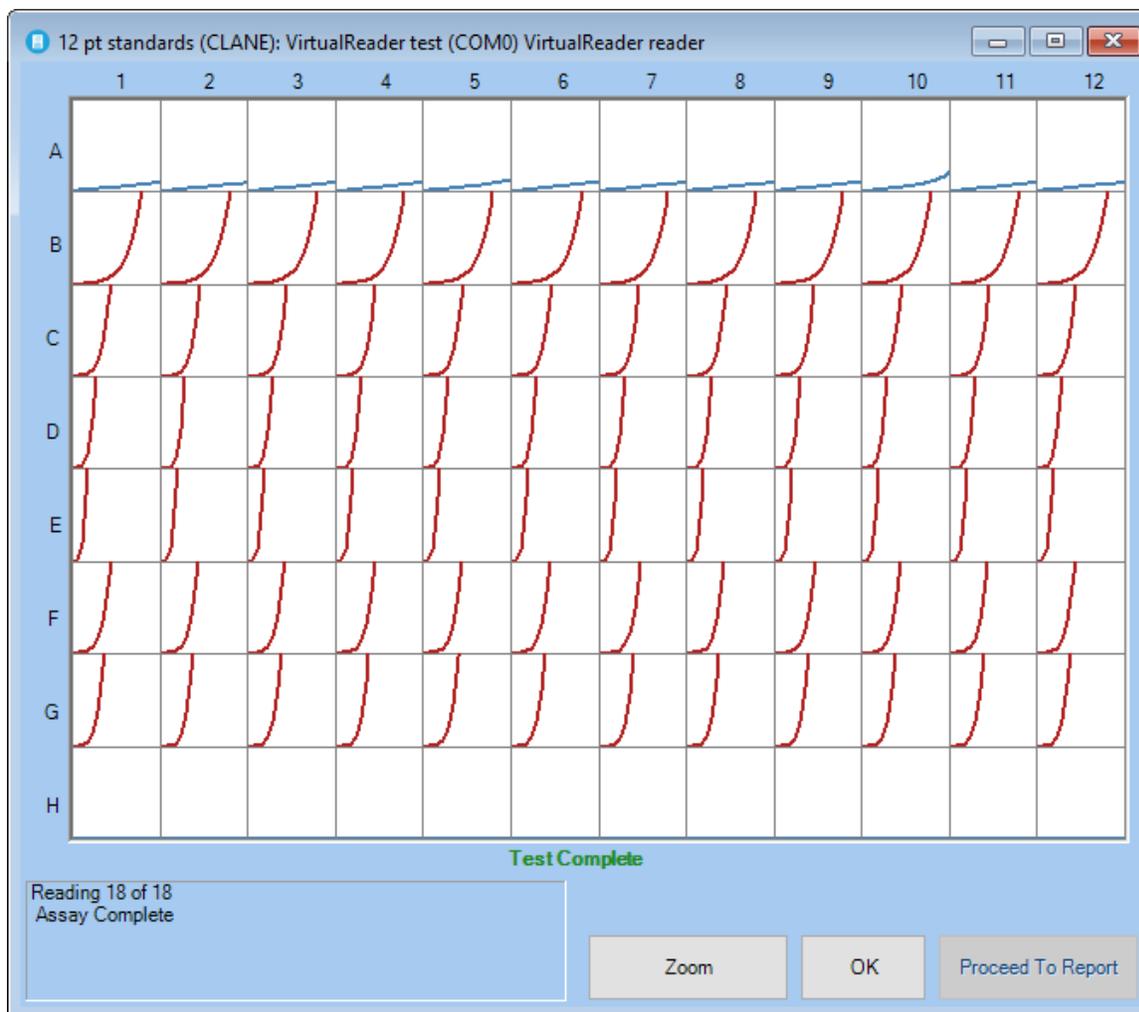
8. The software confirms the placement of the assay plate and displays a progress bar to count down the incubation period. The 96-well plate must be incubated for a minimum of

10 minutes before the reagent is added. When the plate is properly incubated, the temperature is uniform and the test results are more accurate. The software prompts to add the reagent to the plate when the incubation period ends. To bypass, click **Skip** to override the incubation timer and proceed to the **Add Reagent** window early.

9. [On a reader that cannot be manually opened, click **Plate out**.] Use a multichannel pipette and add the reagent to the plate. Start at the left side of the plate and work to the right. Maintain a constant interval between additions. Do not allow bubbles to form in the microplate wells. After adding the reagent to the last column, immediately close the cover or if required, click **Plate in**. Run this test with the microplate lid off. Click **OK** to start the test.

NOTE: It is important to add the reagent from left to right, maintaining a constant interval between additions. When a template is configured in automatic layout mode, the WinKQCL® Software will apply a correction factor to the calculated reaction time for kinetic tests. This correction factor assumes reagent is added from left to right and compensates for the time it takes to add the LAL reagent to the plate. In custom layout mode, the correction factor is not applied.

- After the system confirms that the reagent is added, a window is displayed that tells how long the plate will be shaken. The reader shakes the plate. After approximately 30 seconds, the reader monitors the absorbance reaction.
- As the system reads the plate, a 96-well plate diagram displays the test progress. The y-axis of each well represents the change in absorbance. The range is from zero (0) to a predefined upper-level onset optical density (OD). The x-axis of the well represents the elapsed time of the assay. The diagram is updated after each read cycle as indicated in the lower left part of the display. The optical density is plotted for each read cycle. The graph will change to red once the onset optical density is reached and a reaction time is determined. Absorbance levels higher than the upper onset are not plotted. When the test is complete, the final graph is part of the Raw Data report.



- This window can be moved or resized during the test. Other WinKQCL® Software features can be accessed during the test. If another reader is available on the workstation, the user can start another test.
 - The user may zoom into individual wells, or a series of wells by clicking on each one then pressing **Zoom**. A well is designated as being selected to zoom if the width of the line increased. The zoom feature supports both mOD and delta mOD analysis.
10. The Proceed To Report feature stops a test before it is complete and saves the data up to the current read cycle. Clicking **Proceed To Report** displays a confirmation dialog. **No** continues the test, and **Yes** ends the test proceeding to the test report.
 11. When a test runs to completion, the WinKQCL® Software displays an Assay Complete message and the **OK** button becomes active. Click **OK** to view the report.

PyroGene® Assay Test Procedure

To run a PyroGene® Assay fluorescence test, follow these steps:

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.

2. Log in as an analyst. When launched, the WinKQCL® Software enables the incubator for all attached readers. If another user is already logged in, the test can run with a separate user account without logging the current user out of the software.
3. In the **Templates** window, select a template in the table, and click **Run**. The **Configure Assay Plate for Run** window is displayed (see "Selecting and Running a Template" on page 54). If editing a template, click **Run** to run the template immediately, or click **Run Merged Plate** to go to the **Configure Assay Plate for Run** window. For more information about the Templates window, see "Templates" on page 344.
4. On the **Configure Assay Plate for Run** window, two or more templates can be merged onto a single physical plate (see "Merging Templates" on page 54).

NOTE: The plate layout can be printed in color to the actual size of the microplate from the Template Manager or the Configure Assay Plate for Run window. The microplate can be placed on top of the printed layout graphic to guide the user when adding blanks/negative controls, standards, products and positive product controls to the plate.

5. Click **Next**. The Reader Selection window is displayed.
6. On the reader selection window, select the workgroup for this test and select an available fluorescence or multimode reader. Click **OK** to proceed. A reader setup dialog is displayed.

WARNING In order to allow the WinKQCL® Software to control the BioTek™ FLx800™ reader, the Main Menu on the reader must be displayed and cannot be changed while the test is in progress. The Main Menu looks like this:

READY	(local time)	(temp)
READ	DEFINE	REPORT
		UTIL

7. The WinKQCL® Software tests the connection with the selected reader and then monitors the reader temperature until it reaches $37 \pm 0.5^{\circ}\text{C}$. When the temperature reaches $37 \pm 0.5^{\circ}\text{C}$, a prompt appears to place the plate on the carriage.
8. [On a reader that cannot be manually opened, click **Plate out**]. Place the 96-well plate containing blanks, standards, and samples on the reader carriage. [If required, click **Plate in**.] Click **OK**.

WARNING Do not leave the carrier door open any longer than is necessary. The incubation chamber and the plate will begin dropping in temperature as soon as the carrier door is opened.

9. The software confirms the placement of the assay plate and displays a progress bar to count down the incubation period. The 96-well plate must be incubated for a minimum of 10 minutes before the reagent is added. When the plate is properly incubated, the temperature is uniform and the test results are more accurate. The software prompts to add the reagent to the plate when the incubation period ends. To bypass, click **Skip** to override the incubation timer and proceed to the **Add Reagent** window early.

10. Prepare a working reagent by mixing the fluorogenic substrate, rFC assay buffer and the rFC enzyme solution according to the package insert.
11. [On a reader that cannot be manually opened, click **Plate out.**] Use a multichannel pipette and add the reagent to the plate. Start at the left side of the plate and work to the right. Maintain a constant interval between additions. Do not allow bubbles to form in the microplate wells. Run this test with the microplate lid off. After adding the reagent to the last column, immediately close the cover. [If required, click **Plate in.**] Click **OK** to start the test.
12. After the system confirms that the reagent is added, a window is displayed that tells how long the plate will be shaken. The reader shakes the plate. After it finishes shaking, the WinKQCL[®] Software takes its first reading of the plate. A window is displayed warning not to open the reader door. After the first read is complete, the Elapsed Time window is displayed. This window indicates the amount of time that has elapsed since the first read began. The progress bar advances as time elapses between the reads.

NOTE: Clicking **Stop Test Early** stops the current test and the system proceeds directly to the second read. A prompt appears to confirm that the WinKQCL[®] Software should proceed to the second read. If **Yes** is clicked, the WinKQCL[®] Software begins the second read. The system also writes the actual incubation time to the results report and to the template that is saved with this test. If **No** is clicked, the Elapsed Time window is displayed.

13. The WinKQCL[®] Software takes the second reading of the plate. When the second read is complete, the data is saved to the database automatically and the results report is displayed.

The Endotoxin Test is Complete

When the endotoxin test is complete, the WinKQCL[®] Software performs the following steps:

1. Automatically stores the results of the test to the database.
2. Prompts to remove the plate from the reader. (If applicable, the window displays the button to open the reader door.)
3. Automatically displays the test in the Endotoxin Test Results window and any assay alerts (see "Endotoxin Test Results Window" on page 72). If multiple tests were run on the plate, use the Previous Test and Next Test buttons to select and view the other tests that were run on the plate.

For more information about analysis, editing, and electronic signatures, see "Endotoxin Tests" on page 70.

The recorded data from the standard curve of a completed Kinetic-QCL[®] or PYROGENT[®] 5000 Assay tests can be used in a new template as the stored standard curve (see "Stored Curve" on page 40).

Test Alerts

Test alerts may occur at the end of the test for the following reasons:

- If the standards react out of order
- If the R-value fails

- If the PowerCurve™ plotted is not monotonic or has a shape that prevents accurate calculation of the standards or samples.
- If the number of standards that reacted was too low

The following AER warnings can be printed on the report:

- Alert! All replicates of a standard masked!
- Alert! Standard with unreacted replicate(s)!
- Alert! All replicates of a blank masked!
- Alert! Blank reacted before lowest standard!
- Alert! Standards reacted out of order!
- Alert! All replicates of a standard high O.D.!
- Alert! All replicates of a blank high O.D.!
- Alert! All replicates of a standard high R.F.U.!
- Alert! All replicates of a blank high R.F.U.!
- Alert! Invalid assay. Unable to perform math transformations!

Products

To display the Products window, click **Products** on the main toolbar. This list of products is often referred to as the "Master Products List" as it is the primary storage location for product information. Analysts running tests can "drag-and-drop" or "pick-and-place" products from this list into the template products list without needing to re-enter that information. Using this feature to pre-define product information for the templates ensures the product naming is consistent, and ensures product data can be properly trended. For example, if a product is spelled two different ways, it will appear to the software as two different products.

Product List

The title bar displays the number of records in the list. Initially the list is sorted by Workgroup and Product Name (descending alphabetically). To sort the list; click a column header (see "Sortable Lists" on page 161). The Name, Lot number, Product ID, unit of measure, release limit, dilution/concentration, and workgroup is displayed for each product (see "Product Edit" on page 64 for more information about these product attributes). The WinKQCL[®] Software will only display products for workgroups to which the users have access. From this window, users with permission to manage products can create new products and edit existing products. Users without permission to manage products can only view and print existing products. Supervisors can allow any user to manage this list by selecting the Manage Products option for a user (see "User Maintenance" on page 139).

For instructions on using the buttons on the right side of the window, see "Products List Buttons" on page 644. For instructions on using the search and filter controls at the top of the window, see "Search and Filter Controls" on page 159.

The screenshot shows a software window titled "Products (Records: 4)". At the top, there is a "Product Search" field, a checkbox for "Allow multiple dilutions", and "Apply" and "Reset" buttons. Below this is a table with the following columns: Product Name, Lot Number, Product ID, ET per, Rel. limit, Dilution/Concentration, and Workgroup. The table contains four rows of data. To the right of the table is a vertical sidebar with buttons for "New", "Edit", "USP Listing", "Delete", "Print", "View Only", "Refresh", and "Close".

Product Name	Lot Number	Product ID	ET per	Rel. limit	Dilution/Concentration	Workgroup
Acylovir for Injection			mg	≤ 0.174	50	Demo
Dextrose (5%-70%)			ml	≤ 0.125		Demo
Polymegacillin			ml	≤ 9		Demo
Water for Injection and St...			mL	≤ 0.25		Demo

Products List Buttons

The buttons on the right side of the window have the following functions:

- **Product (Search):** These search controls include the Product field, an "Allow Multiple Dilutions" checkbox, the Apply button, and the Reset button at the top of the window (see "Search and Filter Controls" on page 159).
- **New:** Click to add a product to the master product list (see "Product Edit" on page 64).
- **Edit:** Click to edit the current selection in the list (see "Product Edit" on page 64).
- **Delete:** Click to delete an existing product. The product is deleted immediately.
- **Print:** Click to display the list in a printable report form (see "Common Report Controls" on page 157).
- **View Only:** Click to display read-only details related to the current selection in the list (see "Product Edit" on page 64).
- **Refresh:** Click to repopulate the list with the most current information from the WinKQCL[®] Software database.
- **Close:** Click to close the window.

Product Edit

The Product Edit window can be used to perform the following actions:

- Edit an existing product in the WinKQCL[®] Software database.
- View an existing product in the WinKQCL[®] Software database (No modifications are possible).
- Add a new product to the WinKQCL[®] Software database.

New Product

Product Name: Dextrose (5%-70%)

Lot Number: [Empty]

Product Id: [Empty]

Endotoxin Concentration per: mL

Sample Count: [Empty]

Release Limit: 0.125

Alert Limit: N/A

Number of Devices: 0

PPC: N/A

Total Extraction Volume in mL: [Empty]

Allow multiple dilutions

Dilution: [Empty]

Comment: [Empty]

Workgroup: Lonza

Buttons: Calculator, OK, Cancel

The controls on the Product Edit window have the following functions:

- **Workgroup:** Select which functional group with which the product is associated.
- **Calculator:** Click to display the Calculator window. This feature is useful when trying to calculate the dilution factor or the release limit.
- **OK:** Click to validate the field entries and save changes.
- **Cancel:** Click to discard changes.

The fields on the Product Edit window have the following attributes:

Attribute	Description	Limits	Required?
Number of Samples / Sample Count	Number of samples of the product that will be tested. Use this field if multiple samples of the same product lot will be used. If a PPC (positive product control) is used with multiple samples, only one PPC will be placed for this group.	Integer from 1 to 94 inclusive.	Yes

Attribute	Description	Limits	Required?
Product Name	Name of the product.	Up to 60 characters.	Yes
Lot Number	Lot number of the product.	Up to 40 characters.	Yes
Product Id	Additional attribute to identify the product. May be useful to categorize products for future testing. Often used to define WFI loop location information or the beginning, middle or end of a lot-manufacturing run.	Up to 40 characters.	No
Release Limit	Release limit of the product. The release limit can be qualified with < or ≤.	Number from 1.0e-9 to 1.0e+9 inclusive.	No
Alert Limit	Alert limit of the product. The alert limit can be qualified with < or ≤.	Number from 1.0e-9 to 1.0e+9 inclusive. If defined then it must be less than the release limit	No
Endotoxin Concentration per	Denominator of unit of measure of endotoxin.	Selection of predefined unit or manual entry of up to 30 characters.	Yes
Dil./Conc. (Routine and Inhibition / Enhancement)	Dilution or concentration (depending on unit) of the product. Units of mL or device result in dilution, all others result in concentration. Dilution entries indicate the denominator of the fraction. For example, a 10-fold (or 1/10)	Dilution: 1.0 to 1.0e+9 inclusive. Concentration: 1.0e-9 to 1.0e+9 inclusive.	Yes

Attribute	Description	Limits	Required?
	<p>dilution is entered as 10. An undiluted sample is entered as 1.</p> <p>Selecting the Allow multiple dilutions/concentrations checkbox in the Products feature will allow multiple dilutions/concentrations to be stored, separated by a semicolon. If a product with multiple dilutions/concentrations is added to a Routine type of template, this will create one template product for each dilution/concentration. If a product with multiple dilutions/concentrations is added to an Inhibition / Enhancement type of template, this will create one template product with all dilutions separated by semicolons.</p>		
PPC	If selected, the PPC concentration field becomes active and a PPC can be associated with the product.	Checked or unchecked.	Yes
PPC Concentration	The concentration of endotoxin that is added to the product.	Within the range of the standard curve.	When PPC selected.
Number of Devices	Defines how many devices the Analyst used when preparing the device rinse that will be tested.	Integer from 1 to 20 inclusive.	For device only.
Extraction Volume	The volume in milliliters of rinse used to extract endotoxin from a set of medical devices.	Number from 1.0 to 1.0e+9 inclusive.	For device only.
Comment/Note	A comment associated with the product.	Up to 60 characters.	No

Accessories

To launch the accessories management window, click **Accessories** on the main toolbar. This window displays information that is related to equipment and ancillary products used in endotoxin testing. The master list is a system-wide list of accessories available to all users.

Accessory List

All users can view accessory information. However, only analysts can create, edit, and delete accessories. Each analyst can customize a default accessories list, which is called the user template defaults. Accessories in the user template defaults list are added automatically to templates that the analyst creates.

User Template Defaults: 3		Master List: 6		
Accessory Name	Lot Number	Accessory Name	Lot Number	Workgroup
13mm Dilution Tubes	123D	10 uL Pipette	V0028	Demo
MP200 Multipipettor	PIP 375	13mm Dilution Tubes	123D	Demo
P20 Pipettor	PIP 008	MP200 Multipipettor	PIP 375	Demo
		P20 Pipettor	PIP 008	Demo
		P200 Pipettor	PIP 489	Demo
		PIPETTOR 1	12631253	Demo

- <<: Click to copy selected master accessories to the user template defaults list.
- >>: Click to remove selected master accessories from the user template defaults list.
- **New**: Click to add a new accessory to the master list (see "Editing an Accessory" on page 69).
- **Delete**: Click to remove selected accessories from the master list.
- **Edit**: Click to modify the selected accessory in the master list (see "Editing an Accessory" on page 69).
- **View Only**: Click to view the accessory details for the selected in either list.
- **OK**: Click to save any changes and close the window.
- **Cancel**: Click to close the window without saving.

Editing an Accessory

The Accessory Edit window can be used to perform the following actions:

- Add a new accessory to the Master Accessory List.
- Edit an existing accessory.
- Update the information for accessories copied to any existing templates in one step.

The controls on the Accessory Edit window have the following functions:

- **Name:** Enter an accessory description.
- **Lot # / SN:** Enter the lot number or serial number for the accessory item.
- **Manufacturer:** Enter the manufacturer of the accessory item. Make sure all accessories made by the same company have the same Manufacturer name.
- **Comment:** Provide any additional metadata associated with the accessory.
- **Calibration Due:** If the accessory is a device that is calibrated, enter that date in this field. The WinKQCL[®] Software will prevent running a template with an accessory that has passed its calibration due date.
- **Expiration:** If the accessory is a product that expires, enter that date in this field. The WinKQCL[®] Software will prevent running a template with an accessory that has expired.
- **Update Template Accessories:** This checkbox is only available when editing an existing accessory. If this checkbox is checked, when the OK button is clicked, all template accessories with the same name and lot number will be updated to match the edited accessory. This action applies only to templates in the workgroups accessible by the current user.
- **OK:** Click to validate the field entries and save changes.
- **Workgroup:** Select which functional group with which the product is associated.
- **Cancel:** Click to discard changes.

Endotoxin Tests

To display the Endotoxin Tests window, click **Endotoxin Tests** on the main toolbar. This window lists all endotoxin tests that were previously run. The title bar displays the number of records currently in the list. Initially, the list is sorted by Workgroup and then Date/Time (most recent first). To sort the list, click a column header (see "Sortable Lists" on page 161).

Endotoxin Tests (Records: 130)

Search/Filter

From: Name: All Test Types Technician: Me

To: 2/27/2019 Product: All Assay Types Signed:

Date	Time	Name	#	Test	Assay	Technician ID	A	R	LIMS	Workgroup
5/24/2018	3:57:30 PM	iq-Cheryl McPhemus	0	Initial Qualification	Kinetic-QCL	CMCP	1	1	0	Demo
5/24/2018	3:45:38 PM	iq-Karsen McShoe	0	Initial Qualification	Kinetic-QCL	KMCS	1	1	0	Demo
5/24/2018	3:37:43 PM	iq-Karsen McShoe	0	Initial Qualification	Kinetic-QCL	KARSON	1	1	0	Demo
5/24/2018	3:29:44 PM	iq-Sheryl McShoe	0	Initial Qualification	Kinetic-QCL	SMCP	1	1	0	Demo
5/19/2018	3:29:32 PM	rse/cse - p jones tu	0	RSE/CSE	PYROGENT-5...	PJONES	1	1	0	Demo
5/19/2018	3:29:32 PM	inh/en - p jones tur	1	Inhibition/Enhancem...	PYROGENT-5...	PJONES	1	1	0	Demo
5/19/2018	3:29:32 PM	routine - p jones tu	2	Routine	PYROGENT-5...	PJONES	-	-	0	Demo
5/19/2018	3:29:32 PM	iq - p jones turb	3	Initial Qualification	PYROGENT-5...	PJONES	1	1	0	Demo
5/17/2018	6:26:46 PM	rse/cse - j smith	0	RSE/CSE	Kinetic-QCL	JSMITH	1	1	0	Demo
5/17/2018	6:26:46 PM	inh/en - j smith	1	Inhibition/Enhancem...	Kinetic-QCL	JSMITH	1	1	0	Demo
5/17/2018	6:26:46 PM	routine - j smith	2	Routine	Kinetic-QCL	JSMITH	1	1	0	Demo
5/17/2018	6:26:46 PM	iq - j smith	3	Initial Qualification	Kinetic-QCL	JSMITH	1	1	0	Demo
5/17/2018	4:25:08 PM	rse/cse - c lane tur	0	RSE/CSE	PYROGENT-5...	CLANE	1	1	0	Demo
5/17/2018	4:25:08 PM	inh/en - c lane turb	1	Inhibition/Enhancem...	PYROGENT-5...	CLANE	1	1	0	Demo
5/17/2018	4:25:08 PM	routine - c lane tur	2	Routine	PYROGENT-5...	CLANE	1	1	0	Demo
5/17/2018	4:25:08 PM	iq - c lane turb	3	Initial Qualification	PYROGENT-5...	CLANE	1	1	0	Demo
5/14/2018	4:10:22 PM	rse/cse - j smith tu	0	RSE/CSE	PYROGENT-5...	JSMITH	1	1	0	Demo
5/14/2018	4:10:22 PM	inh/en - j smith tur	1	Inhibition/Enhancem...	PYROGENT-5...	JSMITH	1	1	0	Demo
5/14/2018	4:10:22 PM	routine j smith turb	2	Routine	PYROGENT-5...	JSMITH	1	1	0	Demo
5/14/2018	4:10:22 PM	iq - j smith turb	3	Initial Qualification	PYROGENT-5...	JSMITH	1	1	0	Demo
5/14/2018	4:06:01 PM	rse/cse - j smith tu	0	RSE/CSE	PYROGENT-5...	JSMITH			0	Demo

View Results
View Raw Data
View Template
Export to LIMS
Analyze
Edit Assay
Unlock E-Sigs
Refresh
Close

Test List

The following information is displayed for each assay.

- **Date / Time:** The date and time a test was run. The time is stored in UTC format in the database and adjusted to the current time zone from where the client software is running. UTC stands for Coordinated Universal Time.
- **Name:** The name of the template used for the test.
- **#:** The numbering for tests that were run with the multiple tests per plate feature of the WinKQCL® Software. Numbering begins at zero (0) for the primary template and goes up. For example, if 4 tests are run on one plate, they are numbered from zero (0) to 3. The value for single tests is always zero.
- **Test:** The test type, purpose, or objective. For example: Routine, Initial Qualification, RSE/CSE, and Inhibition Enhancement.
- **Assay:** Refers to the type of chemistry used. Assay types are Kinetic-QCL®, PyroGene®, and PYROGENT® 5000.
- **Technician ID:** ID of the user that ran the test.
- **A / R:** These columns display the signature status of the test. A **1** in the A (analyst) or R (reviewer) column indicates that the analyst or reviewer has signed the test. A "-" (hyphen symbol) in either column indicates that the test was fully signed once, but the signature was unlocked for further analysis. A **2** in either column indicates that the test is electronically signed for a second time (following removal of first signature).

- **LIMS:** Indicates the number of times the assay has been exported to Laboratory Information Management System (LIMS).
- **Workgroup:** Lab group and/or location where the test was created. By default, the WinKQCL[®] Software sorts by this list first.

Endotoxin Tests Button Controls

The buttons on the right side of the window have the following functions:

- **View Results:** Click to display the results of the test in a printable report format. Users can edit, analyze, review, electronically sign, and export data from this window (see "Endotoxin Test Results Window" on page 72).
- **View Raw Data:** Click to display raw test data. For kinetic tests, the 96-well graph will be displayed at the top of the report (see "View Raw Data" on page 164).
- **View Template:** Click to display the test's template information (see "Edit Assay and View Template Buttons" on page 163).
- **Export to LIMS:** Exports the test to an external system. These external systems include laboratory information management systems and environmental monitoring systems, such as Lonza's MODA[®] Solution (see "LIMS Options" on page 147).
- **Analyze:** Allows the analyst who ran the assay or a user with the **Sign other analysts' Endotoxin tests** permission to analyze it (see "Analyze" on page 161).
- **Edit Assay:** This button is present only for an analyst or reviewer. Click to edit the template for the test (see "Edit Assay and View Template Buttons" on page 163).
- **Unlock E-Sig:** This button is only active for users who have permission to unlock electronic signatures. Click to unlock a set of Analyst and Reviewer electronic signatures so the test may be edited (see "Unlocking an Electronic Signature" on page 166).
- **Refresh:** Click to repopulate the list with the most current information from the WinKQCL[®] Software database.
- **Close:** Click to close the window.

Endotoxin Test Results Window

The Endotoxin Test Results window displays a printable report of details for a particular test. To see this window, click **View Results** on the Endotoxin Tests window. The Endotoxin Test Results window displays the test selected from the Endotoxin Tests window.

The screenshot shows the 'Endotoxin Test Results' window for 'sample 2 [654CDA1abcdefg]'. The main report area displays the following information:

Integration & Testing - Demo		Displayed In Version : 6.0.0
Report Generated: 2/27/2019 11:24:14PM (UTC+2)	KQCL Reader	Calculated In Version : 6.0.0
Results Generated: 2/23/2019 1:19:14AM (UTC+2)	Lonza - WinKQCL Version 6.0.0	Page 1 of 3
Performed By: PJONES	LAL Lot No.: 3L388R	Time: 3:29:32PM (UTC+3)
PYROGENT-5000 - Routine Test	Water Lot No.: 3L2960	Date: 5/19/2018
Template: routine - p jones tu	Endotoxin Lot No.: 3L3380	ELX805
Temperature: 36.9°C - 37.1°C	Recon. Buffer Lot No.: 3L4940	S/N 1345
Linear Regression: Correlation Coefficient = -0.996	Slope = -0.270	Y-intercept = 2.950

The graph shows Reaction Time (secs) on the y-axis (0 to 2500) and Concentration (EU/mL) on the x-axis (0.100 to 1.00). Three data points are plotted at concentrations of 0.05, 0.5, and 5 EU/mL, showing a linear decrease in reaction time as concentration increases.

The left sidebar contains the following sections:

- Print Now:** Print Products as Separate Reports (checked), sample 2 [654CDA1abcdefg]
- Show AER:** Select All (checked), Correlation Coefficient, Slope, Y-Intercept, CV Replicates, PPC Recovery, Release Limit, Alerts
- Page Options:** Header First Page/Footer Last Page, Show Graph (checked), Show Standards (checked), Page Break Between Products, Include AER in Results Tables, Reader Parameters, Accessories (checked), Log Summary (checked), Display System Generated Ids

The bottom toolbar includes buttons for Report Options, Analyst 2, Reviewer 2, Edit Assay, View Raw Data, Analyze, Export to LIMS, Linear Regression, PowerCurve, Temperature, Close, Next Test >>, and << Previous Test.

Pane	Description
1	The title bar shows the title of the window, followed by the number of tests selected from the list. As the Next Test and Previous Test buttons are clicked, the test count will change as the new results report is loaded. The title bar displays the name of the test, the template number if multiple templates are merged on one plate, and the date and time the test was run.
2	Controls to export the report, print the report, go to first page, go to previous page, go to next page, go to last page, current page of total pages, search report text, and zoom (see "Common Report Controls" on page 157).
3	This section displays the endotoxin test report.
4	This left panel of controls changes what is displayed on the report and how the information is displayed. This section is divided into five sections:

Pane	Description
	<ul style="list-style-type: none"> ▪ The print buttons at the top ▪ The Products checkbox list ▪ The Show AER checkboxes ▪ The Page Options checkboxes ▪ The two buttons at the bottom <ul style="list-style-type: none"> ○ Report Options: For showing and hiding this panel. ○ Apply Options: For applying the selected options. <p>For more information on these controls, see "Endotoxin Test Results Controls and Functionality" on page 73.</p>
	<p>Additional buttons at the bottom of the page add and unlock electronic signatures; view, edit and analyze template and report data; change standards plot regression; export data to a LIMS, LIS or EM system; view the detailed temperature trend; close the window; and go to previous or next tests in the endotoxin tests list.</p> <p>For more information on these controls, see "Endotoxin Test Results Controls and Functionality" on page 73.</p>

Endotoxin Test Results Controls and Functionality

The Endotoxin Test Results window has the following controls and functionality. Only users with the **Use Endotoxin Report Options** permission can modify the report options while viewing a report.

- **Print buttons:** These print options are different than and in addition to the standard printer icon button that is at the top of the report (see "Common Report Controls" on page 157).
 - **Print now:** Clicking this button immediately sends all pages of the displayed report to the default printer with the default printing preferences. If any changes have been made to the configuration of the report using the checkboxes in the left pane, press the **Enter** key or click the **Apply Options** button before printing the report.
 - **Print Products as Separate Reports:** Clicking this button will print each selected product in a separate report. Each selected product report will have all of the common report information printed. All product reports will be printed at the same time.
- **Products:** Selecting the products checkboxes and pressing the **Enter** key or clicking the **Apply Options** button will refresh the report with only the product information showing for the selected products. Additionally, clicking the **Print Products as Separate Reports** button will only print reports for the products selected.
- **Show AER:** Selecting and unselecting checkboxes in this section and pressing the **Enter** key or clicking the **Apply Options** button will refresh the report and will show and hide assay evaluation report (AER) information for the items selected. If all items are unchecked, no AER report will be displayed.

- **Page Options:** Press the **Enter** key or click the **Apply Options** button to refresh the report and apply the selected options.
 - **Header First Page/Footer Last Page:** Selecting this option will only display the header information at the top of page 1, and the footer information at the bottom of the last page.
 - **Show Graph:** This checkbox shows and hides the standard curve graph.
 - **Show Standards:** This checkbox shows and hides the standards table.
 - **Page Break Between Products:** This checkbox adds and removes a page break in-between products.
 - **Include AER in Results Table:** Selecting this checkbox creates a condensed report format. It removes the replicate information from the standards and products table and shows only the average reaction time. PPC recovery and coefficient of variation information is added to the standards and products tables. Checking this option and unselecting the **Show AER** checkboxes creates a much shorter report.
 - **Reader Parameters:** This checkbox shows and hides the Reader Parameters section of the report.
 - **Accessories:** This checkbox shows and hides the Accessories section of the report.
 - **Log Summary:** This checkbox shows and hides the Log Summary section of the report.
 - **Display System Generated Ids:** This provides unique identifiers on sample test results for easy identification in the case of retests.
- **Report Options:** Clicking this button shows and hides the left pane.
- **Apply Options:** Clicking this button or pressing the **Enter** key, applies the checkbox selections made in the left pane.
- **Analyst E-Signature:** Click for an analyst to apply an electronic signature to the test (see "Electronic Signatures" on page 164).
- **Unlock Analyst E-sig:** This button will be visible if only an analyst has electronically signed the test (see "Unlocking an Electronic Signature" on page 166).
- **Reviewer E-Signature:** Click for a reviewer to apply an electronic signature to the test (see "Electronic Signatures" on page 164).
- **Unlock E-Signature:** This button will be visible if both an analyst and a reviewer have electronically signed the test (see "Unlocking an Electronic Signature" on page 166).
- **Edit Assay / View Template:** Edit Assay is visible if the test has not been electronically signed and allows a user with sufficient privileges to edit the template information for the test. If the test is electronically signed, the View Template button is displayed and the template information cannot be changed (see "Edit Assay and View Template Buttons" on page 163).
- **Analyze:** Click for the analyst to mask and unmask well information, to change the regression of the curve, and to analyze the kinetic raw data (see "Analyze" on page 161).
- **View Raw Data:** Click to display raw test data (see "View Raw Data" on page 164).
- **Export to LIMS:** Click to export the test to laboratory information management system (LIMS) (see "LIMS Export File Naming" on page 168).

- **Linear Regression:** Click to calculate and display the curve using linear regression (see "Linear Regression" on page 167).
- **PowerCurve™:** Click to calculate and display the curve using polynomial regression (see "Error! Reference source not found. on page 166).
- **Previous Test:** Click to navigate to the previous test in the list. If multiple tests were highlighted when the report was open, this will navigate to the previously highlighted test.
- **Next Test:** Click to navigate to the next test in the list. If multiple tests were highlighted when the report was open, this will navigate to the next highlighted test.
- **Temperature:** Click to display detailed information about reader temperature during the test.
- **Close:** Click to close the window.

Additional Information

If the supervisor selects the Show by Default checkbox in the AER parameters window or the AER checkboxes are selected in the reports pane, the assay evaluation report (AER) is shown with the test results (see "AER Parameters" on page 116).

- In the AER report, assay data within specification displays "PASS". Assay data that does not fall within specification displays "FAIL".
- Sometimes one or fewer replicate values are associated with any given data point, or no reaction time is recorded. In these cases, results such as the coefficient of variation (%CV) are reported as "N/A" and the status is reported as "Undefined".
- When neither the analyst nor the reviewer has electronically signed the assay results, the signature information area will appear as shown here. (The "FOR REVIEW ONLY" watermark is present as long as it has not been disabled. See "Global Options" on page 1365 for information on enabling and disabling this feature.)

Signed By: _____ e-signature not applied Date/Time: _____
 Reviewed By: _____ e-signature not applied Date/Time: _____

FOR REVIEW ONLY

(! = Masked, **** = reaction time > 5950, ????? = atypical, # = Modified, >>>> = High OD, See Comment Page)
 (In Notes : ! = Masked Point(s), * = Point(s) Did Not React, ? = Atypical Point(s), # = Modified, > = High OD, <LS = Less than the lowest standard)

If signatures are applied, the signature box is updated and the FOR REVIEW ONLY watermark is removed. To apply a signature, click the signature buttons in the view results window and provide the appropriate user IDs and passwords.

Signed By: Mr. Analyst Only (et1-sig) Date/Time: 2/28/2007 4:14:11 PM
 Mr. Analyst Only (ANALYST ONLY)

Reviewed By: المهندس محمد بن علي (eb1-sig) Date/Time: 2/28/2007 4:14:28 PM
 reviewer (REVIEWER)

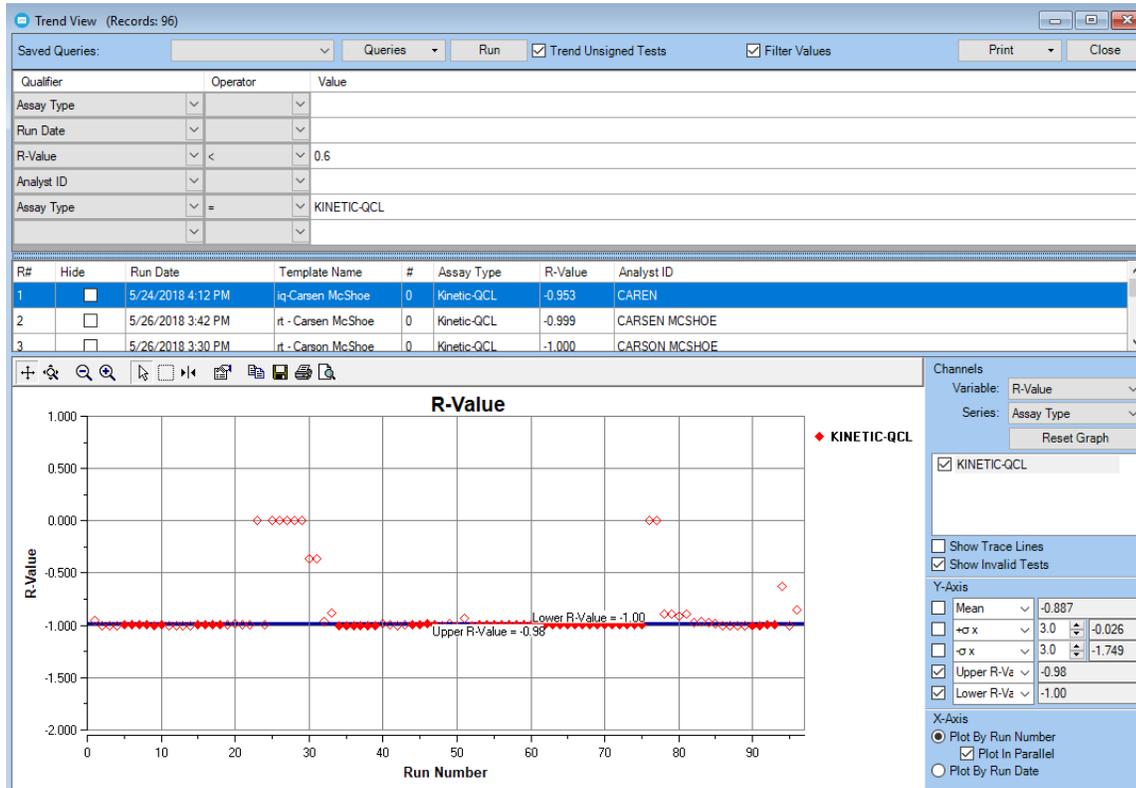
(! = Masked, **** = reaction time > 300, ????? = atypical, # = Modified, >>>> = High OD, See Comment Page)
 (In Notes : ! = Masked Point(s), * = Point(s) Did Not React, ? = Atypical Point(s), # = Modified, > = High OD, <LS = Less than the lowest standard)

This example shows that the analyst who created the template and ran the assay ("Mr. Analyst Only") and a reviewer (Reviewer) have applied their electronic signatures. A user with the Manage Users Permission has uploaded a bitmap signature for the reviewer, and this bitmap signature (eb1-sig) is displayed. A bitmap signature was not uploaded for the analyst so the text signature (et1-sig) is displayed. Records of the signature applications are also stored in the record audit log. When the signatures were applied, both the analyst and reviewer had the opportunity to add

a signature comment to the end of the results report. If the permission is enabled, an analyst can sign a test run by another analyst.

Trending

To display the Trend View window, click **Trending** on the main toolbar. This window specifies criteria to query test data in the WinKQCL® Software database. Query qualifiers can be used to make the results of a query as general or as specific as desired. These queries generate reports and graphs. This window is divided into three sections. The dividers between each section can be used to resize each section.



Query Definition Section

This section provides controls for specifying the query criteria. Queries are comprised of one or more qualifiers. Qualifiers specify what test data is retrieved from the database. Optional operator and value pairs can be applied to each qualifier to make the query more specific. The controls in the query definition section have the following functions:

- **Saved Queries:** Click a Saved Queries drop down list and select a saved query. By default, a saved query can be used by all users. Queries can also be saved so that only the user that created the query can use them. Queries saved for an individual user are not visible to other users.
- **Queries:** Click to save, rename (saved as), or delete trending queries. Click **Clear Query Criteria** to clear the trending window.
- **Run:** Click to execute the current query based on the user-specified criteria. The results of the query are displayed in the table and graph. New content replaces the previous content of the table and graph. If the results do not include numerical data, then the graph is hidden.

If the query returns no results, then a message indicates that the trending query returned no records.

- **Trend Unsigned Tests:** Check to include all endotoxin tests in the query results. If not checked, only tests signed by an analyst and reviewer are included in the results.
- **Filter Values:** Check to automatically filter the options for new criteria based on previously selected ones. For instance, if *Run Date* is selected as a qualifier with the between operator and two dates selected, then the user attempts to select *Water Lot Number*, the only lot numbers that will appear were those on tests run during that timeframe. If not checked the selection lists will not be filtered by the other qualifiers.
- **Print:** Click an option to print the query results.
- **Close:** Click to close the window.

Query Results List Section

This section lists the tests returned by the query. The columns display test information for each test in the list. The Query Results List section has the following controls and functions:

- **Column Sort:** Click a column header to sort the list (see "Sortable Lists" on page 161).
- **Hide:** Check to exclude the test results on the graph plot area and from the statistical calculations of the graph.

Shortcut Menu

Right-click any row in the query results list to display a shortcut menu for the selected test.

R#	Run Date	Template Name	#	Analyst ID
41	5/7/2004 10:47 AM	custom rse/cse	0	ANALYST ONLY
42	5/7/2004 10:47 AM	custom inh	2	
43	5/7/2004 10:47 AM	custom routine	2	
44	5/7/2004 10:47 AM	custom IQ	3	
45	5/7/2004 4:27 PM	custom rse/cse	0	
46	5/7/2004 4:27 PM	custom inh	1	
47	5/7/2004 4:27 PM	custom routine	2	
48	5/7/2004 4:27 PM	custom IQ	3	

Show Selected Row On Graph

Hide Selected Rows

Unhide Selected Rows

Unhide All Rows

Copy Selected Rows To Clipboard

Copy All Rows To Clipboard

The items in the shortcut menu have the following functions:

- **Show Selected Row On Graph:** Click to display cross hairs on the plot that correspond to the selected row in the table. Whenever a different row is selected in the table, the cross hairs move to the corresponding point on the plot. When unselected, the cross hairs are disabled.
- **Hide Selected Rows:** Click to check the **Hide** checkbox for all the selected rows.
- **Unhide Selected Rows:** Click to clear the **Hide** checkbox for the rows currently selected.
- **Unhide All Rows:** Click to clear the **Hide** checkbox for all rows.

- **Copy Selected Rows To Clipboard:** Click to place a comma-separated list of all selected rows on the Windows® clipboard. Column header names are included. Data can be pasted into another application that accepts comma-separated data or text.
- **Copy All Rows To Clipboard:** Click to place a comma-separated list of all rows on the Windows® clipboard. Column header names are included. Data can be pasted into another application that accepts comma-separated data or text.

Qualifier, Operator, and Value Grid

This grid allows users to specify criteria on which query results are based. The Qualifier and Operator columns and their Values are described here.

Qualifier Column

Before running a query, specify one or more qualifiers. Click a control in the qualifier column and choose a value. Qualifiers will define the query used to return a set of results.

To limit the tests included in the results, specify operators on one or more of the qualifiers (see "Operator Column" on page 81).

Different qualifiers provide different operators. The qualifiers selected and their order determine the data that is displayed in the results list when a search result is generated. To remove a qualifier, click **None** for that qualifier.

Qualifiers are grouped and displayed according to the following types:

- General
- Lot Number
- Curve
- Product
- Accessory

Each qualifier group is described here. Information is provided about their corresponding members and the data that is displayed in the results list for each test.

[General]

- **Assay Type:** Displays the assay type. This qualifier is important to specify when searching for standard curve information in a database that has multiple assay types.
- **Test Type:** Displays the test type. This qualifier is important to specify if searching for product information if the database contains product information in both inhibition/enhancement and routine test types.
- **Analyst ID:** Displays the ID of the analyst that performed the test. This qualifier can be used to compare analyst performance.
- **Template Name:** Displays the name of the template used for the test.
- **Run Date:** Displays the date and time of the test.
- **Reader Serial Number:** Displays the serial number of the reader that performed the test. This qualifier can be used to compare reader performance.
- **Reader Type:** Displays the type of reader that performed the test.

- **Units:** Displays the standard and product units used for the test. This qualifier only supports the “=” operator to filter results. Queries including Product Results requires each test retrieved to share a common single standard unit and product unit pair. The Units qualifier will automatically appear after adding the Product Results qualifier.
- **Min/Max Temperature:** Displays the minimum and maximum assay temperature of the test. The min/max temperature supports operators <, >, between, and not between to filter the results of the query. The minimum and maximum values are returned, so the operators are applied to the two values in these ways.
 - **< :** Includes tests where the minimum assay temperature is less than the specified value.
 - **> :** Includes tests where the maximum assay temperature is greater than the specified value.
 - **Between:** Includes tests whose assay temperature is within a certain range. The minimum assay temperature is greater than or equal to the specified From value. The maximum assay temperature is less than or equal to the specified To value.
 - **Not Between:** Includes tests whose minimum assay temperature is less than the specified From value or whose maximum assay temperature is greater than the specified To value.
- **Workgroup:** Displays the workgroup. Data is implicitly filtered by the workgroups the active user can view.
- **Sensitivity:** Displays the reader sensitivity with which a PyroGene® Assay test was run.

[Lot Number]

Displays the lot numbers used for the test. Selections include LAL/rFC lot number, endotoxin lot number, water lot number, buffer lot number, and substrate lot number.

[Curve]

Displays the selected curve value for the test. Selections include R-value, slope, and y-intercept.

[Products]

- **Product ID:** Displays the product name, product number, and product ID.
- **Product Name:** Displays the product name and product number.
- **Product Lot Number:** Displays the product name, product number, and lot number.
- **Product Result:** Displays the product name, product number, sample number, concentration, product result, standard units, and product units.
- **Product PPC Rec.:** Displays the product name, product number, and positive product control (PPC) recovery.
- **Product PPC Conc.:** Displays the product name, product number, and positive product control concentration.
- **Product PPC % Rec.:** Displays the product recovery, concentration, and percent positive product control recovery.
- **%CV (Samples):** Displays the product name, product number, sample number, concentration, and coefficient of variation.

- **%CV (PPCs):** Displays the product name, product number, sample number, coefficient of variation for the positive product control, and the concentration for the positive product control.
- **%CV (Samples/PPCs):** Displays the product name, product number, sample number, sample concentration, coefficient of variation for the positive product control, and concentration for the positive product control.
- **Release Limit:** Displays the release limit.
- **Alert Limit:** Displays the alert limit.

[Accessory]

Displays the selected accessory property for the test. Selections include accessory name, accessory lot number, and accessory manufacturer. If a specific accessory needs to be selected, use the accessory lot number to ensure multiple lots or multiple manufacturers for accessories with the same name are not shown.

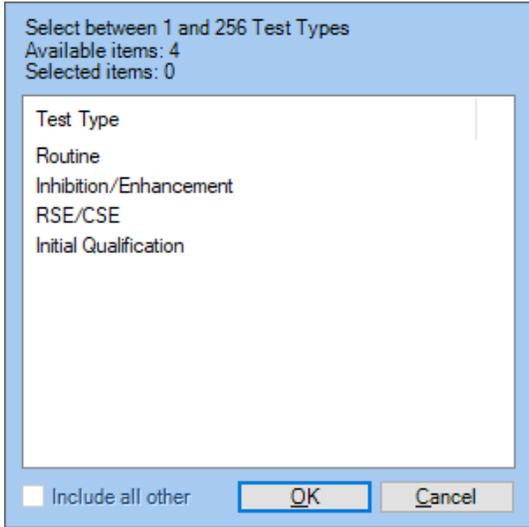
[Standards]

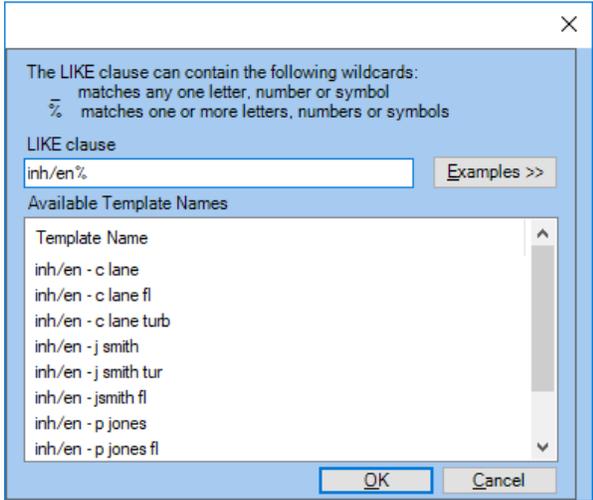
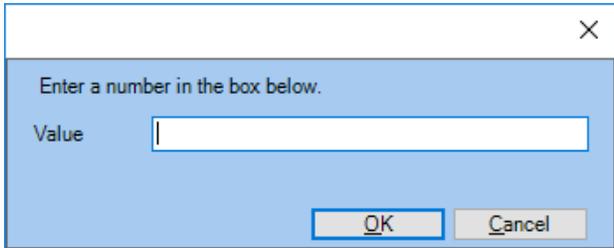
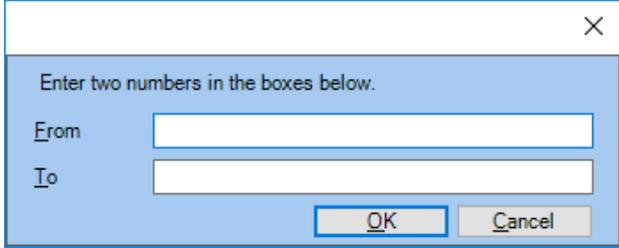
When trending standard data, it is important to select a single assay type and to select the concentrations to be evaluated.

- **Standard Reaction Time:** Displays the reaction time for the standard concentrations selected.
- **Standard RFU:** Displays the relative fluorescence for the standard concentrations selected.
- **Standard % CV:** Displays the coefficient of variation for the standard concentrations selected.
- **Standard Concentration:** Use this qualifier to specify which standards will be compared.

Operator Column

Operators can be used to filter query results. Different qualifiers permit different operators. Select an operator, and then enter a value. Selecting **None** deletes the operator for that qualifier.

Operator	Description	Graphic Example
= Not =	When selecting one or more of the names listed, the query returns only those results that match, or do not match, the selected names. For the = operator, when the query results are displayed, all results matching each selected name are plotted as a separate channel on the graph. Checking the Include all other checkbox returns all results, regardless of which names are selected. When the query results are displayed,	

Operator	Description	Graphic Example
	all results that do not match the selected names are plotted into an additional channel added to the graph.	
Like Not Like	<p>When specifying a pattern, the query returns only those results that match, or do not match, the specified pattern. To find all phrases that contain a given word, use the % symbol to match any number of values. For example, to find all phrases that contain the word "water", enter "%water%".</p> <p>Click Examples to display other usage examples.</p>	
< >	When specifying a number, the query returns only those results less than, or greater than, the specified value.	
Between Not Between	When specifying a number in the From and To fields, the query returns only those results equal to or between, or not equal and not between, the specified values.	

Graph Section

Each numeric qualifier defined in the query definition can be graphed. If the query does not include numeric qualifiers, then the graph is hidden. By default, the first numeric qualifier is automatically plotted on the graph each time the query is run.

Each test result that is returned by the query is plotted. The results can be plotted by run number or run date. When plotted by run number, the results are plotted in the order that is returned by

the query, regardless of run date. When the results are plotted by run date, they are plotted on the x-axis at the date and time that the result was generated.

Test Results Plotting Markers

Each test result is plotted, and a marker represents the result on the graph.

The markers have the following general meanings:

- ◆ The test is valid.
- ◇ The test is invalid.

When product results are being plotted, the plotting markers have meanings that are more specific:

- ◆ The result value is within range.
- ▲ The result value is high.
- ▼ The result value is low.
- The result value is outside the plotted range.

Channels Subsection

Nonnumeric qualifiers that implement = operators can be used to separate the plotted results into channels. One channel is displayed for each value that is selected for the qualifier. If the query does not include nonnumeric qualifiers using an = operator, then a single channel is used. By default, the first nonnumeric qualifier using an = operator is automatically used to separate the graphed values into channels.

The following controls are included in the Channels subsection:

- **Variable:** Click the numeric qualifier to be plotted on the graph. The selected qualifier is plotted on the y-axis, and the y-axis automatically scales to show all values retrieved. Click **All Variables** to plot all numeric qualifiers. Multiple y-axes are used, if necessary, to scale each value based on its data type.
- **Series:** Click the nonnumeric qualifier that is used to separate the plotted data into channels. One channel is created for each name that is filtered by the qualifier = operator. Click **None** to plot all data in a single channel.
- **Reset Graph:** Click to restore the original scaling of both x- and y-axes.
- **Channel List:** Lists each channel that is plotted on the graph. Channels that are checked are displayed on the graph. Channels that are not checked are not displayed. By default, each channel is initially checked.
- **Show Trace Lines:** Select to draw a line between successive markers on the graph. (Each marker identifies one test result.) By default, trace lines are not shown.
- **Show Invalid Tests:** Select to display invalid tests (marker = ◇). Invalid tests that are not displayed are excluded from the statistical calculations. By default, invalid tests are shown.

Y-Axis Subsection

The y-axis supports up to five labels. These can be custom labels, or from the six predefined labels: Mean, +StdDev, -StdDev, UCL, LCL, and Trendline. (Click **None** to clear the label from the y-axis.)

- **Mean, +StdDev, -StdDev:** Each is calculated from the plotted test results. The standard deviation (StdDev) range is 0.1 to 9.9 standard deviations.
- **UCL, LCL:** Stands for upper and lower control limits. The range is 0.1 to 9.9 from the calculated mean.
- **Trendline:** Calculated from all plotted test results.
- **Action & Alert:** When Product Result is selected as a qualifier, Release Limit will have a data column. In addition, the Y-Axis will be auto populated with the Upper Release Limit (Action) and the Lower Release Limit (Alert).
- **Upper & Lower:** When R-Value is selected as a qualifier, the Y-Axis will be auto populated with the Upper and Lower R-Value's from AER Parameters.
- **Upper & Lower:** When PPC % Recovery is selected as a qualifier, the Y-Axis will be auto populated with the Upper and Lower PPC % Recovery from AER Parameters.
- **CV Replicates:** When Standard %CV or Product %CV are selected as a qualifier, the Y-Axis will be auto populated with CV Replicates using the value of CV Replicates from AER Parameters.

Check the checkbox of a label to display it on the plot. If the label location is outside the visible y-axis, then the y-axis limits are automatically adjusted to bring the label into view.

To specify a custom label, enter the label name to the right of the checkbox. Then enter a number to the right of the name.

Change the number to reposition a custom label on the plot area.

X-Axis Subsection

The x-axis subsection has the following controls and functions:

- **Plot By Run Number:** Click to plot each result within its channel in the order it was returned by the query. Run date is not considered. By default, results are plotted by run number.
- **Plot In Parallel:** Available only when **Plot By Run Number** is selected. Click to plot results in parallel or in series. When selected, all channels are plotted in parallel from run number 1. When not selected, each channel is plotted in series. Channels are plotted starting at the next run number of where the previous channel ended. By default, results are plotted in parallel.
- **Plot By Run Date:** Click to plot each result within its channel at the date and time the result was generated. Run number is not considered. By default, results are not plotted by run date.

Plot Area Subsection

The following functions are available in the plot area subsection:

- Click a channel name in the plot legend to select that channel and bring all of its markers to the top on the plot area.

- Click a marker on the plot area to view the row in the Query Results list that corresponds to the selected marker. The trending table automatically selects that row and scrolls it into view.
- Click and drag the mouse on an axis to scroll or zoom that axis. The action depends on whether the Scroll or Zoom button on the plot toolbar is selected. By default, this action scrolls the axis in the direction the mouse is being dragged.
- Use the toolbar that is above the plot area to zoom or pan the plot, alter the display properties, or capture data for export.



Other Tests

In addition to the four major endotoxin tests, the WinKQCL® 6 Software also supports several other types of tests. On the main toolbar, select **Other Tests**. The WinKQCL® Software supports these other tests:

- **Reader Validation Tests (Other Tests > Validation):** Tests used in the validation of microplate readers and the Endotoxin Detection assays. It is important that the requirements and specifications of the validation tests be closely followed. Validation tests are available for the following:
 - **Absorbance Readers:** Validation tests that apply to absorbance readers or the absorbance features on a multimode reader (see "Validation Tests for Absorbance Readers" on page 85).
 - **Fluorescence Readers:** Validation tests that apply to fluorescence readers or the fluorescence features on a multimode reader (see "Validation Tests for Fluorescence Readers" on page 99).
 - **Multimode Readers:** Validation tests that apply to the Synergy™ 2 and Nebula® Multimode reader (see "Validation Tests for Multimode Readers" on page 111).
- **Quick Read Tests (Other Tests > Quick Read):** Quick Read tests are used to capture a single scan of a microplate at a user-defined wavelength and print optical density or fluorescence readings without performing data analysis (see "Quick Read Tests" on page 113).

Validation Tests for Absorbance Readers

The following validation tests are supported on absorbance readers and on the absorbance part of multimode readers.

- **OD Validation Test (Other Tests > Validation > [Reader Name] > OD Validation):** Tests the reproducibility of the measurement values within a region of constant optical density. Also tests the linearity of the optical measurement value with increasing optical density (see "OD Validation Test" on page 87).
- **Absorbance Uniformity Test (Other Tests > Validation > [Reader Name] > Absorbance Uniformity):** Tests the uniformity of the assay environment across the 96-well plate (see "Absorbance Uniformity Test" on page 88).

The following validation tests are only supported on the BioTek™ ELx808™ reader.

- **ELx808™ System Test (Other Tests > Validation > ELx808 > ELx808 System):** The first part of the system test verifies the function of the lamp, filters, and photodiodes. The second part of the system test verifies the minimum and maximum temperature in the four incubation zones (see "ELx808™ Reader System Test" on page 91).
- **ELx808™ Absorbance Plate Test (Other Tests > Validation > ELx808 > ELx808 Absorbance Plate):** Verifies plate linearity, accuracy, repeatability, and alignment (see "Absorbance Plate Test (ELx808™ Reader)" on page 92).

The following validation tests are only supported on the BioTek™ Eon™ reader.

- **Eon™ System Test (Other Tests > Validation > Eon > Eon System):** The first part of the system test verifies the function of the lamp, filters, and photodiodes. The second part of the system test verifies the minimum and maximum temperature in the four incubation zones (see "Eon™ Reader System Test" on page 94).

The following validation tests are only supported on the BioTek™ Eon™ and Synergy™ 2 readers.

- **Absorbance Plate Test (Other Tests > Validation > Eon > Absorbance Plate, Other Tests > Validation > Synergy > Absorbance Plate):** Verifies plate linearity, accuracy, repeatability, and alignment (see "Absorbance Plate Test (Eon™ and Synergy™ 2 Readers)" on page 95).

The following validation test is a legacy test and is only shown if Kinetic-QCL® Assay reader data exists in the database.

- **Diodes Test (Other Tests > Validation > KQCL > Diodes):** May be present if a WinKQCL® Software database from a previous version has been merged into the current database. Running new tests on a Kinetic-QCL® Assay reader is no longer supported.

OD Validation Test

Two aspects of the optical density measurement of a plate reader require validation:

- The reproducibility of the measurement values within a region of constant optical density
- The linearity of the optical measurement value with increasing optical density

The OD Validation test is designed to validate both aspects of optical density measurement.

Material Required

Stepped Neutral Density (SND) Plate (P/N 25-342 or equivalent)

OD Validation Test Procedure

To validate the optical density measurement of a plate reader, follow these steps:

1. Turn on the reader that will be validated. Ensure that the reader is listed as Available in the Readers List. If applicable, ensure that the Main Menu appears on the LCD.
2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.
4. Select the appropriate filter. Enter the Neutral Density Plate lot number, and then click **OK**.
5. If necessary, click **Open door**, and then place the SND plate in the reader. Click **OK**.
6. The plate is read and a Validation of Optical Density Measurement report is generated.

Test results are stored in the OD Validation Result list.

- To view the OD Validation Result list, click **Other Tests > Validation > [Reader Type] > OD Validation** on the main toolbar.

- To electronically sign and print the OD Validation test results, click **View Results**.
- To view the raw data from the test, click **View Raw Data**.

Approval Criteria

Linearity

Correlation coefficient $|r| \geq 0.990$

Reproducibility

%CV for each standard

- $0.062 < 10.00\%$
- $0.125 < 5.00\%$
- $0.250 < 2.00\%$
- $0.500 < 2.00\%$
- $1.000 < 2.00\%$

Absorbance Uniformity Test

The Absorbance Uniformity test verifies the assay environment is uniform across the entire 96-well microplate in a multimode or absorbance reader. The following procedure identifies variations in the reaction time of a common standard over an entire 96-well plate.

This test can indicate unacceptable variability. However, the root cause may be impossible to determine. Variations that are outside of the desired range can indicate any combination of problems. Below are the most common causes of variation:

- Use of accessories not suitable for endotoxin testing. Ensure all pipette tips, reagent reservoirs, and 96-well plates used are certified endotoxin free at or below the lowest standard used for endotoxin testing.
- Variations in delivery volumes due to:
 - Mis-calibrated or faulty micropipettes
 - Improper pipetting technique
 - Using pipette tips that do not fit the micropipette properly
 - Not having all 8 or 12 tips pressed on to a multichannel pipette with the same amount of force. This usually occurs when the center of the pipette box bows in when pressing the tips on to the multichannel pipette. When using a multichannel pipette, ensure the center tips are pressed on with the same force as the outer tips. It may be necessary to pull or push the center tips onto the pipette with additional force.
- Fluctuations in incubator temperature across the plate

Material Required

- Kinetic-QCL[®] Assay (P/N 50-650U or equivalent)
- PYROGENT[®] 5000 Assay (P/N N383, N384, or equivalent)
- 96-well plate (flat bottom) (P/N 25-340 or equivalent)
- Pipettes and micropipettes

- Endotoxin-free pipette tips (P/N 25-415, 25-416, 25-417, or equivalent)
- Glass dilution tubes (P/N N207 or equivalent)
- Test tube rack
- Control Standard Endotoxin (CSE, for kits without included endotoxin)
- LAL Reagent Water (LRW) (P/N W50-640, W50-100, W50-500, or equivalent)
- Vortex mixer
- Timer
- Reagent reservoirs (P/N 00190035 or equivalent)

Uniformity Test Procedure

This tests for uniformity by placing a single endotoxin standard across the 96-well plate and using a Kinetic-QCL[®] Assay or PYROGENT[®] 5000 Assay to analyze the reaction time across the plate. Read the Kinetic-QCL[®] Assay or PYROGENT[®] 5000 Assay package insert for specific procedural information before beginning.

To perform the Uniformity test, follow these steps:

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL[®] Software.
2. Log in as an analyst. When launched, the WinKQCL[®] Software enables the incubator for all attached readers.
3. Reconstitute a fresh vial of CSE with the appropriate volume of LAL Reagent Water (LRW, also known as Water for BET)) according to the Certificate of Analysis. Mix this CSE with the vortex mixer according to the package insert.
4. Dilute the CSE to obtain either an endotoxin concentration of 0.5 EU/mL (for Kinetic-QCL[®] Assays) or 1 EU/mL (for PYROGENT[®] 5000 Assays). Prepare in excess of 10 mL.
5. Use a calibrated micropipette to dispense 100 µl of the diluted endotoxin standard into every well of a 96-well plate.
6. On the main toolbar, click **Other Tests > Validation > [Reader Type] > Absorbance Uniformity** to open the **Absorbance Uniformity Tests** window.
7. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



8. On the reader selection window, select the workgroup for this test and select an available absorbance or multimode reader. Click **OK**. The **Absorbance Uniformity Test** window is displayed.

Lot numbers	Value	Expiration Date
LAL Reagent	LAL	4/ 1/2023
LAL Water	Water	4/ 1/2023
Endotoxin	Endo	4/ 1/2023
Buffer		2/ 2/2021

- Fill in the appropriate information, and then click **Run**. The WinKQCL[®] Software tests the connection with the selected reader and then monitors the reader temperature until it reaches $37 \pm 0.5^{\circ}\text{C}$. When the temperature reaches $37 \pm 0.5^{\circ}\text{C}$, a prompt appears to place the plate on the carriage.

NOTE: Lonza endotoxin reagent labels include 2D barcodes. ("2D" stands for two-dimensional.) The software supports scanning in lot number information with a 2D barcode scanner. The barcode encodes the part number, lot number and expiration date information. As long as a field in the lot number tab is selected, when the barcode is scanned, the WinKQCL[®] Software automatically determines which lot number field and expiration date field to update. See "Optional Accessories" for compatible barcode readers.

- [On a reader that cannot be manually opened, click **Plate out**]. Place the 96-well plate on the reader carriage. [If required, click **Plate in**.] Click **OK**.

WARNING Do not leave the carrier door open any longer than is necessary. The incubation chamber and the plate will begin dropping in temperature as soon as the carrier door is opened.

- The software confirms the placement of the assay plate and displays a progress bar to count down the incubation period. The 96-well plate must be incubated for a minimum of 10 minutes before the reagent is added. When the plate is incubated, the temperature is uniform and the uniformity test results are better. The software prompts to add the reagent to the plate when the incubation period ends. To bypass, click **Skip** to override the incubation timer and proceed to the **Add Reagent** window early.
- [On a reader that cannot be manually opened, click **Plate out**.] Use a multichannel pipette and add the reagent to the plate. Start at the left side of the plate and work to the right. Maintain a constant interval between additions. Do not allow bubbles to form in the

microplate wells. After adding the reagent to the last column, immediately close the cover or if required, click **Plate in**. Run this test with the microplate lid off. Click **OK** to start the test.

NOTE: It is important to add the reagent from left to right, maintaining a constant interval between additions. The WinKQCL[®] Software will apply a column correction factor to the calculated reaction time for kinetic tests. This correction factor assumes the reagent is added from left to right and compensates for the time it takes to add the LAL reagent to the plate.

11. The Uniformity test will run for the maximum number of reads or until all wells have reacted. After the test is complete, the data is saved to the database automatically and the results report is displayed. The report includes the following information:
 - Reaction times for all 96 wells.
 - Percent CV for each column and row.
 - Overall plate percent CV.
12. The test is available for review from the Uniformity Tests list. The analyst and a reviewer should electronically sign the report.
 - To view the results report, click **View Results** on the Absorbance Uniformity Tests window.
 - To view the raw data, click **View Raw Data**.

Date	Time	Analyst ID	A	R	Reader S/N	Reader Header	Workgroup
4/21/2015	11:36:34 AM	DROOP	x		1307101	ELx808 reader	PM Service
4/21/2015	9:26:43 AM	DROOP	x		252481	ELx808 reader	PM Service
3/11/2015	2:10:08 PM	DROOP	x		1403101	ELx808 reader	PM Service
3/10/2015	4:19:49 PM	DROOP			183669	ELx808 reader	PM Service
3/10/2015	3:26:38 PM	DROOP	x		183669	ELx808 reader	PM Service
3/10/2015	9:48:22 AM	DROOP	x		1209044	ELx808 reader	PM Service
3/9/2015	1:38:34 PM	DROOP	x		183668	ELx808 reader	PM Service
3/9/2015	11:37:27 AM	DROOP	x		183632	ELx808 reader	PM Service
2/11/2015	12:41:53 PM	DROOP	x		219115	ELx808 reader	PM Service
2/11/2015	10:56:19 AM	DROOP	x		183635	ELx808 reader	PM Service

Approval Criteria

No regulatory specification exists for this assay. Therefore, internal specifications serve only as monitors. Lonza recommends that the overall plate CV not exceed 5.0%.

ELx808™ Reader System Test

When the reader is turned on, it performs the system test automatically. If this automatic system test fails, an error is displayed. However, a report of the results of the power-on system test is not available.

To obtain a system test report that can be electronically signed and printed, click **Other Tests > Validation > ELx808 > ELx808 System** on the main toolbar. This feature can be used for periodic testing and documentation or for troubleshooting.

To create a new report, the analyst that performs the test can click **Run** from the **Systems Tests** window. The system test report will be displayed when the test is complete.

Select a test in the list and click the **View Results** button to view, sign, export, and print previously run system tests.

ELx808™ Reader System Test Procedure

To perform the ELx808™ system test, follow these steps:

1. Turn on the BioTek™ ELx808™ reader. Ensure that the reader status is shown as **Available** in the Readers List.
2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.

Approval Criteria

The system self-test will present an error code or report “FAIL” if any of the built-in Failure Mode Effects Analysis (FMEA) specifications fail. Verify the A/D Test and all temperature range and thermistor tests indicate: PASS and SYSTEM TEST PASS is printed at the bottom of the report. If the system test completes without error and all tests pass, then the reader is passing its operational specifications.

NOTE: Engineering specifications are used during the execution of preventative maintenance procedures. Engineering specifications are much more stringent than FMEA specifications and are intended to identify drift on the reader before it reaches operational failure.

Absorbance Plate Test (ELx808™ Reader)

The linearity, accuracy, repeatability, and alignment of the reader optics and plate carrier can be verified using the BioTek™ absorbance test plate. This plate uses neutral density filters and precision-machined alignment holes to confirm the reader is performing to required specifications. The WinKQCL® Software performs the test and enables storage, export, signing, and printing of the Absorbance Plate Test results.

Material Required

The BioTek™ Absorbance Test Plate (Lonza P/N 7260522) and its matching Absorbance Test Plate Calibration Certificate.

Absorbance Plate Test Procedure

The following procedure is for running the BioTek™ reader absorbance plate test with the WinKQCL® Software. For additional information, please see the BioTek™ ELx808™ Reader Operator's Manual.

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.
2. Log in as an analyst. When launched, the WinKQCL® Software enables the incubator for all attached readers.

- On the main toolbar, click **Other Tests > Validation > ELx808 > ELx808 Absorbance Plate** to open the **ELx808 Absorbance Plate Tests** window.
- Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



- On the reader selection window, select the workgroup for this test and select an available ELx808™ reader. Click **OK**. The **ELx808 Absorbance Plate Test** window is displayed.
- Locate the Absorbance Test Plate Calibration Certificate for the plate. From the Absorbance OD Standards section of the certificate, determine at which wavelength to run the test. The wavelength normally used for readers used for endotoxin testing is 405 nm. Select the desired wavelength from the dropdown list in the WinKQCL® Software.
- Enter the serial number for the plate. If this plate was previously run on a reader in this database, the optical density values will be automatically filled in the Standards table. Review these values and make sure they match the certificate. If the table is not automatically populated with the values, enter the values in the column for the selected wavelength.

Absorbance OD Standards

Well	405nm	450nm	490nm	550nm	620nm	630nm	690nm	750nm
C1	0.125	0.124	0.127	0.124	0.141	0.142	0.125	0.123
E2	0.636	0.591	0.589	0.573	0.589	0.585	0.492	0.443
G3	1.214	1.125	1.122	1.089	1.121	1.115	0.933	0.838
H6	1.784	1.652	1.648	1.600	1.647	1.638	1.367	1.227
F5	2.217	1.978	1.939	1.897	1.861	1.837	1.488	1.237
D4	2.833	2.477	2.397	2.311	2.262	2.233	1.839	1.590

(This figure shows an example of the Absorbance OD Standards section of the plate certificate with the column data that is used to test the reader optics.)

- When the Place Plate window is displayed, place the absorbance test plate in the plate carriage of the reader with A1 in top left and close the lid.
- Click **OK** to start the absorbance plate test.
- The plate will be read. When prompted, rotate the plate 180°, close the reader door and click **OK**.
- After the absorbance test plate is read again, the data is saved to the database automatically and the results report is displayed. The report includes the following information:
 - Alignment Results
 - Accuracy Results

- Repeatability Results
12. The test is available for review from the ELx808™ Reader Absorbance Plate Tests list. The analyst and a reviewer should electronically sign the report.
- To view the results report, click **View Results**.
 - To view the raw data, click **View Raw Data**.

Approval Criteria

If the reader is functioning properly, all results will show: PASS. PASS / FAIL results are not reported for the accuracy calculations if the value is greater than 2.500, since this exceeds the upper limit of the calibration range. In this case, a value of N/A will be reported.

- The Alignment reads must be less than or equal to 0.015 OD for each well.
- The Accuracy results section compares the Absorbance OD Standards values that were entered into the Standards table in the WinKQCL® Software against the actual reads. The tolerance for the Accuracy specifications is a combination of the reader accuracy specifications for a normal read mode 96-well plate and the glass filter accuracy specifications. The actual read must be within this cumulative tolerance.
- The Repeatability results section compares two consecutive reads of the optical standards wells. Read 1 is compared to read 2. The tolerance for the Repeatability specifications is derived from the reader repeatability specifications for a normal read mode 96-well plate. Read 2 must be within the tolerance range of read 1.

NOTE: When performing the absorbance plate test, the WinKQCL® Software turns the reader's incubator off. After the test is complete, the WinKQCL® Software turns the incubator back on.

Eon™ Reader System Test

When the reader is turned on, it performs the system test automatically. If this automatic system test fails, the reader will beep and the light will flash. To determine the cause of the failure or to obtain a system test report that can be electronically signed and printed, click **Other Tests > Validation > Eon > Eon System** on the main toolbar. This feature can be used for periodic testing and documentation or for troubleshooting.

To create a new report, the analyst that performs the test can click **Run** from the **Systems Tests** window. The system test report will be displayed when the test is complete.

Select a test in the list and click the **View Results** button to view, sign, export, and print previously run system tests.

Eon™ Reader System Test Procedure

To perform the Eon™ system test, follow these steps:

1. Turn on the BioTek™ Eon™ reader. Ensure that the reader status is shown as **Available** in the Readers List.
2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.

Approval Criteria

The system test report lists results in a pass/fail format and can be viewed and printed.

NOTE: If the Eon™ Reader fails the system test, it does not perform a read until the error condition is cleared. An error condition normally requires that the reader is powered off and back on again.

Verify the following criteria on the Eon™ Reader System Test:

- For all wavelengths, if the capacitor reset value is 1, the gain must be less than 10.
- For all wavelengths, if the capacitor reset value is 8, and the gain is less than 1.5, then the measurement channel light reading must be less than 55,000.
- For all wavelengths, the total air for the reference channel must be 1500 or more.
- For all wavelengths, the total air for the measurement channel must be between 36000 and 55000.
- For all wavelengths, the dark air values for both the reference channel and the measurement channel must be between 8800 and 10800.
- For the noise test, the delta values for both the reference channel and the measurement channel must be 5 or less.
- In the Autocal Analysis section, delta 1 and 2 must be between -32 and 32 and delta 3 and 4 must be between -58 and 58.
- For the incubator section, verify the A/D test and all thermistor tests pass.
- Verify "System Test Pass" is displayed at the end of the report.

If FAIL appears on the system test report or any values are outside of their range, contact Lonza Scientific Support.

Test results are stored in the System tests list under **Validation > Eon > Eon System**.

To electronically sign and print the system test results, click **View Results**.

Absorbance Plate Test (Eon™ and Synergy™ 2 Readers)

The linearity, accuracy, repeatability, and alignment of the reader optics and plate carrier can be verified using the BioTek™ reader's absorbance test plate. This plate uses neutral density filters and precision-machined alignment holes to confirm the reader is performing to required specifications. The WinKQCL® Software performs the test and enables storage, export, signing, and printing of the Absorbance Plate Test results.

Material Required

The BioTek™ Reader Absorbance Test Plate (Lonza P/N 7260522) and its matching Absorbance Test Plate Calibration Certificate.

NOTE: In order to properly test the monochromator in the reader, the plate must have an Erbium or Holmium glass filter in the C6 position. The plate certificate must have a "Wavelength Accuracy Standards" section with expected wavelength peaks and ranges.

Absorbance Plate Test Procedure

The following procedure is for running the BioTek™ reader absorbance plate test with the WinKQCL® Software. For additional information, please see the BioTek™ Synergy™ 2 or BioTek™ Eon™ Operator's Manual.

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.
2. Log in as an analyst. When launched, the WinKQCL® Software enables the incubator for all attached readers.
3. On the main toolbar, click **Other Tests > Validation > Synergy > Absorbance Plate** or **Other Tests > Validation > Eon > Absorbance Plate** to open the **Absorbance Plate Tests** window.
4. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



5. On the reader selection window, select the workgroup for this test and select an available Synergy™ 2 or Eon™ reader. Click **OK**. The **Absorbance Plate Test** window is displayed.
6. Locate the Absorbance Test Plate Calibration Certificate for the plate. From the Absorbance OD Standards section of the certificate, determine at which wavelength to run the test. The wavelength normally used for readers used for endotoxin testing is 405 nm. Select the desired wavelength from the dropdown list in the WinKQCL® Software.
7. Enter the serial number for the plate. If this plate was previously run on a reader in this database, the optical density values will be automatically filled in the Standards table. Review these values and make sure they match the certificate. If the table is not automatically populated with the values, enter the values in the column for the selected wavelength.

Absorbance OD Standards

Well	405nm	450nm	490nm	550nm	620nm	630nm	690nm	750nm
C1	0.125	0.124	0.127	0.124	0.141	0.142	0.125	0.123
E2	0.636	0.591	0.589	0.573	0.589	0.585	0.492	0.443
G3	1.214	1.125	1.122	1.089	1.121	1.115	0.933	0.838
H6	1.784	1.652	1.648	1.600	1.647	1.638	1.367	1.227
F5	2.217	1.978	1.939	1.897	1.861	1.837	1.488	1.237
D4	2.833	2.477	2.397	2.311	2.262	2.233	1.839	1.590

(This figure shows an example of the Absorbance OD Standards section of the plate certificate with the column data that is used to test the reader optics.)

8. Newer versions of the BioTek™ Reader Absorbance Test Plate (Lonza P/N 7260522) have Erbium glass in the C6 position. This glass is used to test the monochromator in the microplate reader. Locate the Wavelength Accuracy Standards section on the certificate. Enter the Expected Peak value(s) and the Test Range values into the Spectral Wavelengths table in the WinKQCL® Software. If multiple values are given for a wavelength, use those in the 2.4 nm Spectral Bandpass table. These values define the wavelength ranges that will be used to read the glass to search for the peak. Example:

Wavelength Accuracy Standards

2.4nm Spectral Bandpass		5.0nm Spectral Bandpass	
Expected Peak nm	Test Range	Expected Peak nm	Test Range
256	-5+5	256	-5+5
365	-5+5	365	-5+5
378	-5+5	378	-5+5
407	-5+5	407	-5+5
488	-5+5	488	-5+5
520	-5+5	521	-5+5
652	-5+5	652	-5+5

9. Click **OK** when all data is entered.

Absorbance Plate Test (SUPERVISOR): VirtualReader Rerun (COM0) VirtualReader reader

Wavelength: 405 Number of Wavelengths: 7

Test Plate Serial No.: 260095 Test Range +/-: 5

Standards
Please enter the values exactly as they are printed on the BioTek® Test Plate certificate.

Well	Value
C1	0.137
E2	0.641
G3	1.208
H6	1.783
F5	2.121
D4	2.909

Spectral Wavelengths
Please enter between 4 and 8 wavelengths to run the spectral scan against.

Value
256
365
378
407
488
520
652

Plate out Plate in OK Cancel

10. When the Place Plate window is displayed, press the button on the front of the reader to eject the reader carriage. Place the absorbance test plate in the plate carriage of the reader with A1 in top left and press the button again to insert the plate carriage.
11. Click **OK** to start the absorbance plate test.
12. After the absorbance test plate is read, the data is saved to the database automatically and the results report is displayed. The report includes the following information:
 - Peak Absorbance Results for well C6
 - Alignment Results
 - Accuracy Results
 - Repeatability Results
13. The test is available for review from the Absorbance Plate Tests list. The analyst and a reviewer should electronically sign the report.
 - To view the results report, click **View Results**.
 - To view the raw data, click **View Raw Data**.

Approval Criteria

If the reader is functioning properly, all results will show: PASS. PASS / FAIL results are not reported for the accuracy and repeatability calculations if the value is greater than 3.000, since this exceeds the upper limit of the calibration range.

- The Peak Absorbance Results for well C6 compares the reference wavelengths that were entered into the WinKQCL® Software and a +/-3 nm tolerance against the actual read. The actual read must be within +/- 3 nm of the peak wavelength.
- The Alignment reads must be less than or equal to 0.015 OD for each well.
- The Accuracy results section compares the Absorbance OD Standards values that were entered into the Standards table in the WinKQCL® Software against the actual reads. The tolerance for the Accuracy specifications is a combination of the reader accuracy

specifications for a normal read mode 96-well plate and the glass filter accuracy specifications. The actual read must be within this cumulative tolerance.

- The Repeatability results section compares two consecutive reads of the optical standards wells. Read 1 is compared to read 2. The tolerance for the Repeatability specifications is derived from the reader repeatability specifications for a normal read mode 96-well plate. Read 2 must be within the tolerance range of read 1.

NOTE: When performing the absorbance plate test, the WinKQCL® Software turns the reader's incubator off. After the test is complete, the WinKQCL® Software turns the incubator back on.

Validation Tests for Fluorescence Readers

The following validation test is supported on fluorescence readers and on the fluorescence part of multimode readers:

- **Fluorescence Uniformity Test (Other Tests > Validation > [Reader Name] > Fluorescence Uniformity):** Tests the uniformity of the assay environment across the 96-well plate (see "Fluorescence Uniformity Test" on page 104).
- **Sensitivity Test (Other Tests > Validation > FLx800 > Sensitivity):** Tests the sensitivity setting for detecting fluorescence within an appropriate RFU range (see "Fluorescence Sensitivity Test" on page 99).

The following validation test is only supported on the BioTek™ FLx800™ reader:

FLx800™ System Test (Other Tests > Validation > FLx800 > FLx800 System): Verifies the function of the filters, lamp, optical sensor, and the minimum and maximum temperature in the three incubation zones (see "FLx800™ Reader System Test" on page 108).

The following validation tests are only supported on the PyroWave® XM reader:

- **PyroWave XM System Test (Other Tests > Validation > PyroWave XM > PyroWave XM System):** Verifies the system is functioning to the manufacturer's specifications (see "PyroWave® XM Reader System Test" on page 109).
- **Fluorescence Plate Test (Other Tests > Validation > PyroWave XM > Fluorescence Plate Test):** Verifies reader alignment, linearity, and sensitivity. (see "PyroWave® XM Fluorescence Plate Test" on page 110).

Fluorescence Sensitivity Test

In many fluorescence readers, the light emitted from the well of the microplate travels through a fiber optic cable and is detected by a photomultiplier tube or PMT. This PMT, as well as an analog to digital converter, convert the light detected into numeric values that can be used by us to interpret the relative light output. The light output is normally recorded in Relative Fluorescence Units or RFU values. Light output can vary significantly from one assay to another. To accommodate this, the instrument can be adjusted according to the amount of emitted light. Use of a higher PMT gain or sensitivity setting will boost a weak signal. Use of a lower PMT gain or sensitivity setting will result in an excessively strong signal. As different reader manufacturers adjust the PMT and Analog to Digital converter in different ways, the user should consult the system Operator's Manual for further instructions.

In the PyroGene® Assay, a 3-log endotoxin concentration range corresponds to approximately a 3-log range in RFU. If the sensitivity is tuned too low, fluorescence at the lowest standard is difficult to detect. If the sensitivity is tuned too high, fluorescence at the highest standard is off-scale.

Before conducting any assays with a reader, determine an appropriate PMT gain or sensitivity setting. The PyroWave® XM, Synergy™ 2 and FLx800™ Readers have a fluorescence range from 0 to 99999. Lonza wanted to establish the 3-log fluorescence range for the standard curve and assure a detectable low standard. Therefore, historically Lonza chose an RFU range from 1000 to 10000 for the 0.5 EU/mL standard. An RFU range from 1000 to 10000 corresponds to a log range from 3 to 4, with a log midpoint of 3.5. Thus, the target delta RFU for the 0.5 EU/mL is approximately 3000 RFU. The PyroWave® XM Reader is more reliable over the entire dynamic range though and the assay has a slope of less than one, so a higher target was set. This device will solve for a log value of 4.00 when determining the sensitivity for the device.

The Nebula® Multimode Reader has a fluorescence range of 0 to 65536. When using this device, the WinKQCL® Software will solve for the log value of 3.7 for the sensitivity assay.

Material Required

- PyroGene® Assay Reagents (P/N 50-658U or equivalent)
- 96-well plate (flat bottom) (P/N 25-340 or equivalent)
- Pipettes and micropipettes
- Endotoxin-free pipette tips (P/N 25-415, 25-416, 25-417, or equivalent)
- Glass dilution tubes (P/N N207 or equivalent)
- Test tube rack
- Control Standard Endotoxin (CSE, for kits without included endotoxin)
- LAL Reagent Water (LRW) (P/N W50-640, W50-100, W50-500, or equivalent)
- Vortex mixer
- Timer
- Reagent reservoirs (P/N 00190035 or equivalent)

Sensitivity Test Procedure

The sensitivity test determines the proper Sensitivity or PMT gain setting for the reader and reagent combination being used. To perform a Sensitivity test, follow these steps:

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.
2. Log in as an analyst. When launched, the WinKQCL® Software enables the incubator for all attached readers.
3. Remove the liquid PyroGene® Assay reagents from cold storage and allow them to equilibrate to room temperature.
4. Reconstitute a vial of CSE with the appropriate volume of LAL Reagent Water (LRW) according to the Certificate of Analysis. Mix this CSE according to the PyroGene® Assay package insert.

5. Dilute the CSE to obtain an endotoxin concentration according to the package insert.
6. Use a calibrated micropipette to dispense 100 µl of the diluted endotoxin standard into the appropriate wells (wells D6 through F7 or the entire plate).
7. On the main toolbar, click **Other Tests > Validation > Nebula > Sensitivity, Other Tests > Validation > Synergy > Sensitivity**, or **Other Tests > Validation > PyroWave XM > Sensitivity** to open the **Sensitivity Tests** window.
8. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



9. On the reader selection window, select the workgroup for this test and select an available absorbance or multimode reader. Click **OK**. The **Sensitivity Test** window is displayed.

Lot numbers	Parameters	Checked	Value
rFC Enzyme Solution	rFC Enzyme	<input checked="" type="checkbox"/>	4/ 1/2023
LAL Reagent Water	Water	<input checked="" type="checkbox"/>	4/ 1/2023
Endotoxin	Endotoxin	<input checked="" type="checkbox"/>	4/ 1/2023
rFC Assay Buffer	Buffer	<input checked="" type="checkbox"/>	4/ 1/2023
Fluorogenic Substrate	Substrate	<input checked="" type="checkbox"/>	4/ 1/2023

Endotoxin concentration unitage: EU

Concentration: 0.5

Wells to use: Pre-defined (D6,7; E6,7; F6,7) Full plate

Target Y-Value in log(avg delta RFU): 3.50

Sensitivity: Count: 6

Settings: 30, 34, 38, 42, 46, 50

10. For the common fields below and to the right of the tabbed windows, the default values are as follows:
 - **Endotoxin Concentration Unit:** EU
 - **Concentration:** 0.5
 - **Wells to use:** Pre-defined (D6,D7; E6,E7; F6,F7)
 - **Sensitivity:** The WinKQCL® Software uses the default reader sensitivity value to automatically calculate a sensitivity range. Manually modify this range by typing in the first value and using the Tab key or down arrow key to move down the list.

- **Target Y-Value in log (delta RFU):** The default value for this will represent Lonza's recommended value for the reader, but it can be configured should a user want to follow his or her own procedure.

11. On the **Lot numbers** tab, enter the Lonza reagent lot number and expiration date information printed on the reagent vials.

NOTE: Lonza endotoxin reagent labels include 2D barcodes. ("2D" stands for two-dimensional.) The software supports scanning in lot number information with a 2D barcode scanner. The barcode encodes the part number, lot number and expiration date information. As long as a field in the lot number tab is selected, when the barcode is scanned, the WinKQCL[®] Software automatically determines which lot number field and expiration date field to update.

12. Click the **Parameters** tab and configure the following criteria:

NOTE: Some fields and controls on this tab will change in availability, ranges and default values as the reader type changes. For example, a BioTek™ FLx800™ TBIE model reader will have both top and bottom read options available, and only has fixed (interference) filters. The tunable filter option will not be available on this reader.

- The time between the reads. The default value for the PyroGene[®] Assay is 1 hour.
- The sensitivity (PMT Gain) setting configured is displayed for the selected reader. Enter a new sensitivity value if needed.
- If the reader has both top and bottom reading options, select whether to read from the **Top** or the **Bottom**.
- Specify if the software should use fixed (interference) filters and tunable filters, this is dependent on the capabilities of the reader.
- Select the excitation and emission center wavelengths and bandpass to use for this test. For the PyroGene[®] Assay, the default excitation center wavelength is 380nm, and emission center wavelength 440nm.

13. Click **OK** when all test criteria are configured.
14. The WinKQCL[®] Software tests the connection with the selected reader and then monitors the reader temperature until it reaches $37 \pm 0.5^{\circ}\text{C}$. When the temperature reaches $37 \pm 0.5^{\circ}\text{C}$, a prompt appears to place the plate on the carriage.
15. [On a reader that cannot be manually opened, click **Plate out**]. Place the 96-well plate on the reader carriage. [If required, click **Plate in**.] Click **OK**.

WARNING Do not leave the carrier door open any longer than is necessary. The incubation chamber and the plate will begin dropping in temperature as soon as the carrier door is opened.

16. The software confirms the placement of the assay plate and displays a progress bar to count down the incubation period. The 96-well plate must be incubated for a minimum of 10 minutes before the reagent is added. When the plate is incubated, the temperature is uniform and the test results are more accurate. The software prompts to add the reagent to

the plate when the incubation period ends. To bypass, click **Skip** to override the incubation timer and proceed to the **Add Reagent** window early.

17. Prepare a working reagent by mixing the fluorogenic substrate, rFC assay buffer and the rFC enzyme solution according to the package insert.
18. [On a reader that cannot be manually opened, click **Plate out.**] Use a multichannel pipette and add the reagent to the plate. Start at the left side of the plate and work to the right. Maintain a constant interval between additions. Do not allow bubbles to form in the microplate wells. Run this test with the microplate lid off. After adding the reagent to the last column, immediately close the cover. [If required, click **Plate in.**] Click **OK** to start the test.
19. After the system confirms that the reagent is added, a window is displayed that tells how long the plate will be shaken. The reader shakes the plate. After approximately 15 seconds, the WinKQCL[®] Software takes its first reading of the plate. A window is displayed warning not to open the reader door. After the first read is complete, the Elapsed Time window is displayed. This window indicates the amount of time that has elapsed since the first read began. The progress bar advances as time elapses between the reads.

NOTE: Clicking **Stop Test Early** stops the current test and the system proceeds directly to the second read. A prompt appears to confirm that the WinKQCL[®] Software should proceed to the second read. If **Yes** is clicked, the WinKQCL[®] Software begins the second read. The system also writes the actual incubation time to the results report and to the template that is saved with this test. If **No** is clicked, the Elapsed Time window is displayed.

20. The WinKQCL[®] Software takes the second reading of the plate. When the second read is complete, the data is saved to the database automatically and the results report is displayed. The report includes the following information:
 - The calculated optimal sensitivity value is displayed under the graph.
 - For each sensitivity setting configured:
 - o Read 1 and read 2 for each well tested
 - o Delta RFU (Read 2 - Read 1 in Relative Fluorescence Units) for all wells tested.
 - o Percent CV for each column and row
 - o Overall percent CV
21. The test is available for review from the Sensitivity Tests list. The analyst and a reviewer should electronically sign the report.
 - To view the results report, click **View Results** on the Sensitivity Tests window.
 - To view the raw data, click **View Raw Data**.
22. A user with permissions to manage readers should log in to the software and enter the resulting sensitivity value in the default sensitivity field in the reader setup window for the tested reader (see "Reader Setup" on page 122). If the resulting value is less than the minimum value the device permits, please enter the minimum value.

Fluorescence Uniformity Test

The Fluorescence Uniformity test verifies that the assay environment is uniform across the entire 96-well microplate in a multimode or fluorescence reader. The following procedure identifies variations in the relative fluorescence of a common standard over an entire 96-well plate.

This test can indicate unacceptable variability. However, the root cause may be impossible to determine. Variations that are outside of the desired range can indicate any combination of problems. Below are the most common causes of variation:

- Use of accessories not suitable for endotoxin testing. Ensure all pipette tips, reagent reservoirs, and 96-well plates used are certified endotoxin free at or below the lowest standard used for endotoxin testing.
- Variations in delivery volumes due to:
 - Mis-calibrated or faulty micropipettes
 - Improper pipetting technique
 - Using pipette tips that do not fit the micropipette properly
 - Not having all 8 or 12 tips pressed on to a multichannel pipette with the same amount of force. This usually occurs when the center of the pipette box bows in when pressing the tips on to the multichannel pipette. When using a multichannel pipette, ensure the center tips are pressed on with the same force as the outer tips. It may be necessary to pull or push the center tips onto the pipette with additional force.
 - Fluctuations in incubator temperature across the plate

Material Required

- PyroGene® Assay Reagents (P/N 50-658U or equivalent)
- 96-well plate (flat bottom) (P/N 25-340 or equivalent)
- Pipettes and micropipettes
- Endotoxin-free pipette tips (P/N 25-415, 25-416, 25-417, or equivalent)
- Glass dilution tubes (P/N N207 or equivalent)
- Test tube rack
- Control Standard Endotoxin (CSE, for kits without included endotoxin)
- LAL Reagent Water (LRW) (P/N W50-640, W50-100, W50-500, or equivalent)
- Vortex mixer
- Timer
- Reagent reservoirs (P/N 00190035 or equivalent)

Uniformity Test Procedure

This procedure involves placing a single endotoxin standard across the entire 96-well plate.

1. Turn on the reader and allow it to complete its startup procedure prior to logging in to the WinKQCL® Software.

2. Log in as an analyst. When launched, the WinKQCL[®] Software enables the incubator for all attached readers.
3. Remove the liquid PyroGene[®] Assay reagents from cold storage and allow them to equilibrate to room temperature.
4. Reconstitute a vial of CSE with the appropriate volume of LAL Reagent Water (LRW) according to the Certificate of Analysis. Mix this CSE according to the PyroGene[®] Assay package insert.
5. Dilute the CSE to obtain an endotoxin concentration of 0.5 EU/mL. Prepare 10 mL minimum.
6. Use a calibrated micropipette to dispense 100 µL of the diluted endotoxin standard into every well of a 96-well plate.
7. On the main toolbar, click **Other Tests > Validation > [Reader Type] > Fluorescence Uniformity** to open the **Fluorescence Uniformity Tests** window.
8. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



9. On the reader selection window, select the workgroup for this test and select an available fluorescence or multimode reader. Click **OK**. The **Fluorescence Uniformity Test** window is displayed.

Fluorescence Uniformity Test (JHOSIE): VirtualReader Test (COM0) Vir...

Lot numbers Parameters

rFC Enzyme Solution	rFC Enzyme	<input checked="" type="checkbox"/>	4/ 1/2023
LAL Reagent Water	Water	<input checked="" type="checkbox"/>	4/ 1/2023
Endotoxin	Endotoxin	<input checked="" type="checkbox"/>	4/ 1/2023
rFC Assay Buffer	Buffer	<input checked="" type="checkbox"/>	4/ 1/2023
Fluorogenic Substrate	Substrate	<input checked="" type="checkbox"/>	4/ 1/2023

Endotoxin concentration unitage: EU

Concentration: 0.5

Sensitivity: 35

OK Cancel

10. For the common fields below the tabbed windows, the default values are as follows:
 - **Endotoxin Concentration Unitage:** EU
 - **Concentration:** 0.5
 - **Sensitivity:** <value from reader setup for the selected reader>
11. On the **Lot numbers** tab, enter the Lonza reagent lot number and expiration date information printed on the reagent vials.

NOTE: Lonza endotoxin reagent labels include 2D barcodes. ("2D" stands for two-dimensional.) The software supports scanning in lot number information with a 2D barcode scanner. The barcode encodes the part number, lot number and expiration date information. As long as a field in the lot number tab is selected, when the barcode is scanned, the WinKQCL[®] Software automatically determines which lot number field and expiration date field the information to update.

12. Click the **Parameters** tab and configure the following criteria:

NOTE: Some fields and controls on this tab will change in availability, ranges and default values as the reader type changes. For example, a Molecular Devices[®] SpectraMax[™] M2 reader does not have bottom read capability and only has tunable filters. The bottom optics position and the fixed filter options will not be available on this reader.

- The time between the reads. The default value for the PyroGene[®] Assay is 1 hour.
 - The sensitivity (PMT Gain) setting configured for the selected reader is displayed. Enter a new sensitivity value if needed.
 - If the reader has both top and bottom reading options, select whether to read from the **Top** or the **Bottom**.
 - Specify if the software should use fixed (interference) filters and tunable filters, this is dependent on the capabilities of the reader.
 - Select the excitation and emission center wavelengths and bandpass to use for this test. For the PyroGene[®] Assay, the default excitation center wavelength is 380nm and emission center wavelength 440nm.
13. Click **OK** when all test criteria are configured.
 14. The WinKQCL[®] Software tests the connection with the selected reader and then monitors the reader temperature until it reaches $37 \pm 0.5^{\circ}\text{C}$. When the temperature reaches $37 \pm 0.5^{\circ}\text{C}$, a prompt appears to place the plate on the carriage.
 15. [On a reader that cannot be manually opened, click **Plate out**]. Place the 96-well plate on the reader carriage. [If required, click **Plate in**.] Click **OK**.

WARNING Do not leave the carrier door open any longer than is necessary. The incubation chamber and the plate will begin dropping in temperature as soon as the carrier door is opened.

16. The WinKQCL[®] Software confirms the placement of the assay plate and displays a progress bar to count down the incubation period. The 96-well plate must be incubated for a minimum of 10 minutes before the reagent is added. When the plate is incubated, the temperature is uniform and the test results are more accurate. The software prompts to add the reagent to the plate when the incubation period ends. To bypass, click **Skip** to override the incubation timer and proceed to the **Add Reagent** window early.
17. Prepare a working reagent by mixing the fluorogenic substrate, rFC assay buffer and the rFC enzyme solution according to the package insert.
18. [On a reader that cannot be manually opened, click **Plate out**.] Use a multichannel pipette and add the reagent to the plate. Start at the left side of the plate and work to the right. Maintain a constant interval between additions. Do not allow bubbles to form in the microplate wells. Run this test with the microplate lid off. After adding the reagent to the last column, immediately close the cover. [If required, click **Plate in**.] Click **OK** to start the test.
19. After the system confirms that the reagent is added, a window is displayed that tells how long the plate will be shaken. The reader shakes the plate. After approximately 15 seconds, the WinKQCL[®] Software takes its first reading of the plate. A window is displayed warning not to open the reader door. After the first read is complete, the Elapsed Time window is displayed. This window indicates the amount of time that has elapsed since the first read began. The progress bar advances as time elapses between the reads.

NOTE: Clicking **Stop Test Early** stops the current test and the system proceeds directly to the second read. A prompt appears to confirm that the WinKQCL[®] Software should proceed to the second read. If **Yes** is clicked, the WinKQCL[®] Software begins the second read. The

system also writes the actual incubation time to the results report and to the template that is saved with this test. If **No** is clicked, the Elapsed Time window is displayed.

20. The WinkQCL[®] Software takes the second reading of the plate. When the second read is complete, the data is saved to the database automatically and the results report is displayed. The report includes the following information:
 - Delta RFU (Read 2 - Read 1 in Relative Fluorescence Units) for all 96 wells
 - Percent CV for each column and row
 - Overall plate percent CV
21. The test is available for review from the Fluorescence Uniformity Tests list. The analyst and a reviewer should electronically sign the report.
 - To view the results report, click **View Results**.
 - To view the raw data, click **View Raw Data**.

Date	Time	Analyst ID	A	R	Reader S/N	Reader Header	Workgroup
4/20/2015	3:14:48 PM	DROOP	x		256516	FLx800 reader	PM Service
3/26/2015	2:45:43 PM	DROOP	x		234688	FLx800 reader	PM Service
3/26/2015	12:40:56 PM	DROOP	x		234688	FLx800 reader	PM Service
3/26/2015	10:41:18 AM	DROOP	x		234688	FLx800 reader	PM Service
3/23/2015	3:37:37 PM	DROOP	x		234688	FLx800 reader	PM Service
3/23/2015	1:40:10 PM	DROOP	x		234688	FLx800 reader	PM Service
3/23/2015	11:03:30 AM	DROOP	x		234688	FLx800 reader	PM Service
2/27/2015	12:18:33 PM	DROOP	x		234688	FLx800 reader	PM Service
2/26/2015	1:45:33 PM	DROOP	x		234688	FLx800 reader	PM Service
2/26/2015	10:25:52 AM	DROOP	x		234688	FLx800 reader	PM Service
2/24/2015	3:07:03 PM	DROOP	x		234688	FLx800 reader	PM Service
2/24/2015	1:48:21 PM	DROOP	x		234688	FLx800 reader	PM Service

Approval Criteria

No regulatory specification is available for this assay. Therefore, internal specifications simply serve as monitors. Lonza recommends an overall plate percent CV of < 20%.

FLx800™ Reader System Test

The reader performs the BioTek™ FLx800™ Reader System test automatically at power up. The WinkQCL[®] Software can be used to perform the System Test and to store, sign, and print the results.

The first part of the System test verifies the function of the filters, lamp, and optical sensor. The second part of the System test verifies the minimum and maximum temperature in the three incubation zones.

FLx800™ Reader System Test Procedure

To perform the System test on the BioTek™ FLx800™ reader, follow these steps:

1. Turn on the BioTek™ FLx800™ reader. Ensure that the reader status is Available in the Readers List.
2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.

Approval Criteria

The System test report lists results in a pass/fail format and can be viewed and printed.

NOTE: If the FLx800™ reader fails the System test, it does not perform a read until the error condition is cleared.

The BioTek™ FLx800™ Reader System test specifications are as follows:

- Evaluates the performance of the analog front-end electronics in the instrument. Bias current offset and offset voltage must be reported as "PASS".
- Checks if the dark current of the PMT is under the acceptable limit. Readings between 750 and 3000 counts may indicate that the reader is due for preventive maintenance. The 750V measurement must be reported as "PASS."
- Top and Bottom Probe Position data will be included in the report.
- A/D Test must be reported as "PASS."
- Incubator Self-test "Range" and "Thermistor" must all be reported as "PASS."
- "SYSTEM TEST PASS" must be reported at the bottom of the test.

An Autocal Analysis is used at the factory to calibrate the carrier axis of the instrument. The results of this test are included in the System test report as a table of Probe Positions. Review the Probe Position data that is included in System test report.

Test results are stored in the System tests list under **Validation > FLx800 > FLx800 System**.

To electronically sign and print the system test results, click **View Results**.

If "FAIL" appears on the System test report or an error code is displayed, record this error code and contact Lonza Scientific Support.

PyroWave® XM Reader System Test

The reader performs the PyroWave® XM Reader System test automatically at power up. The WinKQCL® Software can be used to perform the System test and to store, sign, and print the results.

The first part of the System test verifies the function of the filters, lamp, and optical sensor. The second part of the System test verifies the minimum and maximum temperature in the four incubation zones.

PyroWave® XM Reader System Test Procedure

To perform the System test on the PyroWave® XM Reader, follow these steps:

1. Turn on the PyroWave® XM Reader. Ensure that the reader status is Available in the Readers List.

2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.

Approval Criteria

The System test report lists results in a pass/fail format and can be viewed and printed. The system self-test will present an error code or report "FAIL" if any of the built-in Failure Mode Effects Analysis (FMEA) specifications fail. Verify all temperature range and thermistor tests indicate: PASS and SYSTEM TEST PASS is printed at the end of the report. If the system test completes without error and all tests pass, then the reader is passing its operational specifications.

NOTE: If the PyroWave[®] XM Reader fails the System test, it does not perform a read until the error condition is cleared.

For System test specifications please refer to the device manual.

An Autocal Analysis is used at the factory to calibrate the carrier axis of the instrument. The results of this test are included in the System test report as a table of Probe Positions. Review the Probe Position data that is included in System test report.

Test results are stored in the System tests list under **Validation > PyroWave XM > PyroWave XM System**.

To electronically sign and print the system test results, click **View Results**.

If "FAIL" appears on the System test report or an error code is displayed, record this error code and contact Lonza Scientific Support.

PyroWave[®] XM Fluorescence Plate Test

The test is comprised of two primary components: Corners and Linearity, and utilizes a plate with an anodized aluminum body and solid fluorescent analogues of NIST-traceable liquid Sodium Fluorescein. The Corners (Alignment) Test will check the alignment of the plate carrier in the reader. The Detection Limit/Linearity Test determines whether the optics of the reader meet the minimum requirement of a ratio of greater than two between the signal (Sodium Fluorescein analogues wells) to noise (buffer) readings at a 1.0 nM or less concentration of Sodium Fluorescein..

Test Procedure

To perform the test on the PyroWave[®] XM Reader, follow these steps:

1. Turn on the PyroWave[®] XM Reader. Ensure that the reader status is Available in the Readers List.
2. Change the Filter Set ID to the filter set which supports Sodium Fluorescein (Excitation 485/20; Emission 528/20). This should be the second filter set in the list.
3. Click OK to save the settings

- Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



- Select the reader that will be tested and then click **OK**. The **Fluorescence Plate Test** window is displayed.
- Locate the Fluorescence Test Plate Calibration Certificate for the plate. Record the information into the interface. And proceed through the interface.
- When the Place Plate window is displayed, place the fluorescence test plate in the plate carriage of the reader with A1 in the appropriate location.
- Click OK to start the Fluorescence Plate Test.
- The plate will be read multiple times.
- When prompted, rotate the plate, close the reader and click OK.
- The fluorescence test plate is read again multiple times, the data is saved to the database automatically and the results report is displayed.
- After the assay edit the reader again and select the Blue filter set.

Approval Criteria

If the reader is functioning properly, the test report will indicate PASS for all qualified fields. To electronically sign and print the test results, click **View Results**.

If "FAIL" appears on the test report or an error code is displayed, record this error code and contact Lonza Scientific Support.

Validation Tests for Multimode Readers

The following validation tests are specific to the BioTek™ Synergy™ 2 multimode reader. All non-reader/vendor specific Absorbance and Fluorescence tests may be run on the multimode readers.

- **Synergy™ 2 System Test (Other Tests > Validation > Synergy > Synergy System):** The first part of the system test verifies the function of the carriers, filters, injectors, lamp, monochromator, and optical sensor. The second part of the system test verifies the minimum and maximum temperature in the four incubation zones (see "Synergy™ 2 System Test" on page 111).

The following validation tests are specific to the Lonza® Nebula® Multimode reader. All non-reader/vendor specific Absorbance and Fluorescence tests may be run on the multimode readers.

- **Nebula® Multicheck Test (Other Tests > Validation > Nebula > Multicheck Test):** This will launch a separate utility for operating a test plate for the device. All information pertaining to this test will be in the system manual.

Synergy™ 2 System Test

When the reader is turned on, it performs the system test automatically. If this automatic system test fails, the reader will beep and the light will flash. To determine the cause of the failure or to obtain a system test report that can be electronically signed and printed, click **Other Tests >**

Validation > Synergy > Synergy System on the main toolbar. This feature can be used for periodic testing and documentation or for troubleshooting.

To create a new report, the analyst that performs the test can click **Run** from the **Systems Tests** window. The system test report will be displayed when the test is complete.

Select a test in the list and click the **View Results** button to view, sign, export, and print previously run system tests.

Synergy™ 2 System Test Procedure

To perform the Synergy™ 2 system test, follow these steps:

1. Turn on the BioTek™ Synergy™ 2 reader. Ensure that the reader status is shown as **Available** in the Readers List.
2. Click **Run** to run as the current logged in user. Click the down arrow and select **Run as** to use an alternative user account. If prompted, enter a valid analyst user ID and password.



3. Select the reader that will be tested and then click **OK**.

Approval Criteria

The system test report lists results in a pass/fail format and can be viewed and printed.

NOTE: If the Synergy™ 2 reader fails the system test, it does not perform a read until the error condition is cleared. An error condition normally requires that the reader is powered off and back on again.

The BioTek™ Synergy™ 2 reader system test only reports PASS and FAIL results in the Filter PCB and the INCUBATION sections of the report.

Bias Current Offset	-0.2	counts	PASS
Offset Voltage	1,546	counts	PASS
750V Measurement	32.8	counts	PASS
750V Noise	16	counts	
750V Offset	1,549	counts	
500V Measurement	6.8	counts	
500V Noise	1	counts	
500V Offset	1,548	counts	
Reset Offset	1,582	counts	
Reference Bias	0.40	counts	PASS
Reference Offset	11,021	counts	PASS
Reference Noise	0.2	counts	PASS

INCUBATION				
Temperature Setpoint : 37.00		Temperature Average : 37.00		A/D Test: PASS
Zone 1: 37.1	Min: 35.1	Max: 37.1	Range: PASS	Thermistor: PASS
Zone 2: 37.0	Min: 35.3	Max: 37.1	Range: PASS	Thermistor: PASS
Zone 3: 37.1	Min: 36.3	Max: 37.1	Range: PASS	Thermistor: PASS
Zone 4: 36.9	Min: 35.2	Max: 36.9	Range: PASS	Thermistor: PASS

Verify the following criteria on the Synergy™ system test:

- Verify the bias current offset and the offset voltage pass.

- The 750-volt measurement for a reader with a standard PMT must be between 0 and 100. If the reader has an extended red PMT, the measurement value must be between 0 and 750.
- For all wavelengths, if the capacitor reset value is 1, the gain must be less than 10.
- For all wavelengths, if the capacitor reset value is 8, and the gain is less than 1.5, then the measurement channel light reading must be less than 55,000.
- For all wavelengths, the reference channel delta must be 1500 or more.
- For all wavelengths, the measurement channel light values must be between 36000 and 55000.
- For all wavelengths, dark values for both the reference channel and the measurement channel must be between 9500 and 10100.
- For the noise test, the delta values for both the reference channel and the measurement channel must be 5 or less.
- For the incubator section, verify the A/D test, and all range and thermistor tests pass.
- Verify "System Test Pass" is displayed at the end of the report.

If FAIL appears on the system test report or any values are outside of their range, contact Lonza Scientific Support.

While the system test is being performed, the results are also being checked against internally coded Failure Mode Effects Analysis (FMEA) criteria, established by BioTek™. If a failure in any of these other criteria occurs, an error code will be reported back to the WinKQCL® Software. The WinKQCL® Software will display the error code. Take a screenshot of this error, or record the error code.

Test results are stored in the system tests list under **Validation > Synergy > Synergy System**.

To electronically sign and print the system test results, click **View Results**.

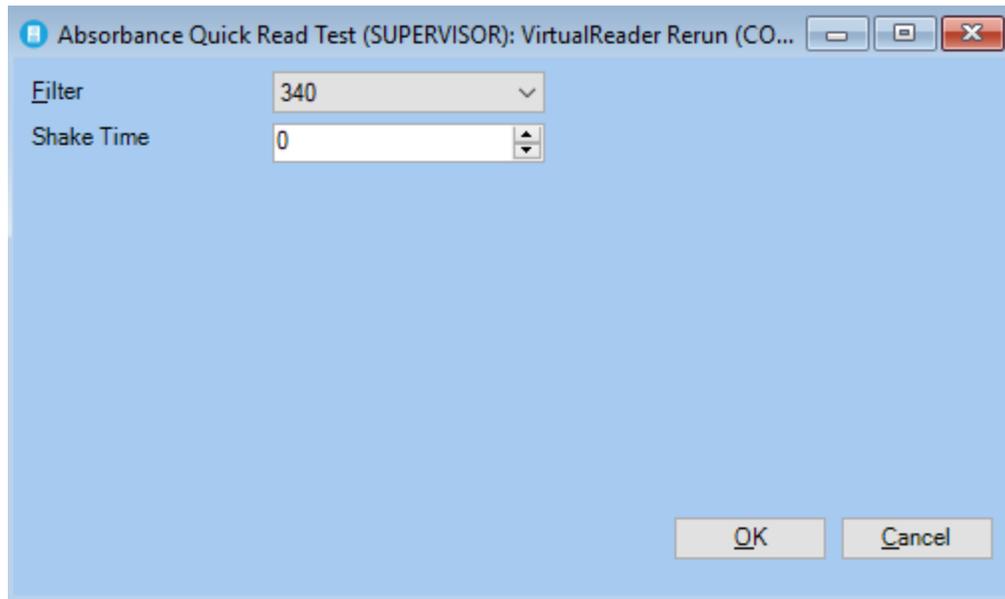
Quick Read Tests

Quick Read tests capture a single scan of a microplate at a user-defined wavelength. The optical density or fluorescence readings may be printed, but data analysis is not performed in a Quick Read test.

To perform a Quick Read test, follow these steps:

1. On the main toolbar, click **Other Tests > Quick Read > Absorbance** or **Other Tests > Quick Read > Fluorescence**.
2. Click **Run**. If prompted, enter a valid analyst user ID and password.
3. Select the reader to use for the test. The following windows are displayed after successful connection to the reader:

Absorbance Quick Read



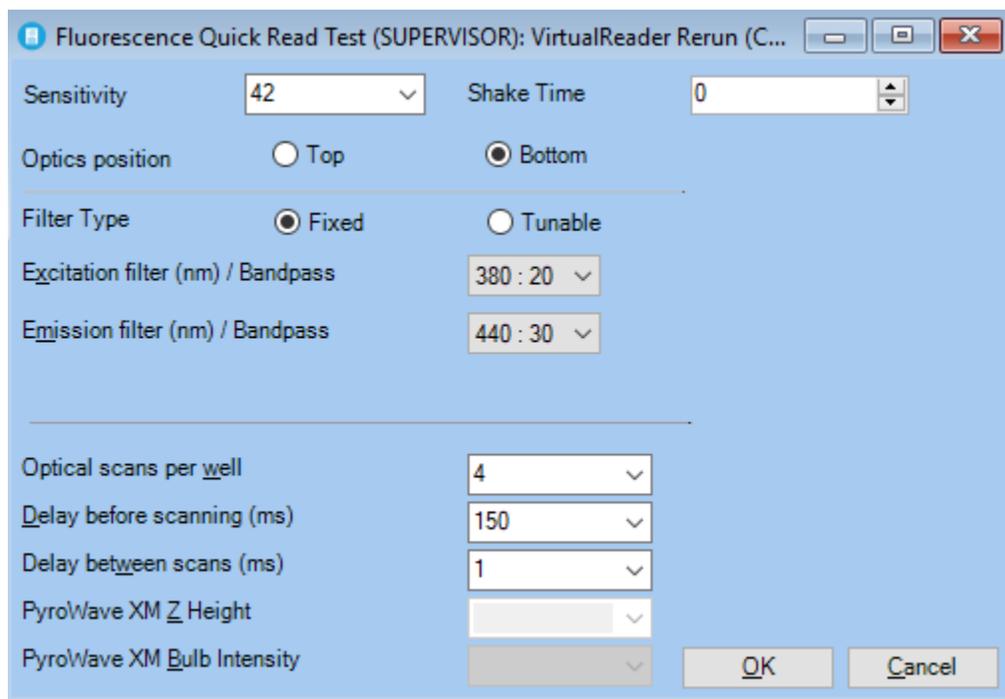
Absorbance Quick Read Test (SUPERVISOR): VirtualReader Rerun (CO... [-] [+] [X]

Filter ▼

Shake Time ▲ ▼

OK Cancel

Fluorescence Quick Read



Fluorescence Quick Read Test (SUPERVISOR): VirtualReader Rerun (C... [-] [+] [X]

Sensitivity ▼ Shake Time ▲ ▼

Optics position Top Bottom

Filter Type Fixed Tunable

Excitation filter (nm) / Bandpass ▼

Emission filter (nm) / Bandpass ▼

Optical scans per well ▼

Delay before scanning (ms) ▼

Delay between scans (ms) ▼

PyroWave XM Z Height ▼

PyroWave XM Bulb Intensity ▼ OK Cancel

4. Configure the appropriate parameters, and then click **OK** to start the test. The plate is read and the OD or RFU values are available to review and print.

Automation

Introduction

The WinKQCL[®] 6 Software supports two unique integrations with the Tecan[®] Freedom EVO[®] Liquid Handling Platform. The PyroTec[®] HT module is designed for high throughput routine testing while the new PyroTec[®] PRO Automation module is designed as a configurable automated solution to free up analysts to perform more complex tasks. More information pertaining to these systems can be found in their corresponding system manuals.

Tools

This main menu item can be used to access functions important to the operation and maintenance of the WinKQCL[®] Software. Click **Tools** on the main toolbar.

NOTE: All tools menu items, except for system diagnostics and reader setup, require supervisor-level access.

NOTE: AER Parameters and Template Defaults apply to all client computers, but the properties may be overridden for a workgroup if necessary.

AER Parameters

An assay evaluation report (AER) is a printout of parameter specifications that a supervisor has defined. The AER report also contains information about how actual assay data conform to the defined specifications. After the AER specifications are defined, when an assay is performed, these settings will be applied by default. Kinetic-QCL[®] and PYROGENT[®] 5000 Assays AER parameters (absorbance) must be configured separately from PyroGene[®] Assay AER parameters (fluorescence).

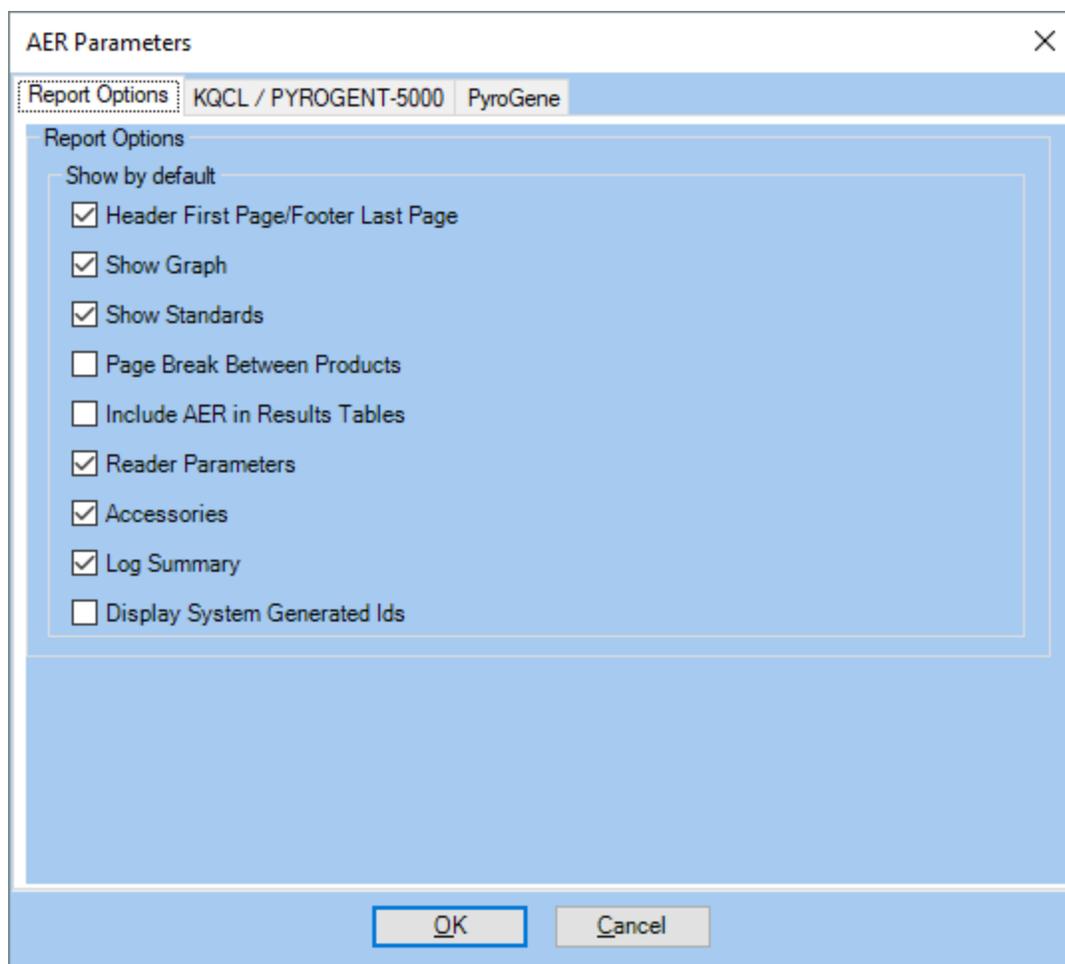
To access the AER Parameters, click **Tools > AER Parameters** on the main toolbar.

The following information applies to AER absorbance parameters and AER fluorescence parameters.

- By default, the parameters are not selected. Select the checkbox for each AER parameter needed for the assay report. If the AER parameter is not selected here, the option to select it is available when viewing a report.
- When entering the specification range for the correlation coefficient, slope, or y-intercept, enter the value for the lower limit of the range in the left box.
- Correlation coefficient and slopes for absorbance assays are negative. Correlation coefficient and slopes for fluorescence assays are positive.
- The AER default values that the WinKQCL[®] Software provides are only suggested values. Each laboratory must decide if these values meet its requirements.

Report Options

To access the default report options that refer to all assays, click **Tools > AER Parameters**, and go to the **Report Options** tab (See “Endotoxin Test Results Controls and Functionality” for more information).



AER Absorbance Parameters

To access AER parameters that relate to Kinetic-QCL[®] and PYROGENT[®] 5000 assays, click **Tools > AER Parameters**, and go to the **KQCL / PYROGENT 5000** tab. The values in the figure below are the default values for the system.

AER Parameters [X]

Report Options: **KQCL / PYROGENT-5000** | **PyroGene**

AER Parameters for Absorbance

Show by default

Parameter	Specification
<input checked="" type="checkbox"/> Select All	
<input checked="" type="checkbox"/> Correlation Coefficient	-1.000 to -0.980
<input checked="" type="checkbox"/> Slope	-0.400 to -0.100
<input checked="" type="checkbox"/> Y-Intercept	2.500 to 3.500
<input checked="" type="checkbox"/> Std-Control % Recovery	100 ± 25
<input checked="" type="checkbox"/> CV Replicates	less than 10.00 %
<input checked="" type="checkbox"/> PPC Recovery	50 to 200 %
<input checked="" type="checkbox"/> Sample Limits	
<input checked="" type="checkbox"/> Alerts	

Default Regression

Linear PowerCurve

Blank/Lowest standard alert based on:

Replicate Average

OK Cancel

The **Std-Control % Recovery** is used to evaluate a standard control only when a stored curve is used instead of the full range of standards on the plate with the products.

The **Default Regression** option determines the default type of regression used to calculate the standard curve when the assay is complete. If **PowerCurve** is selected but it cannot be used when an assay is complete, the WinKQCL® Software uses linear. For more information on regression models refer to Error! Reference source not found. and **Error! Reference source not found.**

The **Blank/Lowest standard alert based on** option determines the method of determining if the blank and lowest standards reacted in the correct order. If **Replicate** is selected then an alert will be raised should any replicate overlap, while if **Average** is selected the alert will only be raised if the averages for the blank or standard are out of order.

AER Fluorescence Parameters

To access AER parameters that relate to PyroGene® Assays, click **Tools > AER Parameters**, then click on the **PyroGene** tab. The values in the image below are the default values for the system.

AER Parameters

Report Options KQCL / PYROGENT-5000 **PyroGene**

AER Parameters for Fluorescence

Show by default

<input checked="" type="checkbox"/> Select All			
<input checked="" type="checkbox"/> Correlation Coefficient		0.980	to 1.000
<input checked="" type="checkbox"/> Slope		0.760	to 1.110
<input checked="" type="checkbox"/> Y-Intercept		2.500	to 5.000
<input checked="" type="checkbox"/> CV Replicates			less than 25.00 %
<input checked="" type="checkbox"/> PPC Recovery		50	to 200 %
<input checked="" type="checkbox"/> Sample Limits			
<input checked="" type="checkbox"/> Alerts			

Specifications

Default Regression

Linear PowerCurve

Blank/Lowest standard alert based on:

Replicate Average

OK Cancel

Template Defaults

A supervisor can set template defaults for Kinetic-QCL[®] and PYROGENT[®] 5000 Absorbance Assays and PyroGene[®] Fluorescence Assays). These default template settings are applied to all systems on the network. These settings are used when new templates are created, but they do not affect previously defined templates.

To access template default settings, click **Tools > Template Defaults** on the main toolbar.

Template Defaults for Absorbance

To access template defaults that relate to the Kinetic-QCL[®] and PYROGENT[®] 5000 Assays, click **Tools > Template Defaults > Absorbance**.

	Kinetic-QCL	PYROGENT-5000
Delta t (seconds)	150	60
Measurement filter (nm)	405	340
Delta mOD	200	30
Max number of reads	40	100
Shake Time	30	30

Kinetic SmartStop
Stop test early when:

- All Standard Replicates React
- No Split Replicates Exist for Products
- All Blank Replicates React

OK Cancel

- **Delta t:** This value defines the amount of time in seconds between reads when running a kinetic test. A read cycle will be as long as the time value defined. The lower limit of this value is dependent on the speed with which the reader can read a 96-well plate.
- **Measurement Filter:** The monochromator center wavelength or the fixed filter that is used when reading the plate. Change in optical density will be monitored at this wavelength.
- **Delta mOD:** The WinKQCL[®] Software will look for an increase in the optical density from read 1 according to this value. When the optical density of the well meets or exceeds the defined change in optical density or "delta mOD", the well is considered "reacted" and the WinKQCL[®] Software will calculate a reaction time for the given well. When a well delta mOD is reached the color of the trace line for the well changes from blue to red in the 96-well plate diagram.
- **Max number of reads:** This is the maximum number of kinetic read cycles the test will run. This feature interacts with the Kinetic SmartStop[™] feature to prevent the WinKQCL[®] Software from running the test any longer than the defined maximum number of reads. To wait for blanks to react or prevent product split replicates (also known as "split pairs"), set this value higher. To have the test always run for the same amount of time, uncheck the three subsequent checkboxes.
- **Shake Time:** The shake time of the assays can be adjusted in order to match end user SOPs.

Kinetic SmartStop[™]

Kinetic SmartStop[™] allows the WinKQCL[®] Software to monitor the progress of the kinetic test and stop the test when specific criteria are met. Since different users have different test requirements, please read this section carefully to determine when the WinKQCL[®] Software should stop the test. This feature monitors each well on the plate and stops the test early when all standards have reacted, all replicates for a given product sample have reacted, and/or when all replicates for the blank (negative control) have reacted.

Stop the assay early when: all checked conditions are met, otherwise run to the maximum number of reads.

- o **All Standard Replicates React:** Check this option to stop tests early when all standard replicates react. The following two options are only enabled when this is checked:
 - **No Split Replicates Exist for Products:** Check this option to stop tests early when all products no longer have both reacted and unreacted replicates.
 - **All Blank Replicates React:** Check this option to stop tests early when all blank replicates react.

Template Defaults for Fluorescence

To access template defaults that relate to PyroGene® assays, click **Tools > Template Defaults > Fluorescence**. The interface is broken into three tabs. One for the defaults for the PyroWave® XM Reader, one for the Nebula® Multimode Reader, and one for all other readers.

Template Defaults for Fluorescence

Time between reads 01:00:00

Shake Time 15

PyroWave XM Nebula Other Readers

Optics position Bottom Top

Excitation filter (nm) / Bandpass 380 / 20

Emission filter (nm) / Bandpass 440 / 30

Optical scans per well 4

Delay before scanning (ms) 150

Delay between scans (ms) 1

Emission cutoff (nm) 420

OK Cancel

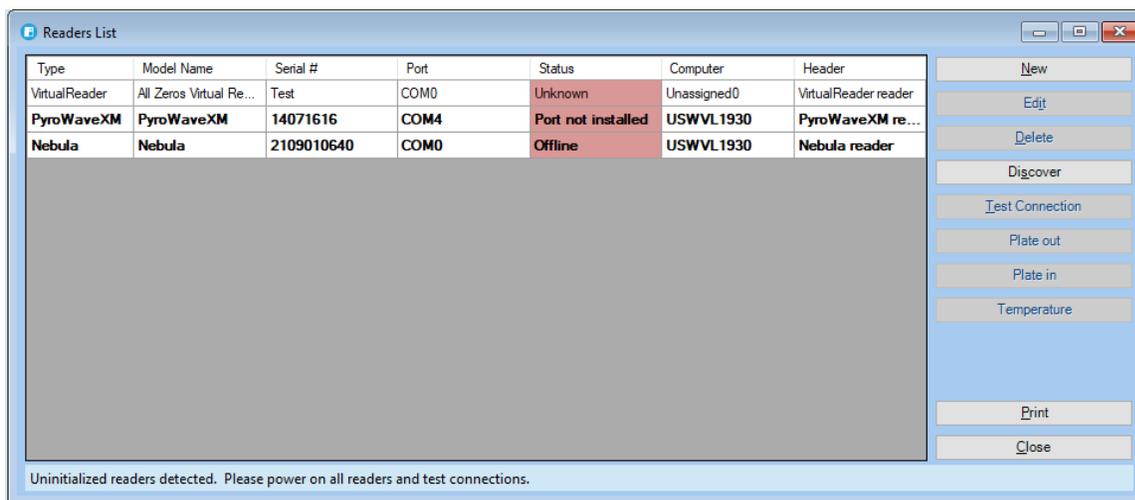
- **Time between reads:** This is the amount of time between the initial read (read 1) and the final read (read 2).
- **Excitation filter (nm) / Bandpass:** This is the default excitation center wavelength and bandpass. It is acceptable to have a bandpass that is different from the default value shown here. Different reader makes and models will have different bandpass values.
- **Emission filter (nm) / Bandpass:** This is the default emission center wavelength and bandpass. It is acceptable to have a bandpass that is different from the default value shown here. Different reader makes and models will have different bandpass values.

- **Emission cutoff (nm):** This is the default emission cutoff filter wavelength used. Emission cutoff filters, sometimes referred to as dichroic mirrors, will help decrease background light when reading the light output and can improve signal-to-noise, especially at low concentrations. Different reader makes and models will have different available cutoff filters. Please contact the reader manufacturer to determine the optimal cutoff filter for the model reader being used. Not all fluorescence readers the WinKQCL® Software interfaces with have cutoff filters.
- **Optical scans per well:** This value defines the number of times the reader will scan the well for one read. Increasing this value will scan the well more often that may decrease variability. Increasing this value increases the amount of time it takes to read a plate.
- **Delay before scanning (ms):** This value defines the amount of time the reader waits after moving to a new well, before scanning the well. Increasing this value increases the amount of time it takes to read a plate
- **Delay between scans (ms):** This value defines the amount of time the reader waits between optical scans for a given well. Increasing this value increases the amount of time it takes to read a plate.
- **Optics position:** This value defines whether the plate reads from the top or bottom. Not all readers have both options.
- **Z-Height:** This value defines the height of the optics that sit above the plate. This specification is only applicable to the PyroWave® XM Reader.
- **Bulb Intensity:** This value defines the strength of the Xenon flash bulb in the PyroWave® XM Reader.
- **Shake Time:** The shake time for the assay can be modified to match end-user SOPs.

Reader Setup

Users with the **Manage Readers** permission can review, edit, or delete the reader configuration for all computers in the WinKQCL® Software network from any terminal.

To display the Readers List window, click **Tools > Reader Setup** on the main toolbar. To sort the list, click a column header (see "Sortable Lists" on page 161).



The buttons on the right side of the window have the following functions:

- **Edit:** Click to edit the reader.
- **Delete:** Click to delete the reader from the list.
- **Test Connection:** Click to test the connection with the selected reader.
- **Plate out:** Click to open the door of the selected reader remotely. This button does not work for all readers.
- **Plate in:** Click to close the door of the selected reader remotely. This button does not work for all readers.
- **Temperature:** Displays the current temperature of the device.
- **Print:** Print the list of devices.
- **Close:** Click to close the window.

Automatically Discovering Attached Readers

Click **Discover** to have the WinKQCL® Software automatically scan all COM ports for powered-on readers or in the case of the Nebula® Multimode reader, USB.

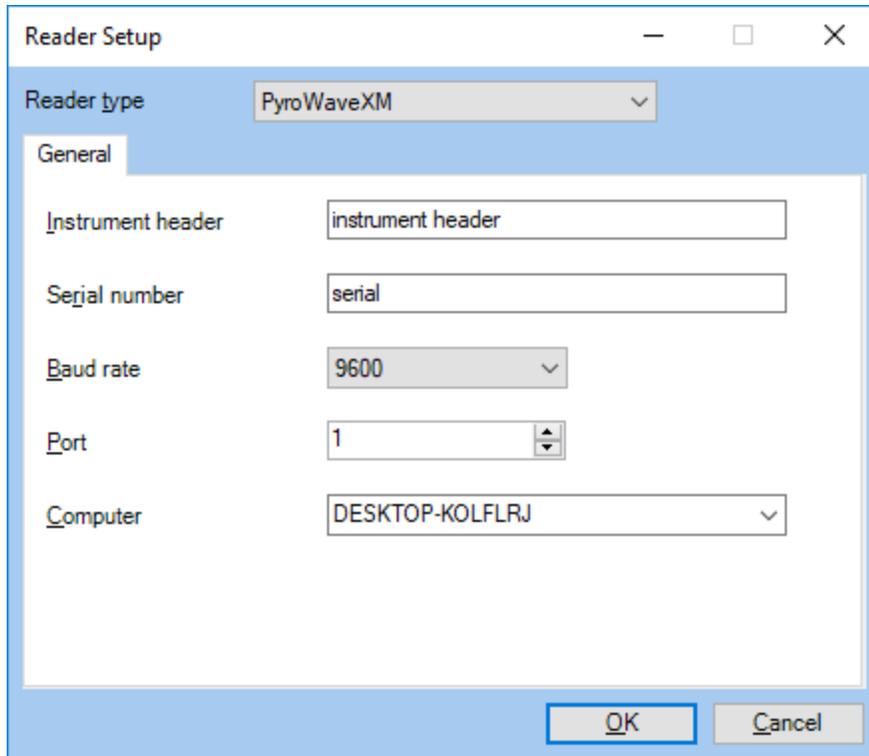
When PyroWave® XM, BioTek™ FLx800™, BioTek™ Synergy™ 2 and Tecan® Sunrise™ Readers are discovered, they automatically provide their serial numbers. When a BioTek™ ELx808™ reader, any Molecular Devices® SpectraMax™ readers or a Virtual reader is discovered, the serial number must be entered manually. In addition, Molecular Devices® SpectraMax™ readers will automatically provide a model name. If multiple readers are connected to the same computer, click the **Identify** button to cause the reader to beep or move its plate carriage to aid in identifying its physical location.

Discovered readers are added to the list automatically and can be used immediately. Before users perform tests with the reader, change the default header of new reader to a meaningful label by clicking the **Edit** button.

Manually Adding a Reader

In general, it is not recommended to manually add a reader as there are some configuration options pulled directly from the device. To add a reader manually, follow these steps:

1. Click **New**. The Reader Setup window is displayed. A user with the Manage Readers permission can configure a new reader on this window.



2. In the **Reader type** list, click the reader type.
3. In the **Instrument header** box, enter up to 80 characters for the instrument header. This text is printed on the line under the report header on each page of reports for tests run by this reader.
4. In the **Serial number** box, enter the reader serial number.
5. In the **Baud rate** list, click the communication port that matches the RS232 serial port of the computer connected to the reader. Select the baud rate that matches the proper baud rate of the reader. Only select 0 if this is a non COM device.
6. In the **Computer** box, enter the name of the computer to which the reader is connected. If another reader is already configured for the same computer, it can be selected. To determine the computer name, see "Testing the WinKQCL[®] Software Network Connectivity" on page 156.
7. If the reader accepts any additional settings, a second tab is displayed to configure those settings. For example, BioTek[™] FLx800[™] readers require a sensitivity setting.
8. Click **OK** to save.

Configuring a Synergy[™] 2 Reader

To change the configured sensitivity setting, filters and/or mirrors on a BioTek[™] Synergy[™] 2 reader, follow these steps:

1. Click **Discover**. Select **Synergy** in the list of readers. Press **OK**.
2. Select the newly discovered reader. Click **Edit**. The Reader Setup window is displayed. A user with the Manage Readers permission can configure a new reader on this window.
3. Click the **Synergy** tab.

4. Change the **Sensitivity** value based on the value determined in the **Sensitivity Test**.
5. Press the **Configure** button.
6. In the **Configure Reader** window there will be two tabs **Filters** and **Mirrors**
7. On the **Filters** tab, there will be options to select wavelengths and bandwidths for each of the four **Excitation** and **Emission** values.
8. On the **Mirrors** tab there will be options to select the Type of the mirror, Polarization, Excitation range and Emission range for each of the mirror slots.
9. Click **Save** to commit the configuration options to the reader, or cancel to reverse the changes.

NOTE: These configuration changes are only to be used when the filters or mirrors have physically changed in the instrument.

Configuring a PyroWave[®] XM Reader

To change the configured filters and/or mirrors on a PyroWave[®] XM Reader, follow these steps:

1. Click **Discover**. Select **PyroWave XM** in the list of readers. Press **OK**.
2. Select the newly discovered reader. Click **Edit**. The Reader Setup window is displayed. A user with the Manage Readers permission can configure a new reader on this window.
3. Click the **PyroWave XM** tab.
4. Press the **Configure** button.
5. In the **Configure Reader** window, there will be configuration options for a mirror block with two mirror sets.
6. Enter the information according to the information provided with the new mirror block being added.
7. Click **Save** to commit the configuration options to the reader, or cancel to reverse the changes.

NOTE: These configuration changes are only to be used when the mirror block has physically changed in the instrument.

Configuring a Sunrise[™] Reader

To change the temperature configured settings on a Sunrise[™] Reader, follow these steps:

1. Click **Discover**. Select **Sunrise** in the list of readers. Press **OK**.
2. Select the newly discovered reader. Click **Edit**. The Reader Setup window is displayed. A user with the Manage Readers permission can configure a new reader on this window.
3. Click the **Sunrise** tab.
4. Enter the appropriate values for the offsets and thresholds as determined in the device qualification procedure.

5. Click **Save** to commit the configuration options to the reader, or cancel to reverse the changes.

Configuring a Nebula® Multimode Reader

To change the configured sensitivity setting on a Lonza® Nebula® Multimode reader, follow these steps:

1. Click **Discover**. Select **Nebula** in the list of readers. Press **OK**.
2. Select the newly discovered reader. Click **Edit**. The Reader Setup window is displayed. A user with the Manage Readers permission can configure a new reader on this window.
3. Click the **Nebula** tab.
4. Change the **Sensitivity** value based on the value determined in the **Sensitivity Test**.
5. Click **Save** to commit the configuration options to the reader, or cancel to reverse the changes.

Configuring a Virtual Reader

To change the data source for a Virtual Reader, follow these steps:

1. Click **Discover**. Select **VirtualReader** in the list of readers, and select an unused COM port. Press **OK**.
2. Enter an identifier for the Virtual Reader to take the place of a serial number.
3. Select the newly discovered reader. Click **Edit**. The Reader Setup window is displayed. A user with the Manage Users permission can configure a new reader on this window.
4. Click the **VirtualReader** tab.
5. Change the **Raw Data Generation Source** to **Raw Data from Existing Tests**.
6. Click **Select a Previously Run Test to Simulate**.
7. Select a test record corresponding to the desired data source and press **OK**.
8. Click **Save** to commit the configuration options to the reader, or cancel to revert the changes.

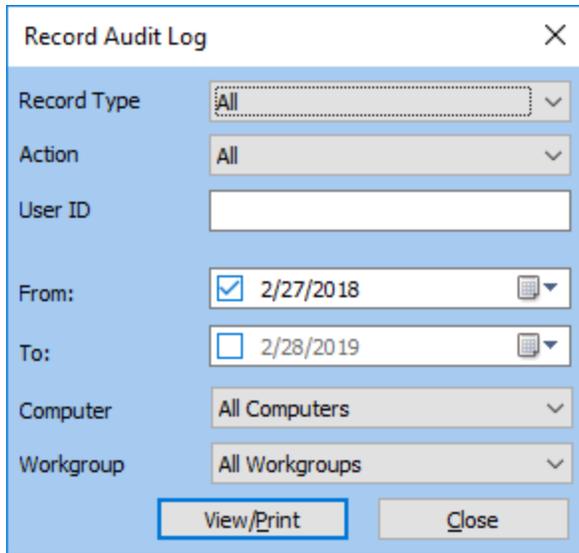
NOTE: The intended use for this reader is solely for computer system validation.

NOTE: This feature is disabled by default; please refer to the **Global Options** for how to enable it.

Record Audit Log Report

All actions that create, modify, or delete global configurations, readers, tests, or users are recorded in the WinKQCL® Software record audit log.

To view the log (or portions of it) in report form, click **Tools > Record Audit Log** on the main toolbar.



NOTE: The **View Audit Reports** permission is required to access the record audit log.

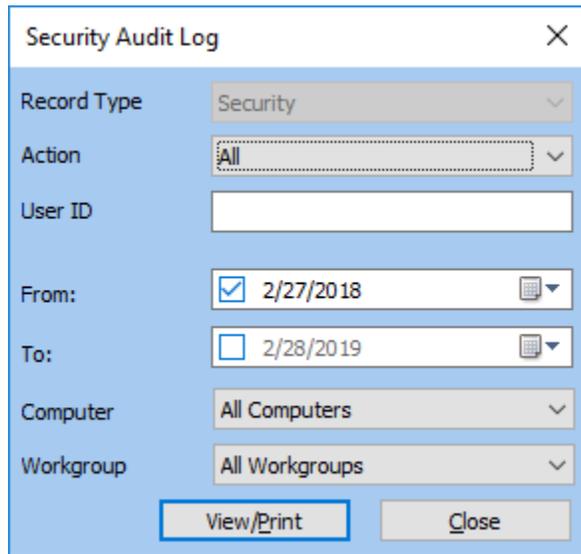
The record audit log window provides controls to define the contents of the record audit log report displayed when **View/Print** is clicked. When the default values are used, the report contains all entries from the record audit log for the last year.

- **Record Type:** Select a record type to display entries related to that record type only in the report. Select **All** to include the log entries for all record types in the report.
- **Action:** Select an action type to display entries related to that action type only in the report. Select **All** to include the log entries for all action types in the report.
- **User ID:** Enter a user ID to display only entries related to that user ID in the report. When left blank the log entries for all user IDs are displayed in the report.
- **From and To:** For a description of how to use these controls, see "Search by Date Range" on page 160. If no date range is specified, the log entries for all dates are displayed in the report.
- **Computer:** Select a computer name to display entries related to that computer only in the report. Select **All Computers** to include the log entries for all computers in the report.
- **Workgroup:** Select a workgroup to display entries related to that workgroup only in the report. Select **All Workgroups** to include the log entries for all workgroups the user has access to in the report.
- **View/Print:** Click to display the record audit log report. The contents are determined by the criteria specified in the rest of the record audit log window.
- **Close:** Click to close the window.

Security Audit Log Report

The security audit log contains entries for all notable security events, such as failed login attempts and lockouts. Supervisors can use the security audit log report to monitor access to the WinkQCL[®] Software. Security audit log entries cannot be modified or deleted.

To view the log (or portions of it) in report form, click **Tools > Security Audit Log** on the main toolbar.



NOTE: The **View Audit Reports** permission is required to access the security audit log.

The security audit log window provides controls to define the contents of the security audit log report that is displayed when **View/Print** is clicked. When the default values are used, the report contains all entries from the security audit log for the last year.

- **Record Type:** This cannot be changed. The search is limited to records that relate to security issues.
- **Action:** Select an action type to display entries related to that action type only in the report. Select **All** to include the log entries for all action types in the report.
- **User ID:** Enter a user ID to display only entries related to that user ID in the report. When left blank the log entries for all user IDs are displayed in the report.
- **From and To:** For a description of how to use these controls, see "Search by Date Range" on page 160. If no date range is specified, the log entries for all dates are displayed in the report.
- **Computer:** Select a computer name to display entries related to that computer only in the report. Select **All Computers** to include the log entries for all computers in the report.
- **Workgroup:** Select a workgroup to display entries related to that workgroup only in the report. Select **All Workgroups** to include the log entries for all workgroups the user has access to in the report.
- **View/Print:** Click to display the record audit log report. The contents are determined by the criteria specified in the rest of the record audit log window.
- **Close:** Click to close the window.

Database Maintenance

To maintain the WinKQCL® Software database, click **Tools > Database**.

Backup the Database

The backup feature can be used to copy the entire WinKQCL[®] Software database to another location or to removable drive media. The WinKQCL[®] Software database can become corrupt or the system on which the WinKQCL[®] Software is installed can suffer a system failure. In these cases, the backup copy of the database can be used to recover stored information up to the date and time the backup was created. The information technology administrator or network administrator must ensure the security of the WinKQCL[®] Software database backup files.

When restoring a backup database, any records in the active database are overwritten. Backups cannot be restored to an active installation of the WinKQCL[®] Software that contains existing completed tests. It is recommended to utilize the Merge function in the database utility to restore a backup.

To import records from a backup into an active installation, use the Merge feature (see "Merge Databases" on page 130).

The backup files must be copied to a location that the SQL Server[®] service logon account has permission to read. The default logon account is the "Network Service" account. This account has limited permissions; however, "Backup" folder is always accessible under the SQL Server[®] Program Files folder.

NOTE: This location is dependent on the SQL Server[®] installation. For the WinKQCL[®] Software install of SQL Server[®] 2019 Express the default location is C:\Program Files\Microsoft SQL Server\MSSQL15.WINKQCL\MSSQL\Backup.

NOTE: The **Manage Databases** permission is required to back up and restore the database.

Back Up from a WinKQCL[®] Software Server or Standalone Workstation

To back up from a WinKQCL[®] Software server or standalone workstation, follow these steps:

1. On the main toolbar, click **Tools > Database > Backup Database**. The backup location selection window is displayed.
2. Select the location where the backup is stored, and then click **OK**.

After the backup is complete, the message "Backup Completed Successfully" is displayed.

Back Up from a WinKQCL[®] Software Client Workstation

To back up from a WinKQCL[®] Software client workstation, click **Tools > Database > Backup Database** on the main toolbar.

The Location\Filename field on the Schedule Database Maintenance window must be configured at the WinKQCL[®] Software server. If it is not, an error message is displayed that the backup location has not been configured (error DB0004). This parameter must be properly configured at the server before executing a database backup from a WinKQCL[®] Software client.

If the Location\Filename field on the Schedule Database Maintenance window is properly configured, the Backup Progress window is displayed. The backup file is saved to the location defined in the Schedule Database Maintenance window. After the backup is completed, the

Backup window will be displayed, with the message "Backup Completed Successfully".

NOTE: The database may also be backed up from the WinKQCL® Database Tool if necessary. This will create a backup in the server's default backup directory.

Merge Databases

The WinKQCL® Software can upgrade, merge, and restore individual databases created on the WinKQCL® Software version 4.0.2 and newer systems into a single database. During this process, first each database is upgraded to the new format. Then the upgraded databases are merged into the single "winkqcldb" database on the server.

NOTE: Backups from Microsoft® SQL Server® 2000 cannot be merged directly into Microsoft® SQL Server® 2012 or newer. Furthermore, backups from prior to the WinKQCL® Software version 4.0.2 will require additional steps for migration as well. Please refer to the supplement *Migrating Legacy Database Procedure* and contact Scientific Support for assistance in this procedure.

Merge Preparation

Before beginning the merge process, back up all databases on each existing WinKQCL® Software system targeted to be upgraded. Copy the backup (*.sbk or *.bak) files from each of these older systems to portable media or a network accessible location.

The merge function processes faster if the backup (*.sbk or *.bak) file for each database is copied onto the server's hard drive. The backup files must be copied to a location that the SQL Server® service logon account has permission to read.

The default logon account is Network Service. This account has limited permissions; however, the Backup folder is accessible under the SQL Server® Program Files folder. This location is dependent on the SQL Server® installation, for SQL Server® 2019 Express the default location is:

C:\Program Files\Microsoft SQL Server\MSSQL15.WINKQCL\MSSQL\Backup.

Steps to Merge Databases

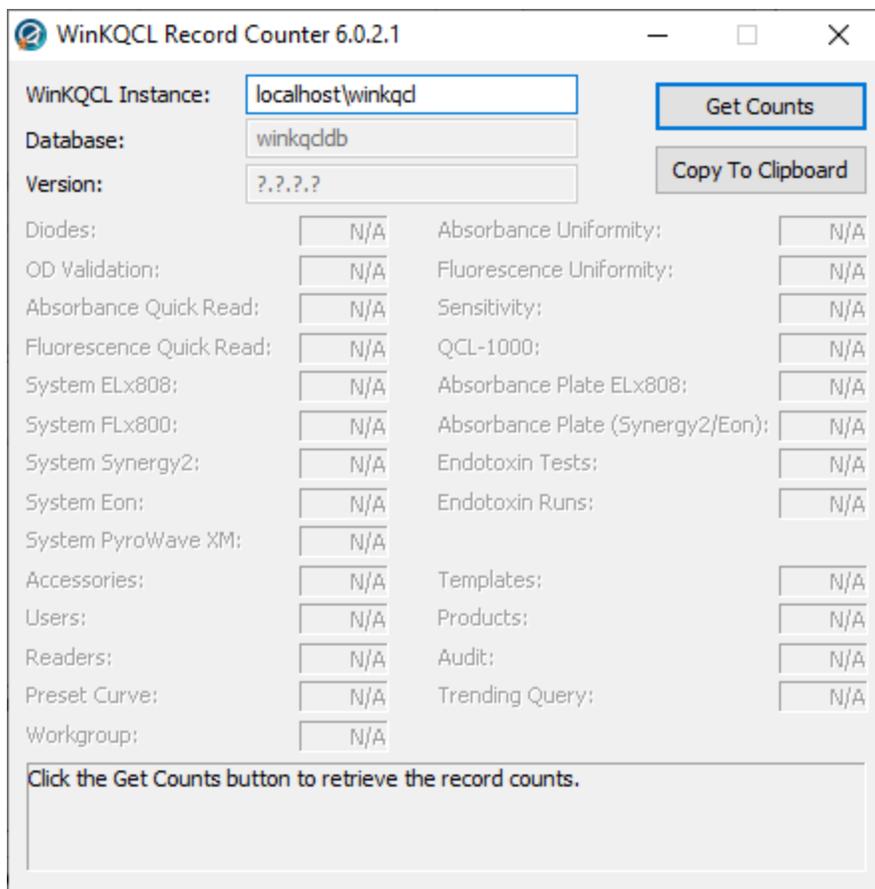
This procedure is used to migrating one or more WinKQCL® Software database over to another server. If more than one database will be migrated, this procedure will also allow for merging of databases. Backup all databases before starting this procedure and copy the backup files over to the server.

Verifying Record Counts

The WinKQCL® Software Record Counter utility can be used to track the record counts before and after the merge procedure to ensure data integrity. Follow these steps to extract the necessary information:

Running the tool on the historic server

Run the **WinKQCL Record Counter.exe** from the WinKQCL® Software installation disk from a system that has a network connection to the historic server (v2 or newer).



- 1) Enter the server name with instance name in the **WinKQCL Instance** field.
- 2) Click **Get Counts**
- 3) Select winkqddb or the database which will be merged, and click **OK**.
- 4) The database version and counts of the various records will appear in the utility.
- 5) Click **Copy to Clipboard** to send a plain text representation of the tool to the clipboard.

Following the merge procedure run this utility with the same steps against the new server name to obtain the new counts.

NOTE: Duplicate records are not merged. The first occurrence of the record is treated as truth. For example, if the same user record exists in more than one of the databases being merged, all information associated with that user ID in the first (top) database, is merged into the new database. None of the information stored with the same user ID contained in any of the other (lower) databases is added and these records are flagged in a log file on the system running the utility. Please contact Scientific Support for a procedure on identifying duplicate records.

Accessing the Merge Tool

Follow these steps to open the Merge module of the WinKQCL® Software Database Tool.

1. Close all programs and insert the WinKQCL® 6 Software installation disc into the drive. If a zip file is provided, extract or decompress the zip file before proceeding.
2. When the installation disc is detected, a window is displayed listing the contents on the disc. If the contents window is not displayed, double click the **WinKQCL Menu.exe** file. If this file cannot be launched, follow the manual steps below.
3. Under the heading **Database management and drivers**, click the link **Manage databases** to launch the WinKQCL® Software Database Tool. If the tool fails to launch, open it manually. Go to the **Deployment Tools** folder and double-click the file **WinKQCLDatabaseTool.exe**.
4. Enter credentials in the WinKQCL® Software Database Tool for a SQL Server® user with sysadmin permission, and click **Connect**.
5. Click **Merge**.

Merging Databases

1. Click the **Add Candidate** button, select one of the database backup files to merge into the WinKQCL® 6 Software database and click **Open**. The database will be restored and added to the **Merge Candidates** list. If this is being run on a client, the user will be prompted for a file location that is relative to the server instead of browsing for a file.
2. When the merge candidate is loaded, click OK on the message box.
3. Repeat steps 1 and 2 for each database backup file that needs to be merged into the WinKQCL® 6 Software database.
4. To remove an undesired candidate, select it in the list and click the **Remove Candidate** button.
5. Before the databases are merged, the list can be reordered. Click a database and click the **Up** or **Down** buttons. When the databases are merged, records are added to the active WinKQCL® Software database in the order that they are listed in the Merge Candidates list.

NOTE: The utility merges and restores records to the active version 6 database. This process uses a significant amount of the server memory, CPU, and hard drive bandwidth. Do not work with any other applications until the process is complete.

6. Merging in global settings is optional; to inherit settings from a merge candidate, uncheck **Preserve Global Settings**.
7. When all databases are added to the **Merge Candidate** list, for each database, select it and click the **Merge** button.
8. When the merge process is complete, a message will be displayed indicating the process was successful. Click **OK** on this dialog and click the **Close** button on the Merge Tool.

Archive Records

Use the Archive feature to move certain test records from the WinKQCL® Software database into a secondary, read-only, archive database. Moving test records to a secondary database, reduces the working size of the WinKQCL® Software database. When tests are archived, an entry is added to the Record Audit Log to record the event (see "Record Audit Log Report" on page 126).

Archive Options
✕

Date From:

Date To:

Tests to be Exported

<input checked="" type="checkbox"/> Endotoxin Tests	<input type="text" value="Run: 0 Test: 0"/>
<input checked="" type="checkbox"/> Diodes	<input type="text" value="0"/>
<input checked="" type="checkbox"/> OD Validation	<input type="text" value="0"/>
<input checked="" type="checkbox"/> System FLx800	<input type="text" value="0"/>
<input checked="" type="checkbox"/> QCL-1000	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Quick Read	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Sensitivity	<input type="text" value="0"/>
<input checked="" type="checkbox"/> System ELx808	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Uniformity	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Absorbance Plate ELx808	<input type="text" value="0"/>
<input checked="" type="checkbox"/> System Synergy	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Absorbance Plate	<input type="text" value="0"/>
<input checked="" type="checkbox"/> System Eon	<input type="text" value="0"/>
<input checked="" type="checkbox"/> System PyroWave XM	<input type="text" value="0"/>

Archive Records to:

New Archive Database:

Existing Archive Database:

Test

Action

Step

NOTE: The **Manage Archive Databases** permission is required to access the Archive feature.

To display the Archive Options window, click **Tools > Database > Archive Records** on the main toolbar. Use this interface to configure and initiate the database archive process.

Controls

The Archive Options window has the following controls:

- **Date From and Date To:** Specify a range of dates for which tests are archived (moved). All tests that were completed within the date range specified are archived.
- **Tests to be Exported:** Select a checkbox to include that test type in the archive. The number of tests within the specified date range is displayed next to each test type.

- **Archive Records to:** Click **New Archive Database** to archive to a new database. Click **Existing Archive Database** to archive to an existing archive database.
- **OK:** Click to begin the archival process using the criteria and configuration defined in the Archive Options window.
- **Cancel:** Click to close the window. No archive is created.
- **Display areas:** Status messages are displayed as the archival process progresses.

Archive Database Manager

To display the Archive Database Manager window, click **Tools > Database > Archive Database** on the main toolbar.

NOTE: The **Manage Archive Databases** permission is required to access the Archive Database Manager.

All currently active archive databases are listed in the table at the top of the window.

Status information is shown under the table as archive operations are performed.

The buttons on the right side of the window have the following functions:

- **Backup:** Click to create an SQL backup file (*.bak or *.sbk file) of the selected Archive Database file.
- **Restore:** Click to display the Restore Location window. Browse or enter the path to the archive database backup file. The file must follow the following format: WinKQCLArchive*.bak or WinKQCLArchive*.sbk where * is any combination of characters.
- **Delete:** Click to remove an Archive Database from the computer permanently.
- **Close:** Click to close the Archive Database Manager.

View Archive

Archived databases and their accompanying archived tests can be opened and viewed. Use the **WinKQCL - View Archive** shortcut to view archived tests. Archived tests are viewed only and cannot be signed or edited. While viewing archive records, users are not restricted by workgroup permissions. Archive databases must match the same version as the WinKQCL® Software. For information about how to upgrade an archive database, see "Archive Database Manager" on page 134.

To view an archive database using the WinKQCL® Software in archive mode, follow these steps:

1. Close the WinKQCL® Software.
2. Click **Start**, and then click **All Programs > Lonza > WinKQCL > WinKQCL – View Archive**.

If only a single archive database exists, the WinKQCL® Software immediately opens it. When multiple archive databases exist, select the appropriate archive database.

In archive mode, the toolbar of the application provides only items related to viewing tests, trending, getting help, and the calculator.



Schedule Database Maintenance

To schedule maintenance of the WinKQCL® Software database, click **Tools > Database > Schedule Database Maintenance** on the main toolbar.

NOTE: The **Manage Databases** permission is required to schedule database maintenance. Scheduled database maintenance is available only with a licensed edition of SQL Server® (such as Workgroup, Standard, or Enterprise Edition). The free Express Edition distributed with the WinKQCL® Software does not support this feature.

Job Types

Backup

Primary and secondary backup jobs perform full backups of the WinKQCL® Software database. Two backup jobs are provided so that a "rolling" backup can be accomplished. Schedule the backups for alternating days or times of the day and configure the WinKQCL® Software to overwrite the previous backup performed by each job. Setting the WinKQCL® Software to overwrite the backups will ensure that the hard drive does not fill up with backup files.

The location and filename for automated backups can be entered only from the server.

Manually enter the backup location and filename, or click **Browse** to select a storage location and enter a filename. If manually entering a network location, specify path along with the backup file name.

Example path: "\\computername\folder1\folder2\primarybackupfile.bak".

Click **Overwrite** to use the input filename and replace the previous backup. Click **Append date/time to filename** to generate a new filename for every backup, and preserve all previous backups.

Database Check

The Database Check job scans the WinKQCL® Software database for errors and consistency. If any errors are found, they are logged to the Record Audit Log (see "Record Audit Log Report" on page 126).

Defragment Indexes

The Defragment Indexes job reorganizes the data on the physical disk for faster access. The results of the defragmentation job are stored in the Record Audit Trail (see "Record Audit Log Report" on page 126).

Schedule Definition

- **One Time:** Select to schedule a job on the selected Start Date at the selected Start Time.

- **Recurring:** Select to schedule a recurring job to begin Daily, Weekly, or Monthly at the Start Date and Start Time.

Button Controls

- **Browse:** Click to select the folder and name for the database backup. This button is active only when the WinKQCL® Software is run on a standalone or server computer.
- **Save:** Click to save the schedule or schedules for the selected job.
- **Run Now:** Click to begin the selected job immediately.
- **Clear Warning:** If a job recorded an error on the previous run, a warning is displayed when the WinKQCL® Software is started up. Click to remove the warning.
- **Close:** Click to close the window.

NOTE: Backups can be scheduled from any computer on the WinKQCL® Software network, but the backup location can be defined only on the server.

Compact Database

The database can be compacted to reclaim disk space that the database no longer needs. This space returns to the pool of free disk space. After an archive operation, compact the database to reduce the size of the database significantly.

NOTE: The **Manage Databases** permission is required to compact the database.

To compact the database, click **Tools > Database > Compact Database**.

When the confirmation prompt appears, click **Yes** to compact the database. After the process is complete, a report window provides details about the size change.

Global Options

The Global Options window allows a supervisor to configure several settings that apply to all workstations and users in the WinKQCL® Software network.

To configure global settings, click **Tools > Global Options** on the main toolbar.

Global Options

These settings apply to all workstations in the WinKQCL network.

Reports

Report header

Suppress report watermark

Open File Location After Report Export

Power and Activity

Require login only after inactivity hh:mm

Suppress Power Warning

Active Directory

Always require password for Active Directory Accounts

Endotoxin Tests List

Highlight assays with out-of-specification standard curve or alerts

Readers

Enable Virtual Reader for replaying test data

PowerCurve

Allow PowerCurve to fall back to a lower regression model

User ID

Allow Changing User Id

OK Cancel

The buttons in the Global Options window have the following functions:

- **OK:** Click to close the window and save any changes.
- **Cancel:** Click to close the window and not save changes.

Report Header: The text entered into this field can be one line of text, up to 40 characters long. This information is printed at the top of each report page. Normally the company name is entered into this field, so the workgroup, which is printed to the right of this field, reads appropriately: company name - workgroup name. The default value is "YOUR REPORT HEADER GOES HERE"; simply change this text to the desired header. The report header is printed on all reports on all WinKQCL® Software clients.

Suppress Report Watermark: Select this checkbox to exclude the "FOR REVIEW ONLY" watermark and "e-signature not applied" text from footers on reports for tests that can be electronically signed. When this checkbox is not selected, the watermark and "e-signature not applied" text is printed on the report.

Open File Location After Report Export: Select this checkbox to open an explorer window to the report export destination.

Inactivity Timeout - Require login only after inactivity: When this checkbox is cleared, a user ID and password are always required for normal authentication actions. (For example, login is necessary to create a template or edit a product.) Select this checkbox and user login is not required as long as authenticated actions are performed within the specified time-period. The timeout is reset each time an authenticated action is performed.

Suppress Power Warning: Selecting this option will disable the warning that may appear if power settings on the system are configured to sleep after a given time-period. In some enterprise settings the detection methods for the warning yields a false positive and users may opt to disable to warning at a system wide level.

Active Directory - Always require password for Active Directory Accounts: When this checkbox is selected, the user must always enter his/her Windows® password. When this checkbox is not selected, the supervisor elects to rely on Windows® to Authenticate. The WinKQCL® Software will assume that if the user is logged into Windows® and has rights to the WinKQCL® Software then he/she does not need to enter credentials to log in to the software. Passwords will always be required for the following situations:

- When canceling a test that has proceeded past the prompt to add reagent (for tests that require reagent).
- When canceling a test that has proceeded past the prompt to insert the plate (for tests that require a microplate but do not require reagent).
- When canceling a test that has proceeded past the prompt to select the reader (for tests that do not require a microplate).
- When signing a test as analyst or reviewer.
- When unlocking electronic signatures from a test.

Highlight assays with out-of-specification standard curve or alerts: Select this checkbox to display Endotoxin tests in red text in the **Endotoxin Test List** when one or more of the following criteria are met:

- All blank replicates are masked.
- Blank reacted before the lowest standard.
- Standards for the curve reacted out-of-order.
- One or more of the standards or blanks has an OD or RFU reading error.
- The standard curve has a slope that is out of range.
- The standard curve has a Y-Intercept that is out of range.
- The standard curve has an R-Value (i.e., correlation coefficient) that is out of range.
- An unmasked %CV for a standard is undefined or exceeds the minimum acceptable %CV

Enable Virtual Reader for replaying test data: Select this checkbox to enable the Virtual Reader as a data source for running tests. This feature is only intended for reusing data for use with computer system validation.

Allow PowerCurve™ to fallback to a lower regression model: Selecting this checkbox modifies the PowerCurve™ algorithm. When unchecked, PowerCurve™ will fit a polynomial to the data and if the polynomial is non-monotonic (there are multiple endotoxin concentrations for a given reaction time or net delta RFU) the software will reject it and revert to a linear model. When checked, PowerCurve™ will reduce the order of the polynomial when classified as non-monotonic until it finds a monotonic curve. This increases the likelihood of utilizing a polynomial model and the standard curves will be closer to the expected values than in a linear model.

Allow Changing User Id: When checked the User Id may be modified for users while editing users.

Manage Workgroups

To display the Workgroup Manager, click **Tools > Manage Workgroups** on the main toolbar. Data can be segregated into different workgroups in the database. For example, a Process Development group can group their data apart from data generated by a Quality Control group or two Quality Control groups at different company locations can group their data separately. A workgroup name typically incorporates the group name and site location. The company name can be configured in a different field, so it does not need to be incorporated into the workgroup name. For example: "Quality Control - New York". The Workgroup Manager has the following controls:

- **List:** Displays the Name and Comment for the Workgroups in the database.
- **View:** Displays a window with the Name and Comment of the selected Workgroup.
- **New:** Displays a window prompting for a Name and Comment for a new Workgroup. Click Save to add the new Workgroup, and Cancel to cancel the operation.
- **Edit:** Displays a window with the Name and Comment of the selected Workgroup. The user may modify either value then click Save to save the change to the Workgroup, and Cancel to cancel the operation. When a workgroup Name is changed this reflects across the entire system for records associated with that workgroup.
- **Settings:** Provides an interface to override global settings for this specific workgroup.
- **Refresh:** Refreshes the list of Names and Comments with the latest records from the database.
- **Print:** Displays a list of all of the workgroups in a printable format.

User Maintenance

To display the User List window or the User Details window, click **Tools > User Maintenance** on the main toolbar. The window that is displayed depends on the current user.

User List window: Displayed when the current user has the **Manage Users** permission (see "User List" on page 139).

User window: Displayed when the current user does not have the **Manage Users** permission (see "User Details" on page 142).

User List

To display the User List window, a user with the **Manage Users** permission clicks **Tools > User Maintenance** on the main toolbar (see "User Roles" on page 144).

Only a user with the **Manage Users** permission can assign the following:

- User ID
- Name
- Signature text
- Signature image
- Domain Name
- Permissions
- Status
- Initial passwords
- Password history
- Password expiration
- Primary Workgroup

Only a user with the **Manage Workgroup** permission can assign the following:

- Accessible Workgroups

The list is initially sorted by user ID. To sort the list differently, click a column header (see "Sortable Lists" on page 161).

User List Window

On the User List window, users with the **Manage Users** permission can add and modify the WinKQCL[®] Software users.

The following information is displayed for each user:

- **Status:** The current system status of the user. The following status codes are used:
 - **N (New user):** Newly established accounts are automatically assigned this status. New status indicates that they are approved to use the system, but have not yet changed their assigned password. To use the WinKQCL[®] Software, the user must change their password.
 - **A (Active user):** Active users have access to the appropriate functions of the WinKQCL[®] Software.
 - **I (Inactive user):** Inactive users cannot use the system until a user with the **Manage Users** permission reactivates the account. Users can be inactive because their passwords have expired. A user with the **Manage Users** permission can inactivate a user account.
 - **L (Locked):** A Locked status indicates five consecutive unsuccessful logon attempts. Users with Locked accounts cannot use the system and must contact a user with the **Manage Users** permission to unlock the account.

- **User ID:** The abbreviated user ID.
- **User Name:** The formal name of the user.
- **Role:** The particular role of the user in the system (see "User Roles" on page 144).
- **Primary Workgroup:** The main workgroup of the user.

User List (Records: 22) ×

Status	User ID	User Name	Role	Primary Workgroup
A	SUPERVISOR	Installation Default	Supervisor/Analyst	Test
A	CAREN	Carsen McShoe	Reviewer/Analyst	Demo
A	CARSEN MCSHOE	Carsen McShoe	Analyst	Demo
A	CARSON MCSHOE	Carson McShoe	Analyst	Demo
A	CHERYL MCPHEMUS	Cheryl McPhemus	Analyst	Demo
A	CLANE	Clark Lane	Reviewer/Analyst	Demo
A	CMCP	Cheryl McPhemus	Reviewer/Analyst	Demo
A	CMCS	Carson McShoe	Reviewer/Analyst	Demo
A	IBASS	Ida Boss	Supervisor	Demo
A	IBOSS	Ida Boss	Supervisor	Demo
*L	JSMITH	Joseph Smith	Reviewer/Analyst	Demo
A	KARSEN MCSHOE	Karsen McShoe	Analyst	Demo
A	KARSON	Karson McShoe	Reviewer/Analyst	Demo
A	KARSON MCSHOE	Karson McShoe	Analyst	Demo
A	KMCS	Karsen McShoe	Reviewer/Analyst	Demo
A	LKENT	Lois Kent	Reviewer/Analyst	Demo
A	MPARKER	Mary Parker	Reviewer/Analyst	Demo

New

Copy

Edit

View Only

Clear Alert

Print

AD Group Import

Refresh

Hide Inactive Users

Close

The User List window controls have the following functions:

- **New:** Click to create a new user in the User Details window (see "User Details" on page 142).
- **Copy:** Click to create a copy of a user in the User Details window (see "User Details" on page 142).
- **Edit:** Click to edit the details of a user in the User Details window (see "User Details" on page 142).
- **View Only:** Click to display details related to the current selection in the list (read-only).
- **Clear Alert:** Click to clear the alert on a locked user.
- **Print:** Click to display the list in a printable report form (see "Common Report Controls" on page 157).
- **AD Group Import:** Click to import a group from Active Directory (see "Active Directory Group Import" on page 145).
- **Refresh:** Click to repopulate the list with the most current information from the WinKQCL[®] Software database.
- **Hide Inactive Users:**
 - **Checked:** Displays the list without users that have a status of inactive (I).
 - **Unchecked:** Displays all users.
- **Close:** Click to close the window.

User Details

To display the User Details window, click **New**, **Copy**, **Edit**, or **View Only** on the User List window (see "User List" on page 140). The User Details window has many purposes. Use it to create, modify, and view the WinKQCL[®] Software users. The window controls and their usage vary depending on the role of the user who accesses the window (see "User Roles" on page 144 and "User Permissions" on page 1454).

Users with the **Manage Users** permission can create and edit users.

Users without the **Manage Users** permission can view their own user details, but only change their own password.

User Controls and Functionality

The User window is broken into five tabs and has controls with the following functions.

User Details: The User Details tab contains the following information:

- **User ID:** The short ID that is associated with the user. When a new user is created, up to 20 characters can be entered into this field. The user uses this ID to log in to the WinKQCL[®] Software.
- **Name:** The formal name of the user. When a new user is created, up to 64 characters can be entered into this field.
- **Signature Text:** The text that is associated with the user signature. The text signature is entered when a user is created. When the user electronically signs an assay record, the Signature Text is displayed and denoted as "et-sig." If a scanned signature is present when the user signs the report, the text signature is not displayed in a signed report. Up to 64 characters can be entered in this field.
- **Load Signature:** Click to load a scanned signature, which is any image file. After a scanned signature is loaded, it can be changed in the event of a name change or a new policy. If a scanned signature is present when an assay is signed, it is used instead of the text

signature. When the user electronically signs an assay record, the scanned signature is displayed and denoted by "eb-sig." Only users with the **Manage Users** permission can upload scanned signatures. To prevent distortion, the signature image file (PNG, BMP, or JPG format), should be a ratio of 7.11 to 1, no smaller than 512 pixels long and 72 pixels high. A larger but similar ratio image can be used, and the WinKQCL® Software will scale the image to fit on the report.

- **Clear:** Click to clear the scanned signature display.
- **Uses Active Directory Authentication:** If this is checked, the User ID must be the same as the name the user uses to log onto his/her domain. The WinKQCL® Software will now defer password management to the domain controller for this user.
- **Domain Name:** Enter the name of the domain associated with the user account when Uses Active Directory Authentication is checked.
- **Directory Server:** Enter the name of the directory server directly to authenticate against an explicit server. By default, the values in this field will mirror those of the domain name.
- **Port:** Specify the port with which to authenticate against the directory server. By default, it is 389 that is the standard communication port for these purposes.
- **Use SSL:** Check this if the directory server requires authenticating on the Secure Socket Layer. The standard port while authenticating over SSL is 636.
- **Check Name:** Click to validate the user ID exists for the domain listed.

Permissions: For more information about permissions see "User Roles" on page 144 and "User Permissions" on page 145.

- **Analyst:** Selected indicates that the user has the analyst role.
- **Reviewer:** Selected indicates that the user has the reviewer role.
- **Supervisor:** Selected indicates that the user has the supervisor role.
- **Apply Defaults:** Click to grant the user the extra permissions a user with the selected roles would have in an earlier version of the software.
- **Additional Permissions:** Select an additional permission to grant the user that permission.

Password: (This tab is disabled if Uses Active Directory Authentication is checked.)

- **Password Expires Every:** When selected, enter in the Days field the number of days until the password expires. When this checkbox is cleared, the password does not expire.
- **Days:** The number of days that a password can be used before it must be changed. Applicable only when the Password Expires Every checkbox is selected.
- **Passwords Remembered:** This number defines how many passwords the user must use before they can re-use an old password. The software prevents a user from reusing their last 3 - 5 passwords.
- **Last Updated:** Displays the date of the last password update.
- **New Password:** Enter a new password. The password must be at least 6 characters in length and must contain both letters and numbers.
- **Confirmation:** Enter the new password, to make sure that they are the same.

- **Change Password:** Click to change the password. When successful, the user password is changed to the value that was entered in the New Password field.

Status:

- **New:** The user is New. When a user account is set to the New status, new password must be assigned. The user uses this password at the next login. After the initial login, the user must change their password.
- **Active:** The user is Active. (If Uses Active Directory Authentication becomes checked, the user is automatically moved to this state.)
- **Security Locked:** When this checkbox is selected, it indicates that the user is locked out of the system for security reasons. An account with status “Security Locked” cannot be used until the status is returned to “Active” or “New”.
- **Inactive:** The user is Inactive. Inactive accounts cannot log in to the WinKQCL[®] Software. When an account is set to Inactive, a user with the **Manage Users** permission must change the status to New and assign a new password.
- **Validated:** Selecting indicates the user is validated.

Workgroup:

- **Primary Workgroup:** The selected workgroup is the primary one associated with the user. All templates created by this user will be associated with this workgroup and all other actions will default to this workgroup. The Name and Comment displayed are associated with the selected workgroup.
- **Accessible Workgroups:** In addition to the primary workgroup, the user may be associated with additional ones that functions the same as the primary workgroup, except the user will not be able to create templates on these workgroups. The user will not be able to access information associated with any workgroup not selected.

Save: Click to save the currently configured information and close the window.

Print: Click to print the user information.

Cancel: Click to close the window and save no information.

User Roles

The following list describes the roles of the WinKQCL[®] Software users. The role of a user determines what actions the user can perform with the software.

Analyst:

- Set up and run tests
- Maintain assay templates, accessories, and products

Reviewer:

- Review assays that were signed by an analyst

Supervisor:

- Configure the software

User [All users by default]:

- View assays and associated items

User Permissions

The WinKQCL® Software offers detailed permission control and lets the user be configured with additional rights beyond the basic analyst, reviewer and supervisor roles. The following permissions can be selected:

- **Manage Products:** User may create, edit, and delete Products.
- **Manage Accessories:** User may create, edit, and delete Accessories.
- **Manage Readers:** User may discover, create, edit, and delete Readers.
- **Manage Template Reader Parameters:** User may modify reader parameters on his/her own Templates. (The user must be an analyst to have this permission.)
- **Edit own Endotoxin tests:** User may edit the assay template, mask points, and change the regression type for tests that he/she ran.
- **Edit other users' Endotoxin tests:** User may edit the assay template, mask points, and change the regression type for tests that any user ran.
- **Sign other analysts' Endotoxin tests:** User may sign as an analyst for endotoxin tests performed by other users. (The user must be an analyst to have this permission.)
- **Export to LIMS:** User may export test data to an external system.
- **Delete any Template:** User may delete any user's Templates.
- **Delete own Template:** User may delete their own Templates.
- **Unlock E-Signature:** User may unlock e-signatures.
- **Manage Users:** User will be able to create, edit, and view other users within its workgroup in User Maintenance.
- **Manage Workgroups:** User will have access to Manage Workgroups under tools. The user will also be able to create, edit, and view other users in any workgroup.
- **View Audit Reports:** User will be able to view the Record and Security Audit Log Reports under Tools.
- **Manage Archive Databases:** User will be able to perform the following Database actions: Archive Records and Archive Database Manager.
- **Manage Databases:** User will be able to perform the following Database actions: Merge, Restore, Backup, Schedule Maintenance, and Compact.
- **Use Endotoxin Report Options:** User will be able to change the layout of an Endotoxin Report.

Active Directory Group Import

To display the Active Directory Group Import window, click **Tools > User Maintenance** on the main toolbar, then click **AD Group Import**. This feature can be used to set up an entire list of the WinKQCL® Software users by importing the users' information from the active directory server. Perform this action with the help of the company's IT department. An active directory group should be configured and all necessary domain users added to that group before using this import feature.

Active Directory Group Import

Group Details | Permissions | Workgroup

Mouse over an option to learn more.

Group Name:

Domain Name:

Directory Server:

Port: 389 Use SSL

Query with different credentials

Name

Password

Associate Domain Users to Existing

Validated Users

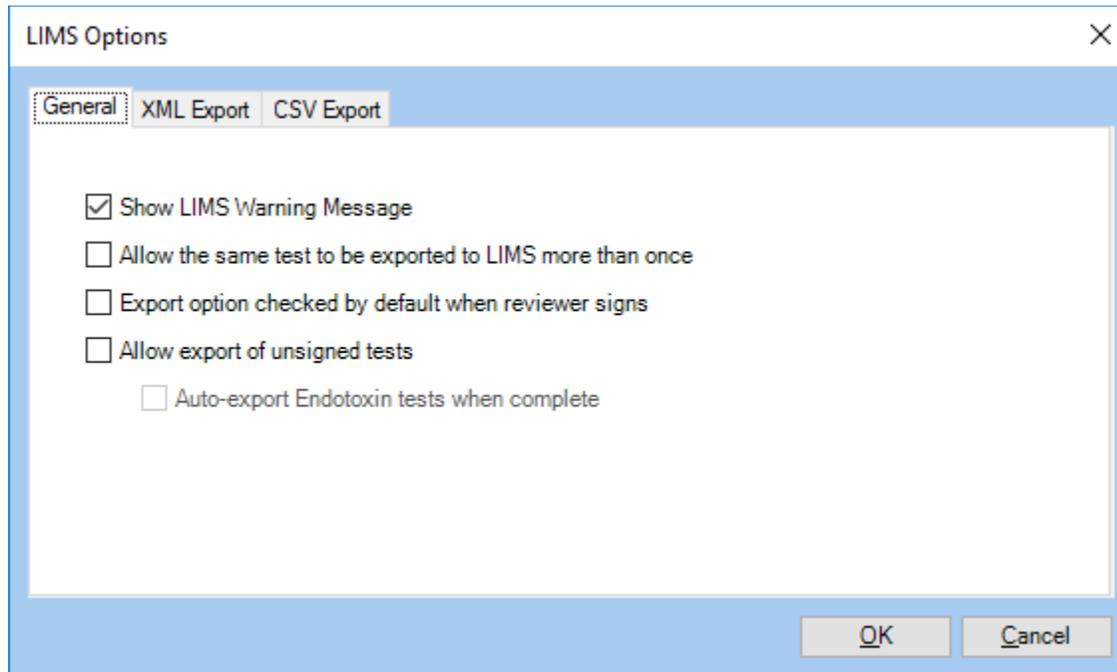
Import Close

- **Group Details:** This feature is only available to users who have the **Manage Users** permission (see "User List" on page 140).
 - **Group Name:** This is the name of the active directory group from which the group of domain users will be imported.
 - **Domain Name:** Enter the name of the domain associated with the user accounts.
 - **Directory Server:** Enter the name of the directory server directly to authenticate against an explicit server. By default, the values in this field will mirror those of the domain name.
 - **Port:** Specify the port with which to authenticate against the directory server. By default, it is 389 that is the standard communication port for these purposes.
 - **Use SSL:** Check this if the directory server requires authenticating on the Secure Socket Layer. The standard port while authenticating over SSL is 636.
 - **Query with different credentials:** If the active directory server requires credentials other than those credentials used for the current Windows® session, check the checkbox and enter the domain user name and password.
 - **Associate Domain Users to Existing:** During the import process, if a user with the same user name already exists in the WinKQCL® Software user list, having this checkbox checked will update that user and associate it with the account in the active directory group.
 - **Validated Users:** Select this checkbox to consider all imported users as "validated" users. Validated users are those that have been properly trained and certified to perform endotoxin tests and work with the WinKQCL® Software.
- **Permissions:** The functionality in this tab is identical to the Permissions tab from the User Window (see "User Roles" on page 144).
- **Workgroup:** The functionality in this tab is identical to the Workgroup tab from the User Window (see "User Controls and Functionality" on page 142).

LIMS Options

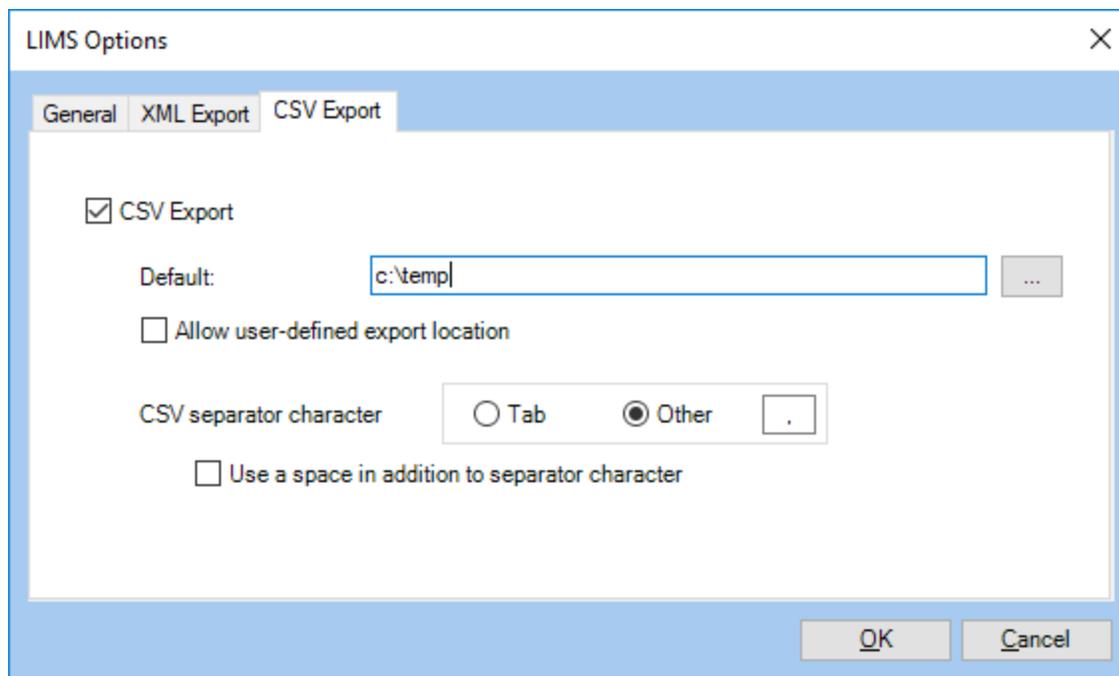
Data for completed endotoxin tests can be exported to specified locations in XML and/or CSV file formats (see "LIMS Export File Naming" on page 168). Data in these formats can be parsed easily and used by a Laboratory Information Management System (LIMS).

To access the LIMS Options window, click **Tools > LIMS Options** on the main toolbar.



- **General**

- **Show LIMS Warning Message:** Check to display a warning message on export.
- **Allow the same test to be exported to LIMS more than once:** Check to export the same test to LIMS multiple times. Uncheck to export tests to LIMS only once.
- **Export option checked by default when reviewer signs:** Check to have the Export to LIMS option checked by default when a reviewer applies an electronic signature (see "Electronic Signatures" on page 164).
- **Allow export of unsigned tests:** Check to export unsigned tests. Uncheck to require tests to be fully signed before exporting.
- **Auto-export endotoxin tests when complete:** Check to automatically export endotoxin tests to LIMS when completed. Uncheck to not automatically export endotoxin tests to LIMS.



- **XML Export and CSV Export:**

The XML and CSV export interfaces share four common controls.

- o **Export Checkbox:** Check to enable the export format.
- o **Textbox:** Enter the path to the folder where exported files will be saved. Different paths may be specified for each file format. This may be a network file share or path local to the WinKQCL[®] Software database server.
- o **Browse:** Click to open a browser to select an export location.
- o **Allow user-defined export location:** Check to prompt the user for an export destination each time **Export to LIMS** is clicked.

- CSV Export-specific options

- o **CSV separator character:** Enter the character to be used as the separator in the exported CSV files.
- o **Use a Tab as a separator character:** When checked, a Tab character will be used to separate fields. This option overrides any character in the CSV separator character field.
- o **Use a space in addition to separator character:** When checked, a space character will be output after the separator character.

- **OK:** Click to close the window and save the changes.

- **Cancel:** Click to close the window and save no changes.

Additional information or support that is related to LIMS interfacing and integration is available. Contact a Lonza Sales Representative or Lonza Scientific Support.

Only supervisors can modify LIMS Options (see "User Roles" on page 144).

System Configuration Report

To display a summary of the configured global settings, click **Tools > System Configuration Report** on the main toolbar. The System Configuration Report is restricted to users with the **Supervisor** role. This report will be used at the conclusion of an installation or upgrade procedure.

The screenshot shows a web browser window titled "System Configuration Report". The report content includes:

- Generated by: SUPERVISOR
- Validation Testing
- Lonza - WinKQCL Version 6.0.0
- System Configuration
- Page 1 of 3
- Time : 3:00:34AM (UTC+2)
- Date : 2/28/2019

Field	Setting
General Information	
USP Version	USP 34-NSF29 S1
USP Verify Date	7/14/2011
Database Creation Date	2019-02-26T17:05:21.553
Registration Code	
AER KQCL/PYROGENT-5000	
Display Correlation Coefficient	True
Correlation Coefficient From	-1
Correlation Coefficient To	-0.98
Display Slope	True
Slope From	-0.4
Slope To	-0.1
Display Y Intercept	True
Y Intercept From	2.5
Y Intercept To	3.5
Display Standard Control % Recovery	True
Standard Control % Recovery	25

At the bottom of the window, there are three status boxes: "Current Page No.: 1", "Total Page No.: 3", and "Zoom Factor: Page Width".

Help

Access the WinKQCL® Software Help by following any of these steps:

- On the main toolbar, click **Help > Help**.
- Click **Help** in a window, when the button is available.
- Press **F1** at any time.

About the WinKQCL® Software

To display the About WinKQCL® Software window, click **Help > About WinKQCL** on the main toolbar. This window displays information that includes the following:

- Version of the WinKQCL® Software that is installed
- Copyright details
- Scientific Support contact phone number
- Installation Code
- Registration Code
- Total physical memory
- Disk space available on the hard drive where Windows® is installed
- SQL version

WinKQCL® Software Logs

When troubleshooting an issue, Lonza may require the log files for the WinKQCL® Software. To open the folder containing the WinKQCL® Software log files on the main toolbar, click **Help > Logs**.

QC Insider

Helpful resources are at the user's fingertips with a quick link to Lonza's QC Insider. Keep up with latest news, and maintain training with the E-Learning program.

eShop

Link to Lonza's eShop, which is an online repository for all of the products in its portfolio.

Revision History

Quick link to see the full list of changes in the WinKQCL® Software system over time.

Calculator

The Calculator window can be opened using the following steps:

- On the main toolbar, click the **Calculator** icon:



- Click **Calculator** in the Product Edit window.

The Calculator performs routine mathematical calculations related to endotoxin testing. Calculations for pharmaceutical products and medical devices can be performed. The following calculations are supported:

- Dilution
- Maximum Valid Dilution (MVD) and Minimum Valid Concentration (MVC)
- Endotoxin Limit
- PPC Concentration

When results are calculated, if the values are less than 0.1 or greater than or equal to 1000000, the WinKQCL[®] Software will display the results in scientific notation if the **Use Scientific Notation** checkbox is selected.

Click **Close** to close the window.

Dilution Calculations

The Calculator can determine the amount of sample and diluent that must be combined to achieve a desired dilution factor when given values for the dilution factor and the final volume.

In the **Dilution Factor** field, enter a number from 1 to 9 characters in length that is greater than or equal to 1. The field accepts decimals or exponential notation.

In the **Final Volume** field, enter a number from 1 to 9 characters in length.

The Sample Volume and Diluent Volume are determined by using the following equations:

$$\text{Sample Volume} = \frac{\text{Final Volume}}{\text{Dilution Factor}}$$

$$\text{Diluent Volume} = \text{Final Volume} - \text{Sample Volume}$$

For example, a sample that must be tested at a dilution of 1:20 and 300 µL of test solution is required. Enter 20 in the **Dilution Factor** field. Enter 300 in the **Final Volume** field. Press **Enter** or **Tab** or click the **Dilution Factor** field or **Final Volume** field. The calculated Sample Volume and Diluent Volume (both in µl) are calculated and displayed. The Calculator displays 15.0000000000 µl for the Sample Volume, and 285.0000000000 µl for the Diluent Volume.

Calculator

Dilution | MVD / MVC | Endotoxin Limit | PPC Concentration

Dilution Factor: 20

Final Volume: 300

Sample Volume: 15.0000000000

Diluent Volume: 285.0000000000

Use Scientific Notation

Print Close

MVD and MVC Calculations

The Calculator can determine the Maximum Valid Dilution (MVD) and Minimum Valid Concentration (MVC) values given for the Endotoxin Limit and the Sensitivity of Assay.

In the **Endotoxin Limit** and **Sensitivity of Assay** fields, enter a number from 1 to 9 characters long and greater than or equal to zero. Both fields accept decimals or exponential notation. Press **Enter** or **Tab** or click the **MVD** field or **MVC** field to calculate and display the appropriate value.

The sensitivity of any particular assay is the concentration of the lowest standard in EU/mL. In the simplest case, an endotoxin limit for a product is entered in EU/mL and the Calculator determines the MVD according to the following formula:

$$\text{MVD} = \left(\frac{\text{Endotoxin Limit (EU / mL)}}{\text{Sensitivity of Assay (EU / mL)}} \right)$$

Calculator

Dilution | MVD / MVC | Endotoxin Limit | PPC Concentration

Endotoxin Limit: 1 EU/ mg

Potency of Product (mg/mL): 100

Sensitivity of Assay (EU/mL): 0.005

MVD: 20,000.00000

MVC: 0.0050000 mg/mL

Use Scientific Notation

Print Close

Example 1

Consider a product with an Endotoxin Limit of 10 EU/mL. That product is tested using a kinetic chromogenic LAL test with a Sensitivity of Assay of 0.005 EU/mL. The result is the following MVD calculation:

$$\text{MVD} = \left(\frac{\text{Endotoxin Limit (EU / mL)}}{\text{Sensitivity of Assay (EU / mL)}} \right) = \left(\frac{10 \text{ (EU / mL)}}{0.005 \text{ (EU / mL)}} \right) = 2000$$

The **EU/** list has other selections besides mL. Select **EU per µg, mg, unit, mEq, device** or enter any custom unit. Selecting a value other than mL implies the sample has a concentration and the Potency of Product field is activated. In the **Potency of Product** field, enter a number from 1 to 9 characters in length. The field accepts decimals or exponential notation.

While using a sample with a concentration, the MVC value is calculated. The MVC value is determined using the following formula:

$$\text{MVC} = \left(\frac{\text{Sensitivity of Assay (EU / mL)}}{\text{Endotoxin Limit (EU / selected unit)}} \right)$$

The MVD calculation is also performed. The following equation is used to account for the Potency of Product:

$$\text{MVD} = \left(\frac{\text{Endotoxin Limit (EU / selected unit)}}{\text{Sensitivity of Assay (EU / mL)}} \right) \times (\text{Potency of Product (selected unit / mL)})$$

Example 2

Consider a product with an Endotoxin Limit of 1 EU/mg. That product is tested using a kinetic chromogenic LAL test with a Sensitivity of Assay of 0.005 EU/mL. The product potency is 100 mg/mL. The test produces the following MVD/MVC calculations:

$$\text{MVD} = \left(\frac{1 \text{ (EU / mg)}}{0.005 \text{ (EU / mL)}} \right) \times (100 \text{ (mg / mL)}) = 20000$$

$$\text{MVC} = \left(\frac{\text{Sensitivity of Assay (EU / mL)}}{\text{Endotoxin Limit (EU / mg)}} \right) = \left(\frac{0.005 \text{ (EU / mL)}}{1 \text{ (EU / mg)}} \right) = 0.005 \text{ (mL)}$$

Endotoxin Limit Calculations

The Calculator can determine the Endotoxin Limit for a given product or device for a given Dose value. In the **Dose** field, enter a number from 1 to 9 characters in length. The field accepts decimals. In the Dosage Units field, mL, µg, mg, unit, mEq, or device can be selected. Enter custom units from zero to six characters in length. When **Systemic** is selected as the route of administration, and dose per hour is set to **Kg Body Weight**, the endotoxin limit is calculated using the following equation. It is assumed that the dosage units are not set to device.

$$\text{Endotoxin Limit} = \frac{5 \text{ EU}}{\text{Dose}}$$

Example

If the dose of a product is 5 mL, the endotoxin limit is 1.0000 EU/mL as shown here. Press the **Enter** or the **Tab** key or click the **Endotoxin Limit** field to display the calculated value.

Changing the route of administration to **Intrathecal**, changes the endotoxin limit calculation to the following formula:

$$\text{Endotoxin Limit} = \frac{0.200 \text{ EU}}{\text{Dose}}$$

In this example, if the dose per hour is changed to **Total Body**, the endotoxin limit increases. If the selection for the average body mass is set to **USP / EP (70 kg)**, the endotoxin limit is increased by a factor of 70. If the selection for the average body mass is set to **JP (60kg)**, the endotoxin limit is increased by a factor of 60.

NOTE: USP / EP stands for *United States Pharmacopeia / European Pharmacopeia* standard. JP stands for *Japanese Pharmacopeia* standard.

When **device** is selected for the dosage units, the calculator displays the device endotoxin limit of 20 EU/device when the **Systemic** route of administration is selected. For devices administered intrathecally, an endotoxin limit of 2.15 EU/device is shown. These limits are displayed regardless of the entries in the dose and dose per hour per fields.

PPC Concentration Calculations

The Calculator can determine the appropriate PPC Concentration for a given sample when the Endotoxin Limit, a Dilution factor, and the Potency of the Product are provided. The Pass/Fail Cutoff value is calculated with the following formula:

$$\text{Pass/Fail Cutoff} = \text{Endotoxin Limit} * \text{Potency} / \text{Dilution Factor}$$

If the resulting value is greater than or equal to 1 then use a value between 1 and 5. Otherwise, use a value between 0.1 and 0.5.

The image shows a software window titled "Calculator" with four tabs: "Dilution", "MVD / MVC", "Endotoxin Limit", and "PPC Concentration". The "Endotoxin Limit" tab is selected. The window contains the following input fields and values:

Field	Value
Endotoxin Limit	10
Dilution Factor	1
Potency of Product	1
PPC Concentration	1 to 5

At the bottom left, there is a checkbox labeled "Use Scientific Notation" which is currently unchecked. At the bottom right, there are two buttons: "Print" and "Close".

Print

The calculator contains a print option to display a report with all formulas and calculations used with the values entered.

Common Operations

Some operations are performed in several areas of the software. They are described in the topics that follow.

Keyboard Shortcuts

The following keyboard combinations are available throughout the application. These combinations cannot be used in pop-up dialog boxes.

Action	Shortcut	Action	Shortcut
Open Templates window	Ctrl + Alt + T	Certificate of Analysis	Ctrl + Alt + R
Open Products window	Ctrl + Alt + P	Open Help Menu	Ctrl + Alt + H
Open Accessories window	Ctrl + Alt + A	Open User Manual	F1
Open Endotoxin Tests window	Ctrl + Alt + E	QC Insider	Ctrl + Alt + Q
Open Trending window	Ctrl + Alt + N	eShop	Ctrl + Alt + S
Open Other Tests menu	Ctrl + Alt + O	Revision History	Ctrl + Alt + V
Open Automation menu	Ctrl + Alt + I	Cascade all open windows	F9
Open Tools menu	Ctrl + Alt + L	Tile windows stacked	F10
Switch Users	Ctrl + Alt + U	Tile windows side-by-side	F11
Calculator	Ctrl + Alt + C		

Testing the WinKQCL[®] Software Network Connectivity

NOTE: The information and procedures presented in this topic apply only when the WinKQCL[®] Software 6 is used in a network environment.

NOTE: The ping procedure may not work if the server is separated from the clients by a firewall. If a firewall is present, a company network administrator will need to make sure the appropriate ports are open on the firewall. See also "Minimum Requirements for a Server System" on page 13.

The WinKQCL[®] Software network is configured in a client-server manner, where the server provides the shared database that all the clients can access. Clients share stored data in the database. (Stored data includes Test Results, Accessories, Products, Templates, Users, Configuration Settings, and the Audit Logs.)

Before installing the WinKQCL® Software on each computer, determine if the computer that is designated as the server is accessible from the designated client computers through the network.

To test the connectivity of the WinKQCL® Software server, follow these steps:

1. Log on to the computer designated as the server.
2. To determine the computer name, right-click the **This PC** icon and click **Properties**. The computer name is specified in the Full computer name field. For demonstration purposes, the full computer name is shown as "EndoComputer" in the following example:

Computer name, domain, and workgroup settings —

```

Computer name:      EndoComputer
Full computer name: EndoComputer
Computer description:
Workgroup:          WORKGROUP
  
```

3. Log on to an existing (or potential) client computer.
4. Click **Start**.
5. Click **All Programs > Accessories > Command Prompt**.
6. At the prompt, type **ping computername**, where computer name is the full computer name of the server.
7. Press **Enter**. If the connection is successful, a reply from the server is displayed. If the connection is unsuccessful, a message states the server could not be found or did not respond. Try repeating the previous step using the fixed IP address of the server instead of the computer name.

Another way to test network connectivity is to verify that a shared folder on the server is visible from the client computer.

Common Report Controls

The following controls appear at the top of all test report windows:



Control	Function
	Export the report.
	Print the report.
	Go to first page.
	Go to previous page.
	Go to next page.

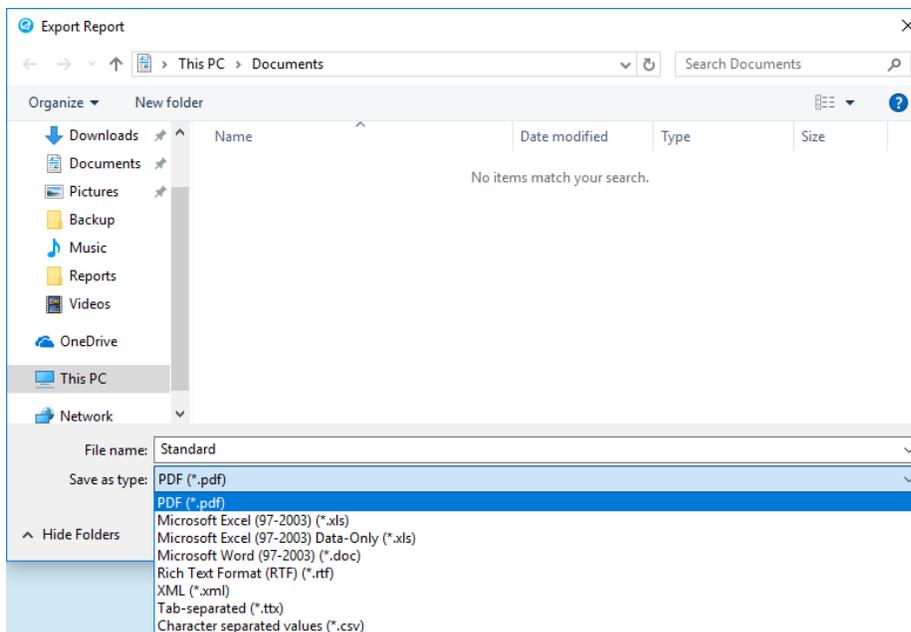
Control	Function
6	Go to last page.
7	Current page / total pages.
8	Search report text.
9	Zoom.

Printing the Report

To print the displayed report using the Windows® printer dialog, click the **Printer** icon. Select which printer to use, which pages, and change any available printer preferences before printing the report.

Exporting the Report

To export the report in various formats, click the **Export** icon. The **Export Report** window is displayed. Enter the file name and select the export format from the **Save as type:** drop-down list.



NOTE: When exporting as an xls file type, the cell format will be "General" and will need to be converted to "Number" in order to use the cells in Microsoft® Excel® formulas. To prevent "General" cell formatting from being applied, export the report as a Tab-separated ttx file and then open the ttx file with Microsoft® Excel®.

- **PDF:** Export the report into a PDF file that can be displayed with a PDF file viewer.
- **Microsoft® Excel®:** Export the report into a standard Excel® spreadsheet format. Exporting as Data-Only removes header and footer information from the exported file.

- **Rich Text** and **Microsoft® Word**: Export the report into a file format that can be opened by Microsoft® Word. The report will be formatted to keep its appearance.
- **XML**: Export the report into a file format where the data is wrapped in "extensible markup language" and marked with field labels. This format is useful if further automated processing of the data is desired using a macro or script. If exporting to a LIMS, LIS, or EM system, such as Lonza's MODA® Solution, use the Export to LIMS button as that format is better suited for parsing to an external data source.
- **Tab Separated**: Export the report into a tab-delimited file that can be imported by Excel® or similar applications, this is ideal for raw data reports or in cases where further calculations need to be performed on the exported data.
- **Character separated values**: Export the report into a comma-delimited file that can be imported by Excel or similar applications, this is ideal for raw data reports or in cases where further calculations need to be performed on the exported data.

Search and Filter Controls

Search and Filter controls sort and fill the WinKQCL® Software lists according to the specified criteria. The following graphic shows all the WinKQCL® Software Search and Filter controls.

From the Endotoxin Tests window:

From the Templates window:

From the Products window:

Clicking the **Apply** button or pressing the **Enter** key, populates the list with the records that meet the search criteria specified in the controls. Clicking **Reset** clears the search and filter fields.

- **From and To**: Returns all records that fall within the specified date range. These fields are only shown in the Endotoxin Tests window and not in the Templates window (see "Search by Date Range" on page 160).
- **Name**: Returns all records where the test Name contains the text that was entered (see "Search by Name" on page 160).
- **Product**: Returns records where product information contains the text that was entered (see "Search by Product" on page 160).
- **Test Types**: Returns all records that match the Test Type that was selected.
- **Assay Types**: Returns all records that match the Assay Type that was selected.
- **Analyst/Technician/Me**: Returns all records where the analyst ID contains the text that was entered (see "Search by Analyst/Technician" on page 161).

- **Signed:** Returns all records that match the test signature states that were selected.
- **Allow Multiple Dilutions:** A user can click this checkbox to search for products that have multiple dilutions defined. This checkbox is only found in the Products List search feature.

NOTE: This graphic and explanation provide information of all possible WinKQCL® Software Search and Filter Controls. Search and Filter Controls are not present on all windows, and some windows contain only some of the possible controls.

Search by Date Range

The From and To date controls allow searching by date range. To enable a control, select the associated checkbox. When a date control is enabled, the date can be changed and is implemented in the search. The From date specifies the start point of the date range. The To date specifies the end point of the date range.

NOTE: When using both dates, the From date must be earlier than the To date.

Examples:

- Search for tests that were conducted from January 1, 2016 to December 11, 2016 (includes both dates):

The screenshot shows two date control fields. The 'From:' field has a checked checkbox and a dropdown menu showing '1/ 1/2016'. The 'To:' field has a checked checkbox and a dropdown menu showing '12/11/2016'.

- Search for tests that were conducted on or before February 28, 2019:

The screenshot shows two date control fields. The 'From:' field has an unchecked checkbox and a dropdown menu showing '1/28/2019'. The 'To:' field has a checked checkbox and a dropdown menu showing '2/28/2019'.

- Search for tests that were conducted on or after June 1, 2017:

The screenshot shows two date control fields. The 'From:' field has a checked checkbox and a dropdown menu showing '6/ 1/2017'. The 'To:' field has an unchecked checkbox and a dropdown menu showing '9/20/2019'.

Search by Name

To search by the name of an item, use the **Name** field.

The results of the search are all items that have a name that contains the text that was entered in the field.

Search by Product

To search by product, use the **Product** field.

The results of the search are all items that have a Product Name, Product Lot Number, or Product ID that contain the text that was entered in the field.

Search by Analyst/Technician

To search by the ID of an analyst, use the **Analyst** or **Technician** field.

The results of the search are all items that have an analyst ID that contains the text that was entered in the field.

Select the **Me** checkbox to populate the current user's user ID in the analyst field. This feature makes it easy to conduct searches relevant to the current user. Click to clear the **Me** checkbox, and the analyst field is cleared.

Sortable Lists

Sortable lists can be sorted according to a particular column. Clicking a column header sorts the list based on the contents of that column. When a list is already sorted by a particular column, clicking that same column sorts the list in the inverse order.

The workgroup column will always place the current user's workgroup first when sorted in ascending order and last when sorted in descending order.

Analyze

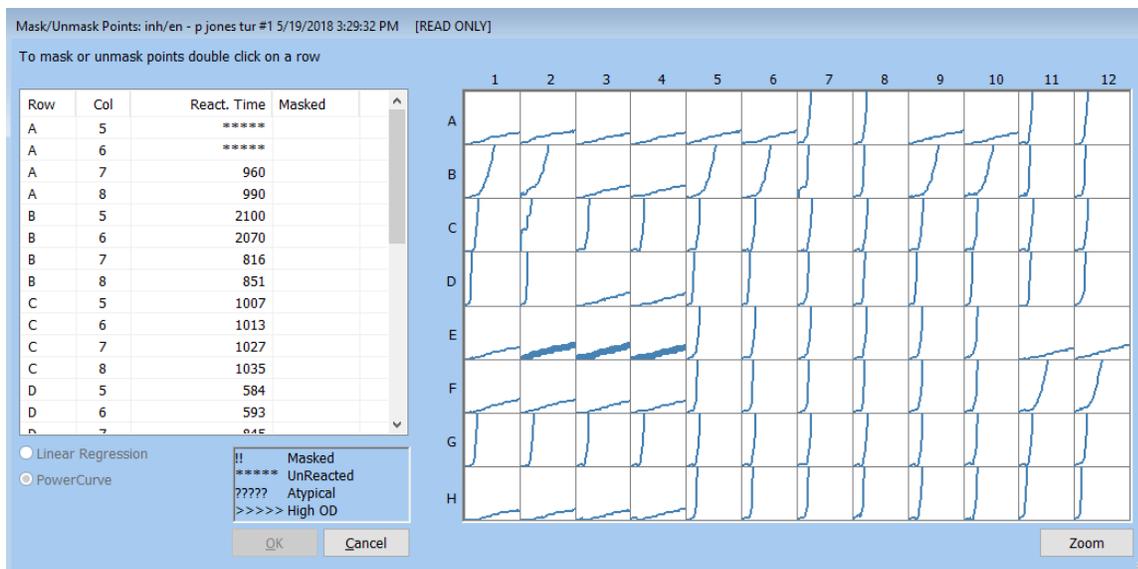
To analyze a test, use the Mask/Unmask Points window. This window is viewable in a read only and editable format depending on permissions. To open it for edit, the following circumstances must be met:

- The current user is the user that ran the test, or has the **Edit other users' Endotoxin tests** permission.
- The test has not yet been signed.

The window displays the well locations and reaction times of the assay. Reaction times can be removed selectively from the analysis using masks. To mask or unmask points, double-click the row. The selected reaction time is marked by **!!**. That reaction time is removed from the assay calculations.

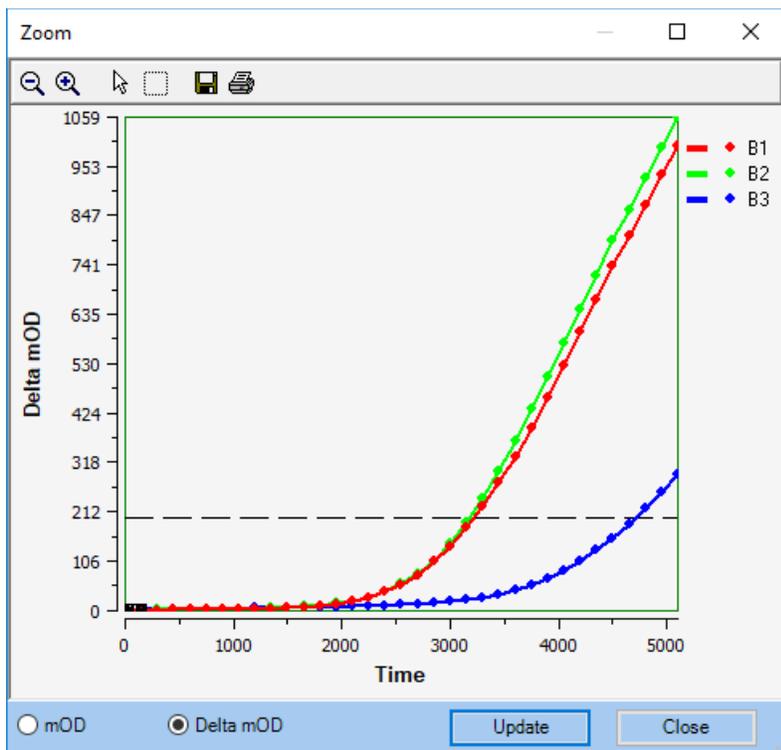
The following character strings have special meanings. The strings appear in the **React. Time** column under the following conditions:

- ********: The well did not react.
- **?????**: An atypical reaction time was detected (see "Atypical Samples" on page 163).
- **>>>>**: The well reacted beyond the measurement capabilities of the reader.



The buttons on the Mask/Unmask Points window have the following functions:

- **Linear Regression and PowerCurve™:** Specify desired data model. PowerCurve™ uses a polynomial curve fit with specific rules about when it can be used. See [Linear Regression and PowerCurve™](#) on page 167 for information about when it can be used.
- **OK:** Click to implement the selections in the Mask/Unmask Points window.
- **Zoom:** For kinetic assays, the user can see the reaction curves for each well, overlay the data, and zoom in on it. Click any number of wells to select them for further analysis then click **Zoom**. A zoom window appears and overlays all the selected wells. The data can be viewed as mOD or Delta mOD.



- **Cancel:** Click to cancel the operation and close the window.

Atypical Samples

The WinKQCL[®] Software has an analysis module that detects atypical increases in optical density. Atypical increases in optical density near the start of an assay can indicate a serine protease in a standard or sample, rather than endotoxin. If a serine protease is present in sufficient quantity, the chromogenic substrate may develop color independent of an endotoxin-LAL reaction. As a result, the endotoxin value reported for an affected sample may be overestimated.

Standards or samples that show atypical increases in optical density are tagged with a series of question marks (?????). The user must decide what correct measures are necessary to obtain proper results. Factors other than the presence of a serine protease can cause atypical increases in optical density. Such factors include high sample pH or extremely high concentrations of endotoxin.

Edit Assay and View Template Buttons

The Edit Assay button is usable in two circumstances:

- The current user is the technician that created the test and has the "Edit own Endotoxin tests" permission, or is another user and has the "Edit other users' Endotoxin tests" permission.
- The test is not electronically signed.

To edit the template information for an assay, click the **Edit Assay** button. A user may edit the test, unless the test is being used as a stored curve for another template. Templates using stored curves are linked to a test and use the test's stored curve. Any field may be edited other than the test's name, assay type, test type and any field on the parameter tab. Any information that is changed is tagged with the “#” symbol on the viewed and printed report. All changes are written to the record audit log and will be listed in the log summary section at the end of the report.

Accessories, products and standards can be added and removed and well positions on the plate can be changed.

The view template button is shown in place of the edit assay button when the test is electronically signed or when the logged on user does not have permission to edit the test.

To review the template details in a read-only mode, click **View Template**.

Incorrectly Placed Wells

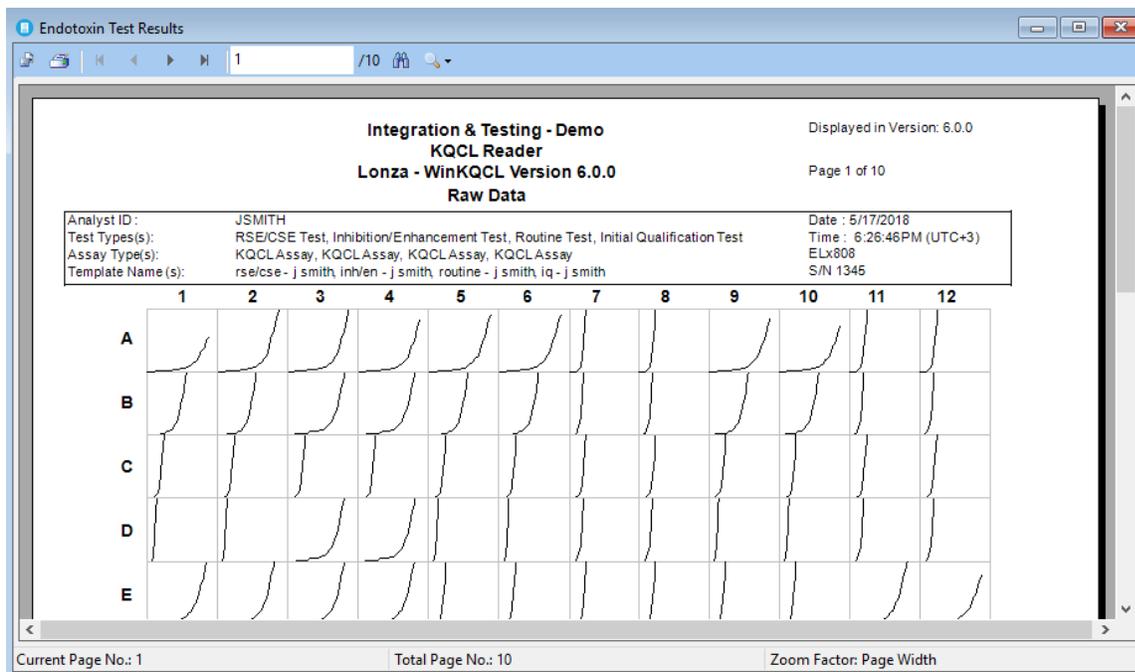
On occasion, an analyst pipettes the plate incorrectly and the locations of the standards or samples do not reflect what is configured in the template for the test. All of the data is recorded. The analyst can use the Edit Assay feature to realign the data. Once the template is open for edit:

- Click **Place** to enable manipulation of the layout.
- Select and delete the contents of each incorrect well.
- To re-add a sample, select the sample in the **Products** grid and click each of the new well locations.
- To re-add a standard, select the standard in the **Standards** list and click each of the new well locations.

- Click Save to have the test reprocessed with the updated locations.

View Raw Data

The Raw Data window displays the raw graph and data values associated with the test. The OD values for each read cycle of the selected assay are displayed.



Electronic Signatures

The WinKQCL® Software can apply secure electronic signatures to test reports. Test reports can be signed with an electronic text signature (et-sig) or an electronic bitmap signature (eb-sig).

The Electronic Signature window allows an analyst or a reviewer to apply an electronic signature to the selected test.

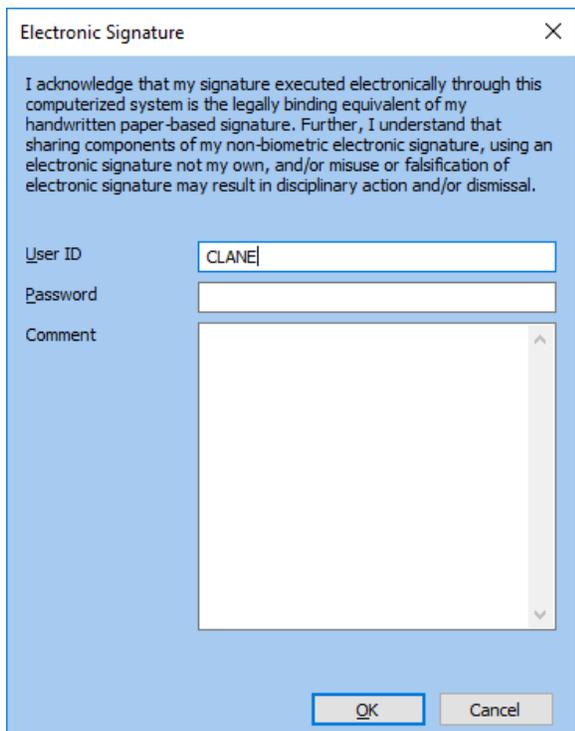
Test reports without both the analyst and reviewer electronic signatures are clearly marked with "FOR REVIEW ONLY". The report watermark can be disabled through the Global Options (see "Global Options" on page 136).

For endotoxin tests only, a user with the **Unlock E-Signature** permission can unlock electronic signatures from a test report so that the test can be edited and corrected (see "Unlocking an Electronic Signature" on page 166). Then the report is signed a second time. A fully signed test can only have the electronic signatures unlocked once.

WARNING Under 21 CFR Part 11, institutions must notify the FDA before they use electronic signatures. Institutions that are not ready to use electronic signatures and prefer to apply ink signatures can disable the report watermark (see "Global Options" on page 136).

Analyst Signs Electronically

When an analyst elects to sign a test electronically, the User ID field is automatically filled with the ID of the current user, which is the analyst or someone with the "Sign other analysts' Endotoxin tests" permission. The analyst must provide a valid password so that the WinKQCL[®] Software accepts the signature. The analyst can add a comment.



Electronic Signature

I acknowledge that my signature executed electronically through this computerized system is the legally binding equivalent of my handwritten paper-based signature. Further, I understand that sharing components of my non-biometric electronic signature, using an electronic signature not my own, and/or misuse or falsification of electronic signature may result in disciplinary action and/or dismissal.

User ID: CLANE

Password:

Comment:

OK Cancel

OK: Click to make the WinKQCL[®] Software complete the following operations:

- Apply the electronic signature to the test.
- Apply the comment (if present) to the test.

NOTE: If the user ID and password are not valid, these operations do not occur and an error message is displayed.

Cancel. Click to cancel the operation. No changes are applied to the test.

Reviewer Signs Electronically

When a user signs as a reviewer, a valid user ID and password must be provided so that the WinKQCL[®] Software accepts the signature. (The valid ID and password are associated with a reviewer.) The reviewer can add a comment. Additionally, if the Export to LIMS checkbox is selected, the test is exported to LIMS.

Electronic Signature

I acknowledge that my signature executed electronically through this computerized system is the legally binding equivalent of my handwritten paper-based signature. Further, I understand that sharing components of my non-biometric electronic signature, using an electronic signature not my own, and/or misuse or falsification of electronic signature may result in disciplinary action and/or dismissal.

User ID: CLANE

Password:

Comment:

Export to LIMS

OK Cancel

OK: Click to make the WinKQCL[®] Software complete the following operations:

- Apply the electronic signature to the test.
- Apply the comment (if present) to the test.
- Export the test to Laboratory Information Management System (LIMS) (if selected).

NOTE: If the user ID and password are not valid, these operations do not occur and an error message is displayed.

Cancel: Click to cancel the operation. No changes are applied to the test.

Unlocking an Electronic Signature

Even if the analyst and the reviewer electronically sign a test, an endotoxin test can be edited. Users with the "Unlock E-Signature" permission can unlock signatures for a fully signed test or a test with only an analyst electronic signature by clicking the **Unlock Analyst E-sig** or the **Unlock E-Signature** buttons.

An analyst electronic signature can be unlocked and re-applied as many times as is needed, until a reviewer electronically signs the test. Electronic signatures for a fully signed test can only be unlocked one time.

When an electronic signature is removed, that action is recorded in the record audit log (see "Record Audit Log Report" on page 126).

After the electronic signatures are unlocked, the technician who created the test with the "Edit own Endotoxin tests" permission or any user with the "Edit other users' Endotoxin tests" permission can edit the test's template information. All edits are clearly marked with a "#" symbol. All edits are written to the record audit log and are visible in the "Log Summary" section of the

report. When the record is fully signed a second time, the second electronic signatures are labeled as et-2 (text-based) or eb-2 (bitmap-based). A reviewer electronic signature can be unlocked from a test only once, but an analyst electronic signature may be unlocked any number of times as long as there is no reviewer electronic signature applied.

NOTE: Electronic signatures cannot be unlocked on any test is used as a stored curve.

Linear Regression and PowerCurve™

This section explains Linear Regression and PowerCurve™ computations. These computations are used to derive a curve used for "back-predicting" endotoxin concentrations.

Linear Regression

During the assay, the reader continuously monitors the absorbance of each well of the microplate. For the Kinetic-QCL® and PYROGENT® 5000 Assay types, the WinKQCL® Software uses the initial absorbance reading of each well as its own blank. If the default values are used, the WinKQCL® Software computes the time required for the absorbance to increase 0.200 (for Kinetic-QCL® Assay) or 0.03 (for PYROGENT® 5000 Assay) absorbance units. This time is called the reaction time. The WinKQCL® Software automatically performs a log-log linear correlation of the reaction time of each standard with its corresponding endotoxin concentration. For the PyroGene® Assay type, the WinKQCL® Software automatically performs a log-log linear correlation of the relative fluorescence of each standard with the corresponding endotoxin concentration.

PowerCurve™

When the absolute value of the linear correlation coefficient (r) is 0.980 or greater, a polynomial regression model can be used to do two things:

- Construct a standard curve.
- Predict the endotoxin concentrations of test samples.

This polynomial model (PowerCurve™) improves the accuracy of predicting endotoxin concentrations over the entire (5-log) endotoxin standard range (4-log with PyroGene® Assay).

When PowerCurve™ is used, a standard curve is generated using the \log_{10} reaction time values and their corresponding \log_{10} endotoxin concentrations to define a polynomial equation. The number of endotoxin standards in the assay determines the order of the polynomial equation that is used to generate the regression curve. The order of the polynomial is always one less than the number of endotoxin standards unless the Global Option "Allow PowerCurve™ to fallback to a lower regression model" is checked. The maximum is a fourth order (quartic) polynomial for tests with five or more endotoxin standards. The minimum is a second order (quadratic) polynomial for tests with three standards.

NOTE: The PowerCurve™ model cannot be used for Initial Qualification assays. Linear regression must be used in those cases.

NOTE: The polynomial must be monotonic for PowerCurve™ to be used. If the first derivative of the polynomial has a solution during the domain of the function an inflection point is present. An inflection point will cause more than one available endotoxin concentration result for a given reaction time or delta RFU value so the model is non-monotonic. If the Global Option "Allow

PowerCurve™ to fallback to a lower regression” is unchecked, the test will be forced to use a linear regression model.

LIMS Export File Naming

The following naming convention is used when exporting data to an external system:

LIMSyyyymmddhhmmss#.xml or LIMSyyyymmddhhmmss#.csv

- **yyyy:** Year the test was run.
- **mm:** Month the test was run.
- **dd:** Day the test was run.
- **hh:** Hour the test was run.
- **mm:** Minute the test was run.
- **ss:** Second the test was run.
- **#:** Number of the template on the merged plate, starting from zero. (For single-template tests, this number is always zero.)

Troubleshooting

Contacting Support

When a problem occurs with the WinKQCL[®] Software, recall the events that led up to the problem. Details can help Lonza Scientific Support to resolve the problem as quickly as possible.

Before calling, gather the following information:

- Your name, organization, and phone number
- Program name and version number
- Operating system and version number (for example, Windows[®] 10 version 20H2)
- Hardware platform (for example, hard disk space available, memory, and CPU type/speed)
- Nature of the problem and any software messages (A screen-shot can be helpful.)
- Installation configuration (for example, standalone or client/server)

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