

Luminex®



**Luminex IS™ Software Manual For
Version 2.3**

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Luminex® IS™ Software Manual for Version 2.3

REF	CN-M007-01
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PN 89-00002-00-110 Rev. A
July 2005

EC	REP
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Luminex[®] 2.3 Software

This manual describes how to use the Luminex IS 2.3 software. It includes a glossary and information regarding the CSV file setup. The software user should have a basic familiarity with computers and Microsoft® Windows®. Commands are often available through more than one method, such as from the main menu bar, the toolbar, or on different windows. However, each procedure in this manual will describe only one method of accessing commands.

This chapter has the following sections:

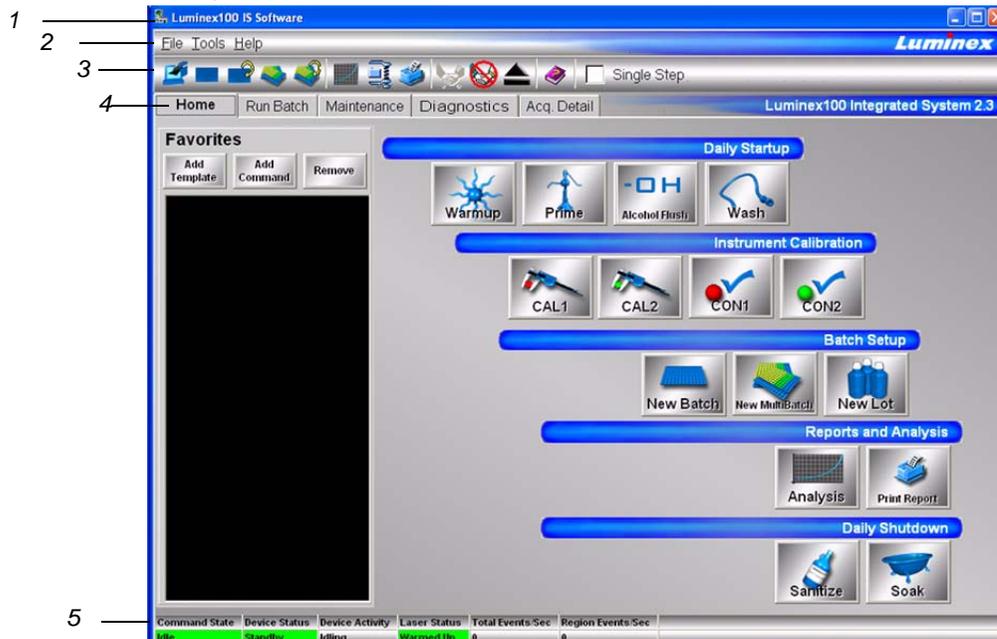
- **Main Window** - This section describes the main window of the Luminex IS 2.3 software, including tabs and commands. Use this section to become familiar with the main functions of the software.
- **Secondary Windows** - This section describes the secondary windows in the Luminex IS 2.3 software, including the Analysis Window and Batch Setup Window.
- **Commands** - This section describes the functions of the commands in the Luminex IS 2.3 software.
- **Procedures** - This section describes how to perform tasks using the Luminex IS 2.3 software.

When using microtiter plates, use plates with wells that will hold at least 185 µL (the extra 25 µL from the sample, plus an extra 160 µL that is dispensed back into the well following acquisition).

Main Window

The Luminex IS 2.3 software starts automatically when you log into Windows.

When the first software User window opens, the Main window is open, with the Home tab displayed, as shown in Figure 1



- 1. Title bar
- 2. Menu bar
- 3. Tool bar
- 4. Tabs
- 5. Status bar

Figure 1 Luminex IS 2.3 Main Window

There are five major parts in the Main window: Title bar, Menu bar, Tool bar, Tabs, and Status bar. A brief description of each of these components is shown below.

The **Title Bar** displays the name of the software.

The **Menu Bar** contains three menus, File, Tools, and Help menu. A more thorough description of the Menu is shown on page 3.

The **Toolbar** - has shortcut buttons for frequently-used commands. A more thorough description of the Toolbar is shown on page 4.

There are five **Tabs**, organized by function. The tab that displays when the software starts up is the **Home** tab. A more thorough description of each of these tabs begins on page 4.

The **Status bar** displays the system status at the bottom of the main window. A more thorough description of the Status bar is shown on page 16.

Menu Bar

The menu bar contains the following menus: File Menu, Tools Menu, and Help Menu.

File menu - contains the following commands:

- Import Template
- New Batch
- Open Batch
- Delete Batch
- Edit Patient List
- Open Incomplete Batch
- Batch Comment
- New Multi-Batch
- Open Multi-Batch
- Data Analysis
- Export Batch Data
- Print Report
- Exit

Tools menu - contains the following commands:

- Connect
- Disconnect
- Database Backup
- Database Restore
- Erase Database
- Update CAL Targets
- Update CON Targets
- New Assay Lot
- Options
- Cleanup

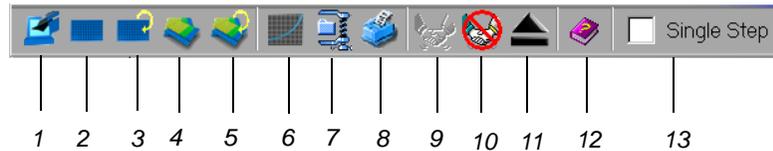
For information on each of these commands, see the Commands section, beginning on page 28.

Help menu - this contains menu selections that open the online help and describe the software and hardware.

- **Contents** opens the online help
- **About the Device** opens a dialog box that shows the version and serial numbers of the Luminex instruments you are using.
- **About the Software** opens a dialog box that shows the version of the Luminex Software you are using.

Toolbar

The shortcut buttons on the toolbar can be found in other locations in the software. The Help button opens the online help. The Single Step option on the toolbar allows you to pause the system in between each command or sample acquisition within a batch.



- | | |
|----------------------------------|---|
| 1. <i>Import Template</i> | 8. <i>Print Report</i> |
| 2. <i>New Batch</i> | 9. <i>Connect to the Instrument</i> |
| 3. <i>Open Batch</i> | 10. <i>Disconnect from the Instrument</i> |
| 4. <i>Create New Multi-Batch</i> | 11. <i>Eject/Retract</i> |
| 5. <i>Open Multi-Batch</i> | 12. <i>Open Help File</i> |
| 6. <i>Start Analysis</i> | 13. <i>Single Step</i> |
| 7. <i>Export Batch Data</i> | |

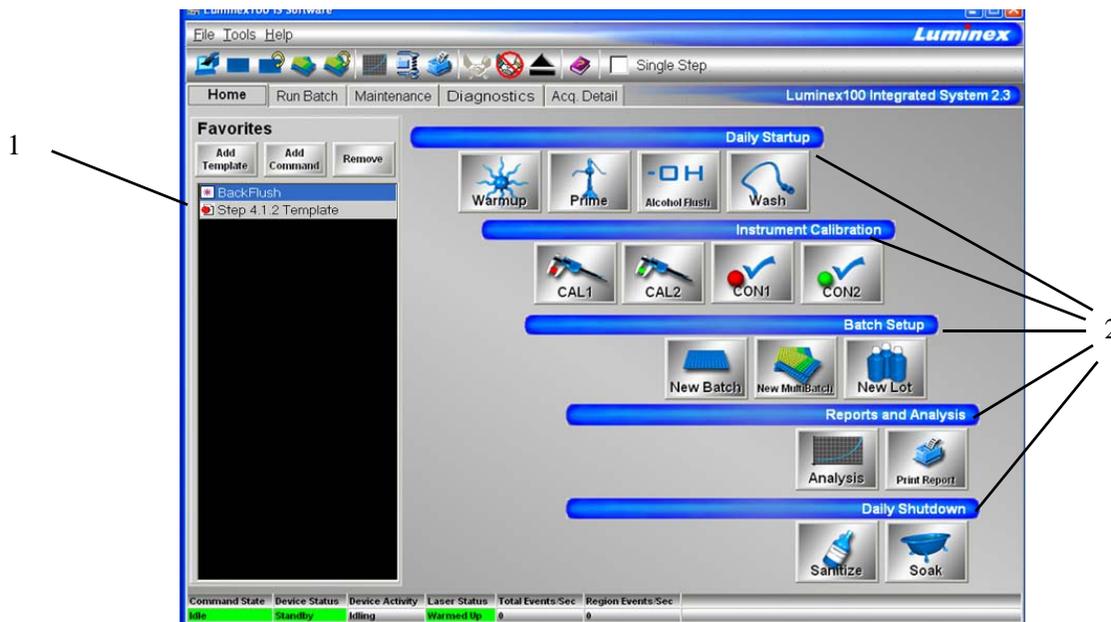
Figure 2 Luminex IS 2.3 Toolbar

Tabs

This section describes the tabs in the Main window.

Home tab

This is the default tab. It is organized by the order of system use. It contains a Favorites list and five button groups representing data acquisition and maintenance categories.



1. Favorites List

2. Button Groups

Figure 3 Home Tab

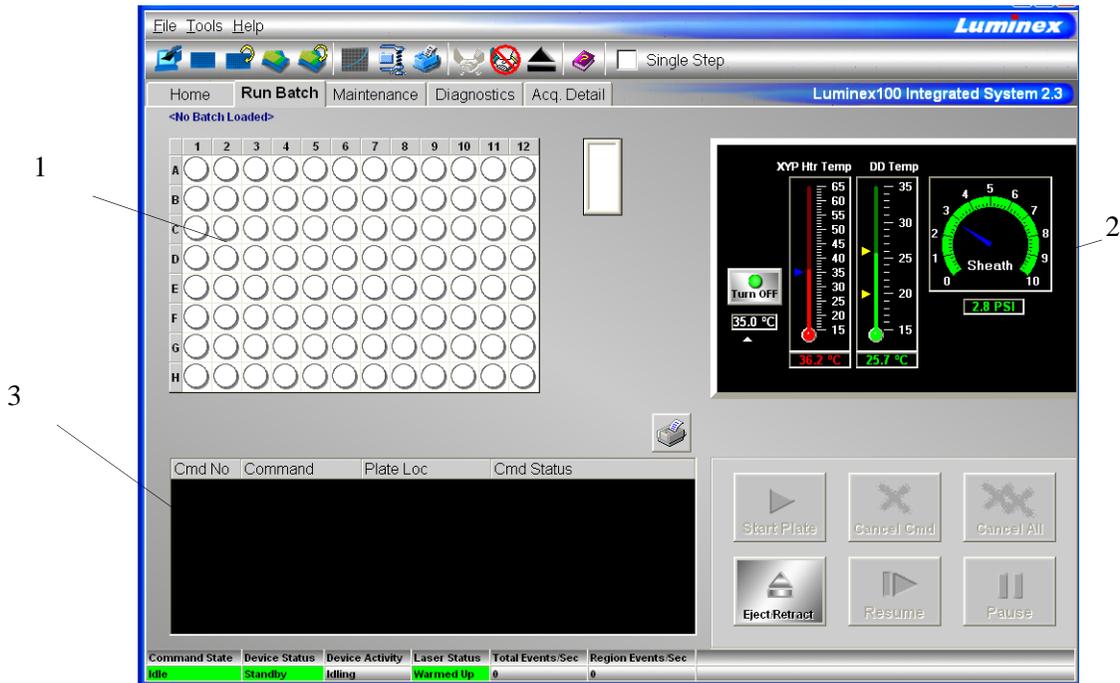
Favorites. You can use the Favorites list to create a customized list of often-used commands and templates. Items appear in alphabetical order for easy locating. For more information on setting up the Favorites list, see page 39.

Button Groups. Button groups are grouped according to function.

- The **Daily Startup** group contains the Warmup, Prime, Alcohol Flush, and Wash Commands. For more information on daily startup, see page 40. For more information on the commands, see the Commands section on page 28.
- The **Instrument Calibration** group contains the CAL1, CAL2, CON1, and CON2 buttons. For more information on calibrating the system, see page 42. For more information about these commands, see the Commands section on page 28.
- The **Batch Setup** group contains the New Batch, New Multibatch, and New Lot buttons. For more information on creating and running batches and multibatches, see page 48. For more information about these commands, see the Commands section on page 28.
- The **Reports and Analysis** group contains the Analysis and Print buttons. For more information on running reports and analyses, see page 82. For more information about the Analyses and Print commands, see the Commands section on page 28.
- The **Daily Shutdown** group contains command buttons that you can use when shutting down the system. For more information on performing a daily shutdown, see page 91. For more information on the Sanitize and Soak commands, see the Commands section starting on page 28.

Run Batch Tab

The Run Batch tab contains a microtiter plate and reservoir image, XYP and DD temperature readbacks, a sheath pressure gauge, print button, command list displaying batch commands and their status, and plate and XYP command buttons. See Figure 4.



1. Microtiter plate/reservoir image 2. Temperature and Pressure Gauges
3. Command List

Figure 4 Run Batch Tab

The command buttons on the Run Batch tab are:

- Print Worklist
- Start Plate
- Cancel Command
- Cancel all
- Eject/Retract
- Resume
- Pause

For more information on these commands, see the Commands section, starting on page 28. For more information on setting up batches, see See “Batch Setup Procedures” on page 48.

The **microtiter plate and reservoir image** represents where you place samples or other fluids used in running or maintaining the system. Samples are analyzed vertically, from top to bottom within the column, and then from left to right for subsequent columns.

The **Temperature and Pressure Gauges** show information about the analyzer and the XYP instrument. The XYP heater temperature measures the internal Luminex XYP instrument plate temperature. The DD temperature measures the doublet discriminator temperature. DD temperature shifting indicates a need for system recalibration. If you have not calibrated, the arrows showing the temperature range

for the DD temperature both appear at the bottom of the thermometer, and the thermometer appears in red. An out-of-range temperature logs an error, but does not halt the acquisition.

For information on setting the XYP instrument heater temperature, see page 42.

The **Command List** displays commands associated with batches, new advanced batches or multi-batches loaded for processing on the system. The Command List shows the status of each command as the system processes it, and whether the command completes successfully or fails. Figure 5 shows that the first two commands were successful, the third command is running, and the rest of the commands are pending. Figure 6 shows that the third command failed.

Cmd No	Command	Plate Loc	Cmd Status
1	XY Heater On	<none>, Plate1	Succeeded (0 sec)
2	Reservoir Wash	Reservoir, Plate1	Succeeded (23 sec)
3	Acquire Lstand	A1, Plate1	Running
4	Acquire	B1, Plate1	Pending
5	Acquire	C1, Plate1	Pending
6	XY Heater Off	<none>, Plate1	Pending

Figure 5 Command List Section of the Run Batch Tab

Cmd No	Command	Plate Loc	Cmd Status
1	XY Heater On	<none>, Plate1	Succeeded (0 sec)
2	Reservoir Wash	Reservoir, Plate1	Succeeded (23 sec)
3	Acquire Lstand	A1, Plate1	FAILED (71 sec)
4	Acquire	B1, Plate1	Running
5	Acquire	C1, Plate1	Pending
6	XY Heater Off	<none>, Plate1	Pending

Figure 6 Command Failure Notation in the Command List

Errors are recorded in the Message Log on the Diagnostics tab. See page 9 for more information about the Diagnostics tab. Double-click on failed commands in the Message Log for additional information. You can right-click a highlighted row to copy data to the clipboard or clear the batch from the screen.

Maintenance Tab Use the Maintenance tab to perform maintenance, XYP, daily startup, calibration, and verification commands to maintain your system and keep it in optimal working order.

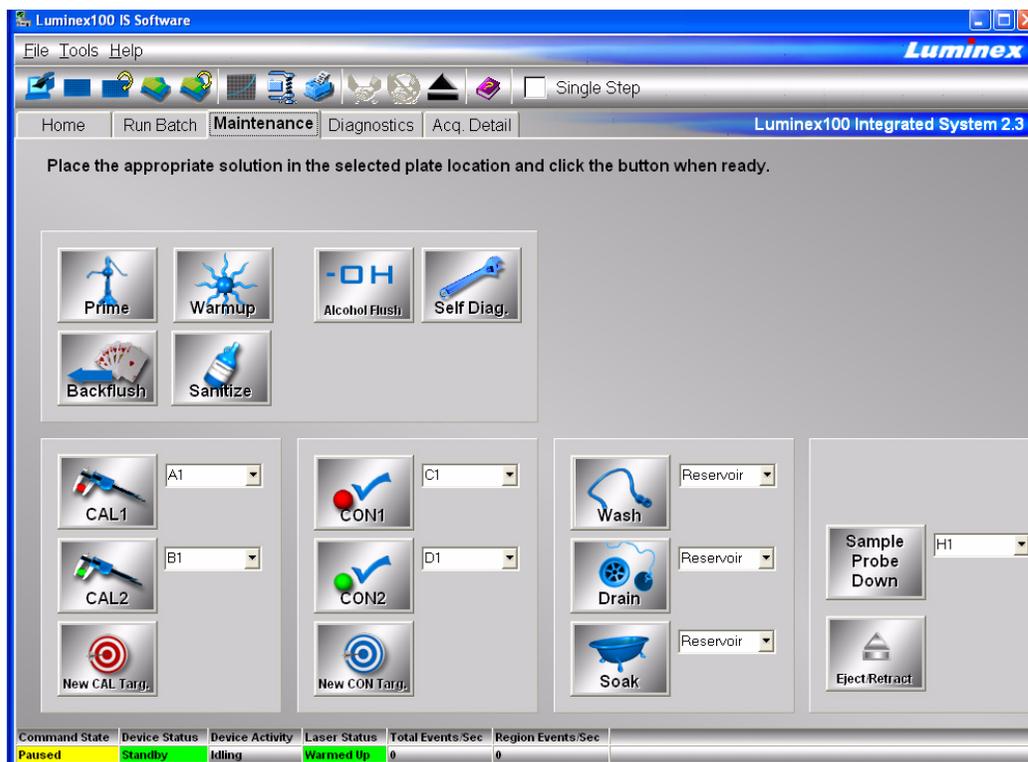


Figure 7 Maintenance Tab

See the Commands section starting on page 28 for detailed information about these commands:

- Warmup
- Prime
- Backflush
- Alcohol Flush
- Sanitize
- Wash
- Drain
- Soak
- Self Diagnostics
- Calibration Commands: CAL 1, CAL2, New CAL target and New CON target
- Sample Probe Down
- Eject/Retract

Instructions for maintenance procedures begin on page 88. Table 11 on page 88 shows a recommended use schedule for maintenance operations.

Diagnostics tab

Use the Diagnostics tab to monitor the progress of commands you initiate in the system. Features on this tab monitor the state of system components. This tab displays the System Monitor, Detailed Sample Progress chart, and Message Log. The Text on the Diagnostics tab turns red if the system encounters an error. The Message Log on the Diagnostics tab indicates where the error occurred.

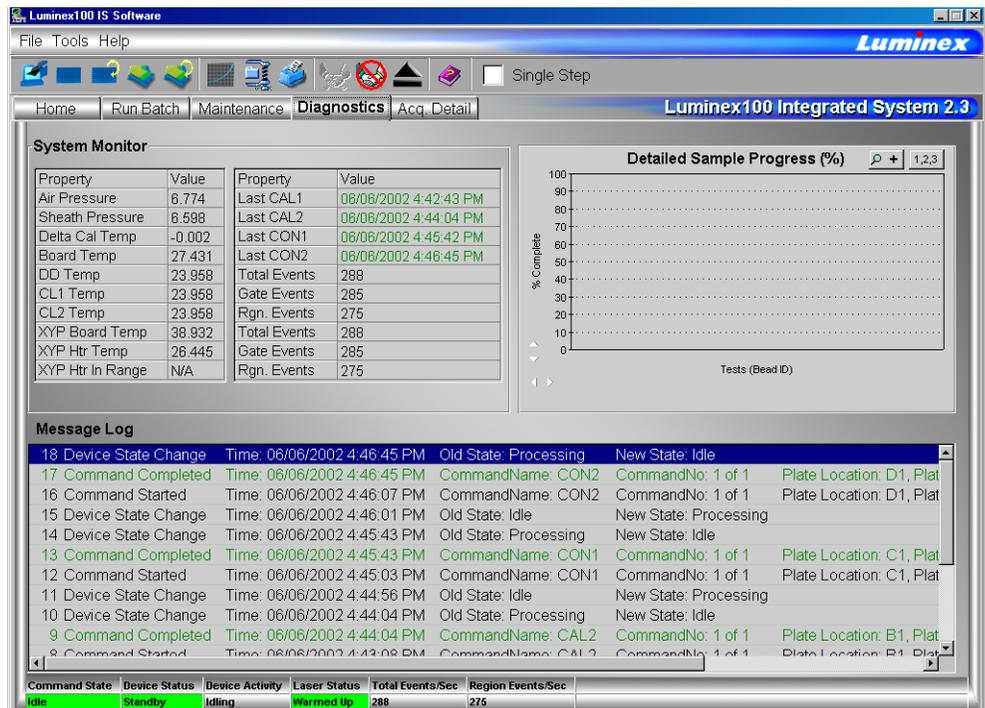


Figure 8 Diagnostics Tab

Use these tools to find information about the system and what occurs during sample acquisition and other functions. For example, you may look on the Message Log to see the last completed command or the one currently in progress.

The **System Monitor** provides information about the physical state of the Luminex analyzer including lasers and system calibration status. The values displayed are reported directly from the Luminex analyzer and the Luminex XYP instrument. It shows whether the calibration or control results completed successfully by displaying green text for successful events and red text for failed events.

The system diagnoses real-time system problems related to fluidics and optics. The system also detects and reports if the Luminex XYP

heater block temperature is out of range or experiencing unacceptable temperature conditions, including these items:

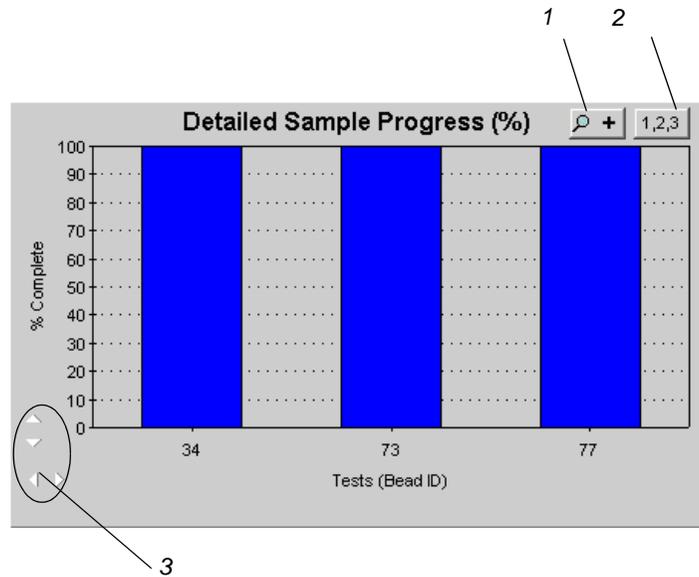
- Luminex XYP heater block temperature time-out
- heat circuit failure
- temperature out-of-range sensing
- temperature change since calibration, or a change in channel temperature

Table 1 defines the values listed in the System Monitor. These values are useful for diagnostic purposes when communicating with Luminex Technical Support.

Table 1. System Monitor Values

Property	Value Units of Measure
Air Pressure	PSI, air pressure to the sheath container from the air pump
Sheath Pressure	PSI, sheath pressure from the sheath container through the system
Delta Cal Temperature	°C, temperature deviation from the last calibration
Board Temperature	°C, temperature of the analog board
DD Temperature	°C, DD temperature at the U block inside the optics platform
CL1 Temperature	°C, CL1 temperature at the U block inside the optics platform
CL2 Temperature	°C, CL2 temperature at the U block inside the optics platform
XYP Board Temperature	°C, temperature of the XYP board inside the Luminex XYP instrument
XYP Heater Temperature	°C, temperature of the XYP heaters inside the Luminex XYP instrument
XYP Heater Temperature In Range	Indicates if the XYP heater is in the set range

The **Detailed Sample Progress** section displays the percentage of completion for each bead ID or test. The graph shows real-time progress, so that as each sample is analyzed, the graph adjusts to show progress. Use the **zoom** button to view up to 20 tests at a time. Use the **toggle** button to view the bead ID or test name. Use the Expand Margin (up/down and left/right) arrows to expand the chart margins and view longer test names. See Figure 9.



1. Zoom button
2. Toggle button
3. Expand Margin arrows

Figure 9 Detailed Sample Progress

The **Message Log** is the lower pane on the Diagnostic tab. It displays a list of completed commands, errors, and warnings. It also displays command progress, time and date, and results. See Figure 10.

Message Log			
55 Database Message	Time: 5/25/2001 11:10:06 AM	Batch data exported.	C:\My Batches\DNA Batch_ID2\Ou
54 Commands Finished	Time: 5/25/2001 11:10:05 AM		
53 Device State Change	Time: 5/25/2001 11:10:05 AM	Old State: Processing	New State: Idle
52 Command Completed	Time: 5/25/2001 11:10:05 AM	CommandName: Acquire Patient 4	CommandNo: 15 of 15
51 Command Started	Time: 5/25/2001 11:09:50 AM	CommandName: Acquire Patient 4	CommandNo: 15 of 15
50 Command Completed	Time: 5/25/2001 11:09:50 AM	CommandName: Acquire Patient 3	CommandNo: 14 of 15
49 Command Started	Time: 5/25/2001 11:09:34 AM	CommandName: Acquire Patient 3	CommandNo: 14 of 15
48 Command Completed	Time: 5/25/2001 11:09:33 AM	CommandName: Acquire Patient 2	CommandNo: 13 of 15
47 Command Started	Time: 5/25/2001 11:09:18 AM	CommandName: Acquire Patient 2	CommandNo: 13 of 15
46 Command Completed	Time: 5/25/2001 11:09:17 AM	CommandName: Acquire Patient 1	CommandNo: 12 of 15
45 Command Started	Time: 5/25/2001 11:08:40 AM	CommandName: Acquire Patient 1	CommandNo: 12 of 15

Figure 10 Message Log

The log displays actions in color-coded text and shading. Items in the Message Log appear in the following color codes:

- Green text represents a successful system calibration, verification command, acquisition, or maintenance functions.
- Red text represents failed commands, errors, or warnings.
- Black text represents normal processes and actions.
- Yellow shading indicates that a detailed description about the processes or actions is available. This color may vary depending on your tool tip color system settings.

To view details of a message, double-click the shaded row. A dialog box opens providing details. To clear the Message log, right-click in the Message Log area, and click Clear on the menu.

Acquisition Detail Tab

The Acquisition Detail tab offers advanced batch sample monitoring and “on the fly” data acquisition without templates. The primary function is real-time monitoring of batch sampling during acquisition through a display of sample bead statistics, histogram, and dot plot data.

During batch acquisition, bead statistics can be useful if batch errors occur. For example, if samples are constantly failing due to insufficient bead count, you can monitor whether the failure is due to low bead concentration or if other assay problems are present.

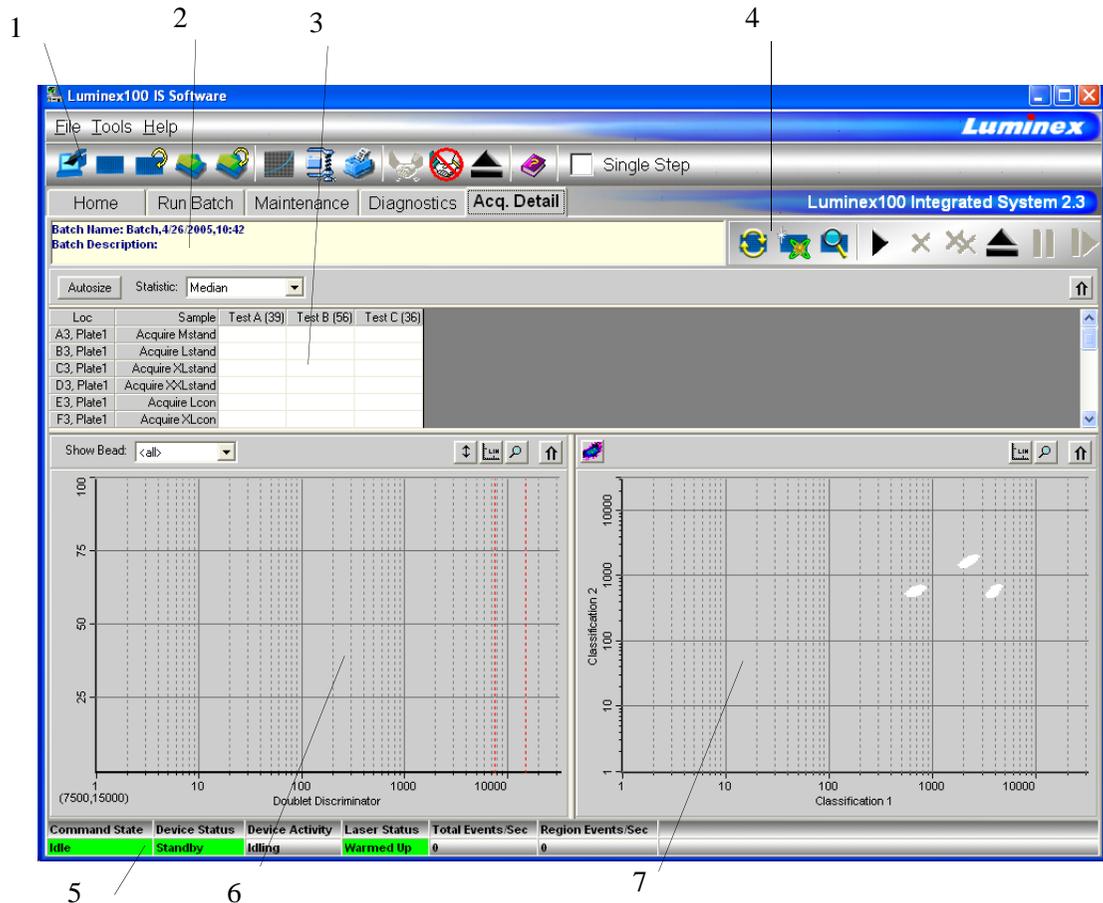
The Acquisition Detail tab provides access to the Developer Workbench (DWB) software features. Details about these features are provided in the *Luminex Developer Workbench Guide Version 2.3* documentation. You must have the DWB software installed to enable these features.

Caution: Do not alter kit manufacturer’s predefined templates or create alternative templates for off the shelf kits unless instructed by the kit manufacturer.

Acquisition Detail tab features:

- Batch Name and Description
- Batch Data Area
- Acquisition Detail Toolbar
- Histogram
- Dot Plot

Figure 11 identifies the major features of the Acquisition Detail tab.



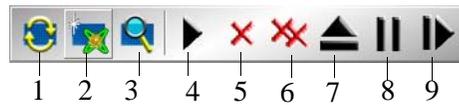
- 1. Luminex IS 2.3 Toolbar
- 2. Batch Name and Description
- 3. Batch Data Area
- 4. Acquisition Detail Toolbar
- 5. Status Bar
- 6. Histogram
- 7. Dot Plot

Figure 11 Acquisition Detail Tab

The **Batch Name and Description** section displays the name of the batch as well as its description.

The **Batch Data** area displays sample results. The left column shows plate location and Sample ID description. The remaining columns display selected bead sets for the assay. Each row represents the data for each bead set from one well.

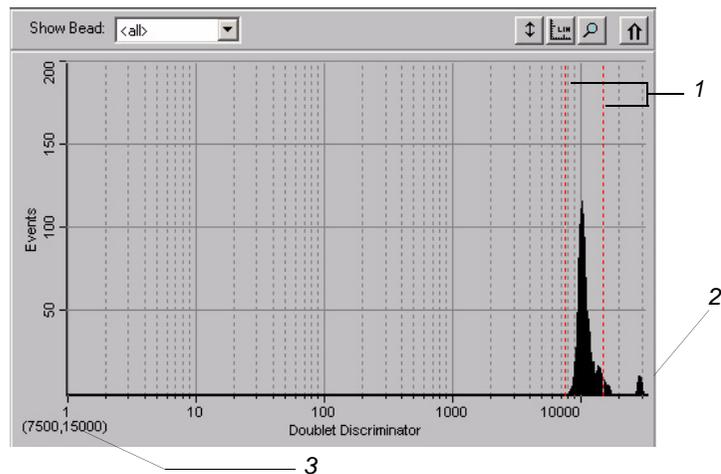
The **Acquisition Detail Toolbar** shown in Figure 12 provides functions to acquire raw data without using templates. The toolbar has additional buttons if you have Developer’s Workbench installed. For more information about the commands on the Acquisition Detail Toolbar, see the Command section, beginning on page 28.



- 1. *Replay Batch*
- 2. *New Advanced Batch*
- 3. *View Batch Data*
- 4. *Start Plate*
- 5. *Cancel Command*
- 6. *Cancel All*
- 7. *Eject/Retract*
- 8. *Pause*
- 9. *Resume*

Figure 12 Acquisition Detail Toolbar

The Histogram, in the lower left section of the Acquisition Detail tab, defaults to display the Doublet Discriminator (DD) on the X axis and Events on the Y axis. Doublets appear when two microspheres stick together, creating undesired results. When you enable the gate, two vertical red, dashed lines appear to represent gate positions determined by the template or settings established within the New Advanced Batch. After setting the gate, everything outside the gate is ignored. You cannot change the gate position during batch acquisition. You can change the gate positions before data acquisition, after the system finishes acquiring data, or after pausing the system. The change is visual. The data is still collected according to the gate positions set in the assay template or New Advanced Batch setup. The gate in effect when the system collects data determines which values to use to obtain the result. Applying a gate or changing a gate for existing data does not change your calculated values. The gate positions, also located in the lower corner of the histogram, are used while collecting data are the numerical values selected in the template or the New Advanced Batch.



- 1. *Gate Boundaries*
- 2. *Aggregate Beads*
- 3. *Numerical Gate Position*

Figure 13 Set DD Gate Example

The Histogram contains the Show Bead menu and four buttons:

- Autoscale
- Zoom
- Log/Linear
- Maximize

For more information on these commands, see the Commands section beginning on page 28.

The **Dot Plot** (or bead map) appears in the lower-right section of the Acquisition Detail tab. See Figure 14. The dot plot shows a graphical display of real-time data collection.

Luminex recommends using the default settings to collect data. The default axes are Classification 1 on the X axis and Classification 2 on the Y axis. To see the dot plot, you must use the default axis. To display the bead set information, hover the mouse pointer over the desired region. You can change the X axis and Y axis of the dot plot for troubleshooting purposes, although you should use the default settings in all other scenarios.

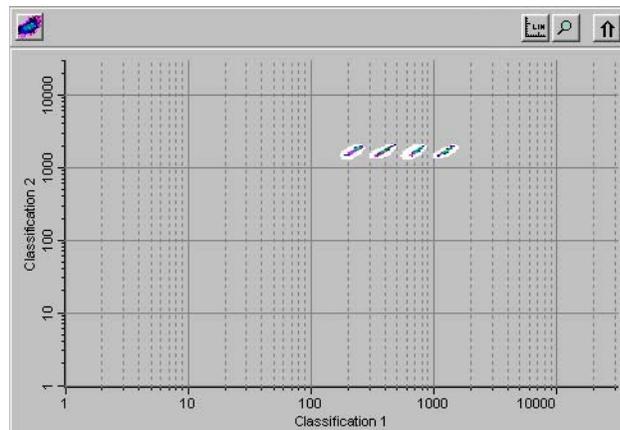


Figure 14 Dot Plot Display Example

Four buttons appear at the top of the frame to control the display:

- Density/Decaying
- Log/Linear
- Zoom
- Maximize

You can toggle between two types of dot plots using the Density/Decaying button. The Decaying Dot Plot plots only the 100 most-recent acquired events. The Density Dot Plot displays a constant

accumulation of events. Increasing density is indicated by contrasting colors. See Table 2 for the density dot plot color legend.

Table 2. Dot Plot Color Legend

Layer	Color
0	none
1	dark blue
2	pink
3	dark green
4	cyan
5	light blue
6	light green
7	orange
8	dark red

The density dot plot allows visual elimination of data values determined to be insignificant to the display. Luminex recommends you collect your data in density dot plot mode to observe all collected events. Post acquisition does not display decaying dot plot; it's only a real-time function.

Status Bar

The Status Bar displays information about the Command State, Device Status, Device Activity, Laser Status, Total Events per Second, and Region Events per Second. Color coding indicates the urgency of each item's status. Device Activity uses no color coding.



Figure 15 System Status Bar

Table 3 describes the types of status bar messages in relation to the message color coding.

Table 3. Status Bar Color Coding

Category	Color	Indicates
Command State		Indicates communication status of the Luminex analyzer or operations being processed
	Green	Idle or processing
	Yellow	Connecting, pausing, or paused
	Red	Disconnected or locked out

Table 3. Status Bar Color Coding (Continued)

Category	Color	Indicates
Device Status		Indicates the current process of or warning about the Luminex analyzer
	Green	Running or standby
	Yellow	Busy, pressurizing, sheath is empty, or warming up
	Red	Not ready or disconnected
Device Activity		Indicates the activity that the Luminex analyzer is performing. Note: The device activity has no color code.
		<ul style="list-style-type: none"> • Idling: waiting for a command • Aspirating: drawing in sample • Collecting Data: collecting data • Sanitizing: sanitizing the instrument • Washing: washing the sample line • Priming: priming the instrument • Calibrating: calibrating the instrument • Canceling: canceling a command • Backflushing: backflushing the instrument • Draining: draining the instrument • Warming Up: warming up the instrument • Verifying: verifying calibration • Soaking: soaking the probe • Adjusting sample probe • Self Diagnosing: performing self-diagnostic routine
Laser Status		Laser temperature and readiness status
	Green	Lasers warmed up
	Yellow	Warmup timer countdown in seconds from 1800
	Red	Lasers off
Total Events/Second		Number of total bead events detected per second
Region Events/Second		Number of bead events detected per second that are classified in a region

The Status Bar displays status information as the software processes commands. Table 4 shows the typical messages that appear in the

status bar. Additionally, information displays as text on the Diagnostics tab.

**Table 4. Status Bar
Communication Message Details**

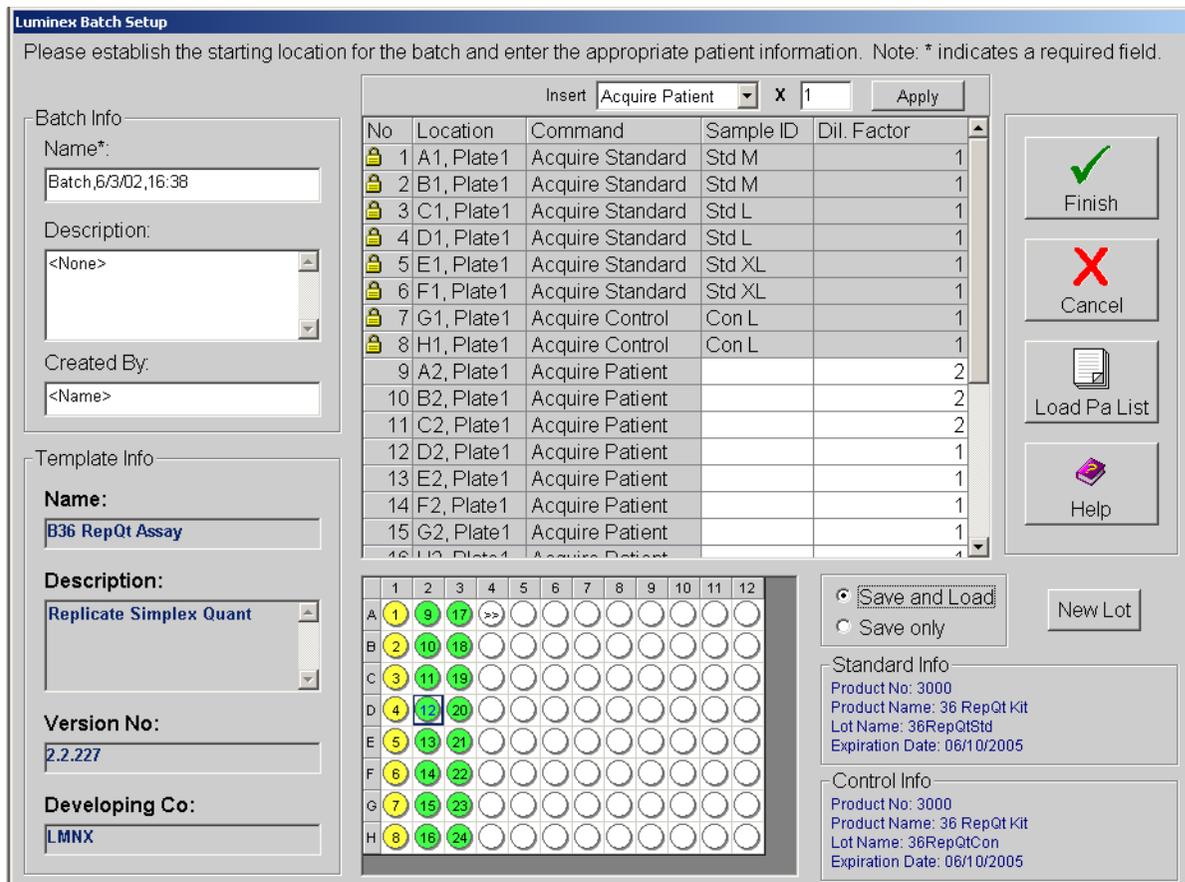
Status Bar Color	Message	Indicates
Green	Idle	Waiting to process the next command.
	Standby	The Luminex analyzer is ready and waiting to perform a command.
Yellow	Connecting	The software is attempting to connect to the instrument.
	Processing	The instrument is communicating with the software as it processes commands.
	Pausing	The instrument has stopped processing the list of commands, but finishing the active command.
	Paused	The software stopped processing the list of commands. A "resume" function becomes available to change the state back to "processing."
	Busy	The instrument is processing a maintenance command.
Red	Disconnected	The software has not yet attempted to connect or fails to connect to the instrument.
	Locked Out	Another application currently has control of the instrument. The software locks out as long as the other application runs. To remove the locked out status, close the other application or wait until the application completes.

Secondary Windows

In addition to the main window, there are other windows that are displayed when you select certain commands. These are the Batch Setup Window and Analysis Window. Additional windows display in the Developer’s Workbench software, if you have it installed on your system. For more information about the Developer’s Workbench, see the *Luminex Developer Workbench Guide for Version 2.3*.

Batch Setup Window

In the Batch Setup window, you define information used to create batches. All of the commands are on the same page; there are no tabs. The window opens when you click New Batch and select a template.



The following features are part of the Batch Setup Window:

- Batch Info group box
- Template Info group box
- Insert command
- Command list
- Microtiter Plate image

- Command button group box
- Save group box
- Standard Info group box
- Control Info group box
- New Lot button

The Batch Info group box has text boxes in which you can input the name, description, and creator name of a new batch.

The Template Info group box shows the name, description, version number, and developing company for the template that you are using in a batch.

The Insert command lets you insert a patient into a batch or skip a well.

The Command list displays the commands that were imported from the template, plus commands added using the Insert command or manually entered. The lock in the far left column indicates that the command was imported from the template and cannot be changed in the Batch Setup window.

The Microtiter Plate image reflects the command information for each well, as defined in the template.

The Command button group contains the Finish, Cancel, Load Pa List, and Help command buttons. For more information on these commands, see the Commands section, beginning on page 28.

The Save group box contains the Save and Load and Save only option buttons. For more information on these commands, see the Commands section, beginning on page 28.

The Standard Info group box is visible only if the template you are using requires the use of standards. If standards are used in the template, the Standard Info group box reflects the Standard information as defined in the template product.

The Control Info group box is visible only if the template you are using requires the use of controls. If controls are used in the template, the Control Info group box reflects the Control information as defined in the template products.

The New Lot button is visible only if the template you are using requires the use of standards or controls. The button opens the Update Lot Information dialog box, in which you can manage lot information.

Analysis Window

When the system analyzes batches, it displays the data in a three-tab format within the Analysis window. The following three tabs present the batch information in greater detail:

- Errors tab—lists errors that occur during batch acquisition, such as controls that failed.
- Standards tab—lists all tests in the batch, a regression chart for each test, and the standards or controls associated with the batch.
- Samples tab—lists background samples and all samples or unknowns acquired in the batch with either a qualitative or quantitative result.

Nine function buttons are available on the lower portion of the Analysis window. These buttons perform tasks or functions that are relevant to the Standards tab although they appear on all three tabs of the Analysis window. The buttons are:

- Next Test (F2)
- Previous Test (F3)
- Invalidate Standard (F4)
- Validate Standard (F5)
- Invalidate Control (F6)
- Validate Control (F7)
- Change Standard - only if Developer's Workbench is installed.
- Change Lot (Alt + F8)
- Recalc (Standards tab only) - only available on the Standards tab, and only if the Auto checkbox is not selected.

For a description of these commands, see “Commands” on page 28. For information on procedures using these commands, see “Validating or Invalidating Standards and Controls” on page 79 and “Change Lot” on page 81.

In addition to the function buttons, you can choose to sort data sequentially by order acquired, or alphabetically by Sample ID. These options are available in the Sort group box next to the function buttons. These sorting functions are helpful in viewing batches containing replicate samples. Replicate samples are defined as samples with identical sample identifications. Replicate standards, controls, and unknown samples are not always acquired in sequential wells and thus make sample viewing difficult. When viewing samples alphabetically all replicate samples are displayed together with the replicate sample's average (AVG), then individual samples. If you view replicate batches sequentially, each sample displays in the order it was acquired, followed by a replicate average summary section.

Errors Tab The Errors tab displays a list of errors that occurred during acquisition. It organizes the errors in two categories: System and assay errors (top section of tab), and Sample errors (bottom section of tab) Table 5 lists the errors in each category

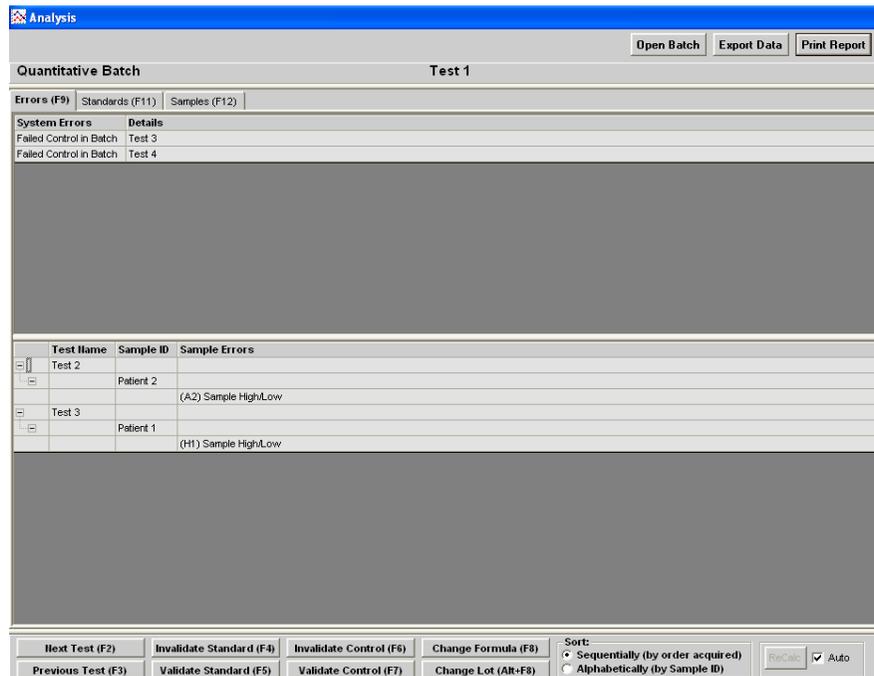


Figure 16 Analysis Window - Errors Tab Open

Table 5. Error Categories

System and Assay Errors	Sample Errors
<ul style="list-style-type: none"> Instrument Not Calibrated Failed Verification (system lists each failed control) Failed Control (verifier failed) Temperature Divergence from Calibration Temperature Failed Curve Fit Analysis Error APD Temp Range Exceeded XYP Temp Unstable Low Voltage High Sheath Pressure Low Sheath Pressure Command Timeout Low Laser Power Cannot Calculate Inverse Function Failed Std in Batch 	<ul style="list-style-type: none"> Insufficient Bead Count Sample High/Low Analyzer Error High Sheath Pressure Low Sheath Pressure Sample Timeout Sample Empty Cannot Calculate Inverse Function Different Qualitative Results

Standards Tab

The Standards tab lists all the batch tests with system comments specific to each test. The detailed test information that is displayed on the three tabs of the Analysis window is determined by the test selected under the Standards tab.

The Standards tab displays the quantitative batch’s standard curve. It displays qualitative batches as a graph plotting the assay standard. Above the graphical information, the tab displays the formula that it used to calculate batch data. Below the graphical information, the tab displays the Standards and Controls values for the selected test.

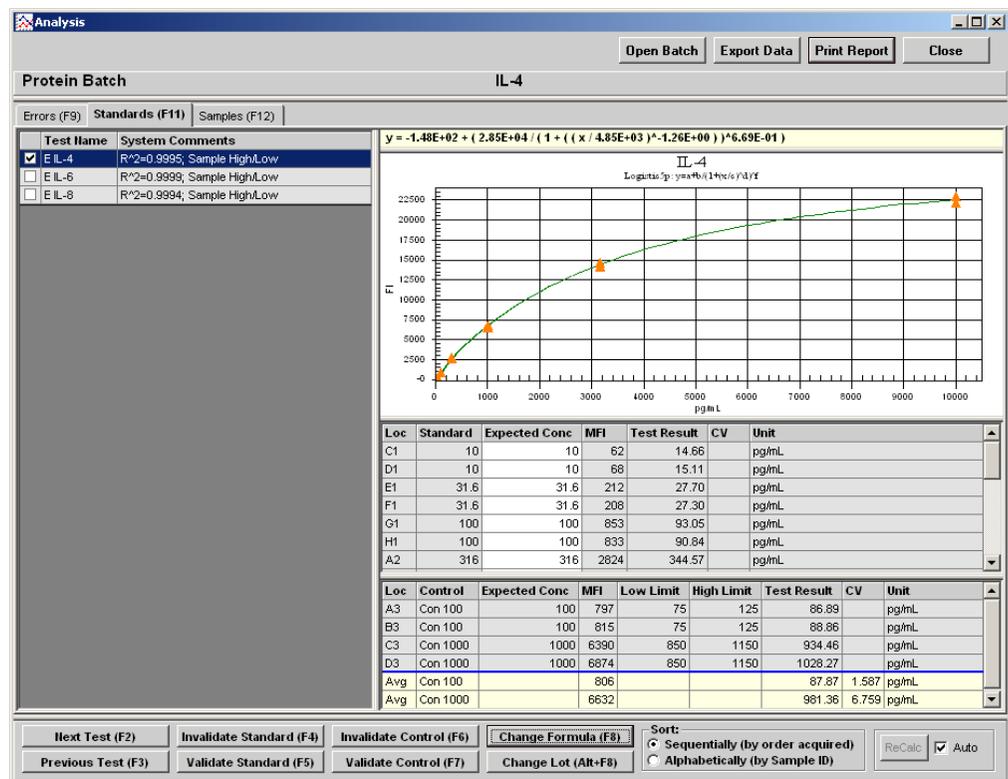


Figure 17 Analysis Window - Standards Tab Open

When a median fluorescence intensity (MFI) value for an unknown sample or control lies outside the standard curve MFI range, the concentration is not calculated. The unknown sample or control result is reported as less than (<) or greater than (>) next to the corresponding standard expected concentration. The out-of-range samples and controls will also have a “Sample High/Low” statement in the comment column. If a sample lies within the standard curve MFI range, but the sample’s MFI value does not intersect the curve, the result will be reported as “Error”. A “cannot calculate inverse function” statement displays in the comments column. This error condition usually occurs when a standard curve “flattens out” at the

high or low end. Examples of out-of-range sample labeling for non-competitive assays are shown in Table 6. Figure 18 shows what a standard curve for a non-competitive assay should look like.

Table 6. Non-Competitive Out-Of-Range Labeling

Condition	Concentration Label	MFI of Standard Referenced
Left of Curve	< min concentration standard	Lowest
Right of Curve	> max concentration standard	Highest

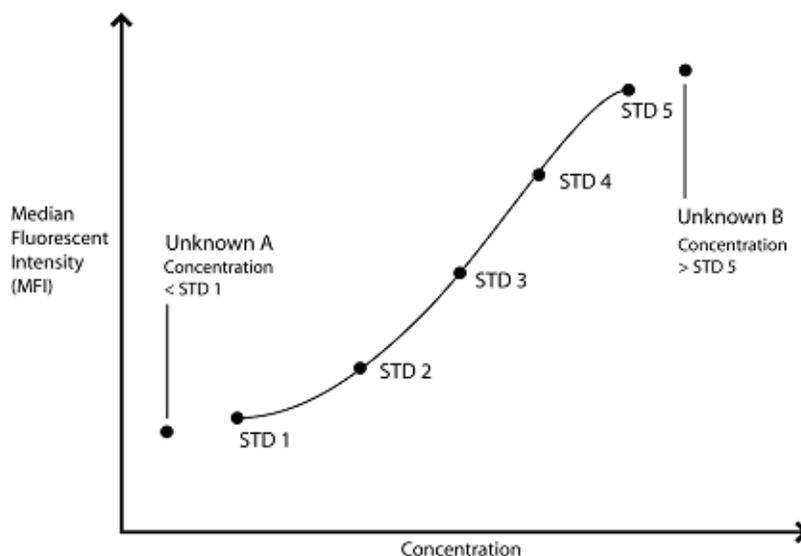


Figure 18 Non-Competitive Assay

Examples of out-of-range sample labeling for competitive assays are shown in Table 7. Figure 19 shows what a standard curve for a competitive assay should look like.

Table 7. Competitive Out-Of-Range Labeling

Condition	Concentration Label	MFI of Standard Referenced
Left of Curve	< min concentration standard	Highest
Right of Curve	> max concentration standard	Lowest

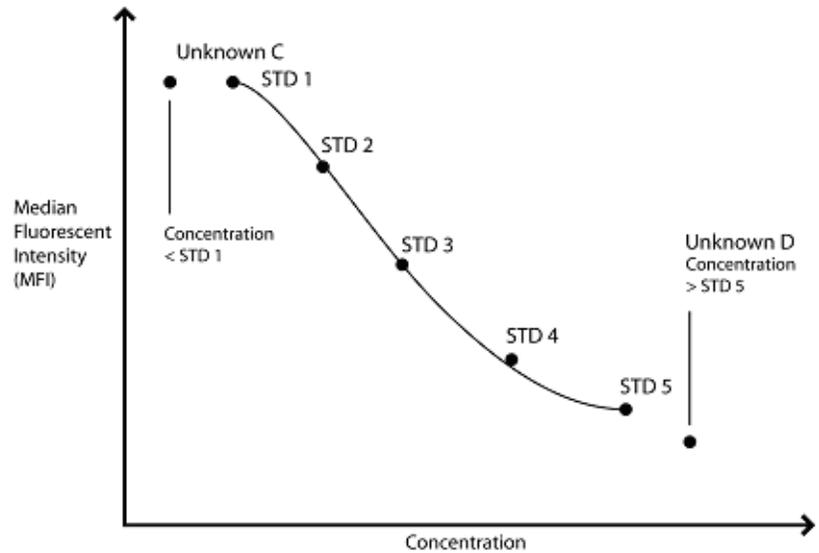


Figure 19 Competitive Assay

The standards tab displays an Expected Concentration column for standard and control samples. The Standards Expected Concentration column allows users to edit the standard concentrations. You can edit controls; however, you must select the control name or Expected Concentration box for that control, then click **Change Lot**.

When editing standard and control lot values the system may prompt you for a new number. If this is the first batch you analyze using this lot number, the system allows editing without requiring a new lot name. However, if you have analyzed a previous batch using this lot, the system will require that you rename the lot if edited or modified.

Background samples are commonly used in the assay process. Although recommended, the discretion on whether to use or not is left to the assay or kit developer. If background samples are included they are defined in the assay template.

Background samples are samples with no active test substance. The system uses background samples to remove assay background noise from the sample results. Typical background samples contain coupled beads, assay buffer, detection reagents, and reporter fluorophore. Background samples do not contain target analytes.

If the background sample is designated accordingly, the system subtracts the background sample's reported fluorescence from all other samples in a batch to report net MFI. If a batch contains more than one background sample, the fluorescence values of the two background samples are averaged together and subtracted from the other samples to obtain a net fluorescence intensity.

Samples Tab

The Samples tab lists tests from your batch and displays the results for each sample.

Figure 20 shows a Sample tab example listing three tests. Notice that the left pane displays Test IL-4, IL-6 and IL-8 with Test IL-4 selected. The right pane shows the IL-4 sample results. Notice that the well G3 location test result is “<10” and the associated Comments column for the third sample indicates a sample out of range error “Sample High/Low” because this sample has an MFI less than the lowest standard in the standard curve for this non-competitive batch.

The first sample is within the standard curve range and thus displays an unflagged test result.

The system does not flag results as normal or abnormal according to a defined range. Error flags only note samples that fall below or above the standard curve.

The Comments column cells are editable and the information is displayed in reports.

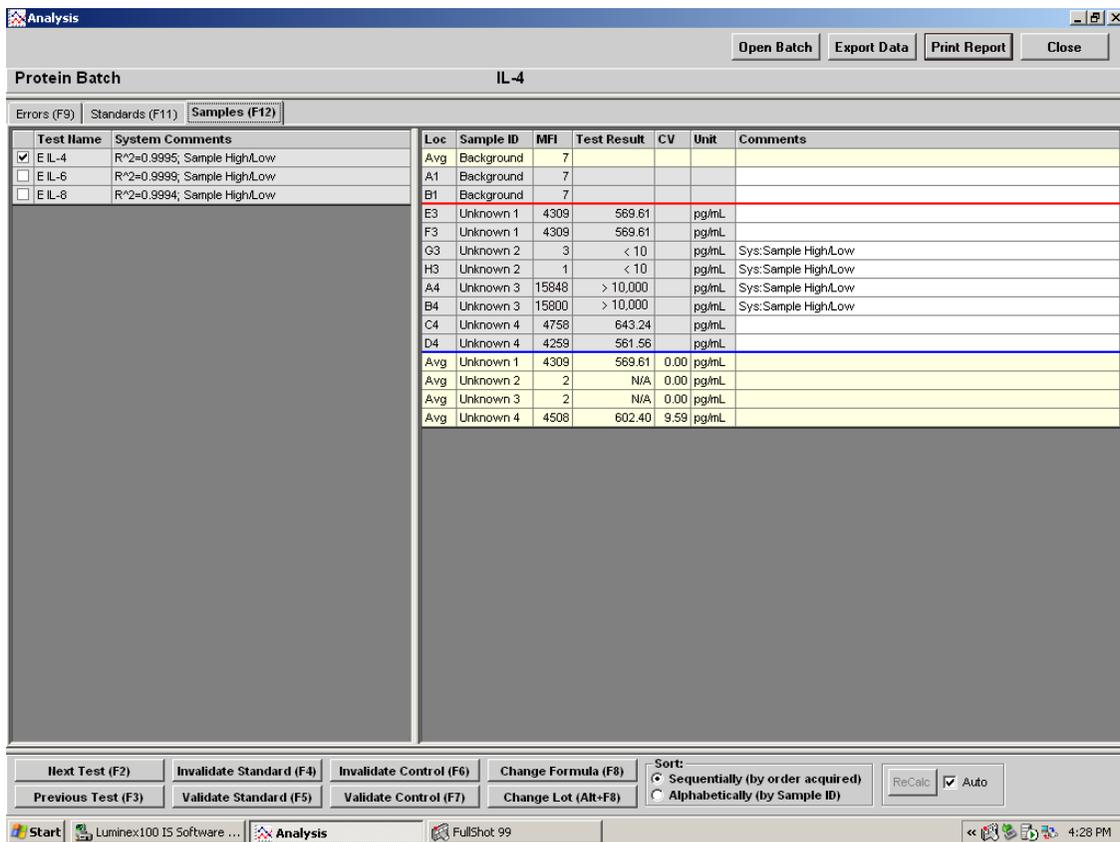


Figure 20 Analysis Window - Samples Tab Open

Replicate Averaging

Standard and control replicates are predefined in the template. You define unknown sample replicates in batch setup indicated by replicate Sample ID.

The data analysis function supports replicate sampling. It calculates each sample as an individual sample, which is then averaged to obtain a replicate average.

- Standards tab—displays standard and control average values.
- Samples tab—displays sample average values.

Replicate averages are displayed with AVG in the Loc (location) column.

The AVG entry appears immediately after the wells being averaged or at the end of the list depending on what you select under Sort (Sequentially or Alphabetically).

If the system fails to determine the results for a replicate due to an excessive skew of one of the samples, you can invalidate the out of tolerance value. Use the **Invalidate Standard (F4)** or **Invalidate Control (F6)** buttons at the bottom of the Analysis window. Be aware that this fixes standards and controls, not patient sample. If any of the replicate standards and/or controls are invalidated, the “Avg” results reflects the average of the remaining standard and/or control replicates.

The system flags the failed sample so you may calculate the replicate set’s average without including the failed result in the equation.

You can sort the batch samples Sequentially (by the order in which they are acquired), or Alphabetically (by sample ID). Select the sorting method in the Sort group box.

Commands

This section describes the different commands used in the Luminex IS 2.3 software. They are grouped Alphabetically

Acquire Patient

This command, which is part of the Insert command/menu, adds patients to the command list. After adding the patients you define the Sample ID and Dilution Factor for each new patient. The Dilution Factor defaults to 1.

Add Batch

When creating a multibatch, adds an existing batch to a multi-batch.

Alcohol Flush

Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The alcohol flush takes about five minutes. Uses the Luminex XYP reservoir due to volume requirement.

Autoscale

Automatically adjusts the maximum number of events shown on the Y axis on the histogram. Click during acquisition to readjust the Y axis scale.

Autosize

Automatically adjusts column widths to fit the data and header sizes.

Backflush

Removes obstructions from the fluidics pathways by drawing sheath fluid from the sheath fluid container. You do not need to supply solution in a plate. A backflush command takes about seven seconds.

CAL1

Runs the Classification portion of the Luminex System calibration.

CAL2

Runs the Reporter portion of the Luminex System calibration.

Cancel (Command)

Cancels the process for the last command initiated.

Cancel All

Cancels all the commands in progress.

Change Lot

Opens the Change Lot dialog box from which you select a lot to apply to a batch.

CON1

Runs the verification for the Classification calibration.

CON2

Runs the verification for the Reporter calibration.

Connect to Instrument

Establishes a connection between the PC and the analyzer.

Create New Multi-Batch	This command opens the Luminex Multi-Batch dialog box, in which you add or create new batches to add to a multi-batch.
Delete Batch	Opens the Delete Batch dialog box, which shows a listing of the unprocessed batches in the database. When you highlight a batch and click Select in this dialog box, the system deletes the selected batch.
Density/Decaying	Toggles between the default density dot plot and the decaying dot plot views.
Display Confirmation Screens	Enables confirmation dialog boxes to display when you initiate many of the maintenance commands.
Disconnect from the Instrument	Disconnects communication between the PC and the analyzer
Drain	Used during troubleshooting to help remove debris from the bottom of the cuvette. When draining, you do not need to supply solution. Draining takes approximately two minutes and should be followed by an alcohol flush with 70% isopropanol or 70% ethanol. Any fluid that drains from the system drains to the Luminex XYP reservoir as the default. However, you can set the system to drain to any unused well on the microtiter plate. The drain function normally expels 125 μ L of fluid.
Eject/Retract	If the XYP plate is retracted, this command ejects the microtiter plate. If the XYP plate is already ejected, this command retracts the plate.
Enable Raw Data Storage	Saves bead event data to the database.
Export Batch Data	Opens the Open Batch dialog box, from which you choose a batch to export to an output.csv file.
Export CAL	Opens a dialog box in which you choose the calibration file to export to an output file.
Export CON	Opens a dialog box in which you choose a control (validation) file to export to an output file.
Export Data	Exports data to a .csv file in the batch folder. There is no dialog box to confirm that the data was exported.

Help	Opens the help file. Use this command if you need instructions on using a feature in the Luminex IS 2.3 software.
Import Calibration	Opens a dialog box in which you select a calibration file that contains calibration lot information to import to use for calibrating the analyzer.
Import Control	Opens a dialog box in which you select a control file that contains control lot information to import for use when verifying calibration.
Import Template	Opens up the Import Template dialog box, from which you select a template to import for use in a batch.
Insert	This combination menu/command on the Batch Setup window allows you to add a user-defined number of patients to the command list, or skip a defined number of wells on the microtiter plate. The two options on the menu are Acquire Patient and Skip.
Invalidate Control	Invalidates or removes a control from the data analysis. Luminex does not recommend invalidating controls.
Invalidate Standard	Removes a standard from the data curve. Use this command if doing so improves the curve fit. Use caution when doing so because invalidating a standard will greatly affect the curve fit and subsequently the sample results.
Load Patient List	Opens the Open Patient List File dialog box, from which you select a patient list text file to append to a batch.
Log/Linear	Toggles the x axis scale on the histogram or dot plot between logarithmic and linear modes.
Maximize/Minimize	Toggles between maximum and minimum histogram and dot plot views.
Next Test	This command is found in the Analysis window. Use this command to view the next test in the batch.
New Advanced Batch	Assay developers use New Advanced Batch to acquire data without having to build templates. This provides the developer with a faster and more convenient tool to develop assays. It does not store the results in the Luminex IS 2.3 database. It writes raw data to the output.csv file if Auto Export is selected, and writes run files if Enable Raw Storage is selected. This feature is the primary use of the

	Acquisition Detail tab. When you click on the New Advanced Batch button, the Options dialog box opens, where you enter information about the batch, define bead events for the session, and define commands for plate layout.
New Batch	Opens a dialog box in which you select a template to create a new batch in the Luminex Batch Setup window.
New CAL Targ.	Opens the Update CAL Targets dialog box, in which you enter information about the calibration microspheres you are using to calibrate the system.
New CON Targ.	Opens the Update CON Targets dialog box, in which you enter information about the control microspheres you are using to verify system calibration.
New Lot	Opens the Open Template dialog box, from which you select a template to which you want to add a lot or edit lot information.
Open Batch	<ol style="list-style-type: none">1. The Open Batch command selected from the file menu or toolbar opens the Open Batch Dialog box, from which you choose an existing batch to use for acquisition.2. The Open Batch command on the Analysis window allows you to view data from a different batch.
Open Help	Opens the online help file.
Open Incomplete Batch	Opens the Open Run dialog box, in which you select a batch to recover.
Open Multi-Batch	Opens the Open Multi-Batch dialog box, in which you select a multi-batch to use for acquisition.
Pause	Pauses the command that the system is currently processing.
Previous Test	This command is found in the Analysis window. Use this command to view the previously run test in the batch.
Prime	Removes air from the system's fluidic pathways by drawing Luminex xMAP Sheath Fluid from the sheath fluid container. You do not need to supply solution in a plate. Priming takes approximately one minute. This command should also be used as part of the daily startup routine.

Print Batch Worklist	Prints the status of each of the commands in the command list, as well as the microtiter plate graphic.
Print Report	Prints the data interpretation report including the standards, controls, graph of standards, and Samples data.
Recalc	Recalculates an affected test after a change is made to lot information. There are two options: Manual recalculate and auto. If the auto checkbox is selected, the Recalc button (manually recalculate) is grayed out. In the auto selection mode, changes automatically trigger the system to reanalyze the affected test. If you are not using the auto mode, the ReCalc button is available after you make a change such as changing a formula or lot, or invalidating or validating a standard or control.
Replay Batch	Replays batch sample acquisition. All batch commands are replayed allowing for batch acquisition viewing exactly as in real-time. You cannot replay New Advanced Batches. When running a Replay Batch command, the original acquisition data is not altered. A new file is created. The most common use is for system demonstration and training.
Report Raw Fluorescence	Enables the median fluorescence intensity (MFI) to appear on the Analyte Report.
Resume	Resumes the process that was paused.
Sample Probe Down	Raises and lowers the sample probe to adjust the probe height. This adjustment is recommended when using different microtiter plates or when changing sample probes. Refer to the <i>Luminex 200 System Manual</i> or the <i>Luminex 100 IS User Manual for Version 2.3</i> for the adjusting procedure.
Sanitize	Uses the Luminex XYP reservoir due to volume requirement. The sanitize command performs a similar function as the alcohol flush command. However, the sanitize command uses 10% to 20% household bleach to decontaminate sample lines and the cuvette after biohazard contact.
Save and Load	If selected, displays the run batch tab immediately after you set up batch information and click Finish.
Save Only	Allows you to save the batch information. User can open the batch later to acquire data.

Self Diagnostics

Performs a self-diagnostics to see if the Luminex 200 analyzer and all system operations are functioning correctly. Self-Diagnostics tests these functions:

- Flash memory test
- Microcontroller RAM test
- Nonvolatile memory test
- DSP program CRC test
- DSP capture test
- High voltage module
- Channel backgrounds test
- Pressurization test
- Actuator test
- Syringe pump test
- Backflush valve test
- Debubbler valve test

Show Bead

After selecting an entry from the drop-down list, sets the histogram to show events for only one beadset [bead set number], <all gated> events within the gate, or <all> events inside and outside the gate. Select <all> (default) before setting the gate.

Single Step

Selecting this option on the toolbar pauses the system in between each command or sample acquisition within a batch.

Skip [wells]

Enables you to deliberately bypass specific wells during batch acquisition.

Soak

Prevents salt crystals from forming in the probe due to air exposure. Soaking the probe replaces sheath fluid in the probe with water. You should perform the soak function at the end of each day. The system uses at least 250 μ L of distilled water.

Start Analysis

Opens the Open Batch dialog box, from which you select a batch to analyze. Once you select the batch, the Analysis window opens.

Start (Plate)

This command initiates data acquisition on New Advanced Batches and New Batches using system templates. During acquisition, the system draws sample from the microtiter plate for processing.

Statistics

This command enables you to display selected statistics for sample data. There are eleven different statistics: %CV, Trimmed %CV, Count, Trimmed Count, Mean, Trimmed Mean, Median, Trimmed Peak, Peak, Trimmed Std Dev, and StdDev.

Test Sort Orders

This command is in the Data Export Tab of the Options tab. You can select Alphabetical by test name, Sequential by Region ID, or by Template Setup Order

- Alphabetical by Test Name - the tests are sorted by alphabetical order
- Sequential by Region ID - the tests are sorted numerically by bead ID#.
- Template Setup Order - the tests are sorted in the order set up in template, regardless of name or ID.

Validate Control

Opens the Validate Control dialog box. In this box, you choose to validate all control tests (click Yes), or only a single test (click No).

Validate Standard

Opens the Validate Standard dialog box. In this box, you choose to validate all control tests (click Yes), or only a single test (click No).

View Batch Data

Click to open a previously acquired batch that is stored in the database. You cannot view New Advanced Batches.

Warmup

Warms up the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on; however, you will need to use the Warmup command if the system is idle for four hours or longer.

Wash

Washes fluidics line. Sends fluid (distilled water) through the fluidic lines in the system. Pulls the fluid from a well or the reservoir and runs it completely through the system to the waste receptacle.

Zoom

Zooms or enlarges a specific area on the histogram or dot plot display. Click and drag right to left to adjust the graph's range.

Procedures

This section explains how to perform functions in the software.

Using the Online Help

Help files describe Luminex System features and capabilities. You may find these topics by searching the contents of books and topics or by searching an alphabetic listing of the topics and books.

Topics provide information and details regarding software features, system capabilities, and any number of related material.

Books usually contain a group of topics. These topics are grouped together because they discuss similar or related topics.

Hyperlinks provide instant access to another topic or subtopic with related information to the linked subject or term.

◆ To open the system's online help:

1. On the **Help** menu, click **Contents**.
2. In the Help dialog box, scroll through the contents and select the desired topic. Also, consider the index to locate information.
3. Double-click the help topic that you want to view. A topical dialog box opens with information on that topic.

◆ To display device information about the Luminex analyzer, Luminex XYP instrument, and the Luminex LXR SDK:

On the **Help** menu, click **About the Device**. The resulting dialog box shows information that may be helpful when contacting Luminex Technical Support. Click **OK** to close the dialog box.

◆ To display information about the system software:

On the **Help** menu, click **About the Software**. The resulting dialog box shows information about the system software. This includes software version, build number, and the system copyright information. Click **OK** to close the dialog box.

◆ To display system information:

1. On the **Help** menu, click **About the Software**. The resulting dialog box opens that displays software information.
2. Click **System Info**. The **System Information** dialog box opens. Click **X** in the top-right corner to close the dialog box.
3. Click **OK** to close the dialog box.

Setting Software Options

Set up and customize the system software and enter your company information in the Options dialog box. The **Software Options** dialog box has three tabs: the General tab, the Company Information tab, and the Data Export tab.

◆ To configure software options:

1. On the **Tools** menu, click **Options**.
2. Click on the tab in which you want to set options. A full description of each tab and its options is listed below.
3. After you have entered and selected all of your preferences, click **OK**.

Define General Tab Information

You define the following options on the General tab.

Default Batch Directory. Names the default directory to store batch information. Click the browse button and navigate to the desired folder (directory).

Current User. Enter the name of the current user or operator. The name appears on reports.

Analysis Display Digits. Use this feature to customize the number of digits shown on the **Data Analysis** dialog box and printed reports. The data is stored with its full precision (that is, including all digits), but the data appears as requested. The default analysis digit display is for two digits to show in the analysis.

Display Confirmation Screens. Enables confirmation dialog boxes to display when you initiate many maintenance commands. If you disable the confirmation screen display option, the confirmation screens remain for commands initiated from the Home tab.

Enable Raw Data Storage. Select this feature to save bead event data that is acquired while processing batches in the database. The system defaults to Enable Raw Data Storage. Raw data storage is necessary particularly when you use file mode (Replay Batch).

Report Raw Fluorescence. Select this feature to enable the median fluorescence intensity (MFI) display to appear on the Analyte Report. This feature was previously used to display MFI values on all reports. In the Luminex IS 2.3 software, the only report affected by this selection is the Analyte Report. All others are hard coded by the system.

Auto-Start Analysis. Select this feature to enable the software to begin analyzing data immediately after processing batches. The automatic analysis feature takes place after the system finishes acquiring data while processing batches.

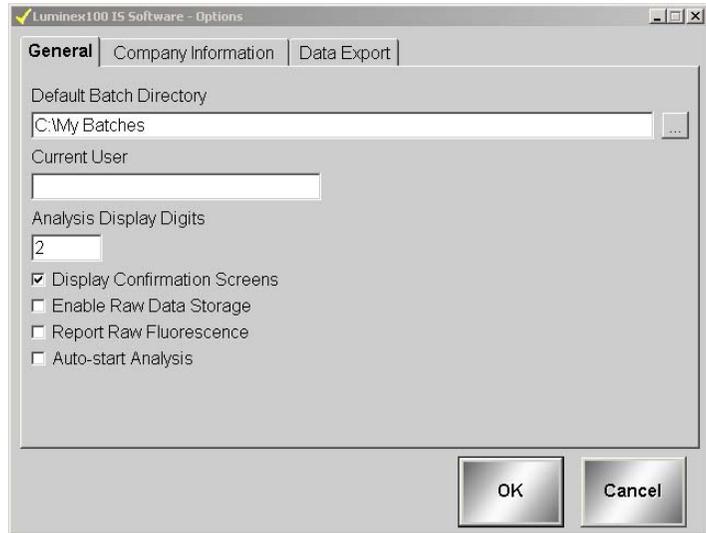


Figure 21 Options Dialog Box—General Tab

Define Company Information Tab

You can enter information about your company and a company logo into the **Company Information** tab. This information is stored in the Registry for reference. The logo will not alter any Luminex IS 2.3 report or screen.

Company Information (name, address, phone and fax numbers, and location of company logo).

Use the browse button  to navigate to the location where the logo is stored.

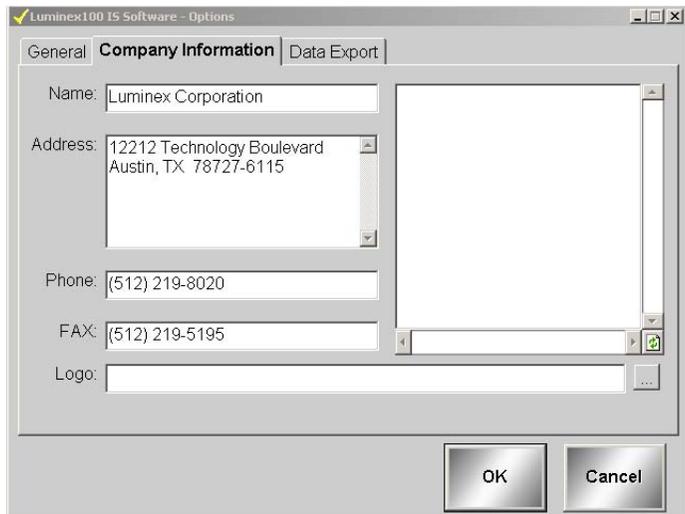


Figure 22 Options Dialog Box—Company Information Tab

Define Data Export Tab Information

Use the Data Export tab to configure your export data. See Figure 23. The following options are available:

Auto Export Batches. Select this feature to automatically export the .csv file formats when the system finishes analyzing the batch. This allows you to run your own programs on exported data without having to manually start the export. This feature also takes place after acquisition completes. If this is not selected while running a New Advanced Batch, you must right-click on the data grid to get your output.csv file.

Copy Output.csv file to Common Output Dir. Select to send a copy of the Output.csv file to the My Batches/Output folder.

Prompt for Batch Comment. Check this button to initiate a prompt for batch commenting when a batch is finished.

Write Sample Comments. Select to add sample comments to the Notes column in the output.csv file.

Additional Export Stats. Select to define which sample statistics to export outside the Luminex IS 2.3 software to the Output.csv file.

Test Sort Order. Choose an option to define the sorting order. For more information on the options, see the Command section, beginning on page 28.

Additional Batch Information. Select one or more options to add additional information to the exported batch file (output.csv).

Export Location Label Style. Choose one of these options to define the label data style exported to the Output.csv file. You can select sequential numbering, by plate location, or both (default).

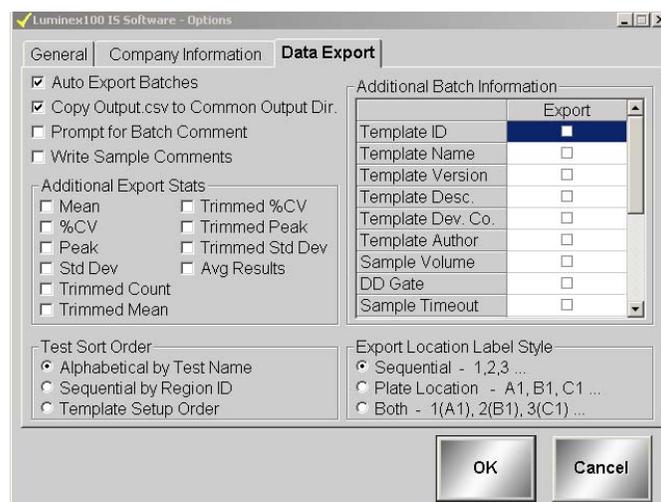


Figure 23 Options Dialog Box—Data Export Tab

Setting up the Favorites List

◆ To add templates to the Favorites list:

1. On the **Favorites** list, click **Add Template**.
2. In the **Open Template** dialog box, double-click the template to add to your Favorites list.

◆ To add commands to the Favorites list:

1. Click **Add Commands** from the **Favorites** list. The **Command List** dialog box opens.

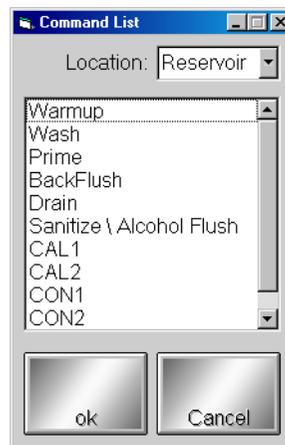


Figure 24 Command List Dialog Box

2. Select the command that you want to add to your Favorites list. For certain commands, you will need to select the location where you want to draw or expel fluid. Use the **Location** drop-down menu to open the microtiter plate image. Click on the microtiter plate location on the image. Ensure that the location you select is compatible with the volume intended for that location.
3. Click **OK** to add the command. The command displays in the Favorites list.

◆ To remove items from the Favorites list:

Select the item you want to remove from the Favorites list, then click **Remove**. The item disappears from the list.

Startup Procedures

Warm Up the System

Warm up the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on. This procedure takes approximately thirty minutes.

Caution: Failure to properly warm up the system will effect assay results and system performance.

After four hours of inactivity, the status bar appears red and indicates that the lasers are off. You need to warm up the system again by manually initiating warmup.

◆ To warm up the system:

Click **Warmup**, then click **OK**. The command list on the Run Batch tab indicates that the system lasers are running. The Device Activity box on the Status Bar indicates that the system is warming. The Laser Status section on the Status Bar is yellow as it counts down from 1800 seconds. Upon completion, the Laser Status bar turns green and displays Warmed Up.

Prime the System

Prime your system as part of the daily startup routine and as necessary to remove air from the system's fluidic pathways after:

- refilling the sheath container
- removing and replacing the sheath container
- observing air in the tubing
- changing the sheath fluid filter
- changing the syringe seal

When priming, the system draws Luminex xMAP sheath fluid from the sheath fluid container and sends it directly out to waste, and takes approximately one minute. You do not supply solution in a plate.

◆ To prime the system:

Click **Prime**, then click **OK** to confirm that you want to prime the system. The status bar indicates that the prime command is processing.

Backflush the System

Backflush the system:

- to remove obstructions from the cuvette
- if fluid does not flow through the waste tubing during prime cycles or during sample acquisition
- if fluid drips from the sample probe during priming and forms puddles of fluid on the plate

During a backflush, the system draws sheath fluid from the sheath fluid container and sends it directly to waste. You do not need to supply solution in a plate. A backflush takes between 10 and 30 seconds.

- ◆ To clear obstructions from the cuvette:

Click **Backflush**, then click **OK** to verify that you want to backflush the system.

The status bar shows that the backflush command is processing.

Run an Alcohol Flush

Alcohol flush the system to remove air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The cuvette is the principal fluid pathway within the optics component of the system where the system reads the sample.

- ◆ To remove air bubbles from the sample tubing and cuvette:

1. On the Maintenance tab, click **Eject/Retract**
2. A confirmation dialog box opens telling you to place solution in the reservoir.
3. Put 70% isopropanol or 70% ethanol in the reservoir.
4. Click **OK**. The plate holder retracts, and the system performs the Wash command.

Run a Wash Cycle

Use the wash cycle after an alcohol flush or as needed. For example, wash four times with distilled water after calibration and twice with distilled water after Sanitize. Place at least 200 μ L in a microtiter well or fill the Luminex XYP reservoir with distilled water. Washing takes about 30 seconds.

You should wash after calibration and verification, between batches and multi-batches, after sanitize, and before daily shutdown.

- ◆ To perform a Wash command:

1. On the Maintenance tab, click **Eject/Retract**.
2. Select **Reservoir** from the dropdown menu next to the Wash button, then click **Wash**. A confirmation dialog box opens telling you to place solution in the reservoir.
3. Put distilled water in the reservoir.
4. Click **OK**. The plate holder retracts, and the system performs the Wash command.

Set Luminex XYP Instrument Heater Temperature

Refer to your assay kit instructions to see if the assay needs to be analyzed at a particular temperature. If the instructions indicate that the Luminex XYP instrument heater is needed, set the heater to the specified heat setting. The user definable heater range is 35°C to 60°C. Use the heater only with the heater block in place.

Luminex recommends using a Costar® Thermowell® thin-wall polycarbonate 96-well plate (nonskirted), model P over the heater block sent with the Luminex System. Do not use standard 96-well microtiter plates if you are using the heater block.

Any temperature that you set remains in effect until you set another temperature or turn off the Luminex XYP instrument plate heater or exit the software.

The system displays the target temperature in the box below the Turn ON button. Before the heater block temperature reaches the new temperature setting, the XYP Heater Temperature thermometer is red. Upon reaching the target temperature, the thermometer turns green. See page 9 for more information about the system monitor.

Warning: The heater plate of the Luminex XYP instrument is hot when in use and may cause burns. Do not touch the heater plate.

◆ To set the Luminex XYP instrument heater temperature:

1. Click **Eject/Retract** to eject the plate holder.
2. Set the Luminex XYP heater block on the plate holder.
3. Click **Eject/Retract** to retract the plate holder.
4. In the **Temperature and Gauges** area of the **Run Batch** tab, click **Turn ON**. The light on the button turns green and the thermometer fluid turns red as it raises to reach the target temperature.
5. Use the up and down arrows beneath the target temperature box to set the temperature you want the Luminex XYP instrument heater block to maintain. The user definable heater range is 35°C to 60°C.
6. Wait for the heater to reach your selected temperature and stabilize before processing samples. The thermometer turns green when the temperature is stabilized.

Calibration Procedures

Calibrator xMAP microspheres are used to normalize the settings for the reporter channel, both classification channels, and the doublet

discriminator channel. Control xMAP microspheres are used to verify calibration and optical integrity for the system.

Calibrate the system at least once a month and:

- Following installation
- if the system is moved.
- if a part is replaced.
- if the delta calibration temperature shown on the system monitor (on the Diagnostics tab) is more than ± 3 degrees.
- if sample acquisition is problematic.

Each step in the calibration procedure usually takes less than one minute. You must run xMAP controls after each calibration. Once calibrated, the calibration values remain until you calibrate again. You can track system calibration and verification results through the Calibration Trend Report and the System Control Trend report. If you need target value information for Calibration or Control microspheres, you can find the information on the Luminex website at <http://www.luminexcorp.com>. Click on the **Support** link then navigate to the FAQ page on the Support page.

Ensure that the Luminex analyzer lasers are warmed up and the probe height is set correctly before calibrating the system. Do not move the system waste line while calibrating.

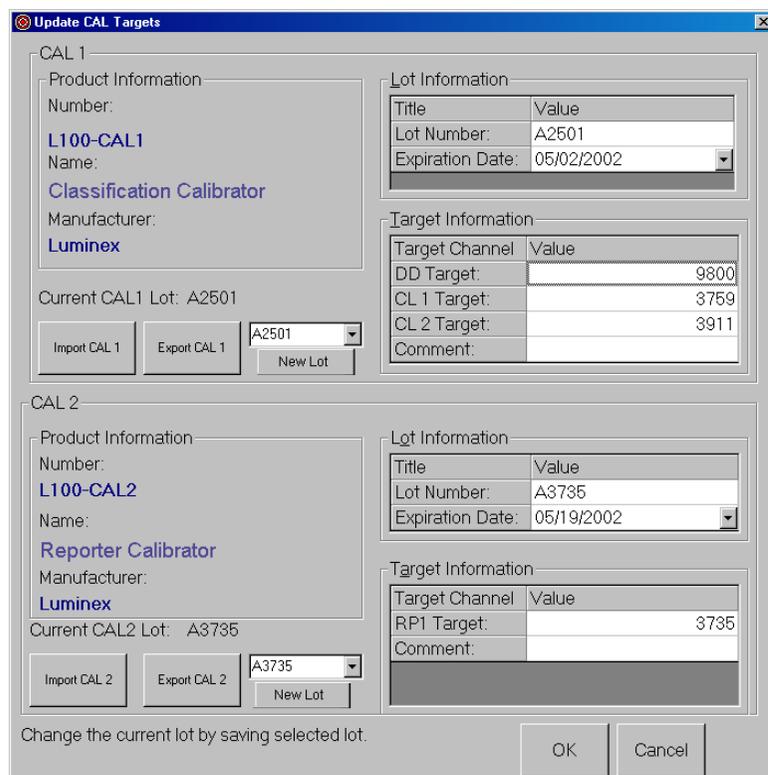
You can run calibration and verification commands from the Maintenance tab. You can import and export calibration and control lots and reuse existing lot information for calibration and controls.

Run System xMAP Calibrators

Note: When dispensing calibration and control microspheres, hold the bottle upside down at a 90-degree angle to the microtiter plate to ensure that you are getting accurate drop volume.

- ◆ To calibrate your system with xMAP calibrators:
 1. Vortex the xMAP calibrator and control containers to ensure homogeneity. Do not dilute xMAP calibrator or control reagents.
 2. Load a microtiter plate with at least five drops of each: CAL1 in well A1, CAL2 in well B1, CON1 in well C1, CON2 in well D1 and distilled water in well E1 through H1 to wash a total of four times. Use different wells as necessary. To select different well locations in the software, click on the drop-down arrow next to the entry cell for the calibrator or control, then click in the well location on the microtiter plate image.
 3. Click **Eject/Retract**, then place the plate on the plate holder.
 4. Fill the Luminex XYP reservoir with a solution of 70% isopropanol or 70% ethanol.
 5. Click **Eject/Retract**.

6. On the **Maintenance** tab, click **Prime**. Click **OK** and wait for the Prime to finish (about 1½ minutes).
7. Click **Alcohol Flush**. Click **OK** and wait until the alcohol flush completes. The **Device Status** section in the status bar changes from yellow to green and displays “Standby”.
8. Click **New CAL Targ.** to enter or confirm calibration lot numbers in the **Update CAL Targets** dialog box. See Figure 25.
9. Enter the CAL1 lot number and expiration date as printed on the bottle. Enter the values listed on the Certificates of Quality (COQ) included with your calibrators into the **CAL1** boxes. If you are using a previously entered lot, select it from the drop-down menu in the **Current CAL1** group box or click **Import** to import the information. See page 47 for more details on importing a Calibration lot.



Update CAL Targets

CAL 1

Product Information
 Number: L100-CAL1
 Name: Classification Calibrator
 Manufacturer: Luminex

Current CAL1 Lot: A2501

Import CAL 1 Export CAL 1 A2501 New Lot

Lot Information

Title	Value
Lot Number:	A2501
Expiration Date:	05/02/2002

Target Information

Target Channel	Value
DD Target:	9800
CL 1 Target:	3759
CL 2 Target:	3911
Comment:	

CAL 2

Product Information
 Number: L100-CAL2
 Name: Reporter Calibrator
 Manufacturer: Luminex

Current CAL2 Lot: A3735

Import CAL 2 Export CAL 2 A3735 New Lot

Lot Information

Title	Value
Lot Number:	A3735
Expiration Date:	05/19/2002

Target Information

Target Channel	Value
RP1 Target:	3735
Comment:	

Change the current lot by saving selected lot.

OK Cancel

Figure 25 Update CAL Targets Dialog Box

10. Repeat step 9 for the CAL2 lot.
11. In the **Maintenance** tab, click **CAL1**, then click **OK**. The device status section in the status bar changes from “Running” to “Standby”.

12. Click **CAL2**, then click **OK**. Wait until CAL2 completes.

The Device Status section in the status bar changes from “Running” to “Standby” and the Diagnostics tab turns red. The System Monitor on the Diagnostics tab displays the date and time in green if CAL1 and CAL2 are successful.

The Diagnostics tab turns red if all substances (CAL or CON) have not been run and under the following conditions:

- the first time the software is opened
- the first time a system is calibrated
- a new database is installed
- an old database is restored
- a CAL or CON fails.

You must run system controls following calibration. Continue with the following “Run System xMAP Controls” section.

Run System xMAP Controls

Run System xMAP controls to verify calibration. Dispense the Control microspheres into the microtiter plate at the same time that you dispense the Calibration microspheres. See “Run System xMAP Calibrators” on page 43.

◆ To verify system calibration with controls:

1. In the **Maintenance** tab, click **New CON Targ**. The **Update CON Target Information** dialog box opens. See Figure 26.
2. Enter the CON1 lot number, expiration date, and the values listed from the COQ included with your system controls into the CON1 entry boxes. If you are using a previously entered lot, select it from the drop-down menu in the Current CON 1 group box or click **Import** to import the information. See page 47 for more details on importing a lot.
3. Repeat step 2 for the CON2 lot information.

Update CON Targets

CON 1

Product Information
 Number: **L100-CON1**
 Name: **Classification Control**
 Manufacturer: **Luminex**

Current CON1 Lot: A1682

Lot Information

Lot Number	Value
A1682	
Expiration Date	12/06/2002

Target Information

Reference	Target A1	Target B1	Target C1
1	9861	769	218
2	9835	75.3	66.4
3	10675	23422	5607
4	8946	2573	17803
5	9386	233	5795

CON 2

Product Information
 Number: **L100-CON2**
 Name: **Reporter Control**
 Manufacturer: **Luminex**

Current CON2 Lot: A1440

Lot Information

Lot Number	Value
A1440	
Expiration Date	09/21/2002

Target Information

Reference	Target A1
1	29.1
2	197
3	1910
4	17429

Change the current lot by saving selected lot.

OK Cancel

Figure 26 Update CON Targets Dialog Box

4. Ensure that the analyzer is set to draw CON1 and CON2 beads from the wells you loaded in step 2 of “Run System xMAP Calibrators” on page 43.
5. In the **Maintenance** tab, click **CON1** then click **OK**. Wait until CON1 completes. The Device Status section in the status bar changes from “Running” to “Standby”.
6. Click **CON2**, then click **OK**. Wait until CON2 completes. The Device Status section in the status bar changes from “Running” to “Standby”. The System Monitor on the Diagnostics tab displays date and time in green if both CON1 and CON2 are successful.
7. Ensure the analyzer is set to the draw distilled water from the well you loaded it in step 2 of “Run System xMAP Calibrators” on page 43.
8. Click **Wash** to wash the system after running the system calibrators. Wash a total of four times. You will need to change the well location. Click on the dropdown menu located to the right of the **Wash** button.

- Click **OK** and wait until the wash completes. The device status section in the status bar changes from “Running” to “Standby”.

If an error occurs during system calibration or verification, an X appears in front of the Diagnostics tab title, and the title text turns red.

Selecting Existing CAL or CON Lots

- ◆ To select an existing lot:
 - On the **Maintenance** tab, click **New CAL Targ** or **New CON Targ**.
 - Select a lot using the arrows located to the right of the Import and Export buttons in the Update CAL Targets and Update CON Targets dialog boxes.

Review the lot information and press **OK** to select the calibration lot.

Importing CAL or CON Lots

- ◆ To import system CAL or CON lots:
 - On the **Maintenance** tab, click **New CAL Targets** or **New CON Targets** as appropriate. An **Update CAL Targets** or **Update CON Targets** dialog box opens.
 - Click **Import CAL** or **Import CON** as appropriate. The **Open** dialog box opens.
 - To select the calibration lot or control lot to import, click the drop-down arrow for the **Look in** box. Browse for the appropriate folder, diskette, or CD location. The file type is a .lif file.

After you select the location, the available lots display in the selection list. Click the name of the lot to import and click **Open**. The lot name appears in the product information box. The lot and target information is displayed on the Update dialog box.

- Click **OK** to complete the operation.

Exporting CAL or CON lots

- ◆ To export system CAL or CON lots:
 - On the **Maintenance** tab, click **New CAL Targets** or **New CON Targets**. An **Update CAL Targets** or **Update CON Targets** dialog box opens. Ensure you have the desired lot to export displayed or selected.
 - Click **Export CAL** or **Export CON** as appropriate.
 - In the **Save As** dialog box, select the folder (directory) where you want to export the lot as the **Save-in** location. The default is

the Backup folder (directory) found in C:\Program Files\Luminex\Luminex 100 IS\Backup.

4. Enter the lot name for the exported lot into the **File Name** box.
5. Click **Save**, then click **OK**. The dialog box closes. After you click **OK**, you can use the lot target values with the next calibration or verification.

The system saves the lot to the existing software as a lot accessible for the next calibration and/or verification. Once you export the desired calibration or control lot you can save it to disk to import to another computer.

Batch Setup Procedures

A batch consists of a group of samples processed under control of a template. Batches are set up using templates defined by assay kit manufacturers. Batches consist of templates and samples for acquisition, and can span more than one plate. Templates contain predefined commands that must be included in every batch acquisition.

You can group batches together as a multi-batch. Multi-batches can consist of any number of batches that have been setup from different assay templates and are processed consecutively.

The assay kit manufacturer may provide templates in the kits, which they distribute on diskette or CD. Templates typically include assay standards, controls, and maintenance commands (such as washes or primes to acquire along with samples). OEM manufacturers may provide templates pre-installed with your system.

The kit manufacturer includes assay reagents in the assay kit. You must provide information about these reagents, such as lot numbers and concentration values for the standards and assay controls.

A batch can include samples across more than one plate. When setting up a batch, if the number of samples exceeds the wells in one microtiter plate, another plate appears for additional samples. The new plate appears to the immediate right of the existing plate image on the screen with a dark line between the adjacent columns of the two plates.

During acquisition, the Run Batch tab displays the wells containing the samples in the microtiter plate. Colors indicate the progress in analyzing the samples. The following well colors indicate well-acquisition states:

- Green well: with command number—sample not acquired.
- Yellow well: sample currently in acquisition
- Red well: sample failed. Check the system monitor for more information
- Green background: with check mark—successfully completed

Common sample errors are due to lower number of events acquired than established in the template.

Importing Templates

You need to import new templates to the system only once. You must enter lot information for the standard and control reagents as specified in the template. This lot information is used for every batch setup using the template until it is changed.

Templates include standards, controls, both standards and controls, maintenance commands, and acquisition commands.

◆ To import a template from a diskette or CD:

1. Insert the kit's diskette or CD into the appropriate drive.
2. On the **File** menu, click **Import Template**. The **Import Template** dialog box opens.
3. Click the **Look in** drop-down arrow and navigate to the diskette or CD drive containing the template. The diskette drive is typically drive A and the CD drive is typically drive D.
4. The kit manufacturer's template appears on the selection list. Click the name of the template.
5. Click **Open** to load the template.

Create a New Batch

◆ To create a new batch:

1. Read the instructions provided with the assay kit you are using. Follow the kit instructions for any preparations.
2. Click **New Batch**. The **Open Template** dialog box opens.
3. Double-click the template you want to apply to the new batch. The template loads, and the **Luminex Batch Setup** window opens. See Figure 27.

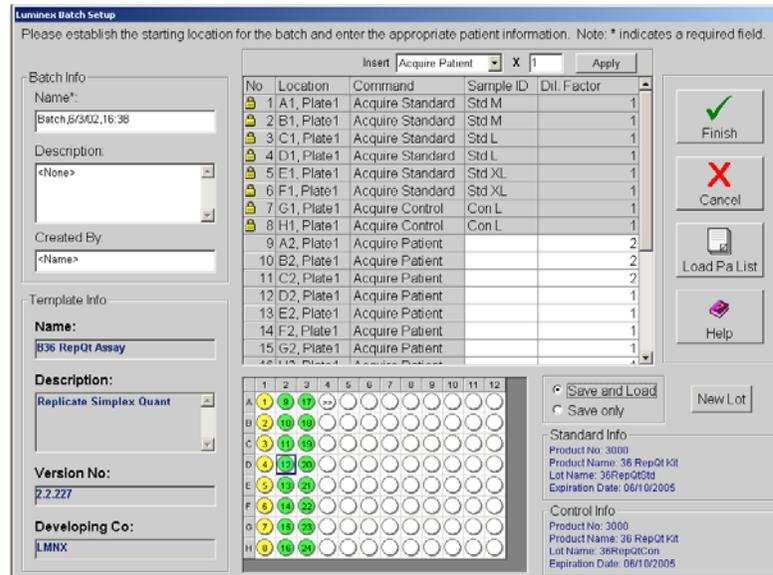


Figure 27 Luminex Batch Setup Window

4. Enter the batch name (if different from the default name), a description (optional), and the creator's name (optional).
5. If you want to insert an Acquire Patient or Skip command, select the command from the **Insert** menu. In the multiplier box, enter the number of patients that you want to add to the list or the number of wells that you want to skip and click **Apply**. Skipped wells and patient wells added to the batch are shown as green wells on the microtiter plate image.
6. If you are running a maintenance template, add any samples (for processing). Then click **Save and Load** (default) or **Save Only**. Otherwise, continue with step 7.
7. If you want to change the well location where you begin acquiring samples, drag the highlighted starting well (default is A1) to the desired location on the microtiter plate.
8. Click the field in the **Sample ID** row that represents the last empty well on the microtiter plate.
9. Enter the sample ID for the sample to add. Repeat this step to add all of the additional samples to the batch. You can enter the sample manually, through a patient list, or using the system barcode reader. Batches may span more than one plate. When the first plate is full, a blue line separates the columns of the first plate with those of a second plate. To add a sample ID to the end of the list, press the **Enter** key or double-click in the last line.

10. To add a patient file to the batch, click **Load Patient List**. An **Open Patient List File** dialog box opens. See Figure 28. If you do not want to add a patient list to the batch, skip to step 11.

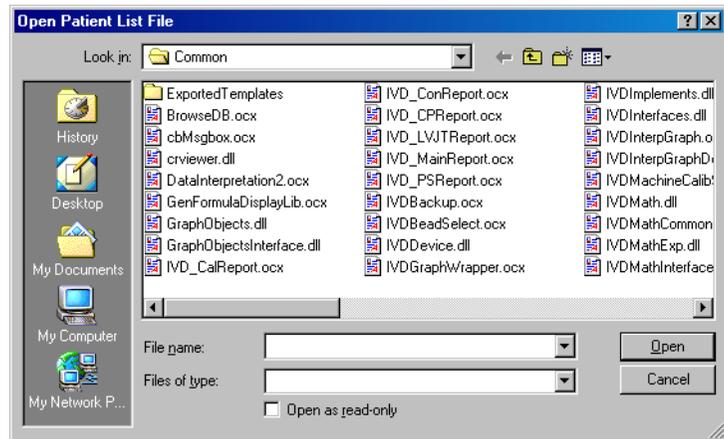


Figure 28 Open Patient List File Dialog Box

Note: If any of the acquire sample commands within the template of the batch has an unassigned Sample ID, the system applies the first patient ID in the list to the unassigned sample acquisition command. The system appends any remaining patient IDs to the end of the command list in the order as they appear in the patient list.

11. Select a patient file to append to the batch and click **Open**. The system appends the patients to the batch.
- If all patient IDs in the batch are identified, the system appends the patient list items to the first empty location following the batch's last command list activity. See "Add a Patient List" on page 58 for information regarding the patient file format.
12. Verify the dilution factor settings, and adjust as necessary. See page 60 for more information.
13. Select **Save and Load** (default) or **Save Only**.
14. Click **Finish**. If you selected Save and Load, the Run Batch tab opens displaying the batch, including the samples you added. If you selected Save Only, the system becomes idle as it waits for you to initiate a command.
15. If you selected Save and Load, load the plate using the Eject/Retract button, then click **Start Plate**.

Open a Batch

Use this procedure to open an existing batch. The batch name and description appear on the Run Batch tab when you load the batch. You can open "Saved Only" batches with this procedure.

- ◆ To open a saved batch for an acquisition:

1. Click **Open Batch**. The **Open Batch** dialog box opens.

2. Double-click on the desired batch. The system loads the batch as you created it in the Run Batch tab.
3. Click **Start Plate** to initiate batch acquisition.

Copying and Exporting Batch Data

- ◆ To export Batch Data:
Right-click in the Batch Data area of the Acquisition Detail tab. In the right-click menu, click **Copy** to copy the currently displayed data to the clipboard. Click **Export** to manually export the currently loaded batch to the appropriate Output.csv file.

Clear a Batch from the System

The Clear Batch command clears the entire batch from the Run Batch tab or the Message Log on the Diagnostic tab. Once you choose to clear the batch and verify that you want to continue with the command, you can recover the cleared batch if it has not been run by clicking **Open Batch**.

- ◆ To clear a batch from the system:
 1. Right-click on the area to clear.
 2. Click **Clear** in the dialog box.
 3. Click **Yes** to confirm that you want to clear the batch.

Replay a Batch

You can reprocess batches through the system multiple times using Replay Batch. Replay Batch uses the data stored in the run files from the initial acquisition to reprocess a batch, creating a new batch output file.

Each time you reprocess a batch using Replay Batch, the system handles it as if it is a new batch; thus, creating a separate processed batch entry and output file. The initial batch data and output file always remain intact and unchanged.

You reprocess a batch using Replay Batch to:

- Run as demonstrations to see how the system processes samples and analyzes the results.
- Test a batch using different parameters, such as setting a different number of events to be collected or using a different bead map or new formula for analysis, also using a different template. The number of beads for collection must be less than or equal to the number of previously collected in the original sample.

If you reprocess a batch with the same template parameters in a different template, the system obtains results identical to the original

batch. If you reprocess a batch using changed parameters, the system may obtain different results. When you replay a batch it labels unknown samples as Pa1, Pa2, Pa3, and so on. If you replay a batch containing replicates, replicate averaging will not be calculated in data analysis.

A number of variables can affect the final test results. You may also change the standards or controls processed with the batch or multi-batch. These variables may effect your test results:

- minimum number of events for acquisition
- formula used to analyze the MFI values
- standards or controls validation or invalidation
- type of analysis (qualitative, quantitative, acquisition only, or maintenance)

◆ To reprocess samples using Replay Batch:

1. On the **Acq. Detail** tab, click **Replay Batch**. The **Browse for Folder** dialog box opens displaying the My Batches folder.
2. Select the desired batch under the **My Batches** folder and click **OK**.
3. The **Open Template** dialog box opens. Click on the desired template and click **Select**.
4. The **Run Batch** tab becomes the active tab. You can monitor the commands as they process. Click on the **Acq. Detail** tab and monitor the data, histogram, and dot plot.

After replaying a batch, you can analyze the data.

◆ To analyze Replay Batch data:

1. Click **Start Analysis**.
2. In the **Open Batch** dialog box, select the batch you want to analyze, then click **Select**. The most recent Replay Batch is the last or has the highest ID number. See Figure 29.

Note: The Open Batch dialog box does not list or show the templates associated to the batches.

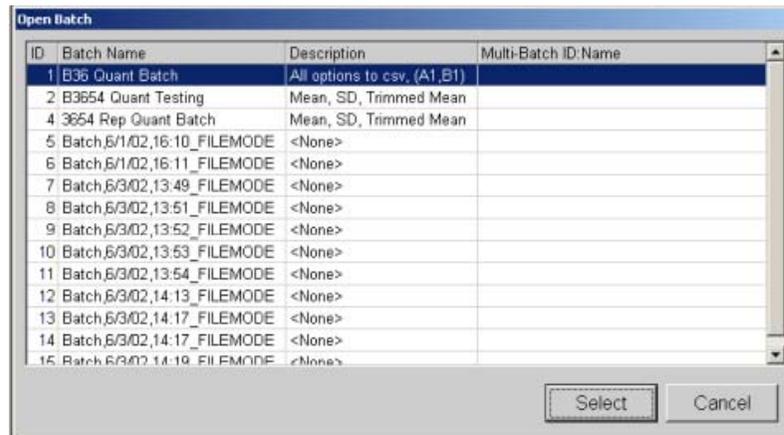


Figure 29 Analyze Open Batch

The **Analysis** window opens, showing the Batch info in the Standards tab. To close the Analysis window click **Close**. See “Analyzing Batches and Multi-Batches” on page 72.

Delete a Batch

You can only delete unprocessed batches. Batches are deleted from the Open Batch list and moved to the Open Incomplete Batch list.

◆ To delete an unprocessed batch:

1. On the **File** menu, click **Delete Batch**. A dialog box opens listing the unprocessed batches in the database.
2. Select the unprocessed batch that you want to delete.
3. Click **Select** to delete the batch.

If you need to recover a deleted batch, select **Open Incomplete Batch** from the **File** menu.

Create a Multi-Batch

A multi-batch is a set of batches that you want to process consecutively. You can add batches to the multi-batch from existing batches in your database, or you can create new batches to add to the multi-batch. You can include as many batches as you need. The software does not limit you to a certain number of batches per multi-batch. Different batches within the multibatch are separated by thick red lines above the first well and below the last well of each batch. Multi-batches may span more than one plate. A blue line separates the graphical representation of the plates. A scroll bar appears along the bottom of the microtiter plate image so you can view additional plates.

◆ To create a multi-batch with new batches:

1. Click **New Multi-Batch**. The Luminex Multi-Batch Setup dialog box opens, shown in Figure 30.

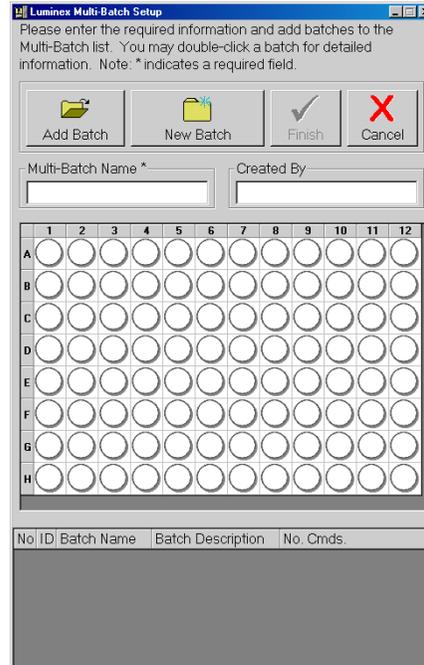


Figure 30 Luminex Multi-Batch Setup Dialog Box

2. In the Luminex Multi-Batch dialog box, click **New Batch**.
3. Create a New Batch. The procedure is shown on page 49. Click **Save and Load** instead of **Save Only** when you are finished setting up the New Batch.
4. To reassign the positions of the batches within the multi-batch, use the mouse to drag the highlighted well to the location on the microtiter plate where you want to begin acquiring data. Make sure that each additional batch is in its desired location.
5. Enter the **Multi-Batch** name and **Created By**, then click **Finish**. The **Run Batch** tab opens, representing the batches you selected or created on the microtiter plate.
6. Click **Eject** and load the first plate of the multi-batch.
7. Click **Start Plate** to begin acquiring data from the multiple batches in the sequence that you set up.

- ◆ To create a multi-batch with existing batches:
 1. Click **New Multi-Batch**.
 2. In the **Luminex Multi-Batch** dialog box, click **Add Batch** to add an existing batch to the multi-batch. See Figure 30.
 3. Select the first batch to add and click **Select**. The batch appears beginning in well A1 of the microtiter plate on the **Luminex Multi-Batch Setup** dialog box. Red lines separate this batch from subsequent batches.
 4. Repeat steps 2 and 3 to add additional batches.
 5. Enter the **Multi-Batch** name and **Created By**, then click **Finish**. The **Run Batch** tab opens, representing the batches you selected or created on the microtiter plate.
 6. Click **Eject** and load the first plate of the multi-batch.
 7. Click **Start Plate** to begin acquiring data from the multiple batches in the sequence that you set up.

Open a Multi-Batch

Use this procedure to open an existing multi-batch. Each batch in a multi-batch appears on the list of available multi-batches. The software differentiates them according to batch ID, name, and description. The software gives all batches comprising a multi-batch the same multi-batch ID number and name.

- ◆ To open a multi-batch:
 1. Click **Open Multi-Batch**. The **Open Multi-Batch** dialog box opens, listing the available multi-batches.
 2. Double-click on the multi-batch you want to open.
 3. Click **Eject/Retract** to eject the plate holder.
 4. Load the first microtiter plate onto the plate holder.
 5. Click **Start Plate** to retract the plate holder and begin acquiring the multi-batch data.

Process Multiple Plates

You can process multiple plates per batch or multi-batch. After loading a batch or multi-batch that spans more than one plate, a new plate appears to the immediate right of the existing plate image on the screen. A dark blue line separates the adjacent columns of the two plates. You can use the scroll bar to see additional plates. See Figure 31.

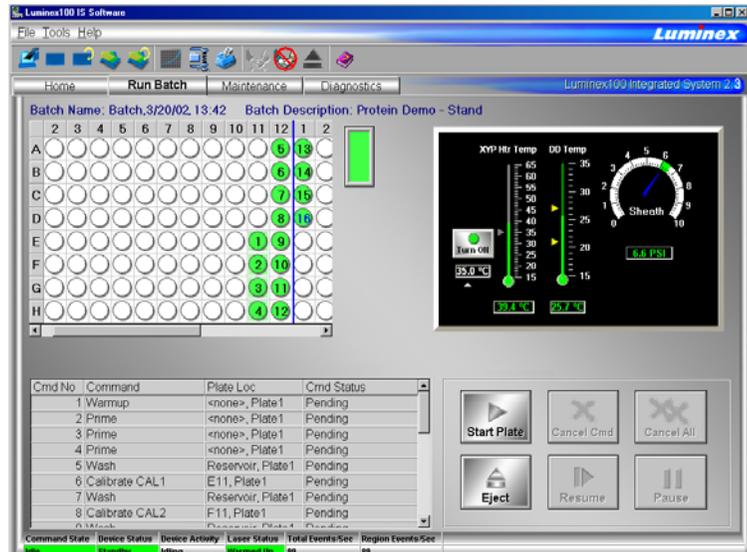


Figure 31 Processing Multiple Plates

After the first microtiter plate in a multiple plate batch has been acquired, the system pauses and prompts you to insert the next plate.

◆ To process multiple plates during a batch or multi-batch:

1. Create the batch or multi-batch. See “Create a New Batch” on page 49 or “Create a Multi-Batch” on page 54.
2. Insert the first plate.
3. On the **Run Batch** tab, click **Start Plate** to begin processing the batch. When the initial plate is through, the system pauses and displays the Insert Next Plate message in red underneath the sheath pressure gauge.
4. Click **Eject**, then remove the acquired plate and load the next plate for processing.
5. Click **Resume**. The system resumes the acquisition process.

Re-Run or Recover Incomplete Batch

An incomplete batch can be caused by situations such as a power failure, software failure, marking a batch for deletion, or clicking Cancel All. Use this procedure to re-run or recover an incomplete batch.

◆ To open an incomplete batch:

1. On the **File Menu**, click **Open Incomplete Batch**. The **Open Run** dialog box opens. Select the batch you wish to recover from the list.

2. Click **Start** to continue where the batch left off. Note that a comment is added to the batch to indicate that the batch is being rerun.

Scan in Samples With a Barcode Reader

The barcode reader lets you quickly enter sample identification numbers or accession numbers. Use the Code 128 barcode label type when scanning barcode labels into the system as patient identities.

Warning: Laser light. Do not stare into the beam. Class II laser product.

- ◆ To scan samples into the system using the barcode reader:
 1. Aim the barcode reader's beam to read the middle of the barcode series, horizontally. The beam must encompass the entire set of bars. See the shaded area in Figure 32.



Figure 32 Barcode Reader Beam Aimed Across Code

2. Squeeze the barcode reader's trigger. The beam activates and reads the barcode. The barcode information appears in the appropriate row.
3. Visually verify that the barcode data scanned correctly. It is critical that you scan (or enter) the correct identification number.

Add a Patient List

You can apply a Patient List to any batch or multi-batch **only** during batch setup in the **Luminex Batch Setup** dialog box.

You can create a Patient List text file using Windows Notepad or a text editor. The text file must meet the following requirements:

- The first line of text in the file must be "LX100IS Patient List".
- The second line of text in the file must be "[Accession#, Dilution Factor]".
- Any following lines of text should be only in the format, "x, y".
Where x = accession ID number for the patient (patient identifier string) and y = dilution factor.
- The dilution factor is **optional**, but if entered, must be a numeric value.
- If the dilution factor is omitted, the system defaults to one.
- Patient list entries are case sensitive. This applies to entries made through the graphical user interface or in a file.

The format must be like the following example or it will not load properly. Double-check all Sample IDs before you save the newly created batch.

An example of a typical patient list file:

```
LX100IS Patient List
[Accession#, Dilution Factor]
a001,1
a002,2
a003,1
b001,4
b002,0.6
c917,4
cee4gf,1
```

- ◆ To add a Patient List file while creating a batch or multi-batch:
 1. On the toolbar, click **Create New Batch** or **Create New Multi-Batch**. The **Open Template** dialog box opens.
 2. Select a template to create a new batch and click **Select**. The **Luminex Batch Setup** dialog box opens showing the template commands and the microtiter plate representation. For multi-batches the **Luminex Multi-Batch Setup** dialog box opens.
 3. Click **Load Patient List**. The **Open Patient List File** dialog box opens.
 4. Double-click on a patient list text file to append to the batch. The patients from that list append to the first unassigned available well. If all patient IDs in the batch or multi-batch are identified, the system appends the patient list to the first empty location after the batch's or multi-batch's last command list activity. If any of the acquire sample commands within the template of the batch has an unassigned value, the system applies the first patient ID in the list to the unassigned sample acquisition command. The system appends any remaining patient IDs to the end of the command list in order as they appear in the patient list.
 5. Choose whether to save the batch or multi-batch for later use. Click **Save only** to save the batch or multi-batch. To run it after you finish creating it click **Save and Load**.
 6. Click **Finish**. The system saves the batch or multi-batch for later use or it loads it for immediate use according to the decision you made when creating it.

Edit a Patient List

Use this procedure to open a previously processed batch and correct the batch's sample names and dilution factors. You can delete a sample from a batch. If you change the patient information in a batch including those imported from a patient list, the system automatically notes the change in the comments box of the sample table within the database.

While editing the database, the system marks the changes you make in red text. This distinguishes the change from the patient information entered into the original batch. Patient list entries are case-sensitive. Figure 33 shows an edited patient list.

◆ To edit a patient list:

1. On the **File** menu, select **Edit Patient List**. The **Open Batch** dialog box opens.
2. Select the desired batch containing the patient list that you want to edit and click **Select**. The **Edit Patient List** dialog box opens similar to Figure 33.
3. Edit the desired patient and associated dilution factor information. Click **Finish** to accept your edits and close the dialog box.

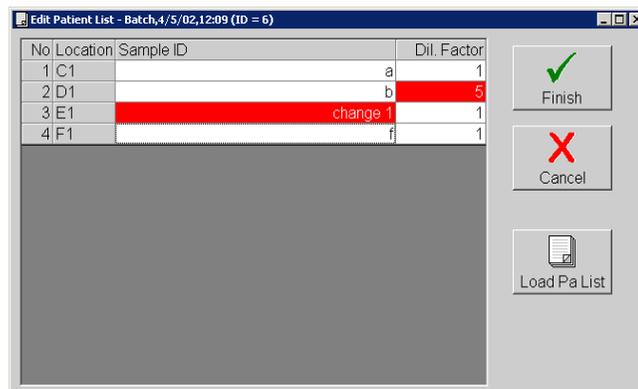


Figure 33 Edit Patient List Dialog Box

Assign Sample Dilution Factors

Indicate the sample dilution factor so the sample analysis in quantitative tests is accurate. The system multiplies the result by the dilution factor for reporting.

Do not use dilution factors for qualitative testing.

You define the dilution factors on a sample-by-sample, or patient-by-patient basis. The list displays each sample's accession number and dilution factor in relation to its well position.

- ◆ To assign sample dilution factors:
 1. On the **File** menu, click **New Batch**. The **Open Template** dialog box opens.
 2. Select the desired template and click **Select**. The **Luminex Batch Setup** dialog box opens. See Figure 34.
 3. Select the item that uses the dilution factor that you are setting. You cannot change any item that is grayed out or locked into the command list.

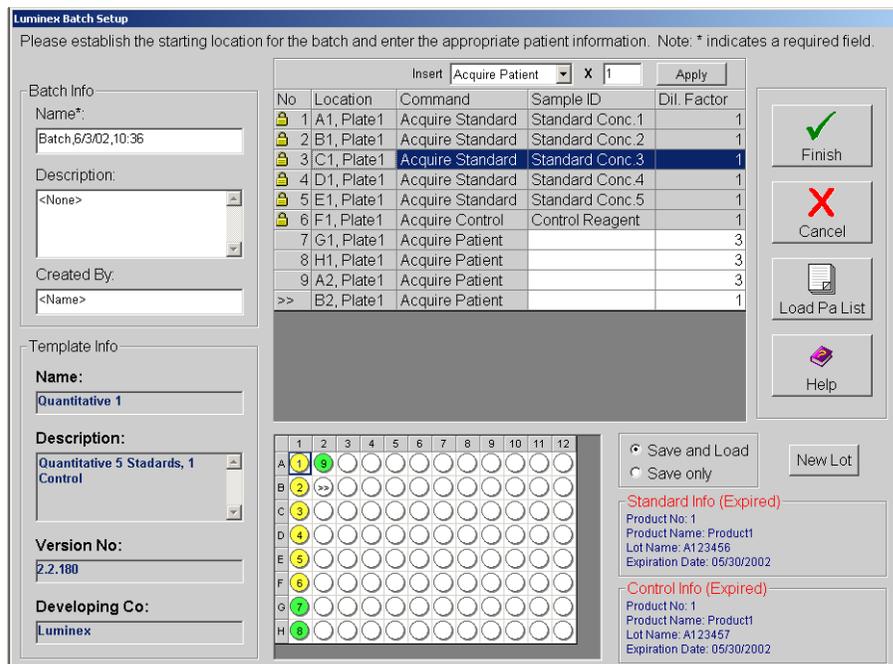


Figure 34 Luminex Batch Setup for Dilution

4. To change the dilution factor, click the **Dil. Factor** field. The white background indicates that you can enter text. Enter each dilution factor as a decimal, not as a ratio.
5. Click **Finish**. The system saves the information you entered.

Create a New Advanced Batch

Use New Advanced Batch to acquire data without creating a template. It writes raw data results to a simple csv file format. You can define parameters for samples, gates, regions, events, on-plate and off-plate commands. This feature does not store the results in the Luminex System database or allow you to perform data analysis on acquired batches. The Luminex analyzer uses only the 100 region bead map. However, in the Acquisition Detail tab, you can view the data for 25, 50, 64, and 100 regions and save the data to a csv file.

Use plates with wells that will hold at least 185 μL (the extra 25 μL from the sample, plus an extra 160 μL that is dispensed back into the well following acquisition).

◆ To create a New Advanced Batch:

1. Open the **Acq. Detail tab**.
2. On the Acquisition Detail toolbar, click **New Advanced Batch**. The **Options Dialog Box** opens with the **General** tab displayed. See Figure 35.

The screenshot shows the 'Options' dialog box with the 'General' tab active. It contains several input fields and controls:

- Name:** An empty text box.
- Description:** An empty text box.
- Operator:** An empty text box.
- Sample size:** A text box containing '50' followed by a unit selector showing 'μL'.
- DD Gate:** A range selector with two text boxes containing '7500' and '15000', separated by 'to'.
- Timeout:** A text box containing '25' followed by a unit selector showing 'sec'.
- Regions:** A dropdown menu currently showing '100 regions'.
- Bead Events:** Two radio buttons, 'Per Bead' (which is selected) and 'Total Beads'. Next to 'Total Beads' is a text box containing '1000'.
- Buttons:** 'OK' and 'Cancel' buttons at the bottom right.

Figure 35 Options Dialog Box—General Tab

3. Enter the **Name**, **Description**, and **Operator** information.
4. Edit the following information as desired:
 - **Sample Size** - use values from 20 to 200 μL . To avoid air uptake, we recommend that your sample well contains at least 25 μL in addition to the sample size.
 - **DD Gate** - use values within the range of 0 to 32767.
 - **Timeout** - use values of 0 to 400, where 0 = no timeout.
5. Click the arrow down next to **100 regions** to select the desired bead map you want to view. The available bead maps are 25, 50, 64, and 100 (default) regions. Select whether you want the Bead Events results to be displayed as **Per Bead** or **Total Beads**. If you select Total Beads, enter the number of total beads in the text box.
 - Select **Per Bead** to continue analyzing until each bead set has met at least the minimum events as determined on the Bead Set tab.

- Select **Total Beads** to continue analyzing until the selected beads meet total beads value. Use Total Beads when you are not using all of your selected bead sets in each well. Set the total to desired high value.
6. Click the **Bead Set** tab. Select the checkboxes next to each desired bead set for this batch. Click **Select All** to select all the listed bead sets, or **Deselect All** to deselect all selected bead sets.

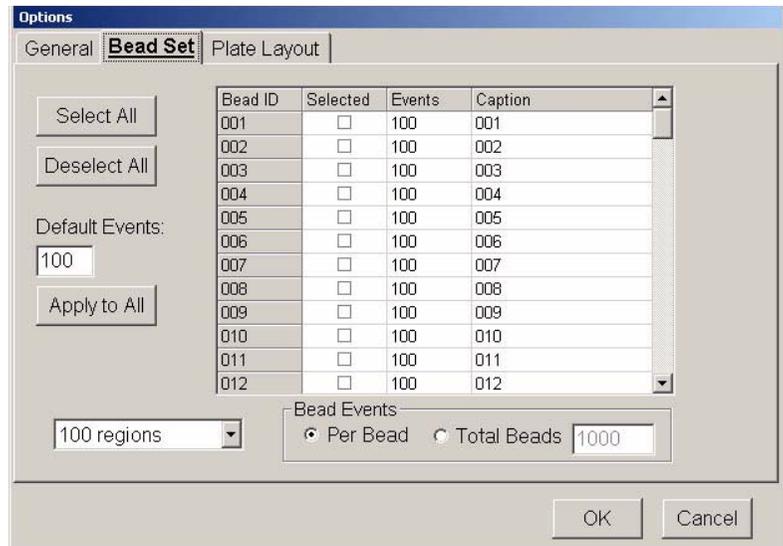


Figure 36 Options Dialog Box—Bead Set Tab

7. Edit the **Events** and **Caption** information for each bead set. Edit the **Default Events** box to change the default value. Click **Apply to All** to apply the default value to all bead sets. Table 8 lists selection shortcuts.

Table 8. Bead Set Tab - Selection Shortcuts

Selected Column	Select by clicking in the box.
Events Column	Select desired field and right-click. The value displayed in the “Default Events” box updates the selected field when you click “Apply Default”.
Caption Column	If names are defined under this column, you can right-click selected rows and “Reset” back to normal defaults.
Entire Column	Select an entire column by clicking the column heading (Selected, Events, or Caption).

Note: The legend at the left side of the tab (No, Cmd Name, and Symbol columns) shows available commands and their colored-coded symbols. Symbol appears in the well when selected from the Command Menu.

Table 9. Symbol Color Codes

Symbol	Color
A	Blue
C1	Red
C2	Green
N1	Teal
N2	Purple
W	Olive
D	Black
S	Fuchsia

- Click the **Plate Layout** tab. See Figure 37. On this tab you define commands for the desired wells on the plate. You can define commands that apply to one or more wells, one or more rows of wells, or one or more columns of wells. You can define on-plate or off-plate commands.

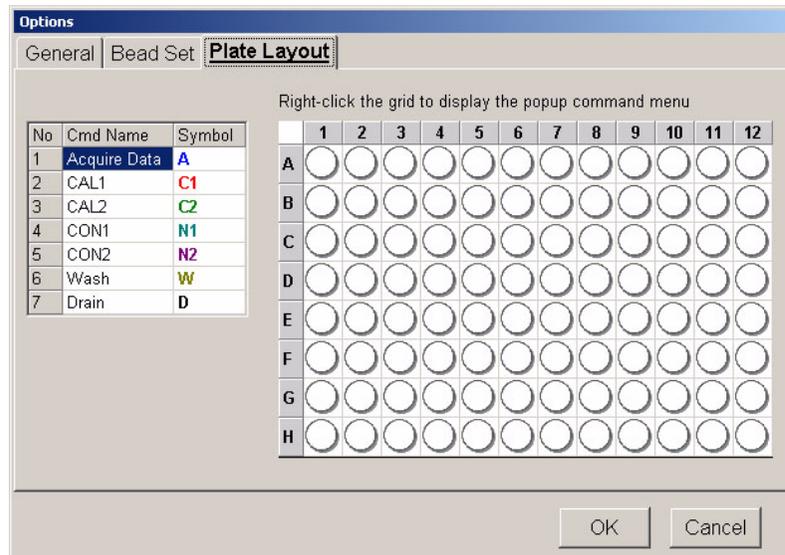


Figure 37 Plate Layout Tab

Note: Wells are always read in rows (letters A to H) and columns (numbers 1 to 12) starting with A1. If partial columns are selected they are still read in the same order. Unselected wells are skipped.

- Select wells. To select a single well, click the well. To select multiple wells in a group, click and hold the mouse button with the cursor over the first well, then drag the cursor around the desired wells. To select a row or column click the letter or number of the row or column.
- Select plate commands. Right-click over the selected wells to display the Command menu. See Figure 38. Select the desired command. The associated command symbol appears in the designated plate well. To make a correction, select the wells (selected wells are outlined in blue), right-click over the selected wells to display the Command menu, and then click **Clear Selection** from the list. Table 10 (following) lists Plate Layout selection shortcuts.



Figure 38 Plate Layout Tab Command Menu

11. Establish preliminary off-plate commands. The system performs preliminary off-plate commands before the first well command. To establish a preliminary off-plate command, right-click anywhere over the plate layout and select **Preliminary Off-Plate Cmd(s)** from the menu. The command list dialog box appears similar to Figure 40.

Click the **OK** button next to the Command List after you select the desired commands. The white corner marker in the top left corner of the plate (above the letter A) turns green to indicate an off-plate command is established. The selected commands run before the plate begins.



Figure 39 Preliminary Off-Plate Command (Corner) Marker

To clear preliminary off-plate commands, right-click on the corner marker or plate layout and select **Clear Off-Plate Cmd(s)**. See Figure 39.

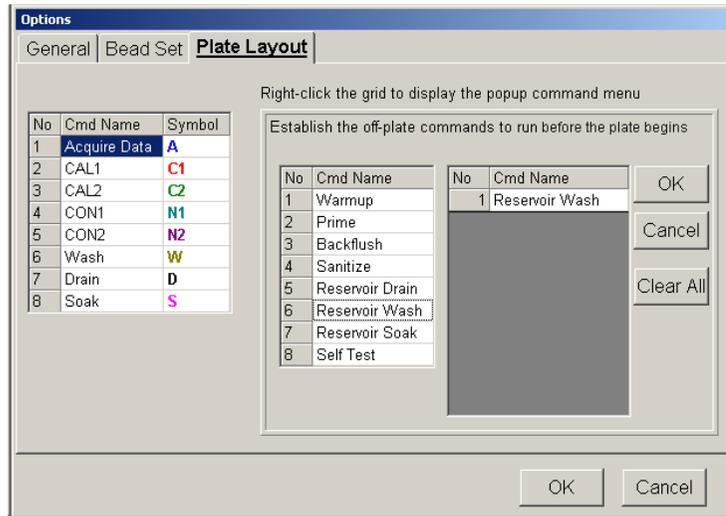


Figure 40 Plate Layout Tab, Off-Plate Commands

12. Insert off-plate commands. You can insert off-plate commands that run after a single well, after a range of wells, or after rows or columns of wells. The prompt sentence displayed should be appropriate for your selection. For example, if you select row B, the prompt “Establish the off-plate commands to run after wells B1 through B12” appears.

To establish insert off-plate commands, select the desired wells, then right-click over the plate layout. Select **Insert Off-Plate Cmd(s)** from the menu. Select the desired commands and click **OK**. The background of the established wells turn green.

To clear insert off-plate commands, select the wells to clear, right-click on the plate layout and select **Clear Selection** from the menu.

13. After you define the information on the **General**, **Bead Set**, and **Plate Layout** tabs, click **OK**. Click **Cancel** to abort.

Table 10. Plate Layout Tab - Selection Shortcuts

Click column heading to select entire column.
Click row heading to select entire row.
Click the top left corner of the plate to select entire plate.

Each well can have a series of off-plate commands that run before the next well is read. You can insert preliminary off-plate commands that run before the first well.

Managing Assay Lots

You can edit standard and control lot information. Once a lot is used, changing or modifying it will prompt you for a new lot name. This includes batches that have been set up, but not yet acquired.

You can modify known lot concentration values. If you change the known concentration for a used lot, the system prompts you to enter a new lot name. If you change the concentration values in an unused lot, the system updates the lot with the new concentration values.

For assay reagents specified in templates, you can create new lots, edit lot information, select pre-existing lots for reuse, import lots, and export lots.

When editing lot numbers, follow these lot handling rules:

- If you have entered lot information for a template, but you have not used the template to set up a batch, you can edit the lot value.
- If you have entered lot information and have used the template to set up a batch (even if it has not been acquired), you must rename the lot.

Create a New Lot

◆ To create a new lot:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 41.

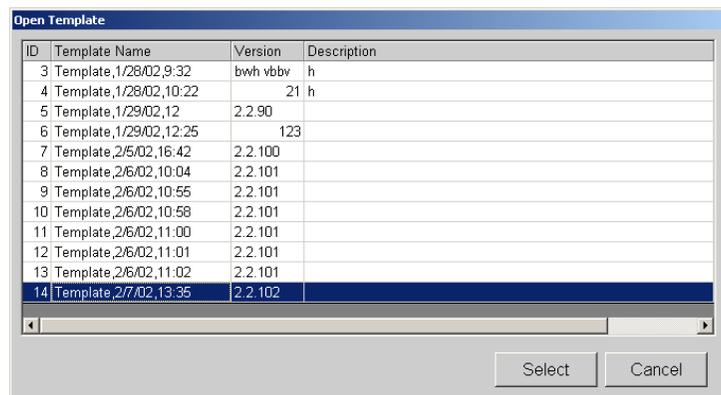


Figure 41 Open Template Dialog Box

2. Highlight the template that will use the new lot information and click **Select**. Then, continue with substep “a” or “b”.
 - a.) If this is a new template with no associated lot information, a **New Standard Lot** or **New Control Lot** dialog box opens as appropriate. Enter the standard and control numbers to continue. Once you enter the numbers, the **Update Lot Information** dialog box opens. See Figure 42 and Figure 43.

b.) If the template has associated lot information, the **Update Lot Information** dialog box opens. To create a new lot when there is an existing lot, click **New Lot** on the Standard or Control section of the dialog box. A **New Standard Lot** or **New Control Lot** dialog box opens. Enter the standard or control lot number. See Figure 42 and Figure 43.

3. Click **OK**.

Note: Depending on the types of products associated with the template that you select, the screen may vary from the example in Figure 43. That is, if you are creating only standard lots, then only the upper part of the screen displays.

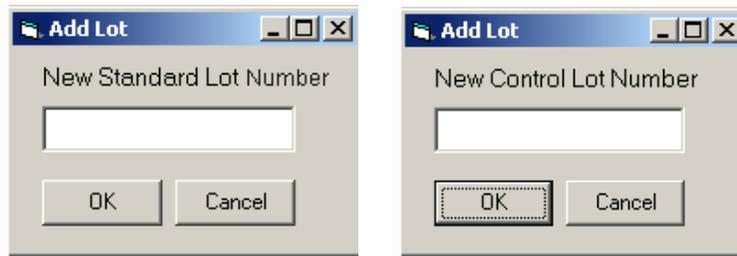


Figure 42 Add Lot Standard and Control Dialog Boxes

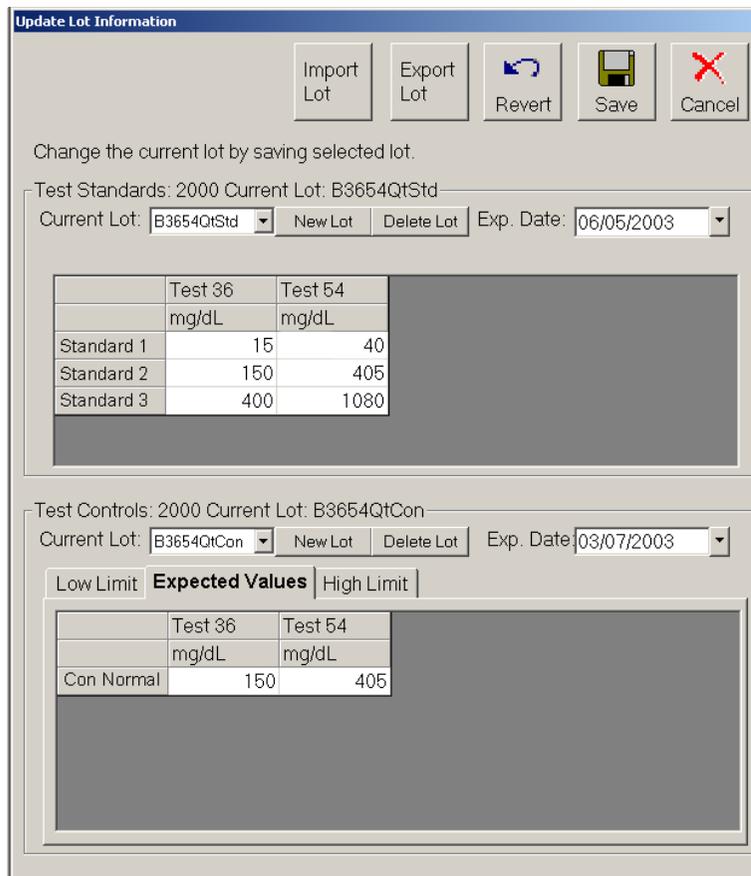


Figure 43 Update Lot Information Dialog Box

4. Enter the expiration date in the **Exp. Date** field.

5. Enter the standard concentration values provided in the kit manufacturer’s instructions. See Figure 43.
6. Enter the control reagent values. The controls are divided into 3 separate tabs: Low Limit, Expected Value, or High Limit. All information must be defined to enable the **Save** button.
7. Click **Save**. The system applies the lot you just created to the template.

Edit Lot Information on an Unused Template

- ◆ To edit information for an existing lot:
 1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens.
 2. Highlight the template that you want to edit and click **Select**. The **Update Lot Information** dialog box opens. See Figure 44.

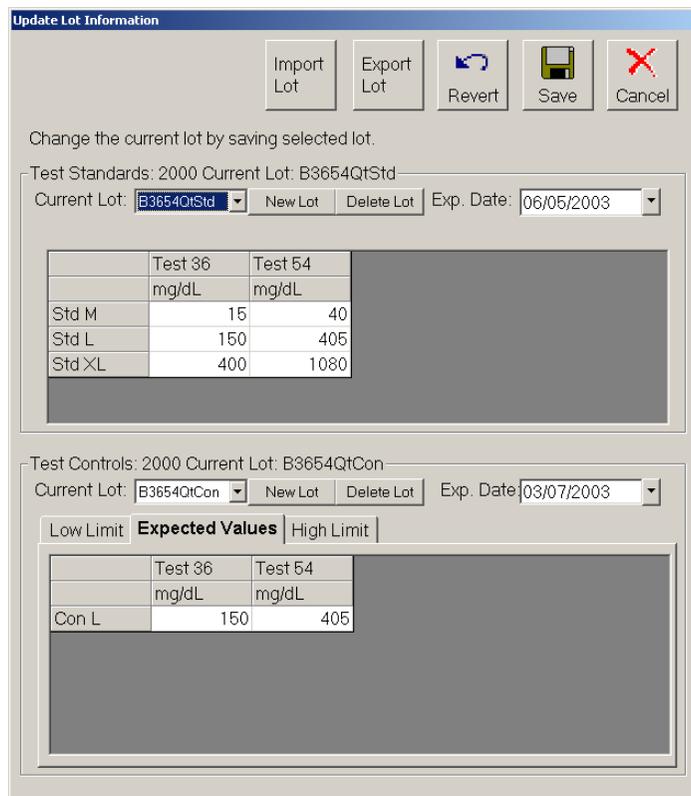


Figure 44 Update Lot Information Dialog Box

3. Change or edit the expiration date and the lot concentration values.
4. Click **Save**. The system updates the lot changes and applies them to the template.

Edit Lot Information on a Used Template

- ◆ To edit lots on a used template (may have new lot number of reagents, but are using same template):
 1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens.
 2. Double-click the template that you want to edit. An **Update Lot Information** dialog box opens. See Figure 44.
 3. Change or edit the lot concentration values.
 4. Click **Save**. A dialog box opens alerting you that this lot has been used to set up a batch and that you must create a new lot to continue.
 5. Respond to the Create New Standard Lot or Create New Control Lot with **Yes**. Rename it in the **New Lot Number** dialog box.

Import Lot to an Existing Template

Use this procedure to import a lot to an existing template from another computer, from a diskette, or from a CD ROM.

- ◆ To import a lot to an existing template:
 1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens.
 2. Select the template to receive the imported lot and click **Select**. The **Update Lot Information** dialog box opens. See Figure 45.
 3. Click **Import Lot**. The **Open** dialog box opens.
 4. Navigate to the desired drive's folder and select the lot that you want to import and click **Open**. The lot imports into your template.

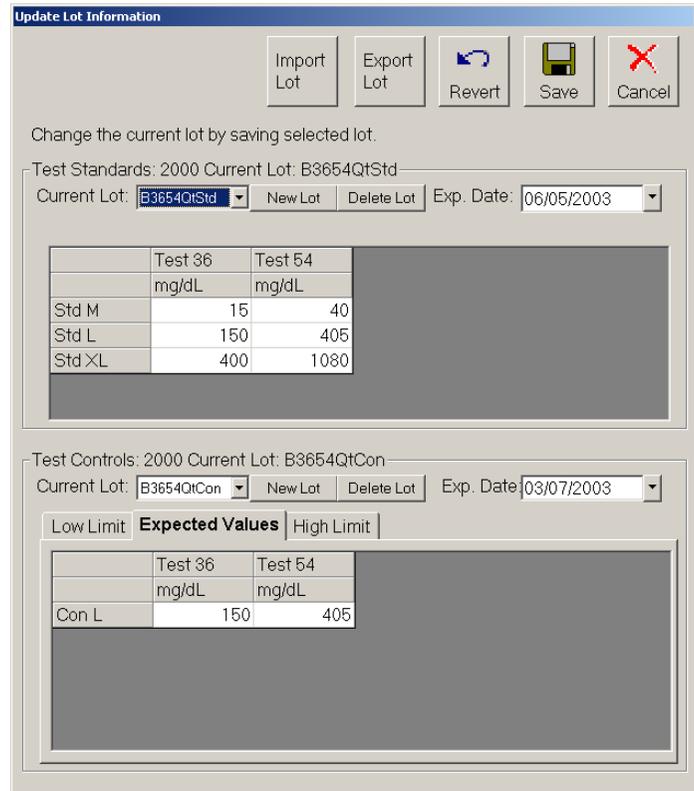


Figure 45 Update Lot Information Dialog Box

Export a Lot from an Existing Template

Use this procedure to export a lot for use on another instrument. Depending on the template and its associated products, you may have standards, controls, or both. Standards and controls can be grouped into the same lot number.

◆ To export a lot from an existing template:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens.
2. Double-click the template containing the lot to export. The **Update Lot Information** dialog box opens. See Figure 45.
3. Click **Export Lot**. A standard or control confirmation dialog box opens verifying that you want to export the current lot for the standard or control.

If you want to export the lot information for the standards, click **Yes**. If you only want to export the lot controls, click **No**. A second dialog box opens to verify if you want to export the current control lot, or current lot for a control.

After responding to the confirmation dialog boxes, regarding standards or controls, a **Save As** dialog box opens.

4. Click the drop-down arrow to select the **Save in:** location where you want to save the lot information.
5. Enter the lot file name into the **File Name:** box.
6. Click **Save**. The system saves the lot.

Analyzing Batches and Multi-Batches

You can analyze an acquired batch using the analysis features of Qualitative and Quantitative algorithms. The algorithm is determined by the kit manufacturer during template creation.

A Qualitative analysis determines results as either positive or negative, reactive or non-reactive, and so on. The system is flexible in defining custom result ranges, such as negative, low positive, high positive, and so on. Refer to the Luminex Developer Workbench Guide Version 2.3 for additional information. All determinations are based on a single standard.

A Quantitative analysis determines the sample concentrations from standard curves using regression methods, such as 4P or 5P logistic curve fitting.

There are two main assay types: non-competitive (such as a “capture sandwich”) and competitive. In a non-competitive assay, the slope of a concentration versus Mean Fluorescent Intensity (MFI) standard curve is a positive number. That is, low concentrations result in low MFIs and high concentrations result in high MFIs. Conversely, competitive assays generate a standard curve with a negative slope, the endpoints of which are high MFI/low concentration on the left, and low MFI/high concentrations on the right.

You may direct the system to acquire samples in replicate regardless of batch type. For qualitative batches, replicate values are averaged and the reported interpretation is determined from this replicate average.

Replicates in quantitative batches are based on a standard curve that is generated by either the “Fit of all standards” or “Mean of replicates”. The chosen curve fit is defined by the assay developer when defining an assay template. The default is “Fit of all standards”. Unknown samples are calculated from the standard curve. Replicate samples are averaged to determine the reported quantitative result denoted as “AVG”.

Note: Luminex does not recommend performing Data Analysis while the Luminex System is performing data acquisition on another batch.

Customize Data Analysis Settings

The system can analyze only batches that it acquires using qualitative or quantitative templates. It does not analyze acquisitions using Data Collection Only or Maintenance templates.

For an overview of the Analysis window, see page 21.

You can customize how the sample data results are displayed in the analysis graph on the Standards tab. There are two options that allow you to customize the display. Use the **Customization** dialog box and the **Graph Menu** (right-click menu); some items are available on both. You can define the general features of the graph, axis settings and increments, fonts, colors, and styles presented in the graph representing the sample data results. You also can export the analysis to a graphic, file, clipboard, and so on.

◆ To modify the general features of the **Standards** tab graph:

1. Click **Data Analysis**.
2. Double-click the desired batch. The **Analysis** window opens displaying the **Standards** tab.
3. Double-click anywhere within the graph to display the **Customization** dialog box. See Figure 46. Notice across the dialog box are five tabs: General, Axis, Font, Color, and Style. Also notice that there are six buttons along the bottom of the dialog box. They are the OK, Cancel, Apply, Original, Export, and Maximize buttons.

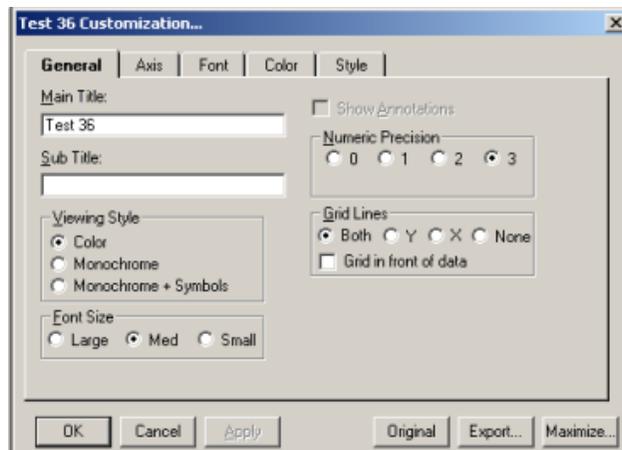


Figure 46 Customization Dialog Box—General Tab

Customization Dialog Box Buttons:

OK: click to update the graph's parameters with the new information and exit the Customization dialog box.

Cancel: click to abort selections and exit.

Apply: Apply is similar to the OK button, but does not close the Customization dialog box. It updates graph parameter with new information.

Original: click this button to restore the edited information to the previous or original values.

Export: click this button to export data from a Metafile or BMP graphic to a .csv output file in the batch folder file, or to the clipboard. You can also export to a printer and specify the object size. Select the desired features and click Export. See Figure 47.

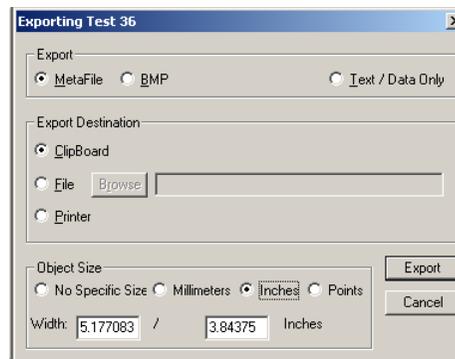


Figure 47 Exporting Dialog Box

Maximize: Click to maximize the graph to full screen. Restore to original size by pressing **Escape** on the keyboard or by clicking in the title bar.

Customization dialog box tabs:

- **General Tab**—Use this tab to define general parameters. See Figure 46.

Main and Sub Titles: These edit-boxes allow you to add, edit, or delete these titles. If no title is present, you can enter one. Delete all characters from a title to remove it.

Viewing Style: The Graph supports three viewing styles:
 Color
 Monochrome
 Monochrome with Symbols

This customization allows you to quickly adjust the image to best suit printing on a monochrome printer. If you include fewer than four subsets in a graph, then the Monochrome setting will probably be the best choice. If four or more subsets are included in the graph, then Monochrome with Symbols will help distinguish the different subsets.

Font Size: The Graph supports three font sizes, Large, Medium, and Small. When printing the graph, a font size of Medium or Small is suggested. On occasion the graph may automatically reduce the size of the font to produce a higher quality image.

Show Annotations: Currently, this feature is not used. This check box allows you to remove or add the annotations from the image.

Numeric Precision: When exporting text and data from the Export Dialog, you can define the number of decimal positions at 0, 1, 2, or 3.

Grid Lines: The Graph can contain vertical grid lines, horizontal grid lines, both vertical and horizontal grid lines, or no grid lines. Select the appropriate radio button.

Grid in front of data: Check this option to place the grid in front of the data graphics. Otherwise, the data graphics are drawn on top of the grid.

- **Axis Tab**—Use the Axis tab to change your X axis and Y axis values and specify whether to display them as linear or log. If you select Log, use “Auto” or ensure that the “Min” value is greater than zero. See Figure 48.

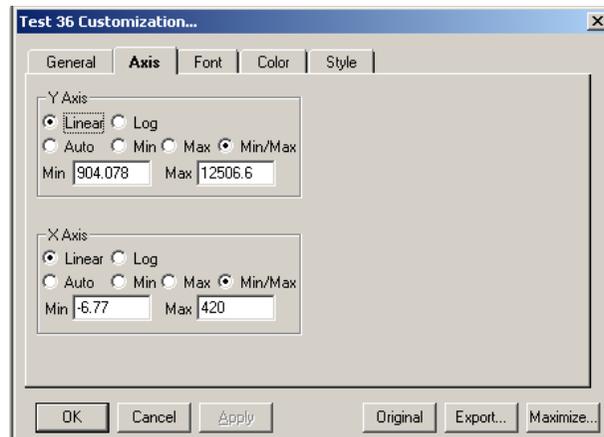


Figure 48 Customization Dialog Box—Axis Tab

- **Font Tab**—Use the Font tab to change the appearance of the fonts that appear in the Main Title, Sub Title, and Subset/ Point/ Axis Label boxes. The bottom of the dialog box displays a sample of the font as you select it. See Figure 49.

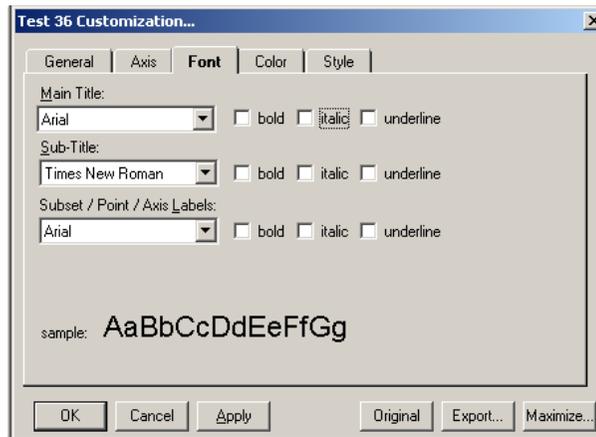


Figure 49 Customization Dialog Box—Font Tab

- **Color Tab**—Use the Color tab to define the various color parameters on the analysis graph. See Figure 50.

Desk Foreground: this is the color that is used when placing text onto the Desk Background. It includes the main title, sub title, subset/point labels, grid numbers.

Desk Background: this is the color that surrounds the bounding rectangle of the graph's grid. That is, the color of the border that appears behind the text labeling.

Shadow Color: the rectangles that make up the graph's grid and table are bounded at the bottom/right edges with shadows. To remove the shadows, choose the same color as the Desk Background.

Graph Foreground: this is the color used for the bounding rectangles of the grid, the grid-lines of the graph, and lines that are used to bound some of the plotting methods (like the bounding line around bars of the Bar Plotting Method).

Graph Background: this is the color that is used as the background color of the graph's grid.

Table Background: This is the color used in filling the table's rectangle. Currently, this feature is not used.

Table Foreground: This is the color used in bounding the table's rectangle, and for the text inside the table. Currently, this feature is not used.

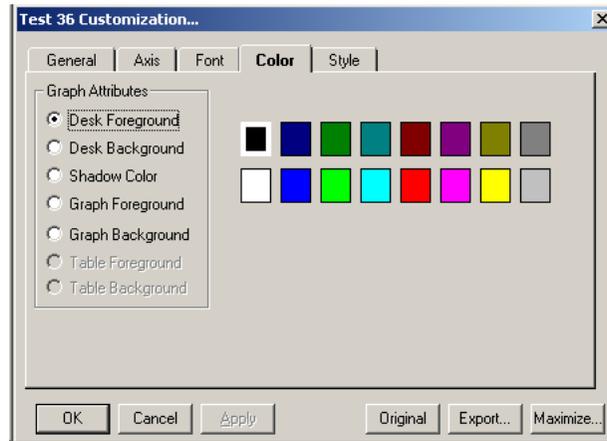


Figure 50 Customization Dialog Box—Color Tab

- **Style Tab**—use the Style tab for control of subset color, subset line type, and subset point type. Subset 1 = line type, and Subset 2 = data point. See Figure 51.

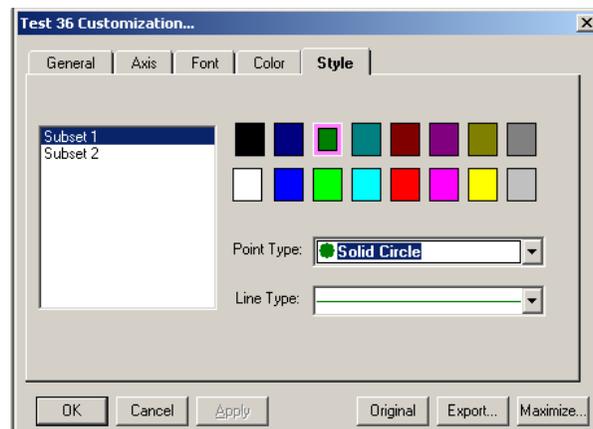


Figure 51 Customization Dialog Box—Style Tab

- ◆ To modify features using the Graph Menu:

Most of these menu items provide a shortcut for many of the features provided in the Customization dialog box. Refer to page 73 for details.

1. Right-click anywhere in the graph on the **Standards** tab. The **graph** menu opens. See Figure 52.
2. Select the desired menu item from the list and it is immediately applied.

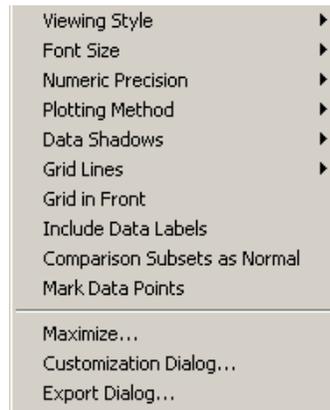


Figure 52 Graph Menu Items

Enable Automatic Analysis

You can configure the system to automatically start analysis (data reduction) immediately following batch acquisition. If you disable the Auto-start Analysis feature, you must select **Analysis** from the **Home** tab or toolbar to analyze a batch. Note that the Auto-start Analysis feature is disabled when processing a multi-batch.

To ensure that calculated data is exported to the output.csv file, you should not select both Auto-Start Analysis and the Auto Export Batches checkbox on the Data Export tab of the Options dialog box. Also note that Analysis and data reduction are synonymous terms.

◆ To enable automatic analysis:

1. On the **Tools** menu, click **Options**, then click on the **General** tab. See Figure 53.

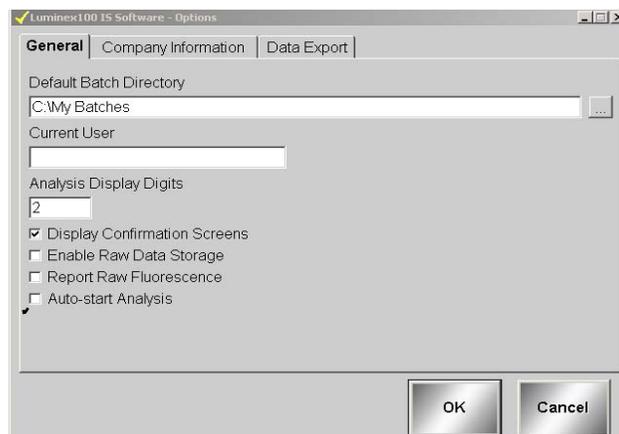


Figure 53 Options Dialog Box—Select Auto-start Analysis

2. Click the **Auto-Start Analysis** checkbox, then click **OK**. When the system completes the batch acquisition, it will automatically begin analyzing data.

Analyze Processed Batch Data

You can analyze only processed batches. If you acquire or process batches as a multi-batch, the system lists them separately and they must be analyzed separately.

All batches within a multi-batch have the multi-batch name listed under the multi-batch ID name column. This allows you to see the batches that have been processed as a multi-batch.

◆ To analyze data from processed batches and multi-batches:

1. On the **Home** tab, click **Analysis**. The **Open Batch** dialog box opens showing only processed batches.
2. Select a batch to analyze and click **Select**. The system loads the batch and the Analysis window displays the **Standards** tab.

View Detailed Test Analysis

◆ To view detailed test analysis:

1. On the **Home** tab, click **Analysis**. The **Open Batch** dialog box opens.
2. Click on the desired batch to analyze and click **Select**. The Analysis window opens showing the progress as the system opens the batch and analyzes the data. Each test displays “Analyzing” as the system calculates.
3. On the **Standards** tab, select the test or analyte you want to view. The system displays this analyte in detail. Switch between tabs to observe the tests errors under the Errors tab and unknown results under the Samples tab.

To view the next test in the batch click **Next Test (F2)**. To view the previous test, click **Previous Test (F3)**. You may also click on the test name in the left grid control.

Validating or Invalidating Standards and Controls

You can invalidate or validate a standard or control in either of two ways. In the **Analysis** window, use the associated buttons on the bottom of the window, or right-click in the row containing the standard or control you want to validate or invalidate.

Invalidating standards—You can invalidate or remove a standard if doing so improves the curve fit. Observe caution when doing so. Invalidating standards greatly affects the curve fit and subsequently the sample results. For further instruction on assay standard curves and the appropriateness of invalidating or removing standards, contact the assay kit manufacturer.

Invalidating controls—You can invalidate or remove a control in data analysis. However, Luminex does not recommend invalidating controls. For further instruction on assay controls and guidelines regarding accepting or rejecting control values, contact the assay kit manufacturer.

◆ To validate or invalidate a standard or control entry using the right mouse-click procedure:

1. Right-click in the row containing the standard or control you want to validate or invalidate. See Figure 54. Select the desired menu item to apply. When invalidating, the **Name** box turns red with an asterisk preceding it. When validating, the Name box reverts to black text.

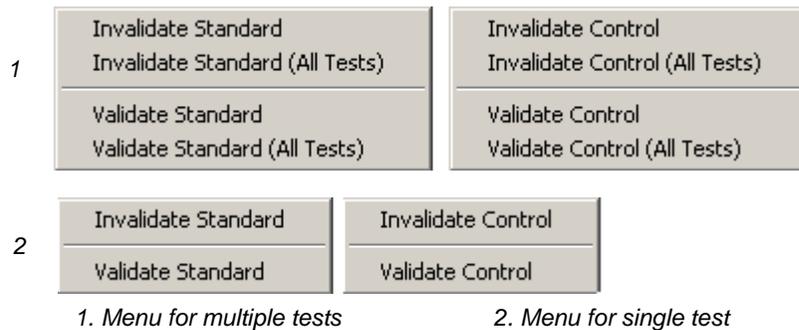


Figure 54 Invalidate and Validate Shortcut Menus

2. Click **Recalc** to recalculate the results if the **Auto** option was not selected.

◆ To validate or invalidate a standard or control entry using the Invalidate and Validate Buttons:

1. Select the desired standard or control name in the **Standards** or **Controls** grid.
2. Click the appropriate buttons at the bottom of the Analysis window: **Invalidate Standard (F4)**, **Validate Standard (F5)**, **Invalidate Control (F6)**, or **Validate Control (F7)**.
3. The appropriate **Standard** or **Control** dialog box opens. To invalidate or validate all tests click **Yes**. For only the single test click **No**. When invalidating, the **Name** box turns red with an asterisk preceding it. When validating, the Name box reverts to black text.
4. Click **Recalc** to recalculate the results if the **Auto** option was not selected.

Change Lot Use the Change Lot command to edit the lot that is applied to the batch currently opened in data analysis.

◆ To change the lot to another available lot:

1. Click **Change Lot (Alt + F8)**, located at the bottom of Analysis window, to display the **Choose Lot** dialog box. See Figure 55.
2. The dialog box displays a list of available standard and control lots that you can apply to a batch. Highlight the desired lot and click **OK** to apply the selected lot to the batch opened in data analysis. Figure 55 shows standard and control. Figure 56 shows standard only.

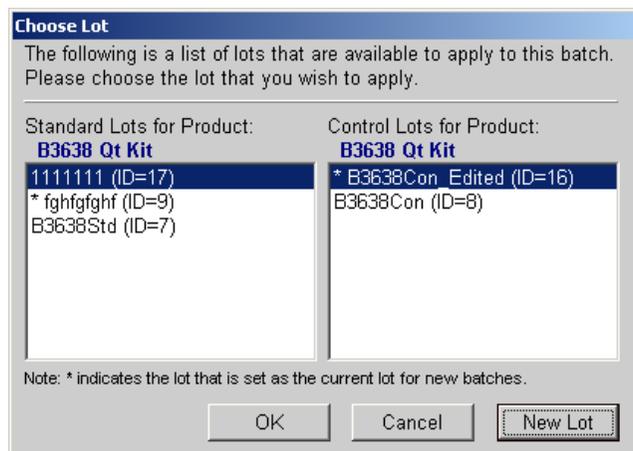


Figure 55 Choose Lot Dialog Box—Standard and Control



Figure 56 Choose Lot Dialog Box—Standard Only

3. To create a new lot from this dialog box as an alternate method, click **New Lot** and follow the steps in the **Create New Lot** procedure on “Create a New Lot” on page 67.

◆ To create a new lot for use within a batch:

1. Click **New Lot**.
2. In the **Update Lot Info** dialog box, select **Standard lot** or **Control lot**, then click **Save** to display the **Choose Lot** dialog box. An asterisk identifies the selected lot. See Figure 55.

Running Reports and Analyses

You can output data by printing reports and exporting batch data.

Report Types

The Luminex IS 2.3 software can format your batch or multibatch results in a variety of export formats and provide different types of information in different types of reports.

Analyte Report - prints some or all of the samples grouped by the test in a batch.

Clinical Patient Report - provides a breakdown of samples according to the test analysis with that sample.

Patient Summary Report - prints all of the test results for a patient; may include all tests or selected tests on the report.

Quality Control Report - used to track the trends of assay standards and assay controls over a period of time.

Maintenance Report - provides a history of all maintenance operations performed during the date range entered by the operator.

Batch Summary Report - prints batch information in a sample versus test grid format; useful for an assay developer to quickly reference a test result for a particular sample.

Calibration Trend Report - provides information about all instrument calibration operations that occurred during the date range entered by the operator.

System Control Trend Report - provides information about all verification operations that were performed during the date range entered by the operator.

Data Analysis Report - displays all the information available in the Data Analysis window. You access this report through the Analysis Window. For more information on printing this report, see page 85.

◆ To print a report from a batch or a specific time frame:

Install the printer before initiating the print command.

1. Click **Print Report**. The **Report Selection** dialog box opens.

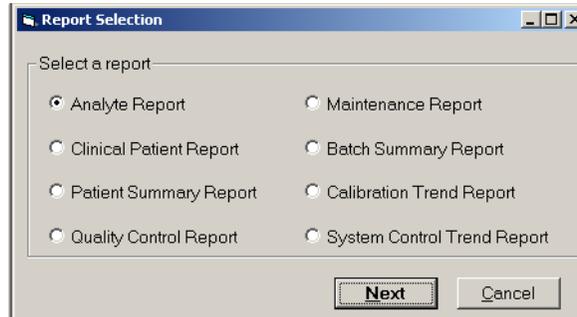


Figure 57 Report Selection Dialog Box

2. Select the type of report that you want to print and click **Next**. For the Analyte, Clinical Patient, and Batch Summary Reports, the **Batch Selection** dialog box opens. Select the batch to print. See Figure 58. For the Quality Control, Maintenance, Calibration Trend, and System Control Trend Reports, a dialog box related to the specific report opens. The system information may vary depending on the type of report you select.

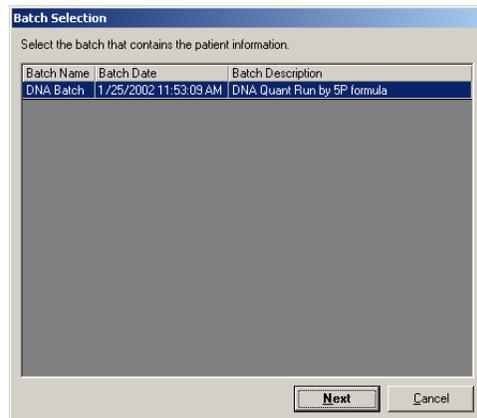


Figure 58 Batch Selection Dialog Box

3. Enter the information (in this example, a patient report) and click **Next**. Another information dialog box opens. Enter specific information for the type of report the system is compiling. Figure 59 shows a Patient Selection example.

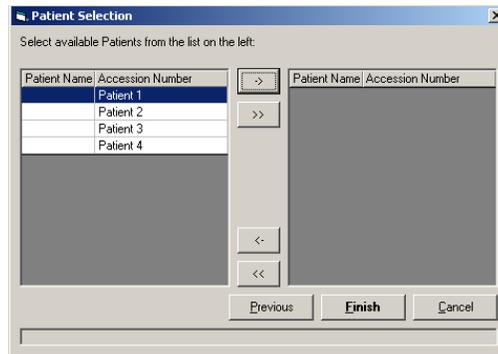


Figure 59 Patient Selection Dialog Box

4. Select the desired entry or click the double arrow (>>) to select all the entries.
5. Click **Finish**. A report print preview appears using the information you entered. You may have more than one dialog box in which to enter information.
6. Click **Print Report** to print the report.
7. The **Print** dialog box opens. Select the desired parameters and click **Print**.

Export Batch Data

◆ To export batch data:

1. On the **File** menu, , click **Export Batch Data**. The **Open Batch** dialog box opens. See Figure 60.

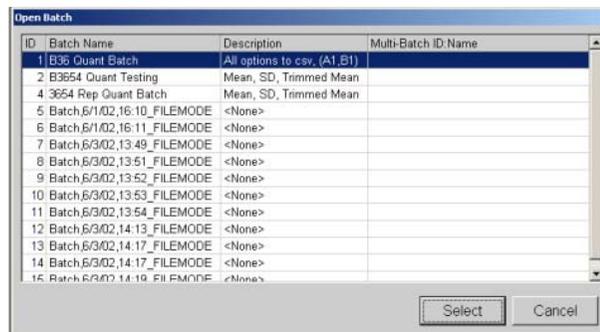


Figure 60 Open Batch Dialog Box—Select Batch

2. Select the desired batch to export.
3. Click **Select**. The system exports the information. The **Export Batch** dialog box opens showing the name and location of the exported data file. Click **OK**.

***Print Data
Analysis Report***

A printed batch report includes the following criteria that is applied to the batch during analysis:

- batch name and test name
- formula used
- curve fit
- standards
- controls
- samples
- graph (this is the only way to print a graph of standards)

◆ To print data analysis reports:

1. On the **Home** tab, click **Analysis**.
2. In the **Open Batch** dialog box, select the desired batch to analyze.
3. In the **Analysis** window, click **Print Report**. The Data Interpretation Report displays a print preview. See Figure 61.
4. Select any print options along the title bar and then click the print button (printer icon).
5. At the **Microsoft Windows Print** window, select your printer, options, and click **Print**.

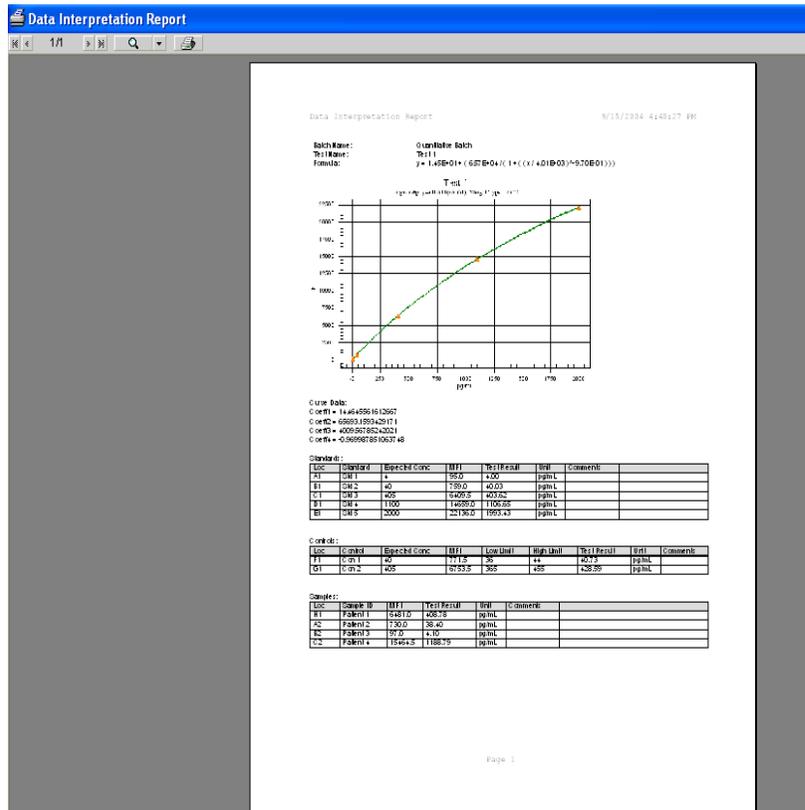


Figure 61 Data Interpretation Report (Print Preview)

Database Management Procedures

To manage the system database, back up and delete saved data and files. The system stores data results for instrument calibrators, instrument controls, assay calibrators, and assay controls. It records acquisition and maintenance data in real-time to minimize data loss in case of system failure. Each batch file records the date and time, command cancellation (if applicable), and voltages used for the commands performed during the batch.

Back Up the Database

Back up the system database following the schedule set by your laboratory. Your laboratory may require you to back the system up weekly, daily, or after you complete each batch.

If your laboratory has no schedule for database backups, the system does inform you when your database approaches its size limit. You should back up the database according to a periodic schedule.

◆ To back up the database:

1. On the **Tools** menu, click **Database Backup**. The **Backup Database To** dialog box opens.

2. Choose the file name and location of the database that you want to back up. The default name is LX100IS(month-date-year).
3. Click **Save**. The **LX100 IS Database Backup** dialog box opens informing you the backup is in progress to the specified location.

Delete Database Entries

You can erase sample information from the database at any time. You will see a warning when the database is 80% full (approximately 200 MB free of a two GB hard drive limit). This provides advanced warning to erase database information.

When the database is 98% full, sample acquisition is prevented. System calibration and control information is not affected when you erase sample information. The system also does not affect standard and control information while erasing data from the database.

◆ To erase information from the database:

1. On the **Tools** menu, click **Erase Database**. The **Choose Date** calendar opens.
2. Choose the day after the last day of the database entries that you want to erase. For example, all data prior to January 16 are erased. January 16 is kept.
3. Click **OK**. The **Delete Database Entries** dialog box opens and warns that you are about to delete database records.
4. If you are sure you want to delete this data, click **Yes**. The system deletes all events stored before the day you select.

Restore Database Data

Restore the database from a previously saved database.

◆ To restore information to the database:

1. On the **Tools** menu, click **Database Restore**. The **Restore Database** dialog box warns you that the Luminex IS 2.3 software will shut down after restoring the database.
2. Click **Yes** to continue to restore a database.
3. From the **Restore Database From** dialog box, select a database backup file to restore and click **Open**. The system restores the previously saved database. Notice that the files are organized by date (month-day-year).
4. A **Database Restored** dialog box opens the next time you start up the system. The dialog box prompts you to verify that the lot

information for CAL 1, CAL2, CON1, and CON2 reagents are correct.

5. Click **OK** to verify that the lot information is accurate.

Maintenance Procedures

Table 11 shows a recommended schedule for maintenance operations.

**Table 11. Maintenance Operations:
Recommended Use Schedule**

Operation	Recommended Use Schedule
Warmup	<ul style="list-style-type: none"> • Daily • After four hours of system inactivity
Prime	<ul style="list-style-type: none"> • Daily • To remove air from sheath fluid tubing • After performing these actions: <ul style="list-style-type: none"> – refilling the sheath container – removing and replacing sheath container – changing the sheath fluid filter – changing the syringe seal
Backflush	<ul style="list-style-type: none"> • Troubleshooting and preventative maintenance purposes only: <ul style="list-style-type: none"> – to remove obstructions from the cuvette – if fluid does not flow through the waste tubing during prime cycles or during sample acquisition – if fluid drips from the sample probe during priming and forms puddles of fluid on the plate
Alcohol Flush	<ul style="list-style-type: none"> • Daily • Before system calibration • After changing the sample probe • To remove air bubbles from the cuvette using 70% isopropanol or 70% ethanol
Sanitize	<ul style="list-style-type: none"> • To decontaminate sample lines and cuvette after biohazard contact using 10% to 20% household bleach <ul style="list-style-type: none"> – daily if working with biohazards – monthly if not working with biohazards
Wash	<ul style="list-style-type: none"> • As needed using distilled water • Four times after system calibration • Twice after sanitize

**Table 11. Maintenance Operations:
Recommended Use Schedule (Continued)**

Operation	Recommended Use Schedule
Drain	<ul style="list-style-type: none"> For troubleshooting and preventative maintenance purposes only: <ul style="list-style-type: none"> – drain the cuvette and refill in preparation for running. Draining the system removes debris from the bottom of the cuvette. – when draining, you do not supply solution. Draining takes approximately two minutes and should be followed by an alcohol flush using 70% isopropanol or 70% ethanol.
Soak	<ul style="list-style-type: none"> Daily, at the end of the day for shutdown To prevent salt crystals from forming in the probe due to exposure to air. Soaking the probe replaces sheath fluid in the probe with water. The system uses at least 250 μL of distilled water.
Self Diagnostics	<ul style="list-style-type: none"> To verify system operation.

Drain the Analyzer

When draining, you do not need to supply solution. Draining takes approximately two minutes and should be followed by an alcohol flush with 70% isopropanol or 70% ethanol.

Any fluid that drains from the system drains to the Luminex XYP reservoir as the default. However, you can set the system to drain to any unused well on the microtiter plate. The drain function normally expels 125 μ L of fluid. Ensure that the location you select to expel fluid has the reserve capacity to hold the volume expelled.

◆ To drain the system:

1. On the **Maintenance** tab, click **Eject/Retract**. Ensure that the reservoir is empty, or insert a plate onto the plate holder.
2. Make sure that the correct location is selected next to the Drain button. Click **Drain**. A confirmation dialog box opens.
3. Click **OK**. The Device Activity box on the Status Bar indicates that the system is draining.

Run Self-Diagnostics

◆ To run self diagnostics:

1. On the **Maintenance** tab, click **Self-Diag**.

2. Click **OK**. The system processes the various self- diagnostic tests. When tests are complete, the Status Bar changes from a “Processing” command state to an “Idle” command state. The self-diagnostic tests should take less than one minute to complete.

If the self diagnosis fails, you can obtain detailed information regarding the results of the self-diagnostic test. See the following “View Self-Diagnostic Details” section.

- ◆ To view details of the self-diagnostics test that passed or failed:
 1. Click on the **Diagnostics** tab and view the Message log. If a diagnostics test failed, an error message displays with a yellow background.
 2. Double-click the yellow row to see a detailed description. An **Errors** dialog box opens showing a list of passed and failed self-diagnostic tests. Click **OK** to close this dialog box.

Using the Cleanup Utility

Use the Cleanup Utility to:

- Perform a disk cleanup
- Delete the Message Log Directory
- Delete the Batch Directory

- ◆ To display the Cleanup Utility dialog box:

On the **Tools** menu, click **Cleanup**. The **Cleanup Utility** dialog box opens. See Figure 62.



Figure 62 Cleanup Utility Dialog Box

- ◆ To perform a disk cleanup:
 1. In the **Cleanup Utility** dialog box, click **Disk Cleanup**.
 2. In the **Select Drive** dialog box, select the desired drive and click **OK**. The **Disk Cleanup** dialog box opens showing it is calculating progress. This can take several minutes.
 3. When Windows finishes calculating the cleanup it displays the **Disk Cleanup for** dialog box. See Figure 63. Check or uncheck

the desired files to delete and click **OK**. Windows deletes the files and closes the dialog box.

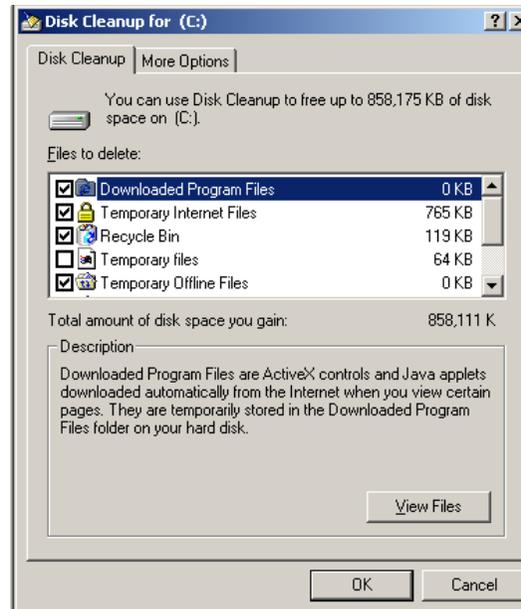


Figure 63 Disk Cleanup for (Selected Drive)

◆ To delete the Message Log directory:

1. In the **Cleanup Utility** dialog box, click **Delete MsgLog Directory**.
2. In the **Cleanup Utility** confirmation dialog box, click **Yes**.

◆ To delete the batch folders:

1. In the **Cleanup Utility** dialog box, click **Delete Batch Directory**.
2. In the **Cleanup Utility** confirmation box click **Yes** to delete all the batch folders. All the folders under C:\My Batches are deleted. The C:\My Batches folder remains.

Daily Shutdown Procedures

Sanitize the System

Sanitize the system with 10% to 20% household bleach to decontaminate the sample lines and the cuvette after biohazard contact. You should sanitize as part of your daily shutdown routine after biohazard contact. Sanitizing uses the Luminex XYP reservoir location because only the reservoir can accommodate the amount of fluid necessary to sanitize the instrument.

◆ To sanitize the fluidics in the analyzer:

1. On the Maintenance tab, click **Eject/Retract**.
2. Put the bleach solution in the reservoir.
3. Click **OK**. The plate holder retracts, and the system performs the Sanitize command.
4. Run two Wash commands.

Run a Wash Command

Use the wash command as part of shutdown procedure, and as needed, especially after calibration and after sanitizing. Place at least 200 mL in a microtiter well or fill the Luminex XYP reservoir with distilled water.

◆ To perform a Wash command:

1. On the Maintenance tab, click **Eject/Retract**.
2. Click **Wash**. A confirmation dialog box opens telling you to place solution in the reservoir.
3. Put distilled water in the reservoir.
4. Click **OK**. The plate holder retracts, and the system performs the Wash command.

Perform a Soak Command

Soak the sample probe to prevent the sheath fluid crystals from forming in the sample probe.

◆ To perform a soak command:

1. On the Maintenance tab, click **Eject/Retract**.
2. Select **Reservoir** from the dropdown menu next to the Soak button, then click **Soak**. A confirmation dialog box opens telling you to place solution in the reservoir.
3. Put distilled water in the reservoir.
4. Click **OK**. The plate holder retracts, and the system performs the Soak command.

Exit Luminex IS 2.3 Software

When you exit the system a confirmation dialog box prompts you to verify that you really want to exit the system.

◆ To exit the system:

On the **File** menu, click **Exit**, then click **Yes**.

Glossary

agglutination	The coalescing of small particles that are suspended in solution; these larger masses are then (usually) precipitated.
ambient temperature	The temperature of the surrounding environment.
analyte	A substance that is detected through assay analysis. Each test or bead set will test for a specific analyte.
analyzer	This term is used to refer to the Luminex 200 analyzer.
APD	Avalanche Photo Diode; Measures the excitation emission intensity of the color coding classification dye mixtures inside the microsphere and the amount of light scattered as particles pass by the lasers.
background (noise)	That portion of a bead set result that can be attributed to excess reporter molecules in the solution, nonspecific binding, or fluorescent spillover from another fluorochrome.
batch	A group of samples that are processed using a selected template.
bead	Shorthand terminology for an xMAP microsphere.
bead set	a set of xMAP microspheres that have a uniquely identifiable ratio of two classification dyes. The unique ratio is identified by a unique spectral address.
calibration	A process used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex System. Calibration ensures optimal and consistent microsphere classifications and reporter readings.
calibrators	xMAP microspheres used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex System.

CL1	Refers to dyes embedded in the microsphere. Also see classification channel.
CL2	Refers to dyes embedded in the microsphere. Also see classification channel.
classification channel	A specific range of wavelengths in which light intensity is measured. Includes the emission of a given classification dye. Classification channels are abbreviated as CL1 and CL2.
control microspheres, assay	Used to verify standards within the kit. Tells you that the curve or thresholds are correct.
control microspheres, system	xMAP microspheres used to verify the calibration and optical integrity for the Luminex 200 analyzer.
cuvette	Principal fluid pathway within the optics component of the system through which the sample is read.
data reduction	The analysis of acquired batch data.
delta cal temperature	The difference between the current temperature of the Doublet Discriminator APD and its temperature at your last calibration. The system displays this value on the Diagnostics tab within the software.
DD temperature	The current temperature of the doublet discriminator avalanche photo diode.
emission spectrum	Wavelength range that an excited fluorochrome emits when its electrons fall from a higher to a lower energy state. Expressed in nanometers (nm).
event	Occurs when the signal processor determines that a particle is being observed. Referred to as one bead as it passes through the laser.
excitation spectrum	Wavelength range that excites a molecule's electrons to a higher energy state. Expressed in nanometers (nm).
fluorescence	Light emission that occurs when the electrons of a fluorochrome drop to a lower energy state.
fluorochrome	A fluorescent molecule.
fluorophore	See fluorochrome.
immunofluorescence	A technique which uses a covalently linked fluorochrome-antibody complex to detect or quantify a particular antigen.

Luminex xMAP microsphere set	Luminex multi-analyte microspheres containing a unique mixture of two distinctly colored fluorochromes to distinguish them from other multi-analyte microspheres.
laser	Light Amplification by Stimulated Emission of Radiation (laser). This highly purified source of light is an efficient way to excite fluorochrome electrons.
microparticle	A solid substance with a diameter in the micrometer range. Often used as a synonym for a microsphere.
microspheres	Polystyrene spheres with a diameter in the micrometer range. Also called beads.
multi-analyte	Several assays or tests performed simultaneously in the same reaction container.
multi-batch	A set of batches to be processed consecutively.
photobleaching	The process in which light absorption converts the fluorochromes inside the beads into different fluorescent or nonfluorescent compounds. Photobleaching prevents beads from being properly classified.
PMT	Photomultiplier tube, measures the excitation emission intensity of the reporter dye bound to the surface of the xMAP microspheres.
product	A group of standards and controls that you use to create a template. Products are analogous to “reagent kits”. They are used in the template’s definition for the multi-analyte assays that will be performed.
Quali	A value that determines a cutoff or threshold. This in, conjunction with ranges using the Lum Qual Formula, Adv Qual Formula, or an edited range specific for your assay, helps to determine qualitative results for unknown samples.
qualitative	Pertaining to calculations that determine the absence or presence of an analyte.
quantitative	Pertaining to calculations that determine the precise numerical measurement of an analyte.
reporter	A molecule (or combination of molecules) with a specific range of excitation and emission wavelengths that is used to identify or

	quantify an analyte. Examples of acceptable reporters are Phycoerythrin and Alexa 532.
reporter channel (RP or RP1)	A specific range of wavelengths that includes the emission wavelength of a designated reporter molecule.
RP1	Refers to the dyes bound to the surface of the xMAP microsphere. Also see reporter channel.
RP	See reporter channel.
sample	The mixture of assay components (microspheres, reporter, patient diluent) that are analyzed.
sample reaction	The reaction that occurs between your reagents and the beads.
sheath fluid	Luminex xMAP Sheath Fluid is the delivery medium of the sample to the optics component. Only Luminex- approved sheath fluid should be used when operating the Luminex analyzer.
signal	Detectable measurement unit of the reporter molecule.
standards microspheres, assay	Assay standards are substances of known concentrations used to derive a standard curve with which unknown samples and controls are compared to determine their concentration or quantity. See control microspheres, assay.
suspension	Solution consisting of homogeneously dispersed microspheres in an aqueous medium.
system controls	Include the xMAP reporter and classification control microspheres. They are used to verify the calibration of the Luminex 200 analyzer.
template	A sequence of commands and predetermined settings defined by the kit manufacturer.
test	Each test represents an analyte and corresponds to a bead set which is represented by a bead ID.
verification	The process using system controls to ensure the analyzer is functioning properly with current calibration settings.
xMAP	See Luminex xMAP microsphere set.

Output.CSV

Overview

This chapter describes the file specification for the Luminex IS 2.3 Output.CSV file. Although this document may refer to older versions of Luminex software for historical purposes, it is intended only to describe the Output.CSV file for the Luminex IS 2.3 software.

Although this chapter was prepared to ensure accuracy, Luminex assumes no liability for errors or omissions or for damages resulting from the application or use of this information. This chapter refers to the Luminex 100 analyzer, but it can also be used for performing tasks in the Luminex IS 2.3 software installed for a Luminex 200 analyzer.

The Output.CSV file was created to provide a simple data report. The file displays general batch information and statistical results. Note that the term Batch is synonymous with Session in other versions of Luminex Software.

Overall Design

The Output.CSV file contains two blocks of information. The first is the header, which contains general batch information. The second block of information is the results section, which contains several subsections displaying statistical analyses in a Sample versus Test format, as illustrated in the following example:

Batch Header

Results

Stat1

Stat1 Header: Sample Location, Sample Name, Test1, Test2, ..., TestN, Total Count, Notes

Sample1

Sample2

....

SampleM

Stat2

StatN Header: Sample Location, Sample Name, Test1, Test2, ..., TestN, Total Count, Notes

Sample1

```

Sample2
....
SampleM
StatN
StatN Header: Sample Location, Sample Name, Test1, Test2, ...,
TestN, Total Count, Notes
Sample1
Sample2
....
SampleM
    
```

Blank Lines

- There is one blank line between the Date and SN fields.
- There are four blank lines between the Operator field (or last optional field) and Samples field.
- There is one blank line between the Samples and Results fields.
- There is one blank line between the Results field and the first statistical data block.
- There is one blank line between each of the statistical data blocks.

Field Definitions

Table D-1 Field Definitions

Field Name	Field Value Description
Program, "value"<,CC>	The name of the Luminex application that created the Output.CSV file. If the file is generated by a non-US operating system, the country code (in hex) is appended.
Build, "value"	The version of the Luminex application that created the Output.CSV file.
Date, "date", "time"	The date & time that the Output.CSV file was created. This field is not related to batch execution time. Note that the date and time values are separated into distinct, adjacent fields ("Date", "04/14/2003", "02:46:45 PM") to maintain compatibility with previous versions of software.
SN, "value"	The serial number of the Luminex 100 device with which the batch was executed.
Session, "value"	The name of the batch. The term Session was used here to maintain compatibility with previous versions of software. Limited to 30 characters.
Operator, "value"	The name contained in the Current User field on the General tab of the Options dialog in the Luminex 100 IS software.
TemplateID, "value"	(Optional) The database ID that is unique to the template used to create the batch.

Table D-1 Field Definitions (Continued)

Field Name	Field Value Description
TemplateName, "value"	(Optional) The name of the template used to create the batch. Limited to 30 characters.
TemplateVersion, "value"	(Optional) The version of the template used to create the batch. Limited to 10 characters.
TemplateDescription, "value"	(Optional) The description of the template used to create the batch. Limited to 200 characters.
TemplateDevelopingCompany, "value"	(Optional) The name of the company that developed the template used to create the batch. Limited to 30 characters.
TemplateAuthor, "value"	(Optional) The name of the person who created the template used to create the batch. Limited to 30 characters.
SampleVolume, "value"	(Optional) The sample volume defined in the template for sample acquisitions. Units = microliters.
DDGate, "value"	(Optional) The DD gate defined in the template for sample acquisitions
SampleTimeout, "value"	(Optional) The sample timeout defined in the template for sample acquisitions. Units = seconds.
BatchAuthor, "value"	(Optional) The name of the person who created the batch. Limited to 30 characters.
BatchStartTime, "date time"	(Optional) The date & time that the batch was started.
BatchStopTime, "date time"	(Optional) The date & time that the batch was finished.
BatchDescription, "value"	(Optional) The batch description. Limited to 200 characters.
BatchComment, "value"	(Optional) Comment entered after the batch has run.
CALInfo:	(Optional) Indicates the start of the CAL1 & CAL2 machine calibration information logged just prior to and anytime during batch acquisition
CONInfo:	(Optional) Indicates the start of the CON1 & CON2 machine verification information logged just prior to and anytime during batch acquisition
AssayLotInfo:	(Optional) Indicates the start of the Lot information for any standards and/or controls associated with the batch
Samples,"num", MinEvents,"0"	"Samples indicate the number of samples run in the batch. The MinEvents field is unused and will always be zero. Note that this field is adjacent to the Samples field ("Samples", "28", "Min Events", "0"), rather than below it to maintain compatibility with previous versions of software.
Min Events	See Samples field above

Table D-1 Field Definitions (Continued)

Field Name	Field Value Description
Results	This field has no associated value. It is used to indicate the beginning of the statistical results section of the Output.CSV file.
DataType:,"type"	This field is the name of the statistic represented in the Sample (versus the Test data block immediately below this field). Possible values for DataType include: Median, Result, Count, Mean, %CV, Peak, Std Dev, Trimmed Count, Trimmed Mean, Trimmed %CV, Trimmed Peak, Trimmed Std Dev, and Avg Result. See Table 2 - Statistics Definitions
CRC Entry	(Optional) CRC indicator for the file data. Used to detect external changes to the file.

Statistics Definitions

Statistical calculations are performed for each test in each sample. The number of events to collect for each test in a sample is defined in the template from which the batch was created. In any equations listed below, N indicates the number of events that were collected for an individual test in a single sample. The trimmed distribution represents the events that were collected for an individual test in a single sample with the lowest 5% and highest 5% of the data points removed to help eliminate outliers.

Table D-2 Statistics Definitions

Statistic	Description
Median	The middle value in the distribution of data
Result	The final test result based on a qualitative or quantitative analysis. This value could have units associated with it, as defined in the template. It may also indicate some error condition in the analysis, such as the sample was beyond the range of the curve fit, a divide by zero error occurred, etc. Some examples include: - "Invalid" - the user invalidated this sample, or a single test within a sample - "<10 pg/mL" - the result could not be calculated because it fell outside the valid range of the curve fit - ">10000 pg/mL" - the result could not be calculated because it fell outside the valid range of the curve fit - "ERROR" - some mathematical error occurred, such as an MFI value that does not intersect the concentration curve. N/A - a result is not applicable for this sample (i.e. a background sample)
Count	The number of data points in the distribution (N). The number of gated events that fell within the test's specified region.
Mean	(Optional) The sum of the data points in the distribution divided by the number of data points. Mean = $\sum x_i / N$

Table D-2 Statistics Definitions

Statistic	Description
%CV	(Optional) The measure of relative dispersion within the distribution. $\%CV = 100 \times \text{Std Dev} / \text{Mean}$
Peak	(Optional) The value that is equal to the largest number of data points within the distribution. For example in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most number of times in the distribution list.
Std Dev	(Optional) The measure of dispersion within the distribution. $\text{Std Dev} = ((N \sum x_i^2 - \sum x_i)^2 / N (N - 1))^{1/2}$
Trimmed Count	(Optional) The number of data points in the trimmed distribution (N_t).
Trimmed Mean	(Optional) The sum of the data points in the trimmed distribution divided by the number of data points. $\text{Trimmed Mean} = \sum x_i / N_t$
Trimmed %CV	(Optional) The measure of relative dispersion within the trimmed distribution. $\text{Trimmed \%CV} = 100 \times \text{Trimmed Std Dev} / \text{Trimmed Mean}$
Trimmed Peak	(Optional) The value that is equal to the largest number of data points within the trimmed distribution.
Trimmed Std Dev	(Optional) The measure of dispersion within the trimmed distribution. $\text{Trimmed Std Dev} = ((N_t \sum x_i^2 - \sum x_i)^2 / N_t (N_t - 1))^{1/2}$
Avg Result	(Optional) The average of any replicate samples' final test results based on a qualitative or quantitative analysis.

Statistics Column Definitions

The blocks of statistical data are displayed such that the first row of data represents the column headers and the following rows represent the samples that were acquired for the batch.

Table D-3 Statistic Column Definitions

Column Name	Description
Location	The location of the sample in terms of the command list sequence (1, 2, 3,...), the well placement (A1, B1, C1, ...) or both (1(A1), 2(B1), 3(C1), ...)
Sample	The name of the sample as defined in the batch setup. Limited to 30 characters.
Test1, Test2, ... , TestN	The number of test columns following the Sample column will depend on the number of tests defined in the Template used to create the batch. Each of the test columns will contain the test name for any given test. Therefore if the Template has 3 tests named Protein A, Protein B and Protein C, then these names will appear in the 3 test column headers in the Output.CSV file. Limited to 30 characters.

Table D-3 Statistic Column Definitions

Column Name	Description
Total Events	The number of events that fell with in the defined DD gate and into one of the defined regions for a test in the batch. For example, if a template had 3 tests defined and the batch had counts of 100, 102 and 105 for the tests, then the total count would be 307, even though more events may have been detected that did not fall within the DD gate or one of the defined regions.
Notes	Sample notes

Luminex 100 IS Output.CSV file with no additional features enabled

```
"Program","Luminex 100 IS",409
"Build","2.3 BETA"
"Date","7/28/2004","2:12:01 PM"

"SN","LX10001298011BE"
"Session","Bead 22 Quant Batch"
"Operator","Joe User"

"Samples","8","Min Events","0"

"Results"

"DataType:","Median"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","57","75",""
"2","Std m","525","75",""
"3","Std l","4341","75",""
"4","Std xl","14316","75",""
"5","Std xxl","25694","75",""
"6","Low Control","58","75",""
"7","Patient 1","532","75",""
"8","Patient 2","14567","75",""

"DataType:","Result"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","2.99 pg/mL","75",""
"2","Std m","15.79 pg/mL","75",""
"3","Std l","126.71 pg/mL","75",""
"4","Std xl","616.93 pg/mL","75",""
"5","Std xxl","3194.84 pg/mL","75",""
"6","Low Control","3.02 pg/mL","75",""
"7","Patient 1","15.98 pg/mL","75",""
"8","Patient 2","636.38 pg/mL","75",""

"DataType:","Count"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","75","75",""
"2","Std m","75","75",""
"3","Std l","75","75",""
"4","Std xl","75","75",""
"5","Std xxl","75","75",""
"6","Low Control","75","75",""
"7","Patient 1","75","75",""
"8","Patient 2","75","75",""
```

Luminex 100 IS Output.CSV file with all additional features enabled

```

"Program","Luminex 100 IS"
"Build","2.3 BETA"
"Date","7/28/2004","2:16:30 PM"

"SN","LX10001298011BE"
"Session","Bead 22 Quant Batch"
"Operator",""
"TemplateID","4"
"TemplateName","Quant Batch"
"TemplateVersion","2.3c"
"TemplateDescription","IS 2.3.137"
"TemplateDevelopingCompany","Luminex"
"TemplateAuthor","MAC"
"SampleVolume","50 uL"
"DDGate","8000 to 15000"
"SampleTimeout","50 sec"
"BatchAuthor","<Name>"
"BatchStartTime","7/28/2004 2:06:44 PM"
"BatchStopTime","7/28/2004 2:10:50 PM"
"BatchDescription","Software Testing"
"BatchComment","Batch Comment for "Bead 22 Quant Batch". This field should be used for general batch information entered by the end user. "
"CALInfo:"
"ProductName","ProductNo","LotName","ExpirationDate","CalibrationTime","BoardTemp","DDTemp","CL1Temp","CL2Temp","Pressure","DDVolts","CL1Volts","CL2Volts","RP1Volts","DDRVal","CL1RVal","CL2RVal","Passed","MachineSerialNo"
"Classification Calibrator","L100-CAL1","A4206","06/07/2006 12:00:00 AM","07/28/2004 09:39:32 AM","26.5625","25.26","25.04","25.26","6.3","74.04","81.33","62.83","-1","556","719","450","True","LX10001298011BE",
"Reporter Calibrator","L100-CAL2","A4110","02/18/2006 12:00:00 AM","07/28/2004 09:43:01 AM","26.7795138888889","-1","-1","-1","6.3","-1","-1","-1","590.5","-1","0","-1","True","LX10001298011BE",
"CONInfo:"
"ProductName","ProductNo","LotName","ExpirationDate","VerificationTime","GatedBeads","MachineSerialNo","Passed"
"Classification Control","L100-CON1","A4153","04/13/2006 12:00:00 AM","07/28/2004 09:45:39 AM","5222","LX10001298011BE","True",
"Reporter Control","L100-CON2","A4137","04/06/2006 12:00:00 AM","07/28/2004 09:52:49 AM","4345","LX10001298011BE","True",
"AssayLotInfo:"
"ManufacturerName","ProductName","ProductNo","ProductType","LotName","ExpirationDate"
"LMNX","Quant Kit","200","Assay Standard","B22std","08/01/2006 11:59:59 PM",
"LMNX","Quant Kit","200","Assay Control","B22con","08/02/2006 11:59:59 PM",

```

"Samples", "8", "Min Events", "0"

"Results"

"DataType:", "Median"

"Location", "Sample", "Test 22", "Total Events", "Notes"

"1", "Std s", "57", "75", ""

"2", "Std m", "525", "75", ""

"3", "Std l", "4341", "75", ""

"4", "Std xl", "14316", "75", ""

"5", "Std xxl", "25694", "75", ""

"6", "Low Control", "58", "75", ""

"7", "Patient 1", "532", "75", "Sample Comment for Patient 1."

"8", "Patient 2", "14567", "75", "Sample Comment for Patient 2."

"DataType:", "Result"

"Location", "Sample", "Test 22", "Total Events", "Notes"

"1", "Std s", "2.99 pg/mL", "75", ""

"2", "Std m", "15.79 pg/mL", "75", ""

"3", "Std l", "126.71 pg/mL", "75", ""

"4", "Std xl", "616.93 pg/mL", "75", ""

"5", "Std xxl", "3194.84 pg/mL", "75", ""

"6", "Low Control", "3.02 pg/mL", "75", ""

"7", "Patient 1", "15.98 pg/mL", "75", "Sample Comment for Patient 1."

"8", "Patient 2", "636.38 pg/mL", "75", "Sample Comment for Patient 2."

"DataType:", "Count"

"Location", "Sample", "Test 22", "Total Events", "Notes"

"1", "Std s", "75", "75", ""

"2", "Std m", "75", "75", ""

"3", "Std l", "75", "75", ""

"4", "Std xl", "75", "75", ""

"5", "Std xxl", "75", "75", ""

"6", "Low Control", "75", "75", ""

"7", "Patient 1", "75", "75", "Sample Comment for Patient 1."

"8", "Patient 2", "75", "75", "Sample Comment for Patient 2."

"DataType:", "Mean"

"Location", "Sample", "Test 22", "Total Events", "Notes"

"1", "Std s", "240.733333333333", "75", ""

"2", "Std m", "503.213333333333", "75", ""

"3","Std l","4450.92","75",""
 "4","Std xl","13478.6666666667","75",""
 "5","Std xxl","24817.8933333333","75",""
 "6","Low Control","60","75",""
 "7","Patient 1","561.12","75","Sample Comment for Patient 1."
 "8","Patient 2","14402.3466666667","75","Sample Comment for Patient 2."

"DataType:","%CV"
 "Location","Sample","Test 22","Total Events","Notes"
 "1","Std s","662.110761559013","75",""
 "2","Std m","42.0677216044823","75",""
 "3","Std l","28.540875012004","75",""
 "4","Std xl","30.4524100927965","75",""
 "5","Std xxl","17.3369506373774","75",""
 "6","Low Control","34.9506301308939","75",""
 "7","Patient 1","27.7364540209588","75","Sample Comment for Patient 1."
 "8","Patient 2","28.9726898443063","75","Sample Comment for Patient 2."

"DataType:","Peak"
 "Location","Sample","Test 22","Total Events","Notes"
 "1","Std s","45","75",""
 "2","Std m","447","75",""
 "3","Std l","3985","75",""
 "4","Std xl","3176","75",""
 "5","Std xxl","12044","75",""
 "6","Low Control","58","75",""
 "7","Patient 1","430","75","Sample Comment for Patient 1."
 "8","Patient 2","371","75","Sample Comment for Patient 2."

"DataType:","StdDev"
 "Location","Sample","Test 22","Total Events","Notes"
 "1","Std s","1593.82742065973","75",""
 "2","Std m","211.690384143302","75",""
 "3","Std l","1270.33151408429","75",""
 "4","Std xl","4104.5788483744","75",""
 "5","Std xxl","4302.66591643698","75",""
 "6","Low Control","20.9703780785363","75",""
 "7","Patient 1","155.634790802404","75","Sample Comment for Patient 1."
 "8","Patient 2","4172.74723003512","75","Sample Comment for Patient 2."

"DataType:","Trimmed Count"
 "Location","Sample","Test 22","Total Events","Notes"

"1","Std s","69","75",""
"2","Std m","69","75",""
"3","Std l","69","75",""
"4","Std xl","69","75",""
"5","Std xxl","69","75",""
"6","Low Control","69","75",""
"7","Patient 1","69","75","Sample Comment for Patient 1."
"8","Patient 2","69","75","Sample Comment for Patient 2."

"DataType:","Trimmed Mean"

"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","56.9855072463768","75",""
"2","Std m","494.463768115942","75",""
"3","Std l","4466.08695652174","75",""
"4","Std xl","13634.5217391304","75",""
"5","Std xxl","25095","75",""
"6","Low Control","58.8695652173913","75",""
"7","Patient 1","551.36231884058","75","Sample Comment for Patient 1."
"8","Patient 2","14594.7391304348","75","Sample Comment for Patient 2."

"DataType:","Trimmed %CV"

"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","23.9771317653444","75",""
"2","Std m","26.4392256987905","75",""
"3","Std l","20.718201051022","75",""
"4","Std xl","25.4309644452528","75",""
"5","Std xxl","14.0816389192424","75",""
"6","Low Control","22.0787072692933","75",""
"7","Patient 1","21.231629005304","75","Sample Comment for Patient 1."
"8","Patient 2","20.5061473536575","75","Sample Comment for Patient 2."

"DataType:","Trimmed Peak"

"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","45","75",""
"2","Std m","447","75",""
"3","Std l","3985","75",""
"4","Std xl","3715","75",""
"5","Std xxl","15788","75",""
"6","Low Control","58","75",""
"7","Patient 1","430","75","Sample Comment for Patient 1."
"8","Patient 2","8163","75","Sample Comment for Patient 2."

"DataType:","Trimmed StdDev"

"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","13.6634901596136","75",""

"2","Std m","130.732391650918","75",""

"3","Std l","925.292874765645","75",""

"4","Std xl","3467.39037575852","75",""

"5","Std xxl","3533.78728678387","75",""

"6","Low Control","12.9976389750536","75",""

"7","Patient 1","117.063202011273","75","Sample Comment for Patient 1."

"8","Patient 2","2992.81871196887","75","Sample Comment for Patient 2."

"DataType:","Avg Result"

"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","2.99 pg/mL","75",""

"2","Std m","15.79 pg/mL","75",""

"3","Std l","126.71 pg/mL","75",""

"4","Std xl","616.93 pg/mL","75",""

"5","Std xxl","3194.84 pg/mL","75",""

"6","Low Control","3.02 pg/mL","75",""

"7","Patient 1","15.98 pg/mL","75","Sample Comment for Patient 1."

"8","Patient 2","636.38 pg/mL","75","Sample Comment for Patient 2."

-- CRC --

CRC32: A398CCAD

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