# Illumina Run Manager for NextSeq 550Dx

## Software Guide


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FOR IN VITRO DIAGNOSTIC USE.

# Revision History

| Document | Date | Description of Change |
| --- | --- | --- |
| 200025239 v00 | March 2023 | Initial release. |

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# Illumina Run Manager Overview

Illumina Run Manager™ software is a server-based solution for setting up a run, setting up sequencing data analysis, monitoring status, and viewing results. Illumina Run Manager is compatible with NextSeq 550Dx in Dx mode only and requires an Illumina DRAGEN Server for NextSeq 550Dx.

| Feature | Illumina Run Manager | Local Run Manager |
|---|---|---|
| Software installation location | On-server | On-instrument |
| Integrates with the instrument control software | Yes | Yes |
| Sets up a run and data analysis according to the selected analysis application | Yes | Yes |
| Shows analysis metrics upon completion of analysis | Yes | Yes |
| Allows sequencing run while secondary analysis from an earlier run is in progress | Yes | No |
| Enables DRAGEN secondary analysis | Yes | No |
| Enables a Requeue Analysis while a sequencing run is in progress | Yes | No |

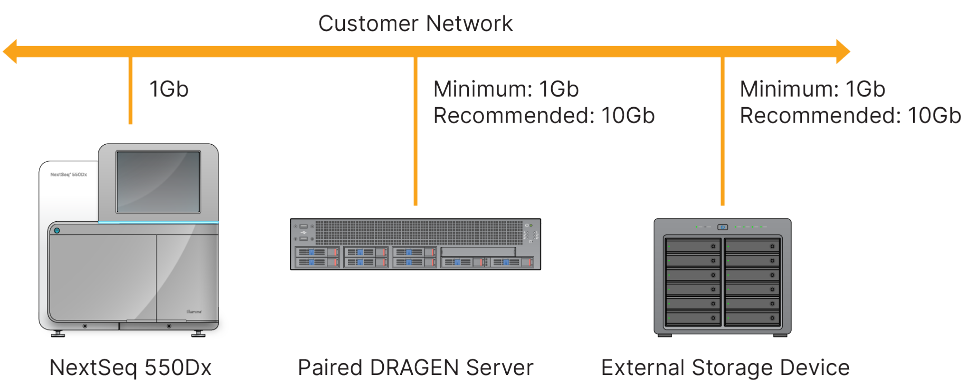
NOTE The system provides the ability to switch between Illumina Run Manager and Local Run Manager when the instrument is paired with a Illumina DRAGEN Server for NextSeq 550Dx. Results are only accessible using the same run manager used when planning the run. This guide includes instructions for the Illumina Run Manager. For information on using Local Run Manager, refer to the NextSeq 550Dx Instrument Reference Guide (document # 1000000009513).

# DRAGEN Server Setup

Installation of the Illumina Run Manager for NextSeq 550Dx is performed by Illumina support personnel. Refer to Illumina DRAGEN Server for NextSeq Site Prep and Installation Guide (document # 200025560) for more information.

The Illumina Run Manager software is installed on the DRAGEN Server. The DRAGEN Server is connected to the NextSeq 550Dx Instrument through the local network using unique IP addresses for the DRAGEN Server and NextSeq 550Dx Instrrument. The minimum network connection required between the NextSeq 550Dx, DRAGEN Server, and external storage is 1 Gb. A 10 Gb connection for the DRAGEN Server and external storage is recommended for faster data transfer times.

Figure 1 NextSeq 550Dx with DRAGEN Server Networking




For more information on networking and pairing, refer to *DRAGEN Server Information* on page 16.

# Software Overview

When you log in to the Illumina Run Manager, the software interface opens. From the software interface, you can perform the following tasks:

- Plan runs
- Sort and filter runs
- View sequencing and analysis status
- Stop or requeue analysis
- Manage run output folder

## Viewing Illumina Run Manager

You can view the Illumina Run Manager interface on a paired sequencing instrument or through a web browser. To view the interface, select one of the following options:

- **Open the Illumina Run Manager interface**—on the instrument monitor home screen by selecting Illumina Run Manager.

- **On a networked computer**—connect to the server by entering the DRAGEN Server name assigned during installation into the web browser url. Refer to *Server Requirements* on page 16 for more information.

## Main Menu

The main menu is located on the left side of the user interface. The main menu contains icons that provide access to the following screens:

- **Runs**—View planned, active, and completed runs. Runs are visible to all users.
- **Applications**—View installed applications. Applications settings are configurable by Administrators via the browser.

# Analysis Applications

The Illumina Run Manager supports a menu of applications to perform data analysis. Each application has a specific set of procedures appropriate for the application and library type. For a description of each analysis application, refer to the Illumina Run Manager support page on the Illumina® Support Center website.

The Illumina Run Manager software does not include any preinstalled analysis applications. Each Dx analysis application is downloaded and installed on your system by Illumina Support Personnel. For more information on installing an analysis application, please contact *Technical Assistance* on page 19.

## Applications Screen Overview

The Applications screen allows Administrators to configure settings for installed applications and assign applications to users. To view the Applications screen, select the **Application** icon on the left side of the main screen, and then select the desired application. The exact fields displayed on the Configuration screen vary depending on the application but may include the following:

- **Application name**
- **Application version**
- **DRAGEN version**
- **Library prep kits**—Select default library prep kits to be used with the application.
- **Index adapter kits**—Select default index adapter kits to be used with the application.
- **Read type**—Select a default read type.
- **Read lengths**—Select default read lengths.
- **Reference genome**—Upload and select a reference genome to be used with the application.
- **Output file formats**—Select the preferred output file formats.

# Workflow Overview

The following steps show an overview of the workflow for creating a run and viewing analysis results in Illumina Run Manager. Specific steps vary for each analysis application. Refer to the application workflow guide for the analysis application that you are using for step-by-step instructions.

| | |
|---|---|
| **Create Run**<br>↓ | Using the Illumina Run Manager interface, set run and analysis parameters based on the chosen Application. |
| **Sequence**<br>↓ | Using the instrument control software, select the run that you set up in Illumina Run Manager, load sequencing consumables, and start the sequencing run. |
| **Analyze**<br>↓ | Analysis begins automatically when sequencing is complete. Illumina Run Manager uses the specified analysis application and performs data analysis according to the parameters specified for the run. |
| **View Results** | From the Illumina Run Manager interface, select a completed run to view the results screen. |

# Runs

The Runs screen displays sequencing runs organized by Planned, Active, and Completed. Each tab includes the number of runs for each grouping shown in parenthesis. Use the navigation arrows at the bottom of the list to view more runs. You can use the search feature to find runs by run name, library tube ID, or application name. Each run includes the following information:

- **Status**—Lists the status of the run and includes a progress status bar.
- **Run Name**—Lists the assigned run name and links to the run results pages.
- **Application**—Lists the analysis application assigned to the run.
- **Owner**—Lists the run creator.
- **Date Modified**—Lists the date and time that a run or analysis session was last modified. By default, the Active Runs screen is sorted by this column.

To sort the run list, select a column heading to list in ascending or descending order.

## Planned Runs

Runs planned on the Illumina Run Manager are displayed in the Planned tab of the Runs screen. Each run on the Planned tab includes the following information:

- **Status**—Displays the state of the run.
- **Run Name**—Displays the assigned run name and links to the Run Details screen.
- **Application**—Displays the analysis application assigned to the run. An IVD label is included if the application is an IVD assay.
- **Owner**—Displays the run creator.
- **Date Modified**—Displays the date and time that a run or analysis session was last modified. By default, the Planned tab is sorted by Date Created.
- **Actions**—Displays a trashcan used to delete the run.

Planned runs can exist in one of following states:

- **Planned**—Run has been created and is available to begin sequencing
- **Needs Attention**—There are issues with the run that require user intervention. Select the run to either edit the run or dismiss the error to change status to Planned.
- **Locked**—In the case that there is an issue with the instrument, it automatically locks the run. To unlock a run, select the run and then select **Unlock**.

NOTE Sequencing Runs planned with Local Run Manager are not visible using the Illumina Run Manager software. For information about how to change the Run Manager, refer to the *Set Run Manager Software* on page 17.

There are two different ways to create a new planned run:

- **Import Run**—Upload a prepared Sample Sheet file (samplesheet.csv)
- **Create Run**—Manually enter run parameters

Runs planned on applications are displayed in the Planned tab of the Runs screen.

## Import Run

Use the following steps to import run using a Illumina Sample Sheet v2 (`samplesheet.csv`).

NOTE A unique run name and file name is required.

1. From the Planned Runs tab, select **Import Run**.
2. Select the sample sheet file (*.csv).
3. Select **Open**.

## Create Run

Use the following steps to create a run by manually entering the run parameters using Illumina Run Manager. Create runs on the instrument or by accessing Illumina Run Manager on a networked computer.

NOTE The exact information required by each analysis application differs. Refer to the Application Workflow Guide for run information specific to the application.

1. From the Planned tab of the Runs screen, select **Create Run**.
2. Select an application, and then select **Next**.
3. Proceed through the settings screens. Depending on your application, the screens displayed can include the following information:
   - **Run Settings**—Enter run parameters.
   - **Sample Data**—Enter sample data manually or by importing a CSV file containing sample information. Sample names must be unique.
   - **Analysis Settings**—Enter settings for analysis.
4. On the Run Review screen, review run information and select **Save**.
   The run is added to the top of the runs list on the Planned tab.

### Edit a Planned Run

1. From the Planned tab of the Runs screen, select the run name. A summary of the planned run displays.
2. Select **Edit**.
3. Edit parameters as needed.
4. When finished, select **Save**.
   The Last Modified date for the run is updated on the Planned Runs screen.

### Delete a Planned Run

There are two ways to delete a run. To delete a planned run, do one of the following:

- From the Planned tab on the Runs screen, locate the run and select the trashcan from the Actions column. The planned run is deleted.
- From the Planned tab on the Runs screen, select the run to open the Run Details screen, and then click Delete.

## Active Runs

The Active tab of the Runs screen lists in progress runs that have not completed all sequencing and analysis steps. Select an active run to display more details about the status or cancel analysis. Runs with errors that have prevented them from completing are also displayed in the Active tab. Select the run to view error messages. Each run on the Active tab includes the following information:

- **Run**—Displays the run name and links to the Run Details screen. The analysis application assigned to the run is also displayed.
- **Started**—Displays the date and time that the run began.
- **Status**—Displays the state of the run.
- **Actions**—Option to Cancel Analysis.

| Icon | Description |
|---|---|
| | Not started |
| | Queued to process, but not started |
| | In Progress |
| | Complete |
| | Issue |

Four icons from left to right indicate the following steps in the workflow:

- Sequencing run
- Sequencing file transfer for analysis
- Analysis in progress or complete
- Analysis file transfer to external storage

After analysis output file transfer completes, the run is visible under the Completed Runs tab.

For additional information about each status, use the arrow icon next to the run name to expand the view. The started and completed date and time are provided for each step in the workflow.

### Cancel Analysis

You can cancel analysis for runs that are queued for analysis or being analyzed. To cancel analysis, do the following:

1. From the Active tab of the Runs screen, locate the run analysis you want to cancel and select **Cancel Analysis**. Alternately, you can cancel analysis from the Run Details screen by selecting **Cancel Analysis** in the lower right corner of the Run Details screen.
2. When prompted to confirm, select **Yes**. The run analysis is canceled.

Canceled runs show as ***Analysis failed*** in Completed Runs tab and ***Analysis failed - canceled by user*** in the Run Details screen.

## Completed Runs

The Completed tab of the Runs screen lists runs that finished all sequencing and analysis. Each run on the Completed tab includes the following information:

- **Status**—Displays the state of the run.
- **Run Name**—Displays the run name and links to the Run Details screen.
- **Application**—Displays the analysis application assigned to the run. An IVD label is included if the application is an IVD assay.
- **%Q30**—Displays the percentage of non-indexed reads with a quality score of 30 (Q30) or greater.
- **Total Yield**—Displays non-indexed total yield (G).
- **Date Modified—**Displays the date and time that a run or analysis session was last modified.

### Run Details

The Run Details screen lists information about the run, a summary of sequencing metrics, and the location of the run folder. To view analysis results, navigate to the Completed tab, and then select the run name.

**A summary of analysis results is displayed including the following information:**

| Section Title | Description |
|---|---|
| Run Name | The run name assigned when the run was created. |
| Run Description | The run description, if provided during run setup. |
| Application Name | The analysis application assigned to the run. |
| Application Version | The version number of the analysis application. |
| DRAGEN Version | The version number of the DRAGEN analysis software. |
| RTA Version | The version number of the Real-Time Analysis software. |
| Created by | The user that created the run. |
| Status | Displays the state of the run and status of each process. |

**Sequencing Information**

| Section Title | Description |
|---|---|
| Instrument | The name of the instrument on which the run was performed. |
| Sequenced By | The name of the user who started the run. |
| Library Prep Kit | The library prep kit used. |
| Index Adapter Kit | The type of index adapter kit used. |
| Read Type | The type of read; single end or paired end. |
| Read Length | The number of cycles for each read and index. |
| External Location | The folder location where the sequencing data was saved. |
| Non-Indexed Total Yield (G) | The number of bases sequenced for the run. |
| Non-Indexed Total % ≥ Q30 | The percentage of reads with a quality score of 30 (Q30) or greater. |

**Requeued Analysis**

When viewing a parent run, the Requeued Analysis Runs section lists the run names that were requeued. Select a run name to view the requeued analysis run details.

When viewing a requeued analysis run, the Requeued Analysis section lists the following information:

| Section Title | Description |
|---|---|
| Parent Run | The run from which the data was originally analyzed. Select the run name to view the parent run details. |
| Reanalysis Reason | The explanation provided for the requeued analysis. |

See section *Requeue Analysis* on page 10 for more information.

**Samples & Results**

The fields displayed vary depending on the application but may include the following:

| Section Title | Description |
|---|---|
| Samples | The number of samples analyzed. |
| Workflow Selection | The workflow used for analysis. |
| Analysis Output Folder | The file path to where the analysis data is saved. |

## View Sample Sheet

You can view the Sample Sheet from the Run Details screen.

1. From the lower left of the Run Details screen, select **Sample Sheet**.
   The Sample Sheet displays.

## Requeue Analysis

You might requeue analysis if analysis was stopped, if analysis was unsuccessful, or if you want to reanalyze a run with different settings. Requeue analysis is a feature located on the Run Details screen but may not be available for certain applications. For more information, refer to the application software guide.

# Administrative Settings and Tasks

The following settings and tasks are available from the Settings menu in the upper left corner of the Illumina Run Manager software:

| Tool | Description | Role Permission |
|---|---|---|
| User Management | Add users, edit users, assign permissions, and set passwords. | Admin |
| Password Policy | Configure password setting. | Admin |
| External Storage for Analysis Results | Configure external storage drive. | Admin |
| Audit Log | Monitor access frequency, user access, user profile changes, and changes to system, run, or analysis parameters. | Admin |
| DRAGEN | Display and sets DRAGEN license information and run a self-test for the server. | Admin |
| Custom Kits | Add custom library prep and index adapter kits. | Admin |
| About | Display Illumina Run Manager information. | Admin, Operator |
| Reboot System | Restart the Server. | Admin |
| Shut Down System | Shut down the Server. | Admin |
| Power Cycle | Power cycle the Server. | Admin |

## User Management

User accounts are listed on the User Management screen. The User Management screen includes the Username, Last Name, First Name, Status, and Actions for each account. The Actions column allows for removal of the user by selecting the trashcan icon.

Admins can manage the role and associated permissions within the details of each account. The two possible roles are:

- **Administrators**—Admin roles have full permissions, by default.
- **Sequencer Operators**—Operator roles are configurable based on a subset of possible permissions. All users can create and edit runs regardless of permission settings.

Only an admin can view the User Management screen.

## User Roles

By default, new user accounts are assigned the role of user. Administrator and operator roles provide additional permissions.

Table 1 User Permissions

| Permissions | Administrator | Operator |
|---|---|---|
| Grant access to administrator functions | X | |
| Configure app settings and permissions | X | |
| Pair instrument and server | X | |
| Upload Site Certificate | X | |
| Initiate wash | X | X |
| Set up and start sequencing runs | X | X |
| View ongoing sequencing runs | X | X |
| Exit and minimize app | X | |
| Access Process Management screen | X | X |
| Access instrument settings | X | |
| Turn off instrument | X | X |
| Change forgotten passwords | X | |
| View instrument audit log | X | |

## Create a New User

1. Select the Settings menu at the upper left of the software interface, and then select **User Management**.
2. From the User Management screen, select **Add User**.
3. In the Add User dialog box, enter a user name and the first and last name of the new user.
   User names must be unique and cannot be reused or changed.
4. Select the **User Enabled** checkbox.
5. In the Password field, enter a temporary password.
   Temporary passwords are not stored in the password history and can be reused.
6. In the Confirm Password field, reenter the temporary password.
7. To select a role, select **Administrator** or **Sequencer Operators**.
8. Select the application access for the new user.
9. Select **Save**.

## Reset a User Password

1. From the Settings menu at the upper left of the software interface, select **User Management**.
2. From the Username column, select the name of the user.
3. In the Password field, enter a temporary password.
   Temporary passwords are not stored in the password history and can be reused. Passwords have the following requirements:
   - between 8 and 64 characters
   - at least one uppercase character
   - at least one lowercase character
   - at least one digit
   - at least one symbol
   - not one of the last five passwords
4. In the Confirm Password field, reenter the temporary password.
5. Select **Save**.

## User Passwords

Illumina Run Manager is a separate independent software and requires its own credentials. You can reset your existing password at any time. You must know your current password to change your password. If you forget your password, an admin can assign a temporary password.

NOTE Use these instructions to change your own password. If you have an admin account, refer to *Reset a User Password* on page 13 to change passwords for other user accounts.

To reset a password, do as follows.

1. Select the person icon in the upper right of the dashboard, and then select **Change Password**.
2. In the Old Password field, enter your current password.
3. In the New Password field, enter a new password.
4. In the Confirm New Password field, reenter your new password.
5. Select **Save**.

## Deactivate a User

1. Select the Settings menu at the upper left of the software interface, and then select **User Management**.
2. From the Username column, select the name of the user.
3. Deselect the **User Enabled** checkbox.
4. Select **Save**.

### Unlock User

1. Select the Settings menu at the upper left of the software interface, and then select **User Management**.
2. From the Username column, select the name of the user.
3. Select the **User Enabled** checkbox.
4. In the Password field, enter a temporary password.
   Temporary passwords are not stored in the password history and can be reused.
5. In the Confirm Password field, reenter the temporary password.
6. Select **Save**.

### Change User Permissions

1. Select the Settings menu at the upper left of the software interface, and then select **User Management**.
2. From the Username column, select the name of the user.
3. Select **Admin** or **Sequencer Operators**.
4. Select which application you want the user to access.
5. Select **Save**.

## Password Policy

You can configure how many days before passwords expire, the number of invalid sign-in attempts before locking the user account, and how many minutes of inactivity before the software automatically signs out the user.

1. Select the Settings menu at the upper left of the software interface, and then select **Password Policy**.
2. Enter a number between one and 180 for the number of days until passwords expire.
3. Enter five, ten, or twenty invalid sign-in attempts.
4. Enter a number between one and 60 minutes a user can be inactive before automatic sign-out.

## External Storage for Analysis Results

You can store run data in an External Storage Location. Setting the External Storage for Analysis Results folder path is done during initial setup. It may be necessary to change the path when requeuing analysis. To set the folder path, do as follows.

1. From the software interface, select the Settings menu at the upper left, select **External Storage for Analysis Results**.
2. For **Server Location**, enter the full path to the output folder.

Follow Universal Naming Conventions (UNC). The UNC path includes two backslashes, the server name, and the directory name. The path does not use a letter for a mapped network drive. Do not use a path to a mapped network drive.

- Paths to the output folder that are one level require a trailing backslash. Example: `\\servername\directory1\`
- Paths to the output folder that are two or more levels do not require a trailing backslash. Example: `\\servername\directory1\directory2`

3. Enter the **Domain** name if needed.
4. Enter the security credentials for the folder location. User name and password are required.
5. Select **Encryption** if the data requires encryption during file transfers.
6. Select **Test Configuration** to make sure that the Server is properly connected to the network location.
7. Select **Save**.

# Audit Log

Audit logs record information about specific actions, such as user access, user profile changes, and changes to system, run, or analysis parameters. Each audit log entry includes the following information:

- **When**—The date and time the action was performed in YYYY-MM-DD and 24-hour time format.
- **Who**— The user name who initiated the action.
- **Type**— The item category (User, Run, Analysis, or System).
- **What or Description**— A short predefined description of the action.

You can filter the audit logs, and then export the filtered list to a report in PDF file format. Refer to *Export Audit Log* on page 16 for more information.

NOTE Only an admin can view the Audit Log screen.

## Filter Audit Logs

You can filter the audit logs list to show specific data. You can apply filters to previously filtered results to refine the list further. To apply a filter to all audit logs, clear previous filters before proceeding. Select the Settings menu at the upper left of the software interface, and then select **Audit Log**.

To filter the audit logs, use the From/To, Who, Type, and What fields. The fields are not case-sensitive.

For example:

- **From**—Enter beginning date.
- **To**—Enter end date.

- **Who**—Enter a user name. You can enter any portion of a user name. Asterisks (*) are not required.
- **Type**—Enter a type of action. Examples: prepared reanalysis, aborted analysis, completed sequencing, etc. This search field functions as a keyword search.
- **What**—Enter any portion of the item description. Examples: user signed in, dismissed, needs attention. This search field functions as a keyword search.

## Export Audit Log

1. Select the Settings menu at the upper left of the software interface, and then select **Audit Log**.
2. **[Optional]** To filter the log, enter the information in the appropriate filter field, and then select **Filter**. Refer to *Filter Audit Logs* on page 15 for more information.
3. Select **Export Log**.
   The software generates a PDF report that includes the user name, date of export, and filter parameters.

# DRAGEN Server Information

From the Settings menu at the upper left of the software interface, select **DRAGEN** to view the following DRAGEN Server information:

- **License Valid Until**—DRAGEN Server license validity date [YYYY-MM-DD]. Some Applications require a specific DRAGEN Server license. To update the license, select **Update**, navigate to the *.zip file, and then select **Open**.
- **FPGA serial number**—The Field-Programmable Gate Array (FPGA) is the hardware used by the DRAGEN Server to provide data analysis. The serial number is for the specific FPGA used on the DRAGEN Server.
- **Current DRAGEN version**—The version number of the DRAGEN Bio-IT Processor Release. The application software installs the required DRAGEN software version for the application.
- **Self-Test Status**—Results from last DRAGEN Server Self-Test. Select **Run Self-Test** to start the test.
- **Last Update**—The date and time the Self-Test was completed [YYYY-MM-DD HH:MM:SS].
- **Available Versions**—A list of the installed DRAGEN Server software versions. If a new version is needed, contact *Technical Assistance* on page 19.

## Server Requirements

The following ports need to be open to allow network communication between the instrument and server.

| Service | Port |
|---|---|
| HTTP | 80/tcp |
| HTTPS | 443/tcp |
| NTP | 123/upd |

You must assign a domain name to the server on your domain name system (DNS). It is recommended to assign Transport Layer Security (TLS) certificates to the server domain name to ensure data encryption during transfer over the local network. If TLS certificates cannot be provided, the system uses self-generated certificates.

## Re-Pair DRAGEN Server to Instrument

An Illumina representative pairs the NextSeq 550Dx Instrument to the server during initial setup. Use the following instructions if the server becomes disconnected from the instrument.

NOTE A Illumina Run Manager (DRAGEN Server) administrator account is required to re-pair. You may also need a Local Run Manager administrator account password and a Windows admin account.

1. From the NextSeq 550Dx Home screen, select **Manage Instrument**.
2. Select **Instrument Pairing**.
3. Enter the DRAGEN Server host name or IP address, and then select **Confirm**.
4. To confirm trust in certificate, select **Confirm**.
5. Log in using a Illumina Run Manager (DRAGEN Server) admin account, and then select **Pair**.
   The software displays a confirmation indicating that the instrument is successfully paired.

## Set Run Manager Software

You can switch between Illumina Run Manager and Local Run Manager when the instrument is paired with an Illumina DRAGEN Server for NextSeq 550Dx. Results are only accessible using the same run manager used when planning the run. This guide includes instructions for the Illumina Run Manager. For information on using Local Run Manager, refer to the NextSeq 550Dx Instrument Reference Guide (document # 1000000009513). To select between Illumina Run Manager and Local Run Manager, do the following.

NOTE A Illumina Run Manager (DRAGEN Server) administrator account is required to switch between the run managers. You may also need a Local Run Manager administrator account password.

1. From the NextSeq 550Dx Instrument Home screen, select **Manage Instrument**.
2. Select **System Customization**, and then select **DRAGEN Server** or **Local Run Manager**.

3. Select **Save** to save settings.

# Add Custom Kits

Some applications may allow the use of Custom Index Adapter Kits and Custom Library Prep Kits. For more information, refer to the Application Guide that is located on the Illumina Support Site.

# Technical Assistance

For technical assistance, contact Illumina Technical Support.

| | |
|---|---|
| **Website:** | www.illumina.com |
| **Email:** | techsupport@illumina.com |

**Safety data sheets (SDSs)**—Available on the Illumina website at support.illumina.com/sds.html.

**Product documentation**—Available for download from support.illumina.com.

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