



## nCounter®

# Dx Analysis System User Manual



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***For In Vitro Diagnostic Use***

The nCounter Dx Analysis System that is the subject of this manual is for use with NanoString's Diagnostic Assays within their intended use in the EU, United States, and other applicable markets.

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# 1 Introduction

## A. Product Use Limitations

The nCounter Dx Analysis System and the nCounter Dx Analysis System with the FLEX configuration (when run in IVD mode) is intended for *in vitro* diagnostic use when used in conjunction with specific IVD cleared or approved assays citing its use. The nCounter Dx Analysis System may only be used with NanoString's nCounter test kits.

The nCounter Dx Analysis System may only be operated by appropriately trained, professional users. NanoString recommends that all users read and understand this manual prior to attempting to operate the system. Keep this manual in close proximity to the instruments for easy access to instructions and safety information. Failure to comply with the instructions in this manual may pose a dangerous risk to the operator and void the manufacturer's warranty.

## B. Product Components

The nCounter Dx Analysis System consists of two instruments: the Prep Station and the Digital Analyzer. A power cable is included with each instrument. The Prep Station also includes a pipette tip rack, a liquid waste container, a solid waste container, and silicone grease.

In addition to instrument software, a web-based software application (web application) is provided to configure runs, to observe sample statuses, and to download sample reports.

## C. Overview of the Procedure

1. The web application is used to identify and annotate samples and define the test to be performed.
2. After sample processing and hybridization has been completed according to the test kit instructions, samples are inserted into the Prep Station for purification and immobilization onto the internal surface of a Sample Cartridge (2–3 hours, depending on the number of samples).
3. The Sample Cartridge is then transferred to the Digital Analyzer for imaging and analysis (about 4.5 hours, or 20–25 minutes per sample).
4. During processing with the nCounter Dx Analysis System, the web application may be used to track sample statuses.
5. Finally, test reports are available for download using the web application.

## D. Manual Conventions

The following conventions are used throughout this manual and are described for your reference.

Text Style	Meaning
<b>Bold</b>	Bold text is typically used to highlight a specific button, keystroke, or menu option. Bold text may appear elsewhere to highlight important text or terms.
<i>Italic</i>	Italic text is typically used to highlight references to another section or chapter of the manual. Italic text may also be used to highlight references to other manuals or instructional material.
Blue	Blue text is typically used to highlight references to specific figures or tables. Blue text may also be used to indicate active hyperlinks to online content or e-mail addresses.



**NOTE:** This symbol indicates general information that may be useful when performing assays. These notes may clarify other instructions or provide guidance to improve the efficiency of the assay workflow.



**IMPORTANT:** This symbol indicates important information that is critical when performing an assay.



**CAUTION:** This symbol indicates the potential for bodily injury or damage to the instrument if the instructions are not followed correctly. Always carefully read and follow the instructions accompanied by this symbol to avoid potential hazards.

## E. Instrument Specifications

<b>Test Samples per Run</b>	1–10
<b>Weight</b>	Prep Station 5s: 265 lbs/120 kg
	Digital Analyzer 5s: 150 lbs/68 kg
<b>Dimensions (W x D x H)</b>	Prep Station 5s: 35.0 x 26.4 x 24.6 in/89 x 67 x 63 cm
	Digital Analyzer 5s: 26 x 26 x 19 in/66 x 66 x 48 cm
<b>Power Requirements</b>	100–240 VAC, 610 VAC
<b>Fuse</b>	8A (100–120 VAC) or 4A (200–240 VAC)



## F. Additional Precautions

- The Digital Analyzer is a Class 1 laser product, and the instrument contains an internal Class 2 laser barcode reader. Class 2 laser radiation exposure is possible while the Digital Analyzer cover is opened. Do not stare into the barcode reader laser beam.
- The Prep Station contains high voltage and heater modules indicated by symbols on the deck. Avoid contacting the heater module and electrodes. The instrument is equipped with a safety interlock that will prevent voltage from being applied while the instrument door is open.
- Do not use this device in close proximity to sources of strong electromagnetic radiation or vibration, which may interfere with proper operation.
- Do not attempt to install, move, or disassemble the instruments.
- Do not override the door sensors (a pinch hazard exists).
- Ensure that all consumables are properly inserted into the system prior to starting a procedure.
- Operate the system using only NanoString nCounter test kits in accordance with their Intended Use.
- Wear gloves while operating or performing user maintenance on the instruments.
- Do not attempt to wash the Prep Station's electrodes or allow water or other solvents to come into contact with the electrodes.
- Do not attempt to wash either instrument's touchscreen or allow water or other solvents to come into contact with the touchscreens.

## G. Caution Symbols



**BIOHAZARD:** Potential hazard from a biological source exists. If you choose to use biohazardous materials on your Prep Station, the instrument may become contaminated with biohazardous materials. Please affix the proper warning labeling to your Prep Station if you use biohazardous inputs. Be careful not to touch this area without gloves or other personal protective equipment.



**ELECTRICAL HAZARD**



**CAUTION HOT SURFACE**

## H. Environmental Requirements

- Temperature: 18–28°C
- Humidity: < 80% relative humidity (non-condensing)

## 2 Hardware Overview

### A. General Information

The instrument serial number and compliance information can be found on the rating plate on the back panel of each instrument. Please refer to the rating plate and declaration of conformity (EU only) for compliance information.

Both instruments contain a touchscreen to enable operation of the instrument. The touchscreen is a touch-sensitive method of controlling the instrument that enables the user to operate the system by touching a selection on the screen. Several buttons will appear in the touchscreen user interface, such as:

- **Next**—Proceeds to the next screen.
- **Back**—Moves back to the previous screen.
- **Cancel**—Returns to beginning of the current workflow or the main menu.

## B. Prep Station

The Prep Station is a multi-channel pipetting robot configured specifically for use with NanoString nCounter Test Kits. The instrument performs liquid transfers, magnetic bead separations, and immobilization of molecular labels on the Sample Cartridge surface (FIGURE 2.1).



FIGURE 2.1: The Prep Station

The Prep Station deck must be loaded with the appropriate consumables prior to use (FIGURE 2.2).

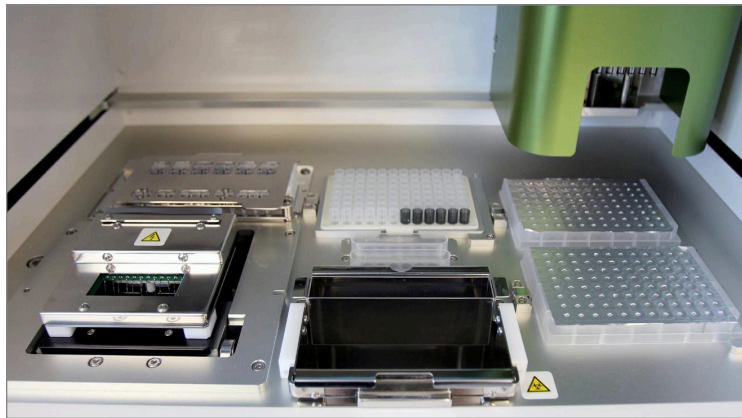


FIGURE 2.2: The Prep Station Deck

## C. Digital Analyzer

The Digital Analyzer is a multi-channel epifluorescence scanner configured specifically for use with NanoString's nCounter Test Kit Cartridges. Up to six Cartridges can be loaded into the instrument (**FIGURE 2.3**). When one or more scans have been completed, the instrument may be paused to allow new Cartridges to be swapped in without disrupting the remaining Cartridges.



**FIGURE 2.3:** The Digital Analyzer

## 3 Selecting the Instrument Mode

Users who have the FLEX configuration are able to run their instruments in either Life Sciences or Diagnostics (Dx) application modes. The FLEX configuration must be enabled by NanoString Support.



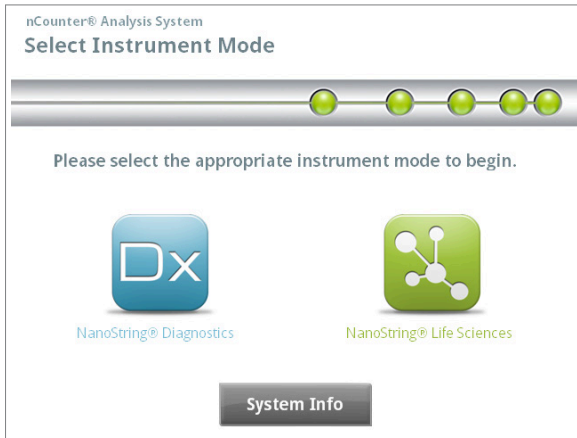
**NOTE:** If the FLEX configuration has not been enabled, the instructions provided in this chapter will not apply; only the Diagnostics application mode will be available. Proceed to Chapter 4.

All NanoString IVD assays must be performed using the Diagnostics mode on these instruments. In Diagnostics mode, procedures and controls are in place to restrict access to data and some features to authorized users only. For all other applications, individuals using nCounter CodeSets or nCounter Elements should choose the Life Sciences mode and refer to the *nCounter Analysis System User Manual* for further instruction.

## A. Prep Station

### Select Instrument Mode

After turning on the Prep Station, the first screen asks the user to select either Diagnostics mode (blue, on the left) or Life Sciences mode (green, on the right).



**FIGURE 3.1:** The Prep Station 'Select Instrument Mode' screen

Touch the blue icon labeled **NanoString® Diagnostics** to enter Diagnostics mode. The system will load the application and present the Welcome screen (**FIGURE 3.2**). Before operating the Prep Station, a user must log on by selecting the **Main Menu** button.



**FIGURE 3.2:** The 'Welcome' screen

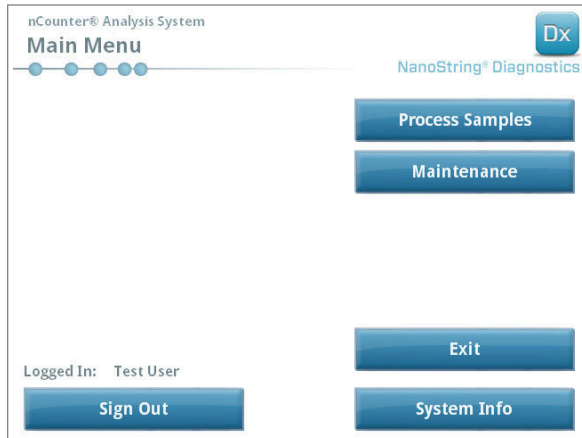
>>> The Sign In screen will appear (**FIGURE 3.3**).

Enter a valid user name and password and touch the **Sign In** button.



**FIGURE 3.3:** The sign in screen

>>> The Main Menu will appear (**FIGURE 3.4**).

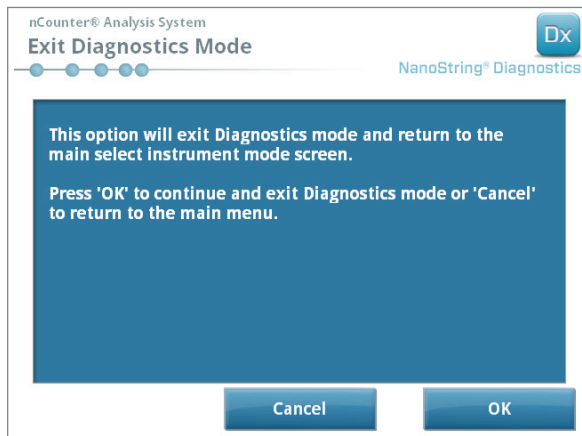


**FIGURE 3.4:** The Prep Station Main Menu in Diagnostics mode

## Switch Instrument Mode

The user may switch between Diagnostics mode and Life Sciences mode from the Main Menu. Press the **Exit** button located at the bottom of the Main Menu (**FIGURE 3.4**).

>>> The 'Exit Diagnostics Mode' confirmation screen will appear.



**FIGURE 3.5:** The Prep Station 'Exit Diagnostics Mode' confirmation screen

Touch **OK** to exit Diagnostics mode and return to the 'Select Instrument Mode' screen (**FIGURE 3.1**). Touch **Cancel** to return to the Main Menu.



## B. Digital Analyzer

### Select Instrument Mode

After turning on the Digital Analyzer, the first screen to appear asks the user to select either Diagnostics mode (blue, on the left) or Life Sciences mode (green, on the right).

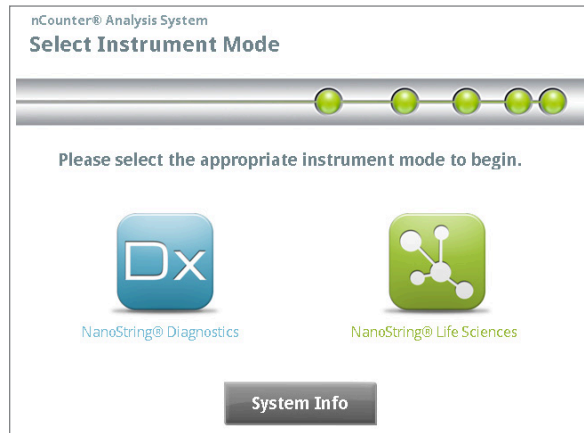


FIGURE 3.6: The Digital Analyzer 'Select Instrument Mode' screen

Touch the blue icon labeled **NanoString® Diagnostics** to enter Diagnostics mode. The system will load the application and present the Welcome screen (FIGURE 3.7). Before operating the Digital Analyzer, a user must log on by selecting the **Main Menu** button.



FIGURE 3.7: The 'Welcome' screen

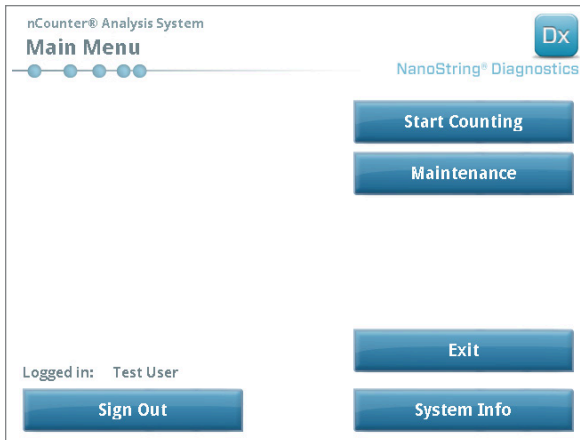
>>> The sign in screen will appear (FIGURE 3.8).

Enter a valid user name and password and press the **Sign In** button.



**FIGURE 3.8:** The sign in screen

>>> The Main Menu will appear (**FIGURE 3.9**).

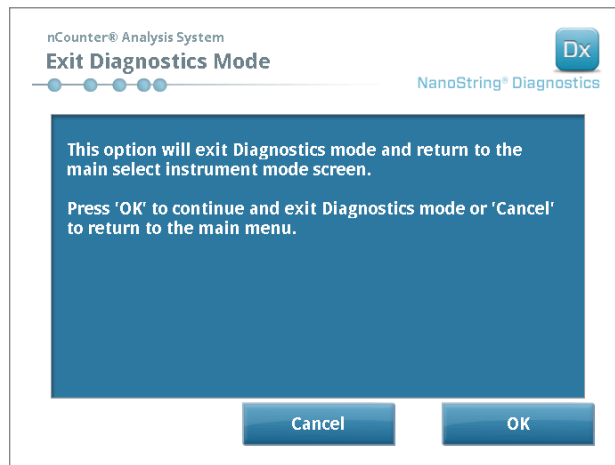


**FIGURE 3.9:** The Digital Analyzer Main Menu in Diagnostics mode

## Switch Instrument Mode

The user may switch between Diagnostics mode and Life Sciences mode from the Main Menu. Press the **Exit** button located at the bottom of the Main Menu (**FIGURE 3.9**).

>>> The 'Exit Diagnostics Mode' confirmation screen will appear.



**FIGURE 3.10:** The Digital Analyzer 'Exit Diagnostics Mode' confirmation screen

Touch **OK** to exit Diagnostics mode and return to the 'Select Instrument Mode' screen (**FIGURE 3.6**). Touch **Cancel** to return to the Main Menu.

# 4 Operating the Web Application

This chapter provides directions for using the nCounter web application, which resides on a server contained within the nCounter Digital Analyzer. When the system is connected to a network, the web application can be used to communicate with both the Prep Station and the Digital Analyzer. Its primary functions are as follows:

- Create and edit Run Sets
- View the statuses of Run Sets
- Download reports
- Perform administrative functions

## A. Sign In and Profile Management

### Sign In

The local nCounter system administrator must provide each user with the URL to access the nCounter web application and will also set up the user account. Navigate to the URL provided from any computer connected to the organization's local network. (It must be the same network used by the Digital Analyzer.)

The Sign In page will appear. Enter the user ID and password provided by the administrator and click on the **Sign In** button (FIGURE 4.1).

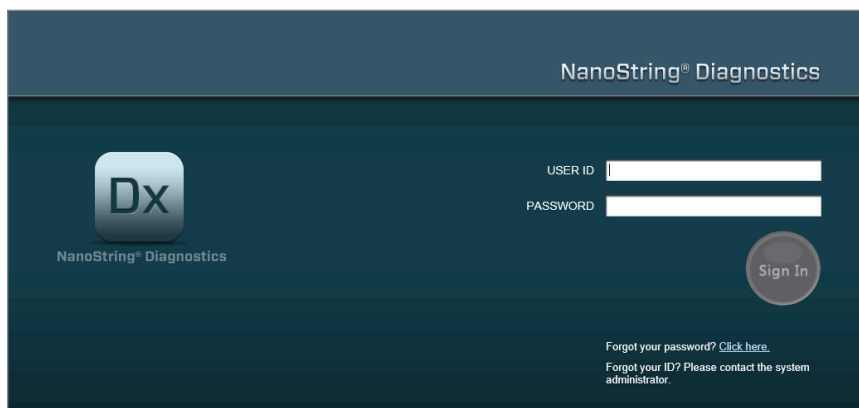
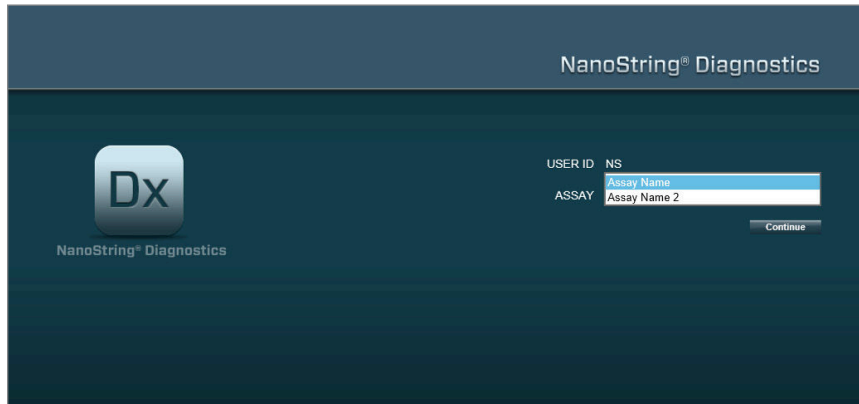


FIGURE 4.1: The nCounter web application Sign In page

- **User permissions for single assay:** If the user has access to only one assay, the Dashboard page for that assay will immediately be displayed (FIGURE 4.15).
- **User permissions for multiple assays:** If the user has access to more than one assay, the **Assay Type** control will be displayed. The user will then need to select an assay, then click **Continue** (FIGURE 4.2).

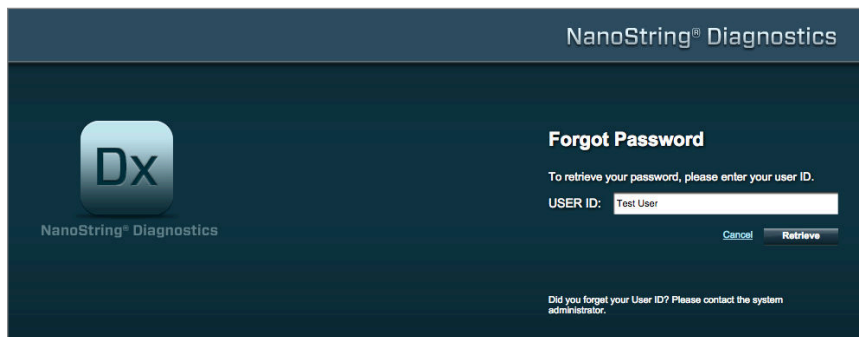


The screenshot shows the NanoString Diagnostics Sign In page. On the left is the 'Dx' logo with 'NanoString Diagnostics' text below it. On the right, there are two input fields: 'USER ID' with 'NS' entered, and 'ASSAY' with 'Assay Name 2' selected from a dropdown menu. A 'Continue' button is located below the 'ASSAY' field.

FIGURE 4.2: The **Assay Type** control on the Sign In page

## Forgot User ID/Password

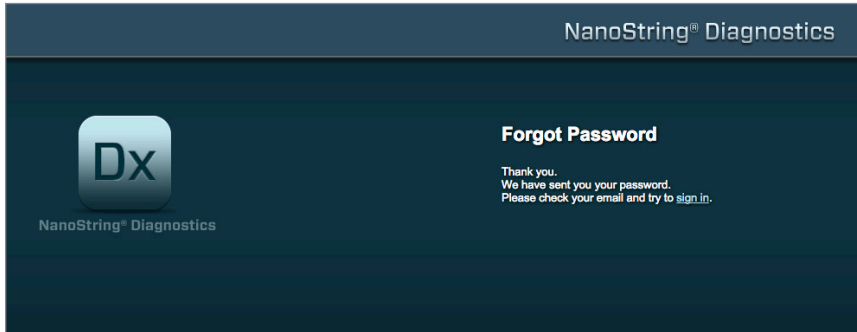
- If you forget your user ID, contact your local nCounter system administrator to retrieve it.
- If the password is forgotten, the nCounter web application may be able to retrieve it.
  - Click the link next to “Forgot your password?” to access the forgotten password submission page (FIGURE 4.3).



The screenshot shows the NanoString Diagnostics 'Forgot Password' page. On the left is the 'Dx' logo with 'NanoString Diagnostics' text below it. The main heading is 'Forgot Password'. Below it, the text reads: 'To retrieve your password, please enter your user ID.' There is a 'USER ID:' label followed by a text input field containing 'Test User'. Below the input field are 'Cancel' and 'Retrieve' buttons. At the bottom, there is a small note: 'Did you forget your User ID? Please contact the system administrator.'

FIGURE 4.3: The submission page for a forgotten password

- Enter your user ID.
  - If the nCounter system finds a matching profile, the password will be e-mailed to the address on record (**FIGURE 4.4**).
  - If a matching profile is not found, you will be instructed to contact your nCounter system administrator in order to reset the password.



**FIGURE 4.4:** The confirmation page after a password has been requested

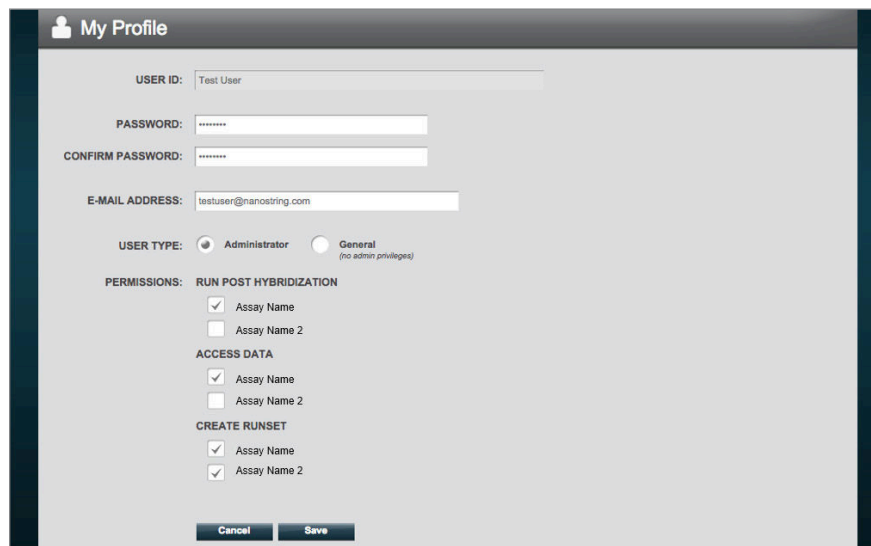
## Updating My Profile

User information can be updated by selecting the **My Profile** button from the menu bar at the top of the page (**FIGURE 4.5**).



**FIGURE 4.5:** Location of the **My Profile** button

The My Profile page enables the user to change the account password and/or e-mail address associated with the profile and view other account information (**FIGURE 4.6**). See *Section G: Manage Users* for more information about user types and privileges.

The "My Profile" page displays the following information:

- USER ID:** Test User
- PASSWORD:** [Redacted]
- CONFIRM PASSWORD:** [Redacted]
- E-MAIL ADDRESS:** testuser@nanosttring.com
- USER TYPE:**  Administrator  General (no admin privileges)
- PERMISSIONS:**
  - RUN POST HYBRIDIZATION:**
    - Assay Name
    - Assay Name 2
  - ACCESS DATA:**
    - Assay Name
    - Assay Name 2
  - CREATE RUNSET:**
    - Assay Name
    - Assay Name 2

At the bottom, there are "Cancel" and "Save" buttons.

**FIGURE 4.6:** The My Profile page

To accept any changes made to a profile, click the **Save** button. To discard any changes and return to the previous page, click the **Cancel** button.

## B. Application Layout and Navigation

### Menu

The nCounter web application has a menu bar at the top that enables users to quickly navigate from one area of the application to another (FIGURE 4.7). The menu items separate the application into five sections:

- **Dashboard** – Common tasks and statuses of recent activities
- **Runs** – Create a Run Set and view run statuses (a Run Set consists of 1–10 diagnostic samples and two mandatory reference samples processed at the same time)
- **Samples** – View sample statuses
- **Reports** – Download reports
- **Admin** – Manage users and other system settings

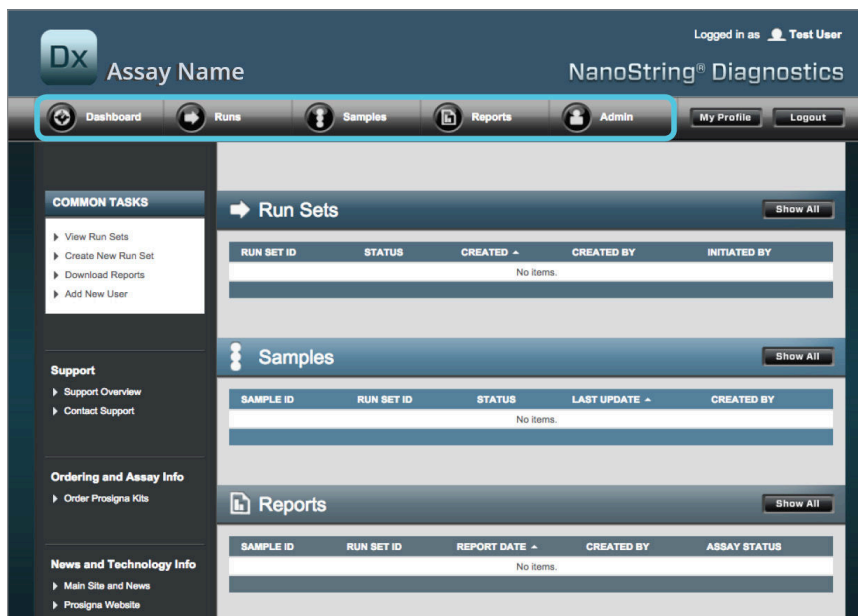


FIGURE 4.7: The web application main menu.

Most of the menu options have sub-menus that are available when a user hovers over the item (FIGURE 4.8). If no sub-menus are available, the user may simply click on the menu item.

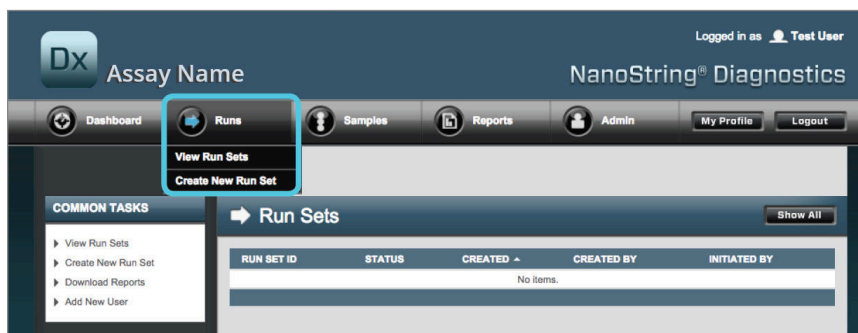


FIGURE 4.8: Sub-menus are available for some menu options.



## Tables

The nCounter web application displays tables to quickly view Run Set statuses, sample statuses, users, and reports.

## Filter

Tables can become large after frequent use of the nCounter web application, making it difficult to find the data of interest. Filtering is available in all tables to enable users to search for and view only data of interest.

By default, filtering is turned off for most status pages. (One exception: By default, reference samples are filtered out on the Samples page.) To turn filtering on, click the + symbol next to the Filter Settings header. The header will expand and display available filter settings (FIGURE 4.9).

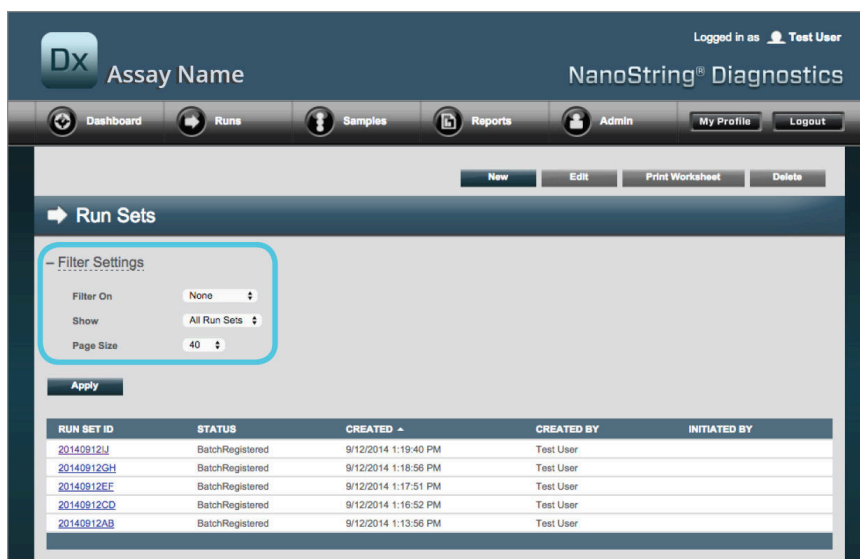
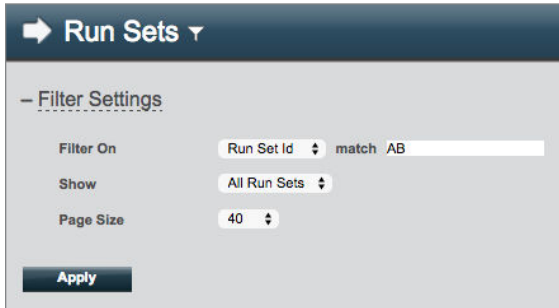


FIGURE 4.9: Filter settings are available when viewing most data



**NOTE:** Filtering is not available for the Manage Users page.

Filter the data using any of the fields in the table. This will return any items that match the entered text anywhere in that field. Likewise, users can choose to show all items or only items created recently by specifying the time frame of interest. To change the number of items displayed per page, select the desired page size from the drop down menu (FIGURE 4.10).



**FIGURE 4.10:** An example of filter settings on the Run Sets page

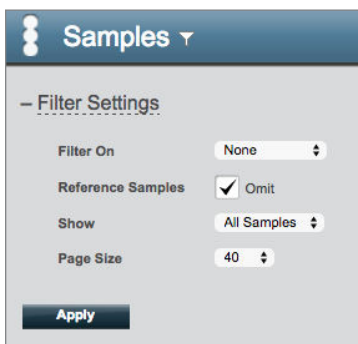
Click **Apply** when finished. Only relevant rows will be displayed in the table (**FIGURE 4.11**).

**NOTE:** The presence or absence of a funnel icon next to the page title indicates whether or not filtering is applied.



**FIGURE 4.11:** An example of the funnel icon and filtered results on the Run Sets page

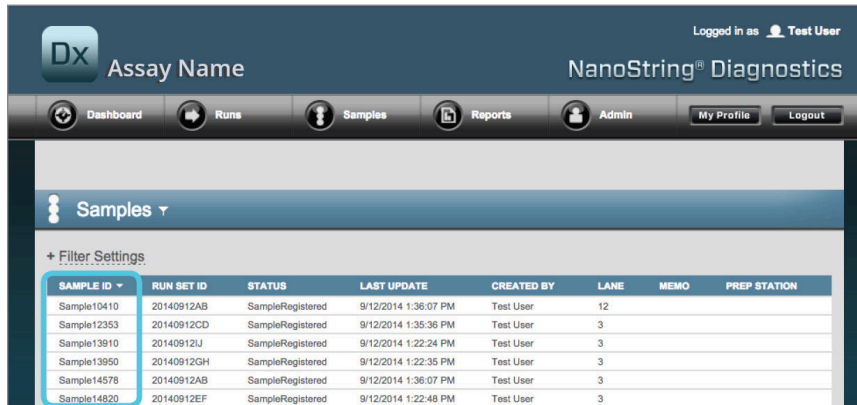
Different filters are available depending on the page displayed. For example, the Samples page provides the ability to hide the two reference samples required for every run (**FIGURE 4.12**).



**FIGURE 4.12:** Check the **Omit** box to show or hide the reference samples

## Sort

All table columns allow users to sort the displayed rows in ascending or descending order. Click on the column heading for the data of interest to sort the rows (**FIGURE 4.13**). To re-sort the data in the reverse order, click again on the same column heading.



The screenshot shows the NanoString Diagnostics web interface. At the top, there is a navigation bar with a 'Dx' logo, 'Assay Name', and 'NanoString® Diagnostics'. The user is logged in as 'Test User'. Below the navigation bar are tabs for 'Dashboard', 'Runs', 'Samples', 'Reports', and 'Admin'. The 'Samples' tab is active, and a 'Filter Settings' dropdown is open. A table of samples is displayed, sorted by 'SAMPLE ID' in ascending order. The table has columns for 'SAMPLE ID', 'RUN SET ID', 'STATUS', 'LAST UPDATE', 'CREATED BY', 'LANE', 'MEMO', and 'PREP STATION'. The rows are sorted alphabetically by Sample ID.

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY	LANE	MEMO	PREP STATION
Sample10410	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	12		
Sample12353	20140912CD	SampleRegistered	9/12/2014 1:35:36 PM	Test User	3		
Sample13910	20140912U	SampleRegistered	9/12/2014 1:22:24 PM	Test User	3		
Sample13950	20140912GH	SampleRegistered	9/12/2014 1:22:35 PM	Test User	3		
Sample14578	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User	3		
Sample14820	20140912EF	SampleRegistered	9/12/2014 1:22:48 PM	Test User	3		

**FIGURE 4.13:** An example of alphabetically sorting samples by clicking on the **SAMPLE ID** column heading



**NOTE:** Tables are typically displayed by default with the most recently added items at the top and the oldest items at the bottom.

## Forms

Forms are pages for manual data entry changes. Users with the 'Create Run Set' account privilege have access to the 'Create Run Set' and 'Edit Run Set' forms. Users who lack this privilege may view Run Set and sample statuses, but may not create or edit Run Sets. Administrators may also access other forms, which include:

- **Add New User**
- **Edit User**
- **Date and Time**
- **IP Address**
- **SSH Settings**
- **E-mail Configuration**

All forms are designed with the expectation that users complete an action prior to moving to another area within the web application (**FIGURE 4.14**). In order to navigate to another function after completing a form, click **Save** to retain the information entered or **Cancel** to exit the form and discard any changes.

The screenshot shows the 'Edit Run Set' form in the NanoString® Diagnostics web application. The form is titled 'Edit Run Set' and contains several input fields and a table. The top navigation bar is highlighted with a red box, indicating it is inaccessible while editing the form.

1. Assay Type: Prosigna

2. Enter Run Set ID: 20140912CD  
Every Run Set ID must be unique. Example: 20120701LB2

3. Test Configuration code: 9+Lky59D2x0

4. CodeSet Kit Number: 012345019  
Scan or manually enter the Kit Lot Number from the sticker included in the CodeSet box.

5. Enter Sample Data:

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO (OPTIONAL)
1	Reference1			
2	Reference2			
3	Sample12353	Zero Positive Nodes	<= 2cm	
4	Sample24213	Zero Positive Nodes	> 2cm	
5	Sample32365	1-3 Positive Nodes	<= 2cm	

**FIGURE 4.14:** The menu bar is inaccessible while editing the contents of a form

## C. Dashboard and Status Pages

### Dashboard

The Dashboard is the landing page, the first screen displayed after logging into the nCounter web application (FIGURE 4.15). The Dashboard can be accessed from other pages by clicking on the **Dashboard** menu item, but it will be unavailable when editing a form until that form has been saved or discarded.

The screenshot shows the NanoString Diagnostics web application dashboard. At the top, there is a header with the NanoString logo, 'Assay Name', and 'Logged in as Test User'. Below the header is a navigation bar with icons for Dashboard, Runs, Samples, Reports, Admin, My Profile, and Logout. The 'Dashboard' icon is highlighted with a blue box. The main content area is divided into sections: 'Run Sets' (with a 'Show All' button), 'Samples' (with a 'Show All' button), and 'Reports' (with a 'Show All' button'). Each section contains a table of data. The 'Run Sets' table has columns for Run Set ID, Status, Created, Created By, and Initiated By. The 'Samples' table has columns for Sample ID, Run Set ID, Status, Last Update, and Created By. A sidebar on the left contains 'COMMON TASKS' (View Run Sets, Create New Run Set, Download Reports, Add New User), 'Support' (Support Overview, Contact Support, Download Version Information), and 'News and Technology Info' (Main Site and News, Prosigna Website). At the bottom left, it shows 'Logged in as: Test User'.

RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
20140912JU	BatchRegistered	9/12/2014 1:19:40 PM	Test User	
20140912GH	BatchRegistered	9/12/2014 1:18:56 PM	Test User	
20140912EF	BatchRegistered	9/12/2014 1:17:51 PM	Test User	
20140912CQ	BatchRegistered	9/12/2014 1:16:52 PM	Test User	
20140912AB	BatchRegistered	9/12/2014 1:13:56 PM	Test User	

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY
Sample14578	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample27456	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample34352	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample48724	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User
Sample52968	20140912AB	SampleRegistered	9/12/2014 1:36:07 PM	Test User

FIGURE 4.15: The Dashboard landing page and the location of the **Dashboard** menu option

The Dashboard provides quick access to the statuses of Run Sets, Samples, and Reports (assuming appropriate privileges have been applied to the user profile). To view the complete status of any of these, click on the **Show All** button on the right hand side of the title bar.

The Dashboard also provides quick access to common tasks located on the left side of the page. Click on the appropriate link to navigate and perform the desired action.

All navigations provided on the Dashboard can be accessed individually by using the menu bar at the top (FIGURE 4.15). The Dashboard provides a consolidated view of these to make it easy to perform any function quickly from one place.

## Run Set Status

The Run Sets page can be accessed from the Dashboard as described above, and is also available by clicking **Runs** on the menu bar.

The Run Sets page displays the statuses of all Run Sets that have been created (**FIGURE 4.16**)

The screenshot shows the NanoString Dx Analysis System interface. At the top, it says "Dx Assay Name" and "NanoString<sup>®</sup> Diagnostics". The user is logged in as "Test User". The navigation menu includes Dashboard, Runs, Samples, Reports, Admin, My Profile, and Logout. Below the menu, there are buttons for New, Edit, Print Worksheet, and Delete. The main content area is titled "Run Sets" and includes a "Filter Settings" section. A table displays the following data:

RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
20140912LJ	BatchRegistered	9/12/2014 1:19:40 PM	Test User	
20140912GH	BatchRegistered	9/12/2014 1:18:56 PM	Test User	
20140912EF	BatchRegistered	9/12/2014 1:17:51 PM	Test User	
20140912CD	BatchRegistered	9/12/2014 1:16:52 PM	Test User	
20140912AB	BatchRegistered	9/12/2014 1:13:56 PM	Test User	

**FIGURE 4.16:** Statuses of all Run Sets

The following information is available:

1. **Run Set ID** – The Run Set ID entered when the Run Set was created
2. **Status** – The current condition or state of the Run Set. Status possibilities include:
  - **BatchRegistered** – Run Set Registered (Run Set is defined but has not started processing yet)
  - **PostHybProcessing** – Prep Station Processing (Run Set is currently processing on the Prep Station)
  - **PostHybComplete** – Prep Station Completed (Run Set has completed on the Prep Station)
  - **PostHybAbort** – Prep Station Abort (manual abort on the Prep Station)
  - **PostHybError** – Prep Station Error (an error occurred during processing on the Prep Station)
  - **ScanProcessing** – DA Scan Processing (currently processing on the Digital Analyzer)
  - **ScanError** – DA Scan Error (an error occurred during processing on the Digital Analyzer)
  - **ScanAbort** – DA Scan Abort (manual abort on the Digital Analyzer)
  - **BatchComplete** – Batch Complete (Run Set has completed processing)
  - **ReportPending** – Report Pending (scanning complete, but waiting for the algorithm to complete)
  - **ReportProcessing** – Report Processing (algorithm is running but the report has not been produced yet)
  - **ReportComplete** – Report Complete (Digital Analyzer has finished scanning and reports are available for download from the Reports page)
  - **ReportError** – Report Failed (all processing for the Run Set is complete but a report was not generated due to an error in the algorithm)
  - **ReportCompleteWithError** – Report Complete with Error (all processing for the Run Set is complete, and a report generated, but the assay failed)
3. **Created** – The date the Run Set was initially created using the web application
4. **Created By** – The User ID that created the Run Set using the web application
5. **Initiated By** – The User ID that started processing the Run Set on the Prep Station

To view more details of the individual samples for a Run Set of interest, click on the hyperlink for that Run Set (**FIGURE 4.16**). The application will navigate to the 'Samples' page and display sample information for the selected Run Set.

## Sample Status

Similar to the Run Sets page, the Samples page can be accessed from the Dashboard and is also available from the **Samples** menu option at the top of the page (FIGURE 4.17).

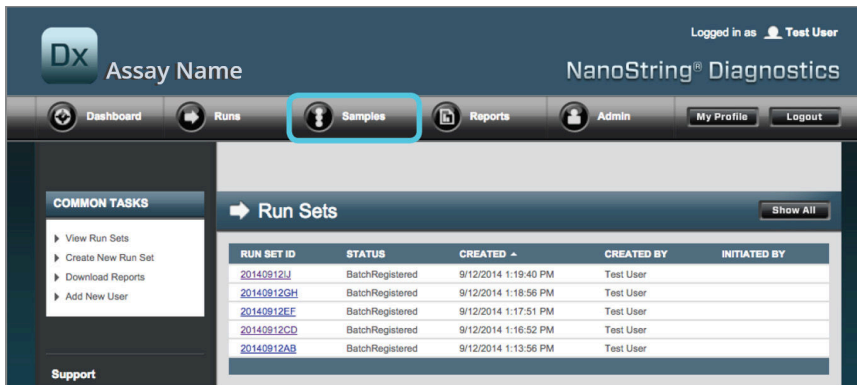


FIGURE 4.17: The location of the **Samples** menu option

The Samples page allows users to view the statuses of all samples for all Run Sets (FIGURE 4.18)

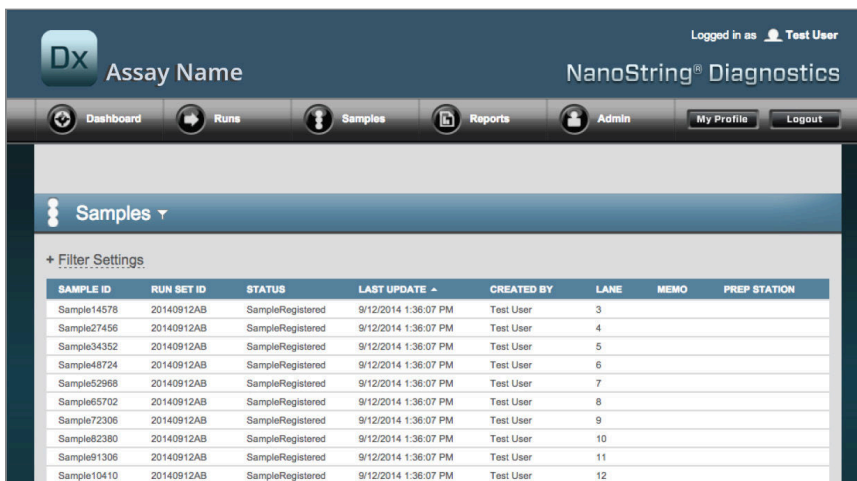


FIGURE 4.18: The statuses of all samples contained within all Run Sets



The following information is available:

1. **Sample ID** – The Sample ID entered manually or via a barcode scanner when creating the Run Set
2. **Run Set ID** – The Run Set ID entered when creating the Run Set in the web application
3. **Status** – The condition or state that the sample is currently in. The following are possible statuses for a sample:
  - **SampleRegistered** – Sample Registered (Sample is defined; has not started processing yet)
  - **PostHybProcessing** – Prep Station Processing (Run Set is currently processing on the Prep Station)
  - **PostHybComplete** – Prep Station Completed (Run Set has completed on the Prep Station)
  - **PostHybAbort** – Prep Station Abort (manual abort on the Prep Station)
  - **PostHybError** – Prep Station Error (an error occurred during processing on the Prep Station)
  - **ScanProcessing** – DA Scan Processing (currently processing on the Digital Analyzer)
  - **ScanError** – DA Scan Error (an error occurred during processing on the Digital Analyzer)
  - **ScanAbort** – DA Scan Abort (manual abort on the Digital Analyzer)
  - **ReportPending** – Report Pending (Scanning complete, but waiting for the algorithm to complete)
  - **ReportProcessing** – Report Processing (Algorithm is running but the report has not been produced yet)
  - **ReportComplete** – Report Complete (Digital Analyzer has finished scanning and reports are available for download from the Reports page)
  - **ReportError** – Report Failed (All processing for the run set is complete but a report was not generated due to an error in the algorithm)
  - **ReportCompleteWithError** – Report Complete with Error (All processing for the run set is complete, and a report generated, but the assay failed)
4. **Last Update** – The date that the sample last changed status
5. **Created By** – The User ID that created the Run Set using the web application
6. **Lane** – The lane where the sample resides on the Cartridge
7. **Memo** (optional) – Notes about the sample entered in the Memo field of the Run Set form
8. **Prep Station** – Name of the Prep Station on which the sample was processed, useful if more than one Prep Station is connected to the Digital Analyzer

## D. Run Sets

This section guides users through creating, editing, printing, and deleting Run Sets.

### Create a Run Set

Users are required to create a Run Set associating the sample IDs with their strip tube well locations using the nCounter web application.

A user can choose to create a new Run Set from several places within the web application. The most common way is to select the option **Runs** from the menu bar at the top of the page and choose **Create New Run Set** from the sub-menu that appears below (FIGURE 4.19).

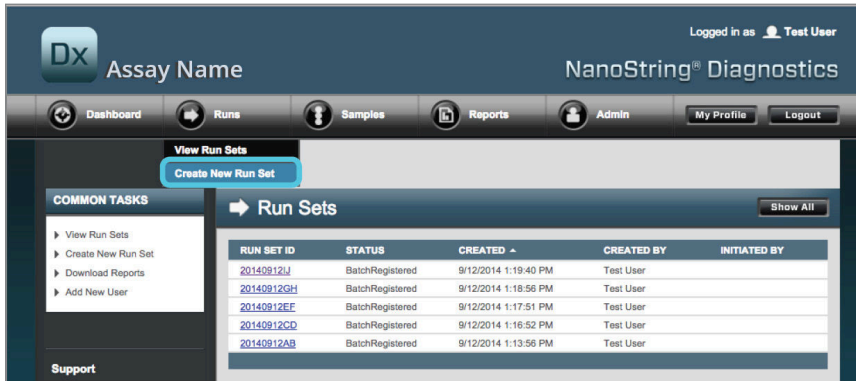


FIGURE 4.19: The **Create New Run Set** option is available in the **Runs** sub-menu

>>> The **Create New Run Set** form will appear (FIGURE 4.20).

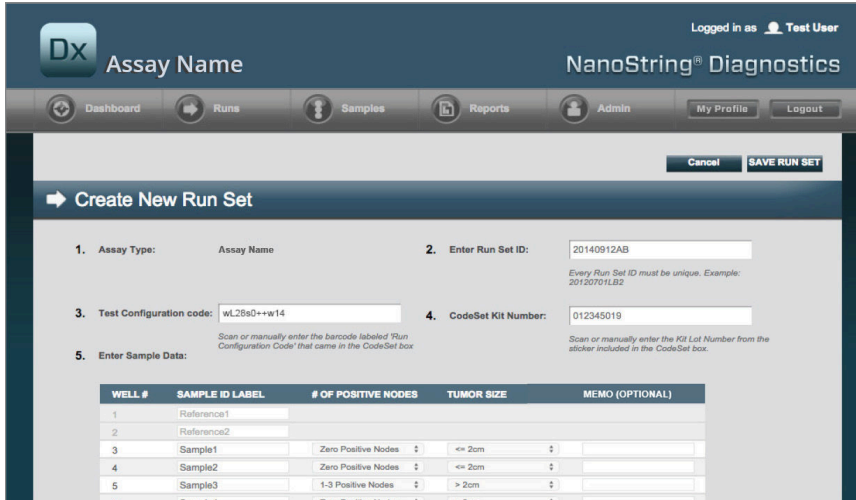


FIGURE 4.20: The **Create New Run Set** form

Enter the following information to create a Run Set:

1. **nCounter Assay Type** – If the user has access to more than one nCounter assay type, the assay that was previously selected during sign in will be displayed (FIGURE 4.2). To change this selection, the user must log out, then sign in again and select a different assay type.
2. **Run Set ID** – The Run Set ID must provide a unique name to identify the Run Set.
3. **Test Configuration Code** – The Test Configuration Code is an alphanumeric barcode located inside the CodeSet box. It determines the number of samples that can be processed.
4. **CodeSet Kit Number** – The CodeSet Kit Number is a numeric barcode located inside the CodeSet box and is also described as a CodeSet Barcode Sticker. It determines the CodeSet expiration date. Because there may be a delay between creating a Run Set and processing the samples, a warning will be provided if the CodeSet is within two weeks of its expiration date when the Run Set is created.
5. **Sample Data** – The Reference Sample is always located in wells 1 and 2; they do not require any input and cannot be edited. Well numbers 3-12 are used for patient RNA samples. Fields may vary for different assay types. As an example, Prosigna® requires the following information:
  - a. **Sample ID Label** (required) – Sample IDs can be entered using barcoded sample tubes and a barcode scanner connected to the computer. If a scanner is not available or if the barcodes are damaged, sample IDs can be manually entered using a keyboard. NanoString recommends using unique sample IDs to track samples.
  - b. **# of Positive Nodes** (required) – Users can choose between zero positive nodes, 1-3 positive nodes or  $\geq 4$  positive nodes (where available).
  - c. **Tumor Size** (required) – Users can choose between  $\leq 2$  cm or  $> 2$  cm.
  - d. **Memo** (optional) – Any notes about the sample can be entered here. There is a maximum limit of 32 characters.



**NOTE:** Leave the remaining fields blank if any strip tube wells are not needed. If additional fields are required for more samples, use a different test configuration that accommodates more samples.



**IMPORTANT:** Some handheld scanners can misinterpret barcodes if they are not properly configured. It is essential that the Test Configuration Code and CodeSet Kit Number be entered correctly. If you encounter errors, contact [dxsupport@nanosttring.com](mailto:dxsupport@nanosttring.com) for assistance.

6. **Set E-mail Recipients** – If desired, choose e-mail recipients by selecting users from the contact list on the left side and clicking the **Add>>** button. Conversely, e-mail recipients can be removed by selecting the users from the list on the right side and clicking the **<<Remove** button (FIGURE 4.21). Press the **Ctrl** key (or the **Command** key if using an Apple computer) on the keyboard while selecting multiple addresses to add or remove multiple recipients at once.
  - a. **E-mail Status Updates to** – Users assigned here will receive e-mail updates anytime the Run Set status has changed.
  - b. **E-mail Report Notifications to** – Users assigned here will receive an e-mail when the sample reports for the Run Set are available for download. E-mails will include a link to log in and download the appropriate nCounter reports.



**NOTE:** A user must have proper permissions set in their user profile in order to be able to receive e-mail report notifications. Attempts to assign a user without appropriate access to receive report notifications will result in an error message. To change these permissions, an administrator must edit the user's profile and add the privilege.

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO (OPTIONAL)
1	Reference1			
2	Reference2			
3	Sample1	Zero Positive Nodes	<= 2cm	
4	Sample2	Zero Positive Nodes	<= 2cm	
5	Sample3	1-3 Positive Nodes	> 2cm	
6	Sample4	Zero Positive Nodes	> 2cm	
7	Sample5	Zero Positive Nodes	> 2cm	
8	Sample6	1-3 Positive Nodes	<= 2cm	
9	Sample7	Zero Positive Nodes	<= 2cm	
10	Sample8	1-3 Positive Nodes	> 2cm	
11	Sample9	Zero Positive Nodes	<= 2cm	
12	Sample10	Zero Positive Nodes	<= 2cm	

6. Set E-mail Recipients:

CONTACT LIST	E-mail STATUS UPDATES to (Optional):
Administrator Alpha Beta Charlie David Elena Frank Gamma Helen Karen Test User	
Add >> << Remove	
	E-mail REPORT NOTIFICATIONS to (Optional):
Add >> << Remove	

Cancel SAVE RUN SET

FIGURE 4.21: The location of the contact list and e-mail alerts on the Create New Run Set form

It is crucial to correctly enter sample information. Complete each well with all required information before entering sample information for the next well. Click on **Save Run Set** when you have entered all information for the Run Set. After you save the Run Set, a prompt to print a worksheet will appear (FIGURE 4.22).



FIGURE 4.22: The Print Worksheet prompt

Select **OK** to print the Run Set Worksheet.



**NOTE:** Clicking the **Cancel** button will navigate the user to the Run Sets page.



**NOTE:** The Run Set will still be saved in the application if a worksheet is not printed, but it is recommended that a printed worksheet be used in the laboratory when preparing samples. The worksheet may also be printed at a later date.

>>>The worksheet will appear in a new window (FIGURE 4.23).

<b>Run Set ID:</b> 20140912AB		<b>CodeSet Kit Number:</b> 0123450199		
<b>Assay:</b> Prosigna		<b>RNA Isolation Kit Lot:</b>		
<b>Date / Time:</b> 9/12/2014 1:14 PM		<b>Email Status Updates:</b> Test User		
<b>Created By:</b> Test User		<b>Email Report Notifications:</b> Test User		

Well #	Sample ID Label	# of Positive Nodes	Tumor Size	Memo
1	Reference1	N/A	N/A	N/A
2	Reference2	N/A	N/A	N/A
3	Sample1	Zero Positive Nodes	<= 2cm	
4	Sample2	Zero Positive Nodes	<= 2cm	
5	Sample3	1-3 Positive Nodes	> 2cm	
6	Sample4	Zero Positive Nodes	> 2cm	
7	Sample5	Zero Positive Nodes	> 2cm	
8	Sample6	1-3 Positive Nodes	<= 2cm	
9	Sample7	Zero Positive Nodes	<= 2cm	
10	Sample8	1-3 Positive Nodes	> 2cm	
11	Sample9	Zero Positive Nodes	<= 2cm	
12	Sample10	Zero Positive Nodes	<= 2cm	

[Close](#) [Print](#)

FIGURE 4.23: An example worksheet

Select **Print** to print the worksheet, and then close the worksheet. The application will return to the Run Sets page.

## Edit a Run Set

Run Sets with the status 'BatchRegistered' can be edited. Users should edit a Run Set to match the final hybridization record if sample information was altered. For example, the Sample ID Labels may be updated if patient samples are swapped out or if a new sample ID is assigned.

To edit a Run Set, select the appropriate Run Set from the list on the Run Sets page and click the **Edit** button (FIGURE 4.24).

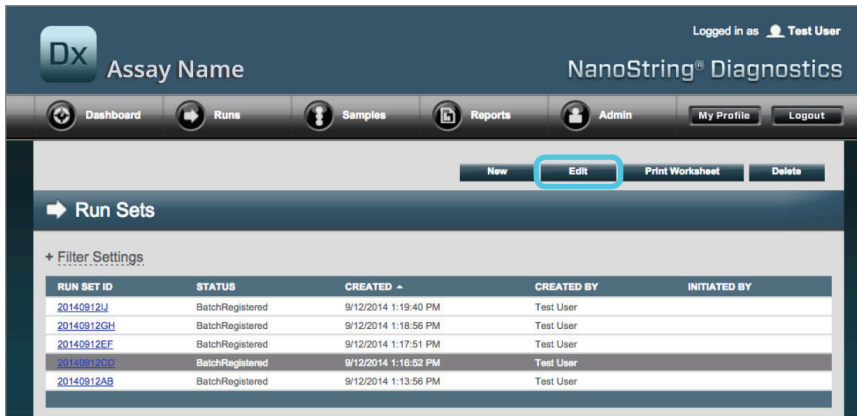


FIGURE 4.24: Location of the **Edit** button on the Run Sets page

>>> The Edit Run Set page will appear (FIGURE 4.25).

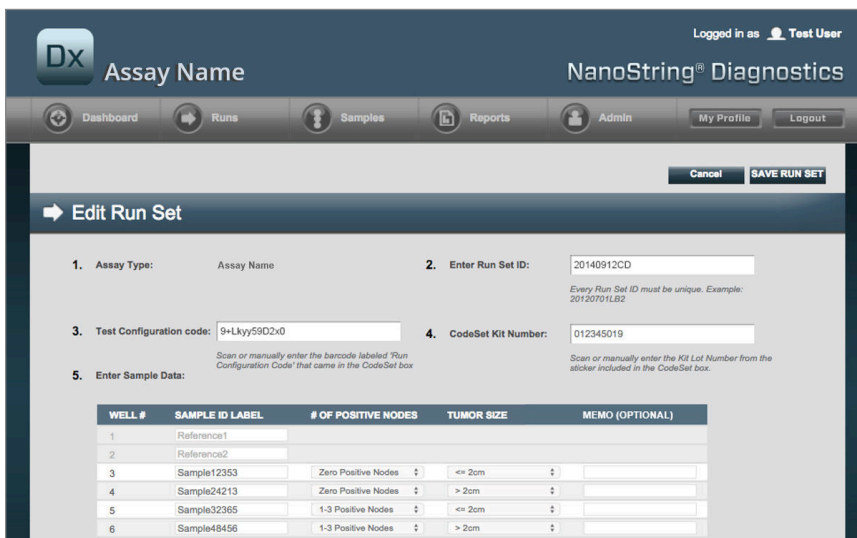


FIGURE 4.25: The Edit Run Set page



**NOTE:** Clicking on the Run Set ID hyperlink will NOT open the Run Set for editing. Clicking the hyperlink will open the Samples status page, pre-filtered to view only that Run Set.

Verify that the correct Run Set has been opened, and then edit the Run Set as needed. Save changes by clicking the **Save Run Set** button at the top. When prompted, print the worksheet as recommended earlier in this section.

## Delete a Run Set

Run Sets with the status 'BatchRegistered' can be deleted if necessary. To delete a Run Set, select the appropriate Run Set from the list and click the **Delete** button (FIGURE 4.26).

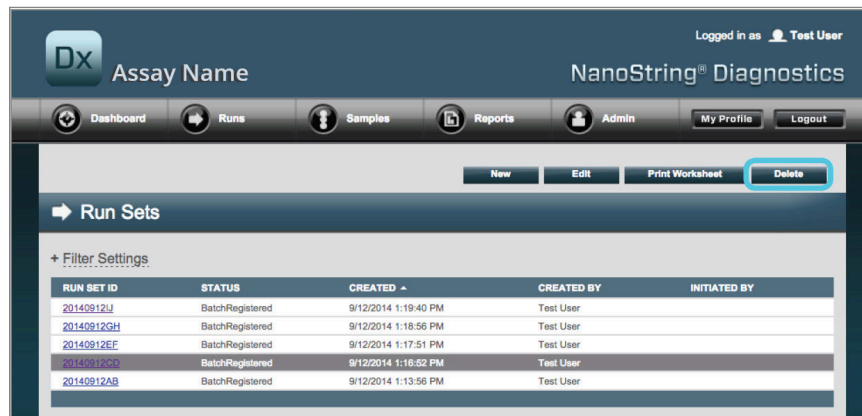


FIGURE 4.26: Location of the **Delete** button on the Run Sets page

>>> A prompt will appear to confirm deletion of the Run Set (FIGURE 4.27).

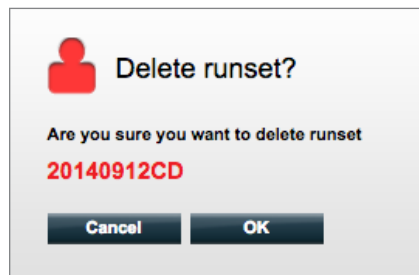


FIGURE 4.27: The 'Delete runset?' prompt

Click **OK** to delete the Run Set or **Cancel** to return to the Run Sets page.

## Editing Sample Information

Occasionally, a report may need to be generated again if one or more sample parameters (e.g., for Prosigna®, # of Positive Nodes (Nodal Status) or Tumor Size) were entered incorrectly. These parameters may be changed in the Create/Edit Run Set page before the sample is started on the Prep Station, but after the sample has started on the Prep Station, only an administrator can edit these fields and generate a new report. This can only be done once per sample. The new report will be marked as a revised report, and for reference, will include the obsolete parameters and results. In addition, if the Prep Station or Digital Analyzer has been initiated prior to realizing the parameters were entered incorrectly, **do not abort the run**, but allow it to fully complete, and then edit the sample parameters to revise the run.



**IMPORTANT:** The user must have administrator privileges to edit an analyzed sample and re-run the report. The report can only be re-run once.

See the Administrator section for details on **Editing Sample Information**.

## E. Print Worksheets

It is highly recommended that worksheets be used when setting up hybridization reactions. As described earlier, when a Run Set is saved the system will prompt the user to print the worksheet. However, it is also possible to print Run Set worksheets at any time from the nCounter web application.

To print a Run Set worksheet, navigate to the Run Set' page, select the Run Set row of interest, and click the **Print Worksheet** button (FIGURE 4.28).

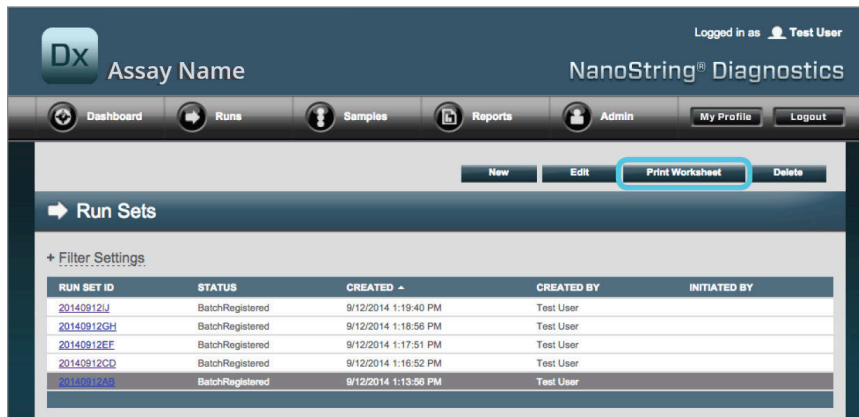


FIGURE 4.28: Location of the **Print Worksheet** button on the Run Sets page

>>> The worksheet (FIGURE 4.29) will appear in a new window.

<b>Run Set ID:</b> 20140912AB	<b>CodeSet Kit Number:</b> 0123450199
<b>Assay:</b> Prosigna	<b>RNA Isolation Kit Lot:</b>
<b>Date / Time:</b> 9/12/2014 1:49 PM	<b>Email Status Updates:</b> Test User
<b>Created By:</b> Test User	<b>Email Report Notifications:</b> Test User

Well #	Sample ID Label	# of Positive Nodes	Tumor Size	Memo
1	Reference1	N/A	N/A	N/A
2	Reference2	N/A	N/A	N/A
3	Sample14578	Zero Positive Nodes	<= 2cm	
4	Sample27456	Zero Positive Nodes	<= 2cm	
5	Sample34352	1-3 Positive Nodes	> 2cm	
6	Sample48724	Zero Positive Nodes	> 2cm	
7	Sample52968	Zero Positive Nodes	> 2cm	
8	Sample65702	1-3 Positive Nodes	<= 2cm	
9	Sample72306	Zero Positive Nodes	<= 2cm	
10	Sample82380	1-3 Positive Nodes	> 2cm	
11	Sample91306	Zero Positive Nodes	<= 2cm	
12	Sample10410	Zero Positive Nodes	<= 2cm	

[Close](#) [Print](#)

FIGURE 4.29: An example worksheet

Click the **Print** button to begin the printing process for the worksheet or the **Close** button to close the window.



## F. Reports

Users with the 'Access Diagnostic Reports' privilege can select and download diagnostic reports from the Reports page.

Users chosen to receive a report notification when setting up the Run Set should receive an e-mail stating that the sample processing is complete and that the report is available for download. A link to download reports from the web application is included within the e-mail notification.



**NOTE:** The download link requires the user to log in to the nCounter web application before diagnostic reports can be accessed.

From the Reports page, select the row(s) of samples to be downloaded and click the **Download** button (FIGURE 4.30).

- If more than one language has been installed for an assay, the Report Languages menu will be displayed in the upper left corner of the Report screen. The user will need to select desired language(s) for downloaded reports before clicking on the **Download** button.
- Language selections will be retained until the user modifies the selection.  
(Note: Language options are assay-specific and are installed on a per-assay basis.)

SAMPLE ID	RUN SET ID	REPORT DATE	CREATED BY	ASSAY STATUS
Reference1	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Reference2	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample1	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample2	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample3	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample4	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample5	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete
Sample6	20140912AB	9/13/2014 5:36:29 PM	Test User	ReportComplete

FIGURE 4.30: The Reports page

Downloaded reports will be compressed into a ZIP file (\*.zip). This file can be opened immediately or saved to a specified location on a computer or network.



**NOTE:** Remember that reports contain confidential information. Be careful when saving to a network or location that may be accessed by others.

## G. Administration

For Administrators, the **Admin** button is available in the top menu bar of the web application. Administrators can choose these functions:

- **Manage Users**
- **System Settings**
- **Add User**
- **Configure Report**

In addition to the functions listed in the **Admin** menu, two additional areas are restricted to Administrators:

- **LIS Integration**
- **Editing Sample Information**

## Add, Delete, and Manage Users

To add a new user, select **Admin** from the top menu bar and click on **Add User** (FIGURE 4.31).

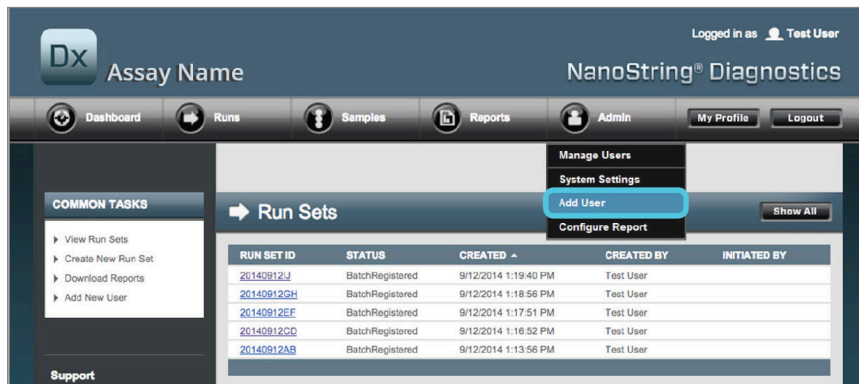


FIGURE 4.31: The location of the **Add User** button in the **Admin** sub-menu

>>> The Add New User form will appear (FIGURE 4.32).

The 'Add New User' form contains the following fields and options:

- USER ID: [Text Input]
- PASSWORD: [Text Input]
- CONFIRM PASSWORD: [Text Input]
- E-MAIL ADDRESS: [Text Input]
- USER TYPE:
  - Administrator
  - General (no admin privileges)
- PERMISSIONS:
  - RUN POST HYBRIDIZATION:
    - Assay Name
    - Assay Name 2
  - ACCESS REPORTS:
    - Assay Name
    - Assay Name 2
  - CREATE RUN SET:
    - Assay Name
    - Assay Name 2

Buttons: Cancel, Save

FIGURE 4.32: The Add New User form

Enter the following information and click the **Save** button.

- **User ID** (required)
- **Password** (required)
- **Confirm Password** (required)
- **E-mail Address** (required)
- **User Type** (required) – choose either:
  - **General** – Access to standard functionality including creating a Run Set (access does not include processing samples)
  - **Administrator** – General user access plus administrative access including user management and system settings
- **Permissions** (at least one permission is required) – choose all that apply:
  - **Run Post Hybridization** – This permission is required to operate the Prep Station and initiate the post-hybridization process for the assay(s) selected
  - **Access Reports** – This permission is required to view the Reports tab on the Web Application and download diagnostic reports for the assay(s) selected
  - **Create Run Set** – This permission is required to create a new Run Set or edit an existing Run Set on the Web Application for the assay(s) selected



**NOTE:** Administrators do not automatically have permission to access diagnostic reports and initiate post-hybridization processing on the Prep Station; permission must still be assigned. Administrators are able to assign permissions to their own accounts.



**NOTE:** Unique permission settings can be assigned for each assay type available on the system. For example, a user may be able to create a Run Set for all assays on their system, initiate post-hybridization for a single assay, and be unable to access any reports.

The Manage Users function allows an administrator to edit or delete users. To manage existing users, select the **Admin** option from the menu bar at the top of the page and click on **Manage Users**.

>>> The Manage Users screen will appear ([FIGURE 4.33](#)).

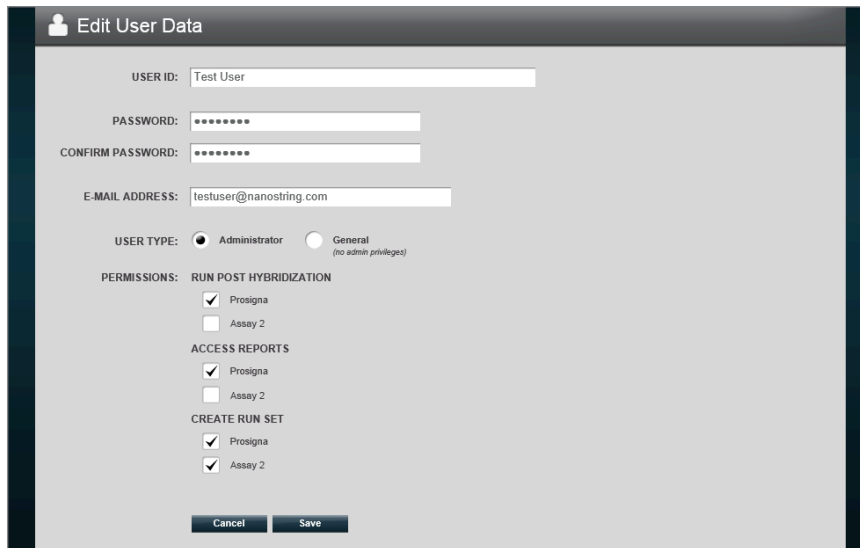
The screenshot shows the 'Manage Users' interface. At the top, there is a navigation bar with 'Dashboard', 'Runs', 'Samples', 'Reports', 'Admin', 'My Profile', and 'Logout'. Below this is a 'Manage Users' section with 'New', 'Edit', and 'Delete' buttons. The 'Edit' button is highlighted with a red box. Below the buttons is a table of users:

USER ID	DATE ADDED ^	LAST MODIFIED	USER TYPE	EMAIL
Gamma	9/12/2014 1:55:01 PM	9/12/2014 1:55:01 PM	General	gamma@nanosttring.com
Beta	9/12/2014 1:54:47 PM	9/12/2014 1:54:47 PM	General	beta@nanosttring.com
Alpha	9/12/2014 1:54:28 PM	9/12/2014 1:54:28 PM	General	alpha@nanosttring.com
Test User	9/12/2014 12:29:00 PM	9/12/2014 12:29:00 PM	Administrator	smackenzie@nanosttring.com

**FIGURE 4.33:** The Manage Users page and the location of the **Edit** button

To edit a user, select the User ID link or select the row for the specified user and click the **Edit** button.

>>> The Edit User Data form will appear (**FIGURE 4.34**).



**FIGURE 4.34:** The Edit User Data form

Edit any of the following information and click the **Save** button to save any changes made.

- **User ID**
- **Password**
- **Confirm Password**
- **E-mail Address**
- **User Type**
- **Assay Permissions**
  - **Run Post Hybridization**
  - **Access Reports**
  - **Create Run Set**

To delete a user, open the Manage Users page, select the row for the appropriate user, and click the **Delete** button (FIGURE 4.35).

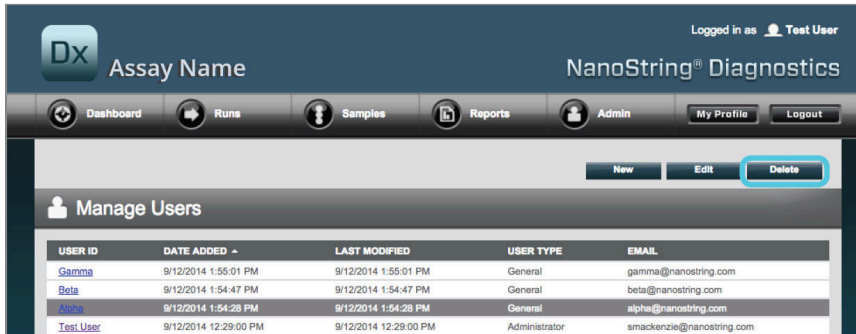


FIGURE 4.35: Location of the **Delete** button on the Manage Users page

>>> A confirmation message will appear (FIGURE 4.36).

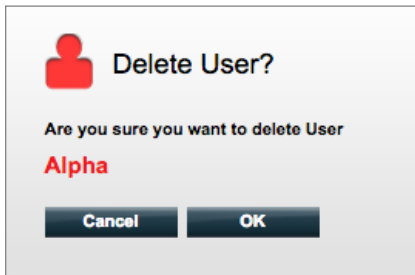


FIGURE 4.36: The 'Delete User?' prompt

Click **OK** to delete the user or click **Cancel** to return to the Manage Users page.

## System Settings

System settings are available to users with the Administrative user type. The System Settings page supports four main functions, which are displayed in separate tabs:

- **Date and Time** (default tab)
- **E-mail Settings**
- **SSH Settings**
- **IP Address**

To access the System Settings page, select the **Admin** option in the top menu bar and select the **System Settings** option (FIGURE 4.37).

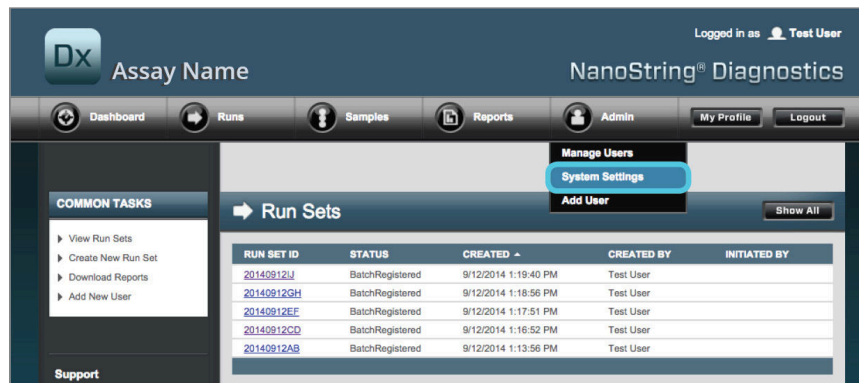


FIGURE 4.37: Location of the **System Settings** option in the **Admin** sub-menu

>>> The System Settings page will appear, with the default **Date and Time** tab visible (FIGURE 4.38).

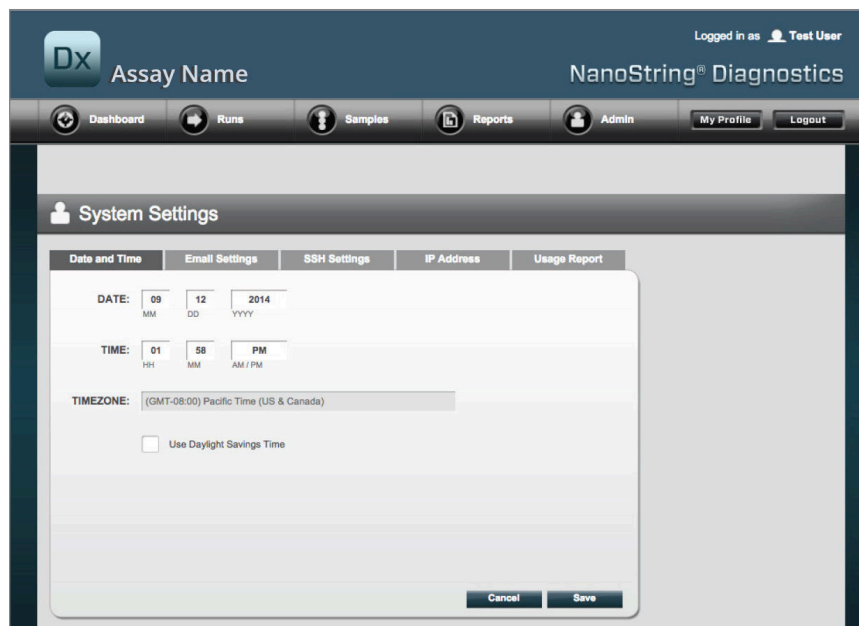


FIGURE 4.38: The **Date and Time** tab on the System Settings page

## Date and Time

Date and time settings are initially set when NanoString personnel set up the nCounter. Change these settings only when necessary. Click **Save** to save any changes or **Cancel** to discard changes and perform another function.



**NOTE:** Administrators cannot adjust the Time Zone or Daylight Saving Time options. Contact NanoString Support if these values need to be adjusted.



**NOTE:** Changing the date and/or time in the nCounter web application adjusts these values on the Digital Analyzer and Prep Station, as well. Take care when making changes to these settings.



## E-mail Settings

E-mail settings (FIGURE 4.39) must be configured in order for the nCounter system to successfully send automated e-mails for status updates such as Prep Station run completion or diagnostic report notifications.

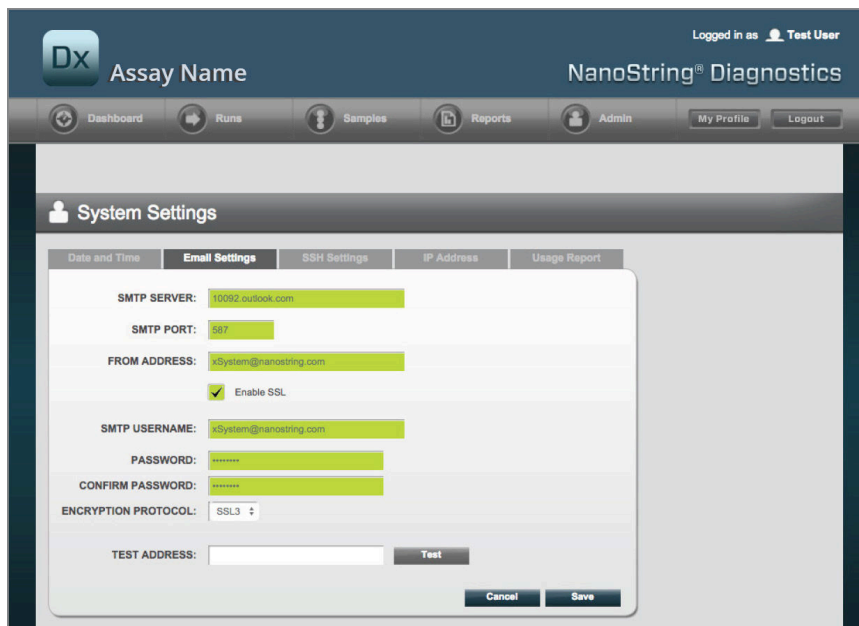


FIGURE 4.39: The E-mail Settings tab

The following fields are available:

- **SMTP Server** (required) – (Simple Mail Transfer Protocol) – E-mail server name
- **SMTP Port** (required) – Port used for e-mail server
- **SMTP Address** (required) – Address from which automated e-mails are sent
- **Enable SSL** – Check if using a secure e-mail server
- **SMTP Username** – Account name for secure e-mail server (required if **Enable SSL** is checked)
- **Password** – Password for SMTP username (required if **Enable SSL** is checked)
- **Confirm Password** – Same password as above (required if **Enable SSL** is checked)
- **Encryption Protocol** – These options effectively encrypt e-mail data sent over the Internet between the client and e-mail server. The following are possible values for encryption protocol (a selection is required if **Enable SSL** is checked):
  - **SSL3 (Secure Socket Layer)** – Widely used encryption protocol
  - **TLS (Transport Layer Security)** – More secure encryption protocol than SSL
- **Test Address** (optional) – This can be used to test if the e-mail settings are configured correctly. Enter an e-mail address you have access to and press the Test button. Check your e-mail account to confirm that the settings are working and the test e-mail was received.

## SSH Settings

The **SSH Settings** tab (FIGURE 4.40) allows an Administrator to configure the Secure Shell server (SSH server). The SSH server allows users to programmatically pull nCounter report data or system backup data from the system in a secure manner. It also allows for unlimited concurrent client connections. See the section "LIS Integration" below for more information.

FIGURE 4.40: The SSH Settings tab

The following fields are available:

### Pre-configured fields:

- **SSH Host Name** – The name of the host used by the client for connecting to the SSH server
- **SSH Port Number** – The port used by the client for connection to the SSH server
- **SSH User Name** – SSH server account name used by the client for authenticating the connection

### Configurable fields:

- **Enable SSH Server** – Check box for enabling or disabling the SSH server.
- **Assay / Backup** – Selection of assay report or system backup data to be accessed by the SSH server. A separate SSH user name and password is required for each assay or system data.
- **Password** – SSH server account password used by the client for authenticating the connection (required when 'Enable SSH Server' is checked)
- **Confirm Password** – Same password entered as above (required when enable SSH server is checked)

Once the **Enable SSH Server** checkbox is enabled, the Administrator can select which type of assay or backup data to configure for SSH access (FIGURE 4.41).

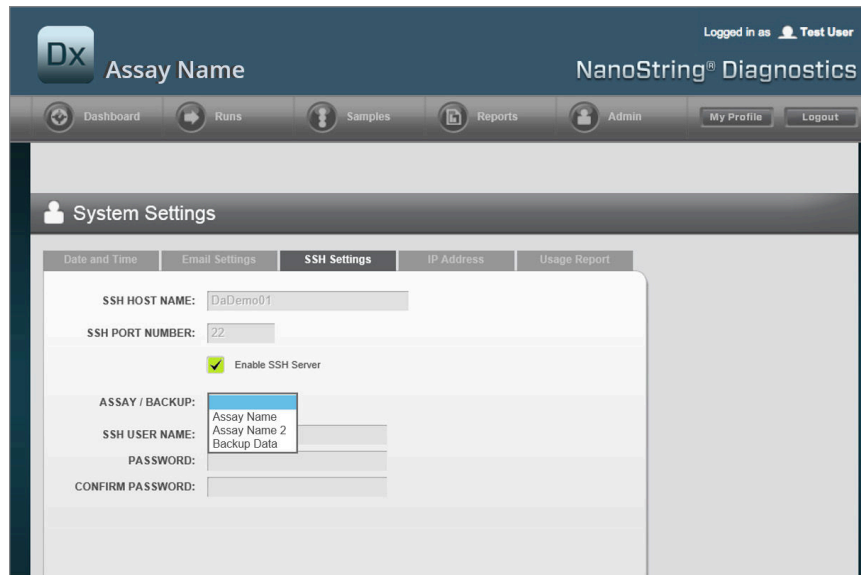


FIGURE 4.41: Assay / Backup menu is active after the **Enable SSH Server** checkbox is selected

## IP Address

IP address function (FIGURE 4.42) is an essential function to enable networking of the instruments. The Prep Station, Digital Analyzer, and nCounter web application are all in frequent communication. The IP address is the basis for setting up this communication. Avoid errors when making changes to fields under the **IP Address** tab.

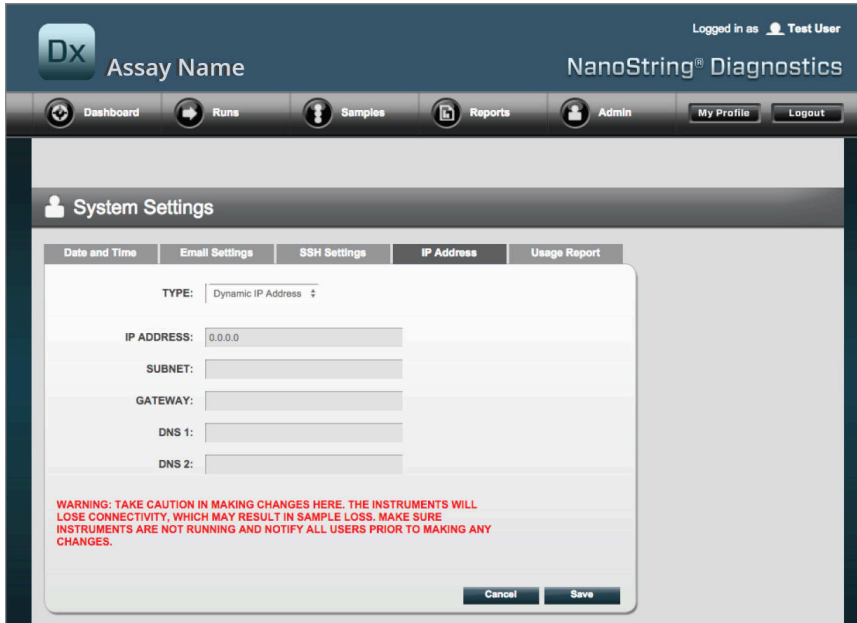


FIGURE 4.42: The IP Address tab

The following fields are available:

- **Type** – The following options are available to choose between:
  - **Static IP Address** – This requires the network administrator to set an address that will never change.
  - **Dynamic IP Address** (default) – Known as DHCP, this option allows the local network to automatically find and assign an IP address. This address is subject to change.
- **IP Address** – IP address provided by the network administrator (for Static IP address)
- **Subnet** – Subnet provided by the network administrator (for Static IP address)
- **Gateway** – Gateway address provided by the network administrator (for Static IP address)
- **DNS 1** – Domain Name Server provided by the network administrator (for Static IP address)
- **DNS 2** – A second DNS is optionally provided by the network administrator and used as a backup (for Static IP address)



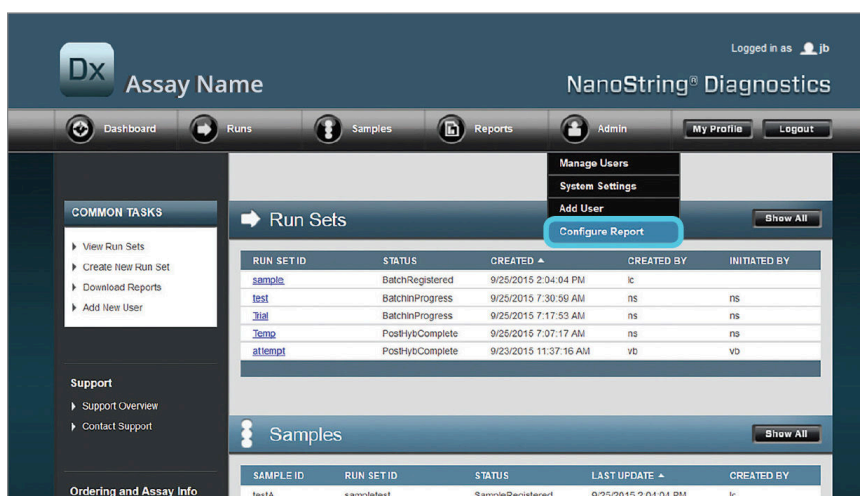
**NOTE:** A Static IP Address is particularly useful because it ensures more reliable communication between the Digital Analyzer and the Prep Station. If the **Dynamic IP Address** option is chosen, the Digital Analyzer may sometimes acquire a different IP address, giving rise to the possibility of intermittent communication issues.

## Configure Report

In many cases, organizations have common report formats standardized across all diagnostic reports produced by the organization. The system allows administrators to customize the header and footer of the report, and as an option, allows a customized signature line on the last page of the report. Administrators can define static text and include certain system-provided information about the sample. Sample parameters which are on the NanoString standard diagnostic report header may be included in custom headers and footers. Additionally, administrators may define fields which will be completed in the output PDF after download from the nCounter Dx Analysis System. These fields may be used for patient name, date of birth, or any other Personally Identifiable Information (PII) desired. (Users will need to save the completed forms outside the nCounter system as it is not currently engineered to support storage of PII). The report body, including assay results, logos, and explanatory graphs and text, may not be modified.

Each installed localized assay is customized independently. The administrator may only make changes to the assay selected at log in, though the administrator may customize any report locale installed for that assay. Changes are first made to a draft report; then, when the draft meets the organization's needs, the administrator can move the draft to production. Administrators are also able to create a new draft from the current production report, from a number of system-provided templates, or with blank header, footer, and signature area.

To access the Configure Report page, select the **Admin** option on the top menu bar and select **Configure Report** (FIGURE 4.43).



The screenshot shows the NanoString Diagnostics web interface. The top navigation bar includes 'Dashboard', 'Runs', 'Samples', 'Reports', 'Admin', 'My Profile', and 'Logout'. The 'Admin' menu is open, showing options: 'Manage Users', 'System Settings', 'Add User', and 'Configure Report' (highlighted with a blue circle). Below the menu, there are sections for 'Run Sets' and 'Samples'. The 'Run Sets' table has columns: RUN SET ID, STATUS, CREATED, CREATED BY, and INITIATED BY. The 'Samples' table has columns: SAMPLE ID, RUN SET ID, STATUS, LAST UPDATE, and CREATED BY.

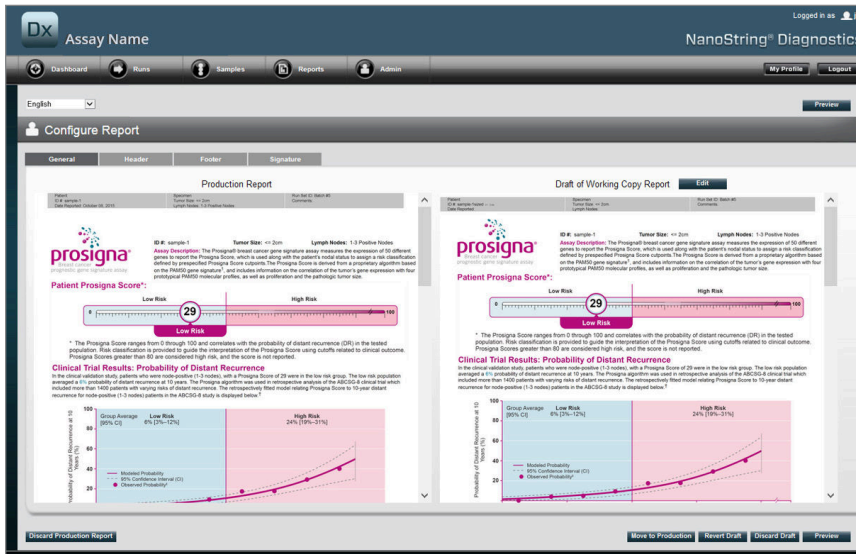
RUN SET ID	STATUS	CREATED	CREATED BY	INITIATED BY
<a href="#">sampleA</a>	BatchRegistered	9/25/2015 2:04:04 PM	lc	
<a href="#">test</a>	BatchInProgress	9/25/2015 7:30:50 AM	ns	ns
<a href="#">trial</a>	BatchInProgress	9/25/2015 7:17:53 AM	ns	ns
<a href="#">temp</a>	Pos#lybComplete	9/26/2015 7:07:17 AM	ns	ns
<a href="#">attemp1</a>	Pos#lybComplete	9/23/2015 11:37:16 AM	vd	vd

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY
testA	sampletest	SampleRegistered	9/25/2015 2:04:04 PM	lc

FIGURE 4.43: Location of the **Configure Report** option in the **Admin** menu

The Configure Report page will then appear, open to the default **General** tab (FIGURE 4.44).



**FIGURE 4.44:** The **General** tab of the **Configure Report** page (Content of report varies by regulatory clearances or approvals)

Within the Configure Report area, the following tabs are available:

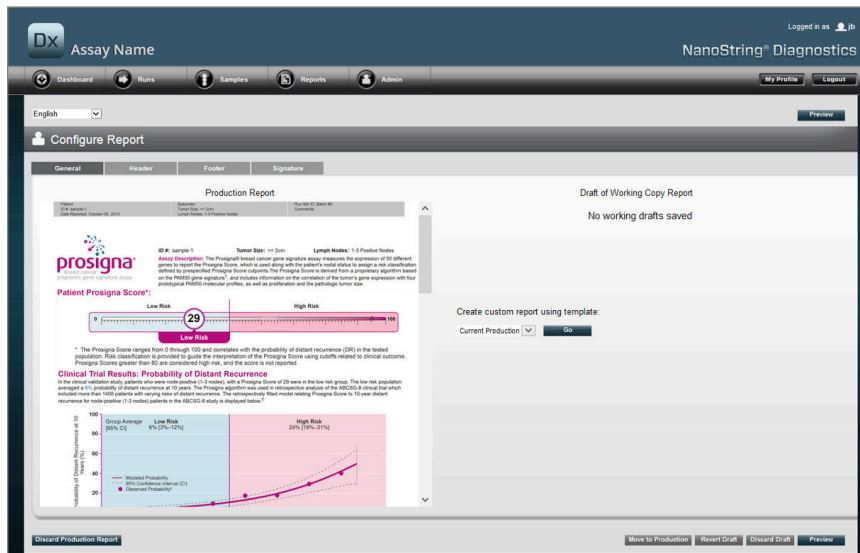
- **General**
- **Header**
- **Footer**
- **Signature**

The Header, Footer, and Signature tabs allow the user to customize individual parts of the report.

The General tab has a **Preview** button (common across all tabs), and a series of buttons to choose and control the production and draft reports:

- **Discard Production Report** – Selecting this button will remove all user-generated customization of the report and will revert to the default, nCounter Dx Analysis System-provided patient report.
- **Move to Production** – Move the current draft report to production. This erases the current production report and cannot be undone.
- **Revert Draft** – Revert all parts of the draft report (header, footer, signature if configured) to their state at the start of this editing session.
- **Discard Draft** – Remove all customization of the header, footer, and signature.
- **Preview** – Identical functionality to the “Preview” at the top of the page; displays a full-page PDF preview of the current Draft report.
- **Edit** – Opens the header editor to allow administrative users to customize their reports

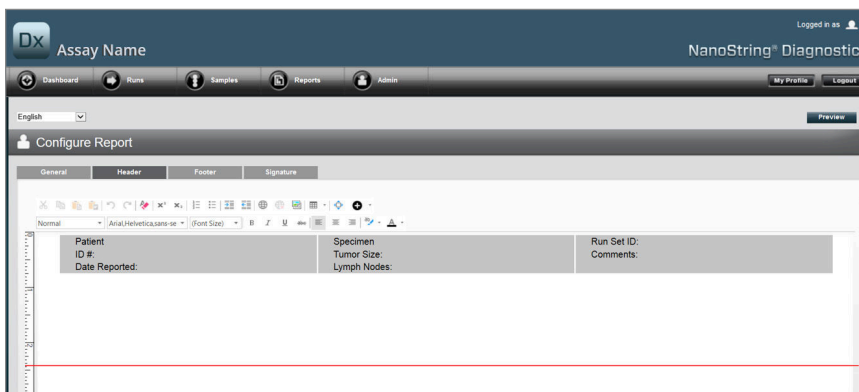
If there is no working draft in progress (See **FIGURE 4.45**), then a dropdown listing of available templates is displayed instead of the thumbnail of the draft report, along with a control to start a new draft. Drafts may be started from the current production report, the NanoString standard header and footer, blank header and footer, or one of a number of pre-supplied templates. These templates are intended to be further modified by administrators to meet their organizations' needs.



**FIGURE 4.45:** The **General** tab of the **Configure Report** page, displaying the menu for starting a new draft (Content of report varies by regulatory clearances or approvals)

## Header Tab

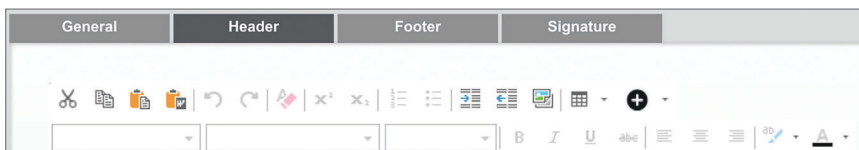
The **Header** tab allows administrators to modify the header for the report (see [FIGURE 4.46](#)).



**FIGURE 4.46:** The **Header** tab of the **Configure Report** page, displaying the NanoString standard header


The main body of the **Header** tab is a text entry area for specifying the content and layout of the customized report header. There is a vertical ruler to assist in placement of content items. The red line represents the maximum size of the header—any content below this line will be hidden by the body of the report and will not be visible. The body of the report will begin immediately following the header; unless the customized header explicitly includes blank lines, there will be no visible gap between the user-generated header content and the NanoString-supplied body. The **Preview** button may be used at any time to generate a PDF with the currently entered header fields.

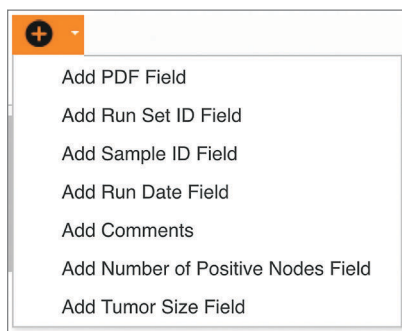
Across the top of the text entry area, the user will find standard text editing and formatting tools ([FIGURE 4.47](#)) that allow text to be inserted and formatted at both character and paragraph level, import graphic images, use tables to more precisely position content, and insert special fields



**FIGURE 4.47:** Text editing and formatting tools



When selected, the  icon displays a menu (FIGURE 4.48) of special fields which can be inserted, formatted, and positioned as needed on the report.



**FIGURE 4.48:** The **Special Fields** menu, displaying example assay-specific fields

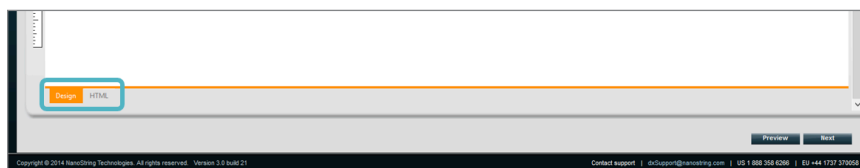
These fields are:

- **PDF Field** – In the output PDF, these are blank fields which the user can complete using standard PDF viewers (Adobe Reader, Apple OS X Preview, etc.). These fields can be used to enter any desired information about the sample, including HIPAA-protected Personally Identifiable Information (PII) such as patient name or date of birth. The edited PDF will need to be downloaded and saved to preserve such user-entered content.
- **Run Set ID** – The Run Set ID entered on the **Create New Run Set** page.
- **Sample ID** – The Sample ID entered on the **Create New Run Set** page.
- **Run Date** – The date that the sample was run on the DA. This date is automatically recorded by the nCounter Dx Analysis System.
- **Comments** – The Memo entered with the sample on the **Create New Run Set** page.
- Remaining fields are assay-specific parameters (e.g., Tumor Size and Node Count). Your specific assay may or may not have user-entered parameters.



**NOTE:** After initial placement, images and tables may be further customized or refined by modifying certain properties. These properties are accessed by right-clicking (control-clicking on systems without a right mouse button) on the object, then selecting the appropriate items from the presented menu.

At the bottom of the text entry area are a pair of tabs, **Design** and **HTML**, (FIGURE 4.49) that allow advanced users to switch between the default interactive design mode and directly editing the underlying HTML. The HTML editor may be used by advanced users to fine-tune layouts or apply affects not directly available through the interactive design mode.



**FIGURE 4.49:** **Design** and **HTML** tabs at the bottom of the text entry area

The **Preview** button at the bottom of the page functions identically to the Preview button at the top of the page. The **Next** button provides an easy way to move from tab to tab when initially entering a customized report; additionally, users may directly select the tab they desire to edit.

## Footer Tab

The **Footer** tab (FIGURE 4.50), allows administrators to modify the footer for the report. The footer is always placed at the bottom of each page, leaving any empty space between the end of the body and the start of the footer. The formatting controls available for the header are available for use in the footer area as well.

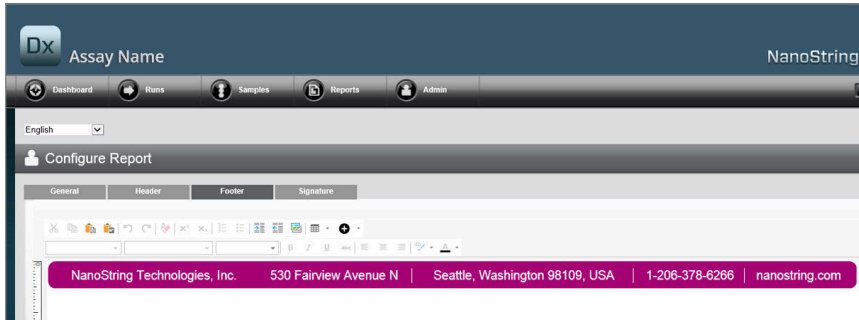


FIGURE 4.50: An example of the standard NanoString footer

## Signature Tab

The **Signature** tab allows an administrator to optionally include a signature line on the last page of the report (FIGURE 4.51). When the checkbox has been enabled, the signature line can be edited and will be included on generated PDF files. The editing tools available for the header are also available for the signature.

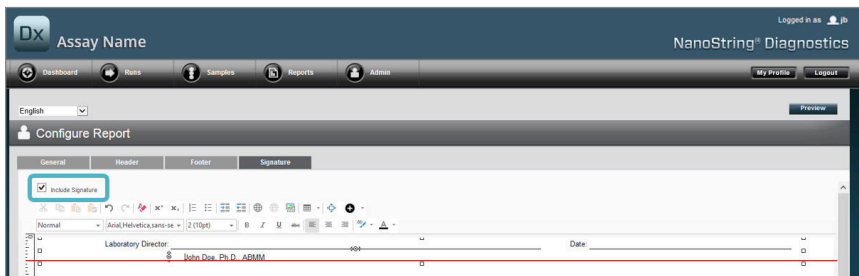



FIGURE 4.51: The Signature tab with checkbox enabled

## Header Configuration Example

To further illustrate how the header can be configured, consider the case of a laboratory with a standard header consisting of the organization logo; patient family name, given name, birth date, and gender; and assay-specific fields. This header example has been customized for a specific assay (**FIGURE 4.52**), and demonstrates how to combine and nest multiple elements and adjust their individual configuration. System-provided fields are used where available, and PDF fields are used for the PII in this example.

 530 Fairview Ave N Seattle, WA 98109, USA Tel: 206-378-6266	Family Name		Given Name	
	DOB		Gender	
	Run Set ID	Batch #5	Node Status	1-3 Positive Nodes
	Run Date		Tumor Size	<= 2cm
	Comments			

**FIGURE 4.52:** Example header

The specific steps to create this header are as follows:

1. Open the report configuration tool with **Configure Report** in the **Admin** menu.
2. If there is no draft in progress, skip to step 4.
3. If there is a current draft in progress, select the **Discard Draft** button at the bottom right of the page. This will delete the current draft and does not have an “undo” function. Select **OK** to confirm your intent to delete the draft.
4. Create a custom report. For this example, choose the **Blank** template, then select **Go**.
5. When the new draft is created, select the **Header** tab to edit the header.
6. Click in the content area to start editing.
7. Select the table tool to create a new table.
8. In the “Insert Table...” dialog, choose the following, then select **OK** when all parameters are entered:
  - a. 5 columns
  - b. 5 rows
  - c. Width: Custom, 90%
  - d. Border color: 4th entry in the 3rd row, “#339966”
  - e. Border size: 2
9. Make sure the cursor is in the upper left cell of the newly created table.
10. Select the image tool to import an image.
11. In the “Insert Image” dialog, choose the following, then select **Insert** when all parameters are entered:
  - a. For the source, choose “From your computer”
  - b. Select “Browse...”, then browse to the image you wish to use for your logo.
12. After the image has been inserted, right click and select **Change Image....** In the “Change Image” dialog which is opened, check the **More options** box to enable fine-tuning of the image display parameters.
  - a. Set **Size**: to “Custom Size”.
  - b. Set the width and height such that the width is less than 250 pixels and the height is less than 300 pixels. The exact values will depend on the relative height and width of the image you have chosen.
  - c. Set the **Position**: to “Left-aligned”.
  - d. Select **Change** to apply these changes.

13. Right click on the logo, then select **Merge Down** from the presented menu. This will merge the top 2 cells of the leftmost column of the table. Repeat until there is only 1 cell in the leftmost column of the table.
14. Enter the address or any additional text below the image.
15. Click in the topmost cell of the second column.
16. Enter the desired text label, "Family Name" and select icon to right-align the text.
17. Click in the second cell of the second column, then enter "DOB" and right-align.
18. Click in the third cell of the second column, then enter "Run Set ID" and right-align.
19. Click in the fourth cell of the second column, then enter "Run Date" and right-align.
20. Click the last cell of the second column, then enter "Comments" and right align.
21. Click in the first cell of the third column, then select **Add PDF Field** from the + menu.
22. Click in the second cell of the third column, then select **Add PDF Field** from the + menu.
23. Click in the third cell of the third column, then select **Add Run Set ID Field** from the + menu.
24. Click in the fourth cell of the third column, then select **Add Run Date Field** from the + menu.
25. Click in the last cell of the third column, then select **Add Comments** from the + menu.
26. Right click in the last cell of the third column, then select **Merge Right**. Repeat so that the cell spans the remainder of the table.
27. Click in the first cell of the fourth column, then enter "Given Name" and right-align.
28. Click in the second cell of the fourth column, then enter "Gender" and right-align.
29. Click in the third cell of the fourth column, then enter "Node Status" and right-align.
30. Click in the fourth cell of the fourth column, then enter "Tumor Size" and right-align.
31. Click in the first cell of the last column, then select **Add PDF Field** from the + menu.
32. Click in the second cell of the last column, then select **Add PDF Field** from the + menu.
33. Click in the third cell of the last column, then select **Add Number of Positive Nodes Field** from the + menu.
34. Click in the fourth cell of the last column, then select **Add Tumor Size Field** from the + menu.
35. Select the **Preview** button at the top or bottom of the window to view a sample of the configured report.

## Report Integration with External Systems

The nCounter Dx Analysis System supports direct integration with existing report generation and management systems, such as Laboratory Information Systems (LIS). Using SFTP for file transfers, external automated processes may retrieve the output report (either in whole or in part), as well as the system backup archive.

The retrieved reports are in formats suitable for integration with existing processes and systems. For downstream integration, the system makes the report available as a PDF file identical to that which can be downloaded through the web GUI, as a PDF of the NanoString default report (if different from the current report), and as a modular set of graphic files which can be incorporated into downstream system output.

## System Access

For LIS integration, the **SSH Server** must be enabled (see **System Settings**). The username and password specified in **SSH Settings** for the assay can be used with any file transfer tool which supports SFTP (SSH File Transfer Protocol). This protocol is widely supported by such tools as WinSCP and PuTTY PSFTP on Windows and Transmit on Mac OS X. Access to the SSH Server is read-only: no files may be modified, uploaded, or moved.

**Assay-specific files:** After gaining access to the SSH server, the assay-specific files are arranged as follows:

Assay directory	Description and contents
/(login directory)	Top-level directory, contains XML export files and all subdirectories listed below
/pdf	PDF files. For each completed sample, the NanoString standard report will always be present; if a customized report has been defined, the PDF of that report will also be in this directory.
/image	Organizing directory for modular images.
/image/<basename>	One directory for each sample, named as described below. Each directory contains a series of images which compose the full assay report and an HTML file to assemble the images in the original order. See below for details.
/deprecated	All files which have been deprecated by using the <b>Edit an Analyzed Sample</b> function to generate a re-run of the report algorithm or other update. These are the original, unchanged files.

## Modular Images

The /image/<basename> directories contain a series of high-resolution (300 dpi+) images which may be used by advanced organizations. Header, footer, and signature images may be modified to include organization-specific information, or may be completely replaced by organization-provided equivalents, or may be omitted entirely. Body images may not be modified and should be used complete and as-is only.

The supplied HTML file serves as an “inventory” and may be used to ensure that downstream systems have retrieved body images and/or headers and footers for every page of the report. It can serve as a template for further modifications.

## Filenames

All formats share a common basename format:

<YYMMDD>\_<cartridgeID>\_<scan>\_<sampleName>\_<Lane>

Where:

<YYMMDD>	Last 2 digits of the year, 2-digit (numeric) month, 2-digit numeric day
<cartridgeID>	Barcode found on the Cartridge
<scan>	Assigned by the system. Typically defaults to 1.
<sampleName>	SampleID as entered in the <b>Create New Run Set</b> or <b>Edit Run Set</b> pages of the web app.
<Lane>	Lane number from the Cartridge.

The filename extensions indicate the file format:

Extension	Contents
.xml	XML. Contains unformatted sample-specific report data.
.pdf	PDF. Fully-formatted, potentially customized report for each sample.
.png	Portable Network Graphics formatted images
.html	HTML formatted files. Used to specify order and placement of image files.
.zip, .zXX	Encrypted ZIP archive of backup data (XX represents a number)

Image filenames have an additional component appended after the <basename> portion. This component serves to identify the precise contents of the file. Elements listed in square brackets (“[ ]”) are optional and may not exist for all reports. The additional elements for image files are:

Component	Contents
_head	Header
_body#	Body content (# indicates page number)
_foot	Footer
[_sig]	Signature line
[_head2]	Secondary header (revised reports only)
[_foot2]	Secondary footer (revised reports only)

In certain cases, additional components may exist between the filename and the extension. These components indicate additional detail about the file, and will appear in the order below:

Component	Details
[_c]	Custom report. Only applies to PDF files. If absent, files are NanoString standard.
[_rev]	Revised report. Blank for unrevised original reports.
[_<lang>[_<locale>]]	Optional language and optional locale for that language. If no language is specified, _en is the default.

## Assay Export (XML) Files

The export XML file is intended for advanced users who need access to the underlying data elements, and is typically useful when integrating results with external systems. It is expected that most users will not need access to this level of detail and will be able to either use a customized PDF file or the modular image files to meet their customization needs. The information in these files is unique for each assay. Organizations and individuals using this export should contact NanoString at [dxsupport@nanosttring.com](mailto:dxsupport@nanosttring.com) for assay specific documentation and to ensure that all appropriate regulatory guidance is properly followed.

## Editing Sample Information

Occasionally, a report may need to be generated again if one or more sample parameters (e.g., for Prosigna®, # of Positive Nodes (Nodal Status) or Tumor Size) was entered incorrectly. These parameters may be changed in the Create/Edit Run Set page before the sample is started on the Prep Station, but after the sample has started on the Prep Station, only an administrator can edit these fields and generate a new report. This can only be done once per sample. The new report will be marked as a revised report, and for reference, will include the obsolete parameters and results. In addition, if the Prep Station or Digital Analyzer has been initiated prior to realizing the parameters were entered incorrectly, **do not abort the run**, but allow it to fully complete, and then edit the sample parameters for the revised run.



**IMPORTANT:** The user must have administrator privileges and “Create Run Set” privileges for the appropriate assay in order to edit the sample and re-run the report. The report can only be re-run once.

First, find the sample that is to have its parameters modified. This may be done either directly on the Samples page or through the Run Sets page. To find the sample on the Samples page, you may wish to filter the list of scans to make it easier to find the sample you are interested in. If you wish to use the runs to find the sample, select View Run Sets on the Runs dropdown menu. On the Run Sets page, select the Run Set of the sample you want to edit. It is also possible to select a single report from the Reports page.

Once you are on the Samples or Reports page, select the item you want to edit.  
(The sample cannot be a Reference sample.)

>>> The **Edit Sample** button will become active (**FIGURE 4.53**).

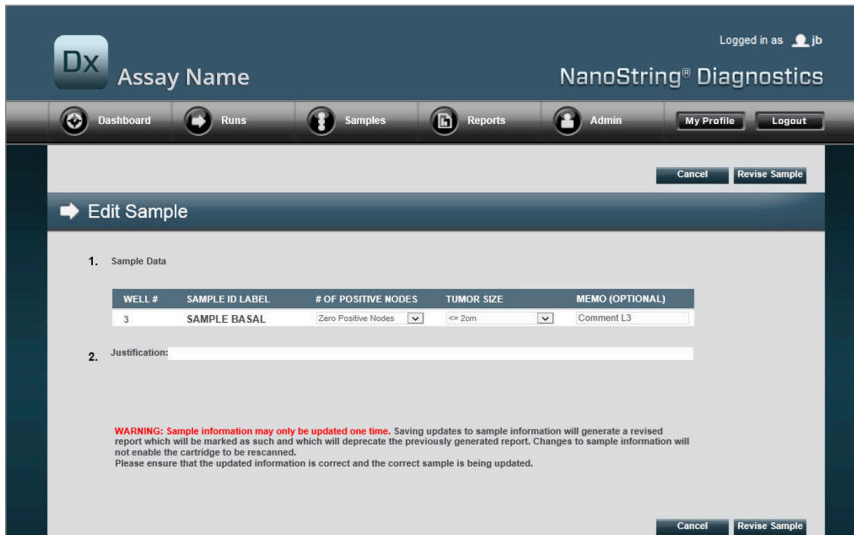
The screenshot shows the NanoString Diagnostics web interface. At the top, there is a navigation bar with 'Assay Name' and 'NanoString® Diagnostics'. Below the navigation bar, there are tabs for 'Dashboard', 'Runs', 'Samples', 'Reports', 'Admin', 'My Profile', and 'Logout'. The main content area displays a table titled 'Samples of Study Ideal C'. The table has columns for 'SAMPLE ID', 'RUN SET ID', 'STATUS', 'LAST UPDATE', 'CREATED BY', 'LANE', 'MEMO', and 'PREP STATION'. The 'Edit Sample' button is active and highlighted in the top right corner of the table area.

SAMPLE ID	RUN SET ID	STATUS	LAST UPDATE	CREATED BY	LANE	MEMO	PREP STATION
Reference1	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	1		1112D0032
Reference2	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	2		1112D0032
Sample Basal	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	3	Comment L3	1112D0032
Sample Her2	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	4	Comment L4	1112D0032
Sample LumA	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	5	Comment L5	1112D0032
Sample LumB	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	6	Comment L6	1112D0032
Sample LumABFlip	Study Ideal C	ReportComplete	10/15/2015 2:05:16 PM	ns	7	Comment L7	1112D0032

**FIGURE 4.53:** Edit Sample button is active

Click the **Edit Sample** button.

>>> The Edit Sample page will appear (FIGURE 4.54).



The screenshot shows the 'Edit Sample' page in the NanoString Dx Analysis System. The page header includes the 'Dx' logo, 'Assay Name', and 'NanoString® Diagnostics'. The user is logged in as 'jb'. The navigation menu includes Dashboard, Runs, Samples, Reports, Admin, My Profile, and Logout. The main content area is titled 'Edit Sample' and contains a table with sample data and a justification text box.

WELL #	SAMPLE ID LABEL	# OF POSITIVE NODES	TUMOR SIZE	MEMO (OPTIONAL)
3	SAMPLE BASAL	Zero Positive Nodes	<= 2cm	Comment L3

2. Justification:

**WARNING: Sample information may only be updated one time.** Saving updates to sample information will generate a revised report which will be marked as such and which will deprecate the previously generated report. Changes to sample information will not enable the cartridge to be rescanned. Please ensure that the updated information is correct and the correct sample is being updated.

FIGURE 4.54: Edit Sample page

The sample parameter fields (**# of Positive Nodes** and **Tumor Size** in this example) and **Memo** (for adding comments, if desired) can be revised. Use the input controls to revise one or more fields. After the field has been revised, the Justification text box will be active. The administrator must enter a justification in order to revise the sample.



**IMPORTANT:** Note the warning on this screen:

**WARNING: Sample information may only be updated one time.** Saving updates to sample information will generate a revised report which will be marked as such and which will deprecate the previously generated report. Changes to sample information will not enable the cartridge to be rescanned. Please ensure that the updated information is correct and the correct sample is being updated.



Please ensure that the correct sample is being updated and the revised fields are correct. Once a justification is entered, click the Revise Sample button. This will bring up a final confirmation of the revision (FIGURE 4.55).

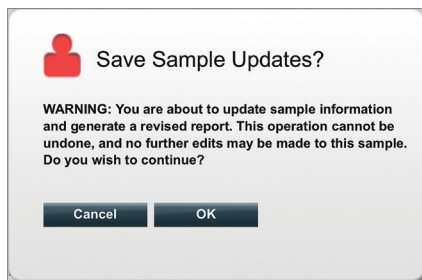


FIGURE 4.55: Save Sample Updates confirmation



**NOTE:** Revising the sample information does not require or allow the Cartridge to be re-scanned in the Digital Analyzer.

A revised report will be generated based on the updated parameters. The revised report will be marked as such, and will also include the original, obsolete parameters and results. When the revised report has been generated, it will replace the original report on the Report download page. Revised reports are indicated by a \* after the Sample ID (FIGURE 4.56). The original report will be retained on the system but will no longer be available for download from the Reports page.

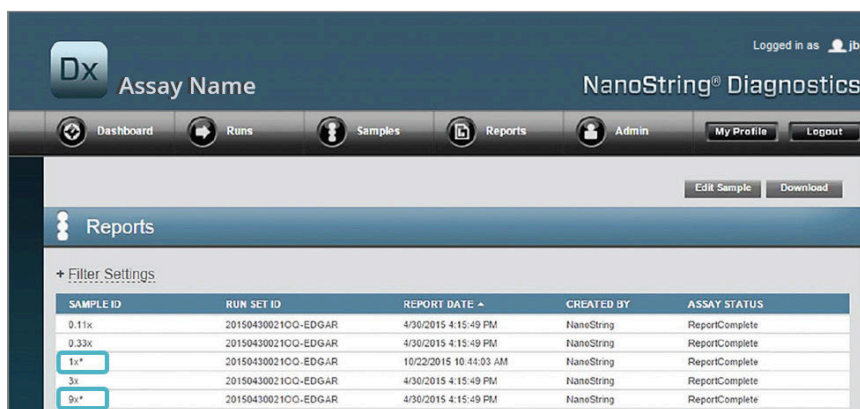


FIGURE 4.56: Reports list displaying updated reports. In this example, 1x\* and 9x\* are reports generated from running the algorithm a second time with updated parameters

## System Backup Archive

System backup data is available as an encrypted archive on the nCounter system’s SSH server. This encrypted backup is automatically created after reports are generated for each nCounter Cartridge.

To ensure that the backup archive is available off-instrument, the customer is responsible for copying it to an off-instrument location using the nCounter SSH server function.

In the unlikely event that the nCounter Digital Analyzer fails or requires system restoration, authorized NanoString service engineers can use the backup archive – when stored off-instrument by the customer – to restore nCounter system configuration and assay data.

- To ensure that the backup data is available in the event of a system failure, IT administrators will need to arrange a regular scheduled “pull” of the encrypted backup data from the nCounter system to their own internal networked server. (This would rely on access to the nCounter SSH server and a scheduled SFTP pull of the backup data.)
- Before scheduled “pulls” can be executed, the customer must first configure the Backup Data aspect of nCounter SSH Server functionality (see **FIGURE 4.41**).
  - **Note:** The SSH Backup Data option is a separate feature from the SSH Assay Data feature. (Assay reports, which are also available via the nCounter SSH server, do not contain system backup data.)
- To access the backup archive, IT administrators will need to use their SSH client of preference:
  1. Log into the Dx system using the appropriate “Backup Data” nCounter SSH account information.
    - This logs the user into the root folder (“/”).

The subfolder “/SystemBackup” will be visible.

Backup directory	Description and contents
/Backup/SystemBackup	Top-level directory, contains the current version of the backup archive

2. Change directories to “/SystemBackup”
  - a. The backup archive will now be visible (e.g. KS001\_20160930-150932.zip)
  - b. The backup archive should be copied to a safe, off-instrument location using the SSH Backup Data option (see above).
  - c. Only the most recent backup archive needs to be retained. (Backup archives are cumulative. Over time, backup archives will grow in size as the nCounter system processes more samples.)
3. For nCounter systems containing, large amount of information, the archive may be split into multiple files.
  - a. **All** archive files in the SystemBackup folder will need to be copied to a safe, off-instrument location.

# 5 Operating the Prep Station

## A. Prior to Initiating a Run

### Waste Removal

Prior to starting a new run, ensure that the waste containers have been emptied. Empty waste containers are required for every run.



**CAUTION:** If waste containers are not emptied, tips could come into contact with waste liquids and contaminate samples, or excess tips could pile up and cause a system malfunction.



**CAUTION:** Used plastic ware such as reagents, Cartridges, and pipetting tips must be collected and disposed of properly in accordance with local safety regulations and laboratory procedures.

1. Remove the combined waste receptacle by lifting it straight up and out of the Prep Station.
2. Remove the liquid waste container from the combined receptacle by using the latch on the front and dispose of the liquid appropriately.
  - Tips should be discarded into the appropriate waste receptacle as outlined in the local organization's laboratory procedures.
  - If biohazardous samples are not being used in the system—and if permitted by the laboratory procedures—liquid waste may be disposed of in the sink or other drain.
3. Verify that the plastic rack holding the used piercers, tip sheaths, Reagent Plates, and strip tubes from the previous run have all been removed from the deck.

### Consumables Required

The consumables required for each run are available as part of the test kit. The kit contains the reagents and consumables required to process 1, 2, 3, 4, or 10 patient samples.

The components of a test kit required to operate the Prep Station include:

- CodeSet Barcode (included inside CodeSet box)
- Sample Cartridges
- Reagent Plates
- Pipette Tips
- Tip Sheaths
- 12-Tube Strips and Caps
- Cartridge Adhesive Covers

## B. Initiating a Run

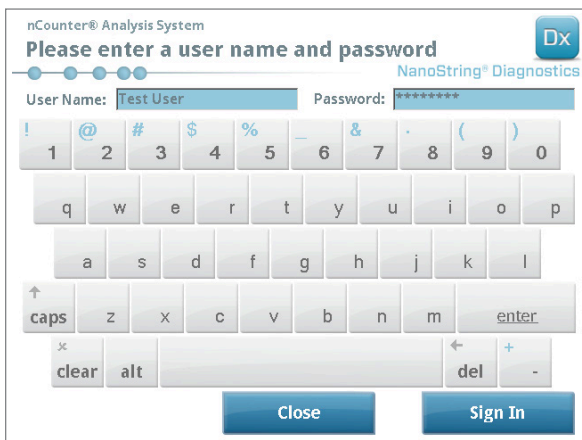
The following steps summarize the workflow beginning from the Welcome screen on the Prep Station touchscreen.

1. To process samples using the Prep Station, a user must log on to the instrument. In order to log on, touch **Main Menu** on the Welcome Screen.



**FIGURE 5.1:** The Prep Station 'Welcome' screen

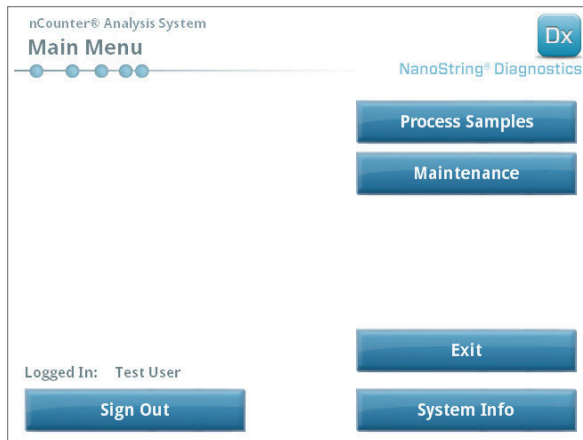
2. Enter a valid user name and password and touch **Sign In**.



**FIGURE 5.2:** The sign in screen

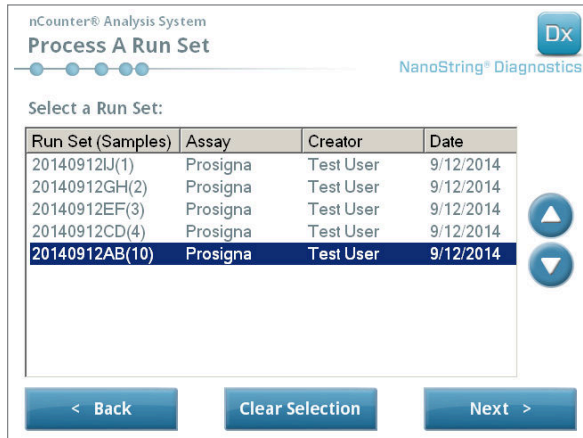
>>> The Main Menu will appear (**FIGURE 5.3**).

- To set up a new run, touch **Process Samples** from the Main Menu.



**FIGURE 5.3:** The Prep Station Main Menu

>>> The 'Process A Run Set' screen will appear.

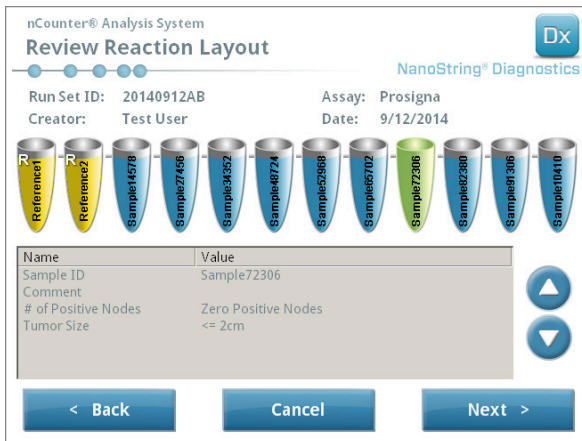


**FIGURE 5.4:** The 'Process A Run Set' screen displays the name of each Run Set, the assay type, and the number of samples it contains.

**NOTE:** The **Exit** button will only appear on the Welcome screen and Main Menu if the user has the nCounter Dx Analysis System with FLEX configuration (see *Chapter 3 – Selecting the Instrument Mode*).

- Select the Run Set to be processed by touching the Run Set name. Use the arrow keys on the right side of the screen to scroll through the selections. Touch **Next** to continue.

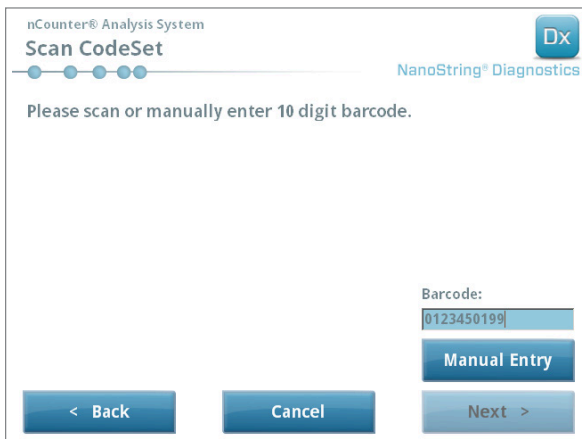
>>> The 'Review Reaction Layout' screen will appear.



**FIGURE 5.5:** The 'Review Reaction Layout' screen with two reference samples (yellow) and 10 patient samples (blue). One patient sample is selected (green).

- Touch individual samples to view their details. Verify that the Run Set and sample information are correct (**FIGURE 5.5**). If not, return to the web application and make the appropriate corrections. (First touch **Cancel** on the Prep Station to make them available for editing.) If they are correct, touch **Next**.

>>> The 'Scan CodeSet' screen will appear.



**FIGURE 5.6:** The 'Scan CodeSet' screen

6. The barcode for the CodeSet must be scanned before proceeding. Hold the barcode of the CodeSet in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is read. When the barcode is successfully entered, the barcode number will appear in the box (FIGURE 5.6).

**NOTE:** The CodeSet barcode must match the CodeSet Kit Number entered when the Run Set was created using the web application (FIGURE 4.19).

>>> The 'Reagents And Cartridge' screen will appear.

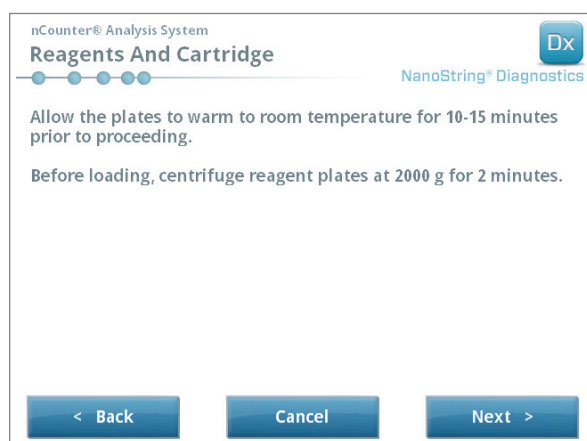


FIGURE 5.7: The 'Reagents And Cartridge' screen

7. Cartridges and Reagent Plate(s) (FIGURE 5.8) must be at room temperature prior to processing.
  - a. Remove the nCounter Reagent Plates from storage at 4°C and the nCounter Cartridges from storage at -20°C. Allow them to equilibrate to room temperature for 10–15 minutes.

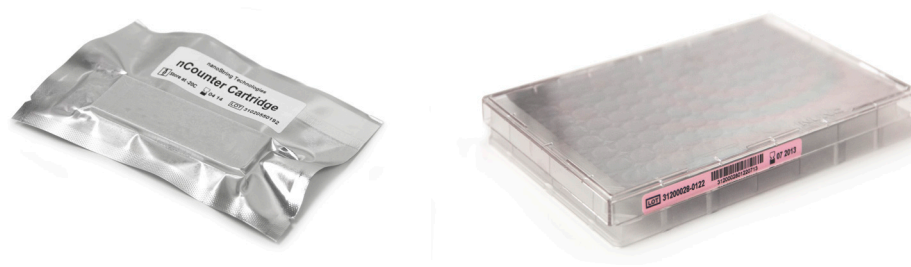


FIGURE 5.8: A sealed Sample Cartridge (left) and Dx Reagent Plate (right)

**NOTE:** Only one Reagent Plate is required for runs performed using a 1-, 2-, 3-, or 4-test.

**NOTE:** Do not open the Cartridge pouch until it has reached room temperature. This will prevent condensation from forming on the Cartridge.

- b. Centrifuge the Reagent Plates at 2000 x g for 2 minutes to collect liquids at the bottom of the wells prior to loading the Reagent Plates onto the Prep Station deck.
  - c. While the Cartridges and Reagent Plates come to room temperature, continue setting up the Prep Station. Touch **Next**.
- >>> The 'Waste Receptacles' screen will appear.

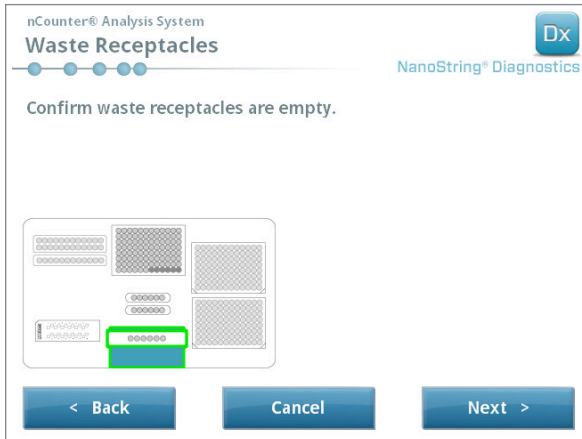


FIGURE 5.9: The 'Waste Receptacles' screen

- 8. Make sure the disposables from the previous run have been appropriately discarded. Press **Next**.
- >>> The 'Scan Reagent Plate' screen will appear.

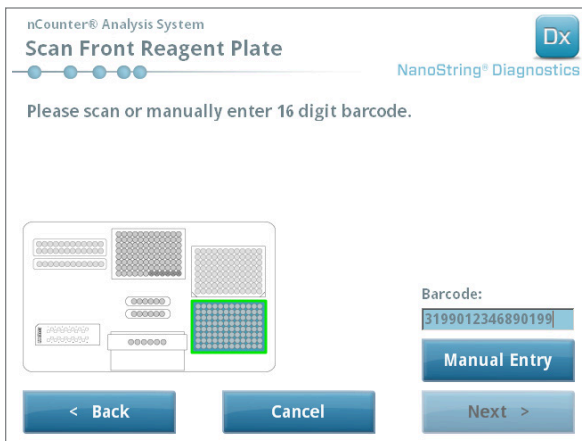


FIGURE 5.10: The 'Scan Reagent Plate' screen



9. Instructions for the 'Reagent Plate' screen:

- a. The barcode for the Reagent Plates must be scanned before proceeding. Hold the barcode in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is recorded. When the barcode is successfully recorded, the barcode number will appear in the box and the **Manual Entry** button will change to **Clear Entry**.

If you encounter any problems scanning the barcode, it may be entered manually. Touch **Manual Entry**; a numeric keypad will appear. Touch the appropriate buttons to enter the number. If you make a mistake, touch **del** to backspace, or **clear** to start over. Press **enter** when finished.

- b. Remove the clear plastic lids and place the Reagent Plates on the deck as indicated on the screen (**FIGURE 5.10**).

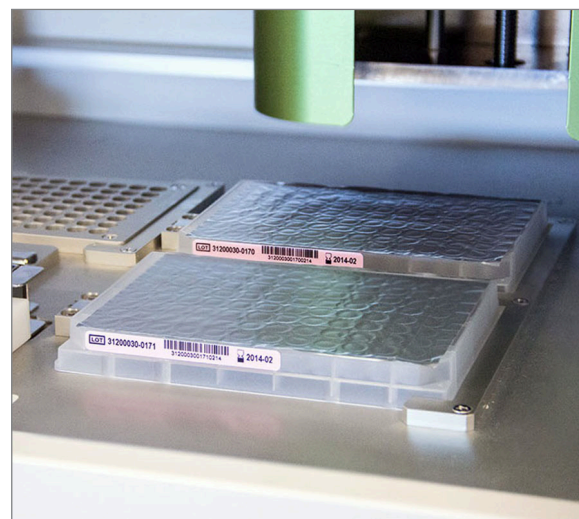
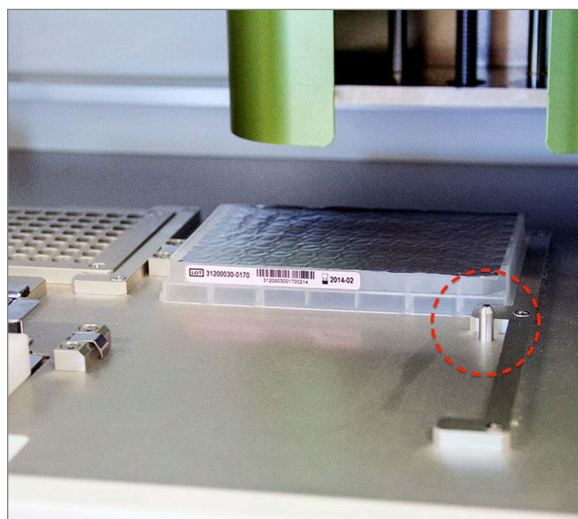
The deck has alignment pins that will allow the Reagent Plates to sit flat only if they are in the correct orientation. The Reagent Plate should be oriented with the barcode facing the user (**FIGURE 5.11**). If the Reagent Plate is placed in the wrong direction, the Prep Station will pause the protocol at the validation step until the user intervenes.



**NOTE:** Only one Reagent Plate is required for runs performed using a 1-, 2-, 3-, or 4-test kit. For these kits, load the Reagent Plate into the front position (nearest the user) on the Prep Station deck



**NOTE:** The Prep Station will not accept barcodes for Reagent Plates that have expired. Make sure the Reagent Plates are used prior to the expiration date.



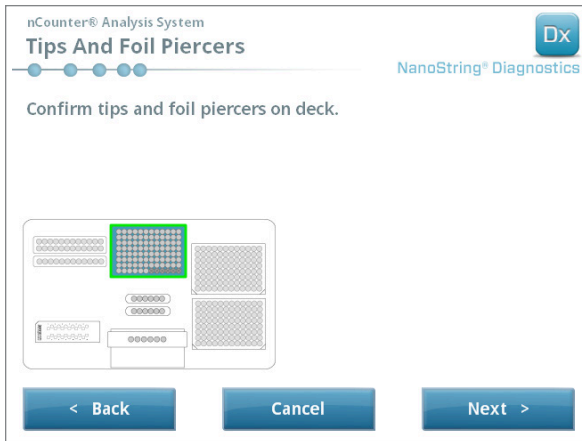
**FIGURE 5.11:** Use the positioning pins to ensure correct placement of the Reagent Plates.



**IMPORTANT:** Do not remove the foil or pierce the wells on the Reagent Plates. The Prep Station pierces the aluminum foil during processing.

- c. Touch **Next**.

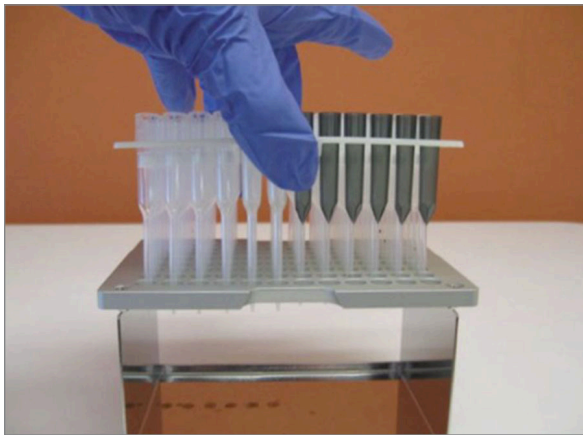
>>> The 'Tips and Foil Piercers' screen will appear (**FIGURE 5.12**).



**FIGURE 5.12:** The 'Tips And Foil Piercers' screen

**10.** Instructions for the 'Tips and Foil Piercers' screen:

- a. Remove the metal tip carrier from the Prep Station deck by lifting straight up.
- b. Place the tips and the foil piercers into the carrier. Hold the plastic tip rack by the center tabs, hold the tip rack over the metal holder, and slowly lower the tips into the metal holder. It is helpful to place the carrier at eye level to align the plastic tips (**FIGURE 5.13**).

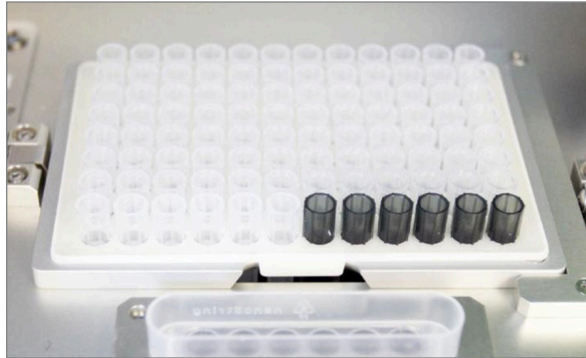


**FIGURE 5.13:** Insert the tips and foil piercers into metal tip carrier



**NOTE:** Each box contains two nested sets of tips; each side of the box contains one set of tips. When opening the box, hold a hand firmly over the bottom of the box to avoid accidentally spilling the second set of tips.

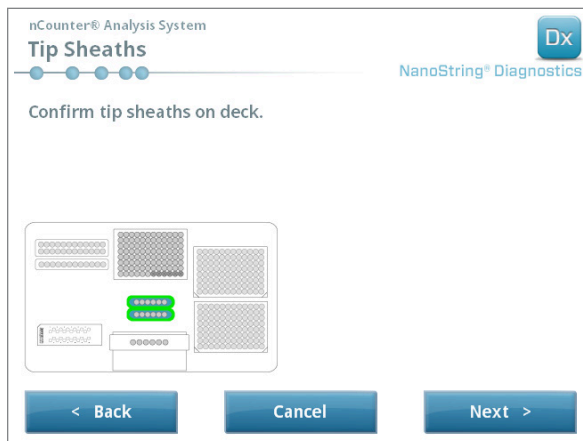
- c. Replace the loaded metal tip carrier back onto the Prep Station deck with the foil piercers closest to the front of the deck (**FIGURE 5.14**).



**FIGURE 5.14:** Proper placement of rack containing pipette tips and foil piercers

- d. Touch **Next**.

>>> The 'Tip Sheaths' screen will appear (**FIGURE 5.15**).



**FIGURE 5.15:** The 'Tip Sheaths' screen



**NOTE:** Tip sheaths are used to reduce the amount of consumable waste. They allow the system to dedicate tips to a set of 6 samples and store them while the other 6 samples are being processed.

11. Place the tip sheaths on the deck and press firmly into place. Touch **Next**.

>>> The 'Empty Strip Tubes' screen will appear (FIGURE 5.16).

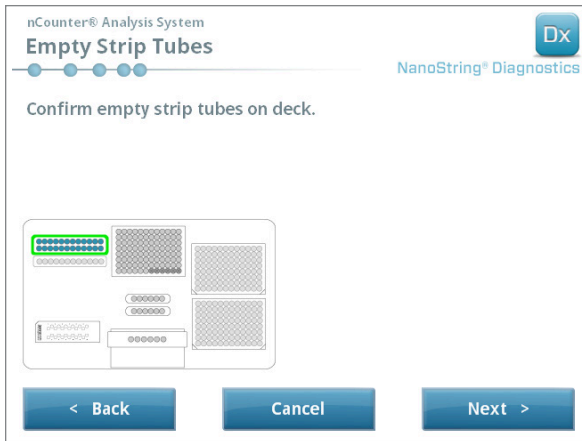


FIGURE 5.16: The 'Empty Strip Tubes' screen

12. Place the empty strip tubes in the heater on the deck. Touch **Next**.

>>> The 'Scan Sample Cartridge' screen will appear.

**NOTE:** Only one empty heater strip tube is required for runs performed using a 1-, 2-, 3-, or 4-test kit. For these Run Sets, load the empty heater strip tube into the front position of the heat block (nearest the user) on the Prep Station deck.

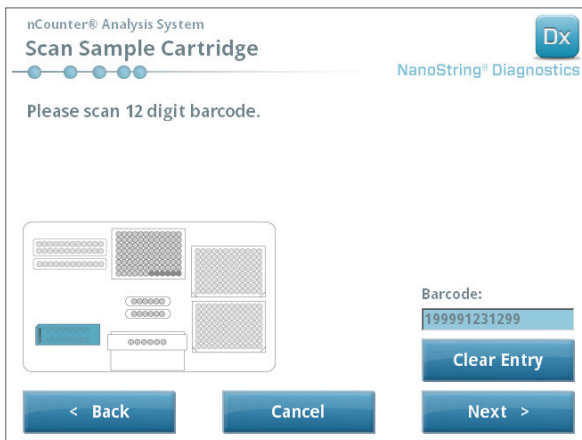


FIGURE 5.17: The 'Scan Sample Cartridge' screen

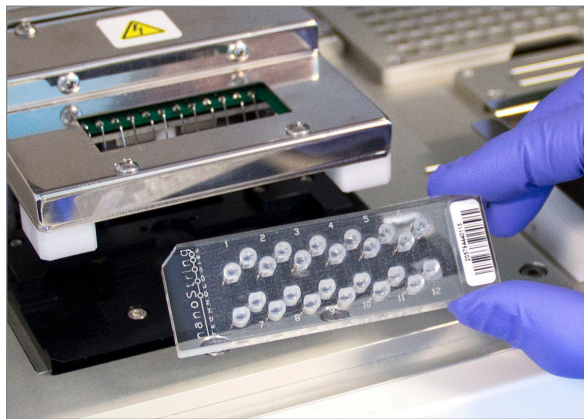
13. Instructions for the 'Sample Cartridge' screen:

- a. The barcode for the Sample Cartridge must be scanned before proceeding. Hold the barcode in front of the barcode reader. A red beam will appear. Move the barcode in front of the red beam until it is scanned and the barcode number appears in the entry field.

**NOTE:** The Prep Station will not accept barcodes for Cartridges that have expired. Make sure the Cartridge is used prior to its expiration date.

**NOTE:** It is not possible to manually enter the barcode for the Cartridge. If a barcode will not scan or is not accepted, use another Cartridge from the same kit lot for the run.

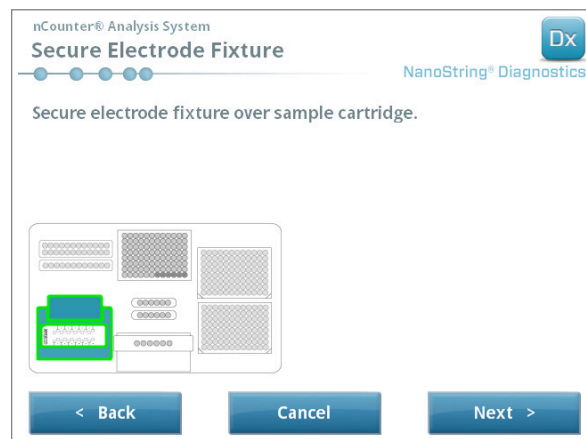
- b. Insert a Sample Cartridge under the electrode fixture in the orientation shown in **FIGURE 5.18**. Place the Cartridge on the deck and slide it into position, avoiding the electrodes. Make sure that it is seated completely in the machined depression. When positioned properly, a latch will activate and hold the fixture in place. If it is not seated properly, the electrodes may become bent when the electrode fixture is closed.



**FIGURE 5.18:** Insert an unused Cartridge into the Prep Station in the orientation shown

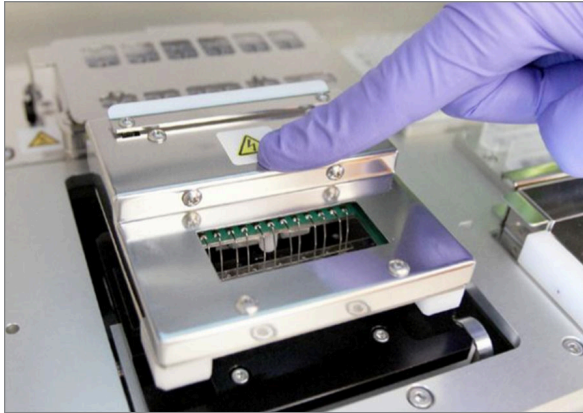
- c. Touch **Next**.

>>> The 'Secure Electrode Fixture' screen will appear.



**FIGURE 5.19:** The 'Secure Electrode Fixture' screen

14. Carefully lower the electrode fixture in place over the Cartridge (**FIGURE 5.20**). The 24 electrodes should insert easily into the 24 wells. Touch **Next**.



**FIGURE 5.20:** Carefully lower the electrode fixture into place over the Cartridge.



**IMPORTANT:** Do not use the release handle to lower the fixture. Doing so will prevent the fixture from locking. Instead, press on the body of the fixture away from the release handle (**FIGURE 5.20**).



**IMPORTANT:** If any resistance is felt while lowering the fixture, stop and adjust the position of the Cartridge slightly. Make sure that the electrodes are correctly aligned. If the electrodes are not aligned, re-align the electrodes using the 'Align Electrodes' workflow under the Maintenance Menu. The Prep Station will not be able to process any of the samples if electrodes are bent.

>>> The 'Hybridized Samples' Screen will appear (FIGURE 5.21).

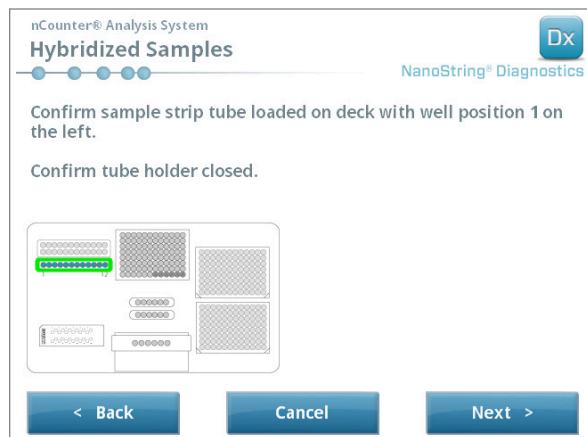
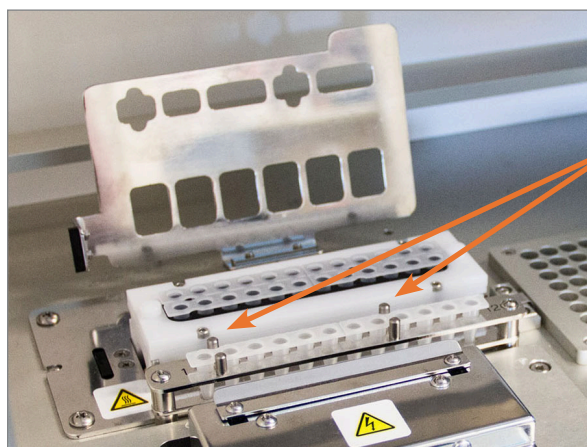


FIGURE 5.21: The 'Hybridized Samples' screen

- Place the hybridized sample strip tube on the deck of the Prep Station, ensuring that well 1 aligns with position 1 (FIGURE 5.22). Note that the strip tube is asymmetrically keyed, and if the strip tube is placed incorrectly the lid will not close properly.



Hybridized sample strip tubes have two notches to ensure proper orientation.

FIGURE 5.22: Hybridization sample strip tubes with notched orientation guides

**i** **IMPORTANT:** Do not let the hybridized samples sit at room temperature longer than 15 minutes. If there are delays between removing the hybridized samples from the heat block and starting the Prep Station, return the samples to 65°C until they can be processed. Do not exceed the maximum hybridization time stated in the assay package insert.

**i** **IMPORTANT:** All tubes should be seated fully and evenly in the rack to ensure proper processing. Ensure that all tube caps are removed from the hybridized samples prior to placing tubes on the deck. Leaving the caps on will pause the protocol and require user intervention.

**i** **IMPORTANT:** Only use strip tubes provided by NanoString. Other tubes have different dimensions and will cause system failure.

- a. Securely close the lid that flips down over the tubes (FIGURE 5.23).

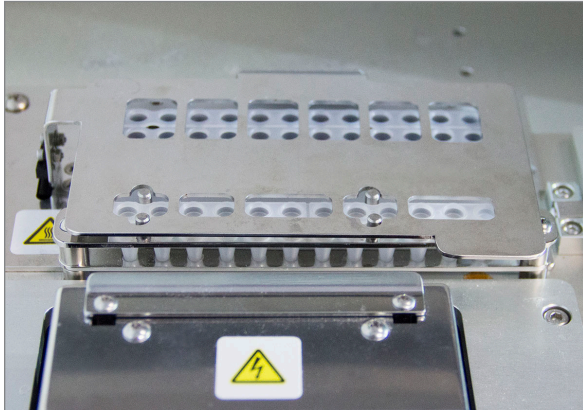


FIGURE 5.23: Lid closed over tubes

- b. Touch **Next**.



**IMPORTANT:** Failure to securely close the lid over the tubes can result in a system malfunction. If the metal lid is not closed completely, then the sensor will return an error message and the run will not initiate until the error is corrected.



>>> The 'Notification Options' screen will appear (FIGURE 5.24).

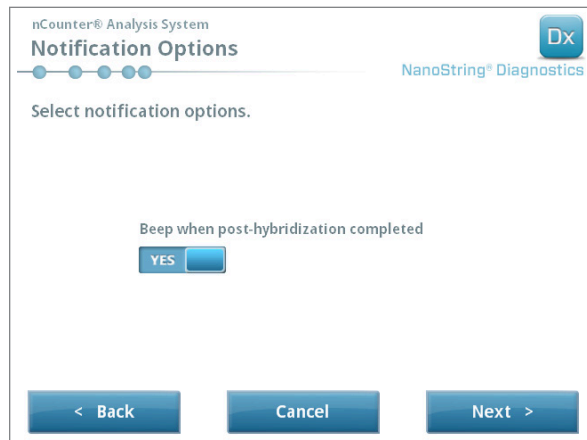


FIGURE 5.24: The 'Notification Options' screen

16. Select whether the Prep Station should make an audible alarm when processing is finished. Touch **Next**.

>>> The 'Start Deck Validation' screen will appear.

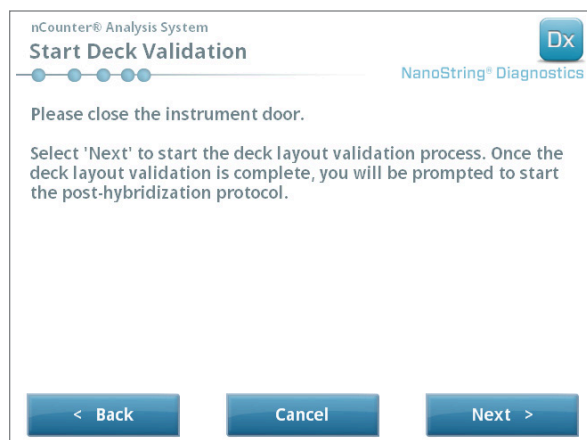


FIGURE 5.25: The 'Start Deck Validation' screen

- a. Touch **Next** to begin validation.

- b. The nCounter Prep Station will now check that all of the consumables and reagents have been placed properly on the deck (FIGURE 5.26). To do this, the Prep Station confirms that the sensors for the Sample Cartridge, electrode fixture, and heater lid are all in the correct state. The pipette head then checks that tips, tip sheaths, strip tubes, and Reagent Plates are all in place by touching them with a set of validation tips. Do not be alarmed that the Prep Station is touching the consumables; this is a part of normal operation. If the Prep Station determines that a consumable is misplaced, it will instruct the user to fix the configuration.

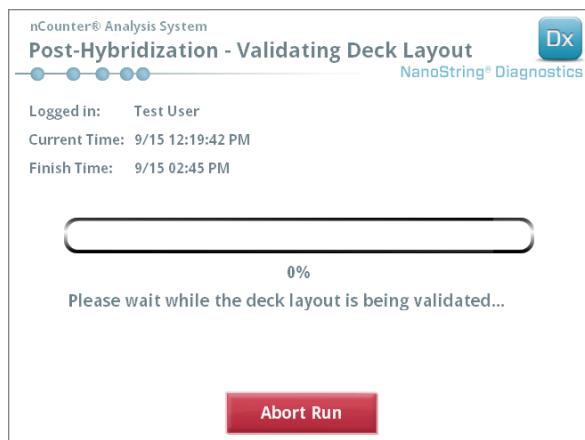


FIGURE 5.26: The 'Post-Hybridization – Validating Deck Layout' screen

- c. After deck validation is complete (FIGURE 5.27), a new screen containing the **Start Processing** button will appear. Touch **Start Processing** to initiate the run.

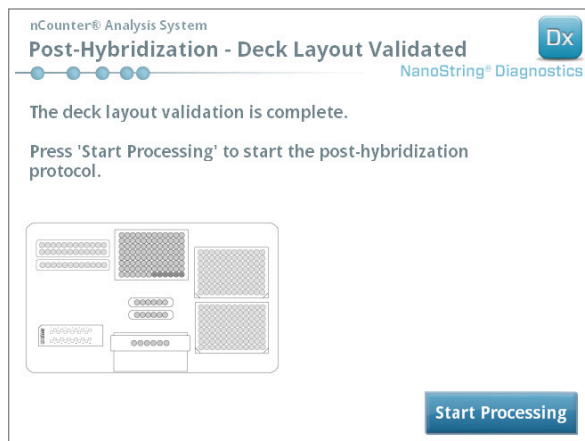


FIGURE 5.27: The 'Post-Hybridization – Deck Layout Validated' screen



**IMPORTANT:** If a run is paused, resume the run as quickly as possible. The system should not be in a paused state for more than 15 minutes or the test must be repeated for the affected samples.



**IMPORTANT:** If a run is aborted, the run cannot be restarted and the test must be repeated for the affected samples. See the assay package insert for more information regarding repeat testing.

17. When the sample processing is finished, a blue screen will appear and the timer will start to count up from when the run was completed (FIGURE 5.28). Touch **Next**.

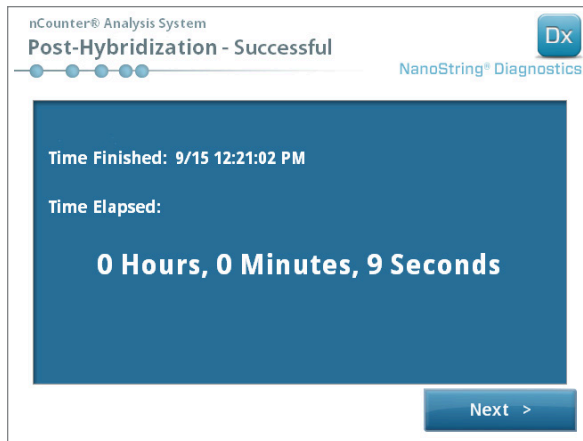


FIGURE 5.28: The System Processing Complete screen

18. The 'Run Successfully Completed' screen lists the steps to follow after sample processing, including:
- Remove and discard empty Reagent Plates.
  - Remove and discard the empty tip racks and foil piercers.
  - Remove and discard all strip tubes.
  - Remove the Sample Cartridge and seal the wells.

19. To release the fixture after the run is complete, pull the latch on the top of the device up and towards the front of the system using a finger as shown in **FIGURE 5.29**.



**FIGURE 5.29:** Releasing the fixture after a completed run

20. After processing is complete, it is important to do the following:
- Seal the wells immediately with the adhesive cover provided to prevent evaporation.
  - Protect Samples from as much light as possible.
  - If the Cartridge will not be scanned on the Digital Analyzer within an hour the sealed Cartridge should be stored at 4°C in an opaque box. The Cartridge can be stored this way for up to one week with minimal degradation.
  - Empty the waste containers.
21. Touch **Finish** to return to the Main Menu.

## 6 Operating the Digital Analyzer

### A. Initiating a Run

1. To scan a Cartridge using the Digital Analyzer, log on to the instrument. In order to log on, touch **Main Menu** on the Welcome screen.

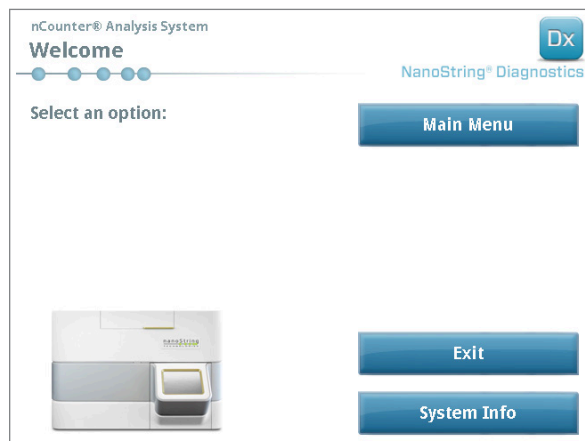


FIGURE 6.1: The Digital Analyzer 'Welcome' screen

2. Enter a valid user name and password and touch **Sign In**.

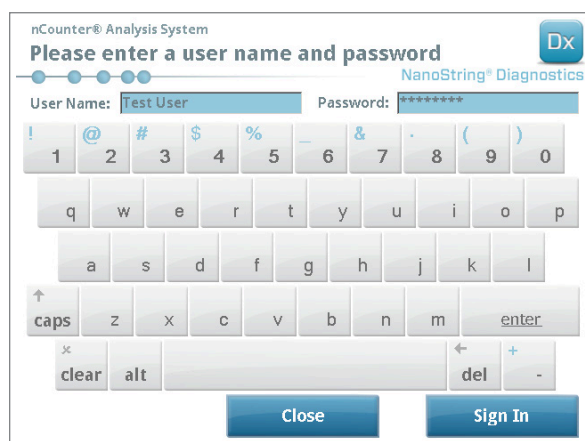
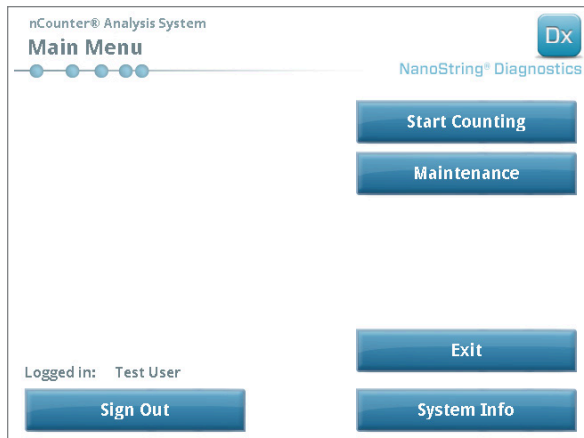


FIGURE 6.2: The sign in screen

>>> The Main Menu will appear.



**FIGURE 6.3:** The Digital Analyzer Main Menu

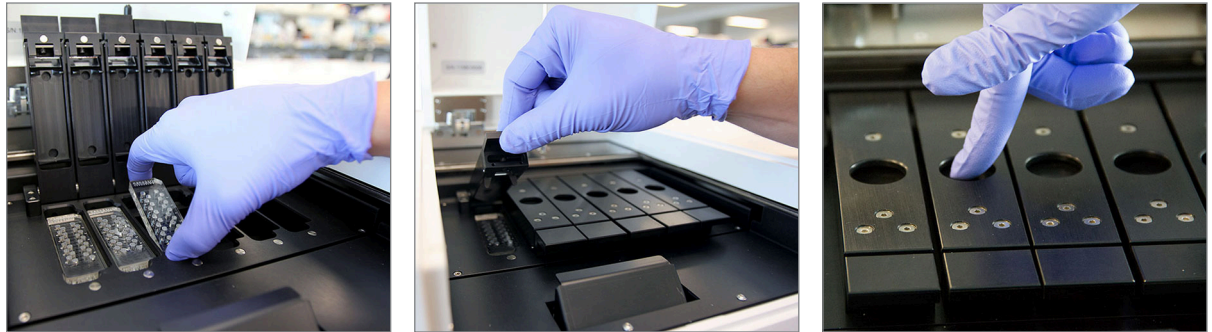


**NOTE:** The **Exit** button will only appear on the Welcome screen and Main Menu if the user has the nCounter Dx Analysis System with FLEX configuration (see *Chapter 3 – Selecting the Instrument Mode*).



**IMPORTANT:** If a laboratory has more than one Digital Analyzer, the Cartridge must be scanned on the same instrument registered to the Prep Station used to process the samples (see *Chapter 4 – Operating the Web Application*).

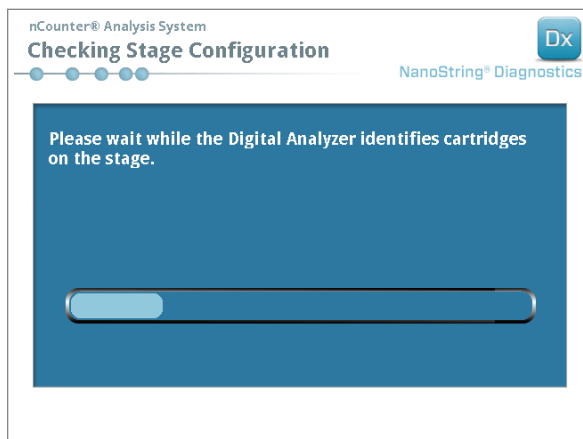
3. Place the Sample Cartridge into an empty slot. Make sure the Cartridge is inserted in the correct orientation (the slot and Cartridge are keyed to help ensure the correct orientation), and is completely flat in the slot. The barcode will be facing up (FIGURE 6.4). Close the magnetic holder over the Cartridge in the slot and close the door to the Digital Analyzer



**FIGURE 6.4:** Orient Cartridges with the barcode toward the user when placing them into the Digital Analyzer. Close the magnetic clips gently and be sure to push down on the metal plate above the Cartridge after the lid is closed to ensure the Cartridge lays flat.

- a. Select the **Start Counting** button.

>>> The 'Checking Stage Configuration' screen will appear.



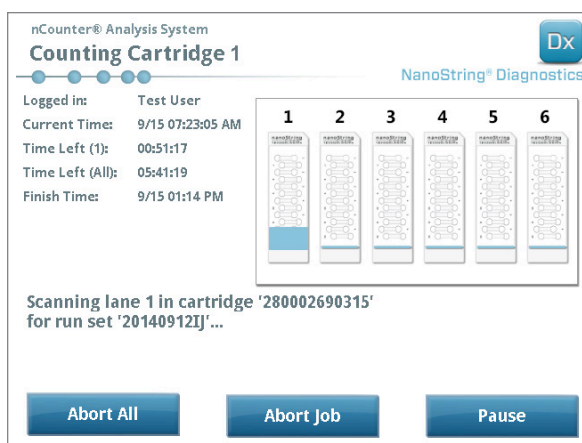
**FIGURE 6.5:** The 'Checking Stage Configuration' screen



**NOTE:** The Digital Analyzer tracks which stage positions have already been scanned, are currently in progress, or are waiting to be scanned.

4. The scanner will use the barcode to look up the Run Set associated with that Cartridge and determine whether the Cartridge is ready to be scanned. Once the six positions have been checked, the Counting Cartridge screen will appear. Each slot has five possible states:
- **Empty location (no graphic)** – This slot is empty and can be loaded with a new Cartridge.
  - **White Cartridge** – This slot contains a Cartridge that is registered, but has not yet been scanned. **DO NOT REMOVE THIS CARTRIDGE.**
  - **Partial blue Cartridge** – This slot contains a Cartridge that has been incompletely scanned. **DO NOT REMOVE THIS CARTRIDGE.**
  - **Completely blue Cartridge** – Scanning of that Cartridge is complete.
  - **Icon and text over a Cartridge** – There may have been a problem encountered during a scan of the Cartridge. Touch the icon or Cartridge to get more information.

In the example shown in **FIGURE 6.6**, the Cartridge in slot 1 is being scanned and Cartridges in slots 2, 3, 4, 5, and 6 are waiting to be scanned.



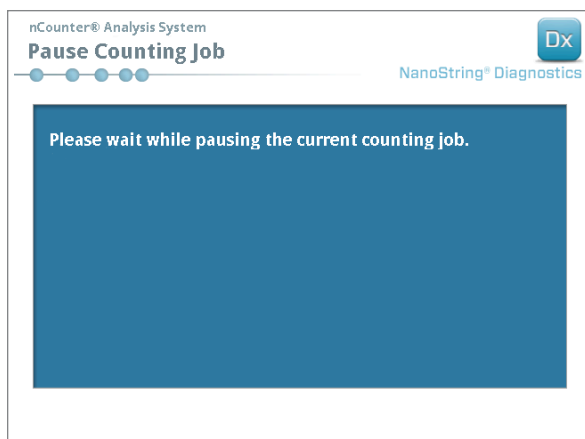
**FIGURE 6.6:** The 'Counting Cartridge' screen, with the current cartridge indicated



**NOTE:** Cartridges previously aborted may be able to be re-scanned. When placed in the Digital Analyzer, the counting Cartridge screen will display 'ABORTED' for that Cartridge. To re-scan a Cartridge, press on the Cartridge's icon. A screen will appear with the option to scan again. If this is performed while a Cartridge is scanning, be aware that the Cartridge status will remain pending until either all other Cartridges have been scanned or until scanning has been paused and resumed.

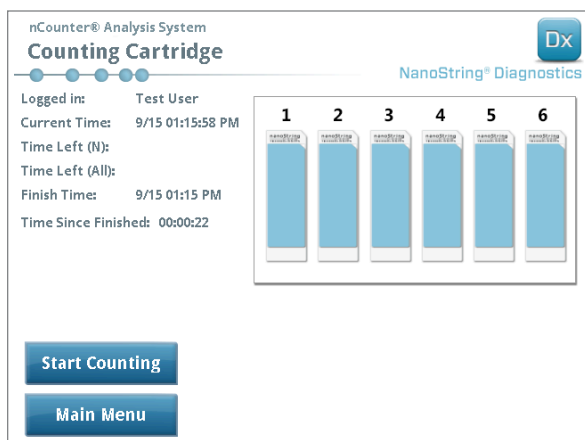


- Confirm that a small blue bar appears at the bottom of the scanning Cartridge, indicating the scan has started. There will be a series of rhythmic clicks as the images are collected.
- To add a Cartridge to a Digital Analyzer that is already counting, touch the **Pause** button on the 'Counting Cartridges' screen. It might take a few minutes for the Digital Analyzer to reach a suitable stopping point (**FIGURE 6.7**). The door will unlock when it does. Place the new Cartridge in an empty slot, or replace a Cartridge that has already been scanned. Touch the **Resume** button. The door should re-lock and resume counting.



**FIGURE 6.7:** The 'Pause Counting Job' screen

- When a Cartridge is finished scanning, an e-mail notification will be sent to the user and the processing screen will change to reflect that the Cartridge has completed (**FIGURE 6.8**). Upon receiving the e-mail notification that the scan has completed, remove the completed Cartridge. In case of an instrument error or reports not being available, store Cartridge in an opaque box (to protect from light) at 4°C for up to one week. Contact [dxsupport@nanosttring.com](mailto:dxsupport@nanosttring.com) for assistance.



**FIGURE 6.8:** The 'Counting Cartridge' screen with six completed Cartridges

- Using the link attached to the notification e-mail, open the web interface and download all the diagnostic reports associated with the Run Set just completed as described in *Chapter 4 – Operating the Web Application*.

# 7 Technical Support and Maintenance

## A. Technical Support

Technical support is available by phone, fax, mail, or e-mail. Please be sure to include the product number and serial number in all communications.



### U.S. Contact Information:

#### NanoString Technologies, Inc.

530 Fairview Ave N

Seattle, WA 98109, U.S.A.

**Phone:** +1.888.358.NANO (+1.888.358.6266)

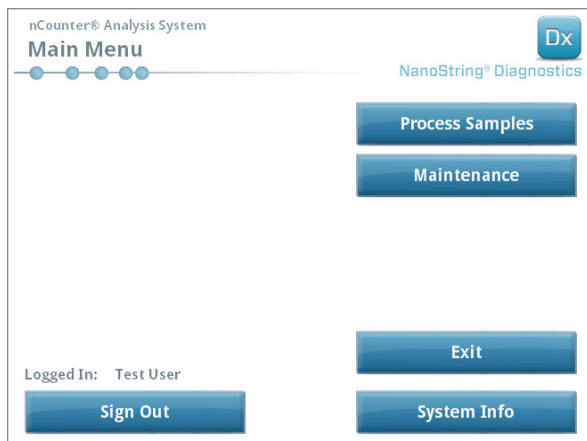
**Fax:** +1.206.378.6288

**E-mail:** [dxsupport@nanosttring.com](mailto:dxsupport@nanosttring.com)

**Website:** [www.nanosttring.com](http://www.nanosttring.com)

## B. Instrument Power Cycling

It is recommended that the system power for each instrument is cycled periodically (for example, once every two weeks after Prep Station O-ring lubrication). Maintenance and support functions can be accessed from the Main Menu of the Prep Station and Digital Analyzer.



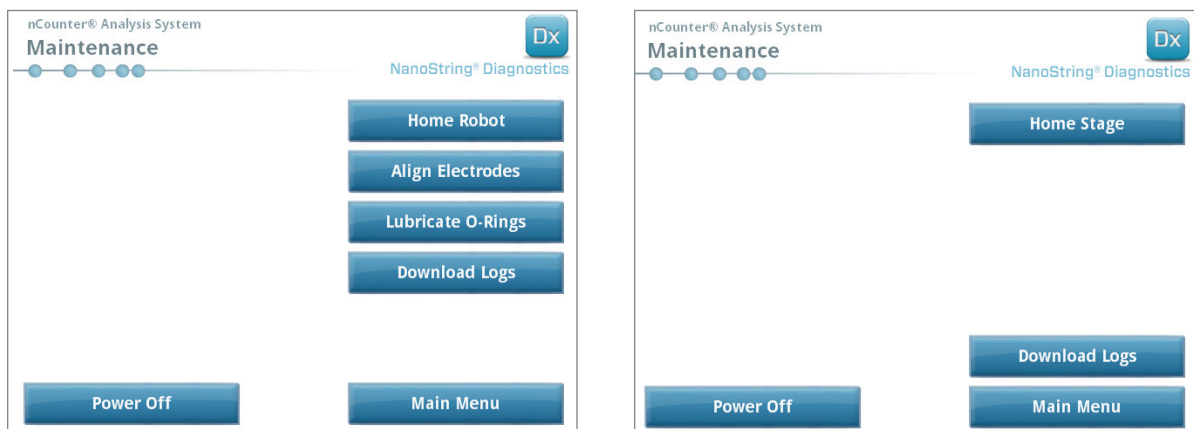
**FIGURE 7.1:** This example shows the **Maintenance** button on the Prep Station Main Menu

**NOTE:** Users must be assigned Administrator privileges by an Administrator to perform these functions. Only Administrators may shut down the system.

**NOTE:** Shutting down the IVD system will interrupt Cartridge preparation and analysis. Please ensure that all Cartridges have finished processing on the Digital Analyzer and the Prep Station is not in use before cycling instrument system power.

The following instructions may be used to cycle the system power on either instrument.

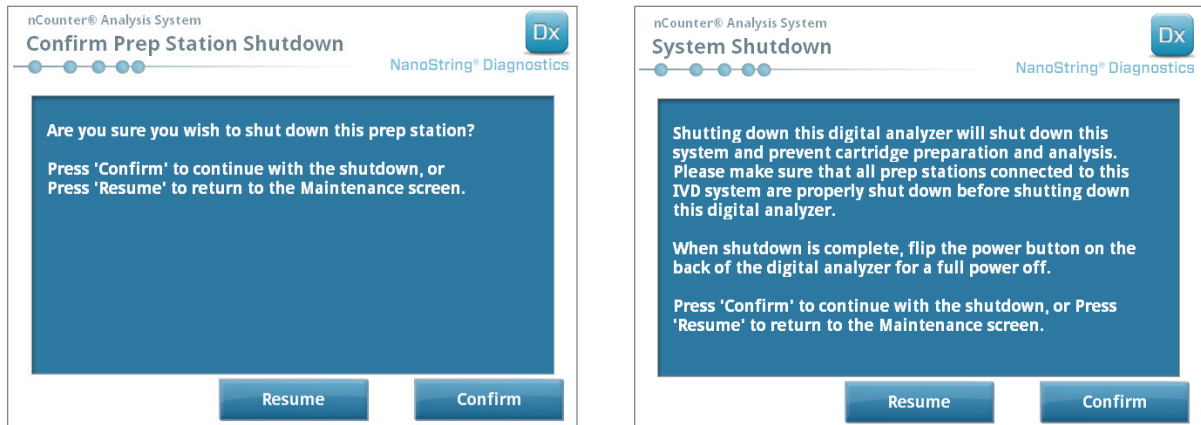
1. Select **Power Off** from the Maintenance Menu.



**FIGURE 7.2:** The Prep Station Maintenance Menu (left) and Digital Analyzer Maintenance Menu (right)

>>> A confirmation message will appear.

2. Select **Confirm** to continue the system shutdown.



**FIGURE 7.3:** System shutdown messages displayed by the Prep Station (left) and the Digital Analyzer (right).

>>> The system will shut down.

3. After the system shuts down (there is a delay of approximately 30 seconds), locate the power switch on the back of the instrument and turn off the power.
4. Wait an additional 30 seconds and then use the power switch to restore power to the instrument.

>>> The system will initialize and display the 'Select Instrument Mode' screen (see *Chapter 3 – Selecting the Instrument Mode*).



**IMPORTANT:** To ensure proper communication between instruments after a power cycle, always restore power to the Digital Analyzer first and allow the instrument to fully initialize before restoring power to the Prep Station.

## C. Prep Station Maintenance

Maintenance and support functions can be accessed from the Main Menu of the Prep Station. Users must be assigned the necessary permissions by an Administrator to perform these functions. Only Administrators may shut down the system.

In addition to instrument power cycling (see previous section), users are expected to perform two principal tasks when required: electrode alignment and O-ring lubrication. Additional, less frequent maintenance functions include homing the robot and downloading log files.

### Electrode Alignment

From time to time, the electrodes used for stretching the reporters may become bent out of alignment and no longer fit into the Cartridge properly. This usually occurs if the Cartridge was not aligned properly when the electrode fixture was depressed causing the electrode to make contact with the Cartridge and bend. The following describes a method for re-alignment of the electrodes using the system hardware interface. This method allows the electrode fixture to tilt at an angle that makes it much easier to view the electrodes during alignment.

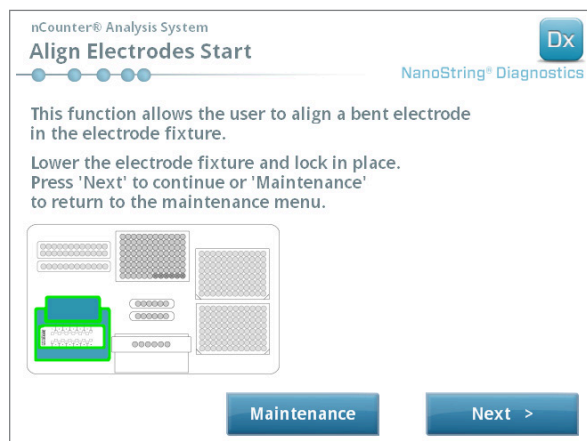
If the electrode is so severely bent that it cannot be inserted into a Cartridge, the process outlined below may need to be repeated twice: once without a Cartridge present to get the electrodes into roughly the right position so that they can be inserted into a Cartridge and a second time with a Cartridge present for fine tuning the placement of electrodes within the Cartridge wells.



**NOTE:** The Prep Station checks electrode function during the validation steps of the process, before any sample processing occurs. If it detects problems with an electrode, the processing will halt and wait for user intervention. The screens described below will then appear, allowing the user to fix the bent electrodes.

1. Select **Align Electrodes** from the Maintenance Menu.

>>> The 'Align Electrodes Start' screen will appear.



**FIGURE 7.4:** The 'Align Electrodes Start' screen, step 1 of 5

2. If the electrode is severely bent to the point where a Cartridge cannot be inserted, close the electrode fixture without a Cartridge in it and adjust the position of the electrode such that it is positioned similarly to the other electrodes. If it is only slightly bent and a Cartridge can be inserted by carefully maneuvering the bent electrode, then insert a Cartridge before closing the electrode fixture. Touch **Next**.

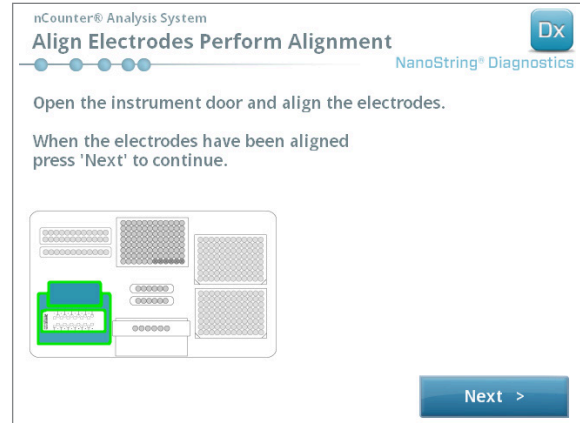
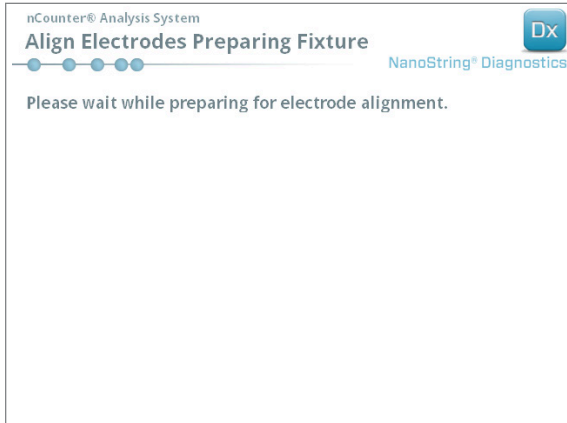
>>> The 'Align Electrodes Close Door' screen will appear.



**FIGURE 7.5:** The 'Align Electrodes Close Door' screen, step 2 of 5

3. Close the door and touch **Next**.

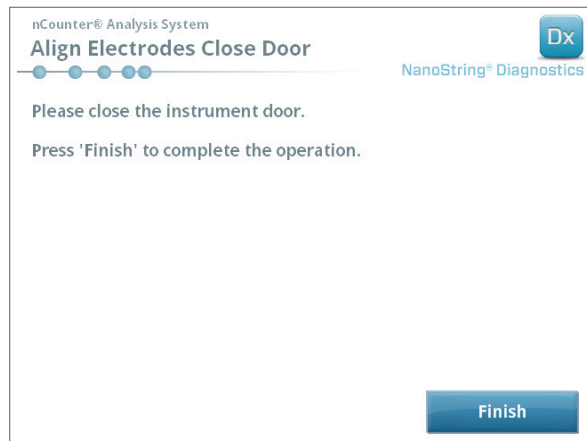
>>> While the door is closed, the electrode fixture tilts towards the operator for easier access to the electrodes. Two screens follow in succession (**FIGURE 7.6**).



**FIGURE 7.6:** The 'Align Electrodes' progress screens, steps 3 and 4 of 5

- Using a pair of tweezers, gently bend the electrodes into alignment by trying to align the tip of the electrode to the center and bottom of the Cartridge well. Touch **Next**.

>>> The final screen will appear when the procedure is complete.



**FIGURE 7.7:** The 'Align Electrodes Close Door' screen, step 5 of 5

- Close the door, and touch **Finish**. The electrode fixture will tilt back to its home position, and then the Maintenance Menu will be displayed.

## O-ring Lubrication

The O-rings on the pipetting nozzles in the Prep Station are present to ensure a seal with the pipette tips thus ensuring accurate liquid volume control. O-rings are the small black rings found on the lower end of the nozzle. These O-rings must be lubricated regularly in order to ensure a good seal.

The Prep Station Maintenance Menu has an interface to facilitate O-ring lubrication by bringing the pipetting head to the front of the deck for easy access.



**NOTE:** An icon will appear on the Main Menu and Maintenance Menu when it is necessary to lubricate the O-rings (FIGURE 7.8).

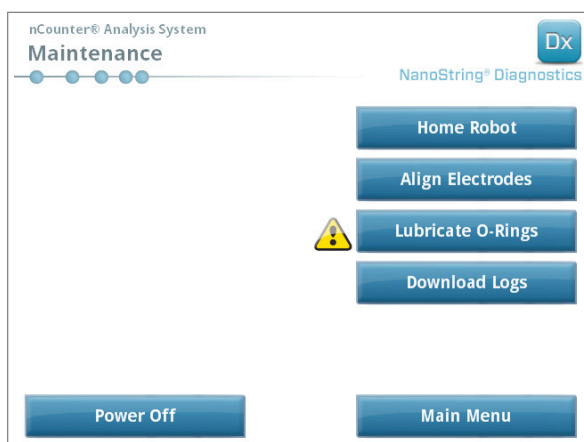


FIGURE 7.8: The yellow 'Lubricate O-rings' symbol



**CAUTION:** When performing maintenance functions, always use appropriate safety precautions including wearing safety glasses and gloves.

Some materials are required but not provided with the kit:

- Silicone grease (provided during system installation)
- Lint-free paper (e.g., Kimwipe™ by Kimberly-Clark®)
- Gloves



**IMPORTANT:** DO NOT USE ANYTHING OTHER THAN THE SUPPLIED SILICONE GREASE ON O-RINGS.



1. Select **Lubricate O-Rings** on the Maintenance Menu.  
 >>> A series of 'Lubricate O-rings' maintenance screens will appear.

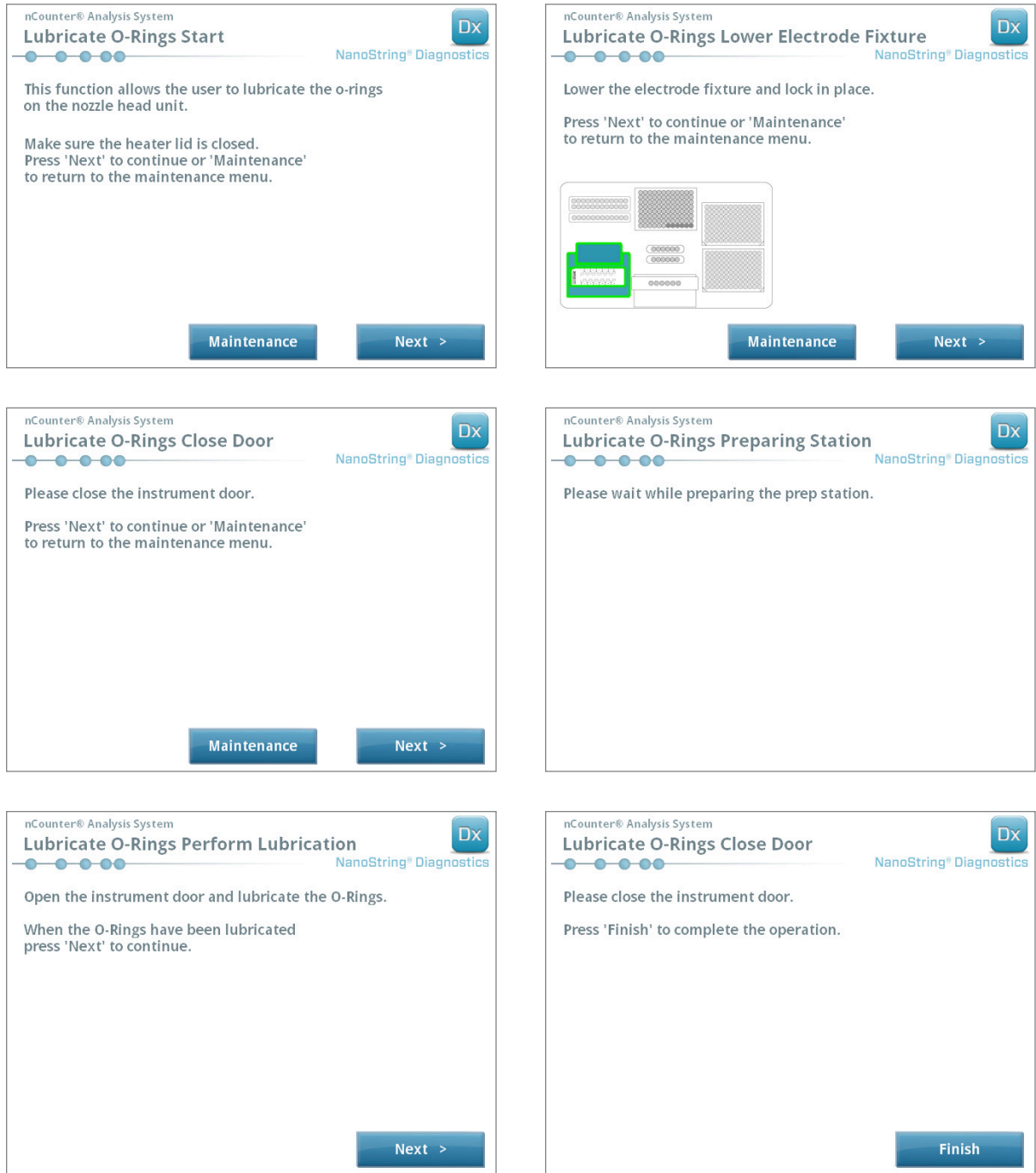
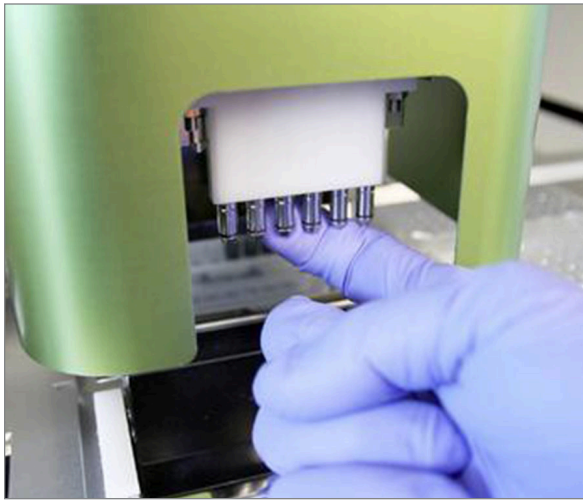


FIGURE 7.9: Screens displayed for the different steps in the Lubricate O-rings workflow.

2. Follow the directions on the screens.
3. To lubricate the O-rings, take a small amount of silicone grease and rub a finger around the O-ring using a gloved hand as shown in **FIGURE 7.10**.



**FIGURE 7.10:** Use a finger to apply a small amount of NanoString silicone grease to the O-rings

4. Using lint-free paper, thoroughly wipe off any excess silicone grease from the nozzles and Tip Ejectors.
5. Gently move that finger around each ring to distribute the grease evenly.
6. Following the instructions on the screen, touch the **Next** and **Finish** buttons to complete the procedure.
7. Completing the 'Lubricate O-rings' workflow will reset the internal timer and remove the yellow warning icon if it is present.



**IMPORTANT:** Excess grease may cause equipment malfunction. Avoid applying grease to the metal portion of the nozzle.

## Downloading Log Files

If an issue is encountered, NanoString Support may request a download of the system log files. In the Maintenance Menu, select the **Download Logs** button. Log files are stored according to the date of each run (FIGURE 7.11). Multiple dated folders may be selected for download by touching each one. Selected folders will be highlighted in blue.

1. Insert a USB flash drive into the Prep Station's front USB port.
2. When the desired folders have been selected, touch **Download** to transfer them to the flash drive.

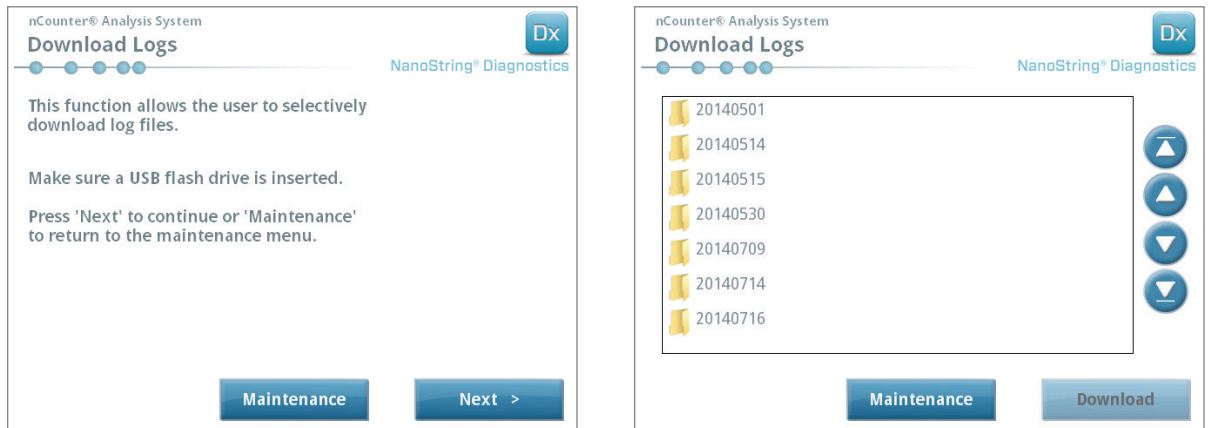


FIGURE 7.11: Screens that appear when downloading log files

## Home Robot

If the robot enters into an undesirable state, selecting the **Home Robot** button can home all the motors. This button should not be needed under normal operation.

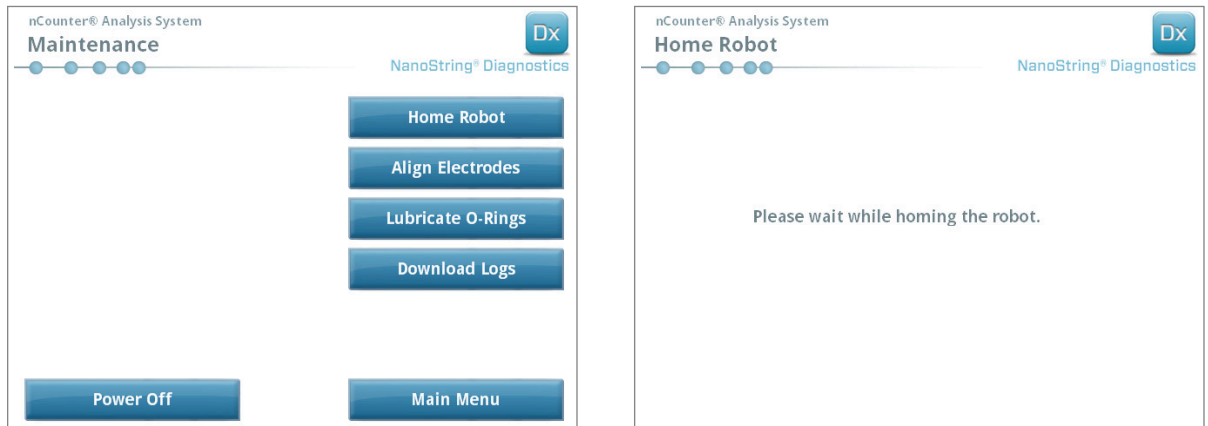


FIGURE 7.12: Screens that appear during the Home Robot process

## D. Digital Analyzer Maintenance

Maintenance and support functions can be accessed from the Main Menu of the Digital Analyzer. Users must be assigned the necessary permissions by an Administrator to perform these functions. Only Administrators may shut down the system.



**IMPORTANT:** If the Digital Analyzer is shut down, the web application will be unavailable and the Prep Station will be inoperable.

The Digital Analyzer has been designed to require no maintenance by the user other than instrument power cycling (see previous section). However, if any issues occur, NanoString Support may request a download of the log files.

### Downloading Log Files

In the Maintenance Menu, select the **Download Logs** button. Log files are stored according to the date of each run. Multiple dated folders may be selected for download by touching each one. Selected folders will be highlighted in blue.

1. Insert a USB flash drive into the Digital Analyzer's front USB port.
2. When the correct folders have been selected, touch **Download** to transfer them to the flash drive.

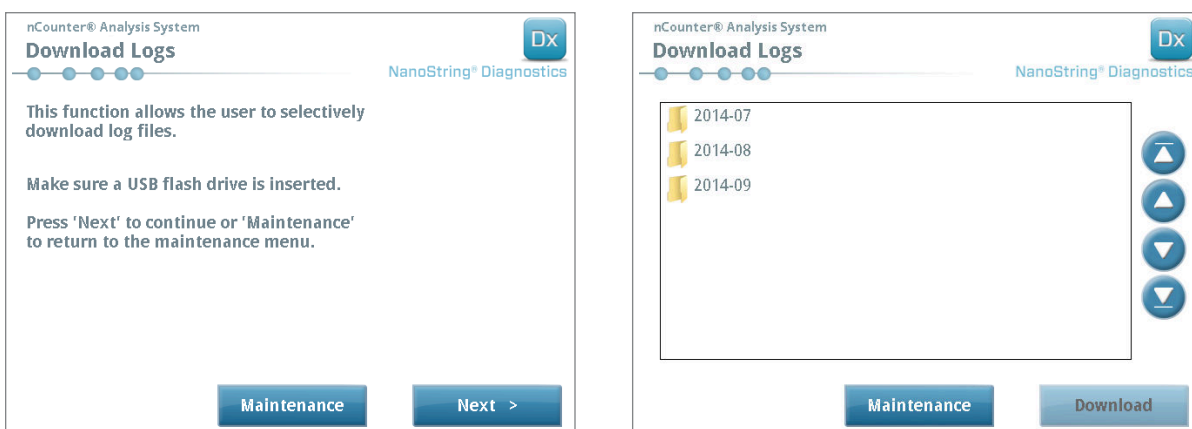


FIGURE 7.13: Screens that appear when downloading log files

## E. Cleaning Instructions

Follow all safety and operating instructions provided in this manual. Use safe laboratory operating precautions, including personal protective equipment such as safety glasses and gloves.

### Prep Station

After a completed run, remove all consumables and waste.

Periodically, clean the stage surface and waste receptacles of the Prep Station by wiping with a disinfectant followed by wiping with water or 70% ethanol. Avoid the electrode fixture. An RNase removal agent such as RNaseZap® from Ambion® may also be used.

Clean the exterior periodically using a diluted neutral soap followed by water. Use a damp towel rather than spraying directly on the instrument.

### Digital Analyzer

Clean the exterior periodically using a diluted neutral soap followed by water. Use a damp towel rather than spraying directly on the instrument.

## F. Disposal of Electronic Equipment

















**IMPORTANT:** This symbol on the nCounter Dx Analysis System is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates that:

- The device was put on the European Market after August 13, 2005.
- The device is not to be disposed via the municipal waste collection system of any member state of the European Union.

For products under the requirement of WEEE directive, please contact your dealer or local NanoString office for the proper decontamination information and take back program, which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of the device.

# Symbols and Definitions

	– Manufacturer
	– Authorized Representative in the European Community
	– <i>In vitro</i> diagnostic medical device
	– Consult Instructions for Use
	– CE Mark
	– Catalogue or Reference Number
	– Batch code / Lot number
	– Serial number
	– Contains sufficient for <n> tests
	– Temperature range storage conditions
	– Lower limit of temperature storage conditions
	– Upper limit of temperature storage conditions
	– For Use by / Expiry Date
	– Date of manufacture

Room Temp. = Room Temperature

HYB = Hybridization

## Regulatory Disclaimer

For *in vitro* diagnostic use.

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