LONZA

WinKQCL™ 5
Endotoxin Detection and Analysis Software
We Analyze Endotoxin Data Every Day

For Endotoxin Detection

WinKQCL™ 5 Endotoxin Detection and Analysis Software From People Who Use It

Evolution of WinKQCL™ Software

Version 1.0 1996	Version 2.0 2002	Version 3.0 2004	Version 4.0 2009
First Windows® compatible endotoxin software	Database-based. 21 CFR Part 11 compliant. First generation built-in trending feature	First true Client-Server endotoxin software. PyroGene™ rFC Assay support. XML export to third party systems (including MODA™, LIMS and LIS)	Drag n' Drop / Pick n' Place Template Manager. Multithreading/multiple readers per computer. Second generation interactive trending. User interface translated into 6 languages (DE, ES, JP, IT, FR, EN)

Leading the Way in Innovation

Lonza has been providing endotoxin detection products and services since the 1970s, leading the way in innovation for products, methods and software. We serve over 70 of the top 100 pharmaceutical companies worldwide. At Lonza, we understand the challenges of operating in a regulated manufacturing environment, as we operate under the same conditions in our various custom manufacturing sites.

Quantitative methods such as the Kinetic-QCL™ Assay generate significant amounts of raw data that require careful analysis before reporting can take place. 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 a decade, we have made significant investments in our WinKQCL™ Software, by continuously developing and advancing the 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
- Maintain regulatory compliance

Version 4.0.3
2011

2D lot number barcode scanning.
User interface, reports, installer, and
Help/Manual translated into 7 languages
(DE, ES, JP, IT, FR, PT, EN)

Version 5
2012

Many new enterprise level and IT-specific features.
Support for BioTek™ Synergy™ 2, BioTek™ Eon™, and Molecular Devices® Readers.
"Split-pair" detection via Kinetic SmartStop™.
Import/Export to third party systems (including MODA™, LIMS and LIS)
Multiple users and multiple readers per computer. Translated into Simplified and Traditional Chinese

« The user interface for the Template Manager is very intuitive, making setting up and running assays quick, easy, and accurate. »

QC Analyst

Developed by Users

Quantitative Methods Fully Supported

The WinKQCL™ 5 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 invite you to experience the new features of the WinKQCL™ 5 Software.
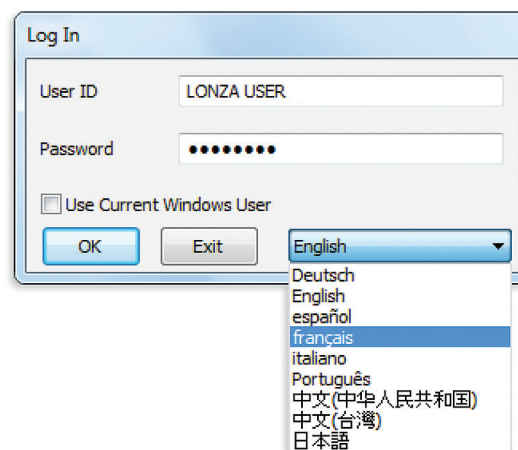
Features
– Enterprise level IT features
– Fine-grain user control
– Multi-user login feature
– Introduction of Kinetic SmartStop™ to address split pair reactions
– Enhanced edit assay feature
– Real-time customizable test reports
– Trending of standard data

Available in 9 Different Languages

The WinKQCL™ 5 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)
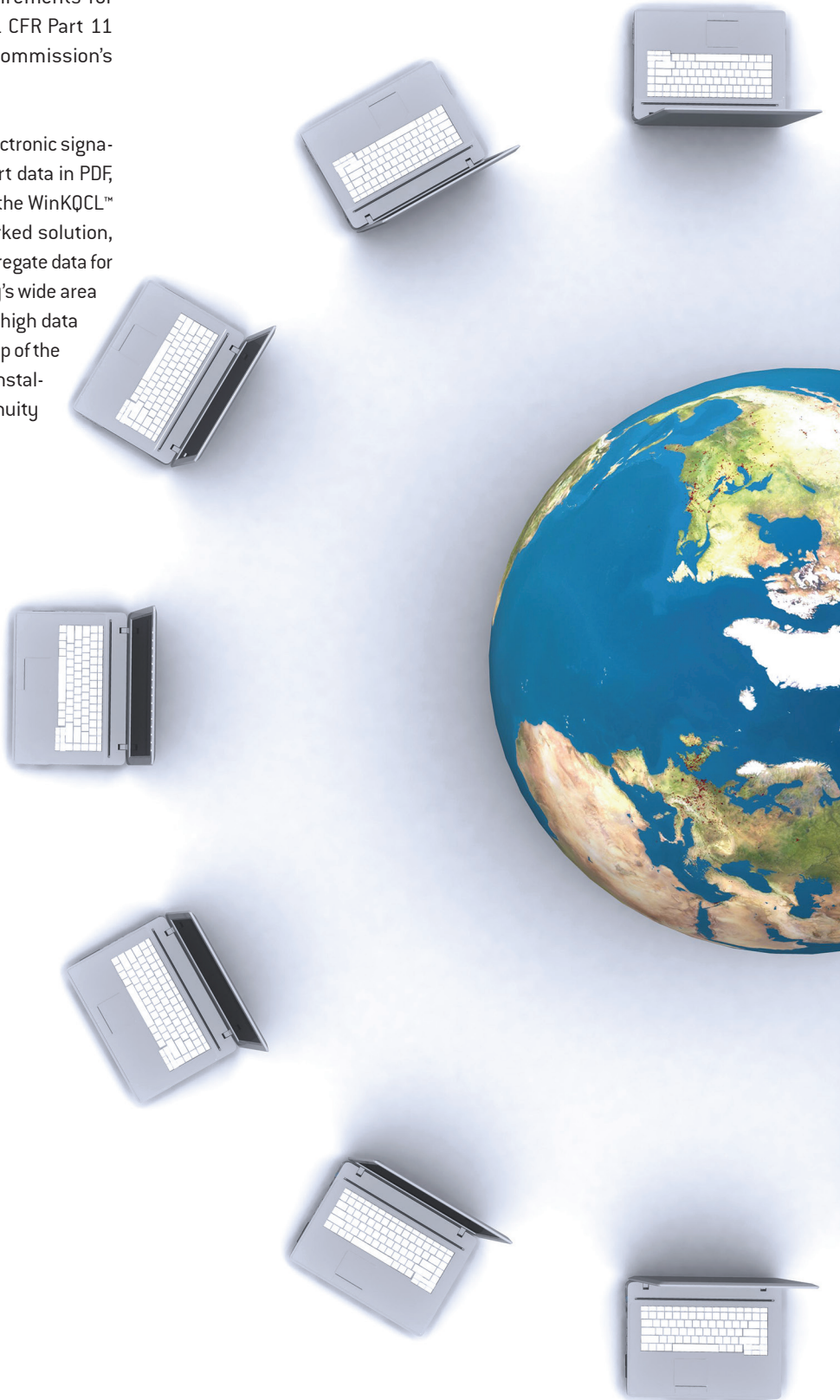– Simplified Chinese (zh-CN)
– Traditional Chinese (zh-TW)

The Copy and Copy All feature in the Template Manager makes it easy to prepare the next template, especially when most of the information is the same.

Technical Specialist 1

Part 11 and Annex 11 Compliant

The WinKQCL™ 5 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™ 5 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.

Instruments Supported by the WinKQCL™ Software

The WinKQCL™ 5 Software is interfaced with a collection of absorbance, fluorescence and multi-mode 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
– BioTek™ ELx808™
– BioTek™ Eon™
– Molecular Devices® SpectraMax® 340PC, 340PC[384], Plus[384] and 190PC
– Molecular Devices® VersaMax™
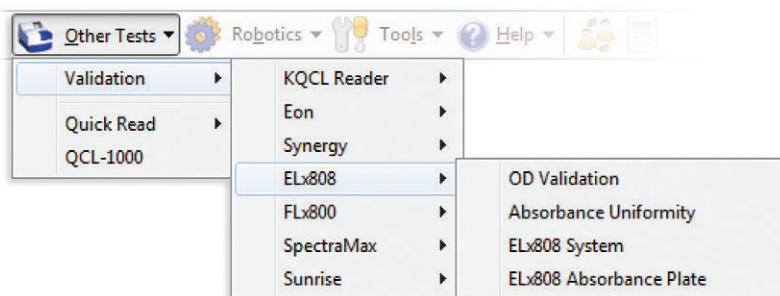– Tecan® Sunrise™

Fluorescence Readers
– BioTek™ FLx800™
– Molecular Devices® Gemini™ EM, Gemini™ XPS and Gemini™ XS

Multi-mode Readers (Absorbance and Fluorescence Readers)
– BioTek™ Synergy™ 2
– Molecular Devices® SpectraMax® M2, M2[e], M3, M4, M5 and M5[e]
– Molecular Devices® FlexStation®

SpectraMax® is a registered trademark of Molecular Devices, LLC.

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Kinetic SmartStop™

Lonza has developed a feature that can save you time while still allowing you to get the results you want. WinKQCL™ 5 Software can be configured to monitor the progress of the kinetic test and stop the test when specific criteria are met. In version 5, you have the ability to configure the software to wait for standards and/or blanks to react before stopping the test. Additionally, a split product replicate detection feature can be enabled to wait for all replicates of a product to react before stopping the test; thereby potentially reducing the need for re-tests.

Enterprise Level IT Features

As the WinKQCL™ Software has become the leading endotoxin software in the industry, version 5 adds new features requested by the IT departments that support it:

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

– WinKQCL™ 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™ 5 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™ 5 Software can now 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

– If application virtualization is an initiative of yours, WinKQCL™ Software can run on thin clients via software such as Citrix® XenApp® or Citrix Presentation Server™
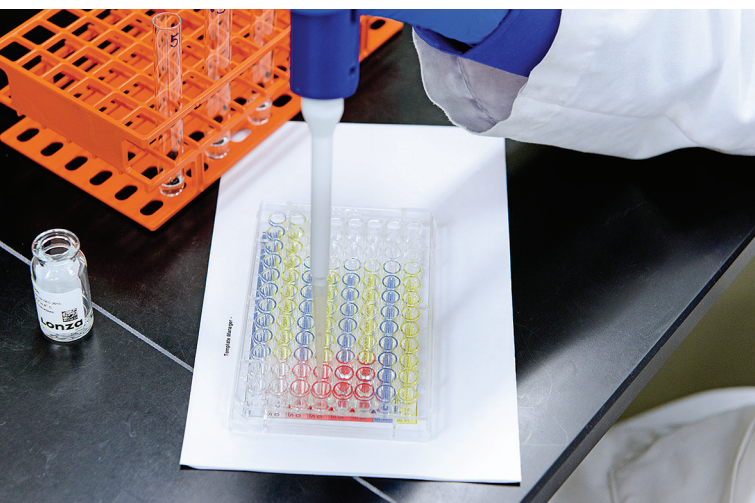

《 As a reviewer in the lab, the **Next Test>>** and **<<Previous Test** buttons are really handy to have when you are reviewing assays back to back. 》

Technical Specialist I

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.

Data Entry Made Easy

The WinKQCL™ 5 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™ Paperless QC Micro Software or a LIMS or LIS system

Print your plate layout for easier plate loading.

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. 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.
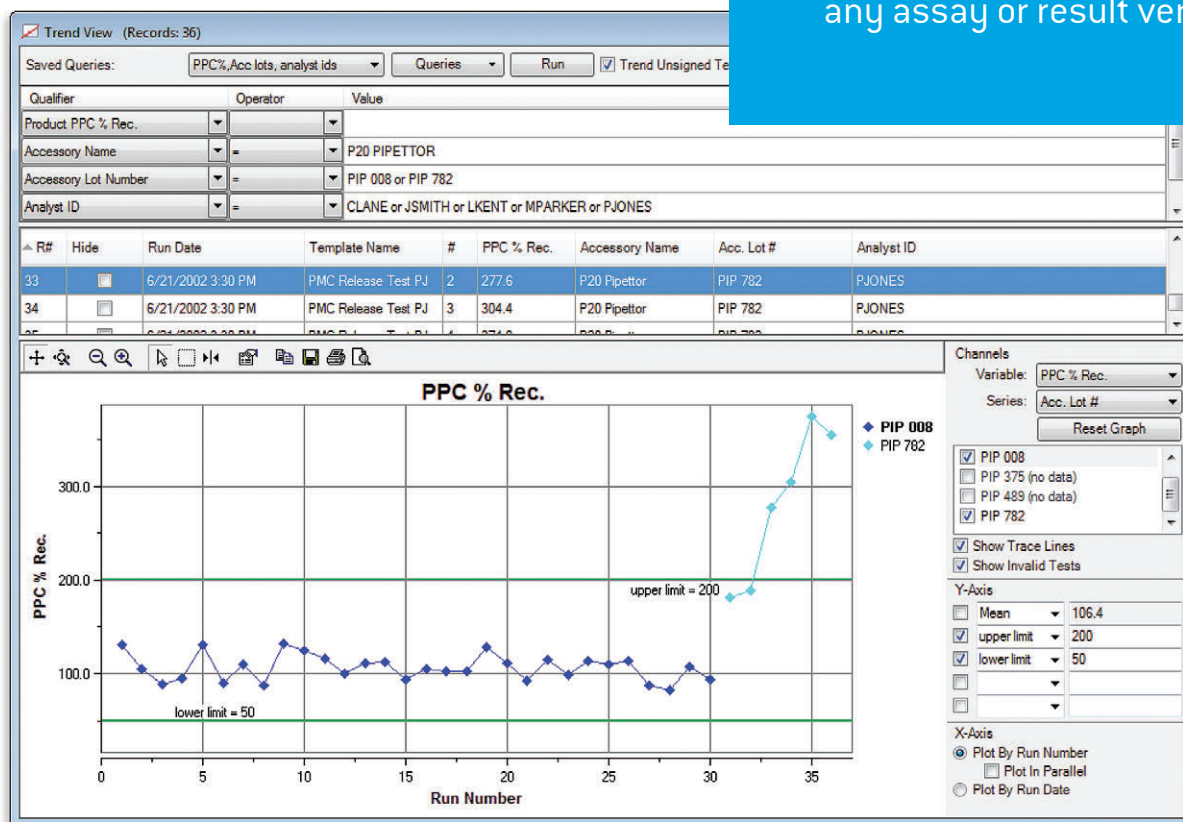
Using the interactive trending tool, you can query and trend product, accessory, Lonza reagent, instrument, curve and general attributes, such as date ranges. The trending tool also enables you to perform trending by User ID. New to WinKQCL™ 5 Software is the addition of standard attributes to the qualifier 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.

« The trending feature makes finding any assay or result very efficient. »

QC Analyst

Multi-user / Multi-reader Control

WinKQCL™ 4 Software introduced multi-threaded software with the ability to control multiple readers from the same computer, at the same time. In version 5, an additional multi-user control allows multiple analysts to run multiple tests from a single WinKQCL™ 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 enhancement is for you. This feature works with application virtualization as well.

Enhanced User Permissions

Several new options are now available when configuring user roles. In addition to the basic analyst, reviewer and supervisor roles, the following permissions can be selected that 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™ 5 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.

New to WinKQCL™ 5 Software is 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. 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.

« Running a query under the trending feature is a great way to quickly access historical testing. It's a feature I use quite extensively to get information about specific products I've tested in the past. »
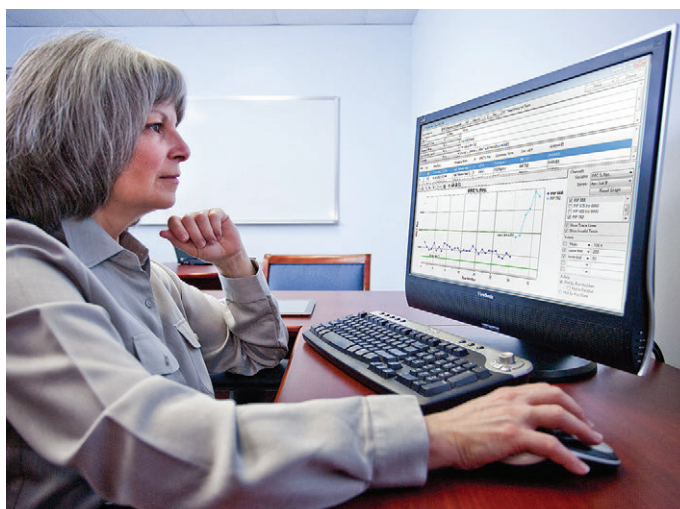
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Ordering Information

Cat. No.	Name	Description
25-501	WinKQCL™ 5 Software Package	Disc, workgroup license, reader license
25-502	WinKQCL™ 5 Workgroup License	Additional workgroup license
25-503	WinKQCL™ 5 Reader License	Additional reader license
25-504	WinKQCL™ 5 Qualification Manual	IOPQ manual for software and readers
25-505	WinKQCL™ 5 Validation Package	Disc containing software validation documentation

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