Growth Direct® System

User Guide

For Environmental Monitoring and Bioburden Testing
Part numbers: E700-GD2, B700-GD2
User Guide: GDOC-MAN-EN
Version: K

Configuration and Version

Instrument Configuration	User Guide Supports Software Versions
E700-GD2; B700-GD2	4.1 or above

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About This Manual

This user guide provides background information and steps for laboratory administrators and scientists responsible for operating and maintaining the Growth Direct® System.

Acronyms

The following acronyms are used in this guide.

Acronym	Meaning
CFU	Colony Forming Units
EM	Environmental Monitoring
GD	Growth Direct
LIMS	Laboratory Information Management System
OOS	Out of Specification
PM	Preventative Maintenance
RMB	Rapid Micro Biosystems

Table of Contents

1. System Overview

This section introduces the Growth Direct® System, including information about:

1.1 Notes, Cautions, and Warnings

Notes, cautions, and warnings appear both throughout this user guide and on the Growth Direct® System itself.

	Note: Indicates important information that you should read.
	Caution! Indicates conditions, hazards, or unsafe practices that may result in minor personal injury, damage to the device, or loss of data.
	Warning! Indicates conditions, hazards, or unsafe practices that may result in serious personal injury or death to the operator.

All operators must read and understand the following cautions and warnings before using the Growth Direct® System. Caution statements appear throughout the manual in the sections where they apply. Some of these symbols appear on the device itself. The Warning! symbol on the device indicates that you must read important information in this manual before using it.

Caution! Do not install any software on the system except that provided by Rapid Micro Biosystems. Installing third-party software could have a negative effect on the system and voids the system’s warranty. Contact Rapid Micro Biosystems if you have specific questions.

Warning! Never attempt to move the system, lean on, or climb onto the system. Never under any circumstances place your head into the system.

Warning! Always use the system in accordance with the specifications provided in this user guide. Never make mechanical modifications or remove any panels from the system. Failure to comply with these requirements may impair the protection provided by the system and could result in serious injury or death.

Electric shock hazard/protective earth (ground). To reduce risk of electrical shock, the system uses a three-wire electrical cable and plug to connect to earth ground; electric cables are either behind panels or locked doors. Never attempt to access electrical cables or wiring; doing so could result in severe injury or death.

Hazardous live voltage! The system design minimizes the risk of exposure to hazardous voltage during normal operation. Rapid Micro Biosystems personnel are trained to maintain and service the system and to disconnect it from hazardous live voltage, when necessary.

Intense pulsed light warning! Laser and high-power LED lights are enclosed in the system and are on only when the system is analyzing cassettes. The system is designed to turn off the laser whenever the front door is opened.

Laser emissions warning. Class I and Class II Lasers are enclosed in the system and are on only when the system is analyzing cassettes. The system is designed to turn off the laser whenever the front door is opened.

Burn hazard/hot surface warning! If you need to open the incubator, avoid touching the inside surface since it could still be hot.

Crush hazard warning! While servicing the inside of the device, be alert for the possibility of a crush hazard. All moving parts should stop when you open the front door of the device; however, maintain caution when putting your hands and fingers into the device.

Crush hazard warning! While servicing the outside of the device, maintain caution for the possibility of a crush hazard. Be especially careful when opening and closing the input/output queue, which poses the risk of pinched hands and fingers.

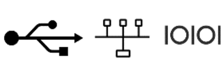
1.2 Additional Instrument Labels

In addition to the international warning symbols in the previous section, the following labels appear on the Growth Direct® System.

Instrument label. Indicates the system model number, serial number, electrical supply specifications (voltage, frequency, current), compressed air supply specifications, and date of manufacture.

Do not dispose with regular trash. Check local requirements for safe, legal disposal.

Universal Power Supply (UPS). Indicates the UPS connection.



Communication ports. Indicates the USB, network, and serial ports, respectively.

CE label. Certifies that a product has met EU health, safety, and environmental requirements that ensure consumer safety.

ETL label. Indicates the system has been tested by an accredited third-party testing laboratory and meets the applicable safety standards and minimal requirements for sale or distribution within North America.

1.3 Growth Direct® System Components

The Growth Direct® System consists of the instrument, consumables, and accessories described below.

1.3.1 Instrument

- Detection unit with imager for analyzing samples
- Integrated robotics to enable sample processing and movement within the system
- Two on-board incubators to maintain required sample temperatures
- Touchscreen monitor for running the system
- Left and right input carousels for loading cassettes
- Trash bin for cassettes that have been analyzed
- Output queue for removing cassettes of interest

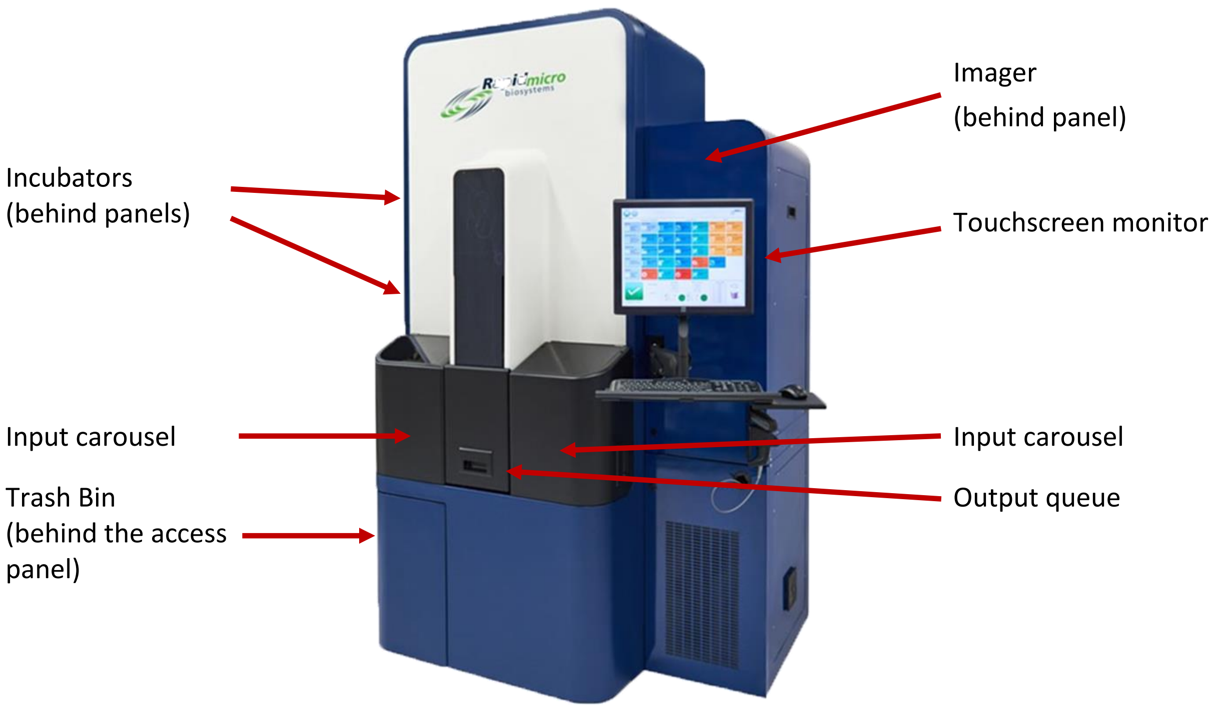


Figure 1-1: Growth Direct® Instrument

1.3.2 Consumables

The following consumables are available for preparing and testing samples:

Environmental Monitoring

- Cassettes
- Vision Lids

Bioburden Testing

- Cassettes
- Vision Lids
- Filtration Funnels

Figure 1-2: EM Cassette and Vision Lid (left), Bioburden Testing Cassette and Funnel (right)

1.3.3 Accessories

- Cassette carousel: capacity 60 cassettes for EM and bioburden testing
- Barcode printer for labeling cassettes (place on a table near the system or connect via your network)
- Handheld barcode scanner

Cassette Carousel Barcode Printer Barcode Scanner

Figure 1-3: Growth Direct® Accessories

1.4 Intended Use

1.4.1 Growth Direct® System

The Growth Direct® System performs common microbiology tests and is intended for use as a rapid microbiology testing and analysis system. The system automates high volume EM, bioburden testing, and water testing samples. Users prepare microbiological samples on Growth Cassettes and load them into the Growth Direct® System. The system then automatically:

- Processes and moves samples within the instrument.
- Images the samples.
- Notifies designated personnel of alarms, alerts, and/or action levels (if this feature is turned on).
- Reports results.
- Returns completed samples to the operator for on-demand subsequent processing, storage, or disposal.
- Moves cassettes between cassette carousels, incubators, the imaging station, and the output queue as well as the trash bin as required by specific assays.

1.4.2 Environmental Monitoring

The media-filled EM growth cassettes mirror current EM use modes for air, surface, and personnel monitoring. These cassettes are used for analysis by the Growth Direct® System.

1.4.3 Bioburden Testing

Filtration funnels are designed for preparing liquid samples (raw material, in-process samples, or water) before analysis by the Growth Direct® System. The Growth Direct® System filters samples through a 0.45 µm nitrocellulose membrane while under vacuum. The membrane retains microorganisms after filtration and is then transferred to a Growth Cassette.

1.5 Starting the Growth Direct® System

Note: These instructions support systems compliant with IEC61010 Version 3. Previously released Growth Direct® systems have power on steps documented in their user guides.

Rapid Micro Biosystems personnel will install and start the system for you. It is designed to be on all the time. If you lose power, the system will attempt to automatically start when power is restored. However, if you need to manually start the system, follow these steps.

1. Unlock the panel on the bottom right by inserting the panel key (inset) into the lock and turning the key clockwise. The panel swings out exposing the circuit panel.

Caution! Rapid Micro Biosystems recommends that you do not turn off the system’s power switch if the system loses power or for any reason when cassettes are in the system. Doing so could affect sample integrity.

Figure 1-4: Unlocking the Circuit Panel Cover

2. If necessary, flip the Main Breaker Switch and UPS Power Switch to their **ON** positions. These switches are located on the lower right.
3. Press the UPS Power Button, in the upper left corner of the UPS. All systems, including the servers, monitor, and software, turn on automatically.

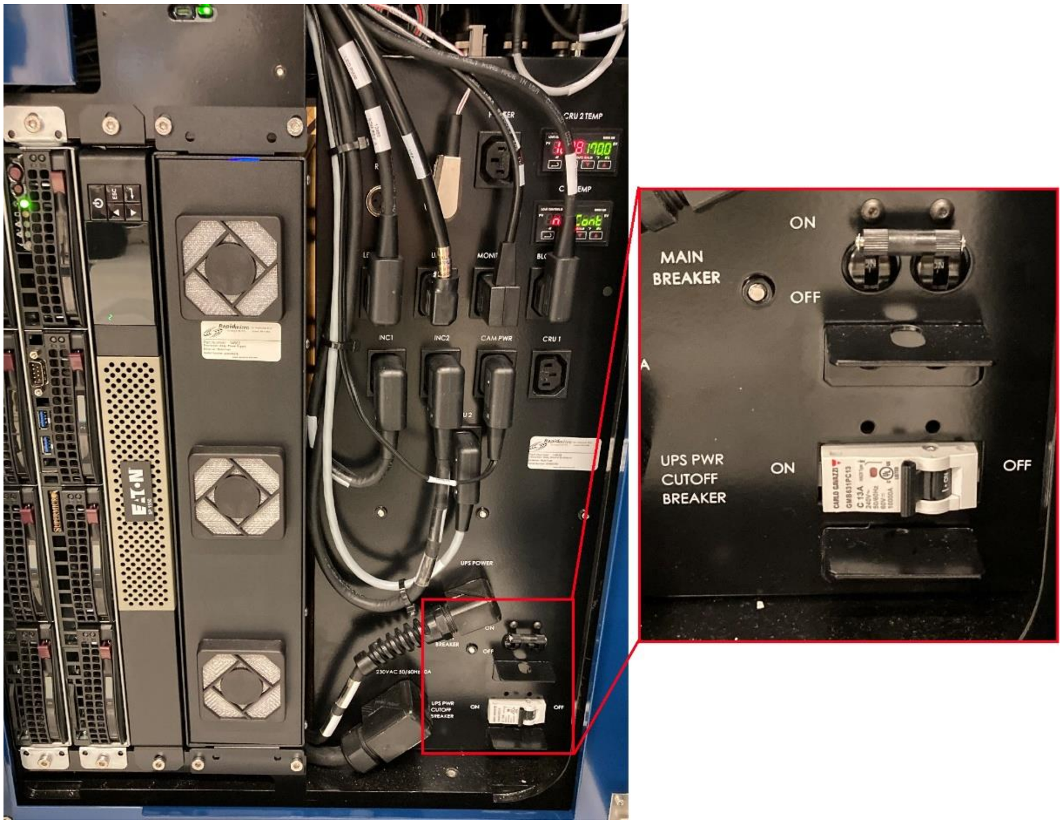


Figure 1-5: Control Panel Breakers and Power

If the system loses power, it uses the power in the UPS to perform a controlled shutdown.

The system waits for approximately 1 minute to see if the outage is temporary:

- If power is restored, the system can resume normal operation.
- If power is restored while the cassettes are being moved to the incubators, the system can resume normal operation.
- If power is not restored, the system moves all cassettes to the incubators.

If power still has not been restored after all cassettes have been returned to incubators, the system waits approximately 1 minute:

- If power is restored within 1 minute, the system can resume normal operation.
- If power has not been restored, the system displays a message, begins shutting down, and sends an email notification, if you have turned on email notifications for System Failures on the **User Email Notification** page.

At that point, the system completes the shutdown, even if power has been restored.

After the shutdown is complete and after power is restored, the system starts up and resumes normal operation. The system sends an email notification about power restoration if you have turned on email notifications for System Failures on the **User Email Notification** page.

Note: We strongly advise that you turn on email notifications for System Failures. If a Rapid Micro Biosystems representative instructs you to shut down the system, see the instructions in Section 10, Troubleshooting.

1.6 Main Software Pages

The Growth Direct® System user interface has two primary pages:

- **Home** Page
- Menu Options Page

1.6.1 About the Home Page

The **Home** page displays important information about continuing tests and the overall system status. The **Home** page also provides access to pages for:

- Printing labels
- Opening the input doors
- Approving test results
- Retrieving and canceling tests
- Emptying the trash bin
- Opening the output queue door

When the device is switched on, the Growth Direct® software application starts automatically and the **Home** page appears.

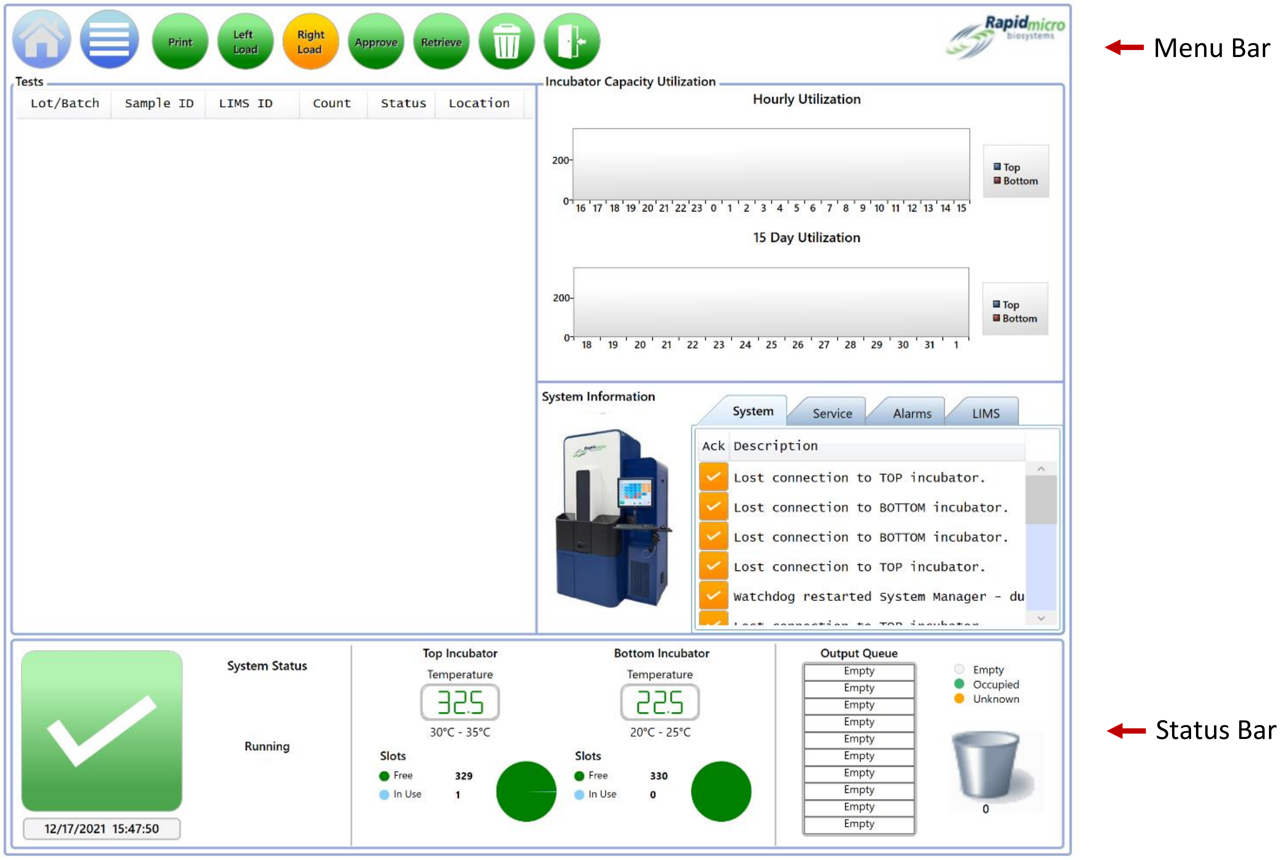


Figure 1-6: Home Page

1.6.2 Menu Bar

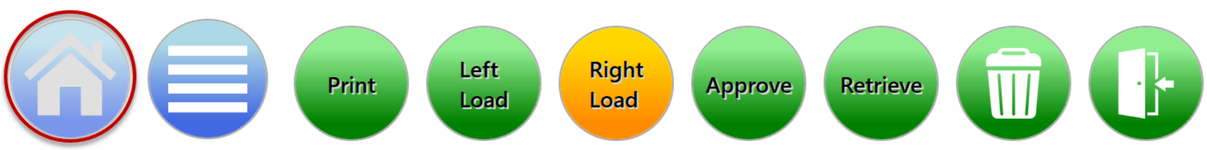


Figure 1-7: Home Page Menu Bar

The Menu Bar appears at the top of the **Home** page. The **Home** button (circled in red above) on the Menu Bar appears on every page. To return to the **Home** page from any area of the Growth Direct® System application, click the **Home** button.

1.6.3 Tests Queue

Located in the top-left area of the page, the Tests Queue shows either all tests or cassettes that are of interest, depending on how the system is configured using the **General Settings** page (See Section 2, Setting Up the Growth Direct® System).

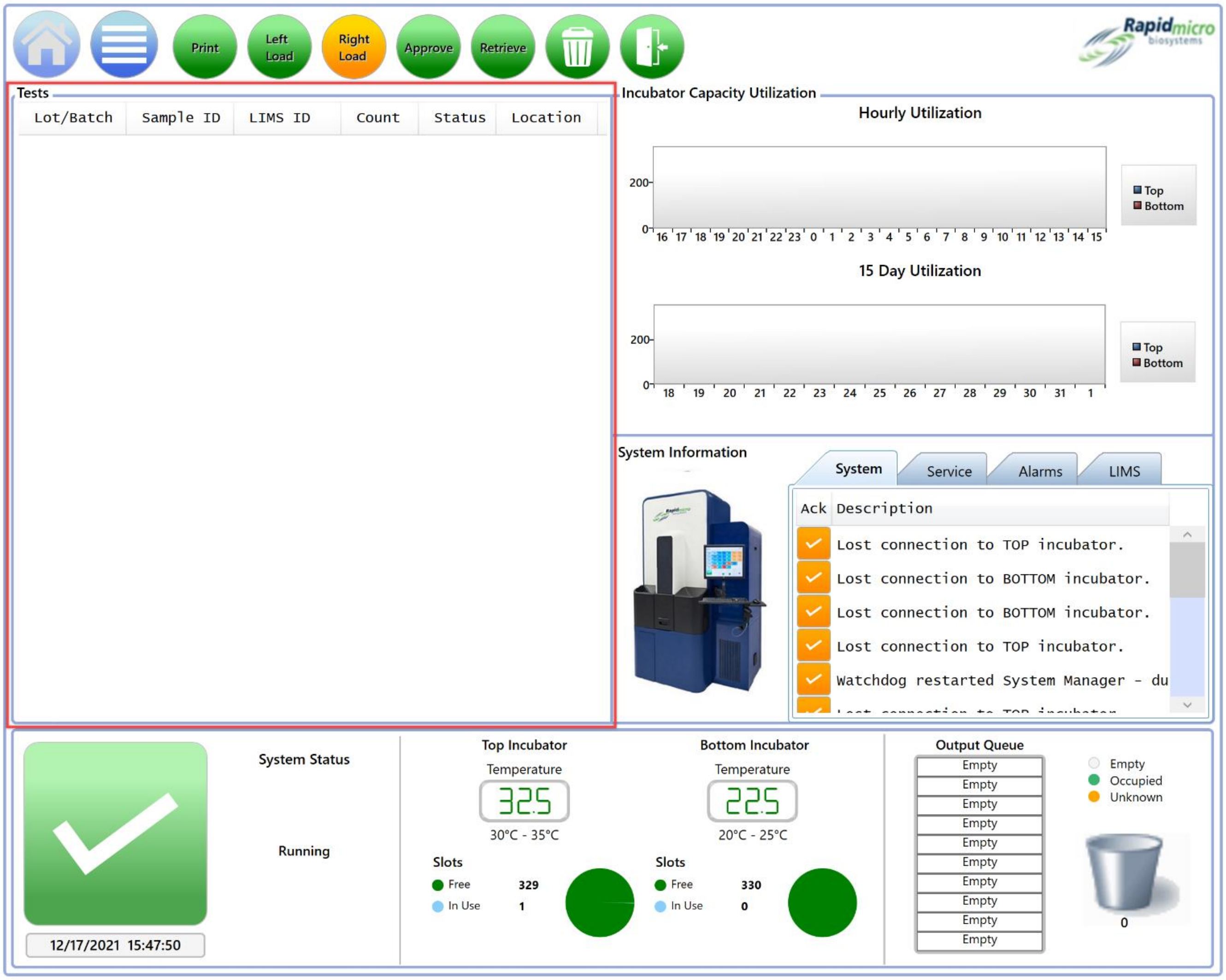


Figure 1-8: Tests Queue Area of the Home Page

1.6.4 Incubator Capacity Utilization

Located to the right of the Test Queue, the Incubator Capacity Utilization area shows how many cassettes are in the incubators. It displays either both charts or a single chart. Click on the chart to change the display. The charts show the number of active cassettes per incubator either by the hour or by the day. Use these charts with the pie charts at the bottom of the page, because the graphs show only active cassettes and the pie charts show active and completed cassettes in each incubator.

1.6.5 System Information

Located below the Incubator Capacity Utilization area, the System Information area includes system events, service notification, alarms, and LIMS information (when installed). Events and alarms happen with normal system use; contact Rapid Micro Biosystems Service Department for service.

1.6.6 Status Bar

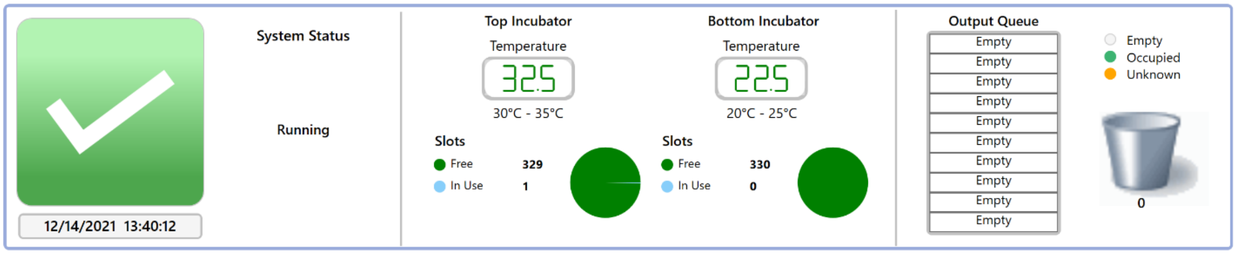


Figure 1-9: Home Page Status Bar

Located across the bottom of the **Home** page, the Status Bar provides information about the:

- **System Status:** The state the system is in.
- **Warning messages:** For example, Door Open.
- **Date and Time**: The current date in month, day, and year; time in hours, minutes, and seconds.
- Top Incubator and Bottom Incubator
- **Temperature:** The actual incubator temperatures for each incubator.
- **Slots:** The number of free slots in each incubator represented by the green portion of the pie chart; the number of slots in use represented by the blue portion of the pie chart.
- **Output Queue List:** The number of cassettes in the Output Queue. A white bar with the word **Empty** indicates no cassettes are in the Output Queue; a green bar indicates the presence of a cassette; **Unknown** indicates the system has identified cassettes of concern. Open the Output Queue to investigate.
- **Trash Bin Icon:** The number below the icon indicates how many cassettes are in the trash bin. The maximum is 110.

1.6.7 Menu Bar Buttons

The Menu Bar contains buttons for performing specific tasks.

Print Button

Click the **Print** button to access the **Print Worklist** page.

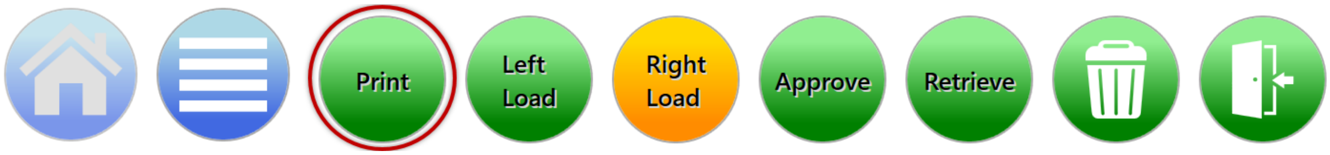


Figure 1-10: Print Button

The **Print Worklist** page lets you print worklist labels on the barcode printer or worklist sheets on a regular printer for scanning into the system (See Section 3).

Load Buttons

Click one of the **Load** buttons to load cassettes into the Growth Direct® System (See Section 3). The green color indicates which door is ready to load the next carousel. The amber color indicates which door was opened last and that the carousel is in the loaded position.

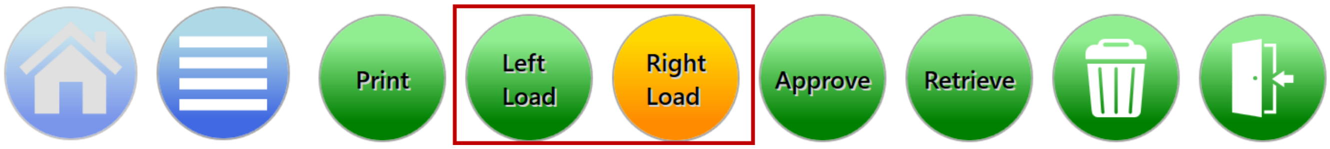


Figure 1-11: Load Buttons

Approve Button

Click the **Approve** button to access the **Approve Tests** page.

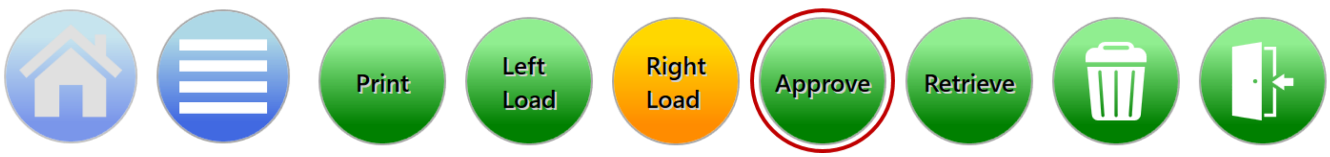


Figure 1-12: Approve Button

The **Approve Tests** page allows you to select, review, add comments, and approve results after a test is completed (See Section 3).

Retrieve Button

Click the **Retrieve** button to access the **Cancel/Retrieve Tests** page.

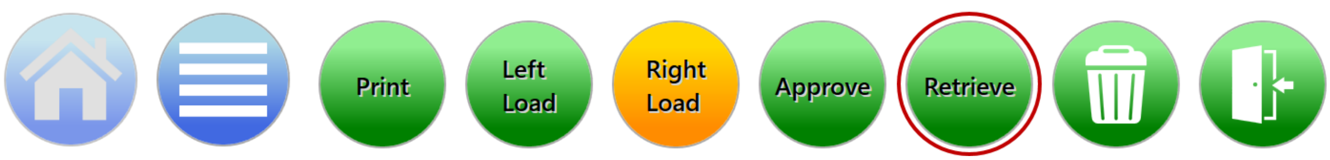


Figure 1-13: Retrieve Button

The **Cancel/Retrieve Tests** page allows you to select tests to cancel, retrieve, or place in the output queue or trash bin (See Section 3).

Trash Bin Button

Click the **Trash Bin** button to open the trash bin door.

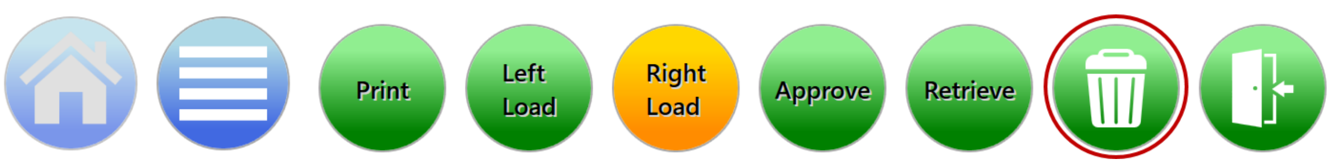


Figure 1-14: Trash Bin Button

Only users with permission can open the trash bin (See Section 2). Enter your username and password and click **OK**. The trash bin door opens and a **Confirmation** page appears. This opens the trash bin for emptying (See Section 3). Ensure all cassettes are removed; the system assumes the trash bin is empty when you close the door.

Output Queue Door Button

Click the **Output Queue Door** button to open the output door to remove cassettes.

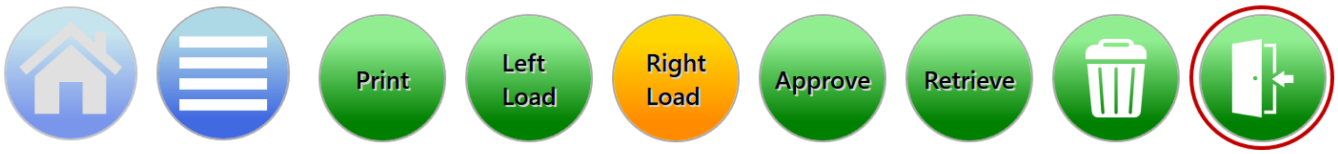


Figure 1-15: Output Queue Door Button

When you click the **Output Queue Door** button, the **Signature** page appears.

Only users with permission can open the door (See Section 2). Enter your username and password and click **OK**.

Note: After unloading cassettes from the output queue, slide the tray to ensure it is fully engaged and locked into place.

Ensure all cassettes are removed; the system assumes the output queue is empty when you close the door.

1.6.8 Signature and Confirmation Pages

After most tasks, the Growth Direct® System prompts you with a Signature or Confirmation dialog like those in the following images:

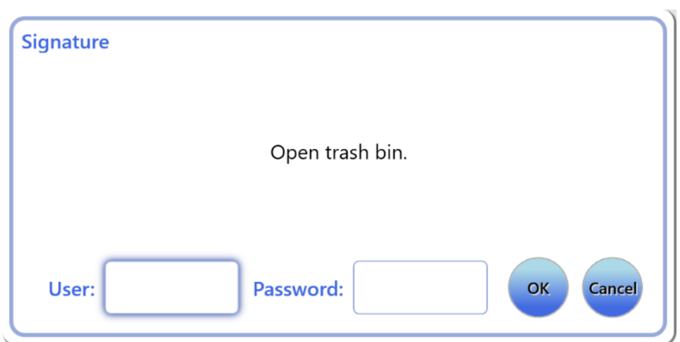


Figure 1-16: Signature Page Example

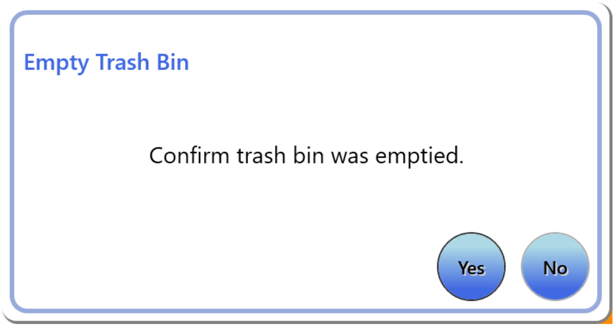


Figure 1-17: Confirmation Page Example

Each dialog matches the task you are completing.

Complete the dialog and click **OK (or Yes)** or **Cancel (or No)** to stop the task.

1.7 About the Menu Options Page

Click the **Menu** button to access the **Menu Options** page, which provides access to all other areas of the Growth Direct® System.

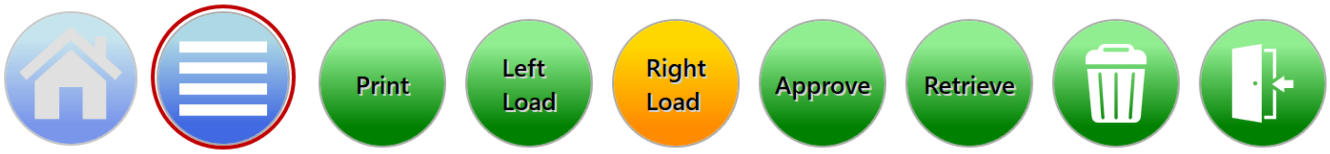


Figure 1-18: Menu Button

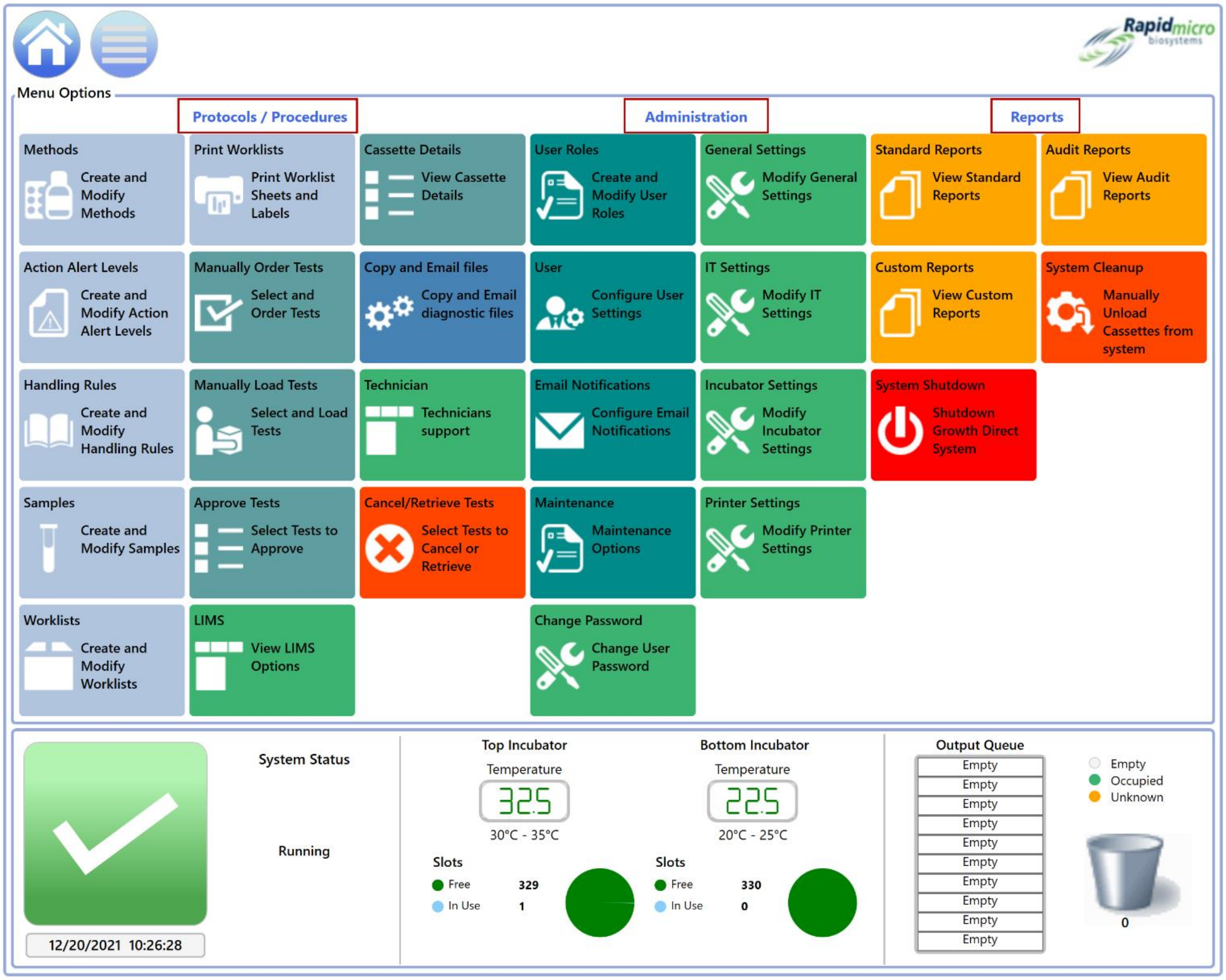


Figure 1-19: Menu Options Page

The **Menu Options** page is divided into three sections:

- Protocols/Procedures
- Administration
- Reports

1.7.1 Protocols/Procedures

- **Methods:** Allows you to specify the type of application (EM or bioburden), incubation duration (in hours), and incubation temperature (in degrees Celsius) for an assay.
- **Action Alert Levels:** Allows you to specify CFU count thresholds (Actions, Alerts, and Specifications) for the test being conducted.

- **Handling Rules:** Allows you to specify the destination of cassettes (output queue, trash bin, or incubator) based on the cassette status: OOS (Out of Specification), Passed, Canceled, or Count Prior to Endpoint.
- **Samples:** Allows you to specify a collection of predefined test parameters, a Method, an Action and Alert Level, and a Handling Rule. Together, these specify all the details required to run a complete test.
- **Worklists:** Allows you to create and modify worklists, which comprise collections of predefined samples.
- **Print Worklists:** Allows you to print sample labels on the barcode printer or sheets of labels on a regular printer. You stick the labels to the cassettes, which you scan into the system.
- **Manually Order Tests:** Allows you to select and order tests manually by worklist or by sample ID.
- **Manually Load Tests:** Allows you to manually select and load tests.
- **Approve Tests:** Allows you to select, review, add comments, and approve results after a test is completed.
- **LIMS (Laboratory Information Management System):** Allows you to modify LIMS settings, configure LIMS result fields, print LIMS labels for pending tests, and resend LIMS result files. This is an add-on feature and not a default program. If you would like to know more about LIMS, contact sales@rapidmicrobio.com. (See Section 4.)
- **Cassette Details:** Allow you to monitor status and CFU count readings once cassettes have been successfully loaded into the system. Also allows you to create and print reports and identify cassette errors.
- **Copy & Email Diagnostic files:** Allows you to select and send system application log files and images.
- **Technician Support:** For service engineers only.
- **Cancel/Retrieve Tests:** Allows you to select tests for cancelation or retrieval and placement in the output queue, trash bin, or incubator.

1.7.2 Administration

- **User Roles:** Allows you to define levels of access and permissions for each user.
- **User:** Allows you to specify user information including name, password, email notification, and role.

Note: If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

- **Email Notifications:** Allows you to set up automatic email messaging (alarm, test is out of specification (OOS), security, licensing for LIMS or mold is about to expire) for users.
- **Maintenance:** Reserved for personnel authorized to maintain the system.
- **Change Password:** Allows you to change your password.

- **General Settings:** Allows you to specify password change notification options, turn page help on and off, set **Home** page cassette display options, define when a weekend (site-specific) starts and ends, choose required test approval comments, enable the Bridge computer, provide the LIMS ID a code for systems where LIMS is used, and activate mold features.
- **IT Settings:** Allows you to specify a database backup schedule, set system email credentials, copy logs, export test results data, and enter network credentials.
- **Incubator Settings:** Allows you to set incubator temperatures and temperature alarm thresholds.
- **Printer Settings:** Allows you to specify printer settings for both a document printer and a barcode printer.

1.7.3 Reports

- Standard Reports
  - **Test Report:** Reports on test status, start and completion times, and any conditions associated with a test.
  - **Lot/Batch Results Report:** Reports on test results by date or by range of dates that a lot/batch was loaded into the system.
- **Custom Reports:** Customer-specific reports created and deployed at the request of the customer beyond the standard and audit reports.
- **System Shutdown:** Allows you to perform a controlled system shutdown.
- **Audit Reports:** Reports on an individual audit history of Methods, Action Alert Levels, Handling Rules, Samples, Worklists, General and IT Settings, Incubator Settings, User Roles, Users, System Events, User Activity, Cancelled Tests, and Focus Calibrations.
- **System Cleanup:** Helps you manually remove all cassettes on the system. Before doing this, see Section 2.8, System Cleanup.

1.8 Growth Direct® System Workflow

Note: The following workflow applies if your lab is not using Central Manager. If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

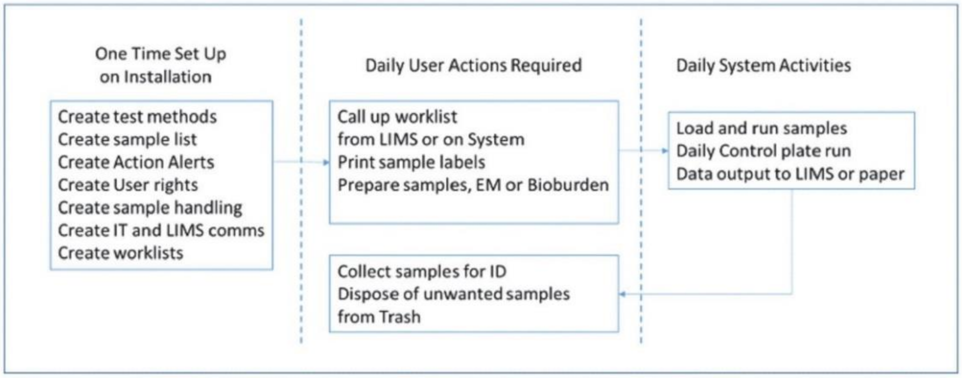


Figure 1-20: Growth Direct® System Workflow

The figure above shows an overview of the initial setup and daily sample runs. The following individual sections describe how to perform each task in detail.

2. Setting Up the Growth Direct® System

This section contains:

2.1 Overview

This section describes the high-level tasks for setting up users and their permissions and for specifying site-specific parameters for your system. You can customize many aspects to best meet the needs of your lab.

Note: If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

To access the permissions, parameters, alarm settings and other Growth Direct® areas, press the **Menu** button to see the **Menu Options** page.

2.1.1 Configuring Permissions

Note: If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

The Growth Direct® System allows you to define User Roles that specify permissions for different groups of users, such as Administrators or Operators. In addition, you must create individual users for each individual who will use the system. Minimally, a user consists of:

- The operator's first and last name
- A unique username and password
- A User Role

The system checks an operator's username, password, and User Role before allowing the operator to perform certain actions on the system.

2.1.2 Defining System Parameters and Alarm Settings

The Growth Direct® System contains several user-defined system parameters that you can modify. The following are configurable parameters:

- automatic email alarm notifications
- time interval for password expiration
- cassette display options
- backing up and saving log and database files
- incubator temperature settings and temperature alarm thresholds

The sections that follow describe the pages you will need to set up your site.

2.2 Creating User Roles and Assigning Permissions

Note: If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

2.2.1 User Roles Page

The User Roles page allows you to create roles and assign permissions to those roles for access to specific system functions. For example, the Administrator role may have permissions to all system functions but an

Operator may have permissions to only the functions necessary to run tests. The **User Roles** page works in tandem with the **User** page, which associates a user with a role and that role's set of permissions.

To access the **User Roles** page, click **User Roles** on the **Menu Options** page. User Roles functions include Create User Roles, Modify User Roles, and Delete User Roles. You must have the correct permissions to create, edit, and delete User Roles.

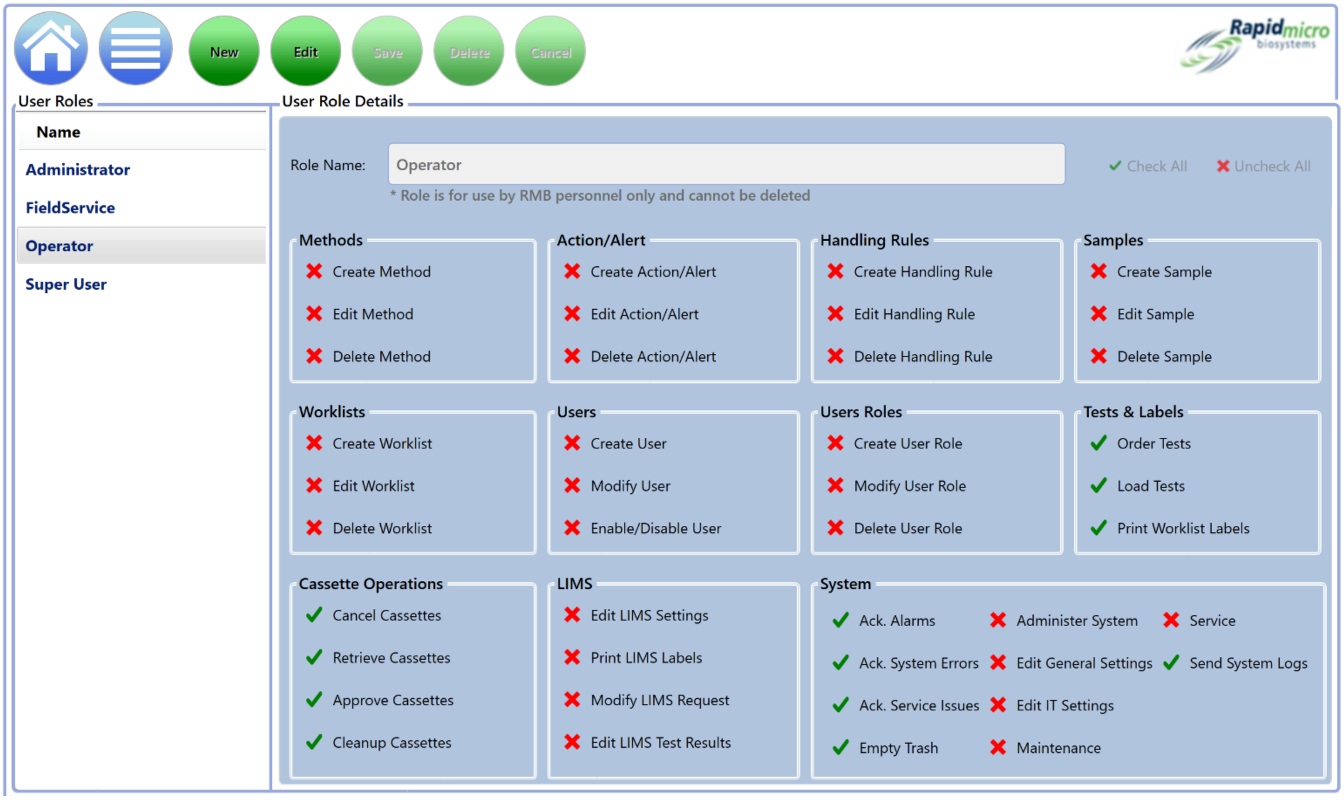


Figure 2-1: User Roles Page

2.2.2 Creating a New Role

To create a new role:

1. Click **New** at the top of the **User Roles** page.
2. Enter the role name in the **Role Name** field.
3. Use the following features to help you select the functions for the role:

    - Click **Check All** or **Uncheck All** to the right of the **Role Name** field to assign all or unassign all functions.
    - Click the name of an individual function to assign it to the role. Functions are grouped by type. For example, all Method functions are grouped together, all Worklist functions are grouped together, and so on.

- Notice the check marks next to each function. A green check indicates the function is selected; a red X indicates it is deselected.

4. Click **Save** to save your choices. A Signature dialog opens asking you to confirm your entries.

Figure 2-2: Signature Page

5. Enter your username and password and click **OK** to save or click **Cancel** to return to the **User Roles** page.

2.2.3 Editing an Existing Role

To edit an existing role:

6. Select the name of the role in the list under **User Roles**. The name appears in the **Role Name** field.
7. Click **Edit** at the top of the **User Roles** page. You must have permission to perform this function.
8. Make any required changes.
9. Click **Save** to save your edits. A Signature dialog opens asking you to confirm your entries.
10. Enter your username and password and click **OK** to save or click **Cancel** to return to the **User Roles** page.

2.2.4 Deleting a Role

Caution! Deleting a Role removes the Role from the available list. Role names cannot be reused after they've been deleted.

To delete an existing role:

1. Select the name of the role in the list under **User Roles**. The name appears in the **Role Name** field.
2. Click **Delete** to remove the role from the system. You must have permission to perform this function. A Signature dialog opens asking you to confirm the deletion.
3. Enter your username and password and click **OK** to finish deleting or click **Cancel** to return to the **User Roles** page.

2.3 Configuring System Users

Note: If your lab uses the Central Manager, User Roles and User accounts are not available in the Growth Direct software. Refer to the Central Manager User Guide for more information.

2.3.1 User Page

The User page allows you to create individual user accounts for everyone that uses the system. It also allows you to disable/enable user access to the system.

To access the **User** page, click the **User** button on the **Menu Options** page.

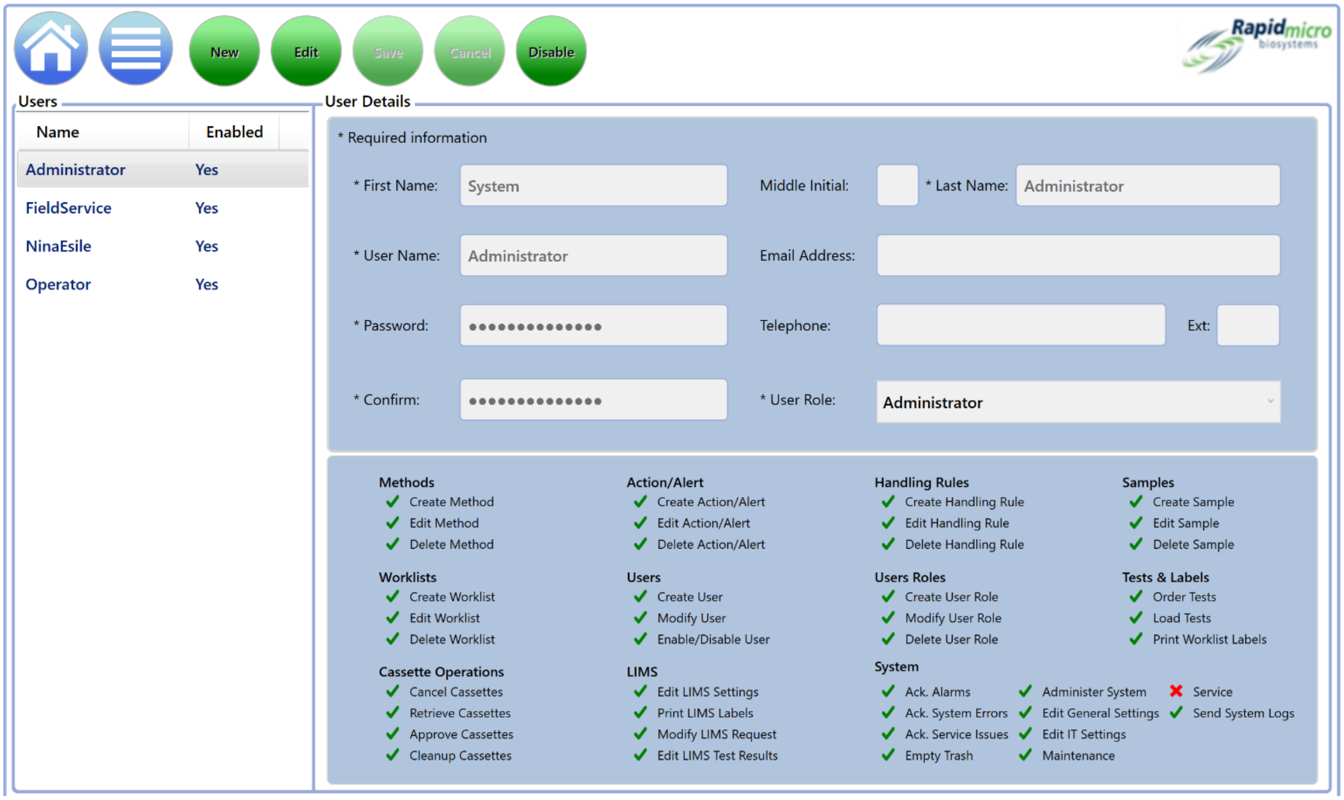


Figure 2-3: Configure Users Page

2.3.2 Creating a User Account

1. Click **New** at the top of the **User** page.
2. Complete the following fields (required fields are marked with an asterisk, *):

- First Name, Middle Initial, Last Name
- User Name
- Email Address

- Password and Confirm – Enter at least 8 alphanumeric characters, including 1 upper case character and 1 numeric. Retype the password to confirm.
- Telephone and Extension
- User Role – Select a role from the dropdown. The permissions allowed (green check) and disallowed (red X) for that role are shown.

3. Click **Save** to save your entries. You must have the correct permissions to create and edit user accounts. A Signature dialog opens asking you to confirm the new account.
4. Enter your username and password and click **OK** to finish adding the user or click **Cancel** to return to the **User** page.

2.3.3 Editing Existing Entries

To edit an existing user:

1. Select the name of the user to highlight it.
2. Click **Edit** at the top of the **User** page.
3. Make any required changes.
4. Click **Save** to save your edits. You must have the correct permissions to edit a user account. A Signature dialog opens asking you to confirm your changes.
5. Enter your username and password and click **OK** to finish editing the user or click **Cancel** to return to the **User** page.

2.3.4 Enabling and Disabling User Access

Use the **Disable** button to prevent a user from accessing the system.

1. To disable user access, choose the name in the list on the left side of the page to highlight it.
2. Click the **Disable** button. You must have permissions to perform this function. A Signature dialog opens asking you to confirm that you are disabling a user.
3. Enter your username and password and click **OK** to finish disabling the user or click **Cancel** to return to the **User** page.

2.3.5 Changing a Password

To access the **Change Password** page:

1. Click **Change Password** on the **Menu Options** page. The **Change Password** dialog opens.
2. Enter the User Name, Old Password, New Password, and then re-enter the new password in the **Confirm Password** field.
3. Click **OK** to save the new password.

2.4 Configuring Email Notifications

The **Email Notifications** page allows you to set up automatic email messages for users based on events in the system. Message types include System Alarms, Test OOS (tests that are out of specification), Security, Data Transfer, and Licensing issues.

To access the **Email Notifications** page, click **Email Notifications** on the **Menu Options** page.

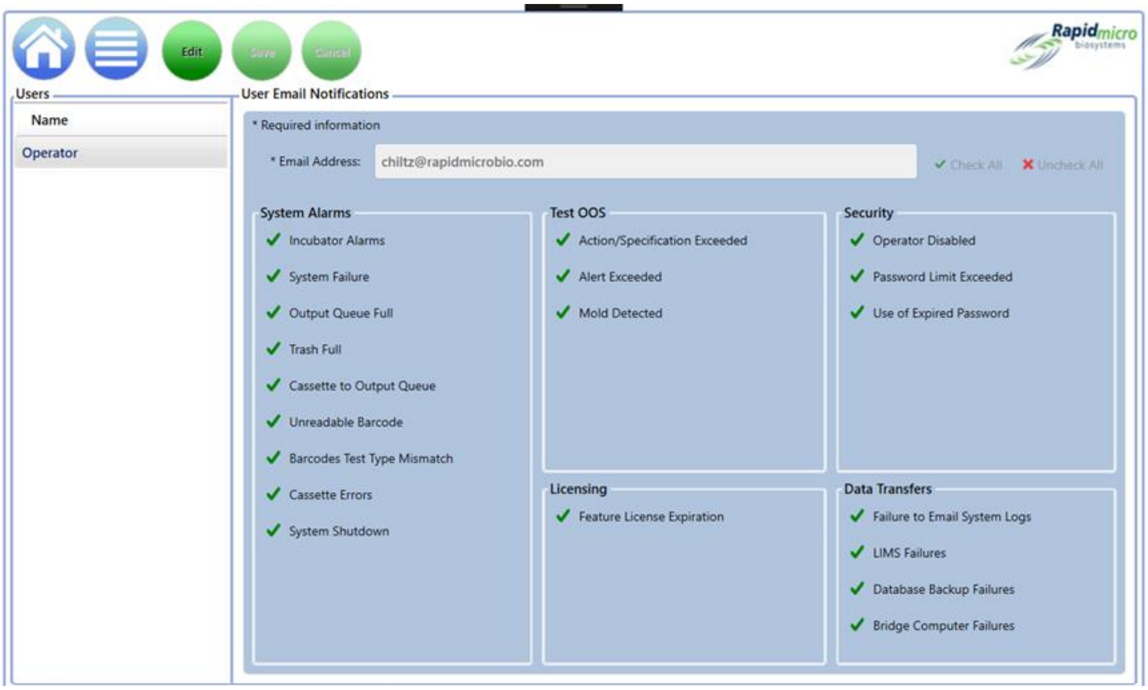


Figure 2-4: Email Notifications Page

2.4.1 Assigning Email Notification Options

To assign email notification options:

1. Select a user name listed under **Users** on the left side of the page and click **Edit**.
2. To assign email notifications to a user, the user account must specify an email address.
   - If the user account already has an email address, it is listed in the **Email Address** Field.
   - If the user account does not already have an email address, click in the Email field and enter a valid email address.
3. Use the following to specify notifications:
   - **Check All** and **Uncheck All** – Click **Check All** or **Uncheck All** to the right of the **Email Address** field to select all or deselect all notifications. Notice the check marks next to each function. A green

check indicates the function is selected; a red X indicates it is deselected. Click to select or deselect all messages listed under the following categories:

- **System Alarms** – Include Incubator Alarms, System Failure, Output Queue Full, Trash Full, Cassette to Output Queue, Unreadable Barcode, Barcodes Test Type Mismatch, Cassette Errors, and System Shutdown.
- **Test OOS** – Includes Action/Specification Exceeded, Alert Exceeded and Mold Detected.
- **Security** – Includes Operator Disabled, Password Limit Exceeded, and Use of Expired Password.
- **Licensing** – Includes LIMS and Mold Detection Licenses.
- **Data Transfers** – Include Failure to Email System Logs, LIMS Failures, Database Backup Failures, and Bridge Computer Failures.

4. Click **Save** at the top of the page to save your entries. You must have the correct permissions to edit email notifications. A **Signature** dialog opens asking you to confirm your changes.
5. Enter your username and password and click **OK** to finish editing email notifications or click **Cancel** to return to the **Email Notifications** page.

Note: To prevent email notifications from being sent to specific users, click **Uncheck All** and **Save** or remove the email address from the **User** page.

2.5 Specifying General Settings

Use the **General Settings** page to set up password notification options, page help (on/off), **Home** page cassette display options, weekend start and end dates (site-specific), the type of comments to accompany test approvals, Test not Loaded intervals, Print out Report options, Feature Licensing, and Bridge Computer settings.

To access the **General Settings** page:

1. Click **General Settings** on the **Menu Options** page. A **Signature** dialog opens asking you to confirm your access. You must be assigned a role that contains Administer System permissions to use the General Settings page.
2. Enter your username and password and click **OK** to access General Settings or click **Cancel**.

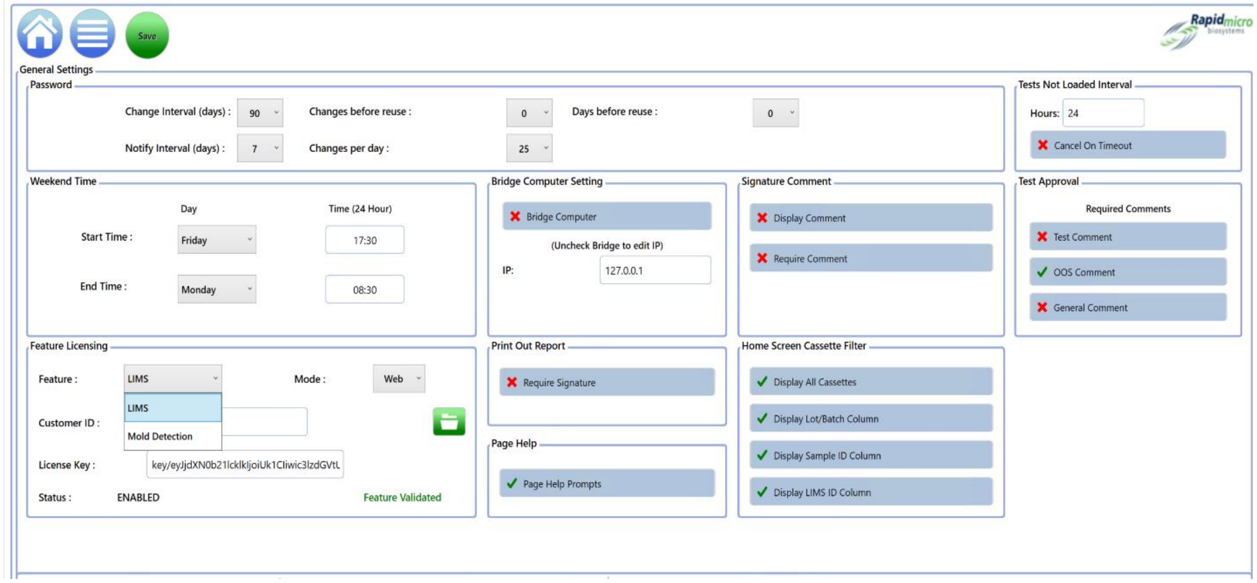


Figure 2-5: General Settings Page

2.5.1 Completing the General Settings

Use the fields in the following sections to define General Settings for your system.

- **Change Interval (Days)** – Specifies the number of days the password is valid before it expires and forces the operator to create a new password.
- **Notify Interval (Days)** – Specifies the number of days, prior to expiration, when the system notifies the operator that their password will expire. Seven days is the default.
- **Changes per day** – Specifies the number of times a single user can change his/her password per calendar day. The default is 25 times per day.
- **Change before reuse** – Specifies the number of password change iterations that an operator must perform before the old password can be reused. By default, this number is 0, which disables this function, meaning that a user can keep the same password indefinitely. This maximum number of change iterations before reuse can be as high as 25.
- **Days before reuse** – Similar to Change before reuse, this option sets the number of days an operator is allowed before the old password can be reused. By default, this number is 0, which disables this function. The Maximum value is 25.

2.5.2 Tests Not Loaded Interval

Compares sample IDs loaded on the system with the expected Worklist. If the sample is not loaded within the time defined, an error message is sent.

2.5.3 Weekend Time

- **Start Time** – Defines the day and hour the weekend starts for your site.

- **End Time** – Defines the day and hour the weekend ends.

2.5.4 Bridge Computer Setting

Activates the TCP/IP connection to the Bridge Computer. This should always be activated.

2.5.5 Signature Comment

- **Display Comment** – Displays a **Comment** field on the Signature dialog.
- **Require Comment** – Requires text in the **Comment** field on the Signature dialog, as shown in the following image.

Figure 2-6: Signature Dialog with Comment

2.5.6 Test Approval Required Comments

Each of the following settings specifies if a user is required to enter text in the **Comment** Fields of the **Approve** page before saving test results.

- Test Comment
- OOS Comment (out of specification). This is on by default.
- General Comment

2.5.7 Licensing

This area of the page contains settings for LIMS.

- **Feature** – Allows you to select LIMS or Mold Detection or both, one at a time.
- **Mode** – Allows you to select **File** or **Web** LIMS. File-based LIMS takes in requests and passes results as a file to a LIMS system. Web-based LIMS requires Central Manager and eliminates the need to exchange files. Available only for LIMS.
- **Customer ID** – Displays your LIMS or Mold Detection customer ID.
- **License Key** – Displays your LIMS or Mold Detection activation code. You can type your license key or import it from a file. Click the Folder button to browse for the file. Click Save at the top of the page to ensure you have activated the license.

- Status – Displays either Enables or Disabled, based on the state of the feature.
- Validated/Not Validated – Displays this message to indicate whether the License Key has been validated.

Note: The Customer ID and Activation Code are available from Rapid Micro Biosystems.

2.5.8 Print Out Report

Requires the user to complete a **Signature** dialog before printing a report. In addition, the user's name is printed in the report footer.

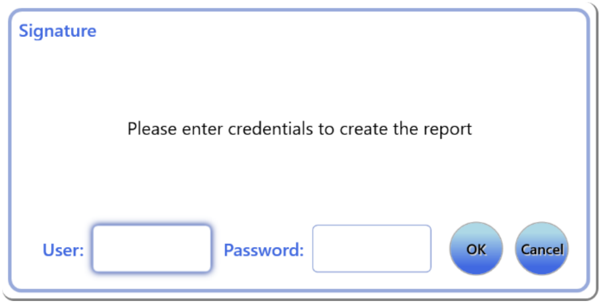


Figure 2-7: Signature Dialog

2.5.9 Page Help

Turns on the page help. Page help provides assistance on pages such as the **Manually Order Tests** page where you are prompted to enter required information.

2.5.10Home Screen Cassette Filter

When selected, displays all cassettes on the **Home** page. When deselected, the default, displays only cassettes that are out of specification (OOS).

Column Filters: Select to display Lot/Batch Column, Sample ID Column, LIMS ID Column.

2.6 Specifying IT Settings

To access the **IT Settings** page, click **IT Settings** on the **Menu Options** page:

1. A Signature dialog opens asking you to confirm your access. You must have a role with Administer System permissions assigned to use the **IT Settings** page.
2. Enter your username and password and click **OK** to access General Settings or click **Cancel**.

After defining settings on any of the **IT Settings** pages, click **Save** at the top of the **IT Settings** page.

1. A **Signature** dialog opens asking you to confirm your entries.
2. Enter your username and password and click **OK**.

2.6.1 IT Settings Page

The **IT Settings** page allows you to specify database backup settings, system email settings, destination for local log files, type and location for exported test results data, and network credentials for saving databases and log files over the network.

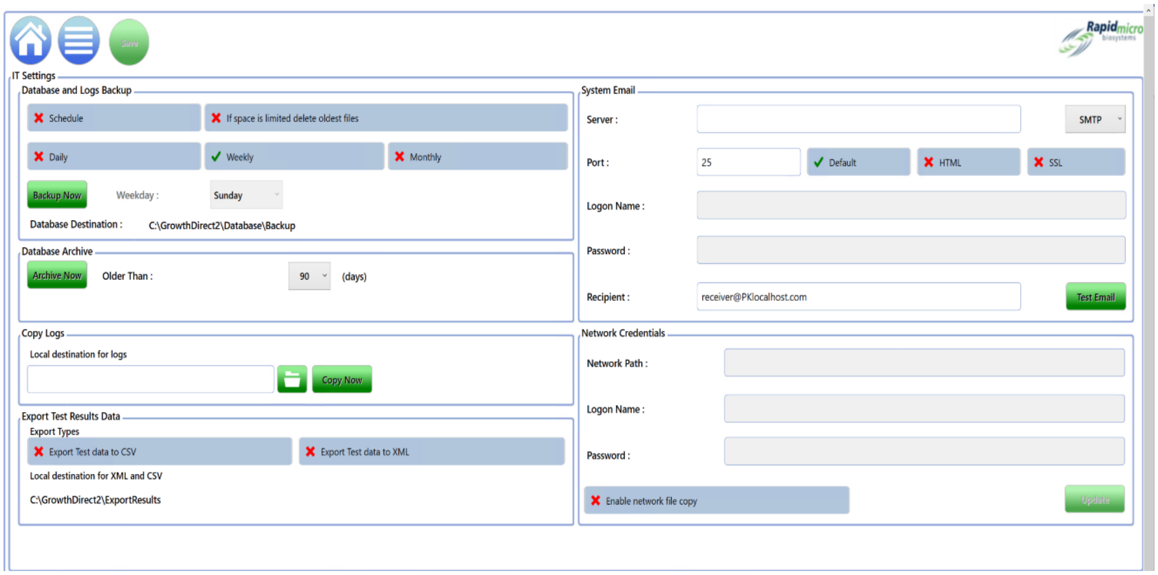


Figure 2-8: IT Settings Page

2.6.2 Database and Logs Backup

Database Backup allows copying Active Databases to an off-instrument location.

Schedule – Click **Schedule** to turn on the Database Backup functions:

- **If space is limited, delete oldest files** – Tells the system to automatically delete old image files after storage space is exceeded.
- **Daily, Weekly, or Monthly** – Tells the system how often to make backups, such as on a daily, weekly, or monthly basis. Click to turn on your selection.
  - **Daily** – Makes a backup each day of the week.
  - **Weekly** – Turns on a dropdown listing the days of the week to choose from.
  - **Monthly** – Turns on two fields: one for specifying the day and the other for specifying the monthly frequency to perform a backup. For example, entering 1 in the **Day** field indicates that the backup occurs on the first day of the month; entering a 1 in the **Month(s)** field indicates that the backup occurs every month, a 2 indicates every two months, and so on.

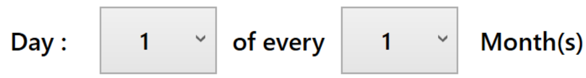


Figure 2-9: Period Dropdowns

Backup Now – Click to start an immediate backup. A **Signature** dialog opens asking you to confirm the backup. Enter your username and password and click **OK** to start the backup or click **Cancel** to cancel.

- **Destination** – Displays the location of the backup. This field is not editable.

2.6.3 Archiving

The system has two databases: Active and Archive. The Archive function makes it possible to move data from the Active Database to the Archive Database as part of a periodic automated maintenance schedule for older data.

To create an archive:

- **Older Than** – Select a period from the **Older Than** dropdown: 30, 60, 90, 180, or 365 days.
- **Archive Now** – Click to immediately archive files that are older than the number of days specified in the **Older Than** field. A Signature dialog opens asking you to confirm the archive. Enter your username and password and click **OK** to start the archive or click **Cancel** to cancel.

2.6.4 System Email

The SMTP credentials and server information is configured on the Growth Direct® System. The Bridge Computer requires the SMTP server utility to be installed to allow communication between the Growth Direct® and the SMTP server.

2.6.5 Copy Logs

Copies log files that have been saved locally (on the system's computer hard drive) to a network destination:

- **Local Destination for Logs** – Enter the path where you want to copy the log files.
- **Browse** – Click the **Browse** button to open the **Browse** dialog. 

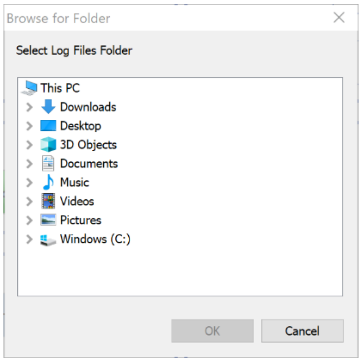


Figure 2-10: Browse for Folder

On the **Browse** dialog, navigate to the folder where you want to copy the logs. Click **OK** on the Browse dialog. The path populates the **Local Destination for Logs** field.

- **Copy Now** – Click **Copy Now** to copy the logs right now. A Signature dialog opens asking you to confirm the copy. Enter your username and password and click **OK** to start the copy or click **Cancel** to cancel.
- **Backup Now** – Initiates an immediate backup of the database.

2.6.6 Exporting Test Results Data

Exports test results data to the specified destination:

- **Export Test data to CSV** – Test data are saved to an Excel CSV format.
- **Export Test data to XML** – Test data are saved to an XML format.
- **Local Destination for XML and CSV** – Specifies the path for the export files. It is uneditable.

2.6.7 Network Credentials

Specifies the network information and credentials for logging into the network:

- Network Path – Specifies the URL to your network.
- Logon Name – The Logon Name that you use when logging on to your network. This name requires the domain, for example, domain\logon name.
- Password – Specifies the Password you use when logging on to your network.
- Enable Network File Copy – Tells **Database Backup** and **Copy Logs** to use the specified Network Credentials instead of the default location on the Bridge Computer.

2.6.8 Remote Monitoring System Options

The Growth Direct® system may be modified to allow a range of actions to occur remotely between Rapid Micro Biosystems and the customer site. The interactions facilitate a superior service experience. During installation (or preventive maintenance) a technician can set the Growth Direct® System to allow one of the following levels of interactions:

Tier Level	Functional Description
0	No remote communication. Log files are cleaned up to prevent filling the hard drive.
1	Communicate with the Rapid Micro Hub. Indicates the Growth Direct® is Online. Send alert messages indicating an event has occurred on the Growth Direct® Computer.
2	Reset alerts so that they may be re-evaluated. Automated uploading of Growth Direct® system log files.
3	Remote Growth Direct® System Reboot and starting/stopping of selected services and processes.
4	Attended running of the Remote Desktop via the Growth Direct® application.
5	Unattended running of the Remote Desktop via remote command to the Growth Direct® application.
6	Attended Remote Desktop only. All other functionality is disabled.

Details of this service are available from Rapid Micro Biosystems. Our staff will work with your IT department to make the Remote Desktop available.

2.7 Specifying Printer Settings

Click **Printer Settings** to open the Printer Settings page. It allows you to set up a document printer and a barcode printer.

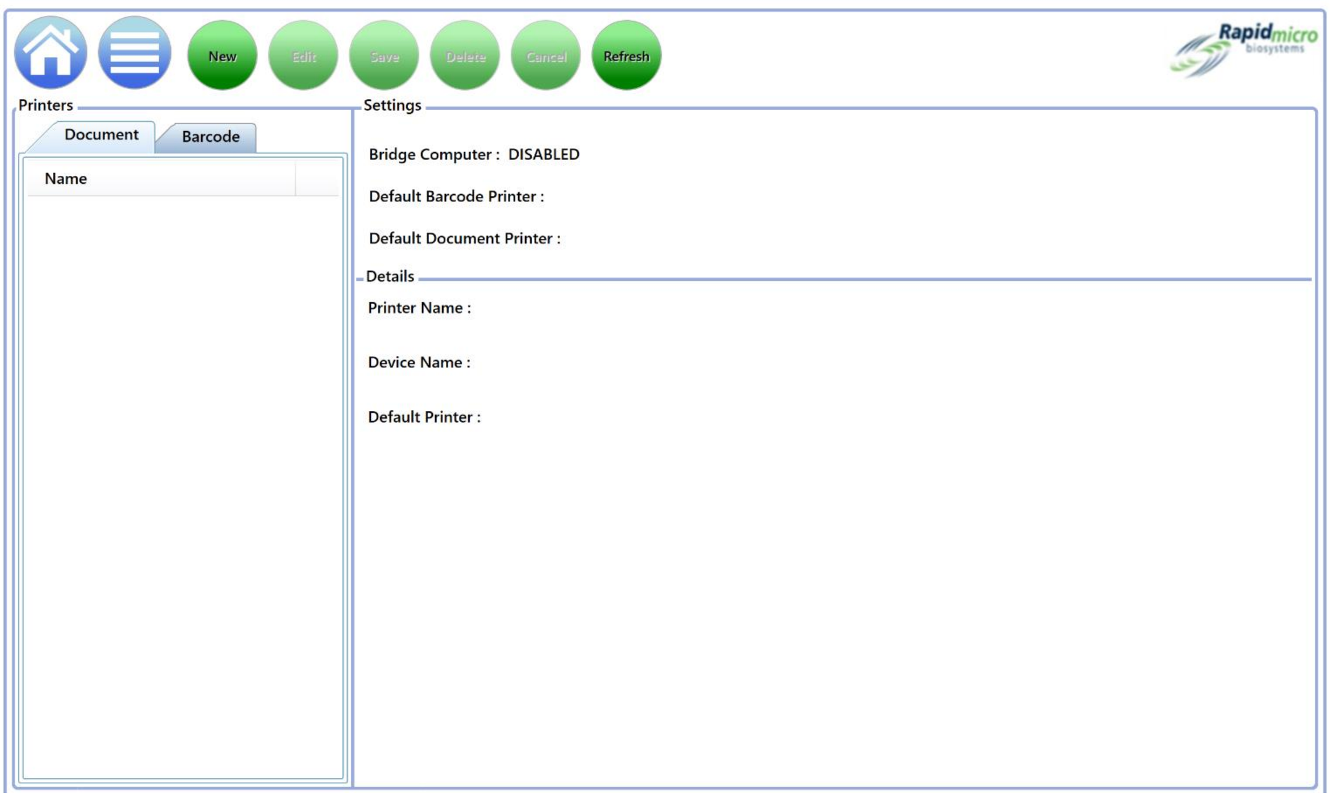


Figure 2-11: Printer Settings Page

2.7.1 Document Printer

You can connect a document printer on the Printer Settings page. To do so:

1. Click the **Document** tab on the left.
2. Click **New** at the top of the page. The Details section of the page changes to display settings for printers.

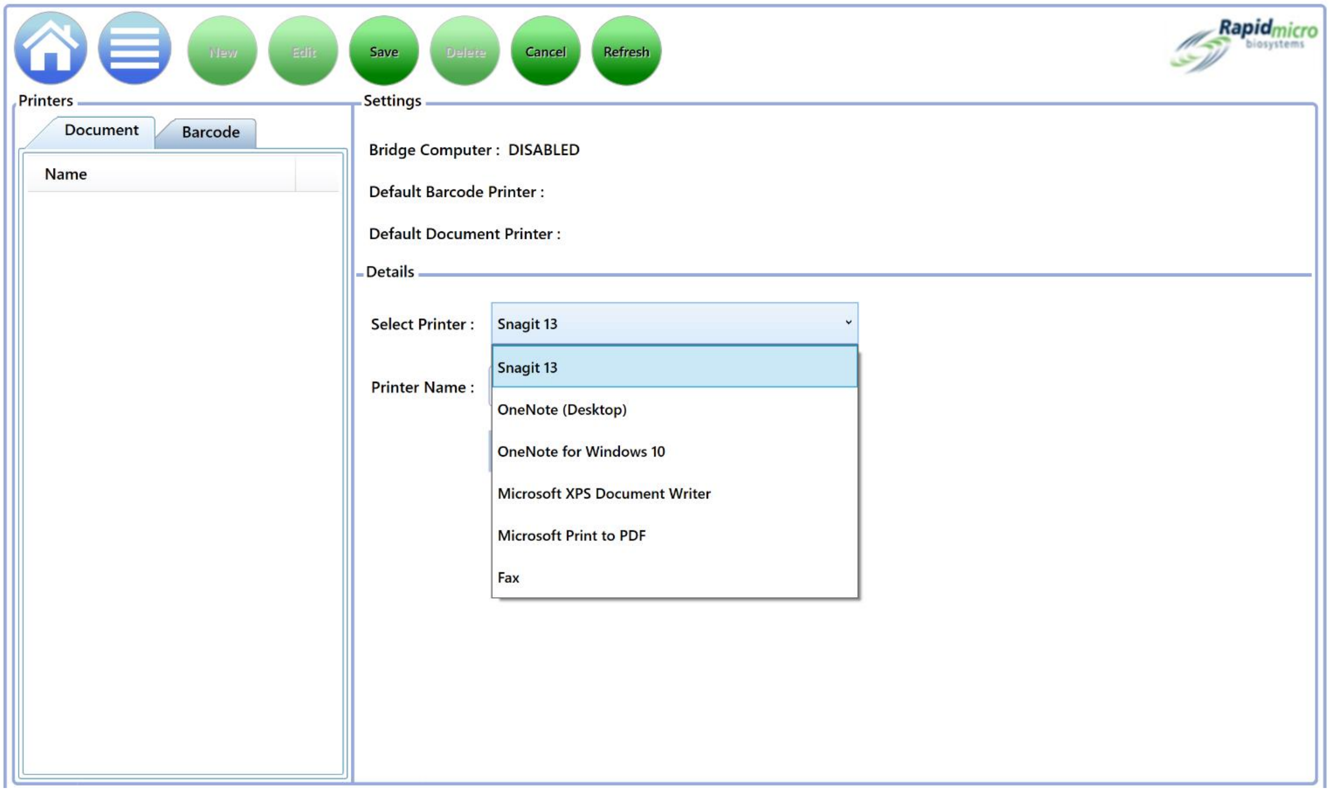


Figure 2-12: Document Printer Details

3. Select a printer from the **Select Printer** dropdown.
4. Enter a name into the **Printer Name** field or leave it as is.

2.7.2 Barcode Printer

The barcode printer can be connected through your network or through the Bridge Computer. A Bridge Computer is always installed on your system. (See Section 5.1.1, Configuring a Barcode Printer).

2.8 Setting Incubator Temperature and Temperature Alarm Thresholds

The **Incubator Settings** page changes incubator temperatures and upper and lower alarm levels (thresholds) for the top and bottom incubators. The system issues an alarm when temperature thresholds are exceeded.

To access the **Incubator Settings** page, click **Incubator Settings** on the **Menu Options** page.

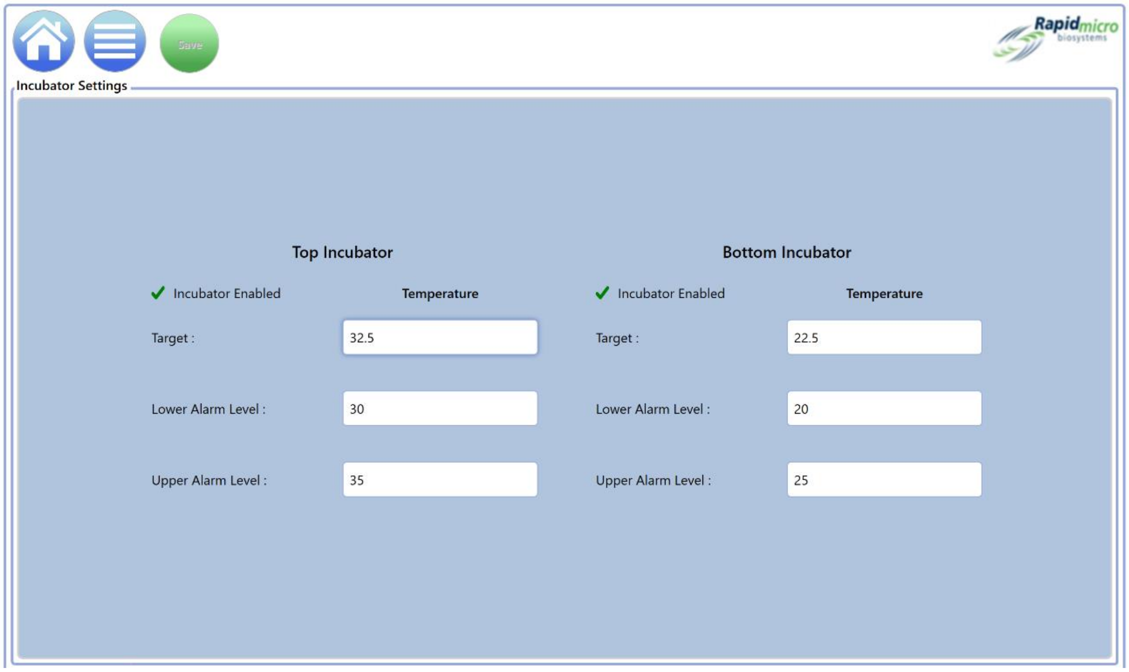


Figure 2-13: Incubator Settings Page

2.8.1 Setting Temperature Ranges

Note: When changing the temperature, it is important to verify the temperature calibration. This is best performed by a Service Technician from Rapid Micro Biosystems.

1. Use the following fields below the Top Incubator and Bottom Incubator headings to set the temperature ranges. A green check indicates that an incubator is enabled; a red check indicates it is disabled.:
   - **Target** – Specifies the top and bottom incubator temperatures. When the incubators are set at different temperatures, we recommend that the lower incubator have the lower temperature.
   - **Lower Alarm Level and Upper Alarm Level** – Specifies the temperatures to initiate an alarm if the incubator target temperature drops below or rises above these thresholds.
2. Click **Save** at the top of the page. A Signature dialog opens asking you to confirm your entries.
3. Enter your username and password and click **OK** to save or click **Cancel** to cancel.

2.9 System Cleanup

System Cleanup helps you manually remove cassettes from the system.

Caution! Contact Customer Support for guidance with these steps.

2.9.1 System Cleanup Page

To access the **System Cleanup** page, click **System Cleanup** on the **Menu Options** page.

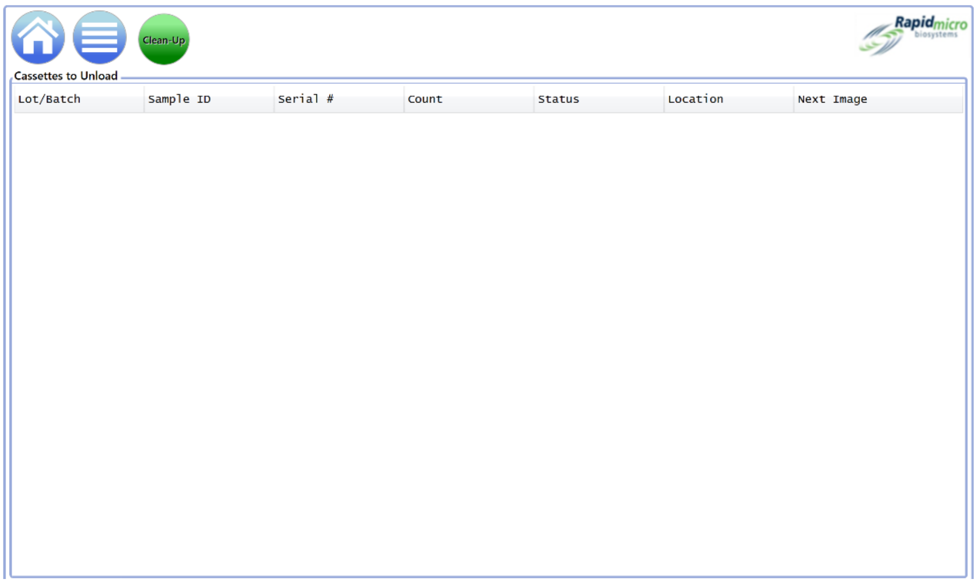


Figure 2-14: System Cleanup Page

2.9.2 Manually Remove Cassettes

1. Contact Customer Support for guidance.
2. Click **System Cleanup**; a list of cassettes populates the left side of the page.
3. Click **Clean-Up** on the **Cassettes to Unload** page. A **Signature** dialog opens asking you to confirm the clean-up. Enter your username and password and click **OK** to start the clean-up or click **Cancel** to cancel.

3. Using the Growth Direct® System

This section contains:

3.1 Overview

This section describes the high-level tasks for using the Growth Direct® System to perform daily tests. You can customize many aspects of the system to best meet your lab's needs.

Defining tests and configuring parameters – In addition to defining samples and grouping them into worklists, the software provides pages for specifying parameters for running tests including the time, in hours, the cassettes occupy the incubators and at what temperature. You can also specify where cassettes will go – output queue, trash, or incubator – based on the cassette status.

System Capacity – Depending on the incubation strategy used for processing samples, the system throughput can vary. The throughput depends on whether a single or serial temperature is used and the number of days the sample is incubated at each temperature. Consult with your Rapid Micro Biosystems specialist to optimize sample throughput.

Automatic cassette analysis and notification – Once cassettes enter the system, you do not need to do anything until the test finishes. Results are recorded on the system and remotely. You can monitor status and CFU count readings, if necessary. If problems occur during a test, for instance if the system cannot inspect a cassette because the label is unreadable, the **Home** page indicates that there is an issue. You can also select tests for cancelation or retrieval.

Approving results and printing reports – At the end of a test, a supervisor with the correct permissions reviews and approves results and can view and print a test report.

The sections that follow describe all the pages you will require to set up your system parameters and run tests.

3.2 Creating and Modifying Methods

The **Methods** page allows you to specify for each test, the incubation time (in hours) and temperature (in degrees Celsius).

To display the **Methods** page, click **Methods** on the **Menu Options** page.

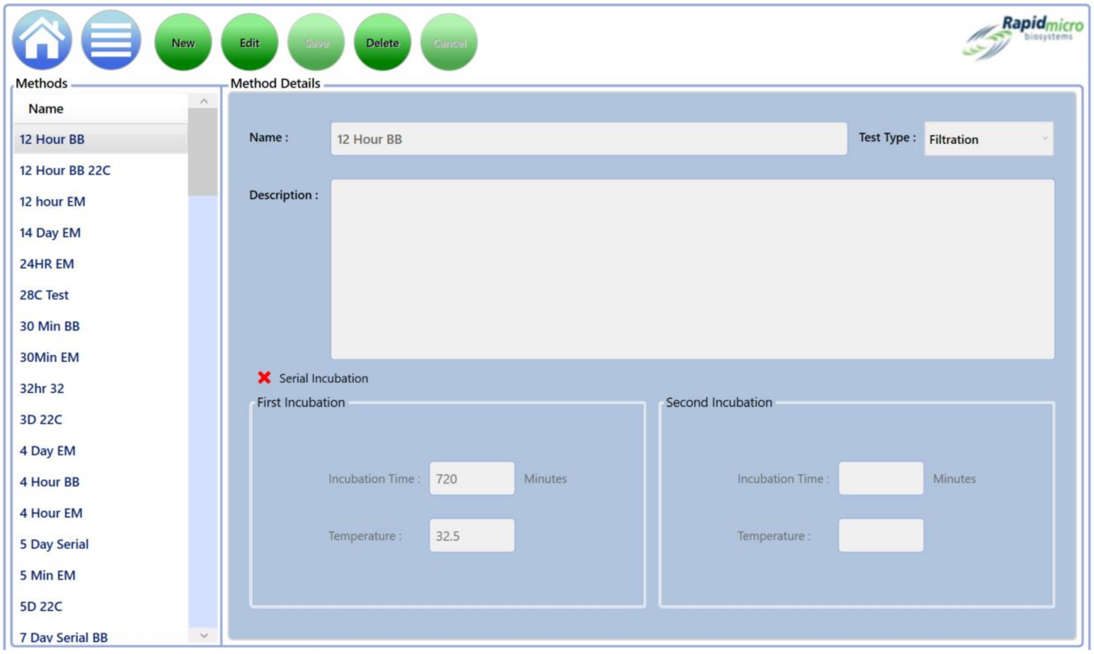


Figure 3-1: Methods Page for EM and Bioburden

3.2.1 Creating a New Method

1. Click **New** at the top of the page.

2. Complete the following fields:

- **Name** – A unique Method name, 46 characters or less. Names can contain alphanumeric characters, spaces, and these special characters of + # - _ ( ) ‘ . and \ .
- **Description** – A detailed description, 1000 characters or less. You can use any characters in this field.
- **Test Type** – The options for method type are:
    - Environmental Monitoring
    - Filtration
- **Serial Incubation** – When Serial Incubation is disabled, the system performs only a single temperature incubation (First Incubation). If you need a second incubation period for a different length of time or different temperature, click the red X to enable the Second Incubation.
- **First Incubation**
- **Incubation Time** – The total time in hours the samples are incubated and imaged. Cassettes are imaged every 4 hours so a Method with a total incubation time of 24 will result in 6 images for the cassettes assigned to this Method.
- **Temperature** – The incubation temperature in degrees Celsius to use for the cassettes.
- **Second Incubation** – If serial incubation has been enabled, enter the Incubation Time and Temperature as with the First Incubation.

3. Click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you’re saving the Method. Enter your username and password and click **OK** to save or click **Cancel**. Once saved, the new Method appears in the list on the left side of the page under **Methods**.

3.2.2 Editing Methods

Use the **Edit** button to modify entries for existing methods. You must have **Edit Method** permissions to perform this function.

1. Select the Method name in the list on the left side of the page under **Methods**.
2. Click **Edit**. The Method populates the right side of the page.
3. Make any necessary changes.
4. Click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you’re saving the Method. Enter your username and password and click **OK** to save or click **Cancel**.

3.2.3 Deleting Methods

Use the **Delete** button to remove a Method from the system.

Caution! Deleting Methods removes the Method from the available list. Method names cannot be reused after they’ve been deleted.

1. Select the Method name on the left side of the page under **Methods**.
2. Click **Delete**. A **Signature** dialog opens asking you to confirm that you're deleting the Method. Enter your username and password and click **OK** to delete the Method or click **Cancel**. The Method name is removed from the list.

3.3 Defining Alerts, Actions, and Specifications

The Growth Direct® system allows you to specify CFU count limits for Alerts, Actions, and Specifications. When you set a count limit for each level (Action, Alert, or Specification) and when the test results exceed that limit, the system alarms and flags the sample.

- **Alert** – When you define a threshold for an Alert, you are telling the system to send a notification when the CFU count reaches the specified level.
- **Action** – When you define a threshold for an Action, you are telling the system to take an action when the CFU count reaches the specified level.
- **Specification** – When you define a threshold for a Specification, you are telling the system that the sample is OOS when the CFU count reaches the specified level.

3.3.1 Action Alert Level Page

The **Action Alert Levels** page allows you to define alarm levels using thresholds for CFU counts. In addition, if mold is enabled, you can use this page to notify you if mold is detected. To access the **Action Alert Levels** page, click **Action Alert Levels** on the **Menu Options** page.

Figure 3-2: Action Alert Levels Page

3.3.2 Creating a New Action Alert Level Record

1. Click **New**. Enter the following information:

   - **Name** – Enter a unique name for the Action and Alert settings. Names can be 46 characters or less and can contain alphanumeric characters, spaces, and these special characters: # _ + ( ) ' . \
   - **Description** – Enter a detailed description, 1000 characters or less. You can use any characters in this field.
   - Alert/Action/Specification:
   - **None** – GD does not create an Alert or Action regardless of CFU count.
   - **Greater Than** – GD creates an Alert or Action if the CFU count exceeds the number shown. Valid values are whole numbers 0 – 99999999
   - **Specification** – If you set a Specification count, the Alert and Action values are reset to None.
   - **Passed if CFU Counts** – Select this option to have cassettes that pass the Action/Alert settings remain in the system for further investigation, e.g., for the presence of mold, rather than sending them to the trash. This setting does not generate any cassette alarms.
   - **Notify if Mold** – Select Mold to receive a notification when mold is present.

2. Click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you're saving the Action Alert Level. Enter your username and password and click **OK** to save or click **Cancel**. The new Action Alert appears in the list on the left side of the page.

3.3.3 Deleting Action Alert Level Designations

Use the **Delete** button to delete an Action or Alert Level.

Caution! Deleting an Action Alert Level removes the Action Alert Level from the available list. Action Alert Level names cannot be reused after they've been deleted.

1. Select the name of the Action/Alert under **Action Alert Levels** on the left side of the page. The name appears in the **Name** Field.
2. Click **Delete** to remove the Action/Alert from the system. A **Signature** dialog opens asking you to confirm that you're deleting the Action/Alert Level. Enter your username and password and click **OK** to save or click **Cancel**.

3.4 Creating and Modifying Handling Rules

3.4.1 Handling Rules Page

The **Handling Rules** page allows you to specify the placement of cassettes into an output queue, trash bin, or incubator based on the cassette status: OOS, Passed, Canceled, or Counts Prior to Endpoint.

You can specify rules for weekdays only, or weekdays and weekends, if site specific weekends are defined on the **General Settings** page.

To access the **Handling Rules** page, click **Handling Rules** on the **Menu Options** page.

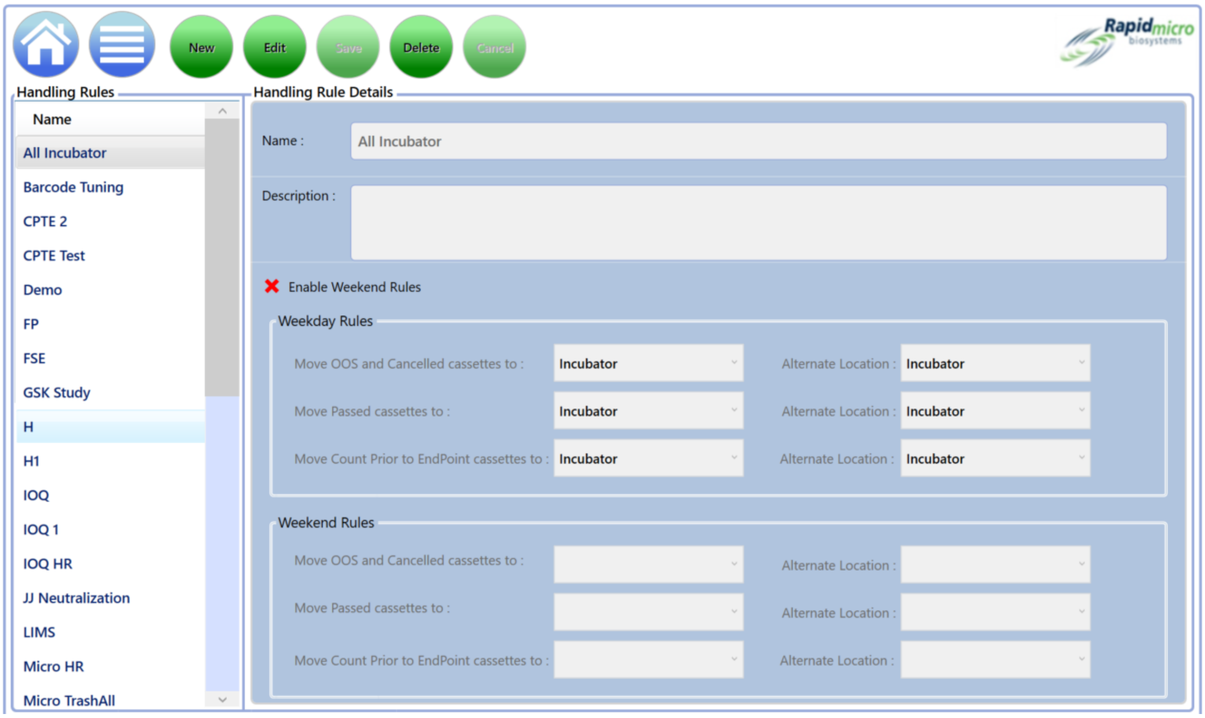


Figure 3-3: Handling Rules Page

3.4.2 Creating a New Handling Rule

To create a new Handling Rule:

1. Click **New** at the top of the **Handling Rules** page.
2. Complete the following fields:

- **Name** – Enter a name for the Handling Rule, 46 characters or less. Names can contain alphanumeric characters, spaces, and these special characters: + # - ( ) ‘ . \
- **Description** – Enter a detailed description, 10 00 characters or less. Definitions can contain alphanumeric characters, spaces, and these special characters: + # - _ ( ) ‘ . \
- **Enable Weekend Rules** – By default, Enable Weekend Rules is deselected, which means rules are used only for weekdays. If you want to include weekend operation, click Enable Weekend Rules. Enabling works only if the weekends are defined on the **General Settings**.
- **Rules:**
- **Move OOS and Cancelled cassettes to** – Select a destination for OOS and Cancelled cassettes. A cassette is considered OOS when it has a CFU count that generates an alert, action, or specification.

- **Move Passed cassettes to** – Select a destination for cassettes that have been tested and passed. Passed cassettes are those that complete the incubation and analysis and have not generated any alerts, actions, or specifications.
- **Move Count Prior to Endpoint cassettes to** – Select a destination for cassettes that have overgrown to the point at which CFUs can no longer be determined.
- **Alternate Location** – Select a secondary destination. Each rule provides for an Alternate Location, which is used when the primary location is full or cannot accept a cassette.

3. Click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you're saving a Handling Rule. Enter your username and password and click **OK** to save or click **Cancel**. The new Handling Rule appears in the list on the left side of the page.

3.4.3 Editing Handling Rules

The **Edit** button allows you to edit existing Handling Rules.

1. Select the Handling Rules name in the list under **Handling Rules**.
2. Click **Edit** at the top of the page. The settings for the Handling Rule appear on the right side of the page.
3. Make your edits.
4. Click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you're saving a Handling Rule. Enter your username and password and click **OK** to save or click **Cancel**.

3.4.4 Deleting Handling Rules

Use the **Delete** button to remove an existing Handling Rule.

Caution! Deleting Handling Rules removes the Handling Rule from the available list. Handling Rule names cannot be reused after they've been deleted.

1. Select the Handling Rules name in the list under **Handling Rules**.
2. Click **Delete** at the top of the page. A **Signature** dialog opens asking you to confirm that you're deleting a Handling Rule. Enter your username and password and click **OK** to continue deleting or click **Cancel**.

3.5 Creating and Modifying Samples

Defining a sample makes it easier to apply the same parameters across multiple tests and correlate individual cassettes to a single test. The **Samples** page allows you to group a collection of predefined test parameters: Methods, Action Alert Levels, and Handling Rules. Together these parameters specify all the details required to run a complete test. You can also use this page to import samples.

To access the **Samples** page, click **Samples** on the **Menu Options** page.

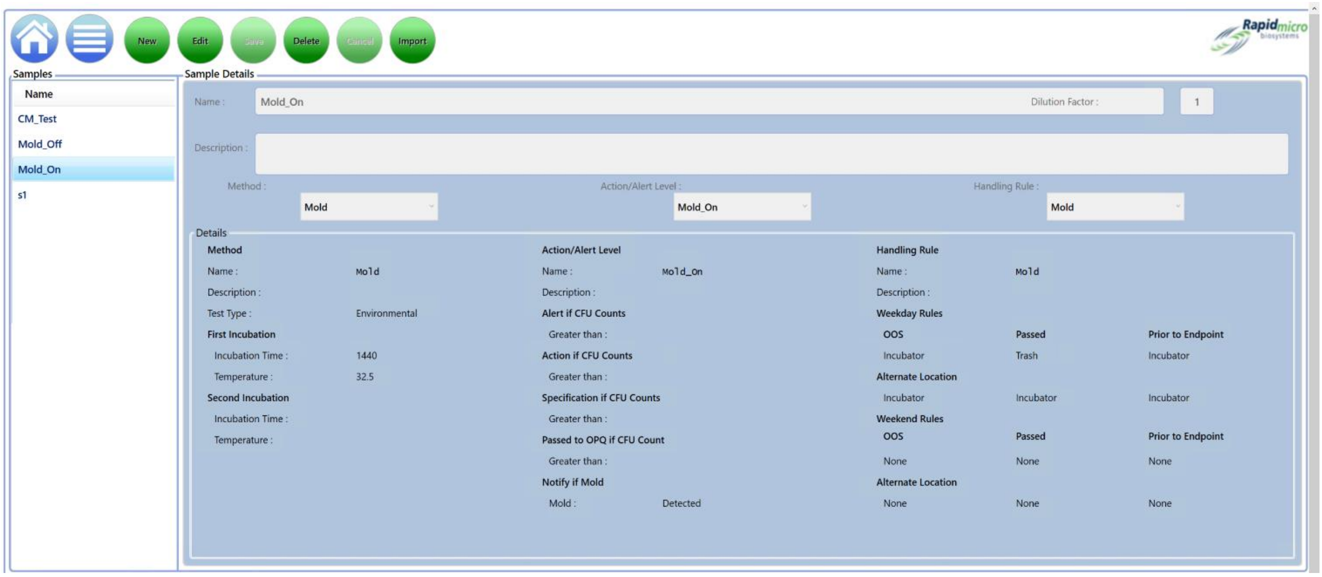


Figure 3-4: Samples Page

3.5.1 Using the Samples Page

1. To create a new Sample, click **New** at the top of the **Samples** page.
2. Complete the following fields:
   - **Name** – Enter a unique Sample name, 39 characters or less. Names can contain alphanumeric characters, spaces, and these special characters: + # - _ ( ) ‘ . \
   - **Dilution Factor** – Enter a value as a whole number in the range 0 - 999.
   - **Description** – Enter a detailed description, 1000 characters or less. Descriptions can contain alphanumeric characters, spaces, and these special characters: + # - _ ( ) ‘ . \
   - **Method** – Select a Method from the dropdown list. Only Methods that have been successfully saved using the **Methods** page appear on the list.
   - **Action/Alert Level** – Select an Action/Alert Level from the dropdown list. Only Action/Alert Levels that have been successfully saved using the **Action/Alert Level** page appear on the list.
   - **Handling Rule** – Select a Handling Rule from the dropdown list. Only Handling Rules that have been successfully saved using the **Handling Rules** page appear on the list.
3. To save these settings, click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you’re saving a Sample. Enter your username and password and click **OK** to continue saving or click **Cancel**. The new Sample appears in the list on the left side of the page.

3.5.2 Importing a Sample

1. To import a sample, click **Import** at the top of the **Samples** page. An **Import Samples** page appears:

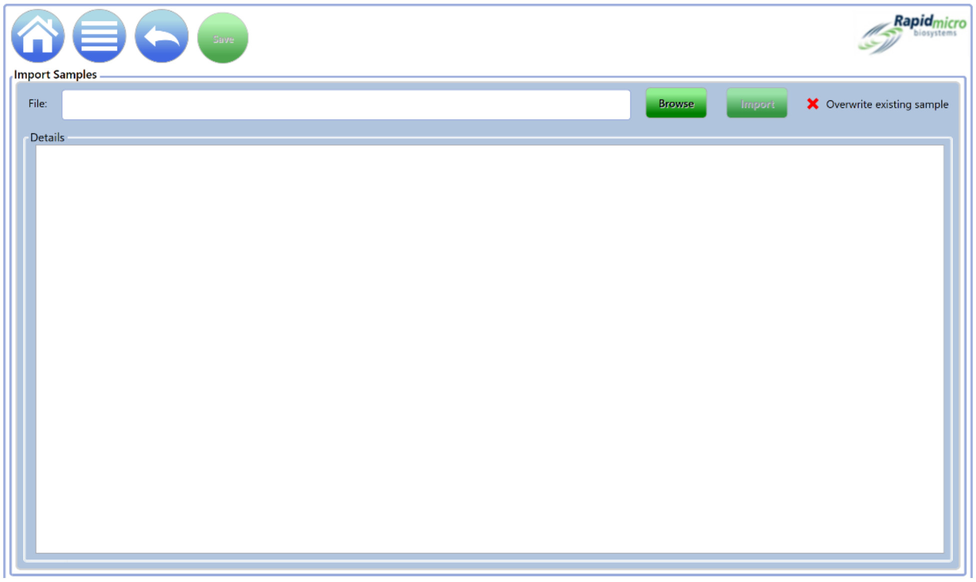


Figure 3-5: Import Samples Page

2. To locate a sample for import, click **Browse**.
3. Navigate to the sample you want to import, select it, and click **Import**.
4. **Overwrite Existing Sample** is off by default. Click it to toggle it on, which tells GD to overwrite samples stored on the system that share the same name. For example, if the sample you are importing is named S1 and a sample named S1 is stored on the system, the imported sample overwrites the resident sample.
5. To save, click **Back** to return to the **Samples** page.
6. Click **Save** at the top of the **Samples** page. A **Signature** dialog opens asking you to confirm that you're saving a Sample. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.5.3 Editing a Sample

1. Select the sample name to highlight and select it in the Samples list on the left side of the **Samples** page.
2. Select the **Edit** button at the top of the page. The Method, Action/Alert details associated with the sample populates the page on the right. Make your changes accordingly.
3. To save, click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you're saving the Sample. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.5.4 Deleting a Sample

1. To delete, first select the sample name under the Samples list to highlight and select it.
2. Select the **Delete** button at the top of the page. A confirmation page appears.

3. Complete the appropriate information and click **OK** or **Cancel**.

3.6 Creating and Modifying Worklists

The **Worklists** page allows you to create and modify Worklists, which comprise collections of predefined samples. Creating worklists follows the sample defining process using Methods for setting up incubation parameters, Action Alert Levels for setting up CFU thresholds, and Handling Rules for determining cassette placement.

To access the **Worklist** page, **Worklists** on the **Menu Options** page.

Figure 3-6: Worklists Page

3.6.1 Creating a New Worklist

To create a new Worklist:

1. Click **New** on the **Worklist** page.
2. Complete the following fields:
   - **Name –** Enter a unique Worklist Sample name, 46 characters or less. Names can contain alphanumeric characters, spaces, and these special characters: + # - _ ( ) ‘ . \
   - **Description –** Enter a detailed description, 1000 characters or less. Descriptions can contain alphanumeric characters, spaces, and these special characters: # _ + ( ) ’ . \
   - **Add Sample –** Click **Add Sample** to add a sample to the end of the list.

- **Insert Sample –** Click **Insert Sample**. Valid values are whole numbers 0-999999.
- **Delete Samples –** Highlight a sample and click **Delete** to remove that sample from the list.
- To save, click **Save** at the top of the page. A **Signature** dialog opens asking you to confirm that you're deleting a Sample. Enter your username and password and click **OK** to continue saving or click **Cancel**.
- Once saved, the new Worklist name appears in the list on the left side of the page.

3.6.2 Importing a Worklist

1. To import a Worklist that was not directly created on the Growth Direct® system, click **Import** at the top of the **Worklists** page. The **Import Worklist** page opens:

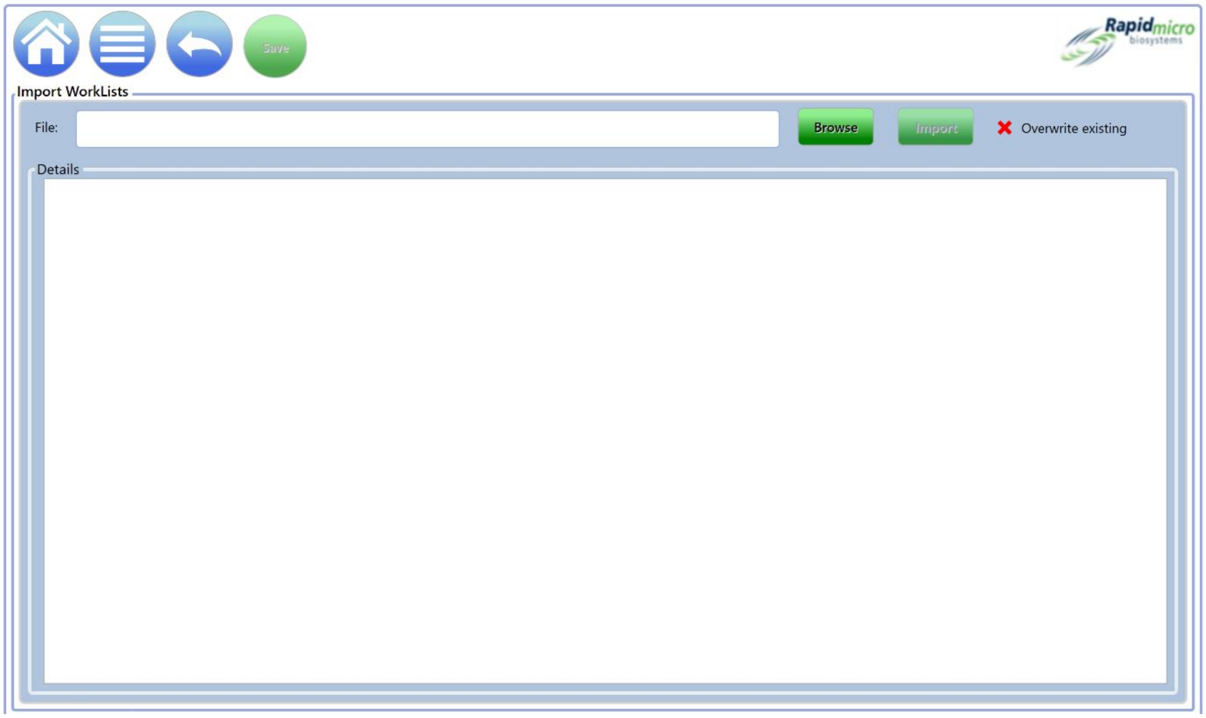


Figure 3-7: Import Worklist Page

2. To locate a Worklist to import, click **Browse**.
3. Navigate to the Worklist you want to import, select it, and click **Import**.
4. The overwrite function is off by default. Click it to turn overwrite on, which tells the system to overwrite a Worklist stored on the system if it has the same name. For example, if the Worklist you want to import is named S1 and a worklist named S1 is stored on the system, the imported Worklist overwrites the resident Worklist.
5. To save it, click **Back** to return to the **Worklists** page.

6. Select the **Save** button at the top of the **Worklists** page. A **Signature** dialog opens asking you to confirm that you're saving a Worklist. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.6.3 Editing a Worklist

1. To edit a Worklist, select it under the **Worklists** heading on the left side of the page.
2. Click **Edit** at the top of the page. The Sample names and details populate the right side of the page.
3. Add, Insert, or Delete samples accordingly.
4. To save, select the **Save** button at the top of the page. A **Signature** dialog opens asking you to confirm that you're saving a Worklist. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.6.4 Deleting a Worklist

1. To delete a Worklist, select it under the Worklists heading on the left side of the page.
2. Click **Delete** at the top of the page. A **Signature** dialog opens asking you to confirm that you're deleting a Worklist. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.7 Printing Worklist Sheets and Labels

Use the **Print Worklists** page to print out sample labels on the barcode printer or sheets of labels on a regular printer for scanning into the system. Use the **Print Worklists** page in conjunction with the **Worklist** page, which allows you to create and modify Worklists.

To open the **Print Worklists** page, click **Print Worklists** on the **Menu Options** page.

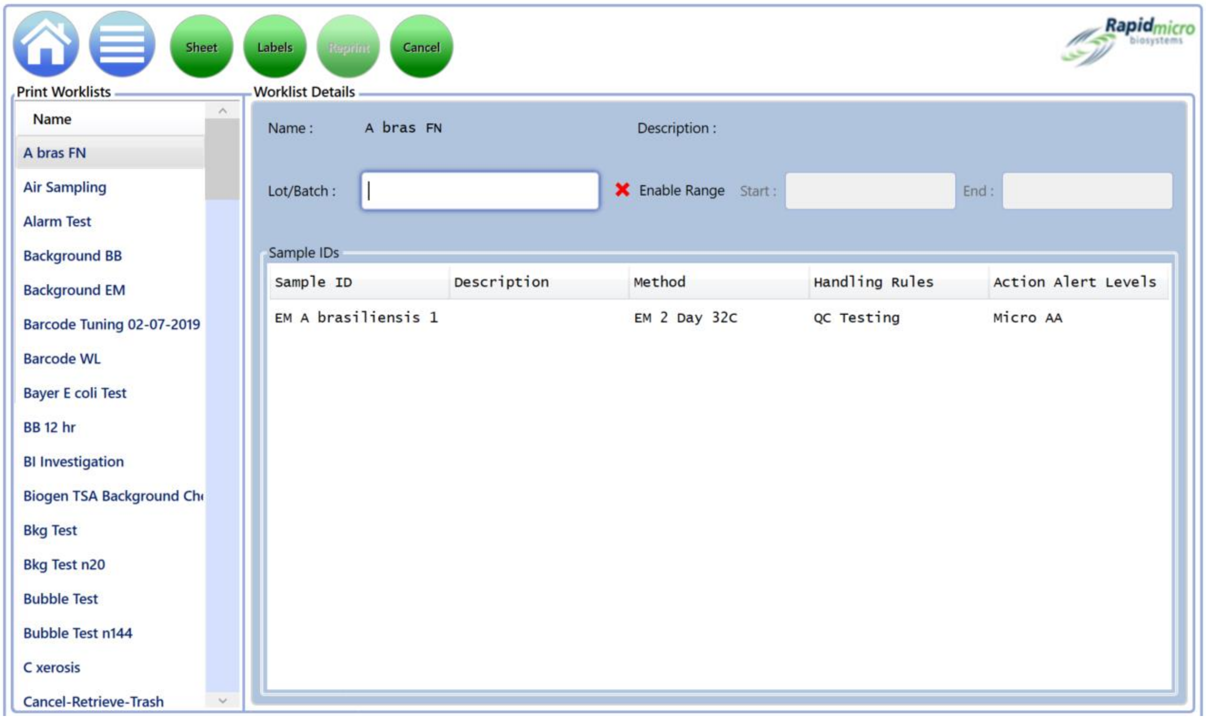


Figure 3-8: Print Worklist Page

1. Select a Worklist name under the Print Worklists heading on the left side of the page.
2. Complete the following fields:
   - Name and Description – These fields are automatically populated when you select a Worklist name.
   - Enter a unique name for the Lot/Batch Name. In combination with the Sample ID name, the Lot/Batch name must be 42 characters or less. Names can only contain alphanumeric characters (a-z, A-Z, 0-9) and under- score (_). We recommend using the current date as an identifier.
   - Enable Range – Enter a range that indicates that the system prints out multiple sets of samples. An entry of 1 in the **Start** Field and a 5 in the **End** Field indicates that 5 sets of samples are to be printed. Be aware that, when using Enable Range, the number and a hyphen (e.g., -5) are added to the Lot/Batch identifier which has a 42-character limit. You must have Print Worklist Labels permission to print labels.
3. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.
4. The **Labels** button tells the system to send the sample labels to the barcode printer, which prints labels that you stick to the bottom of the cassettes. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel.**

5. The **Reprint** button tells the system to reprint the Worklist labels. Select a Worklist under the **Sample IDs** Heading. Click **Reprint** at the top of the page. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.8 Selecting and Ordering Tests

3.8.1 Manually Order Tests Page

Use the **Manually Order Tests** page to select and order tests Manually, by Worklist, or by Sample.

To open the **Manually Order Tests** page, click **Manually Order Tests** on the **Menu Options** page.

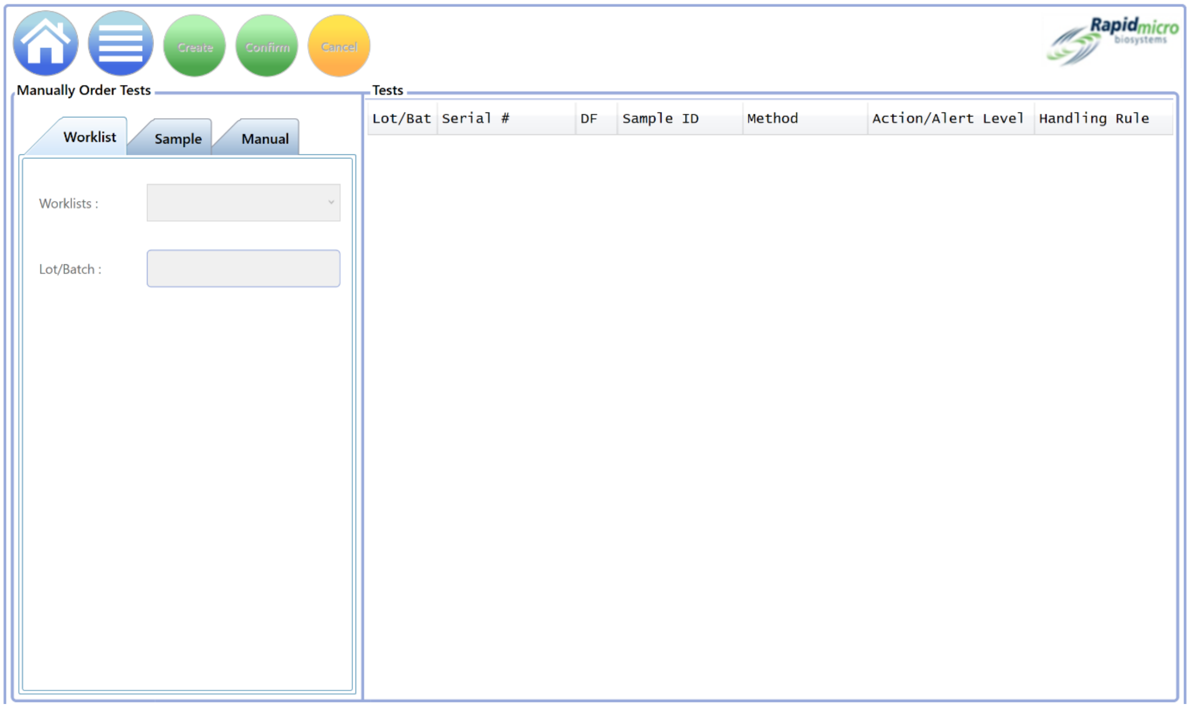


Figure 3-9: Manually Order Tests Page

3.8.2 Worklist Tab

1. If you are using predefined Worklists, select the **Worklists** tab.
2. Select a Worklist from the **Worklists** dropdown.
3. Enter a unique name for the Lot/Batch name. In combination with the Sample ID name, the Lot/Batch name must be 42 characters or less. Names can contain only alphanumeric characters (a-z, A-Z, 0-9) and underscore (_).
4. Click **Create** at the top of the page. The tests appear on the right side of the page with its test parameters.

5. If a serial number has not been entered, scan a serial number with the barcode scanner or type the number into the **Serial #** field. Each test within an order is required to have a serial number. The cassettes are not loaded until a unique ID is assigned.
6. To cancel the order, click **Cancel** at the top of the page before confirming.
7. To save the order, click **Confirm** at the top of the page. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**. The order is complete.

3.8.3 Sample Tab

1. If you are using predefined Samples, select the **Sample** tab.
2. Select the desired Samples from the drop-down list. The associated Method, Action/Alert Level, Handling Rule, and Test Type fields are automatically populated.
3. Enter a unique name for the Lot/Batch name. In combination with the Sample ID name, the Lot/Batch name must be 42 characters or less. Names can contain only alphanumeric characters (a-z, A-Z, 0-9) and underscore (_).
4. Click **Create** at the top of the page. The specified number of tests appears on the right side of the page with its test parameters.
5. If a serial number has not been entered, scan one with the barcode scanner or type the number into the **Serial #** field. Each test within an order is required to have a serial number. The cassettes will not be loaded until a unique ID is assigned. To cancel the order, click **Cancel** before confirming.
6. To save the order, click **Confirm** at the top of the page. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**. The order is complete.

3.8.4 Manual Handling Rules

1. If you are not using a predefined Worklist or Sample, select the **Manual** tab.
2. Select a Method, an Action/Alert Level, and a Handling Rule from the dropdown lists. The test type automatically populates.
3. Enter the following:
    - Number of Tests – Enter the number of cassettes in the order.
    - Enter a unique name for the Lot/Batch name. In combination with the Sample ID name, the Lot/Batch name must be 42 characters or less. Names can contain only alphanumeric characters (a-z, A-Z, 0-9) and under- score (_).
    - Dilution Factor – Enter a whole number from 0 - 999.

4. Click **Create** at the top of the page. The specified number of tests appears in the window on the right with its test parameters.

5. If a serial number has not been entered, scan one with the barcode scanner or type the number into the **Serial #** field. Each test within an order must have a unique serial number.

6. The cassettes cannot load until a unique ID is assigned. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**. The order is complete.

3.9 Selecting and Loading Tests

3.9.1 Manually Load Tests Page

Use the **Manually Load Tests** page to select and load tests.

To open the **Manually Load Tests** page, click **Manually Load Tests** on the **Menu Options** page.

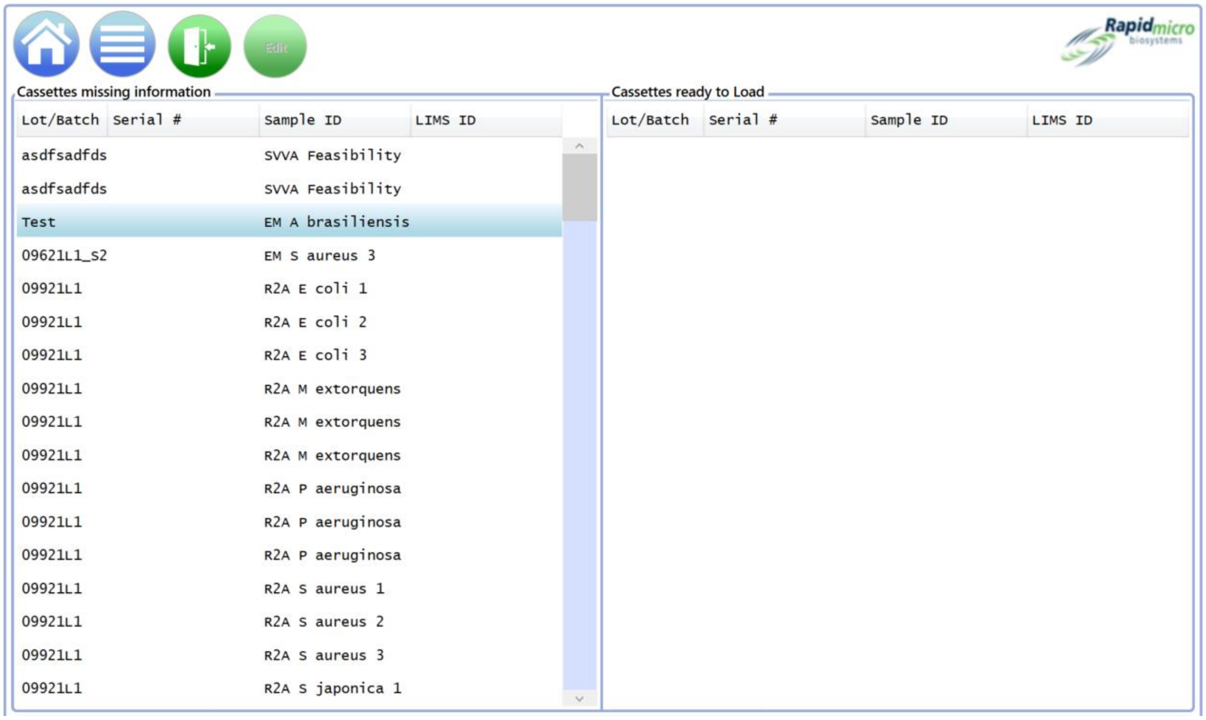


Figure 3-10: Manually Load Tests Page

3.9.2 Changing and Updating a Serial Number

The **Manually Load Tests** page shows all cassettes with a serial number on the right side of the page under **Cassettes Ready to Load**. All cassettes missing a serial number appear under **Cassettes Missing Information** on the left side of the page. Each cassette must be assigned a serial number prior to loading.

To change or update a serial number:

1. Select the cassette from the list under **Cassettes Ready to Load** on the right side of the page.
2. Click **Edit** button. The cassette moves to the left side of the page.
3. Use a barcode scanner to scan the serial number from the bottom of the cassette or use the keyboard to type the number. Once you enter the serial number, the cassette entry moves back to the right side of the page and is ready to be loaded.

To enter a serial number:

1. Select the cassette from the list under **Cassettes Missing Serial Number** on the left side of the page.
2. Use a barcode scanner to scan the number from the bottom of the cassette or use the keyboard to type the number. Once you enter the serial number, the cassette entry moves to the right side of the page and is ready to be loaded.
3. Click **Door** at the top of the page to load your cassettes. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.

3.10 Selecting Tests for Approval

3.10.1Approve Tests Page

The **Approve Tests** page allows you to select, review, add comments to, and approve results after a test is complete. To approve tests,

1. Click **Approve Tests** on the **Menu Options** page.

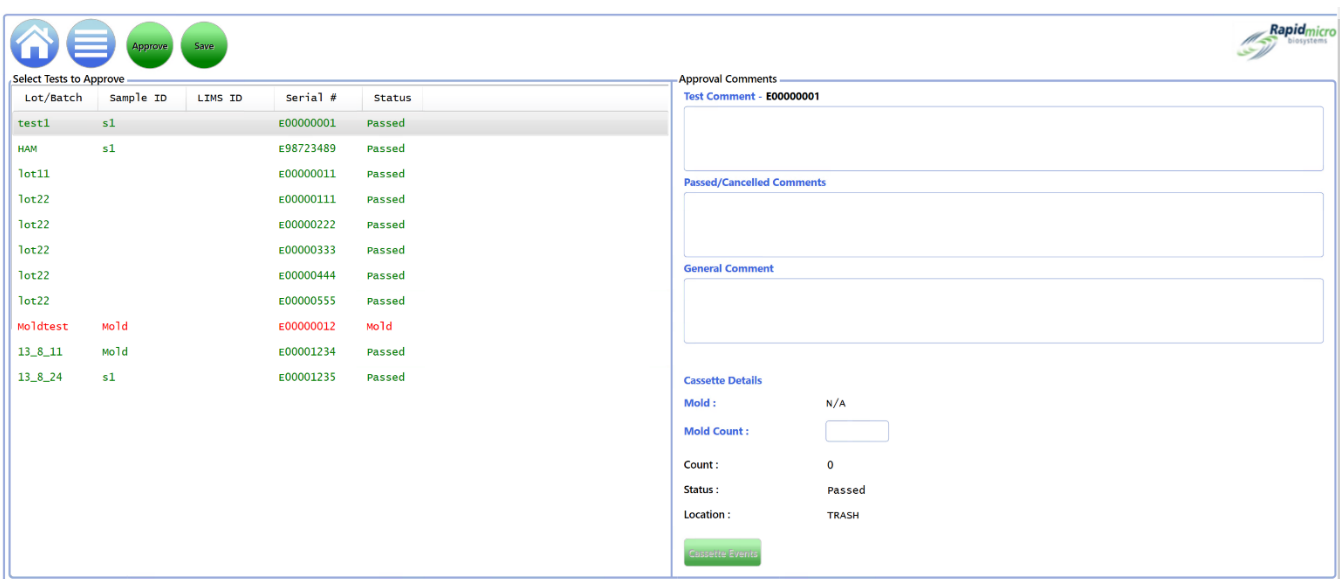


Figure 3-11: Approve Tests Page

2. Select tests on the left that you want to approve.
3. Click **Approve** at the top of the page.

To return to the **Approve Tests** page, click **Back**.

3.10.2 Approving Tests

When you click **Approve** on the Select **Tests to Approve** page, a list of tests appears on the left side of the page.

1. Select a cassette for approval. Depending on in the settings in the Test Screen Approval/Required Comments fields on the General Settings page, one of three possible options appears on the right side of the page:
    - Test Comment
    - OOS Comment
    - General Comment
2. To add comments, enter text. If a comment field is outlined in red, then a comment is required.
3. To add a Mold count, enter the numerical count.
4. Click **Save** to save comments for one cassette. If you leave the page, the system does not save the comments unless you click **Approve**.
5. Click **Approve** to approve the tests you selected.

3.11 Viewing Cassette Details

3.11.1 Cassette Details Page

The **Cassette Details** page allows you to monitor the current status and CFU count readings once cassettes have been successfully loaded into the system. It also allows you to create and print reports.

To open the **Cassette Details** page, click **Cassette Details** on the **Menu Options** page.

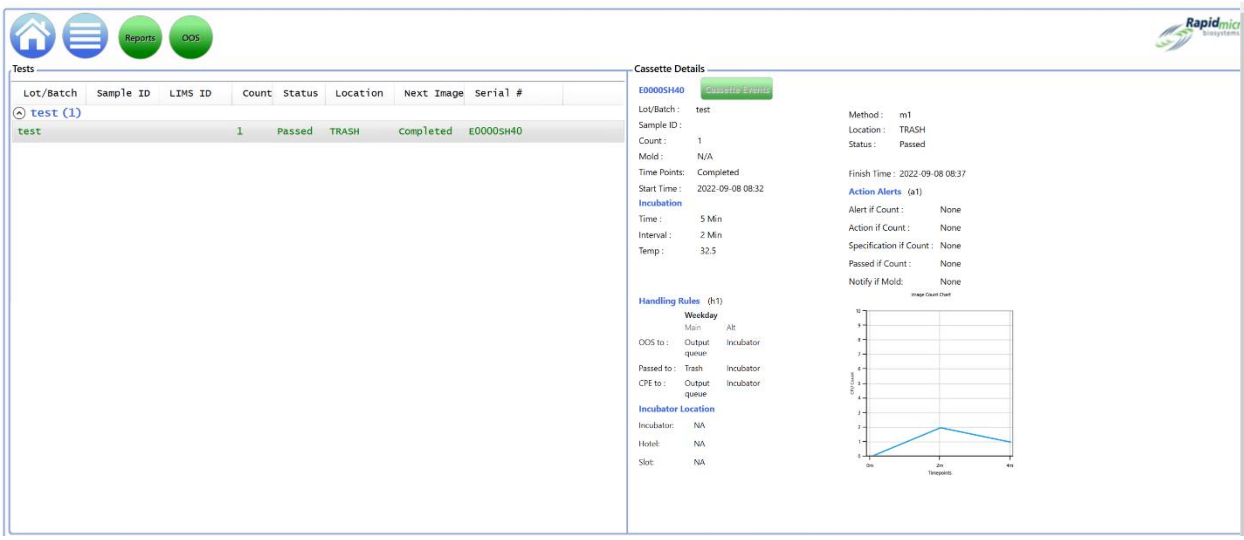


Figure 3-12: Cassette Details Page

3.11.2 Selecting Tests to View

1. To view the details of a test, select it on the left side of the page. Details associated with the test populate the fields on the right side of the page. If a cassette is out of specification, the **Cassette Events** button is active.
2. Click **Cassette Events** to review the root cause of the event.

Figure 3-13: Cassette Event

3.11.3Creating and Printing a PDF Report

For a full description of the options bar at the top of the page, see Section 5.2.2, About Viewing Options.

1. To create a test report for a specific test, click **Reports** at the top of the page.
2. Select **Active** from the Database dropdown.

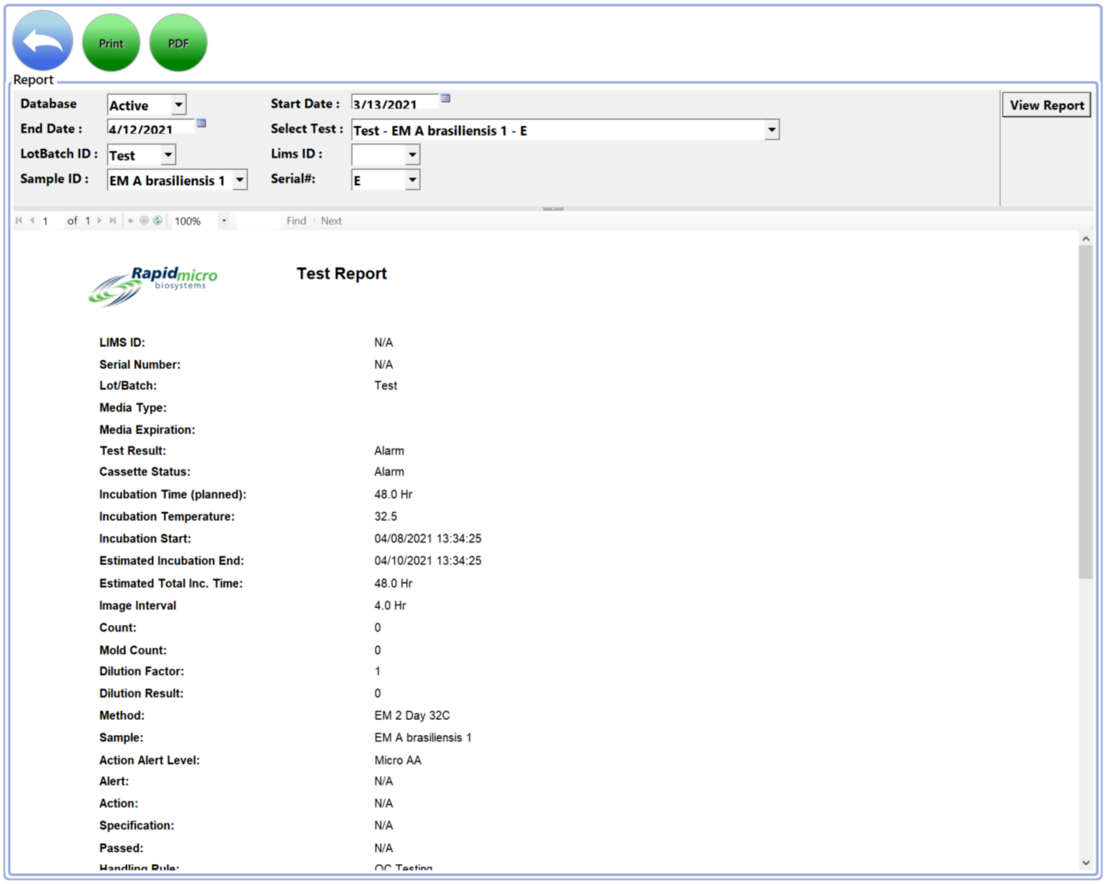


Figure 3-14: Test Report Page

3. Use the **Start Date** and **End Date** fields to specify tests run within a range of dates.
4. Click **View Report**.
5. To magnify or reduce the size of the test report, click the **Zoom** field and select a percentage from the dropdown list.
6. To print a test report, click **Print** at the top of the page. A **Print** dialog opens.

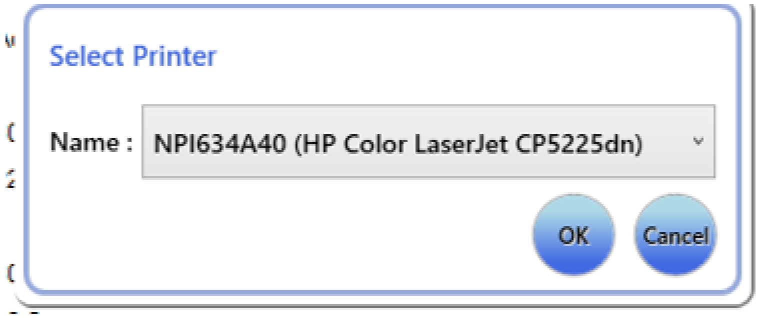


Figure 3-15: Printer Dialog

7. Make your selections and click **OK**.
8. To save a Report in a PDF format, click the **PDF** button.
9. Browse and select the location where you want the report to be stored.
10. Click **OK**.

3.12 Selecting Tests to Cancel or Retrieve

The **Cancel/Retrieve Tests** page allows you to select tests to cancel or retrieval and place in the output queue, trash bin, or incubator depending on what was specified using the **Handling Rules** page.

To access the **Cancel/Retrieve** page, click **Cancel/Retrieve Tests** on the **Menu Options** page.

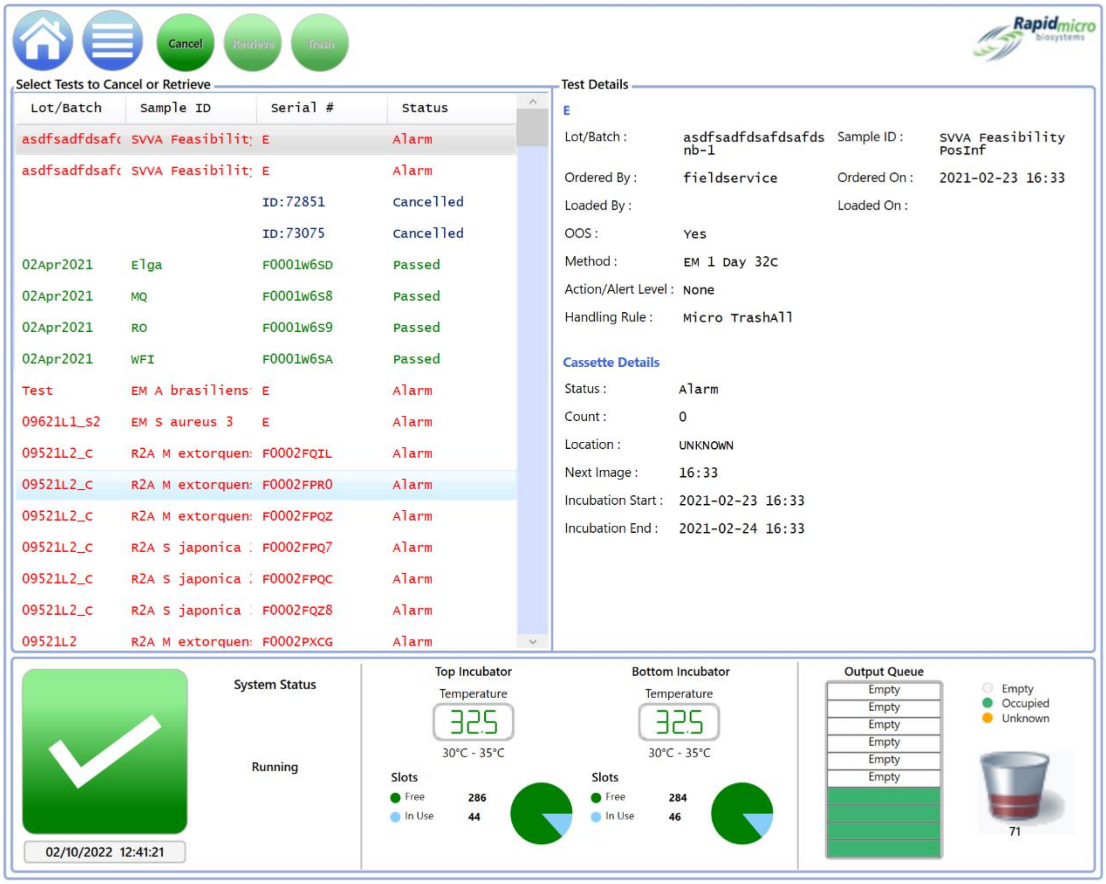


Figure 3-16: Cancel/Retrieve Page

3.12.1Selecting Tests to Cancel or Retrieve

When you click **Cancel/Retrieve**, a list of tests populates the left side of the page.

1. Select a test to retrieve or cancel. The details associated with the selected test appear on the right side of the page. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.
2. To cancel the test, click **Cancel** at the top of the **Select Tests to Cancel or Retrieve** page. The test is marked **canceled,** and the system stops all further imaging activity for this cassette. Canceled tests follow the specified handling rule.
3. To retrieve orders and move the cassette from the incubator to the Output Queue, click **Retrieve** at the top of the page. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.

The Output Queue has a maximum limit of 10 cassettes. If more than 10 cassettes are requested, then the first 10 go into the Output Queue and the rest remain in the incubator until you empty the Output Queue. Once the Output Queue is empty, the system unloads the remaining cassettes.

To send tests to the Trash, select the cassette and click **Trash**.

3.13 System Processing

When the instrument is busy, it displays a **System Status** message if you try to perform an action. This requires no action; the system will perform the required operation after a delay.

Figure 3-17: System Processing Page

3.14 Emptying the Trash Bin

To ensure uninterrupted performance, remove used cassettes from the Growth Direct® system when you begin new tests and when the system notifies you the trash is full. The capacity of the trash bin is 110 bioburden and/or EM cassettes. The number may be slightly less, due to the way the cassettes land when they fall into the trash.

Caution! Follow proper biohazard procedures when emptying the trash.

1. Click the **Trash** button on the **Home** page. A **Signature** dialog opens.

Figure 3-18: Signature Dialog

2. Enter your username and password and click **OK** to continue or click **Cancel**.
3. The **Empty Trash Bin** confirmation dialog opens. Do not click anything.

Figure 3-19: Empty Trash Bin Confirmation Dialog

4. Open the trash bin door and lift out the full biohazard bag. Dispose of the bag according to your company's disposal policies.

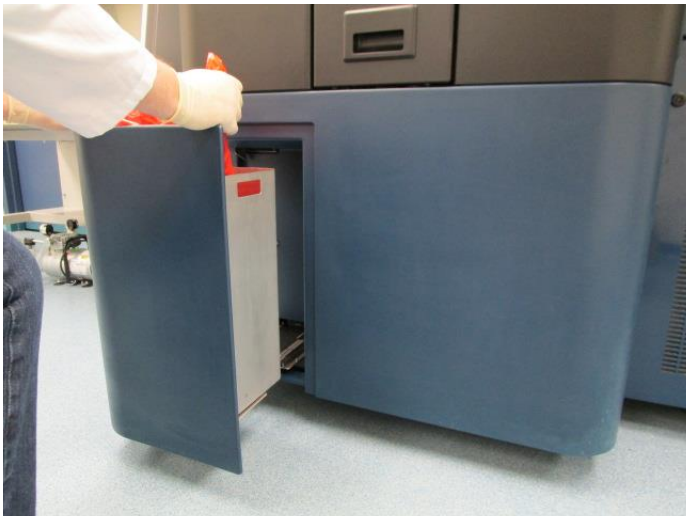


Figure 3-20: Remove Biohazard Bag from Trash Bin

5. Open a new biohazard bag completely. The recommended size is 23 x 28 inches (58 x 71cm).
6. Place the bag into the metal trash bin and ensure several inches of the bag hangs over the outside of the metal trash bin.
7. Place your hand into the new biohazard trash bag and ensure the bag touches the bottom of the trash bin.

Figure 3-21: Inserting a New Biohazard Trash Bag

8. Ensure the trash bin is seated securely.
9. Close the trash bin door.
10. Click **Yes** to confirm that you emptied the trash bin. The number of cassettes in the Status Bar resets to zero and the system is ready.

4. Laboratory Information Management System (LIMS)

LIMS is an add-on feature. To learn more about LIMS contact sales@rapidmicrobio.com.

This section contains:

4.1 Overview

This section describes the Laboratory Information Management System (LIMS) interface on the Growth Direct® System that performs daily tests. The sections that follow contain all the pages you will require to set up your system parameters and run tests.

You must be assigned a role with permission to edit any of the LIMS options modes. (See Section 2.2.1, User Roles Page).

The LIMS system allows for the automatic processing of data to defined directories, which become storage locations for result, request, and receipt files from LIMS. Result files contain the data from a particular test or tests; request files contain user requests for ordering or canceling tests; receipt files are for acknowledging receipt of data.

4.2 About the LIMS Page

The **LIMS** page allows you to modify LIMS settings, configure result fields, and print labels. To access LIMS options, LIMS first must be validated and enabled using the **General Settings** page. (See Section 2.5, Defining General Settings). When LIMS is enabled, the **View LIMS Options** button appears on the **Menu Options** page.

Click **View LIMS Options** to access the **LIMS** page.

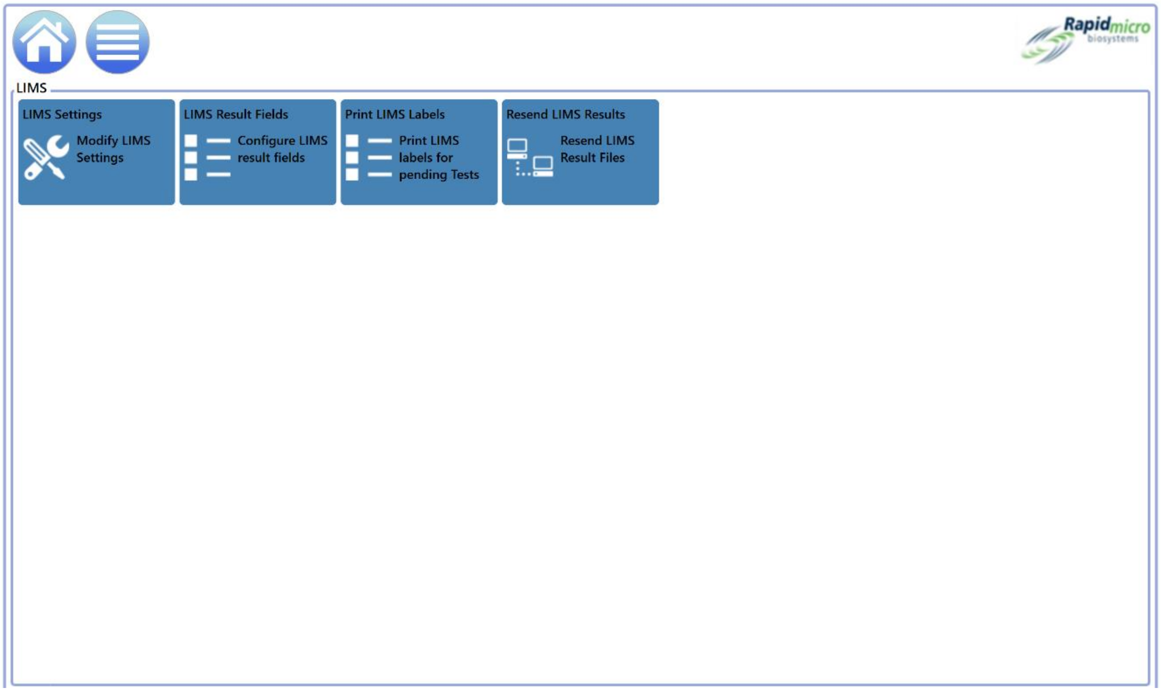


Figure 4-1: LIMS Page

4.3 Modifying LIMS Settings

To modify LIMS settings, click **LIMS Settings** on the **LIMS** page. The **LIMS Settings** page opens.

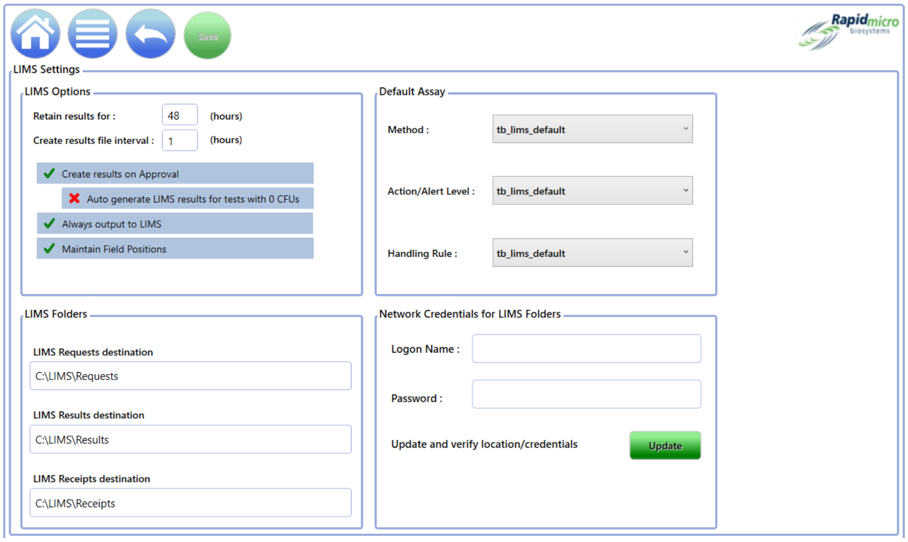


Figure 4-2: LIMS Settings Page

4.4 Choosing LIMS Options

1. Complete the LIMS Options as follows:

   - **Retain results for** – Tells the system to retain result files for a specified number of hours before they are automatically deleted from the computer. Enter any whole number in the field to change the result retention rate. The default is 48. (Note that the result file size is negligible and should not take up much computer space.)
   - **Create results file interval** – Tells the system to create result files (assuming the data exists) at this interval. Enter any whole number in the field to change the hourly interval. 1 is the default, which means that the system creates result files every hour.
   - **Create results on Approval** – Indicates whether the system can provide results with (green check) or without approval (red X). (See Section 3.10, Selecting Tests for Approval).
   - **Autogenerate LIMS results for tests with 0 CFUs** – Automatically sends results to LIMS if you run the cassette and there are 0 CFUs.
   - **Always output to LIMS** – Indicates that LIMS result files are created for all test results. This should be off in normal operation.
   - **Maintain Field Positions** – Tells the system to maintain the comma-separated field positions in the result file (green check).

2. Click **Save**. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

4.5 Setting the Default Assay

You can set up a default assay (i.e., the combination of Method, Action/Alert Level, Handling Rule) for tests that have no assays pre-assigned.

Note: LIMS test orders that do not define Method, Action/Alert Level, and Handling Rules use the defined default assay.

1. Select the following from the dropdowns in the Default Assay box:
    - Method (See Section 3.2 Creating and Modifying Methods).
    - Action/Alert Level (See Section 3.3 Defining Actions, Alerts, and Specifications)
    - Handling Rule (See Section 3.4 Creating and Modifying Handling Rules)
2. Click **Save**. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

4.6 Specifying LIMS Folder Destinations

This section specifies the destination folders on the main server for the LIMS files.

1. Type a destination path for:
    - **LIMS Requests destination** – the destination path for request files
    - **LIMS Results destination** – the destination (local only) path for results files
    - **LIMS Receipts destination** – the destination path for receipt files
2. Click **Save**. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

4.7 Setting Network Credentials for LIMS Folders

The Network Credentials for LIMS Folders feature is enabled when the Bridge Computer is activated on the **General Settings** page. To configure the LIMS file destination to a location other than the Bridge Computer, enter login name and password credentials.

4.8 Configuring LIMS Results Fields

To open the **LIMS Export Fields** page, click **LIMS Result Fields** on the **LIMS** page.

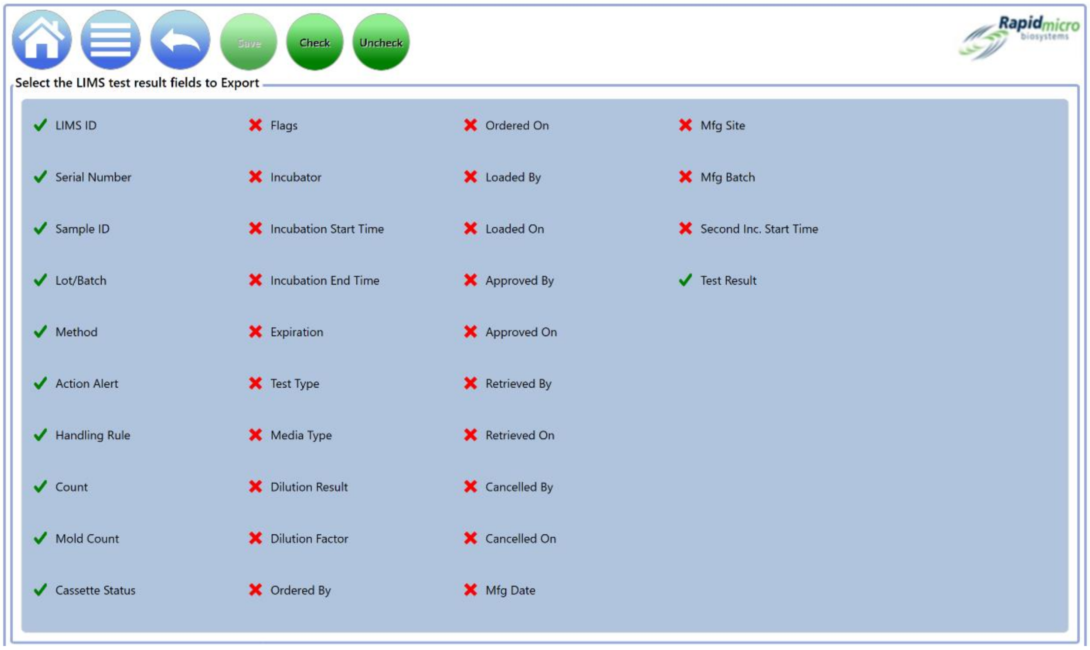


Figure 4-3: LIMS Test Results Page

1. Select a field to activate (green check) or deactivate it (red X).
2. To activate all the fields, click **Check** at the top of the page. To deactivate all the fields, click **Uncheck**.
3. Click **Save**. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

4.9 Printing LIMS Labels for Pending Tests

1. To open the **Print LIMS labels** page, click **Print LIMS Labels** on the LIMS page.

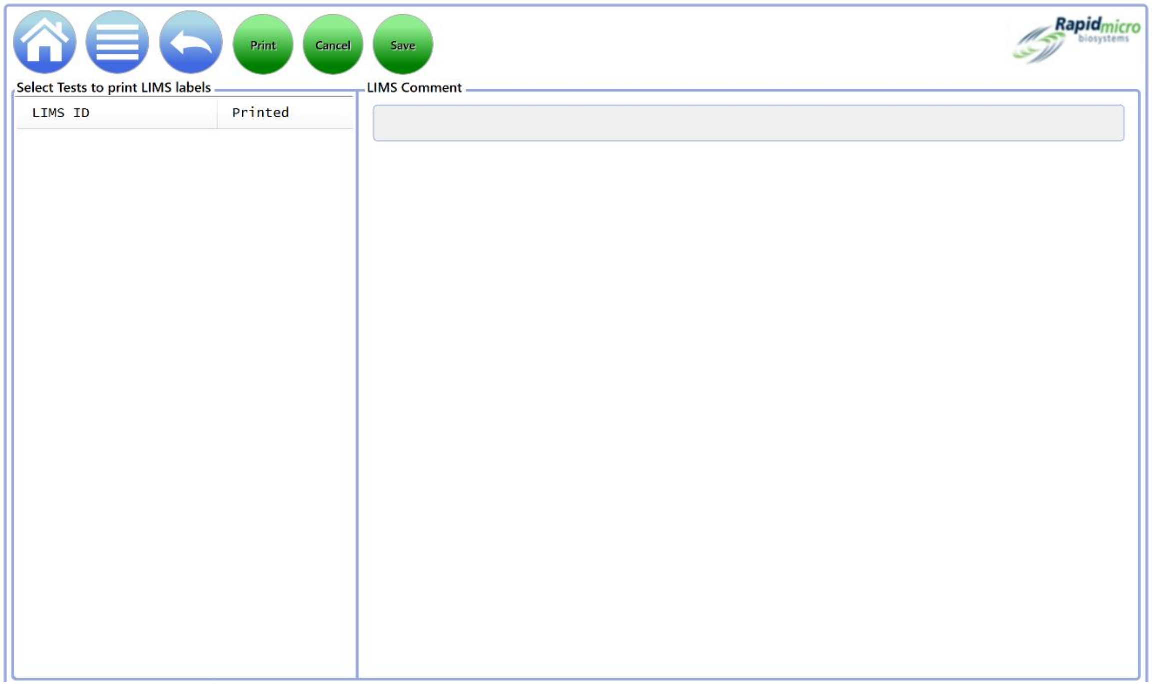


Figure 4-4: Print LIMS Labels Page

2. Select tests from the list on the left, add a LIMS Comment if needed (this adds information to the label), and click **Print**. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

4.10 Resending LIMS Results

1. To open the **Resend LIMS Results** page, click **Resend LIMS Results** on the LIMS page.

Figure 4-5: Resend LIMS Results Page

2. To list results for a specific time period, specify a range of dates using the **Start Date** and **End Date** fields and click **Apply**.
3. To resend results to the LIMS Result folder, select results from the list. Select a range of results by clicking the first result and holding the Shift key while selecting the last result in the desired range. Select multiple, non-contiguous results by holding down the CTRL key while selecting.
4. Click **Resend**. This generates a LIMS result file in the LIMS Results folder.

5. Specifying Printer Settings and Viewing and Printing Reports

This section contains:

5.1.1 5.7 Cancelled Tests Report

The **Cancelled Tests Report** displays the following information about cancelled tests, for the specified date range:

- Lot/Batch
- Sample
- LIMS ID
- Serial Number
- Method
- Action Alert Level
- Handling Rule
- Test Status
- Date and time cancelled
- Who cancelled by
- Comment

Notes: For a description of the viewing options at the top of the page, see Section 5.2.2, About Viewing Options.

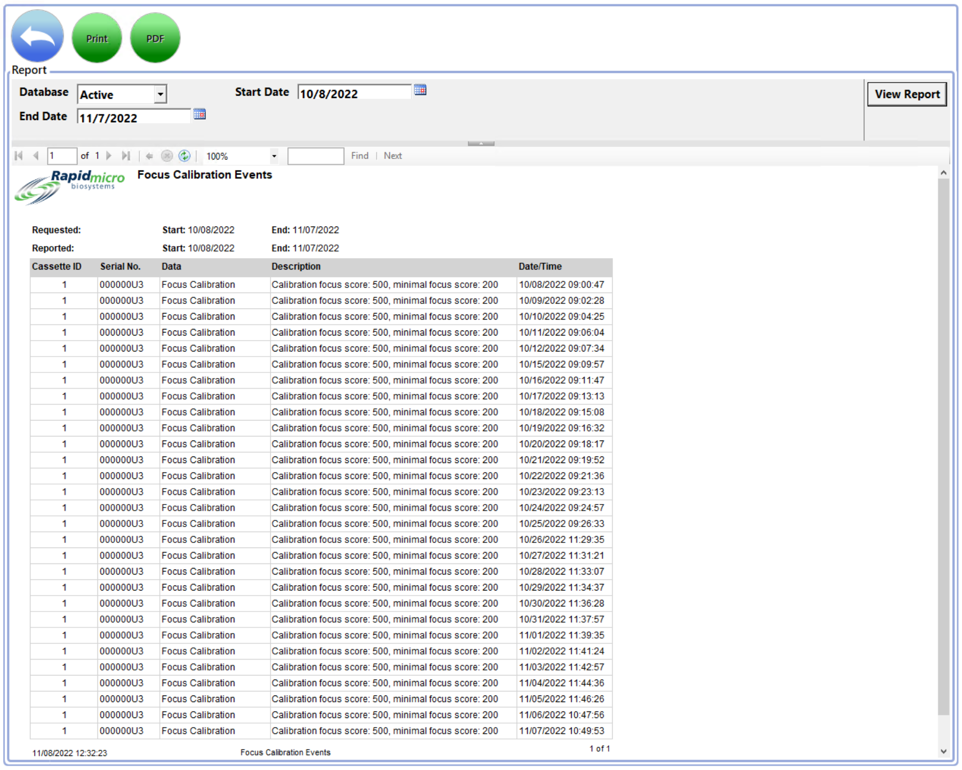
To print the report, see Section 5.4.2, Printing a Test Report.

To save the report as a PDF, see Section 5.4.3, Saving a Test Report as a PDF.

5.1.2 Focus Calibration Audit Report

The **Focus Calibration Audit Report** page displays the following information, for the specified date range:

- Cassette ID
- Serial Number
- Data
- Description
- Date and Time



Requested: Start: 10/08/2022 End: 11/07/2022

Reported: Start: 10/08/2022 End: 11/07/2022

Cassette ID	Serial No.	Data	Description	Date/Time
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/08/2022 09:00:47
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/09/2022 09:02:28
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/10/2022 09:04:25
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/11/2022 09:06:04
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/12/2022 09:07:34
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/15/2022 09:09:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/16/2022 09:11:47
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/17/2022 09:13:13
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/18/2022 09:15:08
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/19/2022 09:16:32
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/20/2022 09:18:17
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/21/2022 09:19:52
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/22/2022 09:21:36
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/23/2022 09:23:13
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/24/2022 09:24:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/25/2022 09:26:33
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/26/2022 11:29:35
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/27/2022 11:31:21
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/28/2022 11:33:07
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/29/2022 11:34:37
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/30/2022 11:36:28
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/31/2022 11:37:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/01/2022 11:39:35
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/02/2022 11:41:24
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/03/2022 11:42:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/04/2022 11:44:36
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/05/2022 11:46:26
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/06/2022 10:47:56
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/07/2022 10:49:53

11/08/2022 12:32:23 Focus Calibration Events 1 of 1

Figure 5-26: Focus Calibration Report

Notes: For a description of the viewing options at the top of the page, see Section 5.2.2, About Viewing Options.

To print the report, see Section 5.4.2, Printing a Test Report.

To save the report as a PDF, see Section 5.4.3, Saving a Test Report as a PDF.

Viewing and Printing Custom Reports

5.2 Configuring Printers

5.2.1 Configuring a Barcode Printer

The barcode printer can be connected through your network or through the USB port on the Bridge Computer. A Bridge Computer is always installed on your system.

1. Click **Printer Settings** on the **Menu Options** page.
2. Complete the **Signature** dialog and click **OK**.
3. Select the **Barcode** tab.
4. Click **New** to add a barcode printer.

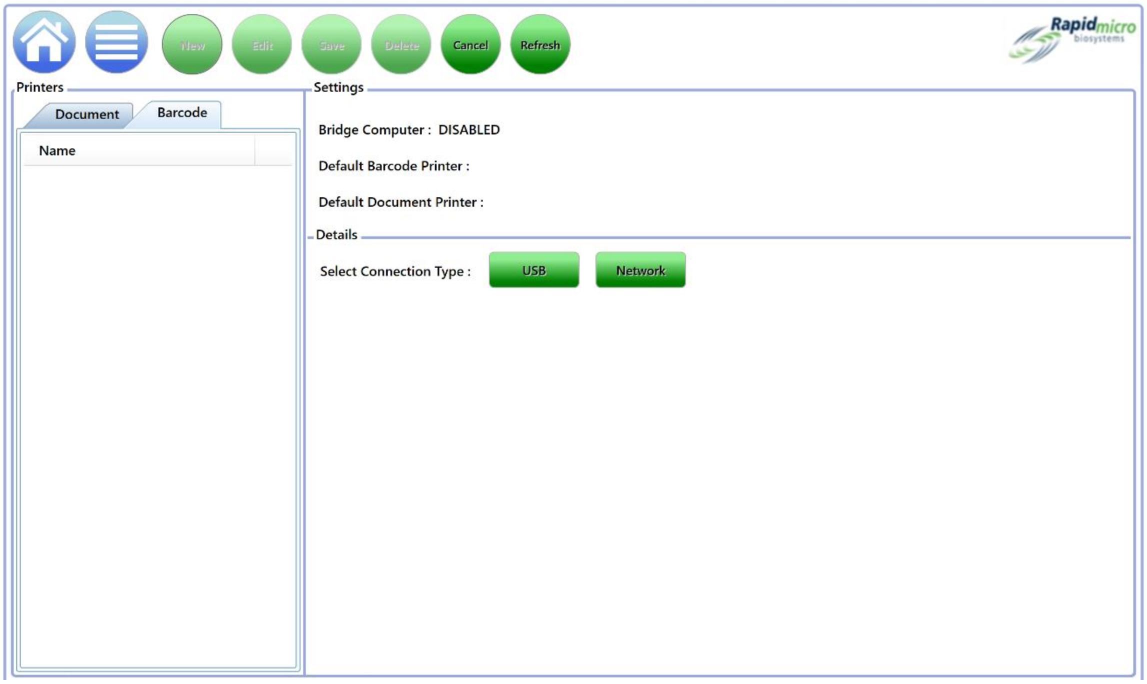


Figure 5-1: Barcode Tab of the Printers Page

5. Use the **Details** area of the page to specify the barcode printer.
6. For a USB printer, click **USB** next to **Select Connection Type**.
   a. Select a printer from the **Select Printer** dropdown.

b. Enter the name of the printer in the **Printer Name** field.

c. Select a size from the **Label** dropdown.

d. Click **Default Printer** to use this printer as the default.

Figure 5-2: USB Printer Details

7. For a network printer, click **Network** next to **Select Connection Type**.

a. Enter the name of the printer in the **Printer Name** field.

b. Enter the IP address in the **Printer IP** field.

c. Enter the IP Port number in the **Port** field (the default is 9100).

d. Click **Default Printer** to use this printer as the default.

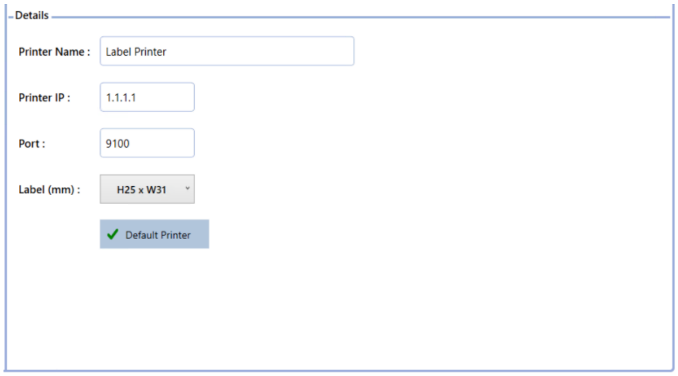


Figure 5-3: Network Printer Details

8. Click **Save** at the top of the page. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

5.2.2 Configuring a Document Printer

1. Click **Printer Settings** on the **Menu Options** page.
2. Complete the **Signature** dialog and click **OK**.
3. Select the **Document** tab.
4. Click **New** to add a document printer.

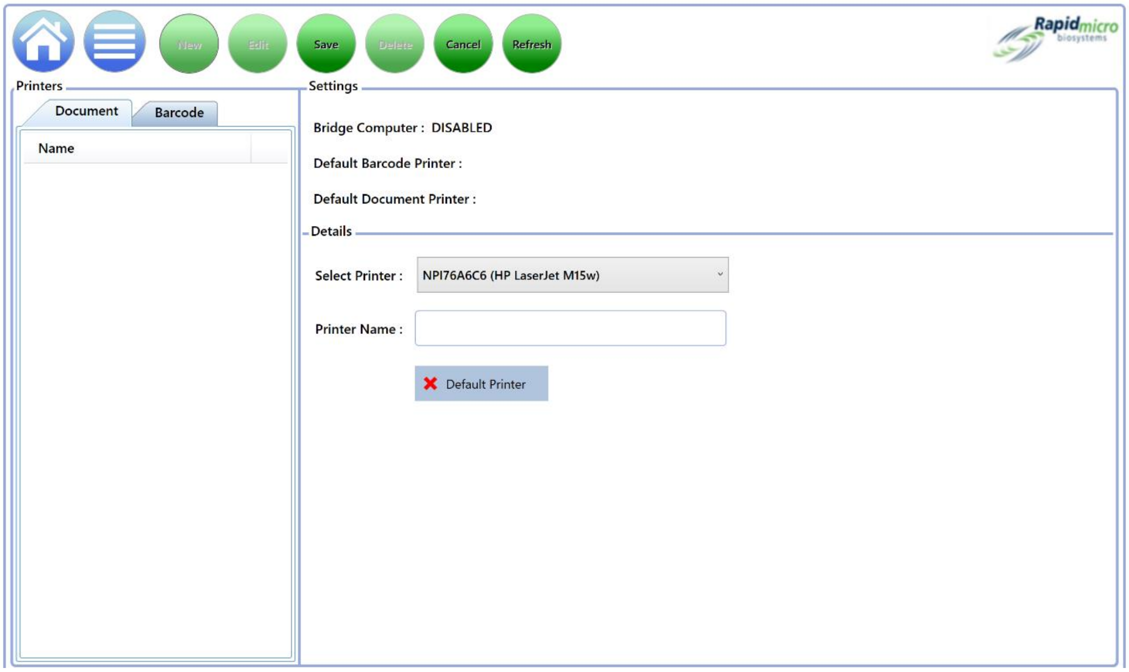


Figure 5-4: Printers Page: Document Tab

a. Select a printer from the **Select Printer** dropdown.

b. Enter the name of the printer in the **Printer Name** field.

c. Click **Default Printer** to use this printer as the default.

9. Click **Save** at the top of the page. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

5.3 Specifying Report Options

5.3.1 About Report Options

Many report pages have an options section at the top that allows you to choose a source database, a date range, and possibly other options. The available options differ by report. Make your selections using the dropdown menus. The following is an example of report options.

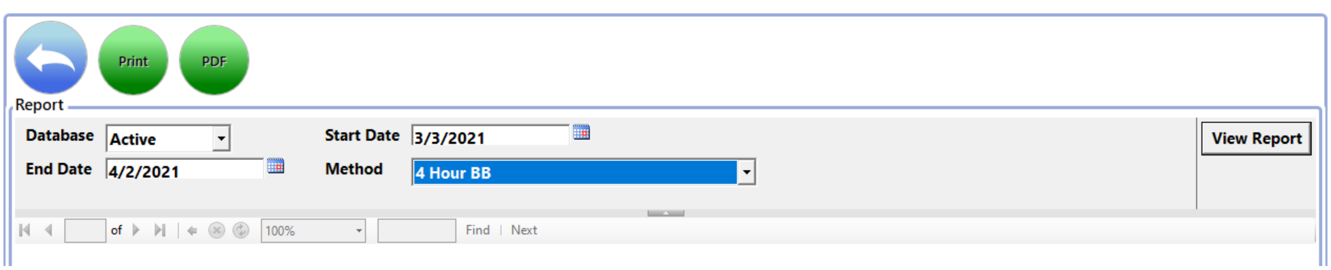


Figure 5-5: Report Options

5.3.2 About Viewing Options

Once the report is rendered, the top of the page contains a collection of viewing options, including view, print, zoom, page through, and set up reports for printing. The following illustration shows the function of each field and icon.

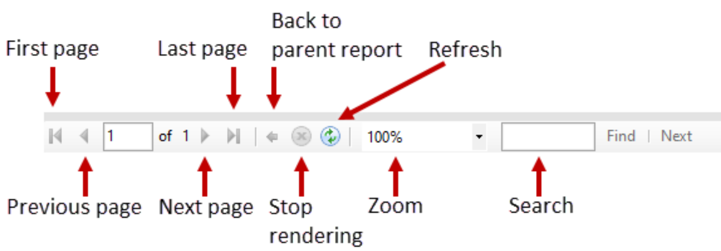


Figure 5-6: View Options

5.4 Choosing a Report

On the **Menu Options** page, the reports are broken down into groups as follows:

- Standard Reports
  - Test Report
  - Lot/Batch Results Report
- Audit Reports
  - Methods
  - Action Alert Levels
  - Handling Rules
  - Samples
  - Worklists
  - General and IT Settings
  - Incubator Settings
  - Users Role
  - Users
  - System Events
  - User Activity
  - Cancelled Tests
  - Focus Calibrations
- Custom Reports

5.5 Viewing and Printing a Test Report

The Test report shows test status, start and completion times, and any conditions associated with the test. When a report is loading, a progress report bar appears. If the report takes too long to load, click **Cancel** to stop the report.

Use the **Test Report** page to view an individual test report.

To access the **Test Report** page:

1. Click **Standard Reports** on the **Menu Options** page.
2. Click **Test Report**.

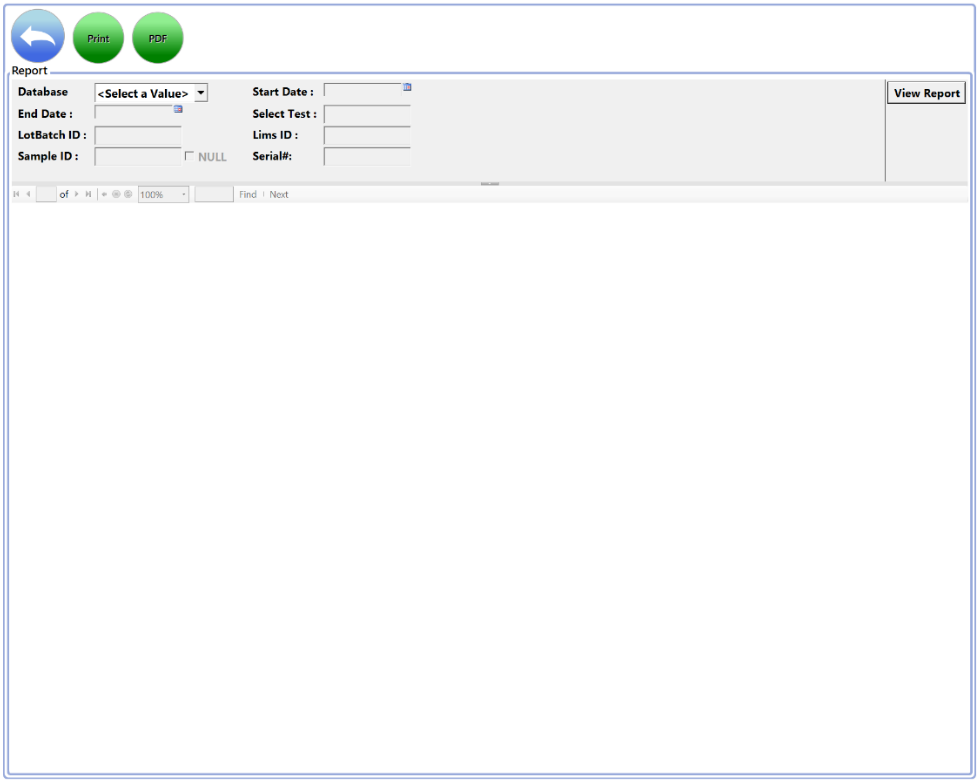


Figure 5-7: Test Report Page

5.5.1 Viewing a Test Report

The options section at the top of the page allows you to determine what appears on the report.

Figure 5-8: Test Report Options

1. Select a **Database**, either **Active** or **Archived**.
2. Select a Start Date and an End Date.
3. Select a specific test from the **Select Test** dropdown.
4. Select a **LotBatch ID**, a **LIMS ID** (optional), a **Sample ID**, and a **Serial #**.
5. Click **View Report** to see a report based on your selections.

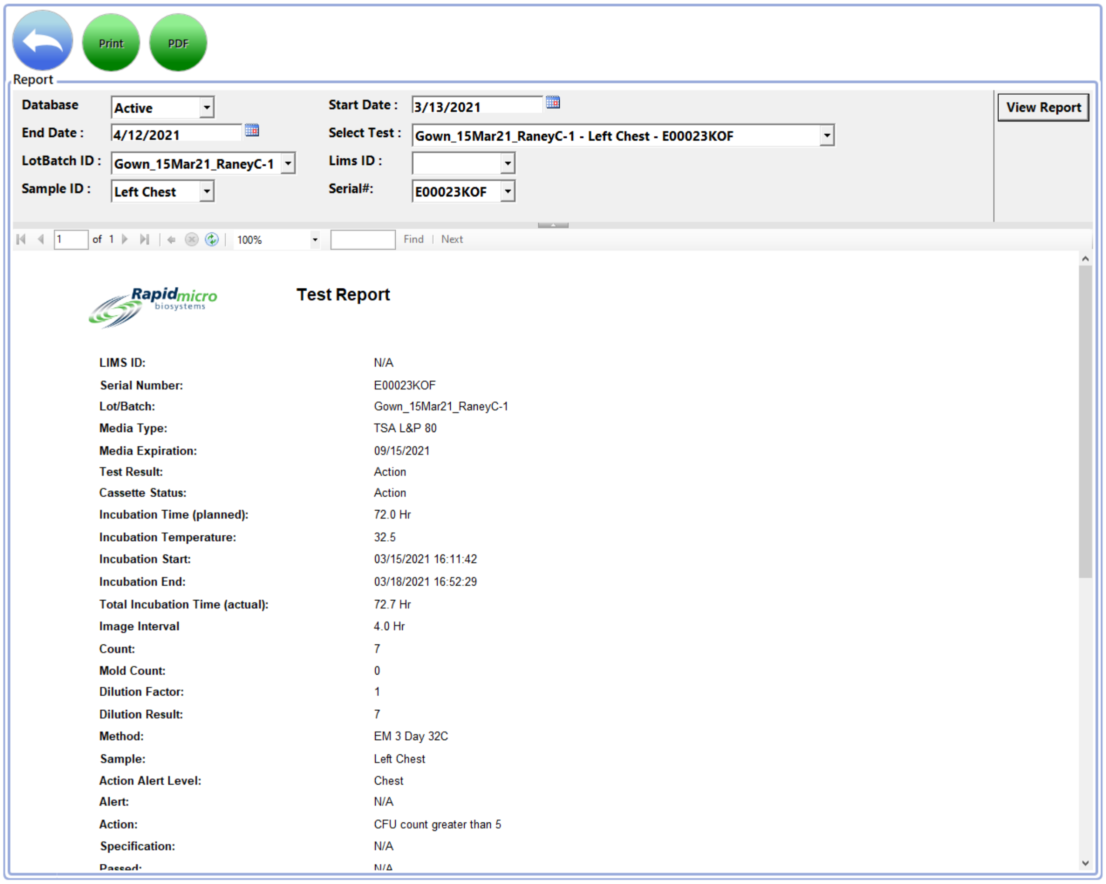


Figure 5-9: Test Report

Note: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

5.5.2 Printing a Test Report

1. To print the test report, click **Print** at the top of the page.

2. A **Print** dialog opens.

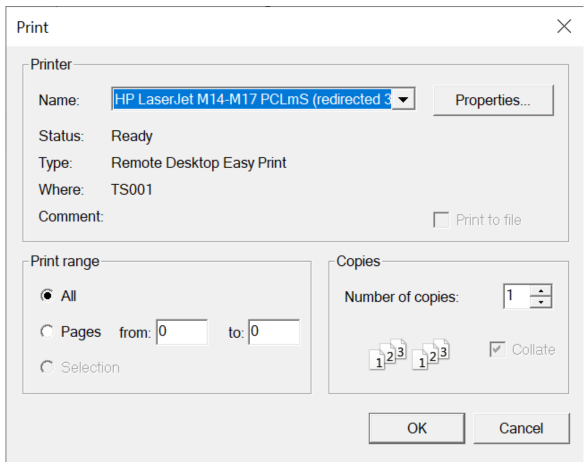
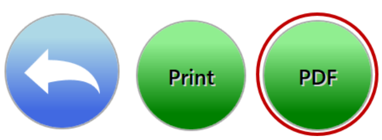


Figure 5-10: Print Dialog

3. Make your selections and click **OK**.

5.5.3 Saving a Test Report as a PDF

1. To save a Report in PDF format, click **PDF** at the top of the page.



2. Navigate to the location where you want to store the report.
3. Click **OK**.

5.6 Viewing and Printing Lot/Batch Reports

The Lot/Batch report shows test results by a lot/batch. When a report is loading, a progress report bar appears. If the report takes too long to load, click **Cancel** to stop the report. Use the **Lot/Batch Results Report** page to specify settings and print the report.

To access the **Lot/Batch Results** page:

1. Click **Standard Reports** on the **Menu Options** page.

2. Click **Lot/Batch Results**.

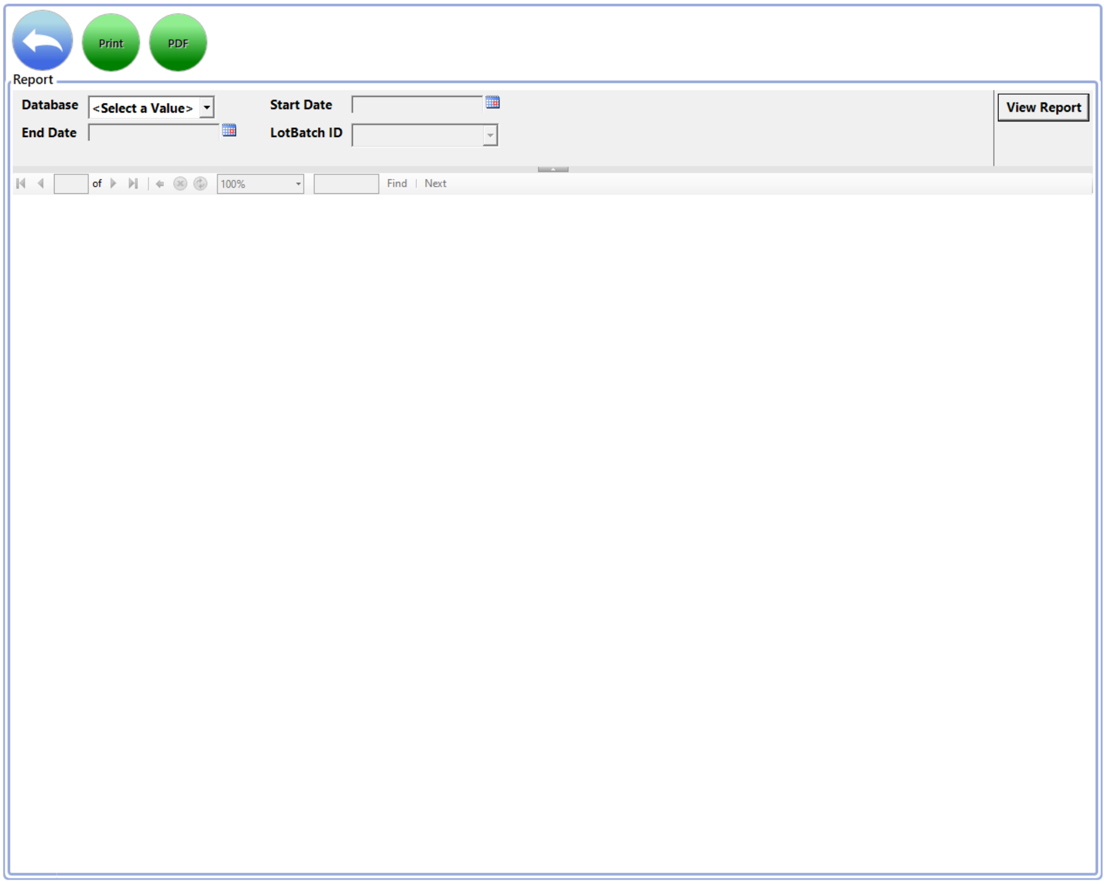


Figure 5-11: Lot/Batch Results Page

5.6.1 Viewing Lot/Batch Results

The options section at the top of the page allows you to determine what appears on the report.

Figure 5-12: Lot/Batch Results Report Options

1. Select a **Database**, either **Active** or **Archived**.
2. Select a **Start Date** and an **End Date**.
3. Select a **LotBatch ID**.
4. Click **View Report** to see a report based on your selections.

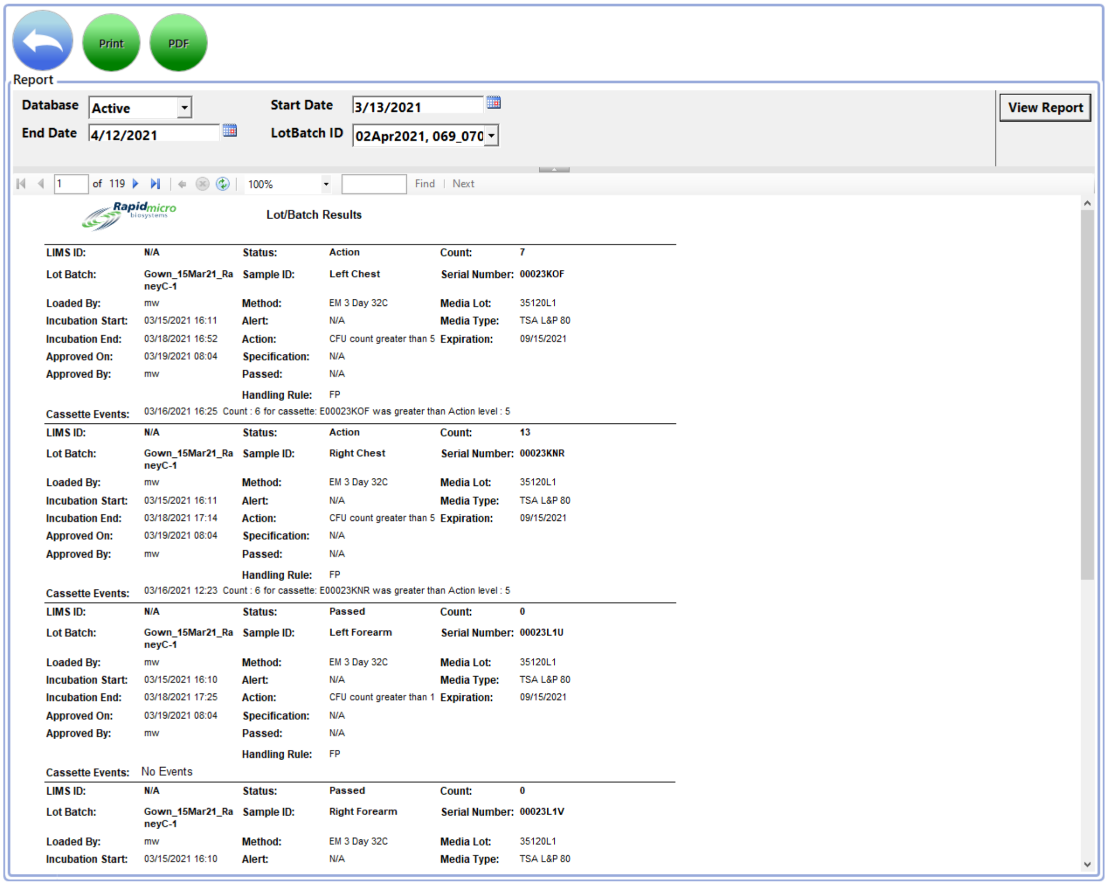


Figure 5-13: Lot/Batch Results Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7 Viewing and Printing Audit Reports

Use the **Audit Reports** page to view or create a PDF of one of the following audit reports:

- Methods
- Action Alert Levels
- Handling Rules
- Samples
- Worklists
- General and IT Settings

- Incubator Settings
- Users Role
- Users
- System Events
- User Activity
- Cancelled Tests
- Focus Calibrations

To access the **Audit Reports** page:

1. Click **Audit Reports** on the **Menu Options** page.

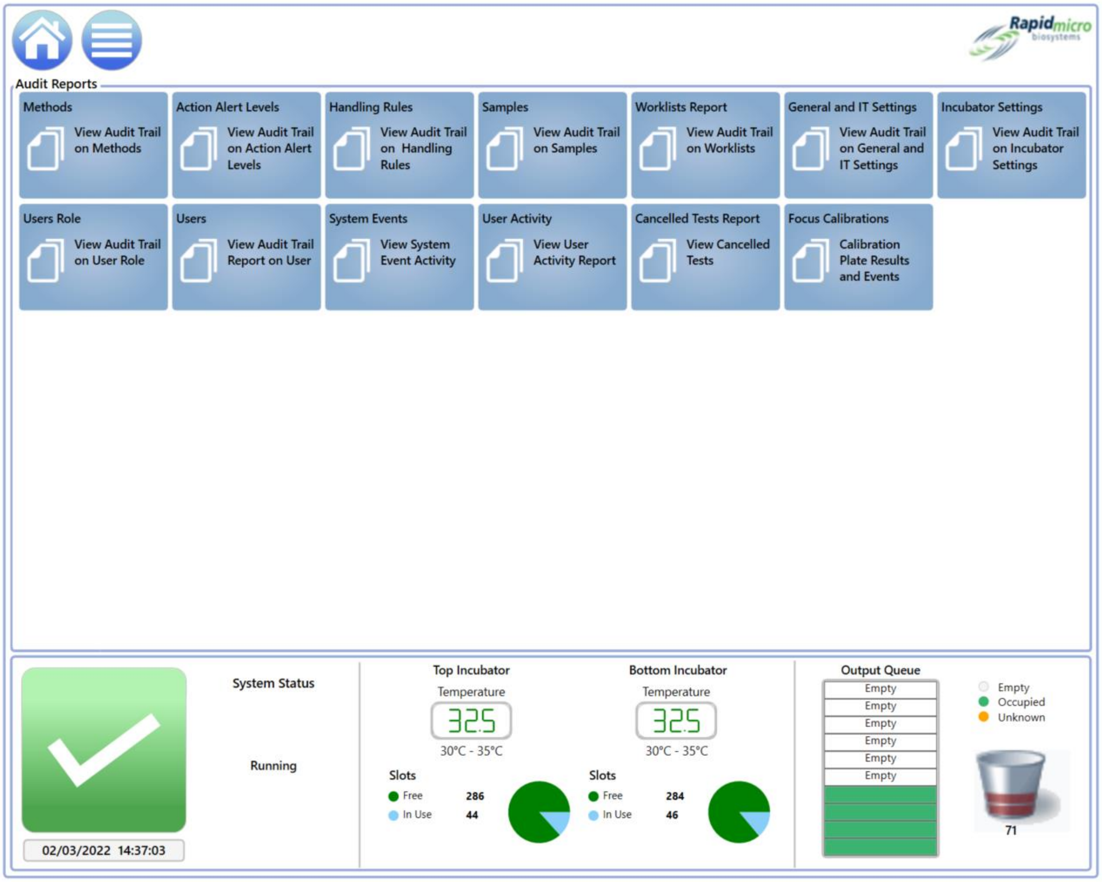


Figure 5-14: Audit Reports Page

5.7.1 Methods Audit Report

For the date range and method specified, the **Methods Audit Report** displays the date and time, operator, comment, description, test type (bioburden or environmental), total assay time, and temperature.

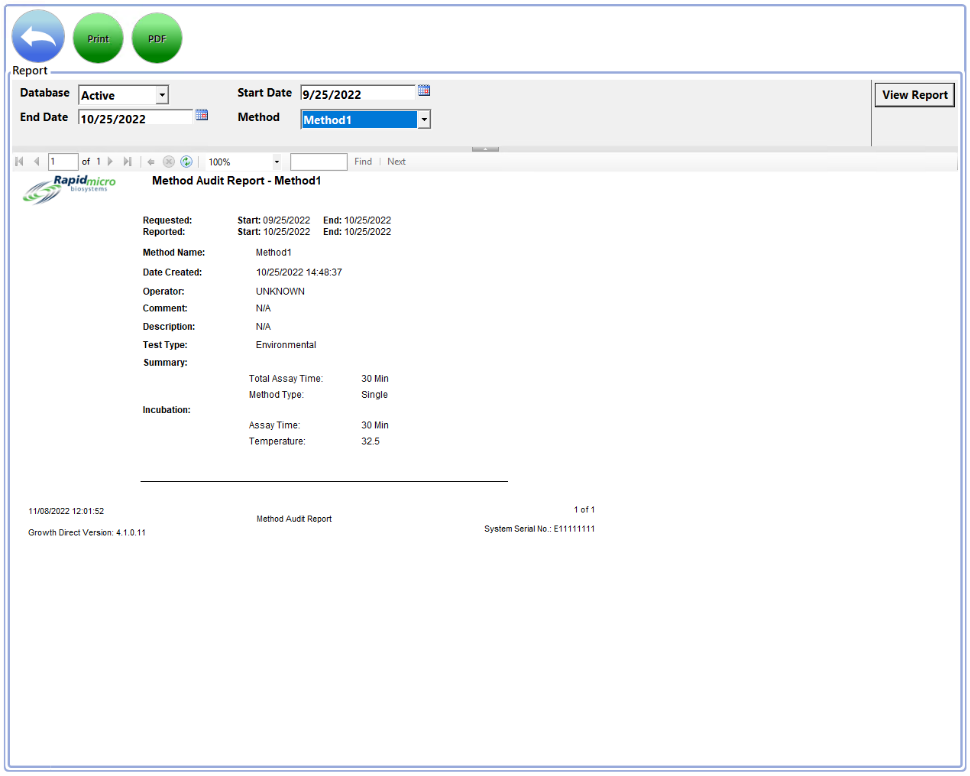


Figure 5-15: Methods Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.2 Action Alert Audit Report

The **Action Alert Levels** page allows you to set a CFU count limit for each level (Action/Alert or Specification). When the test results exceed the count limit, the system alarms and flags the sample. The **Action Alert Levels Audit Report** page displays CFU thresholds, who defined them, and when.

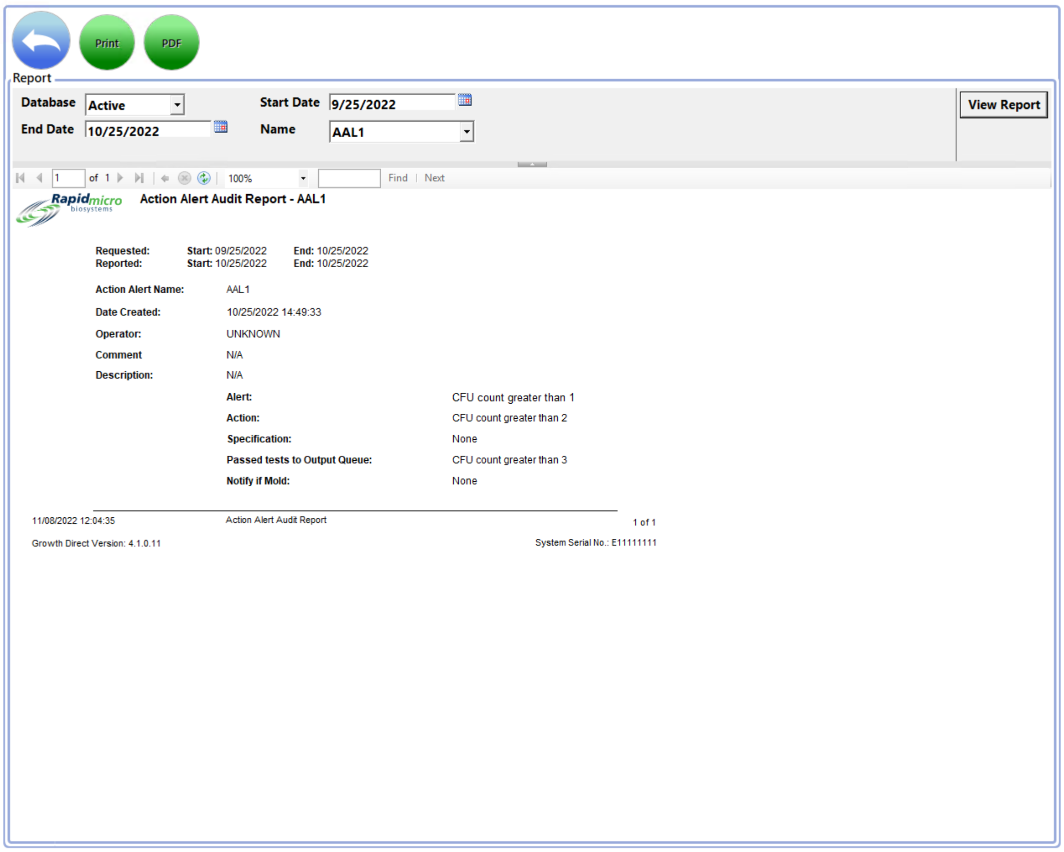


Figure 5-16: Action Alert Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.3 Handling Rules Audit Report

The **Handling Rules** specify the placement of cassettes into an output queue, trash bin, or incubator based on the cassette status: OOS (Out of Specification), Passed, Canceled, Prior to Endpoint. The **Handling Rules Report** page displays who defined the rules, the date they were created and modified, and how the rules were defined.

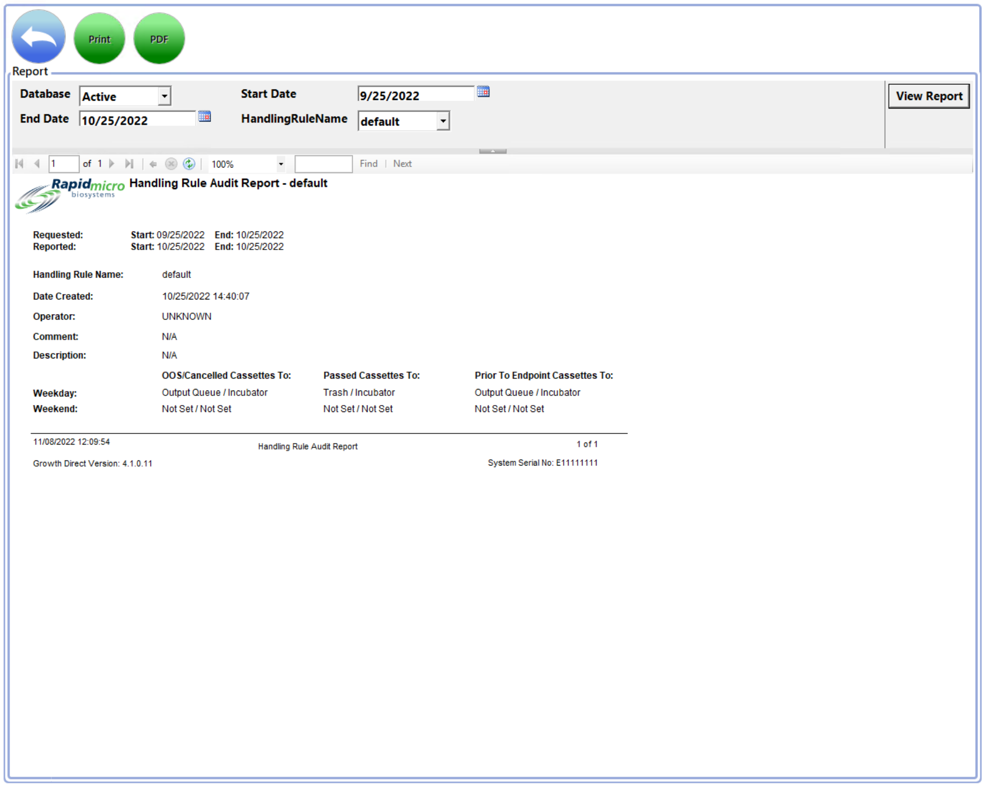


Figure 5-17: Handling Rules Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.4 Samples Audit Report

The **Samples** page groups a collection of predefined test parameters: Methods, Action Alert Levels, and Handling Rules. The Samples Audit Report displays who created a particular sample; the date it was created; the names of the Methods, Action Alerts, Handling Rules, and the dilution factor.

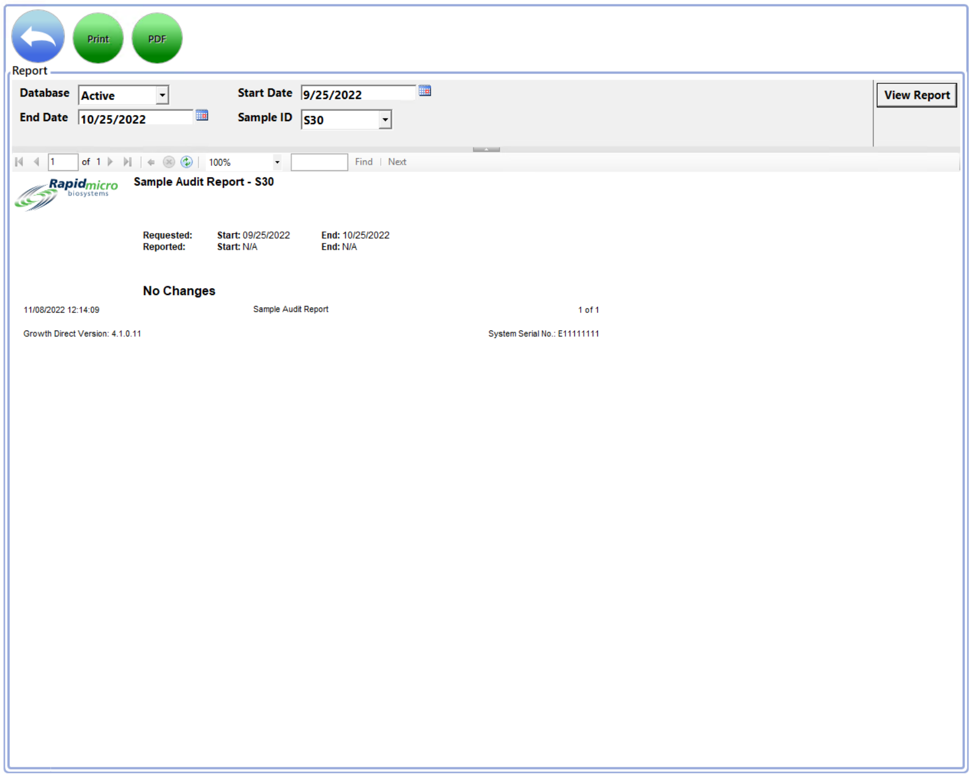


Figure 5-18: Sample Audit Page

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.5 Worklists Audit Report

The **Worklists** page creates and modifies worklists, which comprise collections of predefined samples. The **Worklists Report** displays who created a particular worklist, the date it was created, a description, the number of samples, and a list of the samples.

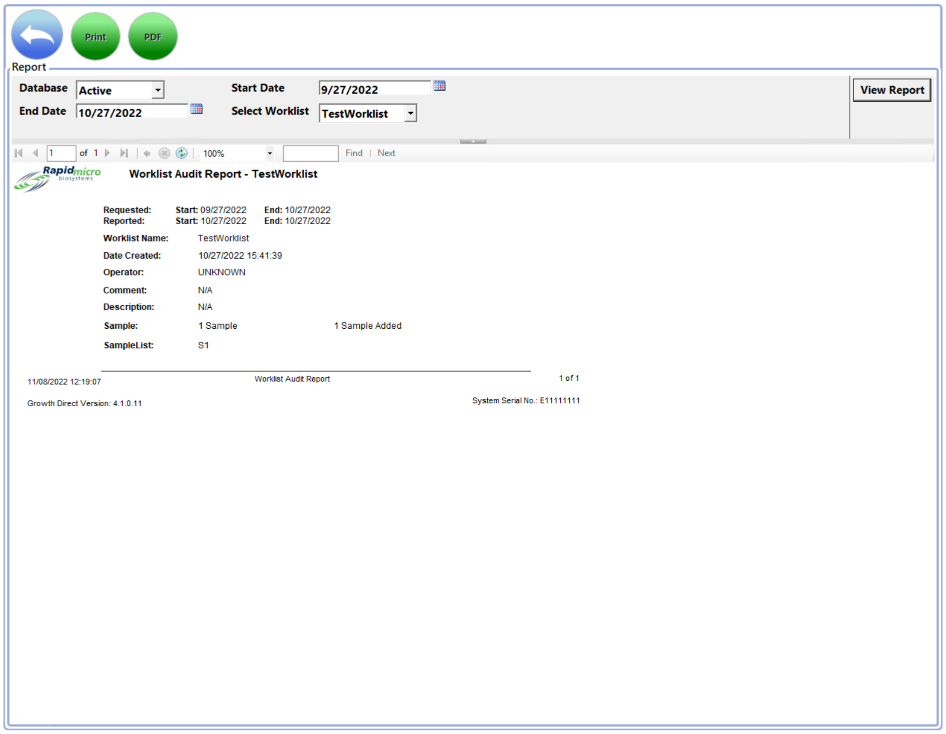


Figure 5-19: Worklists Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.6 General and IT Settings Audit Report

The **General Settings** page defines general settings at your site. The **IT Settings** page defines the specific IT settings and requirements for your site. The **General/IT Settings Report** page combines the General and IT Settings data and displays the date entries made, who entered the parameters, and how the following were set up and defined:

General Settings	General Settings (cont'd)	IT Settings
Date Modified	Weekend Time	Database Backup
Operator	Test Approval	Copy Logs
Comment	Test	System Email
Page Help Prompts	LIMS	Export Test Results Data

General Settings	General Settings (cont'd)	IT Settings
Main Page Cassette Filter	Mold	Main Page Cassette Filter
Barcode Printer	Print Out Report	Network Credentials
Password		

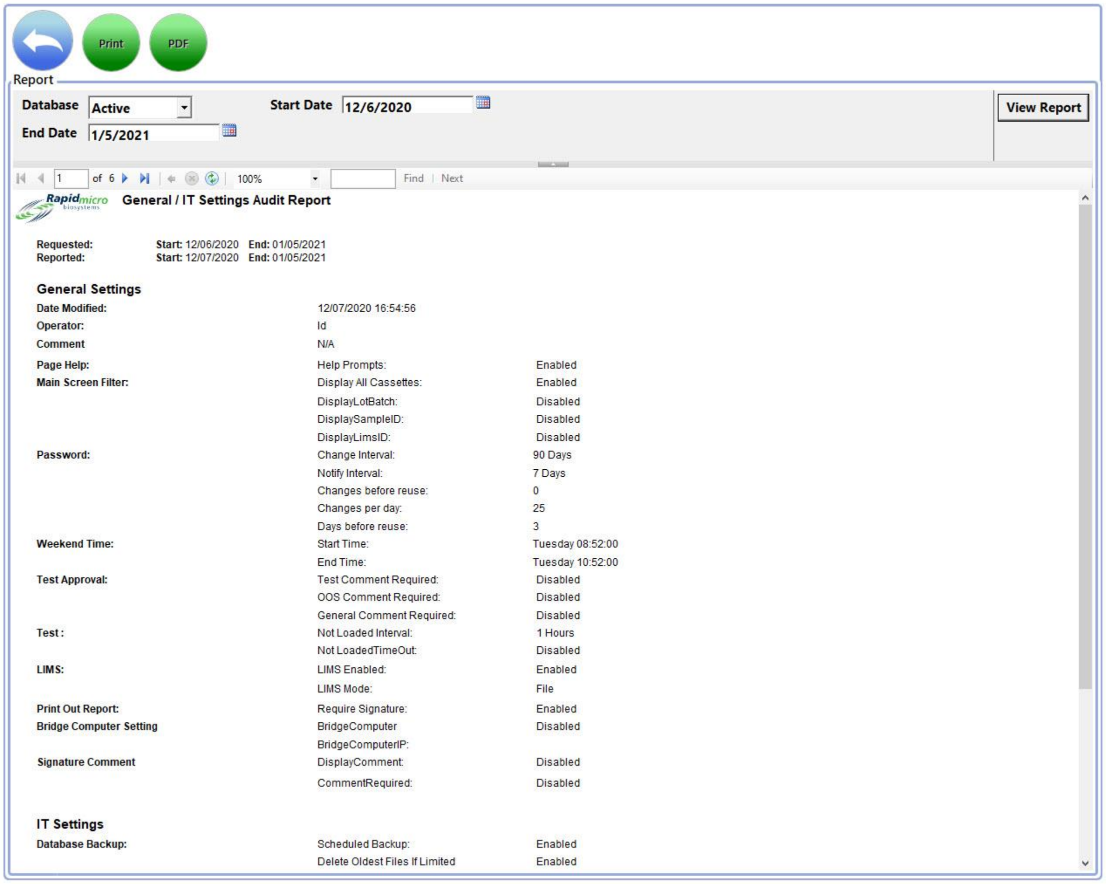


Figure 5-20: General/IT Settings Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.7 Incubator Settings Audit Report

The **Incubator** page specifies temperature settings and upper and lower alarm levels (thresholds) for top and bottom incubators. The **Incubator Settings Report** page displays when the parameters were entered, who entered them, whether the top and bottom incubators are enabled, and the following:

Top Incubator Temperatures

- Target
- Lower
- Upper

Bottom Incubator Temperatures

- Target
- Lower
- Upper

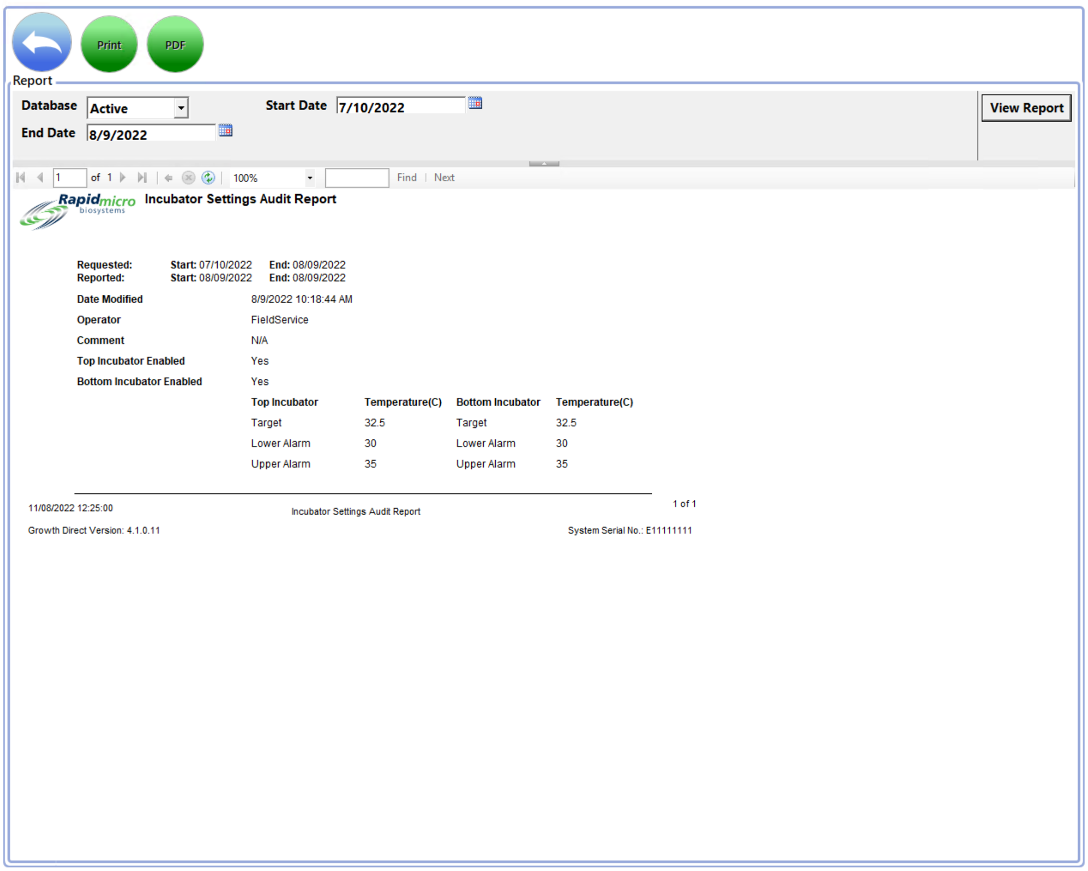


Figure 5-21: Incubator Settings Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.8 User Roles Audit Report

The **User Roles** page shows roles and permissions to specific functions to which that role has access. The **User Role Audit Report** page displays the permissions assigned to a selected user role.

Figure 5-22: User Role Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.9 User Audit Report

The **User Audit Report** page displays a user's personal information (name, phone number, email, role) and set up for email notification.

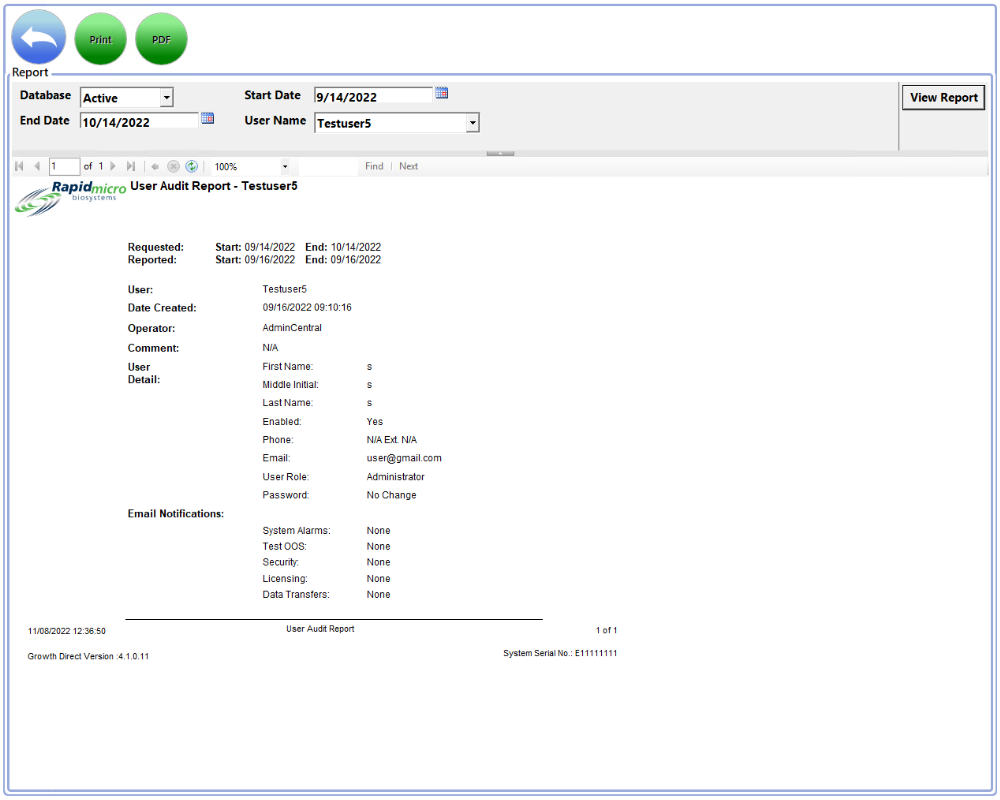


Figure 5-23: User Audit Report

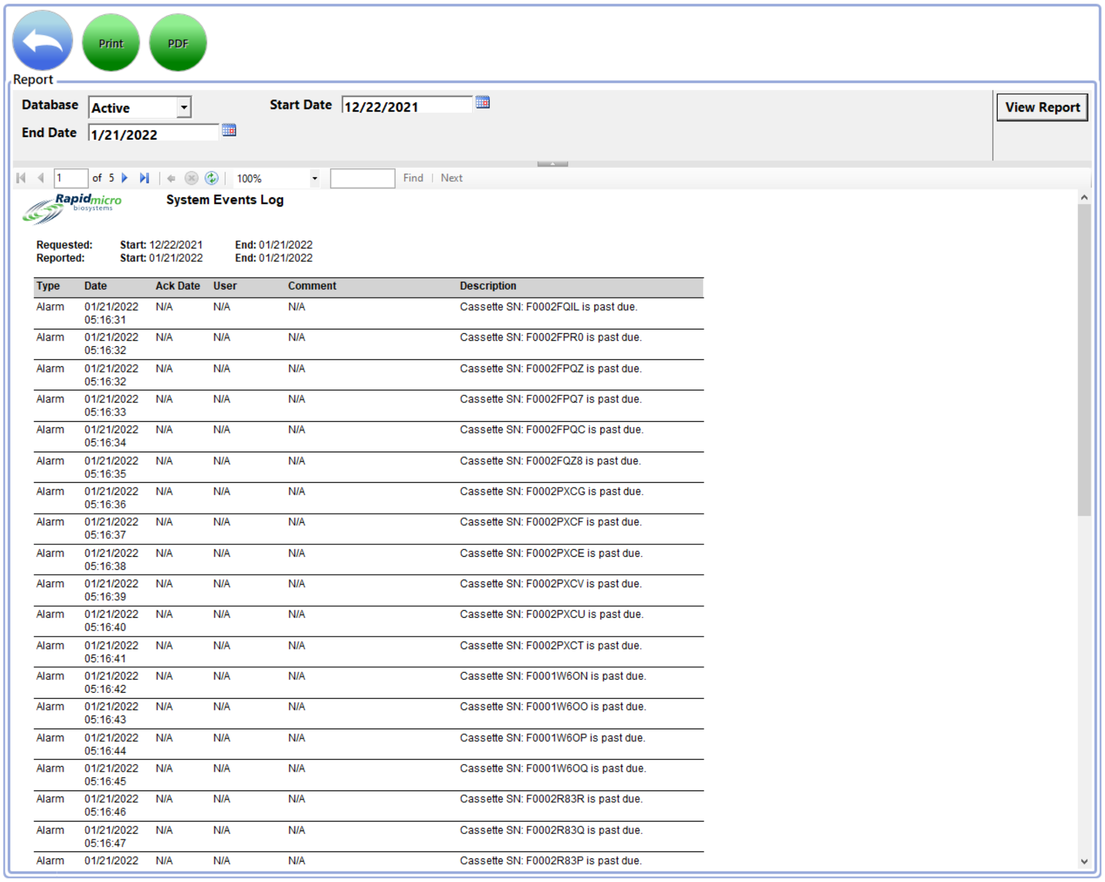
Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.10System Events Audit Report

The **System Events** page shows recorded system activity.



Type	Date	Ack Date	User	Comment	Description
Alarm	01/21/2022 05:16:31	N/A	N/A	N/A	Cassette SN: F0002FQIL is past due.
Alarm	01/21/2022 05:16:32	N/A	N/A	N/A	Cassette SN: F0002FPR0 is past due.
Alarm	01/21/2022 05:16:32	N/A	N/A	N/A	Cassette SN: F0002FPQZ is past due.
Alarm	01/21/2022 05:16:33	N/A	N/A	N/A	Cassette SN: F0002FPQ7 is past due.
Alarm	01/21/2022 05:16:34	N/A	N/A	N/A	Cassette SN: F0002FPQC is past due.
Alarm	01/21/2022 05:16:35	N/A	N/A	N/A	Cassette SN: F0002FQZ8 is past due.
Alarm	01/21/2022 05:16:36	N/A	N/A	N/A	Cassette SN: F0002PXCG is past due.
Alarm	01/21/2022 05:16:37	N/A	N/A	N/A	Cassette SN: F0002PXCF is past due.
Alarm	01/21/2022 05:16:38	N/A	N/A	N/A	Cassette SN: F0002PXCE is past due.
Alarm	01/21/2022 05:16:39	N/A	N/A	N/A	Cassette SN: F0002PXCV is past due.
Alarm	01/21/2022 05:16:40	N/A	N/A	N/A	Cassette SN: F0002PXCU is past due.
Alarm	01/21/2022 05:16:41	N/A	N/A	N/A	Cassette SN: F0002PXCT is past due.
Alarm	01/21/2022 05:16:42	N/A	N/A	N/A	Cassette SN: F0001W6ON is past due.
Alarm	01/21/2022 05:16:43	N/A	N/A	N/A	Cassette SN: F0001W6OO is past due.
Alarm	01/21/2022 05:16:44	N/A	N/A	N/A	Cassette SN: F0001W6OP is past due.
Alarm	01/21/2022 05:16:45	N/A	N/A	N/A	Cassette SN: F0001W6OQ is past due.
Alarm	01/21/2022 05:16:46	N/A	N/A	N/A	Cassette SN: F0002R83R is past due.
Alarm	01/21/2022 05:16:47	N/A	N/A	N/A	Cassette SN: F0002R83Q is past due.
Alarm	01/21/2022	N/A	N/A	N/A	Cassette SN: F0002R83P is past due.

Figure 5-24: System Events Audit Report

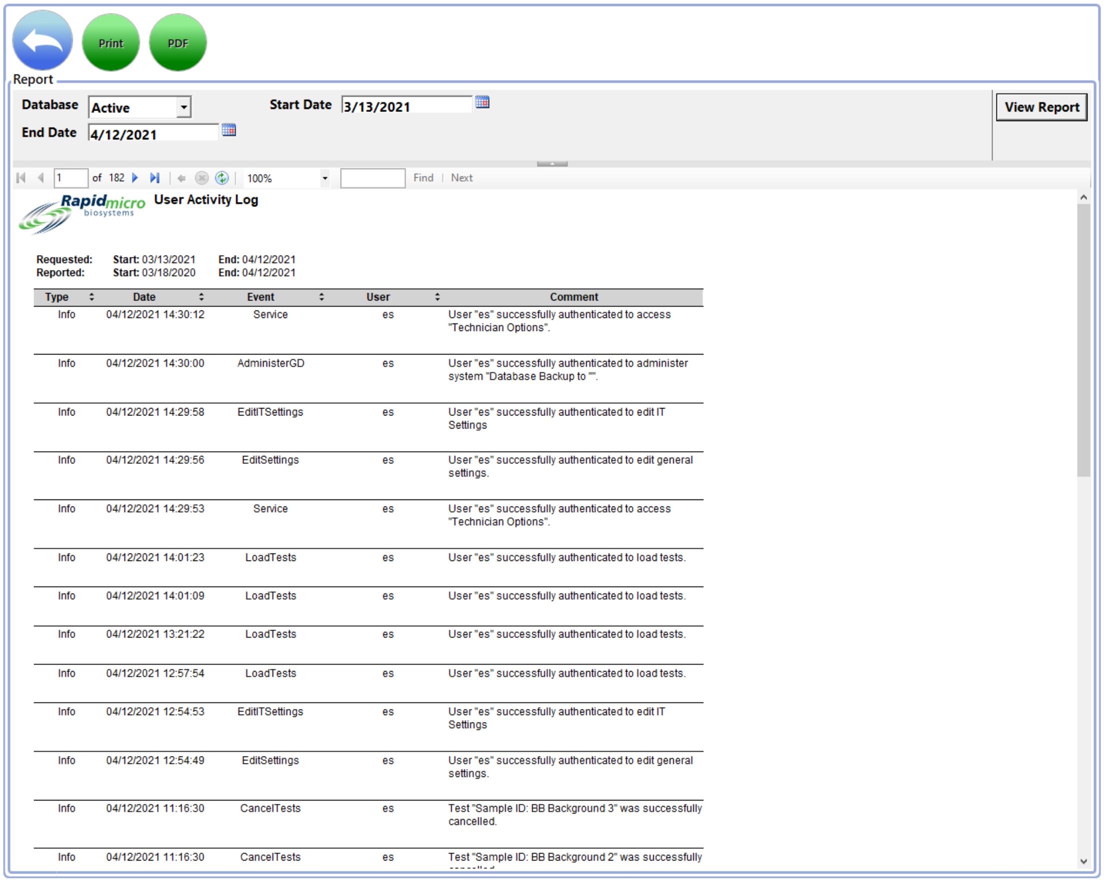
Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.11User Activity Audit Report

The **User Activity Audit Report** displays events, users that performed them, the dates and any comments associated with them.



Type	Date	Event	User	Comment
Info	04/12/2021 14:30:12	Service	es	User "es" successfully authenticated to access "Technician Options".
Info	04/12/2021 14:30:00	AdministerGD	es	User "es" successfully authenticated to administer system "Database Backup to "".
Info	04/12/2021 14:29:58	EditITSettings	es	User "es" successfully authenticated to edit IT Settings
Info	04/12/2021 14:29:56	EditSettings	es	User "es" successfully authenticated to edit general settings.
Info	04/12/2021 14:29:53	Service	es	User "es" successfully authenticated to access "Technician Options".
Info	04/12/2021 14:01:23	LoadTests	es	User "es" successfully authenticated to load tests.
Info	04/12/2021 14:01:09	LoadTests	es	User "es" successfully authenticated to load tests.
Info	04/12/2021 13:21:22	LoadTests	es	User "es" successfully authenticated to load tests.
Info	04/12/2021 12:57:54	LoadTests	es	User "es" successfully authenticated to load tests.
Info	04/12/2021 12:54:53	EditITSettings	es	User "es" successfully authenticated to edit IT Settings
Info	04/12/2021 12:54:49	EditSettings	es	User "es" successfully authenticated to edit general settings.
Info	04/12/2021 11:16:30	CancelTests	es	Test "Sample ID: BB Background 3" was successfully cancelled.
Info	04/12/2021 11:16:30	CancelTests	es	Test "Sample ID: BB Background 2" was successfully

Figure 5-25: User Activity Audit Report

Notes: For a description of the viewing options at the top of the page, see Section 5.3.2, About Viewing Options.

To print the report, see Section 5.5.2, Printing a Test Report.

To save the report as a PDF, see Section 5.5.3, Saving a Test Report as a PDF.

5.7.12Cancelled Tests Report

The **Cancelled Tests Report** displays the following information about cancelled tests, for the specified date range:

- Lot/Batch
- Sample
- LIMS ID
- Serial Number
- Method
- Action Alert Level
- Handling Rule
- Test Status
- Date and time cancelled
- Who cancelled by
- Comment

Notes: For a description of the viewing options at the top of the page, see Section 5.2.2, About Viewing Options.

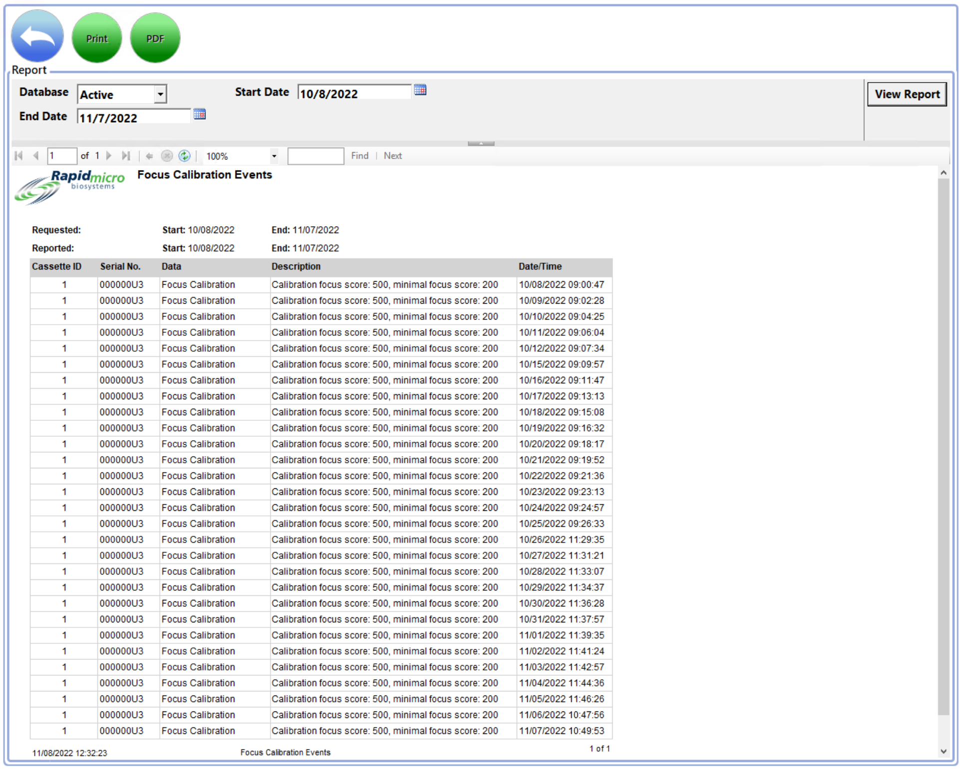
To print the report, see Section 5.4.2, Printing a Test Report.

To save the report as a PDF, see Section 5.4.3, Saving a Test Report as a PDF.

5.7.13Focus Calibration Audit Report

The **Focus Calibration Audit Report** page displays the following information, for the specified date range:

- Cassette ID
- Serial Number
- Data
- Description
- Date and Time



Requested:		Start: 10/08/2022	End: 11/07/2022	
Reported:		Start: 10/08/2022	End: 11/07/2022	

Cassette ID	Serial No.	Data	Description	Date/Time
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/08/2022 09:00:47
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/09/2022 09:02:28
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/10/2022 09:04:25
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/11/2022 09:06:04
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/12/2022 09:07:34
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/15/2022 09:09:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/16/2022 09:11:47
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/17/2022 09:13:13
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/18/2022 09:15:08
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/19/2022 09:16:32
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/20/2022 09:18:17
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/21/2022 09:19:52
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/22/2022 09:21:36
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/23/2022 09:23:13
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/24/2022 09:24:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/25/2022 09:26:33
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/26/2022 11:29:35
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/27/2022 11:31:21
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/28/2022 11:33:07
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/29/2022 11:34:37
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/30/2022 11:36:28
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	10/31/2022 11:37:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/01/2022 11:39:35
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/02/2022 11:41:24
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/03/2022 11:42:57
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/04/2022 11:44:36
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/05/2022 11:46:26
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/06/2022 10:47:56
1	000000U3	Focus Calibration	Calibration focus score: 500, minimal focus score: 200	11/07/2022 10:49:53

11/08/2022 12:32:23 Focus Calibration Events 1 of 1

Figure 5-26: Focus Calibration Report

Notes: For a description of the viewing options at the top of the page, see Section 5.2.2, About Viewing Options.

To print the report, see Section 5.4.2, Printing a Test Report.

To save the report as a PDF, see Section 5.4.3, Saving a Test Report as a PDF.

5.8 Viewing and Printing Custom Reports

Rapid Micro Biosystems can create custom reports according to your requirements. To access the **Custom Reports** page:

1. Click **Custom Reports** on the **Menu Options** page.
2. A **Signature** dialog opens. Enter your username and password and click **OK** to continue or click **Cancel**.

6. Preparing and Loading Bioburden Samples

This section contains:

6.1 Overview

This section provides an overview of the steps for preparing bioburden sample cassettes and loading them onto the Growth Direct® System.

- A membrane filters samples..
- An operator places the membrane on a cassette, which contains growth media.
- The operator then places a vision lid on the cassette. Each cassette comes labeled with a unique serial number.
- The operator places the cassettes in one of two carousels that are inserted into the system. The operator can load prepared samplesusing a fully loaded carousel, in stacks, or as individual cassettes.
- The system automatically transports cassettes to the appropriate incubator for the length of time specified.
- Once testing is completed, results are recorded, and the completed samples are sent for subsequent processing, storage, or disposal.

The sections that follow provide detailed steps for sample preparation and procedures for loading bioburden cassettes into the system.

6.2 About Bioburden Cassettes

The following table lists bioburden testing components.

- Cassettes
- Filtration Funnel
- Vision Lids

See Appendix B, Ordering Products for ordering information.

Figure 6-1: Bioburden Components

Caution! Use only cassettes from Rapid Micro Biosystems. If you use any other type of cassette, you will invalidate the inspection procedure and may damage the system. All warranties will be voided.

Each cassette consists of:

- A base that contains a growth medium. After sample filtration, place a sample membrane from the filtration kit over the base.
- A vision lid that seals the cassette that prevents external contamination and enables accurate imaging of the membrane.

Each filtration kit consists of:

- A filtration funnel with a 0.45-micron cellulose ester membrane that fits a specified filtration head or size-8 stopper with the filtration manifold provided.

6.3 Printing Cassette Labels

Use the **Print Worklists** page (see Section 3.7, Printing Worklist Sheets and Labels) to print labels for the bottoms of the cassettes. Click **Print** on the menu bar at the top of the Home page or click **Print Worklists** on the **Menu Options** page.

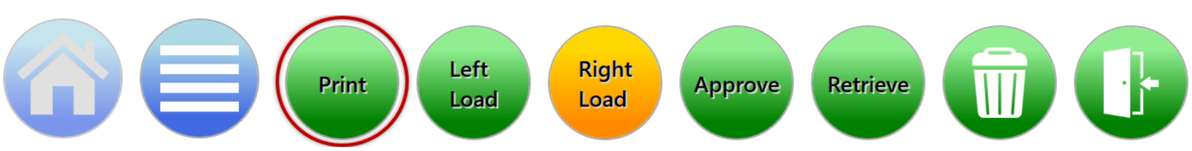


Figure 6-2: Click Print

1. On the left side of the **Worklist** page, under the **Print Worklists** Heading, select a worklist name.

2. On the right side of the **Worklist** page, in the **Lot/Batch** Field, enter a unique name for the Lot/Batch ID. In combination with a Sample ID, the name must be 42 characters or less. We recommend using the current date as an identifier.
3. Click **Label** on the **Worklist** page to print the sample labels.
4. Attach a sample label to the bottom of each cassette within the specified sample label area.

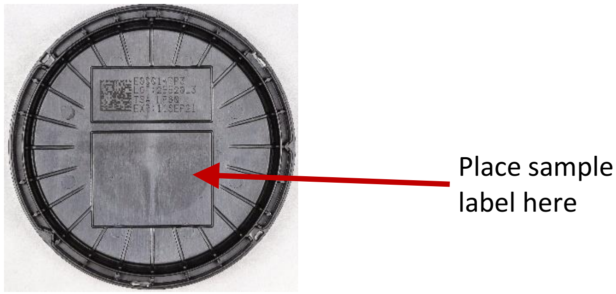


Figure 6-3: Sample Label

Caution! Before loading samples, check each label to ensure that the print quality is dark and that the label is flat, without any creases or tears. Reprint the labels, if necessary.

Caution! In lieu of a sample label, use a silver Sharpie Pen® to write on the bottom of the cassette. Never write on the vision lid or the top label.

6.4 Preparing and Filtering Bioburden Samples

6.4.1 Preparing Apparatus and Equipment

Recommended equipment includes:

- Microsart Pump, Millivac Maxi Pump
- Filtration Manifold
- Sterile forceps
- Proper biohazard disposal

If you use an in-house vacuum source, contact Rapid Micro Biosystems Technical Services for a representative to verify vacuum pressure.

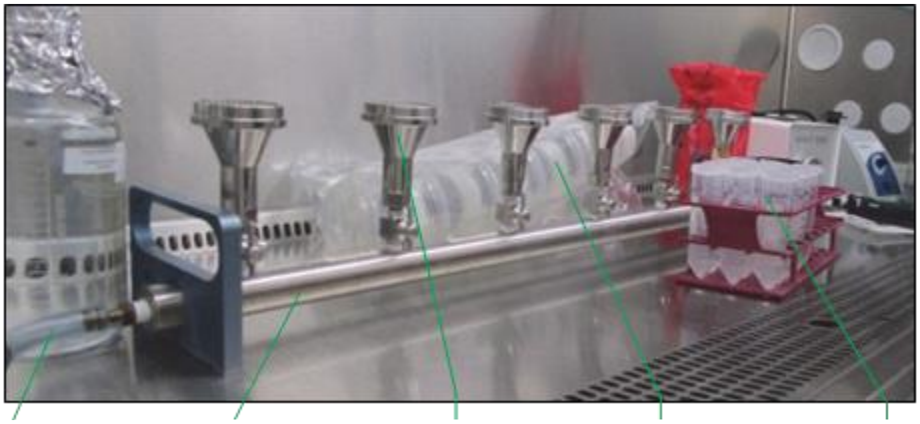


Figure 6-4: Filtration Apparatus and Equipment

Ensure you:

- Never preheat cassettes in an incubator.
- Store cassettes at 2-8°C.
- Equilibrate cassettes to room temperature for at least two hours, but no more than 24 hours before filtration.
- Use cassettes with the required media type.
- Check the expiration date on each cassette.
- Spray the cassette bag, vision lid bag, and filtration kit sleeve with either sterile 70% ethanol or 70% isopropyl alcohol and place them in the biosafety cabinet.
- Wipe down to disinfect all materials required before you place them in the biosafety cabinet.

Caution! Never spray a cassette or vision lid outside of the bag. If either piece is sprayed, dispose of it and get a new one.

Avoid touching the top surface of the vision lids.

6.4.2 Filtering the Samples

1. Remove the filtration kits, cassettes with covers, and vision lids from their bags and keep them within the biosafety cabinet.
2. Turn on the vacuum and open all the manifold valves being used for filtration.

Caution! To prevent the membrane from wrinkling, apply the vacuum before and throughout sample filtration.

3. Remove the lids from the filtration kits if necessary and place a filtration kit securely on each tulip.

Figure 6-5: Attach Filtration Kits to Manifold

4. Pour the sample fluid into the first filtration kit funnel. The membrane becomes a darker color. Wait until the fluid filters through the funnel completely before you pour the sample into the next filtration kit.

Figure 6-6: Fluid Filtration

5. Remove the filtration funnels from each filtration kit base. Dispose of the used funnels according to your company's biohazard policy.

6.4.3 Transferring the Cassette Membrane

1. Remove the protective cover from one cassette.
2. With the vacuum still on, use sterile forceps to lift the edge of the membrane from the base by placing the forceps in a groove along the base and lifting the membrane up.

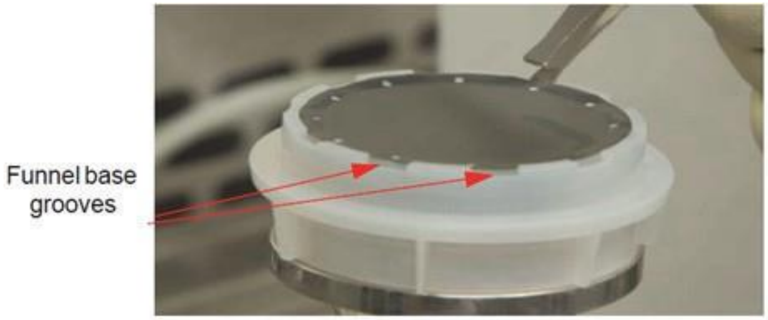


Figure 6-7: Remove Membrane from Funnel Base

3. Carefully place the membrane in the center of the media in the cassette.

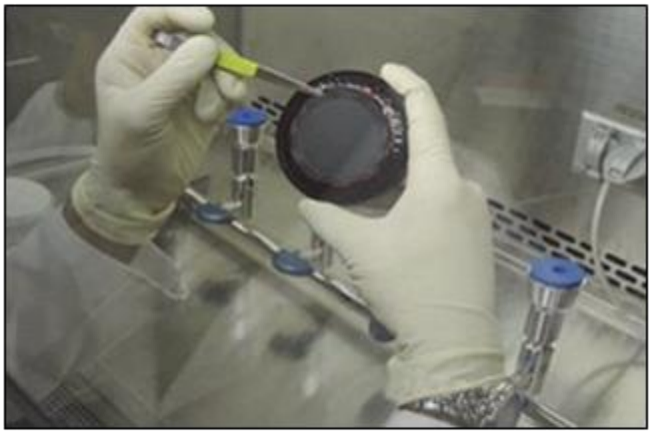


Figure 6-8: Place Membrane on Cassette

Caution! Avoid excessive contact with the membrane surface. Scratches from the forceps can interfere with sample analysis.

4. Roll the membrane onto the media, making sure that it is completely centered within the printed red targets and lays flat (no bubbles or wrinkles).

Caution! Center the membrane within the targets on the cassette. If the membrane is grossly off center or outside the red targets, it will impair the Growth Direct® System's ability to process the cassette.

5. Inspect the membrane to make sure there are no air bubbles.

Caution! If the membrane has any air bubbles or does not appear to maintain uniform contact with the growth media below, gently lift and reposition the membrane. If there are any scratches, rips, or marks from forceps in the sample filtration area, repeat the sample set-up procedure using a new kit.

6. Position the vision lid over the cassette body. Push down and rotate the lid clockwise until it locks into place. It is extremely important that the vision lid is completely seated in the cassette. Limit handling to the vertical sides of the vision lid, being careful not to touch the top surface of the lid.
7. Once all filtrations are completed, turn off the vacuum and close all the manifold valves.

6.4.4 Finishing Sampling and Troubleshooting

1. Check that the membrane is uniformly flat, examining it for any defects such as cracks or air bubbles. Discard any cassettes that exhibit these irregularities. To prevent membrane irregularities, adhere to these procedures.
2. Use an aseptic technique and adapt your site's protocol for filtering samples when performing these steps. To minimize dust and foreign particles, perform as many steps as possible within a biosafety cabinet.

Caution! When the lid is on, no agar should be visible. If you see any agar, open the lid, and reposition the membrane to completely cover the agar.

If you drop a cassette, place the membrane on a new cassette and attach a new vision lid. If you break a cassette, follow your site's protocol for cleaning biological spills and dispose of the cassette properly.

Cassettes and filtration kits are for one-time use only; never re-use a cassette for any reason, and never attempt to use a new membrane with a previously used funnel.

6.5 Loading Cassettes into the Growth Direct® System

1. If you are using the carousel to transport cassettes, wipe it prior to use to avoid accumulation of dust.
2. Place the cassettes into a carousel.

Caution! Always place cassettes in the carousel with the vision lid facing up. If placed in upside down, the cassettes will not be analyzed and will stop system operation.

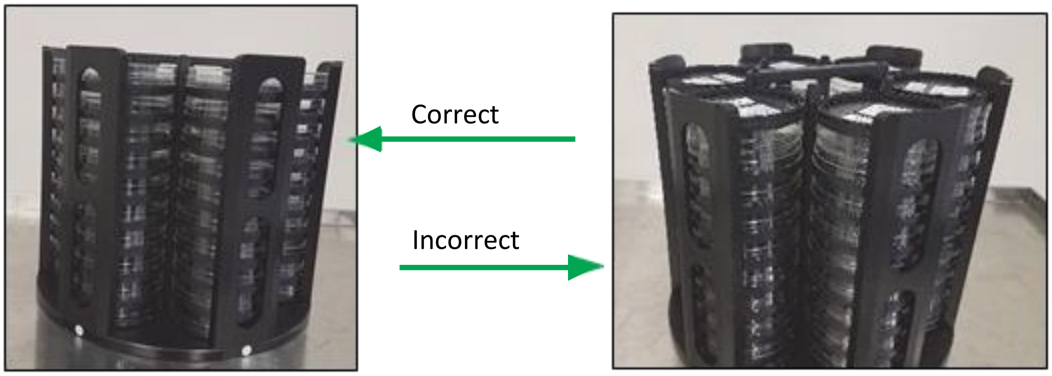


Figure 6-9: Cassettes loaded vision lid up (to the left), Cassettes loaded vision lid down (to the right)

Caution! When loading the cassettes, make sure they are lying flat in the carousel and are not askew.

Figure 6-10: Cassette askew in carousel

Each carousel holds 60 cassettes, up to 10 cassettes per stack.

3. If the cassettes do not have sample labels, see Section 3.8.1, Manually Order Tests Page. If the cassettes have sample labels, press the left or right **Load** button on the **Home** page. An orange **System Status** Message appears on the **Home** page, indicating the available input queue.

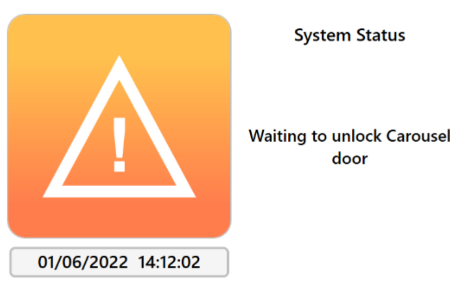


Figure 6-11: System Status

4. Open the input queue door by pulling straight outwards. Place the cassettes into the carousel indicated by the software. The indicated door will unlock.

5. If the carousel is removed from the input queue, ensure that it is locked into place by turning the carousel clockwise. Shut the carousel door; this initiates the loading process.

6. Confirm the carousel is locked into place after loading the cassettes. The system then automatically:

   - processes and transports the samples in the instrument
   - images the samples
   - notifies designated personnel of alarms, alerts, and action levels, if this feature was configured using the **Action Alert Levels** page. (See Section 3, Using the Growth Direct® System)
   - reports results
   - returns completed samples for subsequent processing, storage, or disposal

After cassettes enter the system, you can monitor current status and CFU count readings on the **Cassette Details** page (See Section 3, Using the Growth Direct® System). To retrieve or cancel a test, use the **Cancel/Retrieve** page (See Section 3, Using the Growth Direct® System).

7. Preparing and Loading Environmental Monitoring Samples

This section contains:

7.1 Overview

This section provides an overview of the steps for preparing EM sample cassettes and loading them onto the Growth Direct® System.

EM sampling includes:

- active air sampling (cassettes are loaded into air samplers and samples are taken)
- settle plates
- surface sampling (a cassette is physically pressed against the surface to be sampled).

Each cassette comes labeled with a unique serial number. The operator places the cassettes in one of two carousels that are inserted into the system. The operator can load prepared samples using a fully loaded carousel, in stacks, or as individual cassettes. The system automatically transports cassettes to the correct incubator for the length of time specified. Once testing is completed, results are reported, and the completed samples are sent for subsequent processing, storage, or disposal.

The sections that follow provide detailed steps for sample preparation and procedures for loading EM cassettes into the system.

7.2 Printing Cassette Labels

Use the **Print Worklists** page (see Section 3.7, Printing Worklist Sheets and Labels) to print labels for the bottoms of the cassettes. Click **Print** on the menu bar at the top of the Home page or click **Print Worklists** on the **Menu Options** page.

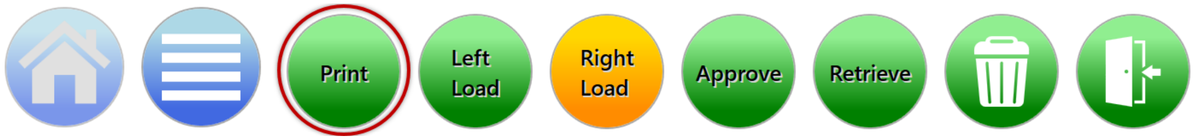


Figure 7-1: Click Print

1. On the left side of the **Worklist** page, under the **Print Worklists** Heading, select a worklist name.
2. On the right side of the **Worklist** page, in the **Lot/Batch** Field, enter a unique name for the Lot/Batch ID. In combination with a Sample ID, the name must be 42 characters or less. We recommend using the current date as an identifier.
3. Click **Label** on the **Worklist** page to print the sample labels.
4. Attach a sample label to the bottom of each cassette within the specified sample label area.

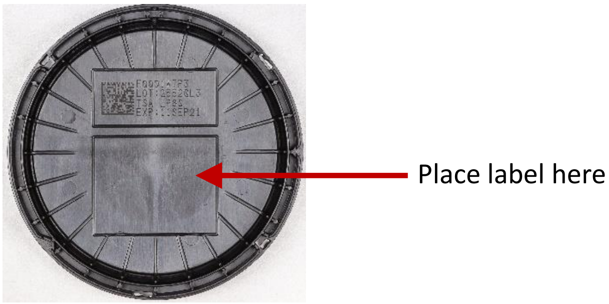


Figure 7-2: Sample Label Placement

Caution! Before loading samples, check each label to ensure that the print quality is dark and that the label is flat, without any creases or tears. Reprint labels if necessary.

Caution! In lieu of a sample label, use a silver Sharpie Pen® to write on the bottom of the cassette. Never write on the vision lid or the top label.

7.3 Processing Environmental Samples

This section provides information about:

- EM Cassettes
- Preparing active air and surface samples
- Printing sample ID labels

- Loading cassettes into carousels and loading them into the system
- Removing cassettes from the system
- Emptying the trash

Before starting, make sure you have the following available for each sample:

- EM Cassettes
- EM Vision Lids

Figure 7-3: Environmental Cassette

Caution! Use only cassettes from Rapid Micro Biosystems. If you use any other type of cassette, you will invalidate the inspection procedure and may damage the system. All warranties will be voided.

7.3.1 About Growth Cassettes

Each cassette consists of:

- A base that contains a growth medium over which is an attached 0.45-micron mixed cellulose ester membrane and a protective cover
- A vision lid preventing external contamination during incubation and enabling accurate imaging of the mem- brane

Caution! Make sure there are no scratches, drops of liquid, glove marks, dust, or other foreign particles on the vision lid. If there are, discard the vision lid and attach a new lid.

If you break a cassette, follow your site's protocol for cleaning biological spills and dispose of the cassette properly.

Cassettes are for one-time use only; never re-use a cassette for any reason.

7.3.2 Preparing Samples

Cassettes are stored at 2-8° C but should be equilibrated to room temperature (for at least 2 but no more than 24 hours) before use. Never preheat Growth Direct® Cassettes in an incubator. Always check the expiration date on each cassette, and visually check that the membrane is uniformly flat, examining it for any defects such as cracks or air bubbles. If there are any defects, discard the cassette. To prevent membrane irregularities, adhere to the procedures in the following sections.

Use an aseptic technique and adapt your site's protocol for environmental sampling when performing the following steps.

7.3.3 Sampling Active Air

Adapter clips for air samplers are required to use the Growth Direct® EM cassettes. Air samplers must be calibrated with the adapter clips installed.

Figure 7-4: Air Samplers and Adapter Clips

1. Remove one EM cassette from its silver bag.
2. Leaving the protective lid on, place the EM cassette into the sampler.

Caution! Ensure by feel or sound that the cassette is secure in the sampler's holding clips.

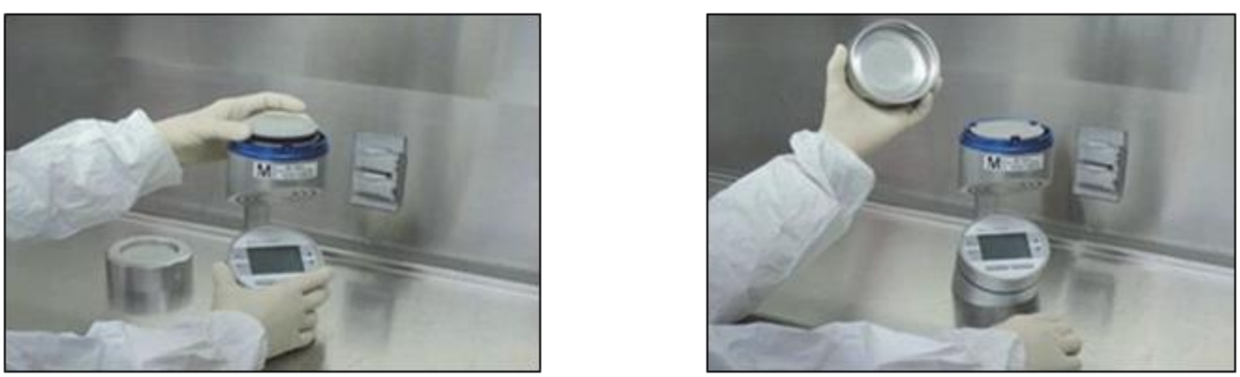


Figure 7-5: Placing the Cassette into the Sampler

3. Using your thumb and index finger, grasp the outer edge of the cassette and with your other hand, remove and discard the protective cover.

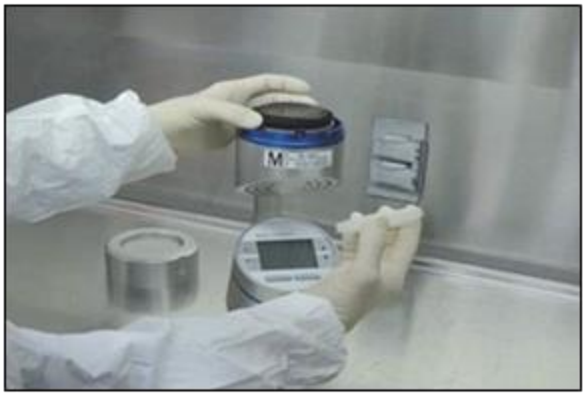


Figure 7-6: Removing the Protective Cover

4. Screw on the air sampler lid and begin air sampling.

Figure 7-7: Screwing on the Air Sampler Lid

5. While air sampling, prepare the packaged vision lids for placement onto the EM cassette. Open the vision lid packaging but do not remove a lid until after air sampling is complete.
6. Upon completion of air sampling, remove the sampler head.
7. Using your thumb and index finger, grasp the outer edge of the cassette, making sure not to touch the sampling surface. With your other hand, remove a vision lid from its packaging.
8. Place the vision lid onto the cassette. Press down, and turning the lid clockwise, lock the lid in place ensuring that it is fully seated.

Caution! It is *extremely important* that the vision lid is completely seated in the cassette. Limit handling to the vertical sides of the vision lid, being careful not to touch the top surface of the lid.

Be sure to put the vision lid on before removing a cassette from the air sampler to prevent potential sample contamination.

9. Remove the EM cassette from the air sampler and prepare for incubation.

7.3.4 Sampling the Surface

1. Remove one EM cassette from its silver bag.
2. Use one hand to grasp and hold the base of the EM cassette and your other hand to remove the protective cover. Make sure that you do not touch the sampling surface.
3. Open the vision lid packaging but do not remove a lid.
4. To use the EM cassette for surface sampling by rolling the cassette. Begin the cassette sampling roll by gently pressing the leading edge of the agar puck against the surface to be sampled.
5. When the cassette reaches the middle of the roll, full contact is made as the membrane and surface are parallel. Hold this position for approximately 3 seconds to ensure complete and uniform contact between the Growth Direct® Membrane and test surface.
6. Finish the rolling technique to the opposite edge of the cassette.

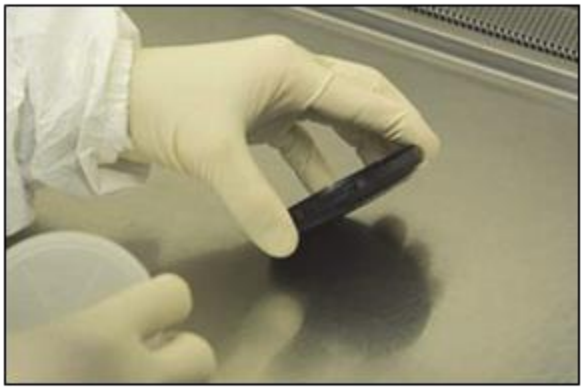


Figure 7-8: Rolling Technique

7. Remove a vision lid from its packaging and place it onto the EM cassette.
8. Turning the lid clockwise, lock it in place and ensure that it is fully seated.

7.3.5 Testing Growth Promotion

If you are using a standard company Growth Promotion method, RMB strongly recommends that any organisms used are diluted to use no more than 50µl for >100cfu. In the unlikely event that the 50µl inoculation volume causes the cassettes to appear overly wet after spread plating, RMB recommends that the operator leave the cassettes open for up to 15 minutes to allow excess liquid to evaporate.

Note: Excess liquid on the cassette membrane does not occur during routine surface or active air monitoring. This membrane wetness only occurs when dilution fluid is added during quality control testing of the consumables. It is not required or recommended that an operator leave a Growth Direct® cassette uncovered during routine active air or surface sampling assays.

7.4 Loading Cassettes into the Growth Direct® System

See Section 6.5, Loading Cassettes into the Growth Direct® System.

8. Bridge Computer

This section contains:

8.1 About the Bridge Computer

A Bridge Computer is a computer with two network adapters. The Growth Direct® System connects to the Bridge Computer using a crossover cable. The Bridge Computer connects to your network by Ethernet. The Bridge Computer can be fully imaged by your IT team to comply with Global IT policies without having any impact on the Growth Direct® System.

8.2 Bridge Computer Error Message

If there is an interruption in service to the Bridge Computer, an error message appears in the **System Status** section:

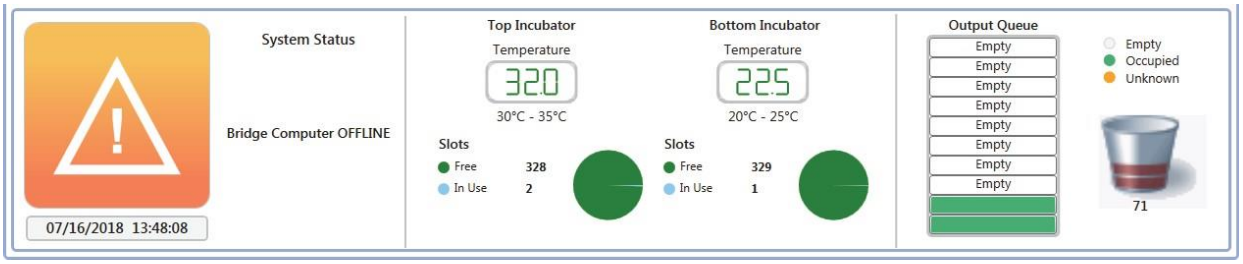


Figure 8-1: Bridge Computer Error Message

To clear the Bridge Computer offline status:

- Ensure the Bridge Computer is turned on in the **General Settings** page (see Section 2, Setting Up the Growth Direct® System).
- Ensure the Bridge Computer Service is running on the Bridge Computer. Contact Customer Support if it is not.

- Ensure the network crossover cable is connected to the Bridge Computer and to the instrument.

8.3 Bridge Computer: Adding/Changing an IP Address

RMB does not recommend that you turn off the Bridge Computer or change the IP address. Contact Customer Support if the Bridge Service IP address needs to be changed.

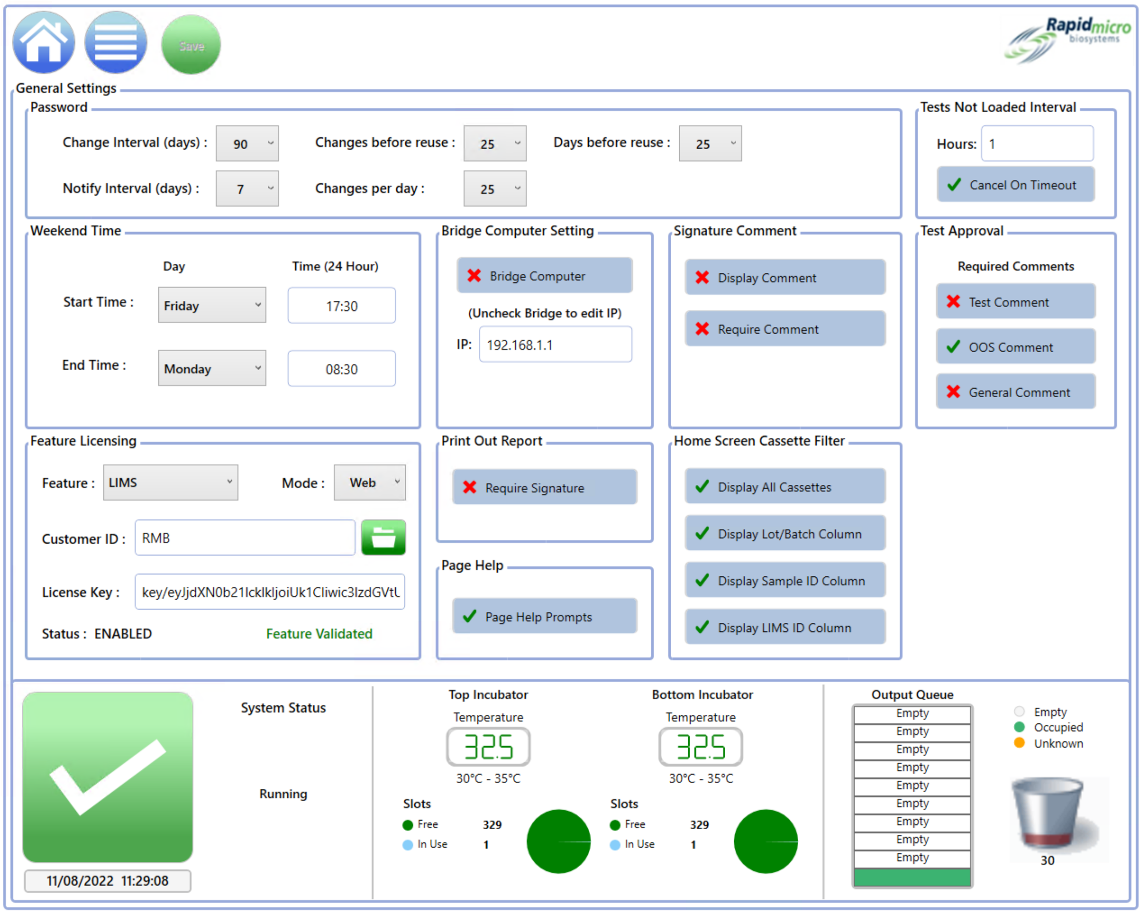


Figure 8-2: Bridge Computer: Add/Change IP Address

9. Cleaning and Maintenance

This section contains the following information on preventive maintenance and cleaning tasks as well as routine service supplied by Rapid Micro Biosystems:

Warning! Any system service or repairs must be performed only by trained Rapid Micro Biosystems personnel. If anyone other than Rapid Micro Biosystems personnel services the system, all warranties are voided.

9.1 Cleaning and Maintenance Schedule

A general schedule of when to perform specific tasks follows. Your site's protocols and your system throughput may require you to perform some of these tasks more frequently.

Interval	General Task	Task Details
Every Day	Check the trash bin and empty it, if necessary.	See Section 1.6.7, Trash Bin Button
	Check if the printer needs more labels.	See Section 9.2.1, Replacing Labels to the Barcode Printer.
Every Week	Clean the system.	See Section 9.4, Cleaning the Growth Direct® Surfaces.
Every Month	Check label quality and change the ribbon, if necessary.	See Section 9.2.2, Changing the Printer Ribbon.
	Check supply inventory and reorder, if necessary.	See Appendix B, Ordering Products.

Interval	General Task	Task Details
Every 6 and 12 months	Schedule 6-month and 12-month maintenance service.	Contact Rapid Micro Biosystems at (+1) 888- RAPID07 (888.727.4307) or (+1) 978-349-3200 in the USA. In Europe, contact your local representative or use service@rapidmicrobio.com internationally.

9.2 Printer Maintenance

9.2.1 Replacing Labels in the Barcode Printer

Before ordering a test, always make sure that there are enough labels in the printer for each cassette in the test.

Figure 9-1: Printer Labels

We strongly recommend that you clean the print head before loading the labels. See Section 9.2.3, Cleaning the Print Head below.

1. Turn off the printer by switching off the power on the back of the printer.
2. Lift the printer cover to an open position.
3. Turn the retainer ring counterclockwise so that the arrow points to the unlock symbol. This releases the retainer ring from the label roll holder.

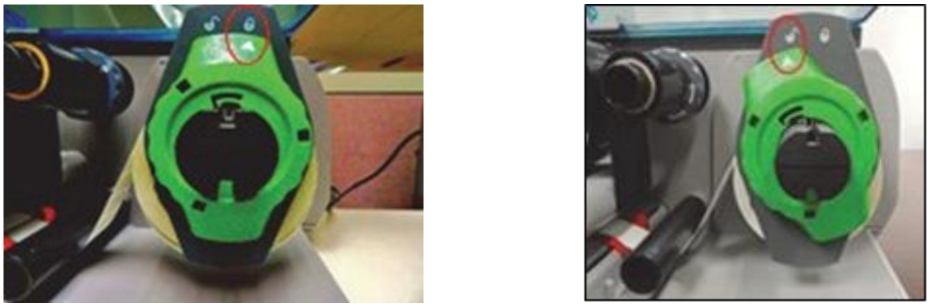


Figure 9-2: Turn the Retainer Ring

4. Pull the retainer ring straight out from the holder. Mount the new roll of labels. Replace the retainer ring pushing it against the label roll as far as it will go. Turn the retainer ring in a clockwise direction so that the arrow points to the lock symbol and secures the ring in place.

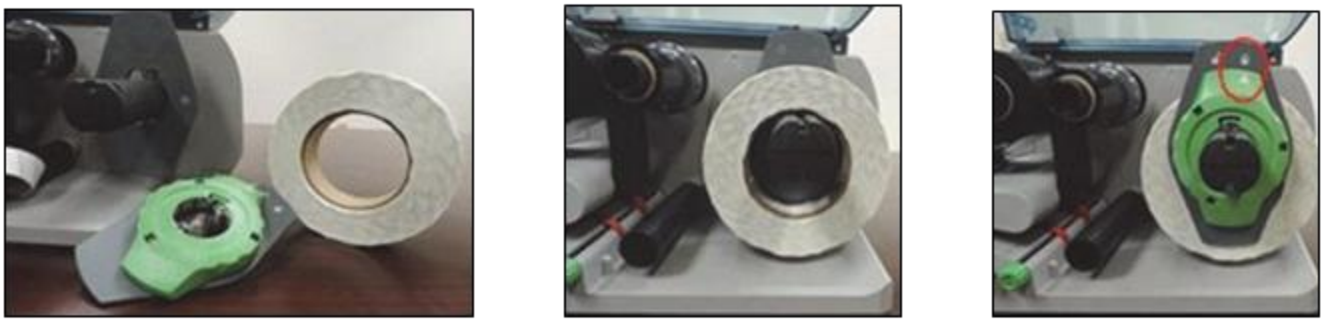


Figure 9-3: Inserting Labels

5. Turn the print-head release lever counterclockwise to unlock the print head.

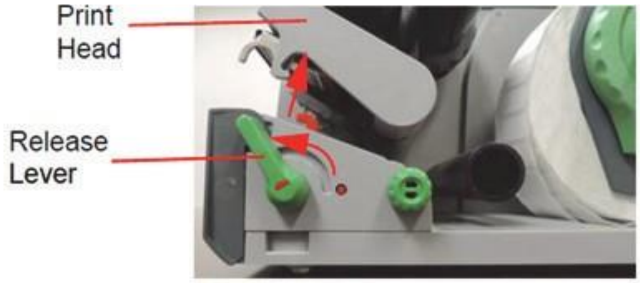


Figure 9-4: Unlocking the Print Head

6. Position the label strip below the belt roller and between the red guides. If necessary, turn the guide adjuster knob to widen the guides so that the label strip fits between them.

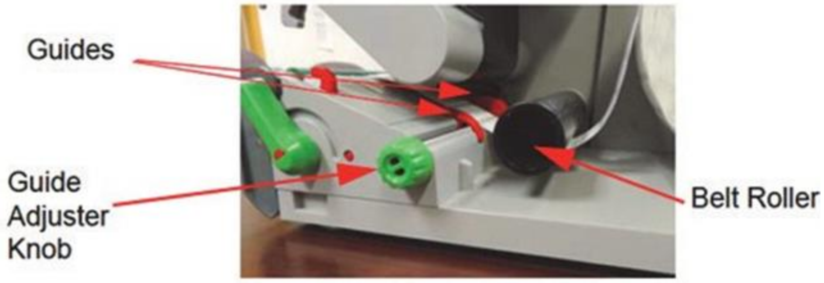


Figure 9-5: Positioning the Label Strip

Be careful to guide the label strip below the label sensor at the front of the printer.

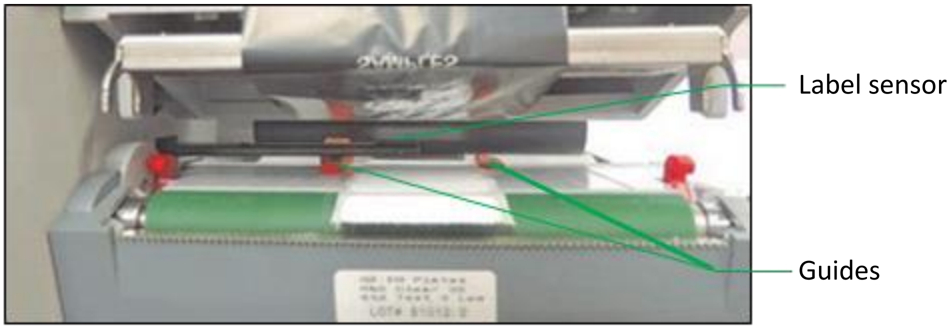


Figure 9-6: Guiding the Label Strip

7. Use the guide adjuster knob to move the guides closely to the edges of the label strip without clamping the strip.
8. If necessary, adjust the label sensor. Use a pointed object to select the red button, which pops out into the label sensor adjuster knob.

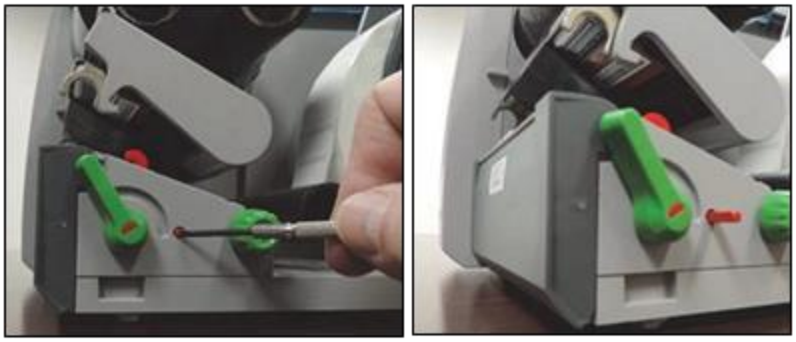


Figure 9-7: Adjusting the Label Sensor

Turn the label sensor adjuster knob so that the sensor can detect the front edge of the label in the direction of the paper flow. Push the knob back into the housing until it clicks into place.

9. Move the print head retainer down and turn the print-head release lever clockwise to lock the print head.

Figure 9-8: Locking the Print Head

10. Close the cover and switch the printer on.

9.2.2 Changing the Printer Ribbon

If printed labels are streaked, faded, or have other print quality problems, replace the printer ribbon.

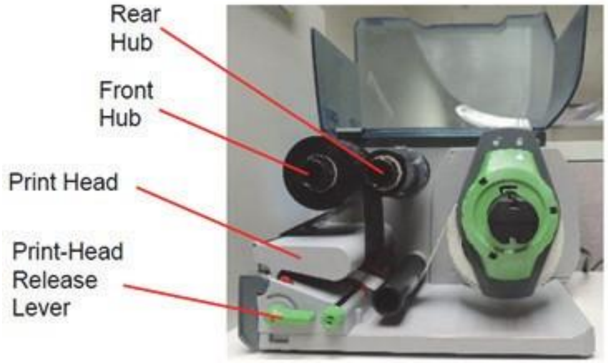


Figure 9-9: Printer Ribbon Parts

1. Turn off the printer by switching off the power on the back of the printer.
2. Lift the printer cover to the open position.
3. We strongly recommend that you clean the print head before loading the ribbon. See Section 9.2.3, Cleaning the Print Head below.
4. Turn the print-head release lever counterclockwise to unlock the print head.

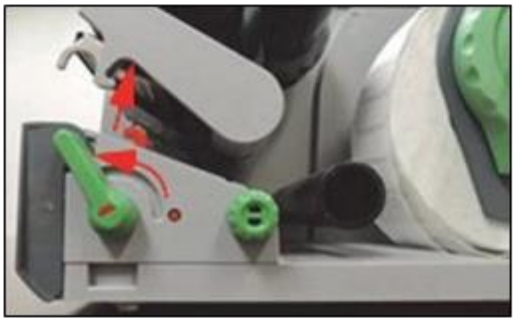


Figure 9-10: Print-Head Release Lever

5. Remove the used ribbon and ribbon cardboard core from the hubs. Do not discard the cardboard core.
6. Unwrap and load the new ribbon on the rear hub until the ribbon presses up against the guide.
7. Guide the ribbon down and under the print head.

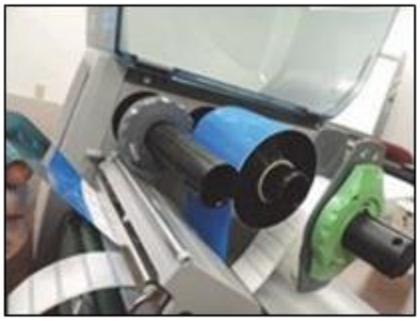


Figure 9-11: Guiding the Ribbon

Be careful to position the ribbon above the label sensor at the front of the barcode printer.

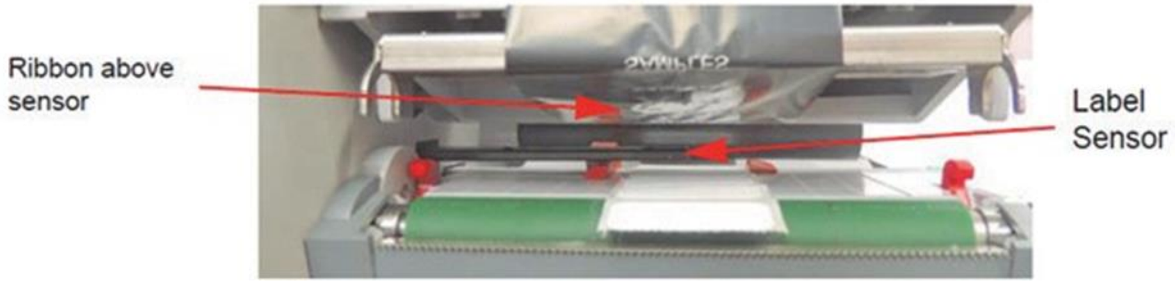


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Figure 9-12: Positioning the Label

8. Tape the ribbon’s loose end to the empty cardboard core and slide the core onto the front hub until the core presses up against the guide.
9. If necessary, set the guide on both hubs to the ribbon width.

   Hold the hub and set the guide on both hubs to the ribbon width. Slide the guide to adjust the guide to the ribbon width using the scale.

   Hold the hub and lock the guide by turning it in a counterclockwise direction.

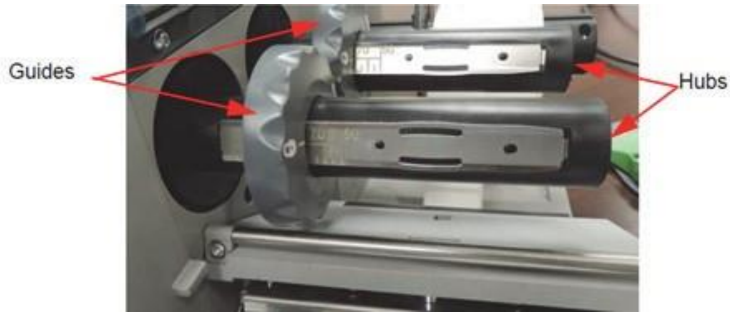

Figure 9-13: Holding the Hub and Locking the Guide

10. Select the print head down and turn the print-head release lever clockwise to lock the print head.

Figure 9-14: Setting the Print Release Lever

11. Close the cover and switch the printer on.

9.2.3 Cleaning the Print Head

It is important to clean the print-head regularly. This will guarantee a good printed image and reduce the print head's wear. Substances may accumulate on the print head during printing and adversely affect print quality. Remove dust and paper fluff from the print area with a soft brush or vacuum cleaner. It is strongly recommended that the print head be cleaned during every:

- Label roll change
- Ribbon change

Warning! Ensure that the print head has cooled before cleaning it. There is a risk of injury from a hot print head line.

Caution! Do not use abrasive cleaners or solvents to clean the external surfaces.

Do not use sharp or hard objects to clean the print head.

Do not touch the protective glass layer of the print head.

1. Turn off the printer by switching off the power on the back of the printer.
2. Lift the cover to an open position.

3. Turn the print-head release lever counterclockwise to unlock the print head.

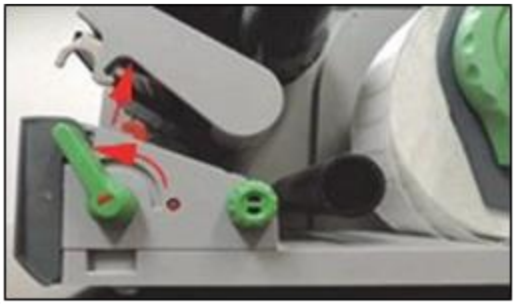

Figure 9-15: Unlocking the Print Head

4. Remove the roll of labels and the ribbon from the printer.
5. Clean the print head line with rubbing alcohol and a soft particle free cloth.
6. Allow the print head to dry for 2-3 minutes.
7. Replace the roll of labels and the ribbon.
8. Press the print head down and turn the print-head release lever clockwise to lock the print head in place.

Figure 9-16: Locking the Print Head In Place

9. Close the cover and turn the printer back on.

9.3 Scheduling Backups of the Growth Direct® Database

Use the **IT Settings** page (see Section 2, Setting Up the Growth Direct® System) for scheduling backups of your system. This feature also backs up the logs daily and sends them to the bridge computer at C:\Logs folder. To access the **IT Settings** page, select the **IT Settings** button on the **Menu Options** page.

You must have a role with Administer System permissions assigned to use the **IT Settings** page (see Section 2, Setting Up the Growth Direct® System).

1. When prompted, enter your user name and password at the Signature prompt and select **OK**.

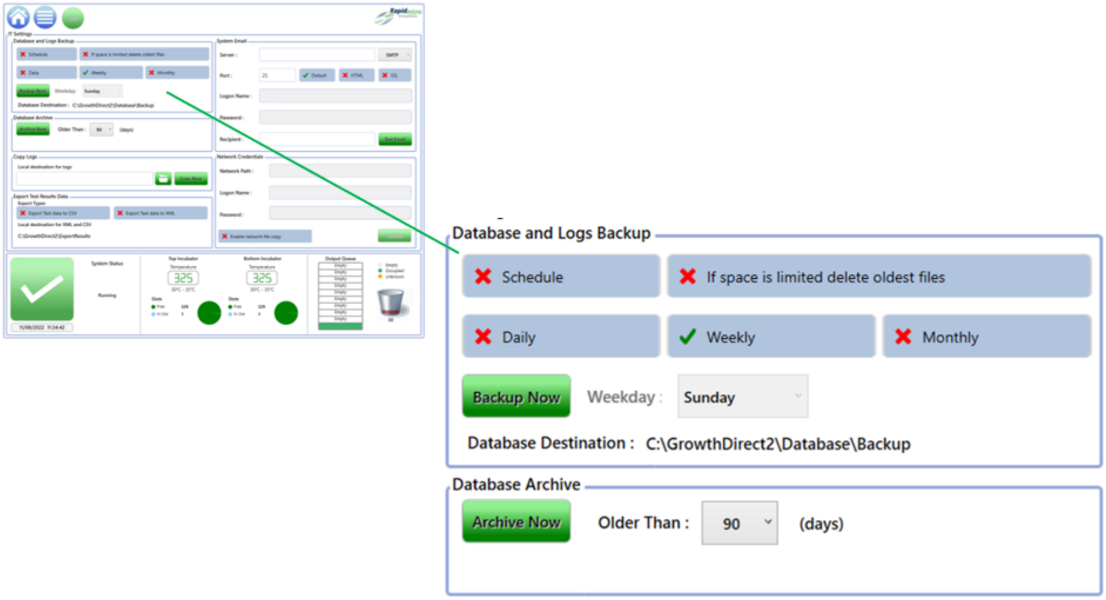

Figure 9-17: Database Backup Settings

2. Use the following to set up backups for your system:

   Database Backup Schedule – select to activate the following functions:

   - **If space is limited delete oldest files:** tells the system to automatically delete old files once storage space has been exceeded. Select to toggle ON (green check) and OFF (red X).
   - **Daily, Weekly, or Monthly:** tells the system how often backups should be made; i.e., on a daily, weekly, or monthly basis. Select the appropriate field to activate it.
   - If Daily was selected, then a backup is performed each day of the week.
   - If Weekly was selected, then an options field appears with a drop-down list of days of the week from which to choose.
   - If Monthly was selected, then two option fields appear with two drop-down menus, one for designating the day and the other how frequently on a monthly basis to perform a backup. For example, entering 1 for the Day field indicates that the backup occurs on the first day of the month. A 1 in the Month(s) field indicates that the backup occurs every month. A 2 indicates every two months, etc.

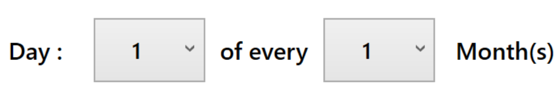

Figure 9-18: Day Dropdown

   Backup Now – select to initiate an immediate backup.

   - Selecting the **Backup Now** button brings up a **Signature Prompt** page.

- You must have permissions to perform this function (see Section 2, Setting Up the Growth Direct® System).
- Enter user name and password at the Signature Prompt and select OK.
- To void your entries, select the **Cancel** button.

Archive Now – select to have the system immediately archive files that are older than the number of days designated in the **Older Than** Field.

- Select the **Older Than** Field to get a drop-down list of options: 30, 60, 90, 180, or 365 days.
- Selecting the **Archive Now** button brings up a **Signature** page.
- Enter user name and password at the Signature prompt and select OK to initiate your entries.
- To void your entries, select the **Cancel** button.

9.4 Cleaning the Growth Direct® Surfaces

Clean user-contact surfaces of the system such as the cassette carousels, shelf, door handle, mouse, keyboard, and monitor at least once every week, and clean all other exterior surfaces at least quarterly. Clean surfaces more frequently if your site's protocol requires.

Clean the LCD monitor surface with a dry lint-free, nonabrasive cloth. Do not use any cleaning solution or glass cleaners on the monitor.

Apply cleaning agents to a cloth first and then wipe the surface clean. Do not spray or soak cleaning agent on any paint surface as this may cause damage to the paint.

Caution! Never clean the inside of the imager optics module. To clean inside the incubators, use standard laboratory practice. Use caution when handling or cleaning the incubator hotel racks. Contact Rapid Micro Biosystems Technical Services for more information.

9.5 Preventive Service

Preventive service is scheduled at 6-month intervals. To ensure optimum system performance, Rapid Micro Biosystems personnel do the following tasks during preventive service and maintenance:

- Calibrate various internal mechanisms and check for wear.
- Check cassette alignment and adjust if necessary.
- Check temperature ranges for various components.
- Clean incubators.

Servicing the system takes 1 to 2 days, but the system cannot contain any samples when it is being serviced. This means that you cannot use the system for up to 2-3 days prior to a service visit. Contact Rapid Micro Biosystems to schedule service.

Caution! Any service to the system must be performed by trained Rapid Micro Biosystems personnel. If anyone else services the system, all warranties are voided.

9.6 System Maintenance

Warning! Entering the system maintenance page stops all imaging.

Prior to pausing the system ensure any running cassettes will not be imaged during the time spent in the **Maintenance Options** page. Cassette Imaging Times are located in the **Next image** column on the **Home** page.

Access to the **Maintenance Options** page is on a limited basis and should be done in consultation with Rapid Micro Biosystems Technical Services. The remainder of the section provides the procedure for safely removing cassettes from the system in the event of an emergency.

1. From the **Home** page, click **Menu** .
2. From the **Menu Options** page, click **Maintenance Options**.
3. Click **OK** for the Caution message box **Entering the Maintenance page will pause system operation**.
4. A signature box appears.
5. Type the username and password, then click OK.
6. You will see these options:
    - Unlock Carousel – Unlocks loading carousel sash located on the IOQ.
    - Unlock Output Queue – Unlocks Output door located on the IOQ.
    - Unlock I/O Queue Door – Unlocks the I/O Queue door.
    - Unlock Imager – Unlocks the imager door. This door also has an additional physical key lock that will need to be unlocked also

Caution! For the remaining options, all doors must be closed for the operations to function.

- Home All Robotics – Returns all robotic subsystems to their home position.
- Clear Fatal State – Clears the Fatal Error message on the GUI.

- Cassettes to incubators – Returns all cassettes to their proper incubator locations.

Caution! It is important to HOME ALL ROBOTS before you leave the Maintenance Options page.

- Clear Contact Service – Clears the contact service warning.
- Remote Desktop – enables Remote Desktop sharing.

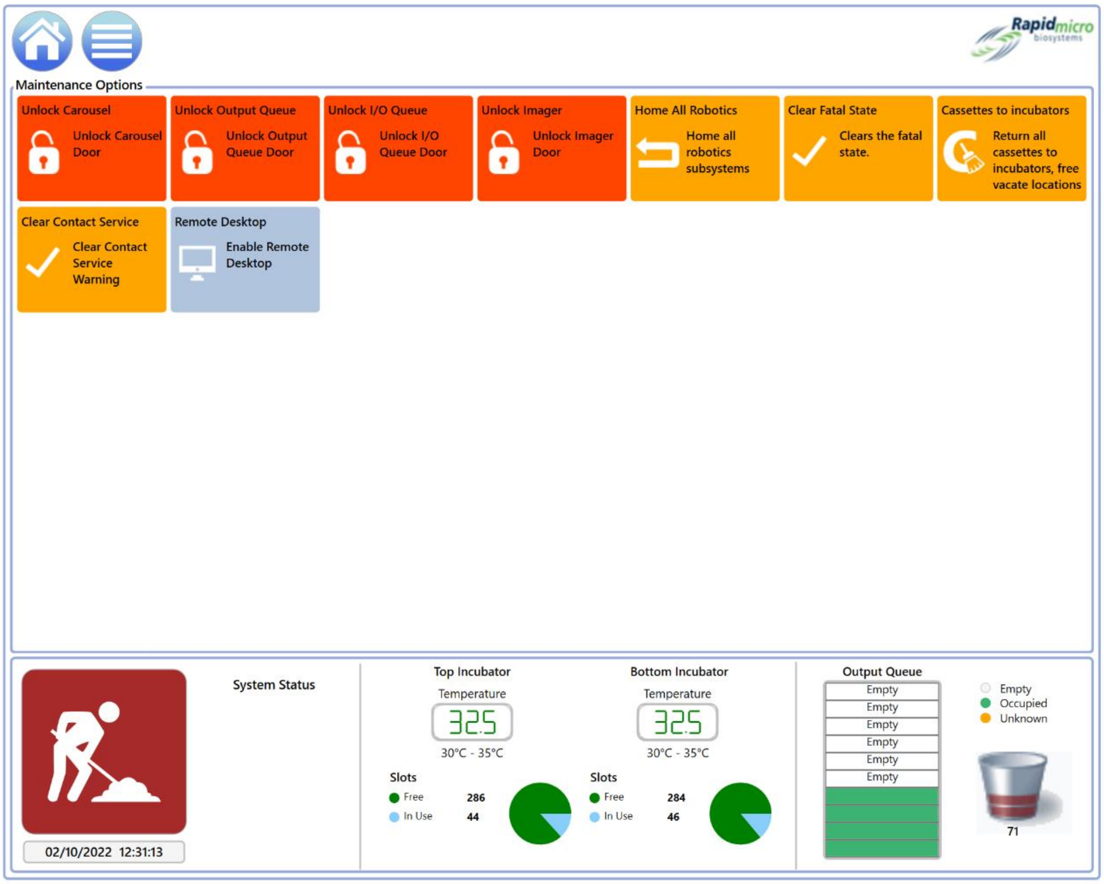

Figure 9-19: Maintenance Options Page

10. Troubleshooting

This section contains:

Warning! Any service or repairs to the system must be performed only by trained Rapid Micro Biosystems personnel. If anyone else services the system, all warranties are voided.

10.1 Pre-Troubleshooting

Caution! Opening the Maintenance Options Window or Service Window will pause any imaging and processing currently taking place in the Growth Direct® instrument. It is recommended that the instrument be allowed to idle before opening either of these windows.

When leaving these windows, the device's robotics MUST be re-homed per the **Home All Robotics** button on the **Maintenance Options** page.

Access to these pages is on a limited basis and should be done in consultation with Rapid Micro Biosystems Technical Services.

A Remote Monitoring System is available to help troubleshoot. See Section 2.6.8, Remote Monitoring System Options.

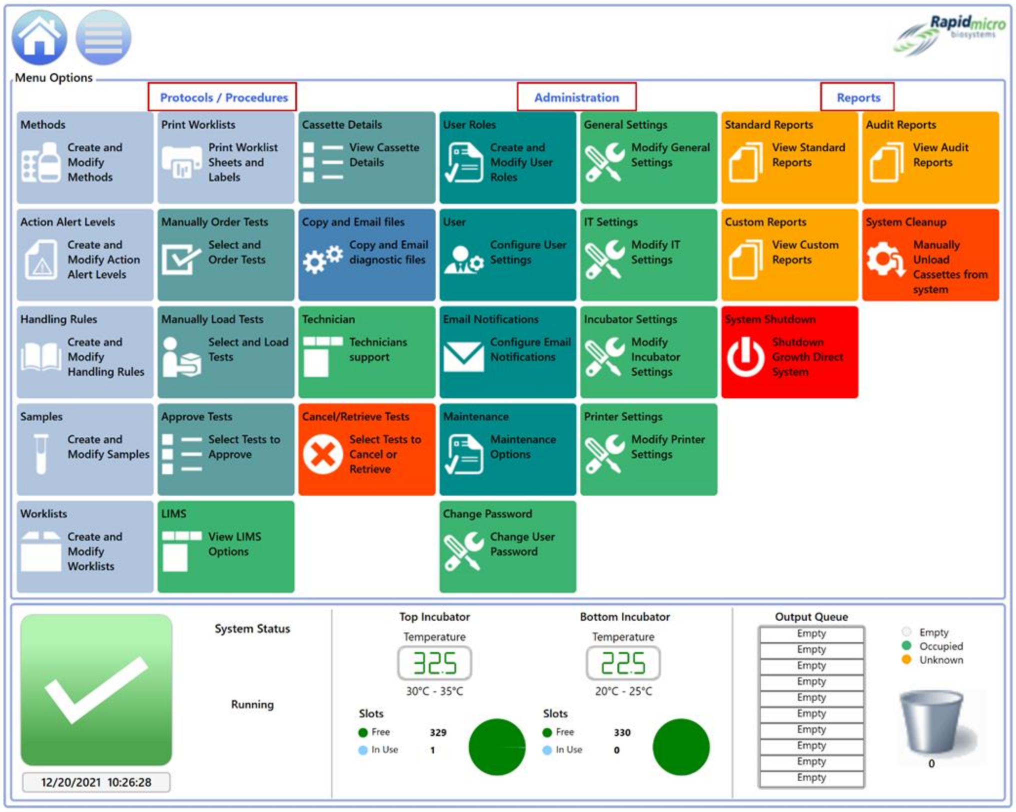

Figure 10-1: Pre-Troubleshooting

10.2 System Shut Down

Note: These instructions support systems compliant with IEC61010 Version 3. Previously released Growth Direct® systems have power shutdown steps documented in their user guides.

Before shutting down the system, contact Rapid Micro Biosystems support to make sure that shutting down is absolutely necessary. If you need to remove cassettes, see Section 3.12 Selecting Tests to Cancel or Retrieve.

Caution! Rapid Micro Biosystems recommends that you do not turn off the system power switch if the system loses power or for any reason if cassettes are in the system; doing so could affect sample integrity. If the system loses power, it shuts down automatically and restarts automatically when power is restored.

If you need to manually shut down the system, follow the steps below. Steps 1-3 shut down the software, the computer, and the monitor. Steps 4–6 remove power from the system.

1. Click **Menu Options** at the top of the page.

2. Click **System Shutdown**. A **Signature** dialog opens asking you to confirm. Enter your username and password and click **OK** to continue saving or click **Cancel**.
3. Unlock the panel on the bottom right by inserting the panel key into the lock and turning the key clockwise.

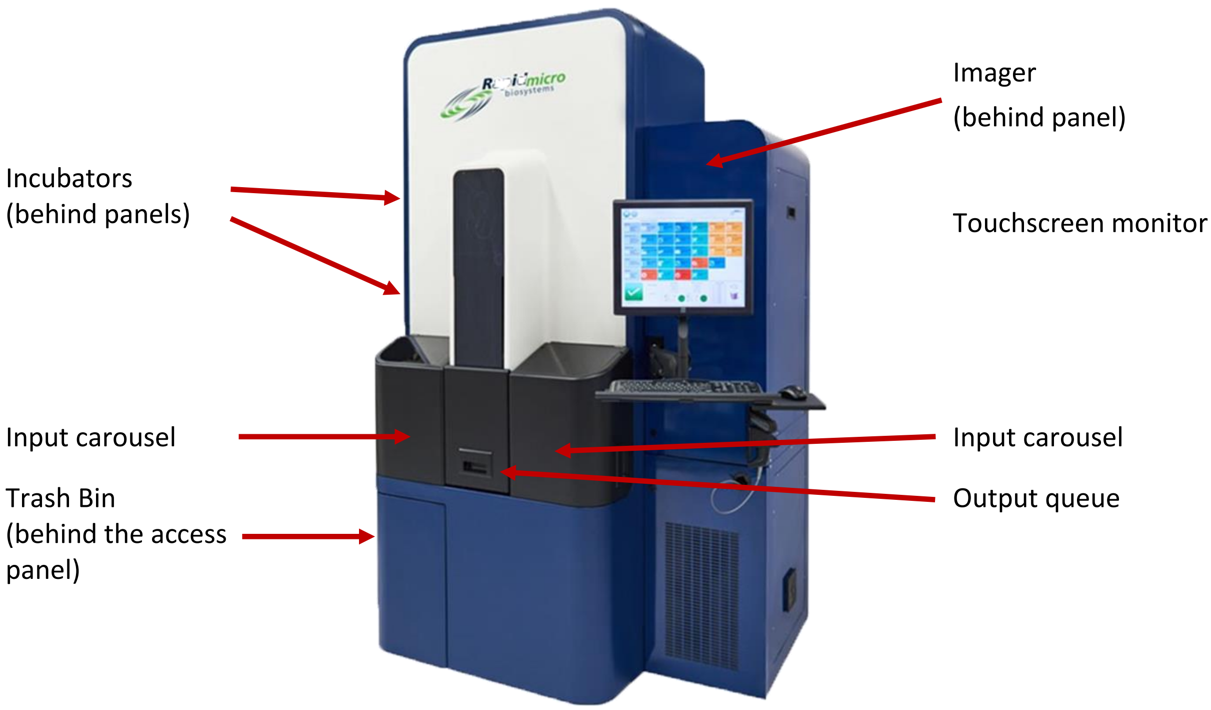

Figure 10-2: Door Panel Key and Lock

Opening the blue panel reveals the circuit panel, which is shown in Figure 10-3.

4. Press the power button, which is located on the UPS in the upper left.
5. Flip the Main and Power Shutoff breaker switches to their **OFF** positions; these switches are located on the lower right.

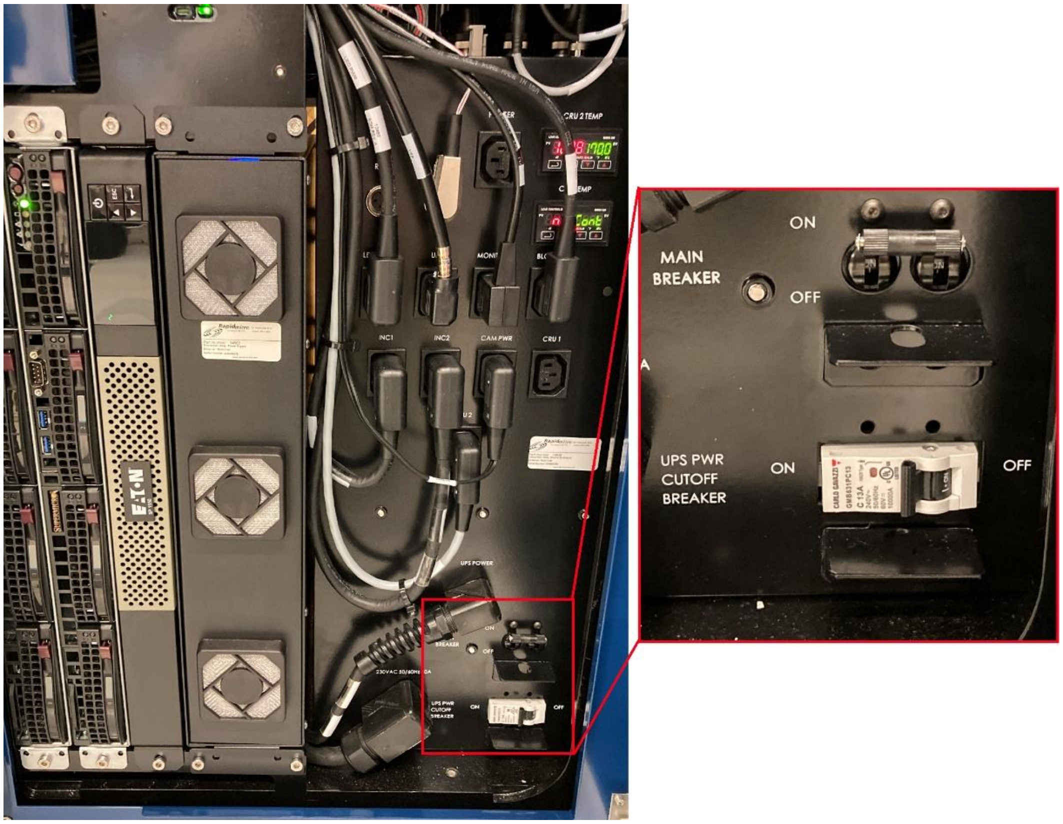

Figure 10-3: Circuit Panel

6. Close and relock the panel.
7. To start up the system, see Section 1.5, Starting the Growth Direct® System.

10.3 Emergency System Shutdown

Caution! Perform an Emergency System Shutdown *only* if there is an immediate danger, NOT as the standard shutdown procedure. See Section 10.2, System Shut Down, for instructions on standard system shutdown.

Note: These instructions support systems compliant with IEC61010 Version 3. Previously released Growth Direct® systems have power shutdown steps documented in their user guides.

In the event of an emergency, you can rapidly shutdown the system using the Power Shutdown breakers located behind the Quick Power Shutdown Access Panel indicated in Figure 10-4.

Figure 10-4: Growth Direct Quick Power Shutdown Access Panel

To perform an emergency system shutdown:

1. Open the Quick Power Shutdown Access Panel.
2. Reach in and toggle the two circuit breakers to their OFF positions as indicated in Figure 10-4.
3. To start up the system, see Section 1.5, Starting the Growth Direct® System.

10.4 Copying and Emailing Diagnostic Files

To access the **Copy and Email Files** page, click **Copy and Email Diagnostic Files** on the **Menu Options** page. This page allows you to send the system application log files to valid email addresses with the option to save these files to a storage location. The page also allows you to save the vision log application files and the vision image files to a storage location.

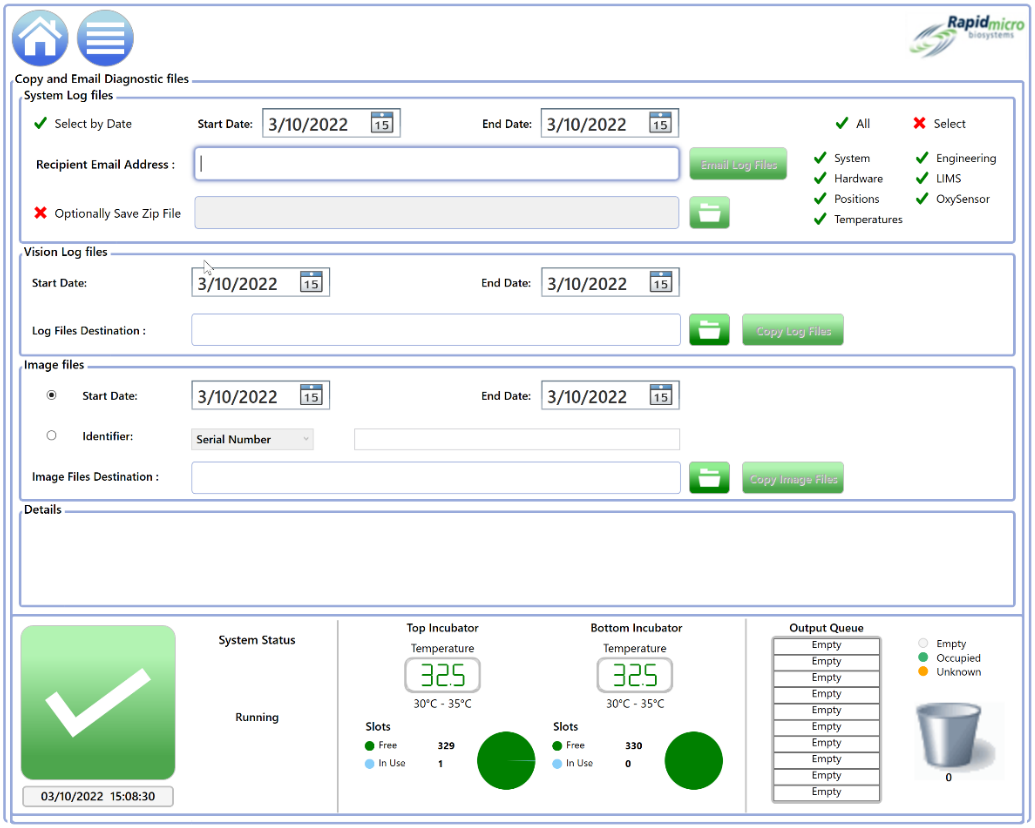

Figure 10-5: Copy and Email Diagnostic Files Page

System Log Files

1. **Start Date - End Date:** Enter a range of dates in the **Start Date** and **End Date** fields.
2. **Recipient Email Address:** Enter valid email addresses to send the files to.
3. Click the **Email Log Files** button to send files.
4. **Optionally Save Zip file:** Select this option to save the system log files to a storage location.

Vision Log Files

1. **Start Date - End Date:** Enter a range of dates in the **Start Date** and **End Date** fields.
2. **Log Files Destination:** Click **Browse**, select the desired storage location, and click **OK**. After clicking OK, click **Copy Log Files**.

Note: You cannot email the vision files because they are too large.

Image Files

1. You can specify image files by date or Identifier. Choose one of the radio buttons.

2. For **Start Date - End Date**, enter a range of dates in the **Start Date** and **End Date** fields. Skip this step if you are specifying an identifier.

3. For **Identifier**, select an Identifier from the dropdown: Serial Number, SampleID/Batch, or LIMS ID.

4. **Image Files Destination:** Click **Browse,** select the desired storage location, and click **OK**. After clicking OK, click **copy image files**.

10.5 Screen Capture

To capture the screen as an image file, press Ctrl+Shift+S. The system displays a file browser dialog box.

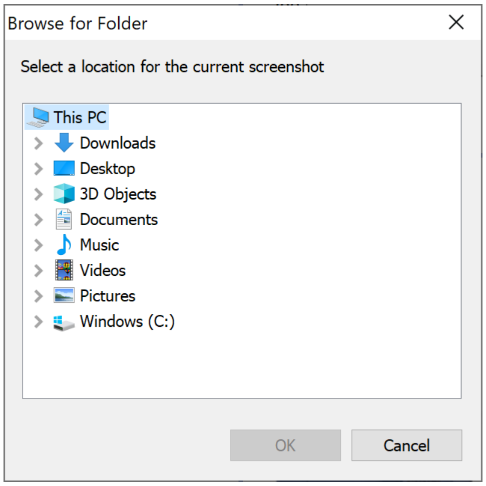

Figure 10-6: File Browser Dialog

Navigate to the location where you want to save the image and click **OK**. The system saves the image in the folder you specify in the following format:

YYYY-DD-MM_<unique-number>_ScreenShot.jpg

Appendix A General System Specifications and Requirements

The following table lists the general system specifications and requirements:

Table A-1: General System Specifications and Requirements

Specification	Detail
General	The system must be installed on a solid, level surface.
Part Number	E700-GD2EM System B700-GD2Multi-test System
Power Requirements	Voltage: 200-240 VAC Single Phase Hertz 50/60 Current: Minimum 15 amps Uninterruptible Power Supply (UPS): UPS system allowing enough power to return all cassettes to incubation and finish imaging
Regulatory Conformance	The Growth Direct® System is designed to meet the following standards: • IEC 60204 Safety of Machinery-Electrical Equipment of Machines Part 1, General Requirements • IEC 61010-2-010: 2003 (2nd Ed) for use with IEC 61010-1: 2001 • IEC 61010-2-081: 2001 (1st Edition) + A1:2003 in conjunction with IEC 61010-1:2001 (2nd edition)

Specification	Detail
Low Voltage Directive 2006/95/EC	• UL 61010-1:2004 Ed.2 +R:28Oct2008 Safety Requirements for Electrical Equipment for Measurement, Control, And Laboratory Use - Part 1: General Requirements • CSA C22.2#61010-1:2004 Ed.2 +G1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements (R2009) • IEC 61010-2-010:2003 Ed.2 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-010: Particular Requirements for Laboratory Equipment for The Heating of Materials • IEC 61010-2-081:2001 Ed.1 +A1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-081: Particular Requirements for Automatic and Semiautomatic Laboratory Equipment for Analysis And Other Purposes • IEC 61010-2-101:2002 Ed.1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements For In Vitro Diagnostic (Ivd) Medical Equipment • IEC 61010-2-101: 2002 (ed.1) used in conjunction with IEC 61010-1: 2001 (ed.2) • IEC 61010-1:2001 (Second Edition)
Electromagnetic Compatibility Directive 2004/108/EC	CENELEC EN 61326-1:2013 CENELEC EN 61326-2-6:2013
Maximum System Noise	65 dB measured 3 feet from all instrument sides
Operating Environment	Ambient temperature: 15-28°C (59-82° F) Altitude: Up to 2,440 meters (7,350 feet) above sea level
Storage and Shipping Environment	Temperature: -18°C to 60°C (0-140°F) Humidity: up to 90% non-condensing
Instrument Dimensions	Depth: 14.5 m (57 in) Width: 1.02 m (40 in) Height: 2.41 m (95 in)
Weight, approximately	1187 kg (2,616 lbs.) Empty 1212 kg (2,672 lbs.) Full
Incubators	Temperature: 20-45°C ±1.5°C Ambient Temperature Operation: 15°C-28°C (64-82°F)
Compressed Air Supply	6-10 bar (87-145 psi) 283 liters/min (10CFM) Air quality: ISO8573-1:2010 7:4:4

Appendix B Ordering Products

Call 888-RAPID07 (888.727.4307) to order the following products from Rapid Micro Biosystems. Or email orders@rapidmicrobio.com.

Table B-1: Bioburden Components

Item Number	Description
BTSA-048	Bioburden Cassettes, case of 48 cassettes. (Tryptic Soy Agar)
BR2A-048	Bioburden Cassettes, case of 48 cassettes. (R2A Agar)
BSDA-048	Bioburden Cassettes, case of 48 cassettes. (Sabouraud Dextrose Agar)
B150-048	Bioburden Filtration Funnel kits, case of 48 (150ml)
B250-048	Bioburden Filtration Funnel kits, case of 48 (250ml)
BBVL-048	Bioburden Vision Lids, case of 48
BCVR1-048	B150 Bioburden Filtration Funnel Covers, case of 48

Table B-2: Environmental Monitoring Components

Item Number	Description
ET80-100	EM Cassettes, case of 100 cassettes (TSA with L&P80)
ET80HT-100	EM Cassettes, case of 100, (TSA L&P80 with Histidine & Thiosulphate)
EMVL-100	EM Vision Lids, case of 100

Table B-3: Additional Components, Instrument Add-ons

Item Number	Description
GC60-GD2	Growth Direct® carousel (holds 60 EM/Bioburden cassettes)
GBCP-RIB	Ink Roll for Label Printer 1 roll
GBCL-GD2	Barcode label kits (2,500/roll)
GBCL-GDS	Gamma sterilized barcode labels (2,500/roll)

Table B-4: Additional Components, EM Add-ons

Item Number	Description
EMMA-001	MAS-100NT Air Monitoring Device Conversion Kit. Height 270 mm QTY 1
EMMA-002	MAS-100 VF. Air Monitoring Device Conversion Kit. Height 179 mm QTY 1
EMSA-001	SAS Conversion QTY 1 - Air Monitor Conversion Kit
EMAI-001	Air Ideal conversion kit QTY 1
Head-SAS	Stainless Steel replacement head for SAS air monitor QTY 1

Table B-5: Additional Components, Bioburden Add-ons

Item Number	Description
BFIL-003	Filtration Manifold only for 3-Place
BFIL-006	Filtration Manifold only for 6-Place
1ZU-0003	Single Stainless Steel Threaded tulip for filtration manifold

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