

PyroTec® PRO

Software user guide

(WinKQCL® Software version 6.5.1)

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Software user guide

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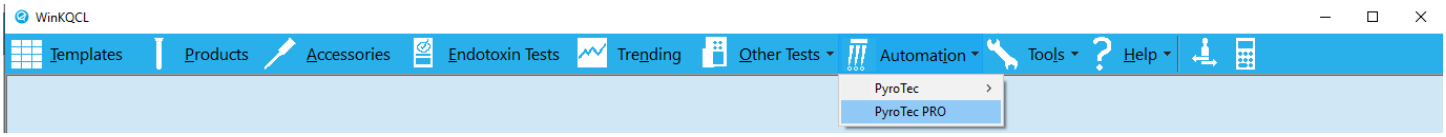
Introduction

Glossary

Term	Definition
LiHa	Liquid Handler Arm (the pipetting arm)
RoMa	Robotic Manipulator Arm (gripper arm)
DiTi	Disposable Tips, pipette tips
Aux Liquid	An auxiliary liquid defined by the user (e.g., an additive such as PYROSPERSE™ Dispersing Agent)
Grid	Location on the deck designated by the number labels on the front of the instrument
Site	Location on a labware carrier. Sites are numbered from back to front starting at Site 1
Position	Location within a labware item. Positions are numbered from back to front starting at Position 1

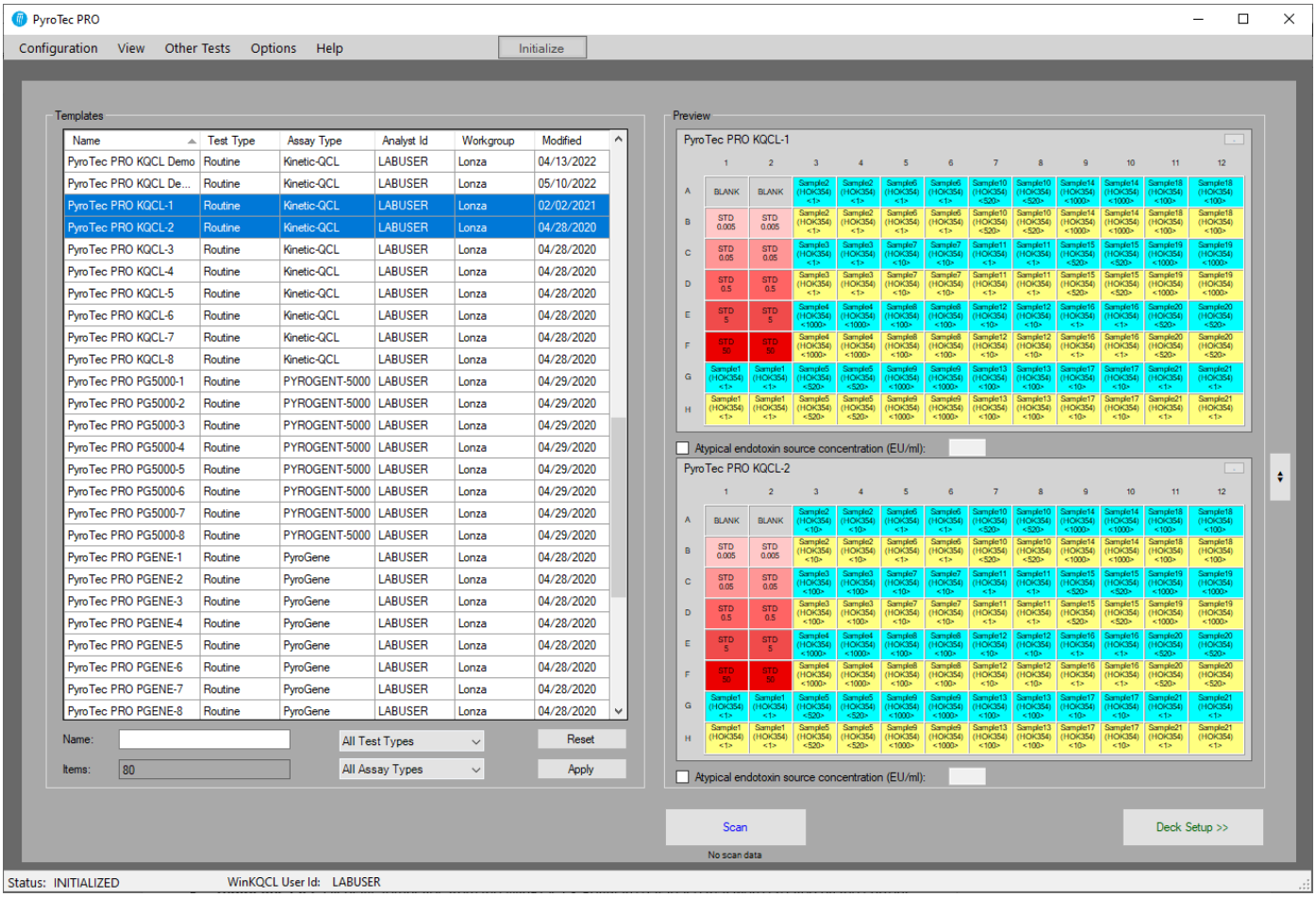
Overview

The PyroTec® PRO System provides an automated “walk-away” solution for performing Lonza endotoxin assays. The system functions as a “plug in” module for Lonza’s WinKQCL® Software. To launch the PyroTec® PRO System click **Automation | PyroTec PRO** on the main WinKQCL® Software toolbar.



Template Select

When the PyroTec® PRO System Software module is initially opened, the Template Select interface is displayed:



Controls

The interface provides the following features and functionality:

- **Initialize**: Initiates communications with the PyroTec® PRO System that is connected.
- **Status**: Displays the status reported by the PyroTec® PRO System that is connected.
- **WinKQCL User ID**: Displays the user currently logged into the WinKQCL® Software.
- **Templates List**: Displays templates from the WinKQCL® Software database that were created by the current WinKQCL® Software user. Lonza assay types Kinetic-QCL®, PYROGENT® 5000 and PyroGene® are supported. The following information is displayed for each template in the list:
  - **Name**: The name of the template.
  - **Test Type**: The test type, purpose, or objective (e.g., routine, initial qualification, RSE/CSE or inhibition/enhancement).
  - **Assay Type**: The type of chemistry used.
  - **Analyst ID**: The User ID of the analyst who created the template.
  - **Workgroup**: Lab group and/or location where the template was created.
  - **Modified**: Date the template was last modified.

The list is initially sorted by “modified” date (descending – most current at top of list). Click a column header (for reference see "Sortable Lists" in the WinKQCL® Software user guide) to sort the list. Up to two templates may be selected for an automated assay run. To select two templates, hold the CTRL key and click on the two desired templates in the list.

Search/Filter Controls

For instructions on applying the search/filter features to the Templates list, see "Search and Filter Controls" in the WinKQCL® Software user guide.

Template Preview

Displays the name and a graphical layout for each template currently selected in the Templates List. Templates may only be previewed. Template additions, deletions or modifications may only be applied in the WinKQCL® Software.

Atypical endotoxin source concentration (EU/mL)

Provides functionality to assign an endotoxin source concentration (i.e. CSE or RSE source vial for standard curve preparation) that is not typical for the type of assay currently displayed in the Template Preview. When the option is selected, a value for the endotoxin source concentration will be required in the associated entry field prior to performing an automated run. When the PyroTec® PRO System Software module determines that the template’s standard curve requires an atypical endotoxin source concentration, the option will automatically be selected.

The required endotoxin source concentration is determined to be ***typical*** when either of the following conditions are true:

- The highest standard on the standard curve is equal to the Default High Standard associated with the Assay Type (refer to the table below).
- The high standard on the standard curve can be derived by log10 serial dilutions relative to the Default High Standard.

When neither of the conditions above are true, the required endotoxin source concentration is determined to be ***atypical***.

Assay Type	Default endotoxin source concentration (EU/mL)	Default High Standard
Kinetic-QCL® Assay	50	50
PYROGENT® 5000 Assay	100	100
PyroGene® Assay	20	5

A default value for the atypical endotoxin source concentration may be configured per assay type (see: Configuration\System\Assays).

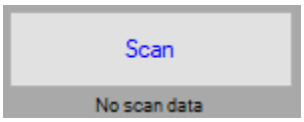
NOTE: When a default value is not configured/set for the atypical endotoxin source concentration, the system will display a zero (“0”) in the field. This must be manually updated by the analyst to the required endotoxin source concentration.

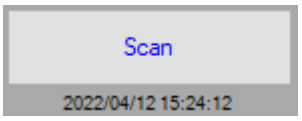
When the PyroTec® PRO System Software module determines that the template’s standard curve requires an atypical endotoxin source concentration the default value will automatically be assigned (but may still be modified manually).

Scan

Displays the Scan Barcodes interface.

A field just below the Scan button indicates scan status, “No scan data” if there is no scan data available, or the date/time of the most current scan for the current session. Examples:

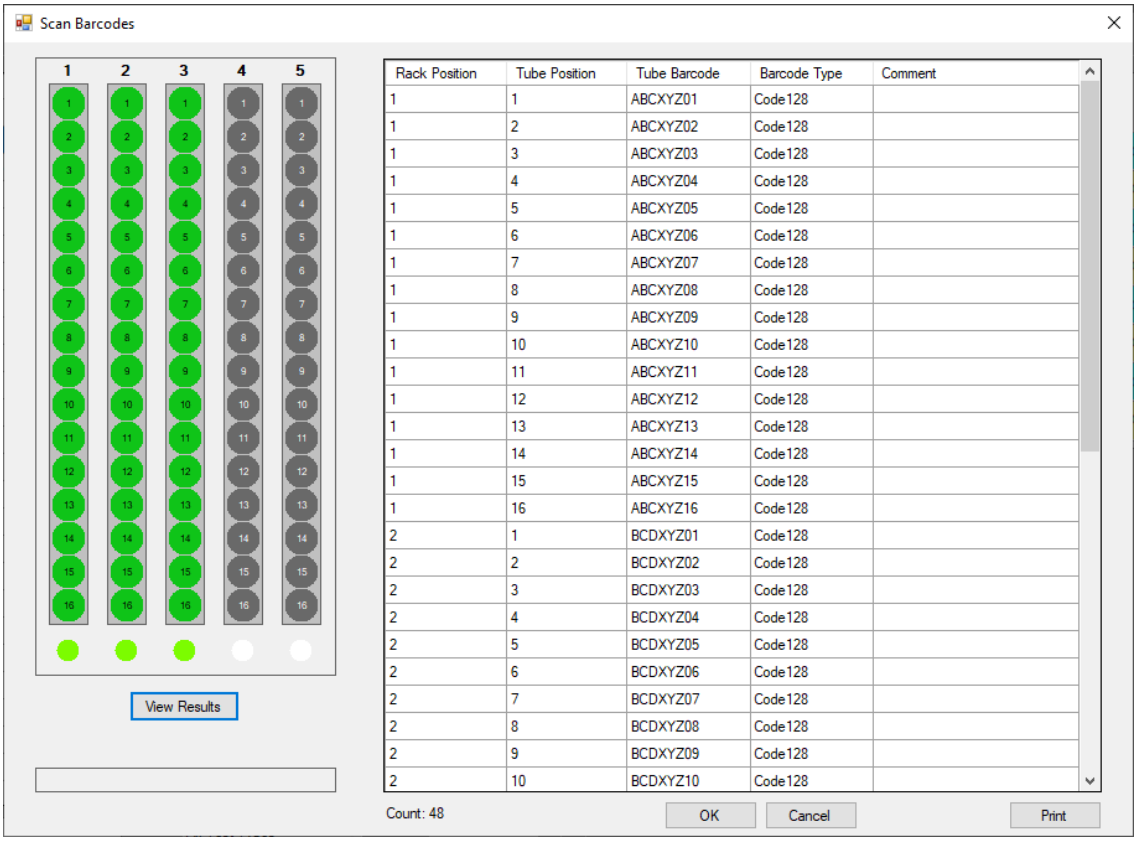




NOTE: This functionality is only available when the optional LoadingID barcode scanning unit is implemented in the system. The Scan Barcodes interface may be opened from both the Template Select interface and the Deck Setup interface using the Scan button present on the respective interfaces.

Scan Barcodes

The interface provides functionality to process a scan of sample tube barcodes using the LoadingID unit.



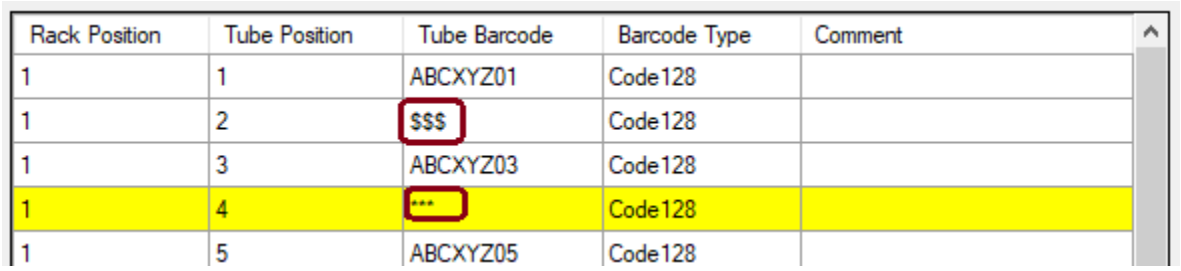
Controls

- **View Results**: After scanning the sample tube runners into the LoadingID, click this button to display the results of the scan.
- **Status**: Displays the status of the scan as the scan results are being processed.
- **Count**: Displays the number of barcode tubes scanned
- **Scan Results List**: Displays the results of the scan
- **Print**: Displays the results of the scan in a printable text file
- **OK**: Stores the scan results for processing and closes the interface (if no error conditions)
- **Close**: Closes the interface

Special case results

The following barcode scan results have special meaning:

- $$$ No barcode detected at position
- *** Barcode detected, but not readable

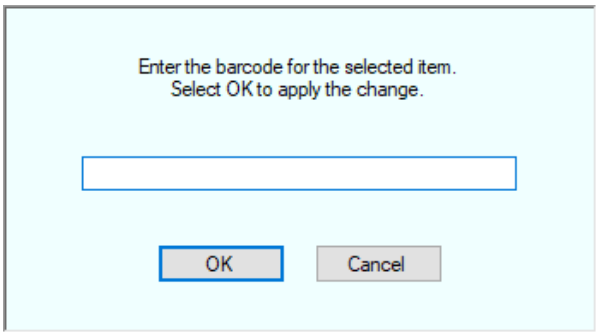


Rack Position	Tube Position	Tube Barcode	Barcode Type	Comment
1	1	ABCXYZ01	Code128	
1	2	$$$	Code128	
1	3	ABCXYZ03	Code128	
1	4	***	Code128	
1	5	ABCXYZ05	Code128	

In the example shown above:

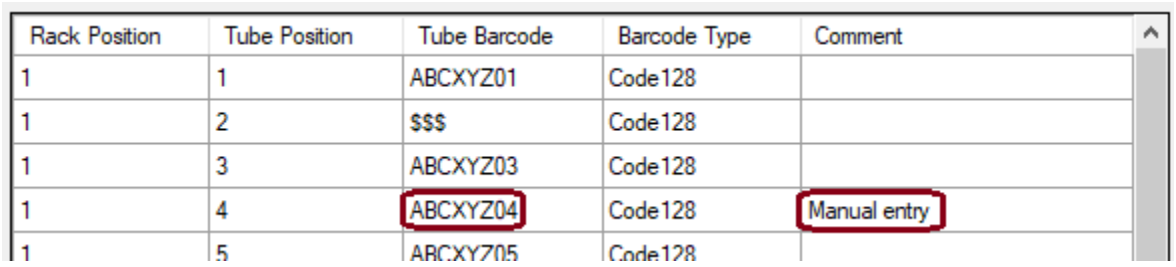
- There was no barcode detected at Runner 1 / Tube 2
- An unreadable barcode was detected at Runner 1 / Tube 4

For unreadable barcodes, functionality is provided to enter the barcode manually. Double click a row having an unreadable barcode to display the following interface:



Manually enter the barcode by typing it in on the computer keyboard, or by scanning the tube barcode into the field using a handheld barcode scanner, and then click OK to apply the change.

Example, if ABCXYZ04 is entered into the field, and then OK is clicked, the Tube Barcode is updated with the manually entered barcode, and the Comment field is updated to indicated that the barcode was entered manually:



Rack Position	Tube Position	Tube Barcode	Barcode Type	Comment
1	1	ABCXYZ01	Code128	
1	2	$$$	Code128	
1	3	ABCXYZ03	Code128	
1	4	ABCXYZ04	Code128	Manual entry
1	5	ABCXYZ05	Code128	

Return to TOC

Constraints

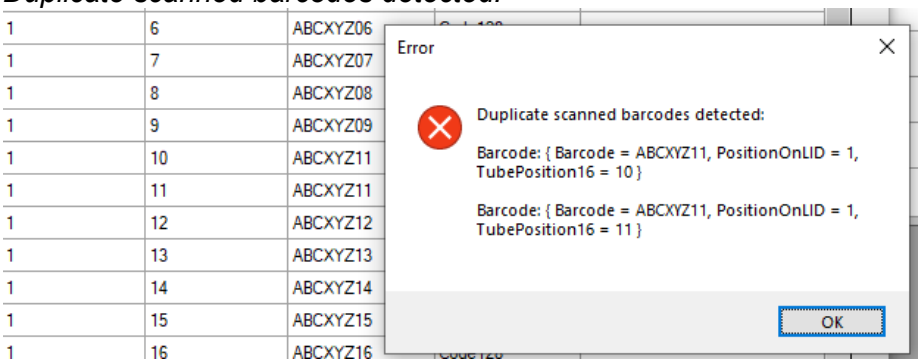
The following constraints are enforced by the system when the OK button is clicked:

- All unreadable barcodes (***) must be assigned a value
- All sample identifiers across all WinKQCL® Software template(s) selected for the run must be unique
- Each scanned barcode must be unique
- Each scanned barcode must match a sample identifier on the WinKQCL® Software template(s) selected for the run

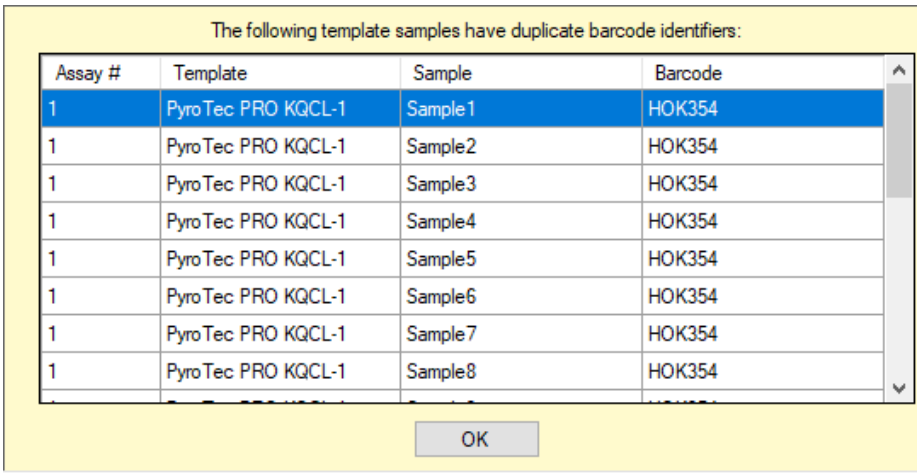
When one of the constraints is violated, a message will be displayed to indicate the error. The scan results will not be accepted by the system when there are constraint violations.

Constraint Violation examples

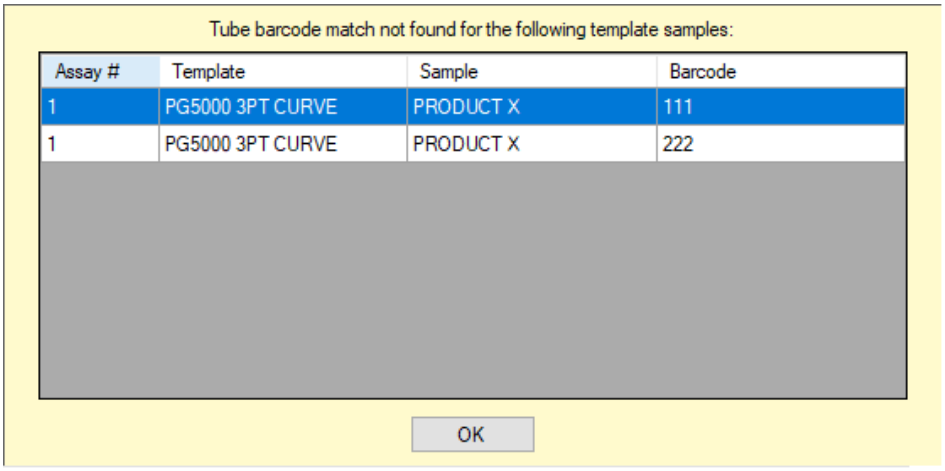
Duplicate scanned barcodes detected:



Duplicate sample barcode identifiers on template(s)



Barcode match not found for sample(s)



NOTE: The field on the WinKQCL® Software template to be used for the sample identifier is configurable. One of the following fields may be assigned: Name, Product ID, or Lot Number (*see:* *Configuration\System\LoadingID*)

Swap



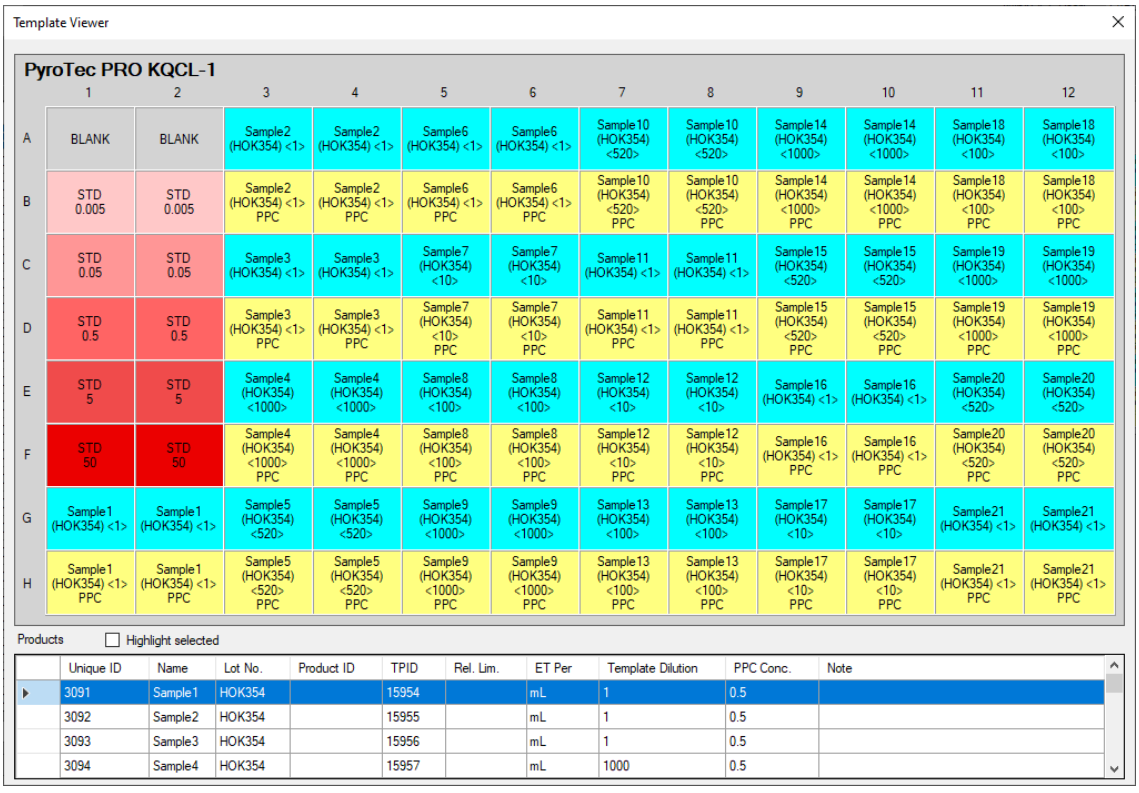
Click the Swap control to invoke the following functionality:

When a single template is displayed in the Template Preview, the template is toggled to the opposite display position (i.e., top/bottom). When two templates are selected in the Template Preview, the display positions of the templates are interchanged (i.e., “swapped”). Templates are processed in the order in which they are displayed in the Template Preview (top processed first and bottom processed second). The template display positions are associated with the following physical system readers:

Template Display Position	Incubator Position	Reader Position
Top	Back	Assay type KQCL/PYROGENT® 5000: Left on-deck reader Assay type PyroGene® Assay: Side-mounted reader
Bottom	Front	Assay type KQCL/PYROGENT® 5000: Right on-deck reader Assay type PyroGene® Assay: Side-mounted reader

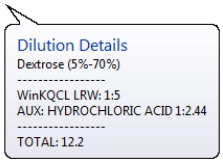
Template Expanded View

Click the Expanded View control  at the upper right of the individual template display interface to display an expanded view of the associated template. The Template Expanded View interface displays the name of the template in the upper left corner, and provides the following features and functionality:



- **Graphical Layout**: A graphic image containing details for each of the 96 wells of the plate. The image is larger than the template viewer from which the expanded view was launched.
- **Template Products List**: A selectable list of the products (i.e., samples) present on the template. The following (non-editable) information is displayed for each product in this list:

- **Unique ID**: A unique identifier automatically assigned by the WinKQCL® Software database. Provided to help easily distinguish products defined in the database.
- **Name**: The name of the product.
- **Lot No**.: The product's lot number.
- **Product ID**: Additional user-defined value to identify the product.
- **TPID**: Template Product Identifier. A template-specific identifier automatically assigned by the WinKQCL® Software database. The TPID identifies a particular product assigned to the microplate and the well locations (i.e., for sample replicates and PPC replicates) where the product is located. Provided to help easily distinguish product locations on the template.
- **Rel. Lim.**: Release limit of the product. Can be qualified with < or ≤.
- **EU Per**: Denominator of endotoxin unit of measure.
- **Template Dilution**: The dilution that will be applied to the product (i.e., final dilution according to what is specified on the WinKQCL® Software template). Right clicking on an item in the list displays the dilution details. For example:



- **PPC Conc.**: The concentration of the endotoxin spike to be added to the sample for positive product control (PPC).
- **Note:** A comment associated with the products on the template. When the software detects error conditions for products on the template, the errors are indicated in the Template Products list with messages and/or RED highlighted text.
- **Highlight selected**: When checked, the sample wells and PPC wells associated with the product selected in the list are highlighted.

Deck Setup

Navigates to the Deck Setup interface.

Deck Setup

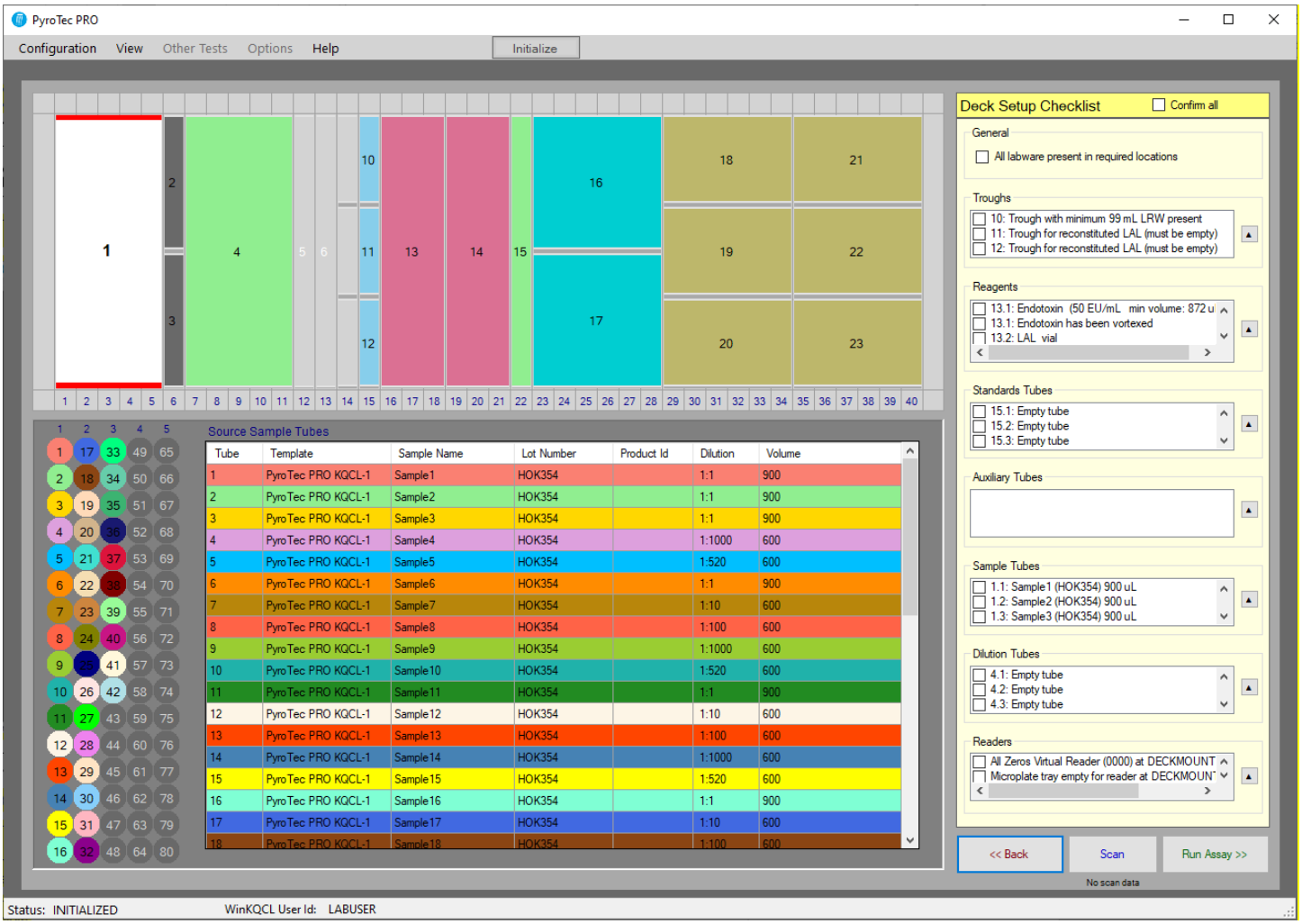
NOTE: If either of the conditions listed below is present, the PyroTec® PRO System by default, will not allow navigation to the Deck Setup interface:

1. Eight (8) hours or more has elapsed since the last Instrument Warm-up was performed
2. One week or more (i.e., 168 hours) has elapsed since the last Pressure Leak Test was performed

If either condition above is present, the respective operation will need to be completed prior to navigating to the Deck Setup interface.

The Deck Setup interface displays informative and instructive text and graphical information that defines the PyroTec® PRO System deck setup required to run the template(s) selected in the Template Select interface. The interface specifies the required locations for labware and liquids, as well as the volume required for each liquid. The content of the interface is generated dynamically based on the selected template(s).

The Deck Setup interface varies slightly for a system that implements a LoadingID versus a system that is implemented without a LoadingID.



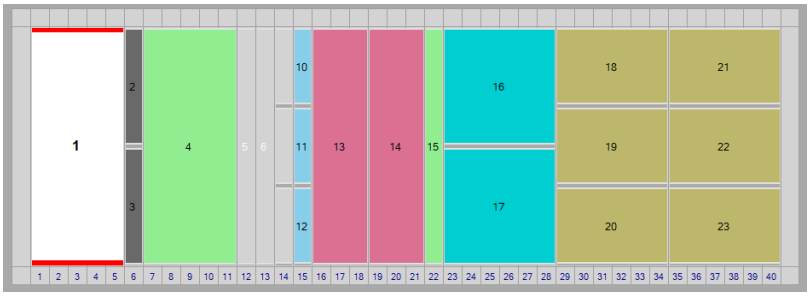
The Deck Setup interface consists of three sections: Deck Layout, Deck Labware Details, and Deck Setup Checklist. Each section is explained below.

Deck Layout

The Deck Layout section displays the labware layout on the PyroTec® PRO System deck in block form. Numbers at the bottom of the display correspond to physical grid numbers on the PyroTec® PRO System deck. Clicking on a labware block in the Deck Layout section displays details associated with the labware block in the Deck Labware Details section. In the image above, the Sample Tubes block (#1) is selected.

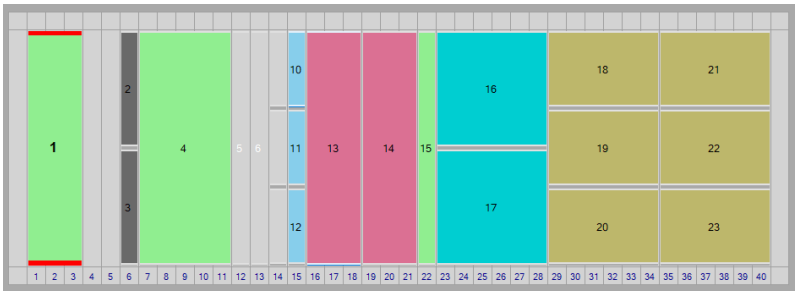
The Deck Setup section differs for a system with a LoadingID versus a system without a LoadingID as indicated below:

LoadingID Deck Layout



Samples Tubes are positioned at block #1 for this setup. The block consists of a set of 5 tube runners, and supports a maximum of 80 tubes. The tube runners are positioned on the LoadingID unit itself.

No LoadingID Deck Layout

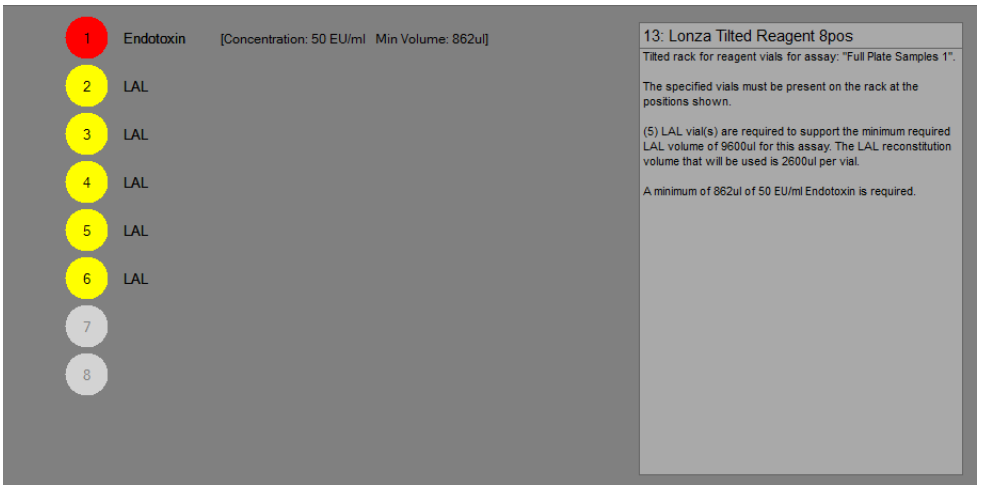


Samples are positioned at block #1 (Sample Tubes block) in this setup. The block consists of a set of 3 tube racks, and supports a maximum of 48 tubes. The tube racks are positioned directly on the deck of the instrument.

Deck Labware Details

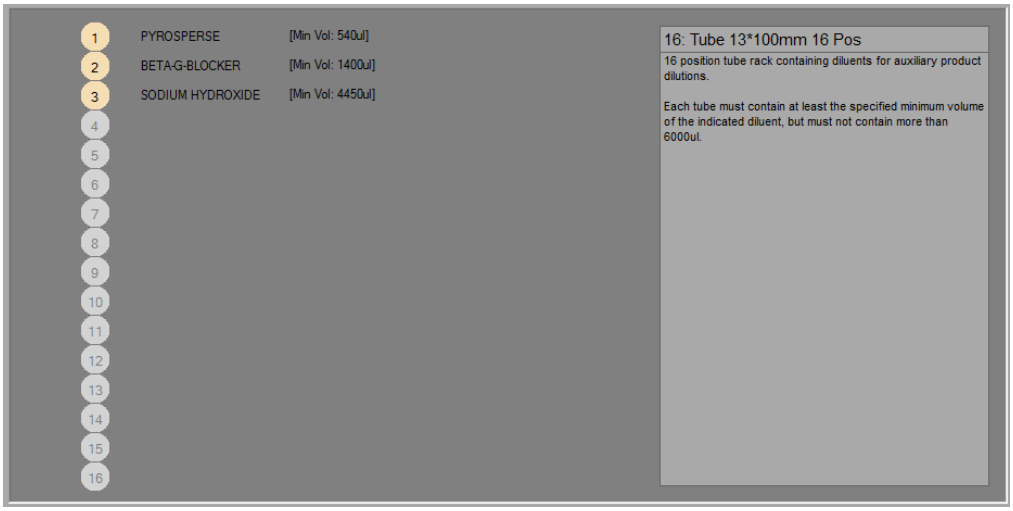
The Deck Labware Details section displays the details associated with the labware block selected in the Deck Layout section. Labware details are dependent on the WinKQCL® Software template(s) selected for the automated run.

The following example shows the information associated with a tilted reagent vial rack block (#13) in the selected Kinetic-QCL® Assay template:



The image above shows the number of reagent vials required, where the reagent vials must be positioned on the carrier, and the minimum volume and concentration of endotoxin required.

The example below assumes the template requires auxiliary liquids for sample treatment. The screenshot shows what is displayed when an Auxiliary Tubes rack block (#5 in this example) is selected:

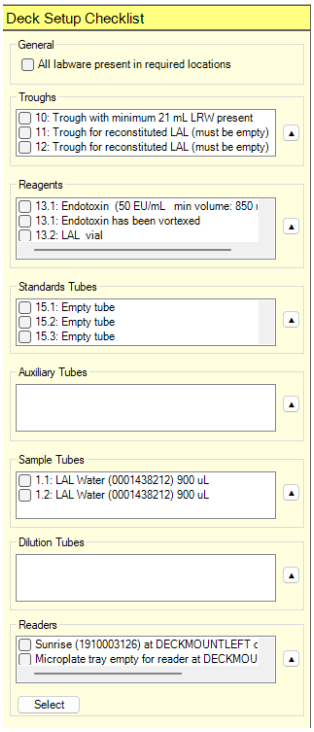


The information shows where tubes containing auxiliary liquids must be positioned on the tube rack, and the minimum volume required for each.

NOTE: Auxiliary liquids are required only for products that are configured to use them. Details for auxiliary liquids are only available for display when one or more products on a template are configured to use Auxiliary Liquids (see: *Products*, *Product Auxiliary Dilution Editor* and *Aux Liquids* for more information).

Deck Setup Checklist

The Deck Setup Checklist section displays a list of all required labware, required liquids and locations, and required liquid volumes. Each item in the list must be confirmed (i.e., checkbox must be checked) prior to proceeding to the next interface.



Select: Allows selection of non-default readers for each assay

<< Back

Navigates back to the Template Select interface.

Scan

See: Scan for details

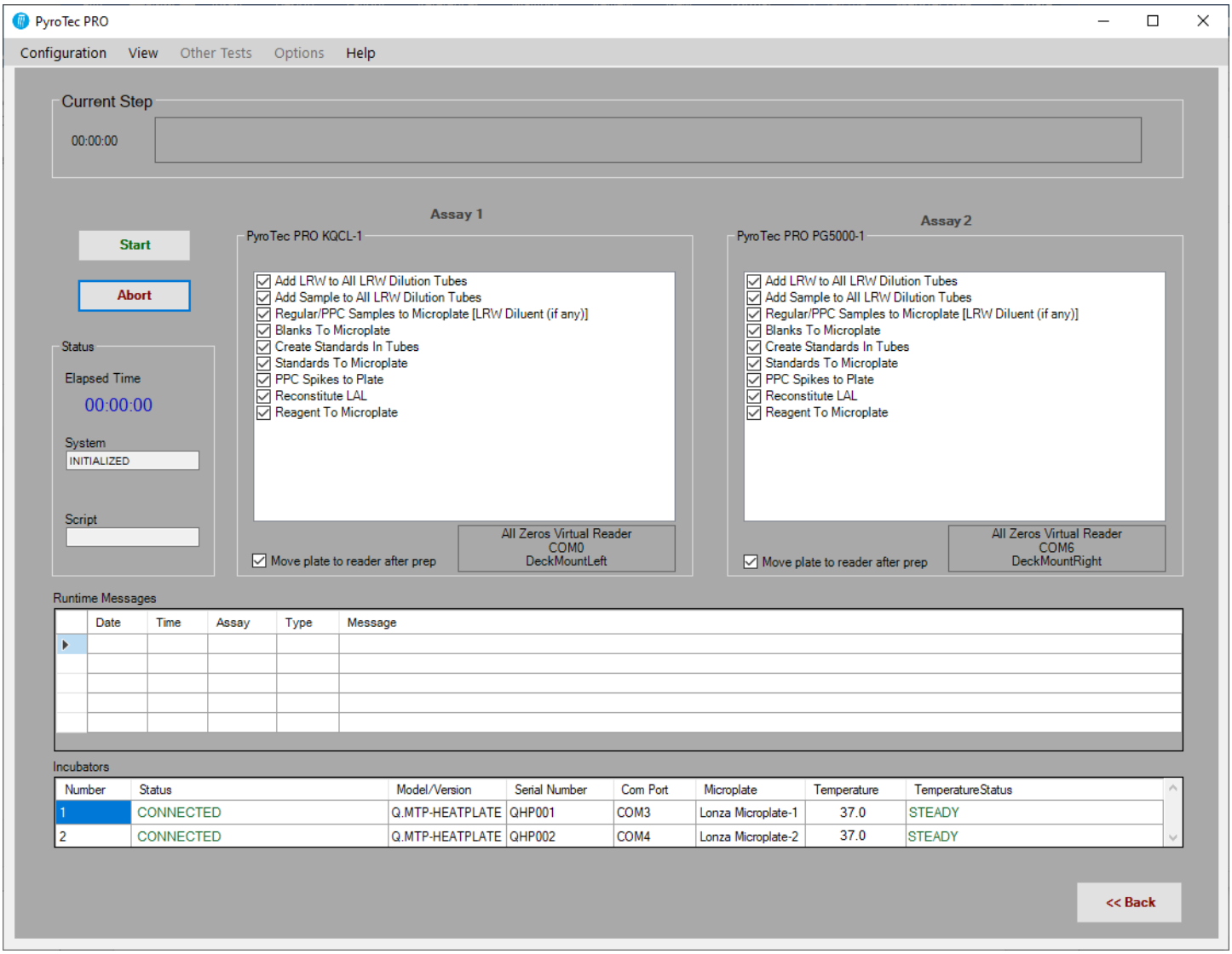
NOTE: This functionality is only available when the optional LoadingID barcode scanning unit is implemented in the system.

Run Assay >>

Navigates to the Run Assay interface.

Run Assay Interface

The Run Assay Interface provides controls to Start/Abort and monitor the progress of assay(s) performed on the automated system.



Assay 1 / Assay 2 Sections

- Displays the name of the template associated with the assay that will be performed.
- Displays the list of steps that will be performed to complete the assay.
- Displays information for the microplate reader associated with the assay.
- **Move plate to reader after prep**: When checked, the system will complete the complete assay workflow including the preparation of the lysate and the addition of it to the microplate, moving the microplate into the microplate reader, and initiating the testing within the WinKQCL® Software. This is the default option and is recommended during most circumstances.
  If the option is unchecked, the system will only add the standards and samples to the microplate. This is only recommended in certain troubleshooting procedures.

Current Step

- Displays a description of the assay step currently being executed.
- Displays the elapsed time for the current step.

Start

- Initiates running of the assay(s) on the instrument.

Abort

- Stops the assay(s) currently running on the instrument following the completion of the current step.

Status Section

- Displays the overall elapsed time for the run, the system status and the status of the script currently running.

Runtime Messages

- Displays messages associated with the assay/instrument actions and conditions during the run.

Incubators Section

- Displays status and information for on-deck incubators used in the run.

<< Back

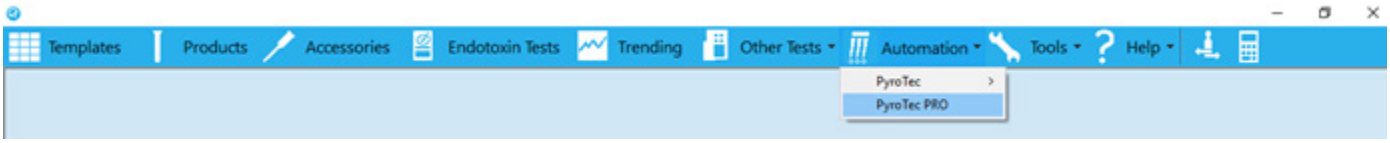
- Navigates back to the Deck Setup interface.

Performing an Automated Run

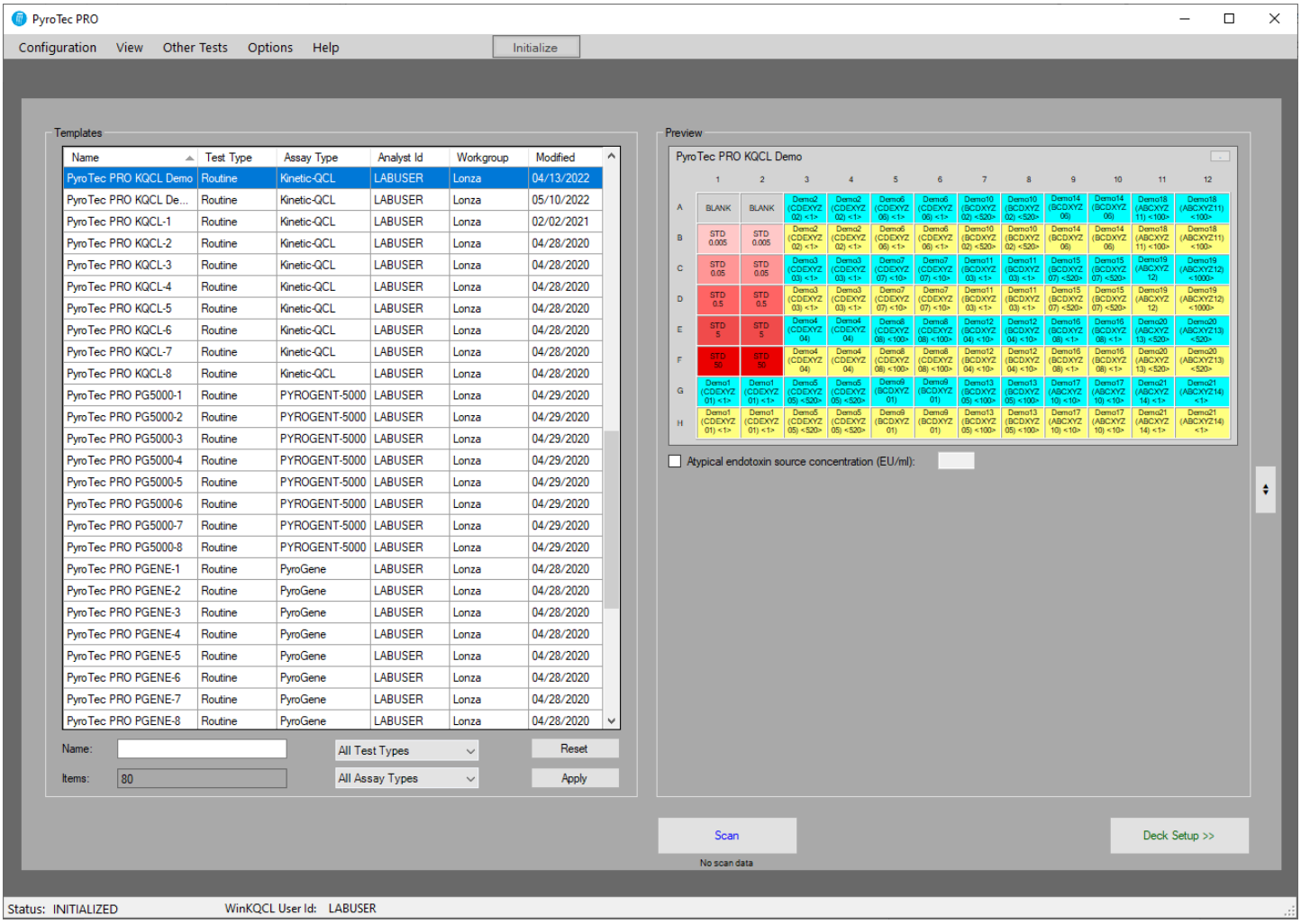
Process

This section provides step-by-step instructions for performing a run on a PyroTec® PRO System that implements the LoadingID option. References to LoadingID may be disregarded for systems that do not implement the LoadingID option.

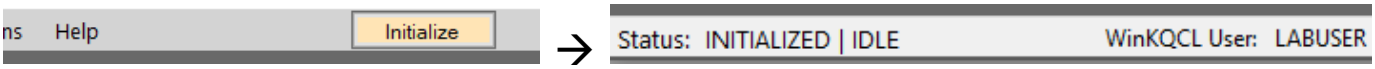
Open the WinKQCL® Software. Select **Automation | PyroTec PRO** in the main menu.



The PyroTec® PRO System Software module initial interface is displayed (i.e., Template Select):



Click the **Initialize** button in the main menu to initiate communications with the PyroTec® PRO System. Wait until the **Status** field displays “INITIALIZED” or “INITIALIZED | IDLE” in the status bar at the bottom of the window:

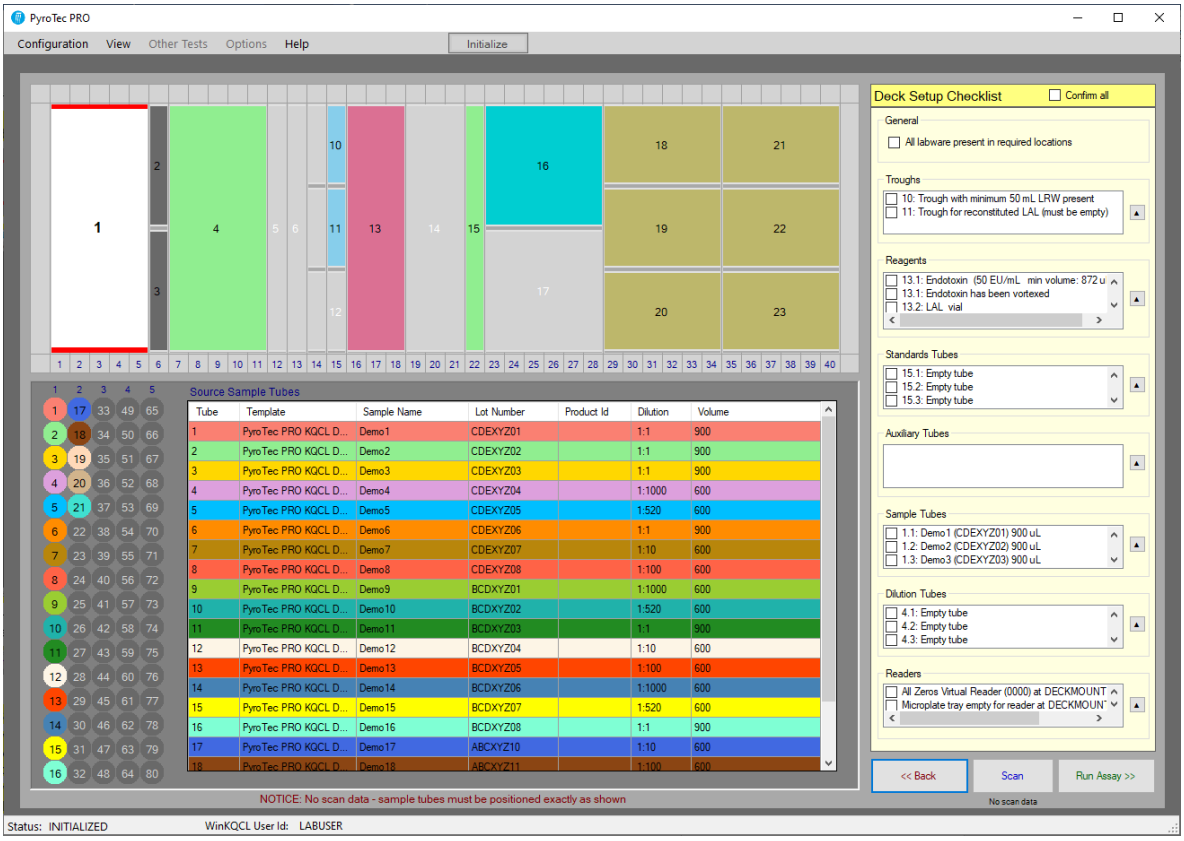


Select the desired template(s) to be run from the **Templates List**.

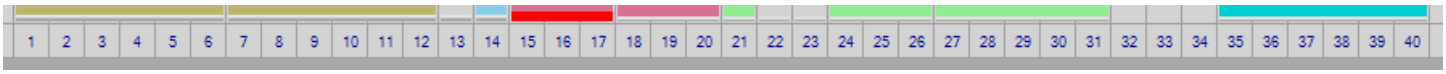
NOTE: The example above shows a single template selected. The system supports selection of up to two templates. To select two templates, hold the CTRL key and click on the two desired templates in the list.

Click the **Deck Setup** button to navigate to the Deck Setup interface that defines the required positioning for labware and liquids and the volume required for each liquid for the template(s) selected.





The grid positions displayed on the Deck Layout interface correspond to physical grid positions on the liquid handling instrument:



NOTE: The total number of DiTis required to perform the run can be determined by clicking on any of the DiTi blocks in the Deck Layout (blocks 18 – 23 in the example above)

Sample Tubes Positions

When there is no LoadingID implemented in the system, sample tubes are assigned static positions on the deck by the PyroTec® PRO System Software module at the Deck Setup interface. Each sample tube must be manually positioned at the exact location specified in the interface.

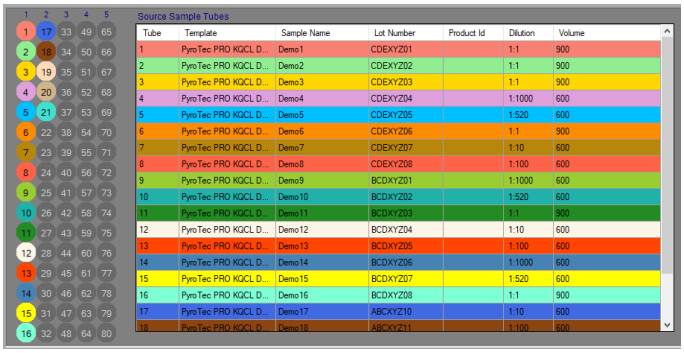
When a LoadingID is implemented in the system, the position of sample tubes are determined according to the following table:

LoadingID Barcodes Scan Completed?	Sample Tubes Positions
No	Sample tubes are assigned static positions on the deck by the PyroTec® PRO System Software module. Each sample tube must be manually positioned at the exact location specified in the interface (same as for *no LoadingID* implementation). A reminder notice will be present on the interface if there is no LoadingID scan data available. NOTICE: No scan data - sample tubes must be positioned exactly as shown
Yes	The PyroTec® PRO System Software module assigns each sample tube location according to results of the LoadingID barcode scan. When the LoadingID is used, it's not necessary to place sample tubes at particular locations, the tubes may be positioned arbitrarily in the tube runners. The LoadingID scan determines the locations of all sample tubes and the PyroTec® PRO System Software module dynamically updates the sample tubes layout interface accordingly.

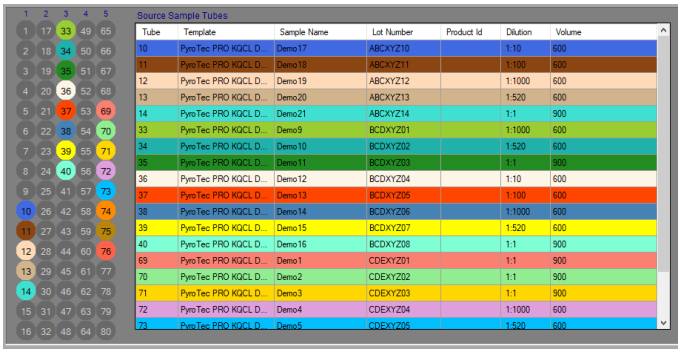
LoadingID Scan

A scan of the sample barcodes may be optionally performed at the Deck Setup interface by clicking the **Scan** button (see: Scan Barcodes). The **Scan** option is also available at the initial Template Select interface. If the **Scan** option was applied at the Template Select interface, the samples tubes will already be displayed according to the results of the Scan, otherwise the sample tubes will be displayed at locations automatically assigned by the PyroTec® PRO System Software module. The following graphic shows an example of how sample tubes might be positioned by the PyroTec® PRO System both before and after a scan of the sample tubes using the LoadingID, with tubes positioned in tube runners on the LoadingID arbitrarily, in no particular order.

Pre-scan:



Post-scan:



Notice that in the *Post-scan* image above, the tubes have been repositioned in the display according to the positions derived from the scan results. The PyroTec® PRO System will automatically process the samples according to those positions.

Click on each block in the **Deck Layout** section and refer to the information displayed in the **Deck Labware Details** section for the selected block. For each block:

- Follow any instructions that are specified.
- Confirm that the specified labware rack is present (if it is required).
- Position all items as specified
- Ensure specified liquids (if any) are present and at the minimum volumes indicated.
- Ensure that all crimps and caps (if any) are removed from tubes and vials prior to placing on the deck.

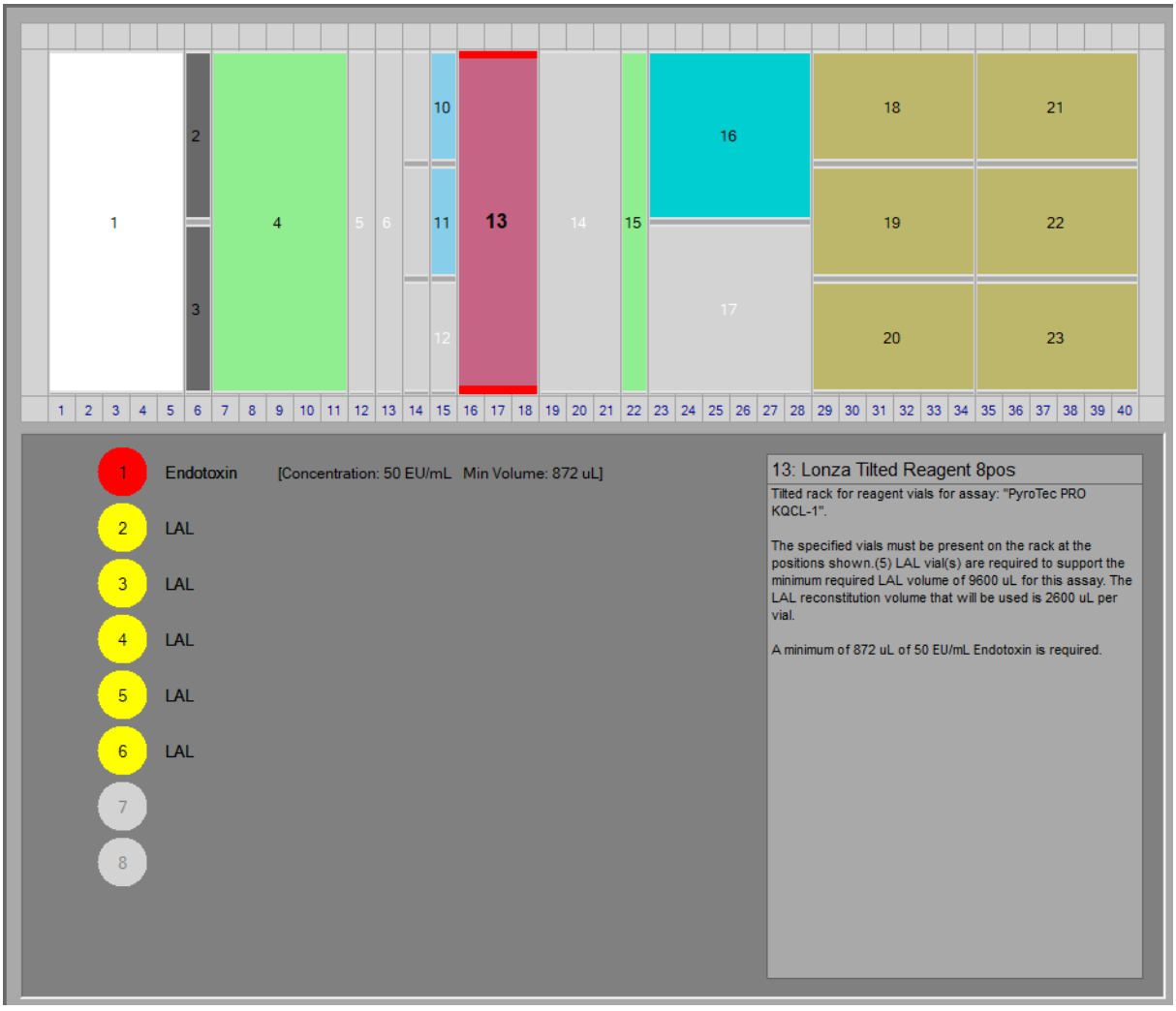
NOTE: Endotoxin must be reconstituted (if not in liquid state) and manually vortexed by the analyst before placement on the deck. The instrument does not perform these steps automatically for endotoxin. LAL reagents, however, are automatically reconstituted and mixed by the instrument.

- Ensure that each required incubator is powered on.
- For each applicable reader: Open the reader door to confirm that there is not a microplate present in the reader. If a microplate is present, remove it. Close the reader door.
- Ensure that each applicable microplate reader is steady at the required temperature (normally 37°C). In the WinKQCL® Software, go to Tools | Reader Setup, and click the Temperature button for each reader to display the Temperature Settings interface. Confirm the current temperature is at the required temperature for each reader to be used in the automated run. Close the Temperature Settings interface.

WARNING: After confirming the temperature(s) in the WinKQCL® Software the Temperature Settings interface, *must be closed* to prevent reader communication errors in the PyroTec® PRO System Software module.

The following examples provide additional detailed information for the **Deck Layout** and **Deck Labware Details** sections:

Example 1: Reagent Rack



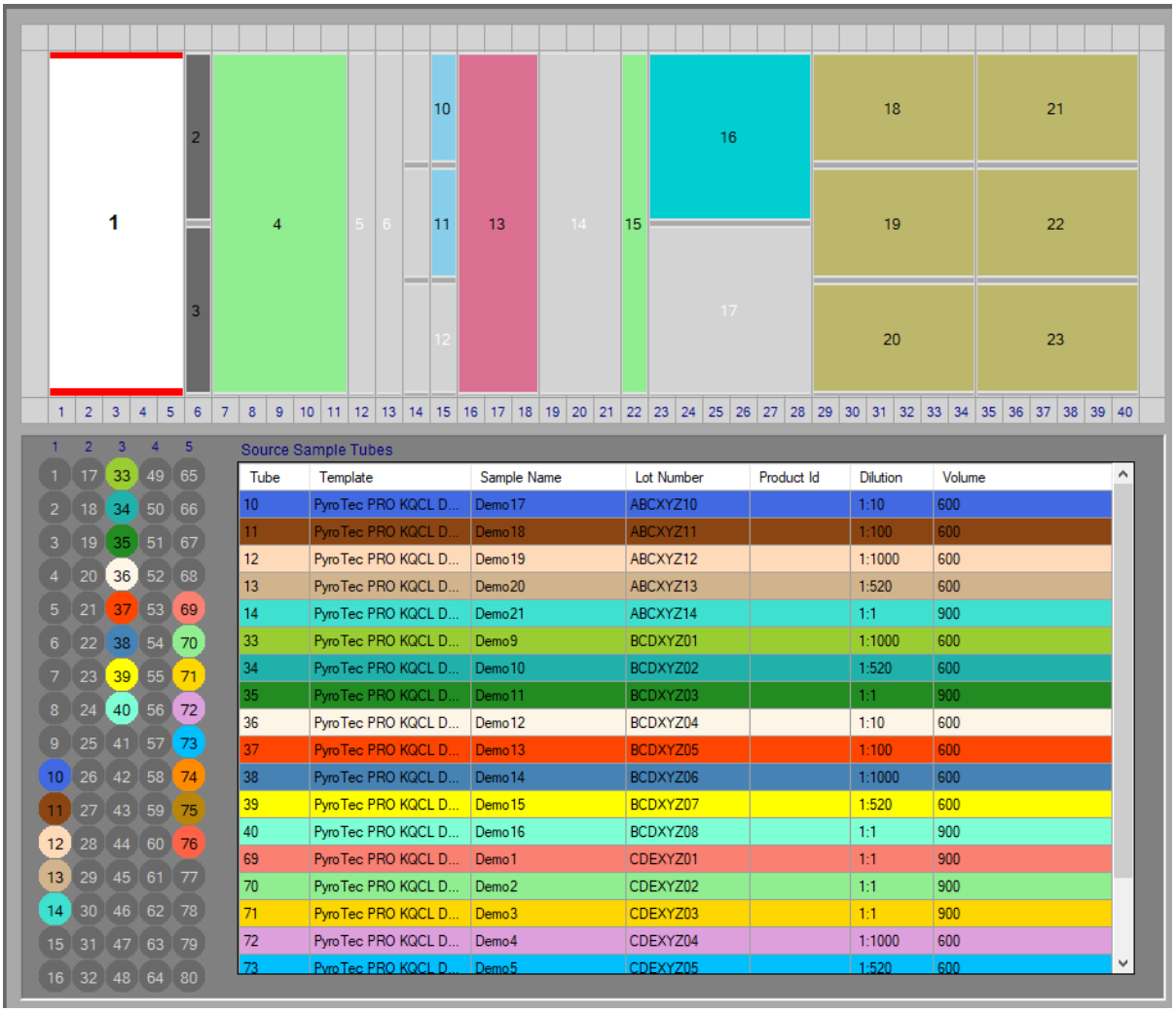
In the image above, block 13 (located at grid positions 16 – 18 on the PyroTec® PRO System deck) is selected.

The **Deck Labware Details** section provides the following information:

- The labware associated with the selected block is a *Lonza Tilted Reagent 8pos* rack
- The endotoxin vial must be placed at position 1 on the rack
- The endotoxin vial must contain a minimum of 872 µL of endotoxin of concentration 50 EU/mL
- Five (5) Lonza LAL reagent vials must be placed at positions 2 – 6 on the rack

NOTE: This example is for a Kinetic-QCL® Assay. PYROGENT® 5000 and PyroGene® Assays use different reagent vial types but with similar setup.

Example 2: Sample Tubes



NOTE: The terms “product” and “sample” are used interchangeably in the following example and are implied to have the same meaning.

In the image above, block 1 (located at grid positions 1 - 5 on the PyroTec® PRO System deck) is selected. The block corresponds to the sample tubes for the automated run (following a LoadingID scan). The **Deck Labware Details** show that the block is associated with 5 x 16-position tube runners (on the LoadingID). The layout for the tube positions is displayed at the left of the **Deck Labware Details** section. Tube positions are numbered 1 through 80 (i.e., 5 x16 = 80 tubes). A tube position may have one of two possible states: 1) contains a sample tube or 2) has no tube present. Tube positions that contain samples are color-coded. Tube positions that have no tube present are dark gray.

The physical grid position on the PyroTec® PRO System deck for each rack of tubes is provided for easy reference:



The corresponding information for each tube position that contains a liquid sample is displayed in the list at the right of the **Deck Labware Details** section.

The *Source Sample Tubes* list contains entries that are numbered and color-coded to match corresponding sample tube positions in the tube position layout. The following information is displayed in the list for each entry:

- **Tube**: Number of the corresponding tube position in the tube position layout
- **Template**: The name of the template with which the sample is associated
- **Sample Name**: The name of the product (i.e., sample) contained in the tube
- **Lot Number**: The lot number of the product
- **Product Id**: Additional product identifier (as defined in the template)
- **Dilution**: The total dilution factor to be applied to the sample (may consist of multiple diluents)
- **Volume**: The minimum volume of liquid sample that must be present in the tube

Specific Volume Samples

When a sample is configured to use a specific volume (see: Specific Sample Volume in Products Configuration) the Dilution and Volume fields have additional information displayed:

- Dilution Field: the total sample dilution is displayed along with the dilution that will be applied directly in the sample tube (in parentheses).
- Volume field: a circular symbol (◉) is displayed to the right of the sample volume to indicate that it's a specific volume. The volume displayed is the *specific* (exact) volume required in the sample tube. When the initial dilution step for the sample will be applied directly in the sample tube, the total volume that will be present in the tube after the dilution is also displayed (in angled brackets).
- Example: The example below shows a sample (see: Tube 12 in the Samples Layout image above) with specific volume = 25µL (configured for the particular Product in the Products Configuration), and total dilution of 1:1000 (this is defined on the WinKQCL template). Notice that the first dilution step is 1:40 and will be applied directly in the sample tube. The total volume in the sample tube following the dilution will be 1000µL (i.e., 25µL sample + 975µL diluent).

Tube	Template	Sample Name	Lot Number	Product Id	Dilution	Volume
12	PyroTec PRO KQCL D...	Demo19	ABCXYZ12		1:1000 (1:40)	25 ◉ <1000>

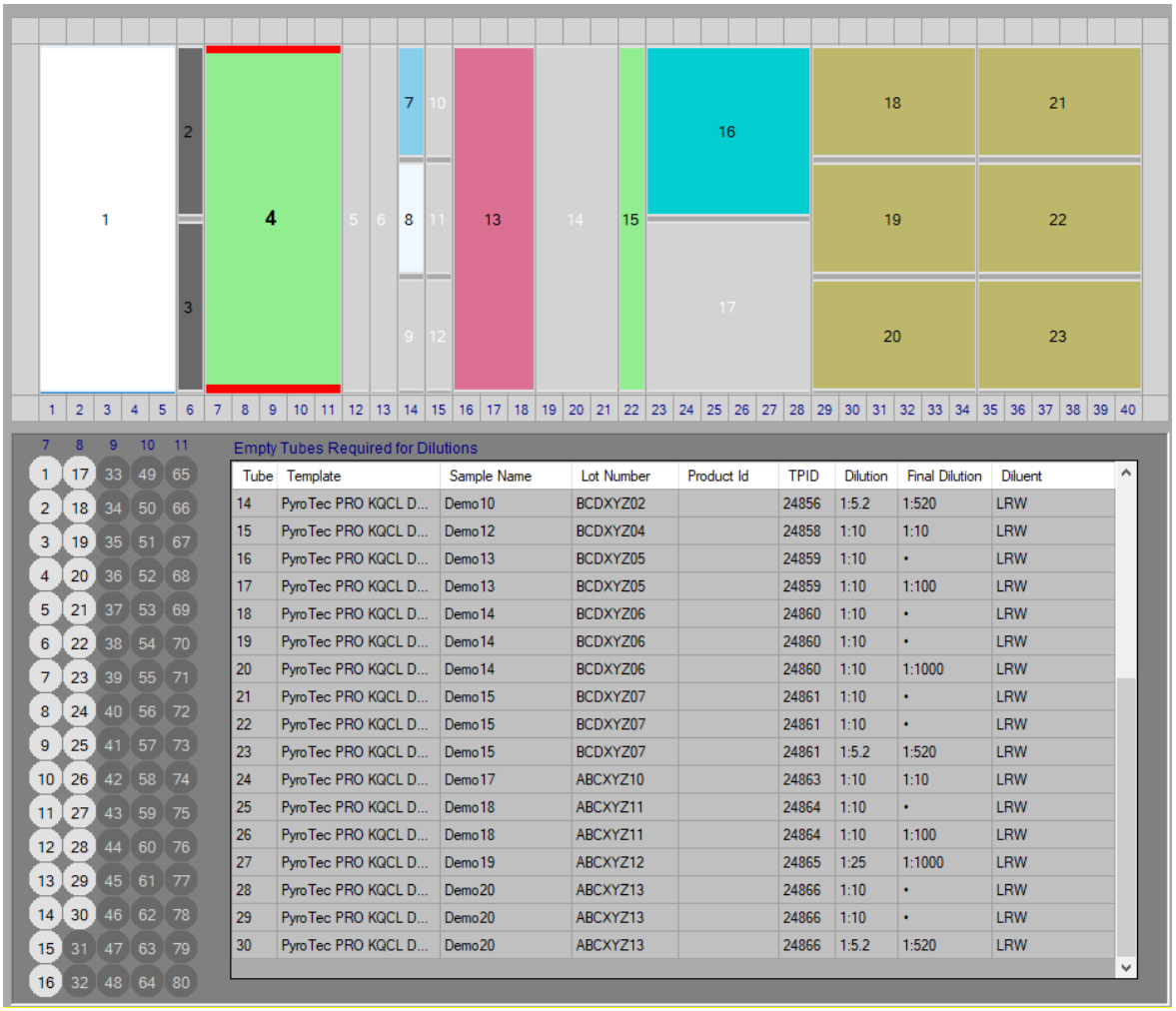
- The remaining steps required to complete the dilution series for this sample will be applied in dilution tubes:

Empty Tubes Required for Dilutions

Tube	Template	Sample Name	Lot Number	Product Id	TPID	Dilution	Final Dilution	Diluent
27	PyroTec PRO KQCL D...	Demo19	ABCXYZ12		24865	1:25	1:1000	LRW

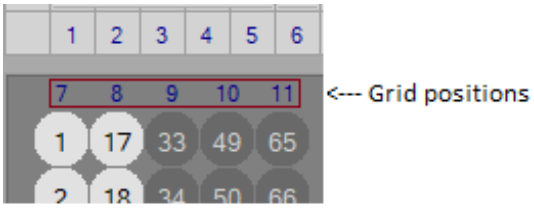
NOTE: If a sample is configured to use a specific volume and requires dilution, PyroTec® PRO will always apply the first dilution step directly within the sample tube if possible (i.e., if the volume in the tube after applying the dilution is ≤ the configured max allowable volume in a sample tube). When not possible to dilute directly in the sample tube, the first dilution step will instead be applied in a dilution tube.

Example 3: Dilution Tubes



In the image above, block 4 (located at grid positions 7 - 11 on the PyroTec® PRO System deck) is selected. The block corresponds to the empty tubes that are required for making dilutions in the automated run. The **Deck Labware Details** shows that the block is associated with 5 x 16-position tube racks. The layout for the tube positions is displayed at the left of the **Deck Labware Details** section. Tube positions are numbered 1 through 80 (i.e., 5 x 16 = 80 tubes). A tube position may have one of two possible states: 1) contains an empty tube or 2) has no tube present. Tube positions that contain empty tubes are light gray. Tube positions that have no tube present are dark gray. In the image above tube positions 1-30 contain empty tubes, and tube positions 31-80 have no tubes.

The physical grid position on the PyroTec® PRO System deck for each rack of tubes is provided for easy reference:



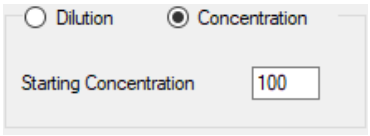
The *Empty Tubes Required for Dilutions* list contains entries that are numbered to correspond to positions containing empty tubes in the tube position layout. The following information is displayed in the list for each entry:

- **Tube**: Number of the corresponding tube position in the tube position layout.
- **Template:** The name of the template with which the sample is associated.
- **Sample Name:** The name of the product (i.e., sample) associated with the dilution tube.
- **Lot Number**: The lot number of the product associated with the dilution tube.
- **Product Id**: The identifier of the product associated with the dilution tube.
- **TPID**: Template Product Identifier of the associated product (see Template Expanded View for details).
- **Dilution**: The dilution factor to be applied in the tube (may be one of multiple serial dilutions required to reach the final total dilution for a particular product).
- **Final Dilution**: For tubes that contain the final dilution for a product, the final dilution factor is displayed (e.g., 1:100). For tubes that contain an intermediate dilution, a dot is displayed (i.e., •). When a product has EU per defined as “mg” or “device” on the WinKQCL® Software template, the processing for the product will be handled as a Concentration versus a Dilution. In this case, the final dilution factor actually applied to arrive at the concentration specified on the WinKQCL® Software template is displayed, along with the concentration specified on the WinKQCL® Software template (in parentheses).

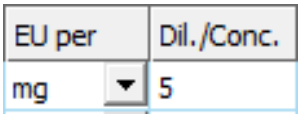
  Example:

  In the PyroTec® PRO system a product is configured to be processed as a Concentration with Starting Concentration = 100. On the WinKQCL® Software template, EU Per “mg” is selected and the Dil. /Conc. value = 5 for the product. To arrive at the required concentration of 5, the PyroTec® PRO system applies a dilution of 1:10, followed by a dilution of 1:2, which results in a 1:20 dilution of the product. Since the product has starting concentration = 100, the final concentration is then = 5.

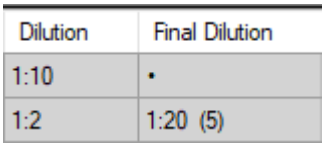
- Starting Concentration



- WinKQCL® Software Template



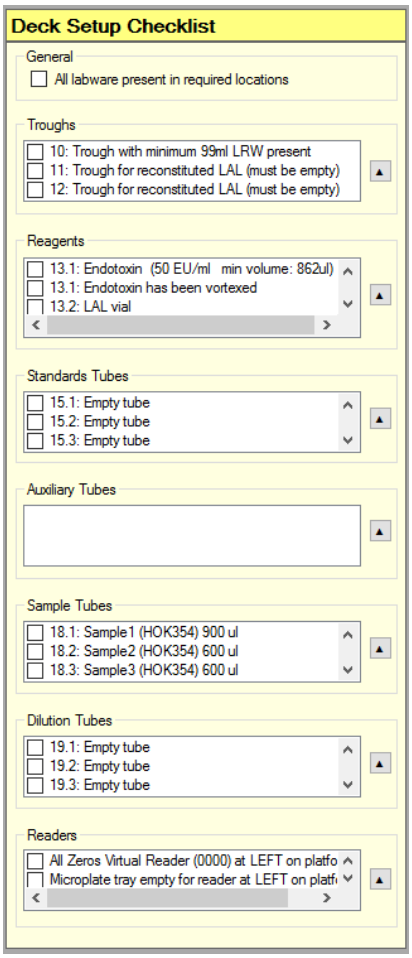
- Processing



- **Diluent**: Name of the diluent applied to dilute the product.

NOTE: When one or more auxiliary dilutions are applied to the product, the diluent name could be something other than LRW (e.g., Beta-Glucan blocker, etc.).

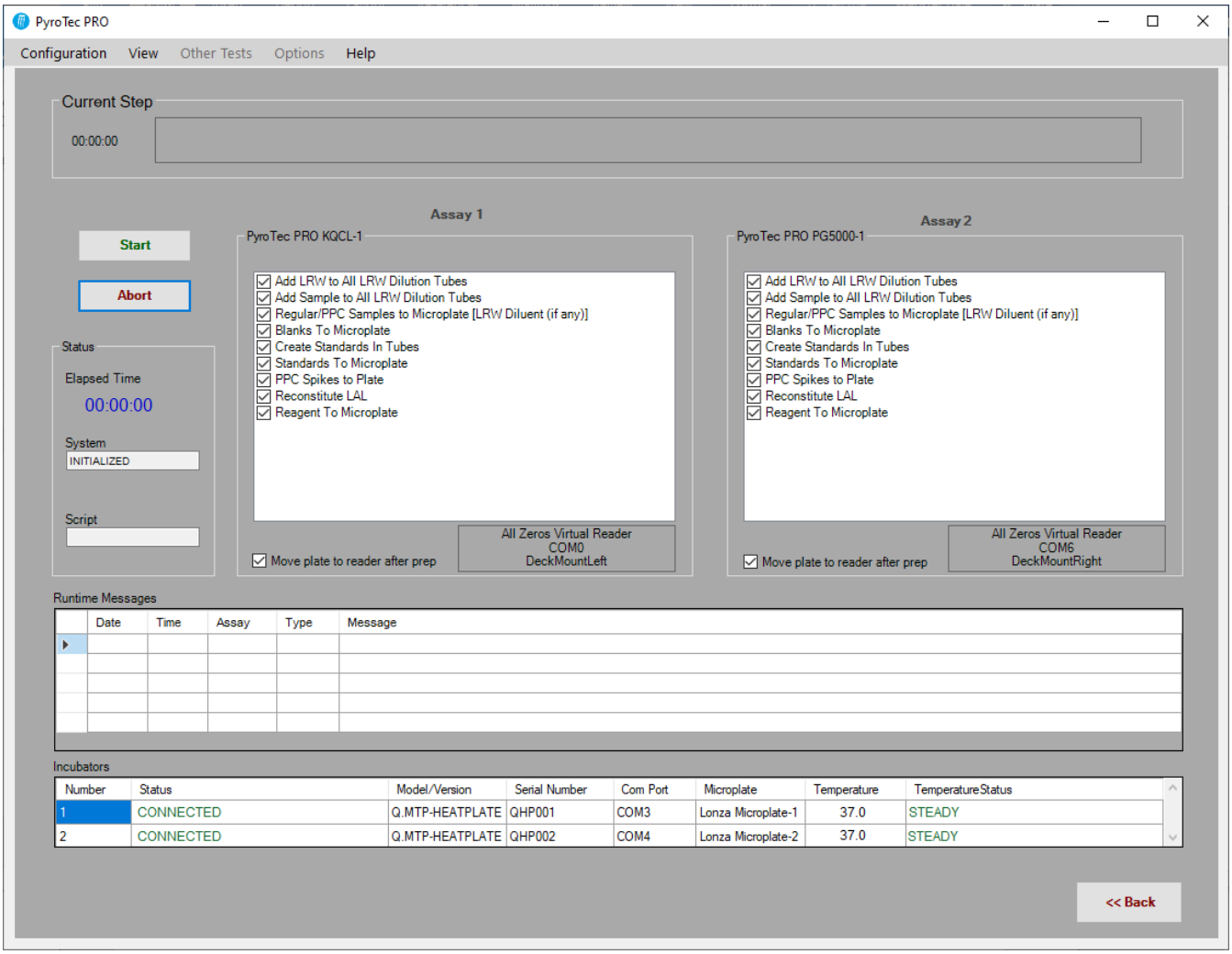
After clicking on each block in the **Deck Layout** section and following the instructions to complete the deck setup, confirm in the **Deck Setup Checklist** that each item is complete by clicking each checkbox so that a check (☑) appears. The software will not allow navigation to the next interface (i.e., **Run Assay** interface) until all checkboxes in the checklist have been checked:



After checking all items in the checklist, click the **Run Assay** button:



The action above displays the **Run Assay** interface which provides controls to Start/Abort and monitor the progress of assay(s) on the automated system:



Click the **Start** button to initiate the automated run after verifying the front cover of the instrument is down and secure for safety.



When the Start button is clicked, the PyroTec® PRO System automatically performs the processing required to complete the assay(s). The following automated processing is performed for each assay:

1. Add LRW (or other required diluent) to appropriate dilution tubes (applicable only to diluted samples, if any).
2. Add samples to dilution tubes (diluents added in step 1) and mix up/down (applicable only to diluted samples, if any).
3. Transfer the samples to the microplate.
4. Transfer the blanks to the microplate.
5. Create the standard concentrations required for the standard curve.
6. Transfer the standards to the microplate.
7. Add required PPC spikes to the microplate.
8. Transfer the microplate from the PyroTec® PRO System deck to the reader for incubation.
9. Prepare reagents while the microplate is incubating (preparation begins on the instrument at a time such that process completes at about the same time as the completion of the microplate incubation).

NOTE: When using Kinetic-QCL® or PYROGENT® 5000 Assays, the PyroTec® PRO System will reconstitute the lysate.

10. Transfer the microplate from the reader to the PyroTec® PRO System deck and add reagent to each non-empty well on the microplate.
11. Transfer the microplate back to the reader and signal the WinKQCL® Software to read the microplate and process the results (just as if the microplate had been manually placed in the reader by a technician).

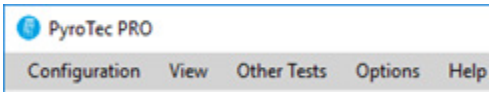
NOTE: It is not necessary for the analyst to be present for the processing described above. The PyroTec® PRO System performs all steps automatically.

WARNING: Do not execute any of the available options provided in the WinKQCL® Software Readers List (i.e., Discover, Test Connection, Plate in, Plate out, Temperature, etc.) while an automated assay is running. Doing so could prevent PyroTec® PRO System from communicating with the readers and may result in assay errors from which the system cannot recover.

Main Menu

Components

The PyroTec® PRO System Software module main menu provides the following menu options: Configuration, View, Other Tests, Options and Help.



Functionality for the PyroTec® PRO System Software module main menu is described below.

Configuration

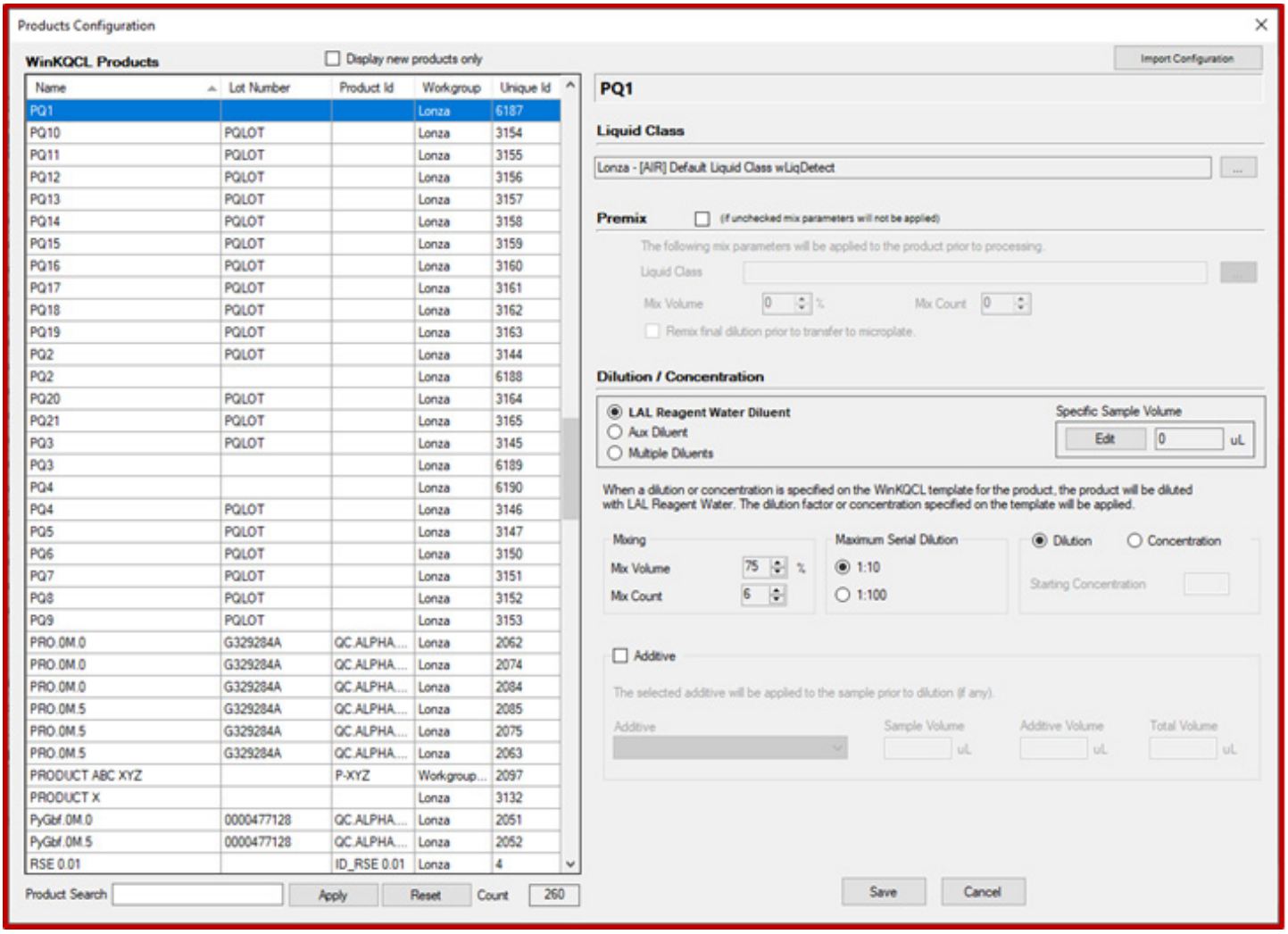
The Configuration menu provides the following submenu items (which are described in the sections that follow):

- Products
- Readers
- Aux Liquids (i.e., Auxiliary Liquids)
- Incubators
- System

NOTE: Some submenu item features are accessible only to WinKQCL® Software supervisors (indicated in the sections below).

Products

NOTE: The Products Configuration feature is accessible only to WinKQCL® Software supervisors.

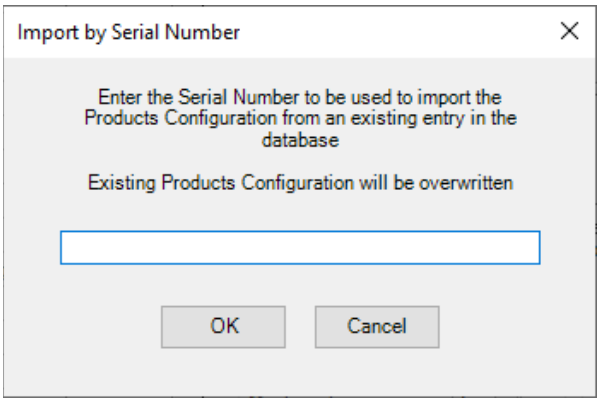


The Products Configuration interface provides functionality to configure products (i.e., samples) for testing in the system. Each product must be configured to define how the system should handle and process it.

The Import Configuration option is provided to allow the import of an existing Products Configuration that is associated with another PyroTec® PRO System.



The Import Configuration option displays an interface where a serial number associated with a different (or previous) PyroTec® PRO System may be entered:



When a valid serial number is entered and OK is selected, the Products Configuration interface is populated with the values derived from the other PyroTec® PRO System.

WARNING: Only knowledgeable users should use the Import Configuration option. Importing and saving a Products Configuration will overwrite the existing Products Configuration, and the information may not be retrievable.

WinKQCL® Software Products

The list initially displays all products present in the WinKQCL® Software database (i.e., products defined and configured in the WinKQCL® Software). Only products that are defined in the WinKQCL® Software are present in the list. The following fields are displayed for each product: *Name, Lot Number, Product ID, Workgroup,* and *Unique Id*. One product in the list is selectable at a time.

NOTE: The Products list displays products associated with all workgroups of which the current WinKQCL® Software user is a member. However, when attempting to perform an automated assay, the PyroTec® PRO System Software module will only accept products associated with the current WinKQCL® Software user's primary workgroup. Products from the user's non-primary workgroups will be considered UNDEFINED by the PyroTec® PRO System Software module when they are present on a WinKQCL® Software template, and the PyroTec® PRO System Software module will not allow the template to be run.

Display new products only

When this option is selected (checked), the Products list is populated *only* with products that are new, i.e., have not previously been configured for use on the automated system. Otherwise, the list contains all products (including new products).

Product Search

This feature provides controls to support searching the WinKQCL® Software Products list.

- **Apply**: Populates the Products list with products where the text in the Product Search text field is present (in full or in part, case-insensitive) in the product's associated Name, Lot Number, Product ID, or Workgroup.
- **Reset**: Repopulates the Products list with all products from the WinKQCL® Software database.

- **Count**: Displays the number of products currently in the Products list.

When a product is selected in the Products list, the sub-fields listed below are available for configuration. The parameters in these fields are required to support testing of the product on the automated system.

Liquid Class

The liquid class assigned to this product.

WARNING: Only knowledgeable users should apply liquid class assignments. Incorrect liquid class assignments may result in invalid assays. Each liquid class used in an assay should be validated prior to use by the end user.

Premix

The system supports premixing of samples prior to utilizing them in the system. When checked, the following configuration components are made available.

- **Liquid Class**: The liquid class assigned for premixing the product. The field is populated by using the associated browse button.

- **NOTE:** A liquid class optimized for mixing must be selected for the premix liquid class. Lonza recommends liquid class "*Lonza - [AIR] Mix Product Default Liq Class"*.

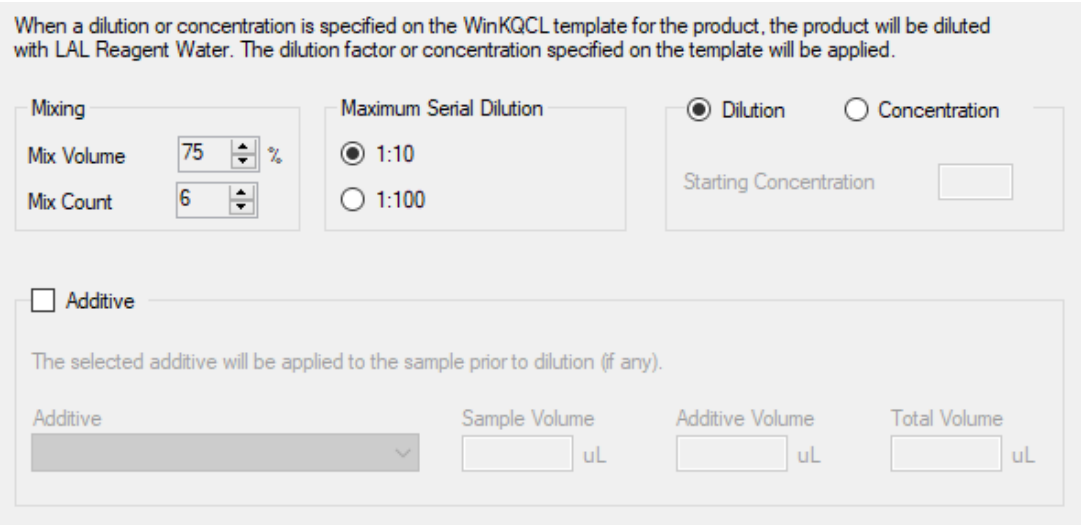
- **Mix Volume**: The percentage of the liquid in the tube used to premix the product.
- **Mix Count**: The number of up/down mixing actions applied to premix the product.
- **Remix final dilution prior to transfer to plate**: When checked, if the product is diluted, the final dilution will be remixed prior to transfer to the microplate. Otherwise, if the product is diluted, the final dilution will not be remixed prior to the transfer to the microplate.

Diluent Options

Selection of one of three options is supported: *LAL Reagent Water Diluent, Aux Diluent,* or *Multiple Diluents*.

LAL Reagent Water Diluent

Provides functionality to configure the LAL Reagent Water dilution to be applied to the product when running an automated assay. The product will be diluted with LAL Reagent Water when a dilution for the product is specified on the WinKQCL® Software template. The dilution factor specified on the template will be applied.



The following configuration parameters are supported:

Dilution Mixing

- Mix Volume: The percentage of the liquid in the tube used to mix the product / LAL Reagent Water.
- Mix Count: The number of up/down mixing actions used to mix the product / LAL Reagent Water.

NOTE: For products loaded for the first time from the WinKQCL® Software database, Mix Volume and Mix Count are populated with the configured default values (see *Product Defaults*).

Maximum Serial Dilution

Either 1:10 or 1:100 may be selected. This is the maximum dilution that will be applied to any dilution in a LAL Reagent Water (also known as Water for BET) dilution sequence.

NOTE: For products loaded for the first time from the WinKQCL® Software database, the selected dilution is the configured default value (see *Product Defaults*).

Dilution / Concentration

- Provides functionality to indicate whether the product should be processed as concentration or a dilution.
- When Concentration is selected, the Starting Concentration field supports entry of a numeric value to indicate the initial concentration of the product. The PyroTec® PRO System requires the initial concentration of the product to determine and apply the required processing to arrive at the concentration specified on the WinKQCL® Software template (Dil. /Conc. field).
- When the product is placed on a WinKQCL® Software template, the EU Per field indicates how the product should be processed (i.e., as a Dilution or as a Concentration). This must line up between the WinKQCL® and PyroTec® PRO System Software module configurations. The table below shows the processing method that corresponds to each EU Per option.

	Processing	
EU Per	**Dilution**	**Concentration**
mL	✓	
device	✓	
µg		✓
mg		✓
unit		✓
mEq		✓

- If the selected EU Per option is not associated with the processing method configured for the product in the PyroTec® PRO System Software module, the template cannot be used for an automated run until the mismatch is corrected by either modifying the template or modifying the PyroTec® PRO System Software module Product configuration (or both).

Specific Sample Volume

- Provides functionality to assign the explicit sample volume (in µL) that will be required when the Product is assigned to a template selected for an automated run. Select the Edit button to assign a Specific Sample Volume. When the Specific Sample Volume currently displayed for the selected Product is zero (0), the default Specific Sample Volume configured in the Product Defaults interface will be displayed by default in

the Edit entry interface. Otherwise, the currently displayed Specific Sample Volume for the selected Product will be displayed in the Edit entry interface. When the Product is configured to use a Specific Sample Volume, it will be indicated at the Deck Layout interface (see Specific Volume Samples).

- When value of zero (0) is assigned, this implies that a Specific Sample Volume is not applicable (i.e., the required volume for the sample will be calculated and displayed by the PyroTec® PRO System Software at the Deck Layout interface).

WARNING: For cases where processing for a Specific Sample Volume requires a dilution directly in the sample tube, only Pyrogen-Free test tubes (catalog #N207) should be used.

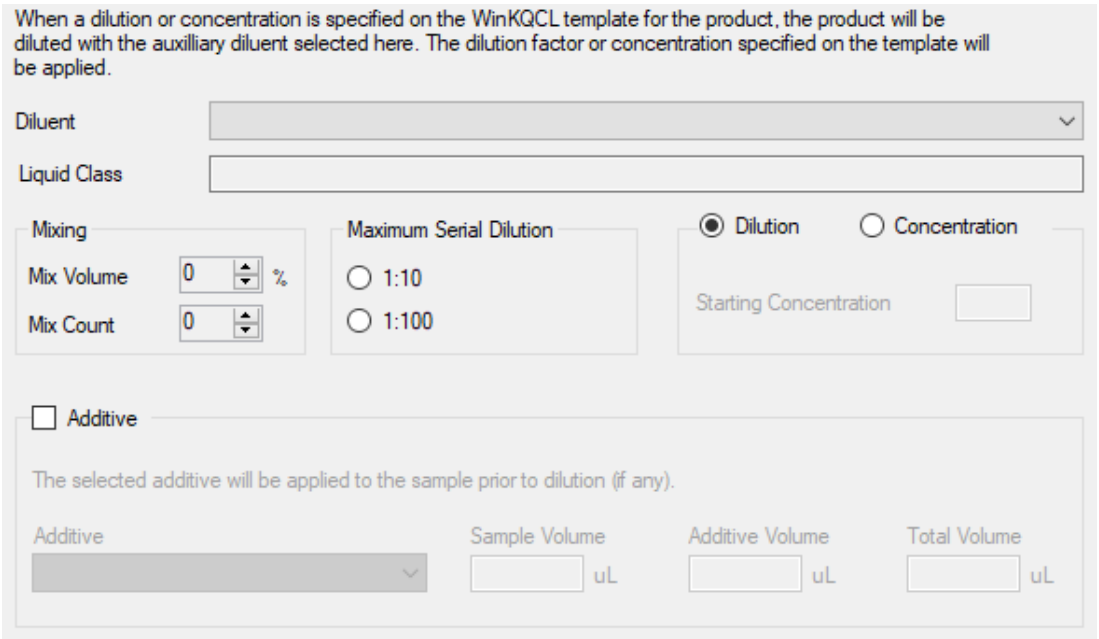
Additive

- Provides functionality to define an additive that is to be applied to the product.
- The name of the additive is selected from a drop-down list containing the names of all auxiliary liquids configured for the system (see Aux Liquids). When values are entered for the Sample Volume and Additive Volume fields, the Total Volume field is automatically calculated.
- The selected additive will always be applied to the sample prior to dilution (if any).

NOTE: Additives function differently than dilutions in the system. A dilution is based on a ratio of the sample and diluent and used to discern the associated endotoxin concentration in the sample. An additive volume is not taken into considerations for calculating endotoxin concentration.

Aux Diluent

Provides functionality to configure a dilution with a single auxiliary diluent that is other than LAL Reagent Water (e.g., Beta-G blocker, etc.) when running an automated assay. The product will be diluted with the selected diluent when a dilution for the product is specified on the WinKQCL® Software template. The dilution factor specified on the template will be applied.



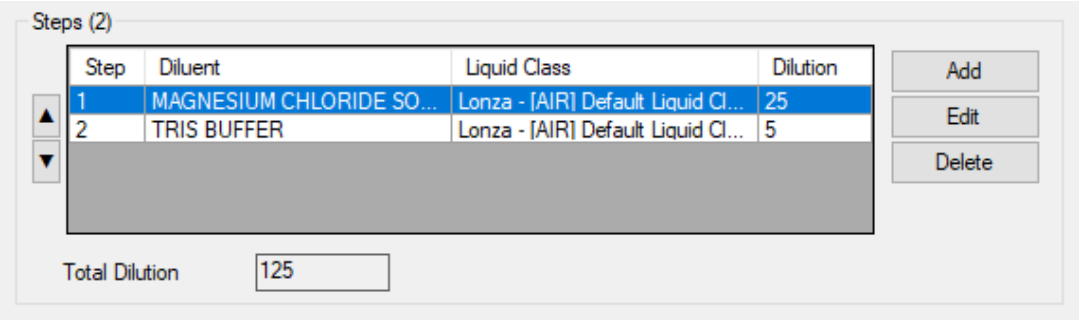
The following configuration parameters are supported:

- **Diluent**: Selectable list of configured auxiliary liquids.
- **Liquid Class**: The name of the liquid class assigned to the diluent.

- **Dilution Mixing**:
  - **Mix Volume**: The percentage of the liquid in the tube used to mix the product / diluent.
  - **Mix Count**: The number of up/down mixing actions used to mix the product / diluent.
- **Maximum Serial Dilution**: Either 1:10 or 1:100 may be selected. This is the maximum dilution that will be applied to any dilution in the dilution sequence.
- **Dilution / Concentration**: Functionality is the same as the Dilution / Concentration functionality provided for diluent option LAL Reagent Water Diluent (see Dilution / Concentration in LAL Reagent Water Diluent section above).
- **Additive**:
  - Provides functionality to define an additive that is to be applied to the product.
  - The name of the additive is selected from a drop-down list containing the names of all auxiliary liquids configured for the system (see section “Auxiliary Liquids Configuration”). When values are entered for the Sample Volume and Additive Volume fields, the Total Volume field is automatically calculated.
  - The selected additive will always be applied to the sample prior to dilution (if any).

Multiple Diluents

Provides functionality to configure multiple diluent steps, as well as additives, to be applied for the product. The Diluent Steps list displays the configured diluent items. The configured diluent steps will *always* be applied for the product.



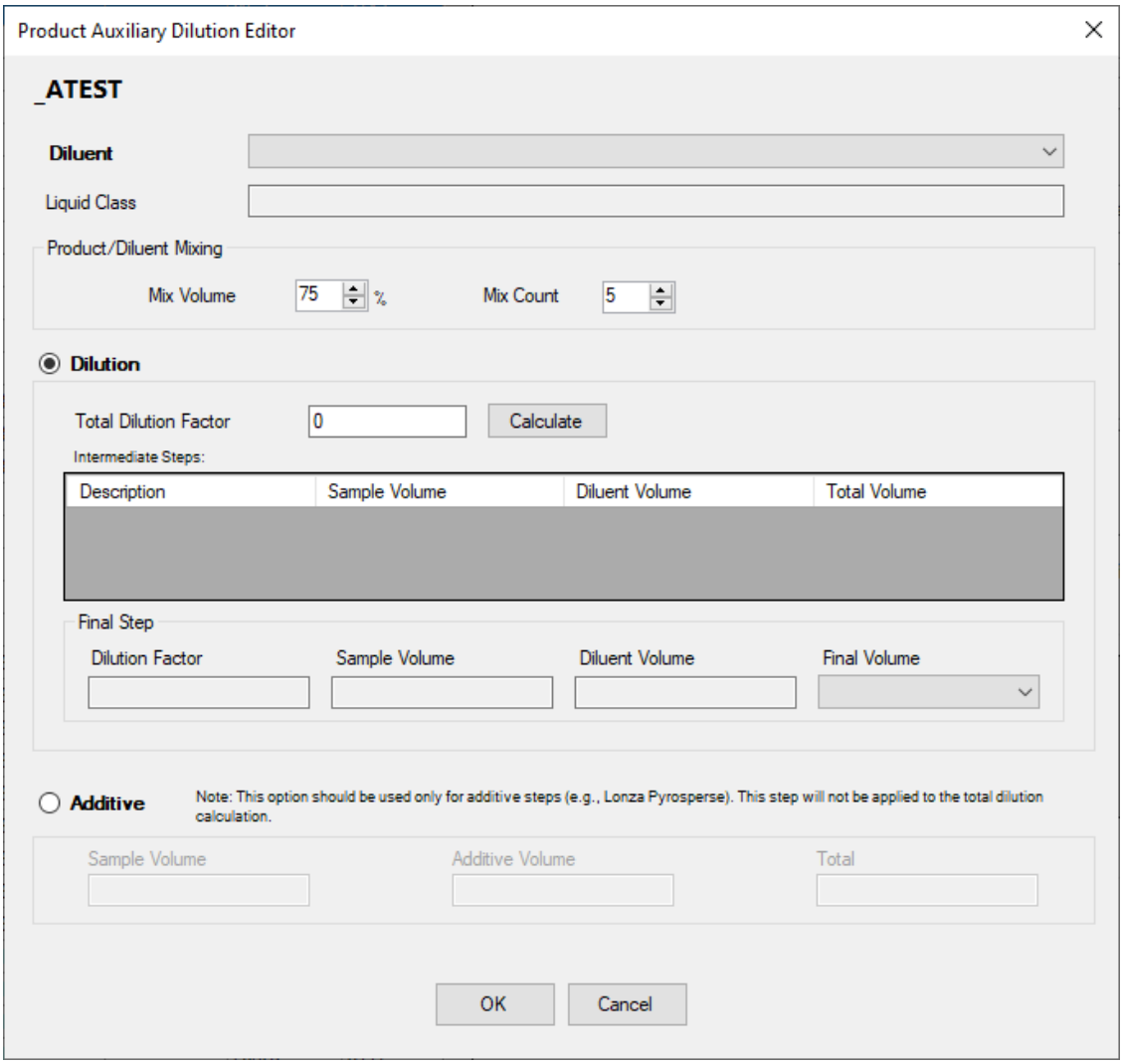
One item in the Dilution list is selectable at a time. Functionality is provided to add, edit, and delete list items:

- **Add**: Displays the Product Auxiliary Dilution Editor interface (see section “Product Auxiliary Dilution Editor”) to define a new product auxiliary dilution or additive step.
- **Edit**: Displays the Product Auxiliary Dilution Editor interface for the selected item in the list (see section “Product Auxiliary Dilution Editor”) to modify the product auxiliary dilution or additive step.
- **Delete**: Removes the selected item in the list.
- **Up/Down Arrows**: Click the up/down arrows to the left of the list to reorder the selected item in the list. The auxiliary dilutions or additive steps are processed in the order they appear in the list.
  - The following parameters are displayed for each item in the list:
  - **Step**: The number of processing step for which the auxiliary dilution/additive will be applied (e.g., Step 1 will be processed first, followed by Step 2…followed by Step n).
  - **Diluent**: The name of the liquid used for the dilution/additive.
  - **Liquid Class**: The liquid class for the diluent/additive.
  - **Dilution**: The dilution factor (e.g., 2 implies a 1:2 dilution, 5 implies a 1:5 dilution, etc.). For additives, the dilution factor is 0.
- **Total Dilution**: The total dilution factor for all dilutions in the dilutions list is calculated and displayed in the Total Dilution field. The dilution specified on the WinKQCL® Software template for the product must be equal to the Total Dilution defined here.

NOTE: As stated previously, when an Additive step is selected for the LAL Reagent Water Diluent and Aux Diluent options, the Additive step will always be processed first, prior to dilutions (if any). For the Multiple Diluents option, however, additives will be processed according to their position in the steps list (i.e., an additive step does not necessarily have to be processed first). More than one additive step may be defined. Additive steps are not included in the calculation of the Total Dilution (since additive steps are not dilutions).

- **Save**: Closes the interface and saves any changes applied.
- **Cancel**: Closes the interface without saving any changes.

Product Auxiliary Dilution Editor



The Product Auxiliary Dilution Editor interface provides functionality to create or edit an auxiliary dilution or additive for a product. The name of the product with which the auxiliary dilution/additive step is associated is stated at the top of the window. The following functionality is provided:

- **Diluent**: The name of the liquid to be used for the dilution/additive. The diluent/additive is selectable from the dropdown list, which is populated with the auxiliary liquids defined in the Auxiliary Liquids Configuration interface (see section “Auxiliary Liquids Configuration”).
- **Liquid Class**: This field is for reference only and is automatically populated when a diluent/additive is selected. The liquid class is the value defined for the selected liquid in the Auxiliary Liquids Configuration interface (see section “Auxiliary Liquids Configuration”).
- **Product/Diluent Mixing**

- **Mix Volume**: The percentage of the liquid in the tube used to dilute the product with the diluent.
- **Mix Count**: The number of up/down mixing actions used to mix the product/diluent dilution.

One of two processing options may be selected: Dilution or Additive.

- **Dilution**: The following functionality is provided when the Dilution option is selected:
  - **Total Dilution Factor**: The target total dilution factor (e.g. 2 implies a 1:2 dilution, 5.2 implies a 1:5.2 dilution, etc.). The field accepts positive decimal numbers.
  - **Calculate**: This button is enabled whenever the value in the Total Dilution Factor field is modified. When the button is clicked, the intermediate steps and the final step to arrive at the value entered in the Total Dilution Factor field are calculated and displayed. Each intermediate step has a dilution factor of 10. The total volume for each intermediate step is the "Total Sample Dilution Target Volume uL" value defined in the system configuration.

    The sample volume and diluent volumes are calculated based on the Dilution Factor and Total Volume values using the following formulas:

    Sample Volume = Total Volume / Dilution Factor

    Diluent Volume = Total Volume - Sample Volume

    When it is not possible to calculate at least one Final Volume value that is less than or equal to the volume specified by the "Total Sample Dilution Max Volume uL" value in the system configuration, an error message is displayed indicating that no solution is possible due to the configuration parameters. No calculation results are displayed for the proposed total dilution factor in that case.
  - **Intermediate Dilution Steps List**: Displays the list of intermediate steps (i.e., steps prior to the final step) to arrive at the dilution factor value entered in the Total Dilution Factor field, as determined by the Calculate action (see Calculate functionality). The following fields are displayed for each intermediate step: *Description*, *Sample Volume*, *Diluent Volume* and *Total Volume*.
  - **Final Step Display**: Displays values for the final dilution step (i.e., post intermediate steps) that are used to arrive at the dilution factor value entered in the Total Dilution Factor field. The following fields are displayed: *Dilution Factor, Sample Volume, Diluent Volume*, and *Final Volume*.
    - **Dilution Factor**: Displays the final dilution factor (i.e., post intermediate steps) required to arrive at the dilution factor value entered in the Total Dilution Factor field.
    - **Sample Volume**: Calculated based on values in the Dilution Factor and Final Volume fields of the Final Step display using the formula:

      Sample Volume = Final Volume / Dilution Factor
    - **Diluent Volume**: Calculated based on values in the Sample Volume and Final Volume fields of the Final Step display using the following formula:

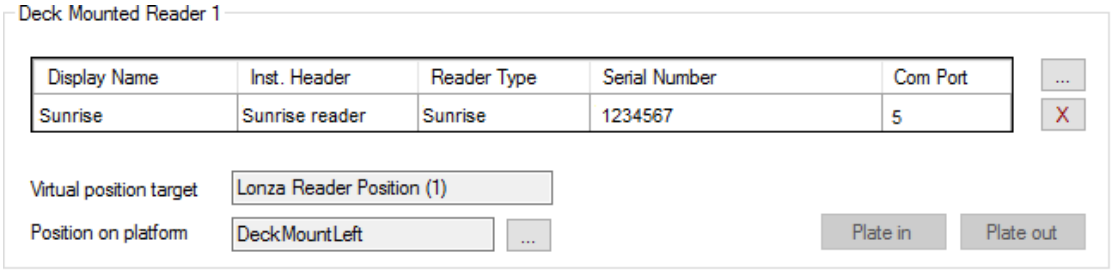
      Diluent Volume = Final Volume - Sample Volume
    - **Final Volume**: This field provides a list of all volumes that are less than or equal to the volume specified by the Total Sample Dilution Max Volume µL value in the system configuration and which may be selected for use to arrive at the dilution factor value entered in the Total Dilution Factor field.

      The default value of the Final Volume (following the Calculate action) is the calculated value that is closest to (but not less than) the value specified by the configured "Total Sample Dilution Target Volume µL" (see Main Menu Configuration \ System \ Volumes/Mixing/Timing). When a value is selected from the Final Volume list, the Sample Volume and Diluent Volume fields are recalculated for the selected value.
- **Additive**: Provides functionality to define an additive that is to be applied to the product. The name of the additive is selected from a drop-down list containing the names of all auxiliary liquids configured for the system (see section "Auxiliary Liquids Configuration"). When values are entered for the Sample Volume and Additive Volume fields, the Total Volume field is automatically calculated.

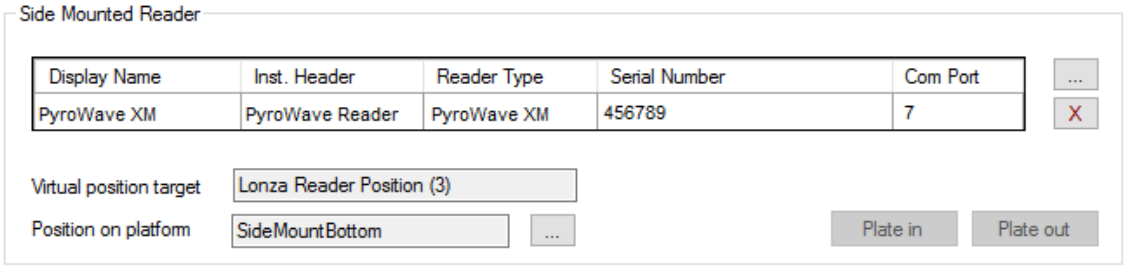
Readers

The Readers Configuration interface provides functionality to define microplate readers used in the system. The interface supports configuration of one or two readers mounted directly on the robot deck, and one reader mounted off the deck at the right side of the robot. When the interface opens, any existing reader configuration data retrieved from the database is displayed. Select the “Deck Mounted Readers” tab to configure readers mounted directly on the robot deck. Select the “Side Mounted Readers” tab to configure a reader mounted off the robot deck at the right side of the robot.

Deck Mounted Reader Example:



Side Mounted Reader Example:

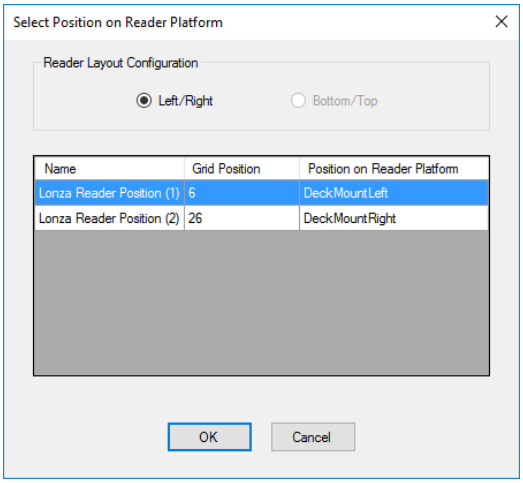


The following functionality is provided for each microplate reader:

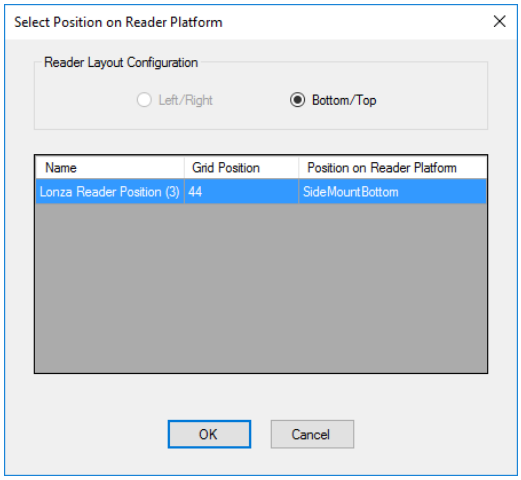
- **Reader Select**: Clicking ... displays the Select Reader interface that lists the available readers (provided from the WinKQCL® Software) for the system. When selected, the following reader parameters are displayed in the interface: *Display Name, Inst. Header, Reader Type, Serial Number* and *Com Port*.
- **Position on platform**: Clicking ... displays the physical position of the reader on the reader platform (i.e., DeckMountLeft, DeckMountRight, or SideMountBottom).

  The editing button is enabled following the selection of a reader. When the button is clicked, the "Select Position on Reader Platform" interface is displayed. The interface displays selectable reader positions for specifying the reader position associated with the target reader. On-deck readers are associated with Left/Right positions on the deck (i.e., positions DeckMountLeft and DeckMountRight). A sided mounted reader is associated with Bottom/Top positions on the right side of the reader (currently only position SideMountBottom is supported).

Deck Mount Selection



Side Mount Selection



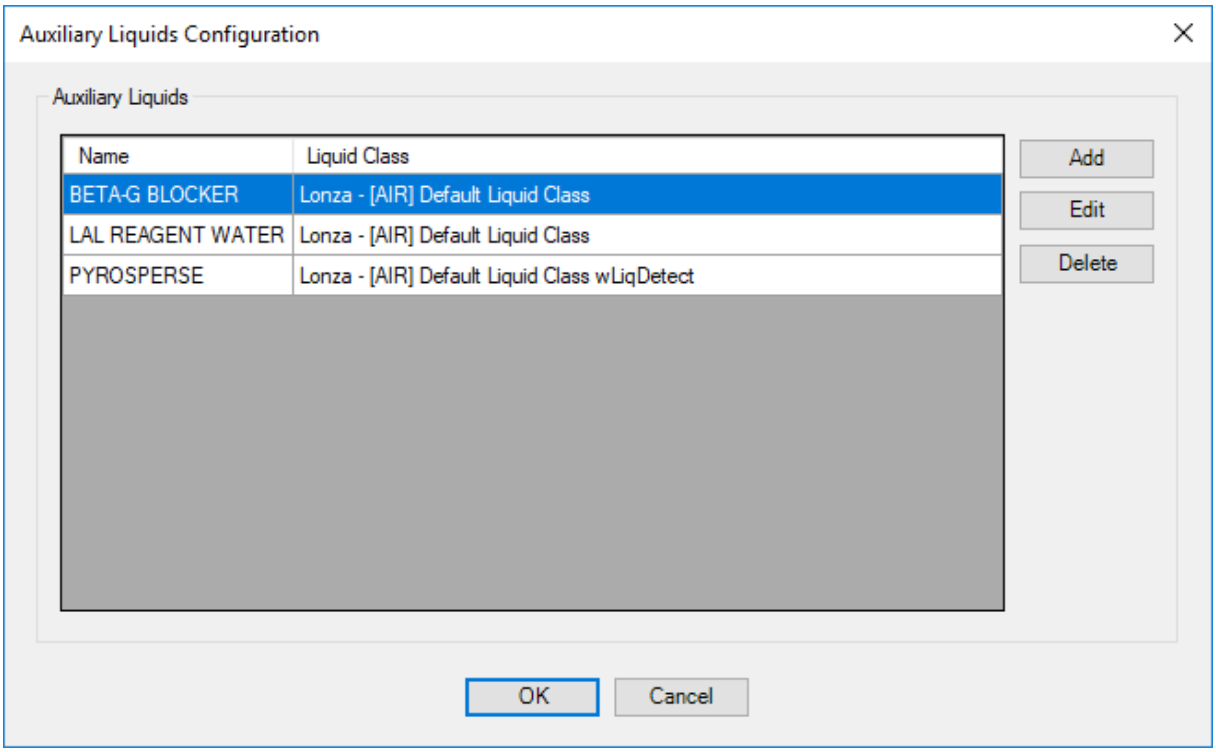
- **Virtual position target**: Displays the selected virtual reader position on the PyroTec® PRO System platform. May be one of the following: Lonza Reader Position (1), Lonza Reader Position (2), or Lonza Reader Position (3).

  Lonza Reader Position (1) and Lonza Reader Position (2) are associated with deck-mounted readers. Lonza Reader Position (3) is associated with a side-mounted reader. The software to associate a physical reader with a virtual software position uses the virtual position target internally.

- **Plate in**: Closes the reader door.
- **Plate out**: Opens the reader door.
- **Remove Reader**: Clicking X clears all values in the associated Reader Parameters.
- **OK**: Closes the interface and saves any changes applied.
- **Cancel**: Closes the interface without saving any changes.

Aux Liquids

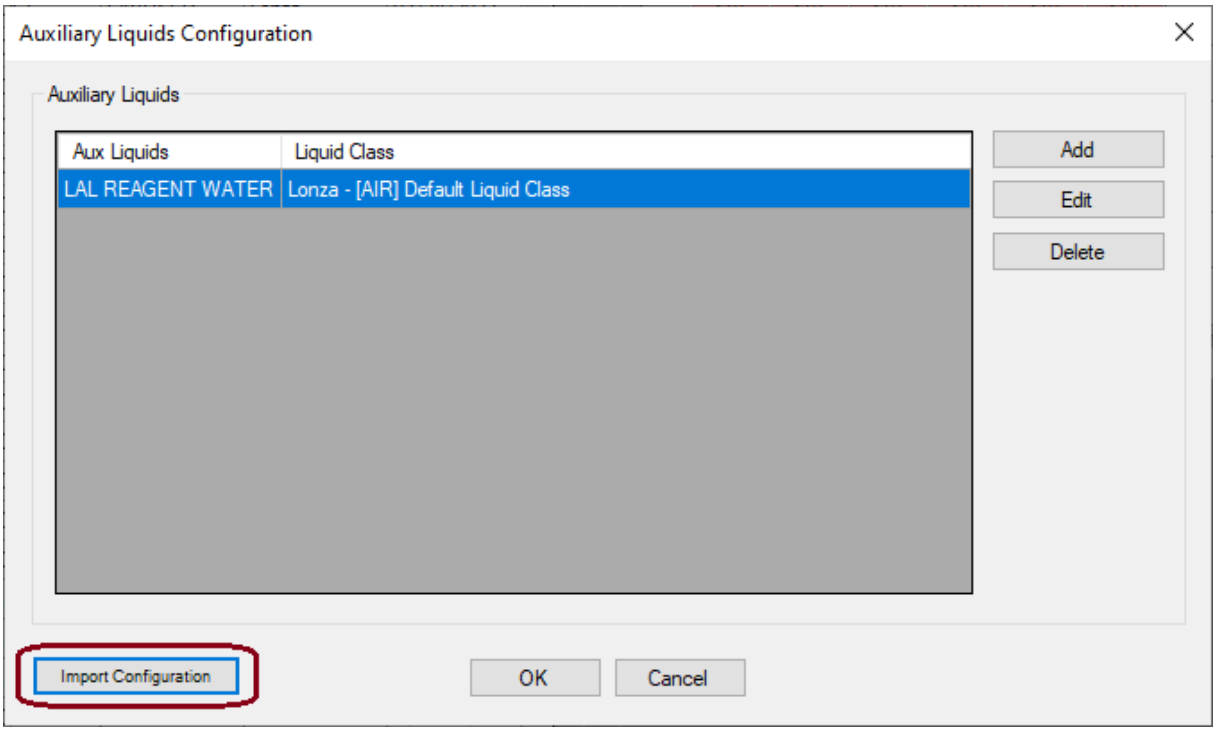
NOTE: The Aux Liquids feature is accessible only to WinKQCL® Software supervisors.



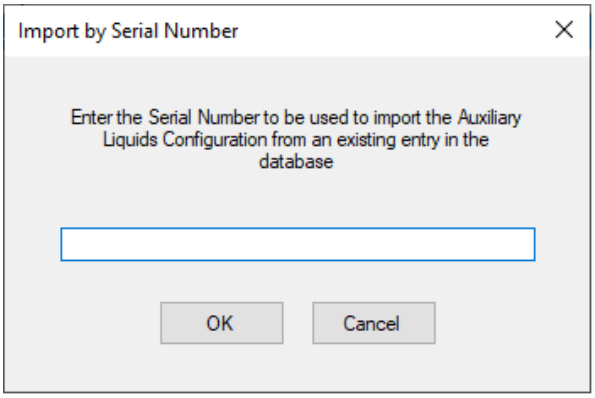
The Auxiliary Liquids Configuration interface provides functionality for configuring auxiliary liquids (e.g., for dilutions, buffering, etc.) used in the system. The following functionality is supported:

- **Auxiliary Liquids List**: Displays a list of Auxiliary Liquids that includes the default auxiliary liquid (i.e., LAL REAGENT WATER), and any other entries that have been added to the list via the Add action (see below). The following fields are displayed for each item in the list: Name, and Liquid Class.
- **Add**: Displays the Auxiliary Liquid Definition interface (see Auxiliary Liquid Definition), where a new auxiliary liquid can be defined.
- **Edit:** Displays the Auxiliary Liquid Definition interface (see Auxiliary Liquid Definition), where the auxiliary liquid currently selected in the Auxiliary Liquids list can be edited.
- **Delete:** Deletes the selected item in the list (LAL REAGENT WATER may not be deleted)
- **OK:** Closes the interface and saves any changes applied.
- **Cancel:** Closes the interface without saving any changes.

When the Auxiliary Liquids list contains *only* the default auxiliary liquid (i.e., LAL REAGENT WATER), the Import Configuration option is provided to allow the import of an existing Aux Liquids configuration that is associated with another PyroTec® PRO System:



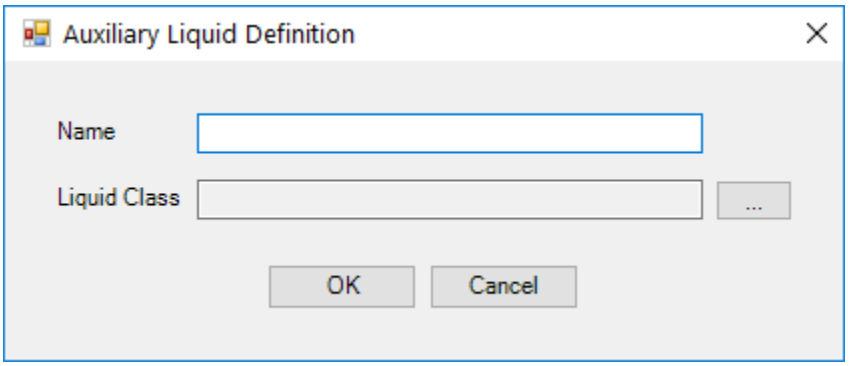
The Import Configuration option displays an interface where a serial number associated with a different (or previous) PyroTec® PRO System may be entered:



When a valid serial number is entered and OK is selected, the Auxiliary Liquids Configuration interface is populated with the values derived from the other PyroTec® PRO System.

WARNING: Only knowledgeable users should use the Import Configuration option. Importing and saving an Auxiliary Liquids Configuration will overwrite the existing Auxiliary Liquids Configuration, and the information may not be retrievable.

Auxiliary Liquid Definition

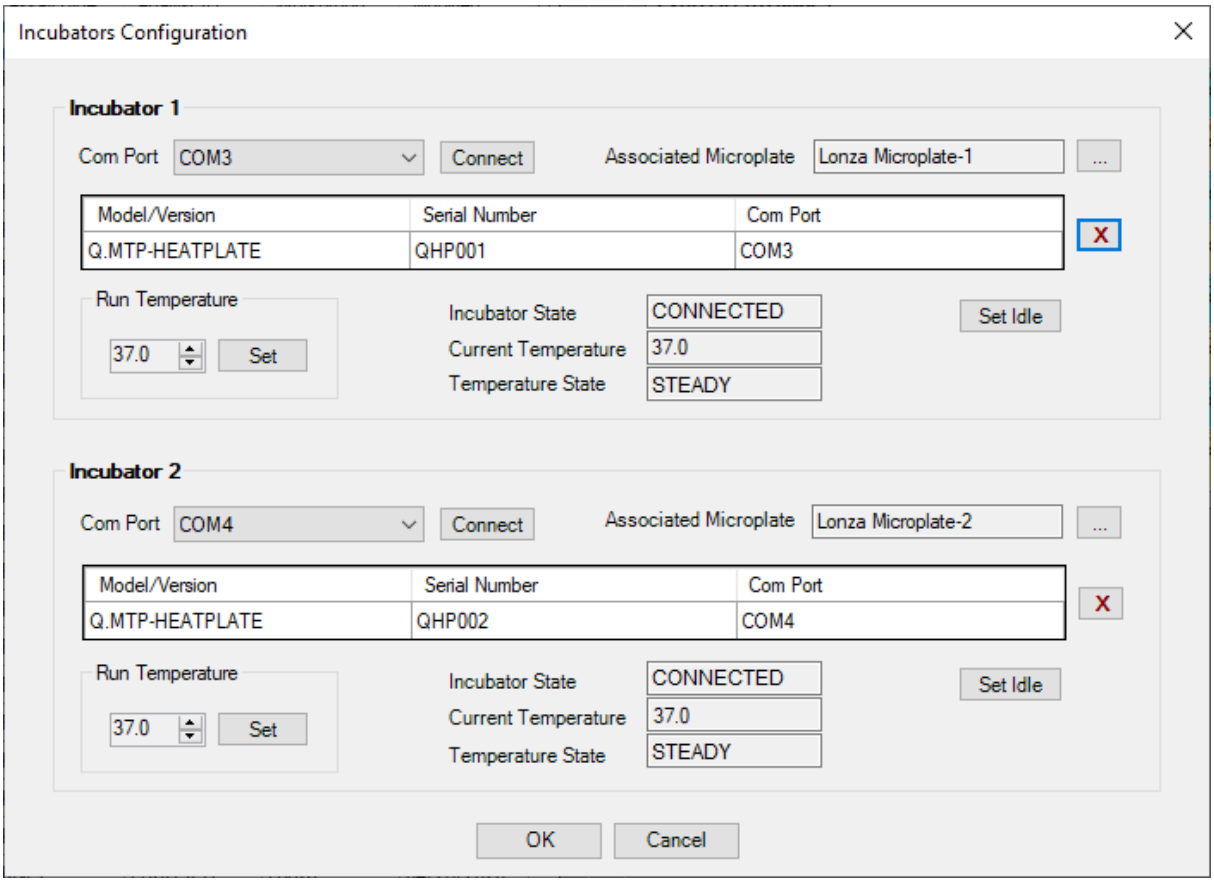


The Auxiliary Liquid Definition interface provides functionality to define parameters for an individual auxiliary liquid (a liquid used for dilutions, buffering, etc.). When the Auxiliary Liquid is the default auxiliary liquid (i.e., LAL REAGENT WATER), the Liquid Class field may be updated, but the Name may not be modified.

The following functionality is supported:

- **Name**: The name assigned to the auxiliary liquid.
- **Liquid Class**: The liquid class associated with the auxiliary liquid. The field is mandatory and may only be populated by using the browse button (i.e., no manual entry) to select a liquid class.
- **OK**: Closes the interface and saves any changes.
- **Cancel**: Closes the interface without saving any changes.

Incubators



The Incubators Configuration interface provides functionality to define and configure microplate incubators used in the system during plate preparation. The following functionality is provided individually for each microplate incubator defined for the system:

- **Com Port List**: The dropdown list provides a list of system communication ports. The selected communication port will be associated with the incubator (provided communications is successfully instantiated – see Connect below).
- **Connect**: Initiates communications with an incubator on the selected com port. If the connection attempt is unsuccessful, an error message is displayed to indicate the issue. If the connection is successful, the parameters for the incubator are displayed in the Incubator Parameters table (see below).
- **Incubator Parameters Table**: Displays the following information for the connected incubator: Model/Version, Serial Number and Com Port.
- **Associated Microplate**: Click the Microplate Select button to the right of the Associated Microplate field to select a microplate to be associated with the incubator.
- **Run Temperature**: Use the controls in this section to set the runtime temperature of the incubator. Update to the desired temperature and then click the Set button.
- **Set Idle**: Sends the command to the incubator to transition to idle mode (in which the temperature is not maintained). Clicking "Set" will cause the system to control the unit again.
- **Incubator State**: Displays "CONNECTED" if the software currently has communications with the incubator, and "NO CONNECTION" if not.
- **Current Temperature**: Displays the current temperature of the incubator (if connected).
- **Temperature State**: Displays the current incubator temperature stability (STEADY, NOT STEADY, or IDLE). It may take several minutes for the incubator temperature to reach a steady state following the setting of the temperature.
- **Remove Incubator**: Click the Remove Incubator button  to remove the incubator from the configuration.
- **OK**: Closes the interface and saves any changes.
- **Cancel**: Closes the interface without saving any changes.

System

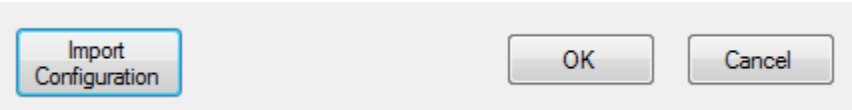
WARNING: The System configuration feature is accessible only to WinKQCL® Software supervisors. Changes to the system configuration should be made only be Lonza or other qualified personnel. Incorrect configuration can result in system malfunction and/or invalid assays. Only knowledgeable users should apply liquid class assignments. Incorrect liquid class assignments may result in invalid assays.

The System configuration interface provides several sub-interfaces used to configure items related to interfacing with the PyroTec® PRO System, physical-to-software position associations, runtime parameters and default parameters applied to the processing of products (i.e., samples). The following sub-interfaces are provided:

- Scripts
- Assays
- Microplates
- Tubes Racks
- Reagent Racks
- Troughs
- Volumes/Mixing/Timing
- Product Defaults
- LoadingID (available only when the LoadingID unit is implemented in the system)

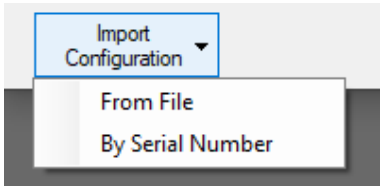
When the System configuration interface is opened, any previously configured and saved items are displayed in the appropriate configuration controls on the various interfaces.

The following buttons are provided to save or cancel modifications and to import a system configuration:

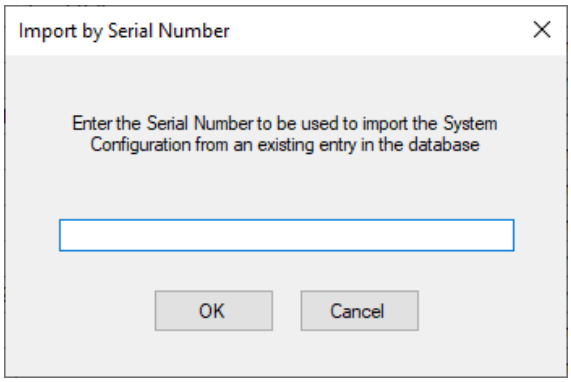


- **OK**: Saves all modified configuration parameters to the database and closes the interface.
- **Cancel**: Closes the interface without saving any modifications.

- **Import Configuration**: Provides the following options:



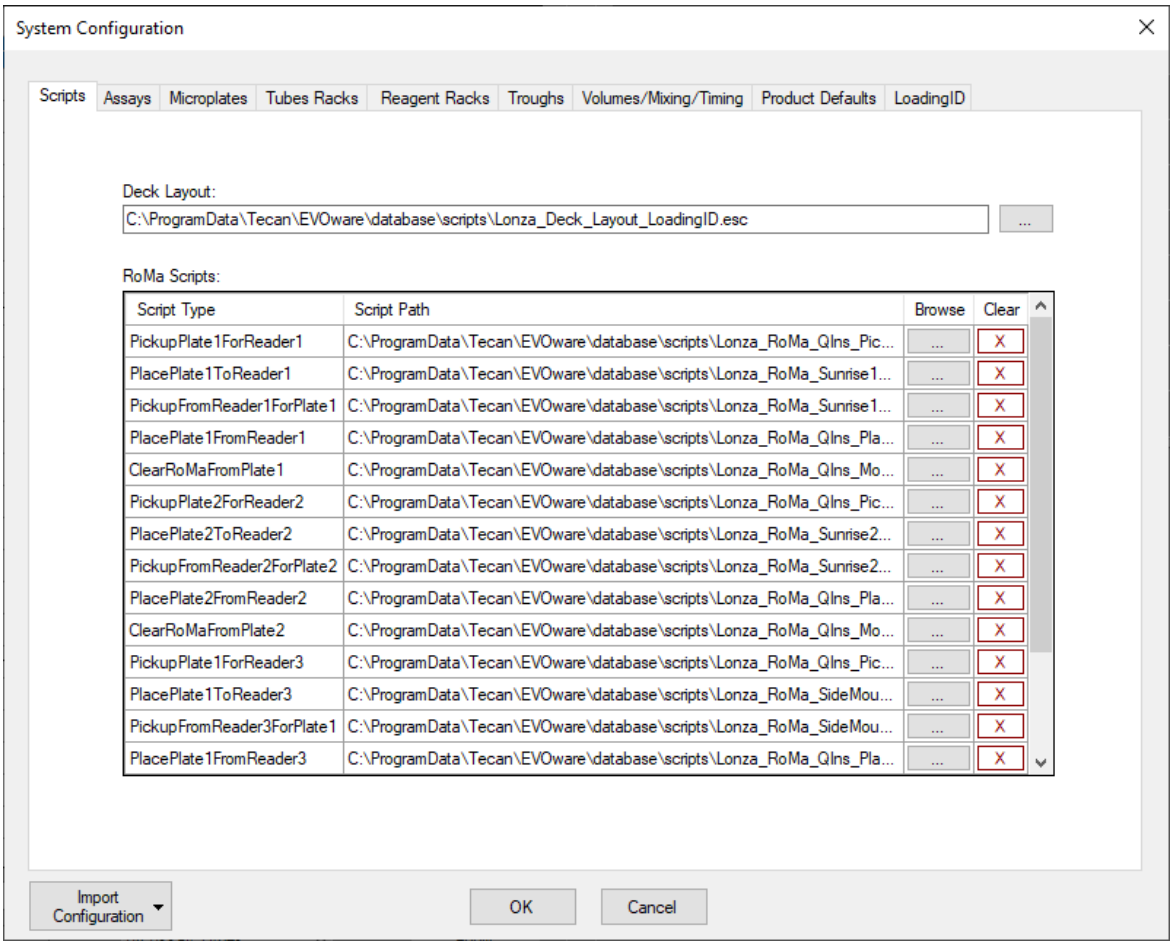
  - **From File**: supports import of a specifically formatted file to populate the configuration parameters.
  - **By Serial Number**: displays an interface where a serial number associated with a different (or previous) PyroTec® PRO System may be entered:



When a valid serial number is entered and OK is selected, the System Configuration interface is populated with the values derived from the other PyroTec® PRO System.

WARNING: Only knowledgeable users should use the Import Configuration option. Importing and saving a System Configuration will overwrite the existing System Configuration, and the information may not be retrievable.

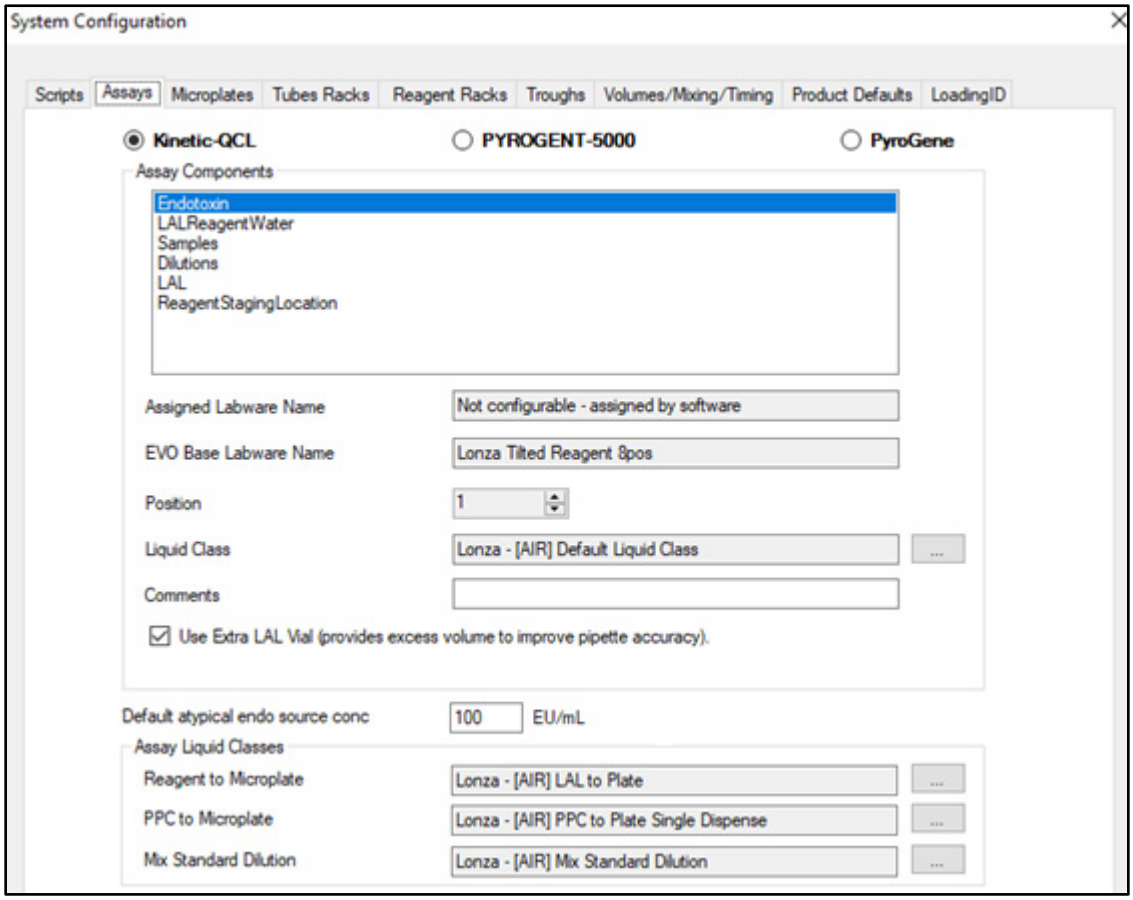
Scripts



The Scripts interface is used to configure the location of the Deck Layout script and the locations of scripts required for robotic arm actions.

NOTE: These parameters are configured by Lonza personnel during system installation and should generally not be modified by users of the system.

Assays



The Assays interface provides functionality to configure labware and liquid classes associated with the supported Lonza endotoxin assay types. Kinetic-QCL®, PYROGENT® 5000 and PyroGene® Assays are currently supported. Each supported assay type is selectable for configuring.

The following fields and functionality are provided for each assay type.

Assay Components

The components associated with the selected assay type are displayed in the list. Each component is selectable. When a component is selected, its associated configuration fields are displayed. The following configuration fields are common to all assay components and have the same functionality:

- **Assigned Labware Name**: This field is mandatory and is modifiable or not modifiable based on the component type (details provided below). When modifiable, a browse button is present that allows the name to be selected from a list of available candidates. The field may only be populated by using the browse button (i.e., no manual entry).
- **EVO Base Labware Name**: The field is for reference only, and is populated automatically by the software.
- **Position (on the labware)**: This field is modifiable or not modifiable based on the component type (details provided below). It is used to specify the position of the component on the labware. When modifiable, the field is mandatory and must contain a positive integer.
- **Liquid Class**: This field is used to specify the liquid class to be associated with this component. The field is mandatory and may only be populated by using the associated browse button (i.e., no manual entry) to select a liquid class.
- **Comments**: This is an optional field provided for arbitrary user-defined text.
- **Default atypical endo source conc**: This specifies the default endotoxin source concentration value to be assigned when the PyroTec® PRO System Software module determines that an atypical endotoxin source may be required to support a selected template's standard curve

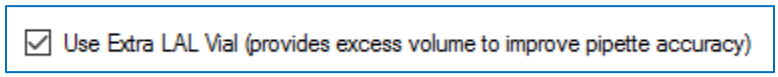
Assay Liquid Classes

- **Reagent to Microplate**: Specifies the liquid class used when transferring reagent to the microplate. The field is mandatory and may only by populated by using the associated browse button (i.e., no manual entry) to select a liquid class.
- **PPC to Microplate**: Specifies the liquid class used when transferring the Positive Product Control (PPC) to the microplate. The field is mandatory and may only be populated by using the associated browse button (i.e., no manual entry) to select a liquid class.
- **Mix Standard Dilution**: Specifies the liquid class used when mixing the dilutions use to create the standard curve. The field is mandatory and may only be populated using the associated browse button (i.e., no manual entry) to select a liquid class.

Assay Dependent

The following fields and functionality are specific to particular assay types as noted below:

- **Use Extra LAL Vial:** Only applicable to assay type Kinetic-QCL®. When this option is checked, an additional vial of LAL reagent will be included in the assay. Using the extra vial provides excess reagent volume to help improve the instrument pipetting accuracy of the PyroTec® PRO System.



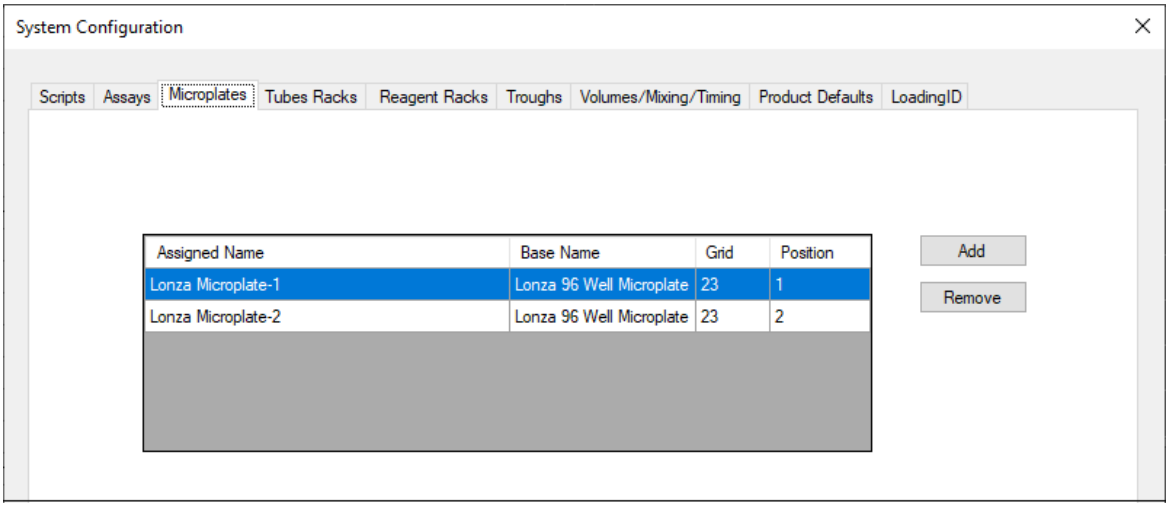
WARNING: When using 100 mL troughs: the PyroTec® PRO System has been validated using the extra LAL vial option. Lonza recommends that this option be selected when 100mL troughs are used for LAL. The user proceeds at their own risk if the Extra LAL Vial option is not selected for this case.

NOTE: When using MAX recovery 25 mL troughs for LAL: the extra vial is *not* required for cases where the template has 79 or more wells.

- **LAL Vial Size:** This option allows selection of one of the two reagent vial sizes supported for the PYROGENT® 5000 Assay. The selected vial size will be used for deck setup and running of the assay.



Microplates

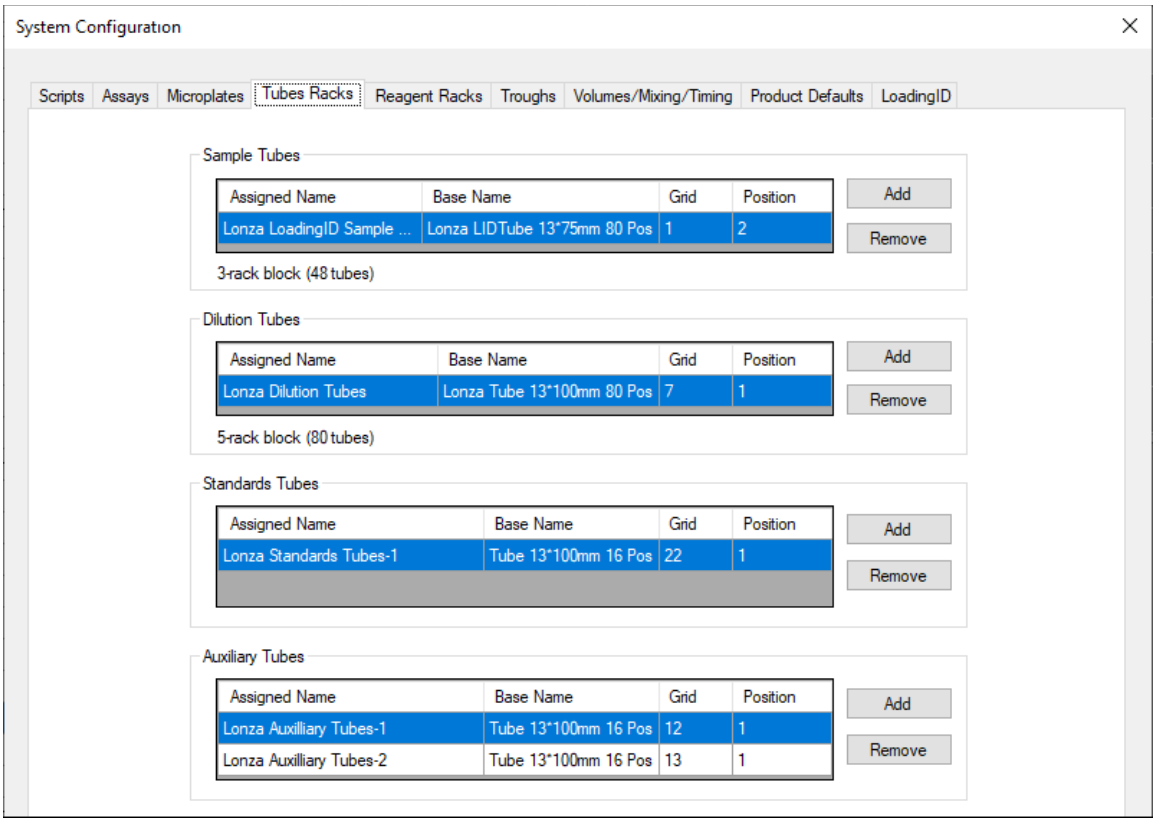


The Microplates interface provides functionality to specify up to two microplates used in the system. The microplates list displays the list of microplates that have been added to the list via the Add action (see below).

The following parameters are displayed for each microplate in the list: *Assigned Name*, *Base Name*, *Grid,* and *Position*. One item in the list is selectable at a time.

- **Add**: Select an available microplate candidate to add to the list.
- **Remove**: Remove the selected microplate from the list.

Tubes Racks



The Tubes Racks interface provides functionality to specify the type, and number of tube racks used in the system:

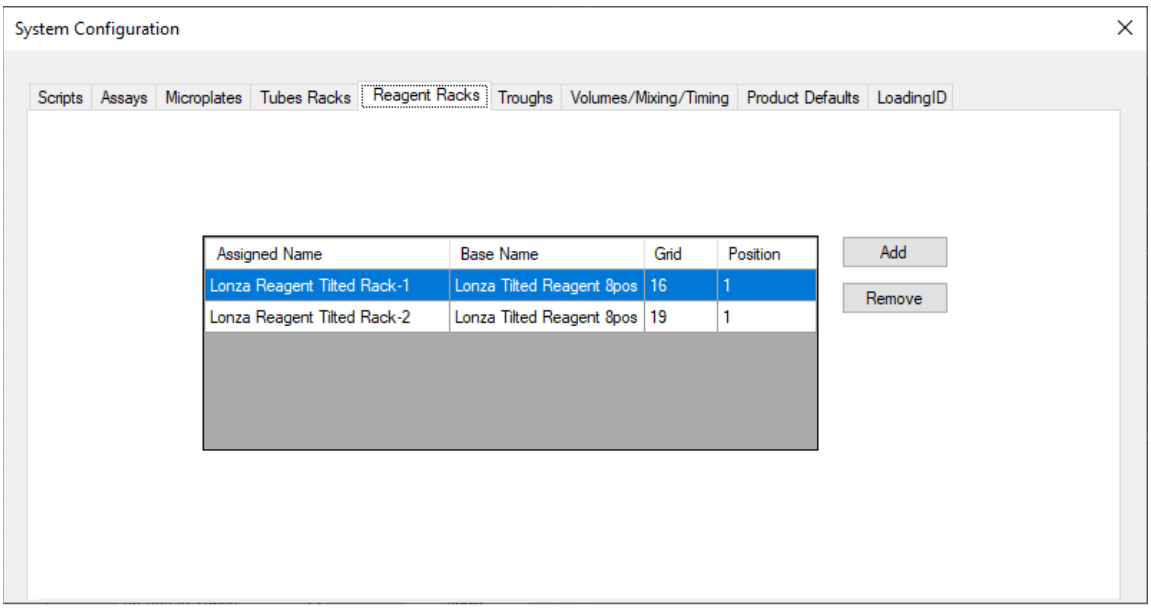
Component	Quantity	Description
Sample Tubes	1	<u>Without LoadingID:</u> A set of 3 racks, supporting a maximum of 48 tubes. <u>With LoadingID:</u> A set of 5 runners (on LoadingID), supporting a maximum of 80 tube positions.
Dilution Tubes	1	A set of 5 racks, supporting a maximum of 80 tubes.
Standards Tubes	1	A single rack.
Auxiliary Tubes	1 or 2	A single rack (for each assay).

The associated list for each tube rack type displays the list of tube racks that have been added to the list via the Add action (see below). The following parameters are displayed for each tube rack in the list: *Assigned Name*, *Base Name*, *Grid,* and *Position*. One tube rack item in each list is selectable at a time.

The following functionality is provided for each of the tube rack types:

- **Add**: Select an available tube rack candidate to add to the list.
- **Remove**: Remove the selected tube rack from the list.

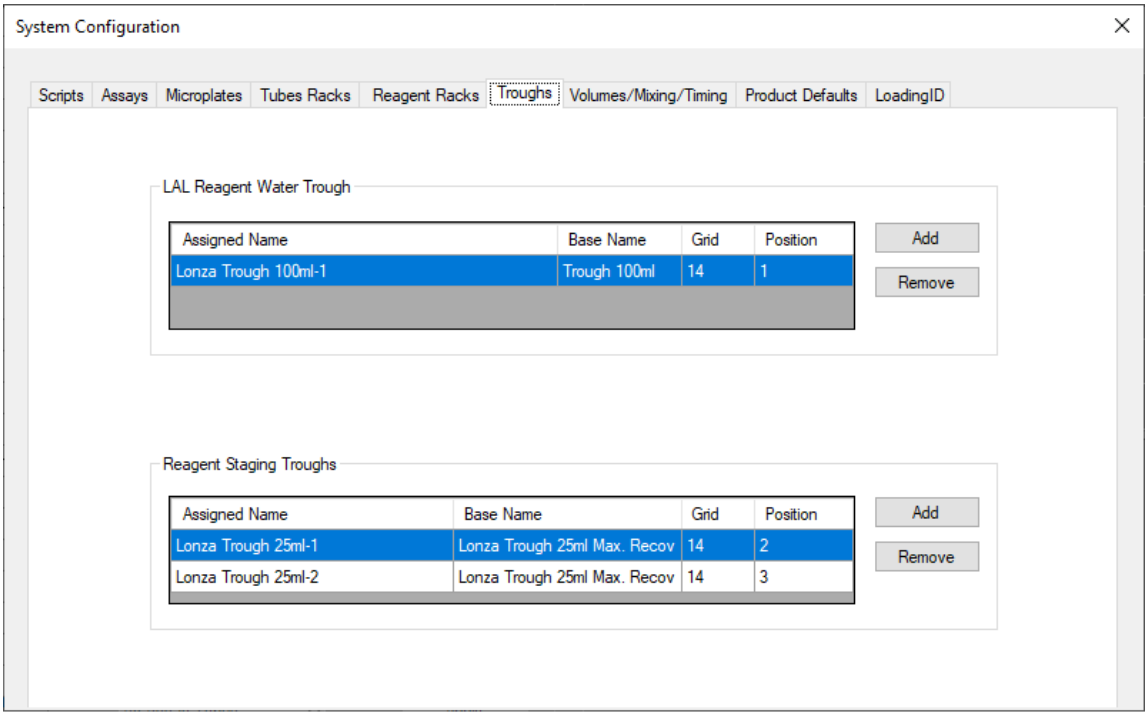
Reagent Racks



The Reagent Racks interface provides functionality to specify up to two reagent racks used in the system. The reagent racks list displays the list of reagent racks that have been added to the list via the Add action (see below). The following parameters are displayed for each reagent rack in the list: *Assigned Name*, *Base Name*, *Grid,* and *Position*. One item in the list is selectable at a time.

- **Add**: Select an available reagent rack candidate to add to the list.
- **Remove**: Removes the selected reagent rack from the list.

Troughs

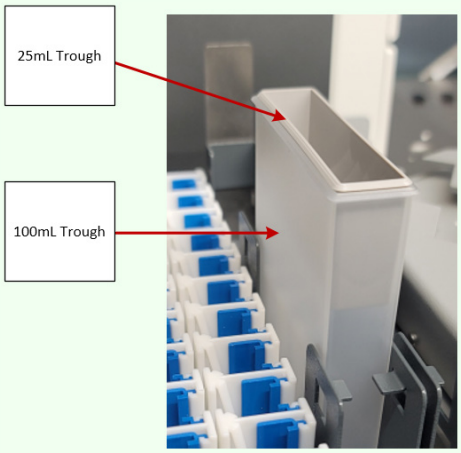


The Troughs interface provides functionality to specify the following trough types used in the system:

- LAL Reagent Water Trough (1 trough)
  - Trough size: 100 mL

- Reagent Staging Troughs (1 or 2 troughs)
  - Trough size: Both 100 mL and 25 mL troughs are supported. When two Reagent Staging Troughs are configured, both must be of the same type.

NOTE: Each 25 mL trough configured for use in the system must be positioned atop a 100 mL trough as shown in the image below:

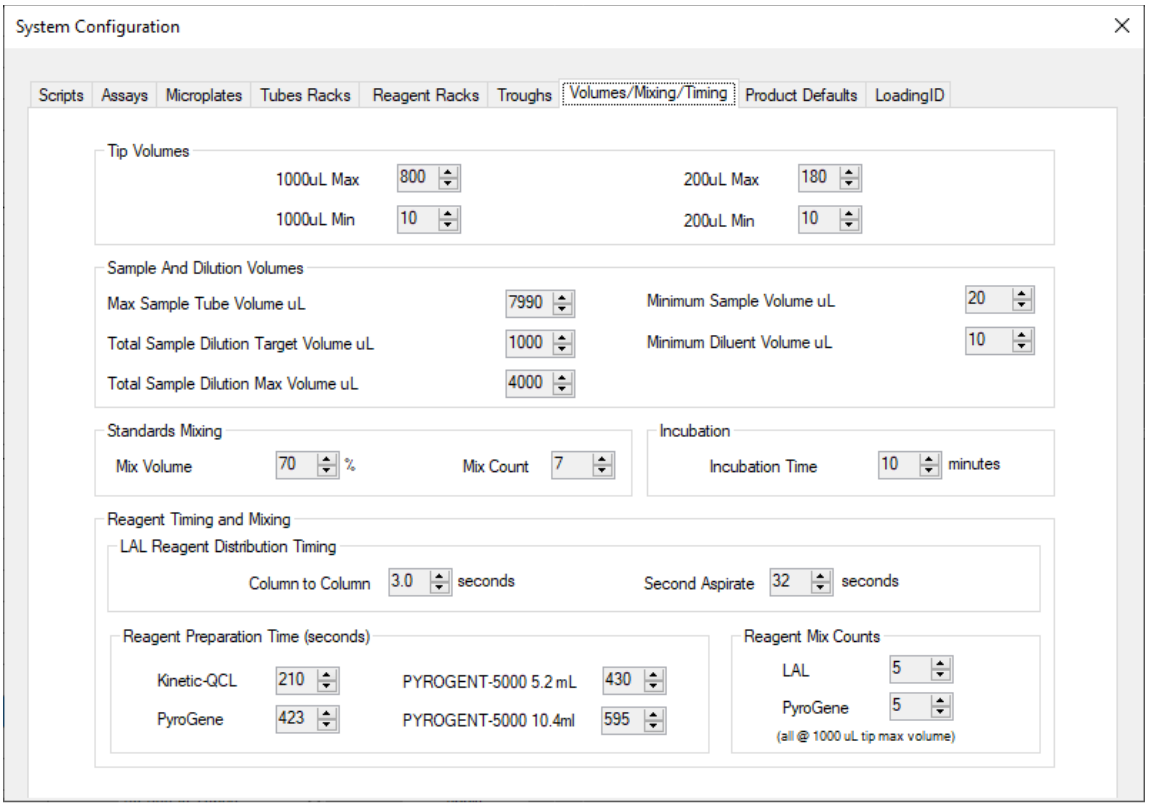


The associated list for each trough type displays the list of troughs that have been added to the list via the Add action (see below). The following parameters are displayed for each trough in the list: *Assigned Name*, *Base Name*, *Grid,* and *Position*. One trough item in each list is selectable at a time.

The following functionality is provided for each of the trough types:

- **Add**: Select an available trough candidate to add the list.
- **Remove**: Remove the selected trough from the list.

Volumes/Mixing/Timing



The Volumes/Mixing/Timing interface provides functionality to specify values for volumes, mixing and timings.

- **Tip Volumes**:
  - **1000 µL Max Volume**: The maximum aspirate or dispense volume when using 1000 µL pipette tip.
  - **1000 µL Min Volume**: The minimum aspirate or dispense volume when using a 1000 µL pipette tip.
  - **200 µL Max Volume**: The maximum aspirate or dispense volume when using 200 µL pipette tip (not currently implemented in the system).
  - **200 µL Min Volume**: The minimum aspirate or dispense volume when using a 200µL pipette tip (not currently implemented in the system).
- **Sample and Dilution Volumes**:
  - **Max Sample Tube Volume**: The maximum volume in µL allowable in a sample tube.
  - **Total Sample Dilution Target Volume**: The target volume in µL for a diluted sample (i.e., sample + diluent).
  - **Total Sample Dilution Max Volume**: The maximum allowable total volume (in µL) for a diluted sample (i.e., sample + diluent).
  - **Minimum Sample Volume µL**: The minimum allowable sample volume in µL used in a dilution.
  - **Minimum Diluent Volume µL**: The minimum allowable diluent volume in µL used in a dilution.
- **Standards Mixing**:
  - **Mix Volume**: The percentage of the liquid in the tube used to mix a standard concentration.
  - **Mix Count**: The number of up/down mixing actions used to mix a standard concentration.
- **Incubation**:
  - **Incubation Time**: The time in minutes to incubate a microplate in the reader prior to adding reagent (default = 10).

NOTE: Assigning a value of zero (0) will result in no reader incubation.

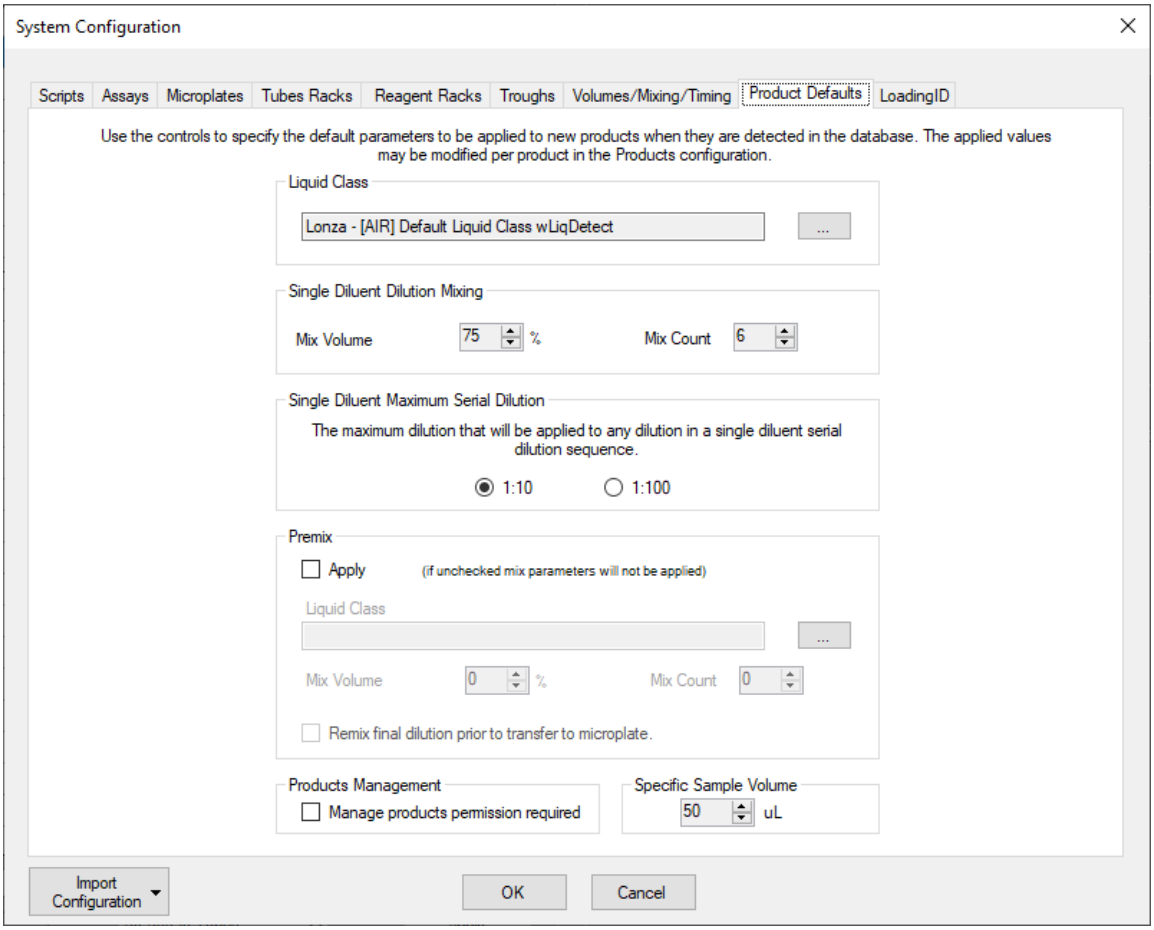
- **Reagent Timing and Mixing**:
  - **LAL Reagent Distribution Timing**:

- **Column to Column**: The time required for the PyroTec® PRO System to move from one column to the next and dispense reagent.
- **Second Aspirate**: The time required for the PyroTec® PRO System to return to the reagent-staging trough, aspirate reagent and dispense in the next required microplate column.

- **Reagent Preparation Time (seconds):**
  - **Kinetic-QCL® Assay**: The time in seconds required to prepare the LAL reagent for a Kinetic-QCL® Assay.
  - **PyroGene® Assay**: The time in seconds required to prepare the working reagent for a PyroGene® Assay.
  - **PYROGENT® 5000 Assay 5.2 mL**: The time in seconds required to prepare the LAL reagent for a PYROGENT® 5000 Assay when reagent vial size 5.2 mL is used.
  - **PYROGENT® 5000 Assay 10.4 mL**: The time in seconds required to prepare the LAL reagent for a PYROGENT® 5000 Assay when reagent vial size 10.4 mL is used.
- **Reagent Mix Counts**:
  - **LAL**: The number of up/down mixing actions used to mix LAL reagent after reconstitution (applied to Kinetic-QCL® and PYROGENT® 5000 Assays).
  - **PyroGene®**: The number of up/down mixing actions used to mix PyroGene® Assay working reagent after creation.

NOTE: Mix volume for both Kinetic-LAL and PyroGene® Assays is the 1000 µL tip max volume as specified by 1000 µL Max Volume setting (see Tip Volumes section above).

Product Defaults



The Product Defaults interface provides functionality to specify the default liquid class and default dilution mix parameters for new products when the software detects the products in the database.

- **Liquid Class**: The default liquid class to be assigned to new products when the product configuration interface is opened. The field may be populated by using the associated browse button.
- **Single Diluent Dilution Mixing**:
  - **Mix Volume**: The percentage of the liquid in the tube used to mix a sample diluted with a single diluent.
  - **Mix Count**: The number of up/down mixing actions used to mix a sample diluted with a single diluent.
- **Single Diluent Maximum Serial Dilution**: Select either 1:10 or 1:100 as the maximum dilution that will be applied to any dilution in a dilution sequence in which a single diluent is used.

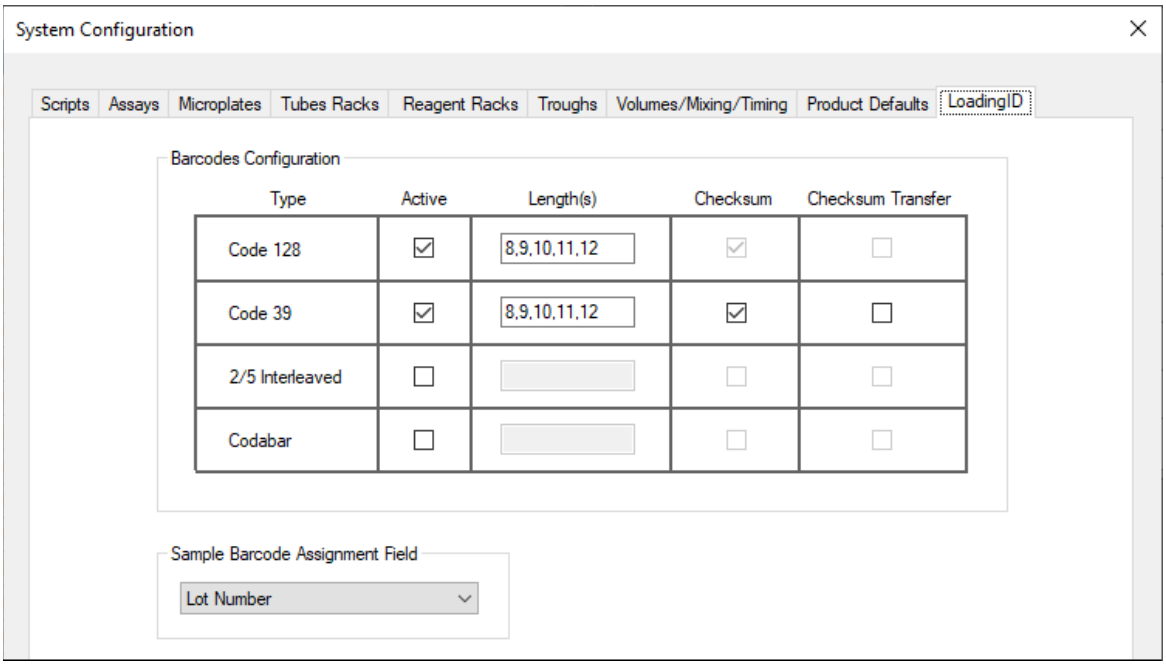
NOTE: The "Single Diluent" default values are applied only to samples that are diluted with a single diluent. Samples (products) that require multiple diluents are configured *per* product in the *Products* Configuration interface.

- **Premix:**
  - **Apply**: When checked, then the default premix parameters will be assigned to new products.
  - **Liquid Class**: The default liquid class to be used to premix a product. The field may be populated by using the associated browse button.

NOTE: A liquid class optimized for mixing must be selected as the premix liquid class. Lonza recommends liquid class "*Lonza - [AIR] Mix Product Default Liq Class"*.

  - **Mix Volume**: The default percentage of the liquid in the tube used to premix a product.
  - **Mix Count**: The default number of up/down mixing actions used to premix a product.
  - **Remix final dilution prior to transfer to plate**: When checked and a product is diluted, the final dilution will be mixed again prior to transfer to plate using the same parameters defined for premixing.
- **Products Management:**
  - **Manage products permission required**: When checked, the logged in user may only edit PyroTec® PRO System Products if the user has been assigned "Manage Products" permission in the WinKQCL® Software. If the user has not been assigned "Manage Products" permission, menu options Configuration \ Products and Configuration \ Aux Liquids will not be available for selection by the user.
- **Specific Sample Volume:**
  The default Specific Sample Volume to be assigned when a Product is configured to use a Specific Sample Volume. See: Specific Sample Volume in Products Configuration.

LoadingID



The LoadingID interface provides the following functionality**:**.

- **Barcodes Configuration:**

  Functionality to configure each supported barcode type. Barcode type Code 128 is recommended for optimum reading efficiency and reliability. This is the only format currently qualified for use with the LoadingID module on the PyroTec® PRO System.

  - Active: check this box to enable barcode configuration for the associated type.
  - Lengths: supports entry of up to 5 barcode lengths.
  - Checksum: calculate a checksum verification character for the scan (required for Code 128)
  - Checksum Transfer: append the checksum verification character to the end of the barcode scan data to verify the integrity.

- **Sample Barcode Assignment Field:**
  Functionality to select the field on the WinKQCL® Software template where the barcode scan data is located

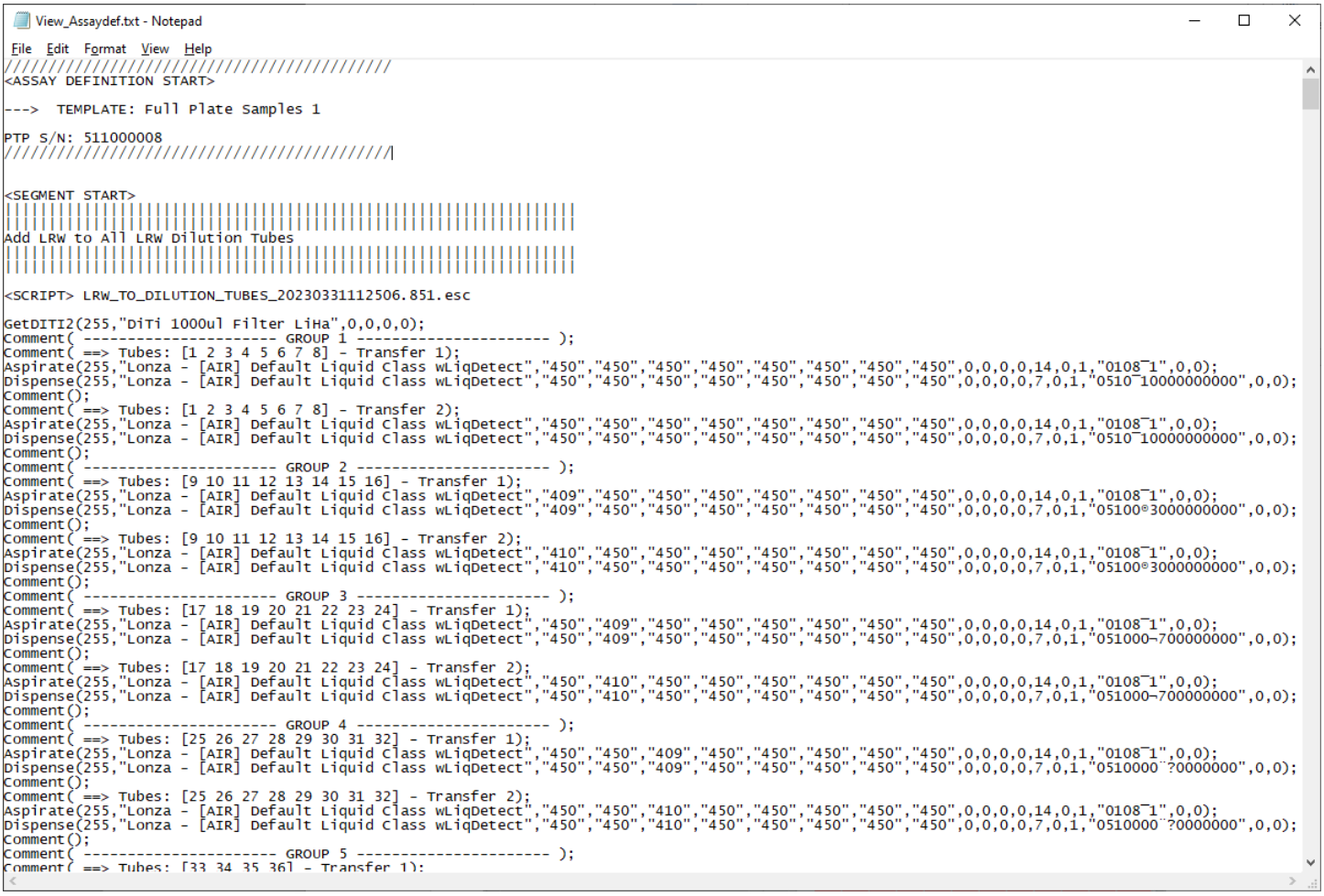
View

The View menu item provides the following submenu item.

NOTE: The View Assay Definition feature is accessible only to WinKQCL® Software supervisors.

Assay Definition

When this menu item is selected, a text file is displayed that shows the robotic commands that will be sent to the PyroTec® PRO System. The information is useful for previewing the sequence of actions that will be performed by the PyroTec® PRO System to complete the assay(s).



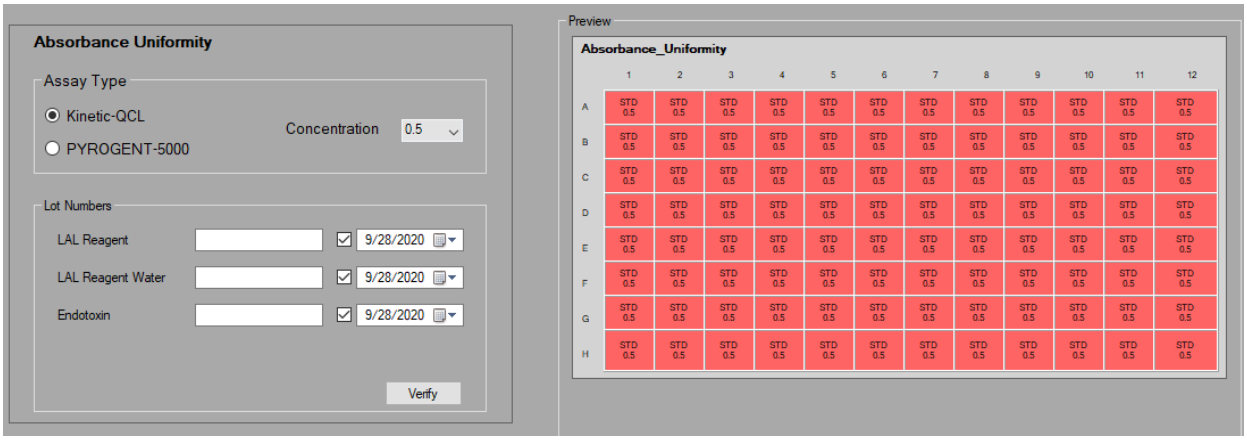
Other Tests

The Other Tests menu provides the following submenu items:

- Absorbance Uniformity
- Fluorescence Uniformity
- Operational
- Pressure Leak Test

Absorbance Uniformity

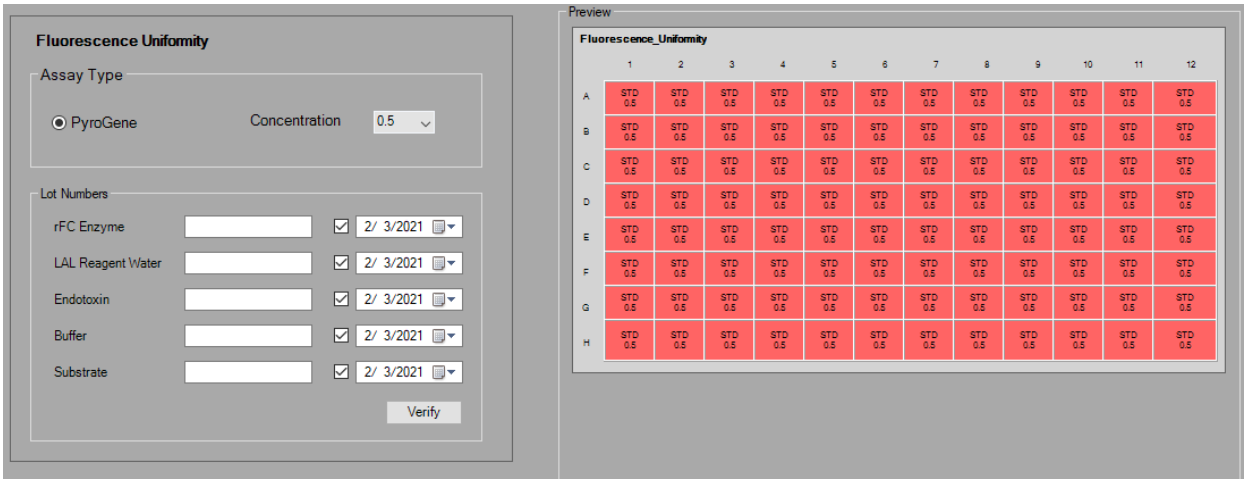
The interface provides functionality to perform an Absorbance Uniformity test.



- **Assay Type**:
  - **Type**: The type of assay (Lonza Kinetic-QCL® and Lonza PYROGENT® 5000 Assays are supported).
  - **Concentration**: The standard concentration to be used in the assay. Select from available values in the dropdown list.
- **Lot Numbers**: Fields to enter lot numbers for the LAL reagent, LAL Reagent Water, Endotoxin, and Buffer (required only for PYROGENT® 5000) used in the assay, and the expiration date for each.
- **Verify**: Checks the validity of data entered for the lot numbers.
- **Template Preview**: Displays the microplate layout that will be used to perform the assay. The layout is generated automatically based on the selected concentration.
- **<< Back**: Closes the Absorbance Uniformity interface and displays the Template Select interface.

Fluorescence Uniformity

The interface provides functionality to perform a Fluorescence Uniformity test.

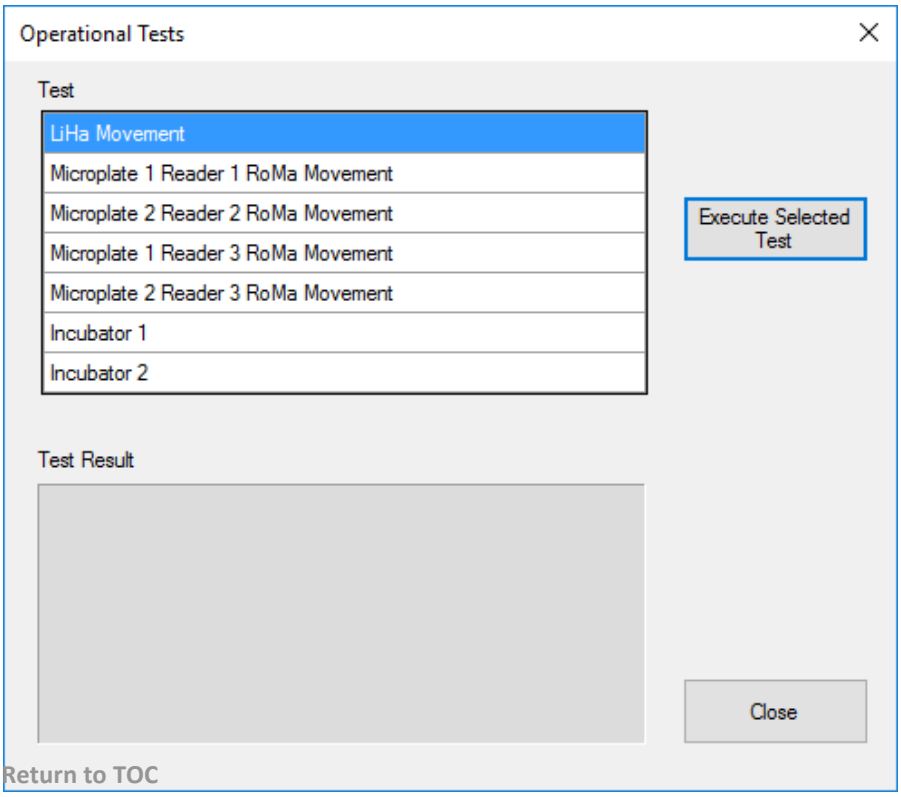


- **Assay Type**:
  - **Type**: The type of assay (Lonza PyroGene® recombinant Factor C ssay is supported).
  - **Concentration**: The standard concentration to be used in the assay. Select from available values in the dropdown list.
- **Lot Numbers**: Fields to enter lot numbers for the rFC Enzyme, LAL Reagent Water, Endotoxin, Buffer, and Substrate used in the assay, and expiration date for each.
- **Verify**: Checks the validity of data entered for the lot numbers.
- **Template Preview**: Displays the microplate layout that will be used to perform the assay. The layout is generated automatically based on the selected concentration.
- **<< Back**: Closes the Fluorescence Uniformity interface and displays the Template Select interface.

Operational

The Operational Test interface provides functionality to perform operational qualification tests.

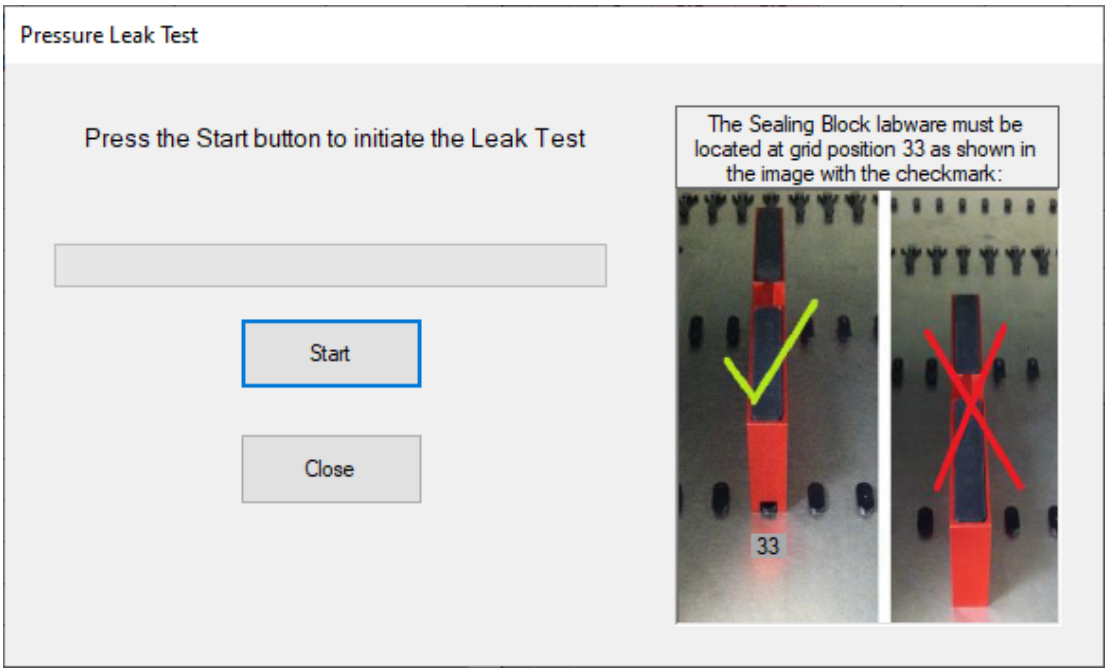
NOTE: The Operational Test feature is accessible only to WinKQCL® Software supervisors. Use of the interface should be limited to Lonza personnel and/or qualified system administrators.



The Test list displays the tests available for execution. One test in the list is selectable at a time. When the Execute Selected Test button is clicked, the test is executed and the result is displayed in the Test Result field.

Pressure Leak Test

When this menu item is selected, the Pressure Leak Test interface is displayed. The interface provides functionality to perform the LiHa Pressure Leak Test. This operation should be performed a *minimum* of once per week.



The interface provides the following functionality:

- **Positioning Instructions**: Text and images are provided to indicate how and where to position the Sealing Block labware required for the Pressure Leak Test.

NOTE: In the example shown above, the Sealing Block is located at grid position 33. This position can vary based on the configured deck setup. At runtime, use the grid position displayed in the Pressure Leak Test interface.

- **Start**: Initiates the Pressure Leak Test. The interface displays a status message to indicate failure or success at the completion of the test.

NOTE: In the event of failure, contact Lonza support.

- **Close**: Closes the interface.

Options

The Options menu item provides the following submenu:

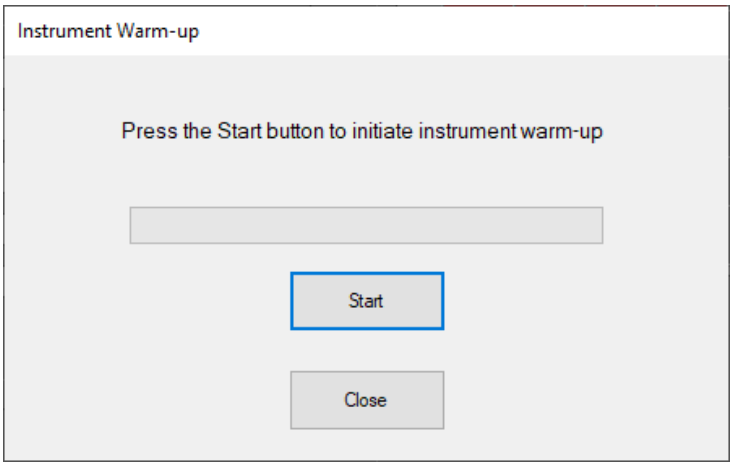
- Instrument Warm-up
- Drop DiTis
- Set DiTi Position

NOTE: A single disposable tip is referred to as a “DiTi” in this section. Multiple disposable tips are referred to as “DiTis”.

Instrument Warm-up

The interface provides functionality to “warm up” the PyroTec® PRO System’s pipetting motors and channels in preparation for use.

This operation should be executed at the start of each day, and/or whenever the instrument has been inactive for several hours. The instrument warm-up takes approximately 60 seconds to complete.



The interface provides the following functionality:

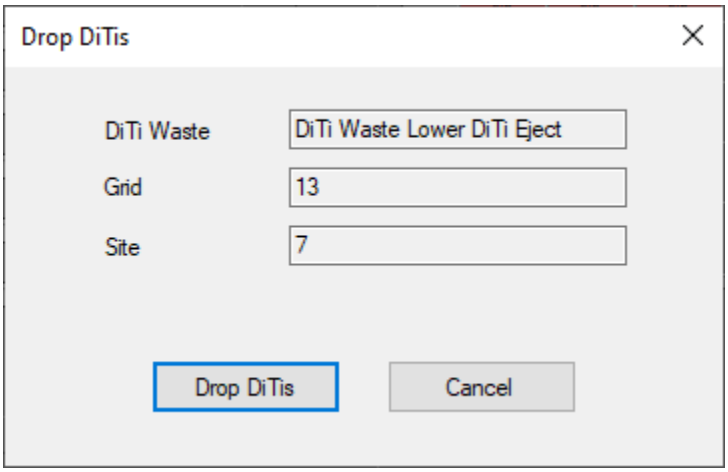
- **Start**: Initiates the warm-up process. The interface displays a status message to indicate failure or success of the warm-up process.

  NOTE: Failure may require replacement of one or more of the pipetting channel inline filters. Please contact Lonza support for assistance.

- **Close**: Closes the interface.

Drop DiTis

The interface may be used to drop mounted DiTis.

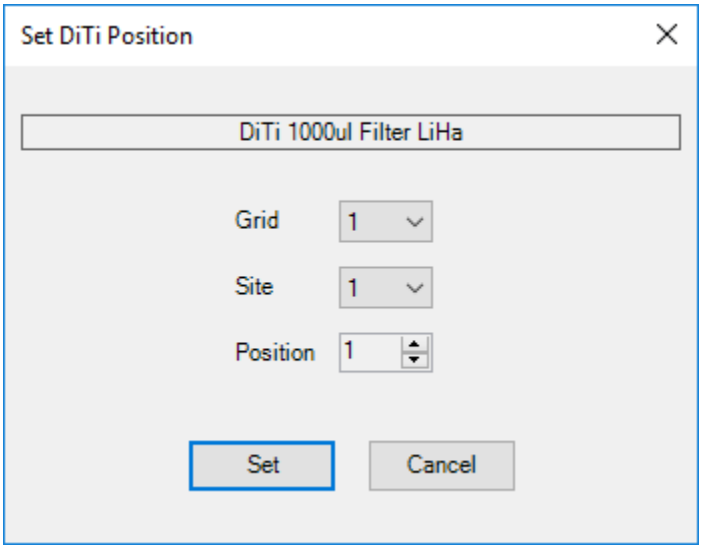


The interface provides the following information and functionality:

- **DiTi Waste**: Displays the name of the DiTi labware where the DiTis will be dropped (non-editable).
- **Grid**: Displays the deck grid position on the PyroTec® PRO System deck where the DiTi waste labware is located (non-editable).
- **Site**: Displays the site position at which the DiTi waste labware is located on the labware carrier (non-editable).
- **Drop DiTis**: Click the Drop DiTis button to send the command to the PyroTec® PRO System to drop all mounted DiTis.
- **Cancel**: Closes the interface without taking any action.

Set DiTi Position

The interface is used to set the location at which the PyroTec® PRO System will retrieve the next DiTi.



The interface provides the following functionality:

- **DiTi Type**: Displays the type of disposable tips being used in the system (non-editable).
- **Grid**: Displays a selectable list of grid positions on the PyroTec® PRO System deck where DiTi labware is located.
- **Site**: Displays a selectable list of site positions at which DiTi racks are located on labware carriers. Options are 1-3, for each of the three positions available on the DiTi rack carrier.
- **Position**: Displays a selectable list of positions on DiTi labware. Options are 1-96, for each of the 96 positions on the DiTi rack.
- **Set**: Click the Set button to send the command to the PyroTec® PRO System to set the next DiTi retrieval location to the location specified by the values of the Grid, Site, and Position parameters.
- **Cancel**: Closes the interface without taking any action.

Help

The Help menu item provides the following submenu items:

About

Displays information about the PyroTec® PRO System.

Logs

Click this menu item to select and view log files associated with the PyroTec® PRO System.

NOTE: Changes to configuration items for Products, Aux Liquids, Readers, System, Incubators in the PyroTec® PRO System are also included in the WinKQCL Audit Report under the Automation Record Type.

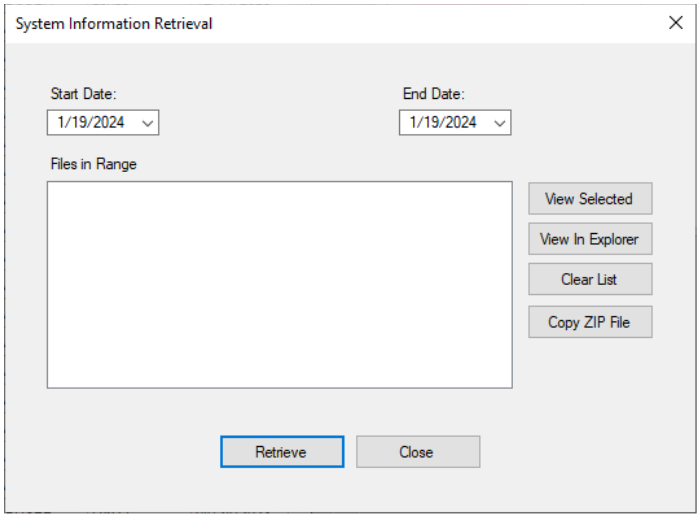
Support

Lonza and its representatives maintain a fully trained staff of technical specialists around the world. If your Lonza product fails to function properly or if you have questions about how to use our products, please contact the nearest Lonza Scientific Support office.

System Information Retrieval

- **Overview**

The System Information Retrieval interface provides functionality to retrieve relevant log and information files from the PyroTec® PRO system computer according to a specified date range. The information can be used to help identify and evaluate issues on a PyroTec® PRO system.



- **Data and Security**

The System Information Retrieval interface accesses only folders that store information associated with PyroTec® PRO, and implements only ***search*** and ***copy*** functionality. The application does not move, modify or delete files. The application searches folders that store information associated with PyroTec® PRO to locate files that meet all of the following criteria:

1. The file has a name (or file name prefix) known to be associated with PyroTec® PRO.
2. The file has a Creation Date and/or Modified Date that falls within the specified Start/End dates.

Files that meet the criteria above are copied (*not moved*) to a folder named "*PTP Info Files".* The folder is located in the same folder as the PyroTec® PRO DLL. After retrieving the files, the application creates a ZIP file in folder "*PTP Info Files"* that contains each of the retrieved files (ZIP file naming convention: PTPInfo_YYYYMMDD.zip). The ZIP file may be provided to Lonza for evaluation and analysis.

- **Instructions**

Enter the Start/End dates to define the information search timeframe. Use Start/End dates that include the dates for which the issue(s) being investigated occurred. Relevant files having a Creation Date and/or Modified Date within the timeframe will be retrieved.

- **Controls and Functionality**

Start Date:	The earliest date for which information files should be included
End Date:	The latest date for which information files should be included
Files in Range List:	List of the information files retrieved based on the Start/End dates
View Selected:	View the selected item in the list
View in Explorer:	View the selected item in Windows Explorer
Clear List:	Clear all items in the Files in Range List
Copy ZIP File:	Copy the current ZIP file to the Windows Clipboard
	NOTE: *The Copy ZIP File button can be used to paste the ZIP file into an email to Lonza to provide the retrieved information. The Copy ZIP File button is only visible when there are one or more files in the Files in Range List.*
Retrieve:	Initiate search for information files based on the Start/End dates
Close:	Close the interface

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