

# WinKQCL<sup>®</sup> Endotoxin Detection and Analysis Software

Advanced analytics and data integrity



## Part 11 and Annex 11 Compliant

The WinKQCL® Software meets the technical requirements for electronic records and signatures under the US FDA 21 CFR Part 11 regulations and provides support for the European Commission's "Annex 11: Computerised Systems" guidance.

The WinKQCL® Software provides user access security, electronic signatures, audit trails, and the ability to archive data or export data in PDF, XML and other formats for review and access outside of the WinKQCL® Software. As the WinKQCL® Endotoxin Detection and Analysis Software is a true networked solution, the database can be installed on a secure server. It can segregate data for each lab and operate across multiple sites over a company's wide area network, providing for a centralized secure solution with high data availability. WinKQCL® Software supports automated backup of the database, rapid recovery of the database and scripted installation of the client software, leading to Business Continuity compliance.



# Leading the way in innovation

Lonza leads the way in endotoxin detection, consistently innovating in products, methods, and software since the 1970s. We understand the challenges of operating in regulated manufacturing environments because we work under the same stringent conditions at our custom manufacturing sites.

We recognize the importance that software plays in data analysis, reporting and trending. Like us, our customers rely on accurate and timely results in order to make proactive decisions before an Out of Specification (OOS) occurs. Therefore, for over two decades, we have made significant investments in our WinKQCL® Software, by continuously developing and advancing our software with our own dedicated in-house software development team.

### Benefits:

- Work smarter and faster with the Kinetic SmartStop™ monitoring feature and the SpeedFill™ and Drag n' Drop features of the Template Manager
- Identify trends and monitor product quality
- Supports consistent data generation aligned with requirements for regulatory compliance

# Developed by users

### Quantitative methods fully supported

The WinKQCL® Software offers a fully integrated solution for your quantitative endotoxin detection testing, data management and reporting needs. There are no complex calculations to make, just results. The software supports all of the quantitative endotoxin detection assays from Lonza and allows users to run all of the endotoxin detection tests typically performed in the Quality Control (QC) laboratory:

- Initial Qualification
- Routine Test
- Inhibition/Enhancement
- RSE/CSE

Lonza's endotoxin detection and analysis software has evolved with your needs and requirements in mind. We know that accuracy, efficiency, and regulatory compliance are of utmost importance to you. That's why we've developed a wide range of features in our software solution to meet your specific needs.

### Features:

- Enterprise level IT features
- Fine-grain user control
- Multi-user login feature
- Introduction of Kinetic SmartStop™ to address split pair reactions
- Enhanced edit assay feature (metadata only)
- Real-time customizable test reports (product data and metadata)
- Trending of standard data
- All data is displayed in an easy-to-read configurable report that can be electronically reviewed and signed



# Available in 9 languages

The WinKQCL® Software has been translated into nine languages. Whether you are installing the software, using the WinKQCL® Software interface, reading help topics or viewing reports, you will have the option to choose from the following languages:

- English (EN)
- German (DE)
- Spanish (ES)
- French (FR)
- Italian (IT)
- Japanese (JA)
- Portuguese (PT)
- Simplified Chinese (zh-CN)
- Traditional Chinese (zh-TW)

## Kinetic SmartStop™

Lonza develops features that save you time while delivering the results you need. WinKQCL® Software is configurable to monitor kinetic tests progress and automatically stops the tests when specific criteria are met. You can set the software to wait for standards and/or blanks to react before stopping the test. Additionally, you can enable the split product replicate detection feature to ensure all product replicates react, reducing the potential need for retests.

## Enterprise level IT features

WinKQCL® Software can be deployed and operated across a company wide area network, even if the server is on the other side of the world.

WinKQCL® Software is time zone aware. Data is stored in UTC/GMT format and will be displayed in the time zone format, reflecting the location where the client computer is running.

The WinKQCL® Software allows for data segregation by functional group. Now, multiple endotoxin testing labs at sites on the same corporate network can share the same server and database, and data can be kept separately by assigning each lab its own workgroup. User accounts, products, accessories, and readers can be associated with a specific workgroup.

The WinKQCL® Software can integrate with your Active Directory® server, allowing users to utilize their Windows® password to log in to the WinKQCL® Software. Import AD groups for rapid user set up. Single Sign On can also be enabled for further log on automation. If rapid recovery is a requirement, scripted installations are supported.

WinKQCL® Software can run on thin clients via software such as Citrix® XenApp® or Citrix Presentation Server™.

## Nebula® Multimode Reader

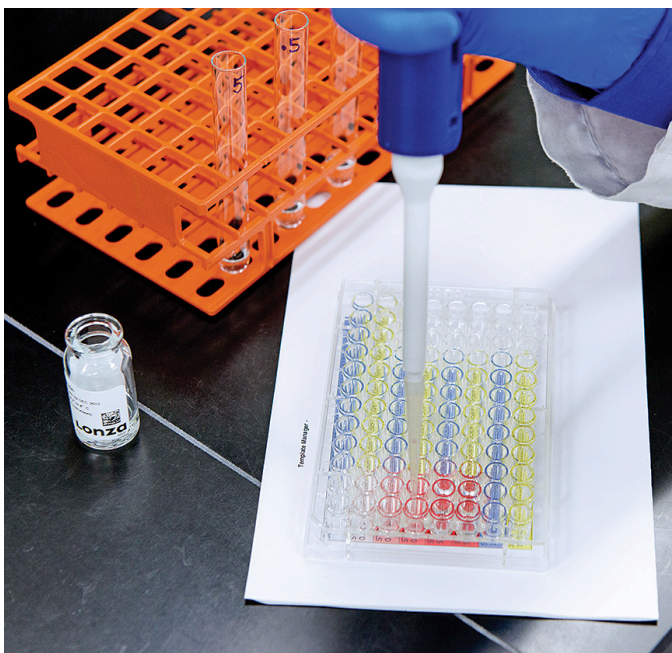


## Template Manager

The WinKQCL® Software has a powerful yet easy-to-use Template Manager feature which allows rapid creation of 96-well plate layouts. The Template Manager allows for tracking of reagents, samples and accessory information to help ensure traceability for Out of Specification (OOS) and root cause investigations.

After your plate template has been constructed, you can print your plate layout in actual size to help guide you as you load the plate.

### Print your plate layout for easier plate loading



## Data entry made easy

The WinKQCL® Software gives users the ability to enter data into the software in an automated manner.

- Users can scan Lonza reagent lot numbers and expiration dates into the software from 2D barcodes found on Lonza reagent vials
- The software's SpeedFill™ feature allows for the copying of information from one product entry to the next, which reduces retyping and helps minimize data entry errors. Using a barcode reader in combination with the SpeedFill™ feature allows product data to be entered in a matter of seconds
- Product information can be dragged and dropped into the WinKQCL® Software from an external product or Environmental Monitoring (EM) information system, such as Lonza's MODA®, GMP Manufacturing and Quality Software or a LIMS or LIS system

### Scanning of 2D barcodes on Lonza reagents



# Detect endotoxin trends early

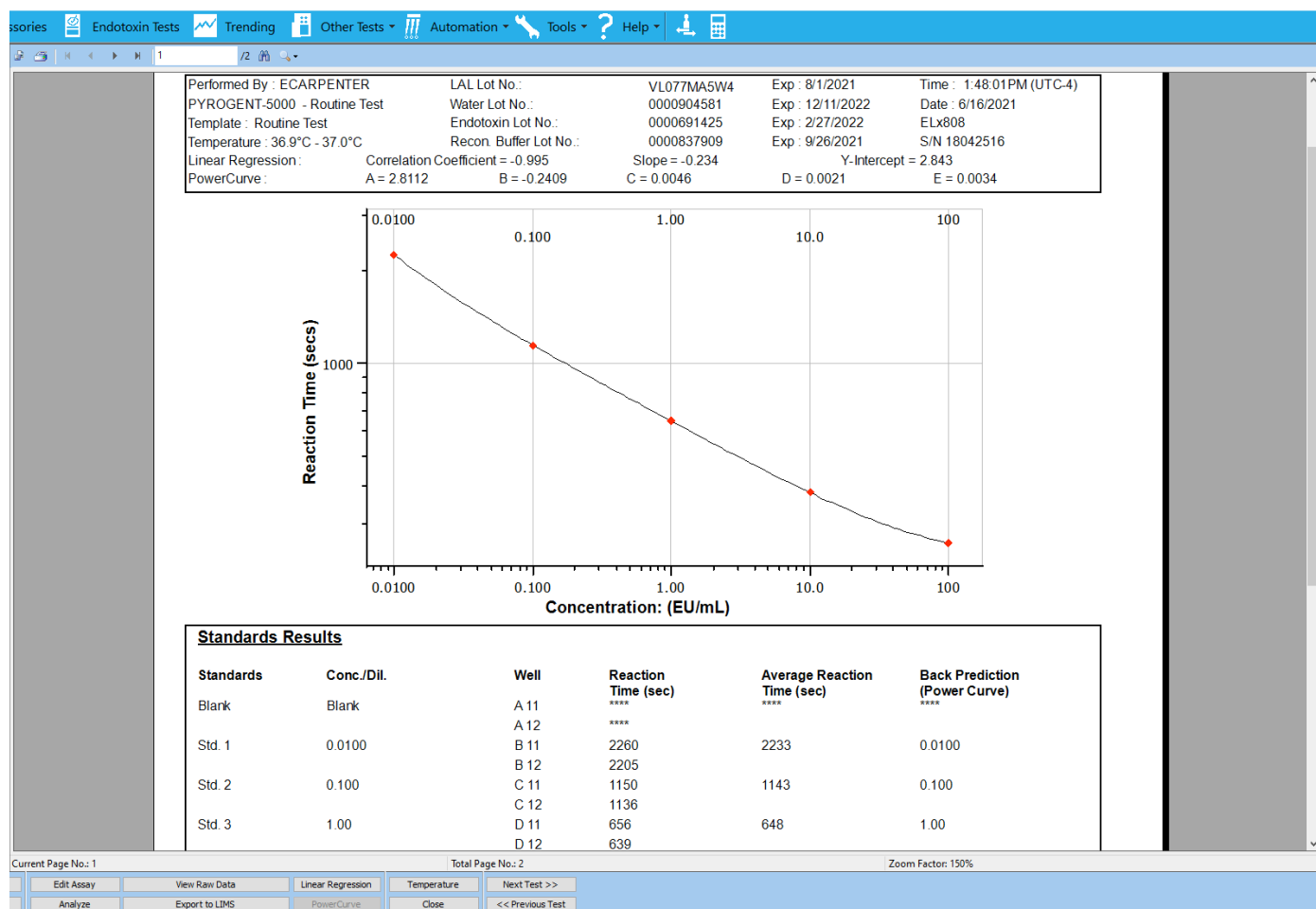
The trending module gives users the ability to review and analyze data on demand (assay performance and product results over time). Since WinKQCL® Software stores its data in one location, there is no need to export to a second piece of software or separate database. Data is available for analysis the moment the assay finishes. With this feature at your fingertips, you can quickly identify trends and respond before an OOS occurs, an important tool for regulated environments, like yours.

Using the interactive trending tool, you can query and trend product, accessory, Lonza reagent, instrument, curve and general attributes, such as date ranges. The trending tool also enables you to perform trending by User ID. You can also find standard attributes to the qualifier list:

- Standard reaction time
- Standard Relative Fluorescence Units (RFU)
- Standard % CV
- Standard concentration

FDA regulations require that an investigation be conducted as a result of an OOS. The WinKQCL® Software provides users with tools that will help with this critical investigation.

## WinKQCL® Software User Interface



## Multi-user / multi-reader control

WinKQCL® Software allows users to control multiple readers from the same computer, at the same time. Additionally, the multi-user control allows multiple analysts to run multiple tests from a single WinKQCL® Software session. The software keeps track of which analyst is running which test, providing flexibility in a busy lab environment that delivers increased efficiencies in your workflow. If you want to minimize the number of computers in the lab, this feature is for you.

## Enhanced user permissions

In addition to the basic analyst, reviewer and supervisor roles, the following permissions can be selected. This allows users to be assigned rights according to their experience, training and role within their company:

- Manage products
- Manage accessories
- Manage readers
- Manage template reader parameters
- Delete any template
- Edit own endotoxin tests
- Edit other users' endotoxin tests
- Sign other analysts' endotoxin tests
- Export to LIMS
- Remove e-signature

## Results editing and reporting

When a test is finished, WinKQCL® Software displays the results in an easy-to-review print preview. Raw data review, electronic signature application and review of test temperature results are all possible from this same dialog.

You also have the ability to easily customize the format of the printout to suit your needs. For example, if you are a testing service lab and you only wish to print certain products, WinKQCL® Software allows this change as required.

Additionally, if a mistake was made when creating the template, users can correct mistakes in a Part 11 compliant manner (metadata only). WinKQCL® Software will record changes that were made and recognize which analyst made them in the log summary section of the report and in the audit trail, in an easy-to-read format.



# Instruments supported by the WinKQCL® Software

The WinKQCL® Software is interfaced with a collection of absorbance, fluorescence and multimode readers, offering even greater flexibility in the lab. Many of the Operational Qualification (OQ) tests are integrated into the WinKQCL® Software, allowing you to record, approve and track reader performance from within the same software.

## Absorbance readers

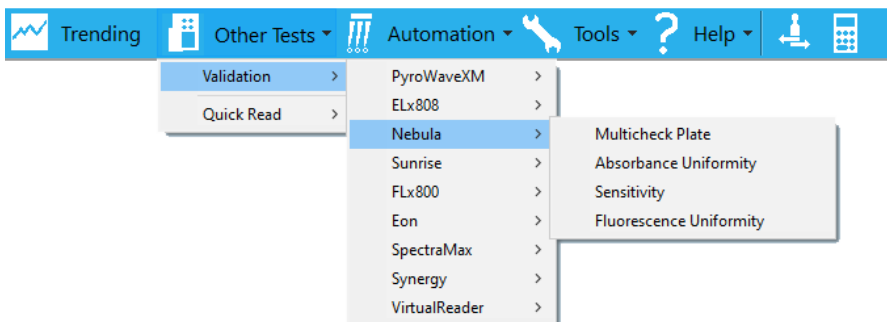
- Nebula® Absorbance Reader
- Agilent ELx808IU™
- Tecan® Sunrise™  
(when used as part of the PyroTec® PRO Automated Robotic Solution setup)

## Fluorescence readers

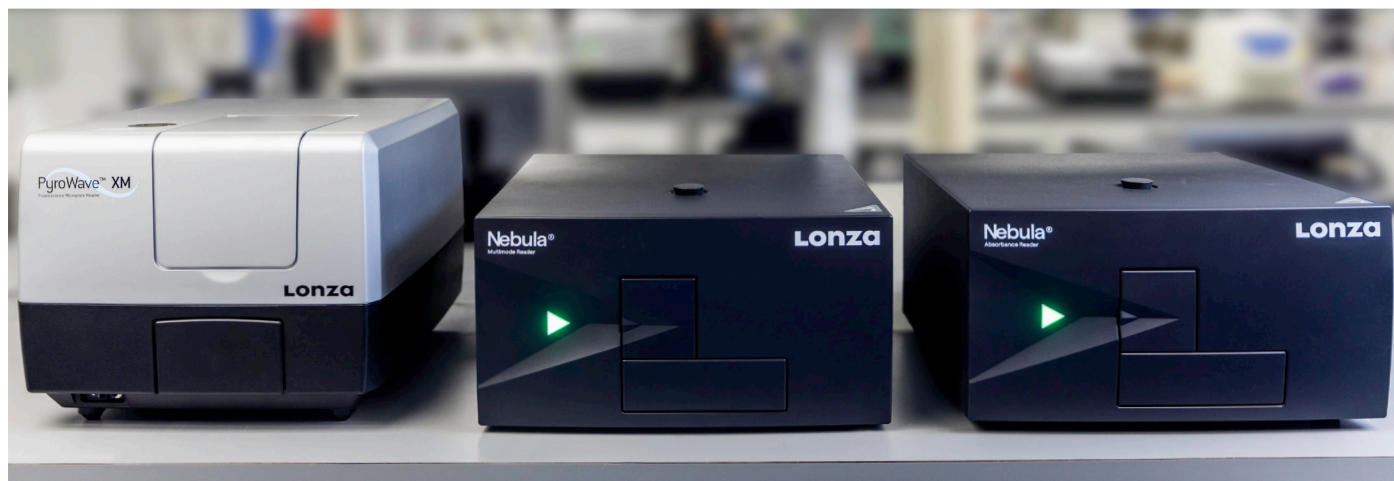
- PyroWave® XM Reader

## Multimode readers (Absorbance and fluorescence readers)

- Nebula® Multimode Reader



WinKQCL® Software may be compatible with other microplate readers to perform common endotoxin tests such as initial qualification, routine tests, inhibition/enhancement tests and an RSE/CSE test. For a complete list of microplate readers, please contact your local Lonza representative.





## Lifecycle services

Lonza's expertly trained service professionals can provide installation, qualification and preventative maintenance to keep your software and instruments qualified and functional. Our services include consultation with Lonza's Global Subject Matter Experts and access to our Scientific Support team for assistance with testing and troubleshooting assay issues.

### Service offering\*

- Onsite WinKQCL® Reader System installation and qualification (IQOQPQ) service
- Remote server setup and database migration support service
- System qualification documentation
- WinKQCL® Validation/audit package
- Annual advance support contract

\* Service offering varies per region. Consult with your local Lonza representative for more information.

### Ordering information – WinKQCL® Endotoxin Detection and Analysis Software

Cat. no. NA	Cat. no. EU	Product name	Product description
25-611E	25-611E	WinKQCL® v6 Software with automation module	Includes one reader and one workgroup license
25-611SUP	25-611SUP	Advanced software support WinKQCL® v6 Software	Required annually for each 25-611E purchased

The graphic features a large blue circle on the left containing a white stylized 'Q' logo. To the right, the text 'WinKQCL® 6' is displayed in a large, white, sans-serif font. Below this, 'Endotoxin Detection and Analysis Software' is written in a smaller white font. A dotted white line curves from the bottom of the 'Q' logo towards a circular icon on the right. The icon depicts a laboratory instrument with three vertical tubes and two small circles below them. Below the icon, the word 'Automation' is written in white.

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