



Quick Guide

SYNCT™ Standard Curve Analysis Software

v1.1u3



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SYNCT™ 1.1u3 Standard Curve Analysis Software Quick Guide

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89-30000-00-419 Rev. E

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SYNCT™ Standard Curve Analysis

Overview

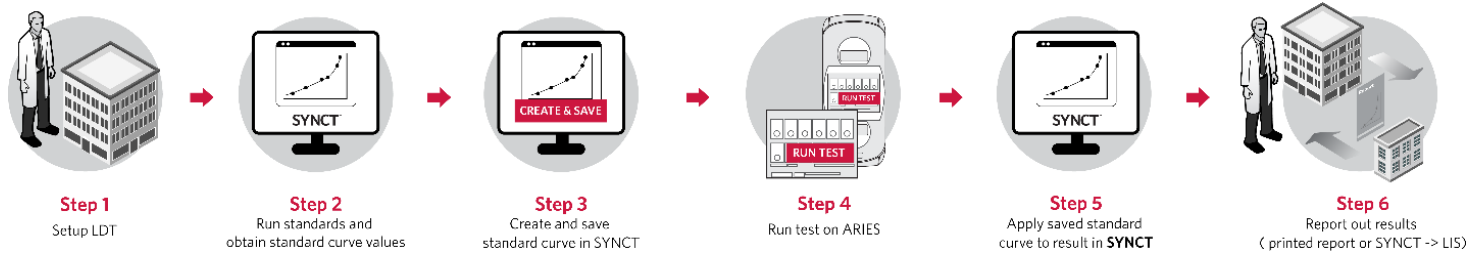
SYNCT 1.1u3 is software specifically created to enable standard curve analysis for Laboratory Developed Tests (LDTs). Labs can still create LDTs using the powerful ARIES UDP App, now with the ability to save and apply standard curves to create quantitative results.

In addition to the ability to manage orders from Laboratory Information Systems (LIS), view test results, prepare test reports, perform administrative functions, and maintain security control, this software offers:

- The ability to save standard curves to easily create quantitative results for LDT results
- Bi-directional LIS interface, enabling the transfer of both orders and results, both qualitative or quantitative
- One connection between SYNCT Software and the LIS, allowing labs to easily connect multiple instruments Results monitoring and management from anywhere in the lab
- The ability to associate cassettes to orders from anywhere

WARNING: This version of SYNCT is For Laboratory Use and cannot process IVD or RUO assay results. Use of IVD or RUO assays may require a separate appropriately-labeled version of SYNCT and ARIES instruments.

Using SYNCT 1.1u3 to create quantitative results from your LDTs can be done using these simple steps:



System Requirements

- Windows 7 only
- Installation of the ARIES UDP application and ARIES Universal Assay template file are required for creating assays. Refer to the *ARIES User-Defined Protocol (UDP) Applications Guide* for more information.

Limitations

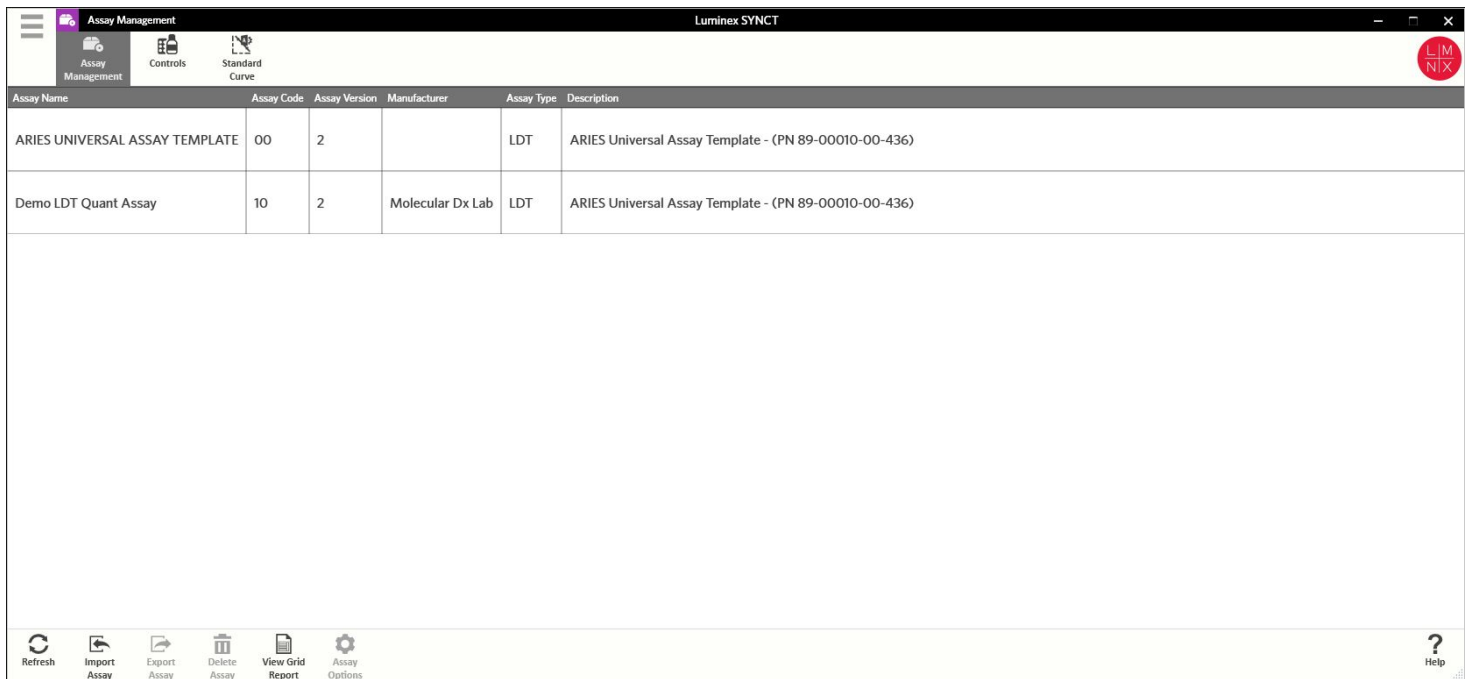
WARNING: For IVD SYNCT users: Do not install on the same PC as the SYNCT IVD software. All IVD data will be lost and the database is irreversibly changed. The standard curve software **MUST** be installed on a separate PC.

NOTE: This product is only compatible with single target per channel UDP assays.

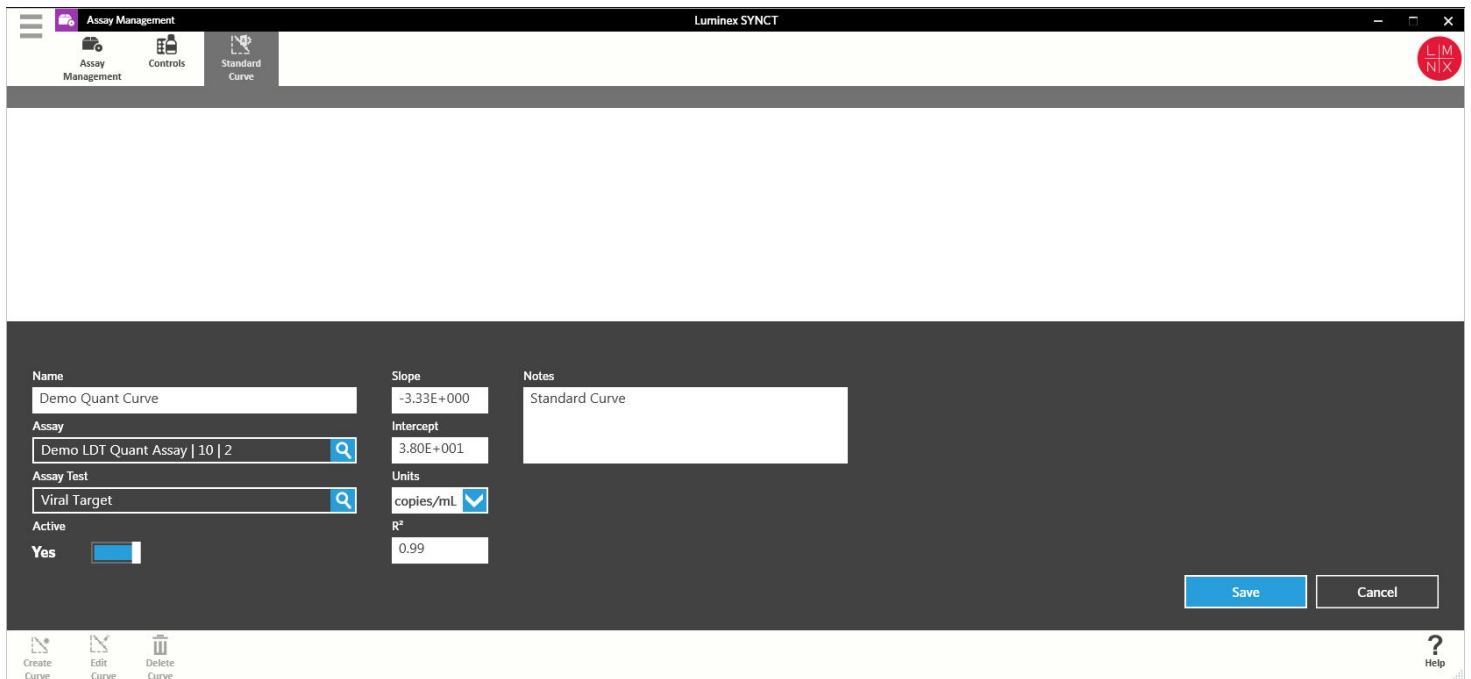
Creating a Standard Curve

1. Navigate to the **Assay Management** page.

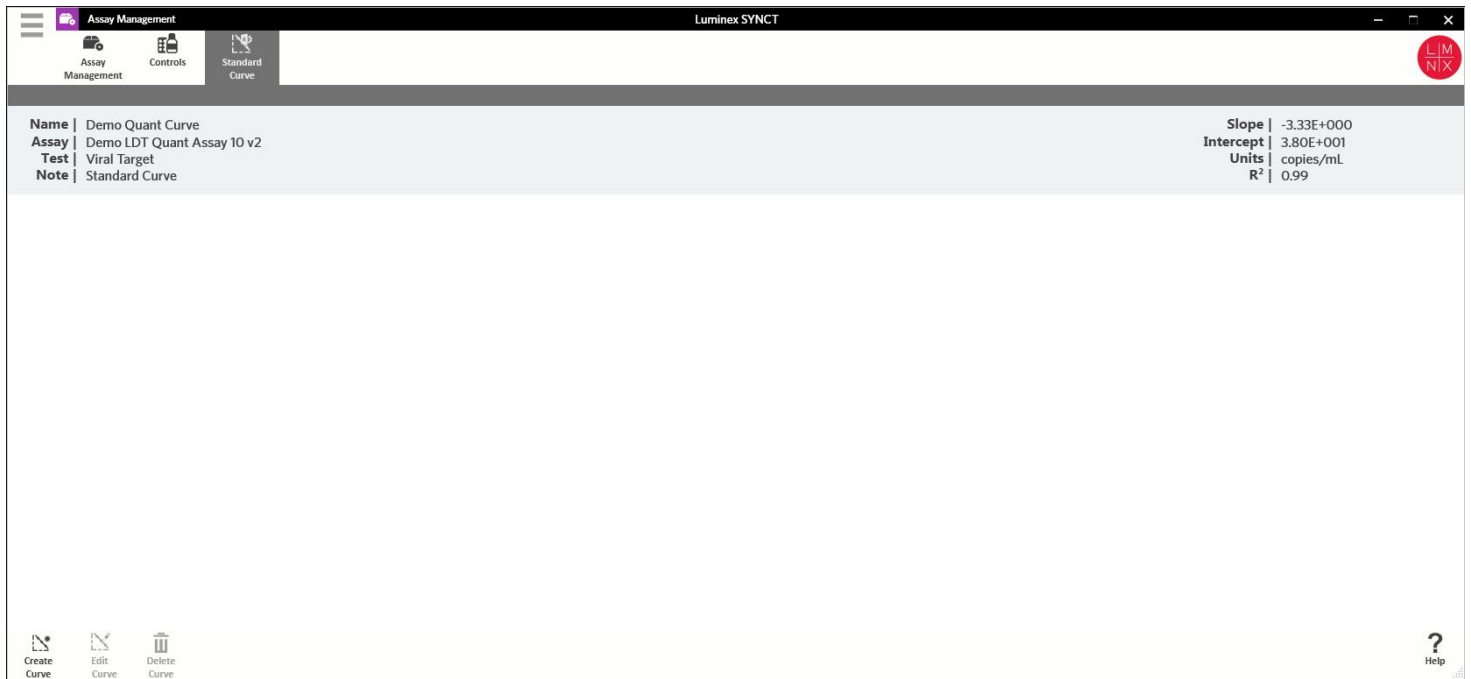
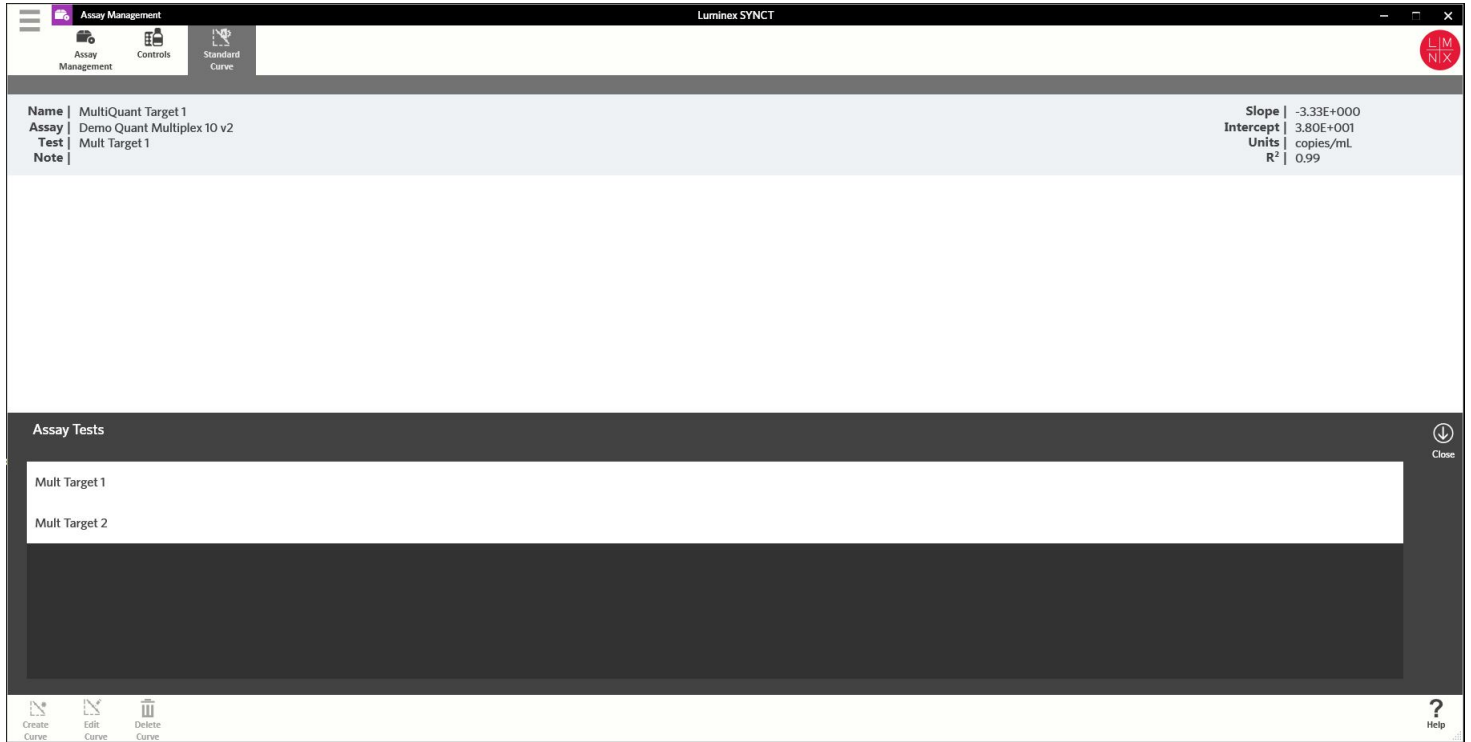
NOTE: The respective assay must be installed prior to creating the standard curve. Refer to the *ARIES User-Defined Protocol (UDP) Applications Guide* for more information.



2. Navigate to the **Standard Curve** page. Any Active and Inactive standard curves previously created will be displayed.
3. Click **Create Curve** from the Page Action bar. Enter the required assay information and standard curve parameters in the dialog box. Click **Save**.



NOTE: To create separate standard curves for individual targets in a multiplex assay, repeat the steps above using a multiplex assay and select the respective target from the **Assay Tests** drop-down menu.



- By default the standard curve status is toggled to **Active**. To inactivate, click **Edit Curve** from the Page Action bar and toggle the **Active** status to **No**. Changing the **Active** toggle to **Yes** allows standard curve to be applied to test results. Standard curve Active status may be changed at any time.

The screenshot displays the 'Assay Management' window in Lumindex SYNCT. The 'Standard Curve' tab is selected, showing a list of curves. The first curve, 'Demo Quant Curve', is active and has a slope of -3.33E+000, an intercept of 3.80E+001, units of copies/mL, and an R² of 0.99. The second curve, 'Demo Inactive Curve', is inactive and has a slope of 3.28E+000, an intercept of 3.50E+001, units of copies/mL, and an R² of 0.97. The interface includes a top navigation bar with 'Assay Management', 'Controls', and 'Standard Curve' tabs. At the bottom, there are icons for 'Create Curve', 'Edit Curve', 'Delete Curve', and 'Help'.

Status	Name	Assay	Test	Note	Slope	Intercept	Units	R ²
Active	Demo Quant Curve	Demo LDT Quant Assay 10 v2	Viral Target	Standard Curve	-3.33E+000	3.80E+001	copies/mL	0.99
INACTIVE	Demo Inactive Curve	Demo LDT Quant Assay 10 v2	Viral Target	Inactive standard curve	3.28E+000	3.50E+001	copies/mL	0.97

Applying a Standard Curve to Results

1. Navigate to the **Results** page.
2. Select a sample result. The result will be highlighted in blue.

The screenshot shows the Luminex SYNCT Results page. At the top, there are tabs for 'Results' and 'Settings'. Below that is a 'Run' header with a filter date range of '1/1/2014 to 12/31/2054'. The main area is a table with columns: Sample ID, Status, Location, Test, Alert, Result, Reported Date, Sample Type, Assay, and Completion Date. The table contains 6 rows of data. The first row, 'Sample 1', is highlighted in blue. Below the table is a toolbar with various icons for actions like Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, and Quant Analysis. A '1' is shown in a box above the Quant Analysis button.

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
Sample 1		B 1	Viral Target	+	Viral Target Positive	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 2		B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
I2910077669		B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 3		B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
High Target Ctl		B 5	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Low Target Ctl		B 6	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

3. Click **Quant Analysis** from the Page Action bar to open the **Add Curve** dialog box. Positive test results from assay targets with an associated standard curve will be listed.

NOTE: The Quant Analysis button will be inactive when selecting a sample with negative target results.

The screenshot shows the Luminex SYNCT Results page with the 'Add Curve' dialog box open. The dialog box has a blue header with the text 'Please select 'Add Curve' button.' Below the header is a table with two columns: 'Test' and 'Result'. The table contains one row: 'Viral Target' and 'Viral Target Positive'. At the bottom of the dialog box are two buttons: 'Add Curve' and 'Cancel'. The 'Quant Analysis' button in the toolbar is now inactive.

Test	Result
Viral Target	Viral Target Positive

- Choose a test. The **Add Curve** button will be highlighted if the selected test result has not had a curve applied. All target tests in a multiplex assay that have available standard curves will be listed in the dialog box.

The screenshot shows the Luminex SYNCT software interface. At the top, there are 'Results' and 'Settings' tabs. Below is a table with columns: Sample ID, Status, Location, Test, Alert, Result, Reported Date, Sample Type, and Assay. The table contains one main entry: '6-Positive-Targets (1 item(s): 0 Failed, 0 Invalid)' with a sub-row for 'Sample 2.5' at location 'B 1'. The 'Test' column lists 'Target a, Target b, Target c, Target d, Target e, Target f'. The 'Alert' column shows a plus sign, and the 'Result' column shows 'Target a Positive, Target b Positive, Target c Positive, Target d Positive, Target e Positive, Target f Positive'. Below the table, a dialog box is open with the title 'Please select 'Add Curve' button.' It contains a table with columns 'Test' and 'Result', listing 'Target a' (Target a Positive), 'Target b' (Target b Positive), and 'Target c' (Target c Positive). At the bottom right of the dialog are 'Add Curve' and 'Cancel' buttons. A toolbar at the bottom includes icons for Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, Quant Analysis, and Help.

- Click **Add Curve** to open the **Standard Curve** dialog box. Active curves will be displayed by default. Select the **Show all available Standard Curves** check box to show all active and inactive standard curves. Only standard curves associated with the selected test result will be displayed.

The screenshot shows the Luminex SYNCT software interface. The table at the top has columns: Sample ID, Status, Location, Test, Alert, Result, Reported Date, Sample Type, Assay, and Completion Date. It contains a main entry 'DemoQuantRun 1 (6 item(s): 0 Failed, 0 Invalid)' with sub-rows for 'Sample 1', 'Sample 2', 'I2910077669', and 'Sample 3'. The 'Test' column for all is 'Viral Target'. The 'Alert' column shows plus signs for 'Sample 1', 'I2910077669', and 'Sample 3', and a right-pointing triangle for 'Sample 2'. The 'Result' column shows 'Viral Target Positive' for 'Sample 1', 'Negative' for 'Sample 2', and 'Viral Target Positive' for 'I2910077669' and 'Sample 3'. Below the table, a dialog box is open with the title 'Select 'Apply Curve' button to apply selected standard curve.' It contains a table with columns 'Name | Demo Quant Curve' and 'Note | Standard Curve'. To the right, it displays 'Slope | -3.33E+000 Intercept | 3.80E+001 Units | copies/mL R² | 0.99'. At the bottom left of the dialog is a checked checkbox 'Show all available Standard Curves'. At the bottom right are 'Apply Curve' and 'Close' buttons. The same toolbar from the previous screenshot is visible at the bottom.

6. Click **Apply Curve**. The quantitative result is displayed for the test along with a message box. Click **OK** to accept quantitative result. The sample log below the result lists the details of the standard curve applied to the test.

The screenshot shows the SYNCT software interface. A message box is open, displaying the text: "2:57:42 PM Quantitative result '1.12E+001 copies/mL' added to Assay 'Demo LDT Quant Assay 10 v2' for Test 'Viral Target' for Sample: 'Sample 1'". Below the message box is a table of results for "DemoQuantRun 1 (6 item(s): 0 Failed, 0 Invalid)".

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
<input checked="" type="checkbox"/> Sample 1		B 1	Viral Target	+	Viral Target Positive: 1.12E+001 copies/mL	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Sample 2		B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> I2910077669		B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Sample 3		B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> High Target Ctl		B 5	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Low Target Ctl		B 6	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

Below the table is a toolbar with various icons for Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, Quant Analysis, and Help.

The screenshot shows the SYNCT software interface with the "Applied Standard Curve" details expanded for "Sample 1". The details include: "Applied Standard Curve: 'Demo Quant Curve' Notes: Standard Curve Test: 'Viral Target' Slope: -3.33E+000 Intercept: 3.80E+001 R²: 0.99 Operator: admin".

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
<input checked="" type="checkbox"/> Sample 1		B 1	Viral Target	+	Viral Target Positive: 1.12E+001 copies/mL	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Sample 2		B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> I2910077669		B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Sample 3		B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> High Target Ctl		B 5	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
<input type="checkbox"/> Low Target Ctl		B 6	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

The toolbar at the bottom is identical to the previous screenshot.

Removing the Standard Curve From A Result

1. Select a sample result.
2. Click **Quant Analysis** from the Page Action bar to open the **Standard Curve** dialog box. Select the test and then click **Remove**. A message box will indicate that the quantitative result is being removed. Click **OK**. The sample log below the result will display that a quantitative result was removed.

The screenshot shows the Luminex SYNCT software interface. At the top, there are 'Results' and 'Settings' tabs. Below is a 'Run' header with a 'Filter Date Range: 1/1/2014 to 12/31/2054'. A table lists sample results for 'DemoQuantRun 1'. The first row, 'Sample 1', is selected. Below the table, a dialog box titled 'Please select the 'Remove' button to remove quantitative result.' is open. It shows the test 'Viral Target' and the result 'Viral Target Positive: 1.12E+001 copies/mL'. At the bottom of the dialog are 'Remove' and 'Cancel' buttons. The bottom toolbar contains icons for Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, Quant Analysis, and Help.

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
Sample 1	<input checked="" type="checkbox"/>	B 1	Viral Target	+	Viral Target Positive: 1.12E+001 copies/mL	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 2	<input type="checkbox"/>	B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
I2910077669	<input type="checkbox"/>	B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 3	<input type="checkbox"/>	B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

The screenshot shows the Luminex SYNCT software interface after the removal action. A 'Messages' dialog box is open, displaying the message: '3:00:09 PM Quantitative result removed from Assay 'Demo Quant LDT Assay 10 v2' for Test 'Viral Target' for Sample: 'Sample 1''. Below the message is an 'OK' button. The background table is still visible, showing the same data as the previous screenshot. The bottom toolbar is identical to the previous screenshot.

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
Sample 1	<input checked="" type="checkbox"/>	B 1	Viral Target	+	Viral Target Positive	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 2	<input type="checkbox"/>	B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
I2910077669	<input type="checkbox"/>	B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 3	<input type="checkbox"/>	B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
High Target Ctl	<input type="checkbox"/>	B 5	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Low Target Ctl	<input type="checkbox"/>	B 6	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

NOTE: You may have to click the **Refresh** button from the Page Action bar to see the updated sample log.

The screenshot shows the 'Results' page in the Luminex SYNCT software. The main area contains a table with the following columns: Sample ID, Status, Location, Test, Alert, Result, Reported Date, Sample Type, Assay, and Completion Date. The table lists several samples, including 'Sample 1' through 'Sample 6', 'High Target Ctl', and 'Low Target Ctl'. A note indicates that a quantitative result was removed for 'Viral Target'.

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
DemoQuantRun 1 (6 item(s): 0 Failed, 0 Invalid)									
Sample 1		B 1	Viral Target	+	Viral Target Positive	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Applied Standard Curve: 'Demo Quant Curve' Notes: Standard Curve Test: 'Viral Target' Slope: -3.33E+000 Intercept: 3.80E+001 R ² : 0.99 Operator: admin									
Quantitative result removed for Test 'Viral Target' Operator: admin									
Sample 2		B 2	Viral Target		Negative	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
I2910077669		B 3	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Sample 3		B 4	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
High Target Ctl		B 5	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P
Low Target Ctl		B 6	Viral Target	+	Viral Target Positive	3/16/2017 5:40:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

The toolbar at the bottom includes buttons for Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, Quant Analysis, and Help.

Deleting a Standard Curve from an Assay

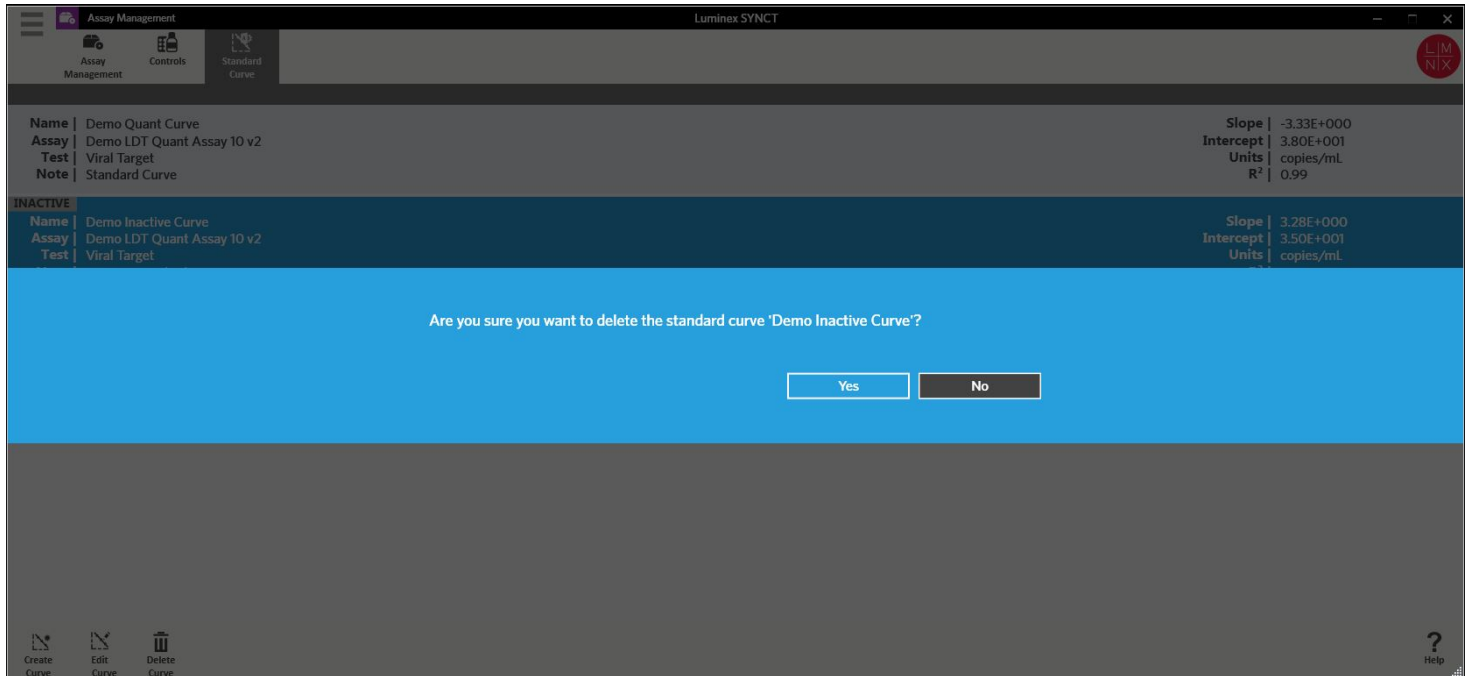
1. Navigate to the **Standard Curve** page under **Assay Management**, choose the Standard Curve to be removed and click **Delete Curve** from the Page Action bar.

The screenshot shows the 'Standard Curve' page under 'Assay Management'. It displays a list of curves with their respective parameters. The 'Demo Inactive Curve' is highlighted in blue, indicating it is the selected curve for deletion.

Name	Assay	Test	Note	Slope	Intercept	Units	R ²
Demo Quant Curve	Demo LDT Quant Assay 10 v2	Viral Target	Standard Curve	-3.33E+000	3.80E+001	copies/mL	0.99
INACTIVE Demo Inactive Curve	Demo LDT Quant Assay 10 v2	Viral Target	Inactive standard curve	3.28E+000	3.50E+001	copies/mL	0.97

The toolbar at the bottom includes buttons for Create Curve, Edit Curve, Delete Curve, and Help.

2. Click **Yes** to confirm that you want to delete the standard curve.



Creating Reports

Refer to the *ARIES User-Defined Protocol (UDP) Applications Guide* for more information on reports.

The screenshot displays the Luminex SYNCT software interface. At the top, there are tabs for 'Results' and 'Settings'. Below this is a 'Run' section with a table of data. The table has columns for Sample ID, Status, Location, Test, Alert, Result, Reported Date, Sample Type, Assay, and Completion Date. A row is highlighted for 'Sample 1' with a 'Viral Target' test and a 'Viral Target Positive' result. Below the table, there are two informational messages: 'Applied Standard Curve: 'Demo Quant Curve' Notes: Standard Curve Test: 'Viral Target' Slope: -3.33E+000 Intercept: 3.80E+001 R²: 0.99 Operator: admin' and 'Quantitative result removed for Test 'Viral Target' Operator: admin'. Below the messages is a section titled 'Generate Reports For 1 Sample(s) in 1 Run(s)' with five report generation icons: Run Report, Sample Summary, Sample Details, Control Summary, and Control Details. At the bottom, there is a toolbar with various icons for Refresh, Export Results, Import Result, Filter By, Reset Filters, Group By Sample, Submit Reports, Create Report, View Grid Report, Add Sample Comment, Rename Run, Edit Sample, Quant Analysis, and a Help icon. A 'Cancel' button is also present in the bottom right corner.

Sample ID	Status	Location	Test	Alert	Result	Reported Date	Sample Type	Assay	Completion Date
DemoQuantRun 1 (6 item(s): 0 Failed, 0 Invalid)									
Sample 1		B 1	Viral Target	+	Viral Target Positive	3/16/2017 5:39:00 PM	Sample	Demo Quant LDT Assay 10 v2	3/16/2017 5:39:00 P

Applied Standard Curve: 'Demo Quant Curve' Notes: Standard Curve Test: 'Viral Target' Slope: -3.33E+000 Intercept: 3.80E+001 R²: 0.99 Operator: admin

Quantitative result removed for Test 'Viral Target' Operator: admin

Generate Reports For 1 Sample(s) in 1 Run(s)

- Run Report
- Sample Summary
- Sample Details
- Control Summary
- Control Details

Cancel

Refresh Export Results Import Result Filter By Reset Filters Group By Sample Submit Reports Create Report View Grid Report Add Sample Comment Rename Run Edit Sample Quant Analysis Help

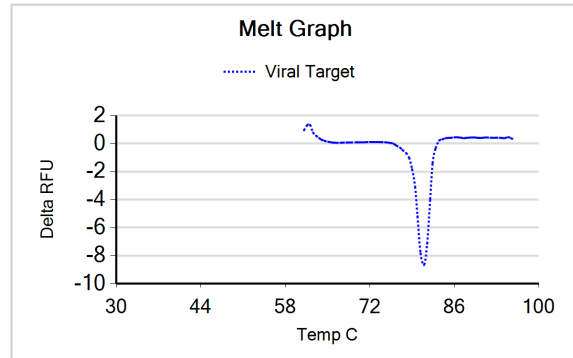
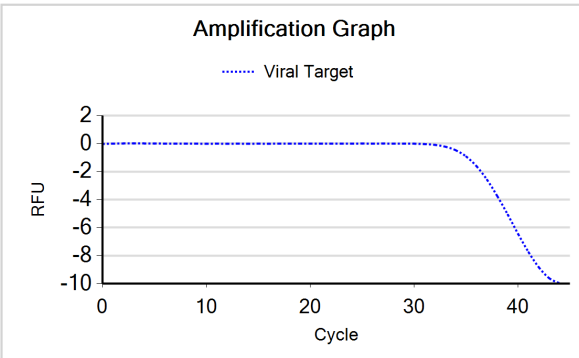


Instrument Name	M12V116098501	Run Name	DemoQuantRun 1
Instrument SN	M12V116098501	Assay Name	Demo Quant LDT Assay
Software Version	1.0.1021.0	Cassette SN	A00139
Assay Protocol Version	10.2	Cassette Lot	AA3425
Date and Time of Run	3/16/2017 3:44 PM	Expires	8/1/2017
		Operator ID	admin

Sample Details

Position	Sample ID	Assay Name	Test Result
B1	Sample 1	Demo Quant LDT Assay	Viral Target Positive: 1.12E+001 copies/mL

Channel	Channel Desc.	Ct	Tm (C)	Channel Result
1	Not Used	-	-	-
2	Viral Target	34.5	80.9	Detected
3	[SPC]	N/A	N/A	N/A
4	Not Used	-	-	-
5	Not Used	-	-	-
6	Not Used	-	-	-



No comments available

Logs

Date	Level	Message
1/23/2018 9:00 AM	1	Applied Standard Curve: 'Demo Quant' Test: 'Viral Target' Slope: -3.33E+000 Intercept: 3.80E+001 Operator: admin