Luminex®

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SYNCT™ Standard Curve Analysis 2.0 Software User Manual

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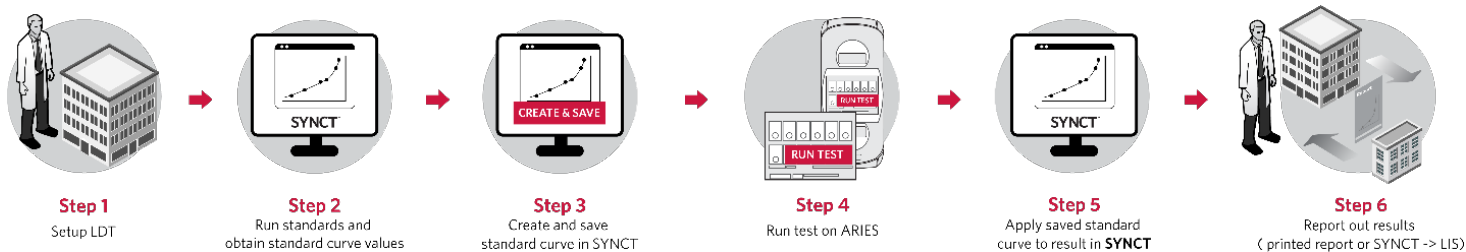# Chapter 1: Software Introduction

Software Overview

The SYNCT™ Standard Curve Analysis software allows you to define standard curves by entering the slope and inter-cept of the line or by defining standards and selecting samples to allow the software to calculate a standard curve. It will allow you to save curves and apply them to results to create a quantitative result. The quantitative result will be shown on the screen, on the reports, and output to the LIS. These curves may only be applied and used with LDT assays; as such the application is labeled "For Laboratory Use Only."

Labs are able to create LDT's using the ARIES® UDP software app. In addition to the ability to manage orders from Lab-oratory Information Systems (LIS), view test results, prepare test reports, perform administrative functions, and main-tain 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

NOTE: 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 SYNCTand ARIES instruments.

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Setup LDT	Run standards and obtain standard curve values	Create and save standard curve in SYNCT	Run test on ARIES	Apply saved standard curve to result in **SYNCT**	Report out results (printed report or SYNCT -> LIS)

Limitations

- SYNCT™ Standard Curve Analysis software: Only LDT assay files are supported. Previously released assay files that are not LDT will not be available for creating orders and reports.
- Assay files of other types cannot be imported into SYNCT™ Standard Curve Analysis software and will not be displayed if installed prior to upgrading from SYNCT 1.1 Update 2.

- Results for non-LDT assays can be viewed and generic reports created, but the non-LDT assay file will not be available for re-analysis or reporting.
- Do not install SYNCT 2.0 on the same PC as SYNCT IVD software. All IVD data will be lost, and the database is irreversibly changed. SYNCT 2.0 must be installed on a separate PC from SYNCT IVD software.
- This product is only compatible with single target per channel UDP assays.

Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-(2323)

Contact outside the U.S. and Canada by calling: +1 512-381-4397

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Fax: 512-219-5114

Email: *support@luminexcorp.com*

Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter *http://www.luminexcorp.com* in your browser's address field.

This manual can be updated periodically. To ensure that you have a current version, contact Technical Support.

Chapter 2: Setting up the Software

Software and PC Requirements

Recommended:

- Windows® 10, 64-bit, Version 1709 (or higher)
- 3.0 GHz Intel Core i5 (or higher)
- 8 GB RAM
- 1 TB Hard drive space (or higher)
- Display Settings:
  - SXGA 1280 X 1024 with 32 bit color
  - 96 DPI Font
  - Default Windows 10 Theme

Install SYNCT™ 2.0 Software

NOTE: Before installing SYNCT 2.0 software, ensure that no other applications are running. Perform a Windows® backup of your system and archive critical application data prior to installation.

1. Insert the SYNCT™ Software USB into a computer and browse to the folder containing the **SYNCTSet-Up** file.
2. Double-click the **SYNCTSet-Up** file to begin installation.
3. A **Security Warning** dialog box may open asking if you want to run the software from an Unknown Publisher; click **Run**.
4. A dialog box may open, asking for permission to allow the unknown publisher for **SYNCTSet-Up.exe** to make changes to the computer. Click **Yes** to continue. It may take Windows® several minutes to launch the installer.

   NOTE: This step may not occur in all installations.

5. On the **Luminex SYNCT Setup** screen, click **Install SYNCT Software**.
6. A **Warning** dialog box will display informing you that SYNCT 2.0 does not support IVD Assay related applications, and will ask if you want to proceed with installation; click **Yes** to continue.

   NOTE: This step may not occur in all installations.

7. A **Warning** dialog box will open informing you that SYNCT will install and configure SQL Server 2012. Click **Yes** to continue.
8. Click **Install**. The installation for SQL Server 2012 will run.

   NOTE: The installation can take several minutes.

9. The **InstallShield Wizard Welcome** screen displays. Click **Next**.

10. Review the EULA, then select the **I accept the terms in the license agreement** radio button. Click **Next**.

11. Select **Typical** for setup type and click **Next**.

12. Click **Install**.

> **NOTE:** The installation may take several minutes.

13. Click **Finish** to complete the installation and exit the wizard.

14. Click **Yes** to restart the PC now or **No** to restart later.

Upgrade SYNCT™ Standard Curve Analysis Software

If you have SYNCT™ 1.1 u3 software installed on a Windows® 10 PC:

1. Uninstall SYNCT 1.1 u3 software, without the USB.

   a. Close all open programs.

   b. Click on the Windows logo and click the **Settings** icon.

   c. Click **Apps**.

   d. Scroll to Luminex SYNCT software, click it once, then click **Uninstall**.

      i. A dialog box displays **This app and its related info will be uninstalled.** click **Uninstall**.

      ii. In some instances, you may get a dialog box asking if you want to let the program make changes to your device, click **Yes**.

      iii. In the **Luminex SYNCT** dialog box, select the appropriate option. Click **OK**.

2. Install SYNCT 2.0.

> **NOTE:** All assay files and results will remain after the software is uninstalled and will appear in SYNCT 2.0 once the software launches.

If you have SYNCT 1.1 u3 installed on a PC without Windows 10:

1. Install SYNCT 2.0 on a Windows 10 PC.

2. Export all results from the PC with SYNCT 1.1 u3 and import the results into SYNCT 2.0.

3. Import the assay files.

Uninstall SYNCT™ Software with the USB

1. Insert the SYNCT™ Software USB into a computer and browse to the folder containing the **SYNCTSet-Up** file.

2. Double-click the **SYNCTSet-Up** file.

3. A dialog box may open, asking for permission to allow the unknown publisher for **SYNCTSet-Up.exe** to make changes to the computer. Click **Yes** to continue. It may take Windows® several minutes to launch the installer.

> **NOTE:** This step may not occur in all installations.

4. Click **Install SYNCT Software**.

5. A **Warning** dialog box may open, click **Yes** to continue.

   NOTE: This step may not occur in all installations.

6. A **Warning** dialog box will open for SQL Server 2012. Click **Yes** to continue.
7. The InstallShield Wizard **Welcome** screen displays. Click **Next**.
8. Select the **Remove** radio button to uninstall SYNCT from your computer.
9. Click **Next**.
10. Click **Remove**.
11. If a **Files in Use** dialog box displays, select the desired radio button and click **OK**.
12. Click **Finish**.

Confirm or Set the Scale and Layout

1. Right-click on the desktop and choose **Display settings**.
2. For **Change the size of text, apps, and other items,** choose **100%.**
3. For **Resolution,** choose **1280 x 1024.**
4. Click **Keep Changes** if these settings are new**.**

Chapter 3: Using SYNCT™ Standard Curve Analysis 2.0 Functionality

Log into SYNCT™ Software

To log into the SYNCT™ software, complete the following:

1. Double-click the **Luminex SYNCT** icon on your desktop.
2. If this is your first time logging in, read the End-User License Agreement (EULA) and click **Accept** to continue.

   NOTE: Select **Don't Show Again** to skip the EULA on subsequent logins.

3. Enter your **User name**.
4. Enter your **Password**.

   NOTE: You can view your password for correctness before logging in by clicking on the eye icon in the Password field. The eye icon can be activated or deactivated by the administrator on the Security Settings page.

5. Click **Login**.

   a. Select the **Stay signed in** check box, to stay signed in to the SYNCT software.

      NOTE: If you select Stay signed in and walk away from the computer, there is potentially a risk for unauthorized user access.

Assay Management

Import an Assay File

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Assay Management**.
2. Click **Import Assay** from the Page Action bar. The **Import File** window displays.

   NOTE: Do NOT double click. SYNCT™ Software requires one click when navigating to the correct file location.

   a. Choose the location under **Devices**.

   b. Choose the location under **Files** for the import.

   c. Click **OK**.

Export an Assay File

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Assay Management**.
2. Choose the assay to export.
3. Click **Export Assay** from the Page Action bar. The **Export File** window displays.

    NOTE: Do NOT double click. SYNCT™ Software requires a single click when navigating to the correct file location.

    a. Choose the location under **Devices**.

    b. Choose the location under **Files** for the export.

    c. Select **Overwrite file**, if you want to overwrite the previous file.

    d. Click **OK**.

    NOTE: Exporting the assay does not remove the assay from the Assay Management page.

Delete an Assay File

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Assay Management**.
2. Choose the assay to delete.
3. Click **Delete Assay** from the Page Action bar.

    a. A dialog box displays asking, "**You are about to delete an Assay. Do you want to continue?**"

    b. Click **Yes** or **No**.

Set Assay Options

NOTE: The assay options available will vary by assay.

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Assay Management**.
2. Choose the desired assay.
3. Click **Assay Options** from the Page Action bar.

    a. Toggle the **Is Default Report** button to **Yes** or **No** to set the default reports for the assay.

    b. Click **Save Changes**.

    c. Click **OK** in the **Messages** dialog box.

Results

Import Results

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Results > Results**.
2. Click **Import Result** from the Page Action bar. The **Import File** window displays.

    NOTE: Do NOT double click. SYNCT™ Software requires a single click when navigating to the correct file location.

NOTE: Modified output .csv files should not be used for diagnostic purposes. The integrity of the ARIES® .csv file will be checked when the file is imported into SYNCT Software. You will be notified if the file has been modified outside of the system.

    a. Choose the location under **Devices**.

    b. Choose the location under **Files** for the import.

    c. Click **OK**.

Export Results

The Exporting Results function exports a .csv file that can be used for importing into SYNCT™ Software on another system. To export results, complete the following:

1.   Click   in the upper left-hand corner of the screen and navigate to **Results > Results**.
2.   Select the result or results to export.
3.   Click **Export Results** from the Page Action bar. The **Export File** window displays.

    NOTE: Do NOT double click. SYNCT™ Software requires a single click when navigating to the correct file location.

    a. Choose the location under **Devices**.

    b. Choose the location under **Files** for the export.

    c. Select **Overwrite file**, if you want to overwrite the previous file.

    d. Click **OK**.

    NOTE: Exporting results does not remove the results from the Results page.

View Results

1.   Click   in the upper left-hand corner of the screen and navigate to **Results > Results**.
2.   When there are multiple pages of results in the SYNCT™ Software, page arrows and numbers will display at the bottom of the screen.

    a. Click on the left and right arrows to scroll through the pages of results or, if you know what page the results are on, click on the page number.

Filter Results

The default filter is set one month prior to the current date.

1.   Click   in the upper left-hand corner of the screen and navigate to **Results > Results**.
2.   Click **Filter By** from the Page Action bar. The **Filter By** window displays.

    a. Choose any of the following filter results options: **Run Name**, **Sample ID**, **Assay**, **Accession ID**, **User**, **Sample Comment**, **Requisition Number**, **Test Name**, **Result**, **Module ID**, **Lot Number**, **Status**, **Instrument ID**, **Time Range**, **Sample Type**, and **Proficiency Only** samples.

    NOTE: When choosing the Time Range, the From and To dates are automatically populated.

    b. Click **Apply**. The **Filter By** icon is highlighted on the Page Action bar.

Standard Curves

Create a Standard Curve

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Standard Curve**.

   NOTE: Any active and inactive standard curves previously created are displayed.

2. Click **Create Curve** from the Page Action bar.

   a. Enter the **Name** for the standard curve.

   b. Click the magnifying glass to choose the **Assay**.

   c. Click the magnifying glass to choose the **Assay Test**.

   d. For **Curve Definition**, select between **Active**, **Calculated**, and/or **Auto Apply**.

      NOTE: If the Calculated check box is selected, SYNCT™ Software will automatically create the standard curve. Clear the Calculated check box to manually enter the curve parameters, including the Slope, Intercept, and R^2 fields.

      NOTE: If the Auto Apply check box is selected, the standard curve is automatically applied to the respective assay results to generate a quantitative result.

   e. Click the drop-down arrow to choose the **Units**.

   f. Click **Calculate**. The **Curve Editor** page displays.

3. Click **Add Standard** from the Page Action bar.

   a. Enter the **StandardName**.

   b. Enter the **Concentration**.

   c. Click **Select Standard Samples**.

   d. Select the desired sample(s) in the assay run(s) that apply to the standard being added to the curve.

      NOTE: Six sample results can be selected per standard curve, for a total of 24 across all standard curves.

   e. Click **Apply**.

   NOTE: Repeat the above steps to add additional standards to the curve. A minimum of two and a maximum of six standards are allowed.

   NOTE: Curve parameters are auto-calculated and displayed in the upper right-hand corner of the screen.

4. Click **Save and Close** from the Page Action bar when all desired standards have been added.

Edit a Standard Curve

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Standard Curve**.
2. Choose the standard curve to edit.
3. Click **Edit Curve** from the Page Action bar.

   a. Edit the standard curve **Name** as needed.

   b. For **Curve Definition**:

      i. Select **Active** to activate or inactivate the standard curve.

ii. If **Calculated** was selected when the standard curve was created, you can not undo this, but if **Calculated** was not selected, you can select it now.

iii. Select **Auto Apply** to automatically apply the standard curve.

c. Click **Save**.

Apply a Standard Curve

1. Click ▬ in the upper left-hand corner of the screen and navigate to **Results > Results**.
2. Select a positive sample result to apply a standard curve to. The result will be highlighted in blue.
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 is inactive if you select a sample with negative target results.

   a. Choose a **Test**.

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

   b. Click **Add Curve** to open the **Standard Curve** dialog box. Active curves will be displayed by default.

   c. 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.

   d. Choose the standard curve.

   e. Click **Apply Curve**. The quantitative result is displayed for the test along with a **Messages** dialog box.

   f. Click **OK** in the **Messages** dialog box to accept quantitative result.

      NOTE: The sample log below the result lists the details of the standard curve applied to the test.

Remove a Standard Curve

1. Click ▬ in the upper left-hand corner of the screen and navigate to **Results > Results**.
2. Select a sample result that has a standard curve already applied to it.
3. Click **Quant Analysis** from the Page Action bar to open the **Standard Curve** dialog box.

   NOTE: The Quant Analysis button is inactive if you select a sample with negative target results.

   a. Choose the desired test to remove the quantitative result from.

   b. Click **Remove**.

   c. Click **OK** in the **Messages** dialog box to confirm the quantitative result was removed.

      NOTE: The sample log below the result lists the details of the removal.

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

Delete a Standard Curve

1. Click ▬ in the upper left-hand corner of the screen and navigate to **Assay Management > Standard Curve**.
2. Choose the standard curve to be removed.

3. Click **Delete Curve** from the Page Action bar.

    a. Click **Yes** to confirm the deletion of the standard curve.

Reports

Create a Report

NOTE: The report options are only available when SYNCT™ Software is used to generate the standard curve parameters. If the standard curve was created by manually entering the curve parameters, then the report options are not available.

1. Click ▤ in the upper left-hand corner of the screen and navigate to **Assay Management > Standard Curve**.
2. Choose the standard curve.
3. Click **Create Reports** from the Page Action bar. The **Select Folder** window displays.

    a. Choose the location under **Devices**.

    b. Choose the folder under **Folders**.

    c. Click **OK**.

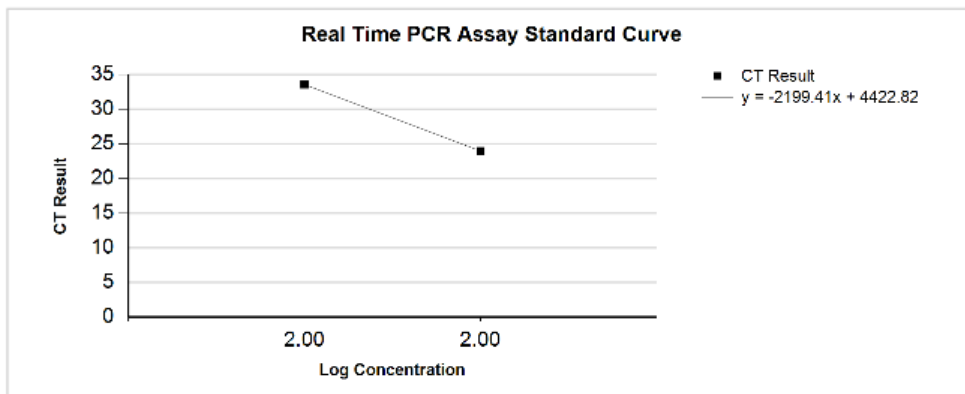   d. Click **OK** in the **Messages** dialog box to confirm the creation of the report.

Figure 1: Standard Curve Report

Luminex.

Curve Name:	Test		**Slope:**	-2.20E+003
Assay:	EBV 600 v3		**Intercept:**	4.42E+003
Test Name:	EBV		**R²:**	1
Auto Apply:	No		**Units:**	copies/mL

Standard Curve

Standard Name	Concentration	Log Concentration	CT Result
Test 1	1.00E+002	2.00	24.00
all	9.90E+001	2.00	33.60

Real Time PCR Assay Standard Curve

■ CT Result
— y = -2199.41x + 4422.82

Standard Samples Details

Standard Name	Sample Name	Run Date	CT Value
Test 1	EDX EBV Panel 5	5/9/2018 7:09:26 PM	24.0
all	EDX EBV Panel 4	5/9/2018 7:09:26 PM	27.7
	EDX EBV Panel 3	5/9/2018 7:09:26 PM	31.5
	EDX EBV Panel 2	5/9/2018 7:09:26 PM	34.9
	EDX EBV Panel 1	5/9/2018 7:09:26 PM	40.3

View Standard Curve Report

The Standard Curve Report displays the curve parameters, a graphical plot representation, and a list of the sample details for each standard.

NOTE: The report options are only available when SYNCT™ Software is used to generate the standard curve parameters. If the standard curve was created by manually entering the curve parameters, then the report options are not available.

1. Click ☰ in the upper left-hand corner of the screen and navigate to **Assay Management > Standard Curve**.
2. Choose the standard curve.

3. Click **View Report** from the Page Action bar. The **Curve Report** displays. You can either print or export the report.

- To print the report, click **Print Report**.
- To export the report, click **Export Report.** The **Export File** window displays**.**

    i. Choose the location under **Devices**.

    ii. Choose the **Files** for the export.

    iii. Click **OK**.

4. Click the **X** in the upper right-hand corner of the **Curve Report** to close the report.

Customize the Report Headers

To customize the report headers, complete the following:

1. Click ☰ in the upper left-hand corner of the screen and navigate to **Administration > Lab/Site Information**.
2. Enter **Line 1**, **Line 2**, and **Line 3** with the desired report headers.
3. Click in the gray box under **Click the Icon below to select a custom report logo.** to choose a logo to add to the report header. The **Import File** window displays.

   NOTE: Do NOT double click. SYNCT™ Software requires one click when navigating to the correct file location.

   a. Choose the location of the logo under **Devices**.

   b. Choose the logo file under **Files**.

   c. Click **OK**.

      NOTE: The information entered is automatically saved.