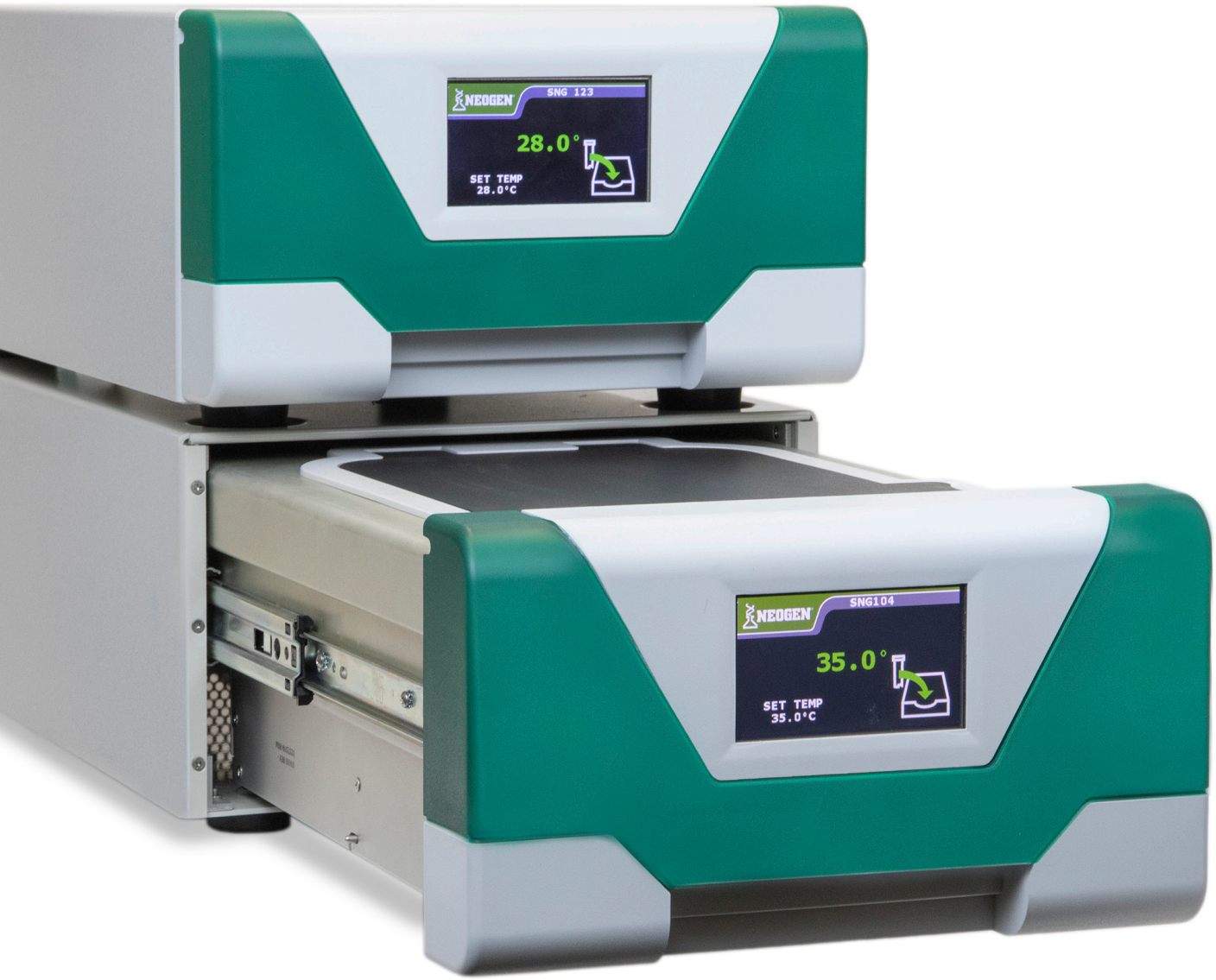

Soleris® Next Generation and Fusion Software User Manual

NEOGEN®

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Caution — Risk of Danger

This instrument is equipped with a UV light. Although the UV radiation is low, use UV protective glasses when opening the instrument. Ordinary protective laboratory glasses can be used to protect from the UV light.

Under normal use, the instrument does not release poisonous, flammable, or injurious gases. Test vial caps should be tightened prior to insertion into the instrument.

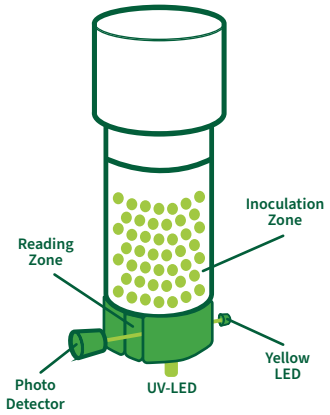
If the equipment (instrument and/or test vials) is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Chapter One

System Technology and Overview

General Features

The Soleris® Next Generation (NG) system provides accurate and rapid microbiological answers in a complete system approach. The system includes instruments (incubating drawers) integrated with the secure Fusion software package. The system uses vials to rapidly detect presence or absence of microorganisms.



A crucial element of the vial technology is the creation of two zones in each vial, the inoculation zone and the reading zone. This two-zone vial eliminates masking of the optical pathway by the product and by microbial turbidity. The technology is based upon the monitoring of changes in either color or fluorescence by an optical sensor to detect microorganisms.

Some of the available assays include:

- Total Aerobic Count
- Coliform
- Enterobacteriaceae
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Salmonella* spp.
- *Staphylococcus aureus*
- Gram Negative Bacteria
- Yeast and Mold
- Lactic Acid Bacteria

The system can be used for a variety of additional tests. The system can be used in a variety of industries, including food, nutraceuticals, and cosmetic manufacturing. The system not only can test finished goods and raw materials, but can also be used for environmental testing, ultra high temperature (UHT) testing, sterility testing, and shelf-life assessment.

The modular structure enables flexible growth of the system as needed; 1–1,024 samples can be tested simultaneously, with up to 32 instruments can be connected to a single computer. There is random access to all instrument vial positions at any time — no batching required.

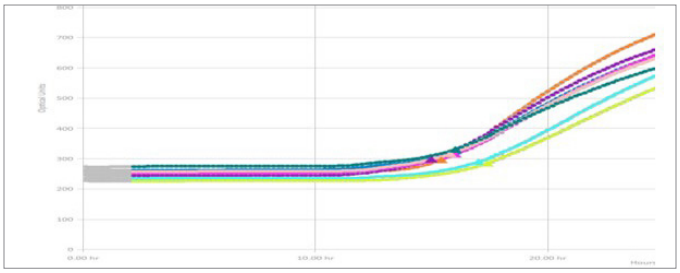
Soleris NG Hardware

The instrument has an integrated incubator and features an independent optical reader and dual light sources in each of the 32 test vial locations. The technology is based on the monitoring of changes in the reading zone of each vial. As growth occurs in the broth medium, detections are the result of changes in color or fluorescence of the reading zone. The reagents change their color or flourescence due to the microbial metabolites. These changes are monitored ten times per hour.

The optical changes are detected by the sensors in each vial location. The system is equipped with two light-emitting diodes (LED), one that uses a yellow light and the other use an ultraviolet (UV) light.

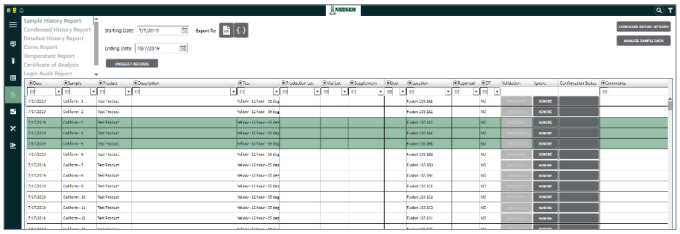
Soleris Fusion Software

The software records any change in color of the vial or fluorescense in the vial. The software takes a scheduled reading of the vial and plots the results. If the change exceeds the test threshold**,** the software will indicate a detection.



S2-EC: Escherichia coli CDC 984 (1.5 CFU/vial), 48-hour Test

The software allows users to access sample records, generate certificates of analysis, and a variety of reports via the sample history report menu. The user simply selects samples of interest, and then selects the desired report.

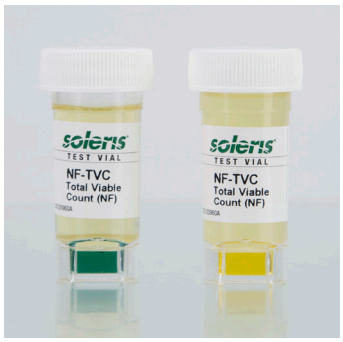


Sample History Report — Main Menu

Example — Certificate of Analysis (CoA)

Soleris Vials

The system utilizes three types of test vials. The first type is a pH indicator vial that contains an enrichment broth medium with a pH dye indicator. As microorganisms grow, they ferment sugars into acid. The pH of the medium changes, causing a color change in the indicator dye. The color change diffuses into the agar plug and is read by optical sensors in the instrument.



The second vial type incorporates a carbon dioxide (CO_2) optical sensor. CO_2 is a universal metabolite produced by all microorganisms. CO_2 vials contain an enrichment broth medium that is separated from the reading frame by a semipermeable membrane. CO_2 produced by the organism growth in the broth diffuses through the membrane into the agar plug and causes the color change, which is read by the instrument. The semipermeable membrane overlay above the agar blocks liquids, microorganisms, and particulate matter and ensures that only gases can penetrate the sensor.

The third vial, (the fluorescense vial) contains a broth enrichment medium with a fluorescent indicator. The reading frame contains a soft agar plug which reduces product interference with the detection of microbial growth. As the organism grows in the broth medium, the utilization of the fluorogen diffuses into the soft agar plug. The fluorescent end product is read by the optical sensors in the instrument.

General Procedure

Most samples need first to be liquefied. Typically, a 1:10 dilution of the solid sample is prepared. For example, 10 g of sample are added to 90 mL of a dilution blank and thoroughly mixed. The mixing can be achieved with a blender or a stomacher. Liquid samples can be added directly into the vial.

The following steps are generally used before the beginning of the test:

1. Add supplement to the vial, if required.
2. Inoculate the vial with the appropriate sample volume.
3. Insert vial into the instrument.
4. Enter the sample details into the software and start the test run.

System Terminology

Above specification: The detection time before which the sample has colony forming unit (CFU) above the specified level.

Algorithm: The formula that the system uses to generate a detection in the system. Each vial type has a unique set of parameters that can be adjusted based on matrix.

Batch: An optional field to reference the batch code of the sample. It can be used to further specify the sample.

Below specification: The detection time after which the product has CFU below the specified level.

CFU: Colony Forming Units.

Sample statuses: The color code is applied to both the main screen and grid view of the instrument. Each color represents a different status: Grey is an available location, green is an active test, yellow indicates a pending test, orange indicates a temperature mismatch, light red indicates a positive detection with time remaining, red indicates a detection and completed assay, light blue indicates the initial vial reading is higher than the set point, and black indicates a disabled cell.

Detection time (DT): The time by which the system has detected the presence of the target organism(s).

Intensity values: The optical values generated by the photo-sensor within the range of 0–999 optical units.

Intercept: This is the point of the calibration line which intercepts the Y-axis. (Also see slope).

Lab Information Management System (LIMS): A system used to integrate all laboratory test results.

Home: The main display of the 32 instrument locations organized by a matrix of 4 x 8.

Operator: A person qualified to work on the system.

Out of spec alert: When an assay sample is found to be out of specification, the software will alert the user with a visual red background.

Power failure: The temporary lack of power to the system.

Product: The name of the product being tested.

Duration: The amount of time (hours) that the test will run for.

Remaining time: The time left before the system will automatically stop monitoring the selected test location.

Shuteye: This allows starting the algorithm after a certain time period has elapsed. The default option is zero. A value of 45 indicates that the detection algorithm will be activated after four and a half hours.

Skip: Determines which data points are used by the detection algorithm. The system's default value is one, indicating that each data point collected is utilized (six-minute intervals) by the detection algorithm. A value of two will indicate the utilization of every second point collected (12-minute intervals).

Status: The sample status (either running or stopped).

Supplement: An optional field indicating the supplement used for testing.

System configuration: The description of the various instruments connected to the computer.

Test: The microbiological assay that is being performed (e.g., total count, yeast and mold, and coliform). This name is chosen from the tests dictionary.

Test type: The specific light source associated with a test: yellow LED or fluorescence UV-LED light.

Threshold: The change in the optical units required for the algorithm to establish detection in the curve. The smaller the detection level, the more sensitive the algorithm is.

Vial lot: An optional field indicating the lot of the vial used for testing.

Well: The location in the instrument where the assay vial is entered.

Hardware Specifications

Capacity	32 samples
Maximum number of instruments per data manager	Up to 32
Scan frequency	Six minutes
Hardware temperature range	20–50°C ± 0.5°C
Environmental operating temperature	23–30°C
Set temperature	Software-controlled
Humidity	20–90% non-condensing
Electrical voltage	85–264 VAC
Electrical frequency	50/60 Hz
Electrical power	120 Watt
Height	7.4 inches
Width	12.5 inches
Depth	22.4 inches
Weight	50.9 lb
Storage/operating conditions — maximum altitude	3,100 meters
Storage conditions — temperature	0–40°C
Storage conditions — humidity	0–90% non-condensing

Soleris NG Hardware Specifications

Chapter Two

Hardware Overview

Instrument Back Panel

The back panel of the instrument contains an on/off switch, a power supply, a cable connecting the power supply to the power outlet, and a network port.

Soleris NG Hardware Back Panel

Shipping Screw

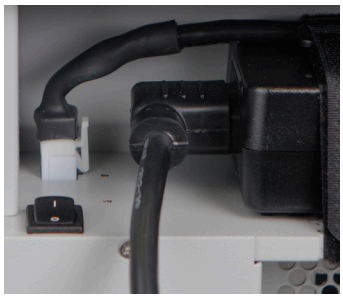
The back panel of the instrument contains a screw, which keeps the drawer closed during transit. Once the instrument is installed at the desired location, the shipping screw should be removed and stored for safekeeping in the dedicated storage location on the instrument, pictured here:

Soleris Shipping Screw

Connecting the Instrument Power Supply

An electrical power cord is included with the instrument. Connect the cable to the power supply and the opposite end to a clean line with a surge protector.

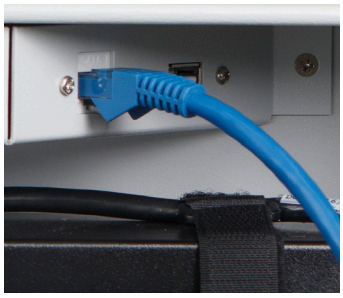
Note: It is recommended that the instrument be connected to a clean line with a surge protector. The power outlet (either the wall outlet, the power strip, or the surge protector outlet) should be placed in an accessible location, so that the power to the instrument can be disconnected at any time.



Soleris Power Cord

Connecting the Network Cable

A network cable is included with the instrument. Connect the network cable to the network port on the rear of the Soleris NG instrument. Connect the other end of the network cable to either the host PC or the host hub.



Soleris Network Cable

Connecting Multiple Instruments to a Single Computer

Up to 32 instruments may be connected to a single host computer. Instruments must be added to the system configuration one at a time and it will require a switch (a greater than 32 port switch).

Chapter Three

Software Overview

System Requirements (Minimum)

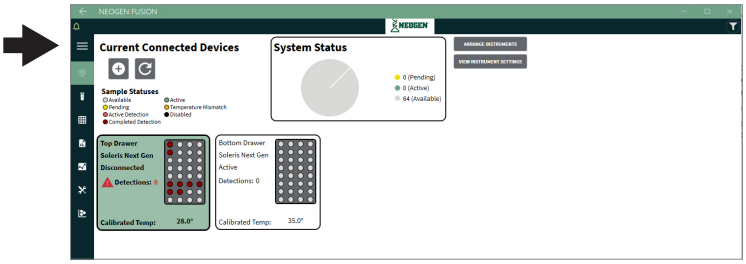
Windows 10 and 11 OS

16 GB free RAM available

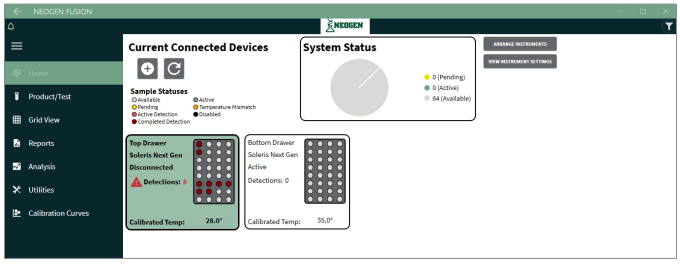
Intel i5 processor or greater

Main Toolbar

The main toolbar can be expanded and collapsed by selecting the icon.



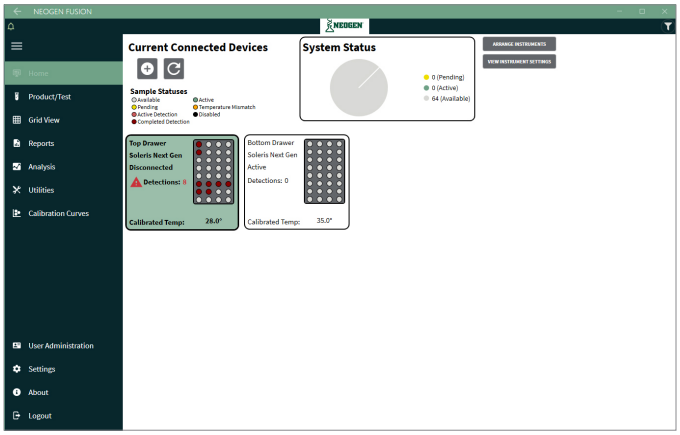
Home Screen — Main Menu Collapsed



Home Screen — Main Menu Expanded

Following is a summary of each menu. See sections below for a detailed description of each menu.

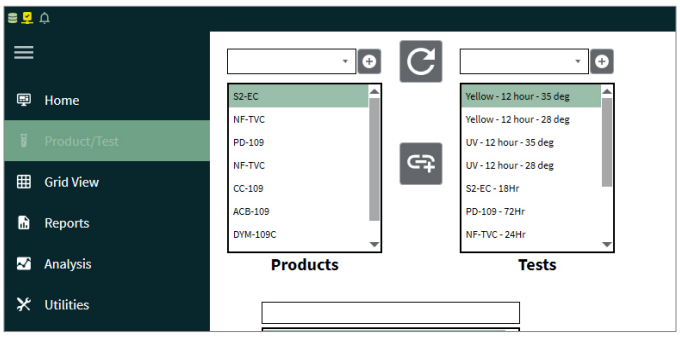
Home menu: Allows users to view active devices and samples, arrange the instruments on the grid, and view the instrument settings, and add new devices to the system.



Home Menu

Software Overview

Products and tests menu: Allows users to view and administer products and tests and associate them for testing samples.

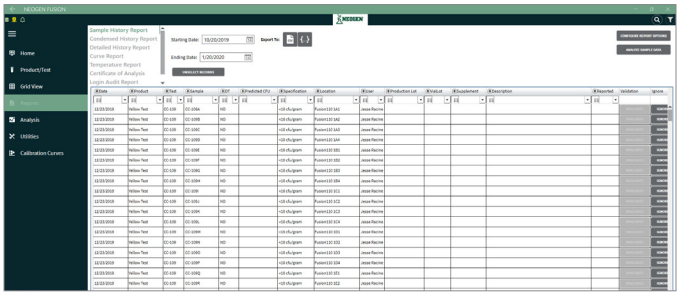


Products and Test Menu

Grid view: Allows the user to start samples, view samples in progress, scan barcodes, create batches, generate reports, and calibrate the instruments.

Grid View

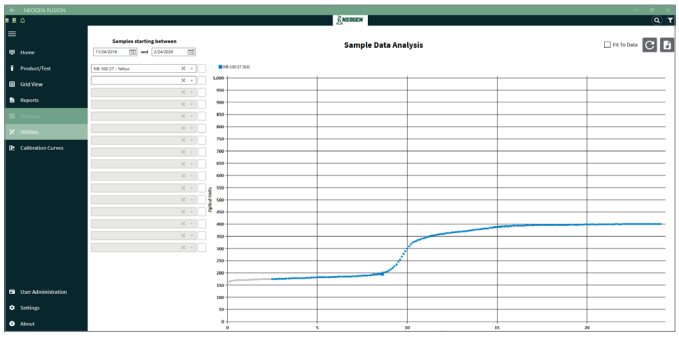
Reports menu: Allows the user to view archived data and generate a variety of reports and a CoA. Data from this page can also be exported to a LIMS program.



Reports Menu

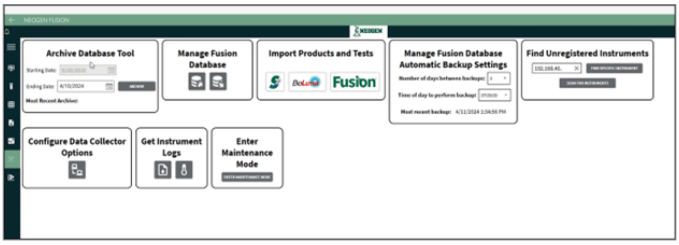
Software Overview

Analysis menu: Based on selected samples, archived data can be plotted, analyzed, and compared with existing algorithms.



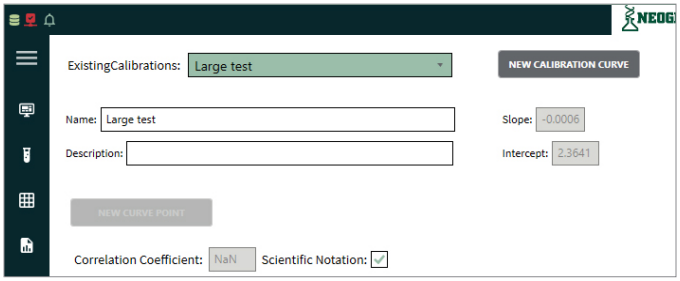
Sample Data Analysis Menu

Utilities menu: Provides user with utilities such as data backup.



Utilities Menu

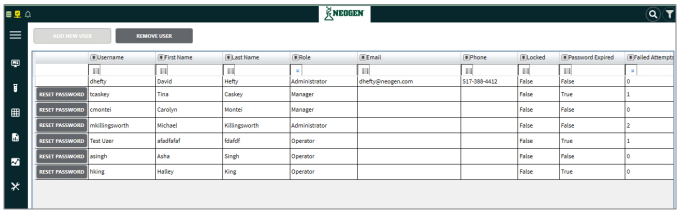
Calibration curve menu: Provides user with the ability to create calibration curves (see the calibration curves section in chapter 11 for additional details) and utilities such as data backup and LIMS export configuration.



Calibration Curves Menu

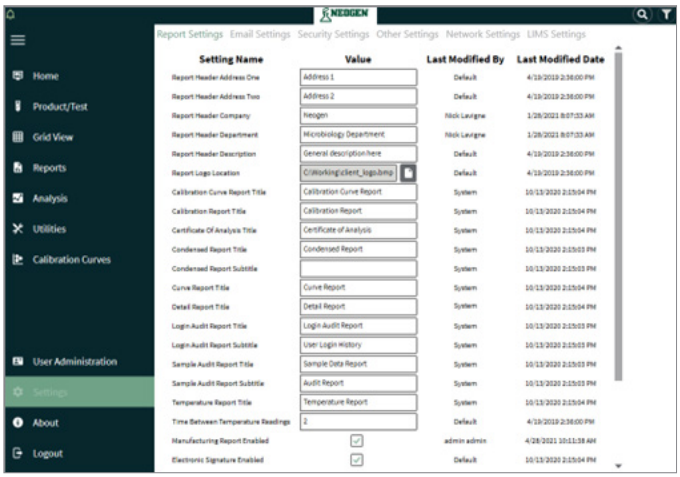
Software Overview

User administration menu: Provides user with ability to add, remove, and administer users.



User Administration Menu

Setting menu: Allows user to update the settings for reports, email, security, network, and LIMS.



Chapter Four

User Administration

Overview

The Soleris Fusion software provides users with various levels of administrative privileges. The Soleris Fusion user types are: administrator, manager, and operator. A summary of the administrative rights for each user is provided in the user privileges section at the end of this chapter.

Security

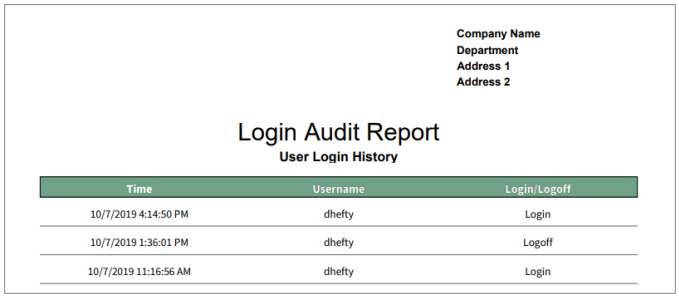
Access to the software is restricted to authorized users. The activity of all users is tracked for auditing purposes. Access to the software is restricted by password, and the system will log out users after a period of inactivity, as decided by the system administrator. Usernames and passwords have the following requirements:

Username: Any combination of characters up to 25 characters long. The username cannot be any previous username assigned to the system.

Password: Must be a minimum of eight characters long. Must include one upper case, one lower case letter, and one special character from the following list: ! @ # $ % ^ & * ( ). The password cannot be any of the previous four assigned passwords.

Password expiration: The password will expire every 90 days. Starting seven days in advance, the user will be notified at every login, “Password will expire in X days. Please update your password.” If the user does not update their password by the specified date, the user will be forced to create a new password upon login. This setting is adjustable by the system administrator in the settings page.

Audit trail: The Soleris Fusion software allows administrators to execute a login, temperature, or sample audit report. The login audit report user interface will provide a selectable date range (full date range for all data) to generate a report of all users accessing the software.



Company Name
Department
Address 1
Address 2

Login Audit Report

User Login History

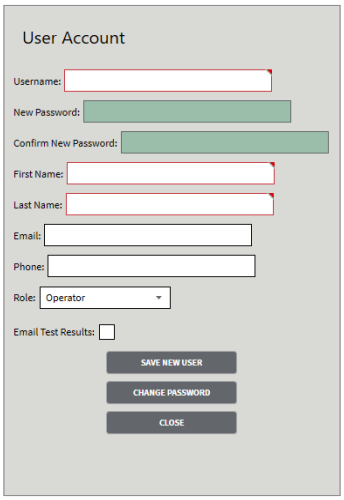
Time	Username	Login/Logoff
10/7/2019 4:14:50 PM	dhefty	Login
10/7/2019 1:36:01 PM	dhefty	Logoff
10/7/2019 11:16:56 AM	dhefty	Login

The report will sort by most recent, and will provide a customized report title and subtitle, which can be configured in the system settings. A dialogue will appear when the login audit report is created stating that the file has been created and will ask the user if the file should be opened.

User Administration

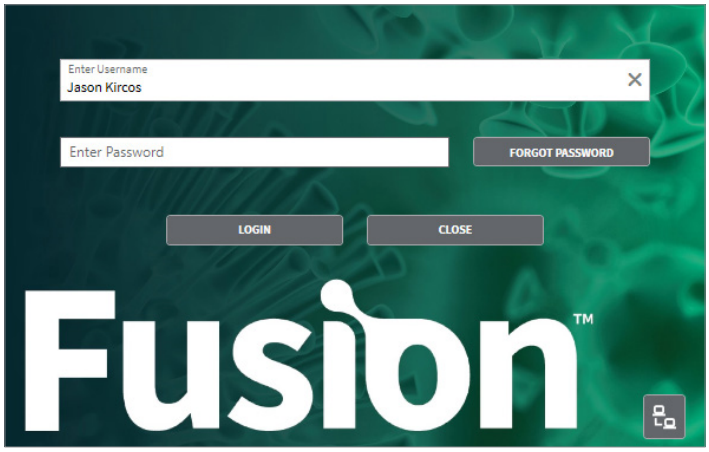
Initial Software Access

Upon first access to the software, the administrator is prompted to create a username and password.



Initial System Access — Create Administrator

Once the administrator username is created, the user will be logged out, and the login screen will appear.

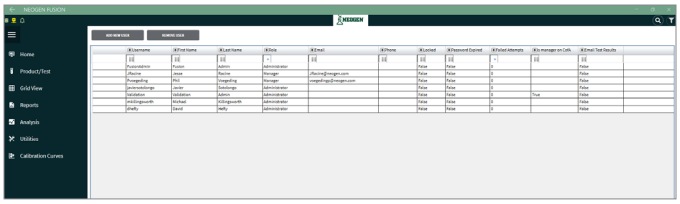


User Login Screen

Once logged back in, the administrator may create other administrator, manager, or operator users. The user will also have to create a new password upon login. This setting is designed to allow the administrator to create new accounts with a generic password, but when the new users log in they can create their own unique password.

Viewing and Administering Active Users

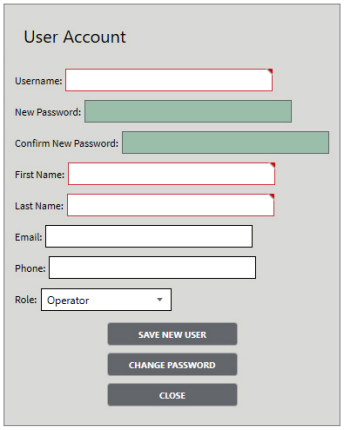
Administrator and manager users may view all active users by selecting the user administration menu. Here, they may add users, remove users, or reset passwords.



User Administration — Main View

Adding New Users

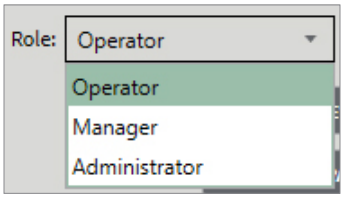
To create new users, select create new user and then complete the new user flyout.



User Administration — Add New User

Required fields are username, password, first name, last name, and role (admin, manager, or operator).

The user role is selected by selecting the role drop-down menu.

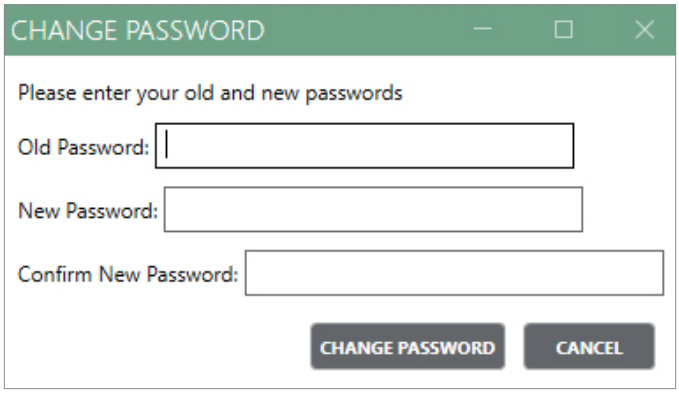


User Administration — Roles

Once the new user information is entered, select SAVE NEW USER and the new user will be added to the list of available users.

Newly Created Users — Accessing the Software

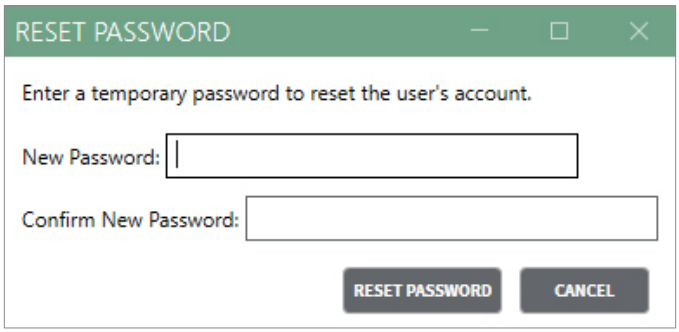
When the new user logs into the software for the first time, they will use the password assigned by the administrator. Once the user logs in with the assigned password, they will then create a new password meeting the above requirements, confirm the password, and log in with the new password.



User Administration — Log In and Create New Password

Resetting User Passwords

Administrator and manager users may reset user passwords by selecting RESET PASSWORD.

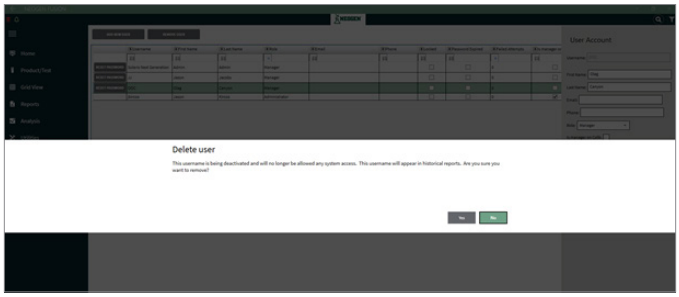


User Administration — Reset Password

Removing Users

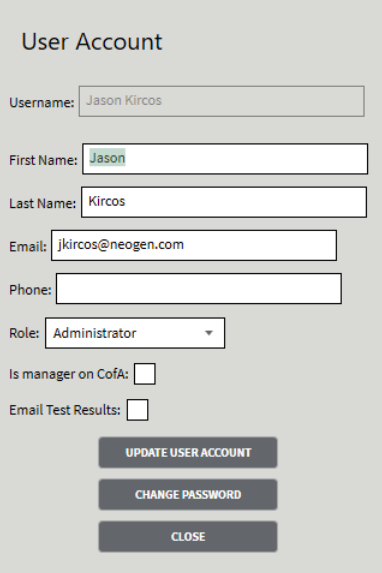
Administrator and manager users may remove users by selecting remove user**.**

Note: Removed users will still be present in audit trail records. Once a username is removed from the system, it cannot be reused. This will pop-up a blocking marque.



Assign Managers to CoA

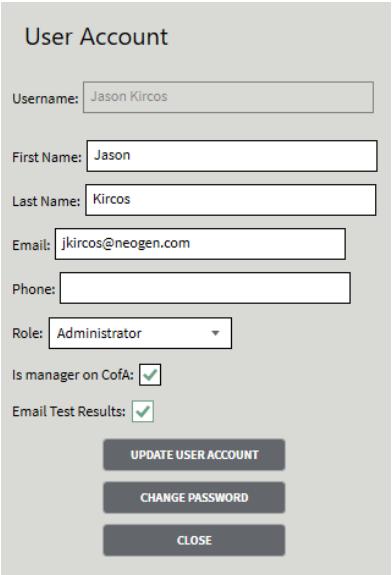
If a manager record is required for the CoA, the reporting manager may be selected by checking the C of A box.



User Administration — Assign Manager to CoA

Enable Email and Text Notifications

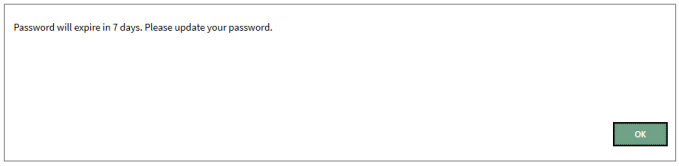
If a user wishes to receive email notification of test completion, the user may enter their email address into the user account detail. Every half hour, a condensed report will be generated and emailed. The report will contain all samples with a detection in the previous half hour. The generated condensed report is emailed to all users who have the email test results setting turned on.



If there are no detections, no report will be generated (no email).

Password Expiration

A user password will expire every 90 days. The user will be notified leading up to the expiration to change their password. If the user fails to change their password, the administrator will be required to reset the password.



Pending Password Expiration Warning

Account Lockout — Unsuccessful Login

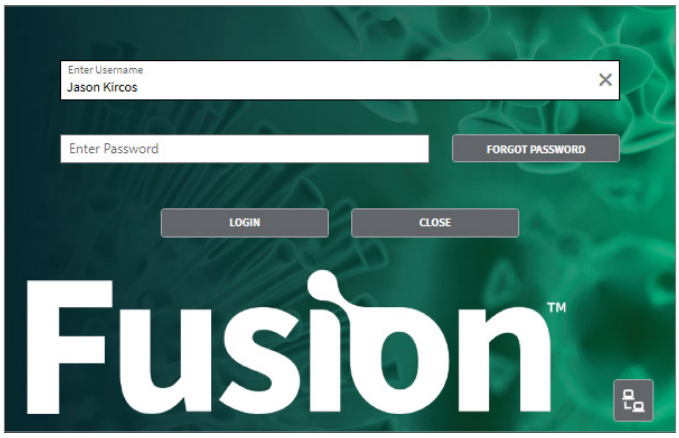
If a user enters their password incorrectly three times, the account will be locked, and the administrator will be required to unlock the account and reset the password.

User Privileges

Software Function	Administrator	Manager	Operator
Perform Calibration	Yes	Yes	Yes
Adjust Temperature	Yes	Yes	No
Start Sample	Yes	Yes	Yes
Stop Sample	Yes	Yes	No
Create Sample Reports	Yes	Yes	Yes
Confirm Samples	Yes	Yes	No
Create Audit Reports	Yes	Yes	No
Create a New User Account	Yes	Yes	No
Reset User Account Password	Yes	No	No
Backup Database	Yes	Yes	Yes
Restore Database	Yes	No	No
System Settings	Yes	Yes	No
Create/Edit Calibration Curves	Yes	Yes	No

User Permissions — Summary

Password Recovery



When a user who has not setup their security questions logs into the application, the user will be presented with the password recovery security questions screen. They have the option to set up questions at a later login with a remind me later button. If the user selects remind me later, user will receive a notification, “Security questions must be answered after third login attempt.” The system must display a counter of attempts; e.g. 1/3, 2/3. The remind me later button is hidden after second login attempt. The following text must appear on the security question screen, “Select three (3) security questions below. These questions will help us verify your identity should you forget your password. Your answers are case sensitive.”

Question 1: Drop down box that contains five security questions

- What is your oldest child’s nickname?
- To what city did you go to the first time you flew on a plane?
- What was the name of the company where you landed your first job?
- What was the first movie you saw in theaters?
- What is your mother’s maiden name?

Question 2: Drop down box that contains five security questions

- What was the first thing you learned how to cook?
- What was your favorite childhood sport?
- What was your high school mascot?
- Where is the coldest location you have ever visited?
- What city were you born in?

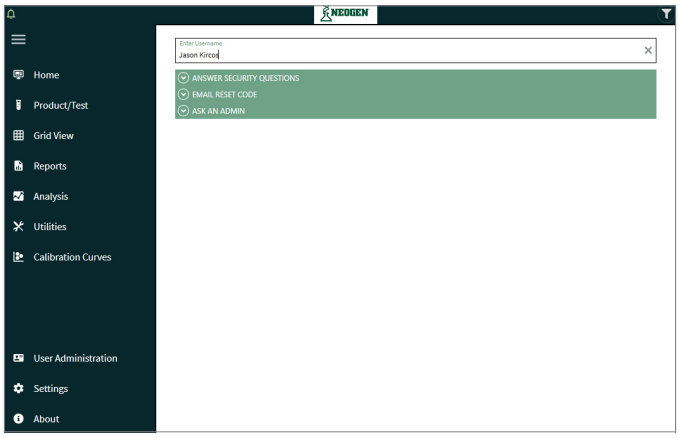
Question 3: Drop down box that contains five security questions

- As a child, what did you want to be when you grew up?
- What was the color of your first car?
- What was the first concert you attended?
- What was the first foreign country that you visited?
- What is your favorite teacher’s last name?

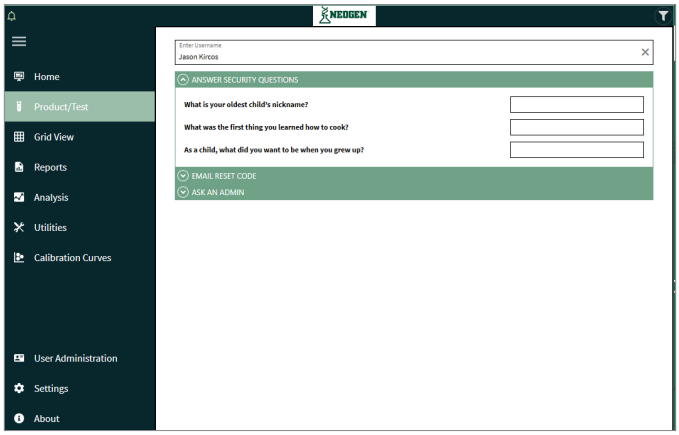
The user must answer text fields that are required fields, and the answers entered are masked.

Forgotten Password Recovery

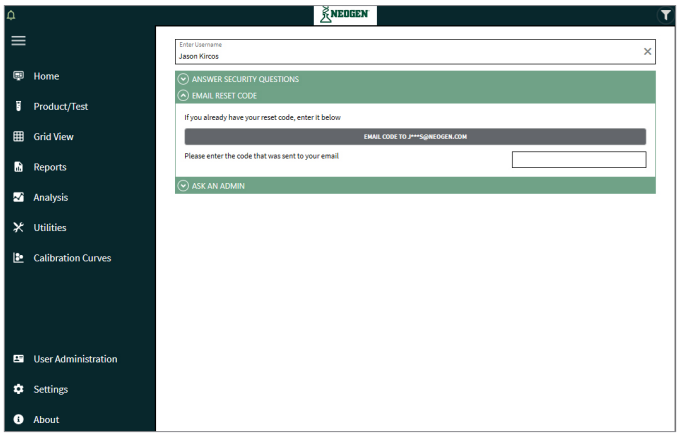
If the user forgets their password, they can use three different options for recovery of the account.



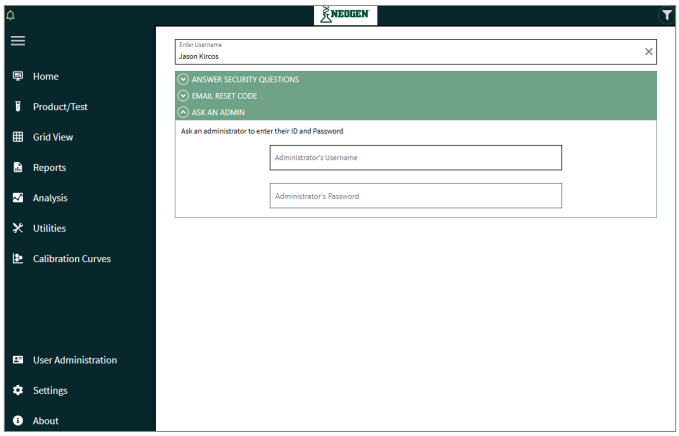
1. Answer security questions: The user can answer the three questions that they used when they created the account.



2. Email reset code: If the user has setup an email account, the system will send a code to reset the user's password



3. Ask an admin: The user can select this option and the administrator can login and reset the password directly.



Chapter Five

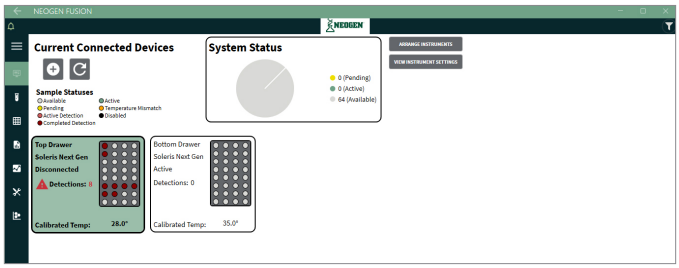
System Configuration

Overview

The software can be configured to control up to 32 instruments simultaneously.

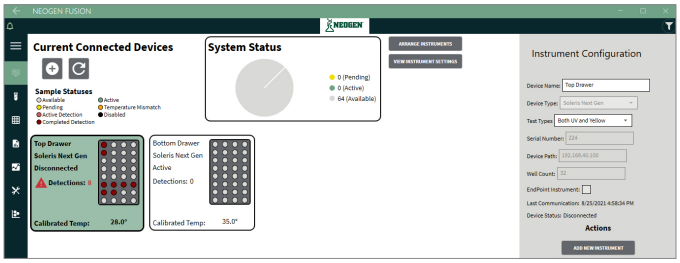
Home Menu

The home menu displays connected and available devices. The home menu allows authorized users to add, edit, remove, or arrange the instruments in the viewing window.



Home Menu — Connected Devices

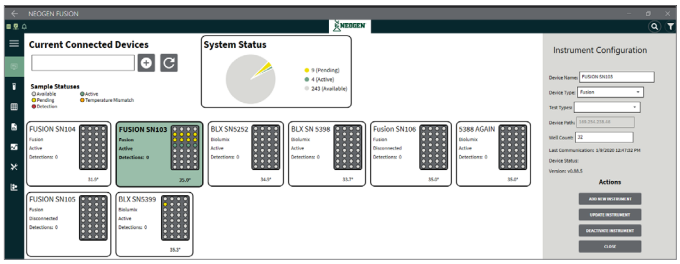
The home menu also displays instrument specific device information. Select a device and click view instrument settings to open the instrument configuration flyout. In the example below, the device named top drawer has been selected, and the associated instrument configuration flyout has appeared on the right side of the screen. The device can be renamed in this configuration flyout.



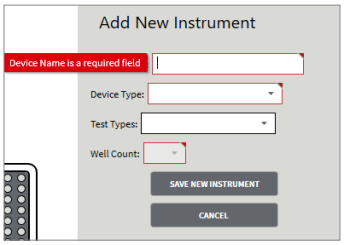
Home Menu — Instrument Configuration Detail

Adding a New Instrument

When first configuring the software, or to add a new device, ensure the instrument hardware is connected to the host PC. (See chapter 2, for further details.) Select the home menu.



Select the add instrument icon  . If a device is available for configuration, the instrument configuration flyout will appear on the right side of the screen.



Instrument Configuration Flyout

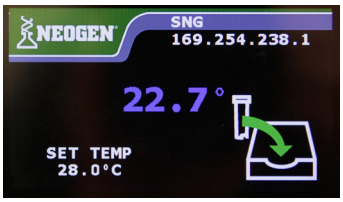
Instrument Configuration

The instrument configuration contains the following parameters to configure the instrument: device name, device type, and well count. Based on the hardware being configured, the user enters the parameters and selects save new instrument.

Device Name

The user can enter a name, up to 25 alpha numeric characters, to identify the device. The device name will appear in the sample history record.

Note: For Soleris NG hardware, the device name will appear in the upper right of the hardware display screen.



Device Name NF-TVC Drawer Assigned to Device

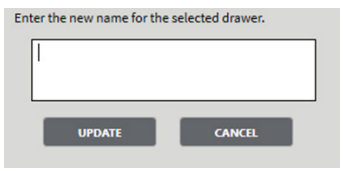
Note: For previous generation hardware, the device name will not appear in the Soleris hardware display screen. The device name will appear in the sample history record.

Drawer Name

For Soleris NG hardware, the user may also assign a drawer name. The drawer name, up to 25 alpha numeric characters, exists in addition to the device name. The drawer name, if assigned, will appear in the sample history record alongside the device name.

Note: For Soleris NG hardware, the device name will not appear in the Soleris hardware display screen. The device name will appear in the sample history record.

The drawer name is assigned by accessing the grid menu. In the more actions flyout, select rename drawer. From here, the user can input a drawer name, which will be used in the sample history and reporting functions to identify the drawer.



Assigning Drawer Name

Instrument Status

The home screen provides a variety of information on instrument status.

A system-level pie chart of sample statuses is displayed. The available statuses are pending, active, and available (which includes available, completed, and stopped statuses).

The home screen displays each configured instrument on a tab. The tab displays:

- *Instrument Name*
- *Device Type*
- *Status*
- *Number of Detections*
- *Calibrated Temperature*

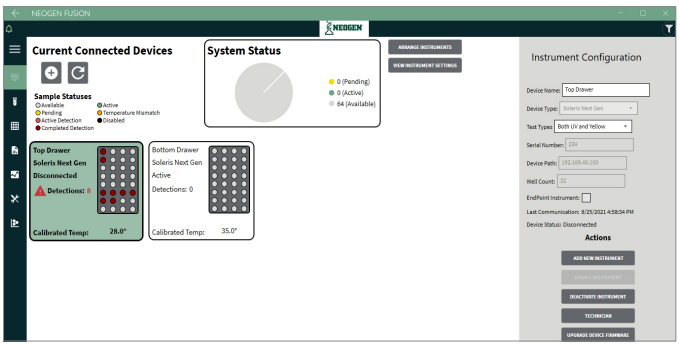
The tab will display a miniature grid showing the color status of each well instead of the doughnut chart. The selected device card changes the text to bold and increases the border thickness. The selected device card is highlighted in green.

The legend displays the following statuses:

- *Yellow status represents a pending sample.*
- *Orange status represents a pending sample that has a different temperature from the drawer temperature.*
- *Green status represents an active sample.*
- *Light red status represents a sample with a detection that has time remaining on the test. A triangle alert icon will also display and indicate the number of detections in that specific device.*
- *Grey status represents a well that is empty or has a sample with a status of complete or stopped.*
- *Dark red status represents if a sample is positive with a detection and complete.*
- *Black status indicates the location has been disabled and no tests can be run in that location. Only an administrator can set a well to this status.*
- *Royal blue status indicates a vial that has triggered the Over Threshold Warning.*
- *Light blue indicates the initial vial reading is higher than the set point created in the test parameter setup page.*

Note: If the user has not defined a name for a drawer, the name will default to the names drawer 1, drawer 2, drawer 3, or drawer 4. The drawer name must be entered.

Once the new instrument configuration is saved, the user may view the instrument configuration and instrument status by selecting the instrument from the current connected devices menu. Once selected, the instrument configuration flyout will appear on the right side of the screen.



Instrument Configuration Menu — Current Connected Devices

- **Device name:** Assigned at configuration and can be edited.
- **Device type:** Assigned at configuration.
- **Device path:** The IP address assigned to the device is displayed.

Note: If an instrument is deactivated, or when received from the factory, the default IP address is 169.254.238.1. The software searches for this IP during configuration and will reassign a different IP address during the above configuration process. See the deactivating instruments section in chapter five for more details.

- **Well count:** Assigned at configuration and can be edited.
- **Last communication:** Last communication between the device and the host PC. In normal operation, the device refreshes with the host PC every six minutes.
- **Device status:** List the device status. The device may have the following statuses:
  - Active: The device is connected properly and is ready to be used.
  - Disabled: The device is connected but has yet to be fully calibrated.
  - Inactive: The device is properly configured and calibrated but has been disconnected.
- **Version:** This list the version of the operating system on the device.

Deactivating Instruments

If removing an instrument from the system, the device must be deactivated. To deactivate the instrument, select the device from the current connected devices menu.

Then select deactivate instrument from the instrument configuration flyout. A message to confirm the action will appear.

Deactivate Instrument Confirmation

Once confirmed, the device will be deactivated. The IP address of the device will be reset to 169.254.238.1.

Chapter Six

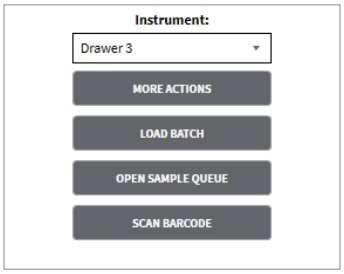
Instrument Calibration

Instrument Calibration

The instrument optical reader needs to be calibrated periodically the system default is set to every 90 days, which is the recommended setting. A system administrator can adjust the number of days for calibration for 30–365 days. It is recommended to always calibrate if any of the following conditions occur:

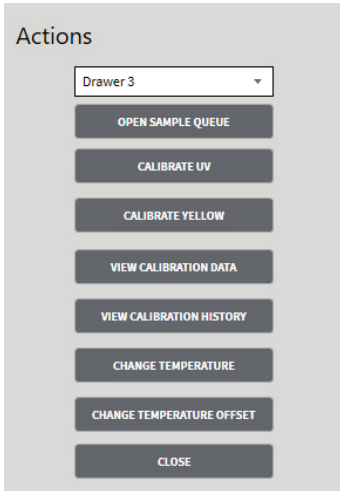
- Before using the instrument for the first time
- If the instrument is moved
- If the instrument temperature is changed
- If the instrument experiences an extended power loss of over four hours

The calibration drawer function is available within the more actions menu of the instrument grid view.



Instrument Grid View — More Actions

Depending on the hardware configuration, the user can calibrate either the yellow or UV test by selecting the calibrate yellow or calibrate UV buttons.

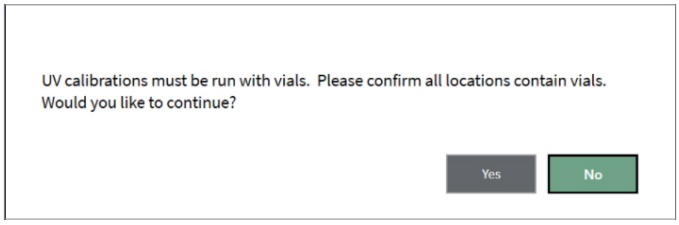


Instrument View — Actions

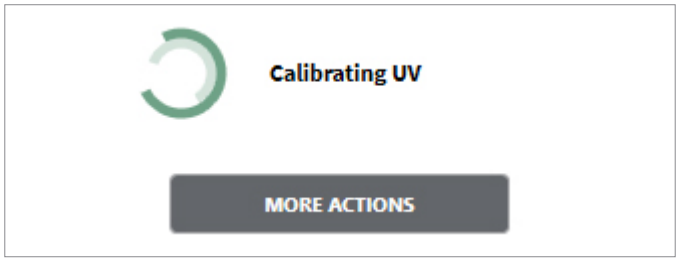
Instrument Calibration

Note: Yellow calibrations does not require any calibration vials. Yellow calibration requires that no vials are present in the instrument. The system will give a pop-up notification: “Yellow calibrations must be run without vials. Please confirm locations are empty. Would you like to continue?”

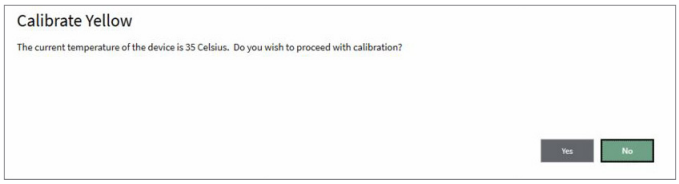
Note: UV calibrations requires calibration vials to be present in all well locations. Vials must be warmed for 30 minutes in the instrument before performing calibration. The system will give a pop-up notification: “UV calibrations must be run with vials. Please confirm all locations contain vials. Would you like to continue?”



Once calibration has been selected the instrument the unit will check its temperature and display the attached message. The temp must be within 0.5°C of the unit set temp. If the user clicks yes then the calibration will start if they click no the calibration won’t start.



Instrument View — UV Calibration in Process



Instrument View — Yellow Calibration in Process

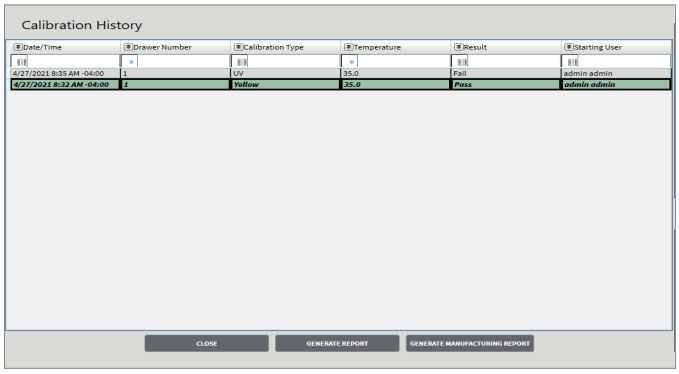
Instrument Calibration

Calibration for UV may take approximately five minutes to complete, while yellow calibration will only take a few minutes. Multiple instruments can be calibrated simultaneously. Once a calibration is complete, the user may view the results by clicking view calibration results.

More Actions Menu — View calibration Results

Viewing Historical Calibration Results

The user may view calibration history by selecting view calibration history. The user may select a calibration record and select generate report to view the full calibration report.

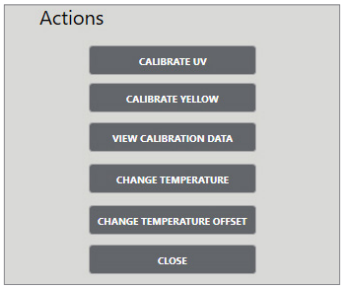


Calibration History Table

Changing the Instrument Temperature

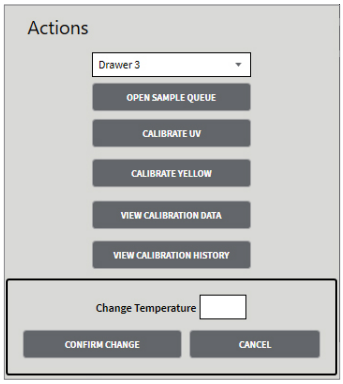
Authorized users may change the instrument temperature.

To change the temperature, access the more actions menu from the instrument grid flyout. Select change temperature.



Instrument View — Actions

The change temperature menu will appear. The user may change the temperature by entering a numeral.



Instrument View — Change Temperature

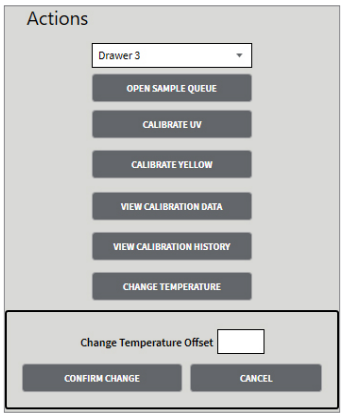
Note: Changing the instrument temperature will require a new calibration be performed at the new instrument set temperature.

Note: The instrument temperature must be within ± 0.5°C of the specified test temperature for a test to start. Please allow 45 minutes for the drawer temperature to stablize.

Changing the Instrument Temperature Offset

Authorized users may change the instrument temperature offset.

To change the instrument temperature offset, access the more actions menu from the instrument grid flyout. Select CHANGE TEMPERATURE OFFSET and change the value by entering a numeral into the box.



Instrument View — Change Instrument Temperature Offset

Note: Refer to fusion temperature verification IQ/OQ for details on performing a temperature offset change.

Chapter Seven

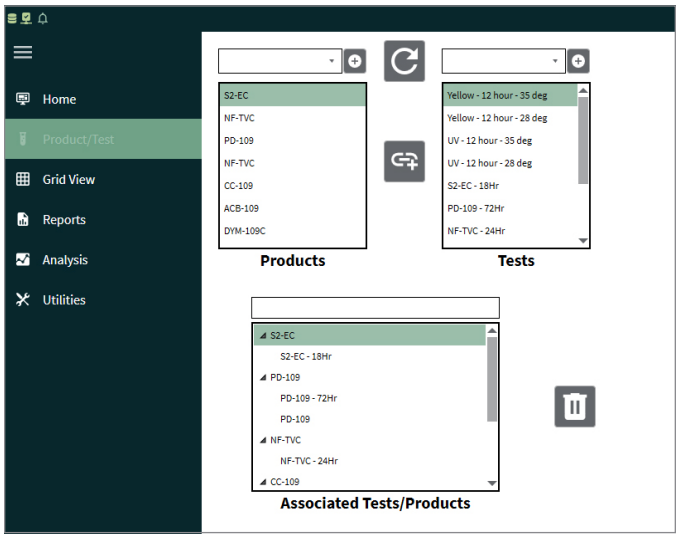
Products and Test Administration

Products

The products and test menu allows the users to create products and tests unique for their testing.

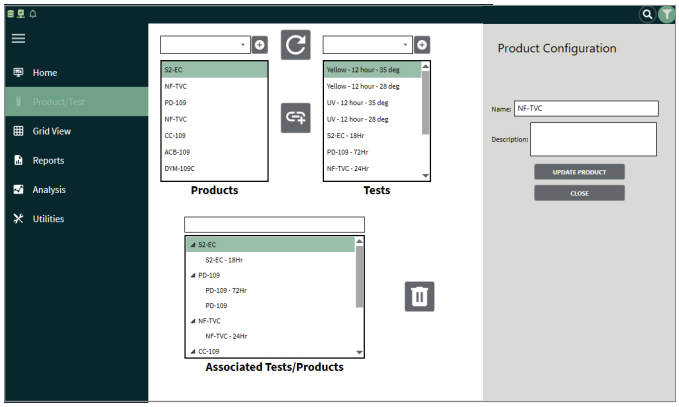
Products can be viewed and administered in the products and test menu.

A product name is the name that describes the product being tested. The products and test menu allows the user to create, modify, or delete products. The user can search for an existing product by either scrolling through the products list or using the drop-down filter.



Products and Test Menu

When a product is selected, the product configuration window will appear.

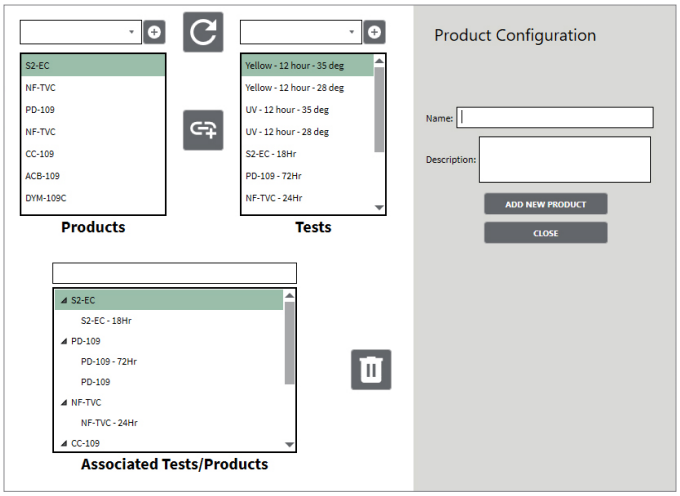


Product Configuration Window

Authorized users can create, modify, or delete a product. To modify an existing product, edit the product properties and select update product.

Creating Products

To create a new product, the user must select the + icon in the products and test menu. This opens the product configuration window.



Product Configuration Window

Enter the following product parameters:

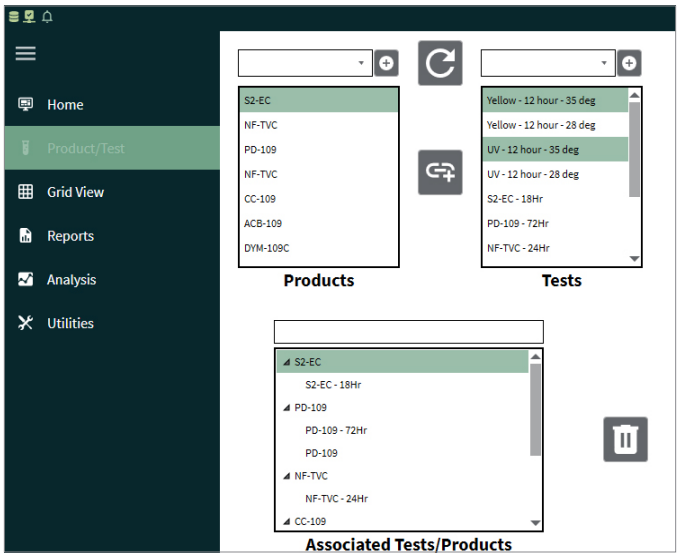
- **Product name:** Examples: Yogurt, Milk, Vitamin C. Can be up to 40 characters.
- **Description (optional):** Example: Vitamin B12 at 1000IU. Can be up to 256 characters.

Tests

Tests can be viewed and administered in the products and test menu.

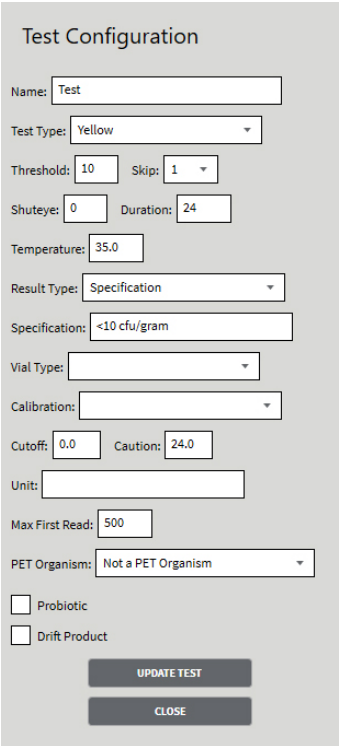
A test is a microbiological assay that can be performed, such as total count, yeast and mold, or coliform, etc. The products and test menu allows the user to view, create, modify, or delete tests.

The user can search for an existing test by either scrolling through the test list or using the drop-down filter.



Products and Test Menu

When a test is selected, the test configuration window will appear.



Test Configuration Window

Creating Tests

To create a test, the user enters the following test parameters:

Test name: A descriptive name for the test.

Test type: The type of light source utilized in the test (yellow or fluorescence).

Threshold level: The required change in optical units to determine a detection point in the curve. A smaller threshold level means a more sensitive algorithm, requiring less change in optical units for a detection time.

Skip: Determines which the detection algorithm uses data points. The default value is one, indicating the system utilizes each data point collected every six minutes in the detection algorithm. A value of two will indicate the utilization of every second point collected every 12 minutes.

Shuteye (number of readings): The algorithm starts looking for a detection time after a certain time period has elapsed. The default option for shuteye is zero, a shuteye value of 25 indicates that the detection algorithm will be activated after two and a half hours or 25 readings.

Duration: The length of the time (in hours) that the assay will run before the automatic stop.

Temperature: The set temperature (in Celsius) that test should be run at. The default setting is 35.0°C. The temperature must be between 15–50°C in order to run a test.

Result type: The user can select specification or presence/absence. This depends on what the user is testing and the test specifications.

Specification/sample size: Depending on the option selected for the result type, the software will automatically reflect the correct type of results.

For specification: It will open a freeform field where the user can enter the required specification (e.g., <10 CFU/g or <100 CFU/mL).

For presence/absence: It will ask for the sample size (e.g., 1 g, 25 g, or 10 g).

Vial type: Optional field where the user can enter the vial type that will be used for this test. This data will show up on the reports page and allow the user to track the number of vials they are using.

Calibration: Allows the operator to choose a calibration curve, relating CFU/g to detection times, to be utilized with the assay.

Cutoff: The sample has counts above the specified level if the detection time is earlier than this time.

Caution: The sample has counts below the specified level if detection times are longer than this time.

Probiotic: The user can click this option, and if detection occurs, the sample is listed as a pass.

Unit: Associated with the calibration curve and the units that the data will be displayed (e.g., CFU/g).

Use as PET prganism: The user can click this option, and it will apply preservative efficacy testing rules.

Max first read: Allows the user to set a maximum first read value to the test. This will allow the user to quickly see if the plug is too light before an assay begins.

Endpoint test: An option if the system is configured for endpoint testing.

Drift product: This check box is related to applying a second derivative to sample analysis.

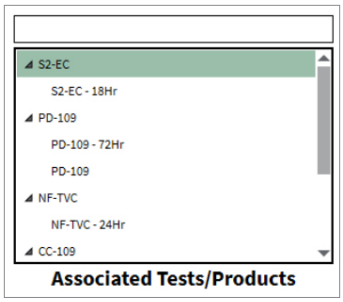
Note: Neogen® will provide initial working parameters for each vial. While initial parameters have been established for each vial type, actual parameters used for testing may differ from the technical sheet, depending on individual matrices being tested.

Associating Products and Tests

Tests can be associated with each product. Select a test and product, and then select the associate icon.

Associate Products and Test Icon

Associated products and tests will be stored in the associated tests and products table.



Associate Products and Test Table

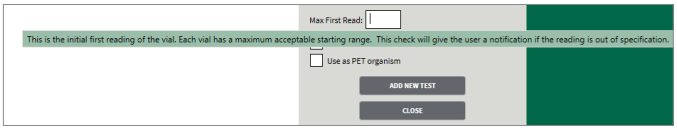
Deleting Products and Tests

Products and tests can be deleted by selecting the product or test, and then selecting the delete icon. Product and test associations can also be deleted in this manner.

Note: If deleted, applicable products and tests will still appear in sample history records.

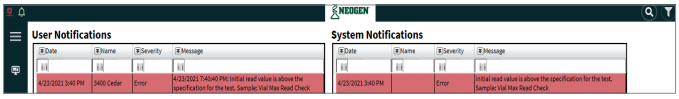
Max First Read Option

This option allows the user to enter a number in the field for each type of test (NF-TVC, CC-109, etc). That will notify the user that the vial used is above that level on the first read and may give an invalid result.



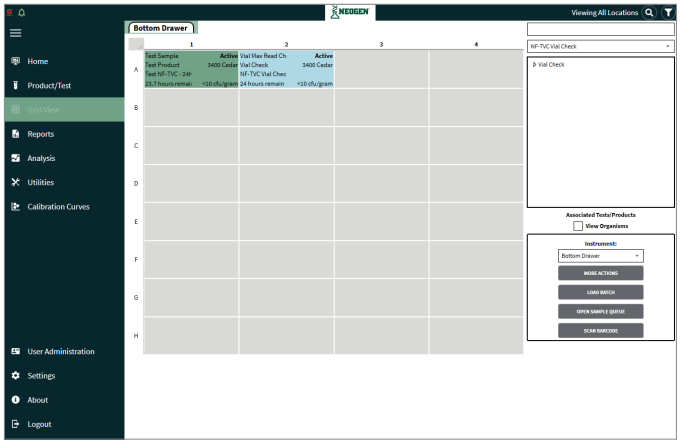
Test Configuration: Max First Read

A notification will appear in the notification table to let the user know about the out of specification first read.



Vial Max Read Error

The grid view will temporarily change the cell location to light blue in the event of the first read being above the set point.

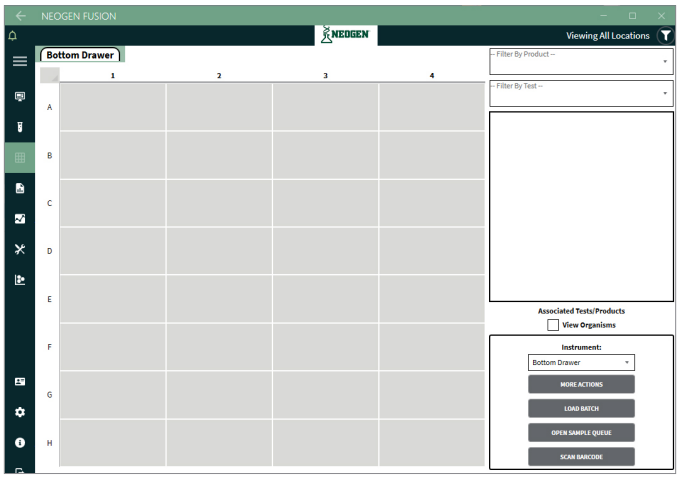


Chapter Eight

Running Tests

Selecting a Test

To start a test, the user must access the grid and instrument menu. The user selects a test from the associated products and tests menu and drags the test to the desired instrument cell location.

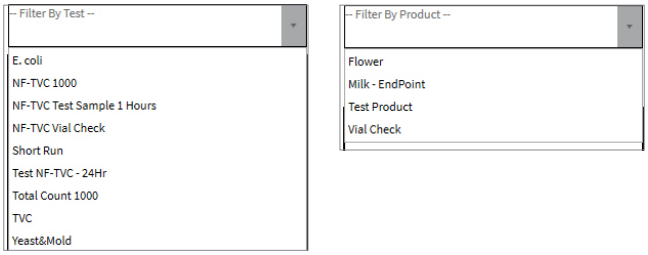


Grid View — No Pending Test

Filter by Test/Product

In the gird view the user can filter the tests by product or test.

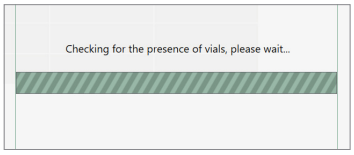
Sample name: up to 100 characters.
Production lot: up to 200 characters.
Description: up to 200 characters.
Vial lot: up to 200 characters.
Supplement lot: up to 200 characters.



Filter View — by Test or Product

Vial Presence Check

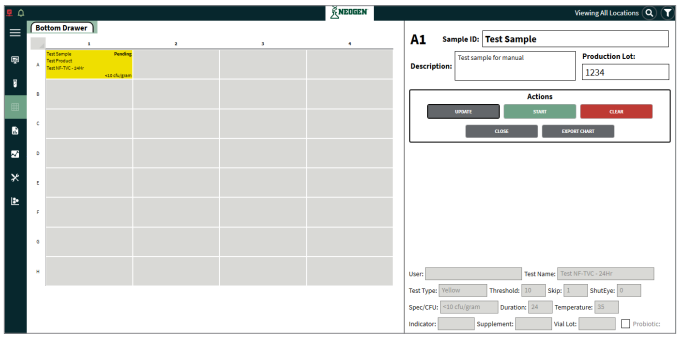
Once the test parameters have been entered, the user must enter the vial and select start test. The system will verify that a vial is present at the desired location. This option can be enabled or disabled in the system settings, along with an option that checks the health of the vial (the over threshold warning). Note that the threshold warning is disabled by default and must be enabled. If the threshold warning is triggered, the vial must be changed in order to proceed.



Dialog — Vial Check

Active Tests View

Once the vial check is complete, the test will begin and be identified as active.



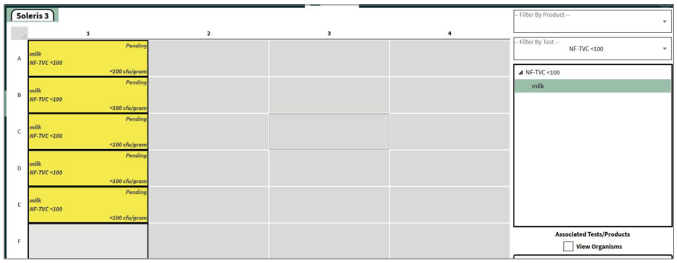
Grid View — Active Test at Location A1

The active test location provides the following detail.

Sample	**Status**
Test	**User**
Product	**Detection Time/CFU**
Time Remaining	**Specification Level**

Multiple Test Locations

The user can select multiple cell locations at once. In the figure below, cells A2, A3, and A4 are all selected.

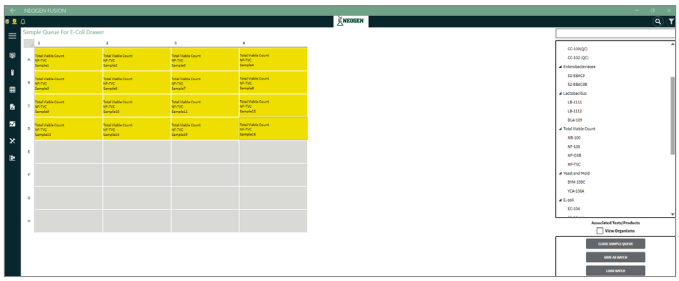


Grid View — Multiple Cells Selected

Pending Test Queue

Users can create a pending test queue.

In the actions flyout, the user selects open sample queue. The user can populate the pending sample queue grid in the same manner as the active test view. The pending grid cell will display sample ID, product name, and test name.



Grid View — Sample Queue View

Note: The cell turns orange when the calibrated temperature of the drawer is more than ± 0.5 from the test temperature set in the test configuration.

Starting a Test from a Pending Queue

Once the pending sample queue has been created, the user can start the samples. The user can either right-click on the cells desired to start or double-click on a cell to start that location.

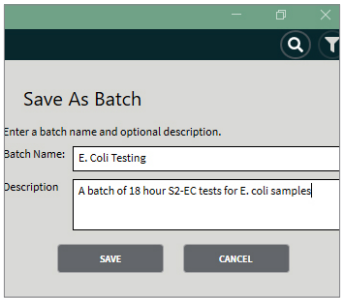
Note: The start button is only enabled if an active cell is available for running sample.

The user can exit the pending queue view by selecting the close sample queue icon. This will return the user to the active grid. Once a sample is started, it is removed from the sample queue.

Batch Testing — Creating and Saving Batch

The user can create, save, and recall a test batch. A test batch comprises up to 32 tests. Any batch will include: batch name, sample id, products, and test.

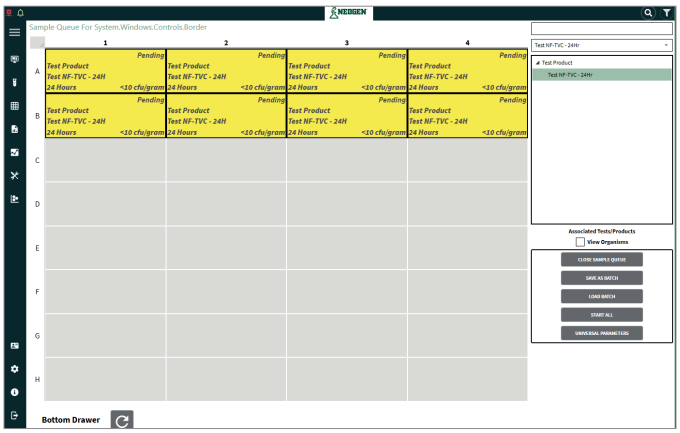
To create a batch, the user populates the pending queue with the desired tests. Once the user has populated the sample queue with the batch, the user selects the save as batch icon and enters a batch name.

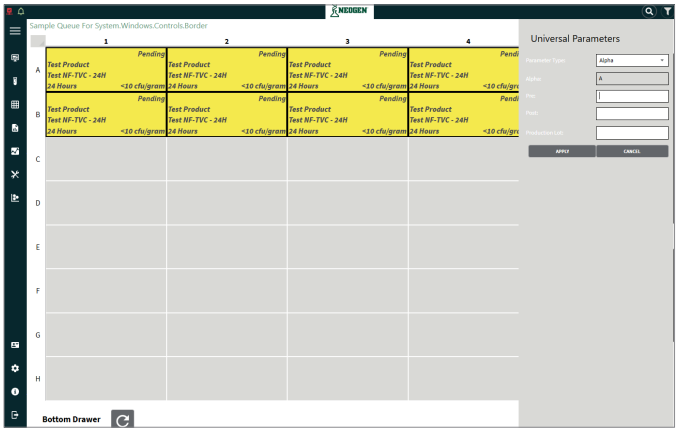


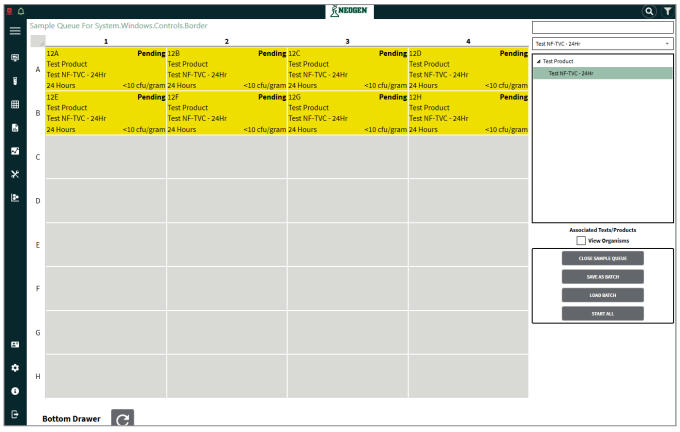
Grid View — Save Pending Queue as Batch

Running Tests

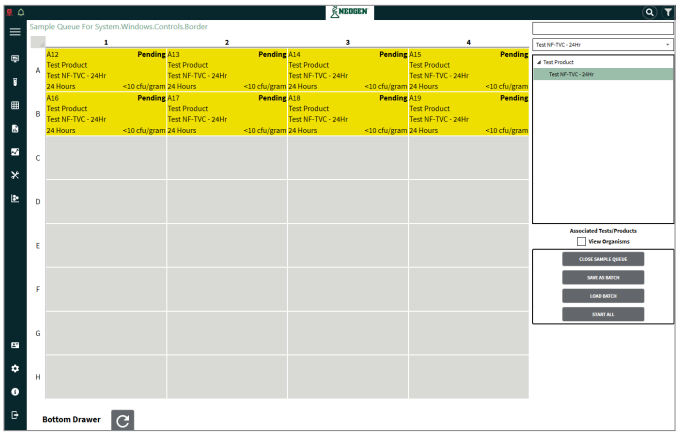
Universal parameters: When in the batch creation sheet, and samples are selected, the universal parameter button appears.

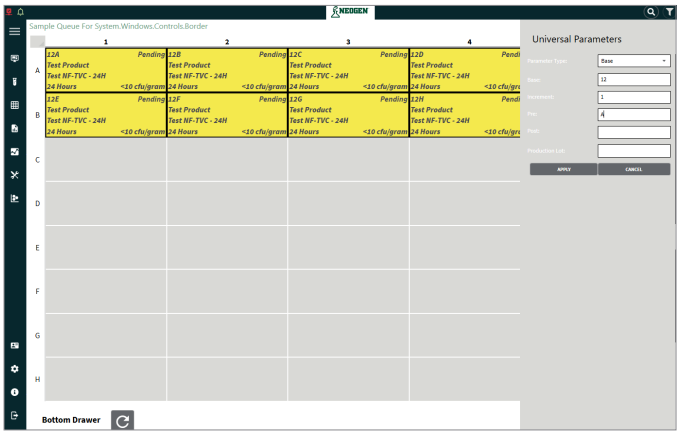






Running Tests





Parameter type: Select sample, alpha, or base.

Sample: Enter the sample ID that will be applied to each cell.

Parameter type alpha: Enter the sample ID, and the universal parameter will apply A–FF depending on the number of cells selected.

Pre: Will put the sample ID first, then the associated alpha or base applied.

Post: Will put the sample ID after the associated alpha or base.

Parameter type base: Enter the sample ID, and the universal parameter will apply a number, depending on the number of cells slectected and the increment that each number will increase by.

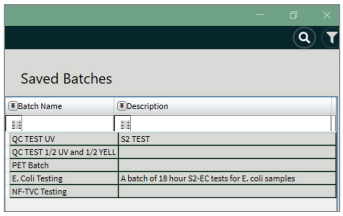
Base: Will use the base number to start the numbers post/pre sample ID.

Increment: Will apply the increment of how much the base number will change as it goes through the number of samples selected.

The saved batch will now appear in the list of saved batches.

Note: If an existing batch name is entered, the user will be notified that batch name already exists and another should be entered.

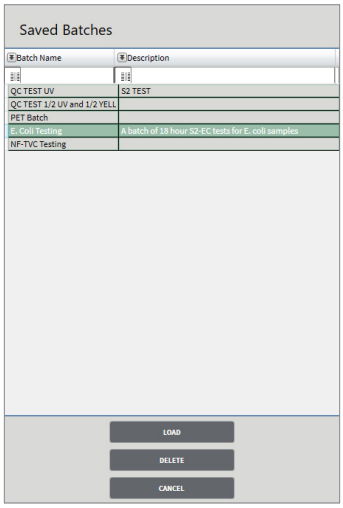
Note: Only system administrators and managers can create a batch.



Grid View — Saved Batch

Batch Testing — Loading a Saved Batch

To load a saved batch, the user selects the saved batch they wish to load, and then selects the load button. The selected batch is brought into the sample queue window.

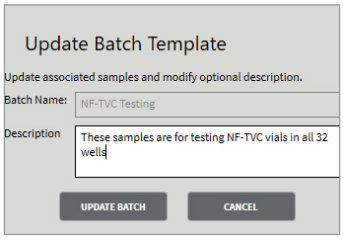


Grid View — Load Batch

When a batch is loaded, the latest test and product parameters are used. The individual test types are validated against the drawer type. Invalid test types are not loaded into the pending queue. Invalid test types will show an error.

Updating a Batch

A user may update a saved batch by loading the saved batch. The user may make any changes to the batch, including samples and description, and then select update batch to apply changes.



Confirm Delete Batch

Note: Only administrators and managers can update a batch.

Deleting a Batch

A user may delete a batch by selecting the saved batch and then selecting delete. The user will be prompted to confirm the action.

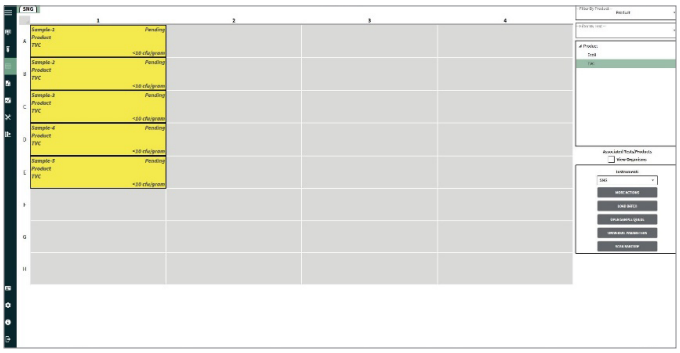
Confirm Delete Batch

Note: Only administrators and managers can delete a batch.

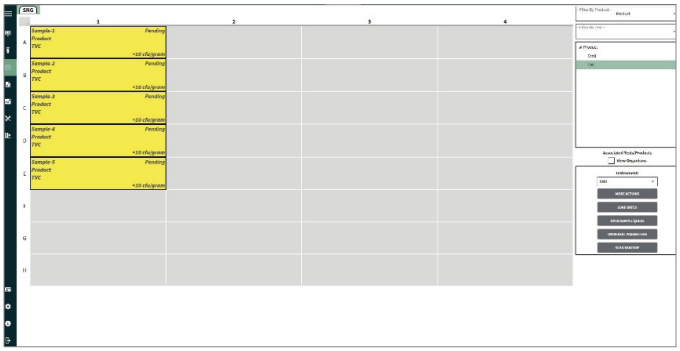
Copy Attributes Feature

The copy attributes feature has been implemented to assist with copying sample IDs from one instrument to another and to limit sample ID errors.

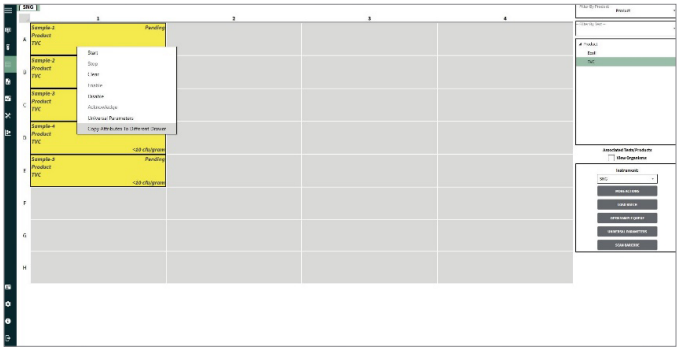
First create new tests with the associated sample ID in one instrument.



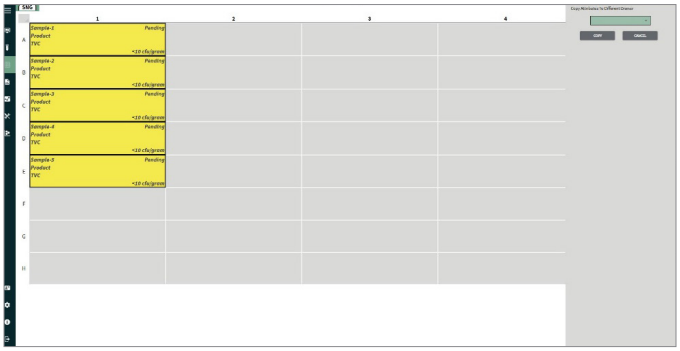
Next, go to another instrument, and select the location on the grid view to where the new tests will be, and the associated sample IDs will be transferred to. The user must select the same number of pending tests to properly copy the sample IDs (i.e., if the user has five pending samples with the sample IDs loaded, they must create five pending samples with the test they would like tested in the instrument).



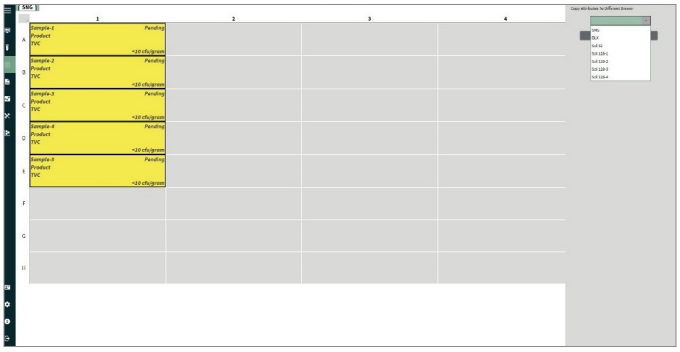
Go back to the original drawer and highlight the tests which the sample ID will be copied from.



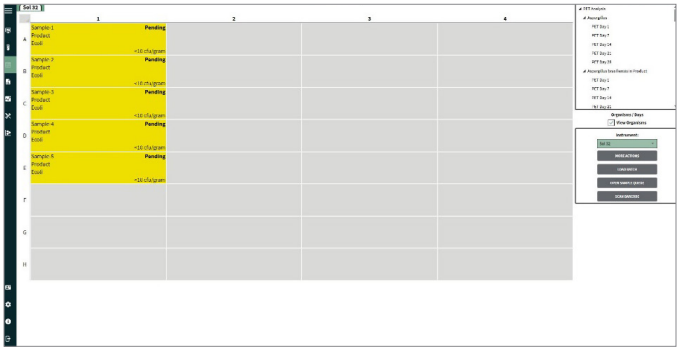
This will prompt the user to select which drawer needs to have the sample IDs copied to.



Select the correct drawer from the drop down menu.

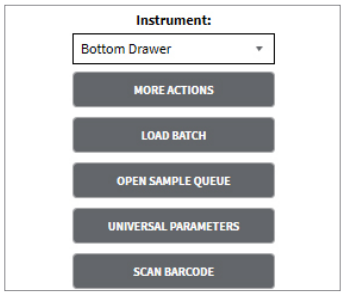


The sample IDs will automatically be copied to the drawer selected that also had the pending samples, then proceed with normal operation of the sample preparation.

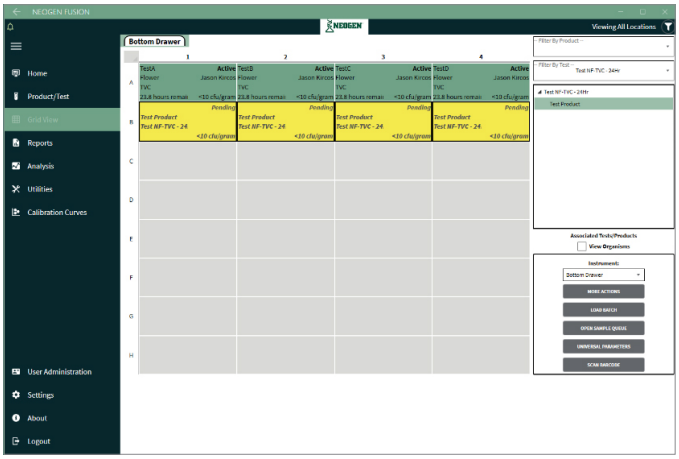


Barcode Scanning

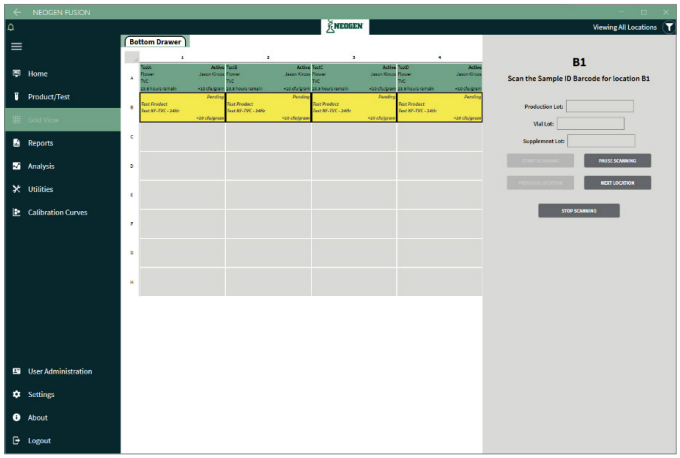
To use the barcode scanning option after selecting tests, click on the scan barcode button.



To use the barcode scanning option after selecting tests, click on the scan barcode button.

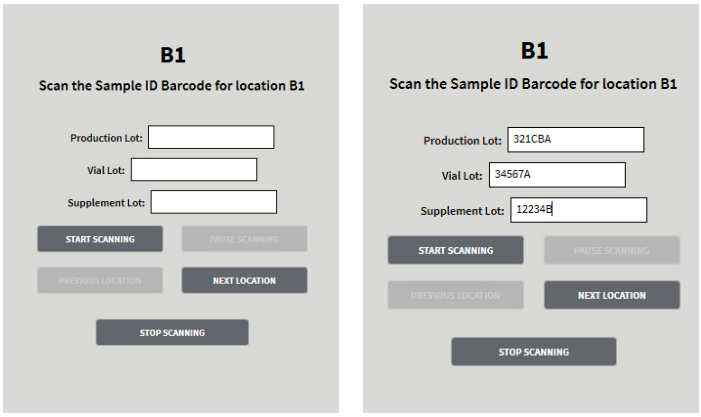


This opens the barcode scanning page.

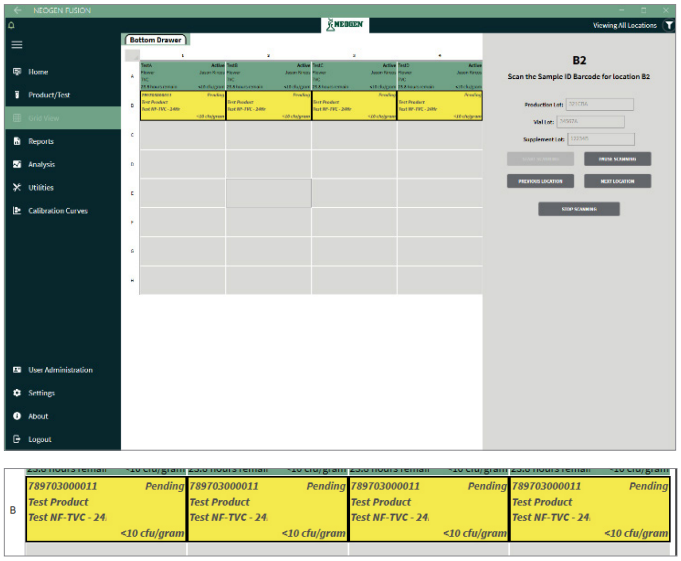


Running Tests

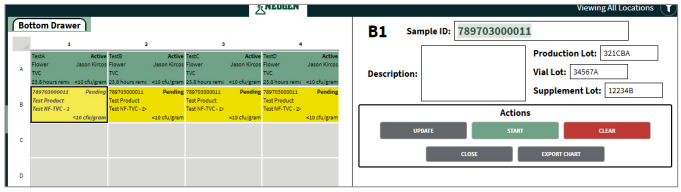
In this field, the user can enter the production lot, vial lot, and supplement lot for the samples that are going to be used. This will apply all entered values to the samples that are scanned. By clicking pause scanning to make the fields editable.



After the user enters all the information in the fields, the they will then be able to click on the start scanning button, which allows the barcode to scan the sample IDs into the grid view.



When the user goes back to the grid view, all of the fields entered will appear.



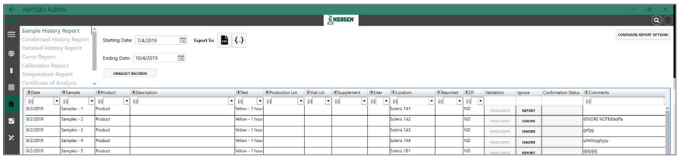
Chapter Nine

Sample History + Reports Menu

Sample History Record

By selecting the reports menu, the user can view a record of all sample history.

Completed samples will appear in the sample history report under the reports menu. Users can filter the record via date range, use prepopulated filters, or create custom filters.

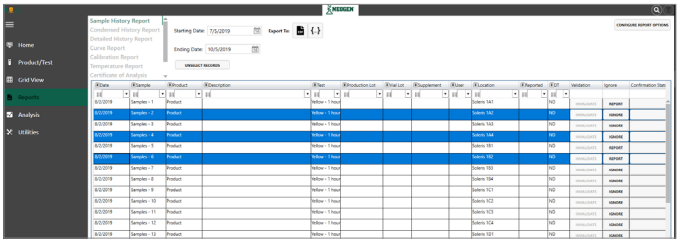


Sample History Report

The following reports are available: sample history report, condensed history report, detailed history report, curve report, temperature report, custom CoA, certificate of analysis, login audit report, sample audit report, calibration report, and efficacy report.

To utilize the available reports, the user can select any samples desired for reporting.

Note: Multiple samples may be selected by pressing the Ctrl key while selecting with the cursor.



Sample History Report — Multiple Samples Selected

Sample history records can be exported to .csv or .json files by selecting the desired records and selecting the export icons.

Export Sample History Records

Confirming Results

The sample history report allows the user to select samples to be exported to .CSV file for use with LIMS systems. The Fusion software provides tools to administer confirmation testing. Users can validate, ignore, or confirm negative samples within the sample history record. The user selects the desired icon to the right of the sample record.

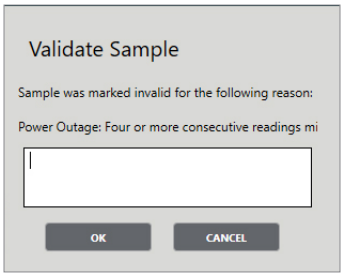
Sample History Record — Confirmation Options

Sample History + Reports Menu

Validate Sample Record

By selecting the record within the sample history record, the user can notate the reason for validation.

The notation will be retained as part of the auditable sample record.

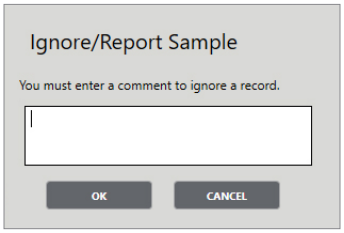


Validate Sample

Ignore Sample Record

By selecting the record within the sample history record, the user can notate the reason for ignoring the sample.

The notation will be retained as part of the auditable sample record.



Ignore/Report Sample

Sample Confirmation

By selecting the record within the sample history record, the user can notate reason for validation.

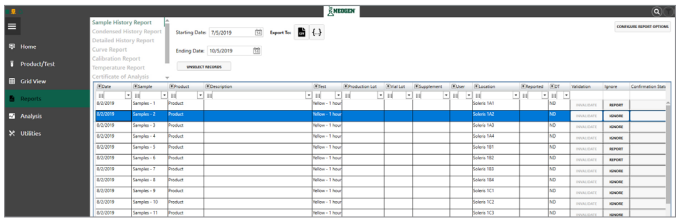
The notation will be retained as part of the auditable sample record.

Sample Confirmation

Condensed History Report

The condensed history report is used to generate a condensed report, based on the following groups: test date, description, detection time, location, product, production lot, reported, sample, supplement, test, and user.

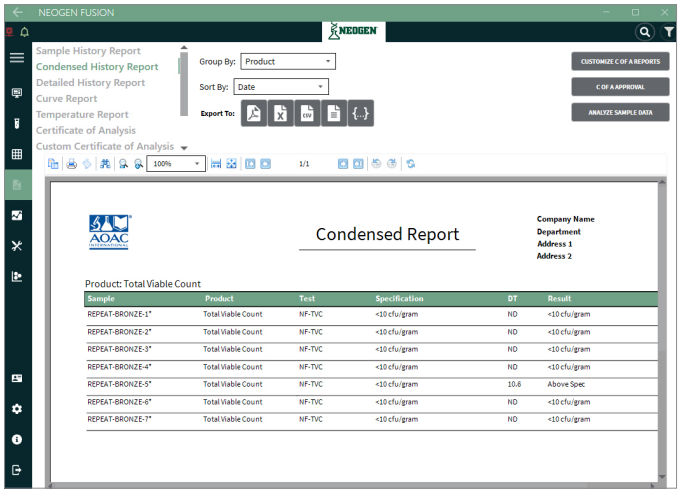
To generate the report, select a sample from the sample history report.



Select Sample from Sample History Report

Then select condensed history report and select group by and date range. The report will update. The report can be sorted by ascending and descending order.

The report is available .pdf, .xls, .csv, .json, and .rtf format.

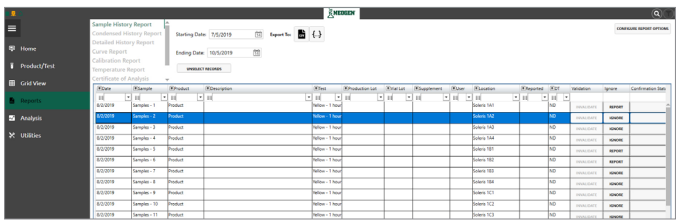


Condensed Report Created

Detailed History Report

The detailed history report is used to generate a detailed report for a single sample, based on the following groups: test date, description, detection time, location, product, production lot, reported, sample, supplement, test, and user.

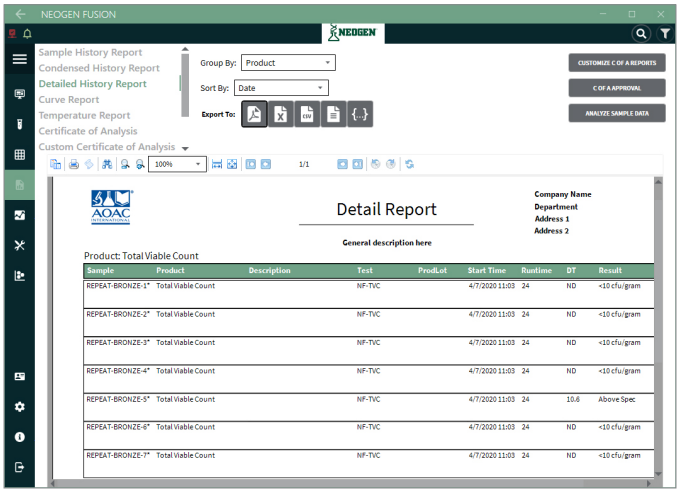
To generate the report, select a sample from the sample history report.



Select Sample from Sample History Report

Sample History + Reports Menu

Then select detailed history report and select group by and date range. The report will update. The report can be sorted by ascending and descending order. The report is available .pdf format.



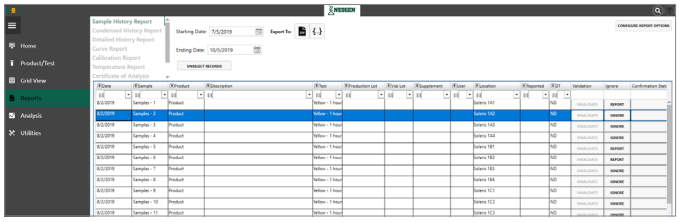
Detailed History Report Created

Calibration Report

This report gives the most recent calibration report of the instrument selected. To see the history of the calibrations of the instrument, go to the grid view, select the instrument, go to more actions and select view calibration history.

Curve Report

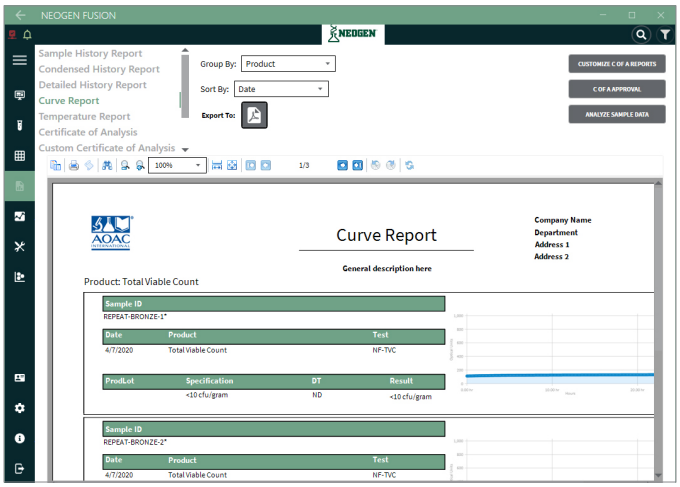
The curve report is used to generate a graph and condensed report for samples based on the following groups: test date, description, detection time, location, product, production lot, reported, sample, supplement, test, and user.



Select Sample from Sample History Report

Then select curve report and select group by. The report will update. The report can be sorted by ascending and descending order.

The report is available in .pdf format.



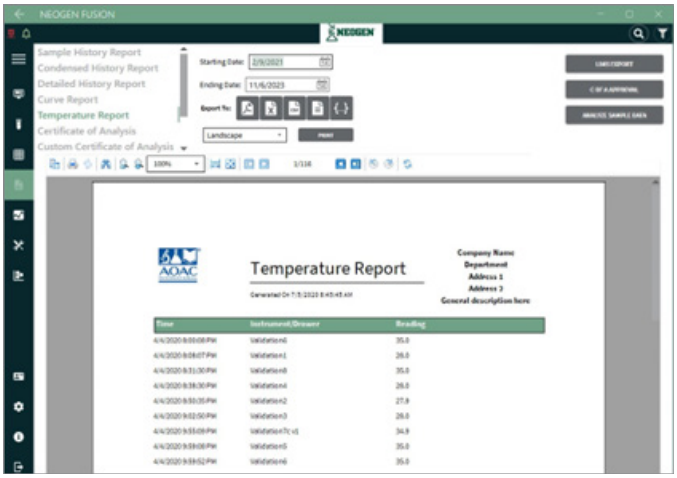
Curve Report

Temperature Report

The temperature report is used to generate temperature reports for a specific range of dates. These reports are used to show temperature readings of each instrument connected to the system. The temperature is recorded every two hours and auto-archived to view in a report. The frequency that the temperature is recorded can be adjusted in the settings menu.

To generate a report, select the date range. The report will update. The report can be sorted by ascending and descending order.

The report is available .pdf, .xls, .csv, .json, and .rtf format.



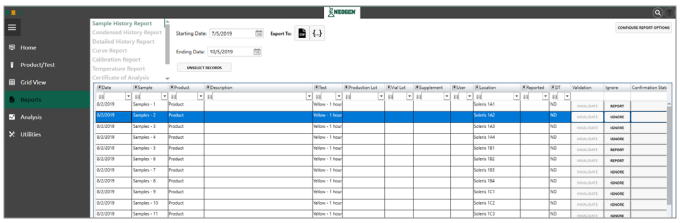
Temperature Report

Certificate of Analysis Report

The CoA report is used to generate certificates for specific samples tested over a range of dates. These reports are used to validate whether a specific sample passed or failed a test.

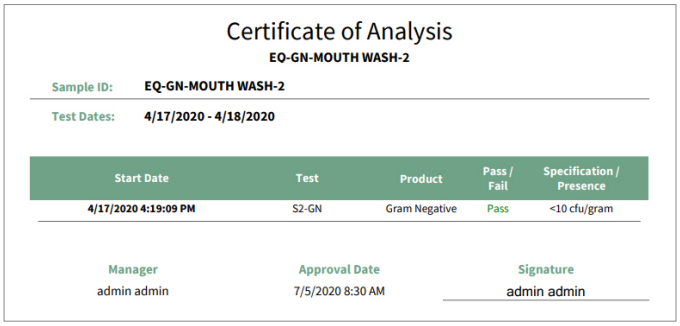
To generate a CoA report, select a sample ID from the sample history record.

Note: The sample ID column, or any column, can be filtered using the custom/default filters available at the left/right of the column header.



Select Sample from Sample History Report

Then, select Certificate of Analysis from the menu on the left. The report will update and is available in .pdf format.



Certificate of Analysis

EQ-GN-MOUTH WASH-2

Sample ID: **EQ-GN-MOUTH WASH-2**

Test Dates: **4/17/2020 - 4/18/2020**

Start Date	Test	Product	Pass / Fail	Specification / Presence
4/17/2020 4:19:09 PM	S2-GN	Gram Negative	Pass	<10 cfu/gram

Manager	Approval Date	Signature
admin admin	7/5/2020 8:30 AM	admin admin

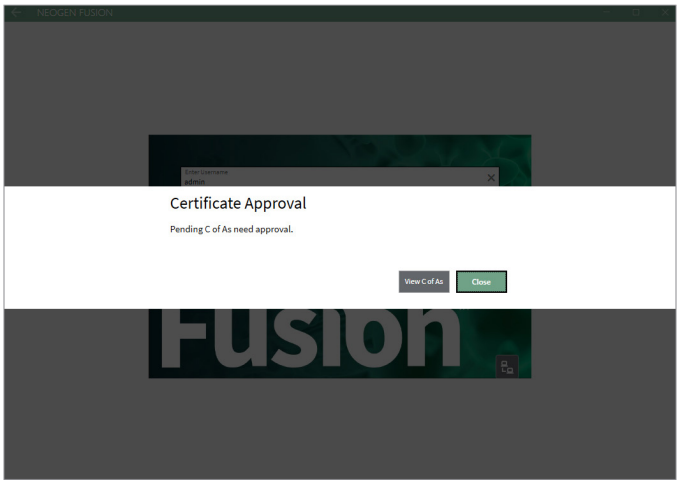
CoA Generated

After the CoA generates, you can submit the CoA for approval. Select the manager responsible for the approval from the available drop-down list, then click Submit C of A for Approval.

Submitting CoA for Approval

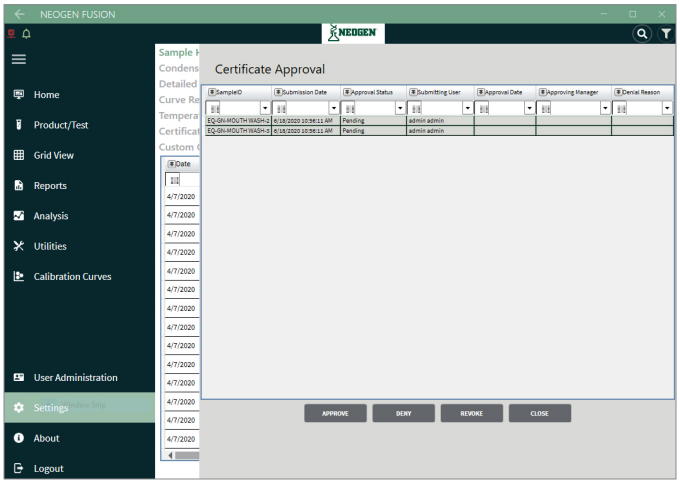
Sample History + Reports Menu

By clicking this option, the CoA is added to the system to be signed off by a manager or admin. When the admin or manager signs in to the system, the following screen displays:



Certificate Waiting for Approval

If the user chooses to view CoA, they are sent to a list of certificates of analysis that are awaiting approval.

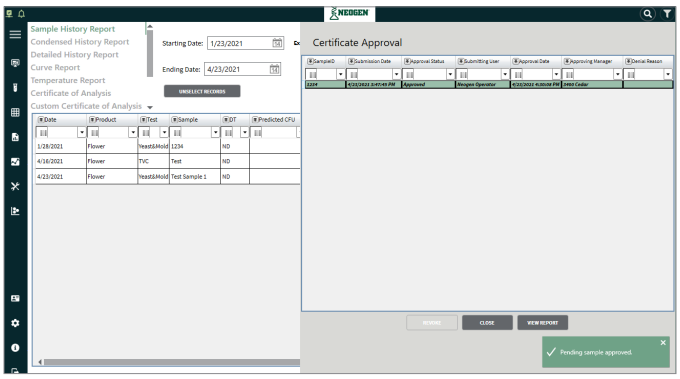


Certificate of Approval Screen

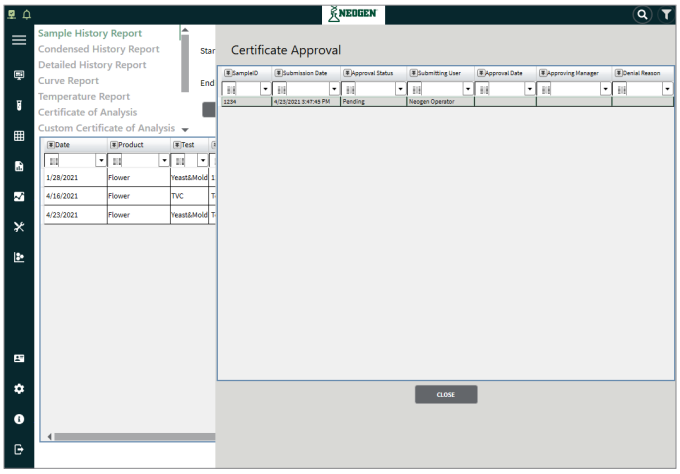
Sample History + Reports Menu

The user can select the following options:

Approve — The CoA is approved, and an electronic signature is applied.

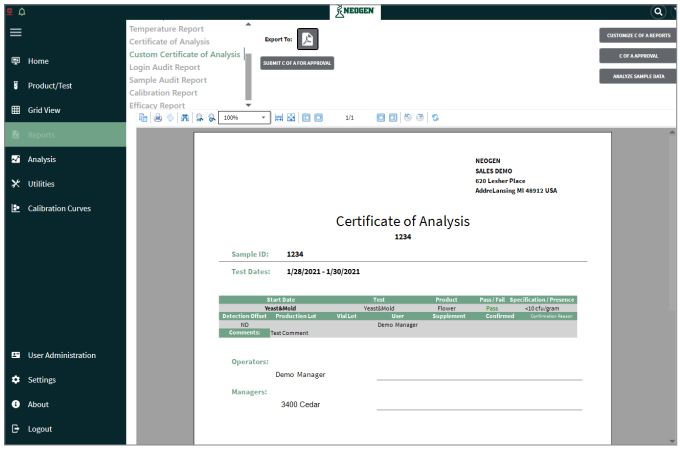


Deny — The CoA is denied, and the electronic signature is not applied.



Custom CoA

The custom CoA report is used to generate certificates for specific samples tested over a range of dates. These reports are used to validate whether a specific sample passed or failed a test. The user can decide which field will show up on the CoA.



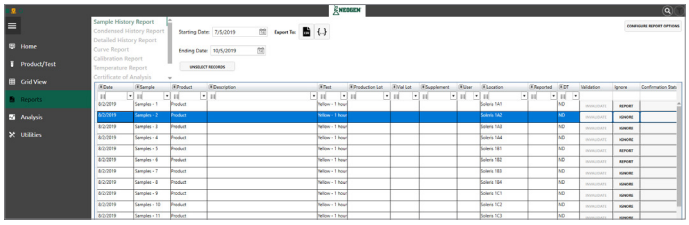
Sample History + Reports Menu

The following fields are optional on the custom CoA:

- Detection Offset
- Production Lot
- Vial Lot
- User
- Supplement
- Confirmed
- Confirmation Reason
- Sample Description
- Comments

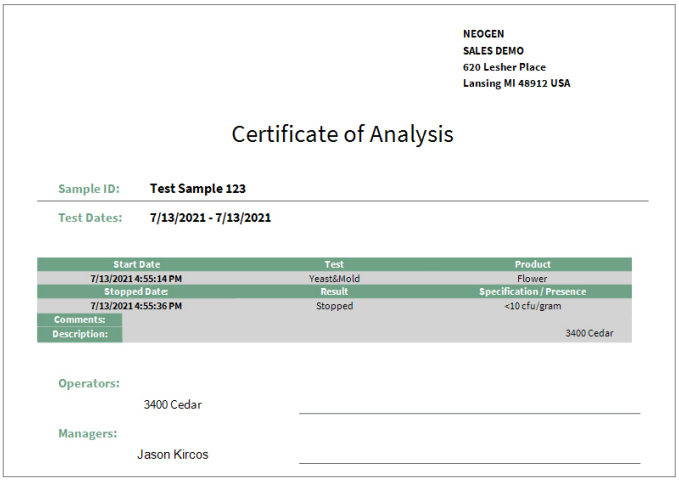
To generate a CoA report, select a sample ID from the sample history record.

Note: The sample ID column, or any column, can be filtered using the custom/default filters available at the left/ right of the column header.



Select Sample from Sample History Report

Then select custom CoA. The report will update and is available .pdf format.



NEOGEN
SALES DEMO
620 Lesher Place
Lansing MI 48912 USA

Certificate of Analysis

Sample ID: **Test Sample 123**

Test Dates: **7/13/2021 - 7/13/2021**

Start Date	Test	Product
7/13/2021 4:55:14 PM	Yeast&Mold	Flower
Stopped Date	**Result**	**Specification / Presence**
7/13/2021 4:55:36 PM	Stopped	<10 cfu/gram
Comments:		
Description:		3400 Cedar

Operators:
3400 Cedar

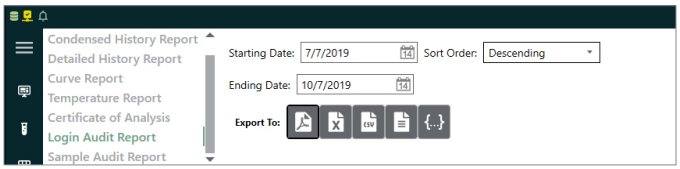
Managers:
Jason Kircos

Custom CoA Generated

Sample History + Reports Menu

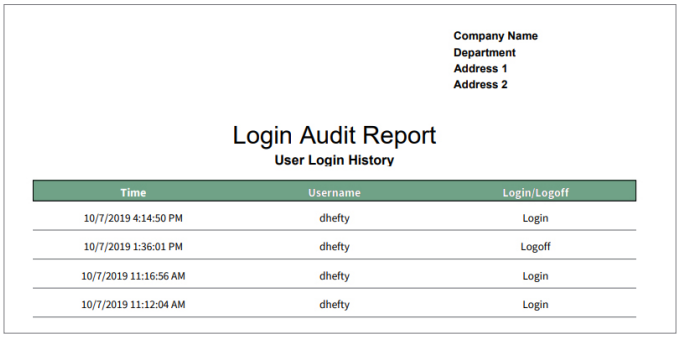
Login Report

The login report is used to generate user login history reports for a specific range of dates. These reports are used to show the login/logout history of each user accessing the system.



To generate a report, select the date range. A dialogue will appear when the file is created, stating that the file has been created and ask the user if the file should be opened. The report is available .pdf, .xls, .csv, and .rtf format.

The report can be sorted by ascending and descending order. The report UI will sort by most recent first and will provide a customized report title and subtitle, which is pulled from system settings.



Company Name
Department
Address 1
Address 2

Login Audit Report

User Login History

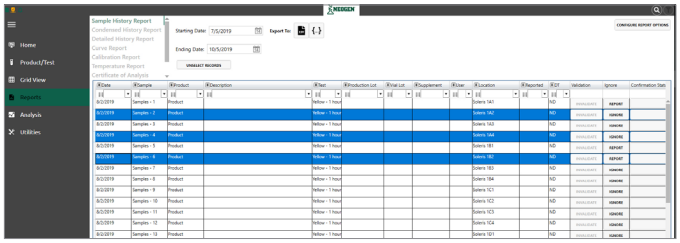
Time	Username	Login/Logoff
10/7/2019 4:14:50 PM	dhefty	Login
10/7/2019 1:36:01 PM	dhefty	Logoff
10/7/2019 11:16:56 AM	dhefty	Login
10/7/2019 11:12:04 AM	dhefty	Login

Login Audit Report

Sample Audit Report

The sample audit report is used to generate detailed reports for a specific range of tests. These reports are used to show the following test results: test date, start time, sample ID, product, test, detection time, test duration, technician, specification tested, stopped by, stopped at, confirmed, unconfirmed by, unconfirmed date, and confirmation reason.

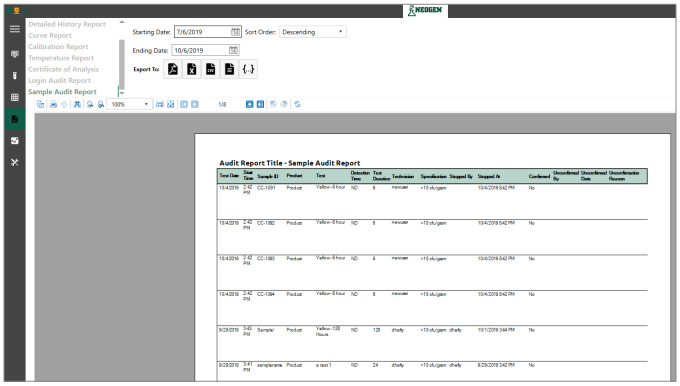
To generate a report, select the desired samples from the sample history report.



Select Samples from Sample History Report

Sample History + Reports Menu

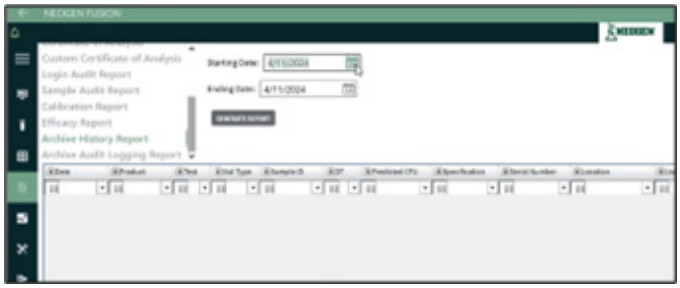
Then select sample audit report from the reports menu. The report will update. The report is available .pdf, .xls, .csv, and .rtf format.



Sample Audit Report

Archive Audit Logging Report & Archive History Report

The archive audit logging report is used to track when data is archived.

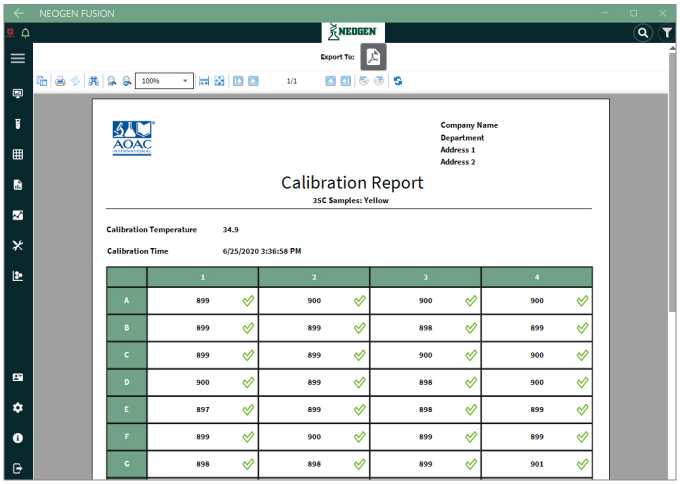


The archive history report is used to generate a report with all archived data for the selected date range. To generate a report, select archive history report from the reports menu, choose a date range, then click generate report.

Calibration Report

The calibration report is used to generate the most recent calibration report that was generated by the system on the current instrument selected.

Then select the calibration report. The report will update and is available .pdf format.



CoA Generated

LIMS Output

The Fusion software is able to export reports to a variety of file types that are compatible with LIMS, including .csv, .xlsx, .rtf, and .json. Please contact Neogen Technical Service Help Desk if assistance is needed.

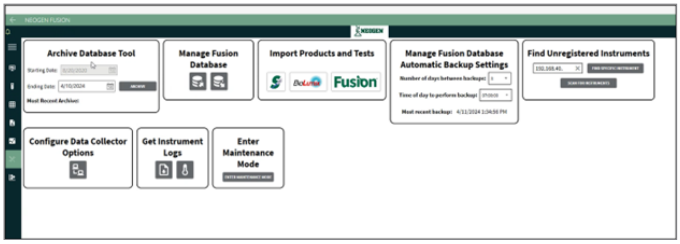
Print a Report

The print option is available on every tab within the Reports section. From the available drop-down list, select either landscape or portrait mode, then click the Print button.

Chapter Ten

Utilities Menu

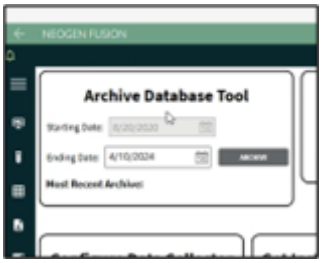
The utilities menu provides authorized users tools to support the software.



Archive Database Tool

Authorized users can perform a database archive, which moves all data from the defined date range into a separate archived database. Archived data does not display in your everyday reporting and instead can be found in an Archive History Report under the Reports menu.

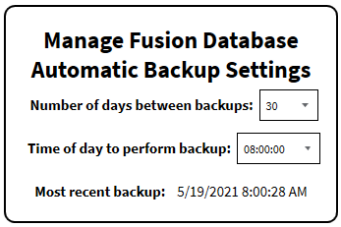
To archive your data, select a date range in the archive database tool, then click Archive. Note that the starting date defaults to the earliest date on record.



After starting the archive process, you will be prompted to confirm your selection. Click Yes to continue, then click Ok. The archive process may take some time depending on the amount of data being archived. Do not close the software or turn off your computer until the system notifies you that the archive process is complete.

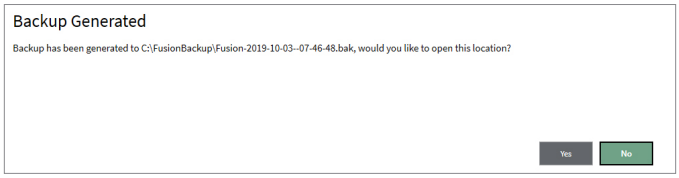
Manage Fusion Database — Generating a Backup File

Authorized users may manage the database by accessing the manage Fusion database utility.



Utilities — Manage Fusion Database

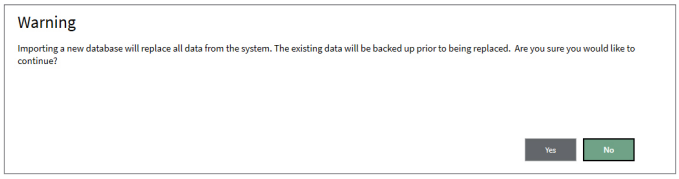
The user may create a backup file of an existing database by selecting the backup Fusion database icon. This will generate a .bak file containing a copy of the entire database, including current usernames and passwords. Once the user selects the backup icon, the user will be notified that the file has been created and be notified of the generated file location.



Confirmation Dialog — Backup Generated

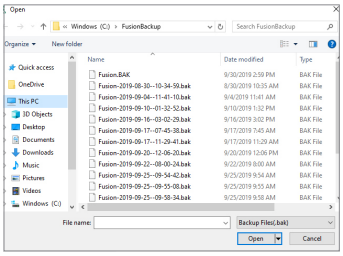
Manage Soleris Database — Restoring a Backup File

Authorized users may restore the Fusion software from a backup file. The user may restore the software to a previous backup file database by selecting the restore Fusion database icon. The user will be notified of the pending update to the system.



Confirmation Dialog — Importing Database

Once the user acknowledges the warning, a Windows File Explorer window will open, allowing the user to select a .bak file.



Windows File Explorer — Selecting .bak File

Once the user selects the .bak file for import, and the restore backup is complete, the user will be notified and logged off.

Note: Usernames and passwords will be restored in accordance with the .bak file. Existing usernames and passwords may be overwritten and restored to the backup status.

Confirmation Dialog — Backup Generated

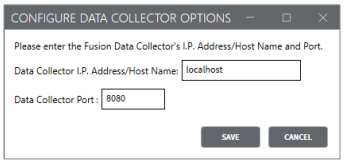
Manage Fusion Database — Import Legacy Products and Tests

Authorized users may restore products and tests only from Soleris, BioLumix®, or Fusion databases.

The user selects Soleris or BioLumix on the Fusion software from a backup file. The user may restore the software to a previous backup file database by selecting associated backup file. The user will be notified of the pending update to the system.

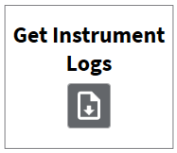
Configure Data Collector Options

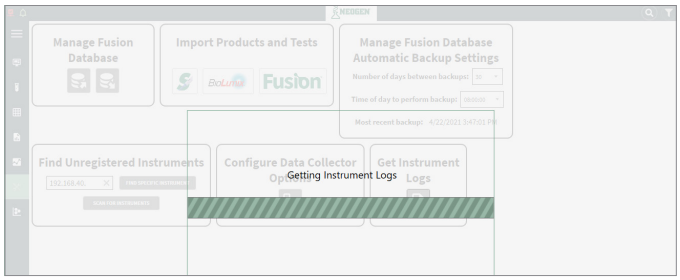
This is an advanced option to use when a customer has multiple Neogen software products. The current configuration is correct, if there are any questions, please contact Neogen Technical Service.

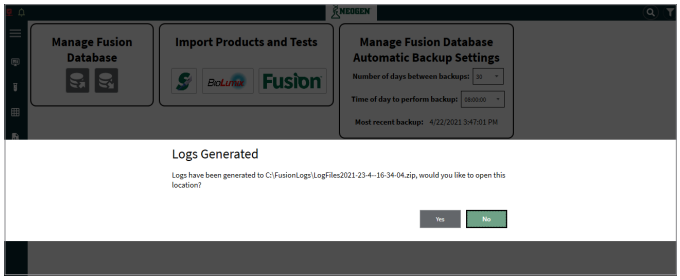


Get Instrument Logs

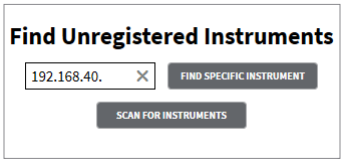
This is a way to collect the most recent log of software issues that can assist the Neogen Technical Service team is solving problems. It will generate a file that can be sent via email. A blocking marquee will appear and block any other function while the log is being created. The user will then be notified once the log has been created and the location of the zip file that can be sent to Neogen.







Find Unregistered Instruments



This tool also finds any instruments that are connected to the computer but not yet registered to use in the software.

Enter Maintenance Mode

This is only used by the Neogen Microbiological Technical Service team to run reports for the preventive maintenance. Accessed through the administrative account.

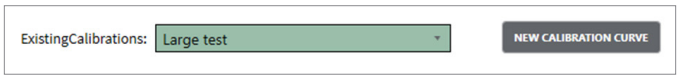
Chapter Eleven

Calibration Curves

General

The calibration curves menu provides tools for correlating CFU with detection time. On the main toolbar, there is an icon for calibration curves.

The calibration curves menu provides a drop-down menu of existing calibrations and a button for creating a new calibration.



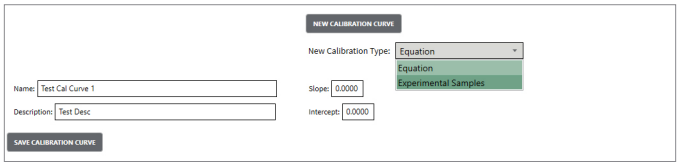
Calibration Curves — Existing Curve Drop-Down and New Calibration Curve Button

There are two types of calibration curves: equation and experimental sample. See detail below for both types of calibration curves.

Note: All users can view, create, and modify calibration curves.

Creating New Equation Calibration Curves

Once new calibration is selected, the user will be presented with a drop-down menu with new calibration type options: experimental samples and equation.



Create New Calibration Curve — Calibration Type Options

When the user selects calibration type equation, the slope and intercept fields will appear. The user must assign a calibration name and description into the respective fields. Slope and intercept fields will auto-populate to four decimal places — they will fill with zeros even if the user does not enter any values.

Note: The slope field will only accept negative numbers.

Note: The intercept field will only accept positive numbers.

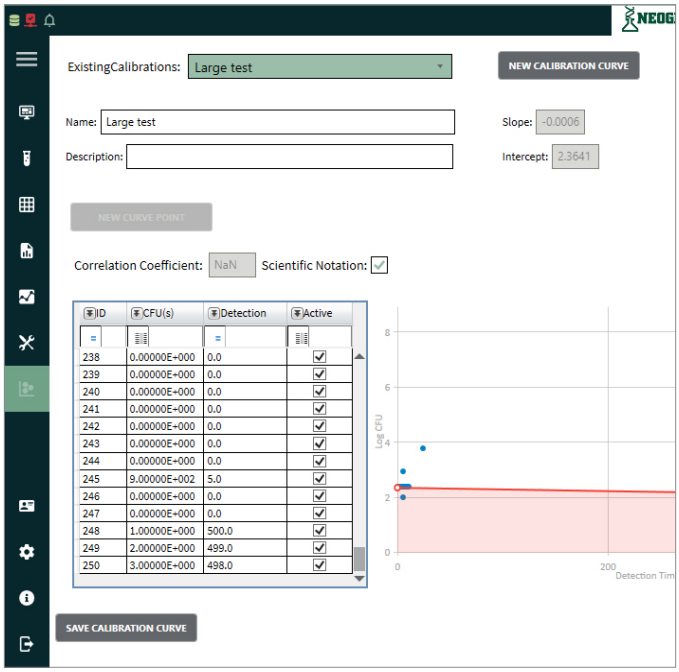
If the user selects save, and the slope and intercept fields are blank, an error message will appear.

The save button will save data to the database and refresh the list of existing calibrations.

Note: All users can view, create, and modify calibration curves.

Creating New Experimental Sample Calibration Curves

When experimental calibration curves is selected from the drop-down menu, the calibration data graph and data entry grid appear. The data entry grid consists of the following columns: ID, CFU, detection, and active.

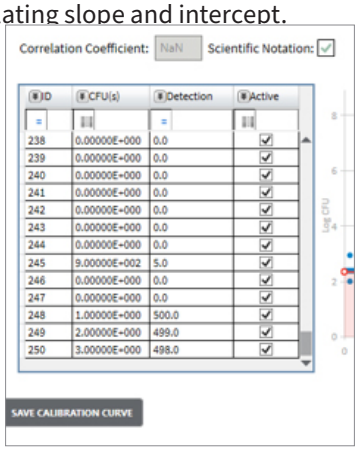


Calibration Curves — Experimental Samples Overview

Experimental Sample Calibration Curves — Data Entry Grid

The first row of the data entry grid will default to one for ID and increment for each additional row. The user can enter up to 250 total points. The user must enter in at least three points in the data entry grid before any calculations are started.

If the active column toggled is unchecked, the point will not appear on the calibration data graph and will not be taken into consideration when calculating slope and intercept.



Experimental Sample — Data Entry Grid

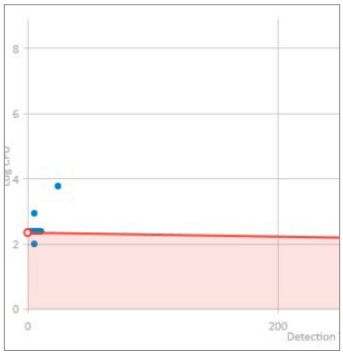
The CFU column defaults to scientific notation view. The active column defaults to checked. If the active column toggled is unchecked, the point will not appear on the data entry grid and will not be taken into consideration when calculating slope and intercept.

Once user selects save, the calibration points, slope, intercept, and correlation coefficient are saved to the experimental calibration curve.

Note: If scientific notation view is off, the user can only enter numbers into CFU (whole numbers) and detection fields (decimals).

Experimental Calibration Curves — Calibration Data Graph

When a point is selected in the data entry grid, it is highlighted in the calibration data graph.



Experimental Sample — Calibration Data Graph

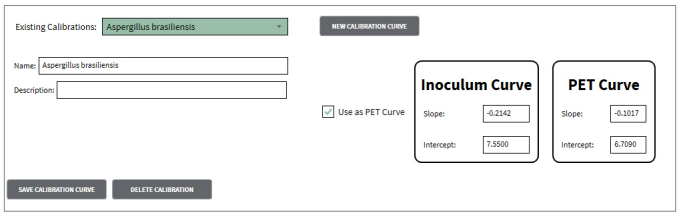
Points are plotted on the calibration data graph as they are entered into the data entry grid. A red line will indicate slope on the calibration data graph.

Chapter Twelve

Preservative Efficacy Testing

Background

The ultimate purpose of the Preservative Efficacy Test (PET) is to determine the effectiveness of the preservative(s) present in a cosmetic or toiletry or pharmaceutical product. USP Chapter <51> Antimicrobial Effectiveness Testing describes the type of products to be tested (categories), the specified microorganisms to be used for testing, and the inoculum and log reduction amounts required per category of product. The product to be tested is inoculated with a high number of bacteria, yeast, and mold, and the reduction in the initial inoculum amount is calculated over a 28-day period.



Key Definitions

D value — Time required to achieve a reduction in counts by 10 fold.

DT — The detection time in hours using Soleris instrument.

Line equation — The equation of the line relating Log CFU to DT, obtained by linear regression.

Efficacy test — There are several terms used interchangeably for this assay, including challenge test, efficacy test, Preservative Efficacy Testing (PET), Antimicrobial Efficacy Test (AET), etc.

USP microorganisms used:

- *Candida albicans ATCC 10231*
- *Escherichia coli ATCC 8739*
- *Pseudomonas aeruginosa ATCC 9027*
- *Staphylococcus aureus ATCC 6538*
- *Aspergillus brasiliensis ATCC 16404*

These are the standard organisms required by USP. Each individual company may have other single organisms they wish to utilize and can create unique calibration curves or contact Neogen Technical Service for assistance.

Products, Inoculum, and Log Reduction

Products are separated into four categories depending upon their composition:

Table 1. Product Catergory and Description

Category	Product Description
1	Injections, other parenterals, including emulsions, otic products, sterile nasal products, and ophthalmic products made with aqueous bases or vehicles.
2	Topically used products made with aqueous bases or vehicles, nonsterile nasal products, and emulsions, including those applied to mucous membranes.
3	Oral products other than antacids, made with aqueous bases or vehicles.
4	Antacids made with an aqueous base.

Preservative Efficacy Testing

Depending upon the category of product being tested, the final concentration of the organism after inoculation into product will vary:

Table 2. Inoculum Amounts per Category

Category	Inoculum Amount
1–3	Between 1 x 10^5 and 1 x 10^6 CFU/mL
4	Between 1 x 10^3 and 1 x 10^4 CFU/mL

Each product composition requires a different log reduction in bacteria, yeast, and mold from the initial inoculated amount:

Table 3. Log Reduction Requirements

For Category 1 Products	
Bacteria:	Not less than 1.0 log reduction from the initial calculated count at seven days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.
Yeast and Molds:	No increase from the initial calculated count at seven, 14, and 28 days.
For Category 2 Products	
Bacteria:	Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.
Yeast and Molds:	No increase from the initial calculated count at 14 and 28 days.
For Category 3 Products	
Bacteria:	Not less than 1.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.
Yeast and Molds:	No increase from the initial calculated count at 14 and 28 days.
For Category 4 Products	
Bacteria, Yeast, and Molds:	No increase from the initial calculated count at 14 and 28 days.

Diluent Broths

Any diluent containing neutralizing agents may be used, but Neogen Culture Media (NCM) TAT broth has shown to be effective across different matrix types. Below are examples of diluents that can be used:

- TAT Broth
- Modified Letheen Tween Broth
- Eugonic Broth
- D/E Neutralizing Broth

A suitability test must be performed before the initiation of the PET test to show that the diluent used does neutralize the product inhibitors and allow proper growth (see USP Chapter <61>).

Preparation of Inoculums

The viable organisms used in PET may not be more than five passages removed from the original stock culture.

- Bacteria and *C. albicans*

A lawn of each organism should be created using the reference agars, incubation times, and temperatures shown in table 4 below. After the lawn has developed, a sterile swab is used to transfer a sufficient amount to phosphate buffer, creating a minimum suspension appropriate to the category. A turbidity meter would be a useful tool to determine the initial concentration of the suspension.

- *A. brasiliensis*

A lawn of the organism should be created using the reference agar, incubation time, and temperature shown in the table below. After the lawn has developed, a sterile swab is used to transfer a sufficient amount to phosphate buffer containing 0.05% polysorbate 80, creating a minimum suspension appropriate to the category.

Table 4. Preparation of Culture Organisms

Organism	Suitable Medium	Incubation Temperature (°C)	Inoculum Incubation Time (hours)	Microbial Recovery Incubation Time (days)
Escherichia coli (ATCC No. 8739)	Soybean–Casein Digest Broth; Soybean–Casein Digest Agar	32.5 ± 2.5°	18–24	3–5
Pseudomonas aeruginosa (ATCC No. 9027)	Soybean–Casein Digest Broth; Soybean–Casein Digest Agar	32.5 ± 2.5°	18–24	3–5
Staphylococcus aureus (ATCC No. 6538)	Soybean–Casein Digest Broth; Soybean–Casein Digest Agar	32.5 ± 2.5°	18–24	3–5
Candida albicans (ATCC No. 10231)	Sabouraud Dextrose Agar; Sabouraud Dextrose Broth	22.5 ± 2.5°	44–52	3–5
Aspergillus brasiliensis (ATCC No. 16404)	Sabouraud Dextrose Agar; Sabouraud Dextrose Broth	22.5 ± 2.5°	6–10	3–7

Alternative Methods of Inoculum

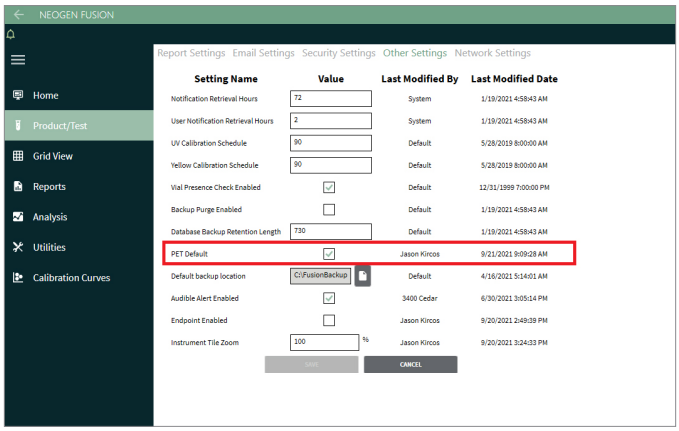
If there is no desire to manage and create a stock of culture, the Snap-Sticks provided by Neogen would be used to inoculate the products. The Snap-Sticks can be rehydrated and provide enough culture to inoculum many different products at once.

Starting the Efficacy Batch

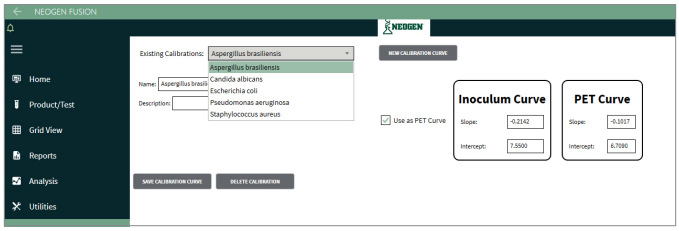
NF-TVC and DYM-109C vials are used in the Soleris NG system together with pre-calculated line equations that will generate a colony forming unit count on the inoculation day and subsequent harvest days.

To Use PET on the Fusion Software

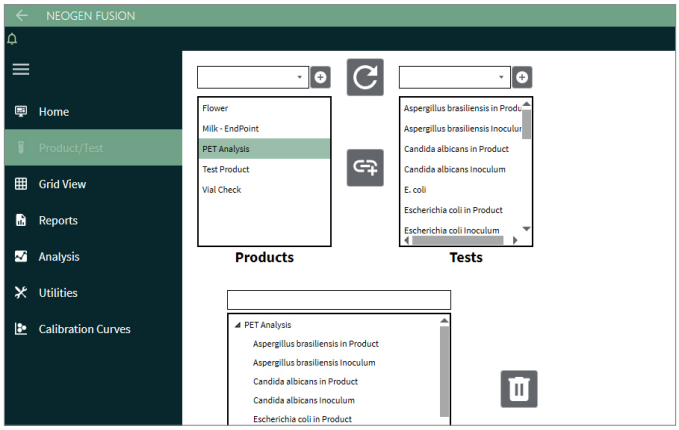
1. Log into the software as the admin.
2. Go to the setting page, navigate to other settings, and check the PET default option.



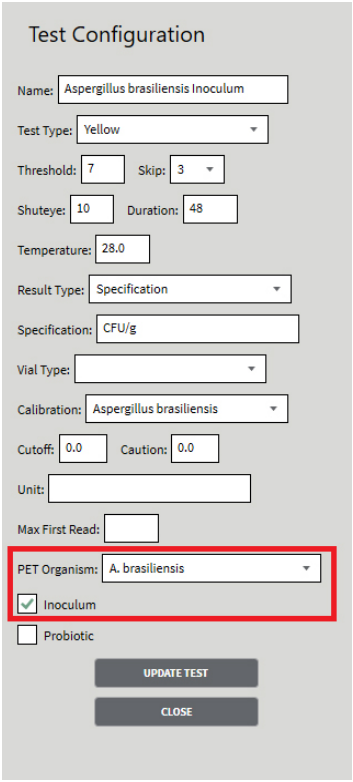
3. Navigate to the calibration curve screen and the PET curves will automatically be added. This will automatically add the PET analysis product and the calibration curves for both inoculum and product.



4. Navigate to the product/test screen and click on the test called organism inoculum on this page to open the test parameter screen.

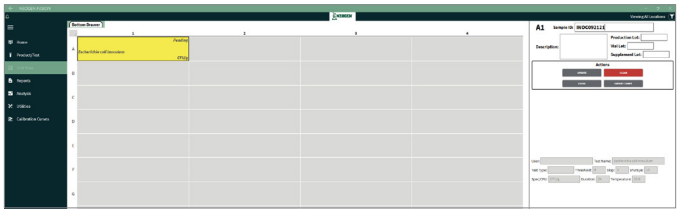


5. Verify that the inoculum check box is checked, and the test has the correct calibration curve associated with it. Please do this for all five organisms to verify the inoculum check box is selected for all inoculum tests.



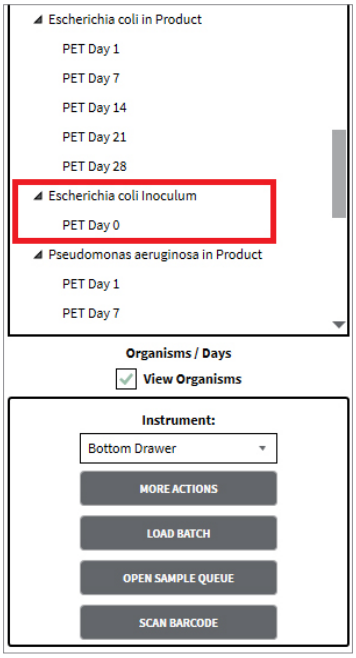
To Start an Inoculum Test

1. Navigate to the grid view, ensure that there are spaces available for testing, and select the first inoculum. In this example, the *E. coli* inoculum is being used.



Preservative Efficacy Testing

2. Select the test *Escherichia coli* inoculum PET day 0 and drag the test to an available location on the grid.

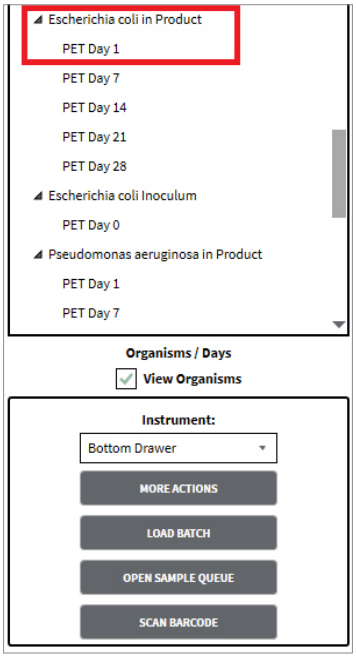


3. Open the test and use the following nomenclature for naming the inoculum.
    a. INOC092221
        i. For inoculum created on September 22, 2021.
4. By using this nomenclature for the inoculum, the user can apply this inoculum to multiple products.
5. Repeat for all required cultures to tie this set of inoculums to the products that will be tested for the PET.
6. Typical use will result in three NF-TVC vials being used at 35.00C and two DYM-109C vials being used at 28.00C.

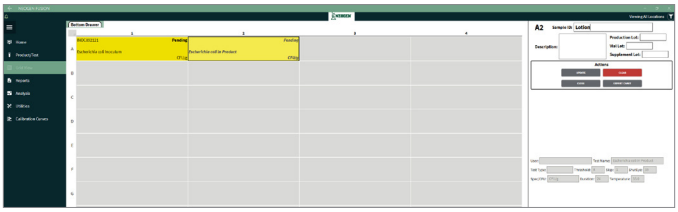
Preservative Efficacy Testing

To Start on 1, 7, 14, 21, or 28-Day Test

1. Navigate to the grid view, ensure that there are spaces available for testing and select the first product test. In this example, the *E. coli* in product is being used.



2. Choose an available cell location; drag the *Escherichia coli* in product, PET day 1 to an available location.

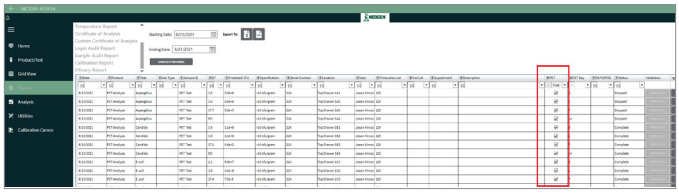


3. The product vial will need to have the same sample ID (the example used here is lotion) for all days and organisms to properly generate the report.
    a. An error that is caught before the test is completed can be corrected and renamed. The sample will be flagged in the database due to 21 CFR part 11 requirements.
4. Repeat this for each organism that is being tested on day 1.
5. If doing multiple products, using the same inoculum the above steps can be repeated for day 1.
6. Repeat these steps for the desired number of harvest days.
    a. Typically, 7, 14, 21, and 28.

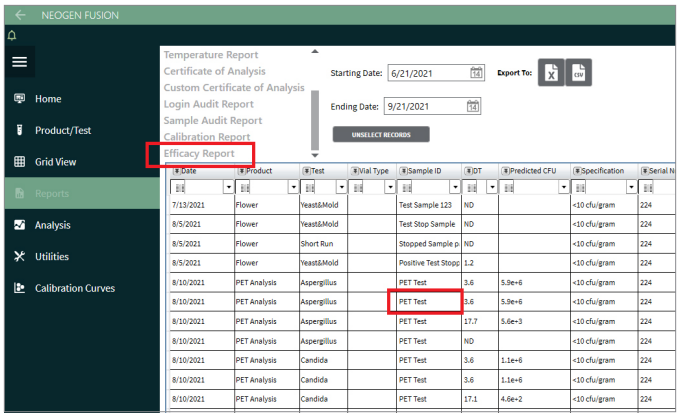
Preservative Efficacy Testing

To Create a Preservative Efficacy Report

1. All tests should be completed before generating the report.
2. Navigate the reports menu.
    a. Optional: Sort by PET tests.



3. Select the sample ID for the product that the report should generate for.
    a. Do not select the inoculum sample ID that was created for this product.

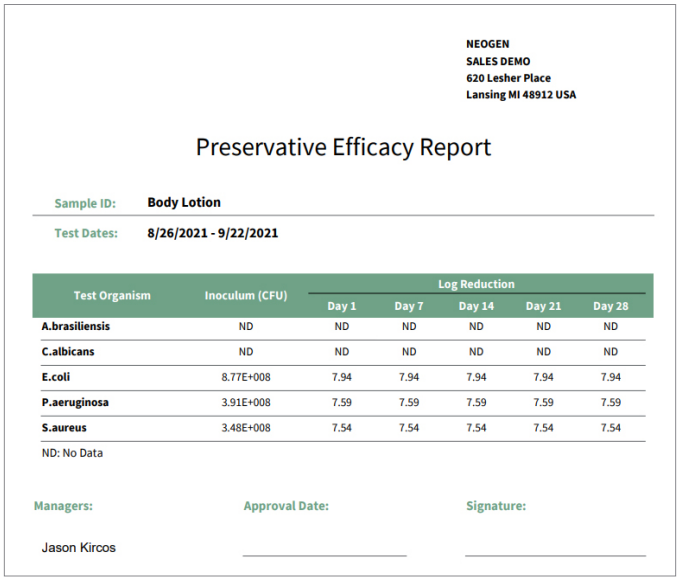


4. Once the sample ID is selected, click on efficacy report.
5. Select the date range of the tests that they were run.
    a. The system will automatically default for the past three months, if you select a date that is after the test has started, it will result in no data on the report.
    b. Select the organisms that were run for this product.
        i. By default, all five PET organisms are selected.
    c. Select the days that the report should generate.
        i. By default, all five days will be selected.
        ii. If the user ran day 1 but it was day 2, this is the location to update the test and it will show up on the report.

6. Enter the inoculum sample ID that was used.

Preservative Efficacy Testing

7. Click generate report and the system will automatically create a preservative efficacy report.
    a. The report will contain the sample ID of the product tested, the initial inoculum in CFU, and the log reduction for each day and organism.



NEOGEN
SALES DEMO
620 Lesher Place
Lansing MI 48912 USA

Preservative Efficacy Report

Sample ID: **Body Lotion**

Test Dates: **8/26/2021 - 9/22/2021**

Test Organism	Inoculum (CFU)	Log Reduction				
		Day 1	Day 7	Day 14	Day 21	Day 28
A.brasiliensis	ND	ND	ND	ND	ND	ND
C.albicans	ND	ND	ND	ND	ND	ND
E.coli	8.77E+008	7.94	7.94	7.94	7.94	7.94
P.aeruginosa	3.91E+008	7.59	7.59	7.59	7.59	7.59
S.aureus	3.48E+008	7.54	7.54	7.54	7.54	7.54

ND: No Data

Managers: Approval Date: Signature:

Jason Kircos

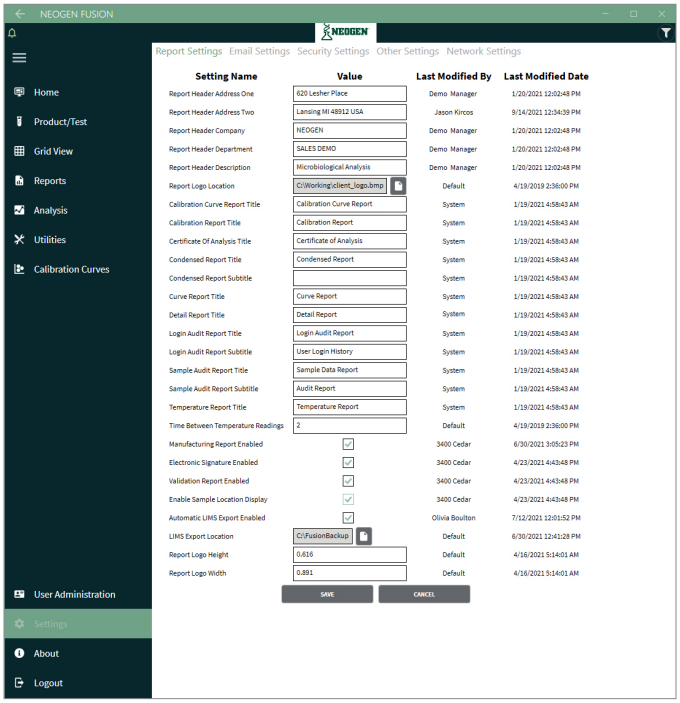
8. Results are in LOG reduction. It is up to the customer to determine if the LOG reduction meets the USP <51> requirements for the product type tested.
9. The report can be saved as a .pdf.

Chapter Thirteen

Settings

General

The settings menu provides all the system settings that are available to the administrator.



Report Settings

This screen allows the administrator for customization of the reports. Below is a list of the options and their functions.

Report header address one: The first line of the company's address.

Report header address two: The second line of the company's address.

Report header company: Company name.

Report header department: Department.

Report header description: General description.

Report logo location: A location that the company can use an image to show the CoA.

Calibration curve report title: Title to be used for the calibration report.

CoA title: Title to be used for the CoA.

Condensed report title: Title to be used with condensed report.

Curve report title: Title to be used with curve report.

Login audit report title: Title to be used with login audit report.

Login audit report subtitle: Title to be used with login audit report subtitle.

Sample audit report title: Title to be used with sample audit report.

Sample audit report subtitle: Title to be used with sample audit report subtitle.

Temperature report title: Title to be used for temperature report.

Time between temperature readings: Used to determine how often the temperature is read for the temperature report (in hours).

Manufacturing report enabled: This is default off and is used by Technical Service to assist the customer.

Electronic signature enabled: Turns on electronic signature option for the CoA.

Validation report enabled: This is default off and is used by instrumentation quality control to verify operation of the unit during initial inspection.

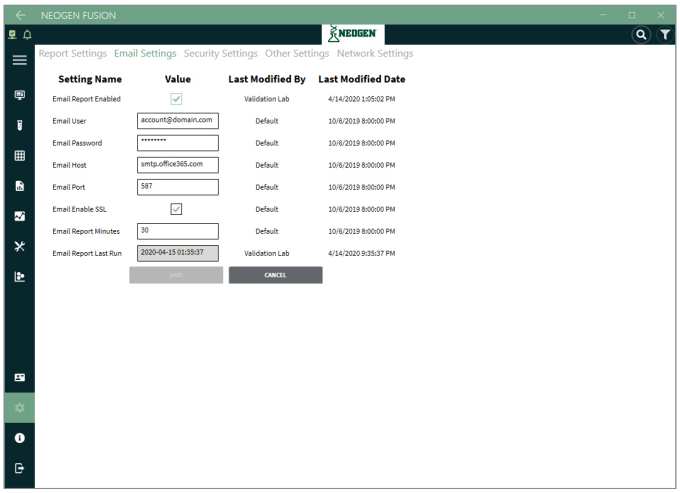
Enable sample location display: This is default off and will add the location (instrument and placement of vial) for the sample.

Report logo height: The height of the logo graphic used on the CoA.

Report logo width: The width of the logo graphic used on the CoA.

Email Settings

This menu allows the administrator to enable email notifications. Please work with your company's IT department to select the correct settings. Emails can be as frequent as every 30 minutes to notify the user of a positive result. This notification can be enabled in the user setup page.



Email Settings Page

Security Settings

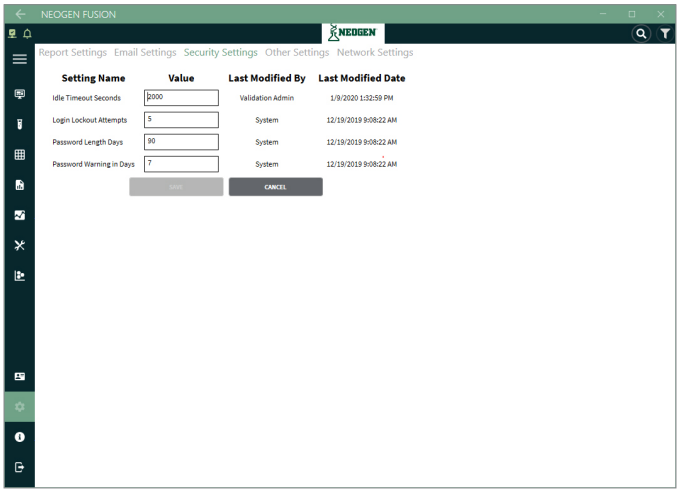
This page allows the administrator to set the security options on the page.

Idle timeout seconds: Default is three minutes. After three minutes, the user is automatically logged out of the system and forced to reenter their login information to use the system.

Log lockout attempts: Default is five incorrect attempts. After five incorrect login attempts, the user account is locked. To unlock the account, the system admin has to log into the system and reset the user.

Password length days: The default is 90 days. This is the length of time that the password will be active before the system requires a new password to be required.

Password warning in days: The default is seven days. This is the warning to the user of when the password will expire and require a change. Failure to change the password in time will result in the user account being locked out.



Security Settings Page

Other Settings

This page allows the administrator to set the other options on the page.

Notification retrieval hours: The default is 72 hours. This stores the most recent system notifications from the system.

User notification retrieval hours: The default is two hours. This stores the most recent user notifications from the system.

UV calibration schedule: The default is 90 days. This is the frequency that the UV-LED calibration is required. Once the calibration expires, the system will not allow any tests until calibration is complete.

Yellow calibration schedule: The default is 90 days. This is the frequency that the yellow LED calibration is required. Once the calibration expires, the system will not allow any tests until calibration is complete.

Settings

Vial presence check enabled: This is default on. This check makes sure that a vial is present before a test is run. This will prevent users from starting tests in a location without a vial.

Over threshold warning: When enabled, the health of the vial is checked prior to testing. If the vial exceeds the preset threshold, the warning displays and the well location turns royal blue. The test will remain in a pending status until the vial is changed. This option can be selected only when the vial presence check is enabled.

Backup purge enabled: This option is on as default. This will purge old backup data once a backup of the system data is created.

Database backup retention length: The default is two years. This is the length of time the system will keep the backup stored on the system before deleting it. The user can move the backup file to a new location to prevent deletion.

PET default: This is default off. If enabled, this will allow for PET organisms and testing to be used.

Default backup location: Allows the user to get the default backup location to save the database in.

Audible alert enabled: If checked this option will cause an audible noise to be produced when a sample is positive.

EndPoint enabled: If checked this box will allow the user to setup instruments for EndPoint testing.

Instrument tile zoom: This option will allow the user to adjust the size of the instrument tiles on the home screen, the default size is 100%. The range is 100–200%.

Device disconnected alert: With this system setting is enabled, after the instrument has been disconnected for 30 or more minutes, a disconnect email must be sent within a minute. The email will state: "{Instrument Name} last communicated at <last communication time>. Please check your system as soon as possible." The email will be sent to all administrators.

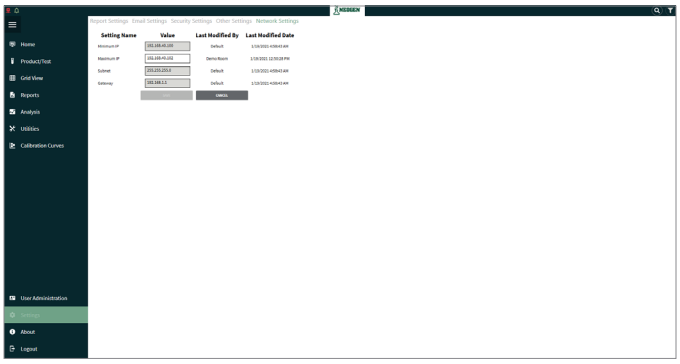
Enable second derivative: A setting that can only be unlocked via Neogen to use a secondary derivative for data analysis.

Other Settings Page

Network Settings

This page allows the administrator to set the network settings options on the page.

This page allows the customer IT department to place the Fusion computer on their domain.



Network Settings Page

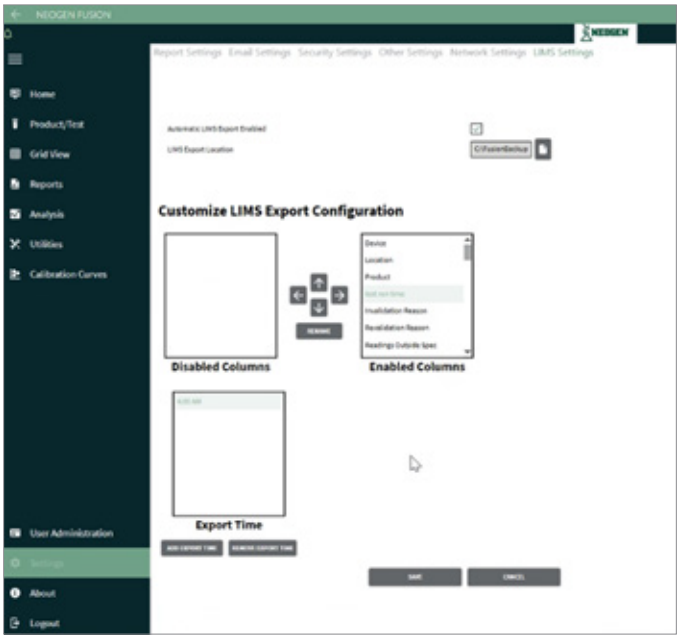
LIMS Settings

This page allows the administrator to configure settings for LIMS.

Automatic LIMS export enabled: If this option is selected, the data is automatically exported to a .csv file after a sample finishes running.

LIMS export location: If the Automatic LIMS Export Enabled option is selected, the .csv file exports to the location entered in this field.

Customize LIMS export configuration: A custom configuration for the LIMS export. Please contact Neogen Technical Services Help Desk for assistance.



LIMS Settings Page

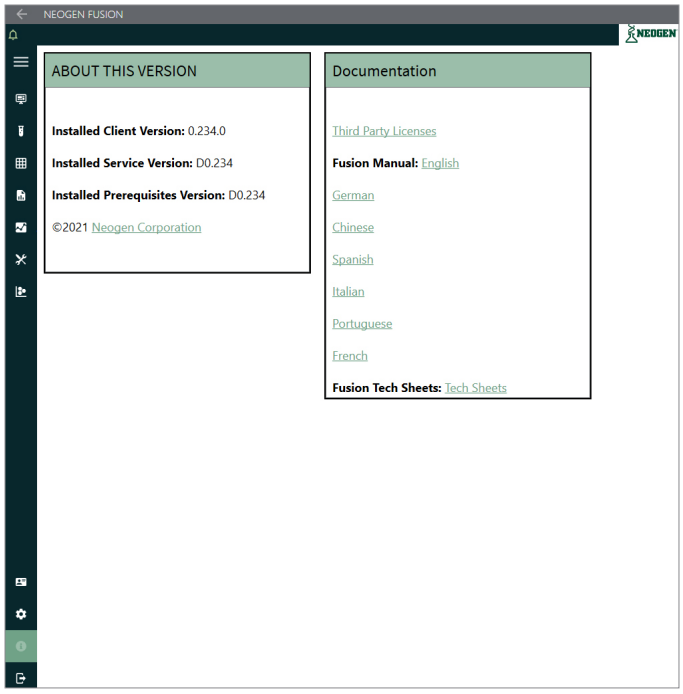
Chapter Fourteen

About

General

The about page contains the current version of the installed client, service, and prerequisites.

This documentation on this page provides manuals in multiple languages, a link to Fusion technical sheets on Neogen.com, and a list of third party licenses used in the software.



Neogen Corporation, 620 Lesher Place, Lansing, MI 48912 USA