

# WinKQCL<sup>®</sup> Software revision history



Automation

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## WinKQCL® Software Revision History

The WinKQCL® Software has had the following revisions since version 2.0. If a particular release does not address a particular patch, then said patch was not widely available and its content was included in the next listed release.

### WinKQCL® Software v6.5 Revisions

#### Released April 2026

The 6.5 release of the WinKQCL® Software is a minor feature release providing enhanced shaking parameters for the readers for the platform. The standard installer may be used to update WinKQCL® Software v6.3.0 and newer, or to perform a new installation. To upgrade the installation of WinKQCL® Software prior to v6.3.0, the client application must be uninstalled and reinstalled with v6.5.0. The following changes have been made:

- PyroTec® PRO
  - The system was updated to support 0.01 curve and 0.05 curve on the Kinetic-QCL® Assay. The system will handle standard curves which include points that are 1:10, 1:5, and/or 1:2 from another point in the curve.

Use Case 1:

This shall permit the 0.01 curve for the Kinetic-QCL® Assay:

- 10 EU/mL
- 5 EU/mL
- 1 EU/mL
- 0.1 EU/mL
- 0.01 EU/mL

Use Case 2:

This shall permit the 0.05 curve for the Kinetic-QCL® Assay:

- 10 EU/mL
- 5 EU/mL

- 1 EU/mL
  - 0.1 EU/mL
  - 0.05 EU/mL
- Technical change to upgrade EVOware dll/driver to v2.9.
- Nebula® and PyroWave® XM Readers:
  - Implemented enhanced mixing on Nebula® and PyroWave® XM Readers for all assay types to ensure robust assay systems. For the Nebula® update, a firmware update on the reader was also required. The reader firmware supporting enhanced mixing is V5.80. Enhanced mixing changes the internal settings to 1 min, 1 mm, linear shaking instead of 15 sec, 3 mm, linear shaking.
- General Updates:
  - Updated software to turn off the heating elements of the readers upon exit of the WinKQCL® Software.
  - Updated software to prevent system crashes when a reader error (e.g. communication error) occurs and updated the audit log to include any errors to support end user investigation.
  - System will now correctly discover two connected Nebula® Readers.
  - Results Table will indicate Pass/Fail correctly when using “Include AER” when only one replicate reacts and the calculation/evaluation is based on the single reaction time.
  - Technical change to update the .NET version to a more current version (v4.8.1).

## WinKQCL® Software v6.4.2 Revisions

### Released October 2024

The 6.4.2 release of the WinKQCL® Software is a minor feature release targeted at expanding the instrument’s compatibility for the platform. This installer may be used to update WinKQCL® Software v6.3.0 and newer, or perform a new installation. To upgrade the installation of WinKQCL® Software prior to v6.3.0, the client application must be uninstalled and reinstalled with v6.4.2. The following changes have been made:

- PyroTec® PRO
  - System now includes functionality on the main menu to retrieve relevant WinKQCL® Software and PyroTec® Pro (PTP) log files for investigations and troubleshooting specific to a date range defined by the user. Previously these files were retrieved through a standalone utility or manually in the folder directories.
  - System now includes functionality to optionally configure a Specific Sample Volume to be used in an assay per Product. Previously the sample volume was calculated by PTP and this value could not be changed. The ability to define the source sample volume was primarily added to support small volumes that require the sample to first be diluted in the sample tube rather than the dilution tube.
  - System now correctly calculates the number of reagent vials required for a PYROGENT® 5000 in all circumstances.

- System now correctly imports the “Use Extra LAL Vial” configuration option for LAL assays from a configuration file.
- Updated Audit Trail to log any changes made to the following PTP Configurations: Products, Readers, Aux Liquids, Incubators, and System.
- Removed deprecated Liquid LiHa system functionality and references (PTP currently supports only Air LiHa systems)
- General:
  - System no longer crashes when LNO is used without a current connection to the database.
  - System now correctly displays WinKQCL® Software report AER parameters in German language.
  - “Delay Between Scans” removed from PyroWave® XM Reader parameters as this is not relevant for endpoint assays performed on a PyroWave® XM Reader. “Delay Between Scans” is only relevant for kinetic assays.
  - Database tool now able to connect successfully when an SQL password contains special characters.
  - Simplified Chinese characters entered in the Comment field when using the Edit Assay option are now displayed fully in the report.
  - Updated export so that result values in tests exported to XML/CSV now have the same decimal precision as do the result values displayed in the WinKQCL® Report.
  - Regional language translations for analyst role description updated/improved.
  - Updated Record Counter tool
  - System now consistently discovers Nebula® Readers.

## WinKQCL® Software v6.4.1 Hotfix 2 Revisions

### Released March 2024

The v6.4.1 Hotfix 2 release of the WinKQCL® Software is a hotfix release surrounding the PyroTec® PRO Module. The hotfix may be deployed onto an existing WinKQCL® Software v6.4.1 installation with the PyroTec® PRO Module, or an installer may be used to perform new installation of the module. The core software is not impacted and the WinKQCL® Software 6.4.1 installation would still be used for all new installs. The follow changes have been made:

- PyroTec® PRO will now correctly calculate the number of vials required to execute a PYROGENT® 5000 Assay. This was a regression in the 6.4.1 release.

## WinKQCL® Software v6.4.1 Hotfix 1 Revisions

### Released February 2024

The v6.4.1 Hotfix 1 release of the WinKQCL® Software is a hotfix release surrounding the FLx800 control interface. The hotfix may only be deployed onto an existing WinKQCL® Software v6.4.1 installations. The follow changes have been made:

- The software will now be able to run a template using the FLx800™ reader. This was a regression with the WinKQCL® 6.3.0 release.

## WinKQCL<sup>®</sup> Software v6.4.1 Revisions

### Released September 2023

The 6.4.1 release of the WinKQCL<sup>®</sup> Software is a minor feature release targeted at expanding the instrument compatibility for the platform. This installer may be used to update WinKQCL<sup>®</sup> Software v6.3.0 and newer, or perform a new installation. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- PyroTec<sup>®</sup> PRO
  - System will now correctly calculate the X-Span of the Loading ID module.
  - When the Loading ID module scans tubes during the Deck Setup layout it will use the updated positioning when running the assay.
  - If the cLLD fails when detecting the lysate the system will not aspirate from the Z Max position. This resolved a regression in the v6.4.0 release.
  - The second assay in a two assay run will now aspirate additive liquids from the proper rack.
  - HeatPlates will now automatically start heating when the user transitions to the run interface.
  - The system will now inform the user if there are too many replicates of a sample prior to running the assay.
  - System will now require the user running the Warm-up test at least once every 24 hours.
  - System will now require the user running the Pressure Leak test at least once every 168 hours.
  - System will now include a utility to gather log files easier.
  - System will now deploy with EVOWare 2.8 SP5.
  - Liquid class changes in auxiliary liquids will now cascade to the samples that utilize the liquid for dilutions.
- General:
  - Improved robustness while merging systems with workgroup level configurations.
  - Global configuration option renamed from “Decimal Plate Precision” to “Significant Figure Precision”
  - Correctly display significant figures based on the global configuration instead of decimal places.
  - Default report layout will now display values in the same format as legacy records.
  - Samples on a PyroGene<sup>®</sup> Assay will now default their PPC to 0.5 EU/mL.
  - Improved error handling when creating a template with standards less than 1E-6.
  - Calculated in Version field will now be correctly hidden when loading a report from a version prior to 5.3 that has not been recalculated.
  - Redraw behavior is improved for the Template manager interface.
  - Sunrise Reader temperature configuration interface will now properly handle regional decimal formats.

- Footer note for an absorbance uniformity test will no longer display information regarding delta RFUs.
- System will no longer throw an error while changing the plate layout for a merged plate assay that was run beyond the first position.
- System will now audit why a test finished. For instance if the user proceeded to the report early, or if the max number of reads were met.
- PyroWave® XMs autogain functionality will query the correct well range.
- Autogain feature implemented for the Nebula® Multimode reader.

## WinKQCL® Software v6.4.0 Revisions

### Released June 2023

The 6.4.0 release (version 6.4.0.92) of the WinKQCL® Software is a minor feature release targeted at expanding the instrument compatibility for the platform. This installer may be used to update WinKQCL® Software v6.3.0 and newer, or perform a new installation. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- PyroWave® XM:
  - Default sensitivity values will not be changed from running a sensitivity assay.
- Nebula® Reader:
  - Added compatibility for the Nebula® Absorbance Reader.
  - Able to operate the instrument over a USB 3.0 hub. At this time, utilizing older technologies such as USB 2.0 are not reliable. While the USB 3.0 hub will function, it is still recommended to connect the instrument directly into the system to avoid risk on the critical interface.
  - Nebula® reader is now able to operate when connected to a Windows® 11 computer.
  - Heating location is reoptimized to better distribute heat to the plate.
  - Updated temperature stabilization algorithm to better incubate the microplate.
- PyroTec® PRO
  - Workflow optimization to improve plate preparation time.
    - The system shall utilize multidispensing during preparation of standards and samples
    - Utilizing multiple tips and parallel dispensing during plate preparation.
  - Added compatibility with a new type of trough designed towards minimizing reagent waste.
  - Improved user experience when aborting an assay.
  - Clearer messages when there is an issue preventing transition to deck setup.
  - Resolve an issue when samples have defined premixing enabled, the unit is not mL, and no dilution is necessary.
  - Ability to copy configurations from other instruments.
  - Remove Flush LiHa functionality from the system. This was only applicable to the liquid LiHa systems and there was no commercial version of the application which utilized those.

- Remove the constraint which prohibited the user from running a plate with gaps. For instance in previous versions PyroTec® PRO would not permit a user to run a plate where column 1 was empty, but there were wells used elsewhere on the microplate.
- Cross system Interoperability
  - Improved detection of sample retests for items queued from other systems while using the PyroTec® PRO.
  - Added seamless bidirectional offering with MODA-EM®.
  - Added configuration option to only permit exporting data when there is at least one signature on the test report.
  - Added an aggregate field in the XML export for overall status of a sample.
  - Added an aggregate field in the XML export for the overall validity of the test record.
- General
  - The installer will now work appropriately when a newer version of the Visual C++ runtime is installed.
  - When click edit assay, the system will no longer display an error about stored curves at the incorrect time.
  - System will resolve the issue that where surrounding bends in the curve samples on occasion would not display a back predicted value.
  - Samples may now be diluted up to 100,000,000,000.
  - Now able to configure number of significant figures for endotoxin results. The default and recommended value remain 3 figures.
  - USP information will no longer be present in the system configuration report
  - Improved message while attempting to delete a template when the user lacks permission.
  - Installer will now default to use the standalone configuration.
  - Running an unmodified template no longer triggers an audit entry for template modification.
  - Product lot number on the plate grid will no longer trim excess information.
  - Added SQL Server 2022 compatibility
  - Add Windows Server 2022 compatibility

## WinKQCL® Software v6.3.1 Hotfix 3 Revisions

### Released August 2023

The v6.3.1 Hotfix 3 release of the WinKQCL® Software is a hotfix release targeted report fix for two critical items with the endotoxin reports. The hotfix may be deployed onto an existing WinKQCL® Software v6.3.1 installation, or an installer may be used to perform a new installation. Given that the initial v6.3.1 and v6.3.1 Hotfix 1 releases were only available to limited early adopters this release may also be referred to as the v6.3.1 Hotfix. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:



- Resolved an error when calculating the rounding position for calculations which sometimes resulted in an incorrect pass/fail comparison for sample values in the Product AER section of the report
- Resolved an issue where the endotoxin values on the test report were reporting to three decimal places instead of three significant figures.

## WinKQCL<sup>®</sup> Software v6.3.1 Hotfix 2 Revisions

### Released March 2023

The 6.3.1 Hotfix 2 release (version 6.3.1.57) of the WinKQCL<sup>®</sup> Software is a hotfix release targeted around Nebula<sup>®</sup> reader communication. This installer may be used to update WinKQCL<sup>®</sup> Software v6.3.0 and newer, or perform a new installation. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- The system will now deploy .net framework 3.5 SP1 as part of the installation.
- PyroGene<sup>®</sup> Assays run with the Nebula<sup>®</sup> Reader will not display reader parameters which do not pertain to the instrument.
- Sensitivity test range for the Nebula<sup>®</sup> Reader is expanded to cover a broader range.
- Sensitivity target for the Nebula<sup>®</sup> Reader will be appropriately displayed when running in regions which use a comma as a decimal indicator.
- The Nebula<sup>®</sup> Reader interface will have improved robustness for connecting and reconnecting to the instrument.
- The “New” button is removed from the reader manager.

## WinKQCL<sup>®</sup> Software v6.3.1 Hotfix 1 Revisions

### Released February 2023

The 6.3.1 Hotfix 1 release (version 6.3.1.45) of the WinKQCL<sup>®</sup> Software is a hotfix release targeted around Nebula<sup>®</sup> reader communication. This installer may be used to update WinKQCL<sup>®</sup> Software v6.3.0 and newer, or perform a new installation. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- WinKQCL<sup>®</sup> Software will now correctly communicate with the Nebula<sup>®</sup> Reader in regions which use a comma as a decimal indicator.

## WinKQCL<sup>®</sup> Software v6.3.1 Revisions

### Released January 2023

The 6.3.1 release (version 6.3.1.44) of the WinKQCL<sup>®</sup> Software is a minor patch release with general system improvements. This installer may be used to update WinKQCL<sup>®</sup> Software v6.3.0, or perform a new installation. If an older version is installed then the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- PyroWave<sup>®</sup> XM:
  - Fluorescence Plate Test will now have the plate in/out button on the rotation screen and when the test is complete.

- Nebula® Reader:
  - When a single reader is connected the software will now automatically detect the serial number of the system and not prompt the user.
  - System will now display the appropriate selection for PMT values.
  - Error messages from the API will now propagate to the interface of the active test.
- Virtual Reader:
  - The reader setup interface will now correctly display which controls are enabled based on the selected data source.
- PyroTec® PRO
  - Double clicking the start button when running an assay will no longer attempt to initiate two automated workflows.
  - System will now be able to establish a database connection when the instance is defined as "mssqlserver".
  - System will now be able to detect sample retests for samples that originated from the import (LIMS) database.
  - Only update sample preparation definitions for sample definitions based on the active user's access control.
- Database
  - Able to merge trending queries when a workgroup identifier is defined but no specification is defined.
  - In the database tool, error messages will now always appear in the foreground.
  - In the database tool, clicking connect when the server field is empty will now display a message to the user instead of connecting to a local default instance.
  - Database tool is now able to connect over an encrypted connection.
  - Database tool will now correctly log underlying SQL errors in the event of an issue.
  - PyroTec® PRO System configuration information will now be migrated during a merge.
  - Database archive manager will now be able to upgrade v5 and newer archive databases. An intermediate step is still necessary for legacy databases.
- General
  - Able to perform scripted installations
  - Audit events for reader errors will now be bound to the time of the event and not the time of the test record.
  - Test interfaces will now render with fewer cutoffs when running Windows at zoom levels greater than 100%.
  - Assessing pass/fail criteria for the release limit on samples will now compare only the values visible on the report. Previously it had used hidden precision which may have resulted in a failure assessment when it should have passed.
  - Improved user experience when no server information is defined in the registry.
  - System configuration report will now display system specifications with the same precision as the configuration interfaces.
  - Client installer has been refactored to allow standalone or enterprise options.

## WinKQCL® Software v6.3.0 Revisions

### Released August 2022

The 6.3.0 release (version 6.3.0.89) of the WinKQCL® Software is a minor feature release targeted at expanding the instrument compatibility for the platform. When upgrading to this version the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- General System Configuration and Usage
  - Support added for the Lonza Nebula® Multimode Reader.
  - Support added for the Fluorescence Test Plate for use with the Lonza PyroWave® XM fluorescence reader.
  - Support added for the Windows® 11 operating system.
  - A medical instrument sample may be configured to have up to 255 instruments in the extraction (increased from 20).
  - System will be able to archive records appropriately.
  - After updating a data set that originated from the WinKQCL® Software version 2.0 the system will now be able to view diode tests.
  - When an instrument error occurs with a Lonza PyroWave® XM Fluorescence Reader it will now correctly be propagated to screen.
  - Removed ability to run QCL-1000 assays.
  - Removed USP listings.
  - Removed System Diagnostics interface.
  - New permission to grant or deny a user the ability to delete their own templates. This was previously part of the Analyst role.
  - Fluorescence read parameters for defaults and templates are now configurable per reader type.
- Database
  - Database files will now be created in default paths defined by SQL Server®.
  - Archive databases will now be able to upgrade appropriately.
- PyroTec® PRO System Software Module
  - Support added for the LoadingID module for the PyroTec® PRO System.
  - Updated user access controls for the PyroTec® PRO System.
  - Introduction of a re-optimized new deck layout for the PyroTec® PRO System.
  - Option to configure alternative starting endotoxin concentration for automated standard curve preparation on the PyroTec® PRO System
  - Explicit instrument level temperature configuration added for the Tecan® Sunrise™ absorbance reader.
  - No longer able to modify values in the reader selection grid

## WinKQCL® Software v6.2.0 Revisions

### Released December 2021

The 6.2.0 release (version 6.2.0.42) of the WinKQCL® Software is a minor feature release designed to address targeted expanded function. It was not a widely distributed release and

nor is it officially validated. The components of this release are validated in the WinKQCL® Software v6.3.0 project. When upgrading to this version the client application will need to be uninstalled then reinstalled with the patch. The following changes have been made:

- Support added for the WinKQCL® Software PyroTec® HT Software Module.
- Updated installer technology to replace a legacy component.

## WinKQCL® Software v6.1.0 Hotfix 1 Revisions

### Released February 2022

The 6.1.0 Hotfix 1 release (version 6.0.1.61) of the WinKQCL® Software is a minor patch release designed to address targeted defects. This installer may be used to update earlier versions of the software or perform a new installation. The database version will not be impacted by this patch. The following changes have been made:

- Users will now be prompted to authenticate and an audit action will capture when attempting to skip the incubation phase of a test.
- Correct permissions check when accessing the Global Options dialog.
- Enhanced robustness for the PyroTec® PRO System initialization process.
- Added filter options for the audit report to include automation actions.
- Action for PyroTec® PRO System audit entries will now correctly be displayed.
- Audit type and file-set are now appropriately set when signing PyroWave® XM Reader system tests.
- Improved robustness of upgrade logic from pre 5.3 databases.
- Improved the WinKQCL® Record Counter's ability to connect to servers with non-standard configurations.
- Command line parameter to connect the WinKQCL® Software to an alternate database is now working appropriately.
- Database Tool will now correctly display version information when registry values are not set.
- Database tool will now extract information from databases with entered credentials opposed to the WinKQCLInternal account.
- Schedule maintenance task to verify the state of the database is now correctly displaying database check.

## WinKQCL® Software v6.1.0 Revisions

### Released April 2021

The 6.1.0 release (version 6.1.0.60) of the WinKQCL® Software is a minor feature release targeted at Localization, modernizing legacy components and expansion of the PyroTec® PRO System. This installer may be used to update earlier versions of WinKQCL® Software v6 or perform a new installation. The following changes have been made:

- General System Configuration and Usage
  - Resolved display issues with exported reports.
  - The system is now able to function when the WMI service is disabled.

- Interfaces will now correctly display, regardless of DPI and zoom settings, within Windows®.
  - Cutoff filters are correctly handled again for the SpectraMax™ M series and Gemini™ readers.
  - Able to correctly trend on robot serial number.
  - Message regarding non-monotonic curves has been reworked to remove the term “invalid”.
  - Re-optimized indexes to improve load times of test records
  - Adjusted the PowerCurve™ Solution algorithm to more consistently display back predictions when an inflection point was outside the range of the model, but near the high or low standard
- Database
    - Migration utilities will now be backwards compatible to WinKQCL® Software v4 databases. Procedures are available for more legacy systems.
    - The database tool is now able to merge remote databases again.
    - Archive is re-implemented in the system.
    - When deploying a standalone installation on a 64-bit system, SQL Server® 2019 Express is now used.
    - Database tool server and instance names fields consolidated into a single field.
    - Record counter utility will now correctly detect PyroTec® PRO System assays.
  - PyroTec® PRO System Software Module
    - The pressure leak test has been added to the system.
    - PyroTec® PRO System Software Module is now localized and will be displayed in the same language as the WinKQCL® Software.
    - Expanded configurations for sample preparation will allow premixing samples.
    - Logging added for the Warmup-Test.
    - Now able to select which position and reader an assay will be performed.
    - The system is now able to perform automated PyroGene® Assays via a side-mounted PyroWave® XM Reader addition to the PyroTec® PRO System deck.
    - The system is now able to perform uniformity tests for the Kinetic-QCL® Assay, PYROGENT® 5000 Assay and PyroGene® Assay.
    - The system is now able to handle a wider array of samples to include medical instruments and samples measuring endotoxin units per units other than just milliliter.
    - Added feedback and notifications when parameters need to be adjusted.

## WinKQCL® Software v6.0.2 Hotfix 1 Revisions

### Released December 2020

The 6.0.2 Hotfix 1 release (WinKQCL® version unchanged, PyroTec® PRO version 2.0.23.0) of the WinKQCL® Software is a minor patch release of only the PyroTec® PRO System Software Module to address unexpected limitations in the system. This installer may be used to update

earlier versions of the PyroTec® PRO System Software Module or perform a new installation. The core WinKQCL® Software will remain unmodified and WinKQCL® Software v6.0.2 can be installed as normal. The following changes have been made:

- Ability to control multiple PyroTec® PRO Systems on an enterprise installation.
- Consistently load un-configured products in the Product Configuration interface.

## WinKQCL® Software v6.0.2 Revisions

### Released June 2020

The 6.0.2 release (version 6.0.2.69) of the WinKQCL® Software is a minor patch release targeted at Localization and system compatibility. This installer may be used to update earlier versions of WinKQCL® Software v6, or perform a new installation. The following changes have been made:

- General System Configuration and Usage
  - Localization is reintroduced into the primary WinKQCL® Software application. It is now usable in the following languages: English, French, German, Japanese, Italian, Portuguese, Spanish, Simplified Chinese, and Traditional Chinese
  - AER Parameters and Template Defaults may now be configured at the Workgroup level permitting different labs on the same installation to have distinct capabilities.
  - The algorithm for the generation of installation codes used to generate LNO (lot number override) codes is now updated to provide easier to read codes.
  - The reset supervisor to factory defaults will now correctly reset the expiration period of the default SUPERVISOR account.
- Endotoxin Tests
  - Signature lines appear again for unsigned tests on assays that are configured to display the signature section on every page.
  - Auto export to LIMS is now working correctly again.
  - Print separate is refactored to generate the intermediate reports in memory only allowing the printing to occur quicker and the algorithm to be more robust.
  - Accessories will no longer display false in the comment field on the test report.
  - The Alert Limit setting will no longer trigger an alert when the limit is undefined.
  - Results generated time will now correctly assign the end of the test and not the start of the test for new runs.
- Database
  - Compatibility is added for SQL Server® 2016, 2017 and 2019.
  - Merge functionality is migrated to the WinKQCL® Software Database Tool from an independent utility.
  - Collision count for products will now factor in all the primary keys.
  - Now compatible with systems where TLS 1.0 is disabled.
- PyroTec® PRO System
  - Module is re-optimized to account for larger datasets and higher latency.
  - Correctly pipettes non-unique samples onto the plate.

- Updated screen transition logic for updated assays to mitigate the risk of errors and application hangs.
- Incubators may now be used in locales where the decimal delimiter is a comma.
- Able to handle truncated curves where the high standard is more than one dilution step from the stock endotoxin solution.
- Updated liquid handling configurations to minimize the risk of droplets and reduce variance.
- Ability to run a split configuration where one assay is Kinetic-QCL<sup>®</sup> Assay and the other is PYROGENT<sup>®</sup> 5000 Assay.
- Embedded Inline filter test into test runs to ensure system functionality.
- Uniformity tests run by PyroTec<sup>®</sup> PRO System will now be classified as such.

## WinKQCL<sup>®</sup> Software v6.0.1 Revisions

### Released September 2019

The 6.0.1 release (version 6.0.1.11) of the WinKQCL<sup>®</sup> Software is a minor patch release targeted at instrument and system compatibility. This installer may be used to update earlier versions of WinKQCL<sup>®</sup> Software v6, or perform a new installation. The following changes have been made:

- Compatibility with the PYROGENT<sup>®</sup> 5000 Assay for the PyroTec<sup>®</sup> PRO System
- Compatibility with PyroWave<sup>®</sup> XM basecode version 2.18.
- Compatibility with Windows Server<sup>®</sup> 2019 with Desktop Experience.
- Improved compatibility of the simple SQL Server<sup>®</sup> 2014 Express installation.
- New configuration option to suppress power warnings.
- New configuration option to prevent modifying User Ids.
- Updated test reports to include units on various fields.
- Optimize database upgrade procedures to take up less space.

## WinKQCL<sup>®</sup> Software v6.0.0 Hotfix 1 Revisions

### Released June 2019

The 6.0.0 Hotfix 1 release (version 6.0.0.74) of the WinKQCL<sup>®</sup> Software is a minor patch release targeted at instrument and system compatibility. This installer may be used to update WinKQCL<sup>®</sup> Software v6.0.0, or perform a new installation. The following changes have been made:

- Compatibility with PyroWave<sup>®</sup> XM basecode version 2.17.
- Display date/time information with the standard method on the Calculator report.
- Display temperature data to only 1 decimal on the uniformity test report.
- Ensure the term used for filtering Automation audit tasks is consistent between the interface and the report.
- Improve the robustness of the system while Lot Number Override codes are not in use.
- Correctly warn supervisors of failed log in attempts on their account.
- Trigger the security alert status bar notification at the appropriate time.

## WinKQCL<sup>®</sup> Software v6.0.0 Revisions

### Released March 2019

The 6.0.0 release (version 6.0.0.73) of the WinKQCL<sup>®</sup> Software is a major new release. Several new features were added to this version of the WinKQCL<sup>®</sup> Software. Significant changes and additions to the software in four primary categories: Automation, Data Integrity, User Interface and General. For information regarding minor changes and defect fixes, refer to the WinKQCL<sup>®</sup> Software validation documentation.

- Automation
  - The software system is now able to handle an optional add-on for the PyroTec<sup>®</sup> PRO System, a fully automated, walkaway endotoxin testing solution driven by WinKQCL<sup>®</sup> Software.
  - Track the lifecycle from when a test is created, run, and analyzed.
  - Analytics geared towards the automated platform with adjustments based on pipetting speed.
- Data Integrity
  - Introduce audit entries for the following activities:
    - Associating or dissociating accessories from users.
    - Creation, modification, or removal of accessories, preset curves, products, and templates.
    - System usage identifying user authentications or logout events.
  - Updated audit reports with more fine grain filtering capabilities, and displaying audit parameters on the report.
  - Introduction of system configuration, workgroup, and reader reports for quick and easy qualification.
  - Provide additional metadata with optional comments on accessories.
  - Display at a glance access time and analysis time on test reports.
- User Interface
  - Updated interface with new soft color palette.
  - Quick access to Lonza's QC Insider<sup>®</sup> and e-Shop.
  - Color override on the template list makes it easier to find out of date templates.
- General
  - Track alert limits to see when a sample is approaching an action point.
  - Add trend on alert and release limits to the ad hoc trending module.
  - Configurable shake time for assays to accommodate different SOPs and workflows.
  - Increased user Id and name field lengths.
  - Additional guides to assist when software or configuration issues occur.



## WinKQCL<sup>®</sup> Software v5.3.4 Hotfix Revisions

### Released October 2019

The 5.3.4 Hotfix release (version 5.3.4.34) of the WinKQCL<sup>®</sup> Software is a minor patch to address critical defects in the 5.3.4 release. This installer may be used to update any release from WinKQCL<sup>®</sup> Software v4.0.0 through WinKQCL<sup>®</sup> Software v5.3.4, or to perform a new installation. This is cumulative and includes all updates through the WinKQCL<sup>®</sup> Software v5.3.4 release. The following changes were made:

- When running a PyroGene<sup>®</sup> Assay the settings window will be displayed again, and the settings will be properly applied to the assay.
- RSE:CSE test records will now always be able to open.

## WinKQCL<sup>®</sup> Software v5.3.4 Revisions

### Released January 2019

The 5.3.4 release (version 5.3.4.33) of the WinKQCL<sup>®</sup> Software is a minor feature release targeted at improving the PyroWave<sup>®</sup> XM Reader experience and continuous improvement. This installer may be used to update any release from WinKQCL<sup>®</sup> Software v4.0.0 through WinKQCL<sup>®</sup> Software v5.3.3 with Hotfix releases, or to perform a new installation. This is cumulative and includes all updates through the WinKQCL<sup>®</sup> Software v5.3.3 with Hotfix release. The following changes were made:

- Expand the LDAP integration to permit explicit server, port, and secure layer settings.
- Provide the checksum information for the PyroWave<sup>®</sup> XM Reader on its System Test report.
- Installation on Windows Server<sup>®</sup> 2016 with Desktop Experience is now supported.
- The system shall now come with the 2.12.28 USB to Serial FTDI driver.
- The system shall now track the selected Workgroup and Time zone information while performing a merge of a data older than version 5 within the merge log file.
- When determining whether a %CV meets specification, the calculated %CV rounds to two decimal places prior to comparing it to the specification, previously it compared the unrounded %CV to the specification.
- The correct offset shall now appear while utilizing Irish Standard Time.
- The sensitivity test shall open appropriately when there are three or more warnings.
- Merge logs shall now correctly indicate the number of collisions of accessories while performing the logical join of the two data sets.

## WinKQCL<sup>®</sup> Software v5.3.3 with Hotfix Revisions

### Released August 2017

The Version 5.3.3 with Hotfix release of the WinKQCL<sup>®</sup> Software is a minor release resolving an issue where the time stamp for the reviewer signature was displaying the timestamp of the analyst signature on the BioTek<sup>™</sup> ELx808<sup>™</sup> system test report in the initial 5.3.3 release. This installer may be used to update any release from WinKQCL<sup>®</sup> Software v4.0.0 through the WinKQCL<sup>®</sup> Software v5.3.3 release, or perform a new installation. This is cumulative and includes all updates through the WinKQCL<sup>®</sup> Software v5.3.3 release.

## WinKQCL® Software v5.3.3 Revisions

### Released June 2017

The 5.3.3 release (version 5.3.3.25) of the WinKQCL® Software is a minor feature release targeted at additional reader functionality, continuous improvement, and meeting customer requirements. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.3.2 release, or perform a new installation. This is cumulative and includes all updates through the WinKQCL® Software v5.3.2 release. The following additional changes were made:

- WinKQCL® Software will correctly display the Database version in the Audit log version section instead of the WinKQCL® Software version.
- WinKQCL® Software will now be able to handle additional special characters for complex SQL Server® user passwords.
- WinKQCL® Software will now require more hard drive space for a merge and will warn if that amount of space is not available on the system.
- The Trending report will now display its UTC offset.
- The User List print report will now correctly display offsets for time zones with negative offset values.
- Added compatibility for displaying the offset on reports where the Time Zone is +/- half hours ex +5:30.
  - Additional support added for PyroWave® XM Reader basecode versions up to 2.15.
- The Z-Height will read at the correct value now for PyroWave® XM Readers.
- During the PyroWave® XM Reader System Test, incubation will be set.
- Fluorescence Uniformity Tests will report the Z-Height when appropriate now.
- The FLx800™ reader Sensitivity value will round instead of taking the floor value.
- The OD Validation plate test is now displaying the correct data in wells (OD instead of mOD).
- The overflow flow alerts on the sensitivity report will now display at the correct time.
- MVD Exceeded will now be based off the low standard of the stored curve opposed to the concentration of the reference point on the assay.
- A warning message will now appear for IQ tests when a standard reacts out of order.
- The R-value warning message will now use the AER values from the time the test was run opposed to fixed values.
- The global option "Highlight failed assays in list" has been renamed to "Highlight assays with out-of-specification standard curve or alerts", as the feature does not explicitly highlight failed tests.
- The German translation will correctly display 400 V on the PyroWave® XM Reader System test.
- The AER Parameter dialog in the Spanish language has been reworded to be consistent throughout the software.
- The French translation will have corrected word wrapping on reports.

- In regards to a change in v5.3.2 regarding Alerts being changed to be based off of Single Wells instead of the Average, we have made the following improvements:
  - There will be a configuration option in Global Settings, which will default to the pre v5.3.2 methodology.
  - For IQ Tests
    - The Blanks / Standards will be analyzed on a single well basis (Not Configurable)
  - For Routine / RSE-CSE / Inhibition Enhancement tests
    - Blanks / Low Standard will be analyzed based on the configuration option (configuration will default to average)
    - Other Standards will be based on the average (Not Configurable)

## WinKQCL® Software v5.3.2 Revisions

### Released January 2017

The 5.3.2 release (version 5.3.2.20) of the WinKQCL® Software is a minor feature release targeted at additional reader functionality, continuous improvement, and meeting customer requirements. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.3.1 release, or perform a new installation. This is cumulative and includes all updates through the WinKQCL® Software v5.3.1 release. The following additional changes were made:

- The LIMS Import feature has been expanded to classify data by workgroup, and to search through the worklist in the template interface.
- Audit messages will now track the version the action occurred.
- The software version the report is displayed in will now be displayed on all test reports.
- The software version in which the test calculations were made will now be tracked for all endotoxin tests. This value will not be filled in for any historical records that were not recalculated.
- Other tests and validation tests will now evaluate all data in the version in which it was originally run (impacted tests are the BioTek™ ELx808™ System Test, BioTek™ FLx800™ System Test, BioTek™ ELx808™ Absorbance Plate Test, and the BioTek™ Sensitivity Test while the PyroWave® XM Reader was being used).
- Signature comments will now correctly appear on the BioTek™ Synergy™ 2/Eon™ Absorbance Test Report.
- The record counter utility can now handle database names up to 255 characters.
- Improved robustness of the automatic LIMS export.
- Improved robustness of the merge utility.
- Overcome plate jam while utilizing a mix of the hardware and software controls of the PyroWave® XM Reader.
- Filter fluorescence on the PyroWave® XM Reader System Test will be correctly handled in all locales.
- Integrity Check has been renamed Database Check under scheduled tasks.

- Changes to significant figures while modifying a template or test record will now properly register as a change and be saved back.
- Template names may now be 60 characters in length.
- Alerts for reactions occurring out of order on endotoxin tests will now be based off individual replicates rather than averages.
- Alerts for reactions of blanks occurring before a standard will now be based off individual replicates rather than averages.
- A 20% CV full plate specification has been added to the Sensitivity Test.
- The Sensitivity Test will no longer consider a sensitivity value valid if the read for any of the replicate wells overflowed.
- The Sensitivity Test will now provide alerts when there are invalid sensitivity values, or when the CV is out of specification.

## WinKQCL® Software v5.3.1 Revisions

### Released July 2016

The 5.3.1 release (version 5.3.1.50) of the WinKQCL® Software is a minor feature release targeted at additional reader functionality, continuous improvement, and meeting customer requirements. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.3.0 release, or perform a new installation. This is cumulative and includes all updates through the WinKQCL® Software v5.3.0 Maintenance Update 1 release. The following additional changes were made:

- The help document will be accessible in the same languages as the software.
- The system will no longer require SQL Server® Program to restart to enable the CLR component during the installation and database deployment procedures.
- The specifications around the Sensitivity Test for the PyroWave® XM Reader are reworked to better accommodate the instrument's dynamic range.
- The PyroWave® XM Reader will now be able to incubate correctly when a lid is on the microplate. The lid still must be removed prior to any optical reads.
- The PyroWave® XM Reader will have additional configuration options opened to the user allowing for configuration of the bulb intensity, z-height and splitting the default for time between reads between the FLx800™ and PyroWave® XM Readers. It is recommended to run the assay with the defaults provided.
- After a test is run, if the low standard is masked and a new low standard is implicitly defined, the software will now utilize the new value for MVD calculations.
- The application will no longer crash when attempting to cut the contents of an empty cell in the product grid in the template manager.
- Upgrading a client from WinKQCL® Software v4.0.3 will now correctly assign a default instance and be able to connect to an upgraded server without a workaround.
- The system shall now support the Microsoft® Windows® 10 Operating System.
- The system shall now support the SQL Server® 2014 database platform.
- Improved robustness of the active directory authentication.
- Improved robustness for connecting to the database server in enterprise environments.

- Improved robustness when loading the endotoxin test list in an archive database.
- Test records with "<", ">", or "&" in their names will now display correctly on the raw data report.
- Negative shifts in OD value will now be displayed correctly in the assay zoom feature.

## WinKQCL<sup>®</sup> Software v5.3.0 Maintenance Update 1 Revisions

### Released March 2016

The 5.3.0 Maintenance Update 1 release (version 5.3.0.146) of the WinKQCL<sup>®</sup> Software is a minor release targeted at specific defects that originated from changes in the 5.3.0 software release. This installer may only be used to update the WinKQCL<sup>®</sup> Software v5.3.0 release. This is cumulative and includes all updates through the WinKQCL<sup>®</sup> Software v5.3.0 release. The following additional changes were made:

- Fix an issue where the Y-Intercept To and From specifications were sometimes not properly copied to the Kinetic-QCL<sup>®</sup> Assay or PYROGENT<sup>®</sup> 5000 Assay test records, resulting in the Y-intercept reporting FAIL when it should have reported PASS.
- The Fluorescence Uniformity Test Report will now properly display the delta RFU and column CV values.

## WinKQCL<sup>®</sup> Software v5.3.0 Revisions

### Released February 2016

The 5.3.0 release (version 5.3.0.145) of the WinKQCL<sup>®</sup> Software is a minor feature release, targeted at additional reader functionality, continuous improvement, and meeting customer requirements. This installer may be used to update any release from WinKQCL<sup>®</sup> Software v4.0.0 through the WinKQCL<sup>®</sup> Software v5.2.1 Maintenance Update 3 release, or perform a new installation. This is cumulative and includes all updates through the WinKQCL<sup>®</sup> Software v5.2.1 Maintenance Update 3 release. The following additional changes were made:

- In the event of a non-monotonic curve, instead of falling back directly to linear regression, PowerCurve<sup>™</sup> will now reduce the power of the polynomial regression.
- The system will now carry additional precision for intermediate values while calculating the result values.
- The raw data zoom feature will now be accessible for signed tests.
- The software help was converted from CHM to PDF format.
- Filter set and block names will now properly be displayed for Lonza's PyroWave<sup>®</sup> XM Reader and BioTek's Synergy<sup>™</sup> 2 readers.
- Allow a PMT Gain value as low as 25 for the PyroWave<sup>®</sup> XM Reader.
- PyroWave<sup>®</sup> XM Reader interface no longer allows users to try to set the read position to a bottom read setting.
- Default PyroGene<sup>®</sup> Assay slope specifications updated to reflect new Lonza specifications.
- Workgroups may now be renamed.
- Identical template name may now be used across multiple Workgroups.

- New “SYSTEM” workgroup introduced for classifying audited activities that influence the installation at a global level.
- Improved auditing for LIMS export activities.
- Restoring and backing up archive databases is now audited.
- Performance improvements introduced for archive and merge procedures.
- Reports now able to be opened in all regional and time zone combinations.
- Reduced load time for the Record Audit and Security Audit reports.
- Able to filter Record and Security Audit reports by all accessible workgroups.
- Time zone offset for reports is now properly identified for all time zones and in daylight savings time.
- PPCs with unreacted replicates will now be classified as FAIL for the %PPC recovery result.
- Exceeding MVD for instrument samples will now be correctly identified.
- Modifications to blank wells will now be properly classified as modified on endotoxin test reports.
- Absorbance Plate Test report no longer displays Read 2 information in the accuracy section when the test was executed in a language other than English.
- Comments and descriptions for endotoxin test reports are now split into two sections for added clarity.
- Release limits are now included on the report for template products.
- New users now able to view historical archived data.
- Improved classification and logging for duplicate records during the Merge procedure.
- Certificate of Analysis interface no longer freezes if the desired CoA is already open.
- Resolved repaint issue when opening tests from the endotoxin test list or trending results.
- Trending will now display correctly when Windows is not set to display text at 100%.
- Integrity check now works correctly for systems using SQL Server® 2012 platform.
- Now able to schedule an integrity check when a backup has never been scheduled.
- Increased the size of the fields for entering electronic signature comments.
- Print template report no longer loses unsaved template information when there is a validation error.
- Record counter utility now reports information on all collections mentioned in the merge utility.
- In the presence of a instrument error, kinetic graphs will no longer overlap each other.

## **WinKQCL® Software v5.2.1 Maintenance Update 3 Revisions**

### **Released June 2015**

The 5.2.1 Maintenance Update 3 release (version 5.2.1.11) of the WinKQCL® Software is a minor patch that is targeted at resolving defects in the software. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.2.1 Maintenance Update 2 release to WinKQCL® Software v5.2.1 Maintenance Update 3, or

perform a new installation. This is cumulative through the WinKQCL® Software v5.2.1 Maintenance Update 2 release; in addition, the following changes were made:

- While calculating the MVD for an instrument, the Potency value field in the calculator can no longer be modified.
- In the calculator, a MVC will no longer be calculated for instruments.
- Consistent translations will be used between the calculator interface and report.
- In the calculator, endotoxin limits for Systemic and Intrathecal instruments will now appear correct.

## WinKQCL® Software v5.2.1 Maintenance Update 2 Revisions

### Released April 2015

The 5.2.1 Maintenance Update 2 release (version 5.2.1.9) of the WinKQCL® Software is a minor patch that is targeted at resolving defects in the software. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.2.1 Maintenance Update 1 release to WinKQCL® Software v5.2.1 Maintenance Update 2, or perform a new installation. This is cumulative through the WinKQCL® Software v5.2.1 Maintenance Update 1 release; in addition, the following changes were made:

- When running an endotoxin test and PowerCurve™ is the default regression model in the AER Parameters configuration interface, the test will now correctly apply the selected regression model.
- When a signature is applied to an endotoxin test, the Analyst and Reviewer can make a comment about the test. This comment is saved and displayed at the end of the report. This comment will now be duplicated to the audit trail and log summary section in case the Analyst signature is unlocked, then reapplied before the Reviewer signs, which would have previously caused the comment to be overwritten.
- The button label “Remove E-Signature” has been changed to “Unlock E-Signature”.

## WinKQCL® Software v5.2.1 Maintenance Update 1 Revisions

### Released December 2014

The 5.2.1 Maintenance Update 1 release (version 5.2.1.8) of the WinKQCL® Software is a minor patch that is targeted at resolving defects in the software. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.2.1 release to WinKQCL® Software v5.2.1 Maintenance Update 1, or perform a new installation. This is cumulative through the WinKQCL® Software v5.2.1 release; in addition, the following changes were made:

- Calculator and AER configuration interfaces will now work properly when the decimal indicator is a comma.
- Sample counts for master products will now be correctly displayed when viewing or editing products.
- Concentrations for master products will no longer append an extra zero when being added to a template.
- IQ tests will now properly show the Standards AER section of the report when selected.

- On absorbance endotoxin reports, the execution time for tasks will now correctly adjust for daylight saving time.

## WinKQCL® Software v5.2.1 Revisions

### Released November 2014

The 5.2.1 release (version 5.2.1.6) of the WinKQCL® Software is a minor release that is targeted at resolving performance issues for large data sets and other defects in the WinKQCL® Software v.2.0 software. This installer may be used to update any release from WinKQCL™ 4.0.0 through the WinKQCL® Software v5.2.0 release to WinKQCL® Software v5.2.1, or perform a new installation. This is cumulative through the WinKQCL® Software v5.2.0 release; in addition, the following changes were made:

- Optimized update time for analyzing or editing endotoxin tests.
- Increased timeout values throughout the software.
- Improved data propagation while using a robotic workflow.
- Add number of reads for tests run using a robotic workflow.
- For “LIMS export”, provide a feature to allow dates to be converted to local time zones.
- Increased robustness of the new Endotoxin Tests list.
- Tests will correctly display reader errors when a hardware error occurs.
- Able to place standards while in place mode and editing a template.
- No longer able to double-click a reader to modify it while logged in with a user that does not have the *Manage Readers* permission.
- Increased the number of decimals for various fields in the calculator.

## WinKQCL® Software v5.2.0 Revisions

### Released August 2014

The 5.2.0 release (version 5.2.0.123) of the WinKQCL® Software is a minor feature release, targeted at additional reader functionality, continuous improvement, and meeting customer requirements. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.1.2 Maintenance Update 6 release to WinKQCL® Software v5.2.0, or perform a new installation. This is cumulative through the WinKQCL® Software v5.1.2 Maintenance Update 6 release. The following additional changes were made:

- Reworked calculator interface for ease-of-use and reporting capabilities.
- AER interface updated for ease-of-use.
- Merge utility updated to improve performance, and allow remote execution.
- Users are now able to merge archive databases back into the primary database.
- New interface under Help to look up a Certificate of Analysis for a kit.
- The Units field allows up to 30 characters, up from 8.
- The Product Lot Number field allows up to 40 characters, up from 20.
- Support added for the Lonza PyroWave® XM Fluorescence Reader.
- Users are able to rerun test data with different options, or process data from a foreign source with the Virtual Reader feature.



- Support added for Microsoft® SQL Server® 2012.
- Support removed for Microsoft® SQL Server® 2005, Windows® XP, Windows® Vista, Windows Server® 2003, and Windows Server® 2008.
- Custom export location for LIMS export now may be defined when exporting.
- Now able to check a reader's temperature from the reader list. Previously a user would have to initiate an assay to do so.
- Enhanced temperature control for the Tecan® Sunrise™ reader.
- The temperature of a reader now must be in the range of 36.5 to 37.5°C in order to initiate an assay.
- Users may now run other users' templates without creating a copy of it first.
- Now able to zoom in on particular wells while reviewing kinetic data and running kinetic assays.
- Additional columns added to the template list to track when a template was last modified and if it contains expired accessories or reagents.
- Templates now automatically open for edit following a copy.
- Template names are now prepopulated with the existing template name when copy is clicked.
- Max number of replicates is increased from 6 to 24.
- While clicking Edit Assay or View Template for an Endotoxin test, the Plate Layout will now be correctly populated.
- The Endotoxin Test list will now only display tests run within the last month by default. Filter options may still be modified to display all of the tests.
- Failed Endotoxin Tests will now be displayed in red in the Endotoxin Test list. A global option is present to disable this feature.
- Users are now able to hide/show the Reader Parameters, Log Summary and Accessories sections on an Endotoxin Test report.
- All test reports will now display failing results in red.
- In the AER Parameters feature, users can control which report options are selected by default.
- Users can define a shake time when running Quick Read tests.
- Absorbance Uniformity test reports now display the assay parameters.
- Absorbance Uniformity test raw data reports will now display the raw data graph.
- Now able to trend on the fluorescence sensitivity (PMT Gain) setting.
- Trending control limits are now inferred from AER parameters.
- Now able to filter columns displayed on a trending report.
- Trending qualifiers will now automatically filter out items to select based on already selected qualifiers.
- Locked out users are now displayed as red on the user list.
- Various permissions have now been abstracted out from the primary roles into fine-grain permissions.

- Various naming and functional inconsistencies were resolved to improve ease of use and reduce confusion.
- Various localization and globalization improvements were made to accommodate the global footprint of WinKQCL® Software.
- Accessories uniqueness constraint will now correctly check against name, lot number, and workgroup, instead of just name, and lot number.
- Audit entries for cancelled Endotoxin tests will now record the workgroup with which the test was associated.

## WinKQCL® Software v5.1.2 Maintenance Update 6 Revisions

### Released January 2014

The WinKQCL® Software v5.1.2 Maintenance Update 6 release (version 5.1.2.53) is a minor patch that is targeted at resolving defects in the software. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.1.2 Maintenance Update 5 release to WinKQCL® Software v5.1.2 Maintenance Update 6, or perform a new installation. This is cumulative through the WinKQCL® Software v5.1.2 Maintenance Update 5 release; in addition, the following changes were made:

- The Release Limit Status will now classify a sample as passing when tested at MVD and using the less than comparison operator and the sample did not react.

## WinKQCL® Software v5.1.2 Maintenance Update 5 Revisions

### Released December 2013

The WinKQCL® Software v5.1.2 Maintenance Update 5 release (version 5.1.2.52) is a minor patch that is targeted at resolving defects in the software. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.1.2 Maintenance Update 4 release to WinKQCL® Software v5.1.2 Maintenance Update 5, or perform a new installation. This is cumulative through the WinKQCL® Software v5.1.2 Maintenance Update 4 release; in addition, the following changes were made:

- The Release Limit Status will no longer classify a sample utilizing the “less than” comparison operator as failing when it did not react.
- When one of the PPCs replicates does not react: the average reaction time for the corresponding product samples will now show the average reaction time; the %PPC Recovery will now be listed as “N/A”; and instead of the Endotoxin recovery being displayed it will display “Invalid Recovery”.

## WinKQCL® Software v5.1.2 Maintenance Update 4 Revisions

### Released November 2013

The WinKQCL® Software v5.1.2 Maintenance Update 4 release (version 5.1.2.51) is a minor patch that is targeted at resolving defects in the software and expanding support to the Windows® 8 operating system. This installer may be used to update any release from WinKQCL® Software v4.0.0 through the WinKQCL® Software v5.1.2 Maintenance Update 3 release, or perform a new installation. This is cumulative through the WinKQCL® Software v5.1.2 Maintenance Update 3 release; in addition, the following changes were made:

- Updated the FTDI USB to serial (RS232) drivers to the latest Microsoft® WHQL certified version (v 2.08.30).
- Added support for the Microsoft® Windows® 8 operating system (Ultimate, Professional and Enterprise Editions).
- Correct time between reads will be displayed for PyroGene® Assays while running in Australian Eastern Standard Time.
- Rounding will now be consistent for the % PPC Recovery between the LIMS export and the test report.
- Time zone information now appears on the endotoxin test reports.
- A crash will no longer occur when a user modified a template on one computer and ran the test on another computer at the same time.
- Failed logins for Active Directory users will no longer preemptively lock out the user Windows® account.
- All failed logins will now be audited for all users, instead of only users with the supervisor role.
- Classification for whether or not the MVD was exceeded for a sample will now be correct.
- Removing a signature on an endotoxin assay as a different user than the user logged in will now result in subsequent actions during that session of WinKQCL® Software being attributed to the user performing the action.
- Version headers for non-test reports will now display the major, minor, and update version number level (Example: 5.1.2).
- The sort order for the PPCs and Samples in the product summary section of an endotoxin report is now consistent.

## WinKQCL® Software v.1.2 Maintenance Update 3 Revisions

### Released July 2013

The WinKQCL® Software v5.1.2 Maintenance Update 3 release (version 5.1.2.49) of the WinKQCL® Software is a minor patch update that must be installed after WinKQCL® Software v5.1.2 is already installed. This update can be installed on top of WinKQCL® Software v5.1.2 if Maintenance Update 1 or Maintenance Update 2 are already present. This patch cannot be installed on WinKQCL® Software v5.1.1 or earlier. In addition to changes in the Maintenance Update 1 update, the following changes were made:

- The Eon™ System Test was only working on the “C” model of the Eon™ Reader. This update adds compatibility with the Eon™ standard model.
- In trending, fixed an issue where some test results would not be returned at the limits of a defined date range.
- In trending, round RFU and reaction time values to whole numbers.
- Fixed an issue where alignment data for the absorbance plate test on BioTek™ Synergy™ 2 and Eon™ Readers was rounding to a whole number.
- Fixed an issue where errors from readers (such as a 23xx error from a BioTek™ ELx808™ Reader) may not be interpreted by the software properly and may cause WinKQCL® Software to freeze instead of being read into the audit trail (this issue was introduced in WinKQCL® Software v5.1.2).

## WinKQCL® Software v5.1.2 Maintenance Update 2 Revisions

### Released July 2013

The 5.1.2 Maintenance Update 2 release (version 5.1.2.48) of the WinKQCL® Software is a new **installer** release that must be installed in place of the standard WinKQCL® Software v5.1.2 installation or upgrade. Maintenance Update 2 includes Maintenance Update 1. In addition to changes in Maintenance Update 1, the following changes were made:

- Fix issue where Microsoft® SQL Server® Express installations were failing for WinKQCL® Software Standalone Server configurations in some locals (example: Microsoft® Windows® 7 running in Japanese).
- Improvement to installation scenarios where the installer requested excessive restarts.

## WinKQCL® Software v5.1.2 Maintenance Update 1 Revisions

### Released May 2013

The WinKQCL® Software v5.1.2 Maintenance Update 1 release (version 5.1.2.47) of the WinKQCL® Software is a minor patch release that must be installed after WinKQCL® Software v5.1.2 is installed. This patch cannot be installed on WinKQCL® Software v5.1.1 or earlier. This Maintenance Update is only needed if WinKQCL® Software v5.1.2 is already installed and there is an issue with non-ASCII characters not allowing the evaluation screen to be displayed. The following change is implemented with this Maintenance Update:

- Fixed an issue where the evaluation screen would cause WinKQCL® Software to crash on systems with non-ASCII characters in the computer name (example: Japanese Kanji characters).

## WinKQCL® Software v5.1.2 Revisions

### Released April 2013

The 5.1.2 release (version 5.1.2.46) of the WinKQCL® Software is a minor feature release, targeted at improving existing features in the software. Significant changes and additions to the software are described below. For detailed information regarding all enhancements and defect fixes, refer to the WinKQCL® Software validation documentation.

- Wide area network performance improvements were implemented in many dialogs in the software through better user interface handling of brief network disconnects. If a network disconnect occurs, many dialogs that gave error messages before, will now rebuild their connection to the database.
- Improvements and fixes to translations for most languages in both the user interface and reports. See the validation documents for details on each change.
- Resolve issues caused when a comma is set as the decimal indicator in Windows® regional settings. See the validation documents for details on each change.
- Add the ability to back up the database directly from the database tool when upgrading the WinKQCL® Software database schema on a server.
- WinKQCL® Software database tools can now be run on Windows® servers where the FIPS encryption security policy is enabled.
- While utilizing the trending feature, users will no longer see qualifier information from workgroups that they do not use.

- Improvements were made to the overall user experience through changes to error messages, user interface instructions/responses, reports and audit trail entries. See the validation documents for details on each change.
- Fix to an issue where clicking the save button a second time while the Edit Assay feature was in the process of saving could disrupt the save in process, causing unexpected results.
- Fix to an issue with Inhibition/Enhancement templates, where copying or inserting products that had "Allow multiple dilutions" enabled, was not copying all of the dilutions.
- Fix to an issue where a master product created with a concentration less than 1 would cause a hang in the Template Manager.
- Fix to the uniformity test report where two fields in the header of the report were reversed.
- Fixed an issue with results reports where multiple templates were run on one plate. If wells were masked on more than one template, the masked well indicator notes would only appear on the last template edited.
- Fix a hang that could occur when selecting multiple templates to run on one plate if both templates start position is the same column with one template using automatic layout and the other using a custom layout.
- Fixed an issue where WinKQCL<sup>®</sup> Software would crash if the status for the last user in the list were set to inactive.
- Fixed an issue where switching from a WinKQCL<sup>®</sup> Software-managed to an Active Directory-managed password would not clear out the password expiration setting and the user would see messages that their password was going to expire.
- Fixed a rare issue where maximizing the template window on Windows<sup>®</sup> XP under specific conditions could cause the software to close unexpectedly.
- Fixed a rare issue where division of a value resulted in a number that ended in exactly 5 at the 4<sup>th</sup> significant figure could sometimes round down instead of up.

## WinKQCL<sup>®</sup> Software v5.1.1 Revisions

### Released October 2012

The 5.1.1 release (version 5.1.1.43) of the WinKQCL<sup>®</sup> Software is a minor feature release, targeted at improving existing features in the software. Significant changes and additions to the software are described below. For detailed information regarding all enhancements and defect fixes, refer to the WinKQCL<sup>®</sup> Software validation documentation.

- To meet customer requirements in cases where customers prevent execution of non-essential applications on corporate servers, the WinKQCL<sup>®</sup> Software database utility used for creating and upgrading databases has been enhanced to allow users to run the utility from a remote system.
- To meet customer requirements that restrict sysadmin permissions on their corporate database servers to a very limited number of user accounts, the WinKQCL<sup>®</sup> Software database utility will now execute scripts using only the authentication mode and the account selected. In some cases, if a specific account was selected, portions of the script may have run with a SQL account or with the logged in Windows<sup>®</sup> account and would be unsuccessful if the sysadmin permissions had been revoked for those accounts.

- WinKQCL® Software v5 helps to ensure correct expiration dates are entered when entering Limulus Amebocyte Lysate (LAL) and recombinant Factor C (rFC) lot numbers. This release resolves an issue where certain lots, although labeled with the correct lot number and expiration date, were not recognized as valid.
- Resolved minor issues when scanning a 2D barcode on a Lonza reagent vial in order to enter lot number and expiration date information.
- WinKQCL® Software will now show Sample Raw EU when that sample's PPC has replicate wells that did not react.
- Fix an issue where, when viewing an endotoxin test report where "Include AER in Results Tables" format is selected and the "%CV" is selected to be displayed, the %CV result for the sample replicates is shown in the PPC %CV column.
- Date and time formats in WinKQCL® Software will now infer their format according to the currently configured Windows® regional settings.
- Installer instructions tell the user to enter a strong password, however the installer still allowed weak passwords to be entered, resulting in an unsuccessful SQL Server® installation. The WinKQCL® Software installer will not continue if the password is not a strong password.
- In the Absorbance Plate Test Report, the label "Read 1" is incorrect in two locations on the report.
- In the Sensitivity and Fluorescence Uniformity Test reports, some minor formatting issues were corrected.
- Resolve translation/localization problems in the trending feature.

## WinKQCL® Software v5.1.0 Revisions

### Released July 2012

The 5.1.0 release (version 5.1.0.52) of the WinKQCL® Software is a minor feature release, targeted at additional reader functionality. Significant changes and additions to the software are described below. For information regarding minor changes and defect fixes, refer to the WinKQCL® Software validation documentation.

- Support for the BioTek™ Eon™ Reader.
- Capability to configure Mirrors and Filters for the BioTek™ Synergy™ 2 Multimode Reader.
- Display reader basecode information on the Synergy™ 2 Multimode Reader System Test.

## WinKQCL® Software v5.0.0 Revisions

### Released May 2012

The 5.0.0 release (version 5.0.0.256) of the WinKQCL® Software is a major new release. Several new features were added to this version of the WinKQCL® Software. Significant changes and additions to the software are described below. For information regarding minor changes and defect fixes, refer to the WinKQCL® Software validation documentation.

- Installation and Setup
  - Registration code storage moved to the database allowing activation of all clients with one code. The installation and registration codes are now visible in the "About WinKQCL®" dialog.

- Improved support for database only installations on existing SQL Server® Servers with SQL Server® instances not named “WinKQCL®”.
- Drivers for the FTDI chip-based USB to Serial adapter (Lonza P/N 25-361) are now included on the WinKQCL® Software setup disk.
- In reader setup, when using the reader “discover” feature, users can specify reader type and baud rate to speed up discover process. To determine which COM port a reader is connected to, a new “identify reader” feature can be used when more than one reader is discovered.
- For Server installations where Microsoft® SQL Server® is not pre-installed, WinKQCL® Software will install Microsoft® SQL Server® 2008 SP1 Express Edition.
- Corporate IT/Database/Network-Related
  - Support for Microsoft® Active Directory integration. Users can link WinKQCL® Software user accounts to the corresponding Microsoft® Windows® domain account and use their Windows® user ID and password.
  - WinKQCL® Software can be configured to allow Single Sign On. If turned on, this feature allows the Windows® authentication to be passed through to WinKQCL® Software so the user is automatically recognized once they log in to Windows® and they do not need to type in their Windows® password a second time when they log in to WinKQCL® Software.
  - Full Citrix® application virtualization support of WinKQCL® Software with readers connected. Reader communication can be passed through the network connection. WinKQCL® Software can be run through thin clients.
  - Wide area network (WAN) support added. Significantly improved network performance for WinKQCL® Software clients communicating over slow or long-distance connections. Removed communication traffic for background reader status. In areas of the software where WAN connections caused the software to run slow, client traffic with the server was reduced by up to 96%.
  - Support for segregating data by workgroups. Existing databases can be merged into a single database and user accounts, products, readers, etc. can be assigned to a new or existing workgroup. Different endotoxin testing labs at sites on the same corporate network can share the same server and database and data can be kept separate by assigning each lab its own workgroup.
  - Time Zone awareness added. Dates and times will be stored in UTC format (GMT equivalent). WinKQCL® Software will detect which time zone client computers are running in and adjust to local times. WinKQCL® Software will adjust database times based upon user input when upgrading and merging databases.
  - Importing product and worklist information from a LIMS, LIS, or EM system is now supported.
  - Added Character Separated “CSV” format as an option when exporting product data to a LIMS, LIS, or EM system.
  - Support for scripted installations through corporate IT software management systems.
- General Improvements
  - Menu item for list of open dialogs allows fast switching between open WinKQCL® Software dialogs.

- Simplified and Traditional Chinese languages added.
- Many new options are now available when configuring user roles and access to workgroups and software features. The User Maintenance interface has been redesigned and improved with a tabbed dialog interface. Helpful “infotips” are displayed as you move the mouse cursor over features.
- When updating a master accessory, the analyst may now update the lot number, expiration date and calibration date for all matching template accessories.
- Setting up a Test (Template/Product/Accessory-related)
  - When a central EM, LIMS, or LIS interface is made with WinKQCL<sup>®</sup> Software, product worklist information is visible from within the Template Manager and users can drag and drop this information directly onto the template product list.
  - The *United States Pharmacopeia* (USP) Products Table has been updated to USP 34 NSF29 S1 and FDA Appendix E information has been removed.
  - Users can drag a single master product with multiple dilutions or concentrations defined onto a template. This single action will automatically create one template product for each dilution or concentration defined.
  - Additional fields added to the Master Products feature. In addition to the Product Name, Units, Release Limit and a single dilution or concentration, now WinKQCL<sup>®</sup> Software can also store the Product Lot Number, Product ID, release limit “≤” or “=” logic, Positive Product Control concentration, and multiple product dilutions or concentrations for a single product.
  - In the Template Manager, the automatic layout feature was enhanced to allow users to control the replicate direction and fill direction separately for the products, the positive product controls and the standards. Users can change the sort order of the standard curve and insert additional standards, blanks (negative controls), and empty wells.
  - In the Template Manager, it is easier to navigate the product grid without using a mouse. The Template Manager is more responsive. CTRL + TAB can be used to navigate the tabbed dialogs.
  - In the Template Manager, users can print the 96-well plate layout graphic to the actual microplate size and set the microplate on top of the printed graphic.
  - WinKQCL<sup>®</sup> Software v4.0.3 and higher allows users to scan reagent lot number and expiration dates into WinKQCL<sup>®</sup> Software from 2D barcodes on Lonza reagent vials. WinKQCL<sup>®</sup> Software v4.0.3 requires that the fields are empty when scanning lot numbers. WinKQCL<sup>®</sup> Software v 5 is able to overwrite fields that already contain lot numbers and expiration dates.
  - In the Template Manager, users can search and filter the master product list.
  - Product and standard concentration lower limits reduced from 0.0001 to 0.000000001.
- Running a Test
  - If multiple readers are set up with one computer, multiple analysts can run tests from that single WinKQCL<sup>®</sup> Software session. WinKQCL<sup>®</sup> Software will track the individual analyst accounts against the concurrently running tests.
  - A new Kinetic SmartStop feature allows users to configure the software to wait for standards, and/or blanks to react before stopping the test. A split product



replicate detection feature can be enabled to wait for all replicates of a product to react before stopping the test.

- Support for the Molecular Instruments® 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.
- Support for the BioTek™ Synergy™ 2 multimode reader.
- Audible notifications now sound after the pre- incubation step and at test completion.
- For the BioTek™ System tests, you are warned if the incubator temperature has not reached its set-point.
- Update BioTek™ absorbance plate test to match new repeatability, alignment and accuracy specifications. Add support for running BioTek™ 7-filter absorbance test plates on BioTek™ readers that have monochromators. Allow entry of up to eight different center peak wavelengths and upper and a lower bandpath specifications.
- Reviewing Data
  - Improved the report load speed up to four times faster the first time a report is opened.
  - In the edit assay feature, users can now fix layout mistakes as well as add and delete accessories.
  - WinKQCL® Software can be configured to allow an analyst to edit and sign another analyst's test.
  - A reviewer can reject a test signed by an analyst and the analyst's signature can be removed and reapplied as many times as needed to correct mistakes. Once all mistakes are corrected, both the analyst and reviewer can sign the test.
  - Feature added to show and hide sections of the endotoxin test report. Users can show and hide individual products. Users can choose to print each product as a separate report with one click.
  - The ability to query and trend standard data. Concentrations, CVs, reaction times, relative fluorescent units have been added to the qualifier list in the trending feature.

## WinKQCL® Software v4.0.4 Revisions

### Released October 2012

The 4.0.4 release of the WinKQCL® Software is a minor patch release that must be installed after WinKQCL® Software v4.0.3 is installed. This patch cannot be installed on WinKQCL® Software v4.0.2 or earlier. Existing features were improved and defects were fixed as described here:

- WinKQCL® Software v4.0.3 helps to ensure correct expiration dates are entered when entering Limulus Amebocyte Lysate (LAL) and recombinant Factor C (rFC) lot numbers. This release resolves an issue where certain lots, although labeled with the correct lot number and expiration date, were not recognized as valid.
- Resolved minor issues when scanning a 2D barcode on a Lonza reagent vial in order to enter lot number and expiration date information.

## WinKQCL® Software v4.0.3 Revisions

### Released November 2011

The 4.0.3 release of the WinKQCL® Software is a maintenance release. Existing features were improved and defects were fixed as described here:

- Portuguese translation added.
- All reports, including audit entries were translated into all currently supported languages (English, French, German, Italian, Spanish, Japanese, and Portuguese).
- The manual and help files were translated into all currently supported languages.
- The installer has been translated into all currently supported languages.
- The OD validation test was improved to allow use of any of the selected reader's installed filters.
- Japanese characters can be displayed on trending graphs.
- Reader manager improved for WinKQCL® Software networks with many active readers.
- Tests using stored curves will run to the full number of reads.
- Compatibility with SQL Server® 2005 SP4 introduced.
- Introduced compatibility with Citrix Presentation Server™ version 4.5 with Maintenance Update Rollup Pack 5 and higher (including Citrix® XenApp®).
- Compatibility with Windows® 7 SP1 and Windows Server® 2008 R2 SP1 introduced.

## WinKQCL® Software v4.0.2 Revisions

### Released May 2010

The 4.0.2 release of the WinKQCL® Software is a maintenance release. Existing features were improved and defects were fixed as described here:

- Minor defects were fixed and the user interface was improved.
- Protection against data loss due to database connection failures was increased.
- The Master Products list in the Template Manager can be sorted by name.
- Compatibility for SQL Server® 2008 was introduced officially. The 64-bit editions of SQL Server® 2008 are also supported.
- Compatibility with 64-bit editions of SQL Server® 2005 was introduced.
- Database Deployment Tool was introduced. This tool allows the WinKQCL® Software database to be deployed to instances of SQL Server® not named "WinKQCL". This tool also allows the WinKQCL® Software database to be deployed, but the application does not need to be installed. This tool allows the WinKQCL® Software to work with existing or new instances of SQL Server®.
- Compatibility with Windows® 7 and Windows Server® 2008 R2 was introduced.

## WinKQCL® Software v4.0.1 Tecan® Freedom EVOware® 2.3 SP1 Compatibility Patch

### Released March 2010

Released as an update to version 4.0.1. No new features were added to this version of the WinKQCL® Software. This patch was released for computers that connect directly to the Tecan® robot and run version 2.3 SP1 of the Freedom EVOware® software.

## WinKQCL® Software v4.0.1 FLx800™ Driver Patch

### Released November 2009

Released as an update to version 4.0.1. No new features are added to this version of the WinKQCL® Software. This patch was released for computers that connect to the FLx800™ Readers. This patch resolved defects.

## WinKQCL® Software v4.0.1 Revisions

### Released August 2009

The 4.0.1 release of the WinKQCL® Software is a maintenance release. No new features were added to this version of the WinKQCL® Software. Existing features were improved and defects were fixed as described here:

- The WinKQCL® Software help was updated with approximately 350 predefined search words and phrases.
- The display of endotoxin test reports was improved:
  - Data on custom reports was aligned better.
  - Font size and style were made more consistent on some reports.
  - Spacing was reduced between sections to allow more products to fit on a page. Most initial qualification test configurations fit all data on the first page.
  - RSE/CSE font formats and data alignments were modified for better viewing.
  - The format of the product results section header was improved. The product ID information was added to the assay evaluation report (AER) summary section header.
- Template manager performance and overall functionality was improved. Users can add products between other products. Users can run tests directly from the template manager by using a "Save & Run" button. Several minor defects were fixed to improve stability.
- All known issues with installing the WinKQCL® Software on non-English versions of Windows® were fixed.
- Translations within the software were improved and defects related to running the WinKQCL® Software in some languages were fixed. Japanese strings are replaced with English strings on graphs due to issues with displaying unicode characters on graphs.
- Easier to use and intuitive validation test dialog box layouts. The BioTek™ absorbance plate test dialog box recalls previously entered data. Users do not have to reenter the same data every time the test is run.
- The trending feature was improved to show temperature data better. Trailing zeros are no longer cut off. Temperature, mean, standard deviation, and limit line accuracy was

increased to improve the appearance of the graph. Endotoxin results are now rounded to three significant figures instead of three decimal places.

- Several other minor defects were fixed throughout the WinKQCL® Software.

## WinKQCL® Software v4.0 Revisions

### Released March 2009

- The user interface was localized to French, German, Japanese, Italian, and Spanish. More languages will be available in the future.
- The WinKQCL® Software was integrated with the Tecan® Freedom EVoware® platform. The WinKQCL® Software templates can be plated automatically.
- The template manager was redesigned so that it is easy to create and edit a template.
- Added the ability to sort, search, and filter the templates and endotoxin results tables. Added the ability to sort and search the products table. Added the ability to sort many other tables.
- Added the ability to switch users without exiting the WinKQCL® Software.
- Redesigned the trending feature to be more flexible and intuitive. Added many new options to customize the plot and associated statistical analysis.
- Added a product I.D. field for template products.
- Added access to raw data, mask/unmask points, view/edit template, laboratory information management system (LIMS) export, and temperatures directly from the test report.
- Added option to export tests to LIMS automatically upon completion.
- Added a logon activity timer to reduce how often login is required (optional).
- Streamlined the electronic signature process.
- The endotoxin test reports load faster.
- Added the option to lock out analysts so that they cannot change template reader parameters.
- Added the ability to merge databases into a database with existing test records.
- Added new scheduled database maintenance features for integrity scanning and index defragmentation.
- Modernized the look and feel.
- Improved the microplate reader system in many ways, including these:
  - Smoother operation of other WinKQCL® Software features while a test is running.
  - Support for Tecan® Sunrise™ Reader.
  - Automatic discovery of connected readers.

## WinKQCL® Software v3.1 Revisions

### Released April 2007

- Performance was improved for dialog boxes and reports that display data from endotoxin tests.

- Audit entries are logged when assays begin. These log entries help to troubleshoot hardware issues that interrupt in-progress tests.
- The WinKQCL® Software User Maintenance table now displays the role of each user and allows you to hide or show inactive users.
- The software can be used for 14 days before you must enter a registration key.
- A new entry in the audit log allows tests to be recorded that started but did not finish due to power outages.
- WinKQCL® Software supervisors can now delete templates.
- Test reports were condensed to save resources and increase readability.
- The in-test graph is now reproduced on Raw Data reports.
- The database of the catalog of assays has been optimized, which boosts performance.
- Added the ability to create multiple accessories with the same name. (The lot numbers must be unique.)

## WinKQCL® Software v3.0.1 Revisions

### Released May 2006

- Dialog boxes, tables, and reports with databases that contain large numbers of records open much faster.
- The Computer Name Field accepts hyphens in the computer name.
- The compatibility for long date and time format and reports formatted for A4 paper was improved.
- Trending can include tests that have not been electronically signed.
- All reports are exportable as \*.pdf, \*.xls and tab-delimited \*.txt files.
- Supervisors can turn off the “FOR REVIEW ONLY” watermark and the “E-signature not applied” text on reports to allow ink-based signatures.
- The Reader Serial Number and Header columns were added to the Quick Read, QCL-1000, and validation tables.
- The user interface was improved, the performance was enhanced, and multithreading was added for the database Merge and Restore utility and for the database Archiving utility.
- The measured incubator temperature is displayed when a kinetic test is performed with a BioTek™ ELx808™ Reader.

## WinKQCL® Software v3.0 Revisions

### Released July 2004

- The version 2.0 and 3.0 databases can be merged together. A common database can be shared over a network in a client-server configuration.
- Full support is provided for the PyroGene® Recombinant Factor C (rFC) assay and the BioTek™ FLx800™ TBIE Fluorescence Plate Reader. The following PyroGene® Assays are supported: initial qualification, routine, inhibition/enhancement, and RSE/CSE tests. The following FLx800™ Validation tests are supported: sensitivity test, system test, and uniformity test.
- The BioTek™ Absorbance Test Plate was integrated.

- You can remove electronic signatures and apply the signatures a second time to allow editing of the template information.
- You can export records to LIMS via a parsable XML file.
- You can export reports to tab-delimited, Microsoft® Excel®, and PDF formats.
- You can save and rerun trending queries.
- You can export trending results in Microsoft® Excel® and PDF formats.
- The *United States Pharmacopeia* (USP) Listing was updated.
- Features of the accessories and template accessories were redesigned to allow a Master accessory list to be created. Users can create their own accessory defaults. You can access the master list from within the Template Manager.
- You can change the incubation temperature of the BioTek™ Reader.

## WinKQCL<sup>®</sup> Software v2.0 Revisions

### Released June 2002

- The WinKQCL<sup>®</sup> Software was migrated from 16-bit to 32-bit.
- Data can be stored in a relational SQL Server<sup>®</sup> 2000 database so that it can be managed and reviewed efficiently.
- 21 CFR Part 11 compliance (Technical Requirements) was added.
- Users are identified and controlled with multilevel passwords.
- You can sign records electronically.
- A record audit trail tracks when electronic records are created, modified, and deleted.
- A security audit trail tracks security-related events.
- You can multitask in the Windows<sup>®</sup> environment.
- You can view trends of historical data.
- Validation tools are provided to audit reader and analyst performance.
- You can program and edit user maintenance, products, accessories, and templates on-screen.
- The assay template can be saved for later use. (The assay template is a map of the layout of the blanks, standards, and samples on the microplate.) Previously defined templates can be recalled, which saves time for plate layouts that are run frequently. You can create automatic and custom microplate layouts.
- A Help section has been included for user reference.
- You can run more than one template on a microplate. Use the new template addition tool, which is referred to as “multiple-assays-per-plate”.
- You can view kinetic assay progress across the entire plate in real time on the screen.
- You can set specifications for various assay parameters with an AER. You can specify parameters such as correlation coefficient, slope, y-intercept, and %CV. Assay data is analyzed to determine the conformance of assay data to those specifications.

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