User Guide for Ella and Simple Plex 4.1 Software

Ella

Immunoassay Platform for Protein Quantification

bio-techne® | protein simple

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User Guide for Ella and Simple Plex 4.1 Software

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ProteinSimple Contact Information

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Scope

For the proper operation of the system and/or all parts thereof, the instructions in this manual must be strictly and explicitly followed by experienced personnel. All of the contents of this guide must be fully read and understood prior to operating the system or any parts thereof. Failure to completely read and fully understand and follow all of the contents of this guide prior to operating the system or parts thereof may result in damage to the equipment or parts thereof and injury to any person operating the same.

Ella User Guide

Chapter 3: Running Ella Cartridges

Chapter 4: Data Analysis

Chapter 5: Maintaining Ella

Chapter 6: 21 CFR Part 11

Appendix A

Appendix B

Appendix C

Appendix D

Appendix E

Chapter 1: **Meet Ella**

Chapter Overview
- Function/Intended Use
- Specifications
- Acquiring Data
- Viewing Ella System Information
- Cautions and Warnings
- Moving Ella
- Interconnections: Ella to Computer
- Contacting Customer Service

Function/Intended Use

Ella™ is a fully automated cartridge-based system that enables researchers to measure biomarkers in multiple sample types. Ella, together with microfluidic technology (Simple Plex™ cartridges), allow for single analyte measurements, the measurement of multiple analytes in parallel (multi-analyte), and also multiplexed measurements. Researchers can also configure Simple Plex cartridges to be unique to their own research.

Using Ella you can:

- Automatically execute an immunoassay protocol
- Automatically acquire and process data
- View and analyze fluorescence and concentration data on a per analyte, per sample basis
- Extract and save fluorescence and concentration information for application-specific analysis

Specifications

This section describes Ella's specifications, including environmental conditions, electrical ratings, physical conditions, laser classification, and external fusing.

TABLE 1-1. Specifications.

Environmental Conditions	For Indoor Use Only Altitude up to 2000 m (6600 ft) Temperature: 18° to 30° C (64° to 86° F) Humidity: 15 to 80% RH, non-condensing Rated Pollution Degree: Degree 2
Electrical Ratings	100-240 V(AC), 300 VA, 45/65 Hz, Class I Installation Category (Over Voltage) II *NOTE: Electrical values listed are nominal.*
Electrical Test Specifications	CB Scheme: IEC 61010-1:2010 Supplemented by IEC 60825-1:2014 TÜV SÜD "CUE" Scheme: CAN/CSA-C22.2 No. 61010-1:2012 UL 61010-1:2012/R:2019-07 EN 61010-1:2012/R:2019-07 EN 60825-1:2014

Physical Conditions	Overall dimensions: 37 cm (w) x 54 cm (d) x 26 cm (h) 14.6 in (w) x 21.3 in (d) x 10.2 in (h) Weight: 18.2 kg (40.1 lb)
External Fusing	Main fuse (appliance inlet): 4 A, 250 V; IEC 60127 rated as T4AL 250 V
Laser Test Specifications	Class 1 Laser Product according to IEC 60825-1:2014 and EN 60825-1:2014 Complies with FDA performance standards for laser products 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

Acquiring Data

The steps involved in acquiring data using Ella are:

1. Initializing Ella
2. Loading a Simple Plex cartridge containing samples and buffer
3. Setting up and starting a run

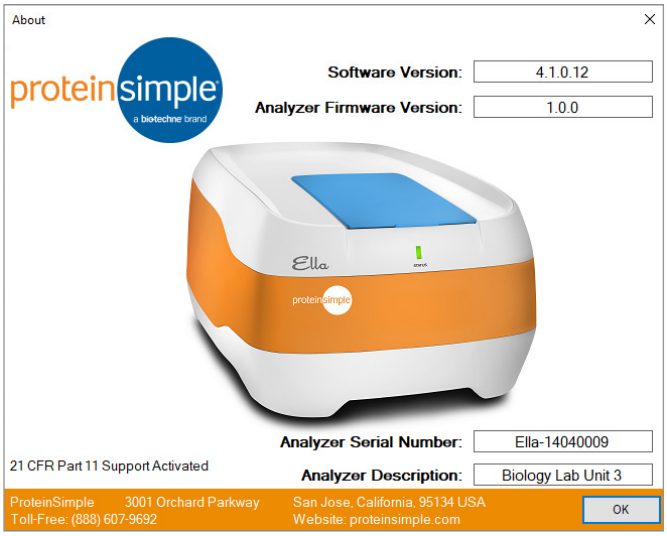
Viewing Ella System Information

In the Simple Plex Runner software interface, you can view current information about Ella including:

- Serial number and firmware version
- Software version information
- ProteinSimple contact information

To view Ella's system information, from the Simple Plex Runner software interface: Click *Help > About*. The About screen will appear as seen in FIgure 1-1.

FIGURE 1-1. Simple Plex Runner About screen.



Cautions and Warnings

The following sections describe the safety precautions you should observe when using Ella.
These include precautions for:

- General safety
- Electrical safety
- Laser light safety

General Safety Precautions

CAUTION: Ella's operator should be trained by qualified personnel on the correct operation of the instrument, and be aware of the safety issues. Heavy lifting can cause injury. This product requires a two person lift. Use proper lifting techniques.

L'opérateur d'Ella doit être formé par un personnel sachant bien faire fonctionner l'instrument, et doit être au courant des problèmes de sécurité qui sont impliqués.

Electrical Safety Precautions

This section describes the electrical safety precautions for Ella's electrical connections and fuse, as well as high voltage hazards.

Electrical Connections

Plug Ella into a grounded circuit capable of delivering at least:

- 15 amps for 100-volt to 120-volt power source
- 12 amps for 200-volt to 240-volt power source

See the rating label on Ella for more information.

Fuse

The primary input fuse holder is on the right side of the back of Ella and contains one 4A, 250V slow-blow fuse. The fuse holder is designed to accept a 5 mm x 20 mm fuse. Replacement fuse specification should meet the IEC 60127 and be rated as T4AL 250V.

CAUTION: Before replacing the fuse, turn Ella off and disconnect the power cord. If a fuse often requires replacement, Ella could have an electrical problem. Do not use Ella. You could expose yourself to electrical shock. Contact ProteinSimple Technical support for assistance.

Avant de remplacer le fusible, éteignez Ella et débranchez le câble d'alimentation. S'il faut souvent remplacer un fusible, il se pourrait qu'Ella ait un problème électrique. Ne l'utilisez pas. Vous risquez de vous électrocuter. Contactez l'assistance technique de ProteinSimple pour obtenir de l'aide.

High-Voltage Hazard and Precautions

Inside Ella, the computer and monitor are high-voltage electronics. See the computer and monitor precautions before opening the computer or monitor.

CAUTION: Do not remove Ella's main cover; there are no user serviceable components inside and you may be exposed to high voltage.

Ne retirez pas le cache principal d'Ella; il n'y a aucun composant à l'intérieur que l'utilisateur puisse réparer et vous prenez le risque de vous exposer à une tension élevée.

Laser Light Safety Precautions

CAUTION: Using controls, making adjustments, or performing procedures other than those specified herein may result in hazardous laser light exposure.

L'utilisation des commandes, la réalisation des réglages ou l'exécution des procédures autres que ceux spécifiés dans les présentes pourraient entrainer une exposition dangereuse à la lumière laser.

Ella is a Class 1 laser instrument that houses a Class 3B laser that operates at 640 nm wavelength. Under the specified operating procedures, Ella does not allow operator exposure to laser light. The laser, with power up to 40mW, is accessible in Ella's interior.

CAUTION: Do not attempt to gain access to Ella's interior through any opening. Exposure to laser light can cause injury. For example, viewing the laser light directly can cause blindness.

Ne tentez pas d'entrer dans Ella par son ouverture. L'exposition à la lumière laser peut causer des lésions. Par exemple, regarder directement la lumière laser peut rendre aveugle.

CAUTION: Use of controls or adjustments, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.

L'utilisation des commandes, la réalisation des réglages ou l'exécution des procédures autres que ceux spécifiés dans les présentes pourraient entrainer une exposition à des radiations dangereuses.

Please observe the following precautions:

Do not remove Ella's main cover. There are no user-serviceable components inside and you may be exposed to laser light.

Do not continue to use Ella if the main cover or cartridge lid becomes damaged and is no longer light-tight. Contact ProteinSimple immediately to arrange for repair.

Caution Markings

Table 1-2 defines the caution markings that appear on Ella.

TABLE 1-2. Label and symbol descriptions.

Symbol	Description
	**CAUTION.** Refer to the accompanying documentation. Reportez-vous à la documentation d'accompagnement.
	NRTL approval mark. Electrical safety approval to UL61010-1:2012; EN61010-1:2010; CAN/CSA C22.2 61010-1:2012.
	The manufacturer's assurance that the product meets the essential requirements of all relevant EU directives.
	Separate collection is necessary for electrical and electronics equipment. Please contact ProteinSimple for disposal instructions.

Moving Ella

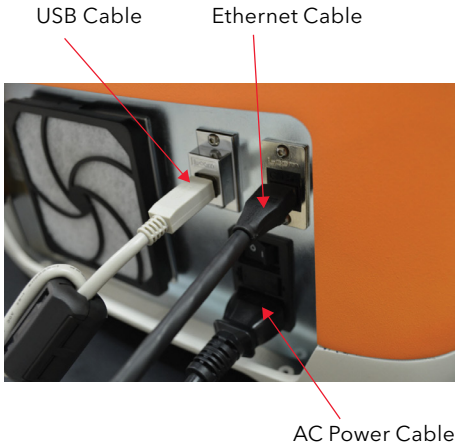
Ella is a sensitive optical instrument and can be damaged if moved improperly. Dropping may result in damage to the instrument. Always power Ella down prior to moving her. See "Preparing Ella for Shipment" instructions on page 39 for guidance on preparing Ella for a move.

Interconnections: Ella to Computer

NOTE: Only one Ella instrument can be connected and controlled per PC or laptop. Multiple instruments cannot be connected to the same PC or laptop

1. AC power cable
   This is used to supply AC power to Ella. The AC power cable shall have IEC 320 female connector on one end (Ella connection) and a country specific male plug on the other end. Power cables are to be UL listed and CSA certified with amp rating that meets the electrical specification of Ella.
2. Ethernet cable (black)
   This is for communication with the high-speed camera inside the instrument.
3. USB cable
   This is for communication with all other capabilities of the instrument.

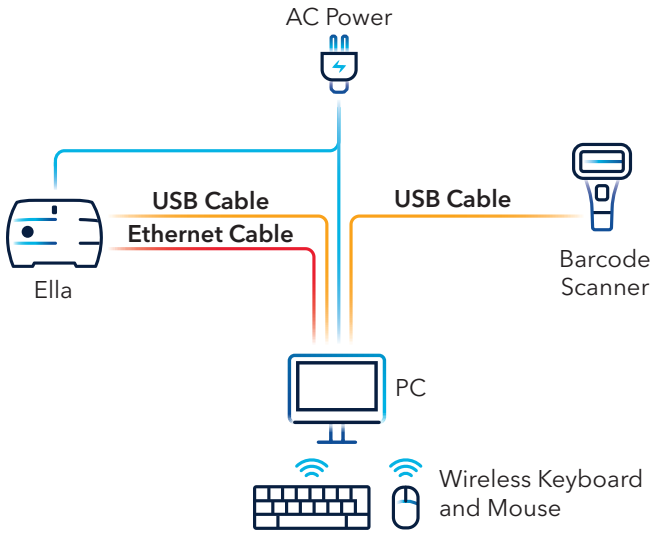
FIGURE 1-2. Ella connections.



Ella System Interconnections

Figure 1-3 is a high-level overview of the interconnections between Ella, the PC, monitor, keyboard and barcode scanner. Refer to the specific setup instructions for your Ella, PC, or laptop.

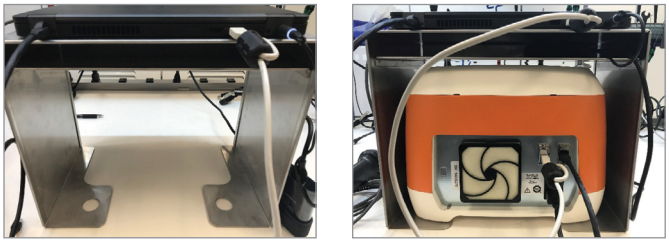
FIGURE 1-3. Ella connection to PC as well as supporting peripherals.



Ella Laptop Stand Setup

To set Ella up with a laptop computer and stand please refer to Figure 1-4. The laptop stand allows the computer to sit directly on top of Ella. The base of the stand has cutouts for Ella's back feet.

FIGURE 1-4. Setting up the laptop stand with Ella.



Contacting Customer Service

For customer support, technical support, or ordering information, contact ProteinSimple using the following information.

Customer Service

Telephone 1-408-510-5500, option 1
1-888-607-9692, option 1
(toll free, US and Canada only)

Fax 1-408-510-5599

E-mail techsupport@bio-techne.com

Web www.bio-techne.com/brands/proteinsimple

Address ProteinSimple
3001 Orchard Parkway
San Jose, CA 95134
USA

Technical Support

Telephone 1-408-510-5500
1-888-607-9692
(toll free, US and Canada only)

E-mail techsupport@bio-techne.com

Chapter 2: **Start Ella**

Chapter Overview
- Introduction
- Ella System Components
- Starting and Shutting Down Ella

Introduction

Ella is a fully automated cartridge-based system that allows you to perform single analyte, multianalyte and multiplexed immunoassays with the specificity of a traditional single-plex ELISA (enzyme-linked immunosorbent assay).

Using Ella you can:

- Automatically execute an immunoassay protocol
- Automatically acquire and process intensity data
- View and analyze intensity and concentration data
- Extract and save intensity and concentration information for application-specific analysis

Ella System Components

Ella is comprised of five main components. The Ella instrument, Simple Plex cartridges, a bar code scanner, a personal computer with dedicated software, and a Verification Cartridge.

FIGURE 2-1. Photograph of Ella system components.

Ella

A main component of the Ella system is a bench top analyzer with no on-board fluidics which significantly cuts down on waste and required preventive maintenance. Designed with a "load and go" philosophy in mind, Ella controls the microfluidic assay by precisely manipulating volumes, flow rates, and flow patterns without human intervention. Following the assay portion of a run, Ella automatically performs fluorescence scanning, raw data processing, and calculates RFU (relative fluorescence units) and concentrations on a per analyte, per sample basis.

Simple Plex Cartridges and Assays

The ready-to-use cartridges are available in multiple validated formats including, single plex, multi-analyte, and multiplex (see Figure 2-2). The cartridge is developed with a panel unique to your research to allow you to scan the barcode, input your samples and buffer into the cartridge, place the cartridge in Ella's cartridge holder, and run the cartridge with the Simple Plex Runner GUI. The Ella platform also accommodates 48-Digoxigenin cartridges that leverage user-defined reagents for custom assay development.

Each cartridge has many sample inlets. Each sample inlet has up to 4 dedicated channels. A single channel contains two or three Glass Nano-Reactors (GNR), depending on the cartridge configuration, that are functionalized with capture antibody, so you obtain two or three reportable results for each sample's analyte. The GNR contains the immunoassay, and is based on R&D Systems reagents to ensure high quality and reproducible sensitivity. The collection of GNRs in a given channel, in a given sample inlet, on a given cartridge are the basis of the set of measurements produced when running a Simple Plex Cartridge.

FIGURE 2-2. Cartridges that run in Ella.

Bar Code Scanner

The Ella system includes a general purpose hand-held 2D imager that is capable of scanning both 1D and 2D barcodes omni-directionally. Every cartridge kit shipped from ProteinSimple is labeled with a data-matrix 2D barcode that contains all relevant cartridge kit data including:

- Lot information
- Biomarker panel information
- Cartridge configuration information

Each cartridge run begins with scanning the cartridge kit barcode so as to provide the user with all the salient cartridge kit information, and the software with the necessary data to perform the cartridge run and raw data processing.

PC and Simple Plex Software

The PC and Simple Plex software included with Ella allow you to control the system. Simple Plex software is comprised of two GUI (graphical user interface) applications:

- **Simple Plex Runner**: is for configuring and running cartridges.
- **Simple Plex Explorer**: is for organizing, analyzing, and viewing your data.

Verification Cartridge

The Verification Cartridge is provided as a reusable reference necessary for performing an instrument Self Test.
See "Ella Self Test" on page 35 for details.

Starting and Shutting Down Ella

Follow the procedures in this section which describe how to position, start up and shut down Ella.

NOTE: When positioning Ella, care should be taken so that the back surface will have adequate clearance such that an operator's hand can access the power switch and power supply cable (see Figure 2-3). With operator facing the front of Ella, the power switch and power supply cable are located at the back panel, lower left side.

FIGURE 2-3. Ella Power Switch

Starting the System

To start Ella:

1. Power up Ella.
2. Power up Ella's computer and monitor.
3. Login to PC and start the Simple Plex Runner software

NOTE: Systems are pre-set with local admin account credentials. *User Id*: Ella *Password*: Ella

4. After power up of Ella the status light will illuminate (Figure 2-4). See Table 2-1 for a description of the status light.

FIGURE 2-4. Ella Status Light

Powering Up Ella

1. Press the power switch on Ella's back panel (see Figure 2-3).

Powering Up Ella's Computer

1. Press power on the computer.
2. Log in to Windows®.

Starting the Simple Plex Runner Program

1. Wait until Ella's status light indicates ready. If the status light indicates something other than ready, an error may appear when you start the software.
2. From the Windows Start menu, select *Programs > Simple Plex> Simple Plex Runner*, or double-click the *Simple Plex Runner icon* on the desktop.

TABLE 2-1. Ella Status Light Indications

Light Color	Status
Green	Ella is powered and ready for use
Blue	Ella is running a cartridge.
Red Blinking	An error has occurred (Ella may optionally emit an audible alarm)

The Simple Plex Runner application opens on the computer desktop

Shutting Down the System

To shut down Ella:

1. Close the Simple Plex Runner application by doing one of the following:
   A. Click File > Exit on the menu
   B. Close the Simple Plex Runner application. (Click X in the window's upper-right corner)
2. Shut down Ella's computer
3. Turn Ella off by pressing the power switch on the back panel.

Chapter 3: **Running Ella Cartridges**

Chapter Overview

- Introduction
- Barcode Labels
- Prepare Samples and Reagents
- Prepare Cartridge
- Configure and Run with Simple Plex Runner

Introduction

To run a cartridge you'll need:

- Your samples
- Your barcode labeled Cartridge Kit (Figure 3-1) that contains:
  1. Wash Buffer A
  2. Sample Diluent component(s)
  3. Cartridge

The typical run sequence is:

1. Prepare reagents.
2. Prepare cartridge
3. Configure and run with Simple Plex Runner application.

FIGURE 3-1. Cartridge Kit

Boxed Kit

Wash Buffer and Sample Diluent

Cartridge

Barcode Labels

Kit Label

Found on the outside of the cartridge bag, highlighted in Figure 3-2.

FIGURE 3-2. Kit Barcode Label

Cartridge Label

The cartridge barcode label (see Figure 3-3) is located directly on the cartridge and is used to track the cartridge to the Kit. This cartridge barcode label is used as a confirmation that the cartridge being run matches the Kit. The default setting of requiring a cartridge to Kit confirmation can be disabled in Runner Settings.

Cartridge ID barcodes are found on the cartridge face near the bottom edge as shown in Figure 3-3.

FIGURE 3-3. Cartridge ID Barcodes

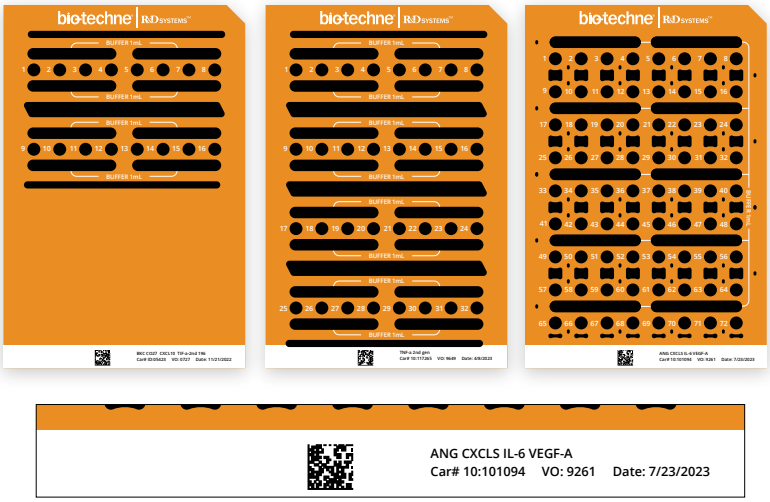


FIGURE 3-3. Cartridge ID Barcodes: 16x4 (top left), 32x4 (top center), 72x1 (top right). Detailed zoom view shows cartridge details and barcode (bottom).

Prepare Samples and Reagents

Plasma (EDTA or Heparin) and Serum Samples

Serum and plasma samples prepared with the protocol recommended on the assay specification sheet, and not containing visible particulate matter, do not require additional centrifugation before use in a Simple Plex assay.

For serum and plasma samples containing visible particulate matter it is recommended to remove particulates by centrifugation and dilute according to the instructions in the Assay Specification Sheets. The method below is designed to preserve sample but may by adjusted as needed based on sample availability and particulate content. The method below simulates the sample preparation for the 1:2 minimum required dilution (MRD) used in most Simple Plex assays. For higher dilution factors serial dilution may be necessary for accuracy.

Centrifugation for Serum and Plasma Samples

1. Aliquot 35 µL of serum or plasma into a microcentrifuge tube.
2. Centrifuge at 8,000-10,000 g for a minimum of 4 minutes.
3. Aliquot 30 µL of the appropriate sample diluent into another microcentrifuge tube.
4. Once centrifugation is complete, remove 30 µL sample taking care not to disturb the pellet at the bottom.
5. Add the 30 µL of centrifuged sample to the 30 µL of aliquoted diluent and mix thoroughly.
6. Pipette 50 µL of the 1:2 diluted sample into the specified cartridge inlet.

Other Specimen Types

Optimal dilutions should be determined by the end user.

Custom Assays

When working with the 48-Digoxigenin cartridge it is necessary to conjugate affinity reagents with digoxigenin and biotin prior to the assay.

Prepare Cartridge

NOTE: When handling cartridges, it is recommended that gloves be worn at all times and the plastic backer be removed only immediately to placing the cartridge into Ella.

Procedure

1. Scan the kit barcode on the outside of the cartridge vacuum bag.
2. Remove the cartridge from the vacuum bag.
3. Scan the cartridge barcode.
   NOTE: If the cartridge is past its expiration date a warning will be displayed. This does not prohibit the cartridge from being run.
4. Pipette volumes into the cartridge in the following order:
   A. Wash buffer as described on your cartridge insert.
   B. Diluted sample matching your cartridge insert.
5. Peel off the protective lining from the bottom of the cartridge.
6. Place the cartridge into Ella's cartridge holder.
   NOTE: After removing the lining, use caution to not touch the bottom of the cartridge or place it on any surface.
7. Close the cartridge clamp and lid.

The sequence for preparing a cartridge is illustrated in Figure 3-4 parts A and B

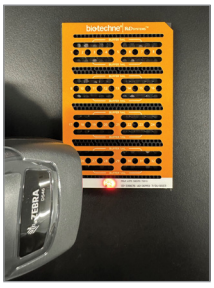
FIGURE 3-4. Step-By-Step Visual Guide to Preparing a Cartridge to Run in Ella

A. Prepare the Cartridge

1. Cartridge in protective casing.

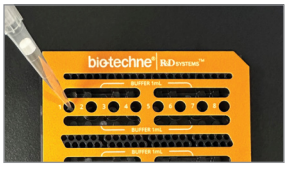
2. Scanning the barcode.

3. Removing cartridge protective casing

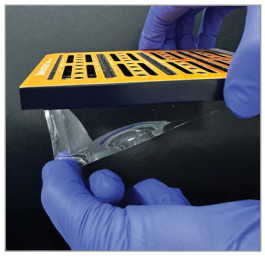


4. Scanning cartridge barcode for confirmation (optional).

5. Loading buffer.



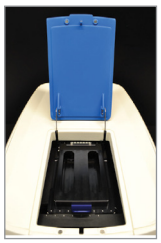
6. Loading sample.



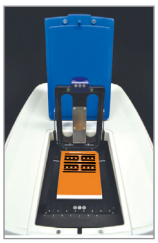
7. Removing protective lining/backing.

FIGURE 3-4. Step-By-Step Visual Guide to Preparing a Cartridge to Run in Ella

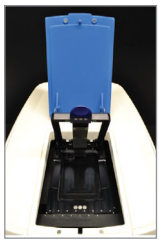
B. Load Cartridge into Ella



8. Ella open door.

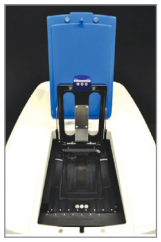


11. Loading cartridge in Ella.

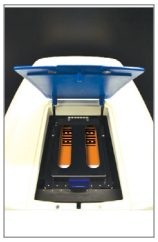


9. Opening cartridge clamp.

12. Closing cartridge clamp.



10. Ella open door and clamp.



13. Closing door.

Configure and Run with Simple Plex Runner

Introduction

The Simple Plex Runner application is a graphical user interface (GUI) application that follows a 'wizard' like motif in that it guides you through the process of:

1. Configuring your run (during this phase you can use the Next and Back buttons until you are ready).

    A. Scanning your kit and cartridge barcodes.
    B. Specifying where you want to store the kit results.
    C. Assigning your samples to the cartridge inlets.
    D. Confirming your run setup.

2. Observing run progress (from this point forward the process is automatic).

    A. Assay protocol progress.
    B. Fluorescence scan progress.

3. Viewing and exporting kit results.

Starting the Simple Plex Runner Program

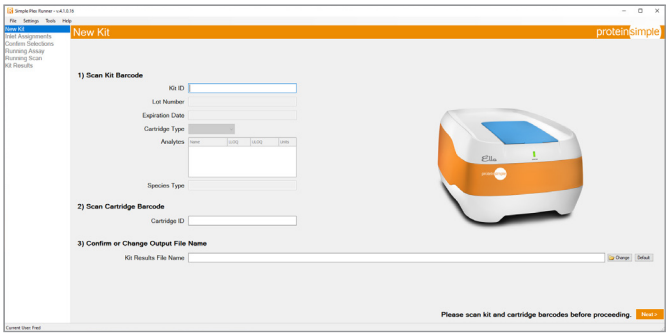
1. Wait until Ella's status light indicates ready. If the status light indicates something other than ready, an error may appear when you start the software.
2. From the Windows Start menu, select *Programs > Simple Plex > Simple Plex Runner*, or double-click the *Simple Plex Runner* icon on the desktop.

Simple Plex Runner application icon

The Simple Plex Runner application opens on the computer desktop as shown in Figure 3-5.

As highlighted in Figure 3-5, on each screen of the Simple Plex Runner application the run sequence is displayed in the left list box and can be used as a reference as you progress through a cartridge run.

FIGURE 3-5. New kit screen.



Configuring Your Run

Kit Barcode Screen

When displayed, the New Kit screen will set the cursor focus in the Kit ID text box. At this point, use the barcode scanner to scan the kit barcode. The kit barcode will be parsed and the kit information will be displayed on the screen.

The most relevant kit information is:

- **Kit ID**. The unique factory serial number of the kit. The Kit ID is utilized for the kit results filename as KitXXXXXX.cydat where XXXXXX is the zero padded Kit ID. For your work with Ella, it is recommended that the Kit ID be used as the primary identifier for your kit results data.
- **Analytes**. The analytes table lists the current panel of biomarkers.
- **Cartridge ID**. The Cartridge ID is obtained by scanning the barcode on the cartridge. This is optionally required as a confirmation that the cartridge matches the Kit scanned.
- **Species Type**. Specifies the analyte species for which the kit has been validated.

The Kit Results File Name is the folder location where the kit run results file (a *.cydat file) will be saved. The Simple Plex Explorer application is for subsequently working with *.cydat files after your run.

NOTE: A valid kit barcode is required to execute a run.

Inlet Assignments Screen

Use the screen shown in Figure 3-6 to provide detailed sample information for each of the cartridge sample inlets. The mouse and keyboard functionality below can be used to select and edit multiple inlets at once. You can also use the buttons below the inlets list to make selections prior to editing the sample data.

Mouse and keyboard functionality:

Left click	Select row and cell.
Shift + left click	Select all rows between current selection and clicked row.
Ctrl + left click	Select clicked row in addition to already selected rows.
Tab	Advance to adjacent cell right. Wraps to next row if on last column.
Shift + tab	Advance to adjacent cell left. Wraps to next row if on last column.
Arrow keys	Moves left, right, up or down to next adjacent cell.
Enter	Completes active data entry.
Escape	Undo active data entry.

Defining values: Values can be assigned to rows in unison by selecting all the rows of interest and then assigning a value to a field. All rows selected will be updated with the same value.

Sample Type: Once a sample type has been assigned to a row, the relevant information for that type of sample can be edited. Information that is not relevant to a specific sample type will be greyed out and populated with N/A.

Defining standards: Once samples have been defined as belonging to a Standard Curve under the sample type field, they can then have their values defined using the ***Setup Standard Curve button*** at the bottom of the screen.

- Curves can be defined by defining a Top Concentration and then specifying the dilution factor in the field marked Divisor.
- All the analytes can be defined simultaneously by selecting the All Analytes Identical button or each can be defined individually with unique top concentrations and divisors by deselecting this option.
- Once this is complete the concentrations will be displayed on the Inlet Assignment screen.

Importing data from Kit Results file: If your inlet assignments will be similar to a previously run kit, you can click Import and From Kit Results File. Then select the CYDAT file, and specify only the particular columns of the previous layout you want to use for the present one by utilizing the check boxes as shown in Figure 3-8.

Automatic importing of data using default cartridge Layouts: In Simple Plex Runner another option for setting inlet assignments is automatic importing. A Kit Results file can be specified in application settings to be used as the initial layout. There are multiple settings based on cartridge type and number of analytes. If set, when a cartridge's kit barcode is initially scanned the inlet assignments will automatically be populated with the contents of the relevant file. In this case all columns are imported. See the DefaultCartridgeLayoutFile16x1 to DefaultCartridgeLayoutFile72x2 application settings for more information.

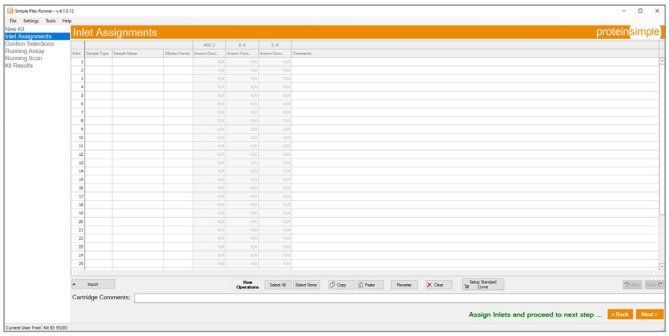
TABLE 3-1. Sample data descriptions.

Field	Applies to Cartridge	Description
Sample Type	All	Unknown - sample with an unknown concentration Standard - sample with a known concentration from which to build a standard curve Control - sample with known concentration of recombinant protein Spike - a biological sample with a known amount of recombinant protein added
Sample Name	All	An alphanumeric string of your choosing.
Dilution Factor	All	Used to compute concentration from RFU. A dilution factor of 1 is considered neat. A dilution factor of 2 is 1 part sample to 1 part diluent.
Comments	All	Your comments concerning that sample.
Known Conc.	All	The known concentration of the sample. A single entry can apply to all the analytes, or you can enter a value for each analyte.
Analyte Name	48-Digoxigenin	The name or identifier for the analyte to be measured.
Units	48-Digoxigenin	The units of concentration used to describe the analyte measured.
Capture Name	48-Digoxigenin	The name or identifier for the capture reagent used in the reaction.
Capture Conc.	48-Digoxigenin	The units of concentration used to describe the capture reagent in the reaction.
Detect Name	48-Digoxigenin	The name or identifier for the detect reagent used in the reaction.
Detect Conc.	48-Digoxigenin	The units of concentration used to describe the detect reagent in the reaction.

Importing data from excel:

- If you have your sample information in an Excel worksheet, you can select the target inlets for the data in Simple Plex Runner, then select the matching number of rows in your worksheet. Next, drag and drop the worksheet selection onto the runner selected inlets.
- Data will be imported starting from the Sample Name field and continuing with subsequent columns. The information in Excel must match the column progression in the Inlet Assignment screen.

FIGURE 3-6. Inlet Assignment screen.



Copy/paste functionality: Information for entire rows can be copied and pasted to replicate those setting for other rows using the Copy and Paste buttons at the bottom of the screen. While focus is in the Inlet column, the copy and paste functionality can also be accessed by using *Ctrl + C* and *Ctrl + V*.

Undo functionality:

- Undo will roll back the most recent action taken in the Inlet Assignment fields. Redo will re-apply the most recent action that was undone in the Inlet Assignment fields.

Entering data on this screen is entirely optional. In other words, you can proceed with a run without entering any data at this point in your run (although a warning will be displayed, see Figure 3-7). With or without sample data, the run will execute the full protocol, scan the entire cartridge, and produce RFU results. You will always have the option of editing the sample data after the run is complete and recalculating concentrations for a given run via use of Simple Plex Explorer.

If all of your selected inlets have a sample type of Standard, the *Setup Std. Curve button* will become enabled. Clicking the Setup Std. Curve button will display the dialog shown in Figure 3-9. With this dialog you can easily setup dilution series concentrations. Click *OK* to place the resulting concentrations into the originally selected inlets and close the dialog.

FIGURE 3-7. Incomplete inlet(s) warning.

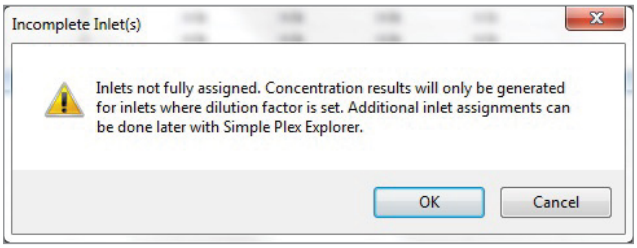


FIGURE 3-8. Import from Kit Results screen.

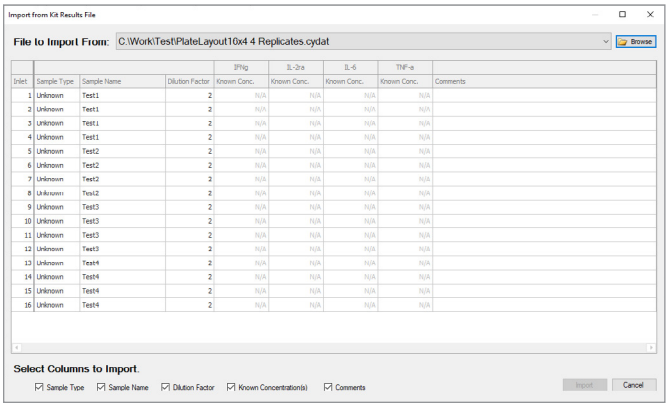
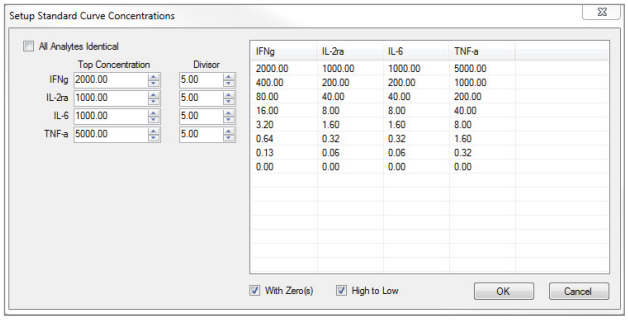


FIGURE 3-9. Compute Std. Curve dialog.



When you have completed your inlet assignments and clicked the ***Next button***, the Confirm Selections screen will be displayed (Figure 3-10). You may now review your inputs for accuracy, and optionally export your prepared run to the clipboard as a tab delimited spreadsheet compatible string.

Clicking ***Start*** on the Confirm Selections screen will display a final confirmation prompt as shown in Figure 3-11.

NOTE: Once a run begins, reagents will be pumped from the inlets to the cartridge interior rendering the cartridge used. A cartridge is a consumable; only good for a single run.

FIGURE 3-10. Confirm Selections screen.

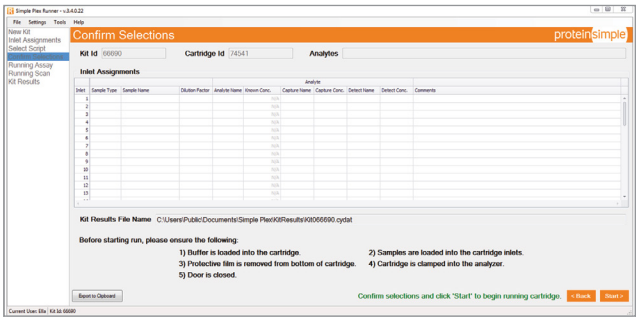


FIGURE 3-11. Run Confirmation dialog.

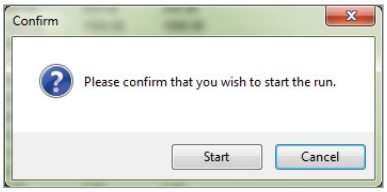
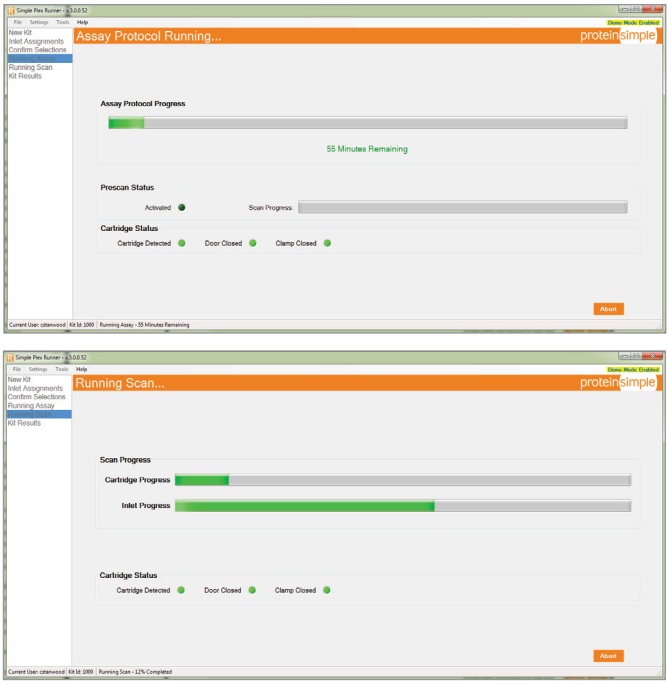


FIGURE 3-12. Running Assay screen (top) and Running Scan screen (bottom).



Observing Run Progress

There are two phases to a cartridge run. The first phase is the Assay phase, and the second is the Scanning phase. Each phase has a dedicated progress screen, respectively, as shown in Figure 3-12.

A run will require approximately 75 minutes. The majority of this time is the Assay phase during which the following sequence is followed:

1. Prime with buffer
2. Flow sample
3. Wash with buffer
4. Flow detect
5. Wash with buffer
6. Flow dye
7. Wash with buffer

In parallel with the Assay phase, Ella also performs a pre-scan that locates the exact scan locations and focus positions in preparation for running the scan in the second phase. When Ella completes the Assay phase the run will automatically proceed from the Assay phase to the Scanning phase and the screen will transition to the Running Scan screen.

During the Scanning phase of your run, Ella performs a fluorescence scan of each GNR-populated analyte channel for each sample inlet, and processes the raw scans into a set of RFU results. For example, if the cartridge has 16 sample inlets and a 4 analyte biomarker panel your run will produce 64 RFU results.

During your run you can opt to cancel the run by clicking the Abort button displayed on the Running Assay and Running Scan screens. If you opt to cancel you will be prompted to confirm that you wish to cancel your run and reminded that canceling is an irreversible option.

When Ella completes the Scanning phase, the run will conclude and the screen will transition to the screen shown in Figure 3-13, the Kit Results screen.

Viewing and Exporting Kit Results

Your run results (see Figure 3-13, Kit Results screen) are initially displayed in a dashboard style such that you can view every RFU/concentration for each GNR for each analyte in each sample inlet. If you opted to proceed with your run without providing complete sample data the results displayed will be RFUs only. In this case, you may subsequently use the Simple Plex Explorer application to complete the sample data and calculate concentrations from your runs RFU results.

Concentrations are calculated using the factory calibration curves provided in the cartridge kit barcode and entered into the software when you scanned the kit barcode while configuring your run. Using the Simple Plex Explorer application, you may subsequently build and utilize alternative calibration curves for calculating concentrations from RFU results.

Using the Export button allows you to export your results to the clipboard as a tab-delimited spreadsheet compatible string, a pdf file or a format compatible with your LIMS.

GNR Filtering (as discussed in GNR Filtering) is also available on the Kit Results Screen and any changes may subsequently be saved.

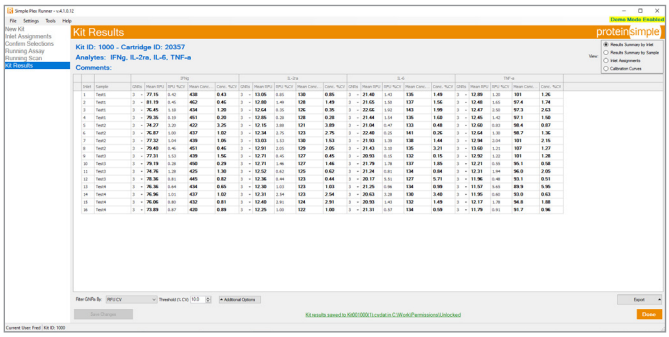
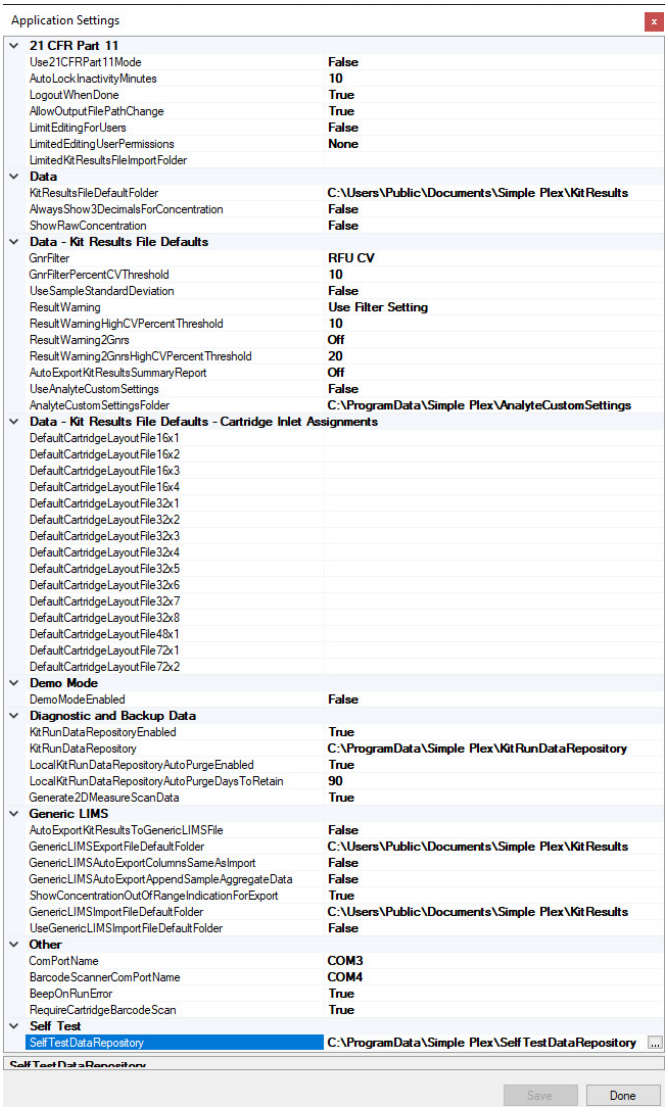


FIGURE 3-14. Simple Plex Runner Settings dialog.



Simple Plex Runner Settings

Clicking *Settings* > *Application* from the menu will display the Settings Dialog as shown in Figure 3-14. Clicking on a row in the settings dialog will display a detailed description of the selected item at the bottom of the dialog. These descriptions are provided in Table 3-2 for reference. If changes are made the Save button will be enabled.

Clicking *Settings* > *Analyzer* > *Description* from the menu will display a dialog box that can be used to rename the Ella instrument. The instrument name defined here is written to the instrument's on-board software and will persist even if the computer is changed. This name will be associated with all .cydat files produced by the instrument.

Clicking *Settings* > *Analytes* from the menu will display a dialog box for analyte settings (see Figure 3-15). To add an analyte to the table, select from the dropdown list and click the Add button. The dropdown list will automatically populate with recently scanned analytes. To see more choices scan your kit barcodes. Once added, a custom range can be specified by setting the LLOQ and ULOQ values. Units are shown but are not editable. Use 'Is Enabled' to turn custom settings for an individual analyte on or off.

NOTE: By default, this menu option will be disabled. This can be changed in application settings by setting UseAnalyteCustomSettings to true.

NOTE: When applying a custom range to a run, if the custom LLOQ is less than the factory value the factory value will be used. Likewise, if the custom ULOQ is greater than the factory value the factory value will be used.

FIGURE 3-15. Analyte settings dialog.

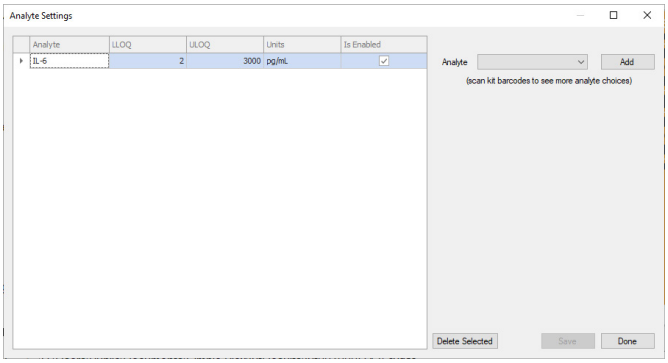


TABLE 3-2. Runner Settings.

Parameter	Description
Use21CFRPart11Mode	Determines whether or not to use 21 CFR Part 11 support (logins, audit trails, data encryption, etc.). 21 CFR Part 11 support must be activated for this setting to take effect.
AutoLockInactivityMinutes	Determines the length of a period of inactivity before the application screen automatically locks when in 21 CFR Part 11 mode. Set to ***0*** to disable this feature.
LogoutWhenDone	When true (default), the current user is logged out after ***Done*** is selected from the Kit Results panel. When false, the current user remains logged in and the application proceeds to the New Kit panel.
AllowOutputFilePathChange	When false, the kit results file name and location cannot be changed. This also applies to the generic LIMS export file (if enabled). This setting only applies when in 21 CFR Part 11 mode.
LimitEditingForUsers	When true, members of the Users group ability to edit kit results will be limited to permissions specified in the LimitedEditingUserPermissions setting. When false, members of the Users group will have full edit ability (default). This setting only applies when in 21 CFR Part 11 mode.
LimitedEditingPermissions	Specific permissions when LimitEditingForUsers is enabled. None indicates that no editing is allowed. This setting only applies when in 21 CFR Part 11 mode.
LimitedKitResultsFileImportFolder	The folder to use for kit results file imports when editing for Users is limited and the 'Allow Kit Results File Import From Folder' permission is enabled. This setting only applies when in 21 CFR Part 11 mode.
KitResultsFileDefaultFolder	The common directory in which to output the kit results file (*.cydat extension).
AlwaysShow3DecimalsForConcentration	Always show 3 decimals for concentration. The default is for the number of decimals displayed to be based on how many significant digits there are in the measurement. This setting also changes how concentration values are exported.

(continued on next page)

TABLE 3-2 Runner Settings. (continued)

Parameter	Description
ShowRawConcentration	Show the 'Raw Concentration' column in the 'Result Summary by Inlet' and 'Result Summary by Sample' data views. This setting also determines if the column is included in 'To Clipboard' and 'To PDF File' exports. 'Raw Concentration' is the measured concentration before adjusting for dilution factor.
GnrFilter	The filter used to select the resulting GNRs. ***None*** indicates select all GNRs found. RFU and Concentration CV performs a GNR outlier removal if the percent CV for all three GNRs is above the specified threshold.
GnrFilterPercentCVThreshold	The percent CV threshold used by ***GnrFilter***.
UseSampleStandardDeviation	Preference used for calculating percent CV. If checked, sample standard deviation is used. Otherwise, population standard deviation is used (the default).
ResultWarning	This setting applies to all cartridge types except 32x8 and 72x2. Determines if an analyte result should be shaded light pink in the ***Results Summary View*** when the relevant CV percent is greater than or equal to the specified threshold. If ***Use Filter Setting*** is selected, the applicable CV and threshold are determined from the ***GnrFilter*** and ***GnrFilterPercentCVThreshold*** settings. The default value is ***UseFilterSetting***.
ResultWarningHighCVPercentThreshold	The percent CV used by ***ResultWarning***. The default value is 10.
ResultWarning2Gnrs	This setting only applies to cartridge type 32x8 amd 72x2. Determined is an analyte result should be shaded light pink in the ***Results Summary View*** when the relevant CV percent is greater than or equal to the specified threshold. The default value if ***Off***.
ResultWarning2GnrsHighCVPercentThreshold	The percent CV used by ***ResultWarning2Gnrs***. The default value is 20.
AutoExportKitResultsSummaryReport	Determines whether to automatically export a kit results summary report at the end of a run and whenever the kit results file is saved. The location and name of the file will be the same as the kit results file (.cydat or .ecydat) except that the file extension will be changed to .pdf
UseAnalyteCustomSettings	Indicate if analyte custom settings should be applied (such as custom LLOQ/ULOQ ranges). Setting to true will also enable the 'Analytes' option in the settings menu and show additional column(s) in the 'New Kit' panel's analyte table.
AnalyteCustomSettingsFolder	The directory in which to store analyte custom settings files (*.cyanalyte).
DefaultCartridgeLayoutFile16x1 to DefaultCartridgeLayoutFile72x2	Specify a default layout for 16x1 to 72x2 cartridges to automatically import into inlet assignments. Leave empty to not automatically import a layout.
DemoModeEnable	Application will operate in demo mode and does not require a connected Ella system.
KitRunDataRepositoryEnabled	Determines if the Kit Run Data Repository (KRDR) is enabled. The KRDR includes all diagnostic run data for a kit as well as a backup of the kit results file. If disabled, kit result file recovery will not be possible.
KitRunDataRepository	The root directory in which to store all diagnostic run data for a kit as well as a backup of the kit results file. Folders are organized by date and then by kit ID with run time.
LocalKitRunDataRepositoryAuto-PurgeEnabled	Determines if older data in a local Kit Run Data Repository (KRDR) is automatically purged. Auto-purge functionality is not applied to a KRDR on a network drive or share.
LocalKitRunDataRepositoryAuto-PurgeDaysToRetain	Determines the number of days of data to retain if ***LocalKitRunDataRepositoryAutoPurgeEnabled*** is set to true. The default number of days to retain local Kit Run data is 90 days.
Generate2DMeasureScanData	Generates additional diagnostic data for measure scans. Will increase space used by the Kit Run Data Repository by as much as 25%. The default is true.
AutoExportKitResultsToGenericLIMSFile	Determines whether or not to automatically generate a generic LIMS export file at the end of the run.
GenericLIMSExportFileDefault-Folder	Default directory location in which to output the auto-generated generic LIMS export file (*.csv).
GenericLIMSAutoExportAppendSampleAggregateData	When true, sample aggregate data is appended to the end of the automatically generated LIMS export file.

(continued on next page)

TABLE 3-2 Runner Settings. (continued)

Parameter	Description
GenericLIMSAutoExportColumns-SameAsImport	Determines whether or not the automatically generated generic LIMS export file uses the same columns as the import file (if available). Otherwise the default format is used.
ShowConcentrationOutOfRange-IndicationForExport	When true, out of range concentration values for generic LIMS exports are shown as the dilution factor scaled LLOQ or ULOQ with a prefix of '<' or '>' (such as '<2.00' or '>5000'). Otherwise if false, out of range concentration values are left blank.
GenericLIMSImportFileDefault-Folder	Default directory location for choosing the generic LIMS import file (*.csv).
UseGenericLIMSImportFileDefault-Folder	Determines whether or not to use the default directory specified in the ***GenericLIMSImport-FileDefaultFolder***. If the default directory is not used then the directory will default to the most recent used.
ComPortName	Communication port to instrument.
BarcodeScannerComPortName	Communication port to barcode scanner.
BeepOnRunError	Indicates if Ella should beep when an error condition is encountered during a run to attract the attention of the user.
RequireCartridgeBarcodeScan	Requires the cartridge barcode to be scanned on New Kit panel.
SelfTestDataRepository	The root directory in which to store all self test data. Folders are organized by Ella number and then by test date and time.

The Data Repositories

Simple Plex Runner software is configured to store the data associated with every kit and self test run. The data is placed into data repositories that are organized by date and run.

Kit Run Data Repository (KRDR)

- Provide for backup/recovery of CYDATs for every kit run.
- Provide diagnostics data in the unlikely event of system issues.

Self Test Data Repository (STDR)

- Provides a retrievable history of all *Self Test* runs.
- Provides diagnostics data in the unlikely event of system issues.

The location of the repositories may be configured using the Simple Plex Runner application settings, and may be specified as a local drive or a network drive. The network drive option is useful because it may be included in regular network data backup, and if you have more than one Ella they can all be configured to use the same network repository which lends itself to Simple Plex data centralization. The KRDR capability may be enabled or disabled. If enabled and using a local drive configured to autopurge files older than a configurable number of days, this ensures the repository does not fill up a local drive with data.

Recovering a CYDAT

If you are using the KRDR and have misplaced or lost a CYDAT from a run, you may recover that Kit's CYDAT using the Recover Kit Results option located in Simple Plex Runner software under *File > Recover Kit Results*. Selecting this option will locate the specified Kit CYDAT in the repository and make a copy of it to the desired storage location.

Browsing/Retrieving the Self Tests

By selecting Self Test History located in Simple Plex Runner software under *Tools > Self Test History*, you can view a list of all Self Tests in the repository organized by Ella system and date. You also have the option to retrieve/save one or more Self Test Reports, and any Self Test's results details may be viewed.

Chapter 4: Data Analysis

Chapter Overview
- Introduction
- Starting the Simple Plex Explorer Programs
- GUI Features

Introduction

The Simple Plex Explorer application is used to work with your results. There are two file formats associated with Ella as presented in Table 4-1.

TABLE 4-1. Data File Types.

File	File Extension	Description
Kit	*.cydat	The run results file. Contains: • Kit meta data • Analyte panel data • Factory std. curves • RFU run results data/Individual GNRresults • User entered sample data • Calculated concentration data
Curve	*.cycurv	Stores a user constructed standard curve. • Curve fitting results • (Known Concentration, RFU) data set used for curve fitting

Using the Simple Plex Explorer application you can:

- Load one or more Kit/Curve files.
- Review Kit/Curve files individually and export to a spreadsheet compatible CSV (comma separated variables) file for further analysis.
- Edit individual Kit samples and calculate concentration results based on the new Kit sampledata.
- 'Save' or 'Save As' Kit/Curve files individually.
- Aggregate multiple kits for export into a CSV file for subsequent multiple run analysis.
- Build your own standard curve using presently loaded Kit/Curve files.
- Apply curves to kits in aggregate or discretely.
- Re-apply factory curves to a kit.

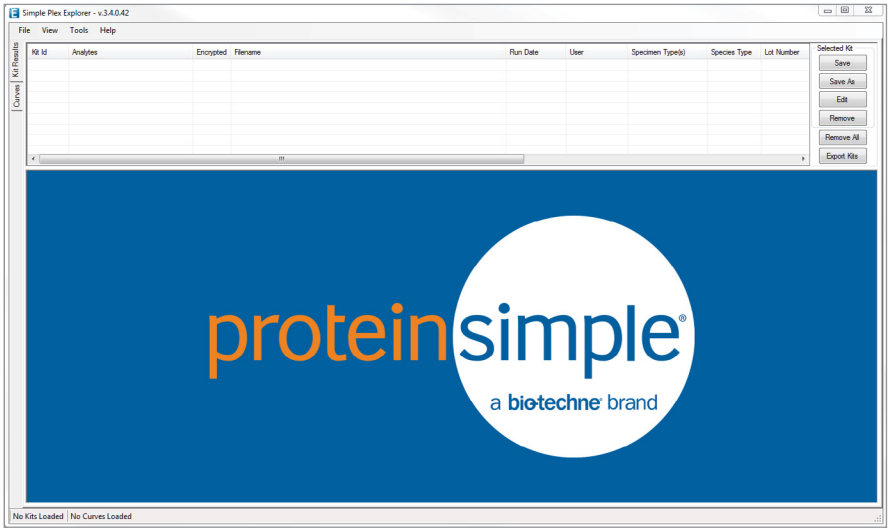
Starting the Simple Plex Explorer Program

1. From the Windows *Start* menu, select *Programs > Simple Plex > Simple Plex Explorer*, or double-click the *Simple Plex Explorer icon* on the desktop. The Simple Plex Explorer application opens on the computer desktop as shown at right.

The Simple Plex Explorer application icon

2. Load Kits and/or Curves you would like to review.

FIGURE 4-1. The Simple Plex Explorer screen at launch.



GUI Features

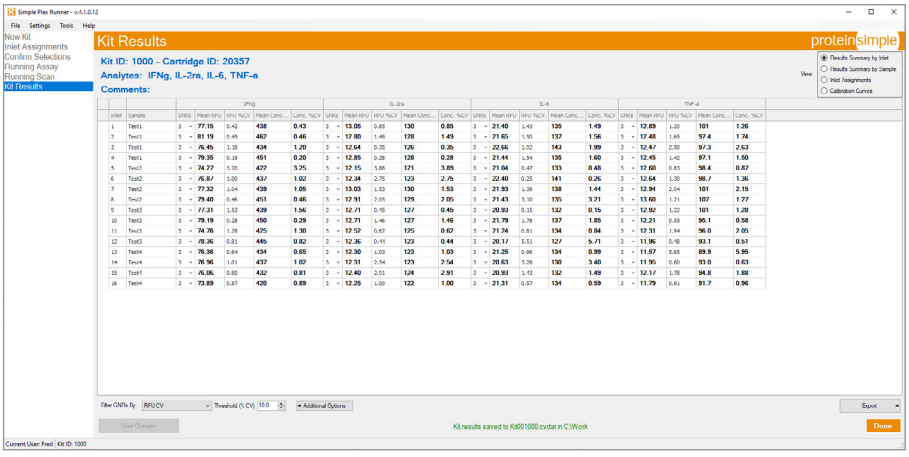
The main navigation features of the Simple Plex Explorer screen are:

- The menu bar in the upper left corner of the form.
- The Kits and Curves Tabs to toggle between the kit and curve views.
- Depending on selected view, the loaded Kits or Curves list at the top of the main panel.
- Buttons to perform actions directly to the right of the Kits or Curves list.
- A status strip in the lower left corner of the application form.
- A sub-panel below the Kits or Curves list that will provide the necessary GUI for the present activity.

Kit Results Tab

The functionality of the Kits tab as shown in Figure 4-2:

FIGURE 4-2. Kit Screen.



- It displays the details of the kit selected from the list.
- Results Summary can be displayed 'By Inlet' or 'By Sample'. For 'By Sample', inlet results are aggregated based on sample name.
- Change GNR Filtering or Standard Deviation preference.
- Review/select individual GNRs per channel.
- You can create a Kit Result Data Summary in pdf format using the ***Export button*** in the bottom right of the screen.
- You can export a spreadsheet compatible string containing kit data to the clipboard by selecting ***Export > To Clipboard***
- You can calculate concentration results from RFU results using the original factory calibration curve by clicking the ***Apply Factory Curves*** menu option, available by clicking the ***Additional Options button***.

GNR Filtering

As briefly described in the "Simple Plex Cartridges and Assays" section, each channel in the 72x1, 16x4, 32x4 and 48-Digoxigenin cartridges contain triplicate GNRs. The channels of the 32x8 and 72x2 cartridge contain four GNRs split between two different analytes which yields duplicate GNRs. When the assay completes, the channels are scanned and the resulting data is processed to produce RFU and concentration values for each located GNR. This is true of GNRs that are 'Located' because there are some circumstances that may result in fewer GNRs being located in a channel scan. The resulting set of GNRs are then used to produce a channel mean RFU and mean concentration.

For cartridges formats with triplicate GNRs, filtering is a capability for automatically triggering the removal of an outlier GNR result from a given channel population. For cartridges formats with duplicate GNRs, there is no option for filtering. The GNR filtering options are as follows:

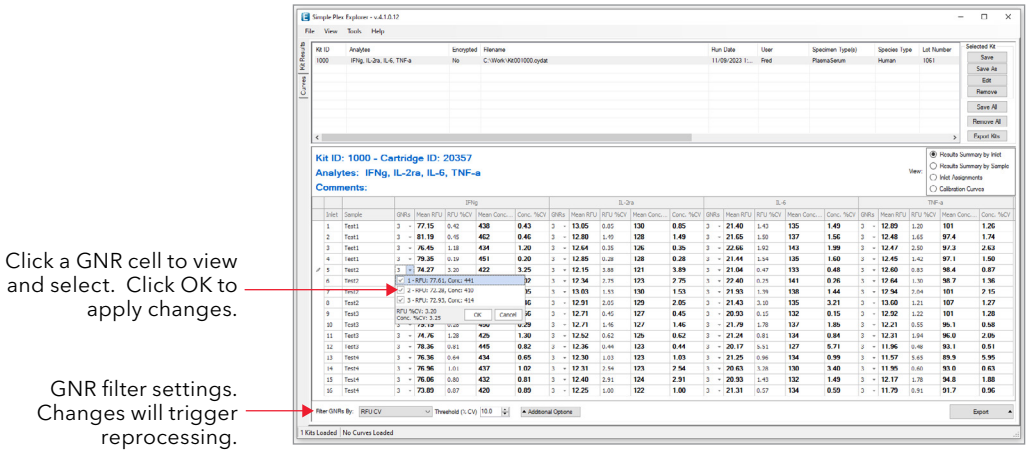
- *None*. No filtering will be performed.
- *RFU*. Filtering will be triggered based on the GNR RFU data.
- *Concentration*. Filtering will be performed based on the GNR concentration data.

If filtering is triggered by the GNR population %CV exceeding the threshold, then the outlier removal will determine the optimal pair of GNRs based on the minimum population standard deviation (or sample standard deviation if ***Use Sample Standard Deviation*** is checked) of the three possible pair combinations.

The results of GNR Filtering may be overridden at any time by simply clicking on a cell in the GNRs column of the Kit screen. This action and adjusting the GNR Filtering are shown in Figure 4-3.

NOTE: The default choice for 'Use Sample Standard Deviation' and 'GNR Filtering' can be set in the Simple Plex Runner application settings.

FIGURE 4-3. GNR Filtering on Kit screen.

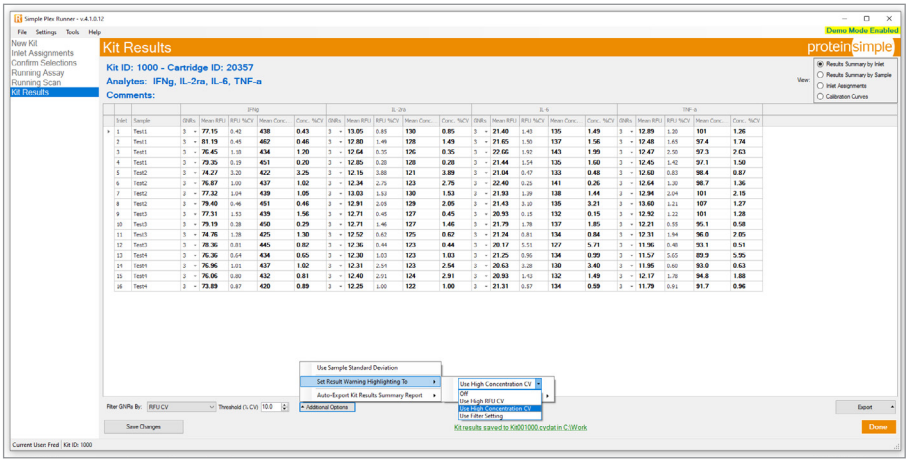


Results Warning

Results warning is feature that can be used to flag data based on a user specified threshold condition. This can be defined by either the RFU CVs, the concentration CVs or turned off by the user. The results warning options for flagging results are accessed under the ***Additional Options button*** and include:

- *Off*. No results warning will be displayed.
- *Use High RFU CV*. Results warning will color cells based on the RFU CV data.
- *Use High Concentration CV*. Results warning will color cells based on the concentration CV data.
- *Use Filter Setting*. This synchronizes the results warning threshold condition with the condition defined for GNR filtering.

FIGURE 4-4. Results Warning settings on Kit screen.

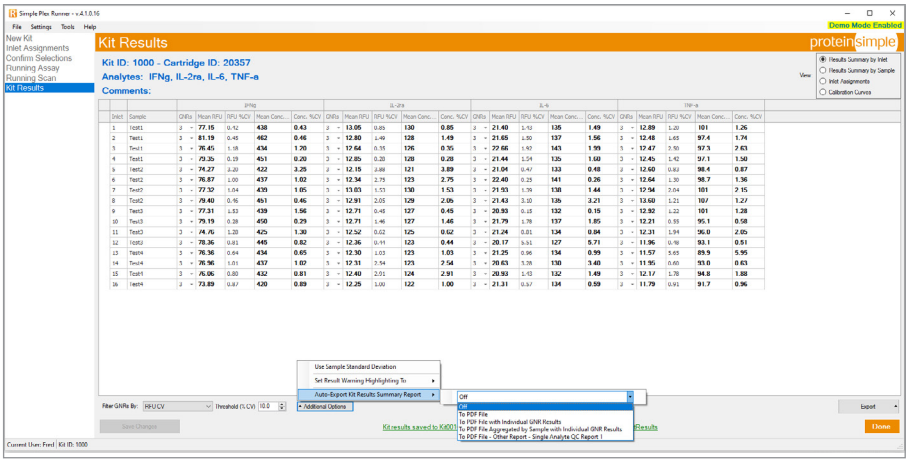


Results Warning Colors:	Light Pink	Indicates relevant %CV is high (above specified threshold). This applies to both Inlet and Sample Aggregate Rows. For Inlet Rows, this can also indicate a single GNR result.
	Light Grey	For Inlet rows, this can indicate No GNRs found, or channel not found. For Sample Aggregate rows, this can indicate no replicates available.

Export Summary Report

Use this menu to change the Auto-Export Kit Results Summary Report setting stored in your CYDAT.

FIGURE 4-5. Auto-Export Kit Summary Report menu.



No GNRs Found

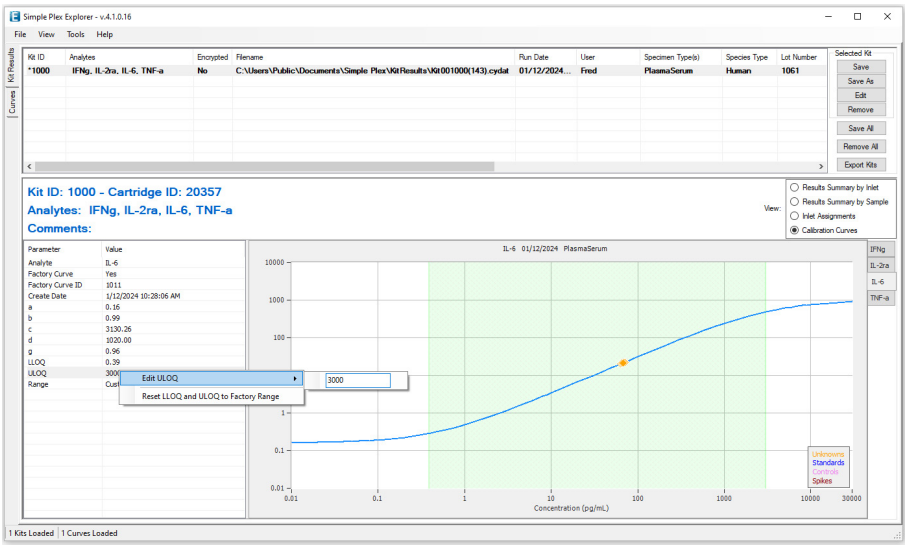
For channels where no GNRs are found the cell is highlighted grey. There are two warning messages:

- No GNRs Detected
  Signal processing recognized the channel was unable to distinguish the GNRs from the background. This can happen when running negative samples.
- Channel Not Found
  Signal processing was unable to successfully locate the channel containing the GNRs.

Edit LLOQ and ULOQ for Factory Curves

If needed the LLOQ and ULOQ values can be edited for the applied factory curve by right clicking the appropriate row (as shown in Figure 4-6).

FIGURE 4-6. Edit LLOQ and ULOQ for factory curves.

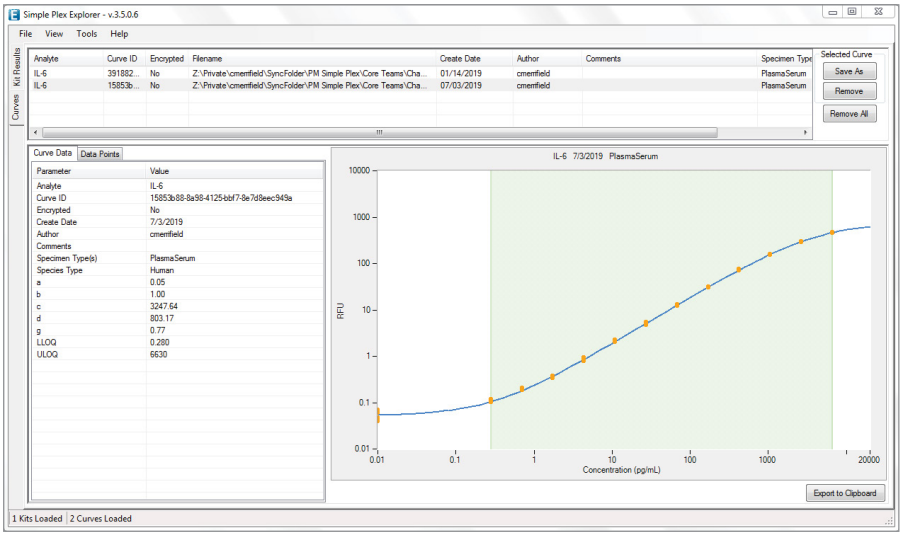


Curve Tab

The functionality of the Curve tab is shown in Figure 4-7:

- It displays the details of the curve selected from the list.
- You can export a spreadsheet-compatible string of the curve to the clipboard with the *Export to Clipboard button*.
- You are able to view all the details of the selected curve.
- By clicking on the extreme axis labels of the graph you can edit the range of the axes.

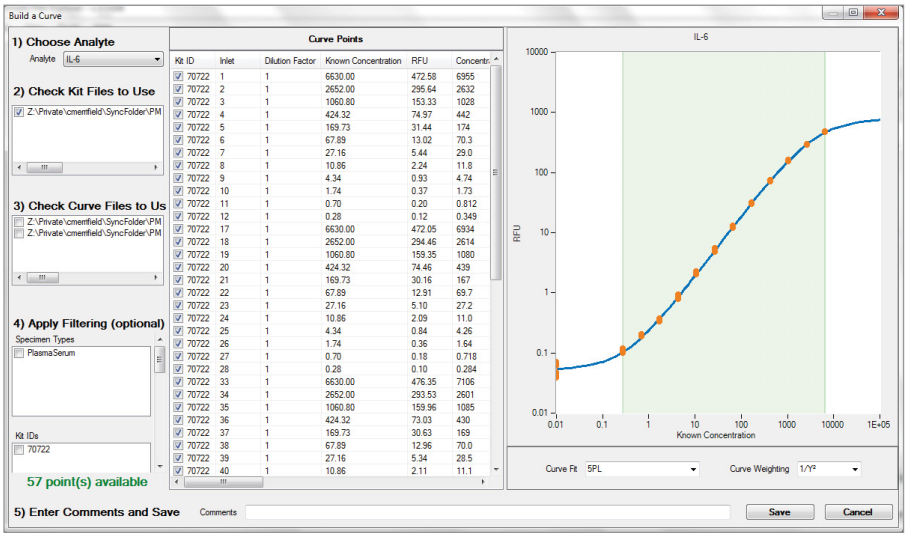
FIGURE 4-7. Standard Curve screen.



Build a Curve Screen

From the *Tools* menu option, select *Build a Curve* to display the screen for building a standardc urve (see Figure 4-8). A standard curve applies to only one analyte, so in order to proceed you must select an analyte from the drop-down box in the upper left corner of the sub-panel. Once you make an analyte selection, the available kits and curves will be displayed in the checklists below the analyte drop-down box.

FIGURE 4-8. Build a Curve screen.



You can now filter the available results by Specimen Types, Kit Ids, etc. with these checklists.

If you're working with the 48-Digoxigenin Cartridge, there are filtering options for curves created against the same analyte but they may leverage different capture and detect reagents and concentrations.

There are also additional curve fitting options available for building your own curve. These include 4PL and 5PL curve fits, as well as 1/Y, $1/Y^2$ and None options for weighting the curve fit.

NOTE: Only samples of type Standard will be available for building curves.

The available RFU results from the Kits and Curves selected will be listed in the list to the right of the filter checklists. Use the list to select the data points to include in your curve by checking the points to include.

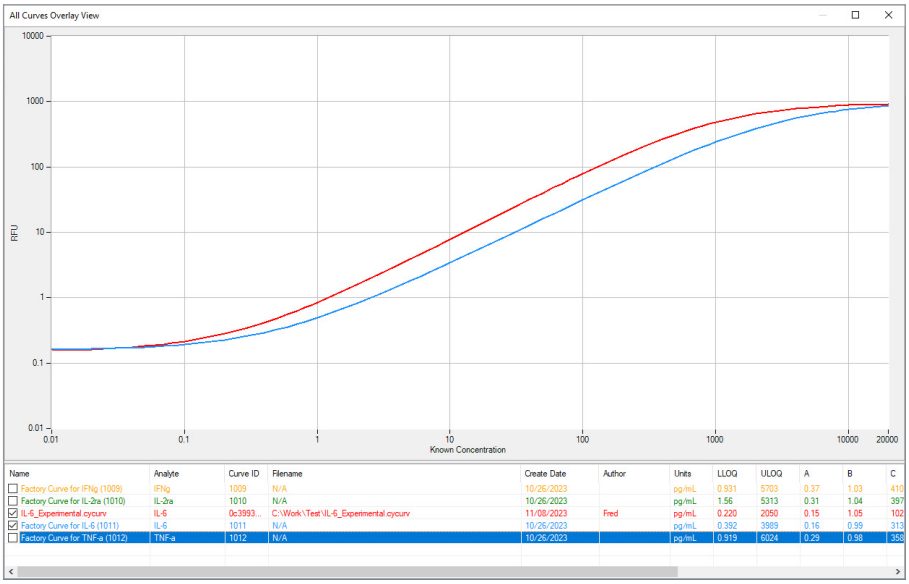
When you check a point to be included in your curve, the point will be displayed on the graph to the right and if there are more than four data points, a 5-parameter sigmoid curve will be fit to your data using a Levenberg-Marquardt algorithm.

Data points on the curve plot can also be selected to highlight the inlet ID in the curve point dialog box.

All Curves Overlay View

From the *View* menu options, select *All Curves Overlay* to display a screen showing curves from all loaded curve files and factory curves from all loaded kit results files (see Figure 4-9). Display of specific curves can be turned on or off using the checkboxes in the Name column. Additional options are available from the context menus on the curve plots and the curve table. Context menus can be accessed by right clicking.

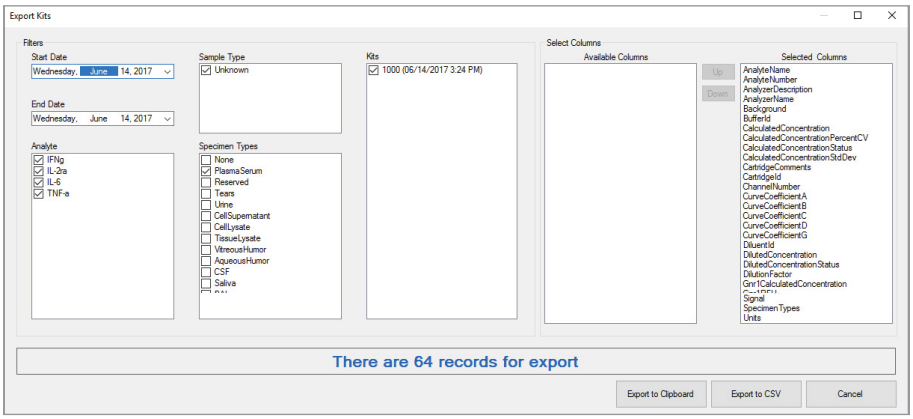
FIGURE 4-9. All curves overlay view.



Export Kits Screen

From the *Tools* menu option, select *Export Kits* to display the screen for configuring an aggregated kit export (see Figure 4-10). Use the filters and indicate the selected columns to prepare your kits export. Right clicking on a checklist will give you the option to *Select All* or *Select None*. A list of exportable columns and their data descriptions are in Table 4-3.

FIGURE 4-10. Export Kits screen.



As you make selections, the number of matching records that will be in your export is displayed at the bottom of the screen. Click the *Export to Clipboard* button for a tab delimited string or click the *Export to CSV* button to create a spreadsheet compatible CSV file.

TABLE 4-2. Export column descriptions.

Column Title	Decscription
AnalyteName	Biomarker name.
AnalyteNumber	Analyte number in inlet layout (1 based) that produced the given result.
AnalyzerDescription	A description stored on the Ella system as set by the user via the Runner Menu (*Settings-->Analyzer-->Description*). The value will be blank if not previously set by the user.
AnalyzerName	A unique system identifier stored on the Ella system by the OEM.
Background	The background fluorescence intensity. This value is subtracted from the signal value to obtain the RFU value.
BufferId	Factory Id of buffer included with the cartridge kit.
CalculatedConcentration	The concentration with dilution factor applied. A numerical value is provided only if the value is within quantification limits.
CalculatedConcentrationPercentCV	%CV of the individual GNR calculated concentrations.
CalculatedConcentrationStatus	Provides concentration status such as IR (for in range) or OOR (for out of range).
CalculatedConcentrationStdDev	Population or sample standard deviation of the individual GNR calculated concentrations (see IsSampleStdDev).
CaptureConcentration	Applies to 48-Digoxigenin Cartridge. The concentration of the capture as entered by the user.
CaptureName	Applies to 48-Digoxigenin Cartridge. The name of the capture as entered by the user.
CartridgeComments	Comments entered for the cartridge run by user.
CartridgeId	Factory Id of cartridge included with the cartridge kit.
ChannelNumber	Channel Number in a given cartridge inlet (1 based) that produced the given result.

(Continued on Next Page)

TABLE 4-2. Export column descriptions. (Continued)

Column Title	Decscription
CurveCoefficientA	Calibration Curve Coefficient A - Estimated response at zero concentration.
CurveCoefficientB	Calibration Curve Coefficient B - Slope factor.
CurveCoefficientC	Calibration Curve Coefficient C - Mid-range concentration (C_{50}).
CurveCoefficientD	Calibration Curve Coefficient D - Estimated response at infinite concentration.
CurveCoefficientG	Calibration Curve Coefficient G - Asymmetry factor.
DetectConcentration	Applies to 48-Digoxigenin Cartridge. The concentration of the detect as entered by the user.
DetectName	Applies to 48-Digoxigenin Cartridge. The concentration of the detect as entered by the user.
Diluent Id	Factory Id of sample diluent included with the cartridge kit.
Diluted Concentration	The as measured concentration without a dilution factor applied. A numerical value is provided only if the value is within quantification limits.
DilutedConcentrationStatus	Provides concentration status such as IR (for in range) or OOR (for out of range).
Dilution Factor	Multiplier used to compute calculated concentration from diluted concentration (for example, 2 is a sample diluted in half).
Gnr1Background	The background fluorescence intensity for GNR 1.
Gnr1CalculatedConcentration	Concentration computed from the RFU of GNR 1 with dilution factor applied.
Gnr1RFU	The RFU of GNR 1(GNR 1 signal - GNR 1 background).
Gnr1Signal	The GNR 1 fluorescence intensity. Subtracting GNR 1 background from this yields GNR 1 RFU.
Gnr2Background	The background fluorescence intensity for GNR 2.
Gnr2CalculatedConcentration	Concentration computed from the RFU of GNR 2 with dilution factor applied.
Gnr2RFU	The RFU of GNR 2 (GNR 2 signal - GNR 2 background).
Gnr2Signal	The GNR 2 fluorescence intensity. Subtracting GNR 2 background from this yields GNR 2 RFU.
Gnr3Background	The background fluorescence intensity for GNR 3.
Gnr3CalculatedConcentration	Concentration computed from the RFU of GNR 3 with dilution factor applied.
Gnr3RFU	The RFU of GNR 3 (GNR 3 signal - GNR 3 background).
Gnr3Signal	The GNR 3 fluorescence intensity. Subtracting GNR 3 background from this yields GNR 3 RFU.
GnrCount	Number of GNRs selected for the given result.
GnrFilter	The GNR filter selection used for the given result: Concentration CV, RFU CV, or None.

(Continued on Next Page)

TABLE 4-2. Export column descriptions. (Continued)

Column Title	Decscription
GnrFilterCVPercentThreshold	The GNR filtering threshold used for the given result.
InletComment	Comment for the given inlet entered by the user.
InletNumber	The inlet number of the cartridge that produced the given result (1 based).
IsSampleStdDev	True if the standard deviation is a sample standard deviation. False if the standard deviation is a population standard deviation.
KitGuid	Global Unique Identifier for the Kit.
KitId	Factory Id of kit. A kit is comprised of a cartridge, buffer, and sample diluent.
KnownConcentration	The known concentration entered by the user. This value is used for the percent recovery calculation.
KnownConcentrationEnteredUnits	Applies to 48-Digoxigenin Cartridge. The concentration units entered by the user.
LotNumber	The factory build lot comprised of N kits utilizing matching assay components.
NonlimitedCalculatedConcentration	The concentration with dilution factor applied. A numerical value is provided regardless of quantification limits.
NonlimitedDilutedConcentration	The concentration without dilution factor applied. A numerical value is provided regardless of quantification limits.
PercentRecovery	Calculated concentration divided by known concentration times 100.
RFU	The mean of the selected GNRs RFU values.
RFUPercentCV	%CV of the individual GNR RFUs.
RFUStdDev	Population or sample standard deviation of the individual GNR RFUs (see IsSampleStdDev).
RunDate	Local time and date the cartridge run took place.
RunUserName	The user name of the account used to login to the OS (CFR mode disabled) or login to Simple Plex software (CFR mode enabled).
SampleName	The sample name entered by user
SampleReplicate	The instance number of a given unique combination of Sample Name and Known Concentration within a Kit. Starting at Inlet 1 the value will be 1. The next inlet with the same unique combination will be 2 and so on. The value will be 0 if no Sample Name is provided.
SampleType	The type of sample as entered by the user. (Control, Standard, Unknown, Spike).
Signal	The mean of the GNRs fluorescence intensity. Subtracting the background from this yields the RFU.
SpecimenTypes	Intended Specimen types for assay, for example: plasma or serum.
Units	Concentration Units, for example: pg/mL.

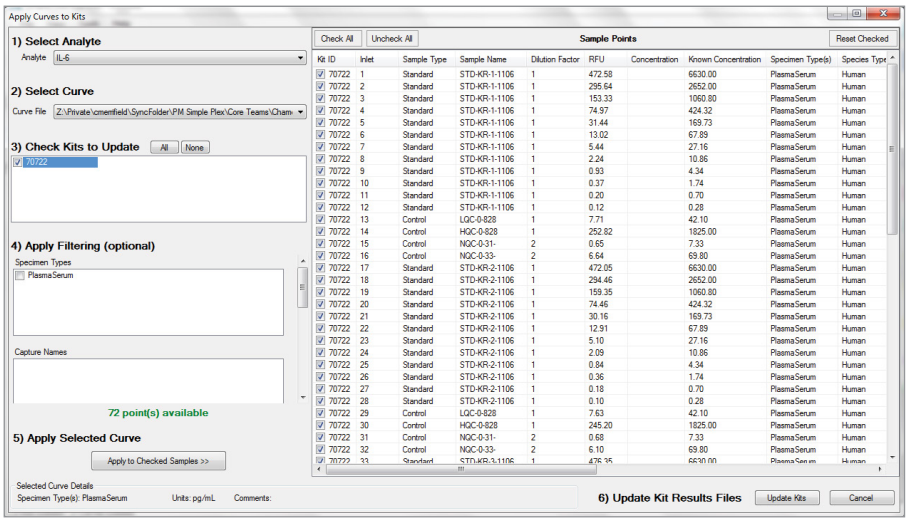
Apply Curves to Kits Screen

From the Tools menu option, select *Apply Curves to Kits* to display the screen for applying selected curves to selected kits (see Figure 4-11). In the sub-panel use the checklists to check the kits to which you wish to apply the curve you have selected. When you have completed your selections, click on the *Apply to Checked Samples* button.

Clicking on the *Apply to Checked Samples button* will calculate concentrations from RFU results of each checked sample point.

Click *Update Kits* to update the loaded kit results files with the applied curve changes.

FIGURE 4-11. Apply Curves to Kits screen.



Check Kits to Update

If data from multiple kits is available in Explorer they can be selected in the Check Kit to Update box.

Sample Points

Curves can now be applied to subsets of kit data by selecting individual data points to be included. Data points from a kit can be included or excluded from the analysis by checking the check box at the far left of the sample row.

Apply Filtering

The Apply Filtering options can be used to sort relevant subsets of data within a kit or multiple kits to be analyzed with a standard curve. Filtering options include:

- **Specimen Types**: Allows for filtering based on the type of biologic matrix being interrogated.
- **Capture Name**: For users working with a customizable cartridge format, filtering is available based on the capture reagent identity.
- **Capture Concentration**: For users working with a customizable cartridge format, filtering is available based on the capture reagent concentration.
- **Detect Name**: For users working with a customizable cartridge format, filtering is available based on the detect reagent identity.
- **Detect Concentration**: For users working with a customizable cartridge format, filtering is available based on the detect reagent concentration.

Chapter 5: **Maintaining Ella**

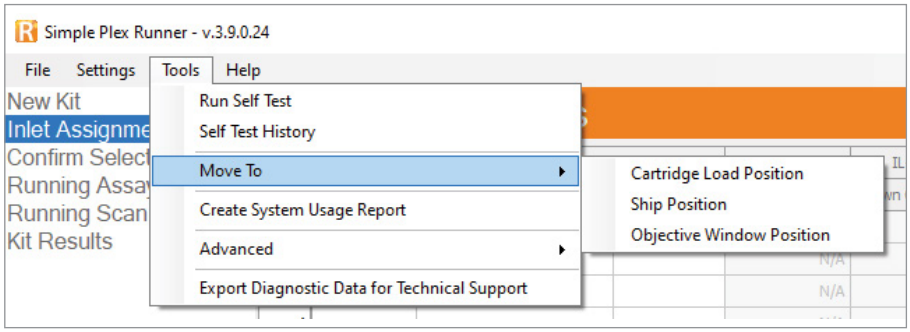
Introduction

This chapter describes maintenance and service tasks for Ella.

Using the Simple Plex Runner Tools Menu

The Tools menu (Figure 5-1) is used to conduct the instrument Self Test, move the XY stage to predefined locations (must be done with the clamp and lid closed), and export diagnostics system logs to a compressed file for use by Technical Support.

FIGURE 5-1. Simple Plex Runner Tools menu.



Ella Self Test

The Ella Verification Cartridge enables the system to perform a series of diagnostic tests that ensures the instrument is running properly. The results are tabulated under the system log files. These results provide valuable troubleshooting information to Bio-Techne personnel in the event system maintenance is required. Accordingly, we advise that the Verification Cartridge is run once a week to create a running history of system performance.

Your Verification Cartridge was provided in a storage box as shown in Figure 5-2 A and B. Whenever handling your Verification Cartridge, wear gloves to avoid getting it dirty. The Verification Cartridge features a surface to seal Ella's pneumatic interface, and an auto-fluorescing surface as an RFU reference.

To perform a Self Test:

1. Remove the Verification Cartridge from the box.
2. From the Simple Plex Runner menu, click ***Tools > Run Self Test*** and the Self Test Dialog will appear. Scan the Verification Cartridge barcode.
3. Place the Verification Cartridge in Ella.
4. Close the cartridge clamp and Ella's lid.

(Continued on Next Page)

5. Click the Start button to commence the Self Test.

   A. An Ella Self Test can take up to 45 minutes.

   B. While the test is running, progress and results are provided in the dialog.

   C. You can mouse over a progress bar for more details about that particular test.

   D. When prompted near the end of the Self-Test, reinsert the Verification Cartridge in the rotated orientation as shown in Figure 5-2 D

   ***NOTE:** The Runner software will detect if the Verification Cartridge is placed incorrectly, e.g., in the wrong orientation. An error message will pop up stating so and will provide an opportunity to fix the placement and continue.

6. When the test completes, you will have the opportunity to save the test results to a CSV or PDF file for historical or support purposes.

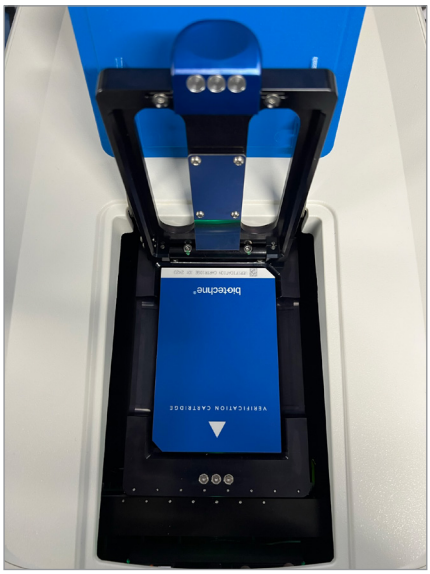
If the test fails please contact Technical Support (page 11)

FIGURE 5-2. Ella Self Test step-by-step procedure.

A. Verification Cartridge box.

B. Cartridge in box, barcode up.

C. Verification Cartridge in Ella.



D. Verification Cartridge in Ella, Rotated Orientation.

FIGURE 5-3. Self Test dialog.

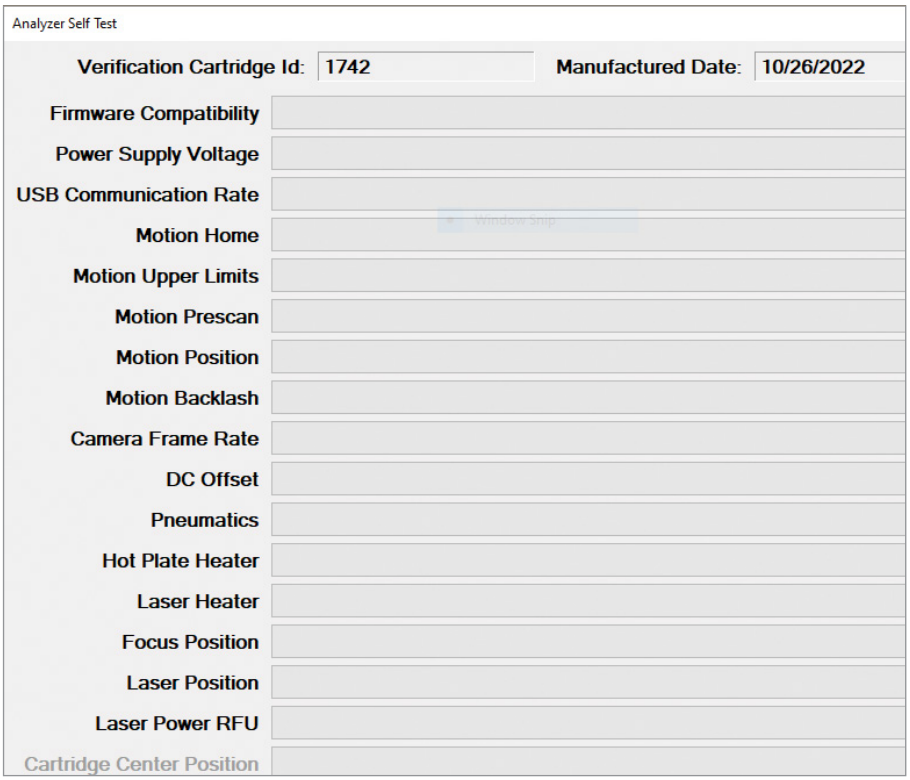


FIGURE 5-4. Self Test dialog - running.

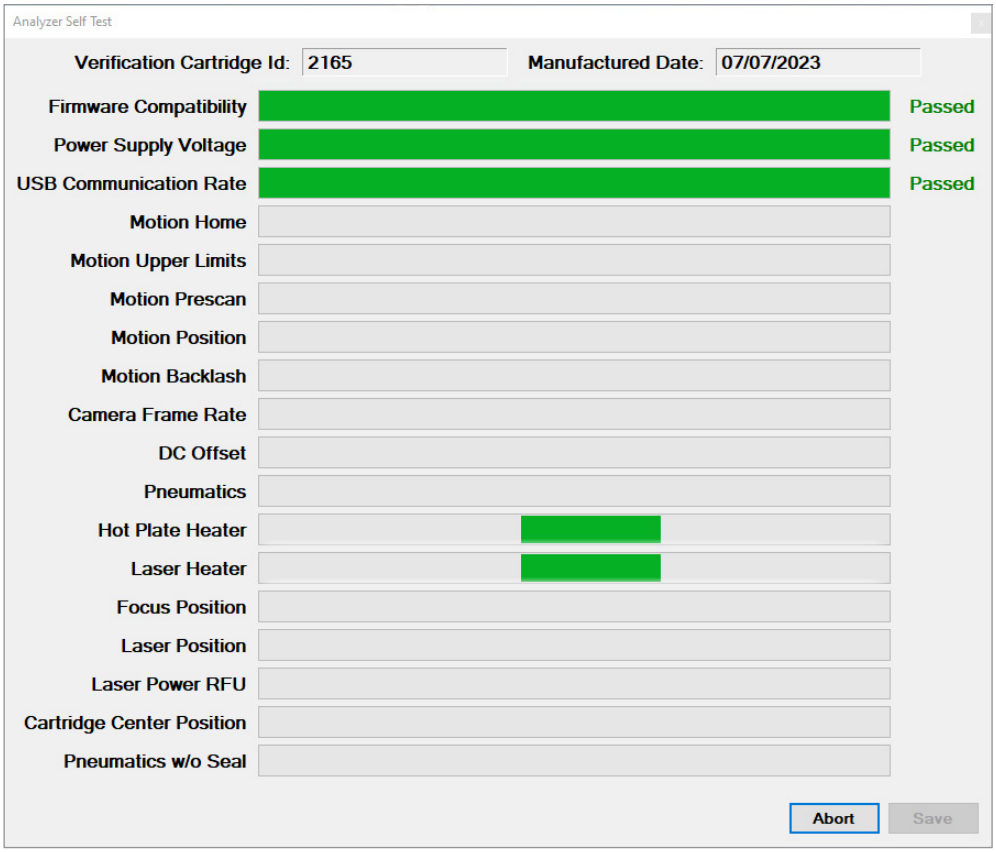


FIGURE 5-5. Self Test dialog- rotate or remove Verification Cartridge depending on version

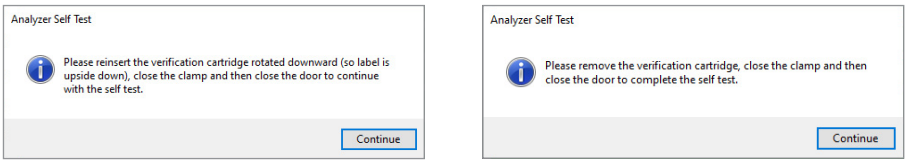


FIGURE 5-6. Self Test dialog - improper Verification Cartridge placement examples.

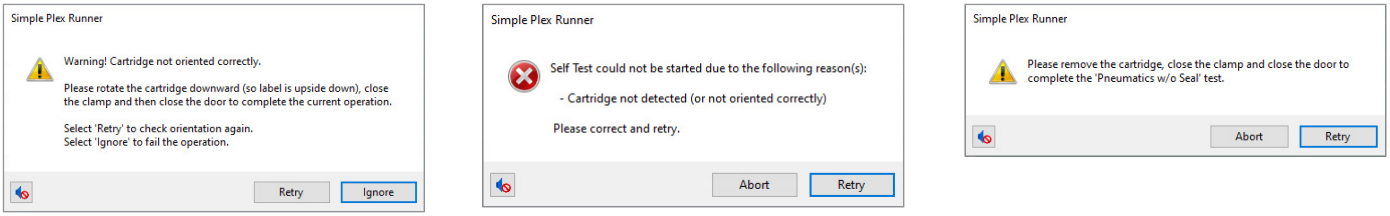


FIGURE 5-7. Self Test dialog - completed.

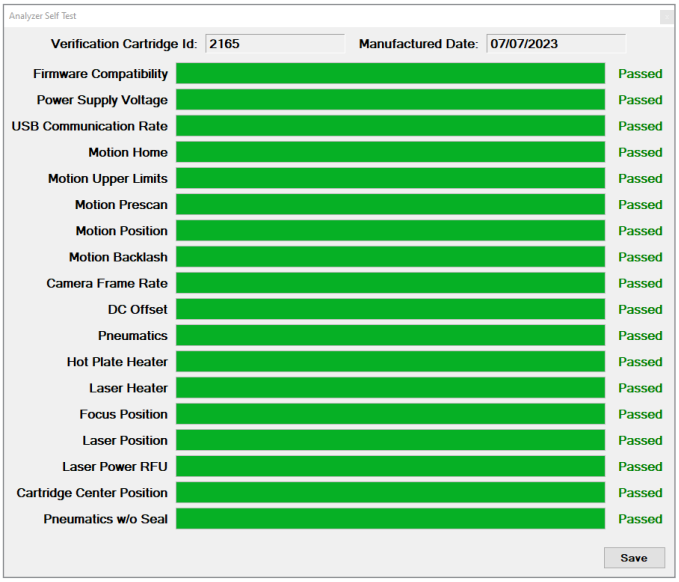
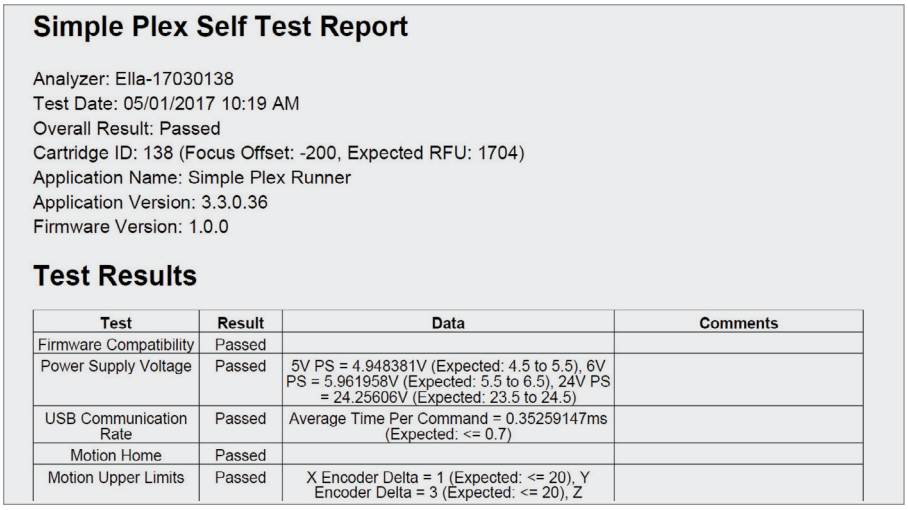


FIGURE 5-8. Self Test results file snippet.



Simple Plex Self Test Report

Analyzer: Ella-17030138
Test Date: 05/01/2017 10:19 AM
Overall Result: Passed
Cartridge ID: 138 (Focus Offset: -200, Expected RFU: 1704)
Application Name: Simple Plex Runner
Application Version: 3.3.0.36
Firmware Version: 1.0.0

Test Results

Test	Result	Data	Comments
Firmware Compatibility	Passed		
Power Supply Voltage	Passed	5V PS = 4.948381V (Expected: 4.5 to 5.5), 6V PS = 5.961958V (Expected: 5.5 to 6.5), 24V PS = 24.25606V (Expected: 23.5 to 24.5)	
USB Communication Rate	Passed	Average Time Per Command = 0.35259147ms (Expected: <= 0.7)	
Motion Home	Passed		
Motion Upper Limits	Passed	X Encoder Delta = 1 (Expected: <= 20), Y Encoder Delta = 3 (Expected: <= 20), Z	

Using the Move To Commands in the Simple Plex Runner Software Menu

Objective Window Position

The *Tools > Move To > Objective Window Position* command is provided to move to the correct position for removing or installing the objective window that is threaded into the heater plate.

Cartridge Load Position

The *Tools > Move To > Cartridge Load Position* command is provided to return to the load position if you have previously moved to the objective window position or ship position. It is also provided in the highly unlikely event that the instrument does not return the stage to the load position. If this occurs, please contact ProteinSimple Technical Support.

Ship Position

The *Tools > Move To > Ship Position* command is provided in the event that Ella is to be packed for shipment.

Preparing Ella for Shipment

To prepare Ella for shipment:

1. Close the clamp and the lid
2. *Click Tools > Move To > Ship Position* on the Simple Plex Runner menu.
3. Wait for the Moving to shipping position pop-up dialog to close.
4. Shut Ella down:

    A. Close Simple Plex Runner either by clicking *File > Exit* from the menu or *Close (X)* in the upper-right corner of the application window.
    B. Shut down Ella's computer.
    C. Turn Ella off by pressing the power switch on the back panel.

Exporting System Logs

Clicking *Tools > Export Diagnostic Data for Technical Support* is used to export diagnostics information to a compressed zip file if requested to do so by Technical Support.

Maintenance and Cleaning

Ella requires minimal preventative maintenance. However, when performing periodic inspections of the system, take note of any damage to Ella's enclosure or the insulation of associated cables. If the enclosure damage indicates that protection of the electronics from moisture intrusion or laser light is compromised or that compromise is imminent, or if the cable damage suggests that cable electrical shorts or opens are imminent, then take the appropriate corrective action depending on the situation – up to and including removal of the product from service until repairs have been performed. Contact Customer Support for information regarding repairs and spare parts.

Fan Filter Cleaning and Maintenance

Ella must always receive adequate ventilation for cooling. Proper cooling is required for Ella to meet specifications, and to avoid overheating. Periodic instrument maintenance should include inspection and cleaning of the fan filter every six months.

To clean the filter:

1. Remove the fan guard and fan filter.
2. Vacuum the fan filter to clean it.
3. If necessary, replace worn-out or damaged fan filters (PN 541401).
4. Reinstall the fan filter and fan guard.

External Surface Cleaning

Turn off and unplug Ella prior to cleaning. If required, wipe down all of Ella's external surfaces using a damp cloth with a small amount of water or a mild detergent.

Cartridge Nest and Objective Window Cleaning

Cartridge Nest. If required, Ella's cartridge nest can be cleaned using a lint-free wipe dampen with ethanol. When cleaning the nest, care should be taken not to contaminate the objective window.

Objective Window. Care should be taken to ensure the objective window is clean. If cleaning is required, use a clean, lint-free wipe dampened with ethanol. Multiple one-time use wipes are recommended to ensure the objective window is cleaned (streak-free), see Figure 5-9.

FIGURE 5-9. Cartridge Nest and Objective Window.

Chapter 6: Simple Plex 21 CFR Part 11 Compliance

Overview

The Simple Plex software 21 CFR Part 11 features can be used to help satisfy regulatory data security requirements when using Ella. When the 21 CFR Part 11 feature is activated and enabled:

- Windows user accounts (located either on the local PC or on a Windows Domain Active Directory) are utilized for user validation.
- Users are required to login to use Simple Plex Runner.
- A run will produce an encrypted data file (ECYDAT) that is electronically signed by the currently logged in user (see Table 6-1).
- Every ECYDAT file contains the file's change history. Any time changes are made to the data in an ECYDAT file, a valid user must sign the changes prior to saving.
- Reviewing and editing ECYDAT files with Simple Plex Explorer requires a user login, and a valid user must sign any changes prior to saving.
- Simple Plex Explorer does not require additional activation to work with ECYDAT files.
- When Simple Plex Explorer is used to create calibration curves from ECYDAT files, an encrypted curve file (ECYCURV) is produced that is signed, saved and potentially utilized to compute concentrations in ECYDAT files.
- Unsecured files (CYDAT/CYCURV) may not be used to create ECYCURV files or compute concentrations in ECYDAT files.

TABLE 6-1. Simple Plex file extensions features summary.

Feature	Simple Plex File Extension			
	CYDAT	CYCURV	ECYDAT	ECYCURV
Encrypted	No	No	Yes	Yes
Editable	Yes	No	Yes	No
Tracks changes	No	N/A	Yes	N/A
Electronically Signed	No	No	Yes	Yes

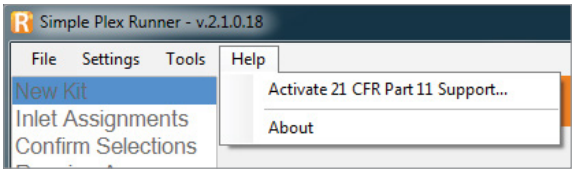
Activating 21 CFR Part 11 Support for Simple Plex Runner

21 CFR Part 11 support for Simple Plex Runner is a purchased add-on that must be activated prior to use.

To activate the 21 CFR Part 11 support:

- Click *Help > Activate 21 CFR Part 11 Support…*(Figure 6-1).

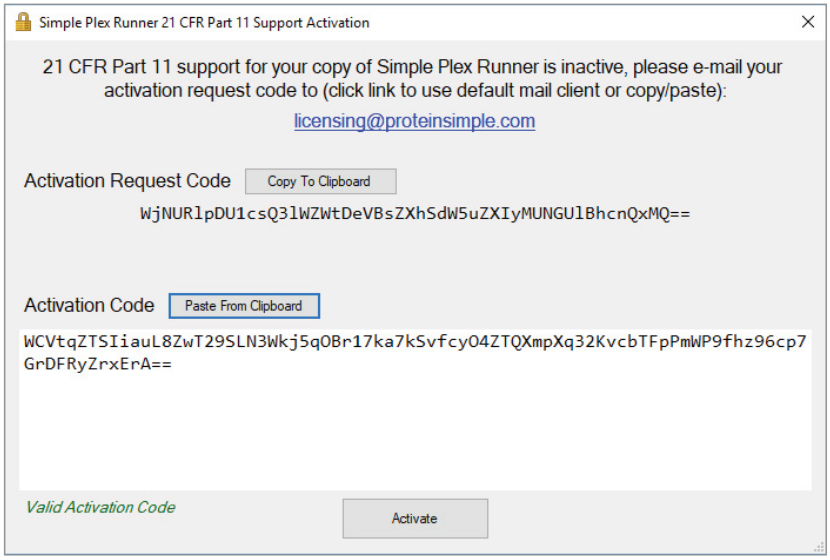
FIGURE 6-1. Help menu.



- The Activation dialog window will display (Figure 6-2)

NOTES: If the Activate 21 CFR Part 11 Support… menu option is not present, your installation has already been activated. If you ordered your Ella system with 21 CFR Part 11 support, the system will be activated prior to being shipped.

FIGURE 6-2. Runner: 21 CFR Part 11 Support Activation Dialog.



2. Click the email link to e-mail the Activation Request Code to licensing@proteinsimple.com. You will receive a reply e-mail within 24 hours with your Activation Code.

3. Copy your activation code into the Activation Code text box, then click the ***Activate*** button.

Enabling 21 CFR Part 11 Mode for Simple Plex Runner

Upon activation, the 21 CFR Part 11 Mode will be enabled by default. It is possible to have an active license and opt to disable the 21 CFR Part 11 Mode.

To enable/disable the 21 CFR Part 11 Mode:

1. Click *Settings* > *Application*.

The Settings Dialog will display (Figure 6-3):

2. Toggle *Use21CFRPart11Mode* to *True* and click *Save*.

3. A message will display to restart the Runner application in order to start using the 21 CFR Part 11 Mode (Figure 6-4).

4. Restart the Simple Plex Runner application. You will be required to login in order to use the application once it relaunches.

FIGURE 6-3. Simple Plex Runner Settings dialog.

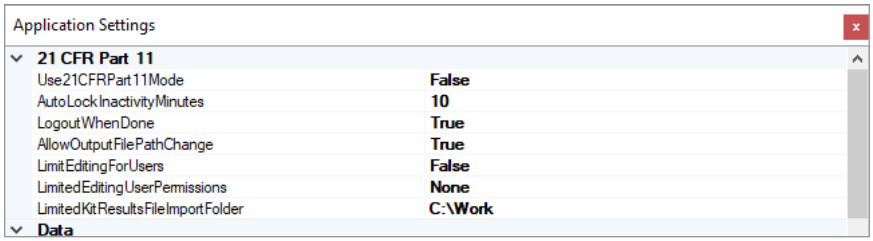
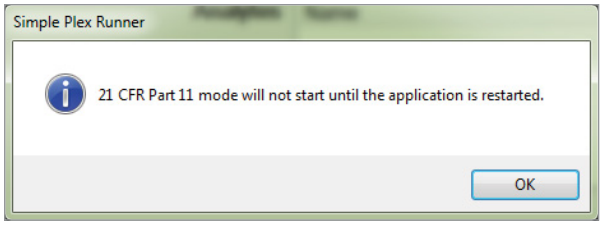


FIGURE 6-4. To use 21CFR Part 11 Mode restart application.



Administering User Groups

If you are not familiar with managing user accounts and security groups, it is recommended that you contact an IT representative for assistance.

When 21 CFR Part 11 Mode is enabled, both Simple Plex Runner and Explorer will perform user account validation via the Local PC and/or Windows Domain Active Directory Security Groups. In both cases, two specifically named Security Groups will be referred to as shown in Table 6-2.

TABLE 6-2. Security groups.

Security Group	Permission
Simple Plex Admins	Members in this group can fully operate Simple Plex software in 21 CFR Part 11 Mode and can modify the settings in the Simple Plex Runner program.
Simple Plex Users	Members in this group can fully operate Simple Plex software in 21 CFR Part 11 Mode, but are prevented from modifying Application Settings in the Simple Plex Runner program.

These two Security Groups are created for you during the Simple Plex Runner or Explorer software installation. In order to perform the following operations, you will need to be a local system administrator.

NOTE: The default login (User Id: Ella and Password: Ella) is a local system administrator.

- **If you wish to use the Local PC security groups**: simply add users to one of the groups to permit the users to use the Simple Plex applications.
- **If you wish to use a Windows Domain Active Directory Security Group**: you will need to contact your IT representative and request that they create the specifically named groups in your active directory, and then add users accordingly.
- **If the user name entered does not specify a Local PC or domain**: to validate users, the Simple Plex software first attempts to validate user credentials and security group membership on the Local PC. If this validation fails, the Simple Plex software will attempt to use the domain (if the PC is a member) to validate user credentials and security group membership.

NOTE: As part of the 21 CFR Part 11 regulation, the user account must have a Full Name associated with it in order to be considered valid.

Providing specific detailed instructions for creating security groups and adding users to these groups is beyond the scope of this manual. A brief 'how-to' for Local PC setup is provided in Appendix B, "Managing Users and Groups for 21 CFR Part 11 Support". If you do not have an IT representative to assist, you can contact ProteinSimple Technical Support for assistance with Local PC configuration.

Limiting Edit Permissions for Simple Plex Users

By default, members of the Simple Plex Users have full edit ability for inlet assignments and kit results when in 21 CFR Part 11 mode. This capability can be restricted if needed by setting *LimitEditingForUsers* to True. Once enabled the *LimitedEditingUserPermissions* setting determines what can be edited. Permissions can be None or a combination of Allow permissions.

FIGURE 6-5. LimitEditingForUsers enabled in Application Settings menu.

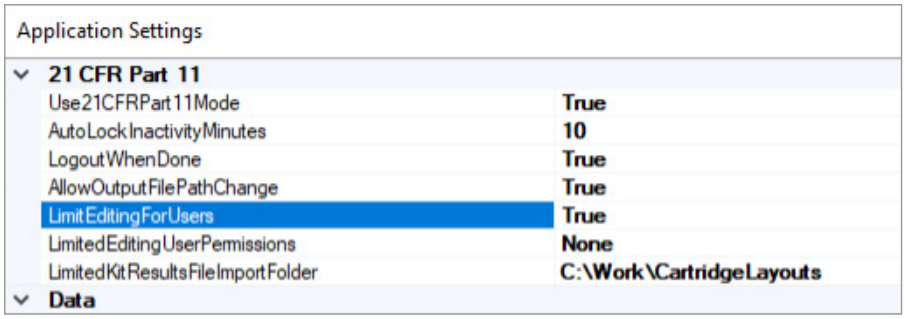


FIGURE 6-6. LimitedEditingUserPermissions in Application Settings menu.

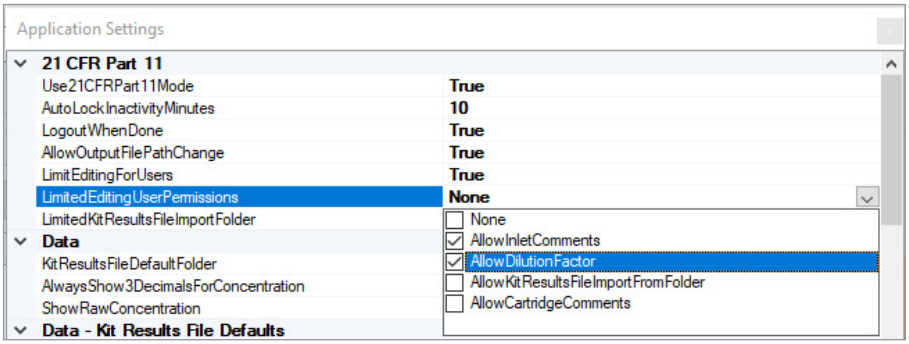


TABLE 6-3. Limited Editing Permission Definitions.

Security Group	Permission
None	No editing permissions. Inlet assignments and kit results will be read-only, and no editing is allowed.
AllowInletComments	Users can edit Inlet Comments in Inlet Assignments.
AllowDilutionFactors	Users can edit Dilution Factor in Inlet Assignments.
AllowKitResultsFileImportFromFolder	Users can perform a kit results file import from a specified folder (setting for this is ***LimitedKitResultsFileImportFolder***).
AllowCartridgeComments	Users can edit Cartridge Comments in Inlet Assignments

TIP: Configure the ***LimitedKitResultsFileImportFolde***r to be read-only for members of the Simple Plex Users group using the file system security permissions in Windows.

NOTE: LimitedEditingForUsers and LimitedEditingUserPermissions settings are carried over to Simple Plex Explorer within the encrypted kit results file generated from Simple Plex Runner. The same restrictions will apply. If needed this can be reconfigured per file by members of the Simple Plex Admins group by using the Additional Options menu (under 21 CFR Part 11) at the bottom of the main kit results view.

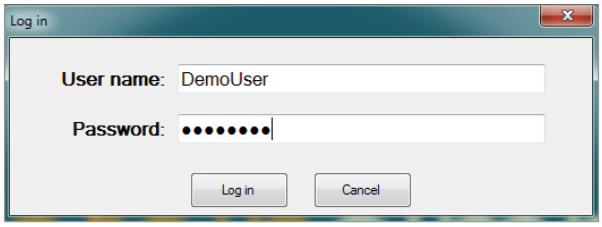
Logging In, Logging Out and Locking

When 21 CFR Part 11 Mode is enabled, you will be required to log in to Simple Plex Runner in order to utilize the system (Figure 6-7). You will also be required to log in to Simple Plex.

FIGURE 6-7. Simple Plex Runner log in.

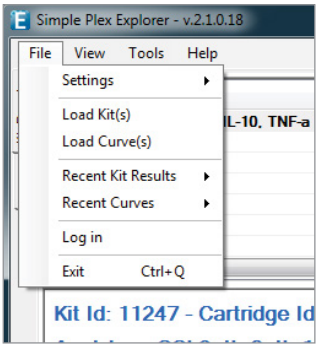
Explorer the first time you load either an ECYDAT or an ECYCURV file for review or modification (Figure 6-8).

FIGURE 6-8. Simple Plex Explorer log in.



You may also opt to log in to Simple Plex Explorer prior to loading encrypted files by selecting *File > Log in* (Figure 6-9).

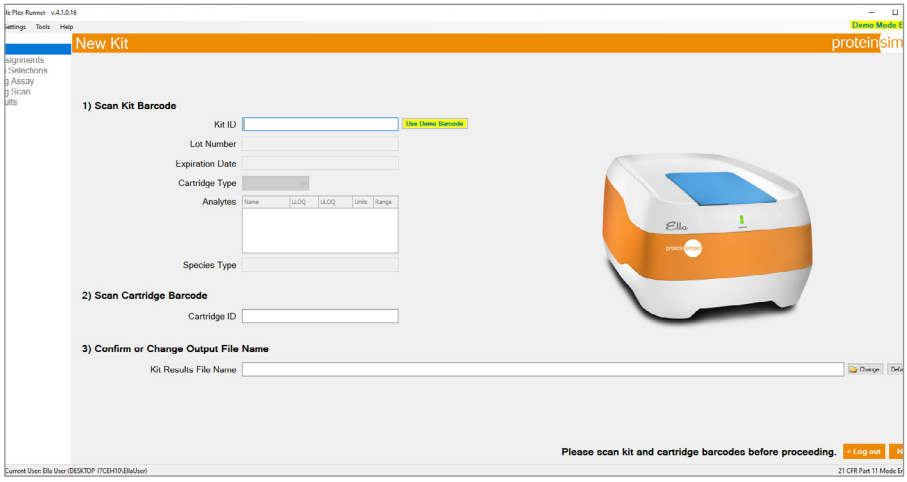
FIGURE 6-9. Logging in to Simple Plex Explorer in the File menu.



In order to successfully log in, your user account must be a member of either the Simple Plex

Users or Simple Plex Admins security groups on the Local PC or your Windows Domain Active Directory. Once you successfully log in, you may proceed with utilizing the application to perform tasks.

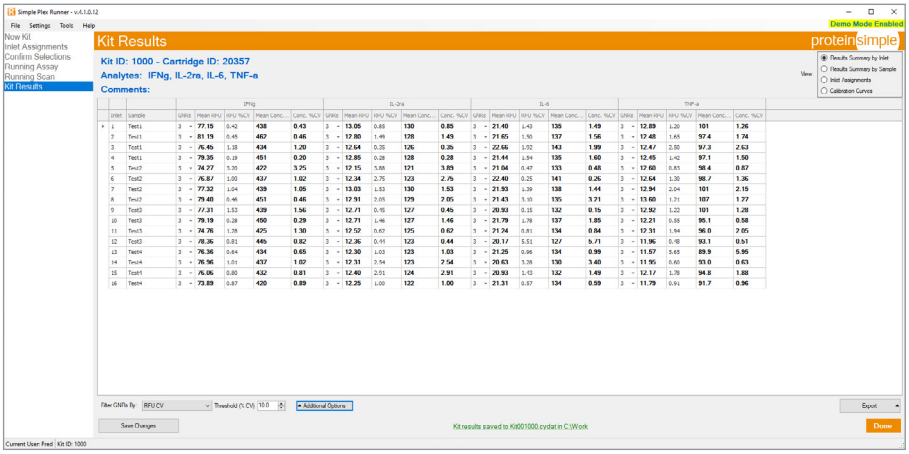
FIGURE 6-10. Simple Plex Runner New Kit screen.



You can logout of Simple Plex Runner by clicking the ***Log out button*** on the New Kit screen (Figure 6-10).

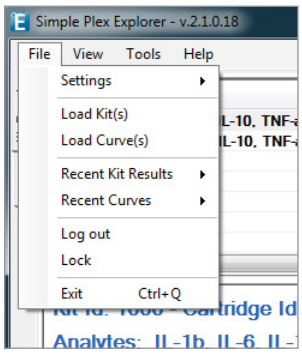
Additionally, if the *LogoutWhenDone* setting is set to *True* (the default setting, see Figure 6-3) clicking *Done* in the Simple Plex Runner Kit Results screen will also log the current user out (Figure 6-11).

FIGURE 6-11. Simple Plex Runner New Kit screen.



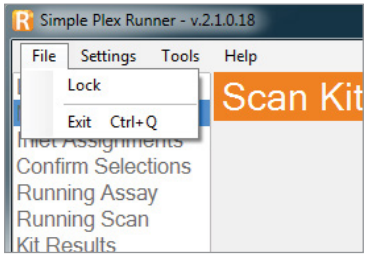
You can log out of Simple Plex Explorer by selecting *File> Log out* (Figure 6-12).

FIGURE 6-12. Logging out or locking Explorer in the File Menu.



Once you have successfully logged in, you have the option to lock the application thereby requiring that you or another valid user (via the *Switch User button*) must unlock the application with valid user credentials. To lock either Simple Plex Runner or Explorer, you can either click the *Lock button* in the lower left corner of the application window, or click *File > Lock* (Figure 6-12 and Figure 6-13). Locking/unlocking will not interrupt any ongoing operations.

FIGURE 6-13. Locking SImple Plex Runner in the File menu.

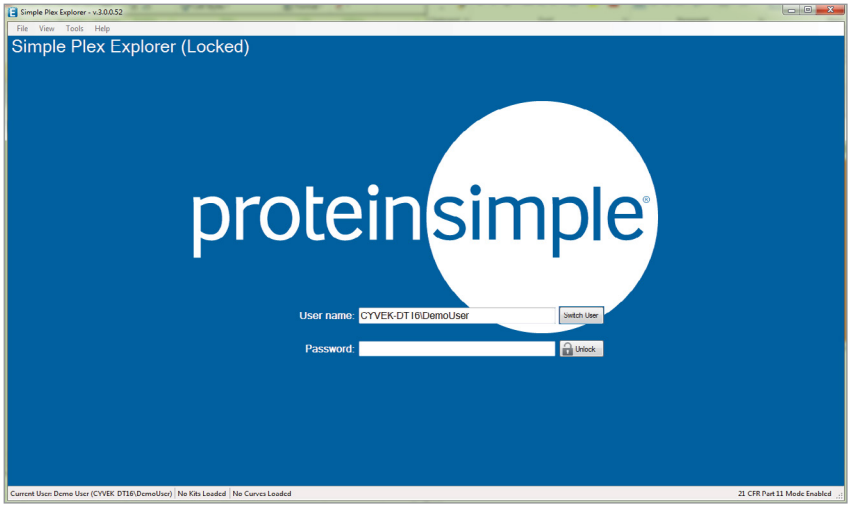


When locked, the application will show the Locked screen (Figure 6-14 and Figure 6-15).

NOTE: Simple Plex Runner will continue to display operations status and progress in the Locked screen and at the bottom of the window.

FIGURE 6-14. Locking Simple Plex Runner in the File menu.

FIGURE 6-15. Simple Plex Explorer - Locked screen.



Simple Plex Runner and Explorer will automatically lock the application after a configurable period of time called *AutoLockInactivityMinutes* that is set to 10 minutes by default. Members of the Simple Plex Admins are permitted to change the settings (Figure 6-16, and Figure 6-17). Please note that in most cases, Simple Plex Runner will be locked at the completion of a run.

FIGURE 6-16. Simple Plex Explorer Settings menu.

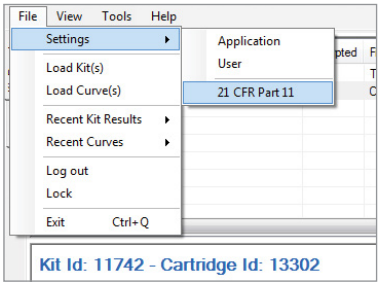
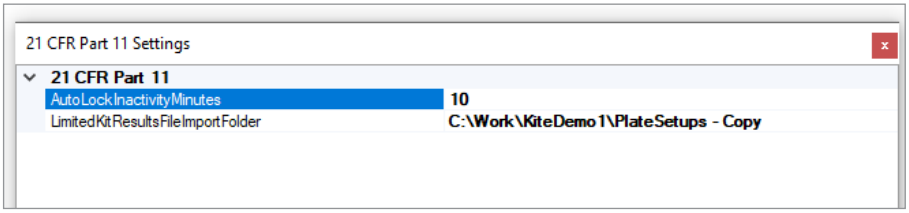


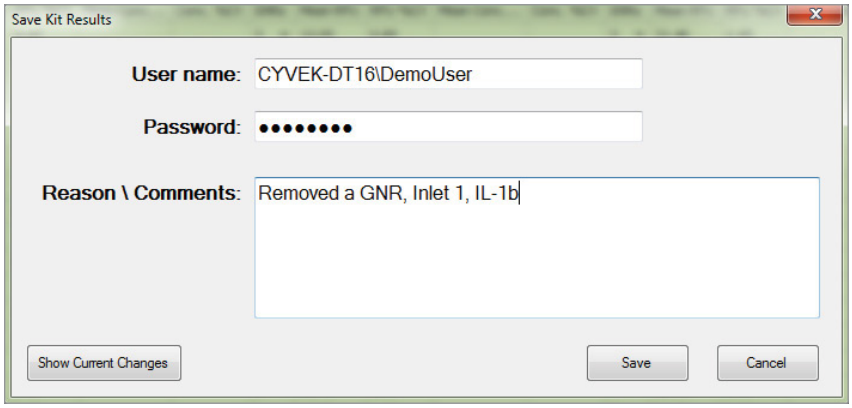
FIGURE 6-17. Simple Plex Explorer Setting dialog.



Saving Changes

In Simple Plex Runner and Explorer, upon choosing to save your changes you will be prompted for an electronic signature in the form of a valid user name and password, and a reason for the change(s) as shown in Figure 6-18.

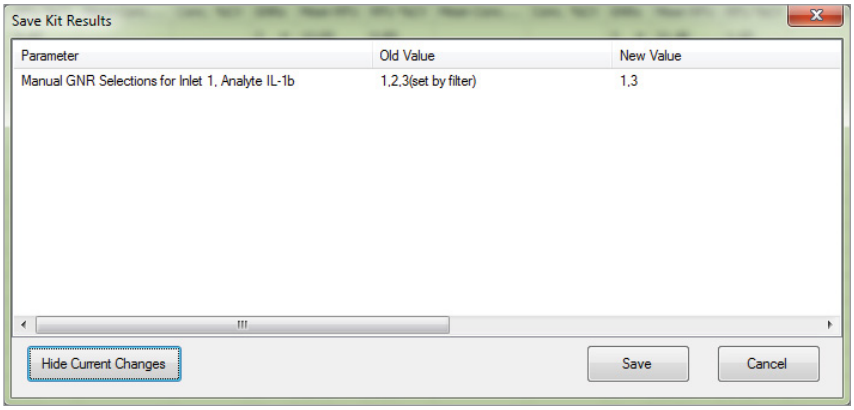
FIGURE 6-18. Save Kit Results dialog - e signature.



Clicking the ***Show Current Changes button*** allows you to review the changes you are signing or saving (Figure 6-19).

It is also possible to add a revision without changes for the purposes of simply adding a note.

FIGURE 6-19. Save Kit Results - current changes.



Viewing Change History

The change history contained in an ECYDAT file may be viewed in detail by clicking the ***Change History*** radio button located on the upper right side of the Kit Results Panel in Simple Plex Runner or Explorer. Additionally, when a kit is saved to a PDF all change history is included. On the Change History panel the details of any particular revision may be viewed by selecting the revision in the upper list of the Change History panel (Figure 6-20 and Figure 6-21).

FIGURE 6-20. Simple Plex Runner Kit Results screen- change history.

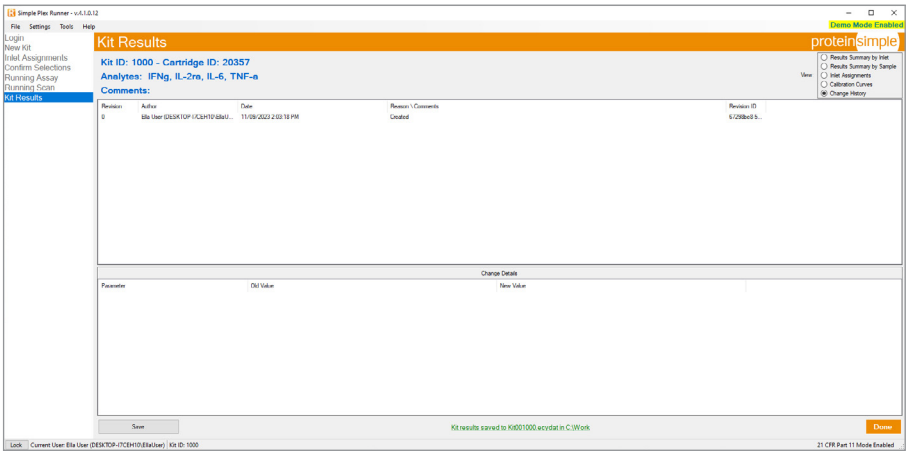
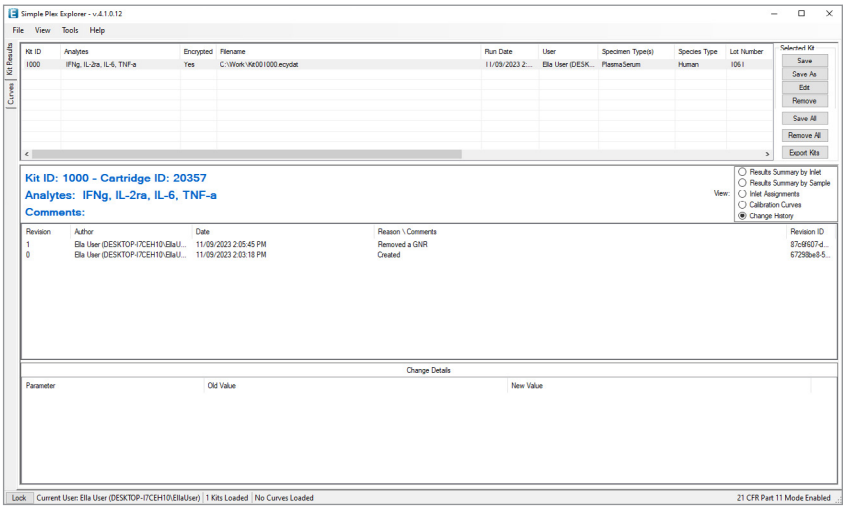


FIGURE 6-21. Simple Plex Explorer Kit Results screen- change history.

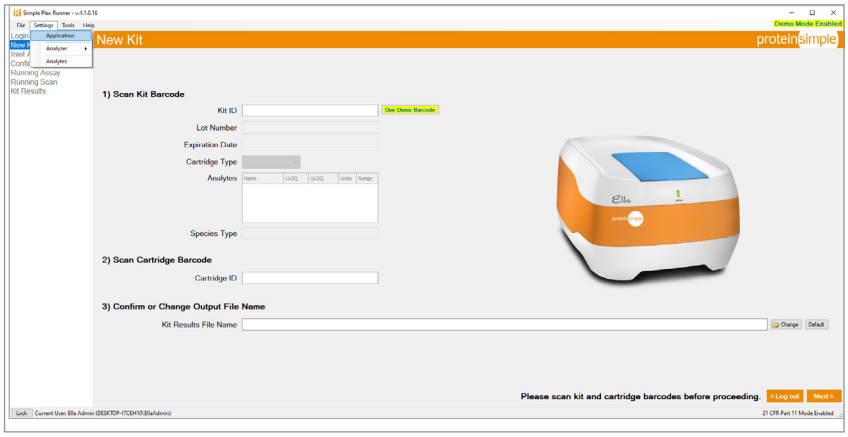


Audit Trail and Reporting

Click *Settings* > *Application* to open the Application Settings Window (Figure 6-22).

Use of this setting (Figure 6-23) determines whether to automatically export a kit results summary report at the end of a run and whenever the kit results file is saved. The location and name of the file will be the same as the kit results file (.cydat or .ecydat) except that the file extension will be changed to .pdf.

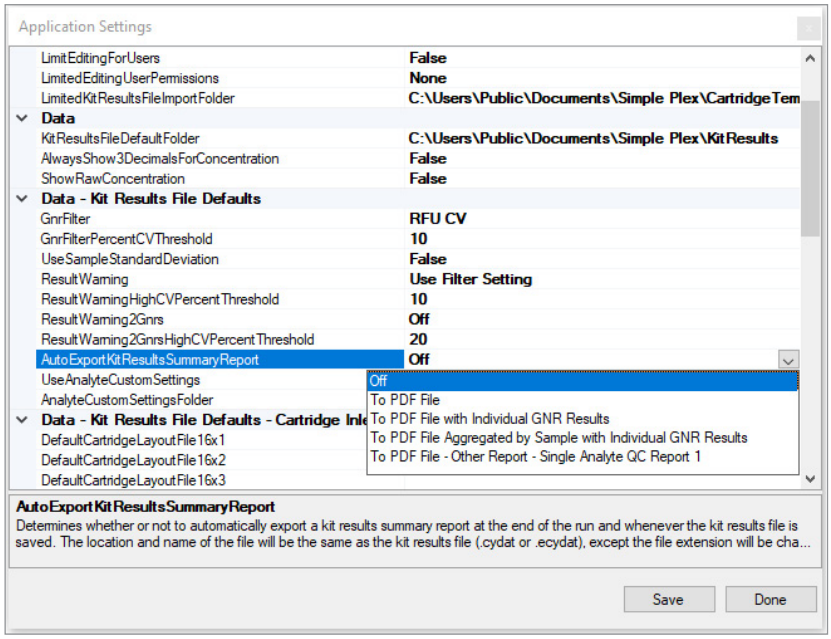
FIGURE 6-22. Accessing the Application Settings window.



Toggle options include:

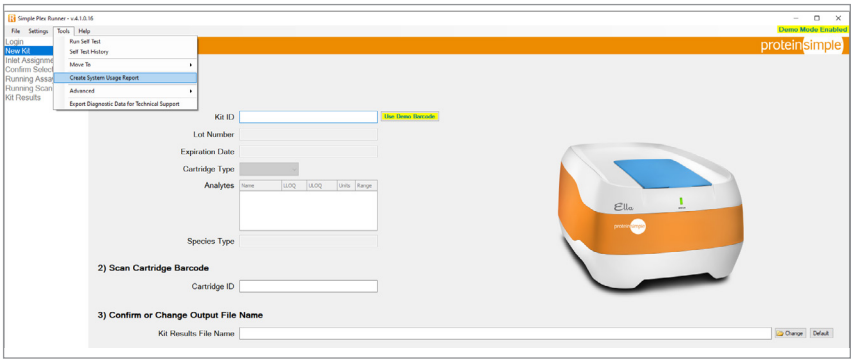
- Off
- To PDF File
- To PDF File + Individual GNR Results
- To PDF File Aggregated by Sample + Individual GNR Results
- To PDF File - Other Report - Single Analyte QC Report 1

FIGURE 6-23. AutoExportKitResultsSummaryReport toggle options.



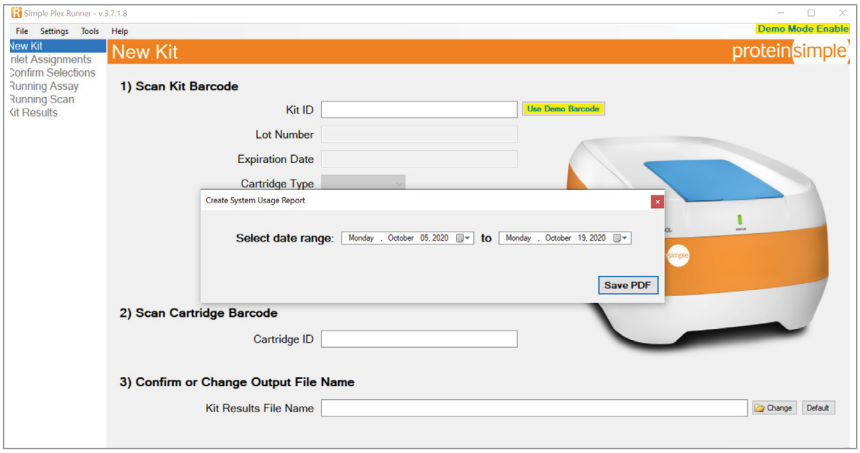
To create a system audit report using the Simple Plex Runner software, click *Tools > Create System Usage Report*.

FIGURE 6-24. Accessing the Create System Usage Report.



An Ella system audit report will contain all logged events for a given Ella from a to-be-specified Start and End date in the form of a PDF that includes page 1 of N numbering. Select a date range and save the PDF.

FIGURE 6-25. Setting start and end dates for system audit report.



Appendix A:

EC Declaration of Conformity

CE

DECLARATION OF CONFORMITY

(According to ISO/IEC 17050-1 and ISO/IEC 17050-2)

Manufacturer's Name: ProteinSimple, Ltd

Manufacturer's Address: 115 Terence Matthews Cres, Kanata, ON, K2M-2B2, Canada

DECLARES THAT THE PRODUCT

Product Name: Automated Ella Immunoassay Analyser

Model Number: Ella

CONFORMS TO THE FOLLOWING EUROPEAN DIRECTIVES

Low Voltage Directive 2006/95/EC

RoHS Directive: 2011 / 65 / EU
WEEE Directive: 2012 / 19 / EU

Supplementary Information:

Safety :	EN 61010-1:2012/R:2019-07
EMC:	EN/IEC 61326-1:2021
Laser Safety:	IEC60825-1:2014

Year in which CE marking was affixed: *2015*

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directives and Standards.

Full Name:	Kurt Wiebe
Title:	Quality Engineer
Location:	Canada
Date:	April 28th, 2023

Signature

European Contact:

Name:	Sarah Hillary
Address:	19 Barton Lane, Abington Science Park, OX14 3NB, UK

Appendix B:

Managing Users and Groups for 21 CFR Part 11 Support

Managing Users and Groups

The following is a guide to managing Local PC Users and Groups. You must be a local administrator in order to perform any of the tasks described herein. This guide does not cover managing users or groups for a local area network.

To manage your Local PC users and groups click on the Windows ***Start button***, right click on ***Computer***, and then click ***Manage*** (Figure B-1). Doing so will display the Computer Management window (Figure B-2).

FIGURE B-1. Accessing the Computer Management in Windows.

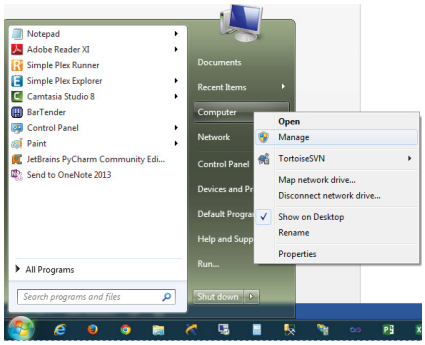
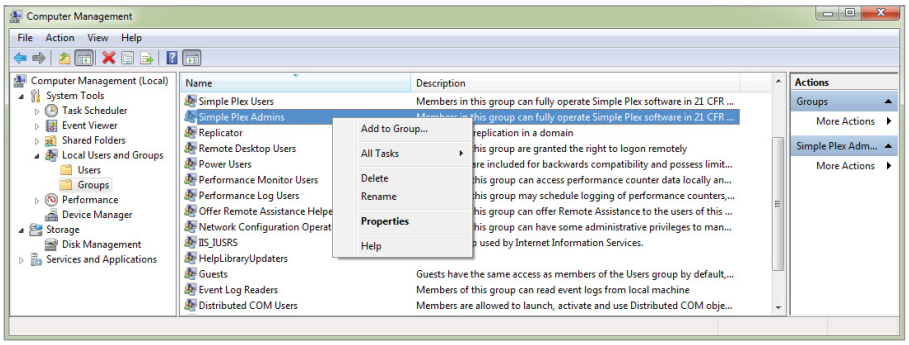


FIGURE B-2. Computer Management



Once the Computer Management window is open, expand ***Local Users and Groups*** under System Tools. To add users, select the ***Users*** folder from the tree on the left of the window. Doing so will display a list of local users in the center section of the Computer Management window. Right click on the list of local users and select ***New User...*** (Figure B-3). A New User dialog will display (Figure B-4). Complete the dialog and click ***Create*** to add a new user.

FIGURE B-3. Computer Management - new user.

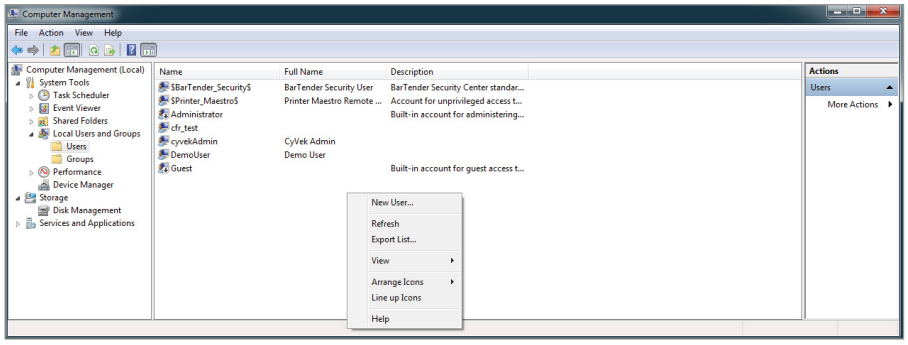
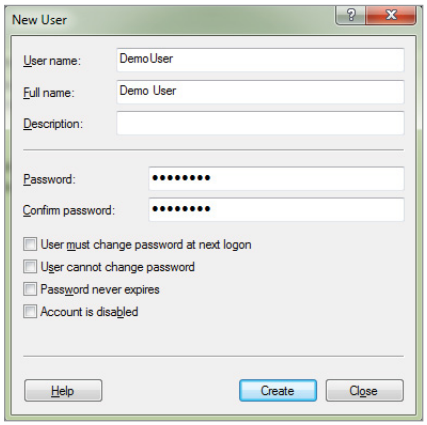


FIGURE B-4. New User dialog.



To manage groups, select the ***Groups*** folder from the tree on the left of the Computer Management window. Doing so will display a list of local groups in the center section of the Computer Management window. To add a group, select and right click on a specific group and click ***Add to Group…*** to manage the group membership (Figure B-5). Clicking ***Add to Group…*** will display the Group Properties dialog which can be used to add or remove members to and from the selected group (Figure B-6).

FIGURE B-5. Computer Management - groups.

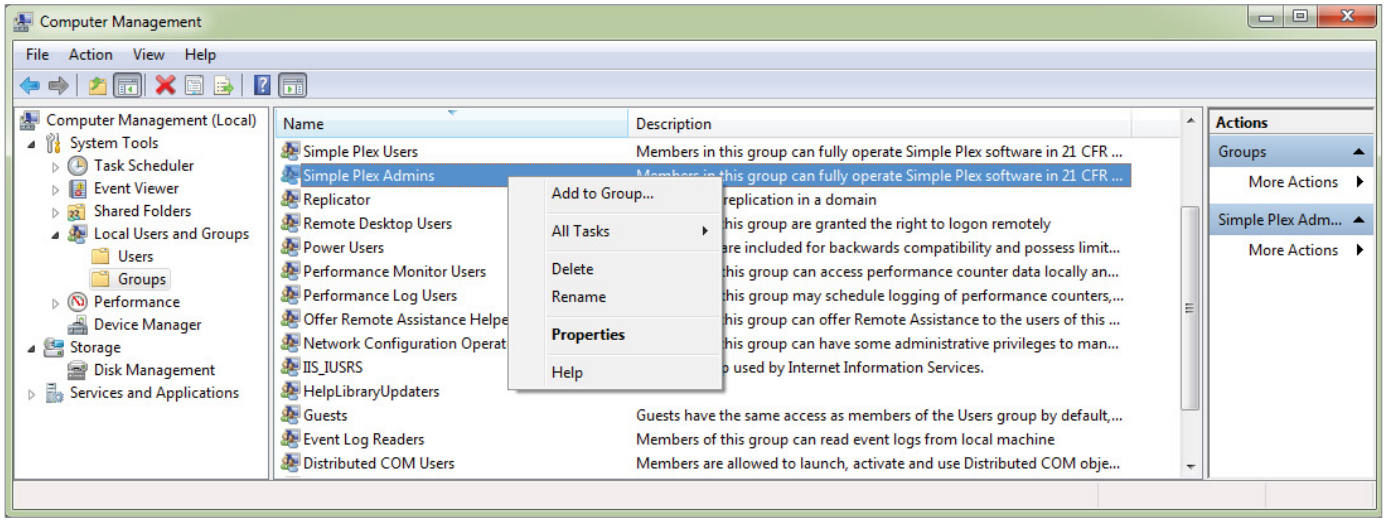
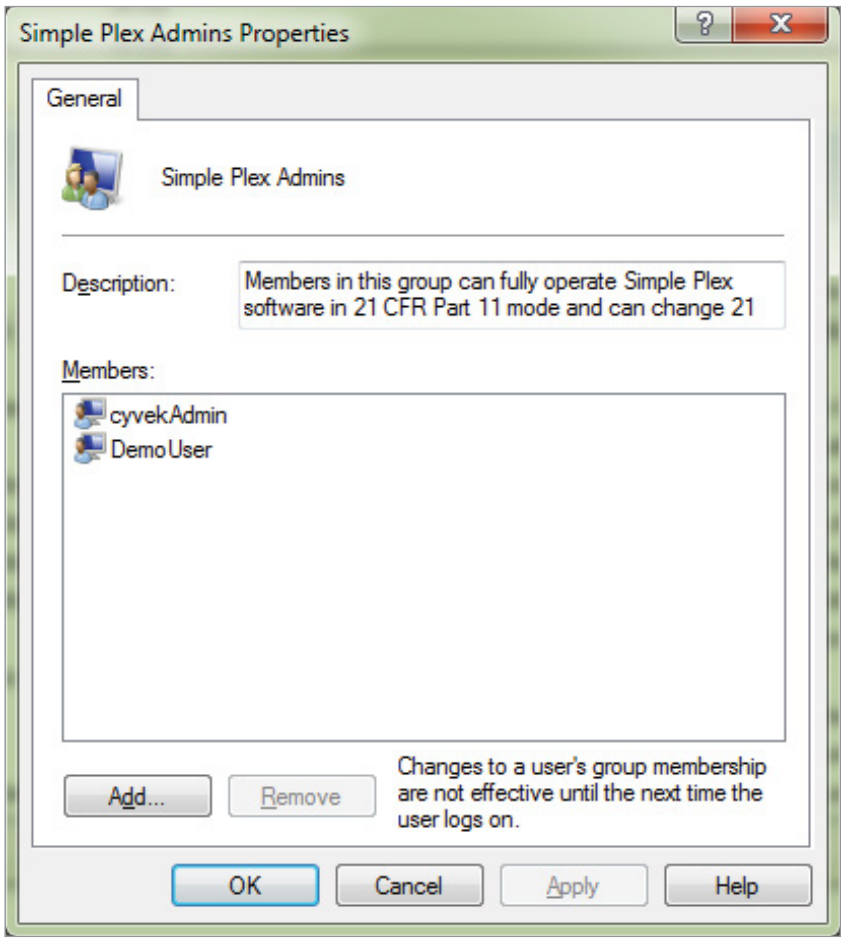


FIGURE B-6. Group properties.



Click the ***Add button*** on the Group Properties dialog. The Select Users dialog will display (Figure B-7).

The Select Users dialog will display (Figure B-7). Enter the names of the users you wish to add and click ***Check Names***. You may need to change the location to search by clicking the ***Locations...*** button. Clicking the ***Locations...*** button will display the Locations dialog (Figure B-8) from which you can specify what location to search for the users names entered in the Select Users dialog. When clicking the ***Check Names*** button results in the entered user being resolved and underlined, click the ***OK*** button to add the users to the Group.

FIGURE B-7. Select users dialog.

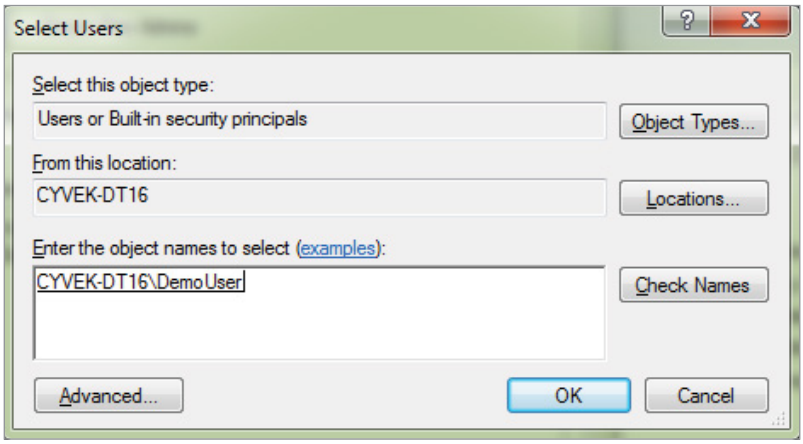
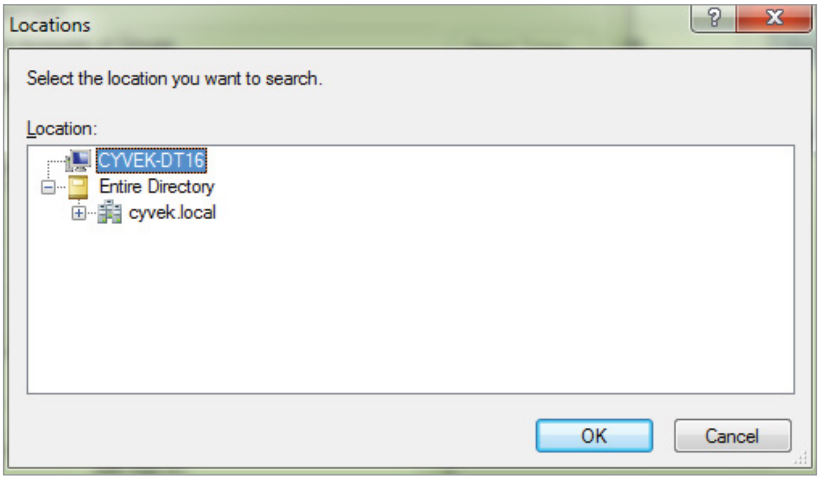


FIGURE B-8. Locations dialog.



Using the Computer Management window is how you add local users, local groups, and configure the membership of the local groups. It should be noted that local groups may contain domain user accounts and/or domain security groups.

Finally it is important to note that in order for a user to utilize the Simple Plex software when 21 CFR Part 11 Mode is enabled, the user must be a member of either the Simple Plex Users or Simple Plex Admins group located locally and/or in the Windows Domain Active Directory.

Appendix C:

Watson LIMS Interface Guide

Overview

This section shows you how to import kit run data from your Simple Plex software into Thermo-Fisher's Watson LIMS system if you have one. To do this, you'll first need to create Sequence files (.SEQ) in Watson using the Generic Raw Data Interface (one file for each analyte). These Sequence files can then be used in Simple Plex Runner or Simple Plex Explorer to import sample names and dilution factors into your Kit Results file (.CYDAT). Once the run is complete, the Sequence files can then be updated with the relative fluorescent units (RFU) from each GNR. The completed Sequence files are then used to import the run data into Watson.

Tips for Configuring Watson LIMS Master Assay

- Set Assay Type to ***RIA***
- Set Instrument Type to ***Ella*** if available.
- An ***Ella*** Instrument Type can be added by your Watson LIMS administrator
    - Select any Instrument Type if Ella is not available
    - Set Instrument Interface to ***Generic-Raw Data (ASCII File)***
- For Standards, set number of replicates to match our CoA or alternatively the number of replicates can be set ***1*** to get a single mean value per concentration.
- For other sample types including QCs, set the number of replicates to ***3***.

Sample Entry Requirements for Watson LIMS

Sample identities for standards, unknowns and QCs must be entered in the specific formats detailed below. Standards information can be requested for some or all concentration levels and should be at the beginning of the sequence. Your Certificate of Analysis (CoA) provides the information necessary (such as concentration and ID). Unknowns and QCs should follow standards in order by cartridge inlet number.

Details for each Sample Type

Standards

Sample identity must be in the following format:

- [...]STD.#
    - [...] = any text
    - STD.# is the concentration level ID
        - STD.1 is first highest concentration
        - STD.2 is next highest concentration, etc.
        - These are available on CoA in high to low concentration order
    - Examples:
        - Test_STD.1
        - Test_STD.2

- Not all standard concentration levels need to be requested. For example, if the highest concentration is to be left out of the curve calculation then the first entry for Standards could be 'Test_STD.2'.

- Number of replicates can be set in two different ways.
  - Either set to a number less than or equal to the number of replicates available.
    Total number of replicates available is on the CoA (as column 'n').
    For example, n=4 means there are 4 replicates (i.e. data points) available for request.
  - Or set to 1 to get a single mean value of all the replicates.
    Using a single mean value might help in cases where one or more of the individual replicates are not meeting your specific acceptance limits.

- Dilution factor must be specified.
- Concentration information is available on the CoA.

Unknowns

Sample identity must be in the following format:
- [...]
  - [...] = any text
  - Example: Test_Sample_A
- Number of replicates must be 3 (1 for each GNR).
- Dilution factor must be specified.

QCs

Sample identity must be in the following format:
- [...]
  - [...] = any text
  - Example: Test_HQC.1
- Number of replicates must be 3 (1 for each GNR).
- Dilution factor must be specified.

Generate Sequence Files in Watson LIMS using Generic Raw Data Interface

Please refer to your Watson LIMS User Manual (currently under Appendix A - Raw Data Interface) on how to export your sample information for a run as Sequence files using the Generic Raw Data Interface. You must create one Sequence file for each analyte.

NOTE: When the Sequence file is exported from Watson LIMS, additional information is added to the sample identity to create the full sample name entry in the first column. Run number and a sequence number are inserted in front. Replicate number (for standards and QCs) and dilution factor are appended to the end.

IMPORTANT
Keep your sample identity names relatively short (less than 60 characters). The combined length of run number, sequence number, sample identity, replicate number and dilution factor should not be longer than 80 characters. At the time of this writing, the current version Watson LIMS truncates any text beyond 80 characters. This causes sample identities to be shortened arbitrarily, and you will not be able to import your run data into Watson.

FIGURE C-1. Example of Sequence file exported from Watson LIMS

1 1 Test_STD.1 1 1	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 2 Test_STD.1 2 1	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 3 Test_STD.1 3 1	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 4 Test_Sam-ple_A_2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 5 Test_Sam-ple_A_2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 6 Test_Sam-ple_A_2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 7 Test_HQC.1 1 2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 8 Test_HQC.1 2 2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time
1 9 Test_HQC.1 3 2	put the File Name	put the Assay Date/ Time	IL-6	put the Raw Data	put the Retention Time

Importing Watson LIMS Sequence Files into Simple Plex Software

Once you've created your Sequence files in Watson LIMS, you'll need to import them into your Kit Results file. To do this in Simple Plex Runner or Simple Plex Explorer:

1. Go to the **Inlet Assignments** screen.
2. Select the **Import button** to bring up the context menu.
3. Select **From LIMS > Watson LIMS**.

This brings up the Import dialog:

4. Use the **Browse** buttons to specify the Sequence file for each analyte and then select the **Import button**. If you have existing information in your inlet assignments you will be prompted to overwrite it.
5. When the import is complete, the sample names and dilution factors will update, and the cartridge comments will list the associated Watson run numbers.

NOTE: Standards are ignored during the import. QCs are imported with a Sample Type of Unknown.

FIGURE C-2. Edit Inlet Assignments with Import button selected.

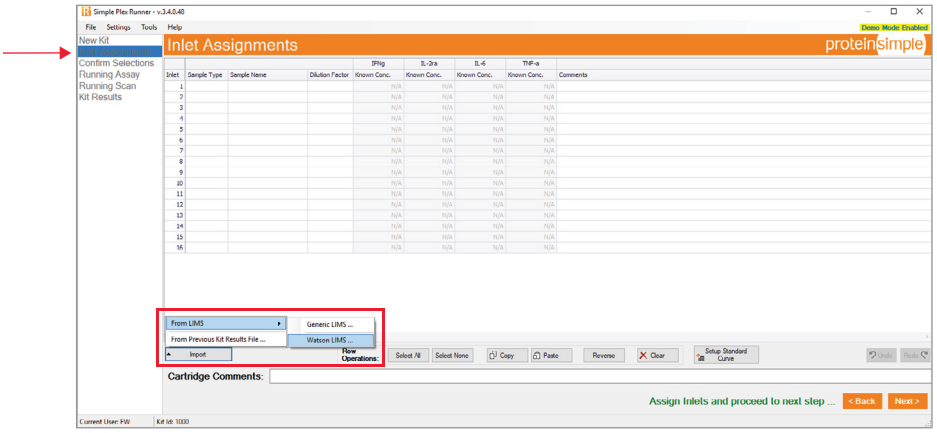


FIGURE C-3. Import from Watson LIMS dialog.

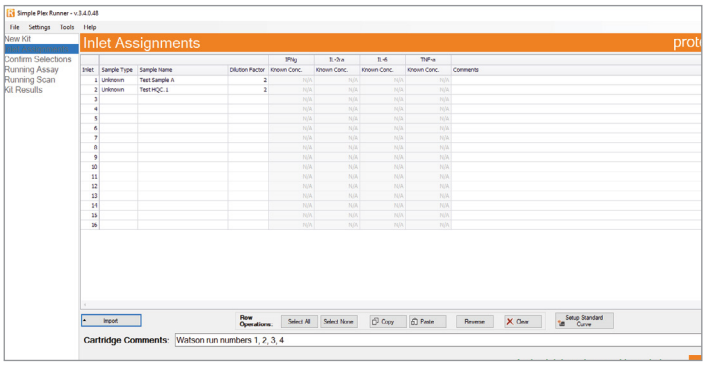
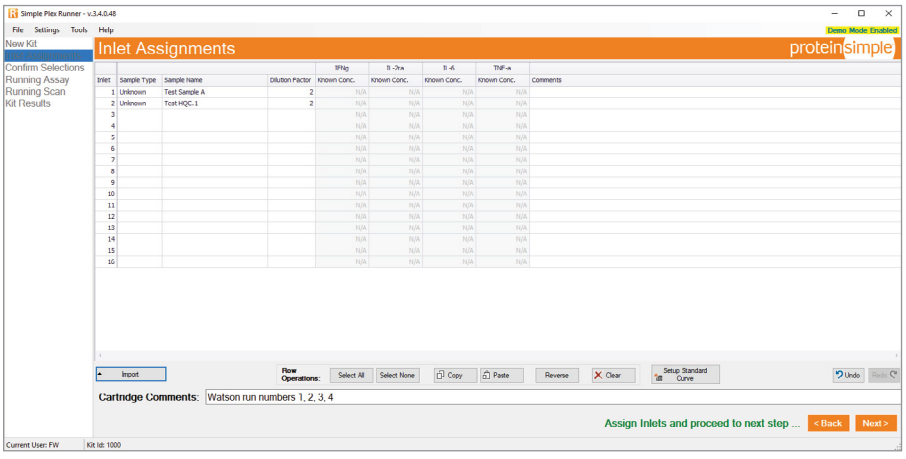


FIGURE C-4. Inlet Assignments with updated sample names and dilution factors.



Exporting Run Data into Watson LIMS Sequence Files from Simple Plex Software

Once the kit run is complete, the Sequence files can be updated with RFU data in either Simple

Plex Runner or Simple Plex Explorer.

1. Go to the Kit Results screen.
2. Select the Export button to bring up the context menu.
3. Select To LIMS - Watson LIMS. This brings up the Export dialog:
4. The Sequence files will automatically populate with the selections used during the import if the application has not since been closed. If it has, just use the Browse buttons to specify a different Sequence file for each analyte.
5. Data from the factory calibration curves will automatically be retrieved if an internet connection is available. If not, you'll need to scan the curve barcodes from your COA.
6. Once the Sequence files have been specified and the Factory Standards data retrieved or scanned, select the Export button to update the files with RFU data. The following dialog displays if the export is successful.
7. Once the export is complete, Watson LIMS can then be used to import the updated Sequence files.

FIGURE C-5. Kit Results Panel with Export Button selected.

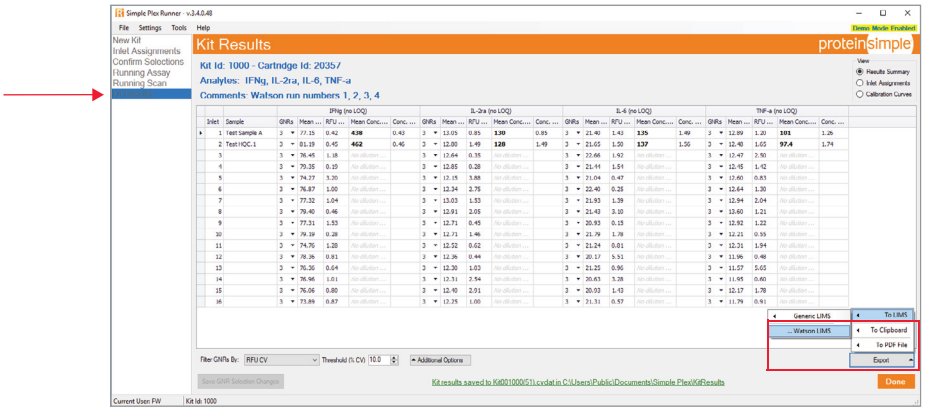


FIGURE C-6. Export to Watson LIMS dialog.

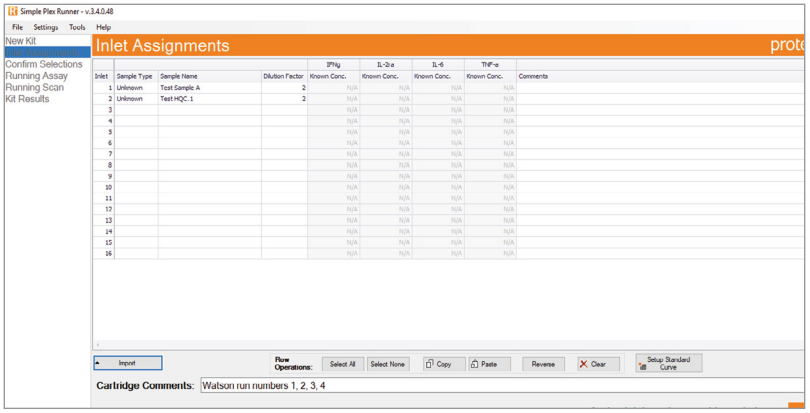


FIGURE C-7. Export to Watson LIMS dialog requiring curve barcode scanning.

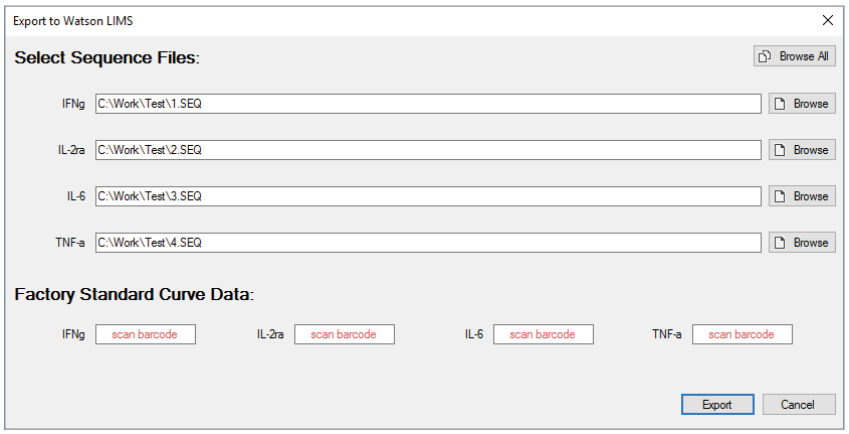
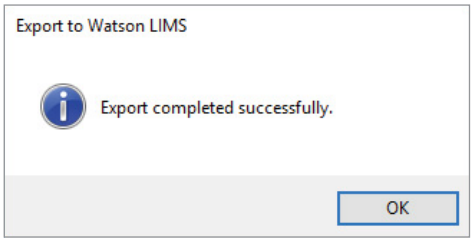


FIGURE C-8. Export successful confirmation.



Appendix D:

Generic LIMS Interface Guide

Overview

The followings steps show how to use the Generic LIMS Import and Export capability in Simple Plex Runner and Explorer. This process uses CSV files to import and export data. The LIMS will need to be configured to be able to load from and save to this type of file with specific column headers and data.

Steps from Simple Plex Runner

1. If importing sample information into Simple Plex Runner, configure this in your LIMS and save to a properly formatted CSV file. See "Supported Columns List and File Specifications" on page 66 for format specifications.

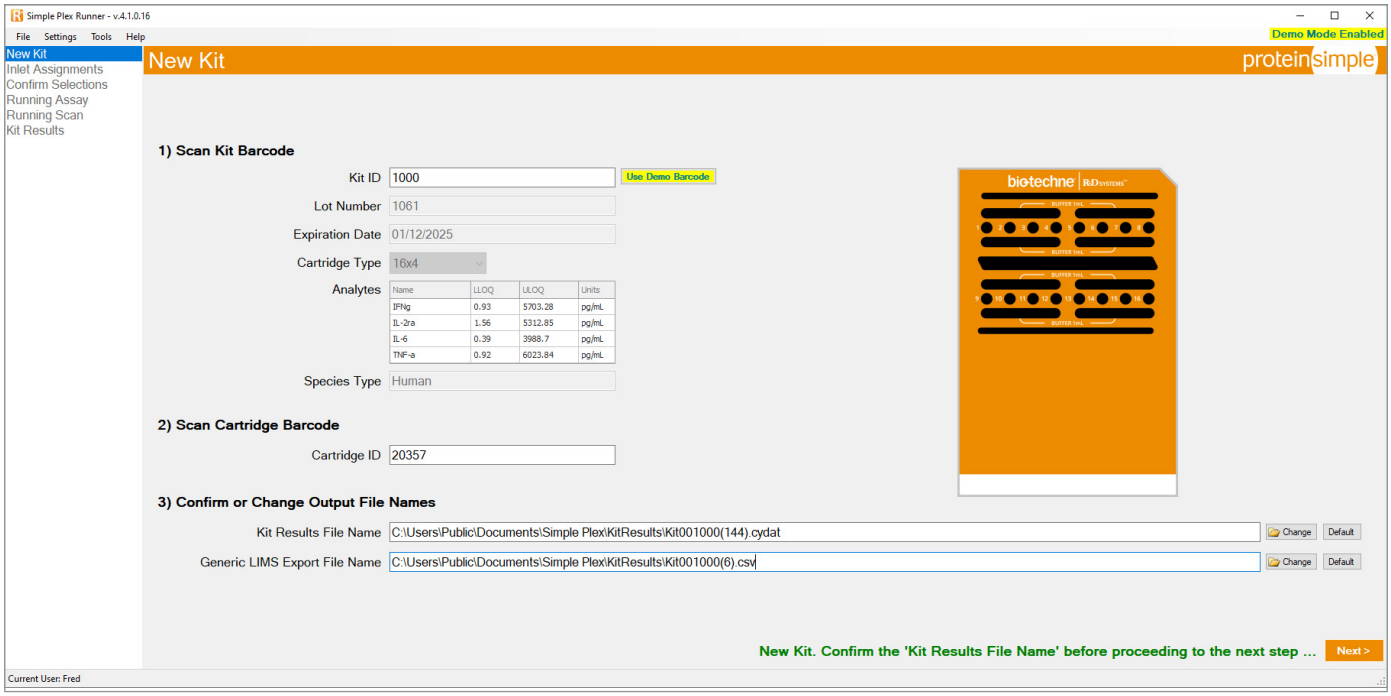
   Tip: To get a sample CSV file, perform a generic LIMS export using any existing Kit Results file. In the Summary Panel in Explorer, click the **Export button** and select **To LIMS-Generic LIMS-Save CSV File with Default Columns**.

2. Open **Runner Application Settings** and enable automatic export of CSV file in the Generic LIMS section using the setting **AutoExportKitResultsToGenericLIMSFile**.

   NOTE: Automatic export is not required. A Generic LIMS export can be performed manually at any time from Simple Plex Explorer or at the end of the run in Simple Plex Runner.

3. From the New Kit panel, scan the kit barcode. If using automatic export, confirm or change the **Generic LIMS Export File Name**. Select **Next** to proceed to Inlet Assignments panel.

FIGURE D-1. New Kit panel



4. From the Inlet Assignments panel, sample information can be imported from a Generic LIMS CSV file. Click the **Import button** and select **From LIMS-Generic LIMS...**. Choose the appropriate CSV file in the open file dialog. See "Supported Columns List and File Specifications" on page 126 for format specifications.

   NOTE: Importing is not required.

   An example of a CSV file used for importing is shown in Figure D-2. Column headers must match to be properly imported. The only required columns are Inlet and Analyte Name.

FIGURE D-2. Example CSV import file.

	A	B	C	D	E	F	G	H	I	J
1	Inlet	Sample Type	Sample Name	Dilution Factor	Analyte Name	Comments				
2	1	Unknown	Test	2	IFNg					
3	1	Unknown	Test	2	IL-2ra					
4	1	Unknown	Test	2	IL-6					
5	1	Unknown	Test	2	TNF-a					
6	2	Unknown	Test	2	IFNg					
7	2	Unknown	Test	2	IL-2ra					
8	2	Unknown	Test	2	IL-6					
9	2	Unknown	Test	2	TNF-a					
10	3	Unknown	Test	2	IFNg					
11	3	Unknown	Test	2	IL-2ra					
12	3	Unknown	Test	2	IL-6					
13	3	Unknown	Test	2	TNF-a					
14	4	Unknown	Test	2	IFNg					
15	4	Unknown	Test	2	IL-2ra					
16	4	Unknown	Test	2	IL-6					
17	4	Unknown	Test	2	TNF-a					
18	5	Unknown	Test	2	IFNg					
19	5	Unknown	Test	2	IL-2ra					
20	5	Unknown	Test	2	IL-6					
21	5	Unknown	Test	2	TNF-a					
22	6	Unknown	Test	2	IFNg					
23	6	Unknown	Test	2	IL-2ra					
24	6	Unknown	Test	2	IL-6					
25	6	Unknown	Test	2	TNF-a					
26	7	Unknown	Test	2	IFNg					
27	7	Unknown	Test	2	IL-2ra					
28	7	Unknown	Test	2	IL-6					
29	7	Unknown	Test	2	TNF-a					
30	8	Unknown	Test	2	IFNg					
31	8	Unknown	Test	2	IL-2ra					
32	8	Unknown	Test	2	IL-6					
33	8	Unknown	Test	2	TNF-a					

Kit001000

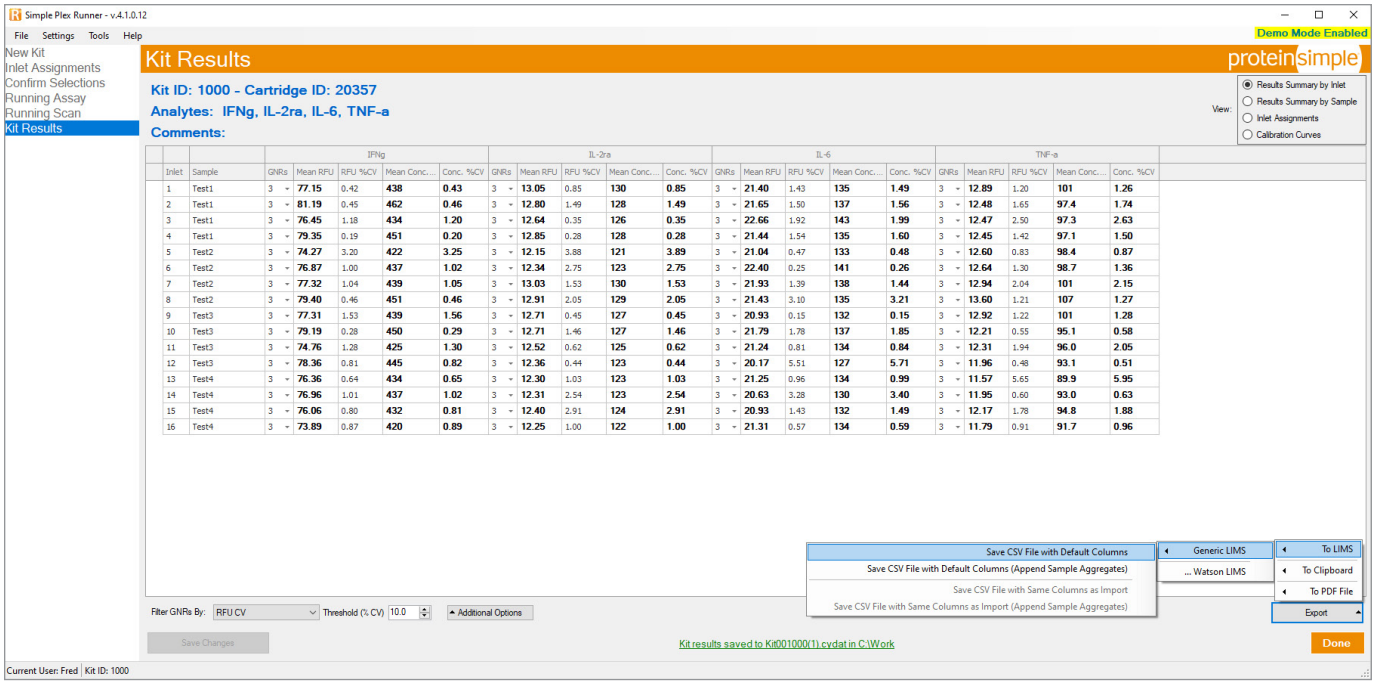
5. Run the cartridge as usual.

6. When the run is complete, if the auto export was enabled then a Generic LIMS Export File (CSV) will be produced in addition to the Kit Results File (CYDAT). Otherwise, click the ***Export*** button and select ***To LIMS-Generic LIMS-Save CSV File with Default Columns*** or to ***LIMS-Generic LIMS-Save CSV File with Same Columns as Import***.

NOTE: LIMS-Generic LIMS-Save CSV File with Same Columns as Import will be disabled if an import was not performed

NOTE: Append Sample Aggregates options are described later.

FIGURE D-3. Kit Results.

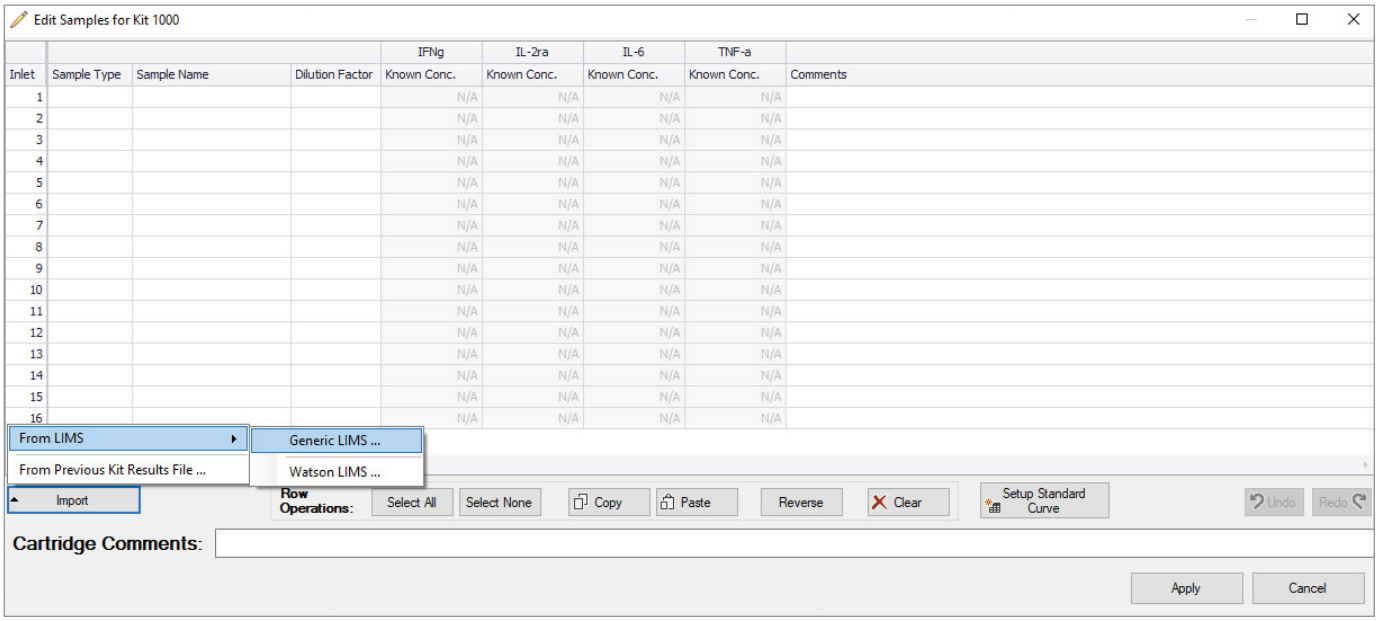


Steps from Simple Plex Explorer

To import a Generic LIMS CSV file in Simple Plex Explorer:

1. Edit the desired kit.
2. From the edit dialog, click the ***Import button*** in the lower left and select ***From LIMS-Generic LIMS ....***
3. Choose the appropriate CSV file in the open file dialog.
   See "Supported Columns List and File Specifications" on page 126 for additional details on importing.

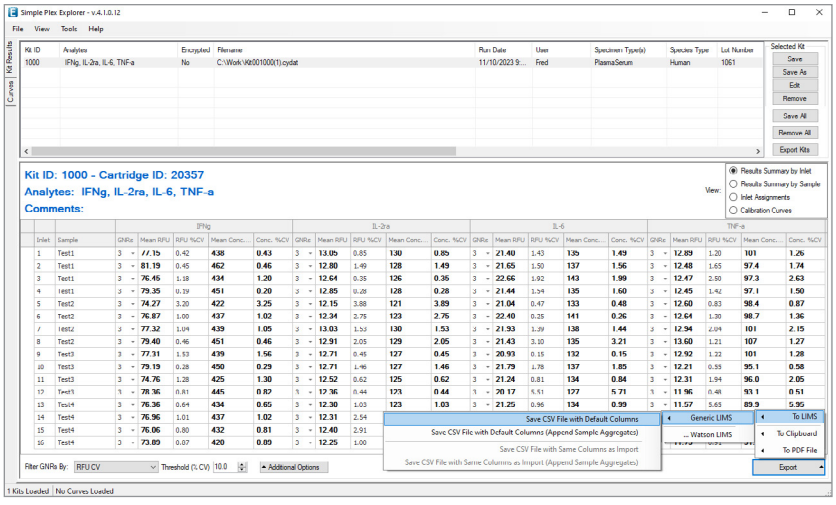
FIGURE D-4. Edit kit samples.



To export a Generic LIMS CSV file in Simple Plex Explorer:

1. Load the desired kit results file.
2. From the Results Summary panel, click the ***Export button*** and select ***To LIMS-Generic LIMSSave CSV File with Default Columns*** or ***To LIMS-Generic LIMS-Save CSV File with Same Columns as Import***.

FIGURE D-5. Results Summary panel.



NOTE: To LIMS-Generic LIMS-Save CSV File with Same Columns as Import will be disabled if an import was not performed. See "Supported Columns List and File Specifications" on page 66 for additional details on exporting.

NOTE: Append Sample Aggregates options are described later.

Supported Columns List and File Specifications

FIGURE D-1. Columns and specifications.

Exact Column Name	Required	Importable	Is Default Column	Additional Details
Kit Id			Yes	Table text
Inlet	Yes		Yes	Inlet number
Sample Type		Yes	Yes	Possible values are Unknown, Standard, Control, or Spike
Sample Name		Yes	Yes	
Dilution Factor		Yes	Yes	
Analyte Name	Yes*	Yes*	Yes	Analyte field is required for all cartridge types except 48x1 Importable for 48x1 only
Known Conc.		Yes	Yes	
Capture Name		Yes*	Yes	Importable for 48x1 only
Capture Conc.		Yes*	Yes	Importable for 48x1 only
Detect Name		Yes*	Yes	Importable for 48x1 only
Detect Conc.		Yes*	Yes	Importable for 48x1 only
GNRs			Yes	The number of selected GNRs
Mean RFU			Yes	The mean of selected GNRs.
RFU %CV			Yes	
Mean Conc.			Yes	The mean of selected GNRs.
Conc. %CV			Yes	
Comments			Yes	Inlet comments
Raw Conc.			Yes	The mean of selected GNRS. Raw Conc. is measured concentration before adjusting for dilution factor.
Units		Yes*	Yes	Importable for 48x1 only

*Indicates there are exceptions based on cartridge format. See Additional Details column.

Additional Specifications

- Columns names must match table.
- Columns can be specified in any order for importing.
- Rows can be specified in any order for importing, but export will be ordered by inlet then analyte name.
- Columns that are not importable and in the table will be ignored during import. For the Same Columns as Import export option, these columns will be filled with the appropriate data during the export.
- Columns that are not in this table will be ignored during import. For the Same Columns as Import export option, these columns will be reproduced with data.

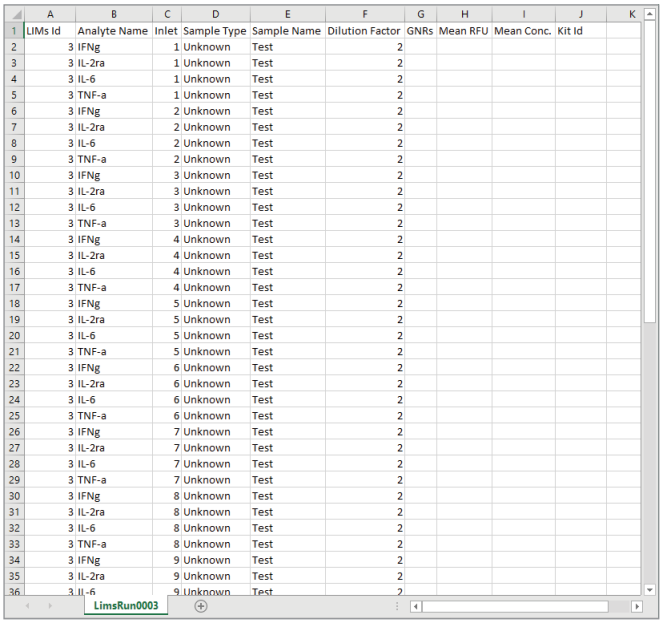
  Tip: This can be used to provide and preserve additional metadata from the LIMS.
- The columns in the Default Columns export option are those marked as Is Default Column. Column order will match the row order in this table.
- Additional default columns may be added to the export in future versions of the Simple Plex software. These would be appended after the Units column. Please ensure your LIMS CSV parsing implementations are not sensitive to this possibility.

Custom Column Import and Export Example Files

The examples below show the import of a CSV file with a custom column and export using the Same Columns as Import option.

Import File: The first column here is a custom column.

FIGURE D-7. Example import file.



	A	B	C	D	E	F	G	H	I	J	K
1	LIMs Id	Analyte Name	Inlet	Sample Type	Sample Name	Dilution Factor	GNRs	Mean RFU	Mean Conc.	Kit Id	
2	3	IFNg	1	Unknown	Test	2					
3	3	IL-2ra	1	Unknown	Test	2					
4	3	IL-6	1	Unknown	Test	2					
5	3	TNF-a	1	Unknown	Test	2					
6	3	IFNg	2	Unknown	Test	2					
7	3	IL-2ra	2	Unknown	Test	2					
8	3	IL-6	2	Unknown	Test	2					
9	3	TNF-a	2	Unknown	Test	2					
10	3	IFNg	3	Unknown	Test	2					
11	3	IL-2ra	3	Unknown	Test	2					
12	3	IL-6	3	Unknown	Test	2					
13	3	TNF-a	3	Unknown	Test	2					
14	3	IFNg	4	Unknown	Test	2					
15	3	IL-2ra	4	Unknown	Test	2					
16	3	IL-6	4	Unknown	Test	2					
17	3	TNF-a	4	Unknown	Test	2					
18	3	IFNg	5	Unknown	Test	2					
19	3	IL-2ra	5	Unknown	Test	2					
20	3	IL-6	5	Unknown	Test	2					
21	3	TNF-a	5	Unknown	Test	2					
22	3	IFNg	6	Unknown	Test	2					
23	3	IL-2ra	6	Unknown	Test	2					
24	3	IL-6	6	Unknown	Test	2					
25	3	TNF-a	6	Unknown	Test	2					
26	3	IFNg	7	Unknown	Test	2					
27	3	IL-2ra	7	Unknown	Test	2					
28	3	IL-6	7	Unknown	Test	2					
29	3	TNF-a	7	Unknown	Test	2					
30	3	IFNg	8	Unknown	Test	2					
31	3	IL-2ra	8	Unknown	Test	2					
32	3	IL-6	8	Unknown	Test	2					
33	3	TNF-a	8	Unknown	Test	2					
34	3	IFNg	9	Unknown	Test	2					
35	3	IL-2ra	9	Unknown	Test	2					
36	3	IL-6	9	Unknown	Test	2					

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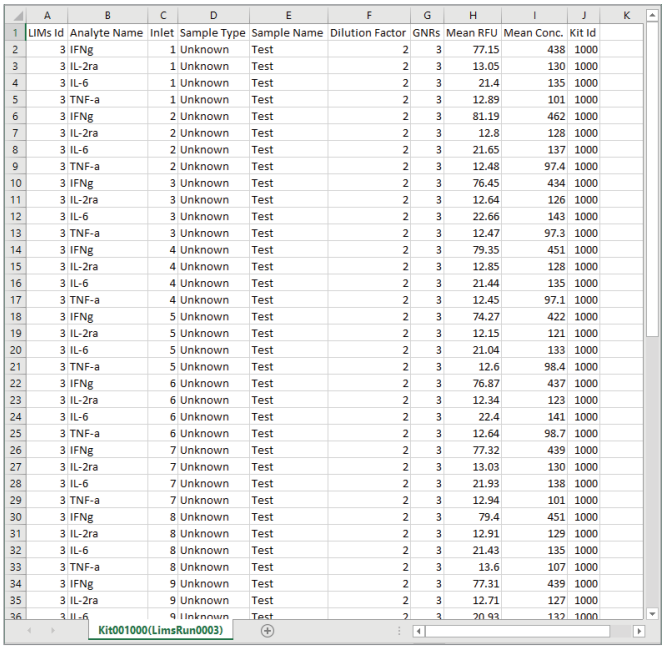
Export File: The first column here was preserved by export. GNRs, Mean RFU, Mean Conc. and Kit Id columns were filled.

FIGURE D-8. Example export file.



	A	B	C	D	E	F	G	H	I	J	K
1	LIMs Id	Analyte Name	Inlet	Sample Type	Sample Name	Dilution Factor	GNRs	Mean RFU	Mean Conc.	Kit Id	
2	3	IFNg	1	Unknown	Test	2	3	77.15	438	1000	
3	3	IL-2ra	1	Unknown	Test	2	3	13.05	130	1000	
4	3	IL-6	1	Unknown	Test	2	3	21.4	135	1000	
5	3	TNF-a	1	Unknown	Test	2	3	12.89	101	1000	
6	3	IFNg	2	Unknown	Test	2	3	81.19	462	1000	
7	3	IL-2ra	2	Unknown	Test	2	3	12.8	128	1000	
8	3	IL-6	2	Unknown	Test	2	3	21.65	137	1000	
9	3	TNF-a	2	Unknown	Test	2	3	12.48	97.4	1000	
10	3	IFNg	3	Unknown	Test	2	3	76.45	434	1000	
11	3	IL-2ra	3	Unknown	Test	2	3	12.64	126	1000	
12	3	IL-6	3	Unknown	Test	2	3	22.66	143	1000	
13	3	TNF-a	3	Unknown	Test	2	3	12.47	97.3	1000	
14	3	IFNg	4	Unknown	Test	2	3	79.35	451	1000	
15	3	IL-2ra	4	Unknown	Test	2	3	12.85	128	1000	
16	3	IL-6	4	Unknown	Test	2	3	21.44	135	1000	
17	3	TNF-a	4	Unknown	Test	2	3	12.45	97.1	1000	
18	3	IFNg	5	Unknown	Test	2	3	74.27	422	1000	
19	3	IL-2ra	5	Unknown	Test	2	3	12.15	121	1000	
20	3	IL-6	5	Unknown	Test	2	3	21.04	133	1000	
21	3	TNF-a	5	Unknown	Test	2	3	12.6	98.4	1000	
22	3	IFNg	6	Unknown	Test	2	3	76.87	437	1000	
23	3	IL-2ra	6	Unknown	Test	2	3	12.34	123	1000	
24	3	IL-6	6	Unknown	Test	2	3	22.4	141	1000	
25	3	TNF-a	6	Unknown	Test	2	3	12.64	98.7	1000	
26	3	IFNg	7	Unknown	Test	2	3	77.32	439	1000	
27	3	IL-2ra	7	Unknown	Test	2	3	13.03	130	1000	
28	3	IL-6	7	Unknown	Test	2	3	21.93	138	1000	
29	3	TNF-a	7	Unknown	Test	2	3	12.94	101	1000	
30	3	IFNg	8	Unknown	Test	2	3	79.4	451	1000	
31	3	IL-2ra	8	Unknown	Test	2	3	12.91	129	1000	
32	3	IL-6	8	Unknown	Test	2	3	21.43	135	1000	
33	3	TNF-a	8	Unknown	Test	2	3	13.6	107	1000	
34	3	IFNg	9	Unknown	Test	2	3	77.31	439	1000	
35	3	IL-2ra	9	Unknown	Test	2	3	12.71	127	1000	
36	3	IL-6	9	Unknown	Test	2	3	20.93	132	1000	

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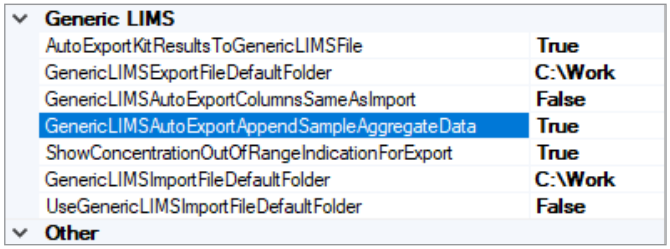
Append Sample Aggregates Option for Exports

Additional options are available to append a second table to the CSV exports to include sample aggregate information.

For automatic exports in Simple Plex Runner, this can be configured using the GenericLIMSAutoExportAppendSampleAggregateData setting.

FIGURE D-9. GenericLIMSAutoExportAppendSampleAggreagteData setting.



Generic LIMS	
AutoExportKitResultsToGenericLIMSFile	**True**
GenericLIMSExportFileDefaultFolder	**C:\Work**
GenericLIMSAutoExportColumnsSameAsImport	**False**
GenericLIMSAutoExportAppendSampleAggregateData	**True**
ShowConcentrationOutOfRangeIndicationForExport	**True**
GenericLIMSImportFileDefaultFolder	**C:\Work**
UseGenericLIMSImportFileDefaultFolder	**False**
Other	

For manual exports choose the option with Append Sample Aggregates in the suffix.

When this option is selected, a second table will append a table with the data aggregated by sample name.

Additional Specifications

- The columns in this table are fixed.
- A single empty row exists between the two tables.
- Rows represent aggregate of inlet / analyte data.
- Aggregations are based on Sample Name.

FIGURE D-10. Append Sample Aggregates Generic LIMS export.

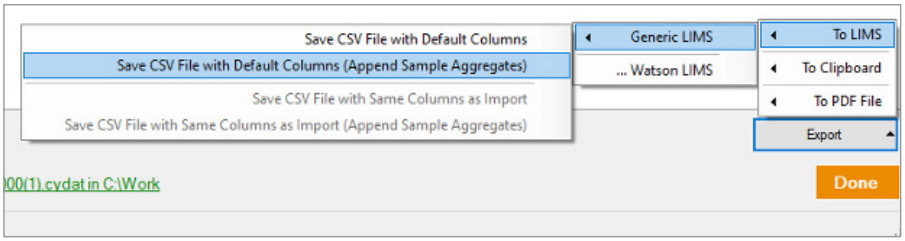
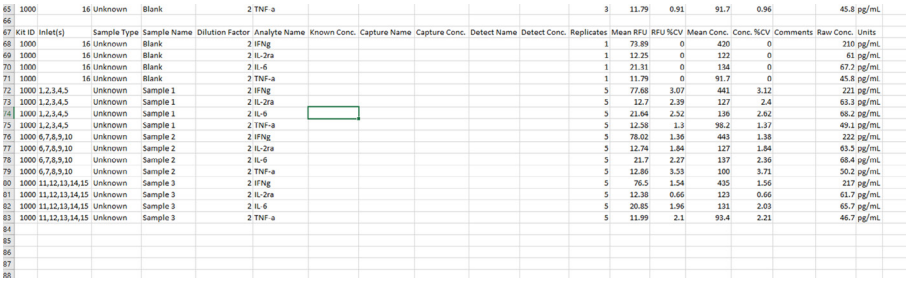


FIGURE D-11. Sample Aggregate Generic LIMS CSV output table.



Kit ID	Inlet(s)	Sample Type	Sample Name	Dilution Factor	Analyte Name	Known Conc.	Capture Name	Capture Conc.	Detect Name	Detect Conc.	Replicates	Mean RFU	RFU %CV	Mean Conc.	Conc. %CV	Comments	Raw Conc.	Units
1000	16	Unknown	Blank	2	IFNg						1	73.89	0	420	0		210	pg/mL
1000	16	Unknown	Blank	2	IL-2ra						1	12.25	0	122	0		61	pg/mL
1000	16	Unknown	Blank	2	IL-6						1	21.31	0	134	0		67.2	pg/mL
1000	16	Unknown	Blank	2	TNF-a						1	11.79	0	91.7	0		45.8	pg/mL
1000	1,2,3,4,5	Unknown	Sample 1	2	IFNg						5	77.68	3.07	441	3.12		221	pg/mL
1000	1,2,3,4,5	Unknown	Sample 1	2	IL-2ra						5	12.7	2.39	127	2.4		63.3	pg/mL
1000	1,2,3,4,5	Unknown	Sample 1	2	IL-6						5	21.64	2.52	136	2.62		68.2	pg/mL
1000	1,2,3,4,5	Unknown	Sample 1	2	TNF-a						5	12.58	1.3	98.2	1.37		49.1	pg/mL
1000	6,7,8,9,10	Unknown	Sample 2	2	IFNg						5	78.02	1.36	443	1.38		222	pg/mL
1000	6,7,8,9,10	Unknown	Sample 2	2	IL-2ra						5	12.74	1.84	127	1.84		63.5	pg/mL
1000	6,7,8,9,10	Unknown	Sample 2	2	IL-6						5	21.7	2.27	137	2.36		68.4	pg/mL
1000	6,7,8,9,10	Unknown	Sample 2	2	TNF-a						5	12.86	3.53	100	3.71		50.2	pg/mL
1000	11,12,13,14,15	Unknown	Sample 3	2	IFNg						5	76.5	1.54	435	1.56		217	pg/mL
1000	11,12,13,14,15	Unknown	Sample 3	2	IL-2ra						5	12.38	0.66	123	0.66		61.7	pg/mL
1000	11,12,13,14,15	Unknown	Sample 3	2	IL-6						5	20.85	1.96	131	2.03		65.7	pg/mL
1000	11,12,13,14,15	Unknown	Sample 3	2	TNF-a						5	11.99	2.1	93.4	2.21		46.7	pg/mL

FIGURE D-12. Column Information.

Exact Column Name	Additional Details
Kit Id	
Inlet(s)	Comma separated inlet numbers (entire cell is quoted).
Sample Type	Single value if same for all aggregated replicates. Otherwise, blank.
Sample Name	
Dilution Factor	Single value if same for all aggregated replicates. Otherwise, blank.
Analyte Name	
Known Conc.	Single value if same for all aggregated replicates. Otherwise, blank.
Capture Name	Single value if same for all aggregated replicates. Otherwise, blank.
Capture Conc.	Single value if same for all aggregated replicates. Otherwise, blank.
Detect Name	Single value if same for all aggregated replicates. Otherwise, blank.
Detect Conc.	Single value if same for all aggregated replicates. Otherwise, blank.
Replicates	Number of replicates with 1 or more selected GNRs. A replicate represents data for a single inlet / analyte. Replicates with 0 GNRS are not counted.
Mean RFU	The mean of replicates.
RFU %CV	%CV of replicate RFU values.
Mean Conc.	The mean of replicates.
Conc. %CV	%CV of replicate concentration values.
Comments	Single value if same for all aggregated replicates. Otherwise, blank.
Raw Conc.	The mean of replicates. Raw Conc. is measured concentration before adjusting for dilution factor.
Units	Single value if same for all aggregated replicates. Otherwise, blank.

NOTE: Additional columns may be appended after Units in future versions of the Simple Plex Software.

Appendix E:

Ella System PC Minimum Requirement and Setup

Ella System PC Minimum Requirements

Operating System - Windows 10 Professional 64bit

Hardware

Processor: Intel Core i7 – 6th Generation - Quad Core

Memory: 16 GB RAM

Storage: 500 GB Hard Drive

Graphics: Intel Integrated Graphics

USB: 2 Ports – USB 2.0 Type A (1 for Ella interfacing, 1 for barcode scanner)
(optional) 1 additional USB Type A or C Port for Ethernet adapter (LAN connectivity)
Note: additional USB port(s) may be required for keyboard and mouse connectivity

Display Resolution: 1600x900 (with 100% Display Scaling), 1920x1080 (with 125% Display Scaling)

Keyboard and Mouse

Network Interface Card (NIC): 1 Intel Based Gigabit NIC for interfacing with the Ella Camera
NIC must be either integrated on PC motherboard or added via an internal expansion slot.
An external Ethernet adapter is not supported.

Additional Hardware

Barcode Scanner: Symbol DS4308-SR7U2100AZW

(Optional) Network Interface Card or USB-A / USB-C based Ethernet adapter: 1 NIC / Ethernet Adapter for LAN connectivity

Ella System PC Setup

IMPORTANT NOTE: Due to the high volume of ethernet traffic between the Ella camera and the PC, many antivirus and monitoring packages may block or interfere with the Runner application. A permanent exception for Simple Plex Runner with the antivirus application is often necessary.

Computers purchased with the Ella system will be pre-configured at the factory. If the Ella-associated PC is upgraded or provided from an outside source, configure according to the directions below.

1. Configure Network Interface Card for Ella Camera under Network Adapters in Device Manager
   A. Confirm Driver Provider is Intel
   B. Configure NIC Advanced Properties
      i. Jumbo Packet to 9014
      ii.Interrupt Moderation Rate to Extreme
      iii.Receive Buffers to 2048 or MAX
      iv. Transmit Buffers to 256

2. Install Simple Plex Runner

3. Connect and Power on Ella (leave Barcode scanner disconnected)

4. Install Ella USB Driver located in "C:\Program Files (x86)\ProteinSimple\Simple Plex Runner\Driver"
   A. Configure the Ella COM Port under Ports in Device Manager
      i.Set COM Port to COM3

1. Connect the Barcode scanner
   A. Configure the Barcode COM Port under Ports in Device Manager
      i. Set COM Port to COM4

2. Set Power & sleep options in the Windows System Settings
   When plugged in, turn off after Screen: Never, Sleep: Never

3. Recommended Windows Update Settings
   A. Change active hours to when the Ella is in operation
      i. Set Maximum allowed
   B. Restart Options
      i. Turn on options to show more notifications

Ella System Barcode Scanner Setup

NOTE: This procedure is specific to the barcode scanner provided with Ella.

Basic Configuration

Computers purchased with the Ella system will have the barcode scanner pre-configured at the factory. If a compatible barcode scanner is provided from an outside source, scan the following barcodes in order top to bottom (left column first, right column second) for the initial scanner config.

Set Sound Volume

Set Tab after scan

Set to COM Port mode

CDC COM Port Emulation

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