

Sievers* Eclipse

User Guide

software v2.00 or later



Sievers Eclipse
Bacterial Endotoxins Testing Platform



Sievers* Eclipse User Guide

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**6060 Spine Road
Boulder, CO 80301 USA
www.sieversinstruments.com**

***For technical support, contact Technical Support or your local service provider.
In the Americas, contact Technical Support at +1 888 245 2595.***

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An electronic version of the Analyzer's *User Guide* is available from our website.

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SAFETY WARNINGS—ENGLISH



This symbol is found on the Analyzer and in the operating manual. This symbol indicates safety notes and instructions. Read these precautions before using the Analyzer for the first time.

- The Eclipse Analyzer is rated IP 21 for incidental exposure to water.
- The Analyzer should be installed on a clean, level surface at least 24 in. (610 mm) deep, 16 in. (406 mm) wide, and free of obstructions up to 12 in. (305 mm) high to allow for the lid to fully open. This is referred to as the clearance envelope for the Analyzer.
- Select a location away from direct sunlight and extreme temperatures. Avoid operating at temperatures greater than 30 °C (86 °F) or lower than 17 °C (63 °F), as temperatures outside this range can prevent correct operation.
- Total weight of the Analyzer is 22 lbs (10 kg).
- The power switch and power cord connection are located at the back of the Analyzer. Maintain a clearance of at least 4 in. (102 mm) from the back of the Analyzer to allow for ease of disconnecting the Analyzer from power when necessary.



The Analyzer is to be connected to a properly grounded electrical source through an IEC 320 C13 power cord. Protective earthing connection is made through the IEC 320 C13 power cord with no provisions for other means of earthing the Analyzer.

Analyzer Operation



If the Eclipse Analyzer is used in a manner not specified by Sievers Analytical Instruments, the safety protection provided by the instrument may be impaired.

- Do not place anything on top of the Eclipse Analyzer.
- Do not lean on the Eclipse Analyzer.
- Do not place or store anything within the Analyzer's clearance envelope while the Analyzer is in use.
- Do not place potentially hazardous materials within the Analyzer's clearance envelope.
- Do not stay within the Analyzer's clearance envelope for longer than necessary for operational reasons.



The Eclipse Analyzer contains rotating devices and heating elements which may pose a hazard if proper precaution is not taken.

- Do not insert microplates or diagnostic plates other than those approved by Sievers into the Analyzer.
- Do not insert anything into the Analyzer injection port openings while a Microplate or diagnostics plate is rotating.
- Never insert anything other than a pipette tip into the Analyzer injection port openings.
- The Analyzer contains two heating elements which may be hot to the touch. The Analyzer will remain locked until the heating elements have reached a safe temperature, however use precaution when cleaning the interior of the Analyzer.
- Do not move the Analyzer while it is running.
- Never open the Analyzer lid until the Microplate or diagnostic plate has stopped rotating and this is confirmed on the screen.
- Do not remove or open the injection port cover while the Analyzer is running an assay or a diagnostic plate test.



Both the Eclipse Microplate and the aluminum Microplate packaging might have sharp edges. Use caution when handling the Microplate, either in the package or after removal from the package. Although the Eclipse Microplate is a closed system, and therefore less susceptible to contamination, you should always employ aseptic techniques when performing endotoxin testing.



This symbol on the instrument indicates that the product is China RoHS II compliant.

AVERTISSEMENTS DE SÉCURITÉ—FRANÇAIS



Ce symbole se trouve sur l'analyseur et sur plusieurs pages du manuel d'utilisation. Ce symbole indique des remarques de sécurité et des instructions. Lisez ces précautions avant d'utiliser l'Analyseur pour la première fois.

- L'analyseur Eclipse est classé IP 21 pour l'exposition accidentelle à l'eau.
- L'analyseur doit être installé sur une surface propre et plane, d'une profondeur minimale de 610 mm (24 po), d'une largeur de 406 mm (24 po), et libre de toute obstruction jusqu'à une hauteur de 305 mm (12 po) afin de permettre au couvercle de s'ouvrir complètement. C'est ce que l'on appelle la zone de dégagement de l'analyseur.
- Choisissez un endroit à l'abri de la lumière directe du soleil et des températures extrêmes. Évitez l'utilisation à des températures supérieures à 30 °C (86 °F) ou inférieures à 17° C (63 °F), car les températures en dehors de cette plage peuvent empêcher le bon fonctionnement de l'appareil.
- Le poids total de l'analyseur est de 10 kg (22 lb).
- L'interrupteur d'alimentation et le cordon d'alimentation sont situés à l'arrière de l'analyseur. Conservez un espace libre d'au moins 102 mm (4 po) à l'arrière de l'analyseur pour permettre de brancher et de débrancher facilement l'analyseur du secteur si nécessaire.



L'analyseur doit être connecté à une source électrique correctement mise à la terre via un cordon d'alimentation CEI 320 C13. La mise à la terre est intégrée au cordon d'alimentation CEI 320 C13, l'analyseur ne dispose pas d'autre méthode de mise à la terre.

Utilisation de l'analyseur



Si l'analyseur Eclipse est utilisé d'une manière non spécifiée par Sievers Analytical Instruments, les protections de sécurité de l'instrument peuvent se voir affectées.

- Ne posez jamais d'objets sur l'analyseur Eclipse.
- Ne vous appuyez jamais sur l'analyseur Eclipse.
- Ne placez et ne stockez jamais rien dans la zone de dégagement de l'analyseur lorsque celui-ci est en cours d'utilisation.
- Ne placez pas de matières potentiellement dangereuses dans la zone de dégagement de l'analyseur.
- Ne demeurez pas vous-même dans la zone de dégagement de l'analyseur plus longtemps que strictement requis à des fins opérationnelles.



L'analyseur Eclipse contient des dispositifs rotatifs et des éléments chauffants qui peuvent constituer un danger si les précautions appropriées ne sont pas prises.

- Ne pas insérer de microplaques ou de plaques de diagnostic autres que celles approuvées par Sievers dans l'analyseur.
- Ne rien insérer dans les orifices du port d'injection de l'analyseur au cours de la rotation d'une microplaque ou d'une plaque de diagnostic.
- Ne jamais insérer autre chose qu'un embout de pipette dans les ouvertures du port d'injection de l'analyseur.
- L'analyseur contient deux éléments chauffants qui peuvent être chauds au toucher. L'analyseur reste verrouillé jusqu'à ce que les éléments chauffants atteignent une température de sécurité. Prenez toutefois des précautions lorsque vous nettoyez l'intérieur de l'analyseur.
- Ne déplacez jamais l'analyseur lorsqu'il se trouve en fonctionnement.
- N'ouvrez jamais le couvercle de l'analyseur avant que la rotation de la microplaque ou la plaque de diagnostic ne soit terminée et que la confirmation s'affiche à l'écran.
- Ne retirez pas et n'ouvrez jamais le couvercle du port d'injection pendant que l'analyseur exécute un essai ou un test sur plaque de diagnostic.

AVVERTENZE DI SICUREZZA—ITALIANO



Questo simbolo si trova sull'Analizzatore e nel manuale d'uso. Questo simbolo indica le note e le indicazioni di sicurezza. Leggere queste precauzioni prima di usare l'Analizzatore per la prima volta.

- L'Analizzatore Eclipse è classificato IP 21 per l'esposizione incidentale all'acqua.
- L'Analizzatore deve essere installato su una superficie pulita e piana di almeno 610 mm (24 poll.) di profondità, 406 mm (16 poll.) di larghezza e privo di ostacoli fino a 305 mm (12 poll.) di altezza per consentire l'apertura completa del coperchio. Ovvero l'ingombro per l'Analizzatore.
- Individuare una posizione lontano dalla luce diretta del sole e dalle temperature estreme. Evitare l'utilizzo a temperature superiore a 30 °C (86 °F) o inferiore a 17 °C (63 °F), poiché le temperature che non rientrano in questo range potrebbero ostacolare un funzionamento corretto.
- Il peso totale dell'analizzatore è 10 kg (22 lb).
- L'interruttore e il collegamento del cavo di alimentazione si trovano sul retro dell'Analizzatore. Lasciare uno spazio di almeno 102 mm (4 poll.) dal retro dell'Analizzatore per scollegare facilmente l'Analizzatore dall'alimentazione quando necessario.



L'Analizzatore deve essere collegato a una sorgente elettrica adeguatamente messa a terra attraverso un cavo di alimentazione IEC 320 C13. La messa a terra è effettuata attraverso un cavo IEC 320 C13 senza disposizioni per altri sistemi di messa a terra dell'Analizzatore.

Funzionamento dell'Analizzatore



Se l'Analizzatore Eclipse viene usato in modi non specificati da Sievers Analytical Instruments, la protezione di sicurezza fornita dallo strumento potrebbe essere compromessa.

- Non poggiare niente sopra l'Analizzatore Eclipse.
- Non accostarsi all'Analizzatore Eclipse.
- Non mettere o conservare niente all'interno dell'ingombro dell'Analizzatore mentre è in funzione.
- Non inserire materiali potenzialmente pericolosi all'interno dell'ingombro dell'Analizzatore.
- Non trattenersi all'interno dell'ingombro dell'Analizzatore per un tempo superiore a quanto necessario per motivi operativi.



L'Analizzatore Eclipse contiene dispositivi rotanti ed elementi riscaldanti che potrebbero rappresentare un pericolo se non vengono adottate le dovute precauzioni.

- Non inserire micropiastre o piastre diagnostiche diverse da quelle approvate da Sievers nell'Analizzatore.
- Non inserire niente nelle aperture della porta di iniezione dell'Analizzatore mentre una micropiastra o una piastra diagnostica è in fase di rotazione.
- Non inserire oggetti diversi dalle punte delle pipette nelle aperture delle porte di iniezione dell'Analizzatore.
- L'Analizzatore contiene due elementi riscaldanti che potrebbero essere caldi al tatto. L'Analizzatore resterà bloccato finché gli elementi riscaldanti non avranno raggiunto una temperatura sicura, tuttavia fare attenzione durante la pulizia degli interni dell'Analizzatore.
- Non spostare l'Analizzatore mentre è in funzione.
- Non aprire il coperchio dell'Analizzatore finché la Micropiastra o piastra diagnostica non ha finito di ruotare e questo è confermato sulla schermata.
- Non rimuovere o aprire il coperchio della porta di iniezione mentre l'Analizzatore sta eseguendo un test o un test della piastra diagnostica.



L'imballaggio della Micropiastra Eclipse e della Micropiastra di alluminio potrebbero avere bordi appuntiti. Prestare attenzione quando si prende la Micropiastra, sia all'interno dell'imballaggio o dopo la rimozione dall'imballaggio. Sebbene la Micropiastra Eclipse sia un sistema chiuso e quindi meno suscettibile alle contaminazioni, devono essere adottate sempre tecniche asettiche durante l'esecuzione di test delle endotossine.

安全警告—中文



此符号可在分析仪和操作手册中看到。此符号代表安全说明和指导。首次使用分析仪之前，请阅读这些注意事项。

- Eclipse分析仪的防护等级为IP 21，可偶尔接触水。
- 分析仪应安装在至少24英寸（610 mm）深、16英寸（406 mm）宽的干净且水平的清洁表面上。分析仪上方12英寸（305 mm）内不可有障碍物，以免使分析仪的盖子不能完全打开。上述是分析仪周围的间隙。
- 应选择无阳光直射和极端温度的安装位置。避免在高于30°C（86°F）或低于17°C（63°F）的温度下操作分析仪，因为极端温度会妨碍分析仪正常工作。
- 分析仪的总重量为22磅（10 kg）。
- 电源开关和电源线接头在分析仪的背面。分析仪背面应留有至少4英寸（102 mm）的间隙，以便在必要时容易断开分析仪的电源。



请用IEC 320 C13电源线将分析仪连接到正确的接地电源上。用IEC 320 C13电源线进行保护性接地连接，不可用其它接地方法。



仪器上的此符号表明此产品符合中国 RoHS II 标准。

分析仪操作



如果不以Sievers Analytical Instruments规定的方式使用Eclipse分析仪，则可能会损害仪器提供的安全保护性能。

- 请勿在Eclipse 分析仪上面放置任何物品。
- 请勿倚靠在Eclipse 分析仪上。
- 在使用分析仪时，请勿将任何物品放在分析仪周围的间隙中。
- 请勿将潜在危险的材料放在分析仪周围的间隙中。
- 请勿为了操作方便而在分析仪周围的间隙内停留超过必要的时间。



Eclipse分析仪装有旋转设备和加热元件，如果不正确预防，可能会造成人体危害。

- 请勿将未经Sievers批准的微孔板或诊断板插入分析仪。
- 当微孔板或诊断板旋转时，请勿将任何东西插入分析仪的注入口。
- 切勿将除了移液枪枪头之外的任何东西插入分析仪的注入口。
- 分析仪装有2个加热元件，可能会很热，不可触摸。在加热元件冷却到安全温度之前，分析仪保持锁定状态。清洁分析仪内部时应非常小心。
- 请勿移动运行中的分析仪。
- 在微孔板或诊断板停止旋转并在页面上得到确认之前，切勿打开分析仪盖子。
- 在分析仪运行测试或诊断板测试时，请勿移除或打开注入口盖子。



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안전 경고 — 한국어



이 기호는 분석기 및 사용 설명서에 나타납니다. 이 기호는 안전 사항 및 지침을 나타냅니다. 분석기를 처음 사용하기 전에 이러한 주의 사항을 읽으십시오.

- * 이 이클립스 분석기는 부수적인 수분 노출을 위한 IP 21 등급입니다.
- * 이 분석기는 최소 610 mm(24 in.) 깊이, 406 mm(16 in.) 폭의 깨끗하고 평평한 표면에 설치해야 하며 리드가 완전히 열리도록 최대 305 mm(12 in.) 높이까지 장애물이 없어야 합니다. 이것을 분석기의 여유 포락선이라고 합니다.
- * 직사일광 및 극한 온도에서 떨어진 장소를 선택하십시오. 30 ° C(86 ° F)보다 높거나 17 ° C(63 ° F)보다 낮은 온도에서는 사용을 피하십시오. 이 범위를 벗어난 온도는 올바른 작동에 방해가 될 수 있습니다.
- * 분석기의 총중량은 10 kg(22 lbs)입니다.
- * 전원 스위치 및 전원 코드 연결부는 분석기 후면에 있습니다. 필요 시 전원에서 분석기를 손쉽게 분리하려면 분석기 후면에서 최소 102 mm(4 in.)의 간격을 유지하십시오.



이 분석기는 IEC 320 C13 전원 코드를 통해 적절히 접지된 전원에는 연결해야 합니다. 보호 접지는 다른 분석기 접지 수단을 제공하지 않고 IEC 320 C13 전원 코드를 통해 이루어집니다.

분석기 작동



이 이클립스 분석기를 Sievers Analytical Instruments에서 규정하지 않은 방식으로 사용할 경우 기기가 제공하는 안전 보호 장치가 손상될 수 있습니다.

- * 이 이클립스 분석기 위에 아무것도 올려놓지 마십시오.
- * 이 이클립스 분석기에 기대지 마십시오.
- * 분석기를 사용 중일 때는 분석기의 여유 포락선 안에 무엇을 두거나 보관하지 마십시오.
- * 분석기의 여유 포락선 안에 위험할 수 있는 물질을 두지 마십시오.
- * 작동상의 이유로 필요한 것보다 더 오래 분석기의 여유 포락선 안에 있지 마십시오.



이 이클립스 분석기에는 적절한 예방책을 실행하지 않을 경우 위험을 제기할 수 있는 회전 장치 및 가열 요소가 포함되어 있습니다.

- * 분석기에 Sievers에서 승인하지 않은 마이크로플레이트나 진단 플레이트를 삽입하지 마십시오.
- * 마이크로플레이트나 진단 플레이트가 회전 중일 때는 분석기 주입 포트 구멍에 아무것도 집어넣지 마십시오.
- * 절대 분석기 주입 포트 구멍에 피펫 팁 이외의 것을 삽입하지 마십시오.
- * 이 분석기에는 만지면 뜨거울 수 있는 2개의 가열 요소가 포함되어 있습니다. 가열 요소가 안전한 온도에 도달할 때까지 분석기가 잠긴 상태로 유지됩니다. 그러나, 분석기 내부를 청소할 때는 주의하십시오.
- * 분석기가 작동 중일 때는 분석기를 옮기지 마십시오.
- * 마이크로플레이트나 진단 플레이트가 회전을 멈추고 이것이 화면에서 확인될 때까지 절대 분석기 리드를 열지 마십시오.
- * 분석기가 검사나 진단 플레이트 시험을 실행 중일 때는 주입 포트 커버를 분리하거나 열지 마십시오.



이클립스 마이크로플레이트와 알루미늄 마이크로플레이트 포장물에는 날카로운 가장자리가 있을 수 있습니다. 포장물에 들어 있거나 포장물에서 제거한 마이크로플레이트를 취급할 때는 주의하십시오. 이클립스 마이크로플레이트는 폐쇄형 시스템이므로 오염에 덜 민감하지만 엔도톡신 시험을 수행할 때는 항상 무균 기법을 사용해야 합니다.

CHAPTER 1: SYSTEM OVERVIEW

The Sievers Eclipse Bacterial Endotoxins Testing (BET) platform is a groundbreaking instrument for the detection and quantitation of Gram negative bacterial endotoxins using Limulus Amebocyte Lysate (LAL) and other lysate reagents.

Eclipse Specifications

Sievers Eclipse* Bacterial Endotoxin Testing Platform			
System Specifications			
BET Method	Kinetic		
Detection Mode	Absorbance		
Range	0.005–50 EU/mL		
Precision	≤ 15% CV onset time		
Accuracy	50–200% of actual		
Sample Type	Aqueous, injected by pipette		
Calibration	Up to 12 months		
Analysis Time	Up to 2 hours		
Sample Temperature	37 ± 1 °C		
Ambient Temperature	17–30 °C		
Capacity	Up to 21 samples in duplicate with positive product controls		
Temperature Control	37 ± 0.5 °C		
Light Source	LED emitter		
Fluidic Failure Detection	1450 nm emitter		
Optical Accuracy	≤ 5% deviation from expected value		
Optical Linearity	R-Value ≥ 0.980		
Optical Wavelength Filter	405 nm		
Read Interval	5 seconds		
Analyzer Specifications			
Outputs	Digital via USB		
Display	OLED		
Power Requirement	100–240 Volts AC @50/60 Hz		
Fuses	T 8 A 250 VAC Fuse, size 5 x 20 mm. ONLY Littelfuse 218008 or Cooper Bussmann S506-8-R.		
Dimensions	H: 17.5 cm (6.9 in); W: 35.1 cm (13.8 in); D: 50.3 cm (19.8 in)		
Weight	10 kg (22.1 lbs)		
Safety Certifications	UL 61010-1:2012Ed.3+R:20Apr2016 CSA C22.2#61010-1-12:2012Ed.3 +U1;U2 UL 61010-2-010:2015Ed.3	UL 61010-2-020:2016Ed.3 CSA C22.2#61010-2-010:2015Ed.3 CSA C22.2#61010-2-020	IEC 61010-1:2010 Ed.3+C1;C2 IEC 61010-2-010:2003Ed.2 IEC 61010-2-020:2016Ed.3
Environment			
Maximum Relative Humidity	85%, non-condensing		
Maximum Altitude	3,000 m (9,800 ft)		
Pollution Degree	2		

The Eclipse Platform

The Eclipse platform uses centrifugal force and pneumatic chambers to evenly distribute and mix precise amounts of lysate, lysate reconstitution solution, and samples across 104 individual optical wells. It then measures the amounts of endotoxins present in each sample.

The 104 optical wells comprise 26 segments:

- 5 standard curve segments (for the option to run a 3, 4, or 5-point standard curve): Pre-deposited with Reference Standard Endotoxin (RSE) derived standard concentrations ranging from 0.005 to 50 EU/mL. Each of these 5 segments contains 1 negative control in triplicate.
- 21 sample segments, each with 4 optical wells, 2 of which are pre-deposited with 0.5 EU/mL Positive Product Control (PPC).

Eclipse Microplate

The Sievers Eclipse Microplate (Figure 1-1) is a precision-crafted centrifugal microfluidic liquid handling device designed to significantly streamline kinetic assays for the detection of bacterial endotoxins. This innovative polystyrene microplate delivers the ability to run a fully compliant endotoxin assay with up to 21 samples per plate.



Figure 1-1: Eclipse Microplate

Eclipse Analyzer

The Eclipse Analyzer (Figure 1-2) rotates the Microplate to distribute and mix lysate and samples into individual optical wells in an exact 1:1 ratio. Once the solution is homogeneous, the optical well is read at 405 nm every five seconds, resulting in high-definition analysis of the reaction.

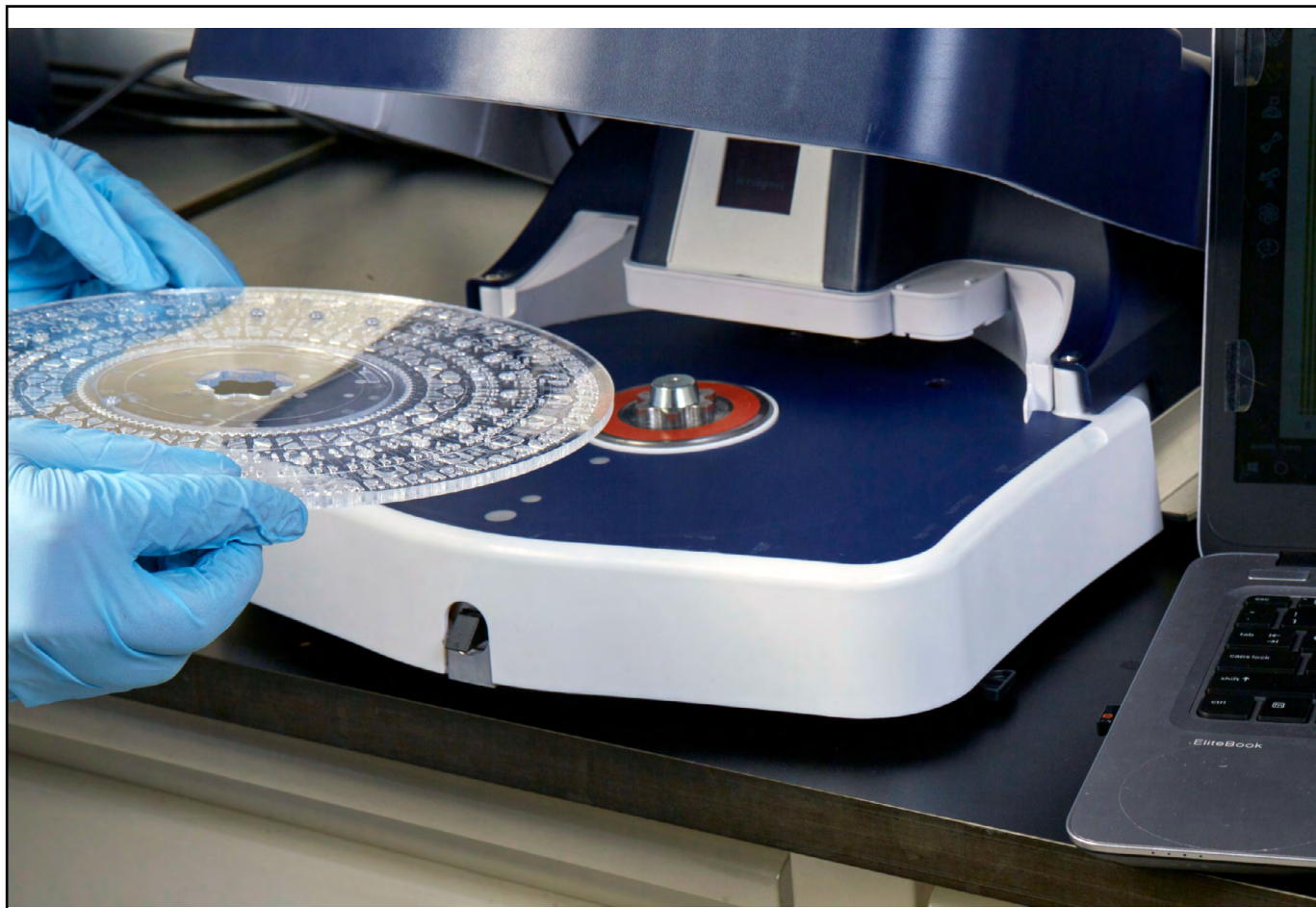


Figure 1-2: Eclipse Analyzer

User Interface

The Eclipse software collects readings from the Eclipse Analyzer, constructs a standard curve, and interpolates endotoxin concentrations from the standard curve and optical density data. Figure 1-3 shows the main Eclipse dashboard.

The screenshot displays the Eclipse software interface for assay setup. It features a vertical sidebar on the left with various icons (1). The main area is divided into sections for 'Assay Settings', 'Lysate Reagent', 'Lysate Reconstitution Solution', and 'Microplate' (2). Each section contains input fields for various parameters, some of which are highlighted with red borders and exclamation marks to indicate required fields (8). At the bottom, there is a 'New Assay' button and a 'Save as Template' button (3). Below these is a row of 21 wells, each with a status indicator (4). The bottom status bar shows the logged-in user 'Smith, Teddy', the analyzer ID '99054321', the status 'Analyzer Ready', the temperature, run time, and the date/time '12 Aug 2023 01:49:11 PM -06:00' (5). Navigation tabs at the top include 'Assay Details', 'Samples', 'Sample Details', 'Accessories', and 'Read Only Settings' (6). A barcode icon is present in the 'Lysate Reconstitution Solution' section (7). A 'Next >' button is located at the bottom right.

Figure 1-3: Eclipse User Interface

- 1: **Main Menu** (collapsed) - click any of the icons to expand the menu and reveal the available sub-menus (see [“Main Menu Selections”](#)).
- 2: **Calendar icon** - click to select a date for the field, or manually enter a date.
- 3: **Buttons** - these provide options to save, cancel, or perform other functions described in the button text.
- 4: **Interactive elements** - Many Eclipse screens feature interactive elements other than buttons. This example shows the wells on the Eclipse Microplate. During an assay, you can click the wells to see their onset activity in real time.
- 5: **Status bar** - shows the logged-in user, the connection status of the Analyzer, and the local date and time.
- 6: **Tabs** - allow navigation within sub-menus. A colored bar under the name indicates which tab is currently open (Assay Details, in the example).
- 7: **Barcode** - Click this icon to use a barcode reader to scan a product and populate the on-screen fields.
- 8: **Red fields** - These fields are required. Hover over the exclamation mark to see a description of the requirements for that field.



Figure 1-4: Eclipse Menu Bar

Main Menu Selections

The icons in the menu bar on the left portion of the screen represent sub-menus. Click the top icon to expand the menu bar and show the name of each menu selection. Click any icon in the menu bar to see its sub-menu options. Figure 1-4 shows the expanded menu bar.



Assay Setup

This menu contains tools for creating and managing assay templates, products, and accessories (see [“Chapter 4: Running Assays” on page 32](#)).

Create Assay

This screen contains options for test setup and details about samples, reagents, and accessories.

Assay Templates

This screen contains a sortable list of all available assay templates. These templates can be used as is, or as a basis for creating other templates.

Products & Accessories

This screen contains a sortable list of products (test samples), a sortable list of accessories (pipettes, tips, and other items), and a color-coded list of sample types that enhance the visibility of assay data.

Calculators

This screen lets the user calculate endotoxin limits, Maximum Valid Dilution volumes, and other values relevant to products and assays.



Analysis Progress

This menu contains graphs showing the current assay's results as they progress in real time (see [“Analysis Progress” on page 51](#)).

ECO-Graph

This screen shows a visual representation of the Microplate wells as they progress towards onset.

Kinetic Curve

This screen shows traditional assay progress as absorption over reaction time.

Standard Curve

This screen shows the standard curve of the assay in progress.

Back Calculations

This screen shows the concentration of the sample, accounting for dilution.



Results

This menu contains assay results and trend information (see [“Results” on page 54](#)).

Assay Results

This screen shows a printable, sortable list of all completed assays in a Work Group.

Product Trend Graph

This screen shows trends associated with endotoxin testing over time. The data is available graphically or in a spreadsheet.



Pharmacopeia

This menu contains system testing for regulatory compliance and analyst qualification (see [“Chapter 5: Pharmacopeia” on page 70](#)).

Product Validation

This screen shows a list of product samples that are eligible for validation review or that have been validated.

Analyst Qualification

This screen shows which users are qualified and unqualified. Analysts cannot run Eclipse assays until they have been qualified.

Microplate Uniformity Test / Microplate Uniformity Results

The Microplate Uniformity Test verifies the uniform measurement of test samples and Positive Product Controls (PPCs) across the Microplate.

The Microplate Uniformity Results screen shows a sortable list of the results of Microplate Uniformity Tests. See [“Microplate Uniformity Test” on page 75](#) for more information.

1:1 Ratio Verification Test

The 1:1 Ratio Verification Test verifies that Eclipse is able to mix product samples and lysate reagent in a 1:1 ratio. See [“1:1 Ratio Verification” on page 77](#) for more information.



Diagnostics

Tools for verifying the platform's health and performance.

Analyzer

This screen lets you update the Eclipse firmware and calibrate the buttons on the Analyzer's lid to your preferred firmness setting.

Optical Verification

The Optical Verification test uses a special diagnostic plate to verify the optical accuracy and intensity of the Eclipse Analyzer, which are crucial to the accuracy of BET assays. Regular verification of the optics ensures continued assay precision and accuracy. See [“Optical Verification” on page 119](#) for more information.

Temperature Verification

The Temperature Verification test uses a calibrated diagnostic plate designed specifically to verify that the operating temperature is within compliance. See [“Temperature Verification” on page 122](#) for more information.



Management

Administrative tools for user accounts, the Eclipse database, audit trail, and more.

My Account

This screen contains tools for managing your password and signature. See [“My Account” on page 82](#) for more information.

Settings

This screen contains system preferences and defaults, lysate settings, and 21 CFR Part 11 compliance settings. See [“Settings” on page 83](#) for more information.

Users & Work Groups

This screen shows a sortable, exportable, printable list of all current and past users and Work Groups, whether active or inactive. Use this menu to reset passwords, change user status, and change roles and permissions. See [“Users & Work Groups” on page 94](#) for more information.

Default Permissions

The Default Permissions screen lets you assign default permissions for the Analyst, Supervisor, and Administrator roles; however, each individual user’s permissions, regardless of assigned role, are fully customizable. See [“Default Permissions” on page 105](#) for more information.

Database

This screen provides tools for backing up your current database, restoring a previous version, or archiving the database. See [“Database” on page 111](#) for more information.

Error History

This screen shows a sortable, exportable, printable list of all errors that have occurred on the Eclipse platform. See [“Error History” on page 114](#) for more information.

Audit Trail

This screen contains complete list of all activities taking place on the Eclipse platform. This information is an important part of compliance and data integrity. See [“Audit Trail” on page 115](#) for more information.



Eclipse

Software version information about Eclipse, links to online user manuals, and technical support contact information, as well as the Lock button, which lets you lock the Eclipse program.

CHAPTER 2: INSTALLATION

This chapter provides installation instructions for the Sievers Eclipse platform. If you need additional assistance, please contact your local service provider or Sievers Technical Support.

Step 1: Unpack and Inspect the Analyzer

Unpack the shipping carton and verify that the shipment contains all of the items in the Packing List, below. Remember to save the original shipping materials in case you need to return the Eclipse Analyzer.

Packing List

- Eclipse Analyzer
- Injection Port Cover
- USB Drive containing Eclipse software
- Power cord
- USB communication cable

Step 2: Select a Location for the Analyzer

Place the Analyzer in a location that meets the requirements set forth in [“SAFETY WARNINGS—ENGLISH” on page 7](#).

Step 3: Connect the Analyzer

To connect the Eclipse Analyzer:

1. Install the Injection Port Cover on the Analyzer lid. Orient the cover as shown in Figure 2-1.
2. Ensure that the power button on the back of the Analyzer is set to OFF and connect the power cord from the Analyzer to an electrical outlet.
3. Connect the USB cable from the Analyzer to the workstation.
4. Turn on the workstation.
5. Turn on the Analyzer by toggling the power switch to the “On” position.



Figure 2-1: Injection Port Cover

Step 4: Install the Eclipse Software

Eclipse has three configuration options: Standalone, SQL Server Database Only, and Client Only. Depending on the configuration you choose, Eclipse will store the assay database either on a local SQL Server Express instance or on your company’s SQL Server. The Client Only configuration accesses an existing Eclipse database on another workstation or server.

Before installing Eclipse, be sure your system meets the minimum requirements shown in Table 2-1.

	Minimum	Recommended
OS	Windows 10 v1607 Windows Server 2016 v1607	Windows 11 Windows Server 2019
.NET Framework	.NET 4.72 or later	
Processor	i5 or later	i7 or later
Memory	at least 8 GB RAM	16 GB RAM
Drive	at least 25 GB free HDD	25 GB free SSD or better
SQL Server (if applicable)	SQL Server 2014, 2016, 2017, 2019, or 2022	
Monitor	1080p or better resolution	

Table 2-1: System Requirements

Eclipse Configuration Options

Eclipse offers three configuration options: *Standalone*, *SQL Server Database Only*, and *Client Only*. Read the description of each configuration below to determine which is suitable for your environment.

The USB drive that contains the Eclipse software also includes software installation guides for each configuration. Be sure to follow the installation guide that is appropriate for the chosen configuration.

Standalone Install

In Standalone configuration, Eclipse runs on the workstation connected directly to the Eclipse Analyzer and creates a local database to store assay results. This installation can run alone, or with client workstations. Eclipse can also be installed on Windows Server OS.

If you plan to use client workstations with a Standalone-configured installation, you must also perform a Client Only configuration on the client workstations.

Installation Guide: *Eclipse Software: Standalone Configuration Installation Guide* (DIN 85002-XX EN)

SQL Server Database Only Install

In SQL Server Database Only configuration, Eclipse runs on a SQL Server instance that is accessed by client workstations.

If you choose a SQL Server Database Only configuration, you must also perform a Client Only configuration on the client workstations.

Installation Guide: *Eclipse Software: Client/Server Configuration Installation Guide* (DIN 85000-XX EN)

To upgrade an existing Client/Server installation

If you are upgrading an existing Client/Server installation, see the *Eclipse Software: Client/Server Upgrade and Troubleshooting Guide* (DIN 85001-XX) for instructions.

Client Only Install

In Client Only configuration, Eclipse runs on the workstation and connects to an Eclipse database that resides either on the site's SQL Server or a Standalone-configured Eclipse workstation.

Installation Guide: *Eclipse Software: Client/Server Configuration Installation Guide* (DIN 85000-XX EN)

After choosing a suitable configuration, proceed with installation of the Eclipse Software using the appropriate software installation guide.

CHAPTER 3: SYSTEM SETUP

This chapter provides instructions on your initial setup of the Eclipse platform. To help you learn to navigate the Eclipse menu structure, these instructions are expanded to show button and menu locations.

 **NOTE:** For system setup, you must right-click the Eclipse icon and select **Run as Administrator**.

The first time you run Eclipse, the *Initial System Setup* screen (Figure 3-1) appears. When you click **Next** to proceed, you will be prompted to create a default Work Group and a System Administrator for the Eclipse platform.

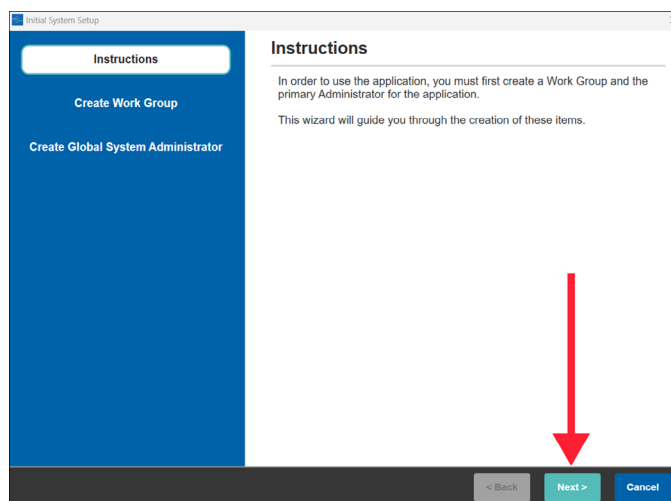


Figure 3-1: Initial System Setup Screen

Initial Setup Steps

Step 1: Create a Default Work Group

Eclipse lets you organize personnel into Work Groups, which help you manage users, assay templates, and products across different locations and functional groups. You will create a default Work Group when you run Eclipse for the first time. You can place all Eclipse users in this Work Group, or create additional Work Groups as needed to organize the Eclipse users in your organization.

1. On the *Create Work Group* screen (Figure 3-2), enter the Work Group Name, Laboratory Location, and any comments you want to include.
2. Click **Next** to proceed with the setup.

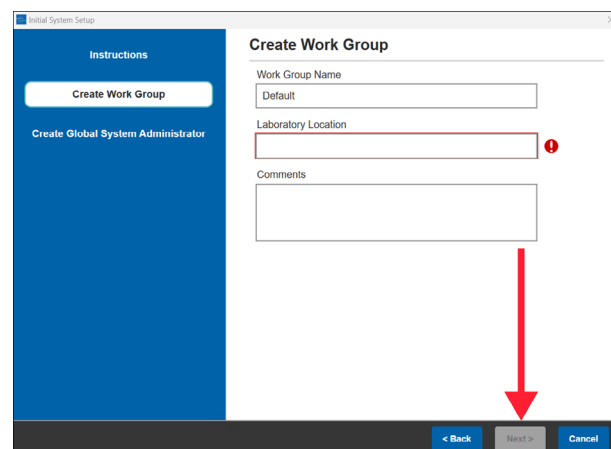


Figure 3-2: Create Work Group Screen

Step 2: Create a System Administrator Profile

The Create Administrator screen appears (Figure 3-3). Here, you will create the System Administrator profile. This profile is responsible for three functions:

- Creating the first group of Eclipse users during initial setup
- Creating Work Groups
- Managing passwords

 **NOTE:** The System Administrator profile does not create or run assays, qualify analysts, or perform any other Eclipse functions. Therefore, it is recommended that you choose a user from your company's IT department for this role.

The username of this profile is Administrator by default, and cannot be changed.

1. Enter the Administrator's first and last name, and create a password for the profile.
2. Click **Finish** to continue to the *Users & Work Groups* screen for the next step.

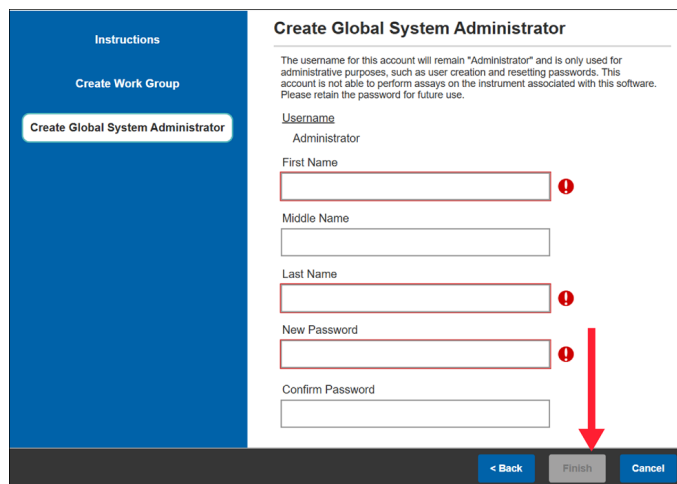


Figure 3-3: Create System Administrator Screen

Step 3: (Optional) Enable Active Directory Support

Eclipse 2.0 and above supports the use of Active Directory (AD) to manage Eclipse user profiles and access. If you enable AD support for Eclipse, the following conditions apply:

- Only users with the Edit User permission can enable AD.
- Once enabled, AD support cannot be disabled without reinstalling the Eclipse software.
- All Eclipse users must log into Eclipse using their AD username and password.
- Any Eclipse user created prior to AD activation will be converted to AD at the next login. The previous Eclipse username and password will be permanently disabled.
- If you restore an Eclipse database backup that was saved prior to enabling AD, you will lose your AD configuration and any associated audit trail entries.

To enable Active Directory support

1. Navigate to **Management > Users & Work Groups** and select the *Active Directory* tab (Figure 3-4).

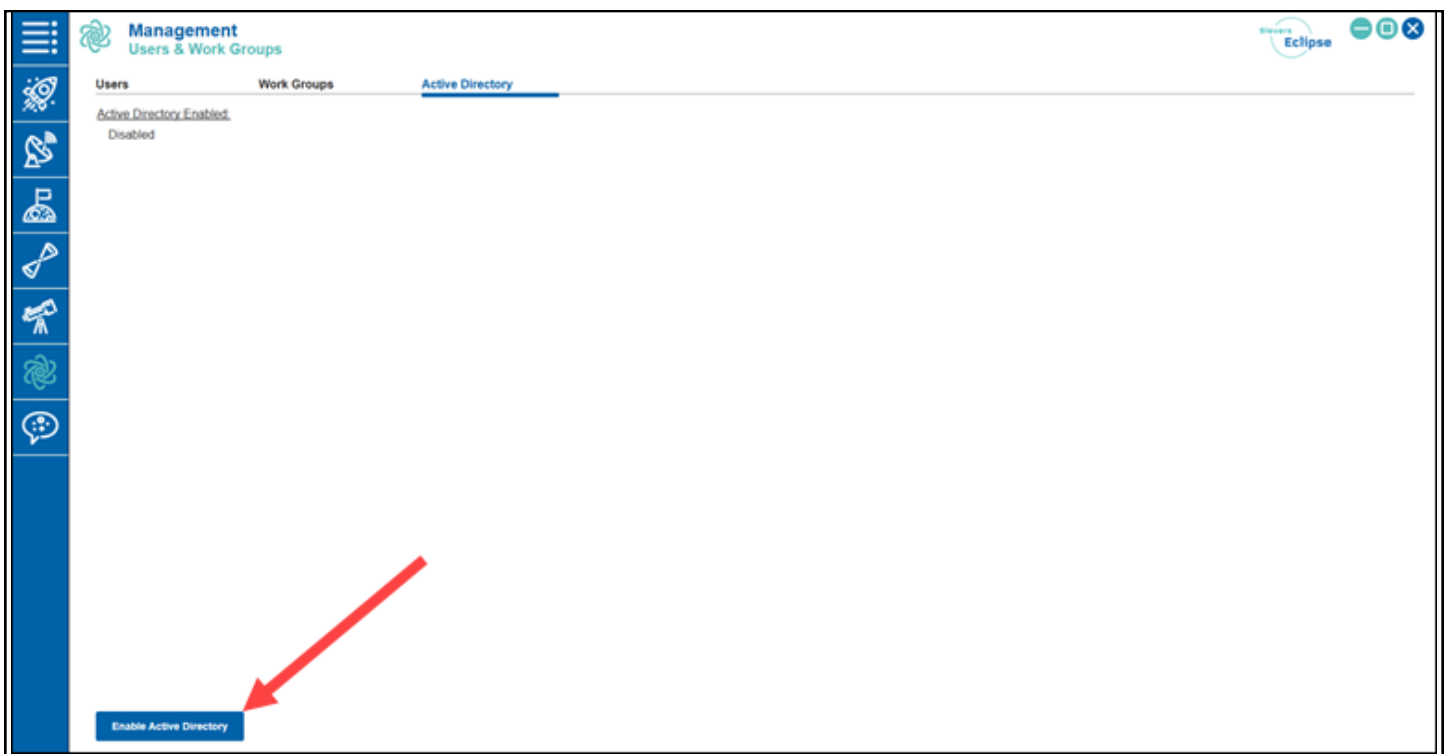


Figure 3-4: Active Directory Screen

2. Click **Enable Active Directory**.

- Click **Yes** on the confirmation dialog box (Figure 3-5) to confirm that the current user will have to log in with an Active Directory username and password.

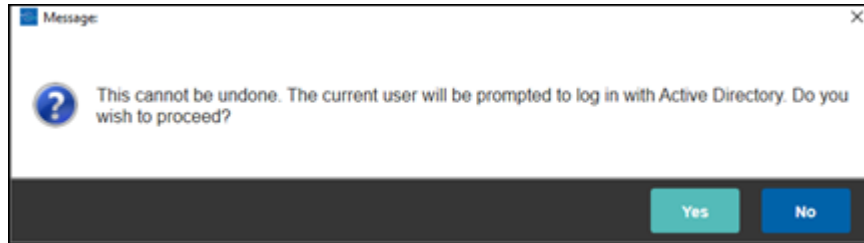


Figure 3-5: AD Confirmation Dialog

- Enter the Active Directory domain and user credentials (Figure 3-6), then click **Accept**.

Figure 3-6: AD Domain and User Info

- Click **Accept** on the confirmation dialog box.

Step 4: (Optional) Create Additional Work Groups

 **NOTE:** Depending on the size of your organization, you may need only the default Work Group. If you require no further Work Groups, skip to [“Step 5: Create User Profiles” on page 28](#).

The *Users & Work Groups* screen has two tabs (Figure 3-7). The *Users* tab is open by default.

1. Select the *Work Groups* tab.
2. Click **Add** (at the bottom left of the screen).
3. On the New Work Group screen, enter the Work Group name and Laboratory Location (required), and any optional comments you want, then click **Accept**.
4. A dialog box appears, asking you to confirm the creation of your new Work Group. Click **Create** to continue. The new Work Group now appears in the list of Work Groups.
5. Repeat Steps 2 and 3 to create additional Work Groups as needed.

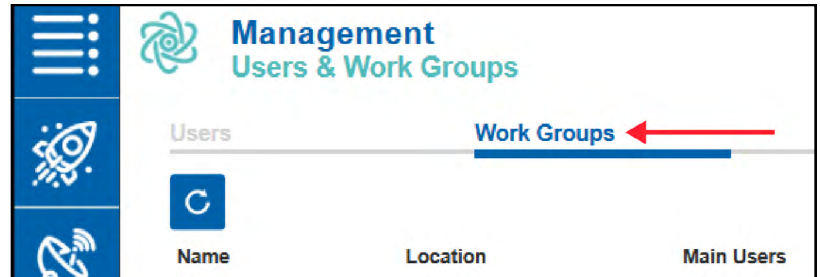


Figure 3-7: Users & Work Groups Tabs

Step 5: Create User Profiles

Eclipse user profiles fall into one of three default user roles: Analyst, Supervisor, and Administrator.

- Analysts typically create assay templates, run assays, and create/view reports based on assays.
- Supervisors typically have the same permissions as Analysts, with additional access to reporting functionality, the ability to change some default settings, comment on the audit trail, and qualify Analysts.
- Administrators have access to user and Work Group settings, database management functions, error reporting, and audit trail information. By default, Administrators don't have the ability to create or run assays.



NOTE: You can customize the default permissions to suit your business needs.

[“Default Permissions” on page 105](#) for a full discussion of Eclipse permissions and customization options.

1. On the *Users & Work Groups* screen (Figure 3-8), click the *Users* tab, then click **Add** in the lower left corner of the screen.

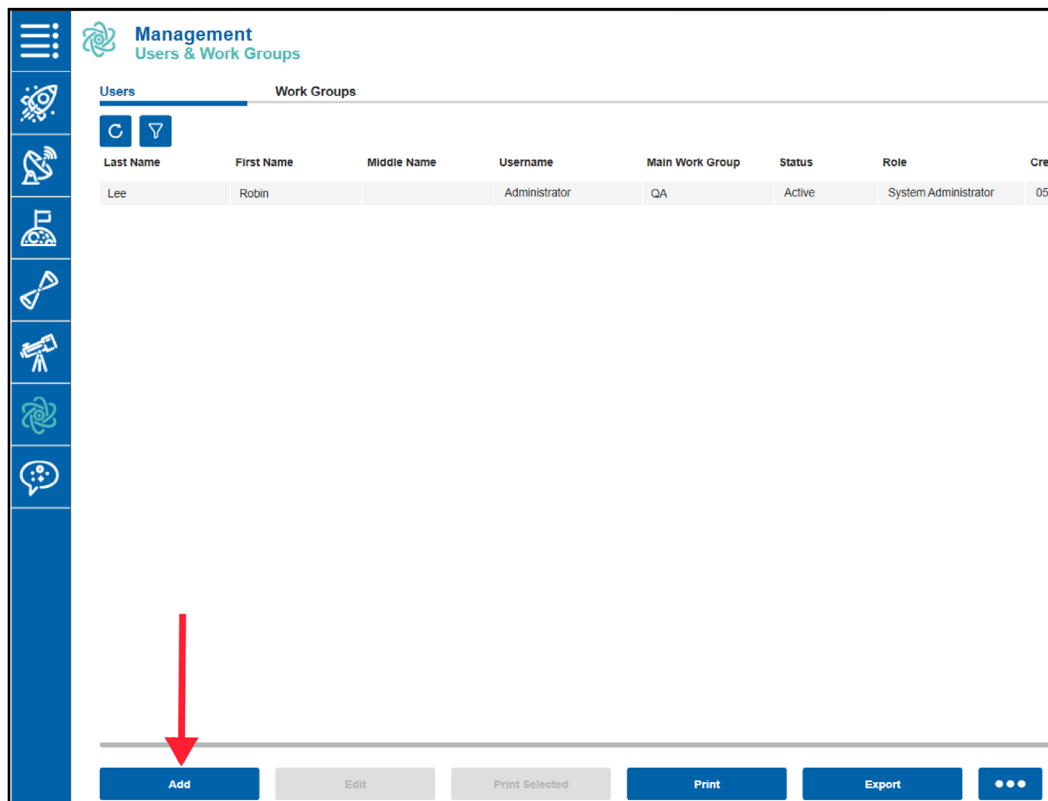


Figure 3-8: Users & Work Groups Screen

2. The *New User* screen appears (Figure 3-9). It has two tabs: *User Information* (open by default) and *Permissions*.
3. Under the *User Information* tab, complete the *Username*, *First Name*, and *Last Name* fields (the *Middle Name* field is optional).
4. Select a primary Work Group from the list. If you want to assign a secondary Work Group, click the appropriate check box under *Secondary Work Groups*.
5. Select a User Role from the drop down list (Figure 3-10).
6. If you select a user role other than *Analyst* (the default), confirm that you want to update the user's permissions to the default for the new role by clicking **Yes** on the dialog box.



NOTE: All Eclipse default user roles are fully customizable, as are individual permissions for each user. See [“Chapter 6: Management” on page 81](#) for more information.

7. Click **Accept** to proceed.
8. Repeat Steps 2–7 to create additional user profiles.



NOTE: The first time these users log into Eclipse, they will be prompted to create a password.

Figure 3-9: New User Information

Figure 3-10: Selecting a User Role and Permissions

Step 6: Create an Administrator Profile

The System Administrator you created in [“Step 2: Create a System Administrator Profile” on page 24](#) should be used only for initial system setup, to create new Work Groups, and to manage passwords if another Administrator is unavailable. Therefore, you need to create user profiles with administrator permissions for each of your Work Groups.



NOTE: For compliance purposes, Administrators should not create or run assays.

1. Click the Menu icon and navigate to **Management** → **Users & Work Groups**.
2. Select the user you want to make Administrator, then click **Edit** (Figure 3-11). The *Edit User* screen appears with the *User Information* tab open by default (Figure 3-12).



NOTE: Ensure that this user has default Administrator permissions before continuing.

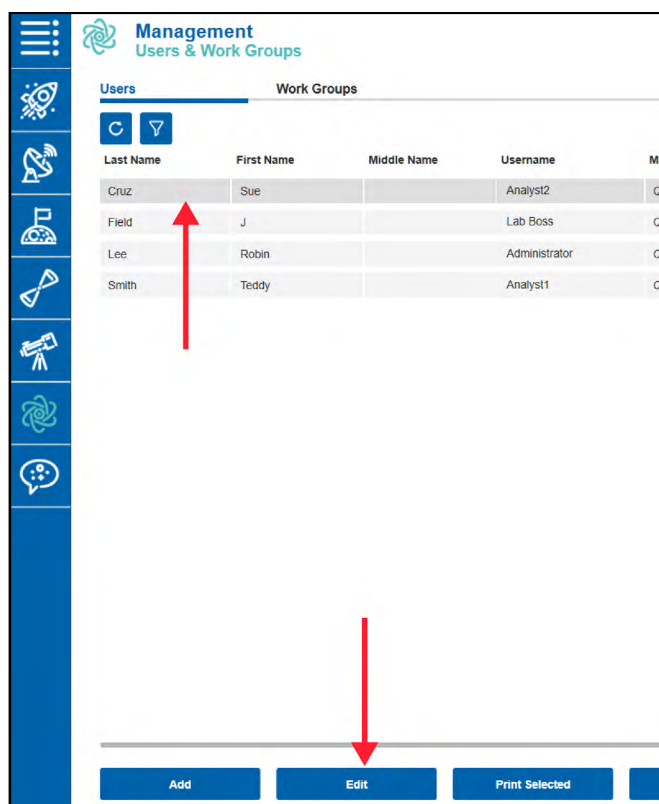


Figure 3-11: Selecting the Administrator

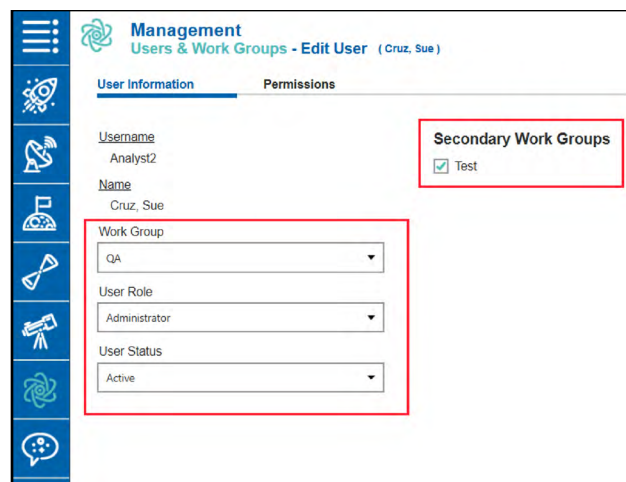


Figure 3-12: Administrator User Information

3. Ensure that the primary Work Group is correct, the appropriate Secondary Work Groups are selected (if applicable).
4. Ensure that the User Role is set to *Administrator*. If changing from a different User Role, accept the default permission changes.

5. Ensure that the User Status is set to *Active*.
6. Select the *Permissions* tab to continue (Figure 3-13).

Management
Users & Work Groups - Edit User (Cruz, Sue)

User Information **Permissions**

Users

- ☒ View
- ☒ Create
- ☒ Edit
- ☒ Deactivate
- ☒ Reset User Password
- ☒ Reset User Signature Image
- ☒ Export
- ☒ Print

Work Groups

- ☒ View
- ☒ Create
- ☒ Edit
- ☒ Export
- ☒ Print

Sample Types

- ☐ View
- ☐ Create
- ☐ Edit
- ☐ Delete
- ☐ Export
- ☐ Print

Products

- ☐ View
- ☐ Create
- ☐ Edit
- ☐ Delete
- ☐ Export
- ☐ Print

Accessories

- ☐ View
- ☐ Create
- ☐ Edit
- ☐ Delete
- ☐ Export
- ☐ Print

Assay Templates

- ☒ View
- ☐ Save
- ☐ Delete
- ☐ Export
- ☐ Print

Assays

- ☐ Start / End

Assay Results

- ☐ View
- ☐ Export
- ☐ Print

Trend Graph

- ☐ View
- ☐ Print

Signatures

- ☐ Sign Approvals
- ☐ Remove Signatures

Pharmacopeia

- ☐ Validate Products
- ☐ Print Product Validation Report
- ☐ Qualify Analysts
- ☐ Print Analyst Qualification Report

Diagnostics

- ☒ Perform Diagnostics
- ☒ Upgrade Analyzer Firmware
- ☒ Apply Calibrations

Database

- ☒ Archive
- ☒ Backup
- ☒ Restore
- ☒ Open Archive File
- ☒ Schedule Backup
- ☒ Change Datastore Archive Location

Errors

- ☒ View
- ☒ Acknowledge
- ☒ Export
- ☒ Print

Audit Trail

- ☒ View
- ☒ Review
- ☒ Export
- ☒ Print

Edit Preferences

- ☒ Regional Work Group Settings
- ☐ Report Settings
- ☐ Export Settings
- ☐ Analyst Qualification Settings
- ☐ Assay Results Settings

Edit Defaults

- ☒ User Default Settings
- ☐ Product Default Settings
- ☐ Accessory Default Settings
- ☐ Assay Default Settings
- ☐ Lysate Default Settings
- ☒ Default Permissions

Edit 21 CFR Part 11

- ☒ Username & Password Rules
- ☒ Account Protection

Accept Cancel Select None Select All

Figure 3-13: Special Administrator Permissions

7. As Figure 3-13 shows, only the default Administrator permissions are selected. For this special Administrator role, select all non-production permissions.
8. Put a check mark next to all selections under Users, Work Groups, Database, Errors, Audit Trail, Edit Preferences, Edit Defaults, and Edit 21 CFR Part 11, then click **Accept**.

CHAPTER 4: RUNNING ASSAYS

This chapter includes information and step-by-step instructions for setting up and running assays using the Sievers Eclipse Bacterial Endotoxin Testing Platform.



NOTE: You must be qualified as an analyst to run an assay in Eclipse. See [“Analyst Qualification” on page 72](#) for more information.

The Assay Setup Menu

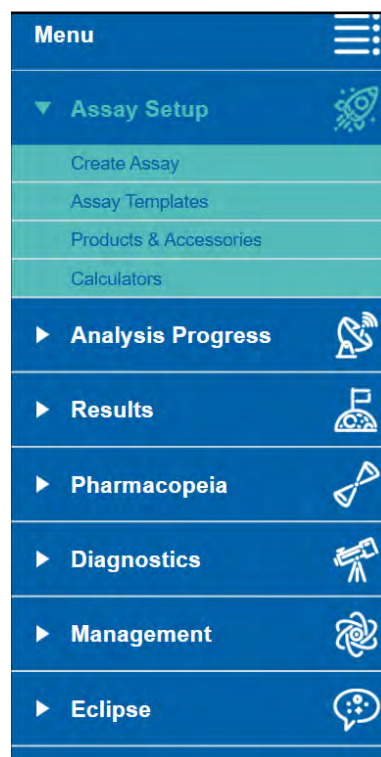
Use the following selections from the Assay Setup menu to set up and run an assay:

Create Assay. Create a new assay template by defining the materials, samples, and accessories to be used. When you’re finished, you can run the assay immediately, or save the new template for later use by your Work Group.

Assay Templates. Select an existing assay template to run, or use the existing data as a starting point for a new template.

Products & Accessories. View and add the products (sample materials to be tested), accessories (pipettes, tips, other items), and sample types currently recorded in the Eclipse platform.

Calculators. Use automatic conversion calculators to conveniently determine volumes required for a specific dilution factor, an endotoxin release limit, a maximum valid dilution, or a minimum valid concentration.



Step 1: Prepare Materials and Samples

Before you begin, review the following list to help organize the materials and samples needed to set up and run an assay.

Equipment	Preparation
Eclipse Analyzer and Software	Set up the Analyzer and install/configure the software as described in Chapter 2 and Chapter 3 of this User Guide.
Eclipse Microplate	The Microplate is manufactured with endotoxin standards (50 EU/mL, 5 EU/mL, 0.5 EU/mL, 0.05 EU/mL and 0.005 EU/mL respectively) embedded in plate Segments 22, 23, 24, 25, and 26, each in triplicate. Each segment 22–26 also contains a single negative control.
Pipettes and Pipette Tips	Capable of accurately dispensing 55 uL and 1 mL quantities
User-defined Samples	(Up to 21 samples to be analyzed in Segments #1-21) Ensure that all the sample types, products, and accessories planned for use are pre-entered/scanned into Eclipse.
Lysate Reagent	1 mL
Lysate Reconstitution Solution (Lysate Reagent Water)	(55 µL for each of Segments #22-26, for negative controls and to reconstitute standards pre-embedded in the Microplate). Reserve enough solution to mix with reagent, per manufacturer's instructions.
Laboratory Sample Rack	Needed for preparing samples.

1. Set aside the pipette tips for use later in this procedure.
2. Prepare the user-defined samples (up to 21 samples for use in Segments 1–21) and place them in a laboratory sample rack. Allow time for dilutions.
3. Turn on the Analyzer and computer, and launch the Eclipse software.

Step 2: Create Products

Products are the samples to be tested on the Eclipse platform. To run assays on products, you must first enter them into the Eclipse software. You can create these product descriptions in advance in the **Assay Setup > Products & Accessories** menu.

Creating a list of products in advance will:

- Make the product information available to others in your Work Group.
- Eliminate the need to re-enter product information every time you run an assay or build a template.

Follow these steps to create a list of products and descriptions for use by your Work Group:

1. Navigate to **Assay Setup > Products & Accessories** and select the **Products** tab.
2. Click **New**.

The **New Product** screen (Figure 4-1) is divided into two sections: **Product Details** and **Additives**. You can enter the **Name** (required), **Description**, **Manufacturer**, and measurement criteria for your sample here.

Assay Setup

Products & Accessories - New Product

Product Details

Name

Sample Type

Clean Steam

Description

Manufacturer

Work Group

QA

Comments

Maximum Valid Dilution

☐ Product Is Validation Eligible

Endotoxin Release Limit (ERL)

ERL Units

EU/mL

ERL By Volume
Dilution Ratio

1

Additives

Sample Diluent Type

LAL Reagent Water

Diluent Manufacturer

- ☐ Use Glucan Blocking Buffer
- ☐ Use Dispersing Agent
- ☐ Use Heat Inactivation

Accept

Cancel

Figure 4-1: New Product Screen

3. Enter a name for your product. This field is required.
4. Choose a **Sample Type** from the list (Figure 4-2). You can choose from **Clean Steam**, **Final Goods**, **In Process Sample**, **Raw Material**, and **Water for Injection**. You can also create new sample types that are relevant for your application (see [“Creating Custom Sample Types” on page 38](#) for more information).



NOTE: The Sample Type you choose is a label to aid in organization—it does not otherwise affect the assay.

5. (Optional) Enter information in the **Description** and **Manufacturer** fields.
6. In the **Work Group** list, choose the Work Group for which the product will be available (only Work Groups that the user belongs to will appear).
7. If dilution is required for the product, enter dilution information in the provided fields.

Figure 4-2: Choosing a Sample Type

Product Details

- Maximum Valid Dilution: The maximum allowable dilution of a sample at which the endotoxin limit can be determined.
- Endotoxin Release Limit (ERL): The maximum allowable amount of endotoxin in a sample.
- ERL Units
- ERL by Volume/Dilution Ratio: The dilution factor for the product (e.g., enter 100 for a sample diluted 1:100). By default, this value is set to 1.
- Product is Validation Eligible: Check this box if you intend to validate the product (see [“Validating Products” on page 71](#) for more information)

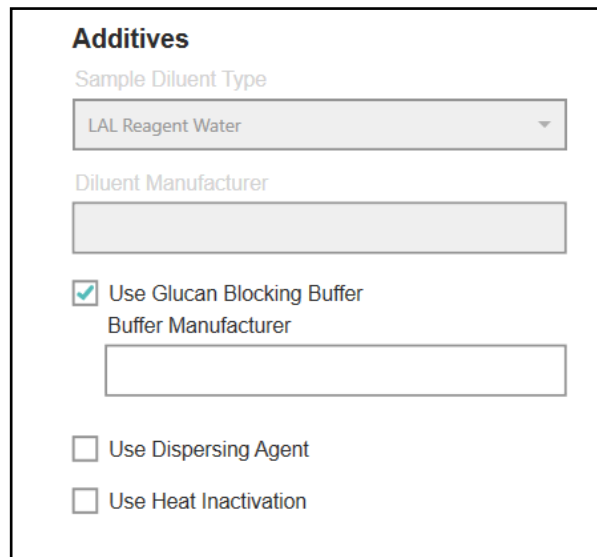
Additives

If you dilute or otherwise modify your product sample, complete the following fields as necessary:

- Sample Diluent Type (Figure 4-3): To select a diluent type, you must enter a value >1 in the Dilution Ratio field.
- Diluent Manufacturer
- Use Glucan Blocking Buffer (check box)
- Use Dispersing Agent (check box)
- Use Heat Inactivation (check box)

Putting a check in Glucan Blocking Buffer or Dispersing Agent will allow you to enter manufacturer information for the additive.

8. Click **Accept** to create the new product.
9. Repeat steps 1–8 for each new product you want to create. As you add new products, they will appear in the Product list:



Additives

Sample Diluent Type

LAL Reagent Water

Diluent Manufacturer

☒ Use Glucan Blocking Buffer

Buffer Manufacturer

☐ Use Dispersing Agent

☐ Use Heat Inactivation

Figure 4-3: Glucan Blocking Buffer Check Box

Step 3: Create Accessories

Accessories include: Dilution Tubes, Pipettes, Pipette Tips, Timer, Vortex Mixer, Other.

Follow these steps to create a list of accessories and descriptions for use by your Work Group:

- 1. Navigate to **Assay Setup > Products & Accessories** and select the **Accessories** tab.
- 2. Click **New**.
- 3. Select an accessory type from the **Type** list. Options include:
 - Dilution Tube
 - Pipette
 - Pipette Tip
 - Timer
 - Vortex Mixer
 - Other
- 4. (Optional) Enter the Manufacturer, Serial Number, Lot Number, Expiration Date, and Calibration Due Date. Include any additional information in the **Comments** field.
- 5. Choose the Work Group that will use the accessory from the Work Group list.
- 6. Click **Accept** to create the new accessory.
- 7. Repeat steps 1–6 for each new accessory you want to create. As you add new accessories, they will appear in the **Accessories** list (Figure 4-4):

Assay Setup

Products & Accessories

Sievers Eclipse

Products

Accessories

Sample Types

C

Name	Type	Manufacturer	Work Group	Serial Number	Lot Number	Expiration	Calibration Due	Comments
Small pipette 123	Pipette	Eppendorf	QA	N536777		---	30 Oct 2023 -06:00	

Figure 4-4: Accessories Tab

Creating Custom Sample Types

Eclipse has a default list of Sample Types for describing the product samples to be tested (Figure 4-5):

- Clean Steam
- Final Goods
- In Process Sample
- Raw Material
- Water for Injection

Sample Types are labeled with colors to visually differentiate samples in the ECO-Graph and Kinetic Curve graphs during the assay process (see [“Analysis Progress” on page 51](#)). You can use the default sample types, or create new ones that are customized for your needs.

To create a new Sample Type for your Work Group

1. Navigate to **Assay Setup > Products & Accessories** and select the **Sample Types** tab (Figure 4-6).
2. Click **New**.
3. Enter the sample type name and choose a color from the list.
4. Click **Accept** to create the new Sample Type.

To edit an existing Sample Type

1. Navigate to **Assay Setup > Products & Accessories** and select the **Sample Types** tab.
2. Click **Edit**, then edit the name and/or the color for the sample type.
3. Click **Accept** to save your changes.

To delete a Sample Type

1. Navigate to **Assay Setup > Products & Accessories** and select the **Sample Types** tab.
2. Click **Delete**.
3. On the dialog box that appears, click **Delete**.

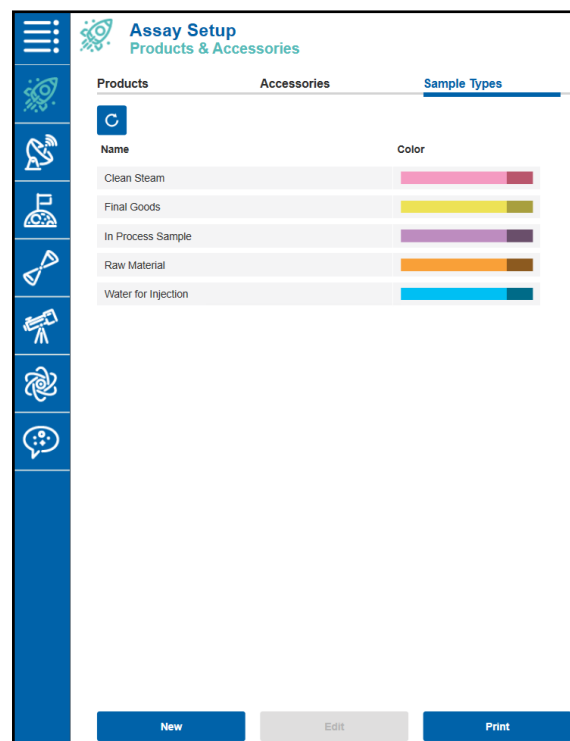


Figure 4-5: Sample Types Tab

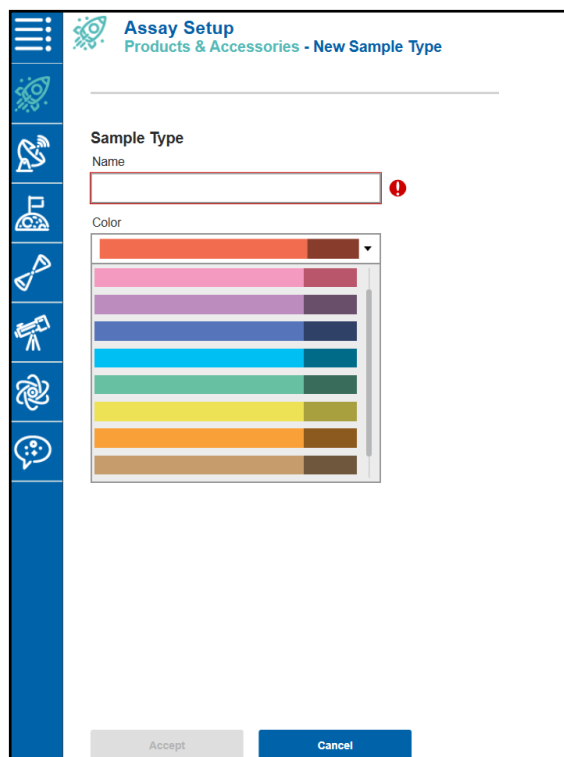


Figure 4-6: Choosing a Custom Sample Color

Step 4: Create an Assay Template

An Eclipse assay template defines the reagents, samples, and accessories to be used for your assay. Once saved in the Eclipse platform, assay templates are available for use by other users in the Work Group, either as-is or with modifications.

If you want to load an existing assay template, see [“Loading an Existing Assay Template” on page 46](#).

Navigate to **Assay Setup > Create Assay**. The **Create Assay** screen is divided into five tabs: Assay Details, Samples, Sample Details, Accessories, and Read Only Settings.

Assay Details Tab

The **Assay Details** tab (Figure 4-7) displays general assay information under four sections: Assay Settings, Lysate Reagent, Lysate Reconstitution Solution, and Microplate.

Figure 4-7: Assay Details Tab

Assay Settings

1. Enter the name of your assay in the **Assay Name** field (Figure 4-8). By default, Eclipse fills this field with a name based on the date/time when you began creating the assay. You can enter any text you want, but be sure to follow your organization's naming conventions so that other Analysts will be able to easily find and use your new template.
2. Select an option from the **Standard Curve Option** list. The **Assay Type** field and the **Optical Density Threshold** setting reflect the lysate reagent you choose in the next step.

Figure 4-8: Assay Settings

Lysate Reagent

3. Select a reagent from the **Lysate Reagent** list (Figure 4-9). The manufacturer for the selected name automatically appears in the **Manufacturer** field. If you choose a reagent of unspecified manufacture (TAL, Other Lysate1, Other Lysate 2), type the name in the **Manufacturer** field. If you have a bar code reader, click the bar code symbol to scan the reagent into Eclipse.
4. In the **Lot Number** field, type the reagent lot number. Be sure to type the number exactly as it appears on the reagent packaging to avoid an error message when you run the assay. If you use a bar code scanner, this field will be correctly populated.
5. Click the calendar icon at the left of the **Expiration Date** field to select the reagent's expiration date, or type it into the **Expiration Date** field. Eclipse automatically reformats the date to the system default. For example, if you type "February 12, 2023" Eclipse will reformat it to "12 Feb 2023" (or the default format set by your system administrator).
6. To incubate the Microplate before the assay begins, click the **Enable Preincubation** check box (Figure 4-10).

Figure 4-9: Lysate Reagent Names

Figure 4-10: Enable Preincubation

Lysate Reconstitution Solution

7. Select a solution type from the **Lysate Reconstitution Solution** list (Figure 4-11). If you have a bar code reader, click the bar code symbol to scan the solution information into Eclipse.
8. In the **Manufacturer** field, type the name of the manufacturer for the lysate reconstitution solution.
9. In the **Lot Number** field, type the lot number for the lysate reconstitution solution. Be sure to type it exactly as shown on the solution's packaging to avoid an error message when you run the assay. If you use a bar code scanner, this field will be correctly populated.
10. Click the calendar icon at the left of the **Expiration Date** field to select the solution's expiration date, or type it into the **Expiration Date** field. Eclipse automatically reformats the date to the system default.

Figure 4-11: Lysate Reconstitution Solution

Microplate

11. Type the serial number and lot number of the Eclipse Microplate to be used in the appropriate fields (Figure 4-12). As with the Lysate Reagent and Lysate Reconstitution Solution sections, the bar code symbol lets you scan this information directly into Eclipse.



NOTE: Remember to use the correct format as shown on the plate's packaging to avoid error messages at the start of the assay.

12. Click the calendar icon at the left of the **Expiration Date** field to select the plate's expiration date, or type it into the **Expiration Date** field. Eclipse automatically reformats the date to the system default.
13. (Optional) When you have completed the fields in the **Assay Details** tab, click **Save as Template** to make these settings available to other users in your Work Group.
14. Click **Next** to proceed to the **Samples** tab, where you will enter your product samples for testing.

Microplate

Serial Number

Lot Number

HL34589

Expiration

29 Dec 2023 -07:00

Figure 4-12: Microplate Information

Step 5: Select Sample Products for Testing

Samples Tab

The **Samples** tab (Figure 4-13) features 21 configurable rows for entering the materials to be tested. These rows correspond to the 21 available segments—each with 0.5 EU/mL PPC predeposited—on the Eclipse Microplate (Segments 22–26 contain embedded PPC).

Sample Type	Product Name	Sample ID	Lot Number	Expiration	ERL	ERL Units	Product Concentration	Devices	Extraction Volume (mL)	Dilutions	Dilution Ratio
Final Goods	Solution Z	56	AC456	15 Sep 2023 -0		EU/mL				1	1
Final Goods	Solution Z	57	AC456	15 Sep 2023 -0		EU/mL				1	1
Final Goods	Solution Z	58	AC456	15 Sep 2023 -0		EU/mL				1	1
Final Goods	Solution Z	59	AC456	15 Sep 2023 -0		EU/mL				1	1
Final Goods	Solution Z	60	AC456	15 Sep 2023 -0		EU/mL				1	1
In Process Sample	Formulation B	679	BD679			EU/mL				1	1
In Process Sample	Formulation F	567	FG345			EU/mL				1	1
None											
None											
None											
None											
None											
None											
None											

Figure 4-13: Assay Samples Tab

NOTE: Figure 4-13 shows an assay that was loaded from a template. See [“Loading an Existing Assay Template” on page 46](#) for more information.

Methods of Entering Samples into the Eclipse Software

- Use pre-configured samples (from “Step 2: Create Products” on page 34)
- Configure new product samples for a single use (see “Create a New Product Sample for a One-time Assay” on page 45)

Use a Pre-Configured Product Sample

This section describes how to set up an assay for products that have already been created in “Step 2: Create Products” on page 34.

Each Work Group has its own unique list of products. You can view only products created within your primary or secondary Work Groups.

- A. Select an available row in the **Samples** section and select the type assigned to the pre-configured sample from the **Sample** Type list (Figure 4-14).

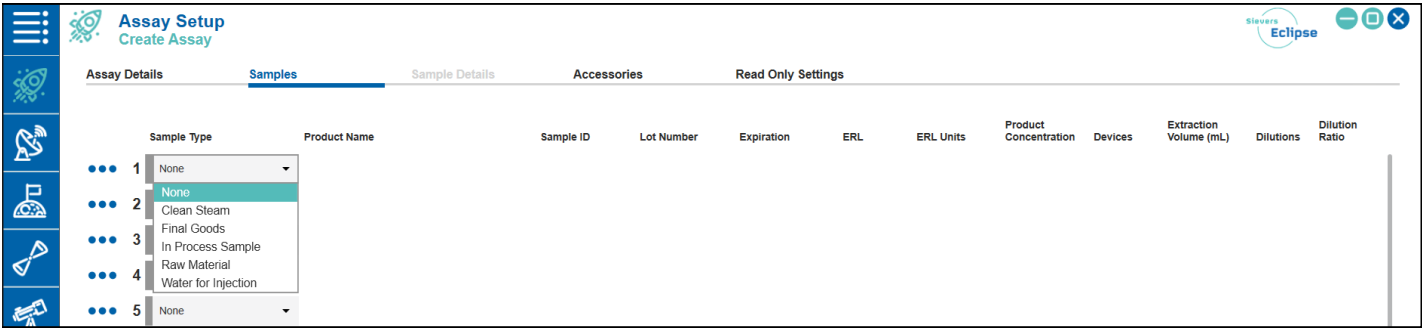


Figure 4-14: New Sample - Sample Type

- B. In the **Product Name** field (Figure 4-15), start typing the name of the sample, or click the dropdown to see a list of existing products.

NOTE: To see a list of all products within a Sample Type, enter an asterisk (*) in the search field.

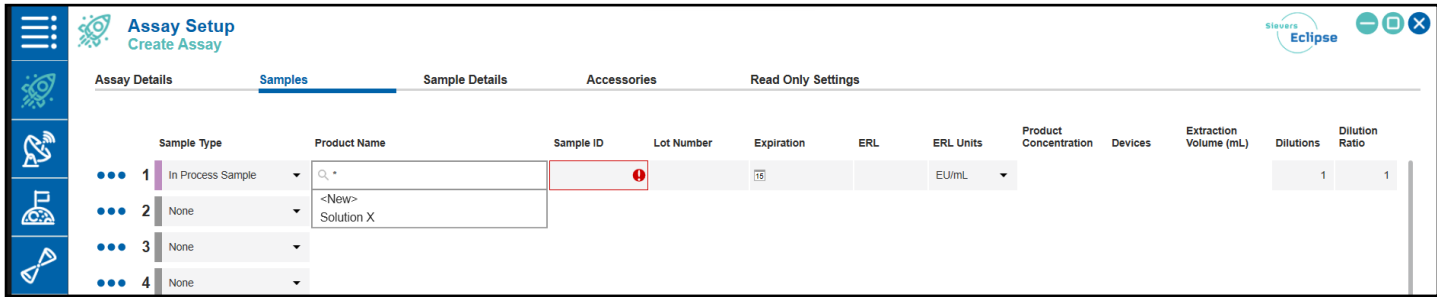
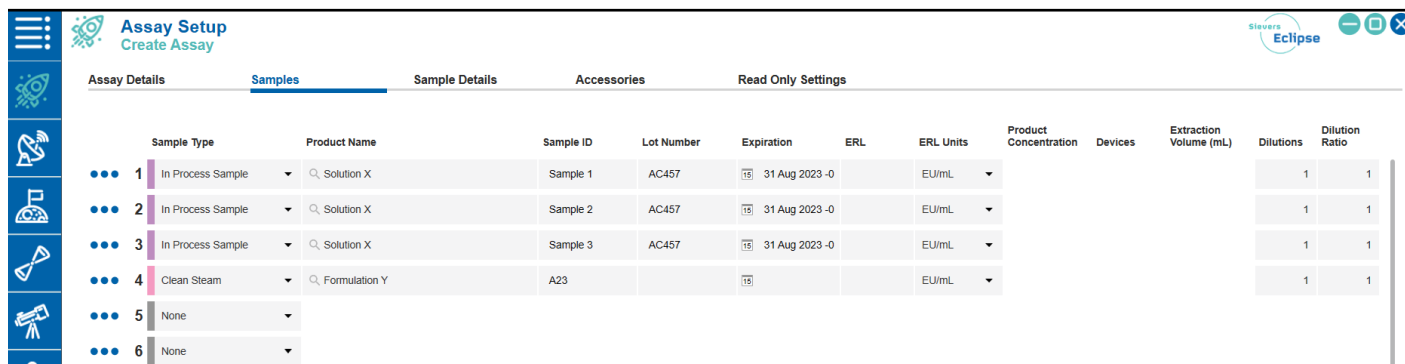


Figure 4-15: New Sample - Product Name

- C. Select the correct product from the list. Eclipse automatically populates the following fields with the pre-configured product data:
- ERL (Endotoxin Release Limit)
 - ERL Units
 - Product Concentration
 - Dilutions (defaults to 1)
 - Dilution Ratio
 - Devices, if applicable
 - Extraction Volume (mL), if applicable
- D. In the **Sample ID** field, type an identifier for the sample.
- E. Revise any of the populated fields (with the exception of **Sample Type**), as needed.
- F. Repeat steps A–E to add more pre-configured samples, if needed. Figure 4-16 shows an example list. Note that you can put the same sample into more than one segment by typing a value into the Dilutions field for that sample.
- G. Continue to Step [15 on page 45](#).



The screenshot shows the 'Assay Setup' window with the 'Samples' tab selected. The table below represents the data shown in the interface.

	Sample Type	Product Name	Sample ID	Lot Number	Expiration	ERL	ERL Units	Product Concentration	Devices	Extraction Volume (mL)	Dilutions	Dilution Ratio
1	In Process Sample	Solution X	Sample 1	AC457	31 Aug 2023 -0		EU/mL				1	1
2	In Process Sample	Solution X	Sample 2	AC457	31 Aug 2023 -0		EU/mL				1	1
3	In Process Sample	Solution X	Sample 3	AC457	31 Aug 2023 -0		EU/mL				1	1
4	Clean Steam	Formulation Y	A23				EU/mL				1	1
5	None											
6	None											

Figure 4-16: Completed Samples

Create a New Product Sample for a One-time Assay

This section describes how to set up an assay for new sample products. If you want to choose from a previously created sample, see [“Use a Pre-Configured Product Sample” on page 43](#).

There are two different methods for creating a new product sample:

- From the **Assay Setup** → **Products & Accessories** menu
 - From the **Samples** tab of the **Create Assay** screen
- A. To create and use a new product configuration, select an available row in the **Samples** section ([Figure 4-16 on page 44](#)) and complete the following for the new sample.
- **Sample Type** — Select a type from the list.
 - **Product Name** — Type a new name.
 - **Sample ID** — Type an identifier.
 - **Lot Number** — Type the lot number.
 - **Expiration Date** — Type the expiration date for the lot, or use the arrows to advance to a future date, or use the far right arrow to select a date from the calendar.
 - **ERL** — Established endotoxin release limit.
 - **ERL Units** — Select a unit value from the list.
 - **Product Concentration** — If applicable, complete this field.
 - **Devices** — Number of devices tested during each extraction.
 - **Extraction Volume (mL)** — Include the volume used for each extraction.
 - **Dilutions** — Type a number for this value. Eclipse will reserve that number of plate segments for testing those dilutions.
 - **Dilution Ratio** — Type a number for this value.
- B. If you want to use the same sample settings in multiple segments, click the three-dot icon to the left of the sample line and select Copy. Click the **•••** icon to the left of the sample line you want to paste the sample into and select Paste.
15. Click **Next** to continue.
16. (Optional) If any samples have been modified by additives, go to the **Sample Details** tab ([Figure 4-17](#)) and enter the relevant manufacturer, lot number, and expiration date for each, then click **Next** to continue.

Assay Details		Samples	Sample Details		Accessories	Read Only Settings	
#	Product Information	Additive	Used	Manufacturer	Lot Number	Expiration	
1	Manufacturer	Diluent	LAL Reagent Water			15	
	Acme	Glucan Blocking Buffer	☐			15	
	Description	Dispersing Agent	☐			15	
	reagent water	Heat Inactivation	☐				

Figure 4-17: Sample Details Tab



17. Enter any Accessories you want to include with the test. See [“Step 3: Create Accessories” on page 37](#) for more information.
18. Click **Start Assay**.
19. Follow the on-screen instructions to inject LRW, samples, and Lysate reagent into the Microplate. See [“Microplate Handling and Loading” on page 47](#) for instructions on handling the Microplate and loading it into the Eclipse Analyzer.

Loading an Existing Assay Template

1. Navigate to **Assay Setup** → **Assay Templates**.
2. Select the template you want to use and click **Load**.
3. Enter the serial number of the Microplate to be used for the assay and make any additional changes necessary to the template.
4. Click **Next**.
5. Enter the sample information and click **Next**.
6. Add any accessory information you want to include in the **Accessories** tab.
7. Click **Start Assay**.
8. Follow the on-screen instructions to inject LRW, samples, and Lysate reagent into the Microplate. See [“Microplate Handling and Loading” on page 47](#) for instructions on handling the Microplate and loading it into the Eclipse Analyzer.

Microplate Handling and Loading

To ensure correct operation and accurate analysis, you should use care when handling the Microplate.



Both the Eclipse Microplate and the Microplate packaging might have sharp edges. Use caution when handling the Microplate, either in the package or after removal from the package.

Additionally:

- Do not expose the Microplate to bright light/sunlight, extreme temperatures, or extreme humidity/wet conditions.
- The Eclipse Analyzer measures the contents of the Microplate optically. Handle the plate by the edge when possible to keep the surface clean and the optical wells free of visual defects.
- Keep the Microplate in its original packaging until you are ready to perform an assay.
- When loading the Microplate into the Analyzer, avoid contact with the Analyzer until the center hole is aligned with the spindle. Scratches on the surface of the Microplate can affect readings.

To load the Microplate into the Analyzer:



NOTE: Use gloves when handling the Eclipse Microplate to prevent cross-contamination and help ensure optical clarity during the assay.

1. Verify that the Analyzer is powered on and connected, and that the status displayed on the lower portion of the Eclipse UI is Insert Microplate (Figure 4-18).

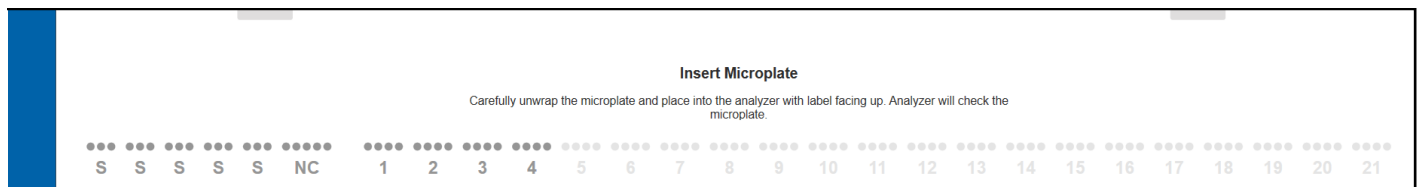


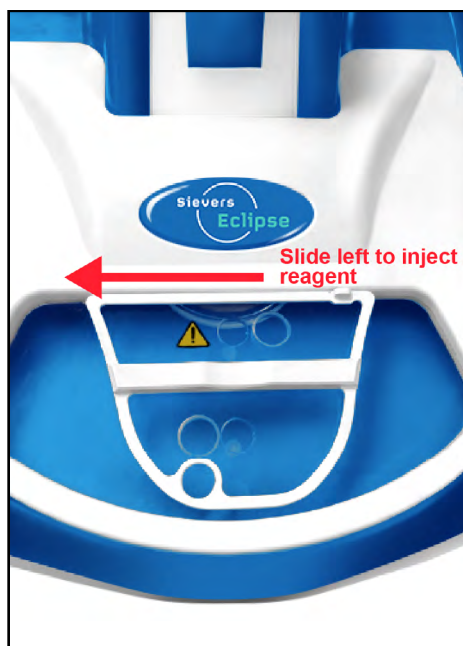
Figure 4-18: Analyzer Status - Insert Microplate

2. Open the lid of the Analyzer by pressing both buttons simultaneously. The lid will lift without assistance.
3. Open the Microplate packaging.
4. Carefully remove the Microplate from the packaging, handling it by the edges.
5. Insert the Microplate into the Analyzer face-up (the word 'LAL' should be readable towards the center of the Microplate, and the injection ports should protrude upwards from the surface), aligning the center hole with the spindle key on the base of the Analyzer. The Microplate is correctly loaded when it is resting on the spindle securely.
6. Close the lid of the Analyzer by pressing down on the front center of the lid until it clicks.

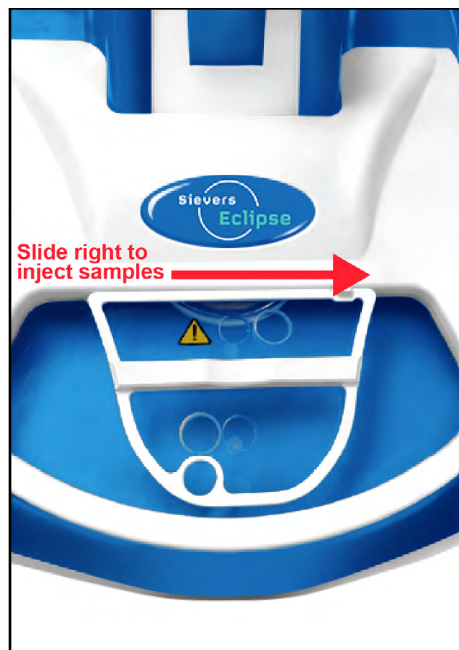
When you close the lid, the Analyzer will register the Microplate and begin to warm it to operating temperature. Do not interrupt this process or attempt to inject samples or water into the Microplate while it is in motion.

The Injection Port Cover

The injection port cover is a sliding panel on the lid window that enables the correct injection of water, samples, and lysate reagent. It has two holes—one for injecting samples and LRW into Segments 1–26, and another for injecting lysate reagent. When the software instructs you to inject liquids into the Microplate, an LED will light at the appropriate position for correctly aligning the injection port cover. Simply slide the door left or right so that the hole is above the lit LED (Figure 4-19 and Figure 4-20).



**Figure 4-19: Injection Port Cover:
Inject Reagent**



**Figure 4-20: Injection Port Cover:
Inject Samples**

After injection, slide the cover to the closed position (neither hole is exposed). The Analyzer will not spin the Microplate until the injection port door is in the correct closed position.

Making Microplate Injections

The Eclipse software will guide you through the process of injecting LRW, samples, and reagent into the Microplate. When you start an assay, the screen will show which Microplate segment is awaiting injection, and what material is to be injected. Figure 4-21 shows Segment 22 awaiting injection of 50 μL LRW for the embedded standard endotoxin:

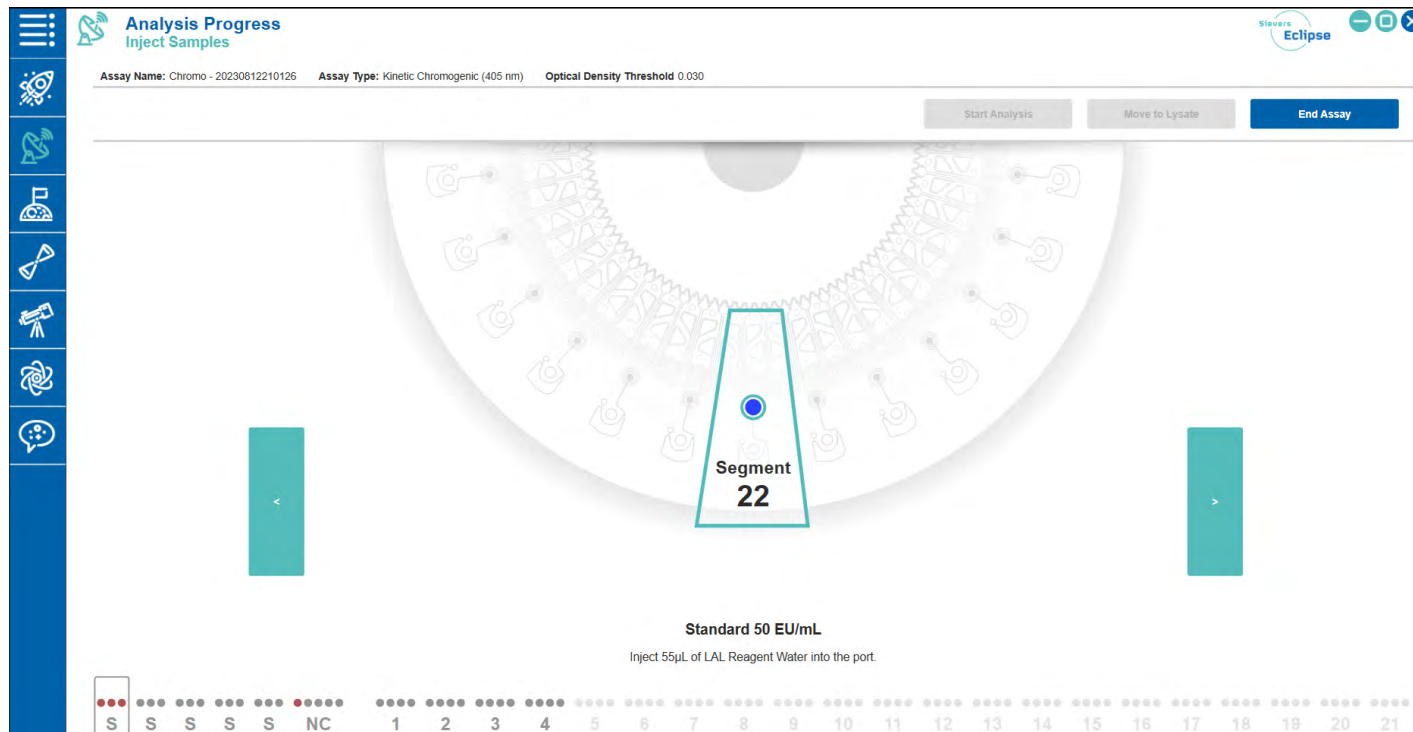


Figure 4-21: Injecting the Microplate

1. Make sure the injection port cover is aligned so that the hole is open over the LED.
2. Load the pipette with the correct tip and material to be injected.
3. Gently insert the pipette tip vertically into the injection port, using the weight of the pipette to seat the tip in the port.

NOTE: The Microplate injection ports are designed to guide the pipette tip into the correct position for injection. Do not hover over the injection port.

4. Fully depress the pipette plunger to deliver the material into the injection port.
5. Keeping the plunger depressed, withdraw the pipette tip from the injection port. Do not release the plunger until the tip is free of the Microplate, or you will pull the liquid back into the pipette.
6. Advance the Microplate to the next Segment by pressing the right-hand button on the Analyzer or by clicking the right-arrow button on the screen.

If you need to return to a previous segment for any reason (before you inject the last sample), click the segment number at the lower portion of the screen.

7. Repeat the process for all Microplate Segments to be loaded.
8. If Microplate pre-incubation was chosen during setup, follow the on-screen instructions to close the lid, click the right arrow button, and begin pre-incubation.
9. When instructed to inject lysate reagent into the injection port (Figure 4-22), you must move the injection port cover all the way to the left to access the port.
10. Inject the lysate, then click the **Start Analysis** button.

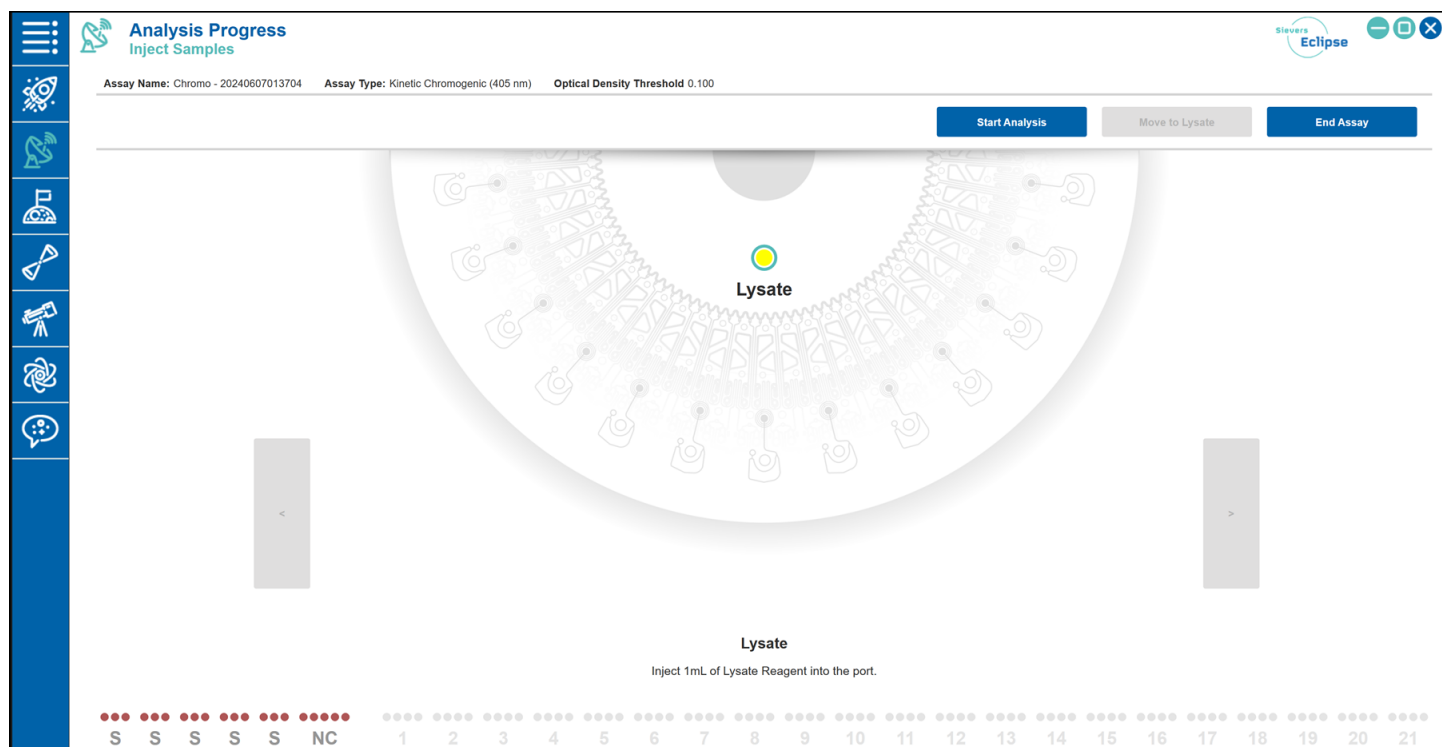


Figure 4-22: Lysate Injection

Analysis Progress

The Analysis Progress Menu

Use the following selections from the Analysis Progress menu to show the current status of the assay being run:

ECO-Graph. A dynamic look at the progress of the injected materials towards the threshold OD.

Kinetic Curve. Log-Log graph displaying the kinetic onset times of standards and samples.

Standard Curve. A summary of standards onset times with their Coefficients of Variation. Standard Curve metrics are also displayed.

Back Calculations. Summary of sample data collected during the assay. Includes CVs for both samples and PPCs, calculated endotoxin values, and dilution information.

Menu

▶ Assay Setup

▼ Analysis Progress

ECO-Graph

Kinetic Curve

Standard Curve

Back Calculations

▶ Results

▶ Pharmacopeia

▶ Diagnostics

▶ Management

▶ Eclipse

ECO-Graph

When an assay is running, the ECO-Graph (Figure 4-23) shows a histogram displaying optical density of the wells being analyzed in real-time. Note that the Sample Type color (see [“Creating Custom Sample Types” on page 38](#)) is shown to help differentiate between samples. Each numbered segment is further broken into individual wells. Hover the cursor over a segment or well to display its information.



Figure 4-23: ECO-Graph

Kinetic Curve

The kinetic curve shows a traditional graph of Optical Density over Reaction Time (seconds).

1. Navigate to **Analysis Progress > Kinetic Curve** while an assay is in progress.
2. Select a segment or well to see a kinetic curve of the sample's onset progress. Figure 4-24 shows the kinetic curve for Segment 6:
3. When you have selected the segments or wells to be viewed, you can zoom in and out by clicking on the screen and dragging up or down to see the information you need.

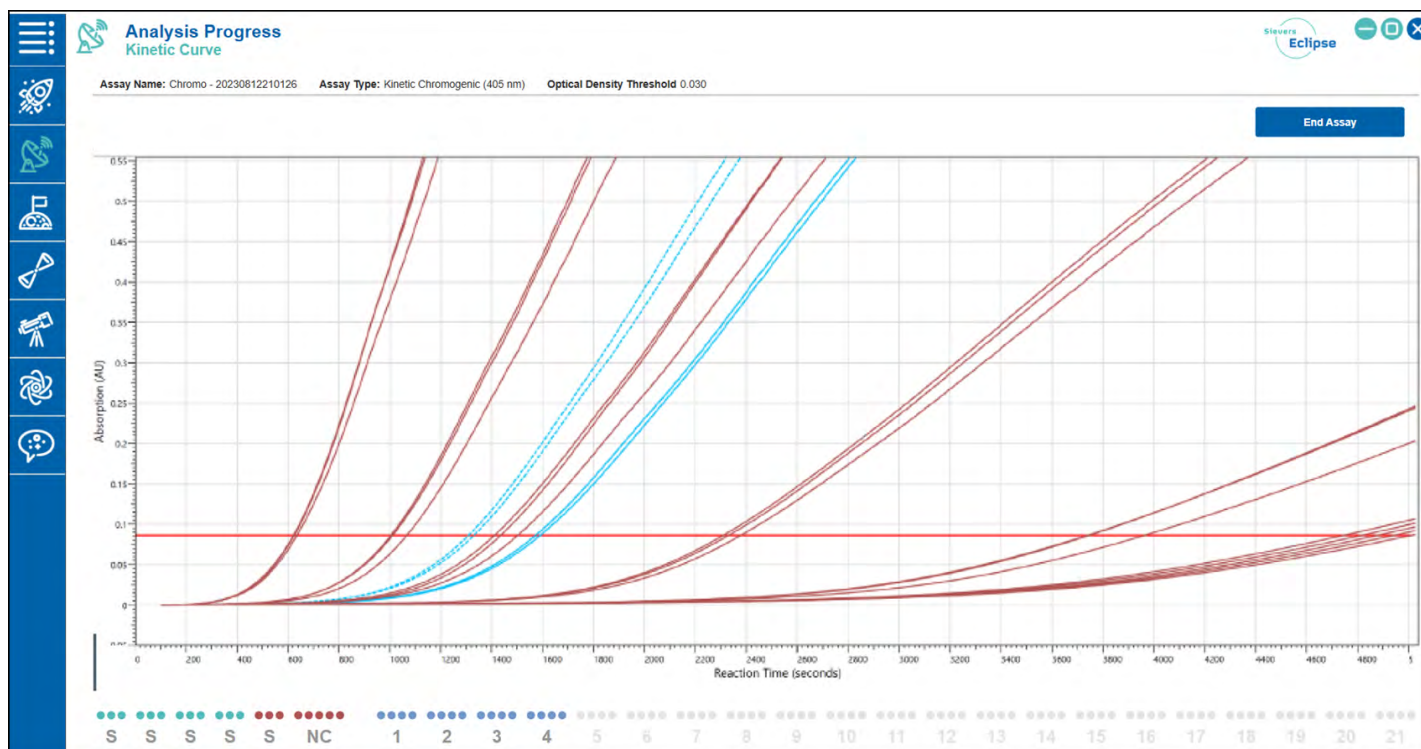


Figure 4-24: Kinetic Curve

Standard Curve

The standard curve graph (Figure 4-25) lets you visualize the onset time, %CV, and endotoxin concentration of the reference standards.

Navigate to **Analysis Progress > Standard Curve** (available only for the assay that is currently running).

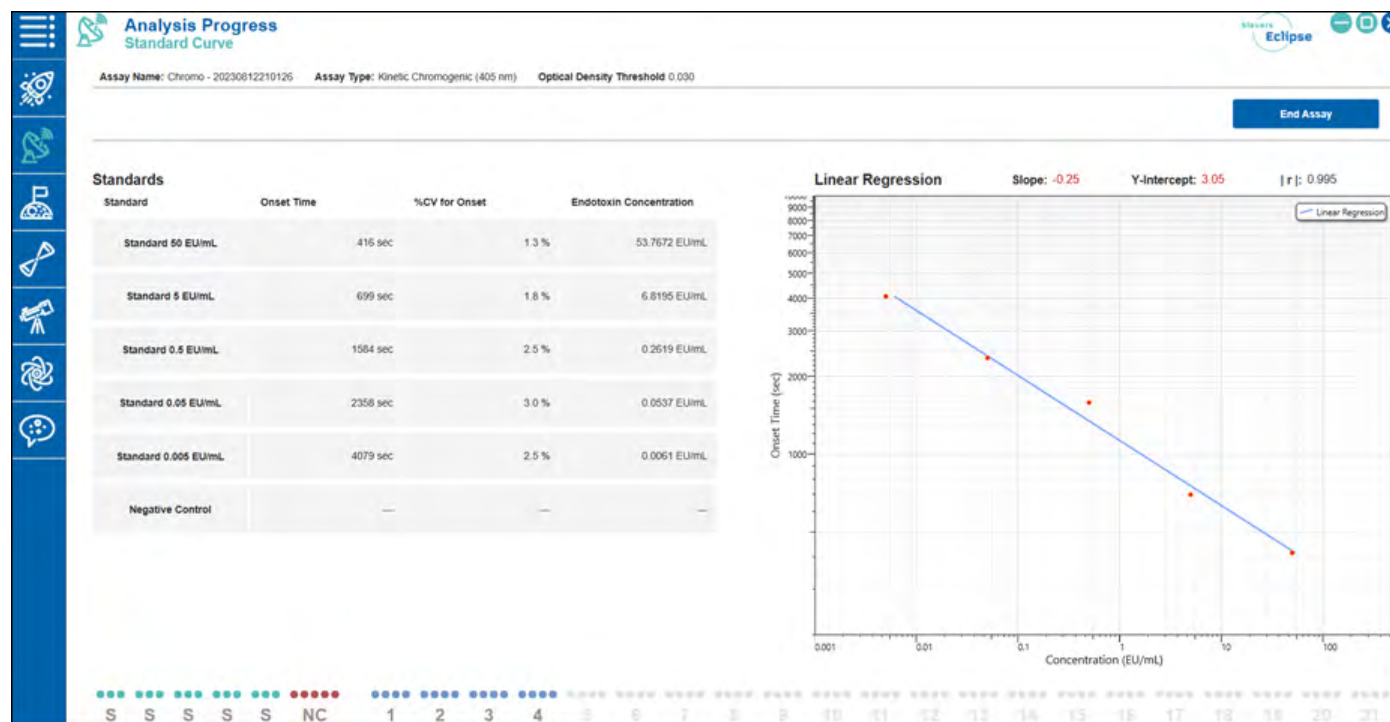


Figure 4-25: Standard Curve

Back Calculations

This screen (Figure 4-26) shows the Onset Time, %CV, Raw Endotoxin Concentration, and (if applicable) Dilution Adjusted Concentration of your samples.

Navigate to **Analysis Progress > Back Calculations** (available only for the current assay).

Assay Name: Chromo - 20230812210126 **Assay Type:** Kinetic Chromogenic (405 nm) **Optical Density Threshold:** 0.030

Back Calculations

#	Sample	Endotoxin Release Limit	Onset Time	%CV for Onset	Raw Endotoxin Concentration	Dilution Adjusted Concentration
1	Solution X	---	Sample	2375 sec	1.2 %	0.0522 EU/mL
			PPC	1733 sec	2.1 %	0.1831 EU/mL
			PPC % Recovery			50.0 %
2	Solution X	---	Sample	1946 sec	10.0 %	0.1155 EU/mL
			PPC	1609 sec	10.0 %	0.2464 EU/mL
			PPC % Recovery			50.0 %
3	Solution X	---	Sample	2375 sec	10.0 %	0.0522 EU/mL
			PPC	1733 sec	10.0 %	0.1830 EU/mL
			PPC % Recovery			49.9 %
4	Formulation Y	---	Sample	2316 sec	10.0 %	0.0577 EU/mL
			PPC	1297 sec	10.0 %	0.5817 EU/mL
			PPC % Recovery			200.1 %

Figure 4-26: Back Calculations

Results

The Results Menu

Use the Results menu to show all of the data about completed assays, apply signatures to results, print and export reports, see the audit trail, and view the Product Trend Graph.

The Results screen (Figure 4-27) contains assay results and product trend data for all assays run within the user’s Work Group(s).

Navigate to **Results > Assay Results** to see a list of the current Work Group’s completed assays.

Assay Results

Click the filter button (indicated by arrow in Figure 4-27) to sort and filter the **Assay Results** list by:

- Assay: Name, Date Started, Analyst
- Product: Name, Lot Number, Manufacturer
- Valid/Invalid result

Menu

Assay Setup

Analysis Progress

Results

Assay Results

Product Trend Graph

Pharmacopeia

Diagnostics

Management

Eclipse

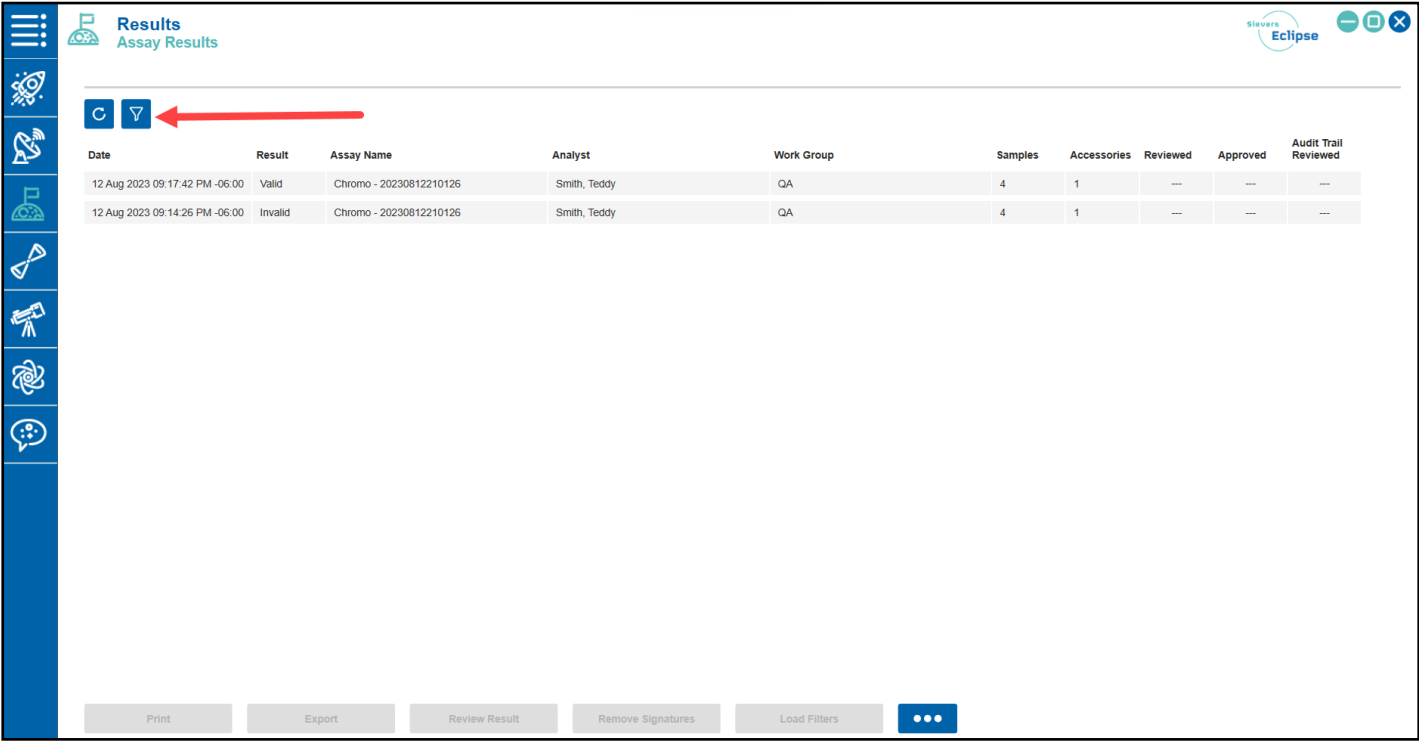


Figure 4-27: Results Screen

Each line item in the Assay Results list contains the following information:

- Date of the assay
- Whether the result was Valid or Invalid
- Assay Name
- Analyst who ran the assay
- Work Group for the assay
- Number of samples tested
- Number of accessories used during the assay
- Whether the assay has been reviewed and approved, and the audit trail reviewed (a check mark indicates that the action has been taken)

When you click an individual assay result, several options become available in the lower of the screen (Figure 4-28):

- Print
- Export
- Review/Approve Result (or Review Audit Trail)
- Remove Signatures (if assay has been signed)
- Load Filters (if you have saved a filter set for the results)
- ... : Lets you Open Archive, Apply Polynomial Regression, Edit Result, Mask Wells, or Save Filters

The screenshot displays the 'Results Assay Results' screen. It features a table with the following data:

Date	Result	Assay Name	Analyst	Work Group	Samples	Accessories	Reviewed	Approved	Audit Trail Reviewed
12 Aug 2023 09:17:42 PM -06:00	Valid	Chromo - 20230812210126	Smith, Teddy	QA	4	1	---	---	---
12 Aug 2023 09:14:26 PM -06:00	Invalid	Chromo - 20230812210126	Smith, Teddy	QA	4	1	---	---	---

Below the table is a toolbar with the following buttons: Print, Export, Review Result, Remove Signatures, Load Filters, and a menu button (three dots).

Figure 4-28: Results Screen

Print

Click **Print**, then select one of the five report types available from the list that appears (Figure 4-29):

- Assay Detail Report
- Assay Result Report
- Assay Audit Trail Report
- Sample Details Report
- Assay Raw Data Report

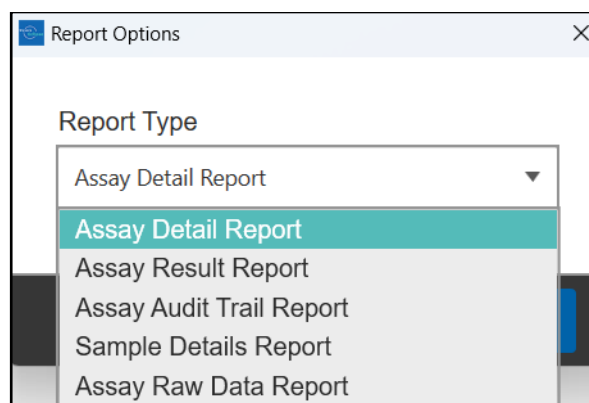


Figure 4-29: Report Types

Assay Detail Report

The Assay Detail Report shows overall assay information, assay results for chosen samples, related audit trail entries and the corresponding signatures for assay review, approval, and audit trail review.

1. Choose **Assay Detail Report** from the list, then click **Accept** to continue.
2. Select the Products to display by checking the box next to the Product, or click the **None** or **All** buttons (Figure 4-30), then click **Accept** to continue.

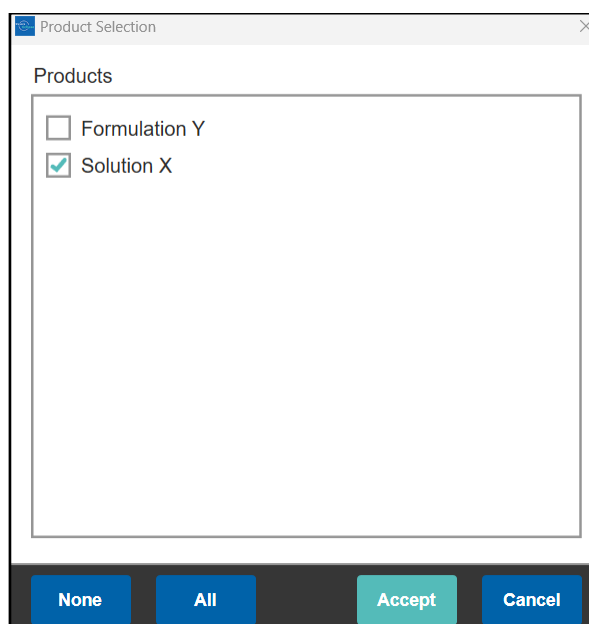


Figure 4-30: Product Selection

Figure 4-31 shows the first page of an Assay Detail Report. This page is organized into the following sections:

- (1) General assay information, such as the assay name and type, the Analyzer serial number, the analyst performing the assay, and time/date information.
- (2) Standard Curve & Negative Control Results
- (3) The Standard Curve
- (4) Microplate, reagent, and LRW information

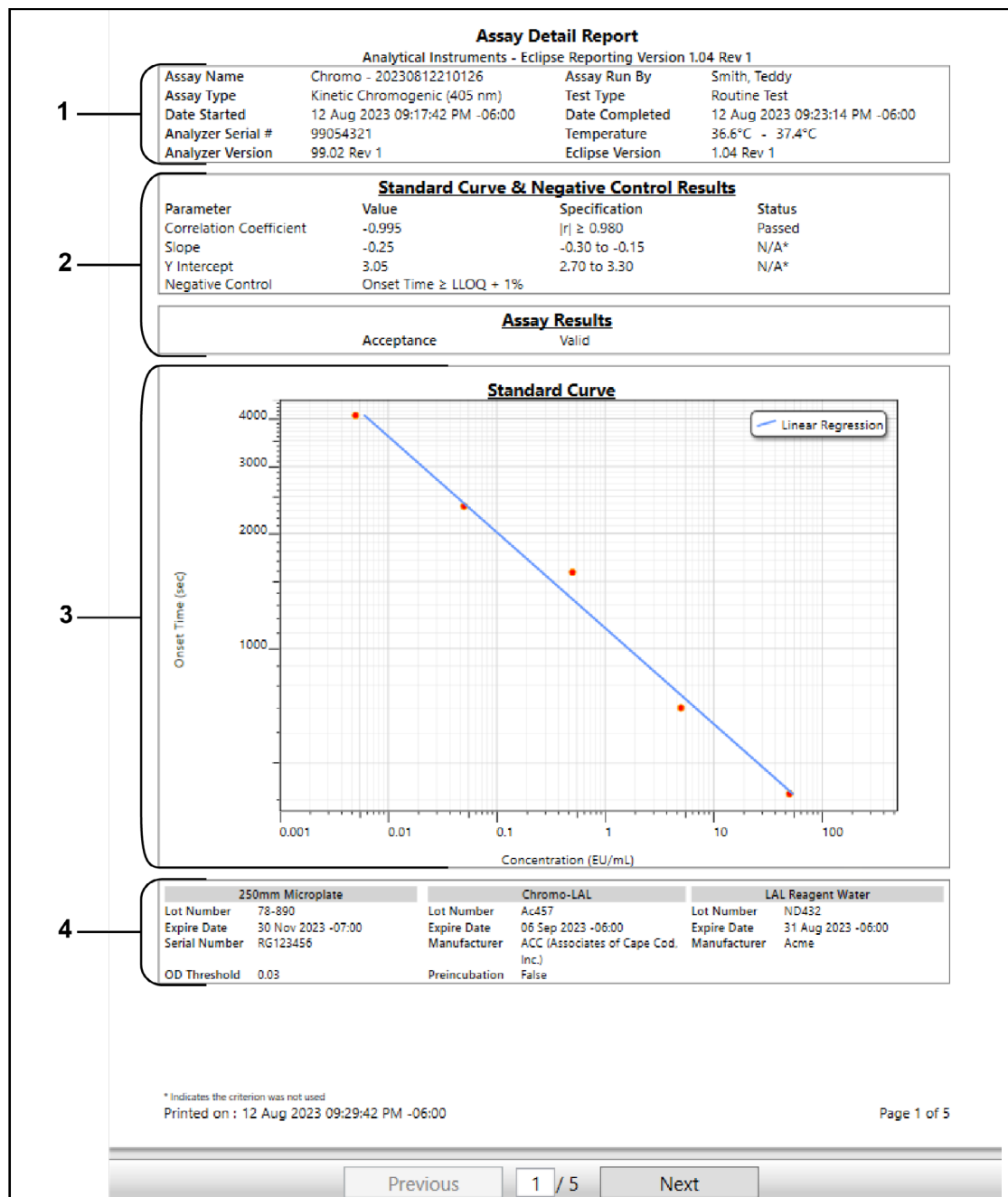


Figure 4-31: Assay Detail Report

Page 2 of the report shows assay results for the selected standards and the negative controls (up to 5, respectively). Figure 4-32 shows the information for Segment 22 (pre-loaded with 50 EU/mL endotoxin). The mean onset time, endotoxin concentration, and %CV are shown, as well as a box displaying the onset time and endotoxin concentrations of the three individual wells in the segment.

Standards Results			
Standard 50 EU/mL (Segment: 22)			
Mean Onset Time	416 sec	Standard (1)	421 sec
Endotoxin Concentration	53.7672 EU/mL	Standard (2)	416 sec
%CV Onset Time	1.3 %	Standard (3)	411 sec
Status	%CV Onset Time ≤ 15.0%	Pass	1.3 %
	Acceptance	Valid	
Standard 5 EU/mL (Segment: 23)			
Mean Onset Time	699 sec	Standard (1)	711 sec
Endotoxin Concentration	6.8195 EU/mL	Standard (2)	699 sec
%CV Onset Time	1.8 %	Standard (3)	686 sec
Status	%CV Onset Time ≤ 15.0%	Pass	1.8 %
	Acceptance	Valid	

Figure 4-32: Assay Detail - Standards

The next several pages contain detailed Products Results (Figure 4-33), as well as a list of the Accessories used during the assay.

Products Results				
Sample Invalid				
Solution X (Segment: 3)				
Expires: 31 Aug 2023 -06:00				
Lot #: AC457	Sample ID: Sample 3	Dilution Ratio : 1		
Sample	Mean Onset Time	2375 sec	Sample (2)	2543 sec
	Dilution Adjusted Concentration	0.0522 EU/mL	Sample (3)	2207 sec
	Raw Endotoxin Concentration	0.0522 EU/mL	PPC (1)	1856 sec
	%CV Onset Time	10.0 %	PPC (4)	1611 sec
PPC	Mean Onset Time	1733 sec		
(0.5 EU/mL)	Endotoxin Concentration	0.1830 EU/mL		
	%CV Onset Time	10.0 %		
	PPC % Recovery	49.9 %		
Status	%CV Onset Time ≤ 15.0%	Pass	10.0 % (SMP)	10.0 % (PPC)
	50.0% ≤ %PPC ≤ 200.0%	Fail		49.9 %
	No Release Limit Defined	N/A		0.0522 EU/mL
Acceptance		Invalid		
Failure Reason(s): PPC Limit Exceeded				
Accessories				
Pipette				
Name	Small pipette 123	Expiration Date		
Lot Number		Calibration Due Date	30 Oct 2023 -06:00	
Serial Number	N536777	Manufacturer	Eppendorf	
Comments				

Figure 4-33: Assay Detail - Products

After the Product Results and Accessories portions of the report, the Related Audit Trail Entries appear (Figure 4-34). Here, every action taken on the assay is logged and saved for future reference—the initial completion of the assay, every signature and signature removal, and every report generated. Audit information is time stamped, and includes the Eclipse username and Windows user and machine that accessed the information.

Related Audit Trail Entries			
Assay is Started			
Related Item Name	Chromo - 20230812210126		
Date Occurred	12 Aug 2023 09:15:13 PM -06:00		
User	Smith, Teddy	Windows Machine Name	AA-HPPAVILLION
		Windows User	AA-HPPAVILLION\alstr
Assay Ended due to Max Assay Time Limit			
Related Item Name	Chromo - 20230812210126		
Date Occurred	12 Aug 2023 09:23:14 PM -06:00		
User	Smith, Teddy	Windows Machine Name	AA-HPPAVILLION
		Windows User	AA-HPPAVILLION\alstr
Assay Report was generated			
Related Item Name	Chromo - 20230812210126		
Date Occurred	12 Aug 2023 09:23:15 PM -06:00		
User	Smith, Teddy	Windows Machine Name	AA-HPPAVILLION
		Windows User	AA-HPPAVILLION\alstr

Figure 4-34: Assay Detail - Audit Trail

The last page of the Assay Detail Report contains the signatures of the assay reviewers and approvers (Figure 4-35). See Creating Products for information on reviewing, approving, and signing assay results.

Once you have reviewed the Assay Detail Report, you can perform several actions to print, sign (or remove signature), or apply polynomial regression to the assay.

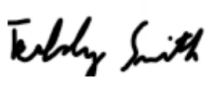
Print Preview			
Print	View	Signatures	Polynomial Regression
Approve Result Remove Signatures			
Assay Report was generated			
Related Item Name	Chromo - 20230812210126		
Date Occurred	12 Aug 2023 09:36:17 PM -06:00		
User	Smith, Teddy	Windows Machine Name	AA-HPPAVILLION
		Windows User	AA-HPPAVILLION\alstr
Performed/Reviewed By :	Smith, Teddy	Date/Time :	12 Aug 2023 09:36:17 PM -06:00
Signature:			
Comment :			
Approved By :		Date/Time :	
Signature:			
Comment :			
Audit Trail Reviewed By :		Date/Time :	
Signature:			
Comment:			

Figure 4-35: Assay Detail - Audit Trail

Assay Result Report

The Assay Result Report is a condensed one-page report that contains general assay information, standard curve & negative control results, and the acceptance and EU concentration information of the sample products.

Choose **Assay Result Report** from the **Report Type** list (shown on [page 56](#)), then like the Assay Detail Report, select the products to display and click **Accept** to continue.

Figure 4-36 shows a sample Assay Result Report.

The Assay Result Report allows the same set of actions from the Print Preview as the Assay Detail Report.

Print Preview

Print View Signatures Polynomial Regression

Assay Result Report

Analytical Instruments - Eclipse Reporting Version 1.04 Rev 1

Assay Name	Chromo - 20230812210126	Assay Run By	Smith, Teddy
Assay Type	Kinetic Chromogenic (405 nm)	Test Type	Routine Test
Date Started	12 Aug 2023 09:17:42 PM -06:00	Date Completed	12 Aug 2023 09:23:14 PM -06:00
Analyzer Serial #	99054321	Temperature	36.6°C - 37.4°C
Analyzer Version	99.02 Rev 1	Eclipse Version	1.04 Rev 1

Standard Curve & Negative Control Results

Parameter	Value	Specification	Status
Correlation Coefficient	-0.995	$ r \geq 0.980$	Passed
Slope	-0.25	-0.30 to -0.15	N/A*
Y Intercept	3.05	2.70 to 3.30	N/A*
Negative Control	Onset Time $\geq$ LLOQ + 1%		

Assay Results

Acceptance Valid

250mm Microplate	Chromo-LAL	LAL Reagent Water
Lot Number 78-890	Lot Number Ac457	Lot Number ND432
Expire Date 30 Nov 2023 -07:00	Expire Date 06 Sep 2023 -06:00	Expire Date 31 Aug 2023 -06:00
Serial Number RG123456	Manufacturer ACC (Associates of Cape Cod, Inc.)	Manufacturer Acme
OD Threshold 0.03	Preincubation False	

Products Results

Name	Lot Number	Sample ID	Dilution	Acceptance	Concentration
Solution X	AC457	Sample 1	1	Valid	0.0522 EU/mL
Solution X	AC457	Sample 2	1	Valid	0.1155 EU/mL
Solution X	AC457	Sample 3	1	Invalid	0.0522 EU/mL
Formulation Y		A23	1	Invalid	0.0577 EU/mL

Assay has NOT been approved

Figure 4-36: Assay Result Report

Assay Audit Trail Report

The Assay Audit Trail Report shows every action taken on an assay from start to completion, and every instance where a user viewed, printed, or otherwise interacted with the assay. It lists the date of the occurrence, assay details and comments, the action that occurred and who performed it, and Windows login information.

Choose **Assay Audit Trail Report** from the **Report Type** list (shown on [page 56](#)) and click **Accept** to continue.

Figure 4-37 shows a typical Assay Audit Trail Report.

You can print the report or add/remove signatures from the Assay Audit Trail Report.

Assay Audit Trail Report		
Analytical Instruments - Eclipse Reporting Version 1.03 Rev 2		
Date Occurred	Action	Performed by
Detail Information Additional Information Comments Windows Info		
18 Aug 2022 07:26:51 AM -06:00	Assay is Started	Little, Anne
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. W0360000DQXVLR2 - GREEN\UQB189		
18 Aug 2022 09:56:59 AM -06:00	Assay Ended	Little, Anne
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. All STDs, PPCs, and samples have reached onset W0360000DQXVLR2 - GREEN\UQB189		
18 Aug 2022 09:57:10 AM -06:00	Assay Report was generated	Little, Anne
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. W0360000DQXVLR2 - GREEN\UQB189		
18 Aug 2022 10:01:57 AM -06:00	Assay result was reviewed	Little, Anne
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. W0360000DQXVLR2 - GREEN\UQB189		
18 Aug 2022 10:01:57 AM -06:00	Assay Report was generated	Little, Anne
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. W0360000DQXVLR2 - GREEN\UQB189		
18 Aug 2022 10:05:30 AM -06:00	Assay result was approved	Stutts, Aimee
Assay 'Potency Test-CR-Endochrome-Beginning' started on '18 Aug 2022 08:21:36 AM -06:00' and cancelled on '18 Aug 2022 09:56:59 AM -06:00'. W0360000DQXVLR2 - GREEN\UQB189		

Figure 4-37: Assay Audit Trail Report

Sample Details Report

The Sample Details Report displays information about the samples used in an assay, including:

- Dilution and Diluent
- Manufacturer
- Lot Number
- Sample ID
- Description
- Date Created/Modified/Expires

The Sample Details Report does not contain any assay results or other calculations—it is simply a list of the product samples assayed.

Choose **Sample Details Report** from the **Report Type** list (shown on [page 56](#)), then like the Assay Detail Report, select the products to display and click **Accept** to continue.

Figure 4-38 shows a typical Sample Details Report.

Sample Details Report			
Analytical Instruments - Eclipse Reporting Version 1.04 Rev 1			
Assay Name	Chromo - 20230812210126	Assay Run By	Smith, Teddy
Assay Type	Kinetic Chromogenic (405 nm)	Test Type	Routine Test
Date Started	12 Aug 2023 09:17:42 PM -06:00	Date Completed	12 Aug 2023 09:23:14 PM -06:00
Analyzer Serial #	99054321	Temperature	36.6°C - 37.4°C
Analyzer Version	99.02 Rev 1	Eclipse Version	1.04 Rev 1

Products			
Solution X (Segment: 1)			
Dilution	1	Diluent	LAL Reagent Water
Manufacturer	Acme	Date Created	12 Aug 2023 09:15:13 PM -06:00
Lot Number	AC457	Date Modified	12 Aug 2023 09:23:15 PM -06:00
Sample ID	Sample 1	Date Expires	31 Aug 2023 -06:00
Description	reagent water		
Solution X (Segment: 2)			
Dilution	1	Diluent	LAL Reagent Water
Manufacturer	Acme	Date Created	12 Aug 2023 09:15:13 PM -06:00
Lot Number	AC457	Date Modified	12 Aug 2023 09:23:15 PM -06:00
Sample ID	Sample 2	Date Expires	31 Aug 2023 -06:00
Description	reagent water		
Solution X (Segment: 3)			
Dilution	1	Diluent	LAL Reagent Water
Manufacturer	Acme	Date Created	12 Aug 2023 09:15:13 PM -06:00
Lot Number	AC457	Date Modified	12 Aug 2023 09:23:15 PM -06:00
Sample ID	Sample 3	Date Expires	31 Aug 2023 -06:00
Description	reagent water		
Formulation Y (Segment: 4)			
Dilution	1	Diluent	LAL Reagent Water
Manufacturer		Date Created	12 Aug 2023 09:15:13 PM -06:00
Lot Number		Date Modified	12 Aug 2023 09:23:15 PM -06:00
Sample ID	A23	Date Expires	
Description			

Figure 4-38: Sample Details Report

Assay Raw Data Report

The Assay Raw Data Report displays the raw optical readings taken during the assay. It is very large—several hundred pages—and lists every reading taken from every well in every segment.

Choose **Assay Raw Data Report** from the **Report Type** list (shown on [page 56](#)) and click **Accept** to continue.

Figure 4-39 shows an example of an Assay Raw Data Report.

Assay Raw Data Report											
Analytical Instruments - Eclipse Reporting Version 1.04 Rev 1											
Assay Name	Chromo - 20230812210126				Assay Run By	Smith, Teddy					
Assay Type	Kinetic Chromogenic (405 nm)				Test Type	Routine Test					
Date Started	12 Aug 2023 09:17:42 PM -06:00				Date Completed	12 Aug 2023 09:23:14 PM -06:00					
Analyzer Serial #	99054321				Temperature	36.6°C - 37.4°C					
Analyzer Version	99.02 Rev 1				Eclipse Version	1.04 Rev 1					

Raw Optical Readings											
Segment Index	1	Well Index		1							
100.0000	0.00000	105.0000	0.00000	110.0000	0.00000	115.0000	0.00000	120.0000	0.00000	125.0000	0.00000
130.0000	0.00000	135.0000	0.00000	140.0000	0.00000	145.0000	0.00000	150.0000	0.00000	155.0000	0.00000
160.0000	0.00000	165.0000	0.00000	170.0000	0.00000	175.0000	0.00000	180.0000	0.00000	185.0000	0.00000
190.0000	0.00000	195.0000	0.00000	200.0000	0.00000	205.0000	0.00000	210.0000	0.00000	215.0000	0.00000
220.0000	0.00000	225.0000	0.00000	230.0000	0.00000	235.0000	0.00000	240.0000	0.00000	245.0000	0.00000
250.0000	0.00000	255.0000	0.00001	260.0000	0.00001	265.0000	0.00001	270.0000	0.00001	275.0000	0.00001
280.0000	0.00001	285.0000	0.00001	290.0000	0.00001	295.0000	0.00001	300.0000	0.00001	305.0000	0.00001
310.0000	0.00002	315.0000	0.00002	320.0000	0.00002	325.0000	0.00002	330.0000	0.00002	335.0000	0.00002
340.0000	0.00002	345.0000	0.00003	350.0000	0.00003	355.0000	0.00003	360.0000	0.00003	365.0000	0.00003
370.0000	0.00004	375.0000	0.00004	380.0000	0.00004	385.0000	0.00004	390.0000	0.00005	395.0000	0.00005
400.0000	0.00005	405.0000	0.00005	410.0000	0.00006	410.8340	0.00006	416.0580	0.00006	421.2810	0.00007
430.0000	0.00007	435.0000	0.00008	440.0000	0.00008	445.0000	0.00008	450.0000	0.00009	455.0000	0.00009
460.0000	0.00010	465.0000	0.00010	470.0000	0.00010	475.0000	0.00011	480.0000	0.00011	485.0000	0.00012
490.0000	0.00013	495.0000	0.00013	500.0000	0.00014	505.0000	0.00014	510.0000	0.00015	515.0000	0.00015

Figure 4-39: Assay Raw Data Report

Export

Click **Export** to save the assay result data in Excel, CSV, or XML format. You can also select whether or not to include raw optical readings.

Review/Approve Result (or Review Audit Trail)

The option that appears on this button depends on the status of the selected assay.

- **Review Result** —The assay needs to be signed by the analyst who ran the test.
- **Approve Result** —The assay result needs to be approved.
- **Review Audit Trail** —The audit trail for the signed, approved assay needs to be reviewed.

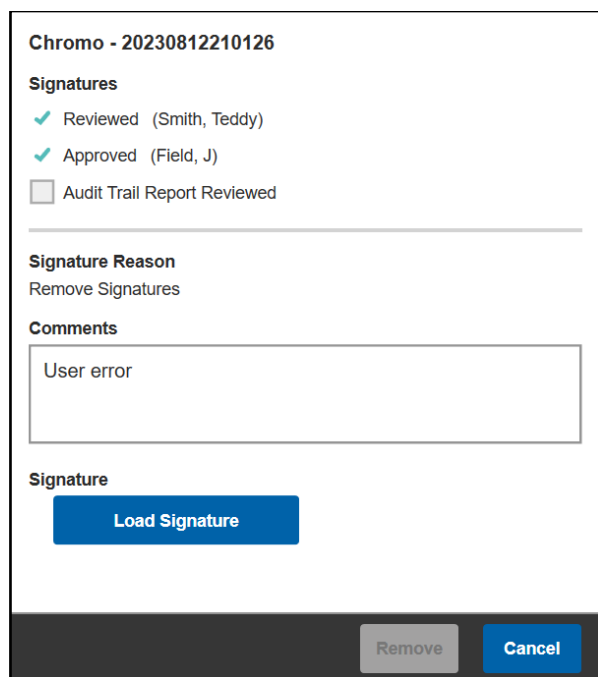
See [“Electronic Signatures” on page 107](#) for more information about signing assay results.

Remove Signatures

The Remove Signatures button becomes available once the assay has been signed by at least one user. You must have the Add/Remove Signatures permission to perform this action (see [“Permissions” on page 103](#) for more information).

1. Select the assay to remove signatures from.
2. Click **Remove Signatures**.
3. On the dialog box that appears (Figure 4-40), enter a reason for removing the signatures in the **Comments** field.
4. Click **Load Signature**. In the dialog box that appears, enter the username and password of a user with permission to Add/Remove Signatures.
5. In the dialog box that appears (Figure 4-41), click **Remove**.

All signatures will be removed from the assay. The **Review Result** button becomes available on the **Assay Results** list.



Chromo - 20230812210126

Signatures

- ✓ Reviewed (Smith, Teddy)
- ✓ Approved (Field, J)
- ☐ Audit Trail Report Reviewed

Signature Reason
Remove Signatures

Comments

User error

Signature

Load Signature

Remove **Cancel**

Figure 4-40: Remove Signatures (1)



Chromo - 20230812210126

Signatures

- ✓ Reviewed (Smith, Teddy)
- ✓ Approved (Field, J)
- ☐ Audit Trail Report Reviewed

Signature Reason
Remove Signatures

Comments

User error

Signature
Field, J

Remove **Cancel**

Figure 4-41: Remove Signatures (2)

Load Filters

When you save a filter set for the **Assay Results** list (see [“Assay Results” on page 54](#)), you can activate it by clicking **Load Filters**.

⋮ (More button)

The **More** button, indicated by ⋮, reveals several options for assays in the **Assay Results** list:

- Open Archive
- Apply Polynomial Regression
- Edit Result
- Mask Wells
- Save Filters

Open Archive

To see archived assays and other data:

1. Navigate to **Results > Assay Results**
2. Click ⋮.
3. Select **Open Archive**.
4. Navigate to the location of the archived.SCA file and click **Open**.

Apply Polynomial Regression

To apply polynomial regression to an assay result:

1. Navigate to **Results > Assay Results**
2. Select an assay that has not been reviewed or signed.
3. Click ⋮.
4. Select **Apply Polynomial Regression**.
5. On the dialog box that appears, click **Load Signature**.
6. Enter the username and password of the analyst who ran the assay and click **Sign**.

Edit Result

To change an entry, add an accessory or sample detail, or otherwise alter the template of an already completed assay:

1. Navigate to **Results > Assay Results**
2. Select the assay to be edited.
3. Click ⋮ and select **Edit Result**.
4. Make your changes to the assay.
5. You can navigate through the assay using the tabs at the top of the screen, or by clicking **< Back** and **Next >**.
6. Click **Save** to confirm your changes, or click **Cancel** to leave the assay unchanged.

Mask Wells

Segments 22–26 are embedded with three replicate endotoxin standards each. Regulations require two replicates per standard. If needed, you can mask one of the replicates and recalculate the curve with only two replicates.



NOTE: Masking a standard only applies to routine testing, not pharmacopeia testing such as lysate qualification, analyst qualification, etc.

1. Navigate to **Results > Assay Results**
2. Select the assay to be edited.
3. Click **...** and select **Mask Wells**. A screen showing the five standards and the negative control appears (Figure 4-42):
4. Put a check mark in the box next to the well(s) you want to mask.
5. Click **Accept**.
6. In the dialog box that appears, enter the reason for the change.
7. Click **Apply Masks** to recalculate the curve with the well(s) masked.

Results

Correlation Coefficient	-0.995	r ≥ 0.980	Passed
Slope	-0.25	[-0.30, -0.15]	N/A
Y Intercept	3.05	[2.70, 3.30]	N/A
Negative Control	Onset Time ≥ LLOQ + 1%	Passed	

Name	Average Onset	Well	Onset (sec)	Mask
Standard 50 EU/mL	416 sec	1	421 sec	☐
		2	416 sec	☐
		3	411 sec	☐
Standard 5 EU/mL	699 sec	1	711 sec	☐
		2	699 sec	☐
		3	686 sec	☐
Standard 0.5 EU/mL	1584 sec	1	1624 sec	☐
		2	1584 sec	☐
		3	1544 sec	☐
Standard 0.05 EU/mL	2358 sec	1	2429 sec	☐
		2	2358 sec	☐
		3	2287 sec	☐
Standard 0.005 EU/mL	4079 sec	1	4180 sec	☐
		2	4080 sec	☐
		3	3978 sec	☐
Negative Control	4530 sec	4	4531 sec	☐
		4	4530 sec	☐
		4	4529 sec	☐
		4	4530 sec	☐
		4	4531 sec	☐

Accept Cancel

Figure 4-42: Mask Wells - Standards

Save Filters

If you apply filters to the **Assay Results** list, you can save the resulting filtered list by choosing this option.

Product Trend Graph

The Product Trend Graph allows users to graphically present testing trends over time against customizable alert and action limits.

1. Navigate to **Results > Product Trend Graph**. The setting for the X Axis is Date Started (Figure 4-43).
2. Click Date Started to change its filter. Options include:
 - <
 - ≤
 - ≥
 - >
 - Between
 - Is
3. Then enter the date for the filter in the Value 1 field (if using the Between criterion, complete Value 2 as well). You can select a date by clicking the calendar icon. When you have entered the date(s), click Accept.
4. Select graph criteria for the Y1 Axis from the Y1 Axis list. Options include:
 - Mean Onset Time
 - %CV on Onset Time
 - Dilution Adjusted Concentration
 - %CV Concentration
 - PPC % Recovery
 - Slope
 - Y Intercept
 - R Value

Click and drag to move around on the graph, and use the mouse wheel to zoom in/out on specific details.

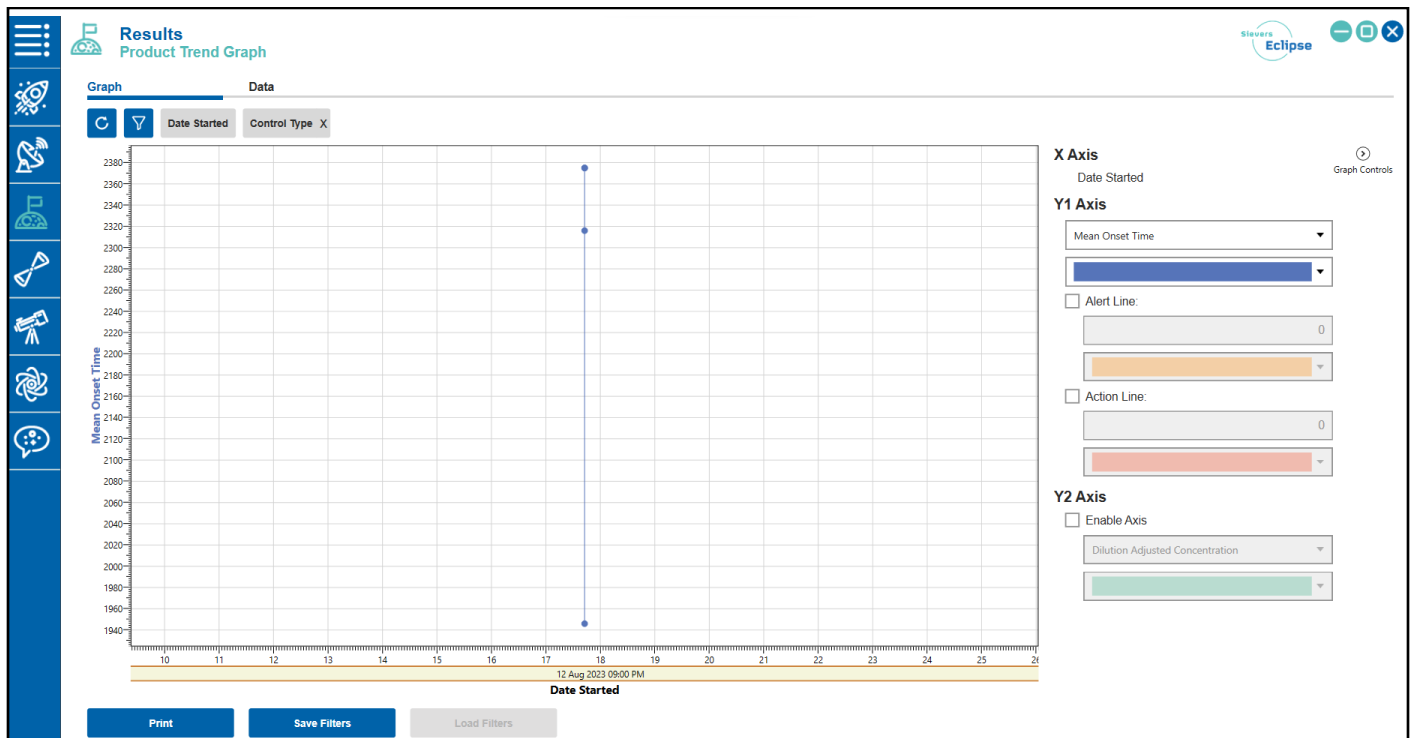


Figure 4-43: Product Trend Graph - no settings

Product Trend Graph Detail

You can hover the mouse cursor over a specific data point to get more information about the product it represents.

Graph Tab

The graph controls to the right of the Product Trend Graph offer several other options to further refine the graph, including an Alert Line and Action Line, and a Y2 Axis for displaying a second filter type. Select the check boxes next to these options to enable them, enter filter criteria, and choose line colors from their corresponding lists. Figure 4-44 shows a sample Product Trend Graph for Mean Onset Time from all assays run between March and April, 2022 with all available filters enabled:

The buttons along the lower portion of the graph provide options to print the graph, save or load filter sets, and open the data archive.

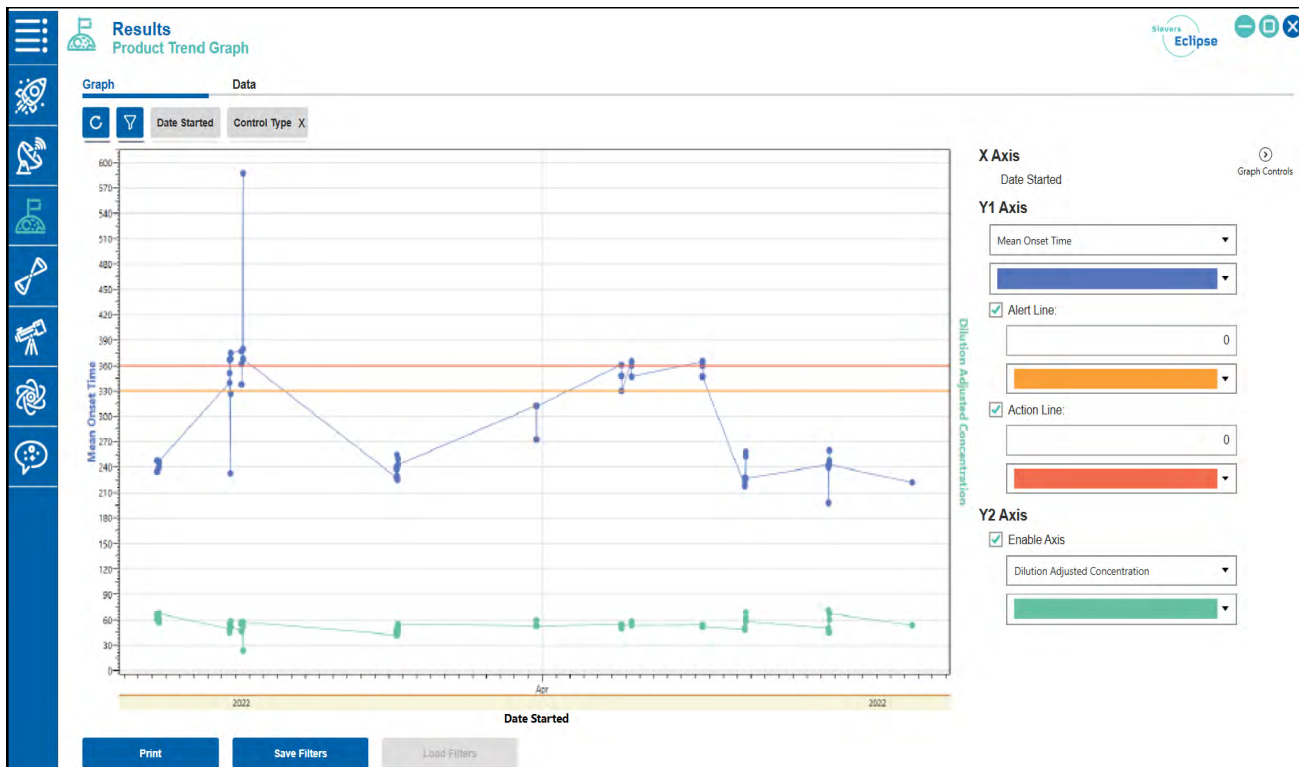


Figure 4-44: Product Trend Graph - Filtered

Data Tab

The Data tab (Figure 4-45) shows a sortable, filterable spreadsheet view of the graph data. Use the scroll bars to move vertically and horizontally around the spreadsheet, and use the < and > buttons to move between pages. The buttons on the lower section of the screen let you print, load/ save filters, and open the archive.

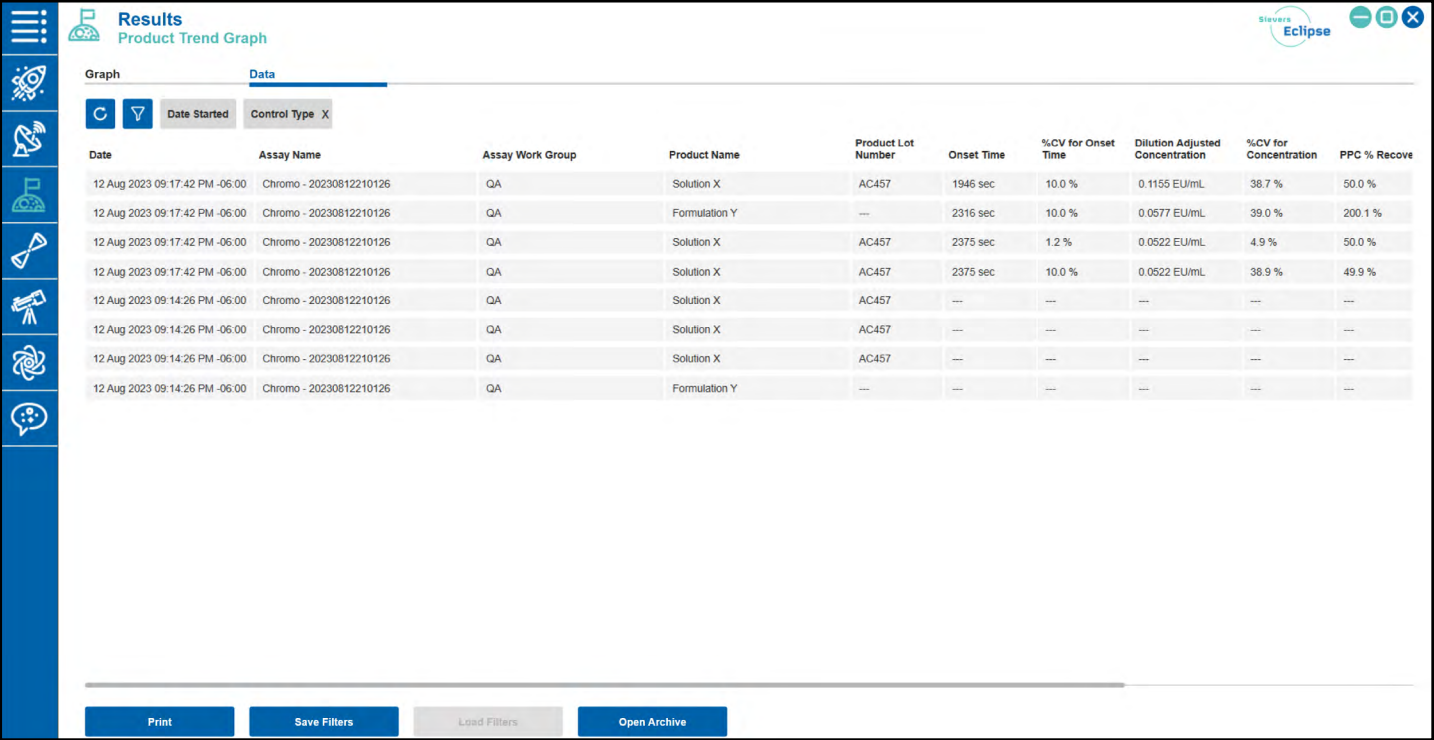


Figure 4-45: Product Trend Data View

CHAPTER 5: PHARMACOPEIA

The Pharmacopeia Menu

Use the following selections from the Pharmacopeia menu to qualify users and verify assay components meet regulatory requirements for use:

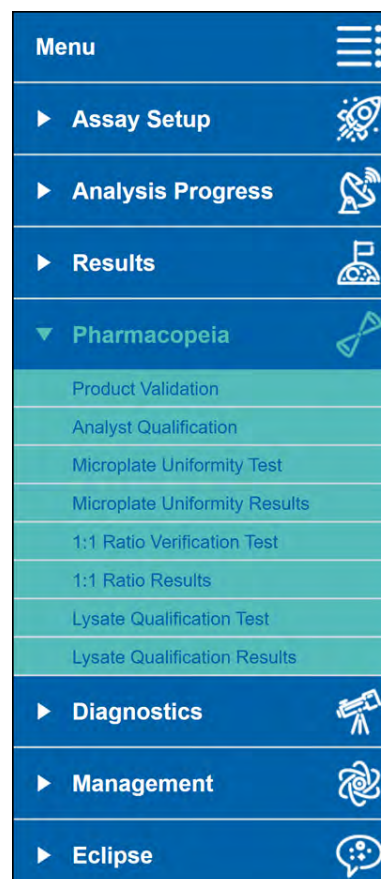
Product Validation. Validate product samples as suitable for use.

Analyst Qualification. Qualify Eclipse users to run assays with samples.

Microplate Uniformity Test. Verify the uniform measurement of test samples and PPCs across the Eclipse Microplate.

1:1 Ratio Verification Test. Verify that the Eclipse platform is able to distribute and mix samples and lysate reagent in a 1:1 ratio.

Lysate Qualification Test. Verify that the current lot of lysate reagent, when mixed with lysate reconstitution solution, meets regulatory requirements for linearity.



Product Validation

The **Product Validation** screen (**Pharmacopeia > Product Validation**) shows a list of product samples that are eligible candidates for validation review (**Validation Eligible** tab, shown in Figure 5-1), or have been validated (**Validated Products** tab).

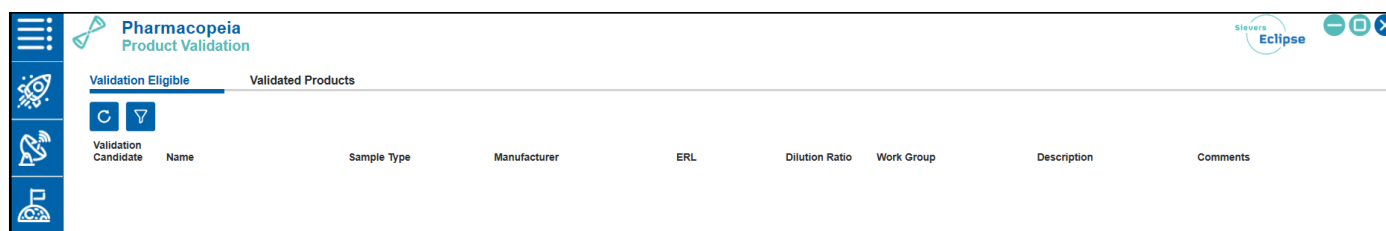


Figure 5-1: Validation Eligible Tab

Eligible Products for Validation

You can make a product eligible for validation when creating it, or you can validate existing products:

1. Navigate to **Assay Setup > Products & Accessories**.
2. Select a product from the list and click **Edit**.
3. Put a check in the box next to **Product is Validation Eligible** (Figure 5-2).

The screenshot shows the 'Assay Setup - Edit Product' interface for 'Solution X'. The 'Product Details' section includes fields for Name, Sample Type, Description, and Manufacturer. To the right, there are fields for Maximum Valid Dilution, Endotoxin Release Limit (ERL), ERL Units, and ERL By Volume/Dilution Ratio. A red arrow points to the 'Product Is Validation Eligible' checkbox, which is checked. Below this, the 'Validation Qualifiers' section lists 'Name', 'Sample Type', 'Dilution Ratio', 'Release Limit', and 'Manufacturer'. 'Name', 'Sample Type', and 'Dilution Ratio' are checked, while 'Release Limit' and 'Manufacturer' are unchecked.

Figure 5-2: Make a Product Validation Eligible

By default, **Name**, **Sample Type**, and **Dilution Ratio** are selected as validation qualifiers. You can also use **Release Limit** and **Manufacturer** criteria.

4. Click **Accept**. The product will now appear in the **Validation Eligible** screen.

Validating Products

To be considered valid, a product must meet the following criteria:

- The samples passed (%CV, PPC recovery, ERL, etc.).
- The standard curve of the assay was good.
- The assay was reviewed and approved.
- The required lot count has been met (This count is configured in **Management > Settings > Defaults > Products > Lot count required for validation**.)

To validate a product that has been made eligible for validation:

1. Navigate to **Pharmacopeia > Product Validation**
2. Select the product to be validated.
3. Click **Validate**. The product will then appear on the **Validated Products** list.

Analyst Qualification

You must be qualified as an analyst to run assays with samples in Eclipse. This section details the steps required to qualify a user as an analyst.

Required Materials

- Lysate reagent water or other lysate reconstitution solution
- 1 mL lysate (reconstituted per manufacturer's instructions)
- 1 new Eclipse Microplate
- Pipette and tips capable of delivering 55 µL and 1 mL volumes

Acceptance Criteria

- Temperature: 37 °C ±1
- Correlation Coefficient $|r| \geq 0.980$
- Negative Control Onset Time > LLOQ Onset Time

Procedure

1. Launch Eclipse and log in. If the user is not qualified, a dialog box will appear notifying you of your unqualified status.
2. Navigate to **Assay Setup > Create Assay > Assay Details** tab (Figure 5-3).
3. Under **Assay Settings**, enter the following information:
 - In the **Assay Name** field, enter Analyst Qualification.
 - Choose a **Standard Curve Option** from the list.
4. Under **Lysate Reagent**, enter the following information:
 - Choose a lysate reagent from the list.
 - If preincubation is directed by the reagent manufacturer (check the Instructions for Use included with the reagent), check the Enable Preincubation checkbox.
 - Complete the fields for **Manufacturer** (which auto-fills when you choose a reagent), **Lot Number**, and **Expiration**.

Figure 5-3: Assay Details Tab (left)

5. Under **Lysate Reconstitution Solution** (Figure 5-4), enter the following information:
 - Select a reconstitution solution from the list.
 - Complete the fields for **Manufacturer**, **Lot Number**, and **Expiration**.
6. Under **Microplate** (Figure 5-4), complete the **Serial Number**, **Lot Number**, and **Expiration** fields.
7. Click **Next**.
8. Add accessories (optional), then click **Start Assay**.
9. Load a new Microplate into the Analyzer and close the lid.
10. Inject 55 μ L of LRW into Segment 22 (or Segment 23 if 3- or 4-point curve is selected), then click the right arrow or press the right button on the Eclipse lid to advance to the next segment (Figure 5-5).

The screenshot shows the 'Read Only Settings' window for the Assay Details Tab. It is divided into two main sections: 'Lysate Reconstitution Solution' and 'Microplate'.
 Under 'Lysate Reconstitution Solution', there is a dropdown menu currently set to 'LAL Reagent Water'. Below it are input fields for 'Manufacturer', 'Lot Number', and 'Expiration', each with a red exclamation mark icon indicating a required field.
 Under 'Microplate', there are input fields for 'Serial Number', 'Lot Number', and 'Expiration', also each with a red exclamation mark icon. A blue square icon is visible next to the 'Expiration' field.

Figure 5-4: Assay Details Tab (right)

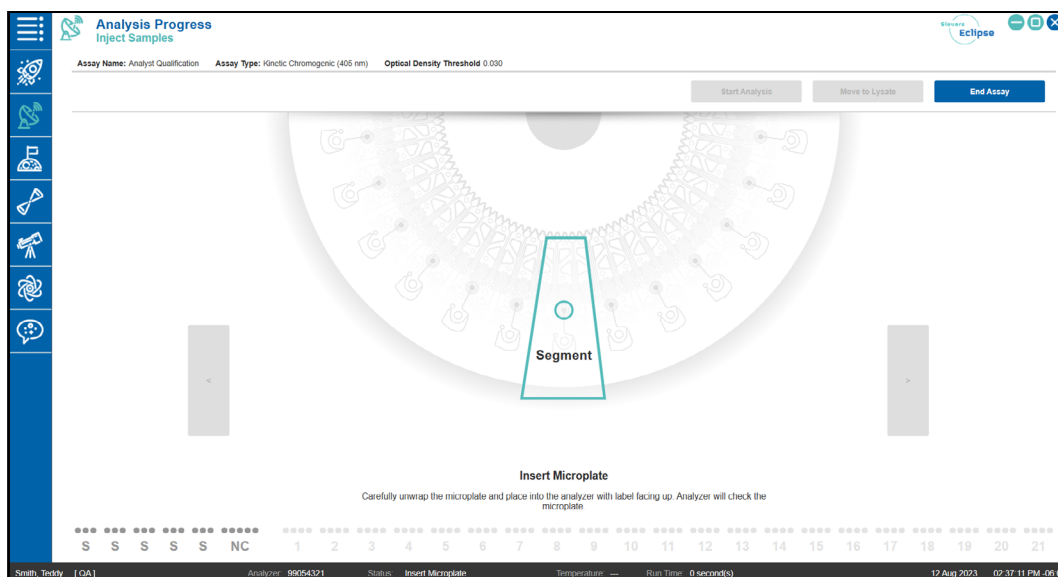


Figure 5-5: Sample Injection Screen



NOTE: You will need to move the injection port cover to inject samples and lysate. See [“The Injection Port Cover” on page 48](#) for more information.

11. Follow the on-screen instructions to inject 55 μ L of LRW into each of the applicable reference standard segments. If preincubation is required:
 - 11a. Click **Start** on the dialog box to confirm that you want to preincubate the Microplate.
 - 11b. Wait for the timer to reach 00:00, indicating preincubation is complete.
12. Click **Inject Lysate**.
13. Follow the on-screen instructions to inject 1 mL of lysate reagent into the injection port, making sure to align the injection port cover with the lysate injection port.
14. Close the port and click **Start Analysis**.
15. Wait for the assay to finish.

Upon completion of analysis



NOTE: The assay will run for the amount of time specified in **Management > Settings > Defaults > Maximum Assay Length**, even if the standards have fully onset before that time. You may abort the test if all standards have reacted and you are confident that the negative control onset time is greater than the LLOQ onset time.

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 7):

1. Click **Accept**.
2. Remove the Microplate from the Analyzer.
3. Navigate to **Pharmacopeia > Analyst Qualification**.
4. In the **Unqualified** tab, select your user profile from the **Analyst** list.
5. Select the appropriate assay.
6. Click **Print**.
7. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.
8. When the assay has been fully reviewed and signed, log in as a user with permission to qualify analysts and navigate to **Pharmacopeia > Analyst Qualification**.
9. Under the **Unqualified** tab, select the user to be qualified from the **Analyst** menu. If the analyst to be qualified does not appear in the list, click the **Reload** icon (Figure 5-6).
10. Verify that all three signatures have been signed (indicated by box in Figure 5-7) and click **Qualify**.
11. On the **Qualify Analyst** dialog box, click **Load Signature**.
12. Enter the username and password of a user who has permission to qualify analysts and click **Accept**.
13. Click **Sign** to approve the qualification. The analyst now appears in the **Qualified** tab with a check mark under **Qualified** (Figure 5-8).

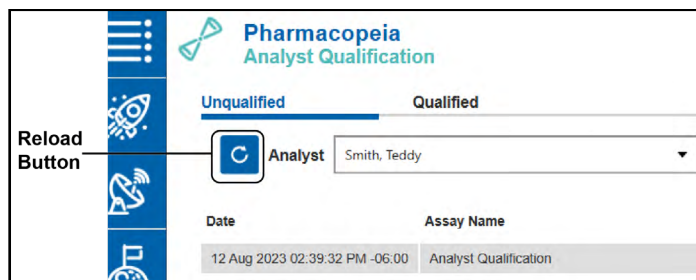


Figure 5-6: Unqualified Analysts

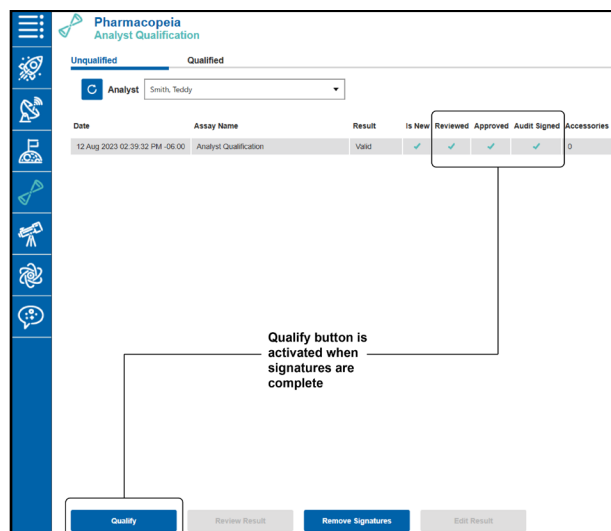


Figure 5-7: Qualifying an Analyst

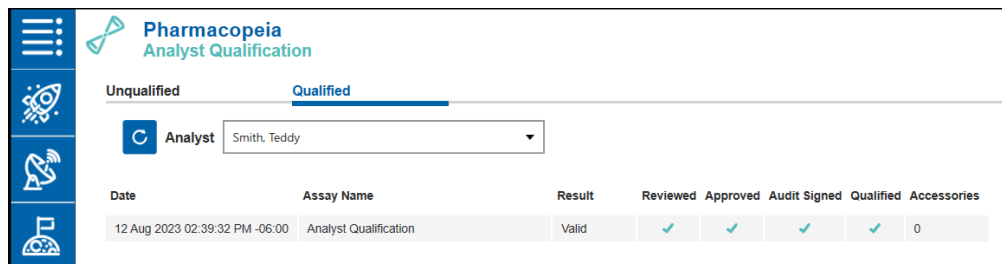


Figure 5-8: Qualified Analyst

Microplate Uniformity Test

The Microplate Uniformity Test (Figure 5-9) verifies the uniform measurement of test samples and PPCs across the Microplate.

Pharmacoepia
Microplate Uniformity Test

Assay Settings
Assay Name: Microplate Uniformity Test
Optical Density Threshold: 0.03

Lysate Reagent
Lysate Reagent: Chromo-LAL
☐ Enable Preincubation
Manufacturer: ACC (Associates of Cape Cod, Inc.)
Lot Number:
Expiration:

Lysate Reconstitution Solution
Lysate Reconstitution Solution: LAL Reagent Water
Manufacturer:
Lot Number:
Expiration:

Microplate
Serial Number:
Lot Number:
Expiration:

Next >

S S S S S NC 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Figure 5-9: Microplate Uniformity Test Screen

Required Materials

- Lysate reagent water or other lysate reconstitution solution
- 2 mL 0.5 EU/mL RSE solution
- 1mL lysate (reconstituted per manufacturer's instructions)
- 1 new Eclipse Microplate
- Pipette and pipette tips capable of delivering 55 μ L and 1mL volumes

The analyst executing the Microplate Uniformity Test must be qualified (see [“Analyst Qualification” on page 72](#) for more information).

Acceptance Criteria

- Temperature: 37 ± 1 °C
- Correlation Coefficient $|r| \geq 0.980$
- Negative Control Onset Time > LLOQ Onset Time
- %CV Onset Time (Sample) $\leq 5\%$
- %CV Onset Time (PPC) $\leq 5\%$



Procedure

1. Navigate to **Pharmacopeia > Microplate Uniformity Test**.
2. Under **Lysate Reagent**:
 - 2a. Choose a Lysate Reagent from the list.
 - 2b. If preincubation is directed by the reagent manufacturer, check the **Enable Preincubation** checkbox.
 - 2c. Complete the fields for **Manufacturer** (auto-fills when you choose a reagent), **Lot Number**, and **Expiration**.

Under **Lysate Reconstitution Solution**:

- 2d. Select a reconstitution solution from the list.
- 2e. Complete the **Manufacturer**, **Lot Number**, and **Expiration** fields.

Under **Microplate**:

- 2f. Complete the **Serial Number**, **Lot Number**, and **Expiration** fields.
3. Click **Next**.
4. Enter a Sample ID in the **Sample ID** field.
5. Click **Next**.
6. (Optional) If using additives, complete the appropriate fields in the **Sample Details** tab.
7. Click **Next**.
8. (Optional) Add accessories.
9. Click **Start Assay**.
10. Follow the on-screen instructions:
 - 10a. Load a new Microplate into the Analyzer and close the lid.
 - 10b. Inject 55 µL of LRW into each of Segments 22–26.
 - 10c. Inject uniformity sample (0.5 EU/mL RSE recommended) in Segments 1–21.
 - 10d. (Optional) If preincubation is required, click **Start** on the dialog box to confirm that you want to preincubate the Microplate, then wait for the timer to reach 00:00, indicating preincubation is complete.
 - 10e. Click **Inject Lysate**.
 - 10f. Inject 1mL of lysate reagent into the injection port.
 - 10g. Close injection port cover and click **Start Analysis**.

Upon completion of analysis

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 5):

1. Remove the Microplate from the Analyzer.
2. Navigate to **Pharmacopeia > Microplate Uniformity Results**.
3. Select the assay you just ran.
4. Click **Print**.
5. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.

1:1 Ratio Verification

The 1:1 Ratio Verification test (Figure 5-10) verifies that Eclipse is able to distribute and mix samples and lysate reagent in a 1:1 ratio.

Pharmacopeia
1:1 Ratio Verification Test

Assay Details **Samples** **Sample Details** **Accessories**

Assay Settings
Assay Name
1:1 Ratio Verification Test

Microplate
Serial Number
Lot Number
Expiration

Next >

S S S S S NC 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Figure 5-10: 1:1 Ratio Verification Screen

Required Materials

- The **1:1 Ratio Verification Test** requires the following materials:
- Eclipse 1:1 Ratio Kit (STD 85000-XX), which contains 1 vial of 1:1 Ratio Verification Sample (dye) and 1 vial of reagent water.
 - One new Eclipse Microplate
 - Pipette and pipette tips capable of delivering 55 µL and 1mL volumes.

Acceptance Criteria

- Ratio Result: 1.9 to 2.1

Procedure

1. Navigate to **Pharmacopeia > 1:1 Ratio Verification Test**.
2. Complete the ***Microplate*** section:
 - Serial Number
 - Lot Number
 - Expiration
3. Click **Next**.
4. Enter the Water Sample ID, Lot Number, and Expiration for Segments 1–13.
5. Enter the 1:1 Ratio Verification Sample ID (dye), Lot Number, and Expiration for Segments 14–21.



NOTE: Segments 22–26 will also hold 1:1 Ratio Verification Sample, but they are not part of the Samples tab.

6. Click **Next**.
7. (Optional) Enter accessory information.
8. Load a new Eclipse Microplate into the Analyzer and close the lid.
9. When prompted, inject 55 µL of water sample into Segments 1–13.
10. Inject 55 µL of the 1:1 Ratio Verification Sample (dye) into Segments 14–26.
11. Inject 1mL of 1:1 Ratio Verification Sample (dye) into the lysate port.
12. Close injection port cover.
13. Click **Start Analysis**.

Upon completion of analysis

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 5):

1. Remove the Microplate from the Analyzer.
2. Navigate to **Pharmacopeia** → **1:1 Ratio Results**.
3. Select the assay you just ran.
4. Click **Print**.
5. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.

Lysate Qualification

The **Lysate Qualification Test** (Figure 5-11) assures that the current lot of lysate reagent to be used, when mixed with the LRW solution in an Eclipse assay, meets the regulatory requirements for linearity. Per USP Chapter 85, lysate qualification must be performed for each lot of lysate reagent.

Figure 5-11: Lysate Qualification Test Screen

Required Materials:

- ~300 µL LRW
- 1 mL lysate reagent
- 1 new Eclipse Microplate
- Pipette and pipette tips capable of delivering 55 µL and 1 mL volumes.

Acceptance Criteria

For each of the standards segments:

- Correlation Coefficient $|r| \geq 0.980$
- Negative Control Onset Time > LLOQ Onset Time
- %CV of standards, if applicable based on global settings



Procedure

1. Log in as a qualified analyst with permission to Validate Products and Start Assays.
2. Navigate to **Pharmacopeia > Lysate Qualification Test**.
3. Complete the **Lot Number** and **Expiration** fields in the **Lysate Reagent**, **Lysate Reconstitution Solution**, and **Microplate** sections, as well as the **Microplate Serial Number**.
4. Click **Next**.
5. (Optional) Add any accessories you want to include in the test. See [“Step 3: Create Accessories” on page 37](#) for more information.
6. Click **Start Assay**.
7. Follow the on-screen instructions to inject 55 uL of LRW into Segments 22–26.
8. Inject 1 mL of lysate reagent into the lysate port.
9. Close the injection port cover.
10. Click **Start Analysis**.

Upon completion of analysis

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 5):

1. Remove the Microplate from the Analyzer.
2. Navigate to **Pharmacopeia > Lysate Qualification Results**.
3. Select the assay you just ran.
4. Click **Print**.
5. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.

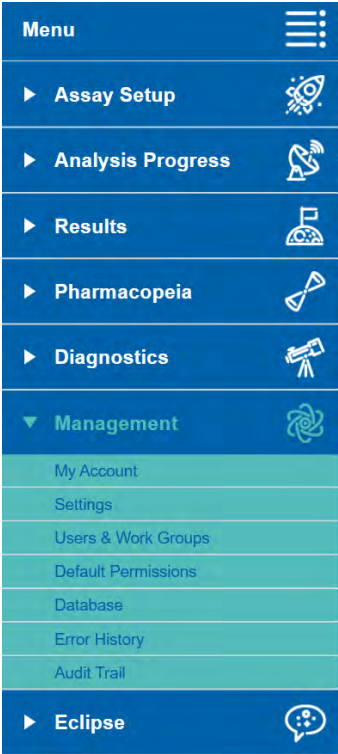
CHAPTER 6: MANAGEMENT

This chapter provides instructions for administering the Eclipse platform. It covers user accounts and permissions, system settings, database backup and restoration, error histories, and audit trail information.

The Management Menu

Use the following selections from the Management menu to administer Eclipse settings and user accounts:

- My Account.** Work with the logged-in user’s password, signature, permissions, and other information.
- Settings.** Modify preferences, system defaults, lysate optical density thresholds and standard curves, and 21 CFR Part 11 settings.
- Users & Work Groups.** View a list of your organization’s Eclipse users and work groups, and (with administrator-level permissions) modify them.
- Default Permissions.** (Administrators only) Assign customized permission sets to each user as needed.
- Database.** Back up, restore, or archive the Eclipse database.
- Error History.** All Eclipse errors displayed in a filterable list, ready to be acknowledged by user with the Acknowledge Errors permission.
- Audit Trail.** The entire history of Eclipse usage within the organization, with each action timestamped and associated with the user that performed the action.



a

My Account

The My Account screen contains the current user's:

- Password
- Signature and Signature Image
- Name, Role, and Work Groups
- Permissions

Changing Your Password

To change your Eclipse password:

1. Navigate to **Management > My Account > Account Settings** tab (Figure 6-1).
2. Enter your current password in the **Password** field.
3. Complete the **New Password** and **Confirm Password** fields, making sure to choose a password that adheres to the established password rules within the current Work Group:
 - Is at least 8 characters long
 - Includes at least 1 uppercase and 1 lowercase letter
 - Includes at least 1 number
 - Is not one of your previous 3 passwords (see [“Password Rules” on page 93](#)).
4. Click **Accept**.

Figure 6-1: Account Settings Tab

User Information

Navigate to **Management > My Account > User Information** tab (Figure 6-2) to see the user's name, role, and Work Groups (Main and Secondary).

Figure 6-2: User Information Tab

Settings

The Settings menu contains three tabs to modify Preferences, System Defaults, Lysate, and 21 CFR Part 11 compliance settings.

Preferences

The **Preferences** tab (Figure 6-3) lets you specify regional settings such as language (English, Chinese, Japanese, Korean) and time/date format, reporting options, and assay result display options. Which settings are visible to the user depends on their permissions.

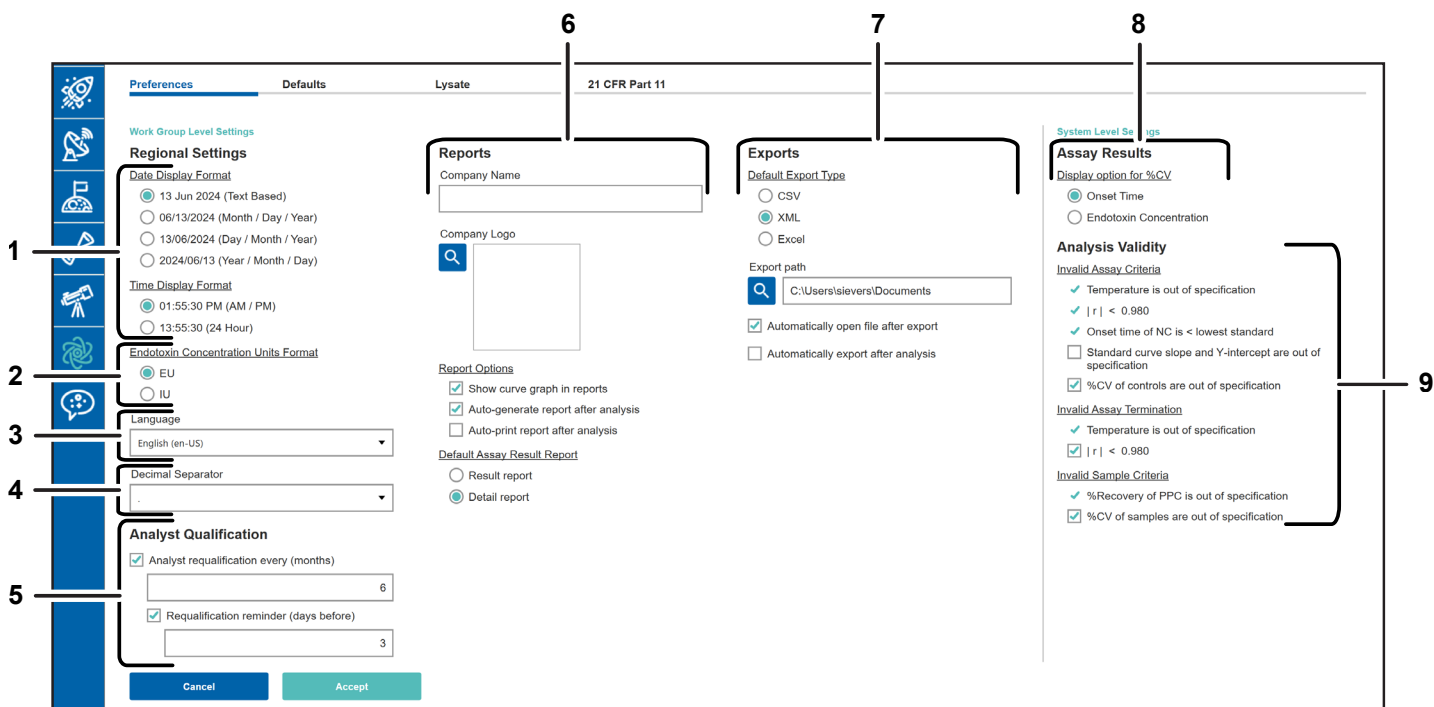


Figure 6-3: Settings—Preferences Tab

1 - Date and Time Display Format	2 - Endotoxin Concentration Units Format	3 - Language
4 - Decimal Separator	5 - Analyst Qualification	6 - Reports
7 - Exports	8 - Assay Results	9 - Analysis Validity

Work Group Level Settings

These settings apply to all users within a Work Group.

 **NOTE:** Click Accept to confirm your changes.

Regional Settings

Date and Time Display Format

To select a date and time format for your Work Group, navigate to **Management > Settings > Preferences** tab, then select the appropriate formats from the available options (Figure 6-4).

Endotoxin Concentration Units Format

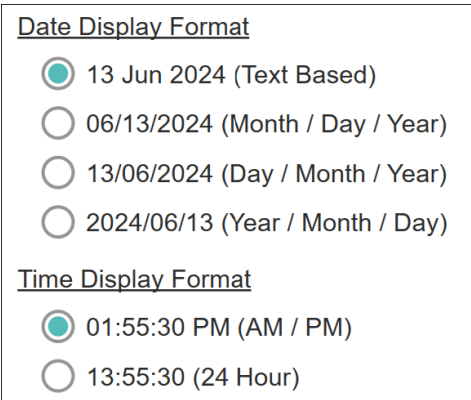
Choose whether endotoxin concentration is displayed as EU or IU (Figure 6-5).

Language

Use the dropdown list to choose the language of the Eclipse software user interface (Figure 6-6).

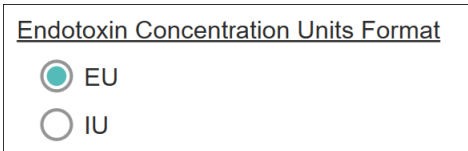
Decimal Separator

Use the dropdown list to choose between a comma or a period (Figure 6-7).



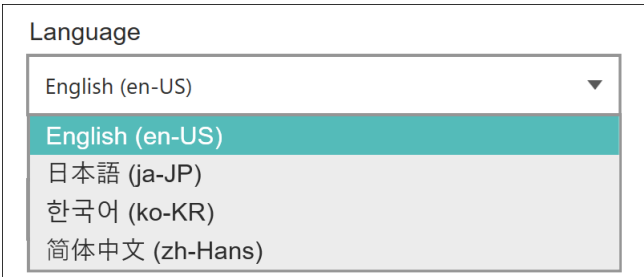
The screenshot shows two sections: 'Date Display Format' and 'Time Display Format'. Under 'Date Display Format', there are four radio button options: '13 Jun 2024 (Text Based)' (selected), '06/13/2024 (Month / Day / Year)', '13/06/2024 (Day / Month / Year)', and '2024/06/13 (Year / Month / Day)'. Under 'Time Display Format', there are two radio button options: '01:55:30 PM (AM / PM)' (selected) and '13:55:30 (24 Hour)'.

Figure 6-4: Date and Time Display Format



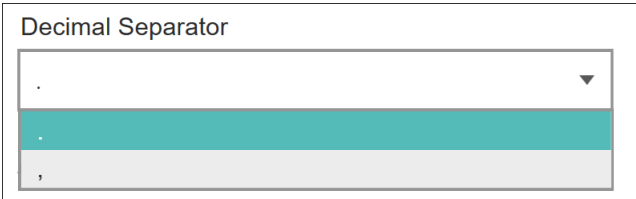
The screenshot shows the 'Endotoxin Concentration Units Format' section with two radio button options: 'EU' (selected) and 'IU'.

Figure 6-5: Endotoxin Concentration Units Format



The screenshot shows the 'Language' dropdown menu. The current selection is 'English (en-US)'. The dropdown list is open, showing the following options: 'English (en-US)' (highlighted), '日本語 (ja-JP)', '한국어 (ko-KR)', and '简体中文 (zh-Hans)'.

Figure 6-6: Language



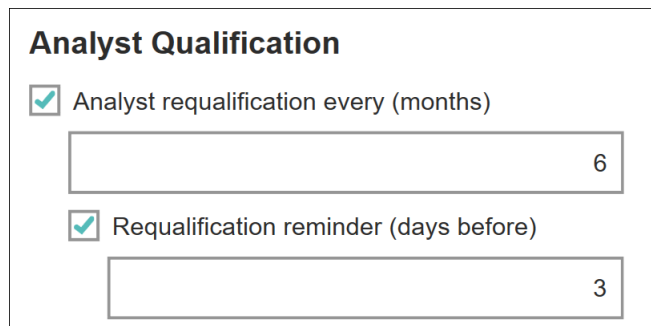
The screenshot shows the 'Decimal Separator' dropdown menu. The current selection is a period '.'. The dropdown list is open, showing the following options: '.' (highlighted), ',', and ' '.

Figure 6-7: Decimal Separator

Analyst Qualification

Set an interval for required analyst requalification, and set the number of days for the requalification reminder that the analyst will see (Figure 6-8).

1. Navigate to **Management > Settings > Preferences** tab.
2. Put a check mark in the box next to Analyst requalification every (months).
3. Enter the number of months between analyst requalifications.
4. Enter the number of days before requalification that you want to send a reminder to the analyst (or, un-check the **Requalification reminder** box if you don't want to send a reminder).



Analyst Qualification

☒ Analyst requalification every (months)

6

☒ Requalification reminder (days before)

3

Figure 6-8: Analyst Qualification

Reports

You can customize your Eclipse reports with your company's name and logo, change the kind of report that is generated by default, or change other report preferences by navigating to **Management > Settings > Preferences** tab (Figure 6-9).

Company Name and Logo

To enter your company's name and logo for display on Eclipse reports:

1. Enter a name in the **Company Name** field.
2. Click the magnifying glass icon to browse your PC for a company logo or other image.
3. Drag the borders of the image so that the logo is visible and click **Accept**.

The name and logo will now display on all Eclipse reports:

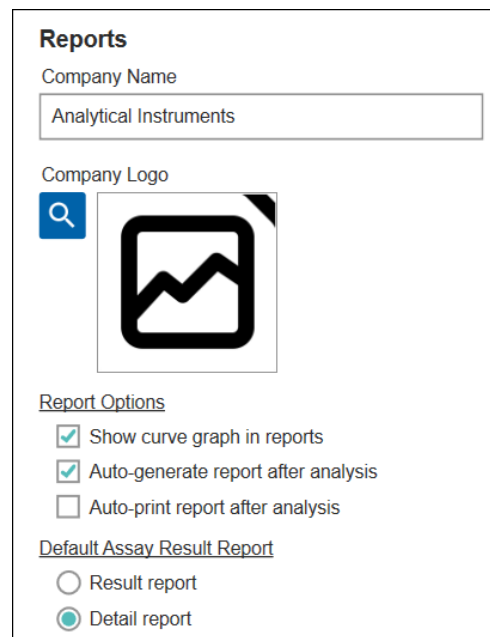
Report Options

Choose whether to:

- Show curve graph in reports
- Auto-generate report after analysis
- Auto-print report after analysis

Default Assay Result Report

Choose a default assay report type—Result or Detail.



Reports

Company Name

Analytical Instruments

Company Logo

Report Options

☒ Show curve graph in reports

☒ Auto-generate report after analysis

☐ Auto-print report after analysis

Default Assay Result Report

☐ Result report

☒ Detail report

Figure 6-9: Reports Settings

Exports

Default Export Type

To choose which default file type and location to export Eclipse assay, user, and other data to:

1. Navigate to **Management > Settings > Preferences** tab.
2. Under the **Exports** section (Figure 6-10), choose the file type from the **Default Export Type** list by clicking the button to the left of your chosen file type (CSV, XML, or Excel).
3. Browse for a destination path by clicking the magnifying glass icon, or type the location in the **Export path** field.
4. Click the check boxes under the **Export path** field to choose whether to automatically open the file after export and/or export after analysis.

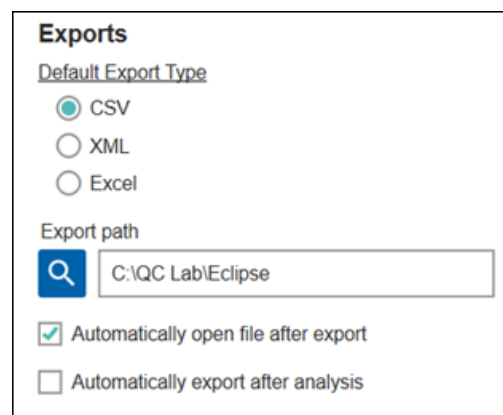


Figure 6-10: Export Settings

System Level Settings

Assay Results

Choose an option for %CV calculation (Figure 6-11):

- Onset Time
- Endotoxin Concentration

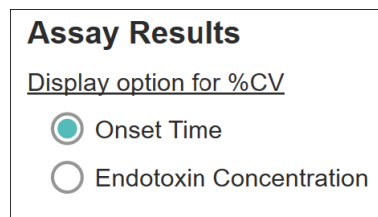


Figure 6-11: Assay Results

Analysis Validity

Define the criteria for the validity of assays and product samples, as well as termination criteria (Figure 6-12). Red text = not user-configurable.

Invalid Assay Criteria

- Temperature is out of specification (36–38 °C)
- $|r| < 0.980$
- Onset time of NC is < lowest standard
- Standard curve slope and Y-intercept are out of customer-defined range
- %CV of controls are out of customer-defined specification

Invalid Termination

- Temperature is out of specification (36–38 °C)
- $|r| < 0.980$
- Onset time of NC is < lowest standard

Invalid Sample Criteria

- %Recovery of PPC is out of specification (50–200%)
- Endotoxin concentration exceeds the release limit (ERL must be set up and saved to each product within the Products & Accessories library)
- %CV of controls are out of specification

Analysis Validity

Invalid Assay Criteria

- ✓ Temperature is out of specification
- ✓ $|r| < 0.980$
- ✓ Onset time of NC is < lowest standard
- ☐ Standard curve slope and Y-intercept are out of specification
- ☒ %CV of controls are out of specification

Invalid Assay Termination

- ✓ Temperature is out of specification
- ☒ $|r| < 0.980$

Invalid Sample Criteria

- ✓ %Recovery of PPC is out of specification
- ☒ %CV of samples are out of specification

Figure 6-12: Analysis Validity

Defaults

You must have permission to Edit Defaults to see the **Defaults** tab and permission for each type of default (e.g., User, Product) to see that group of settings. Figure 6-13 shows the **Management > Settings > Defaults** tab screen when all Edit Default permissions are active.

The screenshot displays the 'Management Settings' window with the 'Defaults' tab selected. The interface is organized into three numbered sections: 1. New Users, 2. Products/Accessories, and 3. Assays. Section 1 shows a 'User Role' dropdown set to 'Analyst'. Section 2 includes fields for 'Sample Type', 'Manufacturer', 'Lot count required for production validation' (set to 3), and 'Accessories' (Type: 'Pipette', Manufacturer: empty). Section 3 includes 'Lysate Reagent' (Chromo-LAL), 'Lysate Reconstitution Solution' (LAL Reagent Water), 'PPC % Recovery Limits (%)' (50.0 to 200.0), '%Onset time range for NC (%)' (1.0), '%CV limits on Onset Time (%)' (15.0), '%CV limits on Endotoxin (%)' (30.0), 'Maximum assay length (seconds)' (7200), and an 'Auto-End Assay' checkbox. The top navigation bar shows 'Preferences', 'Defaults' (selected), and 'Lysate'. The bottom has 'Cancel' and 'Accept' buttons.

Figure 6-13: Settings—Defaults Tab

1 - New Users	2 - Products/Accessories	3 - Assays
-------------------------------	--	----------------------------

New Users

To choose a default New User Role for new Eclipse users:

- 1. Choose a role from the **User Role** list (Figure 6-14).
- 2. Click **Accept** to save your changes.

New Users

User Role

Analyst

Analyst

Supervisor

Administrator

Figure 6-14: Default New User Role

Products

(Optional) To choose a default Sample Type for product samples:

- 1. Choose a Sample Type from the list (Figure 6-15).
- 2. Enter the Manufacturer name and the Lot count required for production validation. See [“Product Validation” on page 70](#) for more information.
- 3. Click **Accept** to save your changes.

Accessories

To choose a default Accessory type:

- 1. Choose a type from the list (Figure 6-15).
- 2. Enter the name of the Accessory manufacturer.
- 3. Click **Accept** to save your changes.

Products

Sample Type

Manufacturer

Lot count required for production validation

3

Accessories

Type

Pipette

Manufacturer

Figure 6-15: Default Products and Accessories

Assays

Eclipse gives you the ability to set defaults for several assay criteria, from Lysate Reagent and Lysate Reconstitution Solution types to maximum assay length, %CV and PPC Recovery Limits, and more. When you have entered your preferred default assay settings, click **Accept** to save them.

Assays

Lysate Reagent

Chromo-LAL

Lysate Reconstitution Solution

LAL Reagent Water

PPC % Recovery Limits (%)

50.0

200.0

%Onset time range for NC (%)

1.0

%CV limits on Onset Time (%)

15.0

%CV limits on Endotoxin (%)

30.0

Maximum assay length (seconds)

7200

☐ Auto-End Assay

Slope Range

-0.30

-0.15

Y-Intercept Range

2.70

3.30

Figure 6-16: Assay Defaults

Lysate Settings

In the **Management > Settings > Lysate** tab (Figure 6-17), the Optical Density Threshold is set according to the manufacturer's instructions for use and calculated for equivalency on the Eclipse Microplate. These fields are editable, but please contact your Veolia representative prior to making any changes. More information is available through technical support and published technical reports.

- You can also choose a default Standard Curve for each lysate brand.
- All Lysate settings are System Level Settings.
- When you have entered your preferred Lysate settings, click **Accept** to save them.

Management Settings				
Preferences Defaults Lysate 21 CFR Part 11				
System Level Settings				
Lysate	Optical Density Threshold	Eclipse Platform Equivalence Threshold	Standard Curve	
Chromo-LAL	0.030	0.01296	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
Endochrome-K™	0.100	0.0432	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
Kinetic-QCL™	0.200	0.08641	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
rCR	0.030	0.01296	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
TAL	0.100	0.0432	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
Wako Turbidimetric	0.015	0.00648	5.0, 0.5, 0.05 EU/mL ▼	
Other Lysate 1	0.100	0.0432	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	
Other Lysate 2	0.100	0.0432	50.0, 5.0, 0.5, 0.05, 0.005 EU/mL ▼	

Figure 6-17: Settings—Lysate Tab

21 CFR Part 11 Settings

The **Management > Settings > 21 CFR Part 11** tab (Figure 6-18) contains security features that ensure your Eclipse platform’s account protection and password policies comply with the regulations set forth in 21 CFR Part 11. You must have Edit 21 CFR Part 11 permissions to view or modify the settings on this screen.

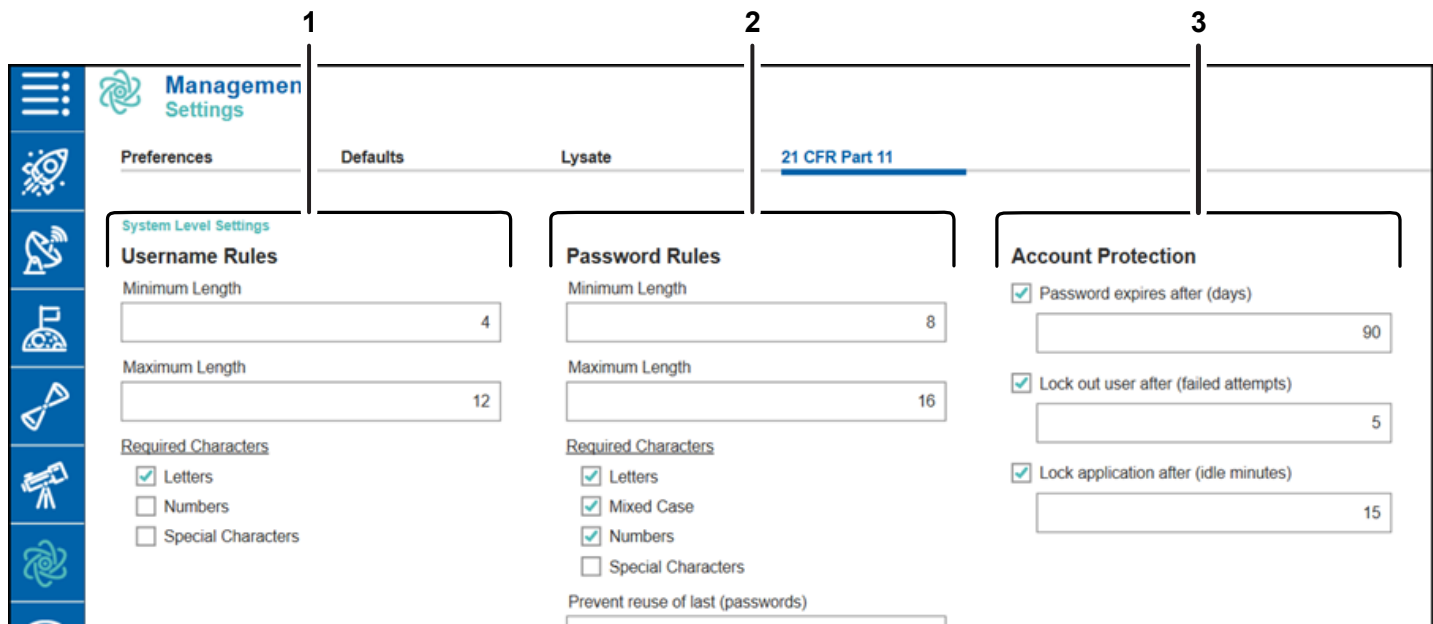


Figure 6-18: Settings—21 CFR Part 11 Tab

1 - Username Rules	2 - Password Rules	3 - Account Protection
------------------------------------	------------------------------------	--

Username Rules

To set the rules for Eclipse usernames:

- 1. Navigate to **Management > Settings > 21 CFR Part 11** tab (Figure 6-19).
- 2. Enter the Minimum Length and Maximum Length for your organization's Eclipse usernames, and put a check mark in the box next to any required character types.
- 3. Click **Accept** to save your changes.

Username Rules

Minimum Length

4

Maximum Length

12

Required Characters

☒ Letters

☐ Numbers

☐ Special Characters

Figure 6-19: Username Rules

Password Rules

To set the rules for Eclipse passwords:

- 1. Navigate to **Management > Settings > 21 CFR Part 11** tab (Figure 6-20).
- 2. Enter the Minimum Length and Maximum Length for your organization's Eclipse passwords, and put a check mark in the box next to any required character types.
- 3. Enter a value in the **Prevent reuse of last (passwords)** field to control the number of unique passwords that must be chosen before the system allows password reuse.
- 4. Click **Accept** to save your changes.

Password Rules

Minimum Length

8

Maximum Length

16

Required Characters

☒ Letters

☒ Mixed Case

☒ Numbers

☐ Special Characters

Prevent reuse of last (passwords)

3

Figure 6-20: Password Rules

Account Protection

The Account Protection section (Figure 6-21) lets you set values for:

- How many days before passwords expire
- How many failed login attempts before locking out the user
- How much idle time before the Eclipse program locks

Click **Accept** to save your changes.

Account Protection

☒ Password expires after (days)

90

☒ Lock out user after (failed attempts)

3

☒ Lock application after (idle minutes)

5

Figure 6-21: Account Protection

Users & Work Groups

Navigate to **Management > Users & Work Groups** to see a list of your organization's Eclipse users and Work Groups.

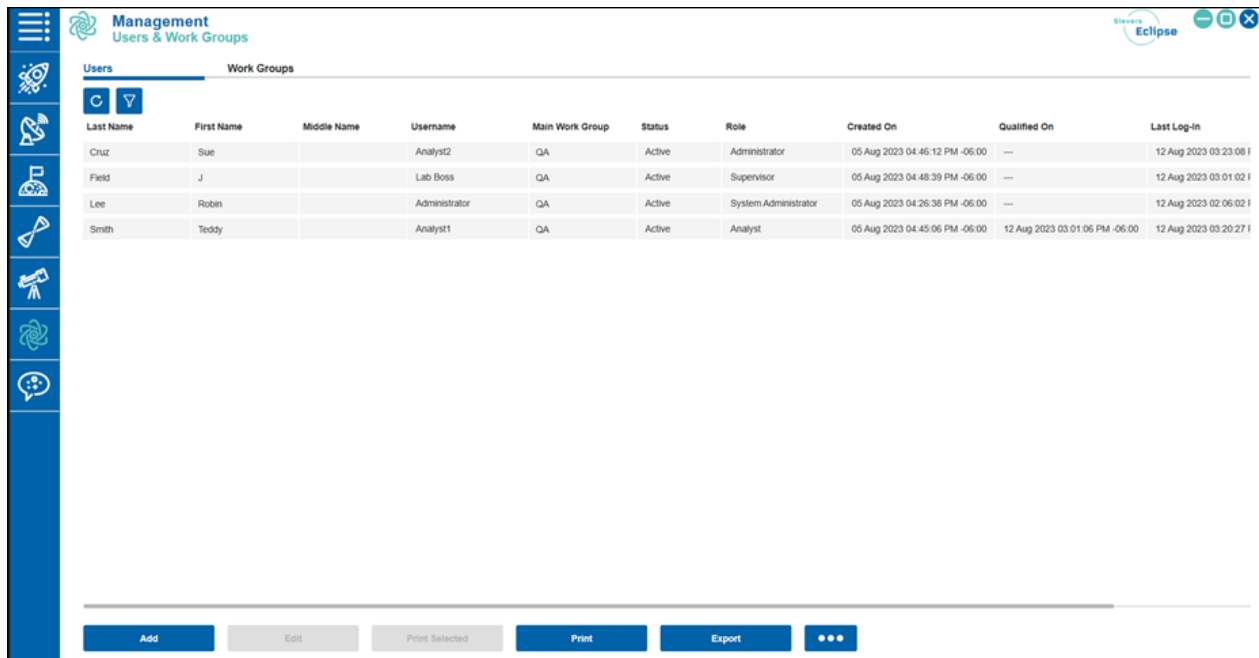
When you first set up the Eclipse platform, you created a System Administrator login to set the initial default Work Groups, user roles, and permissions. You should have also created an Administrator whose ongoing role is to manage these users, permissions, and other functions. See "Create an Administrator Profile" on page 53 for more information. Administrator-level access is required to change (or even see) most user and permission settings.

Managing Users and Work Groups

Managing Users

From the **Management > Users & Work Groups** screen (Figure 6-22), an Eclipse user with administrator-level permissions can:

- Sort users by name, status, and other criteria
- Add or Edit users
- Print or export the user list
- Reset passwords and deactivate users



Last Name	First Name	Middle Name	Username	Main Work Group	Status	Role	Created On	Qualified On	Last Log-in
Cruz	Sue		Analyst2	QA	Active	Administrator	05 Aug 2023 04:46:12 PM -06:00	—	12 Aug 2023 03:23:08 f
Field	J		Lab Boss	QA	Active	Supervisor	05 Aug 2023 04:48:39 PM -06:00	—	12 Aug 2023 03:01:02 f
Lee	Robin		Administrator	QA	Active	System Administrator	05 Aug 2023 04:26:38 PM -06:00	—	12 Aug 2023 02:06:02 f
Smith	Teddy		Analyst1	QA	Active	Analyst	05 Aug 2023 04:45:06 PM -06:00	12 Aug 2023 03:01:06 PM -06:00	12 Aug 2023 03:20:27 f

Figure 6-22: Management—Users & Work Groups

Sort the User List

1. Navigate to **Management > Users & Work Groups > Users** tab.
2. Click the **Add Filter** icon at the upper left of the user list.
3. Choose a sort criteria from the list that appears (Figure 6-23).
4. On the window that appears, click the lists to select a Filter and Value for the criteria, then click **Accept** to sort the list. Figure 6-24 shows the filter set for analysts qualified before October 4, 2022.

The filtered, sorted list of users (Figure 6-25) is ready to print or export, or you can further sort the list by repeating steps 1–4.

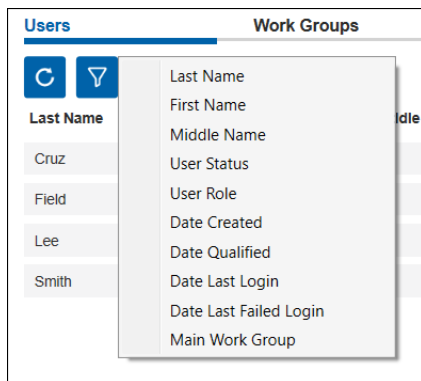


Figure 6-23: Sort Criteria

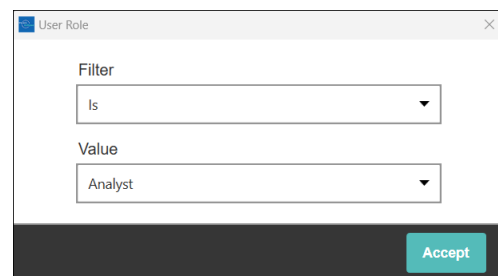


Figure 6-24: Filter Setting

Last Name	First Name	Middle Name	Username	Main Work Group	Status	Role	Created On
Smith	Teddy		Analyst1	QA	Active	Analyst	06 Aug 2023 04:45:06 PM -06:00

Figure 6-25: Filtered User List

Print the User List

1. Navigate to **Management > Users & Work Groups > Users** tab.
2. See **Sort the User List** if you want to sort or filter the user list.
3. Click **Print** to print the current list to a local or networked printer or a PDF. If you want to print only selected users, click them in the list (Ctrl-click to select multiple users), then click **Print Selected**.
4. On the Print Preview that appears, click **Print**, then select **Send to Printer** or **Save to PDF**.

Export the User List

1. Navigate to **Management > Users & Work Groups > Users** tab.
2. See **Sort the User List** if you want to sort or filter the user list.
3. Click **Export**.
4. In the **Export File Type** window that appears, select a file type (Excel, CSV, XML) from the list, then click **Accept**.
5. Choose a filename and location, then click **Save**.

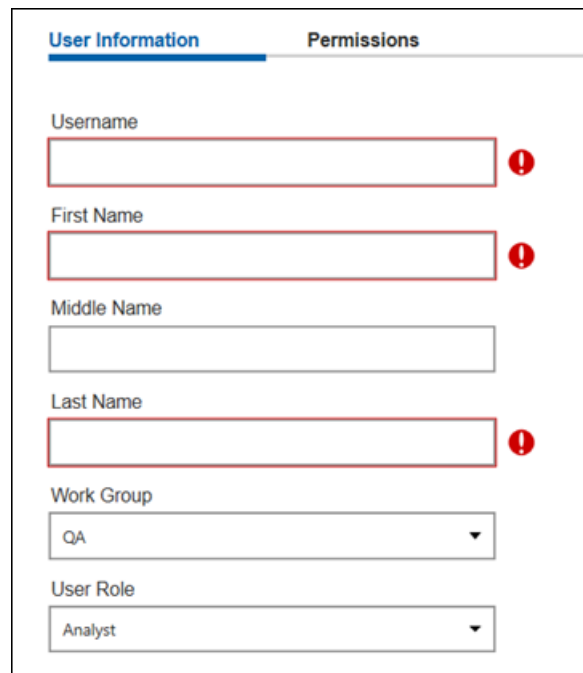
Managing User Profiles

This section details the options available for user management:

- Creating, editing, activating, and deactivating user profiles
- Resetting passwords and signature images
- Editing user default settings
- Implementing account protection and username/password rules

Creating new user profiles

1. Navigate to **Management > Users & Work Groups > Users** tab.
2. Click **Add**.
3. On the **New User** screen, the **User Information** tab appears by default (Figure 6-26). On this screen, fill in the **Username**, **First Name**, and **Last Name** fields (required).
4. Select a primary Work Group from the list. If the user will belong to any additional Work Groups, select them from the **Secondary Work Groups** list.
5. Select a User Role from the list.
6. (Optional) The new user has the default permissions for their User Role. To add or remove individual permissions from the new user, click the **Permissions** tab, then click the check box next to each permission that you want to add or remove.
7. Carefully review the information on both tabs of the **New User** screen and click **Accept** to create the new user.



User Information	Permissions
Username	
First Name	
Middle Name	
Last Name	
Work Group	
User Role	

Figure 6-26: Create New User

Editing user profiles

1. Navigate to **Management > Users & Work Groups > Users** tab.
2. Select a user to edit from the list.
3. Click **Edit**.

User Information

The **User Information** tab (Figure 6-27) lets you edit the user's Work Groups, User Role, and User Status.

Editing Work Groups

To change the user's primary Work Group, choose an option from the Work Group list.

To change the user's Secondary Work Group(s), click the check box next to the name of the Work Group to be added or removed for that user.

Selecting a User Role

Select a role from the **User Role** list. When you change the User Role, the default permissions for that role will be applied to the user. Any previous customized permissions will be lost, however, you can apply custom permissions from the **Permissions** tab.

Changing User Status

Eclipse User Status determines whether a user is Active, Inactive, or Locked. To change User Status, select an option from the **User Status** list.

Figure 6-27: Edit User Information

Changing User Permissions

The Eclipse platform allows access to features and system settings based on permissions. Each User Role has an associated set of default permissions (see [“Default Permissions” on page 105](#)). However, you can also set individual permissions for each user. See [“Changing Individual User Permissions” on page 106](#) for instructions.

Qualifying Analysts

Before running assays, analysts must be qualified on the Eclipse platform. See [“Analyst Qualification” on page 85](#) for instructions.

Resetting a User Password

- 1. Log in as an Administrator or other user with permission to Reset User Password.
- 2. Navigate to **Management > Users & Work Groups > Users** tab.
- 3. Select the user whose password you want to reset.
- 4. Click the **...** button (Figure 6-28) and select **Reset Password**. The user will be prompted to create a new password upon login.

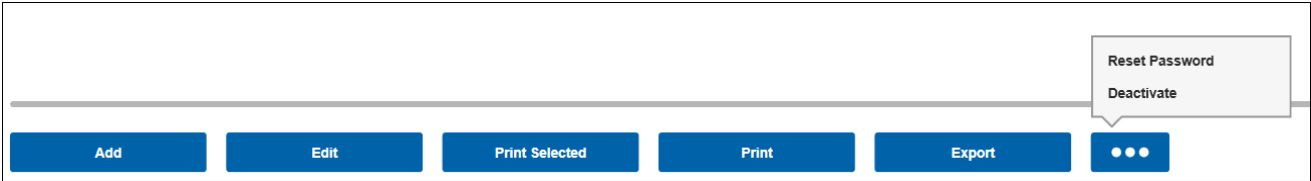


Figure 6-28: Resetting Password (... Button)

Resetting a User Signature Image

- 1. Log in as an Administrator or other user with permission to Reset User Signature Image.
- 2. Navigate to **Management > Users & Work Groups > Users**.
- 3. Select the user whose signature image you want to reset.
- 4. Click **Edit**.
- 5. Below the **User Status** setting, if the user has set an image for their signature, there will be a **Reset User Signature Image** check box (Figure 6-29). Click the box to check it.
- 6. Click **Accept** to reset the signature image.

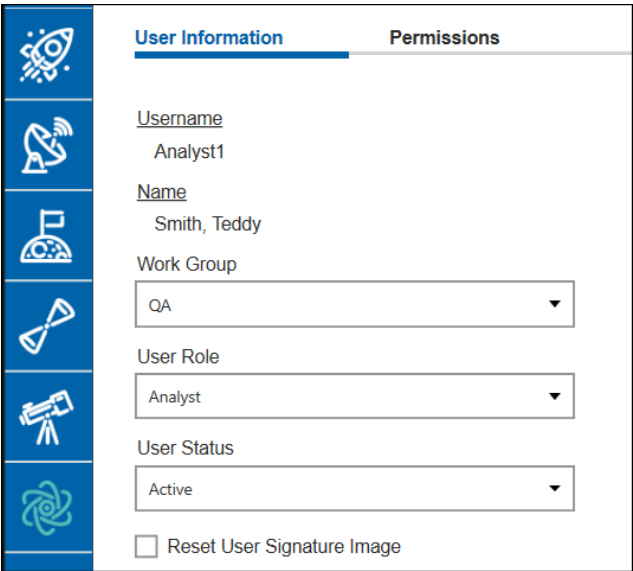


Figure 6-29: Reset User Signature Image Checkbox

Deactivating a User

1. Navigate to **Management > Users & Work Groups > Users**.
2. Select the user that you want to deactivate.
3. Click the **⋮** button and select **Deactivate**.
4. In the **Confirm Deactivate** dialog box, click **Deactivate** to complete the deactivation. The user will now appear as **Inactive** in the User List, and can neither log in nor perform any Eclipse functions.

Reactivating an Inactive User

1. Log in as an Administrator or other user with permission to Edit Users.
2. Navigate to **Management > Users & Work Groups > Users**.
3. Select the inactive user that you want to reactivate.
4. Click **Edit**.
5. In the **User Status** list, select **Active**.
6. Click **Accept** to reactivate the user. The user will now appear as **Active** in the **User List**.



NOTE: You can also use this method to deactivate a user—just select an **active** user in Step 3, and select **Inactive** in Step 5.

Locking a User

To lock a user and prevent them from logging in:

1. Log in as an Administrator or other user with permission to Edit Users.
2. Navigate to **Management > Users & Work Groups > Users**.
3. Select the user that you want to lock out.
4. Click **Next**.
5. In the **User Status** list, select **Locked**.
6. Click **Accept** to lock the user. The user will now appear as **Locked** in the **User List**. You can change their status to **Active** or **Inactive** using the method described above.

Managing Work Groups

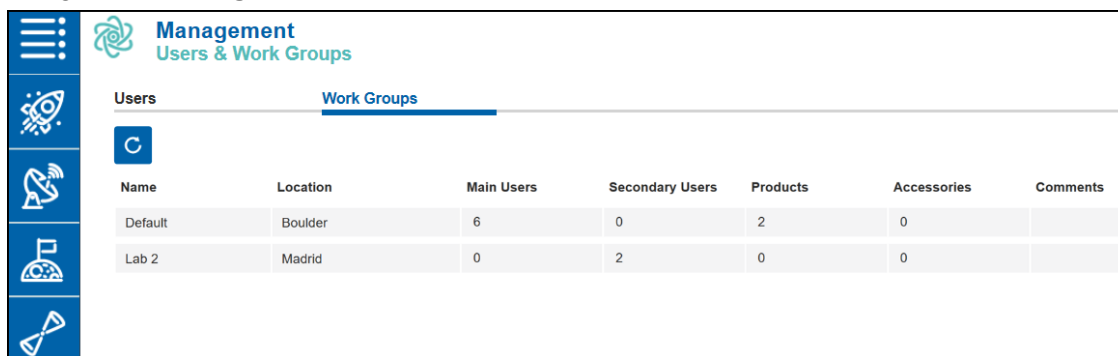
If your organization uses the Eclipse platform in multiple departments or locations, Work Groups let you organize users, product information, and assay data more efficiently.

Every Eclipse user belongs to a main Work Group (which is created during Eclipse setup—see [“Create a Default Work Group” on page 23](#)), and their Eclipse activity is limited to that Work Group. However, you can create additional Work Groups for use as main or secondary groups across the organization.

The Work Groups tab (Figure 6-30) shows a list of your organization’s Work Groups and their respective Main Users, Secondary Users, Products, and Accessories.

Creating a new Work Group

1. Log in as an Administrator or other user with permission to Edit Users and Create Work Groups.
2. Navigate to **Management > Users & Work Groups > Work Groups** tab.



Management Users & Work Groups						
Users		Work Groups				
Name	Location	Main Users	Secondary Users	Products	Accessories	Comments
Default	Boulder	6	0	2	0	
Lab 2	Madrid	0	2	0	0	

Figure 6-30: Management—Work Groups Tab

3. Click **Add**.
4. Complete the fields for **Work Group Name**, **Laboratory Location**, and **Comments** (Optional). For this example, “New York” is the new Laboratory Location (Figure 6-31)
5. Click **Accept**.
6. On the dialog box that appears (Figure 6-32), click **Create** to create the new Work Group.

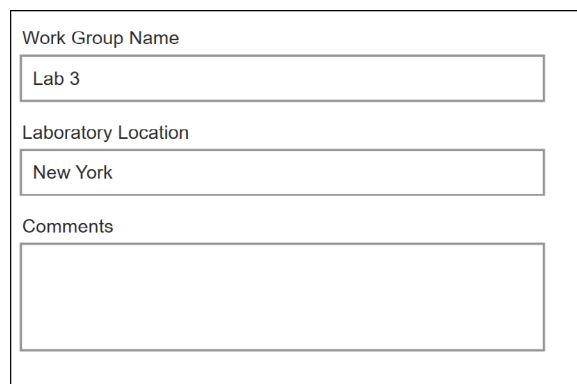


Figure 6-31: Create New Work Group

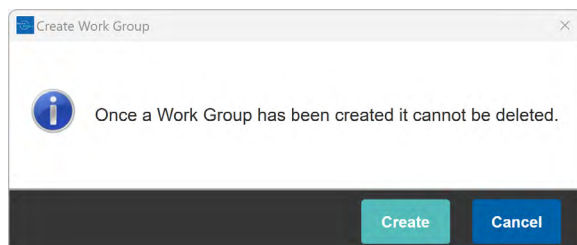
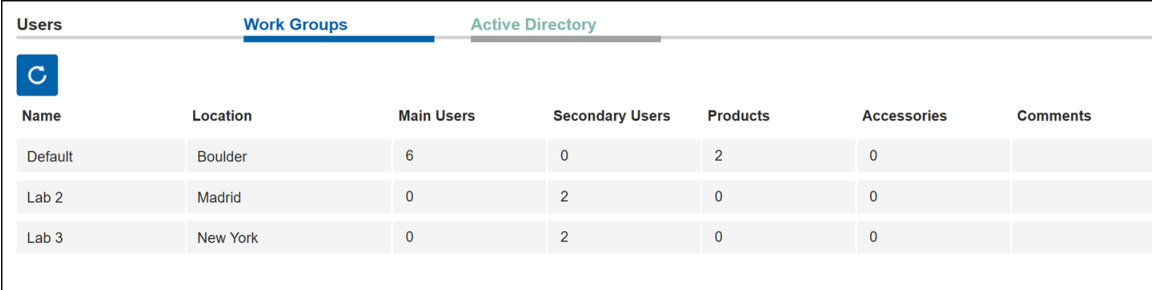


Figure 6-32: Confirm New Work Group

The new Work Group (Figure 6-33) will appear as a secondary Work Group for the user that created it. Only this user and the Global System Administrator profile will be able to see it until more users are added.



Name	Location	Main Users	Secondary Users	Products	Accessories	Comments
Default	Boulder	6	0	2	0	
Lab 2	Madrid	0	2	0	0	
Lab 3	New York	0	2	0	0	

Figure 6-33: New Work Group in List

- 7. Navigate to the **Users** tab.
- 8. Select a user to add to the Work Group and click **Edit**.

Only users in your current Work Groups are shown. The Global System Administrator must add you to other Work Groups if you want to add a user from a Work Group not currently in your profile.

- 9. On the **Edit User > User Information** tab, you can either:
 - Make the new Work Group the main group for the user by selecting it from the Work Group list

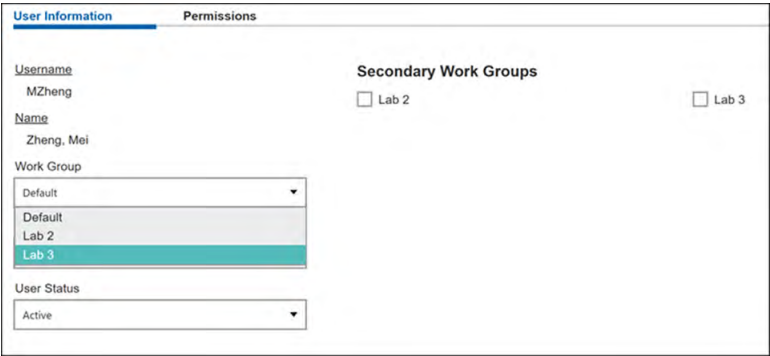


Figure 6-34: Changing Main Work Group

- Make it a secondary Work Group by selecting a different Work Group in the list as the primary one, which will automatically make the new Work Group a Secondary one. Add a check mark to the Secondary Work Group to activate it for the user.

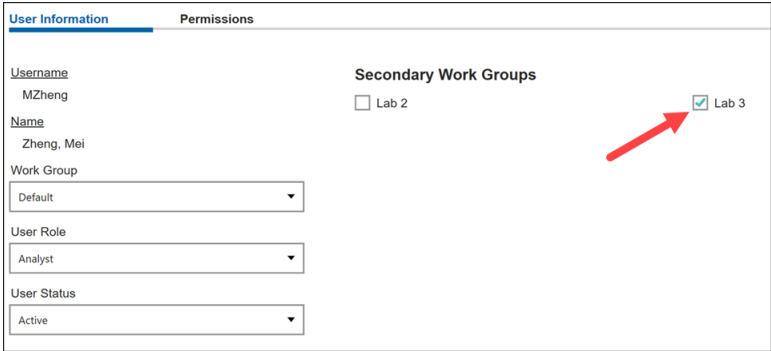
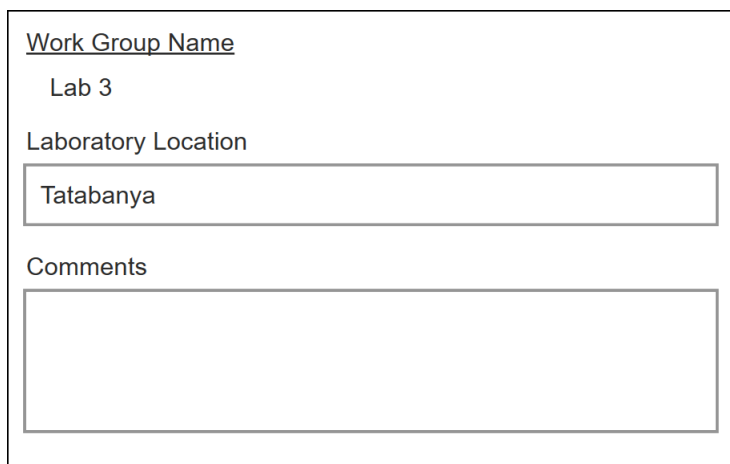


Figure 6-35: Adding Secondary Work Group

Editing an existing Work Group

1. Log in as an Administrator or other user with permission to Edit Users and Edit Work Groups.
2. Navigate to **Management > Users & Work Groups > Work Groups** tab.
3. Click **Edit**.
4. Edit the **Laboratory Location** and **Comments** fields (the Work Group Name cannot be modified). For this example, the Laboratory Location has changed from New York to Tatabanya (Figure 6-36).



The screenshot shows a form for editing a work group. It contains the following fields:

- Work Group Name:** A text field containing "Lab 3".
- Laboratory Location:** A text field containing "Tatabanya".
- Comments:** A large, empty text area.

Figure 6-36: Editing Work Group Location

5. Click **Accept**. The Work Group list should display the new information.
6. To add users to an existing Work Group, follow Steps 7–9 in [“Creating a new Work Group” on page 100](#).

If you are not planning to act as the Administrator of the new Work Group, assign this User Role to another user. See [“Step 6: Create an Administrator Profile” on page 30](#)

Permissions

Access to Eclipse functions is governed by permissions. The Analyst, Supervisor, and Administrator user roles each have their own default set of permissions with different levels of system access, but an administrator can assign customized permissions to each user, independent of their role.

Eclipse Permissions

Users:

View, Create, Edit, Deactivate, Reset User Password, Reset User Signature Image, Export, Print.

Work Groups:

View, Create, Edit, Export, Print

Sample Types:

View, Create, Edit, Delete, Export, Print

Products:

View, Create, Edit, Delete, Export, Print

Accessories:

View, Create, Edit, Delete, Export, Print

Assay Templates:

View, Save, Delete, Export, Print

Assays:

Start / End

Assay Results:

View, Export, Print

Trend Graph:

View, Print

Signatures:

Sign Approvals, Remove Signatures



Pharmacopeia:

Validate Products, Print Product Validation Report, Qualify Analysts, Print Analyst Qualification Report

Diagnostics:

Perform Diagnostics, Upgrade Analyzer Firmware, Apply Calibrations

Database:

Archive, Backup, Restore, Open Archive File, Schedule Backup, Change Datastore Archive Location

Errors:

View, Acknowledge, Export, Print

Audit Trail:

View, Review, Export, Print

Edit Preferences:

Regional Work Group Settings, Report Settings, Export Settings, Analyst Qualification Settings, Assay Results Settings

Edit Defaults:

User Default Settings, Product Default Settings, Accessory Default Settings, Assay Default Settings, Lysate Default Settings, Default Permissions

Edit 21 CFR Part 11:

Username & Password Rules, Account Protection

Default Permissions

Each of the three User Roles (Analyst, Supervisor, Administrator) has its own set of default permissions.

The list of permissions is extensive, and changes to it affect access to user settings, assay settings, products, Eclipse diagnostics, 21 CFR Part 11 rules and settings, and system-wide preferences. When assigning permissions to individual users or changing default permissions for a user role, be mindful of data integrity and regulatory concerns.

From the **Management > Default Permissions** screen (Figure 6-37), an Eclipse user with administrator-level permissions can view and change the default permission sets for each User Type.

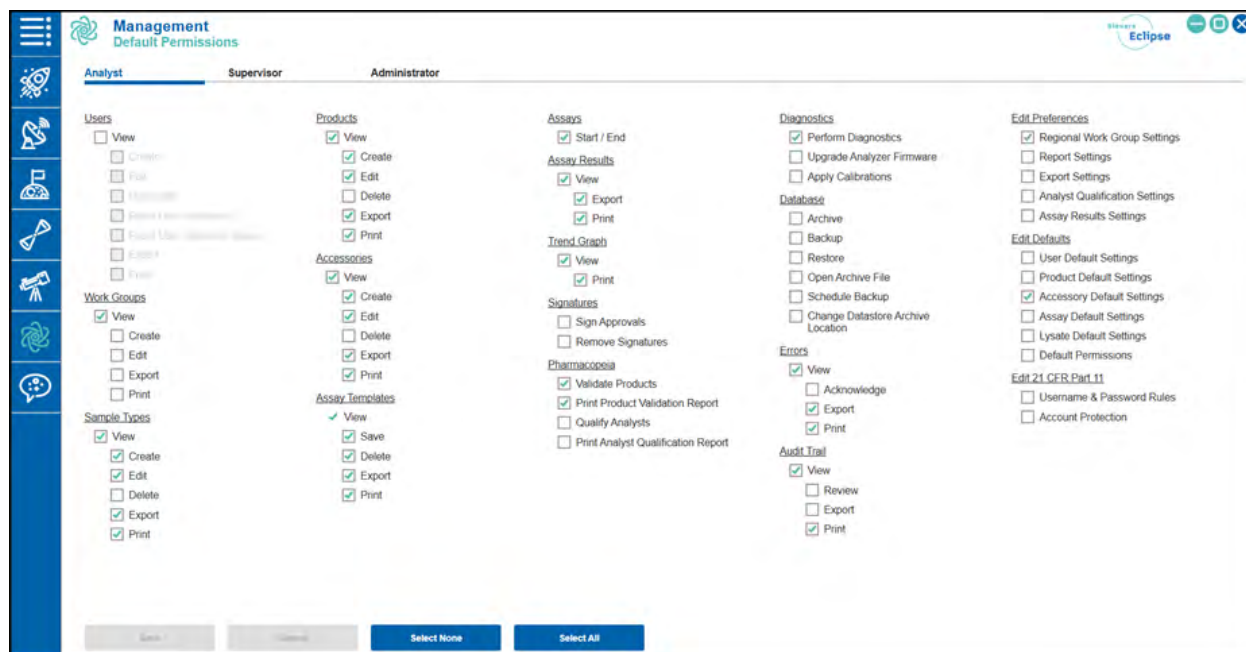


Figure 6-37: Default Permissions Screen

Analysts

Analysts can (for their Work Group) create products, sample types, and accessories; start and abort assays; view, export, and print assay results and trend graphs; perform some diagnostic and calibration activities; and view and print error logs and audit trails.

Supervisors

Supervisors have most of the same default permissions as Analysts, as well as additional permissions to view their Work Group's user list; delete products, accessories, and sample types; sign approvals and audit trails; remove signatures; acknowledge errors; edit system default settings; and qualify Analysts.

Administrators

Administrators have a default permission set that is limited to administrative functions within Eclipse—for compliance purposes, Administrators should not have access to assays, products, or other production-related functions. Rather, they should manage their Work Group's users, passwords, system defaults, and database and audit trail activities.

Changing Default Permissions

To change the default permissions for a User Role:

1. Log in as an Administrator or other user with permission: Edit Default Permissions.

2. Navigate to **Management > Default Permissions**. The three User Roles are separated by tabs at the top of the screen (Figure 6-38).

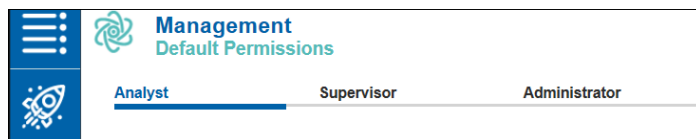


Figure 6-38: User Role Tabs

3. Click the User Role you want to assign default permissions to.
4. Click the check box next to a permission to enable or disable it.
5. The permissions you select will be available to all users who have that User Role. If you want to change a permission for an individual, see the next section.
6. Click **Save** to save the default permission set for the User Role.

Changing Individual User Permissions

To add or remove permissions for an individual user:

1. Log in as an Administrator or other user with permission to Edit Users in the Work Group of the user you want to modify.
2. Navigate to **Management > Users & Work Groups**.
3. Select the user whose permissions you will modify and click **Edit**.
4. Select the **Permissions** tab.
5. Click the check box next to a permission to enable or disable it.
6. Click **Accept** to save the permission set for the user.

Electronic Signatures

Electronic signatures are required to approve assay results, qualify analysts, and validate other activities within Eclipse.

Setting up Signatures

Each user has an electronic signature (first/last name) associated with their user profile by default. You can customize your signature text and/or add a signature image by navigating to **Management > My Account** (Figure 6-39).

To change the signature text, click in the **Signature** field, enter the text you want to use, and click **Accept**. Changing this text will not change the user profile associated with the signature.

If you want to add a visual element to your electronic signature, you can add a Signature Image.

1. Click the magnifying glass icon next to **Signature Image** and browse for the image you want to use.
2. After selecting the image, click and drag the crop box to define the visible area for the Signature Image, then click **Accept**. Figure 6-40 shows a scanned image of the user's actual signature.

Your Signature Image will now appear anywhere your signature appears in Eclipse, such as assay result reports Figure 6-41):

Figure 6-39: Signature Settings



Figure 6-40: Select Signature Image

Figure 6-41: Result with Signature Image

Signing Assay Results

To be considered complete, an assay must be signed three times, in the following order:

1. To review the result (by the analyst who ran the assay).
2. To approve the result (by a second user with appropriate permissions, except the user who ran the assay).
3. To review the audit trail report (by any user with appropriate permissions, except the user who ran the assay).

The Eclipse software automatically presents the correct signature option, and all three signatures are executed the same way in the signature dialog box.

Step 1: Review the Assay Result

You can sign an assay result either from the Print Preview of the assay report or from the **Results > Assay Results** screen. Regardless of which method you choose, it is important that you review either a paper copy or the Print Preview of the Assay Report before entering each signature.

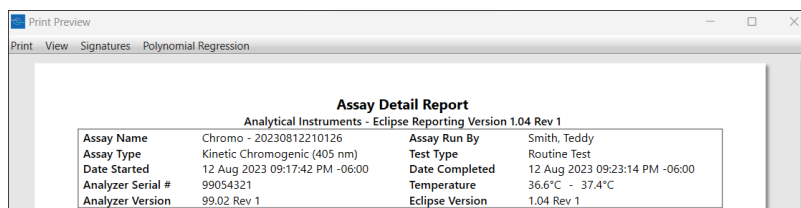


Figure 6-42: Print Preview Screen

Signing from the Print Preview

1. Click **Signatures** at the top of the Print Preview (Figure 6-42).
2. Click Review Result.
3. On the **Assay Result signature** dialog box, click **Load Signature** to continue.

The initial Review Result signature must be completed by the user who ran the assay.

4. Enter the testing analyst's username and password and click **Accept**
On the **Review Assay Result** screen, the **Sign** button is now highlighted and the user's signature image (if applicable) is populated (Figure 6-43).
5. Click **Sign** to apply the signature.

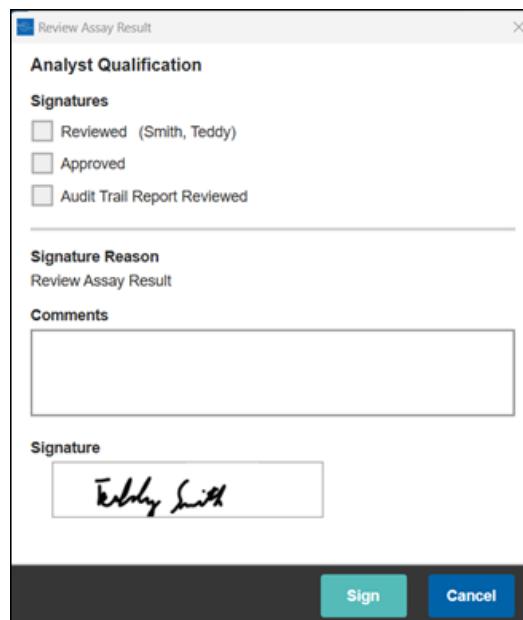


Figure 6-43: Review Assay Result Dialog Box

Step 2: Approve the assay result

After the assay result has been reviewed by the testing analyst, a second user (with Sign Approvals permission) must review the assay report and approve it.

1. After you enter the Review Result signature, click **Signatures > Approve Result** in the Print Preview (Figure 6-44).
The signature dialog box will now display a check mark next to the first signature line to show that the result has been reviewed by the tester.
2. Enter the username and password of a user who has permission to approve assay results and click **Accept**.
3. Click **Sign** to apply the signature.

Figure 6-44: Approve Assay Result Dialog Box

Step 3: Review the audit trail

1. On the Print Preview, click **Next** until you reach Related Audit Trail Entries.
2. Review the Audit Trail.
3. Click **Signatures > Review Audit Trail**.

The signature dialog box will now display a check mark next to two signature lines to show that the result has been reviewed and approved.

4. Enter the username and password of a user who has permission to Approve Assay Results and click **Accept**.
5. Click **Sign** to apply the signature.

When the assay has been completely reviewed and signed, you can view the signatures on the last page of the assay result report (Figure 6-45):

Performed/Reviewed By	Signature	Date/Time	Comment
Smith, Teddy		12 Aug 2023 10:06:50 PM -06:00	
Field, J		12 Aug 2023 10:07:50 PM -06:00	
Cruz, Sue		12 Aug 2023 10:08:16 PM -06:00	

Figure 6-45: Signed Assay Result Report

Signing from the Assay Results Screen

1. Navigate to **Results > Assay Results**.
2. Select the assay in the **Assay Results** list.
3. Click the button shown in Figure 6-46. The button will display the type of signature needed, either Review Result, Approve Result (shown below), or Review Audit Trail.

17 Aug 2022 11:51:33 AM -06:00	Valid	Instrument User Acceptance Test (CRE)	Little, Anne	Eclipse QC Team
17 Aug 2022 11:51:28 AM -06:00	Valid	Instrument User Acceptance Test (CRE)	Little, Anne	Eclipse QC Team
11 Aug 2022 11:30:21 AM -06:00	Valid	Instrument User Acceptance Test (CRE)	Little, Anne	Eclipse QC Team
11 Aug 2022 11:30:17 AM -06:00	Valid	Instrument User Acceptance Test (CRE)	Little, Anne	Eclipse QC Team
29 Jul 2022 09:26:01 AM -06:00	Valid	Eclipse Microfluidic Solution	Little, Anne	Eclipse QC Team


Print
Export
Review Result
Remove Signatures
Load Filters
⋮

Figure 6-46: “Review Result” Signature Button

Clicking this button performs the same function as clicking **Signatures > (Review/Approve/Review)** on the Print Preview—it simply opens the signature dialog box.

When you sign the assay result, you are certifying that you have reviewed it. Before you access the signature dialog box from the **Results > Assay Results** screen, review the results, either in the Print Preview or from a paper copy.

Removing Signatures

To remove signatures from an assay result:

1. Navigate to **Results > Assay Results**.
2. Select the assay that you will be removing signatures from.
3. Click **Remove Signatures**.
4. On the **Remove Assay Result Signatures** dialog box, click **Load Signature**.
5. Enter the username and password of a user with permission to remove signatures and click **Accept**.
6. Click **Remove**. The signatures will be removed from the assay and the audit trail will record this change. When you select the assay on the **Results > Assay Results** screen, the **Review Result** option will be available. If you want to sign the assay again, repeat the steps outlined at the beginning of [“Electronic Signatures” on page 107](#).

Database

The Database screen (Figure 6-47) lets you immediately back up or schedule a future backup for the Eclipse database, restore a previous version of the database, or archive the database.

The difference between Backup and Archive is important. When you back up the Eclipse database, you are simply creating a copy of the database that can be restored in the event of a catastrophic event. When you create an archive, Eclipse removes the sample data and audit trail information and places **ONLY** that data into a separate file. This improves the performance of the working database while maintaining a record of all Eclipse assay data. For more information about archives, see [“Archive a Database” on page 113](#).

The screenshot displays the 'Management Database' interface. On the left is a vertical navigation bar with icons for various functions. The main area is divided into three sections: 'Backup', 'Restore', and 'Archive'. The 'Backup' section includes a 'Last Backup' link, an 'Auto Backup Enabled' checkbox, an 'Initial Start Date' field (12 Aug 2023 -06:00), a 'Start Time' field (12:00 AM), a 'Frequency (days)' field (7), and a 'Storage Path' field (C:\ProgramData). The 'Restore' section has a 'Last Restore' link. The 'Archive' section has a 'Last Archive' link and a 'Data Store Location' field (C:\ProgramData\Sievers\Sievers Eclipse\De). At the bottom are buttons for 'Backup...', 'Restore...', 'Archive...', 'Cancel', and 'Accept'.

Figure 6-47: Management—Database

Perform a Backup

To perform a backup of the Eclipse database:

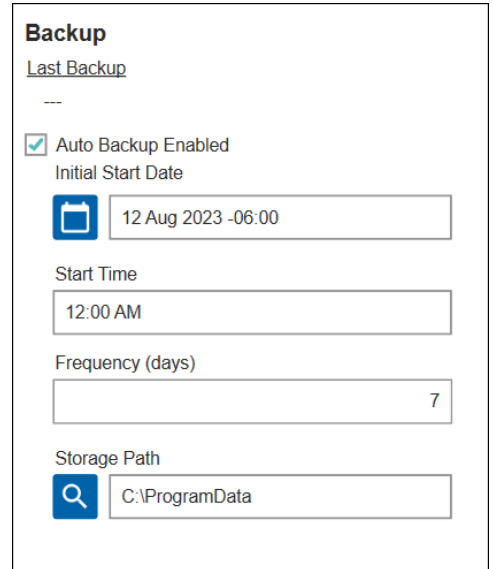
1. Navigate to **Management > Database**.
2. Click **Backup....**
3. Choose a location for the backup file. It will be named AIBET_Backup_[date/time stamp].scb.
4. Click **Save**.

Schedule an Automatic Backup

To schedule an automatic, recurring backup of the Eclipse database:

1. Navigate to **Management > Database**.
2. In the **Backup** section (Figure 6-48), put a check mark in the box next to **Auto Backup Enabled**.
3. Click the calendar icon to choose a date for the first backup, or enter the date in the **Initial Start Date** field.
4. Enter a start time for the backup in the **Start Time** field.
5. Enter the frequency in days that you want the backup to reoccur (the default is 7 days).
6. Click the magnifying glass icon to browse for a location to save the backup, or enter the location in the **Storage Path** field.
7. Click **Accept** to save the changes.

To discontinue recurring automatic backups, deselect **Auto Backup Enabled**.



Backup

[Last Backup](#)

☒ Auto Backup Enabled

Initial Start Date

 12 Aug 2023 -06:00

Start Time

12:00 AM

Frequency (days)

7

Storage Path

 C:\ProgramData

Figure 6-48: Auto Backup

Restore a Database

To restore a previously backed up database:

1. Navigate to **Management > Database**.
2. Click **Restore....**
3. Locate the backup file and click **Open**. The restored database will become active again.

Archive a Database

To archive the current Eclipse instance, including all assays, users, and other data:

1. Navigate to **Management > Database**.
2. Click **Archive....**
3. Choose a location for the archive file. It will be named AIBET_Archive_[date/time stamp].sca.
4. Click **Save**.

About the Data Store

A full Eclipse assay compiles about 25 MB of data in the form of raw optical density (OD) readings from each of the 104 wells on a Microplate. The final calculations on the raw data take up much less space, but the raw OD data must still be stored for compliance purposes.

To keep the program running quickly and efficiently, Eclipse automatically archives the raw OD readings every week into a data store that is separate from the assay data, user accounts, audit trails, and other data that must be accessed regularly.

If you need to print the raw OD data report, you can find it in the location listed in the **Data Store Location** field on the **Management > Database** screen.

Error History

The Error History screen shows all Eclipse errors in a filterable list that displays:

- Date of the error
- Error Number
- Acknowledged On
- Acknowledged By
- Comment
- Analyzer Serial Number
- Analyzer Firmware Version

For compliance purposes, these errors must be acknowledged by a user with the Acknowledge Errors permission.

1. Navigate to **Management** → **Error History**.
2. Select the error to acknowledge.
3. Click **Acknowledge**.

Audit Trail

The Audit Trail is one of the most important components of Eclipse's data integrity. It ensures that all activity within the system is accurately and completely logged, timestamped, and associated with the user who performed each action. It records the entire history of Eclipse usage within the organization, and meets and exceeds the requirements set forth in CFR 21 Part 11.

To view the audit trail, navigate to **Management > Audit Trail** (Figure 6-49).

Date Occurred	Action	Performed by	Detail Information	Additional Information	Comment	Windows Info
12 Aug 2023 03:29:19 PM -06:00	Default Export File Type is Modified	Cruz, Sue	The value changed from 'XML' to 'CSV'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Default OD Threshold for Wako Turbidimetric is Modified	Cruz, Sue	The value changed from '0.0432' to '0.043'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Default OD Threshold for Wako Chromogenic is Modified	Cruz, Sue	The value changed from '0.0432' to '0.043'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Default OD Threshold for Charles River Turbidimetric is Modified	Cruz, Sue	The value changed from '0.1' to '0.089'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Default OD Threshold for ADC Turbidimetric is Modified	Cruz, Sue	The value changed from '0.03' to '0.026'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Allowed inactivity Period is Changed	Cruz, Sue	The value changed from '5' to '15'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:29:19 PM -06:00	Allowed Login Attempts is Changed	Cruz, Sue	The value changed from '3' to '5'.			AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:23:08 PM -06:00	A user logged in.	Cruz, Sue				AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:23:08 PM -06:00	User login authenticated.			Cruz, Sue		AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:22:53 PM -06:00	The application is launched.					AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:22:53 PM -06:00	Database Integrity Check was Successful					AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:22:46 PM -06:00	The application is closed.	Smith, Teddy				AA-HPPWILLION AA-HPPWILLION@st
12 Aug 2023 03:20:27 PM -06:00	User login authenticated.	Smith, Teddy		Smith, Teddy		AA-HPPWILLION AA-HPPWILLION@st

Figure 6-49: Management—Audit Trail

The Audit Trail shows (by date, in descending order):

- **Date Occurred**—the date and time that the action took place
- **Action**—a concise description of what occurred
- **Performed by**—the user that initiated the action
- **Detail Information**—a precise description of the action
- **Additional Information**—details about the action, such as an assay description or the name of a user whose profile was modified
- **Comment**—further clarifying information, if provided at the time of the change
- **Windows Info**—the Windows workstation and user login from which the action was initiated

You can filter the displayed audit trail entries by clicking the filter icon and choosing a filter criterion.

Printing or Exporting the Audit Trail

To generate a printable report of the Audit Trail, click **Print**. You can either send the report to a printer (use caution, the entire Audit Trail will be printed) or to a PDF file.

To export the Audit Trail to Excel, CSV, or XML, click Export.

Archived Audit Trails

To see the Audit Trail from an archived Eclipse database, click **Open Archive**, browse for the data file, and click **Open**.

CHAPTER 7: MAINTENANCE & DIAGNOSTICS

Upgrading the Eclipse Firmware

To upgrade the firmware:

1. Navigate to **Diagnostics > Analyzer**.
2. Enter the location of the firmware (or click the magnifying glass icon to browse for the file).
3. Click **Upgrade**.

Preventative and Routine Maintenance

There are no user-serviceable parts on or inside the Analyzer. Only trained service technicians in your region should perform service or repairs on an Eclipse Analyzer.

Inspection:

Inspect the Eclipse Analyzer lid assembly for mechanical damage before each use. If you observe any damage such as cracks or missing or loose parts, remove power from the Analyzer, discontinue use, and contact your local Technical Support.

Routine Maintenance:

Routine maintenance is limited to cleaning of the Analyzer. Sievers Analytical Instruments recommends a monthly cleaning of the Eclipse Analyzer (or more frequently, if desired).

Clean the inside surfaces of the Analyzer and lid using a non-abrasive material dampened with a 70% isopropyl alcohol or 10% bleach solution.

Caution: Do NOT use water or cleaners on the display screen, as they can damage or discolor the display. Wipe away any condensation or spills immediately.

Special Care:

For proper operation of the Analyzer, ensure that items 1–3 in Figure 7-1 are dry and free of dust and debris before inserting a Microplate. Ensure that items 2 and 3 are free of fingerprints and scratches. Perform maintenance cleaning of the Analyzer as frequently as necessary to keep these items clean.

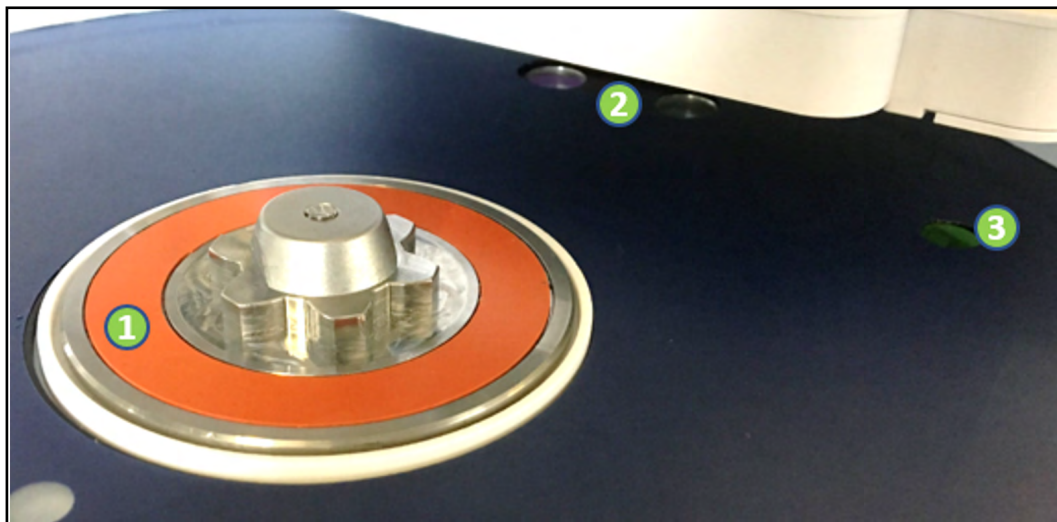


Figure 7-1: Analyzer Floorplate

Item	Description
1	Microplate support
2	Optical measurement windows
3	Temperature sensor window

Diagnostics

Optical Verification

Optical verification verifies the Analyzer's optical density (OD) measurement accuracy and consistency.

Required Materials:

- Eclipse Analyzer
- A calibrated Optical Verification Plate (OVP) provided by Veolia

About the OVP:

The OVP is a diagnostic tool that allows light to travel at various intensity levels through nine NIST-traceable filters, shown in Figure 7-2. During Optical Verification, the Eclipse Analyzer measures the intensity of the light through the filters to confirm that the platform's optics are correctly calibrated.



Figure 7-2: Optical Verification Plate

Acceptance Criteria:

- Deviation from expected values $\leq 5.0\%$
- % Intensity @ 400–410 nm $> 95.0\%$

Preparation:

The Optical Verification requires that the OVP be free of dust, powders, and any other small particulates that might interfere with the measurements taken through the nine filters on the OVP.

To ensure the OVP is clean and particle-free, keep the OVP in its original packaging (inside the dust sleeve and foam-padded box) until the software instructs you to load it into the Eclipse Analyzer in Step 5 of the Optical Verification.

Use a can of compressed air to remove any suspected particulates from the OVP filters (Figure 7-3). Remember to clean both sides of the filters.



Figure 7-3: Using compressed air to clean OVP filters

Procedure:

1. Navigate to **Diagnostics > Optical Verification** (Figure 7-4)

The screenshot shows the 'Diagnostics Optical Verification' interface. On the left is a blue sidebar with icons for various functions. The main area has three tabs: 'Optical Verification Setup' (selected), 'Optical Verification Test', and 'Optical Verification Results'. Under the 'Setup' tab, there are two columns. The left column, 'Test Details', contains four fields: 'OVP Calibration Doc #' (empty), 'OVP Serial #' (empty), 'OVP Calibration Date' (calendar icon), and 'OVP Calibration Due Date' (calendar icon). Each of these fields has a red exclamation mark icon to its right. The right column, 'Expected Values', contains seven filter input fields labeled 'Filter #1' through 'Filter #7', each with a value of '0.000'.

Figure 7-4: Optical Verification Plate

2. In the **Optical Verification Test** tab, complete the **Test Details** section:
 - OVP Calibration Doc #
 - OVP Serial #
 - OVP Calibration Date (available on the certificate provided with each OVP)
 - OVP Calibration Due Date (available on the certificate provided with each OVP)
3. In the **Expected Values** section, use the values provided with the OVP certificate to complete the fields for Filters 1–7.
4. Click **Start**.
5. The screen will display: “Insert OVP: Please insert the optical verification plate and close lid.”
 - 5a. Load the OVP into the Eclipse Analyzer and close the lid. A dialog box will appear on screen that says: “Injection Port state is unknown. Please open and close the Injection Port twice.”
 - 5b. Open and close the injection port cover twice.
 - 5c. Click **Start**.
6. A progress bar will advance as the test runs. When the test is complete, remove the OVP from the Analyzer.
7. On the Print Preview of the test results, click **Signatures** to sign the results of the Optical Verification (see [“Electronic Signatures” on page 107](#) for more information).

Upon completion of analysis

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 5):

1. Remove the OVP from the Analyzer.
2. Navigate to **Diagnostics > Optical Verification > Optical Verification Results**.
3. Select the appropriate test from the list.
4. Click **Print**.
5. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.

Temperature Verification

Temperature Verification ensures that the temperature of the Analyzer and Microplate is within operating range.

Materials Required:

This test requires a calibrated Temperature Verification Plate (TVP) provided by Veolia.

About the TVP:

The TVP is a diagnostic tool that verifies the Eclipse Analyzer’s ability to accurately measure plate temperature. The TVP has a temperature measurement range of 15-45 °C, 12 bits of resolution (with 12 LEDs for output), and a NIST-traceable calibrated accuracy of ± 0.1 °C. During Temperature Verification, sensors on the Analyzer measure the temperature on the top and bottom of the TVP, and the Eclipse software compares that data with the measurements reported by the TVP.

Figure 7-5 shows:

1. Power switch
2. Battery status LED
3. Battery cover

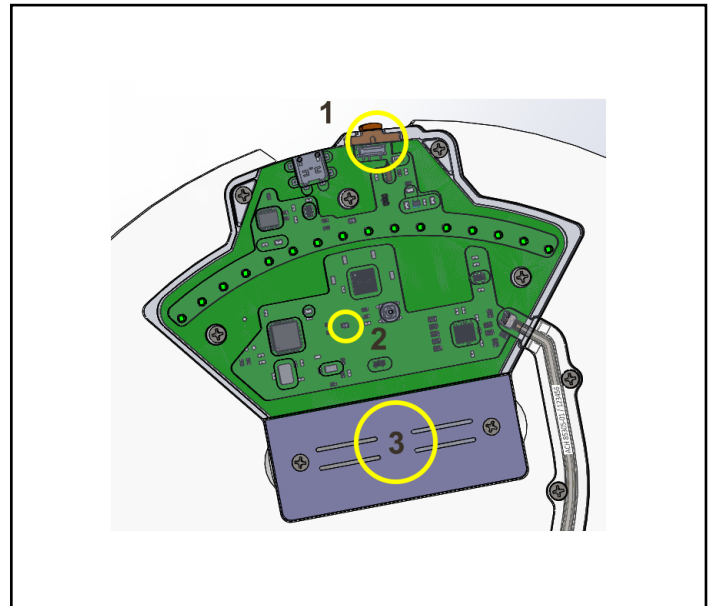


Figure 7-5: TVP Board

When the power switch is ON, the color of the battery status LED shows the amount of battery life left:

- Green—full charge
- Orange—charge depleted, replace batteries soon
- Red—replace batteries immediately

The TVP will accurately measure temperature until the LED goes out.

To change the batteries:

The TVP is powered by two CR2016 button cell batteries. To change them:

- Use the power switch to turn off the TVP.
- Use a small cross-head screwdriver to remove the two battery cover screws and remove the battery cover.
- Remove the spent batteries, and insert two fresh CR2016 batteries with the positive (+) sides facing up.
- Replace the battery cover and gently tighten the battery cover screws (do not over-tighten).

Acceptance Criteria

- Temperature $37\text{ }^{\circ}\text{C} \pm 1$
- Temperature is calibrated to $\pm 0.5\text{ }^{\circ}\text{C}$. If the test reports that the temperature is within the spec, but outside of the $0.5\text{ }^{\circ}\text{C}$ range, you will be prompted to apply temperature adjustment.

Procedure:

1. Log in as a user with permissions to run diagnostics.
2. Navigate to **Diagnostics > Temperature Verification** (Figure 7-6).
3. In the **Temperature Verification Test** tab, complete the **Test Details** section:
 - TVP Calibration Doc # (available on the certificate provided with each TVP)
 - TVP Serial # (available on the TVP label or TVP certificate)
 - TVP Calibration Date (available on the certificate provided with each TVP)
 - TVP Calibration Due Date (available on the certificate provided with each TVP)
4. Click **Start**.
5. The screen will display: "Please turn on the temperature verification plate (the LEDs will light up), insert it into the Eclipse Analyzer, and close the lid."
6. Turn on the TVP—the lights on the plate will blink.
7. Insert the TVP into the Eclipse Analyzer and close the lid.
8. A dialog box will appear on screen that says: **"Injection Port state is unknown. Please open and close the Injection Port twice."**
9. Open and close the injection port cover twice.
10. Click **Start**.

Figure 7-6: Temperature Verification Screen



Upon completion of analysis

When the assay is complete (unless a Print Preview auto-generates, in which case skip to Step 5):

1. Remove the TVP from the Analyzer and turn it off.
2. Navigate to **Diagnostics > Temperature Verification > Temperature Verification Results**.
3. Select the appropriate test from the list.
4. Click **Print**.
5. Follow the assay signature procedure outlined in [“Electronic Signatures” on page 107](#) to review and approve the assay and audit trail, then apply signatures to the completed assay.

Notes
