Arti Patel

NeuMoDx Northeast
Field Application Specialist

NeuMoDx 96 Molecular System – Operator Training

Part I

Welcome & Introduction

NeuMoDx Molecular Systems Address All Key Customer Desires

Key Customer Desires

- Easy to Use
- Full Automation/‘Sample-to-Result’
- True Random Access
- Fast Time to Result
- Assays Stored On-Board
- Low Cost per Test
- High Throughput
- Long In-Use Reagent Stability
- Open System/LDT capability
- Continuous Loading

NeuMoDx Solutions

NeuMoDx™ 96 Molecular System

NeuMoDx™ 288 Molecular System

Visit Objectives

- Be able to successfully place reagents and consumables in correct carriers and locations on both instruments
- Navigate NeuMoDx™ software to run samples with Assay
- Run calibrators*, daily controls*, and samples
- Interpret results of calibrators*, daily controls* and samples
- Properly dispose of waste generated by instruments
- Perform Weekly Maintenance & Cleaning of Instrument
- *As needed per assay

NeuMoDx 96 Molecular System

Overview

The Concept

The NeuMoDx™ 96 Molecular System (N96) automatically performs all the steps required:

- to extract the target nucleic acid,
- prepare the isolated DNA/RNA for real-time Polymerase Chain Reaction (PCR) amplification, and
- (if present) amplify and detect the products of amplifications

General Overview

What is the NeuMoDx™ 96 Molecular System?

- Fully automated sample-to-result molecular diagnostic systems
- Minimal operator interaction with intuitive user-friendly software
- Monitors inventory of onboard reagents & consumables
- Used with reagents that are room temperature stable

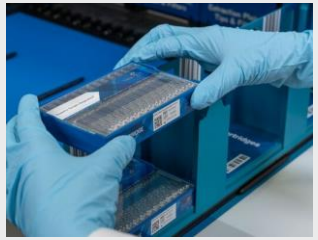
What does the NeuMoDx™ 96 Molecular System consist of?

- A liquid-handling instrument with touchscreen computer, accessories, reagents, and consumables

NeuMoDx Molecular Systems offer Industry Best Workflow

STEP 1*

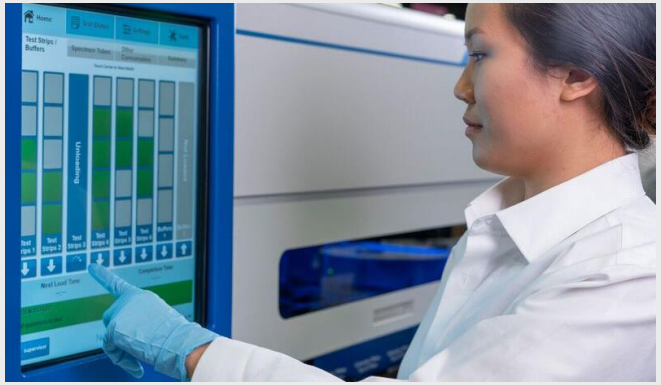
If required, load reagents, consumables & tests



STEP 2

Add patient samples in any order for any test

STEP 3



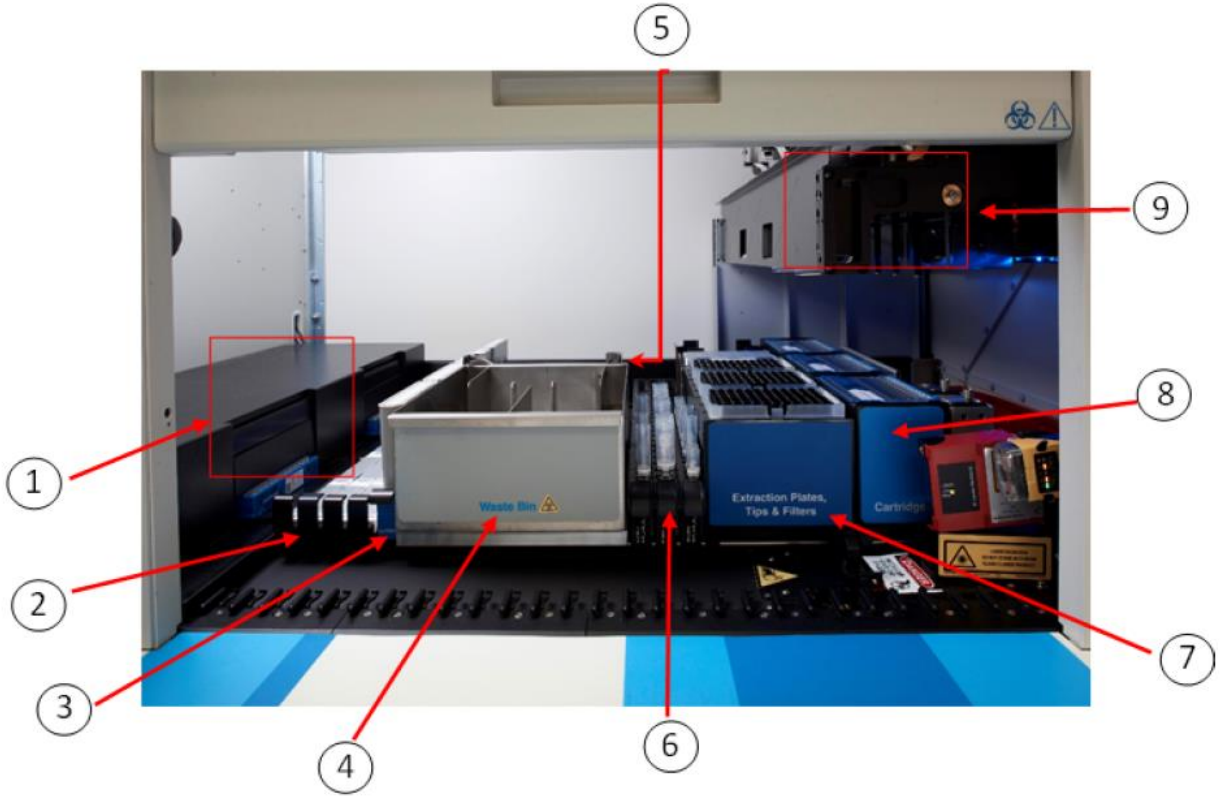
Touch ‘Load’ button

*Step 1 is not necessary if system has sufficient consumables, reagents and tests to complete the desired testing. If insufficient, the system will prompt the operator to load the required product(s).

NeuMoDx™ 96 Molecular System - Instrument Description

	Area
1	Touchscreen computer
2	On/Standby button
3	Handheld barcode scanner
4	Autoloader & Autoloader shelf
5	Reagent Drawer
6	Service Door
7	Biohazard Tip Waste Bin
8	Status light
9	Biohazard Waste Bin

NeuMoDx™ 96 Molecular System - System Worktable



	Area
1	XPCR Modules
2	Test strips
3	Buffer carrier
4	Biohazard Waste Bin
5	Extraction plate heaters (not shown; located behind Biohazard Waste Bin)
6	Specimen tube carriers
7	Tips, Extraction Plates, and Filters carrier
8	Cartridge carrier
9	Liquid handling robot (LHR)

NeuMoDx™ 96 Molecular System - Reagent Drawer & Tip Waste Drawer

1

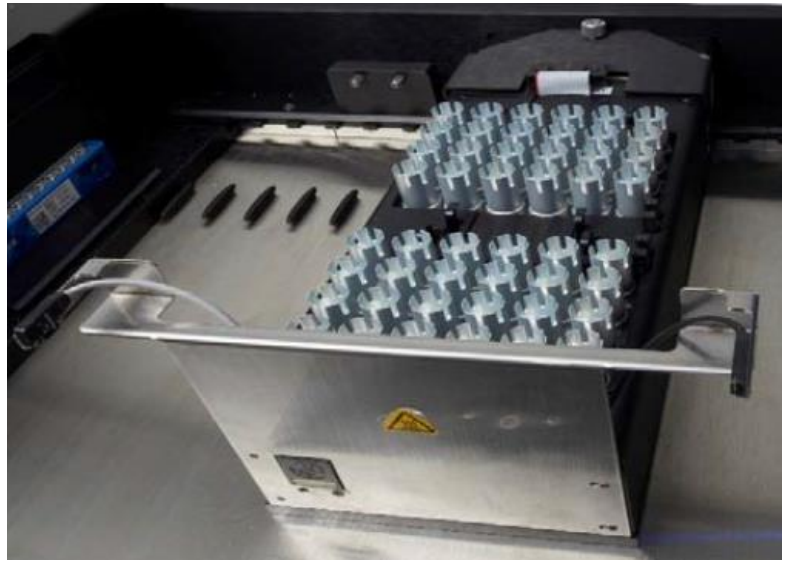
2

	Area
1	Tip Waste Drawer
2	Bulk Liquid Reagent Drawer

NeuMoDx™ 96 Molecular System

Extraction Heater Modules

- Extraction Plate Heater Modules
  - N96 has one Extraction Heater Module
- Independently controlled heater lysis wells
- Performs the Lysis Heating Step of extraction



NeuMoDx™ 96 Molecular System

XPCR Modules

- XPCR Modules
  - N96 has two XPCR Modules
- Purification and amplification of nucleic acids in combination with the microfluidic cartridge

Component (per Module)
Valve & nozzle assembly
Magnetic capture module
Release heater module and magnet heater module
Thermal cycling module
Fluorescence detection module
Scissor jack mechanism

NeuMoDx™ 96 Molecular System

UPS & Handheld Barcode Scanner

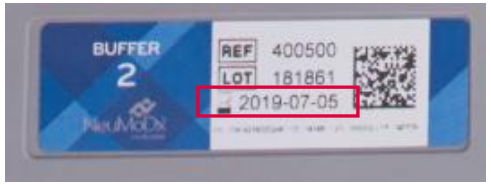
- Uninterruptible Power Supply (UPS)
  - System **must always be plugged into UPS to function properly**
  - Serves as a power conditioner
  - Provides a temporary source of power to System allowing certain processing of samples to continue in the event of a power loss

- Handheld Barcode Scanner
  - Mostly used for bulk reagent scanning
  - Can also scan specimen tubes, external controls, test strips, cartridges, lysis buffers – as necessary

Part II
Reagents & Consumables Overview

Brief Information

- All consumables are room temperature stable
- Most reagents are universal (can be used with DNA or RNA) – only lysis buffers & test strips are specific per test
- Product stability are on labels on outside of packaging and on product itself



- All items on the system are kept track of by barcode
  - Cannot “re-arrange” tips
  - Cannot share reagents between instruments (as of the current SW)
- All products by NeuMoDx have Instructions For Use (IFU’s) and Safety Data Sheets (SDS’s) that are available online

Reagents & Consumables Required

- NeuMoDxTM Extraction Plate
- NeuMoDxTM Test Strip
- NeuMoDxTM Lysis Buffer

Worktable Reagents

- NeuMoDxTM Wash Reagent
- NeuMoDxTM Release Reagent

Bulk Reagents

- NeuMoDxTM Tip Tray (reusable)
- CO-RE Tips 1000 µL with Filters (1000 µL tips)
- CO-RE Tips 300 µL with Filters (300 µL tips)
- NeuMoDxTM Cartridge

Consumables

- NeuMoDxTM Priming Waste Bottle (reusable)
- Biohazardous Waste Containers
- NeuMoDxTM Biohazardous Waste Bag

Waste Containers

Reagents & Consumables

For your information: NeuMoDx™ Reagents & Consumables

Item	Tests per Item	# Items per Box
NeuMoDx™ Test Strip	16 per test strip	6 strips per box
NeuMoDx™ Lysis Buffer	80mL per Container	4 Containers per box
NeuMoDx™ Extraction Plate	24 per plate	16 plates per box
NeuMoDx™ Cartridge	12 per cartridge	48 cartridges per box
NeuMoDx™ Wash Reagent	2L per bottle	2 bottles per box
NeuMoDx™ Release Reagent	1L per package	2 packages per box
CO-RE 1000 µL Tips	96 tips per tray, 5 trays per rack	8 racks per box
CO-RE 300 µL Tips	96 tips per tray, 5 trays per rack	12 racks per box
NeuMoDx™ Biohazard Waste Bag	500 per bag	5 bags per box
NeuMoDx™ Tip Tray	N/A	12 per box

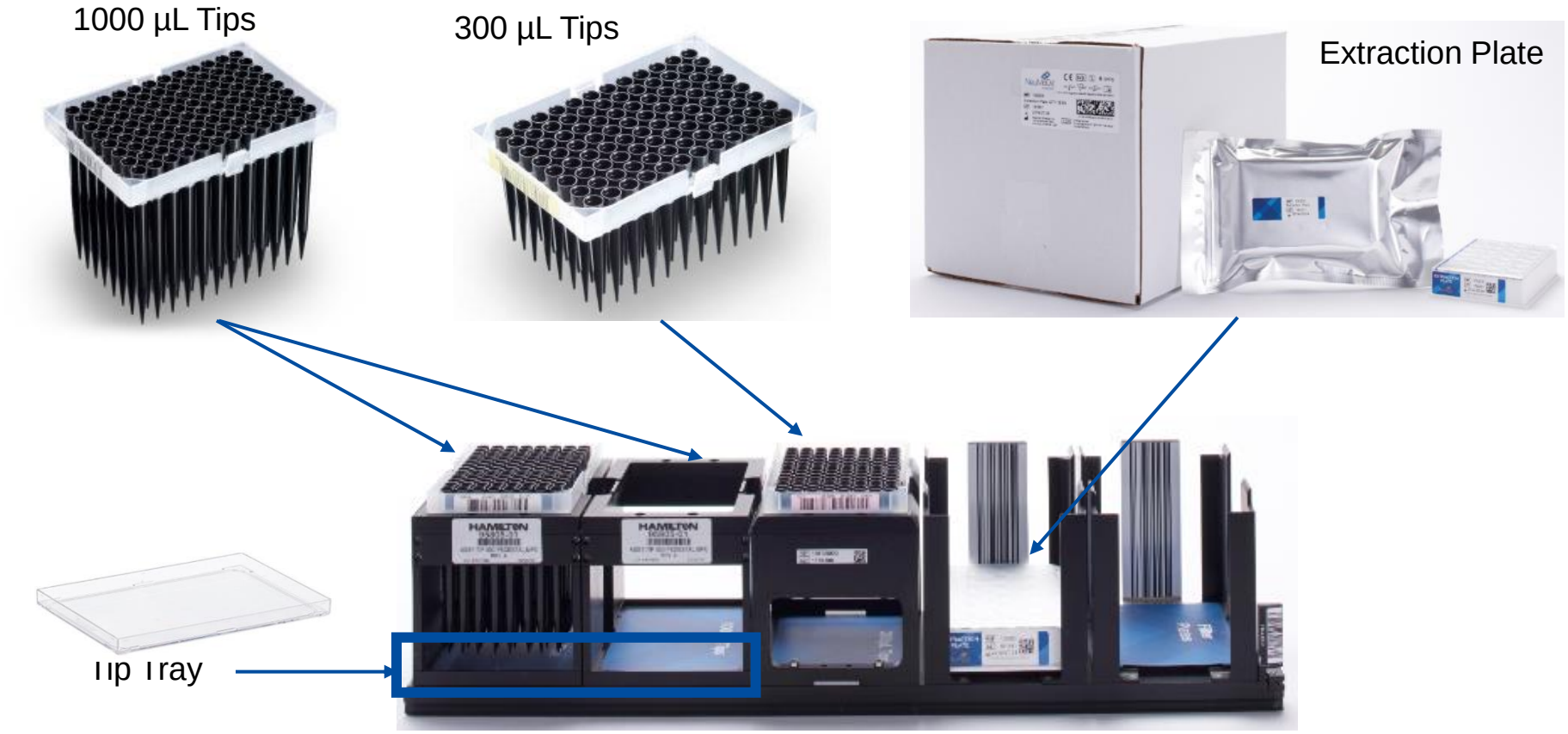
Reagents & Consumables

- NeuMoDx Test Strips go in the Test Strip Carrier (up to 5 per carrier)

- NeuMoDx Lysis Buffer goes in the Buffer Carrier (up to 4 per carrier)
  NOTE: remove the foil before loading into carrier

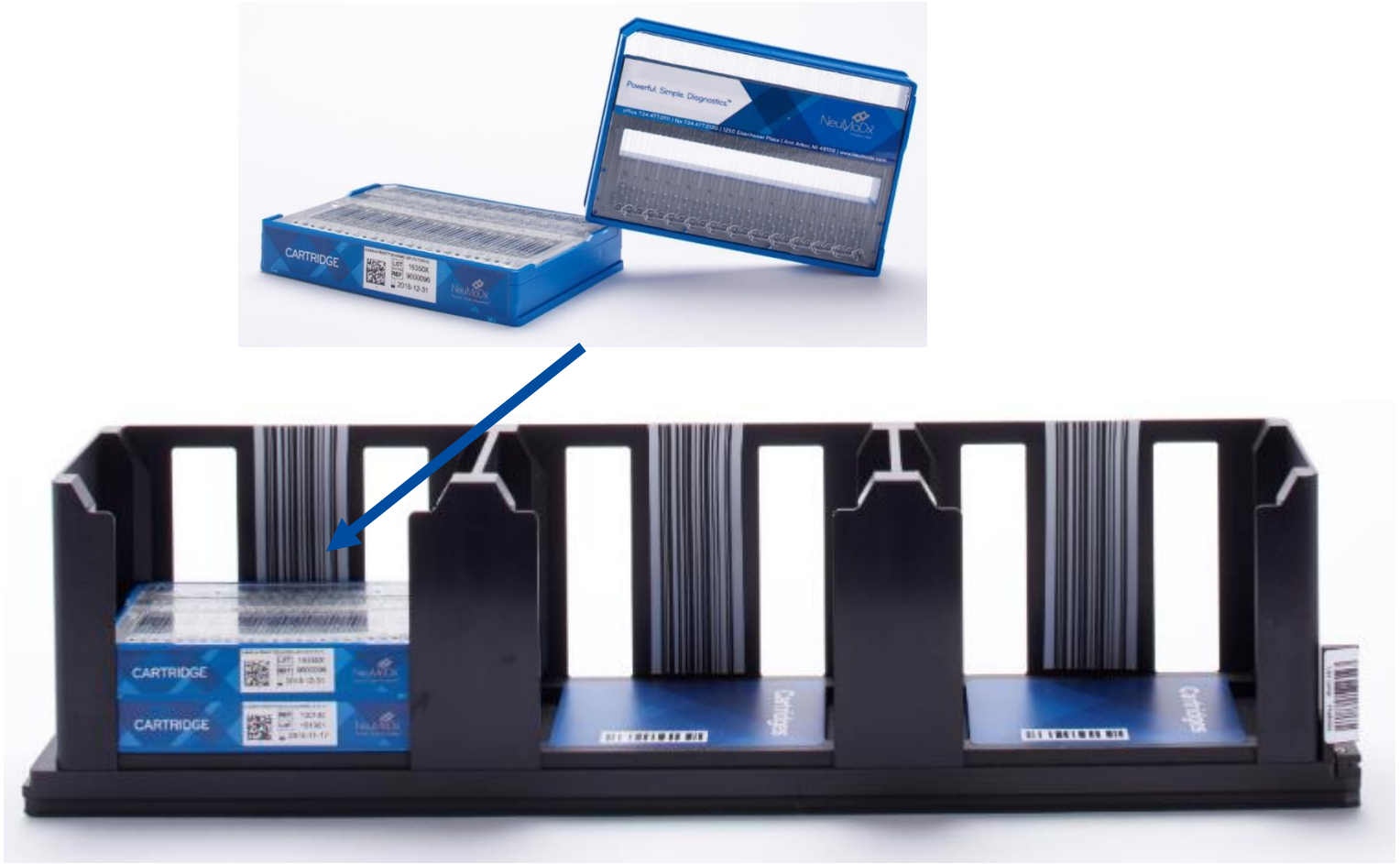
Reagents & Consumables

- NeuMoDx Extraction Plate (up to 4 per carrier), CO-RE Tips 1000 µL Tips (2 racks per carrier), 300 µL Tips (1 rack per carrier), and Tip Trays (1 under each 1000 rack) go in the Multi-Carrier



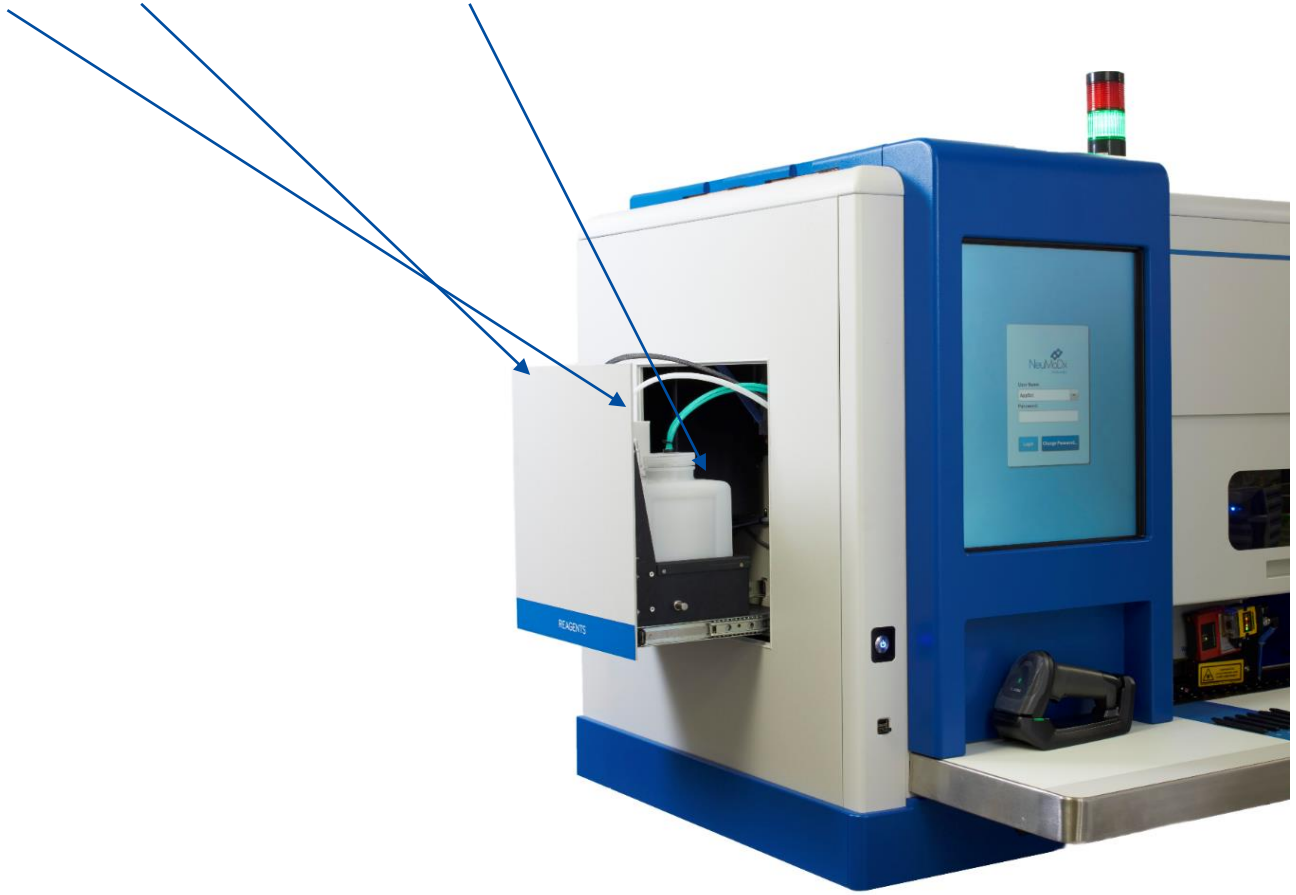
Reagents & Consumables

- Cartridges go into the cartridge carrier (up to 5 per slot, 15 total per carrier)



Reagents & Consumables

- Release, Wash, and the Priming Waste go into the Reagent Drawers

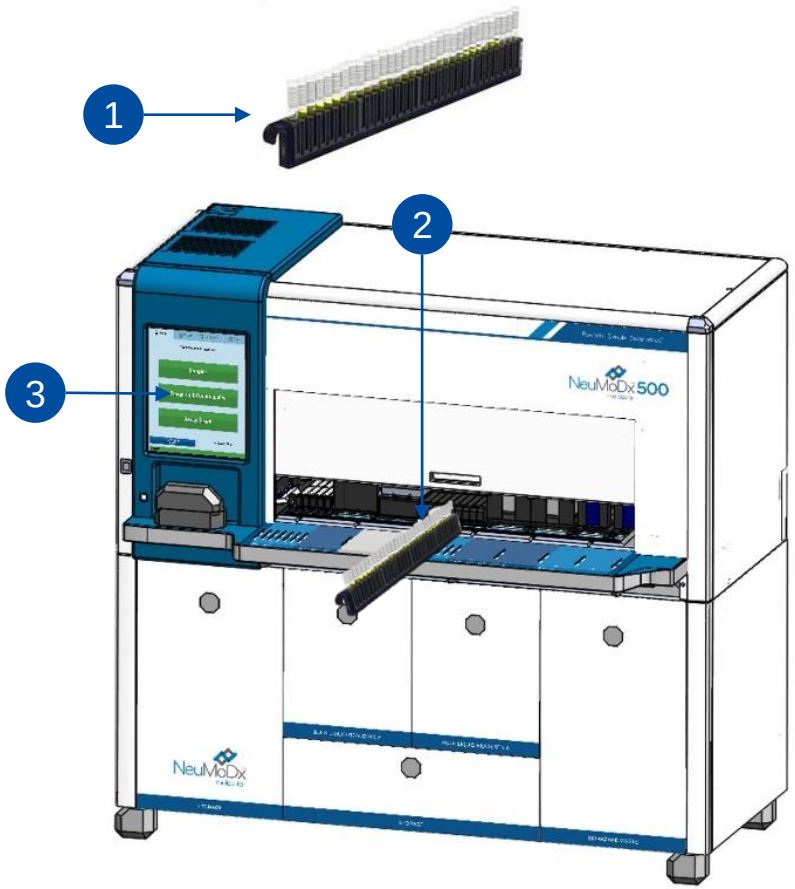


N96

System Operation & Workflow

System Operation

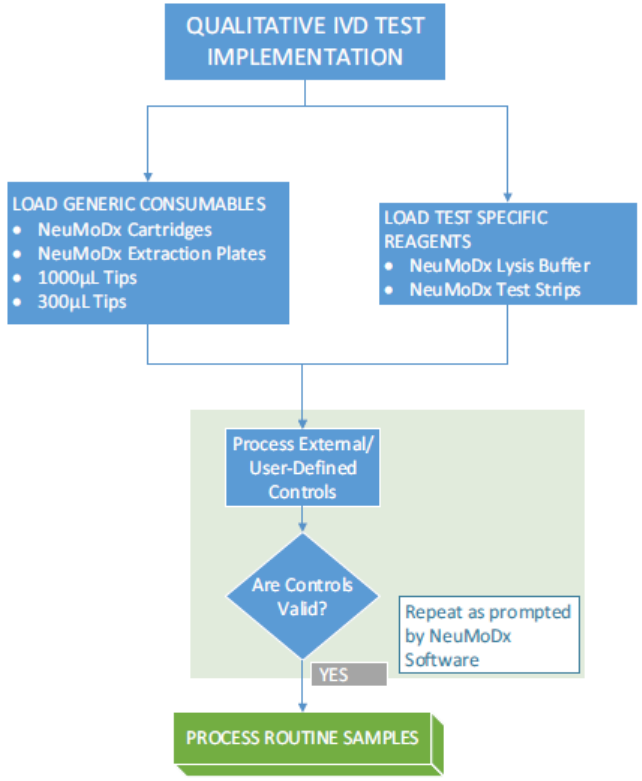
1. Operator loads specimen tube in Specimen Tube Carrier;
2. Operator places Specimen Tube Carrier on Autoloader Shelf;
3. Operator touches ‘load’ arrow on touchscreen user interface; and
4. Operator walks away.*

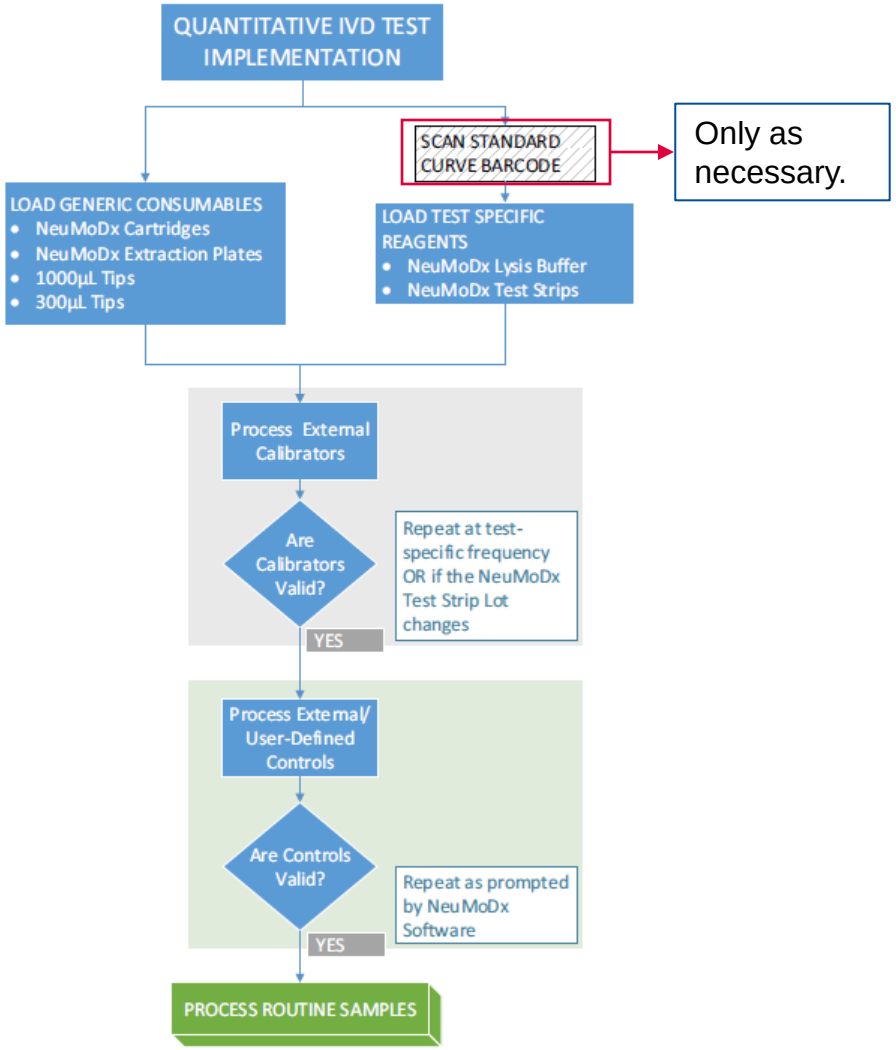


So long as the system has sufficient consumables to complete the testing, the results will be available without further operator interaction.
NOTE: Instrument shown is N288, but overall operation is the same.

*Specimen tubes can be assigned to specific tests before or during sending in the specimen tube carrier

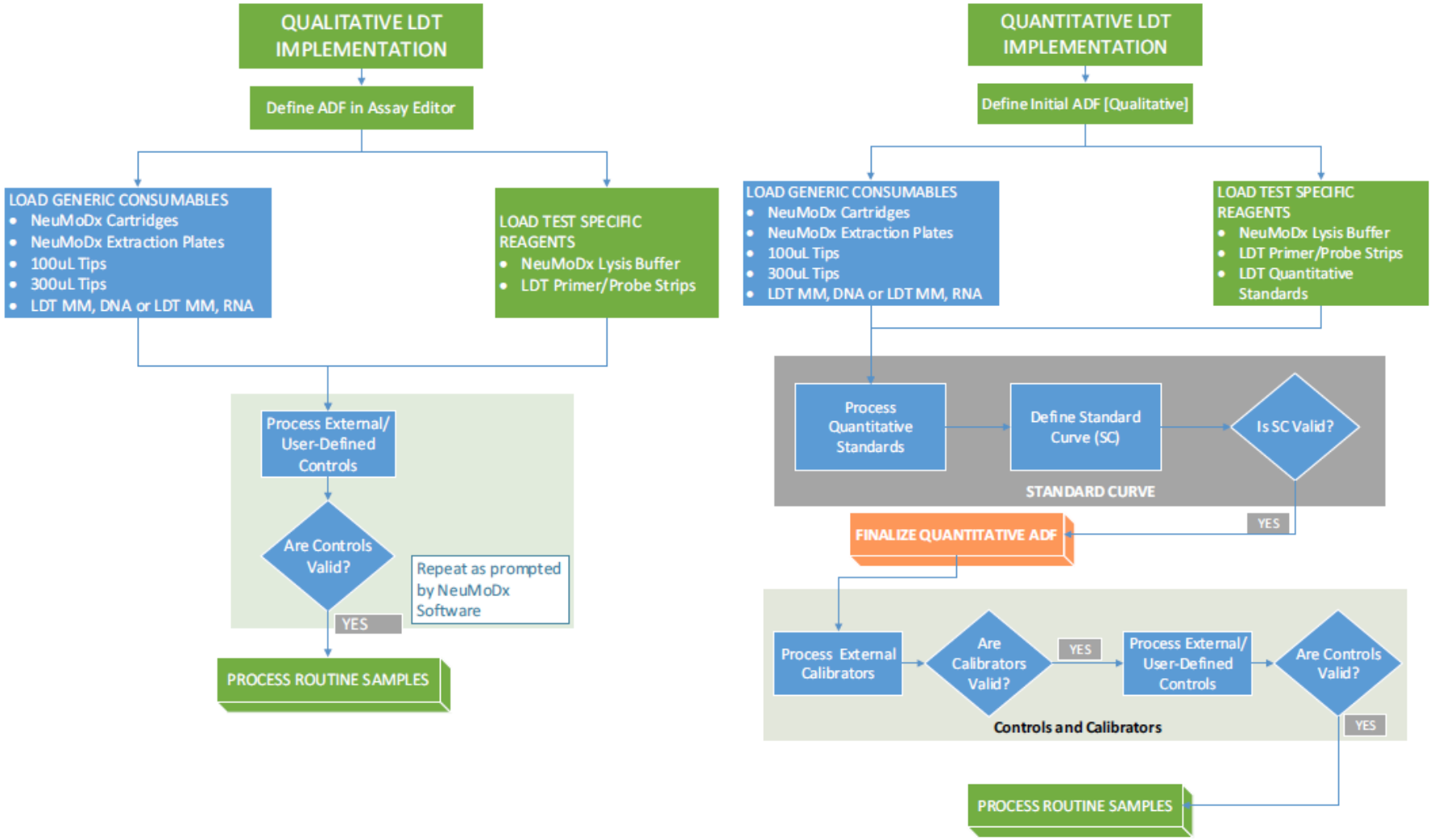
IVD Workflow





*Note: Mostly applicable to outside US

LDT Workflow



Assay Definition Files

- Assay Definition Files (ADFs) for IVD tests are provided and controlled by NeuMoDx
- Some LDT templates are available as a starting point for laboratories interested in LDT applications
- Contains all the Assay-specific extraction, PCR, and results processing parameters
  - Can be qualitative or quantitative
    - Qualitative is an absence or presence type test, usually used in diagnosis
    - Quantitative detects the viral load, usually used in patient monitoring

Process Control

- Internal Control (or Sample Process Control) is present in the extraction plates and is co-extracted, purified, and detected with the target
  - SPC1 for DNA
  - SPC2 for RNA

- Results Processing algorithm uses detection of the Internal Control only if the target of choice is not detected in order to determine if the result is Negative

Principles of Procedure

- Two main components of patented technology fuels the sample-to-result system

- (1) NeuDry™ Chemistry
  - Room-temperature stable, dried reagents require no re-hydration by the operator

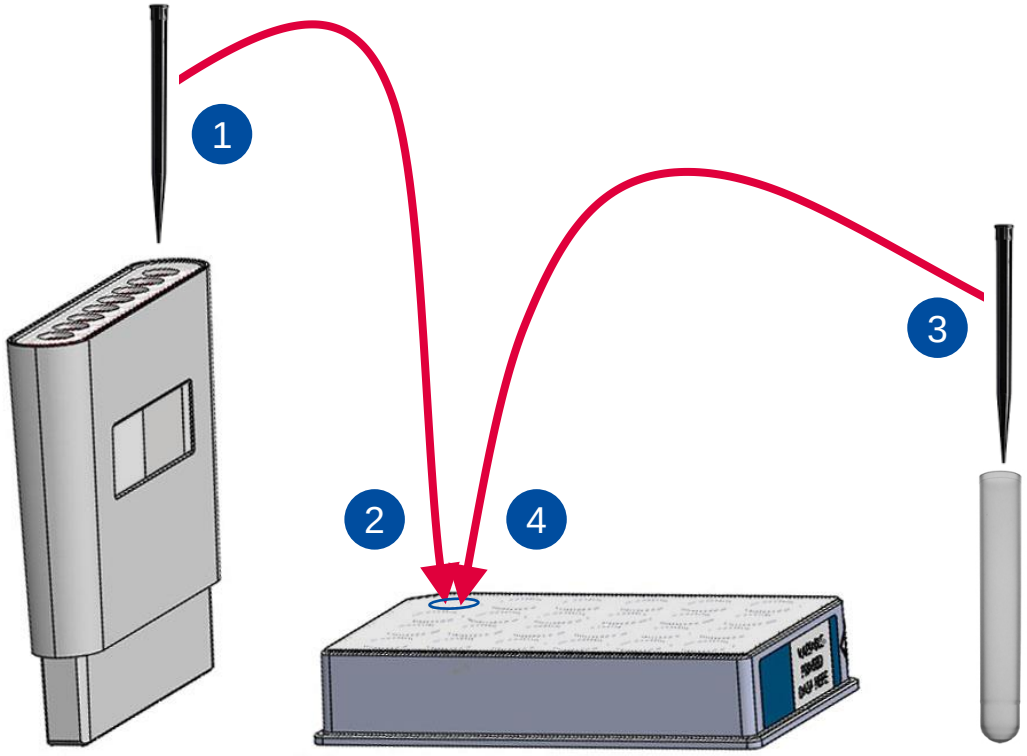
- (2) Microfluidic Cartridge
  - All extraction and PCR is executed within the Microfluidic Cartridge
  - Not batched, so each lane can process a different sample

Key Processing Steps

As specimen tubes are loaded, sample processing is initiated as follows:

No.	Step	Description
1	Liquid Handling Process A (LHPA)	Samples are mixed with buffer in the extraction plate.
2	Lysis/Binding	Cell lysis and nucleic acid binding takes place in the extraction plate.
3	Liquid Handling Process B (LHPB)	The lysate and magnetic bead mixture is aspirated from the extraction plate and loaded into the cartridge.
4	XPCR Extraction	Further purification and release of bound nucleic acid occurs within the cartridge.
5	Liquid Handling Process C (LHPC)	Eluted nucleic acid is mixed with dried PCR reagents in the test strip and then delivered into the PCR regions of the cartridge.
6	PCR/Real-Time PCR	Thermal cycling and detection of the desired targets and internal controls occurs in the PCR regions of the cartridge.

Key Processing Steps LHPA



No. 2 = Lysis/Binding

LHPA

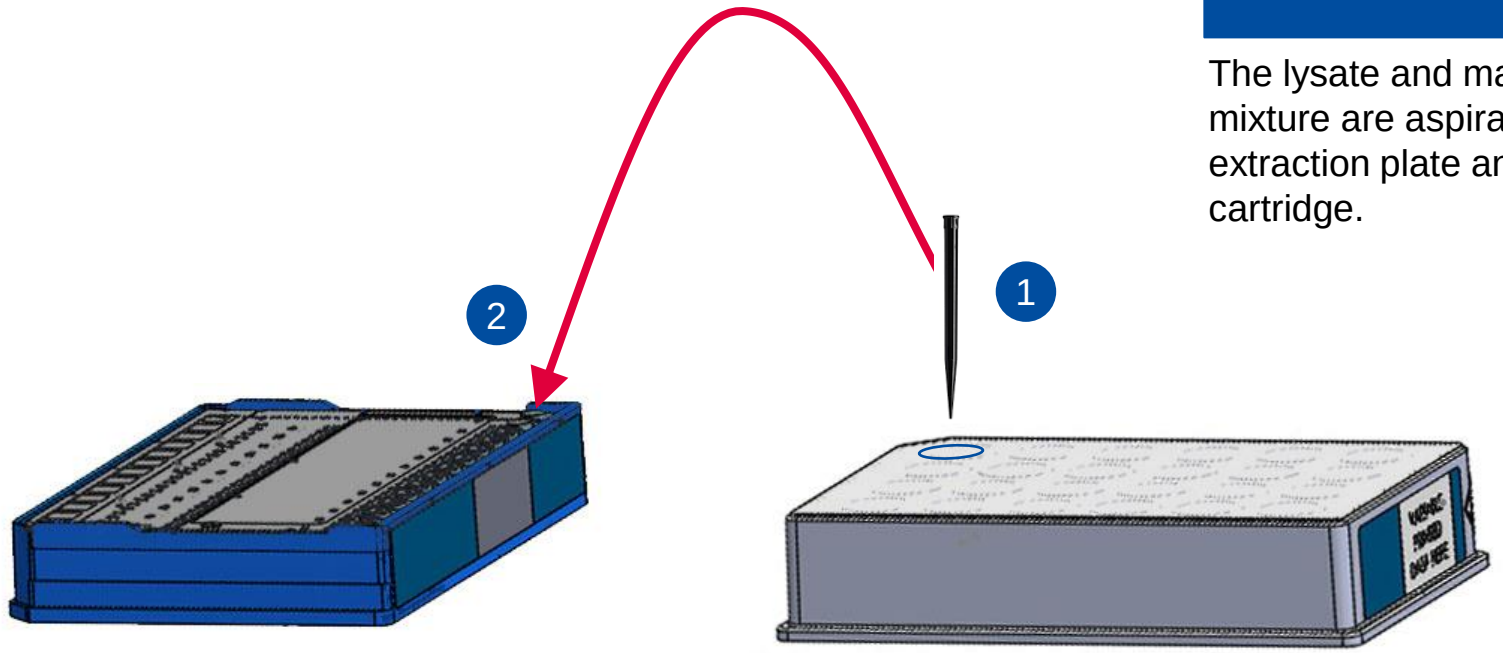
Samples are mixed with buffer in the Extraction Plate

1. Aspirate Buffer from Buffer Carrier.
2. Dispense Buffer into Extraction Plate well.
   This tip is placed back into the tip carrier.
3. Aspirate sample from Sample Tube (with a new tip).
4. Dispense sample into Extraction Plate well.
   Mix sample/buffer and discard this tip.

Key Processing Steps LHPB

No. 3 = LHPB

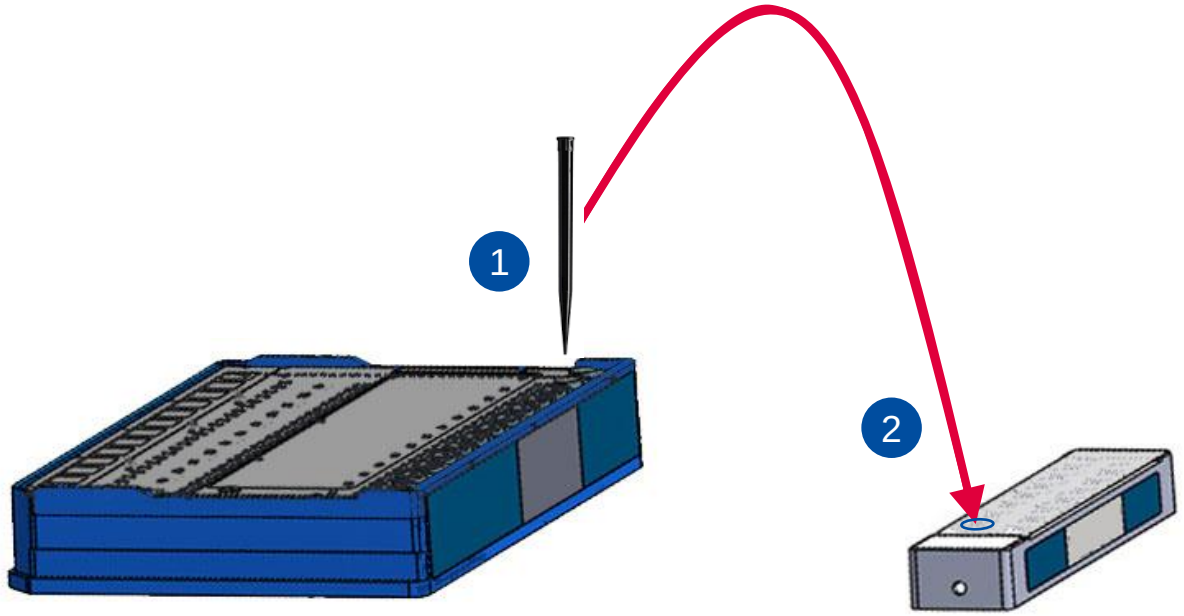
The lysate and magnetic bead mixture are aspirated from the extraction plate and loaded into the cartridge.



No. 4 = xPCR Extraction

1. Aspirate sample from Extraction Plate with the tip that was used for aspirating buffer.
2. Dispense sample into Cartridge.
   Tip is discarded, XPCR Extraction begins.

Key Processing Steps LHPC



No. 6 = PCR/Real-time PCR

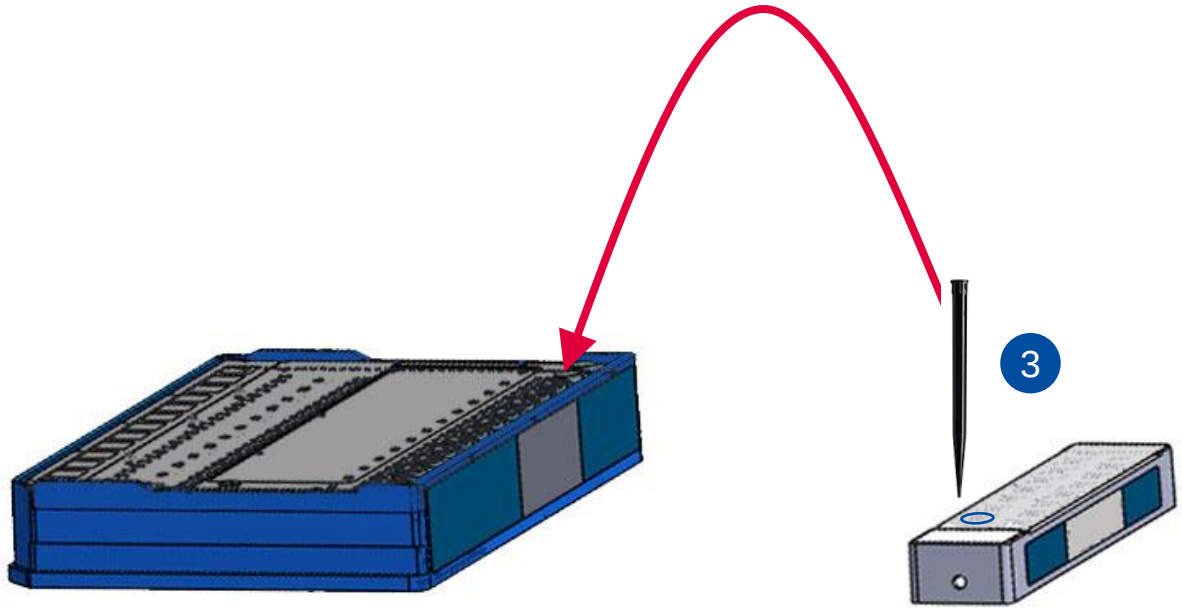
Liquid Classes in blue

No. 5 = LHPC

Eluate is mixed with dried PCR reagents in the test strip, then transferred back to the cartridge.

1. Eluate is aspirated out of cartridge.
2. Eluate is mixed with the NeuDry MasterMix Reagents.
3. PCR-ready mixture is aspirated out of the Test Strip and placed back into the cartridge for PCR.

Key Processing Steps LHPC



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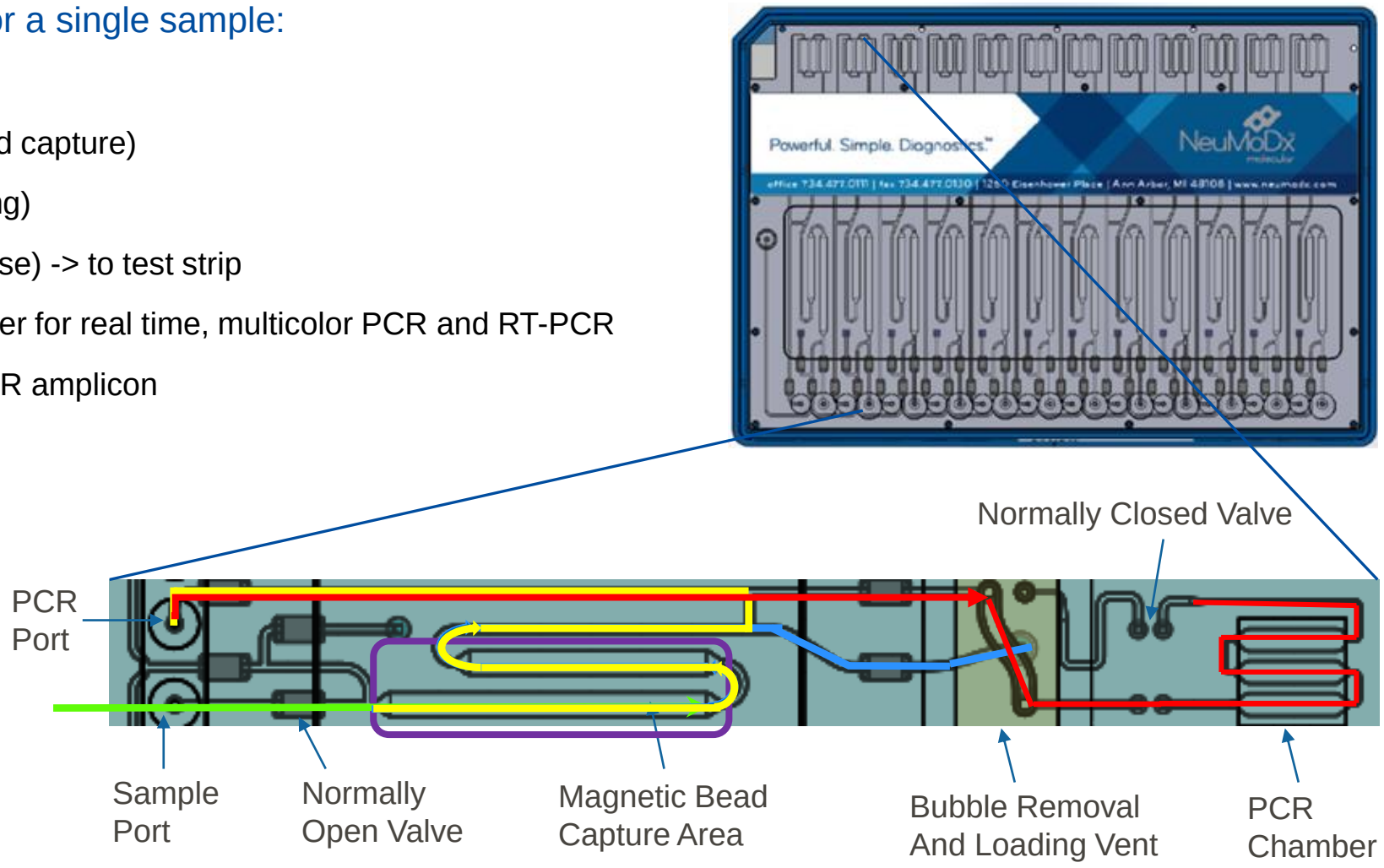
3. PCR-ready mixture is aspirated out of the Test Strip and placed back into the cartridge for PCR.

Proprietary chemistry & microfluidics

Performs the following operations for a single sample:

- Lysed Sample Insertion
- Nucleic acid isolation (magnetic bead capture)
- Reduction of PCR inhibitors (Washing)
- Concentration of nucleic acid (Release) -> to test strip
- PCR-ready mixture into PCR chamber for real time, multicolor PCR and RT-PCR

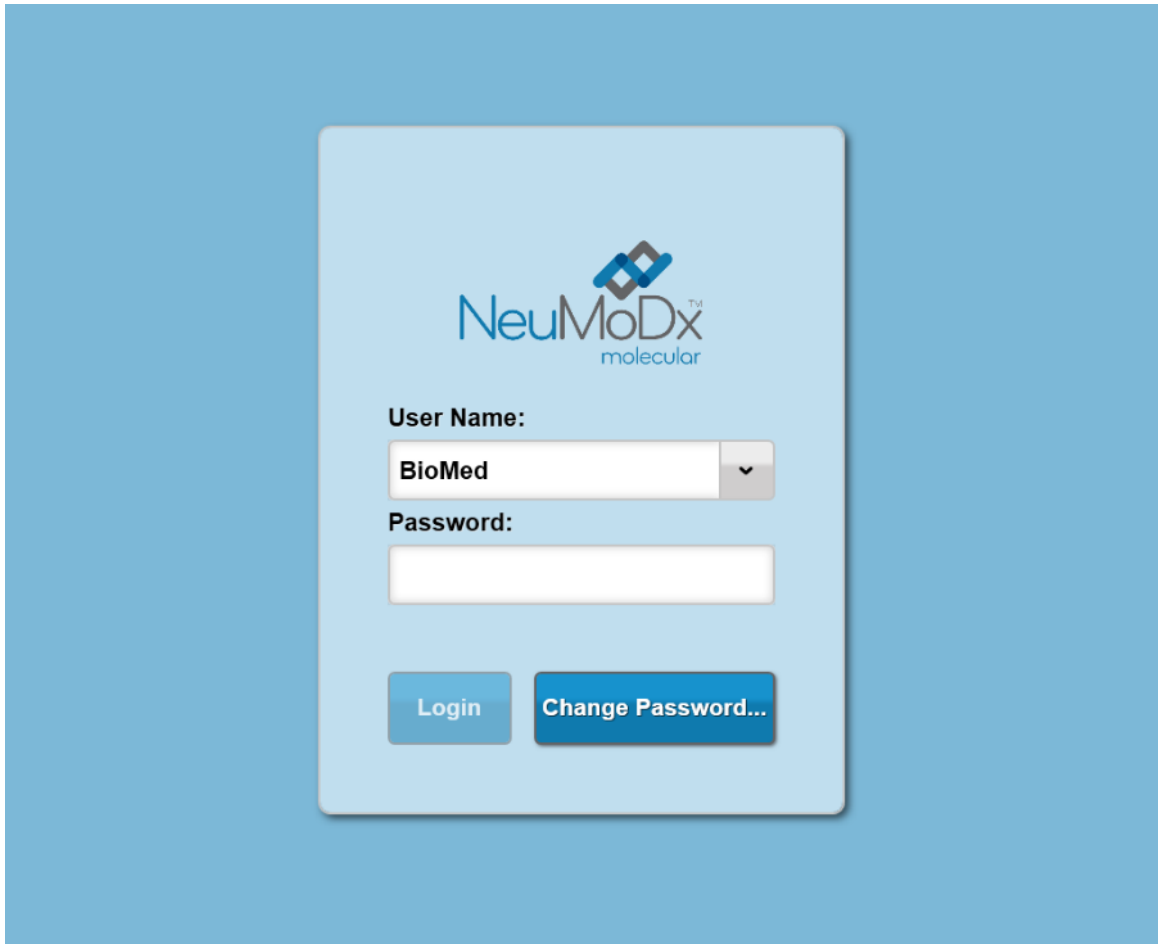
Isolation of all waste sample and PCR amplicon



Part III
NeuMoDx Software Guide

NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

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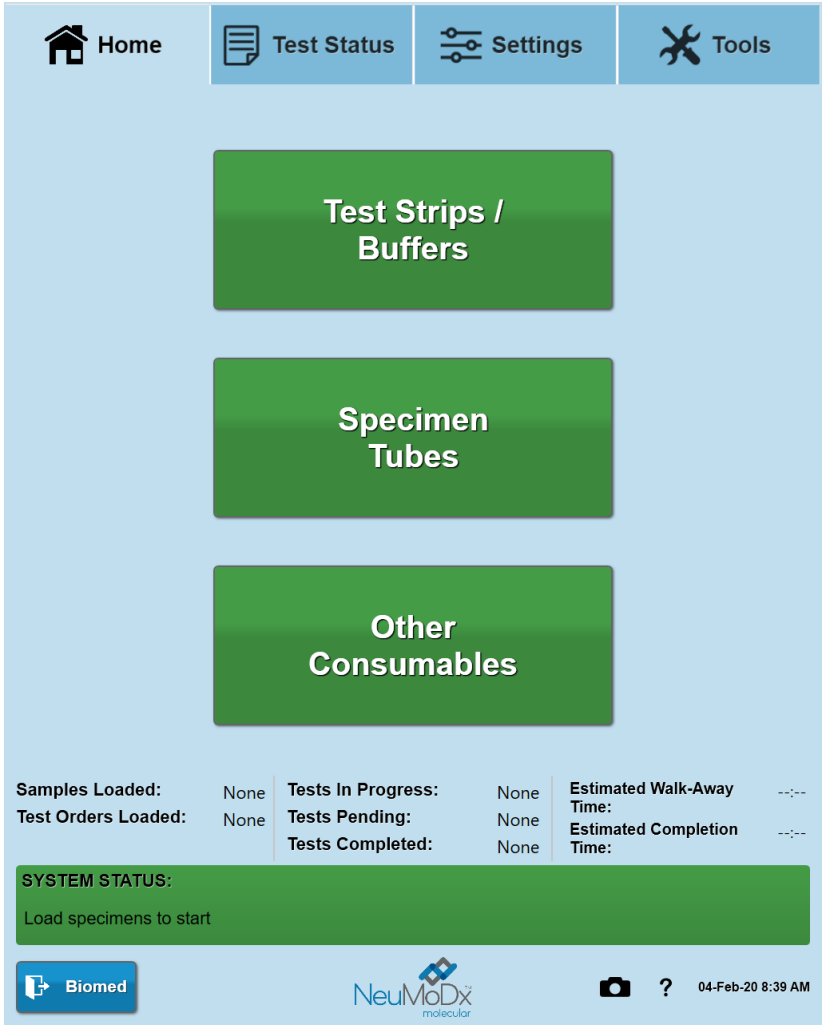

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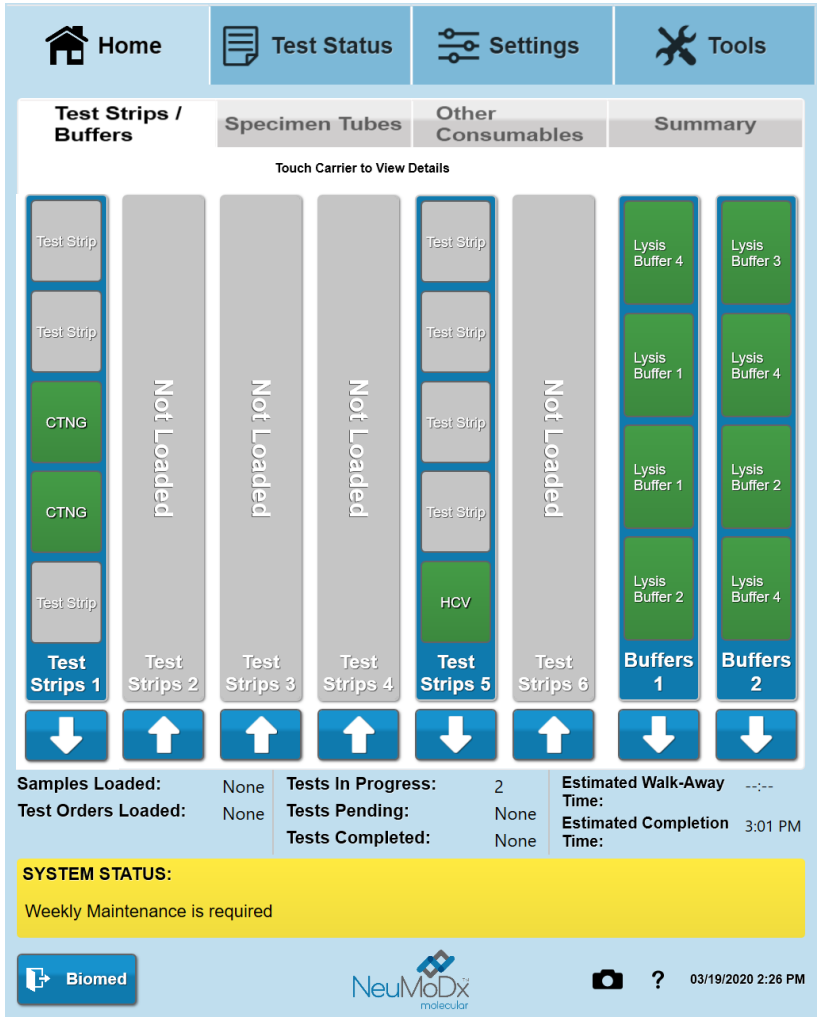

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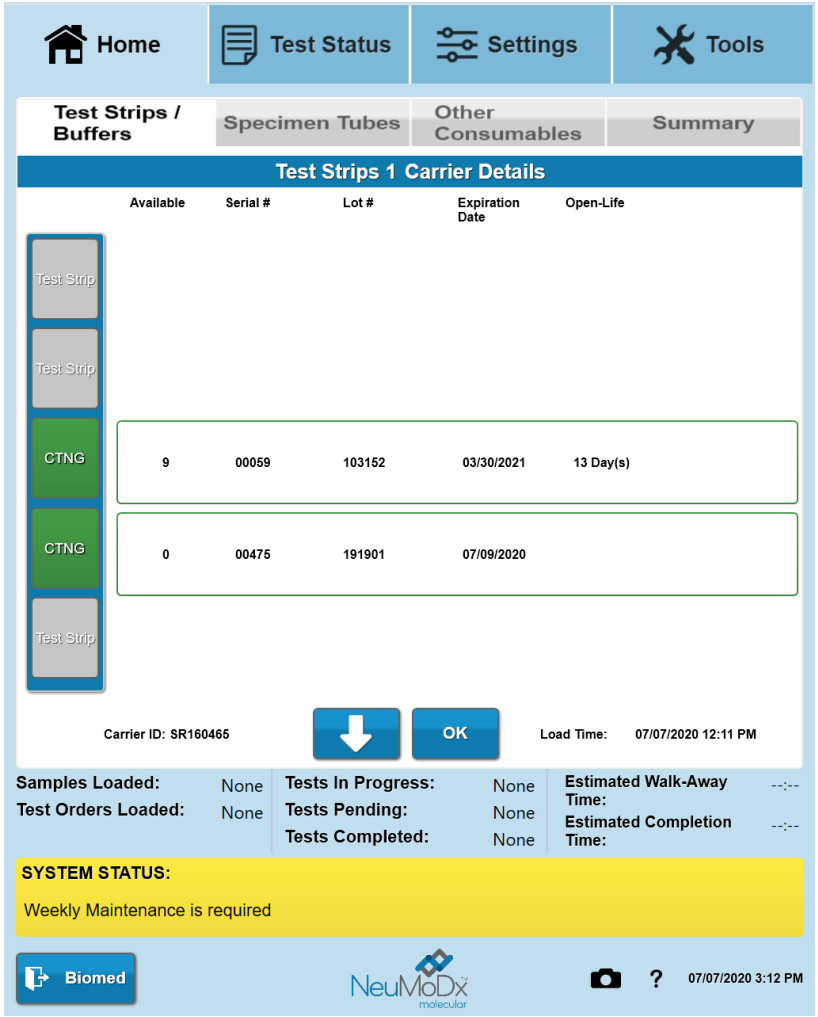

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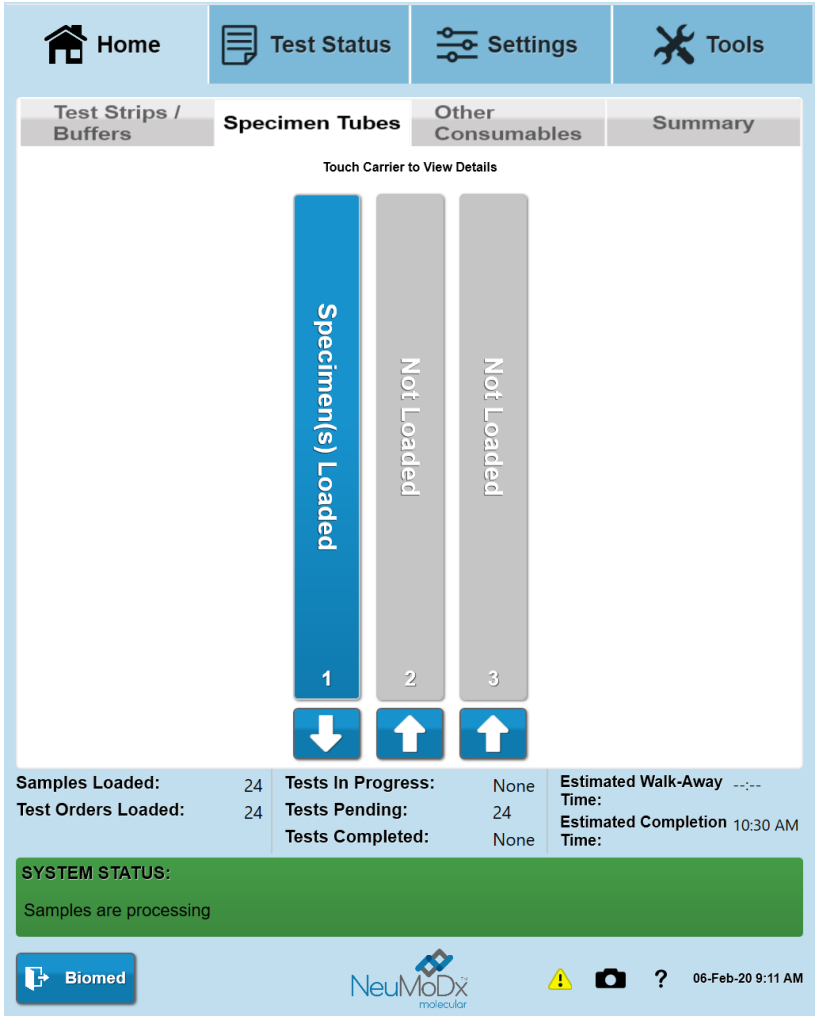

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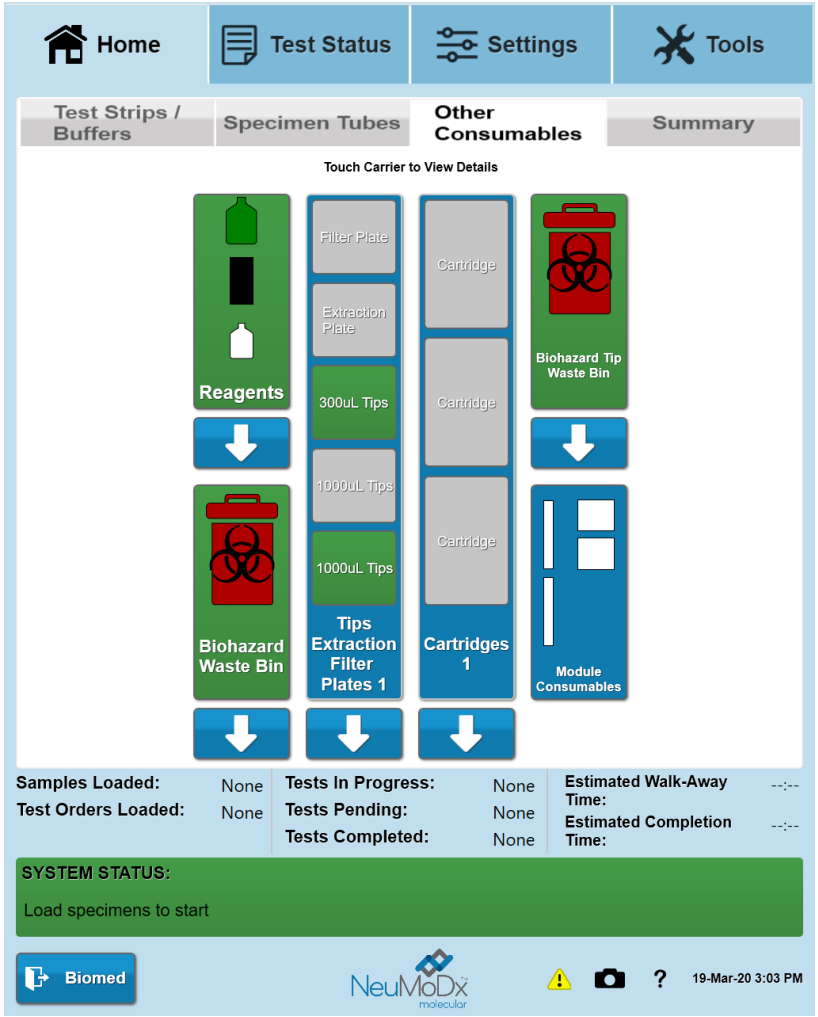

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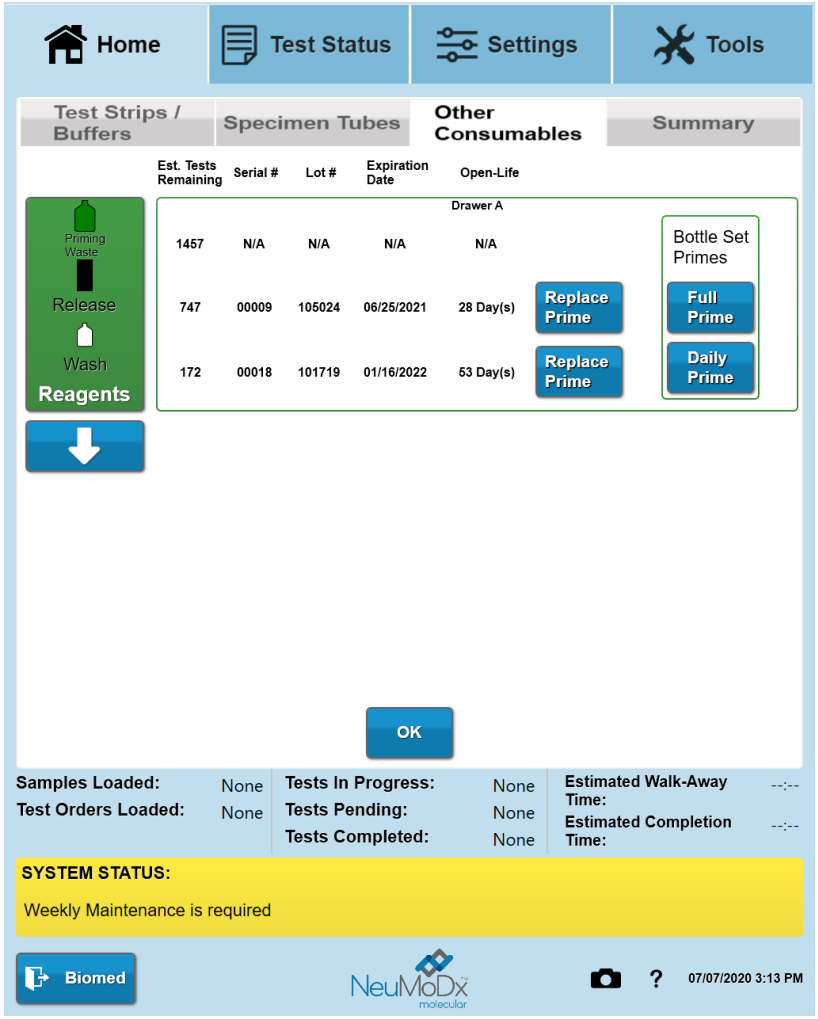

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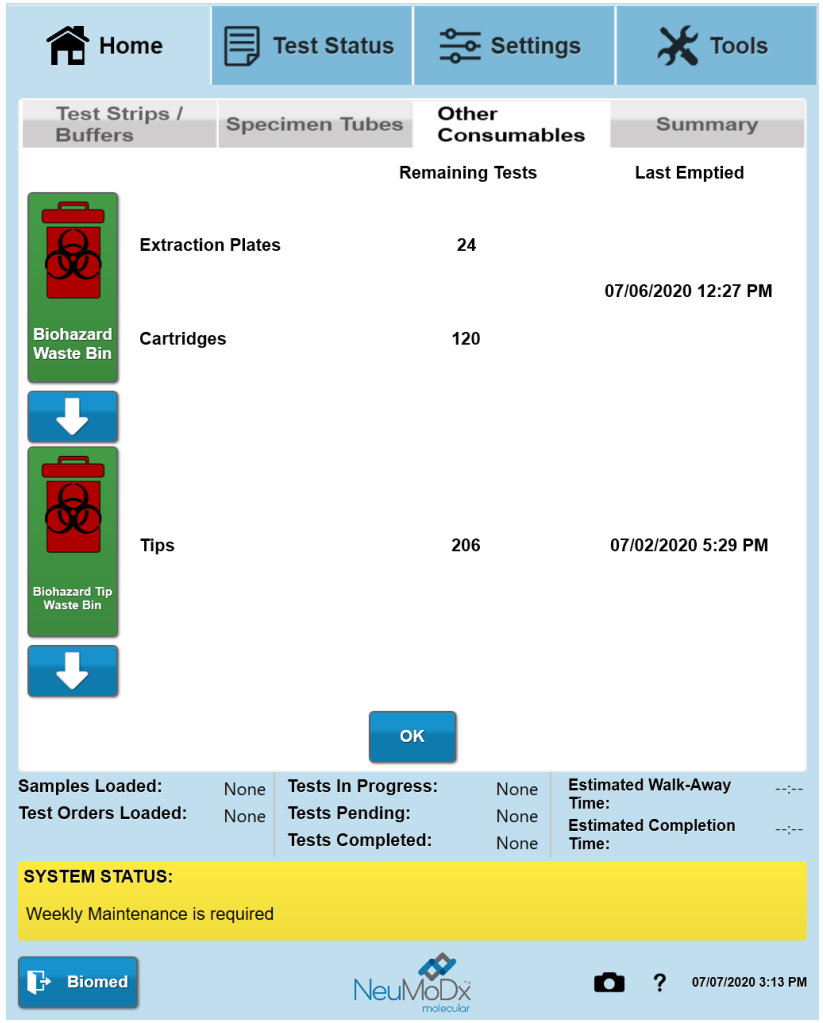

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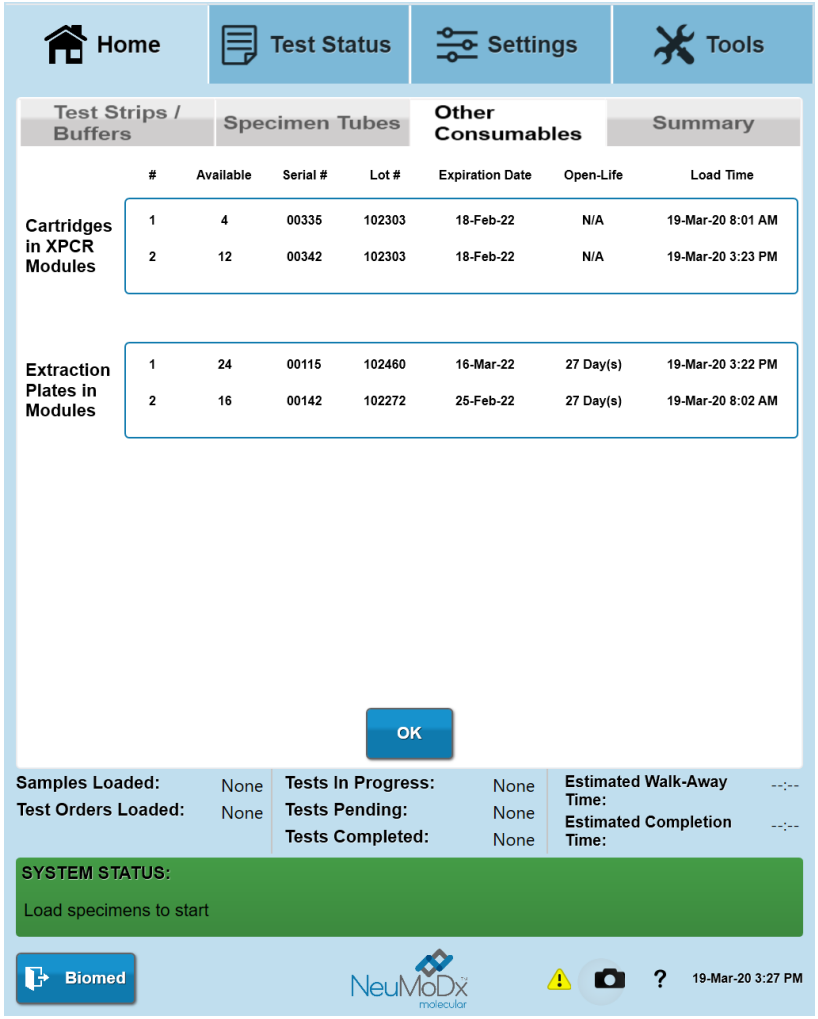

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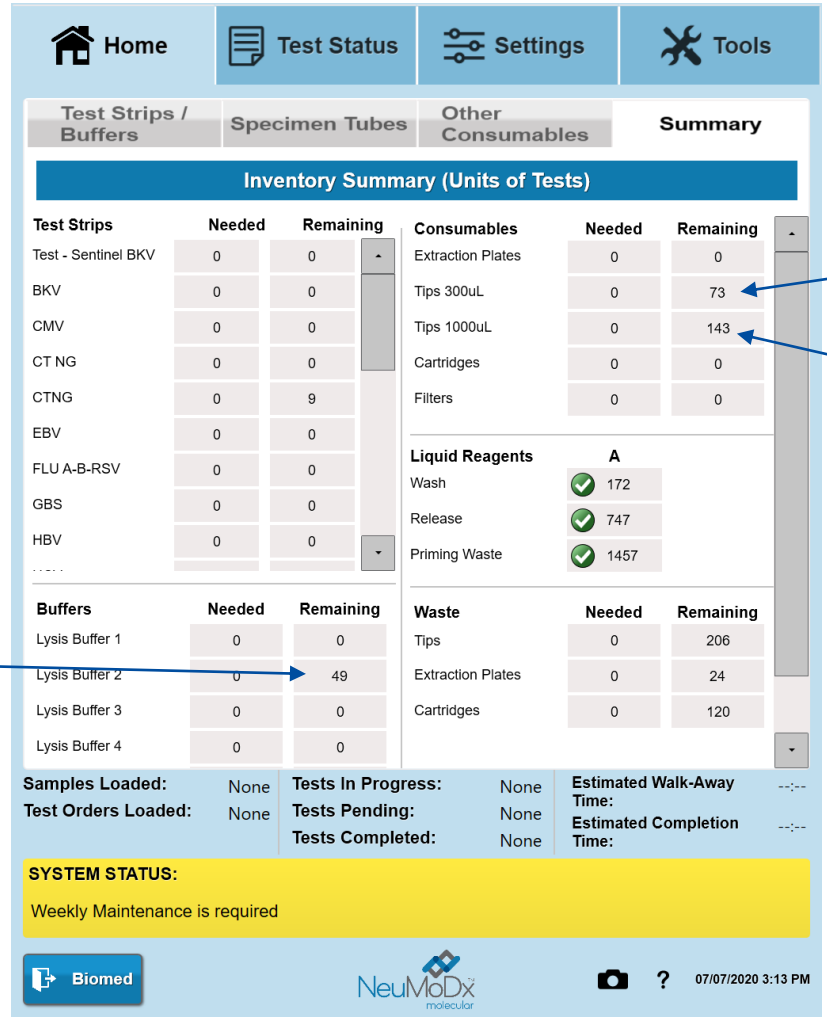


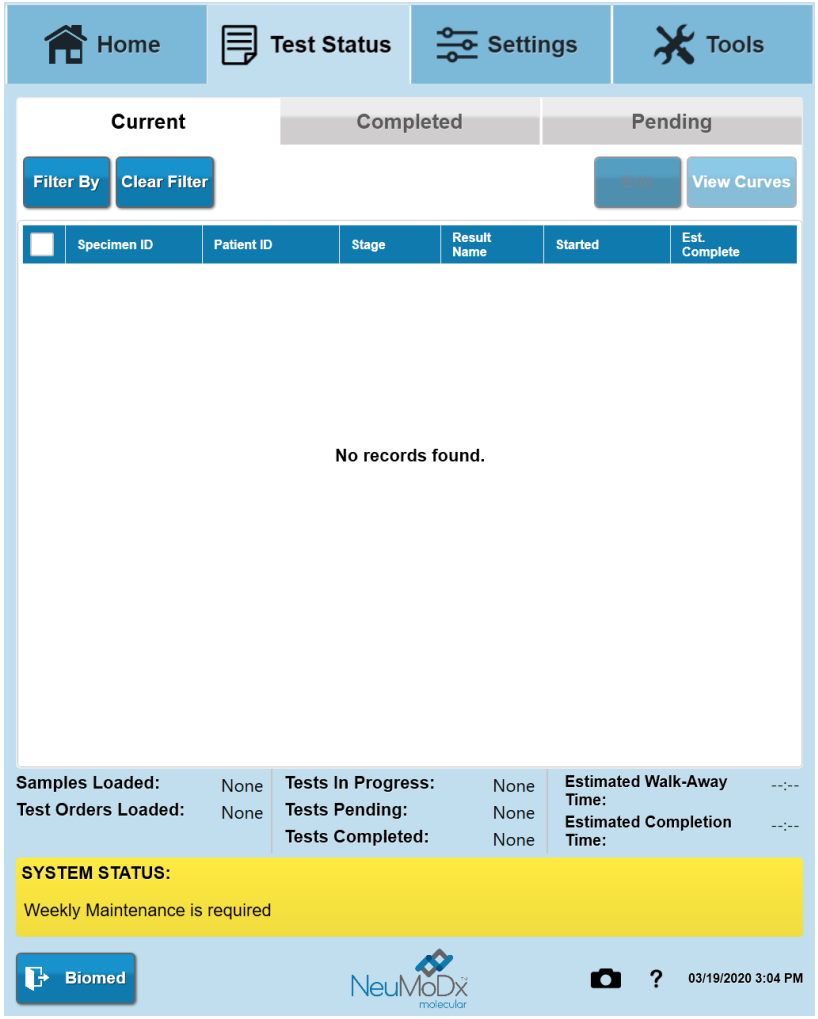
one 300 µL tips/test but

2 tips/test; ~71 tests

Lysis Buffers are in mL

NeuMoDx 96 Software Screen

BioMed Level User



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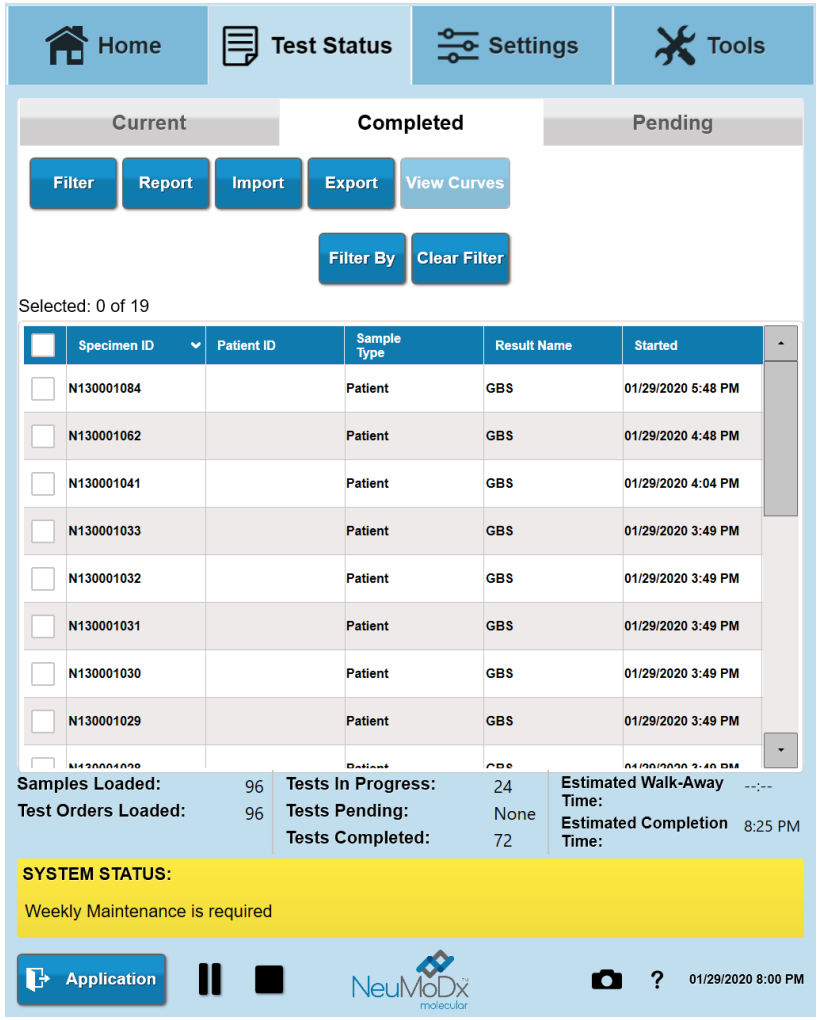

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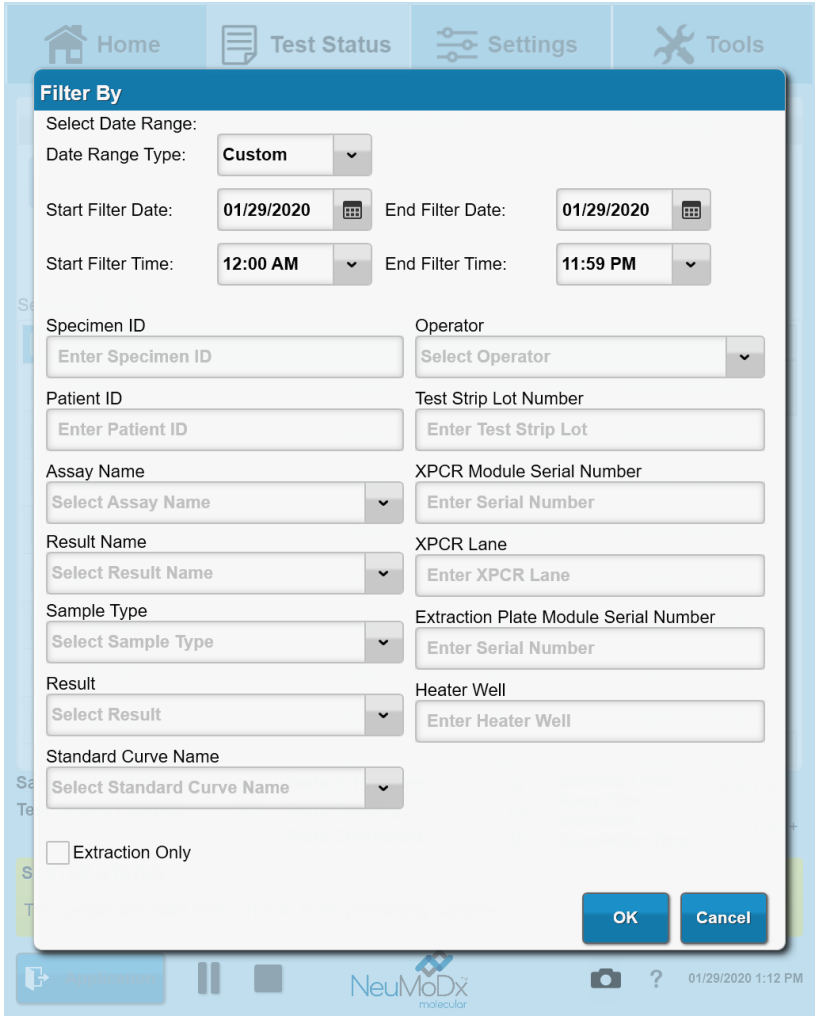

NeuMoDx 96 Software Screen

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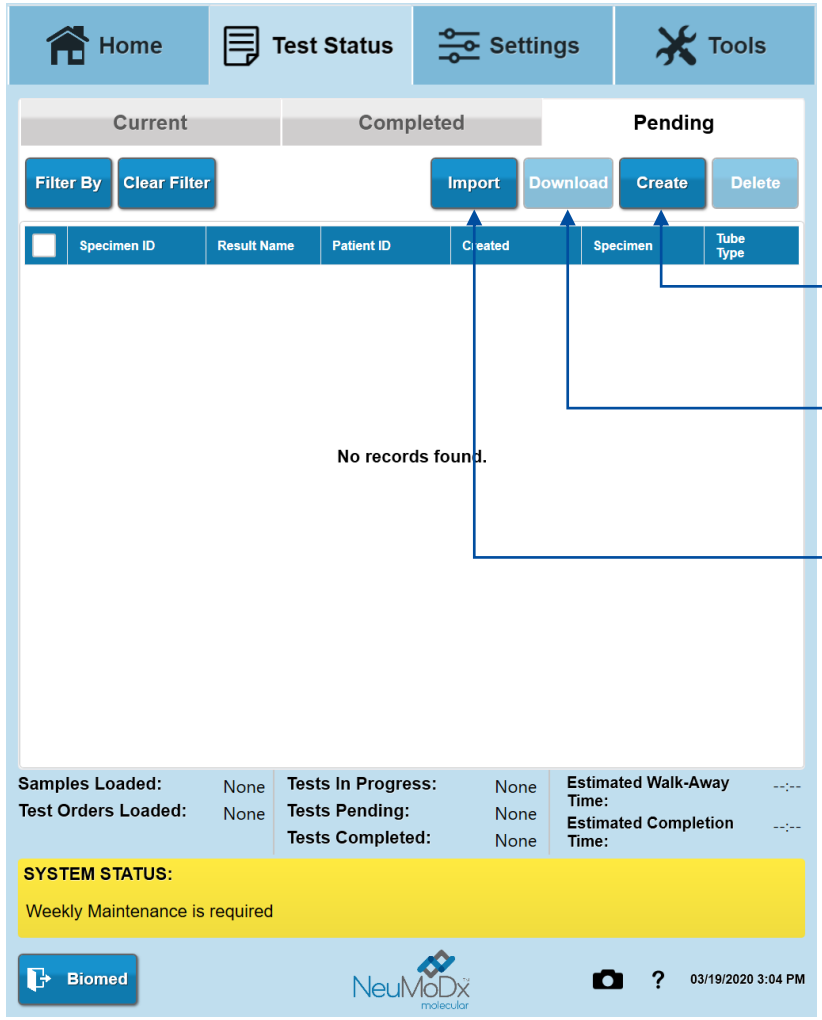
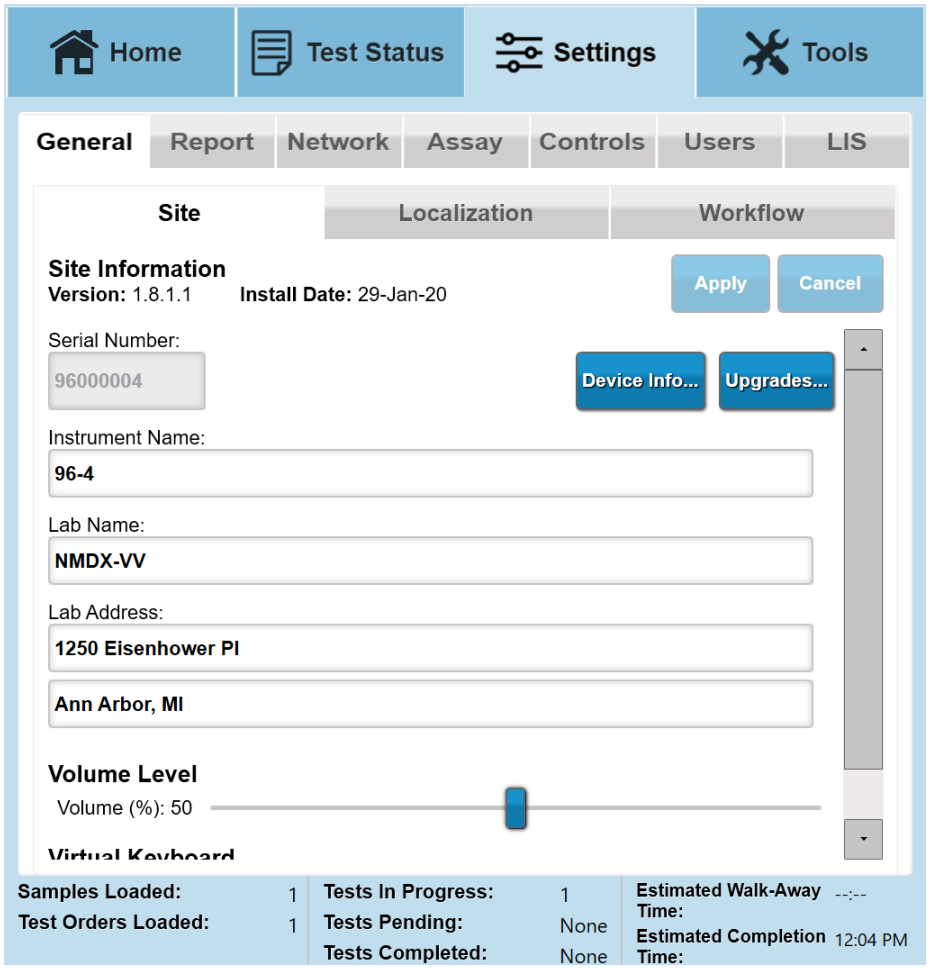
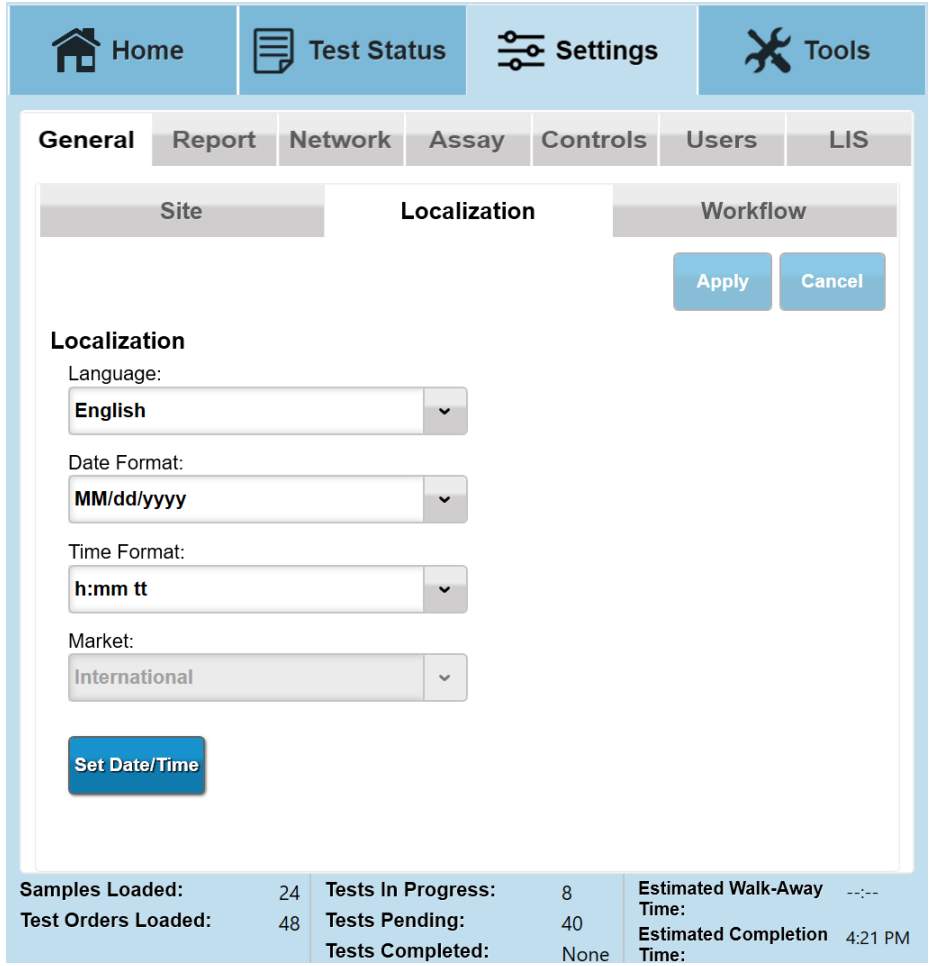


Create individual test order

Download from:
- LIS

Import excel from:
- USB
- Network


Home
Test Status
Settings
Tools
General
Report
Network
Assay
Controls
Users
LIS
Site
Localization
Workflow
Site Information
Version: 1.8.1.1
Install Date: 29-Jan-20
Apply
Cancel
Serial Number:
96000004
Device Info...
Upgrades...
Instrument Name:
96-4
Lab Name:
NMDX-VV
Lab Address:
1250 Eisenhower Pl
Ann Arbor, MI
Volume Level
Volume (%): 50
Virtual Keyboard
Samples Loaded: 1
Test Orders Loaded: 1
Tests In Progress: 1
Tests Pending: None
Tests Completed: None
Estimated Walk-Away Time: --:--
Estimated Completion Time: 12:04 PM


Home
Test Status
Settings
Tools
General
Report
Network
Assay
Controls
Users
LIS
Site
Localization
Workflow
Apply
Cancel
Localization
Language:
English
Date Format:
MM/dd/yyyy
Time Format:
h:mm tt
Market:
International
Set Date/Time
Samples Loaded: 24
Test Orders Loaded: 48
Tests In Progress: 8
Tests Pending: 40
Tests Completed: None
Estimated Walk-Away Time: --:--
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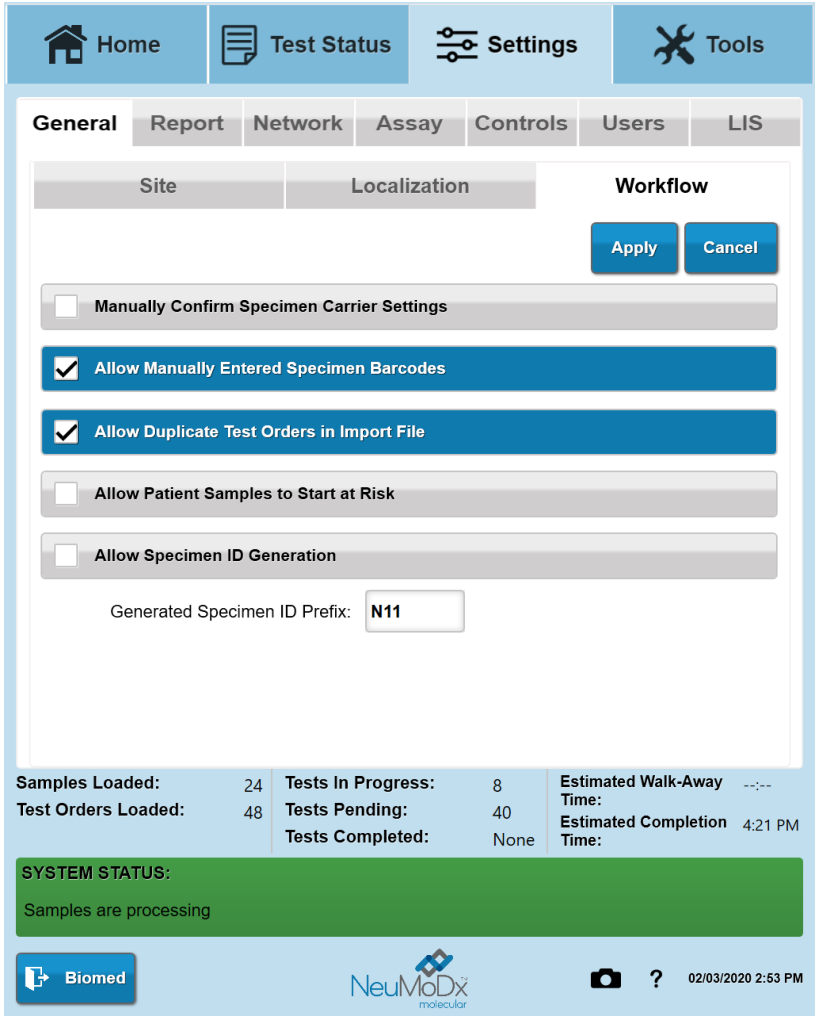
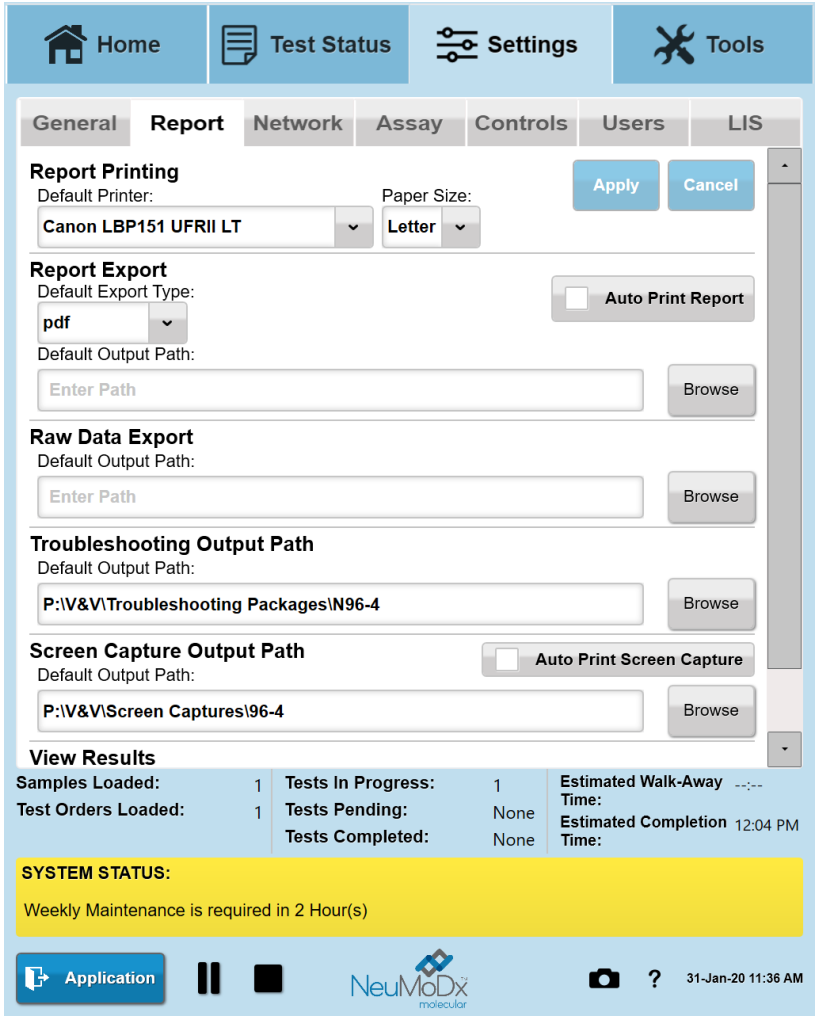
NeuMoDx 96 Software Screen

BioMed Level User



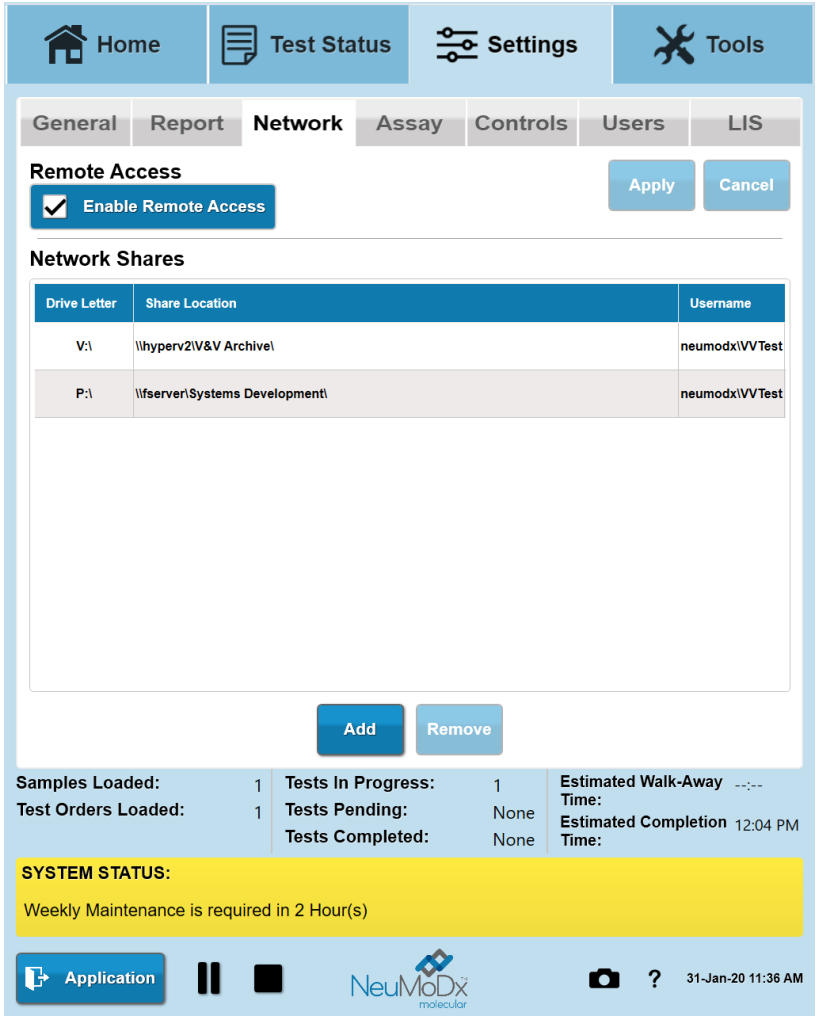
NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

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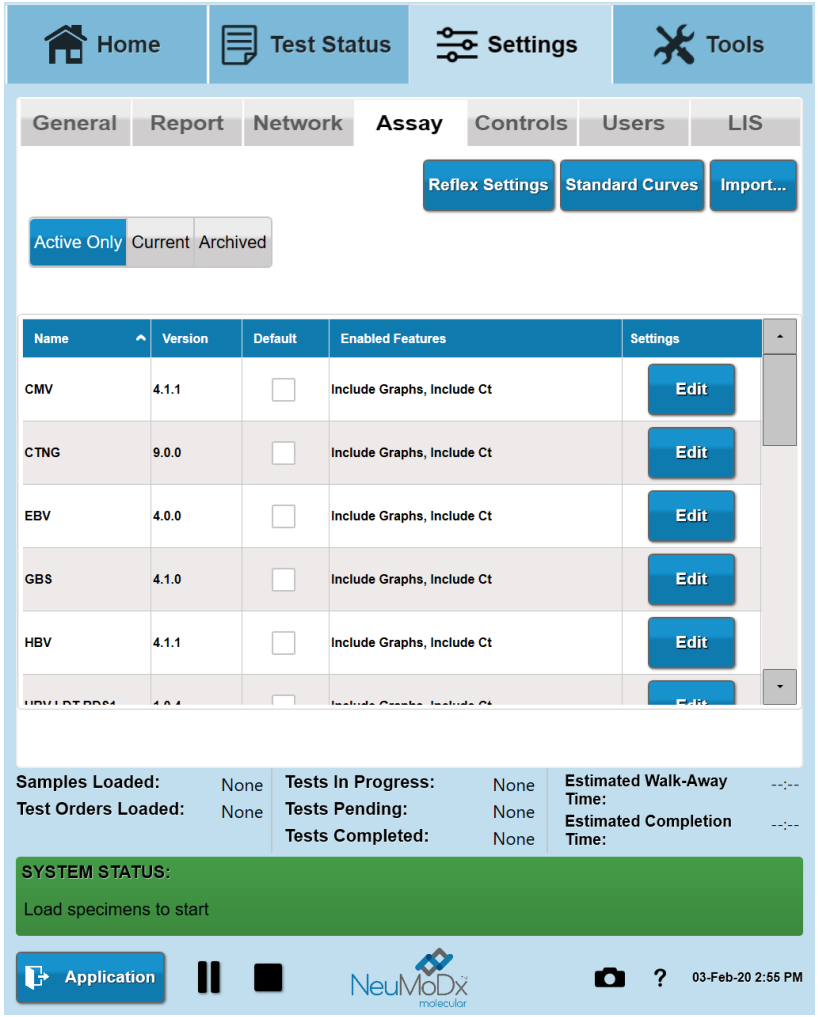
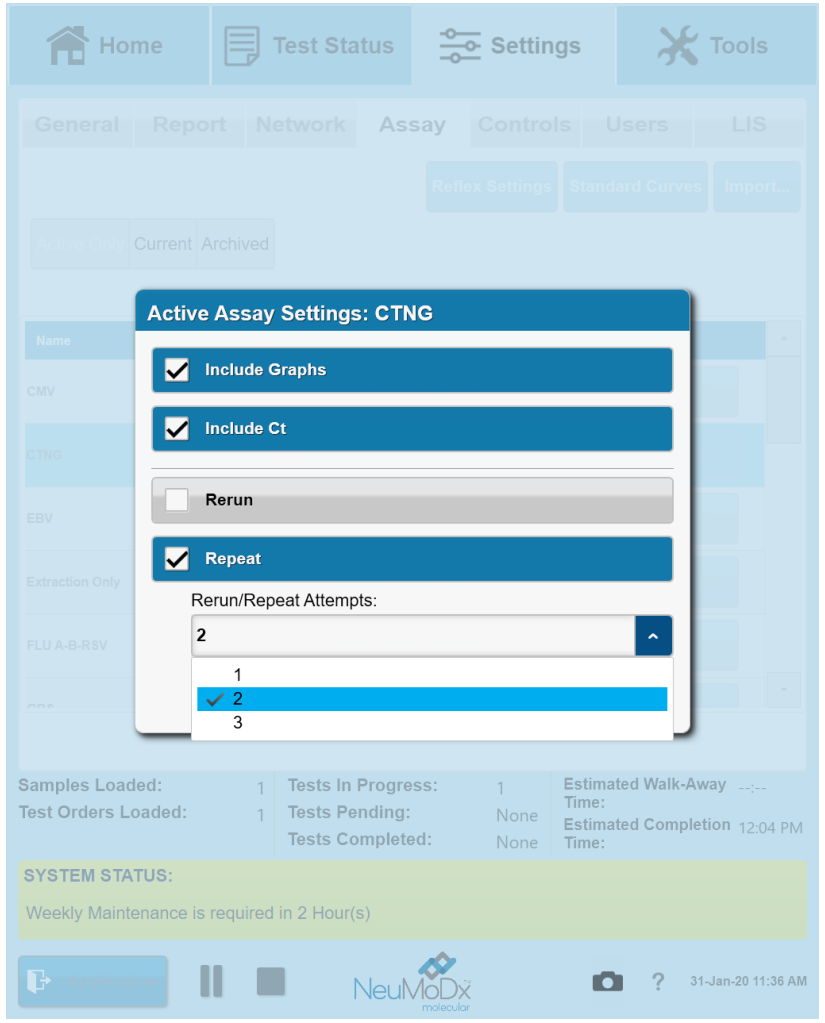


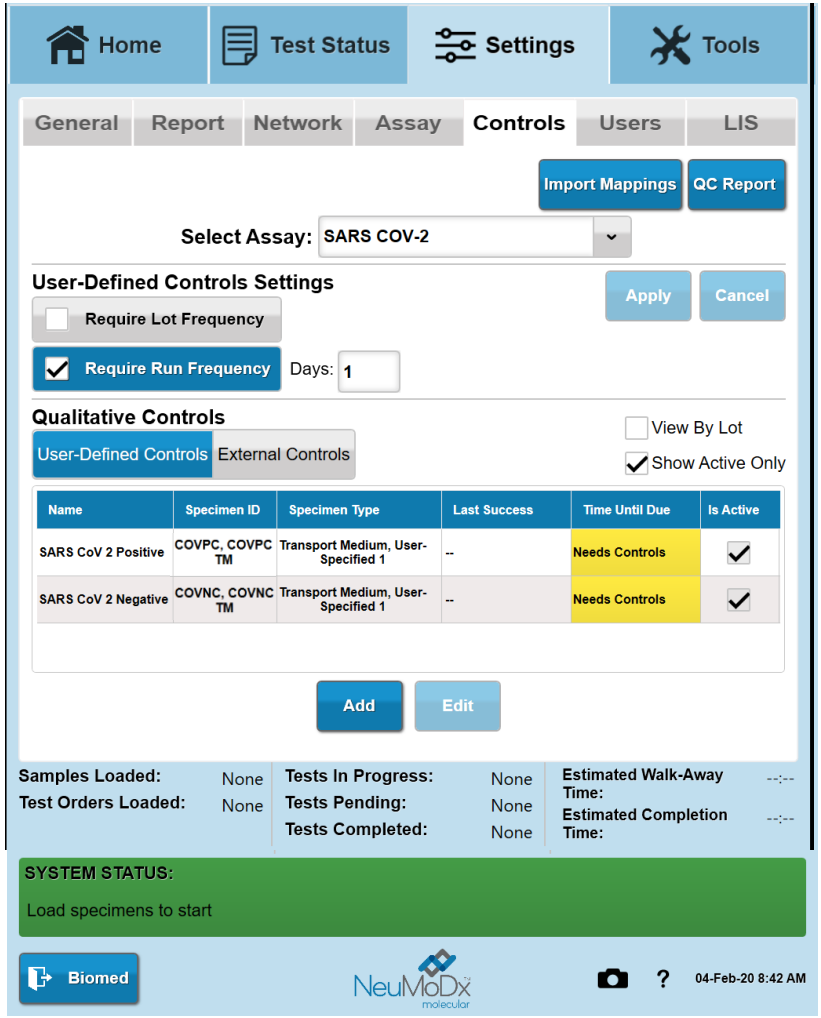
NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

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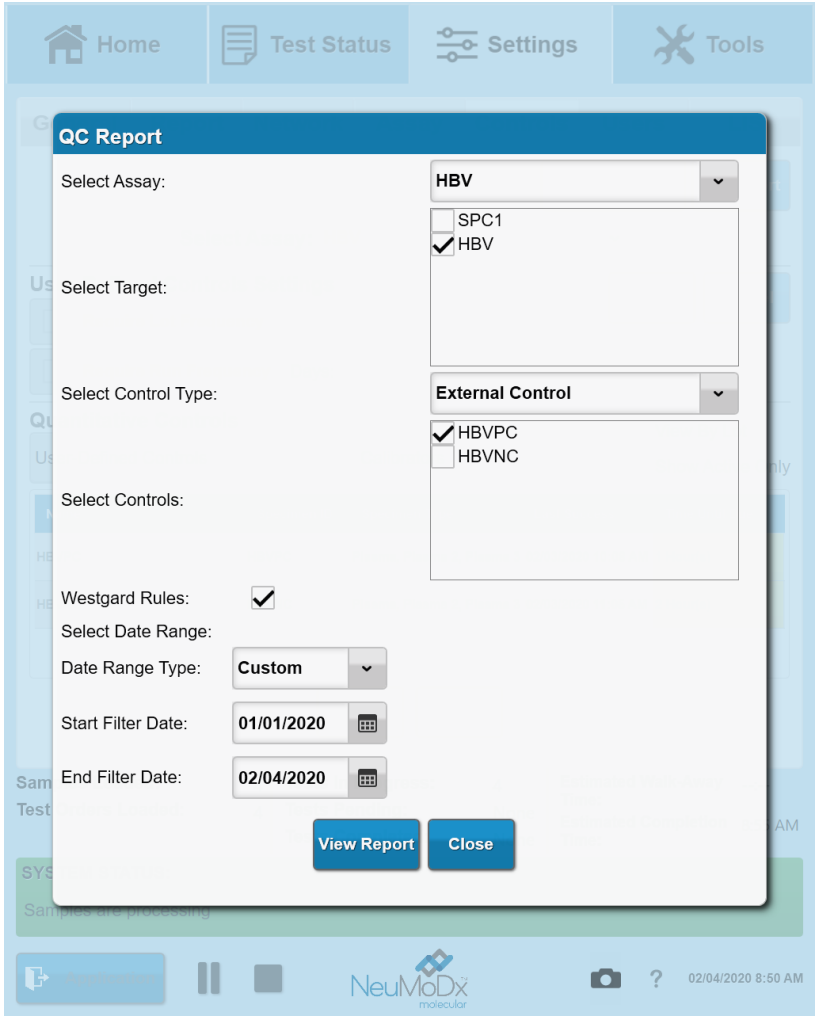

NeuMoDx 96 Software Screen

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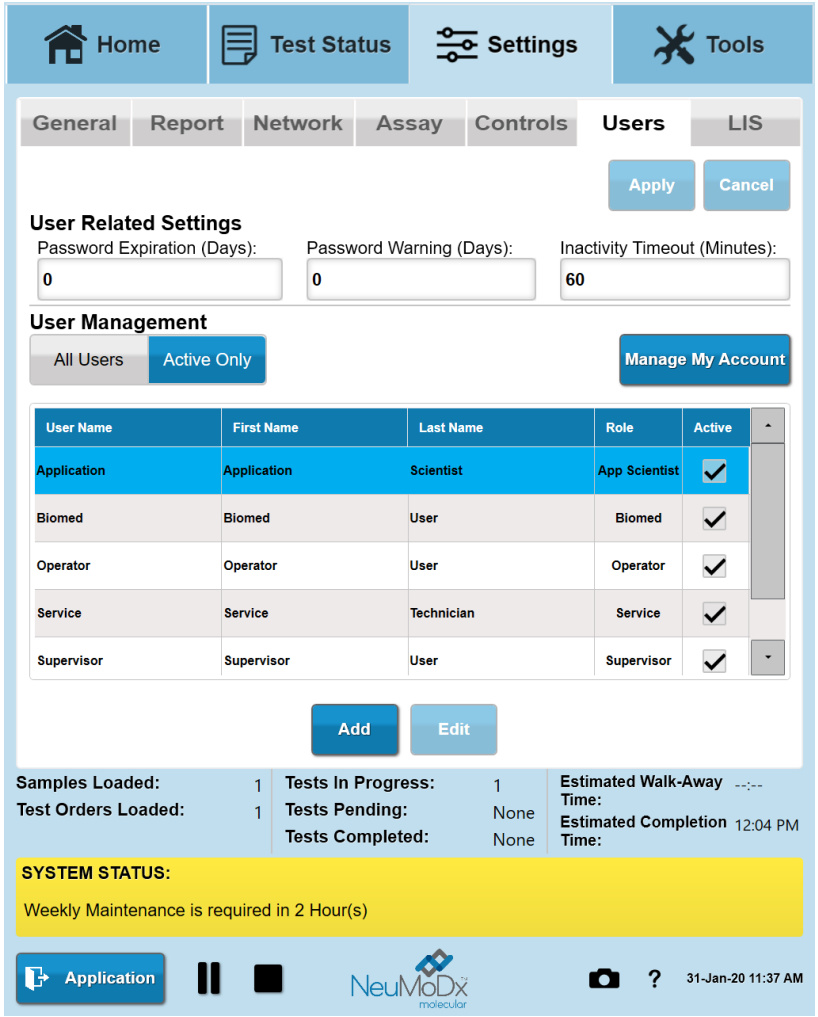

NeuMoDx 96 Software Screen

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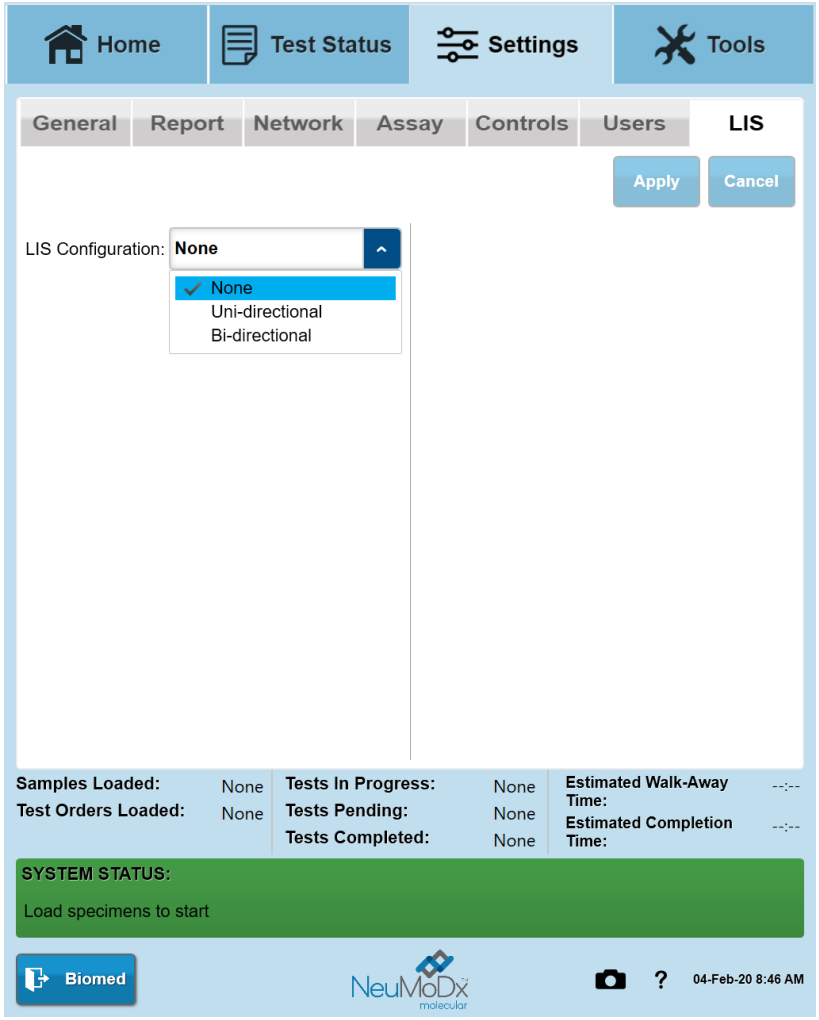
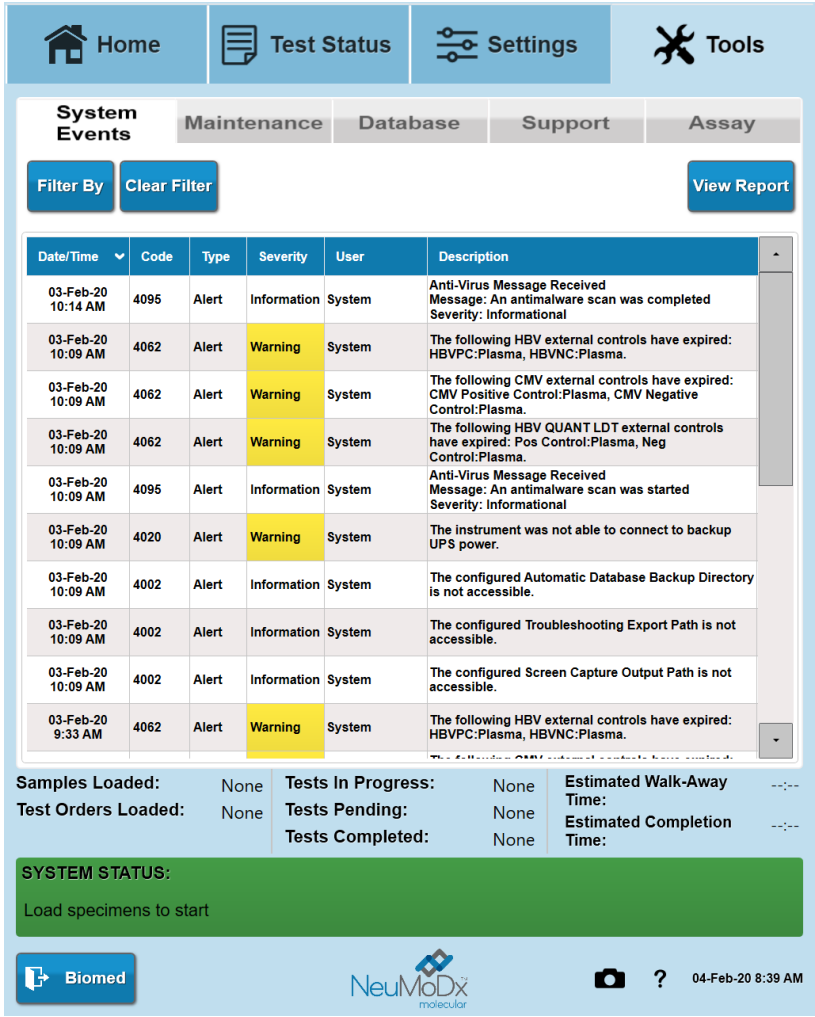


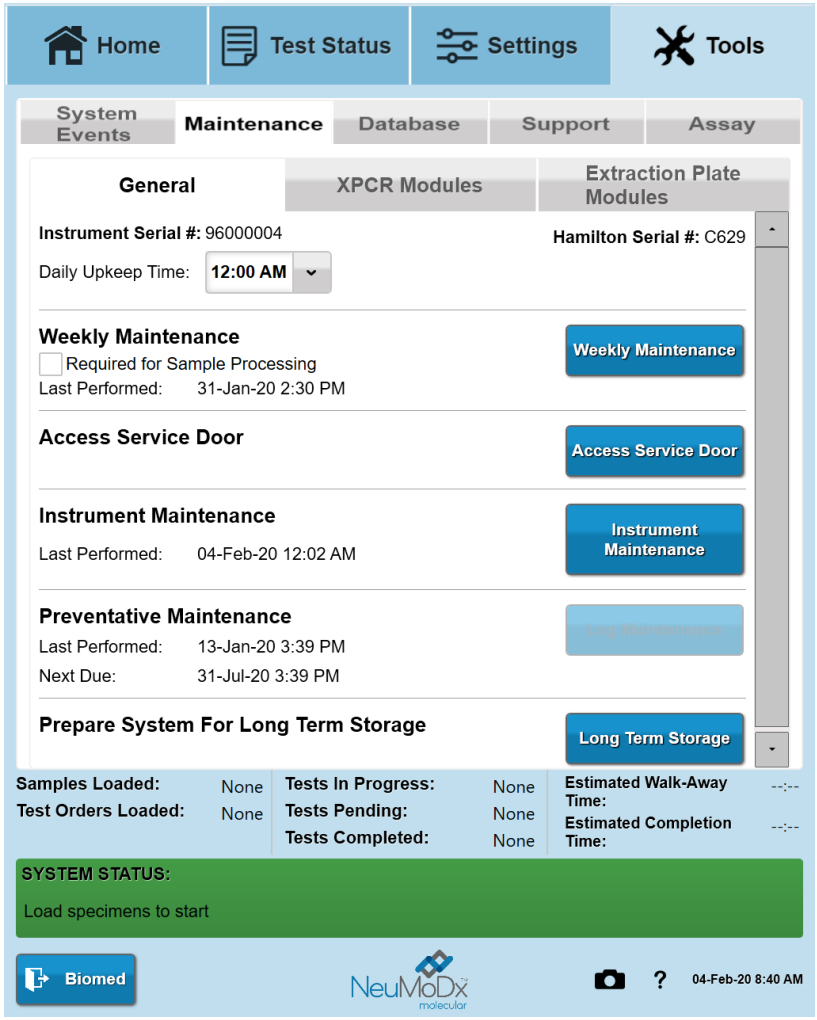
NeuMoDx 96 Software Screen

BioMed Level User



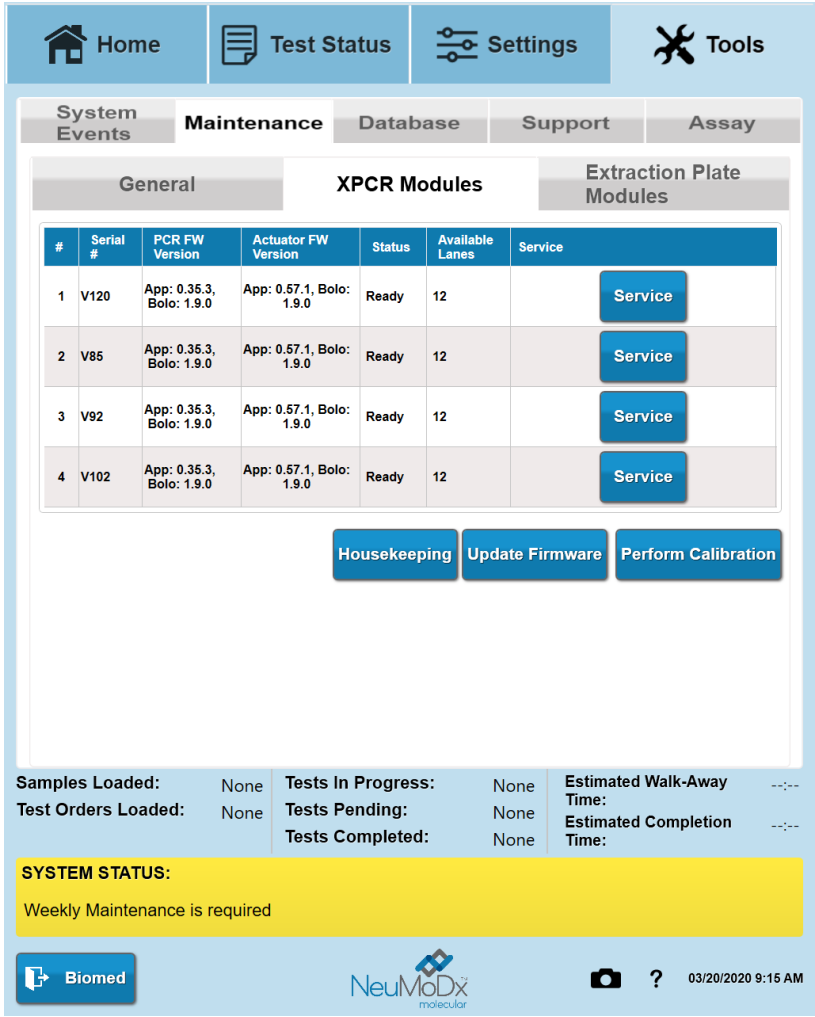
NeuMoDx 96 Software Screen

BioMed Level User



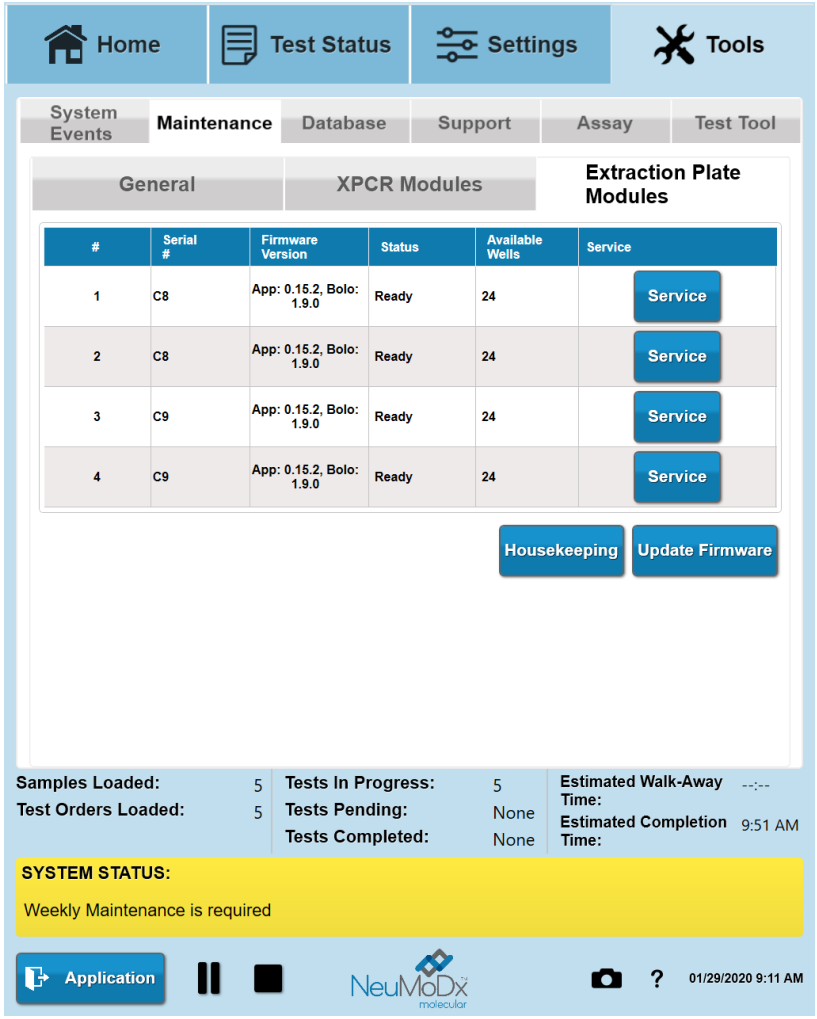
NeuMoDx 96 Software Screen

BioMed Level User



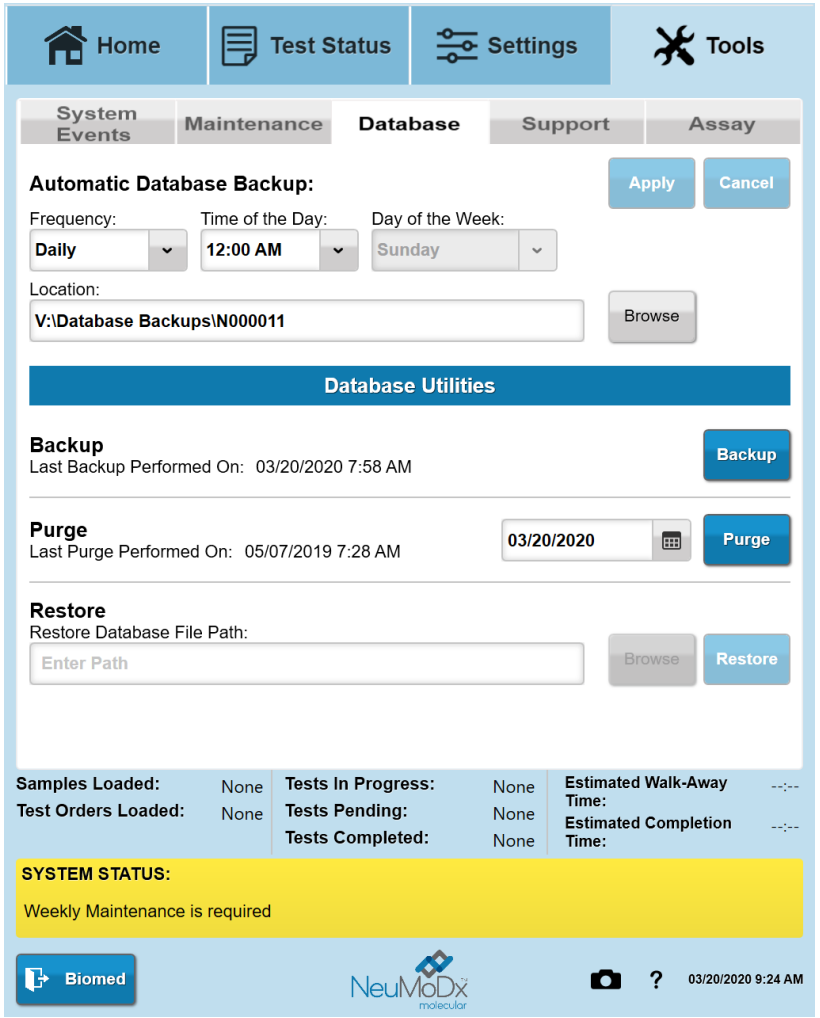
NeuMoDx 96 Software Screen

BioMed Level User



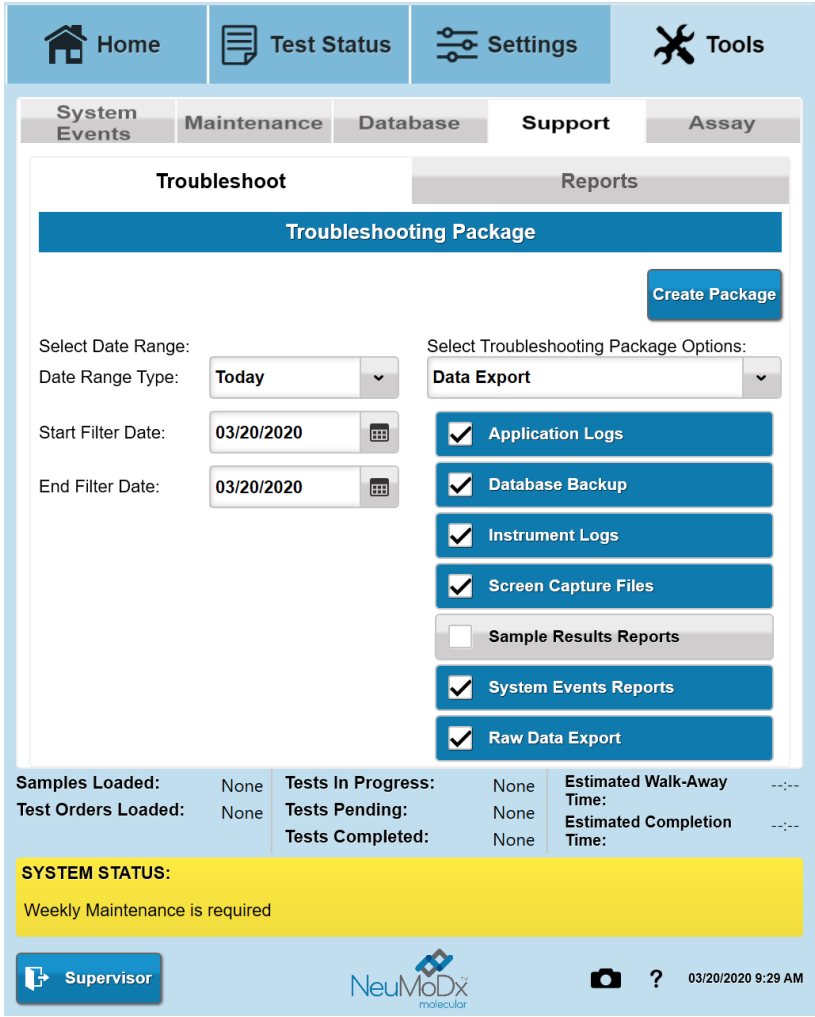
NeuMoDx 96 Software Screen

BioMed Level User



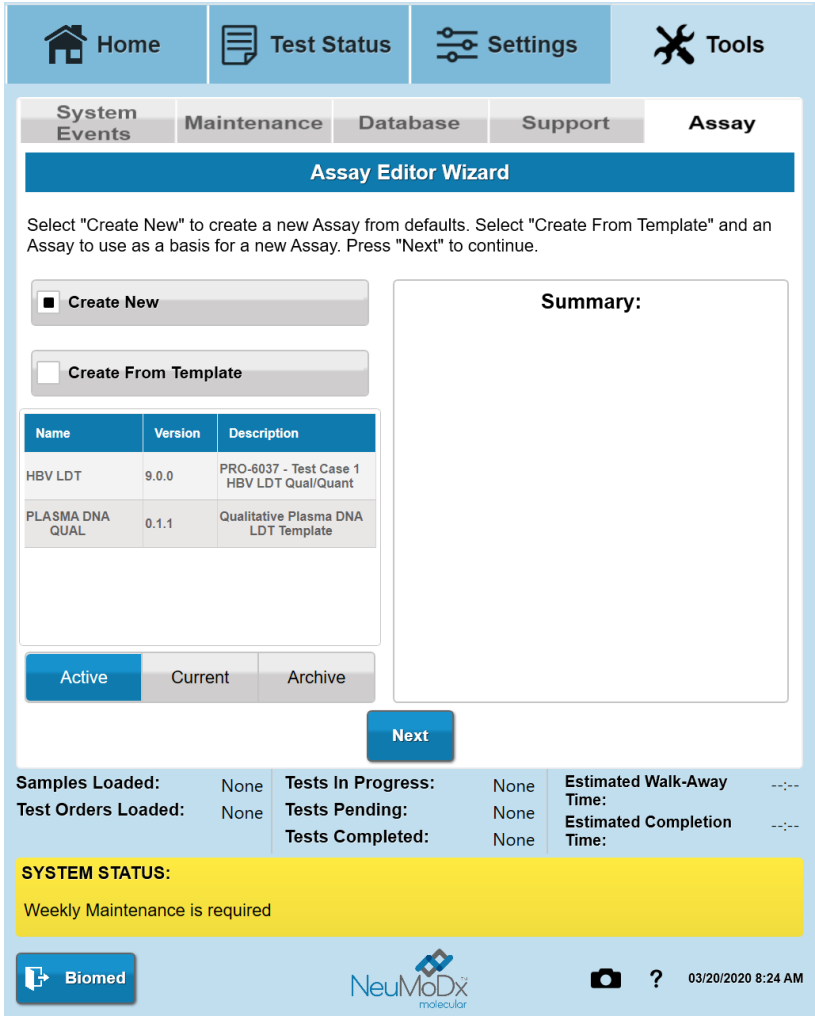
NeuMoDx 96 Software Screen

BioMed Level User



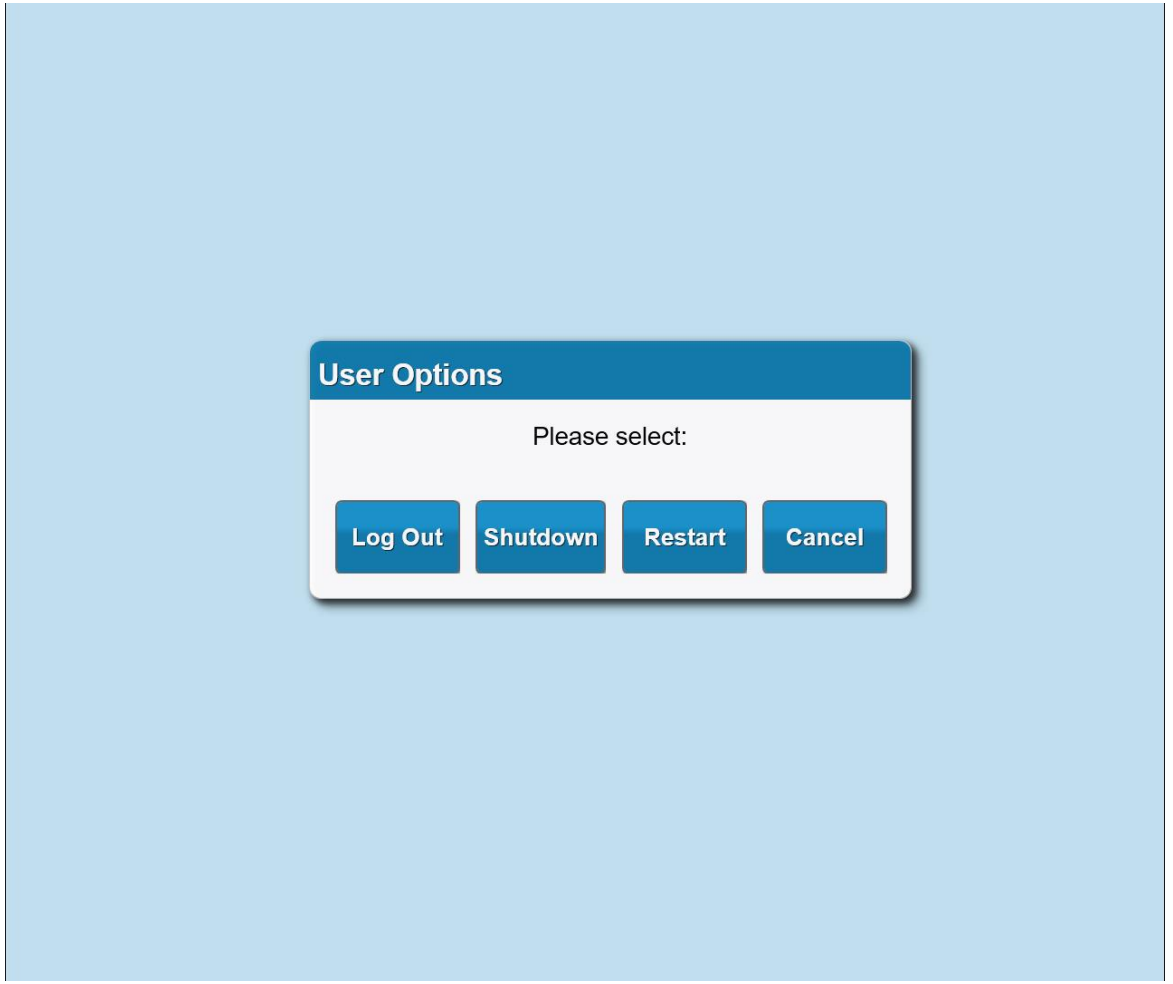
NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

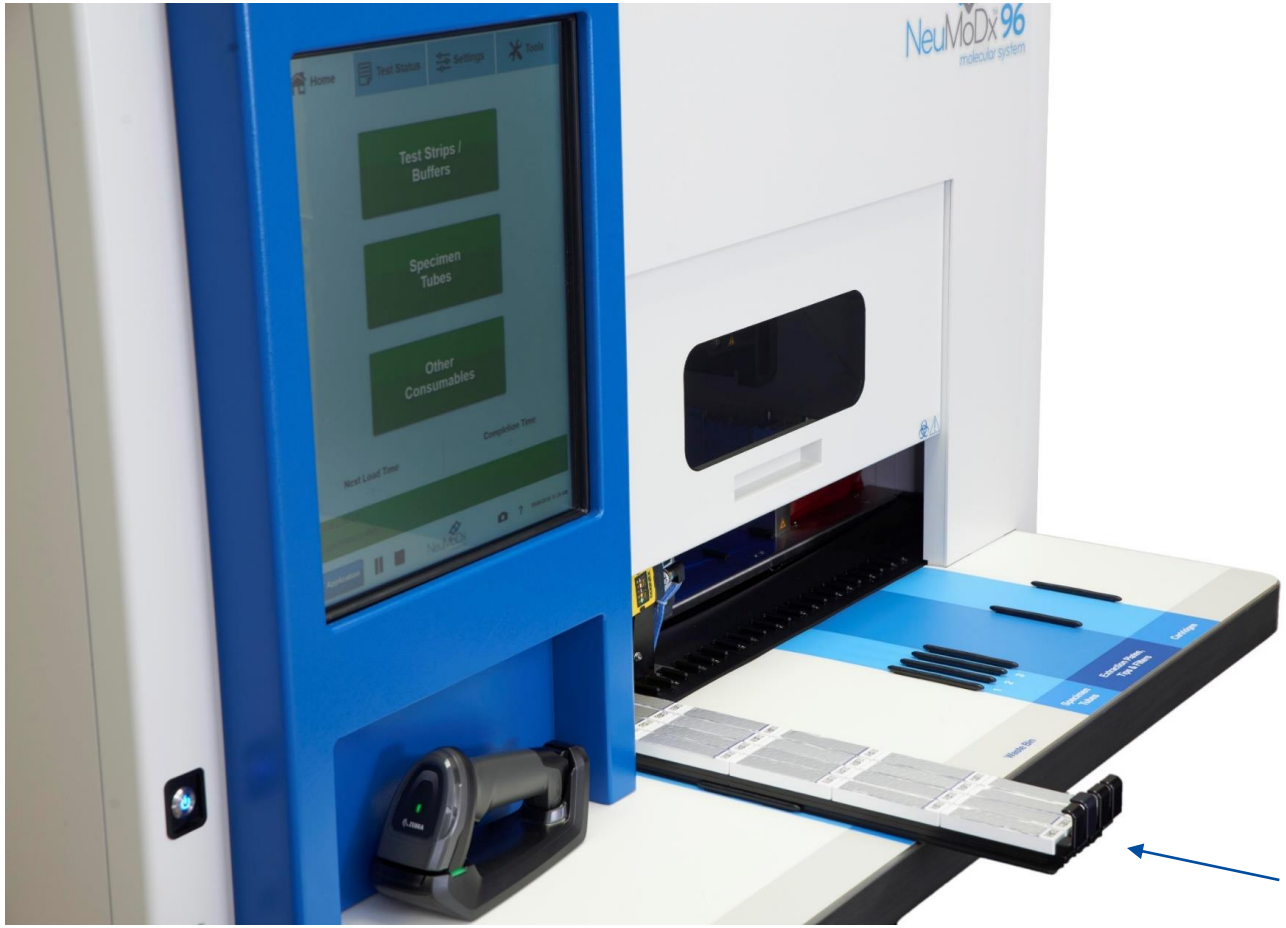
BioMed Level User



Loading Consumables

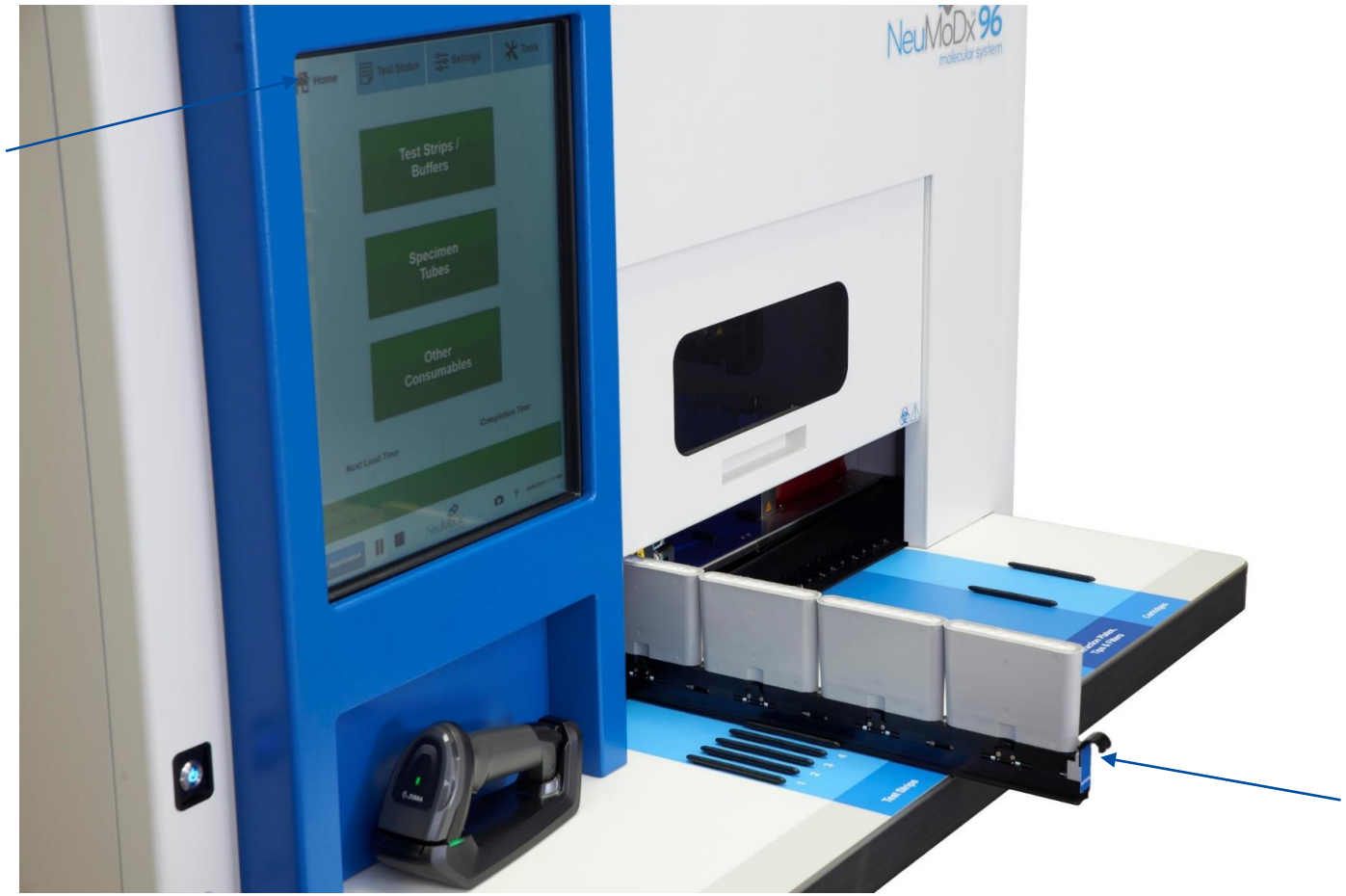
Loading Consumables

Test Strips and/or Buffers



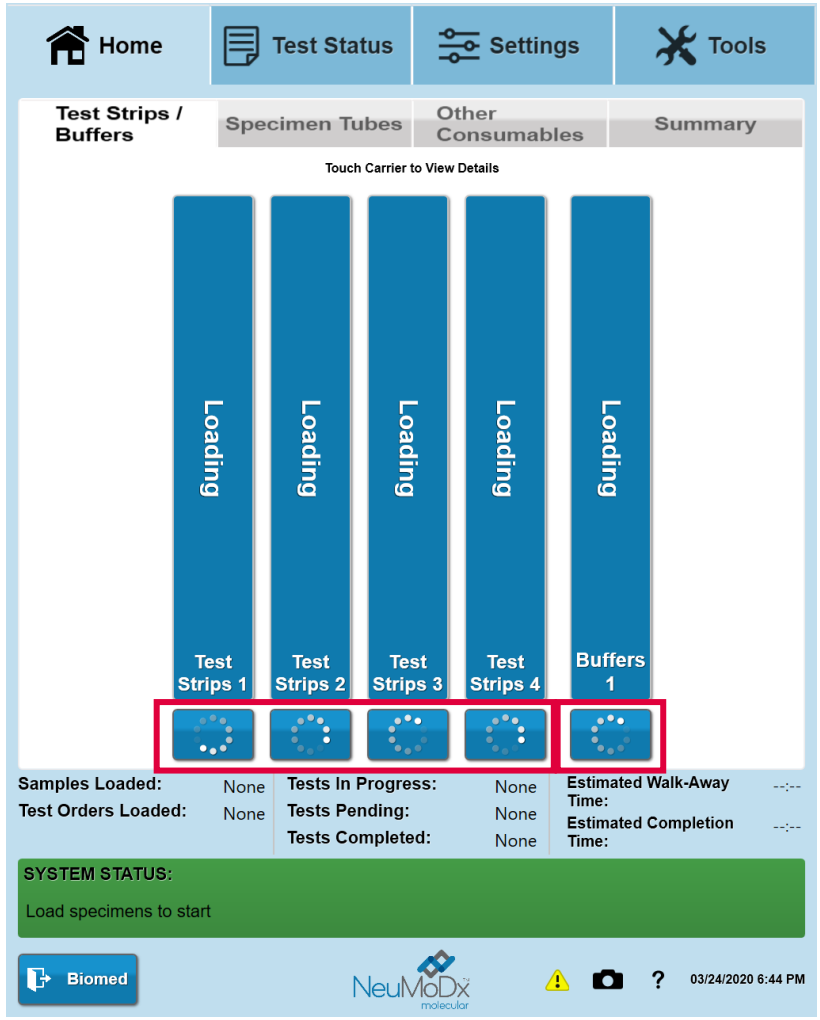
Loading Consumables

Test Strips and/or Buffers



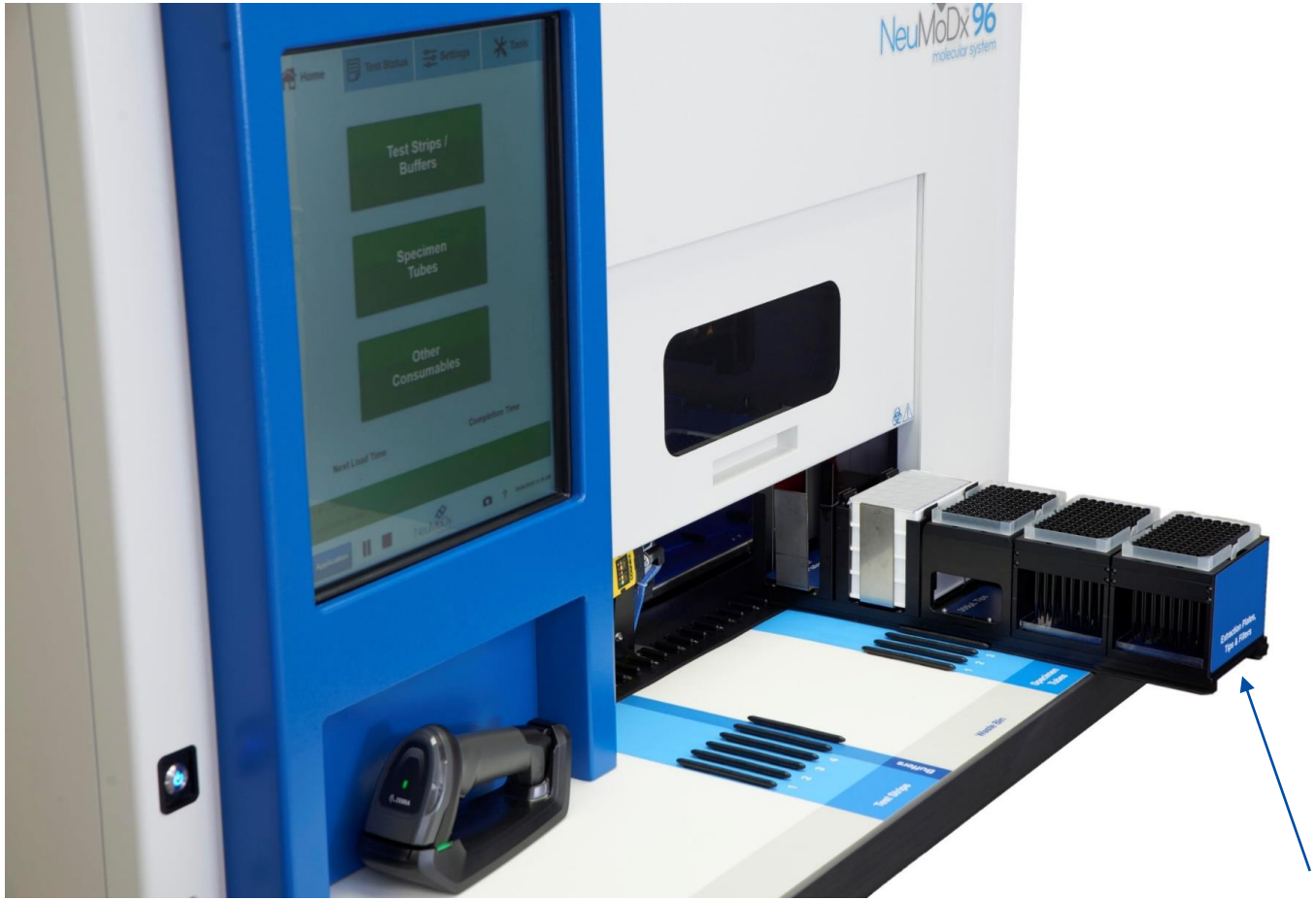
Loading Consumables

Test Strips and/or Buffers



Loading Consumables

“Other Consumables”



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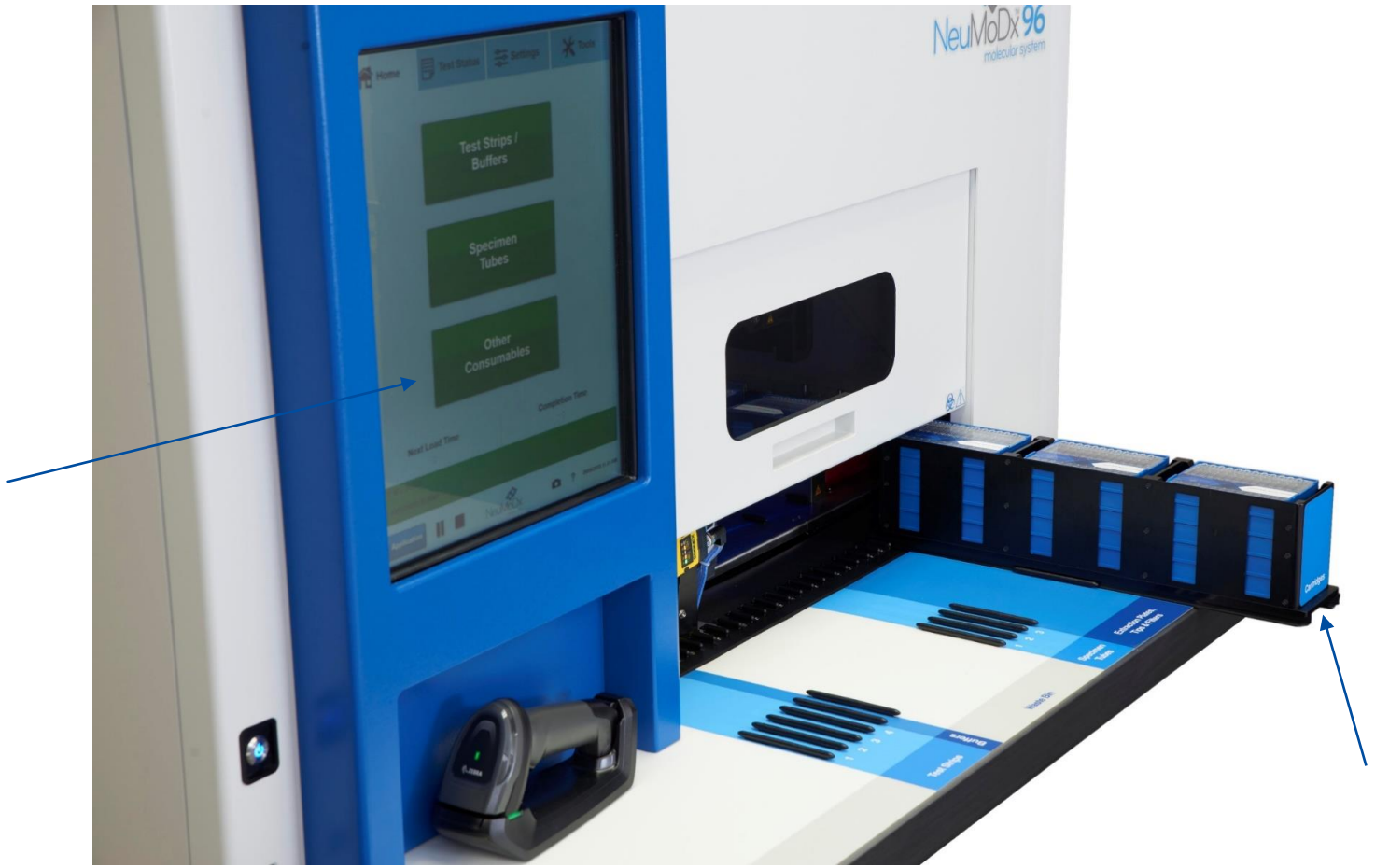
“Other Consumables”



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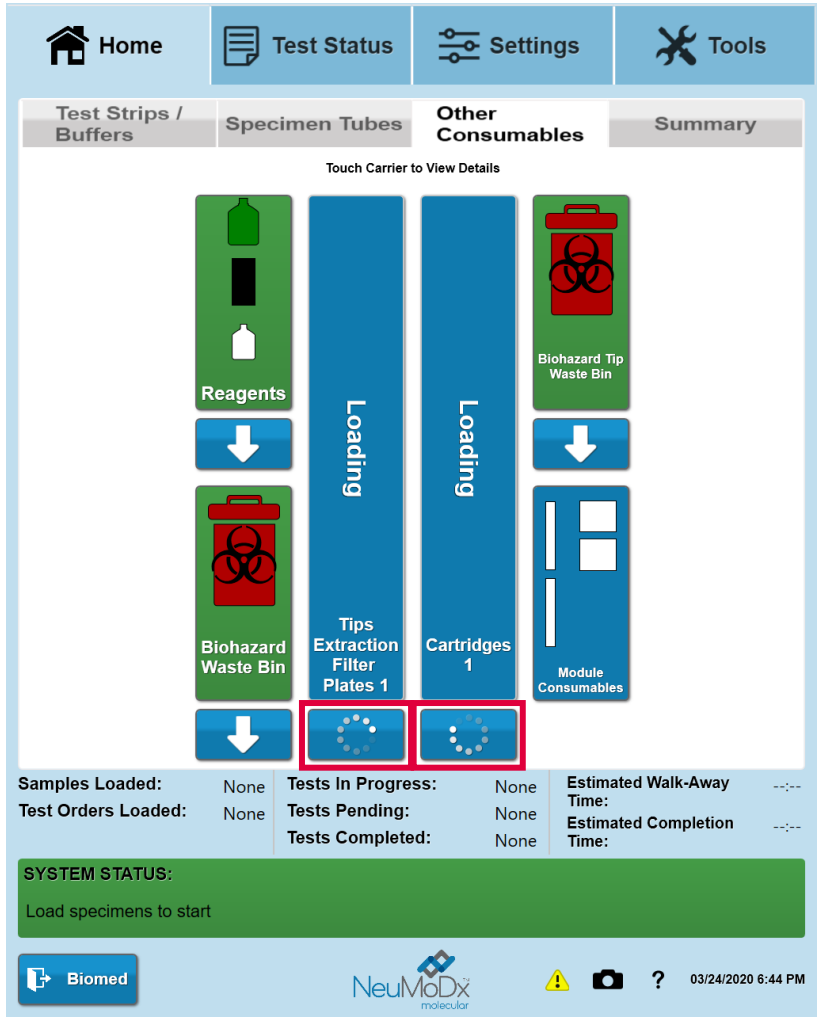
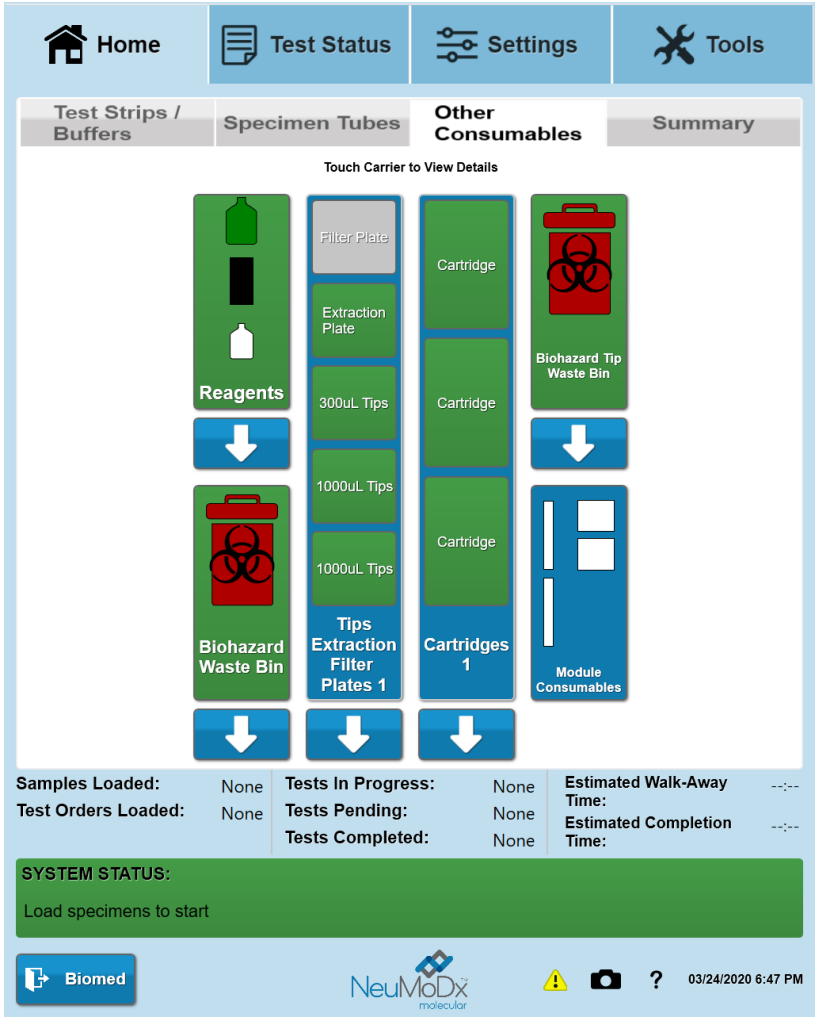
“Other Consumables”



Loading Consumables

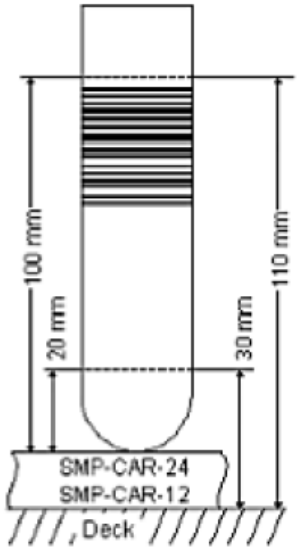
“Other Consumables”



Loading Consumables

Placing Barcodes on Samples

- Barcodes should be placed between 20 mm and 100 mm from the bottom of the tube
- Place the tubes in a 32-tube or 24-tube carrier with the barcodes facing outwards



Loading Samples

Sample Carriers

24-Sample Carrier

32-Sample Carrier
Also a 32-Sample Carrier for Low Volume Tubes

Loading Samples

Sample Tube Dimensions & Volumes

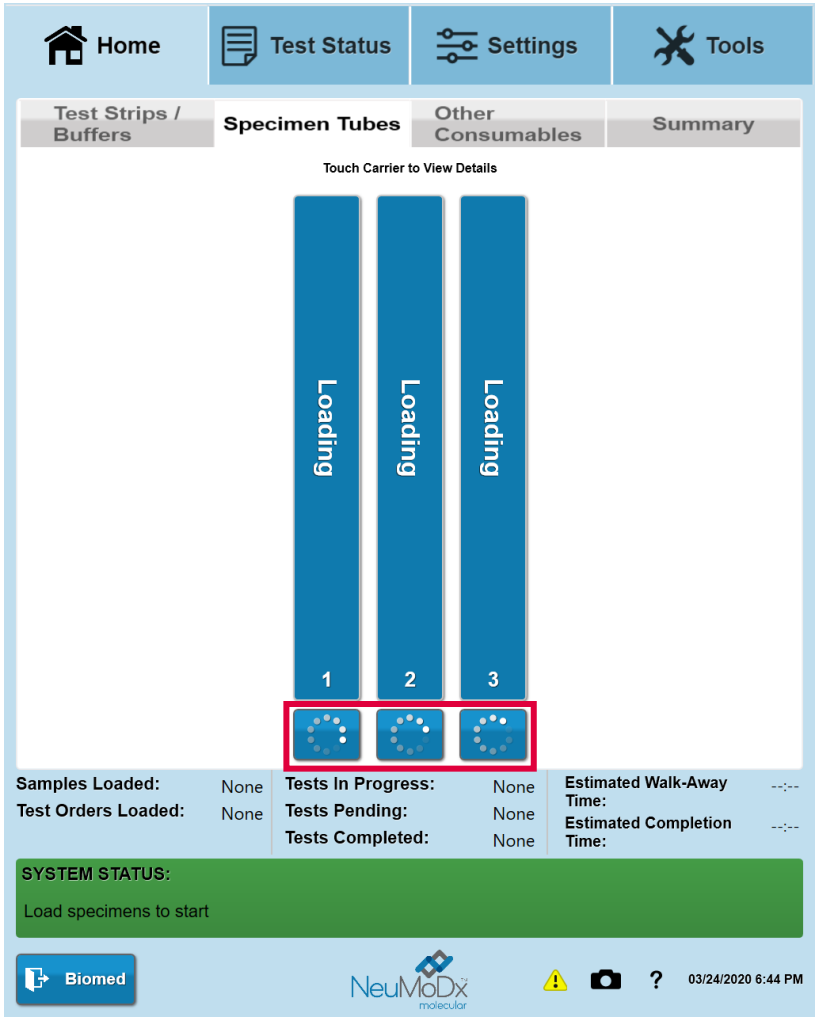
Specimen Carrier	Dimensions
32-Tube	Diameter: 11-14mm Height: 60-120mm
24-Tube	Diameter: 14.5-18mm Height: 60-120mm
Low Volume Tube	1.5mL round-bottom microcentrifuge tubes with screw caps (Simport Scientific REF T335-6STP)

Specimen Aspirate Volume (µL)	32-Tube Specimen Tube Carrier*	24-Tube Specimen Tube Carrier*	Low-Volume Specimen Tube Carrier*
200	400	800	300
250	400	850	350
400	550	1,000	500
550	700	1,150	650
600	750	1,200	700

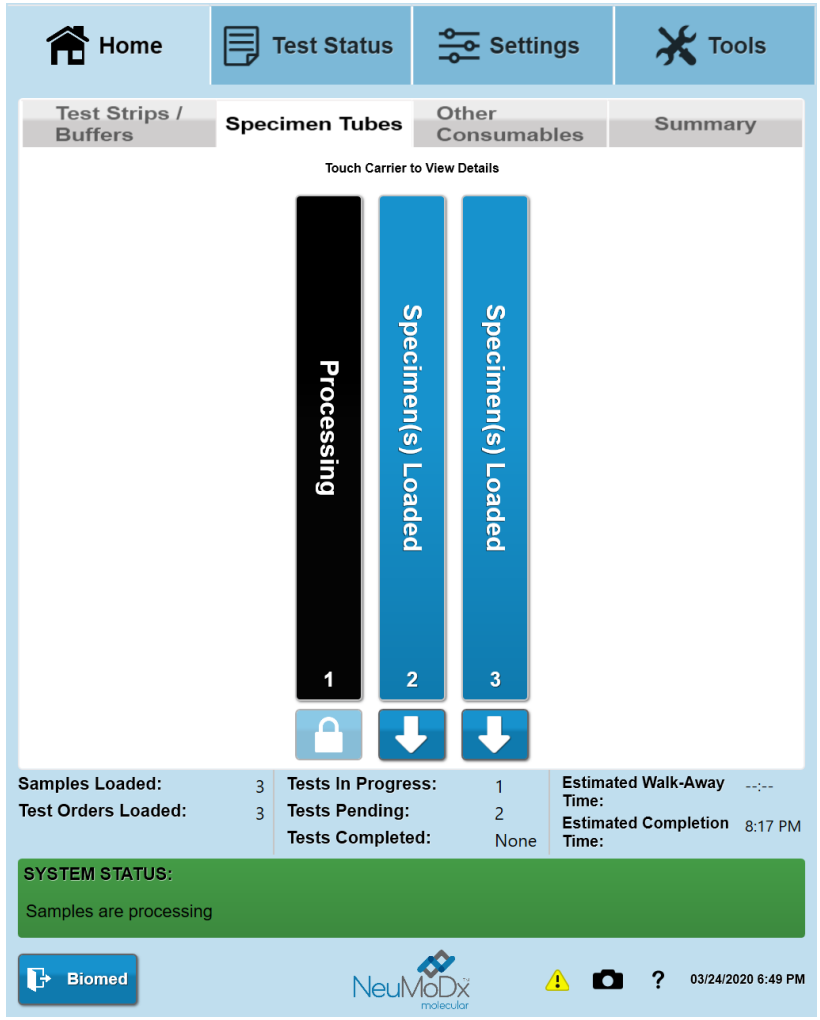
* For the 32-tube carrier, the minimum recommended fill volume is 400 µL for specimen volumes of 250 µL or lower.
** For the 24-tube carrier, the minimum recommended fill volume is 800 µL for specimen volumes of 200 µL or lower.

Loading Samples

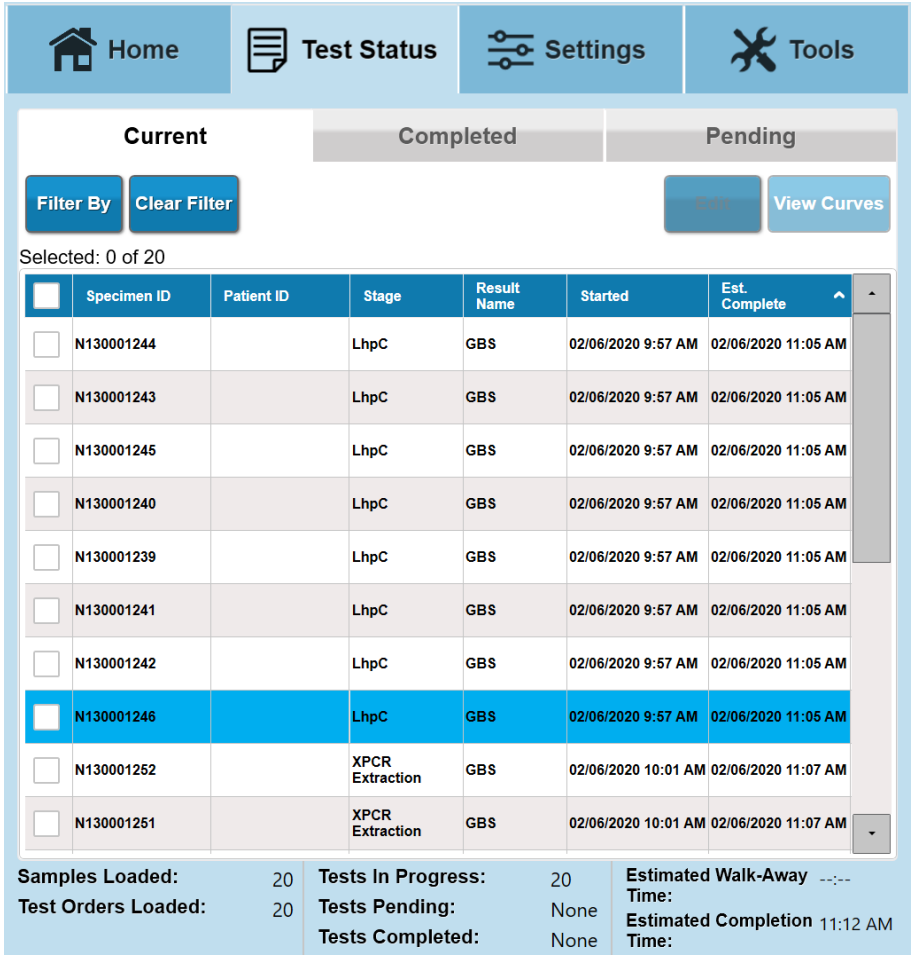
Loading Samples



Loading Samples



Viewing Current Samples



- Navigate to Test Status, then Current to view currently running samples and their status

Changing Wash & Release, and Emptying Priming Waste

Follow the prompts on the GUI to:

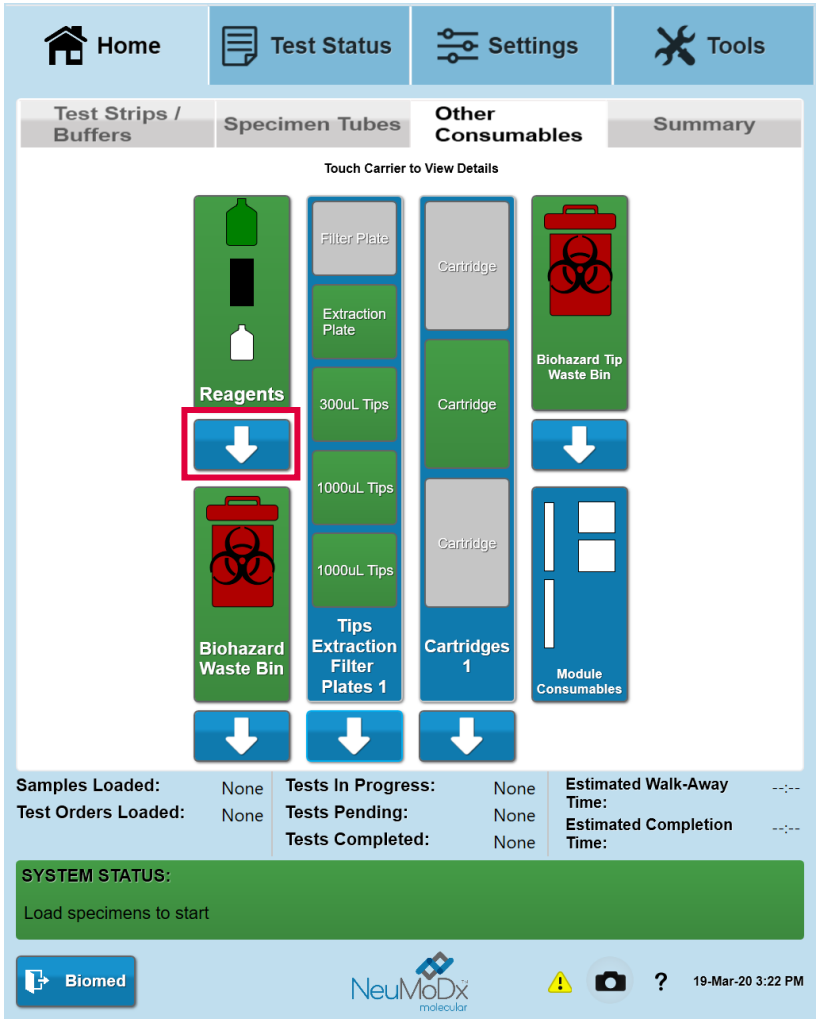
- Change Wash & Release
- Empty Priming Waste

0.02% Sodium Azide

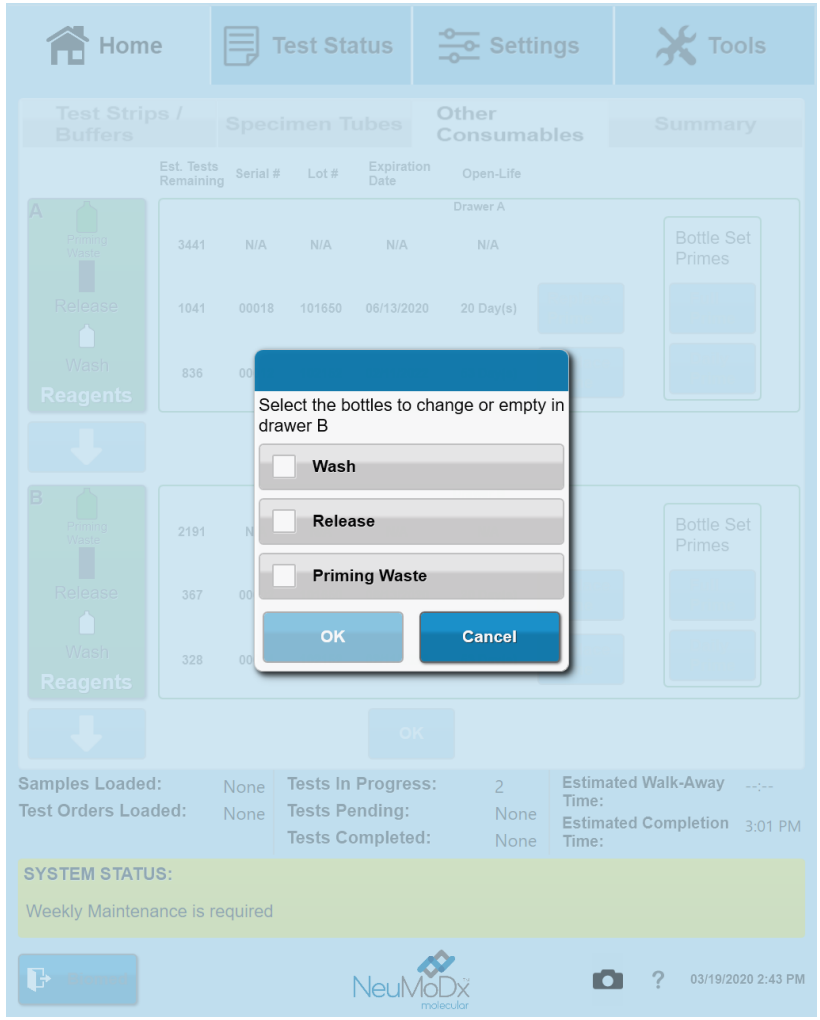
<1% Sodium Hydroxide

Combination of Wash and Release

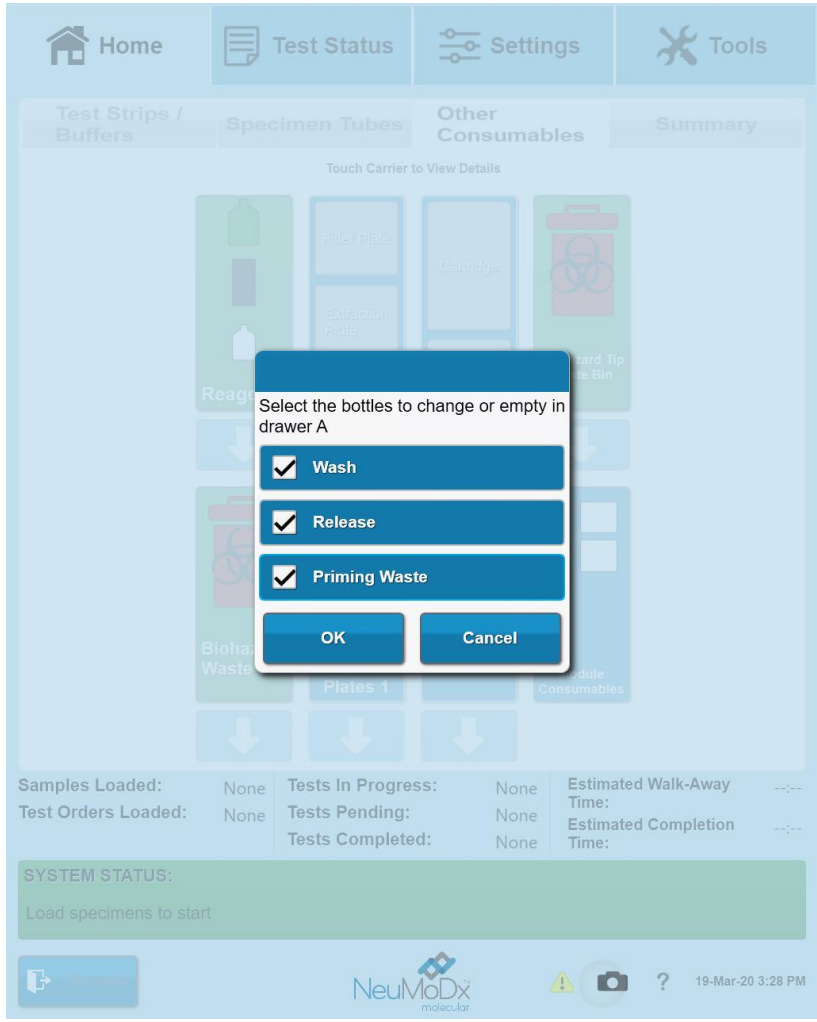
Changing Wash & Release



Changing Wash & Release

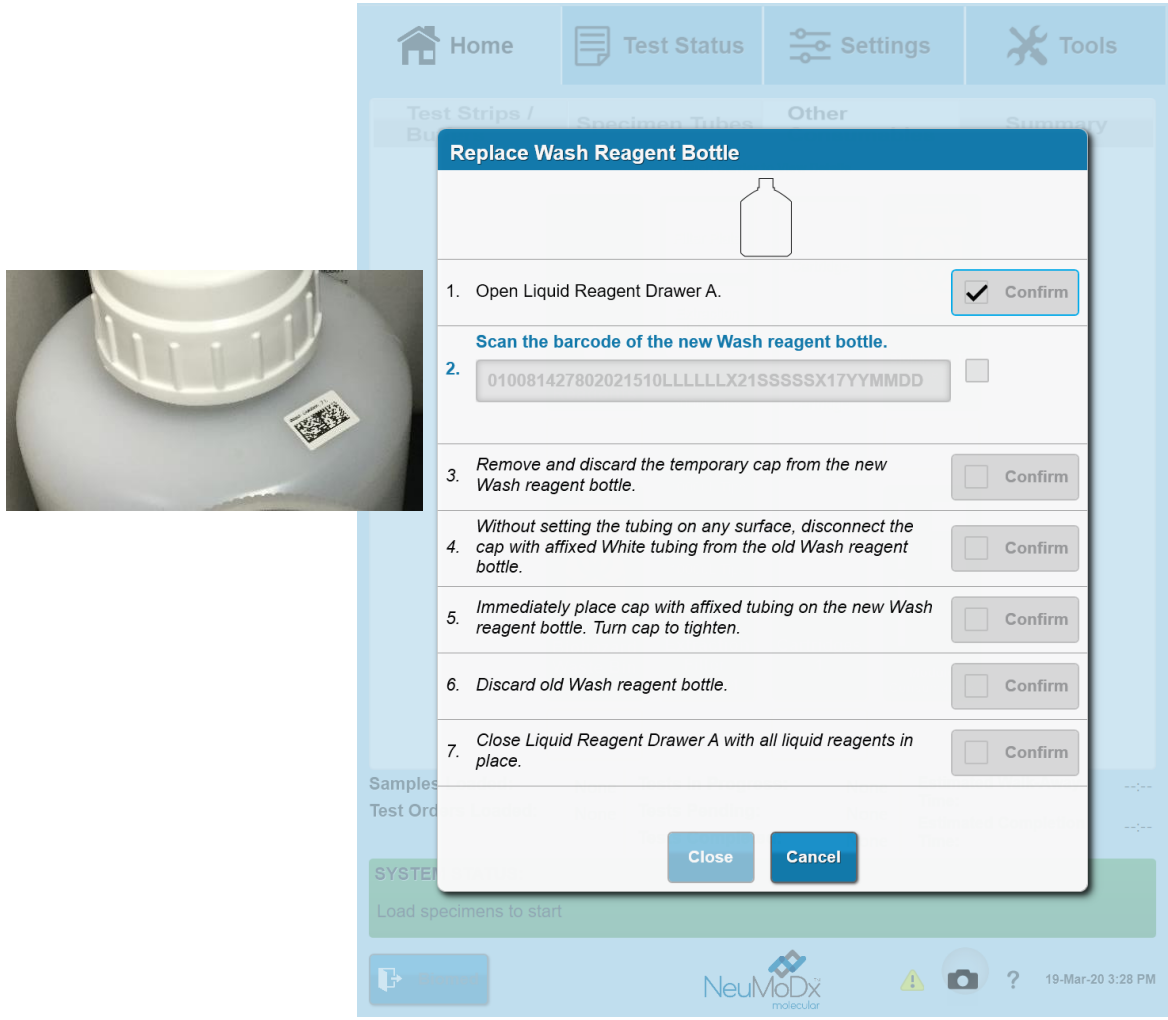


Changing Wash & Release

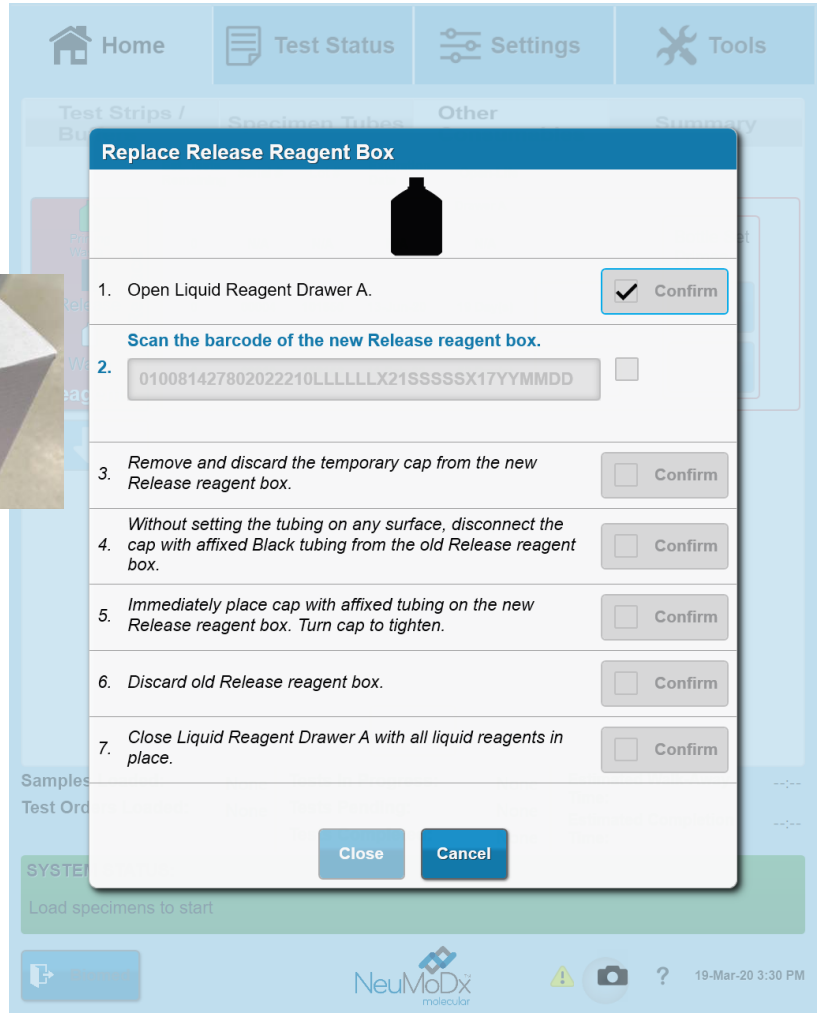


Changing Wash & Release

Changing Wash & Release



Changing Wash & Release



Changing Wash & Release

Emptying Priming Waste

CAUTION: When disposing of Priming Waste, follow all federal, state, and local regulations; flush the contents with water if drain disposable is permissible.

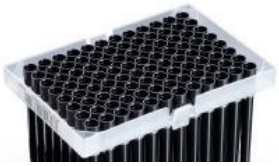
Waste Handling & Weekly Cleaning

NeuMoDx Molecular System

Used Consumables

- The following reagents/consumables after usage are considered **biohazardous** and should be discarded in **appropriate biohazard waste**:
  - Test Strips
  - Extraction Plates
  - Cartridges
  - All Tips

- The following reagents/consumables after usage can be discarded in regular trash:
  - Buffer Troughs
  - Tip trays (if desired)
  - Plastic tip holders (once tips are gone)



- The following bulk reagents can be discarded down the drain with water (if it follows city/municipal waste):
  - Priming Waste (not the bottle)
  - Leftover Wash (bottle can be recycled)
  - Leftover Release (aluminum pouch can be thrown away, cardboard recycled)

NeuMoDx 96 Molecular System

Biohazard Waste Handling

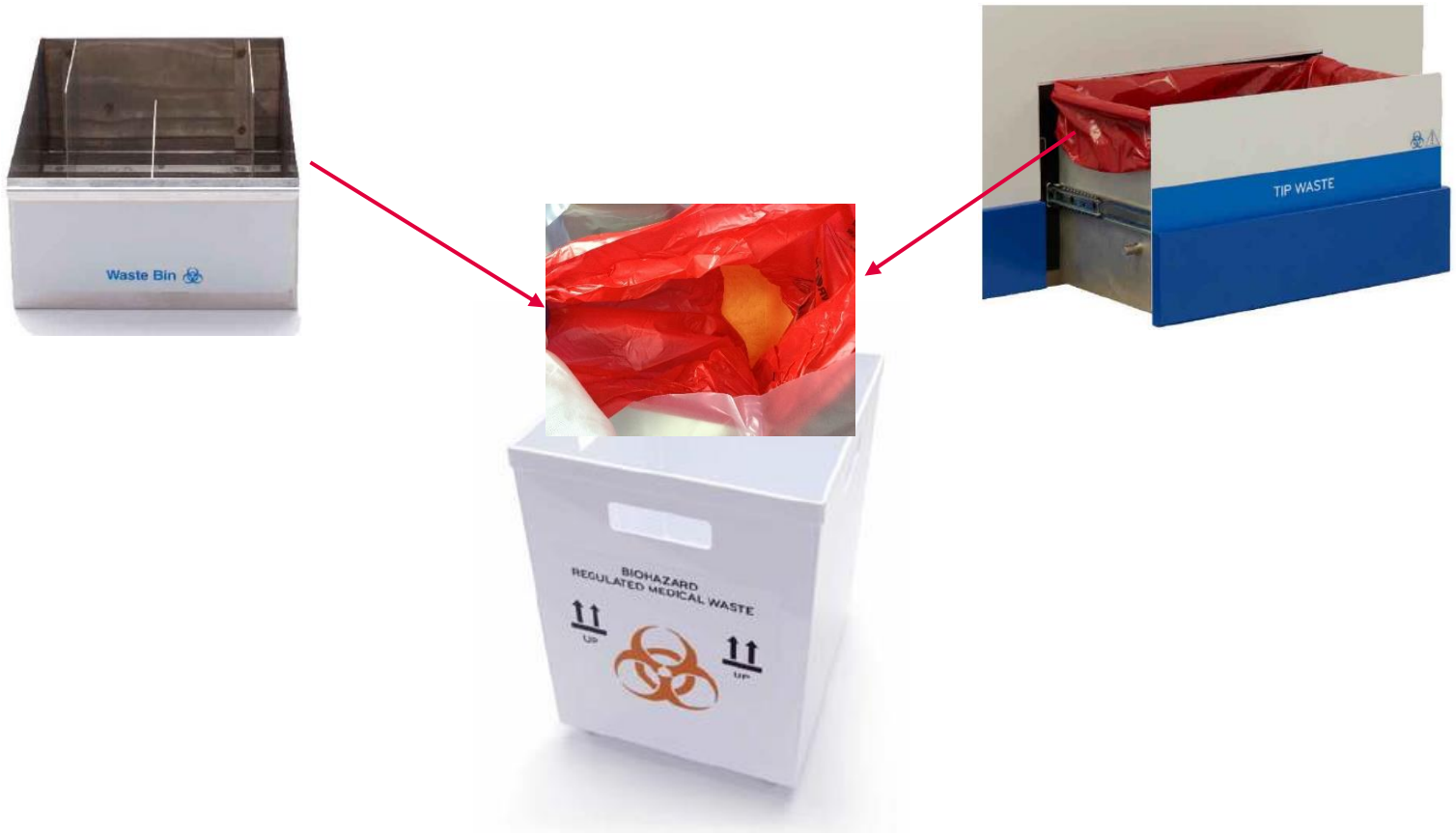
- The NeuMoDx 96 Molecular System has two biohazard waste bins
  - The NeuMoDx Biohazard Waste Bin is on deck for the automated disposal of extraction plates and cartridges

  - The NeuMoDx Biohazard Tip Waste Bin is at the rear for automated disposal of tips
  - Has red biohazard waste bag lining

NeuMoDx 96 Molecular System

Biohazard Waste Handling

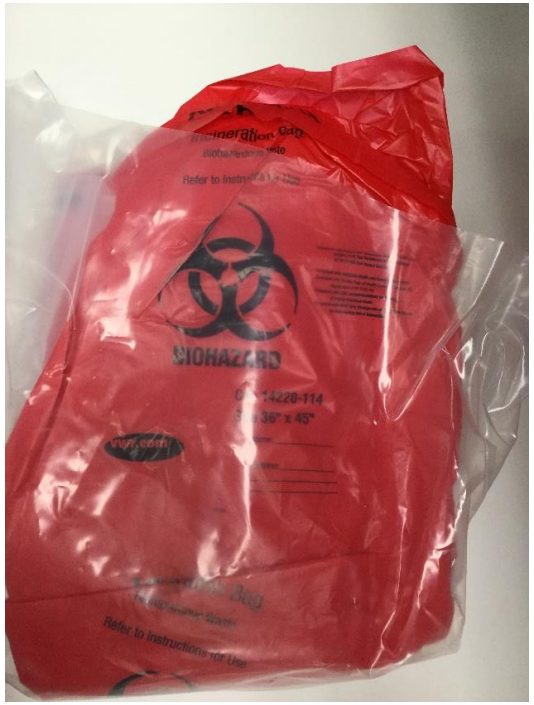
- When either waste bin is **full as prompted by the Software**, the waste should be emptied into a NeuMoDx Biohazard Waste Container lined with the NeuMoDx Biohazard Waste Bag



NeuMoDx 96 Molecular System

NeuMoDx™ Biohazard Waste Bag

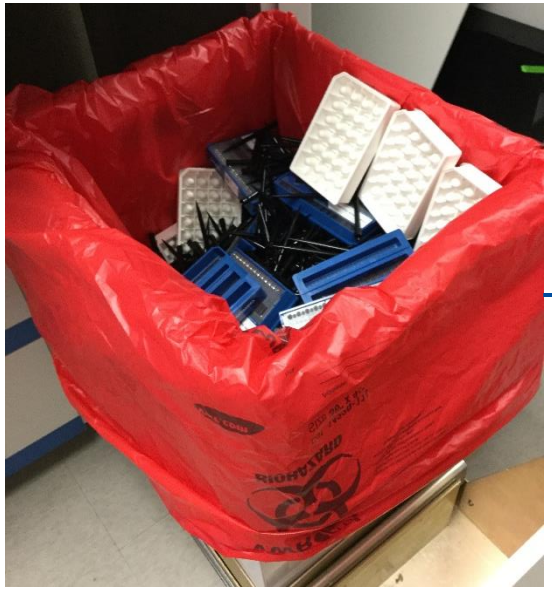
- It is imperative that NeuMoDx™ consumables (namely the NeuMoDx™ Extraction Plates and NeuMoDx™ Cartridges) are disposed in the NeuMoDx™ Biohazard Waste Bag



NeuMoDx Biohazard Waste Bag

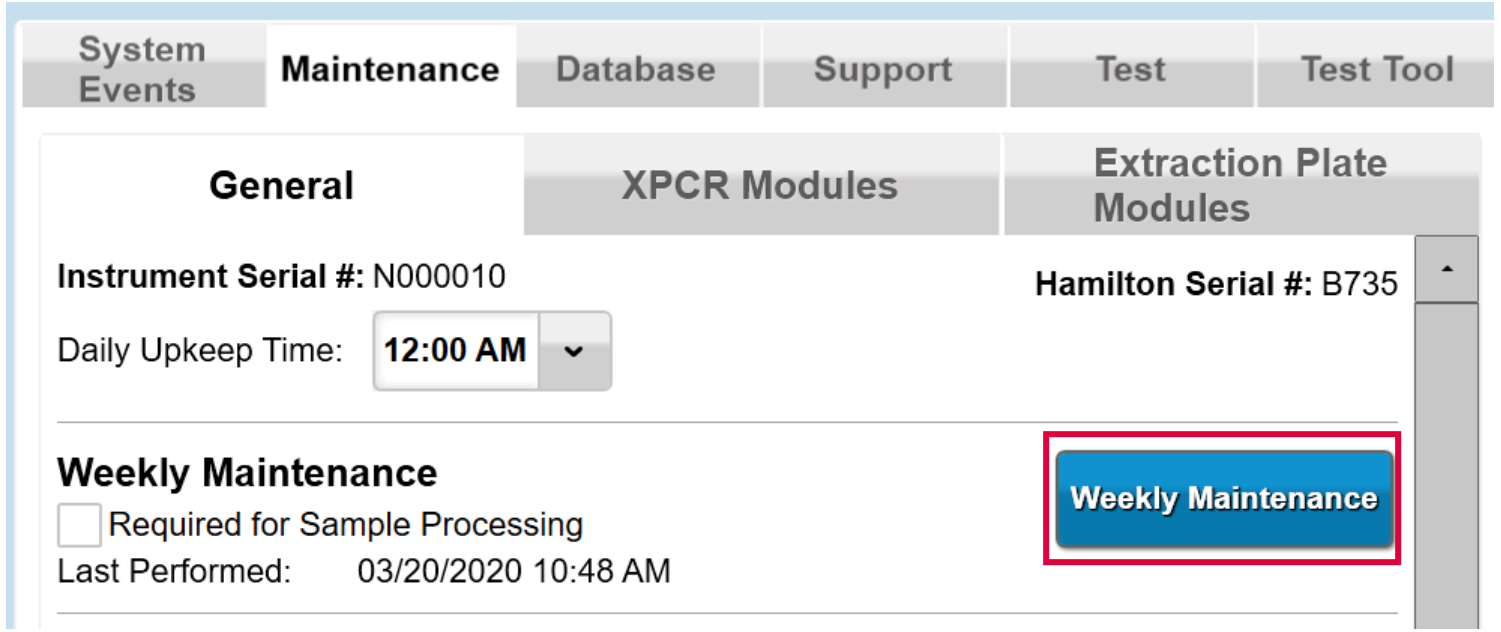
Handling once full

- Once the external Biohazard Waste Bag associated with the NeuMoDx 96 is full (confirm visually, should not be overflowing), follow these instructions:

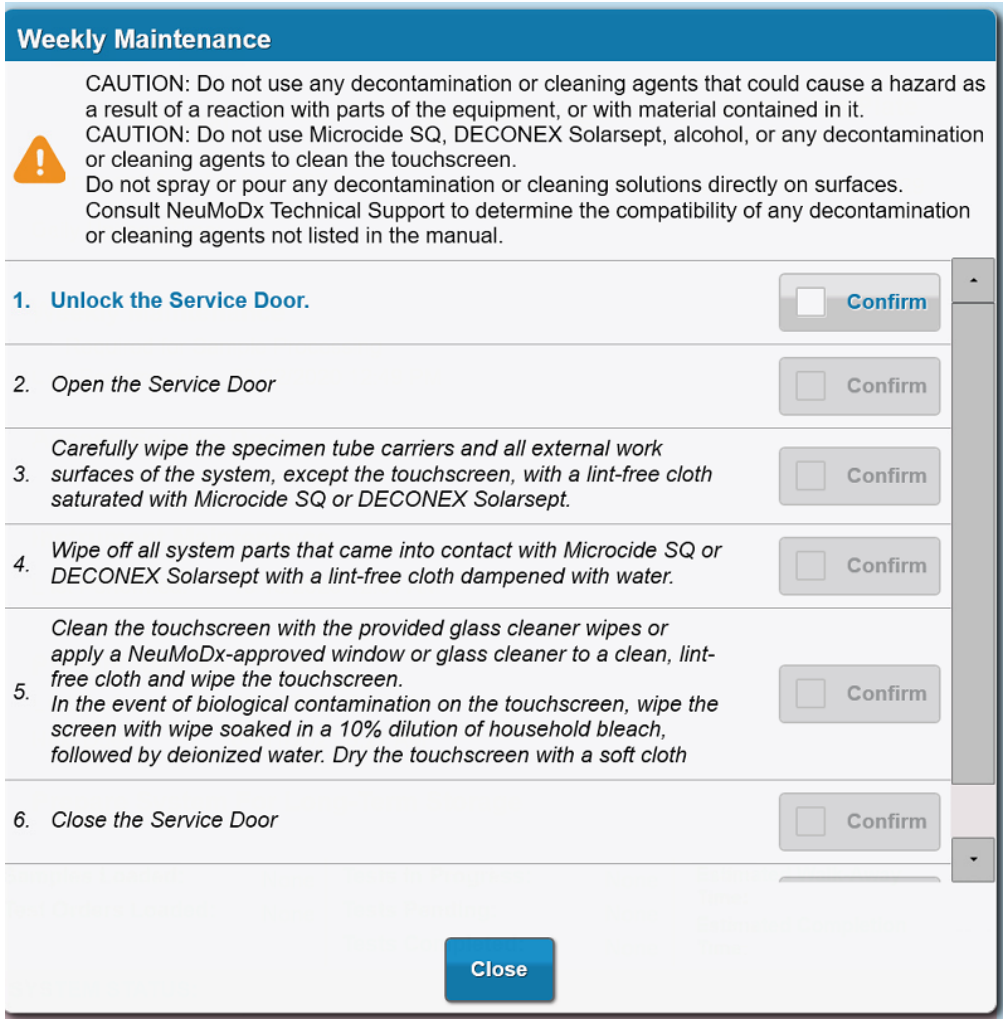


1) Secure the inner red lining.
2) Zip tie the clear outer waste bag with the provided zip tie.

Weekly Cleaning & Weekly Shutdown



Weekly Cleaning & Weekly Shutdown



Weekly Cleaning & Weekly Shutdown

- Remove all carriers that are on deck with the touchscreen.
  - Remove all consumables/ reagents that are currently on the carriers and set aside. For tips, place in empty locations of the Hamilton tip trays.

Weekly Cleaning & Weekly Shutdown

- Carefully wipe specimen tube carriers and all external work surfaces of the system, (except the touchscreen) with a lint-free cloth saturated with **Microcide SQ** or **DECONEX Solarsept.**
- Follow the Microcide SQ cleaning with a lint-free cloth dampened with water. Set cleaned carriers aside on separate bench.

Weekly Cleaning & Weekly Shutdown

Wait 1 minute before turning instrument back on

Can also wipe the touchscreen while instrument is shut off

Be sure to shut the Service Door before turning instrument back on

Weekly Cleaning & Weekly Shutdown

Some Cautions

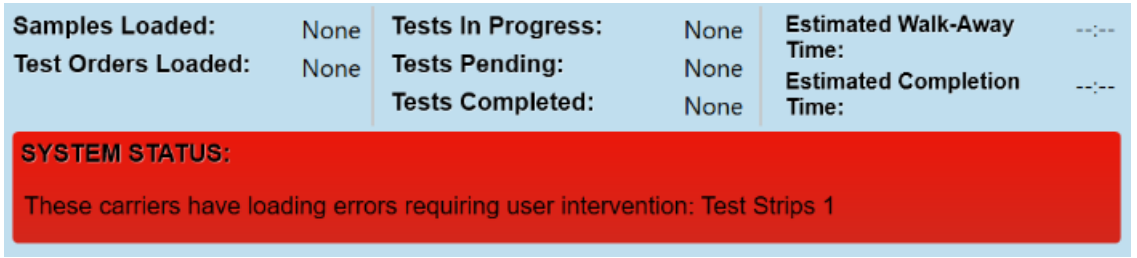
- Before starting the cleaning, it is very important to make sure there is no movement inside the instrument
- Follow the cleaning instructions in the correct order
- Do not touch the red part of the autoloader

- You must wait the full 1 minute before turning the instrument back on

User Accounts / Permissions

	Operator	Supervisor	BioMed
View user accounts, software settings, system events	X	X	X
Load and unload reagents, consumables, and specimen carriers	X	X	X
Edit specimen information	X	X	X
Configure limited application settings	X	X	X
Create a troubleshooting package	X	X	X
Empty Biohazard Waste Container	X	X	X
Perform database backup	X	X	X
Manually send results to LIS	X	X	X
View System Manifest Report, Quality Control Report, Results Summary Report, System Events Report	X	X	X
Run Weekly Maintenance	X	X	X
Initiate access to the worktable via service door	X	X	X
Manage user accounts, user account settings, test orders	X	X	X
Purge the database		X	X
Configure all application settings		X	X
Set the system upkeep time		X	X
Perform software configuration and ADF upgrades		X	X
Add network shared drive		X	X
Manage assays, including user-defined controls		X	X
Approve sample results		X	X
Perform XPCR Module calibration, if applicable			X
Perform user-initiated syringe pump priming on bulk reagents			X
Run instrument maintenance			X
Perform firmware and software upgrades			X

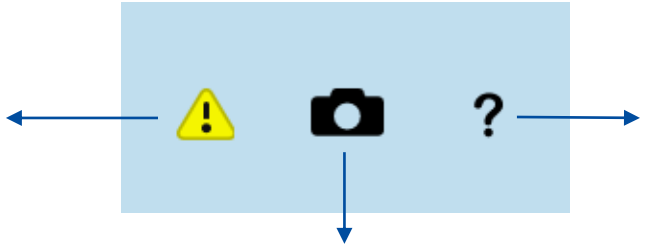
Overview of icons



Status Bar: Can be Green, Yellow, or Red. Clicking on the status bar will bring you to the page that requires attention.
Green – system or consumable status is ready to be used, no issues
Yellow – system or consumable is ready to be used but may require user intervention for optimal performance
Red – system or consumable cannot be used, some sort of error

Samples, Test Orders Loaded: Number of samples currently loaded, and the corresponding test orders to samples.
Tests In Progress, Pending, Completed: Number of tests that are processing on the system, pending tests are tests that still have not processed but are waiting to start. The numbers here are based on samples that are in currently loaded sample carriers.
Estimated Walk-Away, Completion Time: Time to load new samples if at capacity. Estimated completion for all samples.

Clicking on this symbol will bring you to the System Events error.



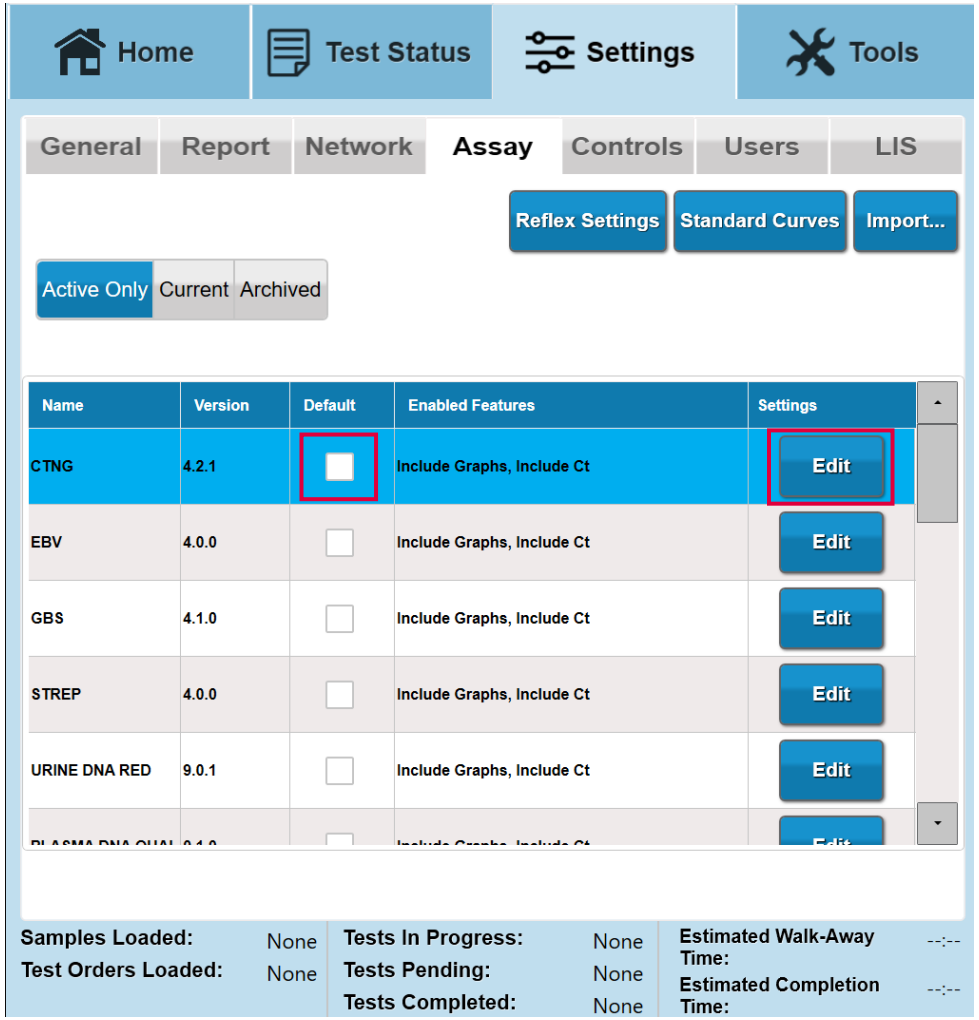
Supposed to give “help” – currently no “help” files available.

Clicking on this will take a screenshot of the current page.

Part IV
NeuMoDx
More Information

Setting Up an Assay

Assay Settings



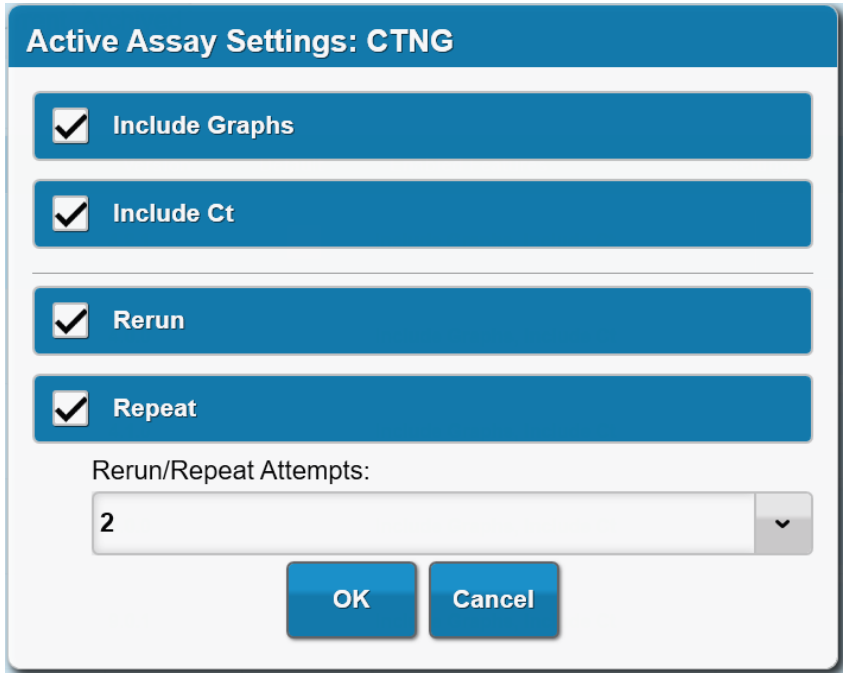
Navigate to Settings, then Assay

To make an assay the default assay, select the checkbox

- This will assign the assay to any samples that are loaded into that system that do not have a test order assigned already

Select Edit to edit the active assay settings

Editing Active Assay Settings



Include Graphs/Ct: Shows the sample Ct and amplification curves in the Sample Results Reports

Rerun: System will automatically rerun a sample with a UNR result

Repeat: System will automatically repeat a sample with an IND result

Select the number of rerun/repeat attempts that the system will perform on each patient specimen with an IND or UNR result (1, 2, or 3)

Setting up:
User-Defined Controls

Defining User-Defined Controls

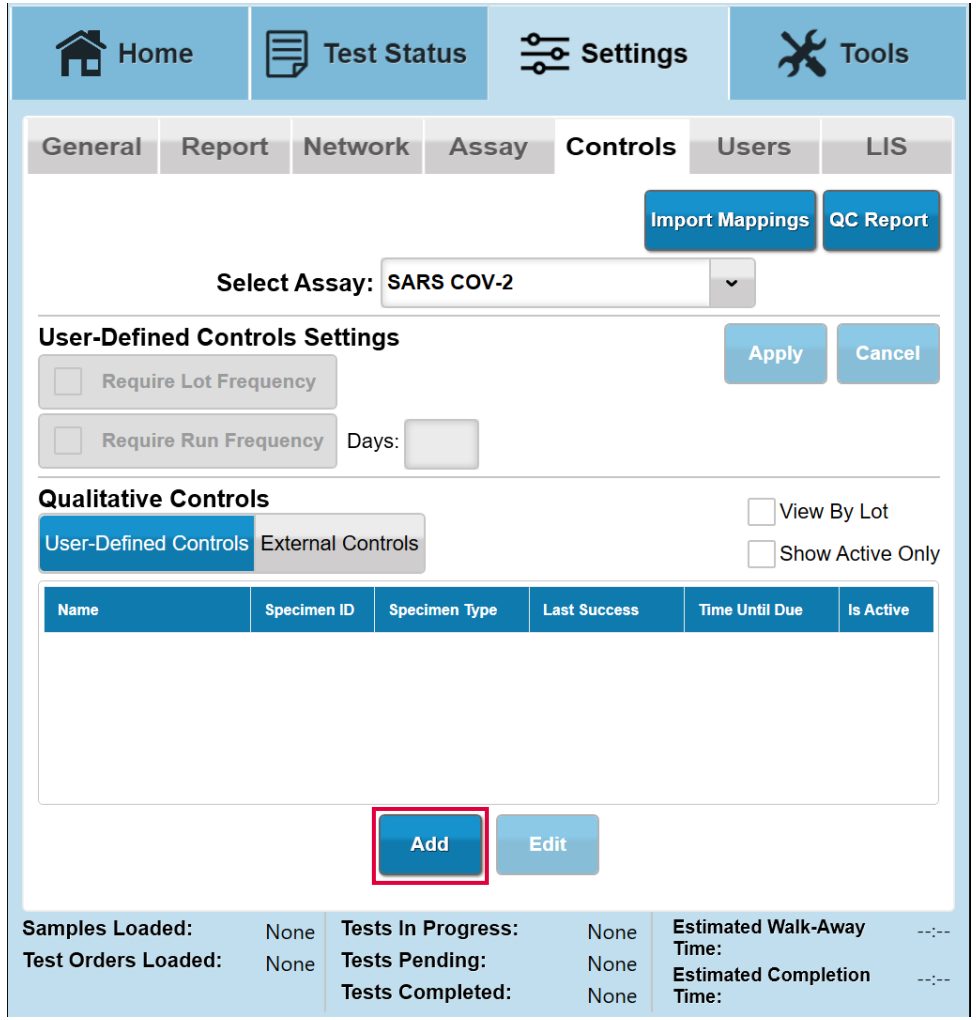
- User-Defined Controls are recommended for NeuMoDx Qualitative Assays
- They may also be created for NeuMoDx Quantitative Assays as an additional Control measure to External Controls

- The same CONTROL NAME can be assigned to One, or BOTH Specimen Types.

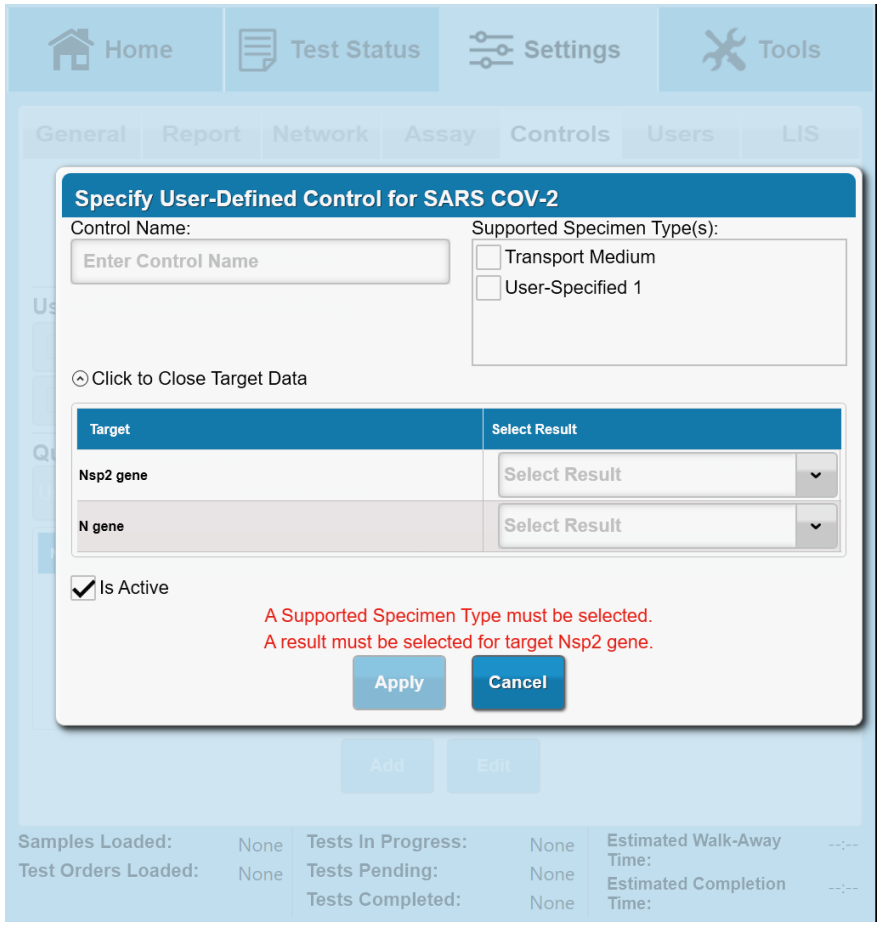
NOTE: The Specimen ID you chose cannot be duplicated elsewhere unless it is deleted.

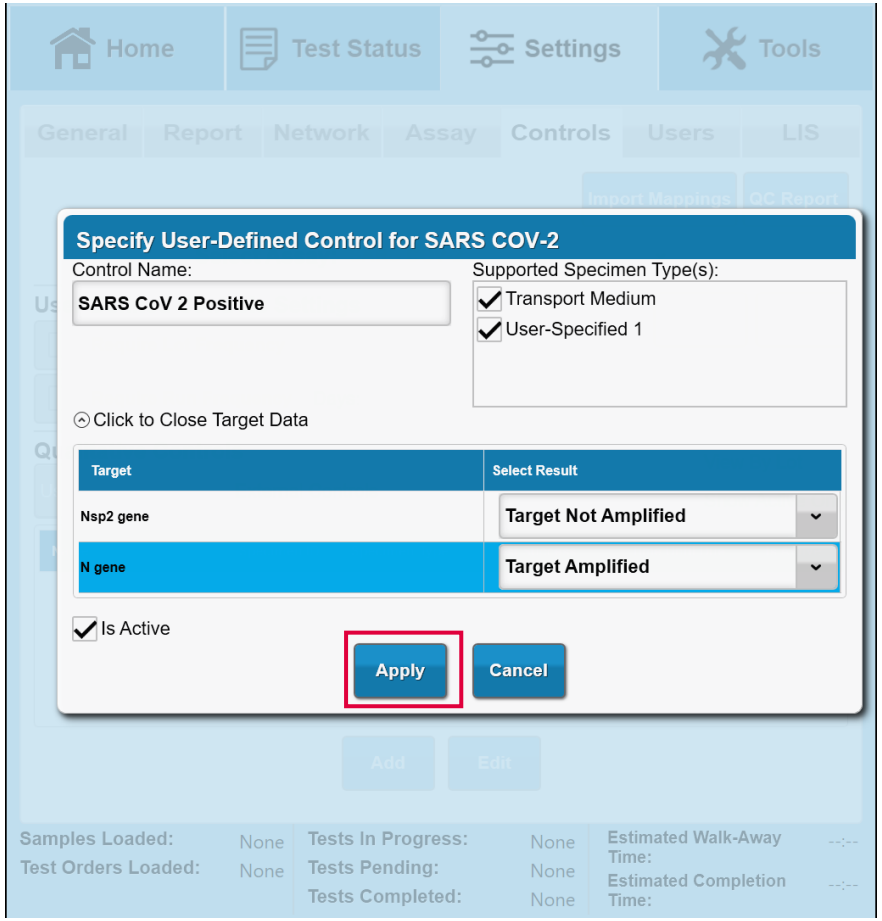
The unique Name + Specimen Type(s) cannot be modified or deleted once it is created.

- Navigate to Settings, then Controls and select the assay from the dropdown
- Select “Add” to define a new control



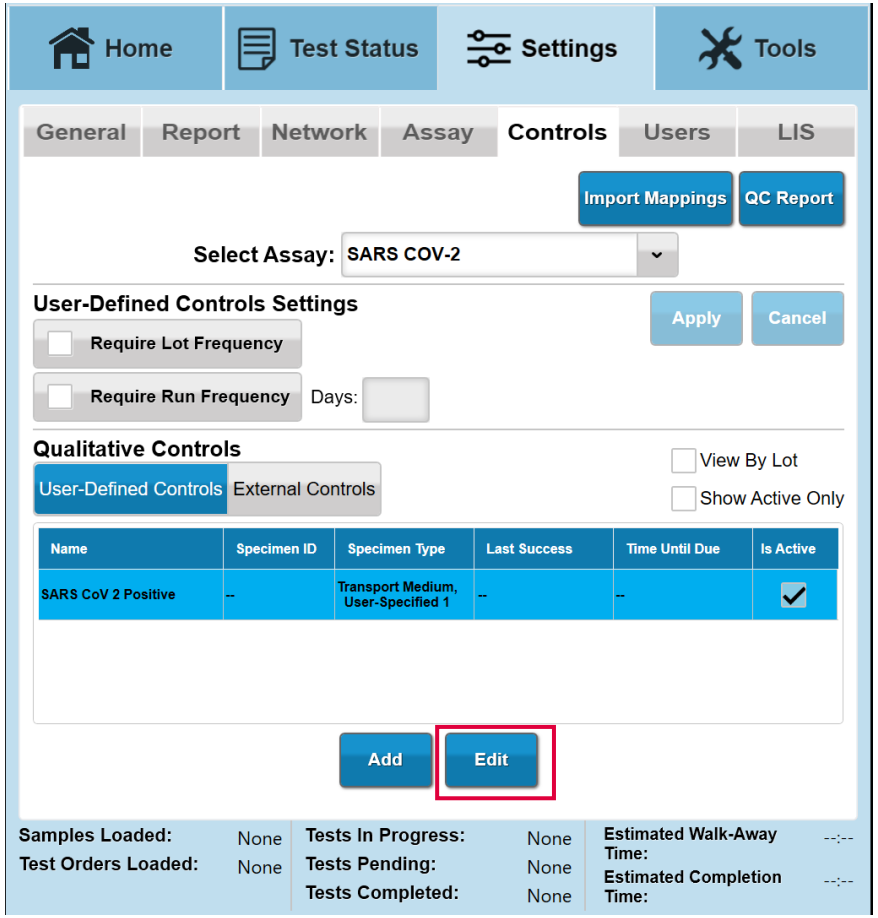
Defining User-Defined Controls





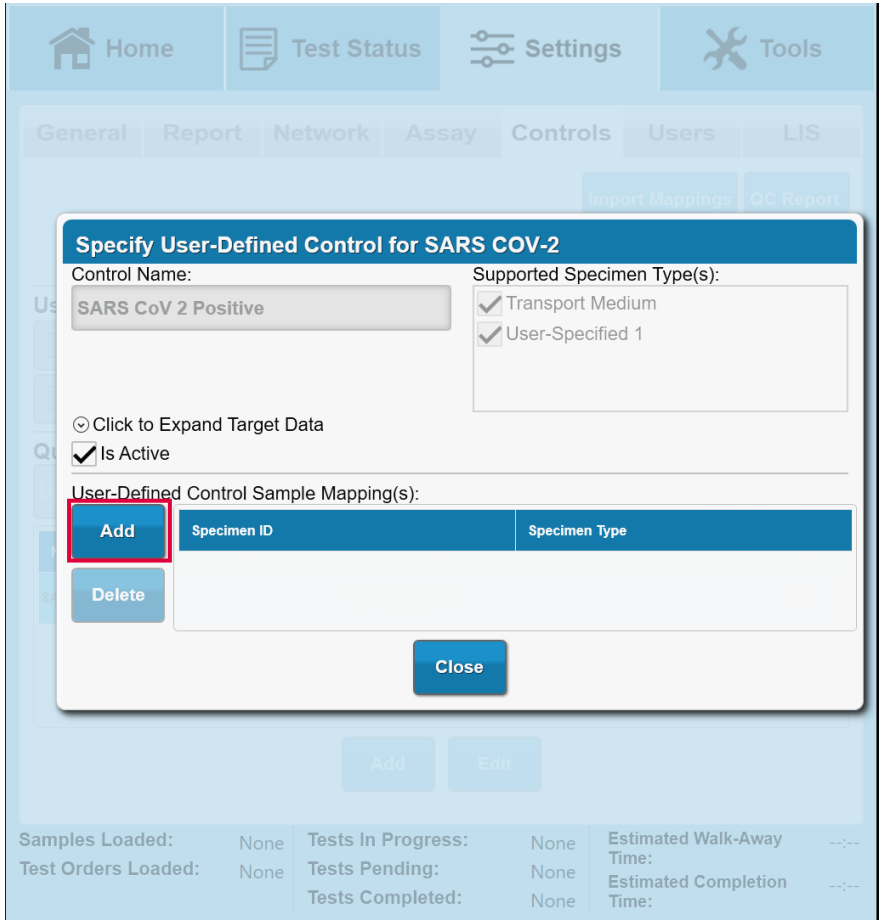
Enter the Name, select the Specimen Type(s) that the control will support, and select the result for each target

Mapping User-Defined Controls



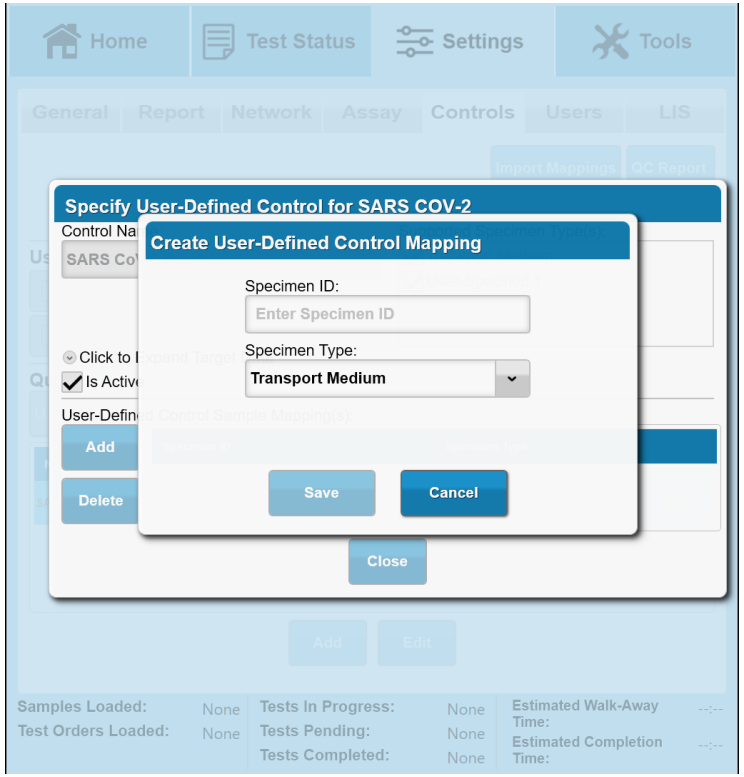
Select “Edit” to add a “mapping” (specimen ID) to the control

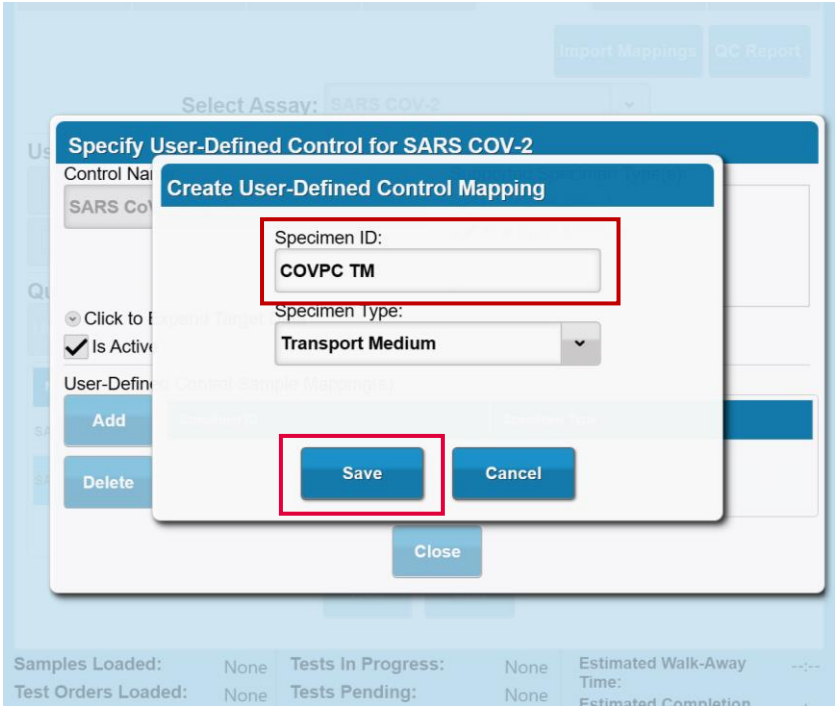
Mapping User-Defined Controls



Select “Add” to add a “mapping” (specimen ID) to the control

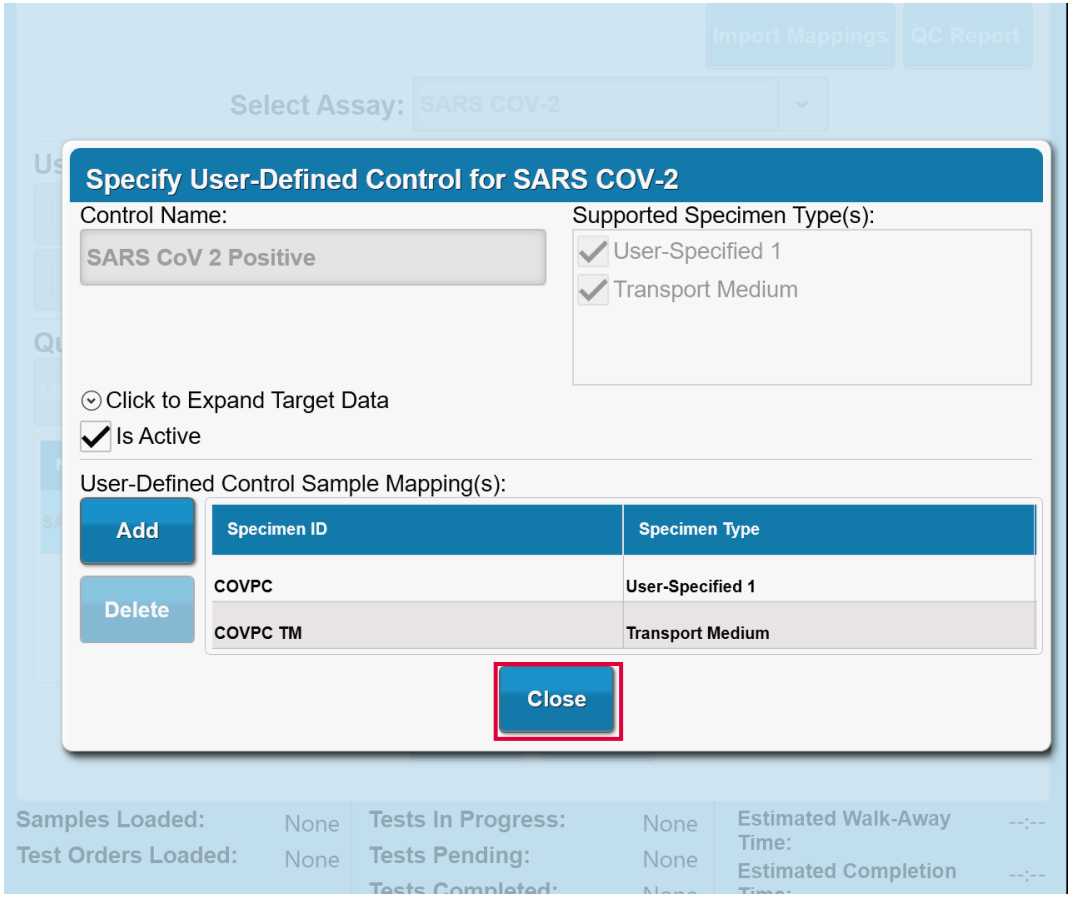
Mapping User-Defined Controls





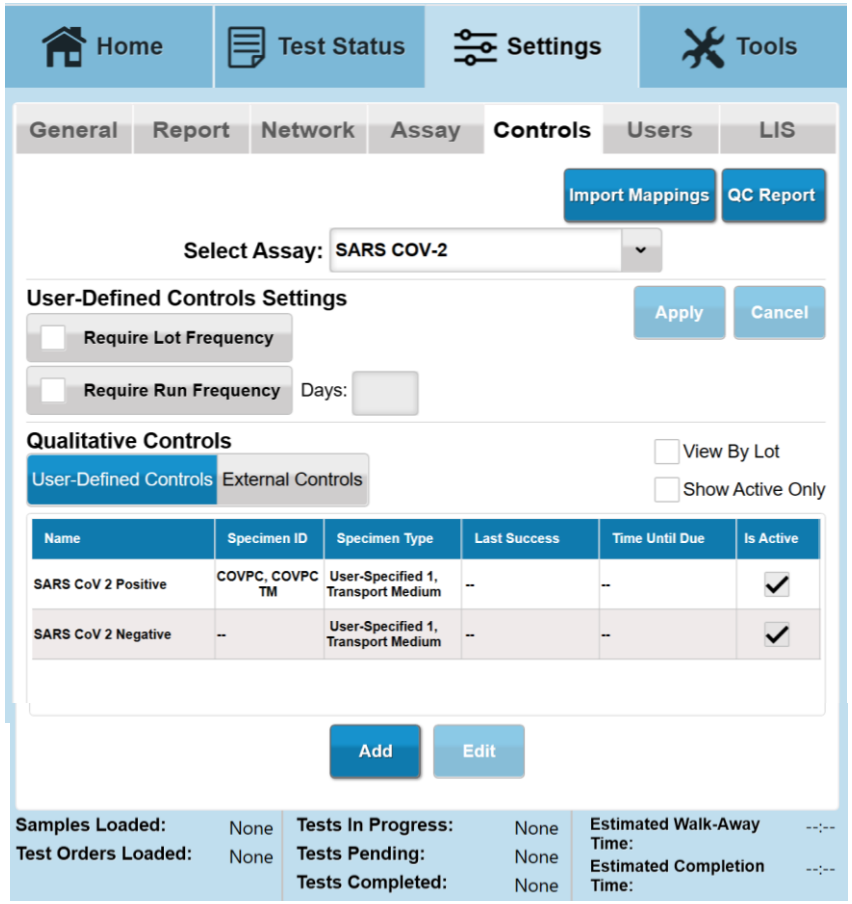
- Enter the Specimen ID and choose the specimen type that the control will be prepared with
  - You can select from the specimen types supported by the control
  - You can choose your own Specimen ID

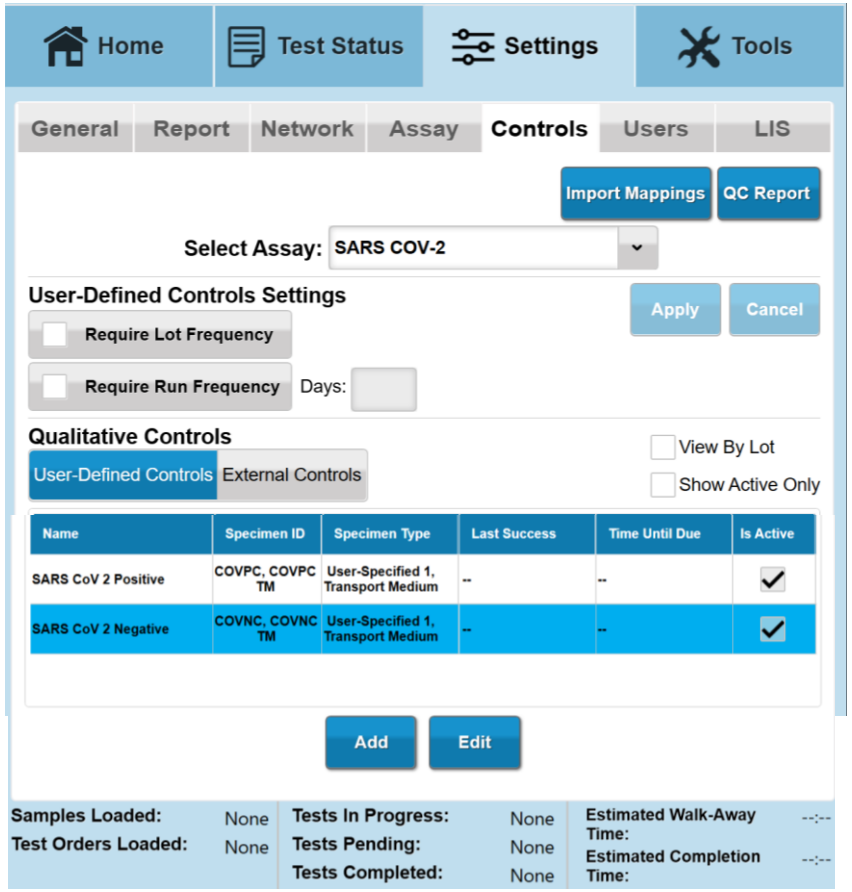
Mapping User-Defined Controls



Select “Close” to return to the Controls tab

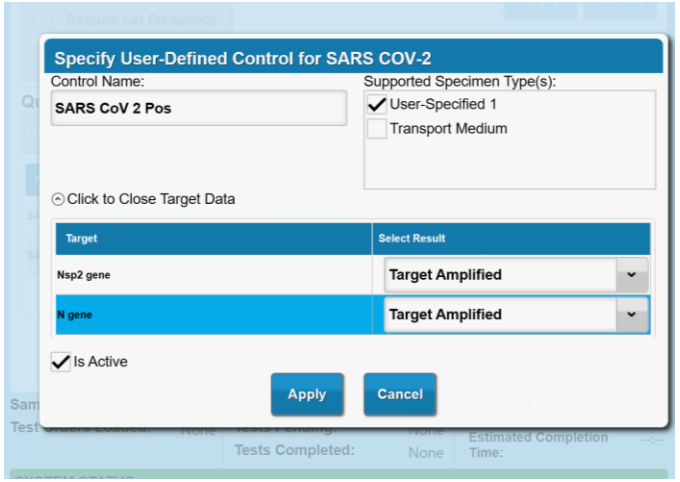
Defining User-Defined Controls

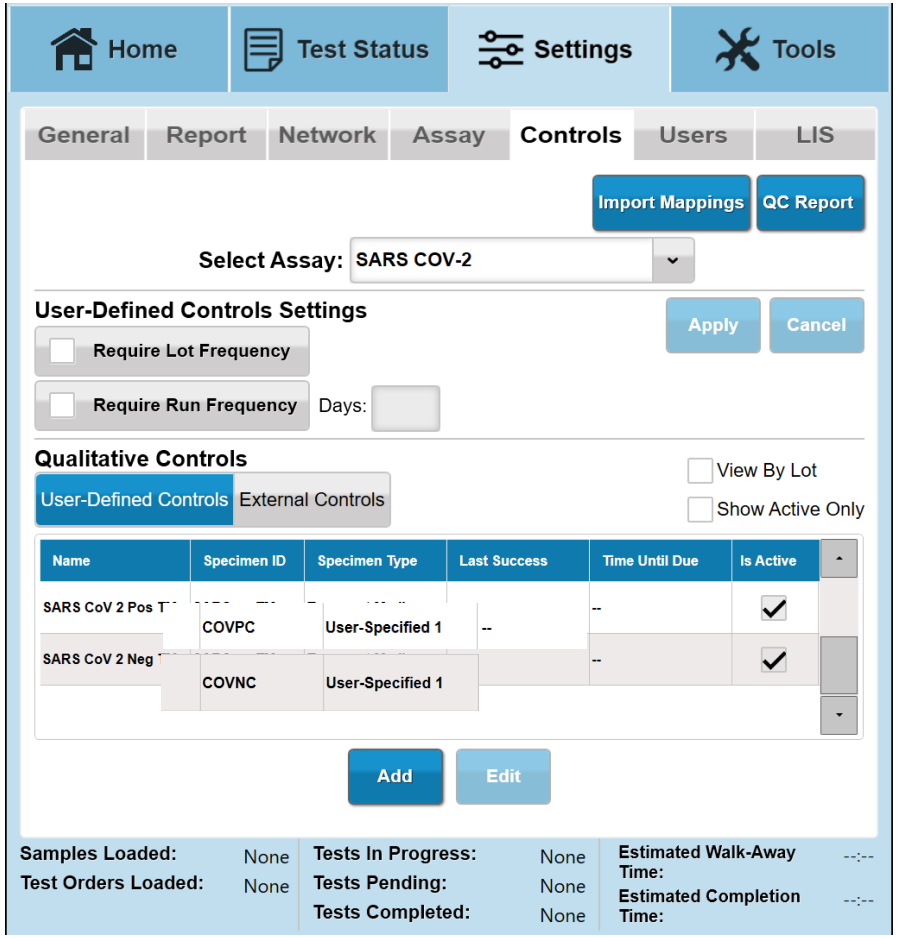




Select “Add” and go through the previous steps to define the negative control

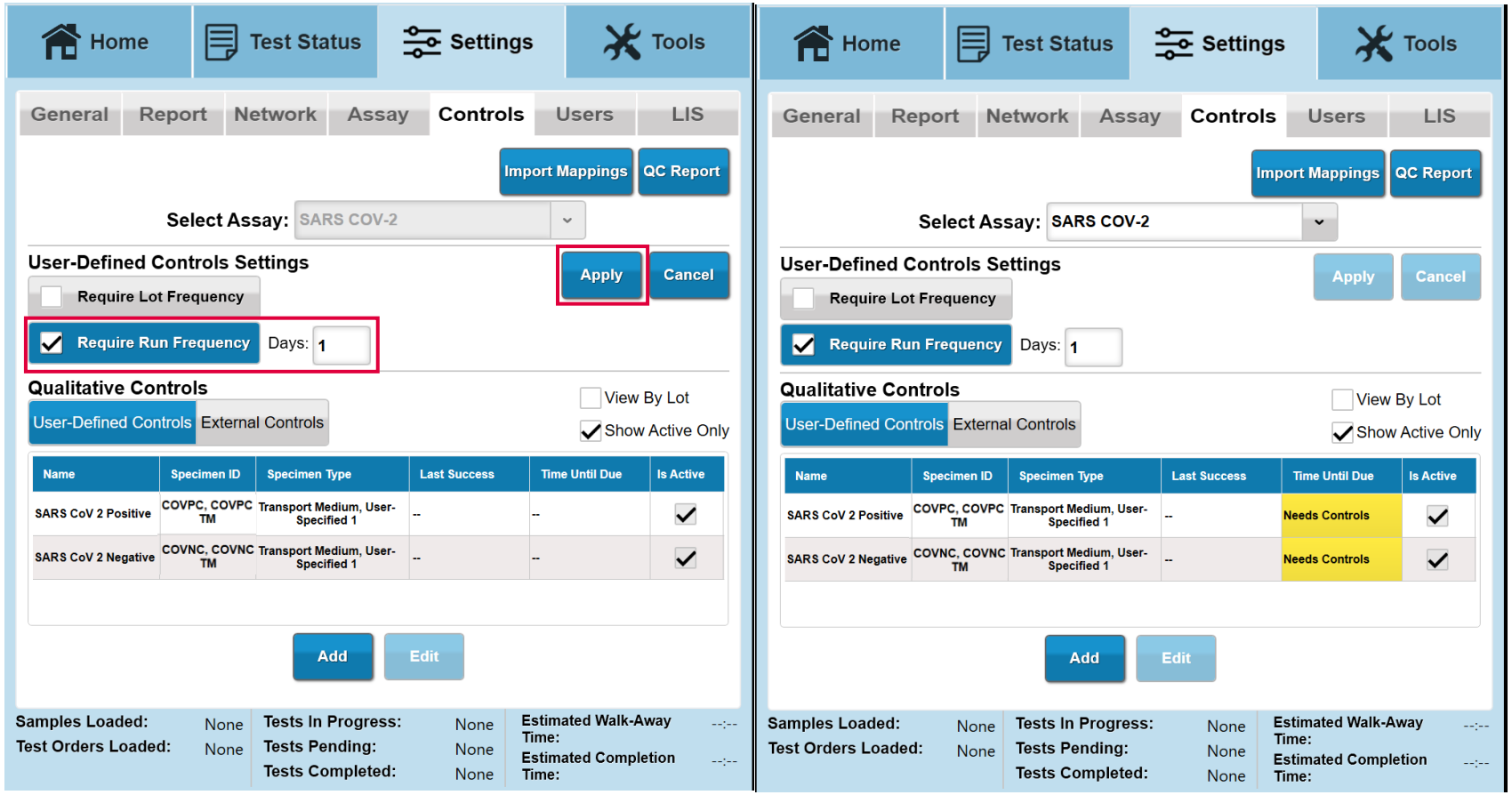
Defining User-Defined Controls





Controls can also be defined for only one specimen type

Requiring User-Defined Controls



- Check “Require Run Frequency” and enter the desired number of days that a control will stay valid
- Select “Apply” to apply the changes

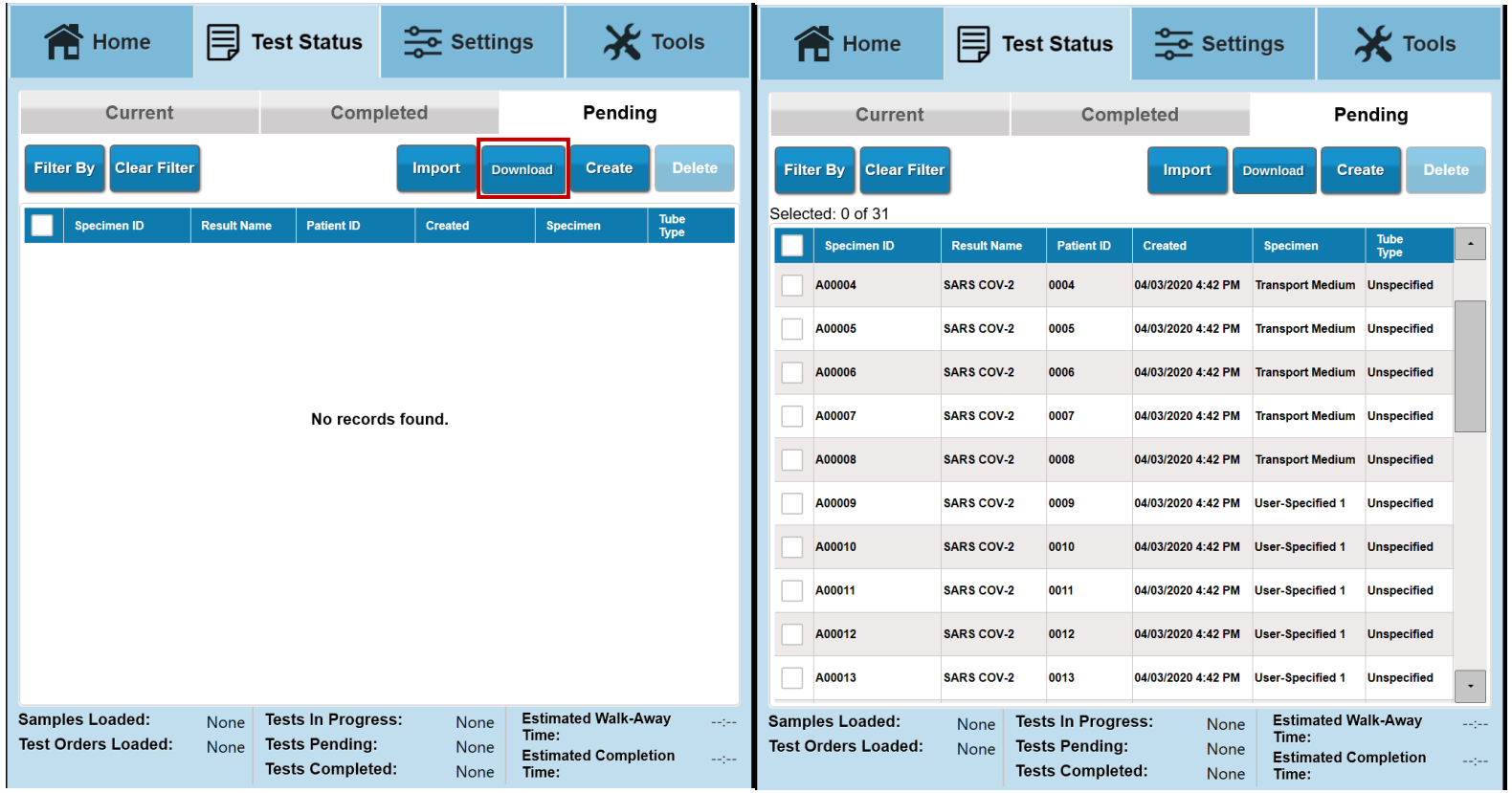
Creating Test Orders

Creating Test Orders

Four ways to add test orders

- Importing from a LIS (if applicable)
- Importing an Excel file (.xlsx)
- Manually on the system
  - From the Pending tab
  - From the loaded carrier screens
  - Refer to the Operator’s Manual for information on these methods

Importing from a LIS



- Navigate to Test Status, then Pending
- If using a uni-directional connection, select “Download”, samples will appear in the table
- If using a bi-directional connection, the system will auto-populate the table with test orders

Importing an Excel File

On a separate computer, open the TestOrders.xslx file

Fill in the columns

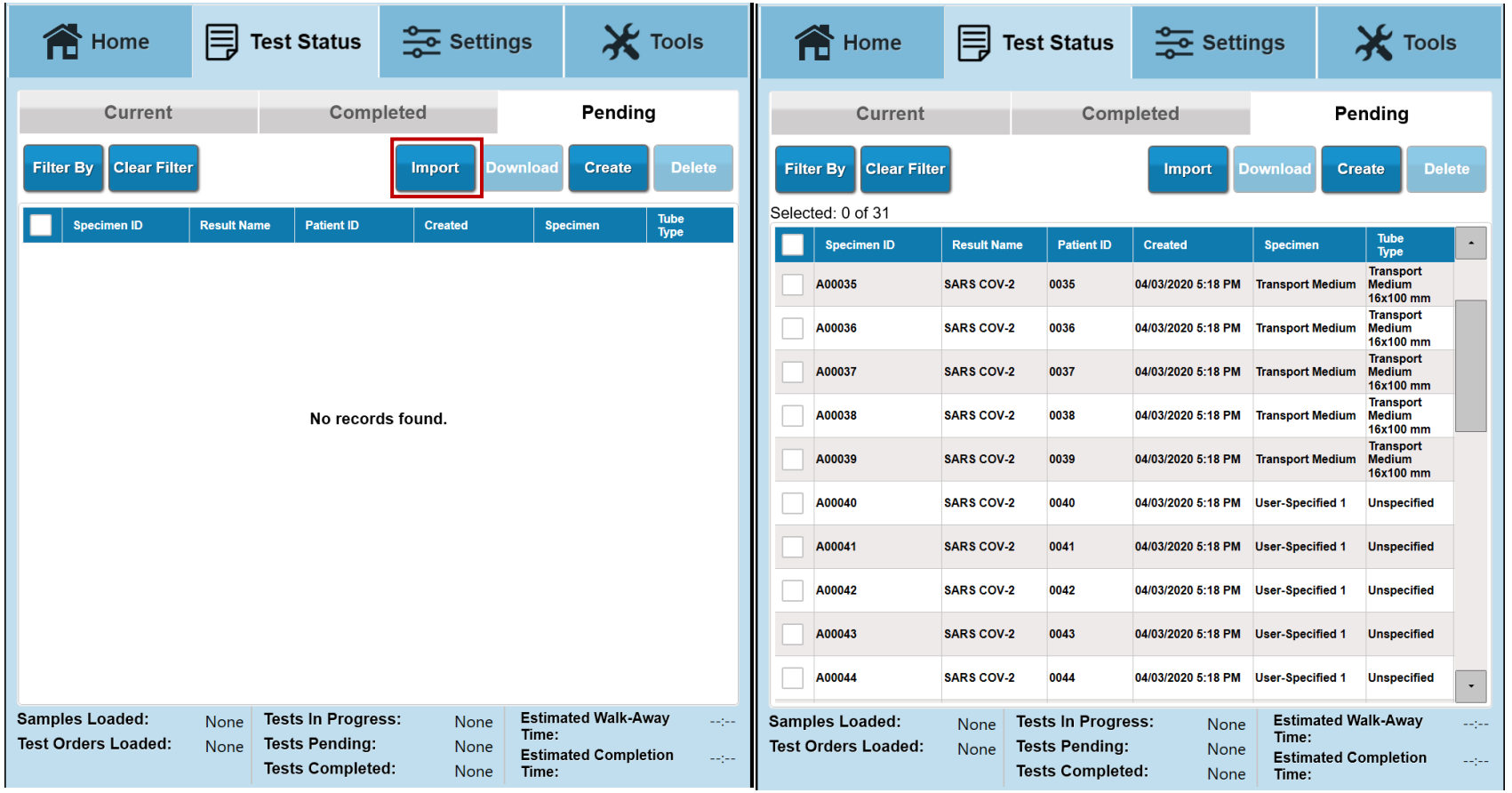
- Specimen ID (required)
- Result Code (required)
- Specimen Type (optional)
  - If nothing is entered, the default specimen type will be used
- Patient ID (optional)
- Comment (optional)
- Specimen Tube Type (optional)
  - If left empty, the 13 x 75 mm secondary tube is the default
  - Excel codes used to define supported specimen tube types for primary tubes relevant to this assay are described in the following section
  - See the Operator’s Manual for Excel codes for other primary tubes

Example Test Order File

Specimen ID	Result Code	Specimen Type	Patient ID	Comment	Specimen Tube Type
A00032	COV1	TransportMedium	0032		UTM3
A00033	COV1	TransportMedium	0033		UTM3
A00034	COV1	TransportMedium	0034		UTM3
A00035	COV1	TransportMedium	0035		UTM3
A00036	COV1	TransportMedium	0036		UTM3
A00037	COV1	TransportMedium	0037		UTM3
A00038	COV1	TransportMedium	0038		UTM3
A00039	COV1	TransportMedium	0039		UTM3
A00040	COV1	UserSpecified1	0040		
A00041	COV1	UserSpecified1	0041		
A00042	COV1	UserSpecified1	0042		
A00043	COV1	UserSpecified1	0043		
A00044	COV1	UserSpecified1	0044		
A00045	COV1	UserSpecified1	0045		
A00046	COV1	UserSpecified1	0046		
A00047	COV1	UserSpecified1	0047		
A00048	COV1	UserSpecified1	0048		
A00049	COV1	UserSpecified1	0049		
A00050	COV1	UserSpecified1	0050		

- UTM3 is the Excel Code that indicates that a 3 mL Universal Transport Medium tube is being used
- An empty cell indicates that the default specimen tube type (13 x 75 mm daughter tube) is being used

Importing an Excel File

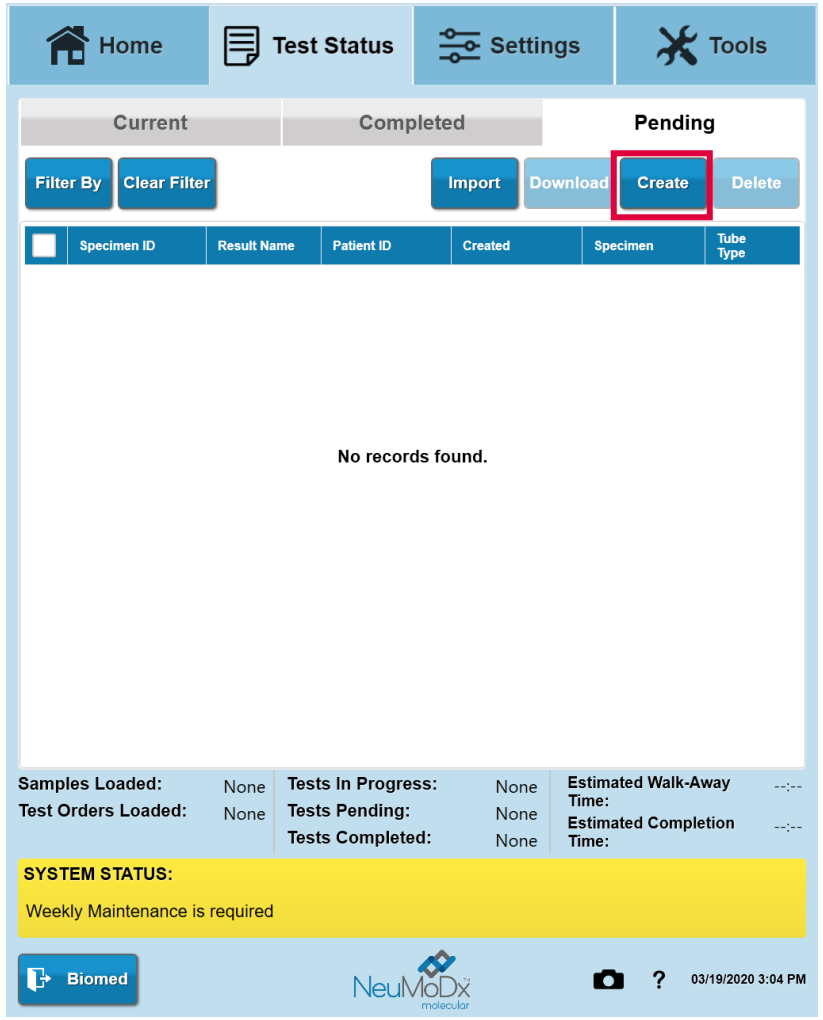


- Navigate to Test Status, then Pending
- Select “Import”, navigate to the file location, and select “OK” to import the test order file

NeuMoDx Molecular System

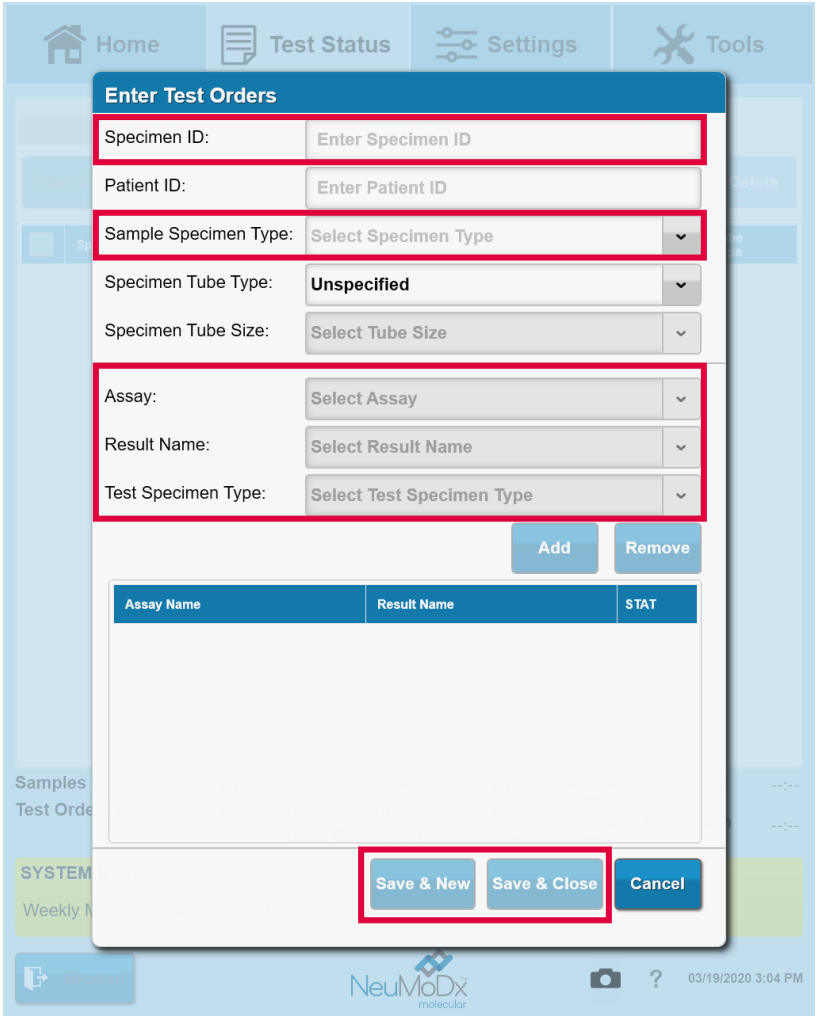
Assigning a Test Manually

Pre-assign test order manually with the “Pending Tab”



NeuMoDx Molecular System

Assigning a Test



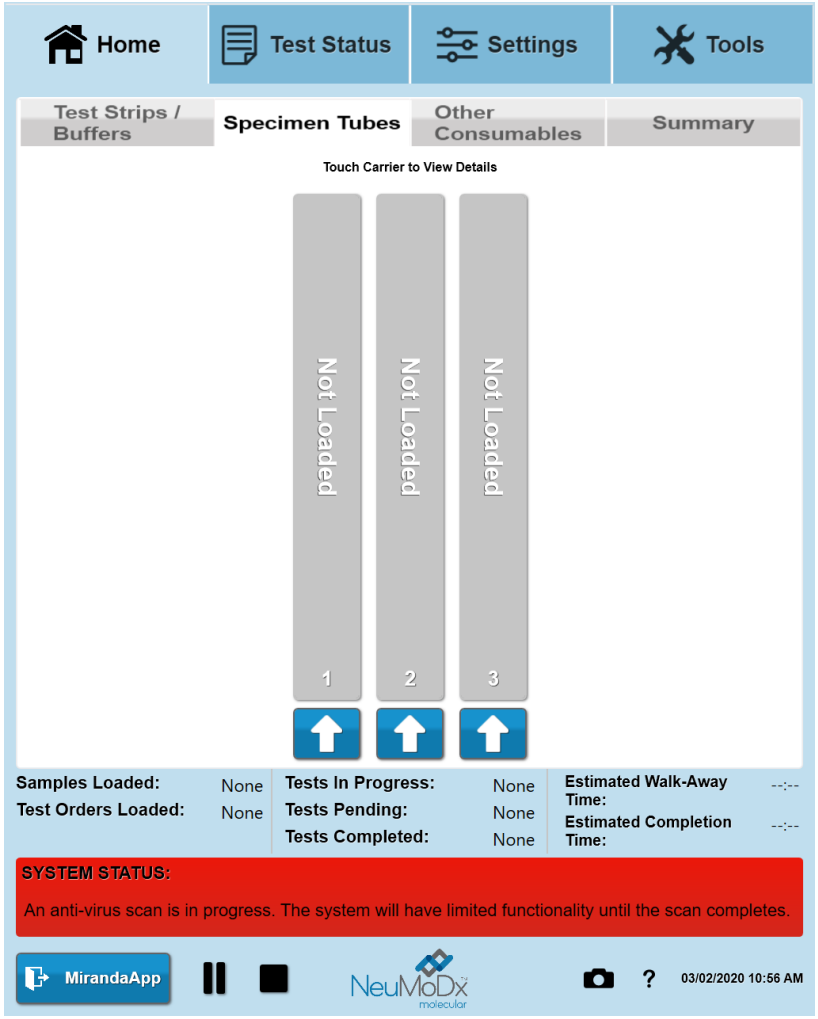
NeuMoDx Molecular System

Assigning a Test Manually

- Send in Sample Rack, assign each specimen individually and manually
  - Software will throw an error saying “No Test assigned” unless there has been a test defaulted

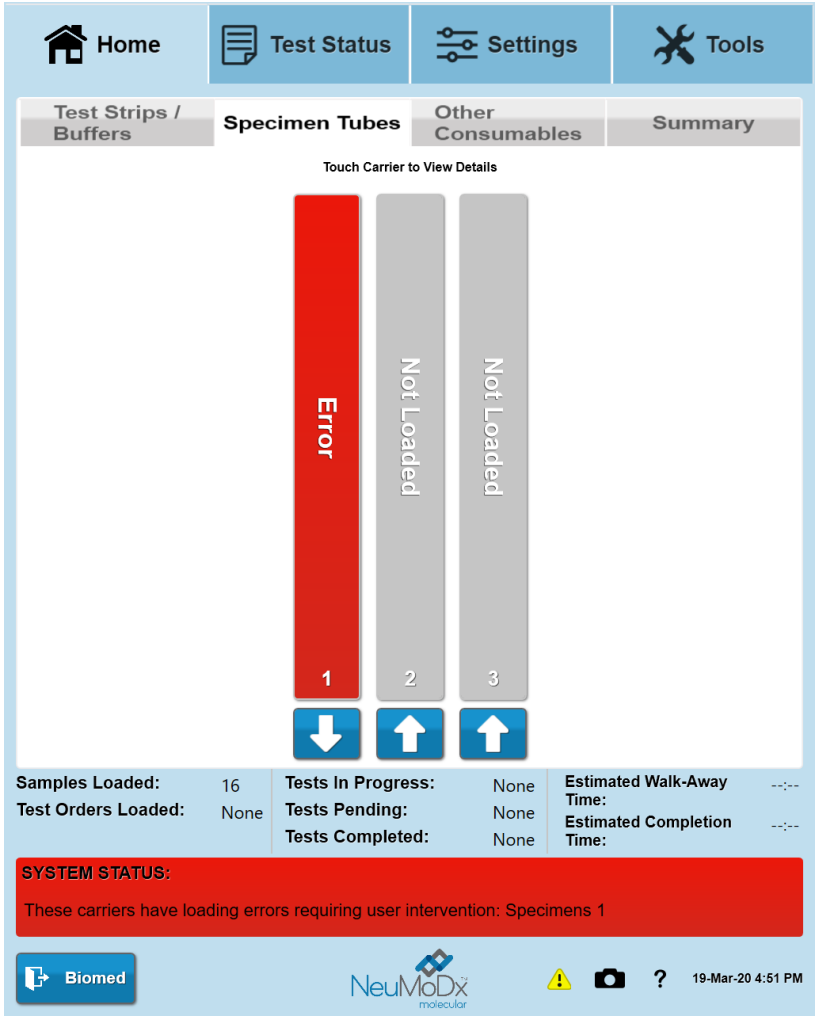
NeuMoDx Molecular System

Assigning a Test



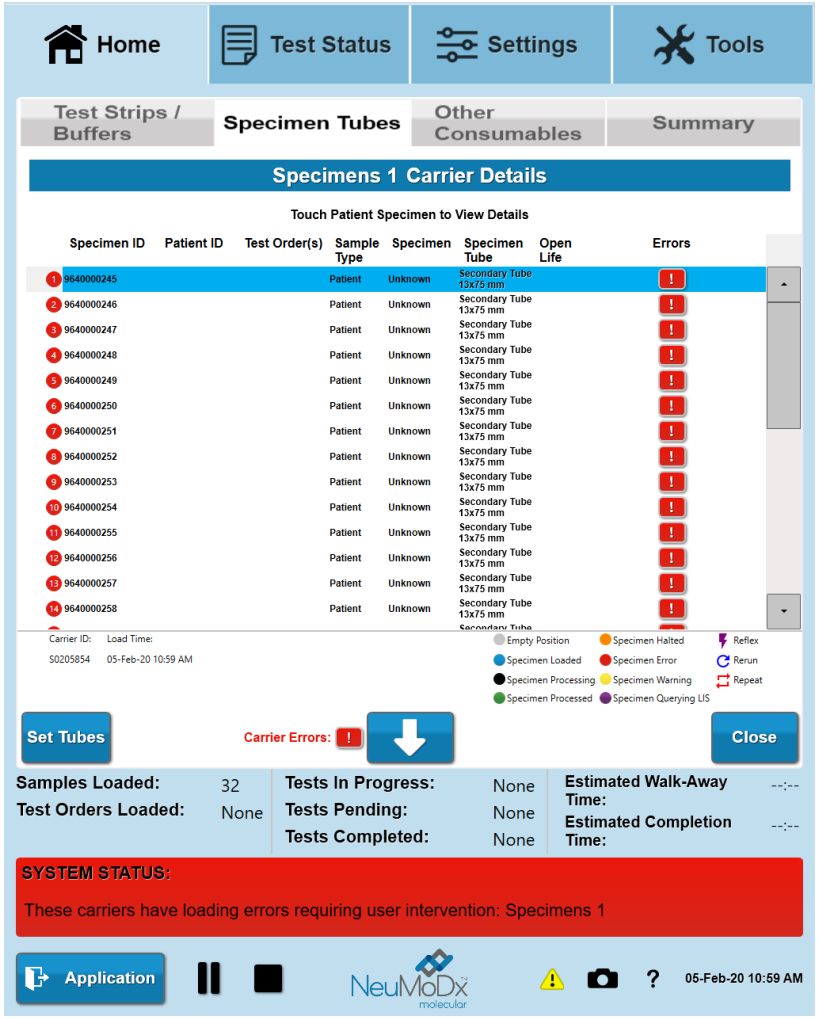
NeuMoDx Molecular System

Assigning a Test



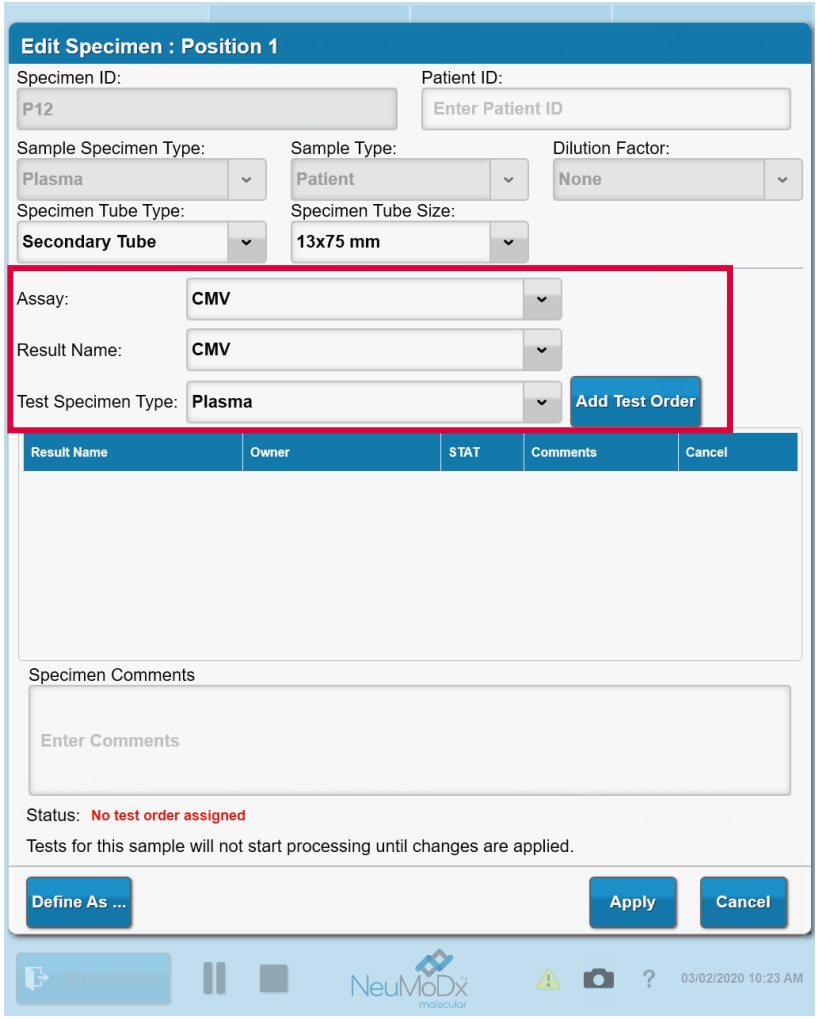
NeuMoDx Molecular System

Assigning a Test



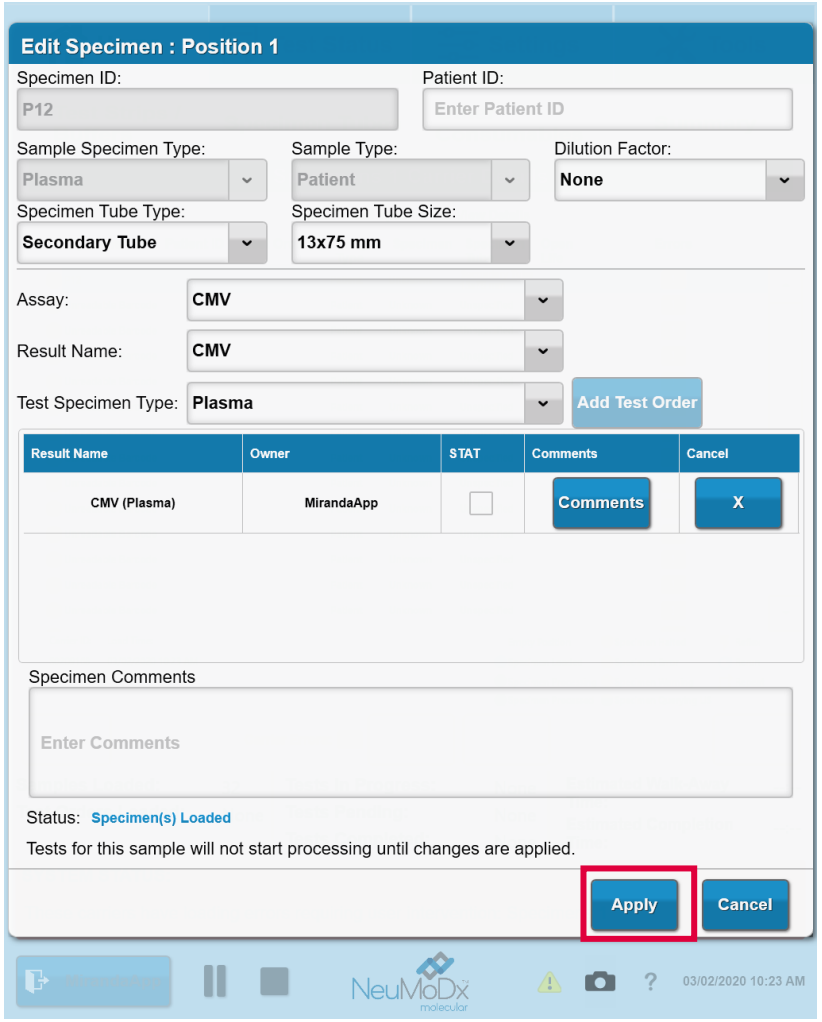
NeuMoDx Molecular System

Assigning a Test



NeuMoDx Molecular System

Assigning a Test



Using Primary Tubes

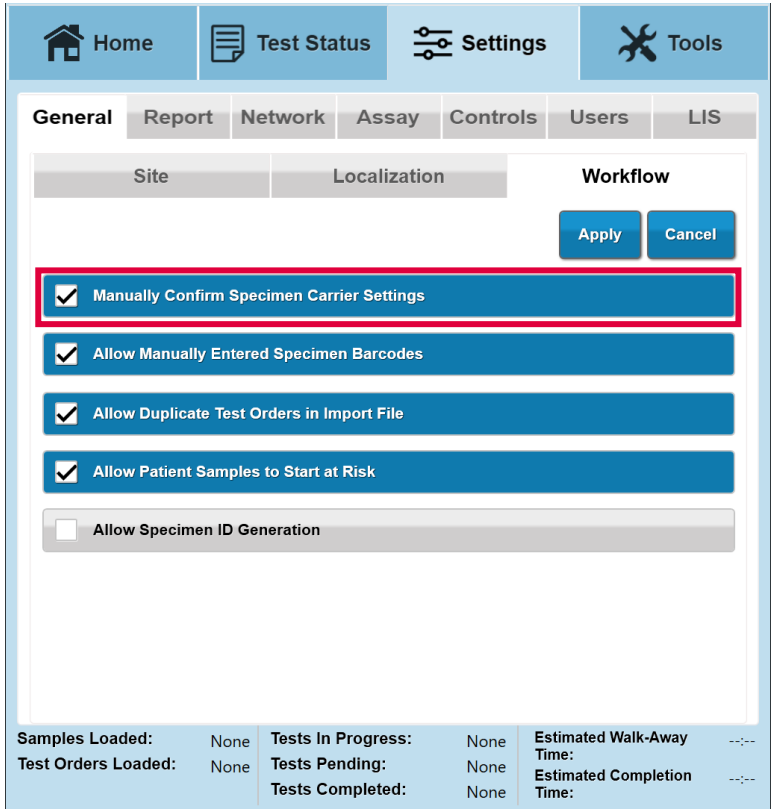
NeuMoDx Molecular System

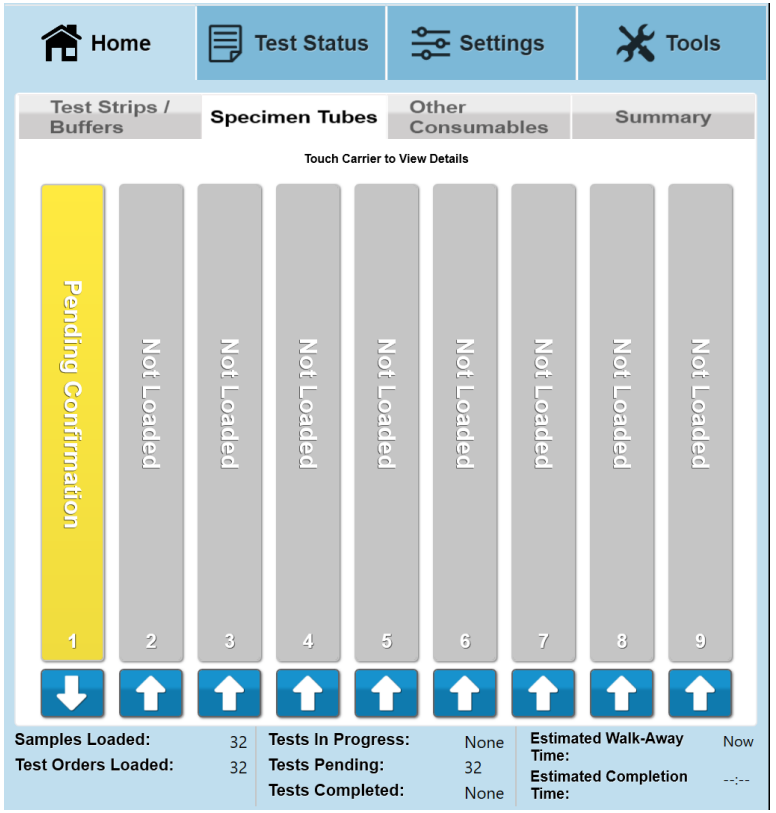
Primary Tubes

Primary tubes that the NeuMoDx Systems support currently are:

Specimen Tube Type		CSV Code
Plasma/Serum Tube	13 x 75 mm	PPS13x75
	13 x 100 mm	PPS13x100
	16 x 100 mm	PPS16x100
BD PPT™/SST™ Tube	13 x 75 mm	PPTSST13x75
	13 x 100 mm	PPTSST13x100
	16 x 100 mm	PPTSST16x100
Whole Blood Tube	13 x 75 mm	WBT13x75
	13 x 100 mm	WBT13x100
	16 x 100 mm	WBT16x100
Secondary Tube	13 x 75 mm	SDT13x75
	13 x 100 mm	SDT13x100
	16 x 100 mm	SDT16x100
Transport Medium	16x100 mm	UTM3
	12x80 mm	UTM1
Swab in Transport Medium	16x100 mm	SIT3
	12x80 mm	SIT1
Low Volume Tube		LVT1

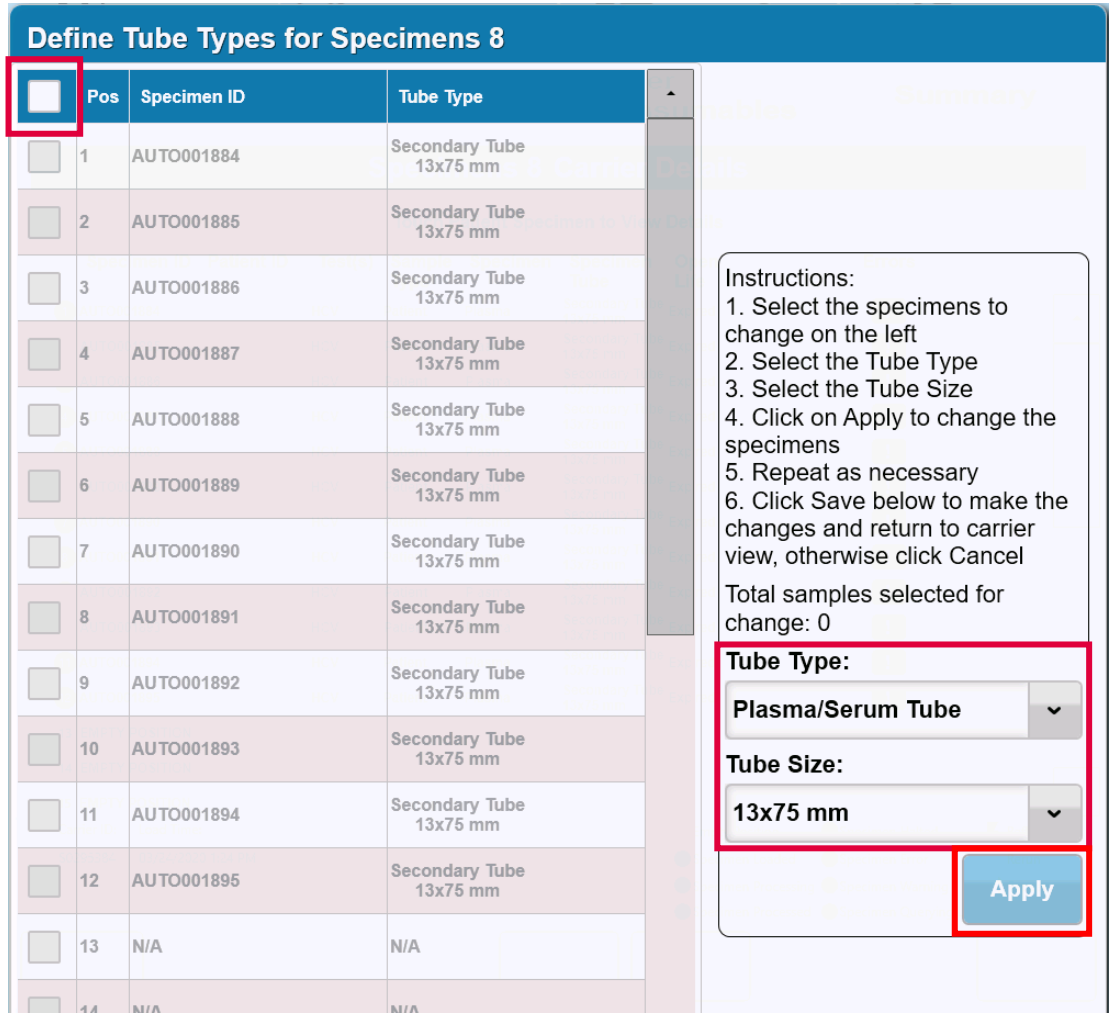
Confirming Sample Processing



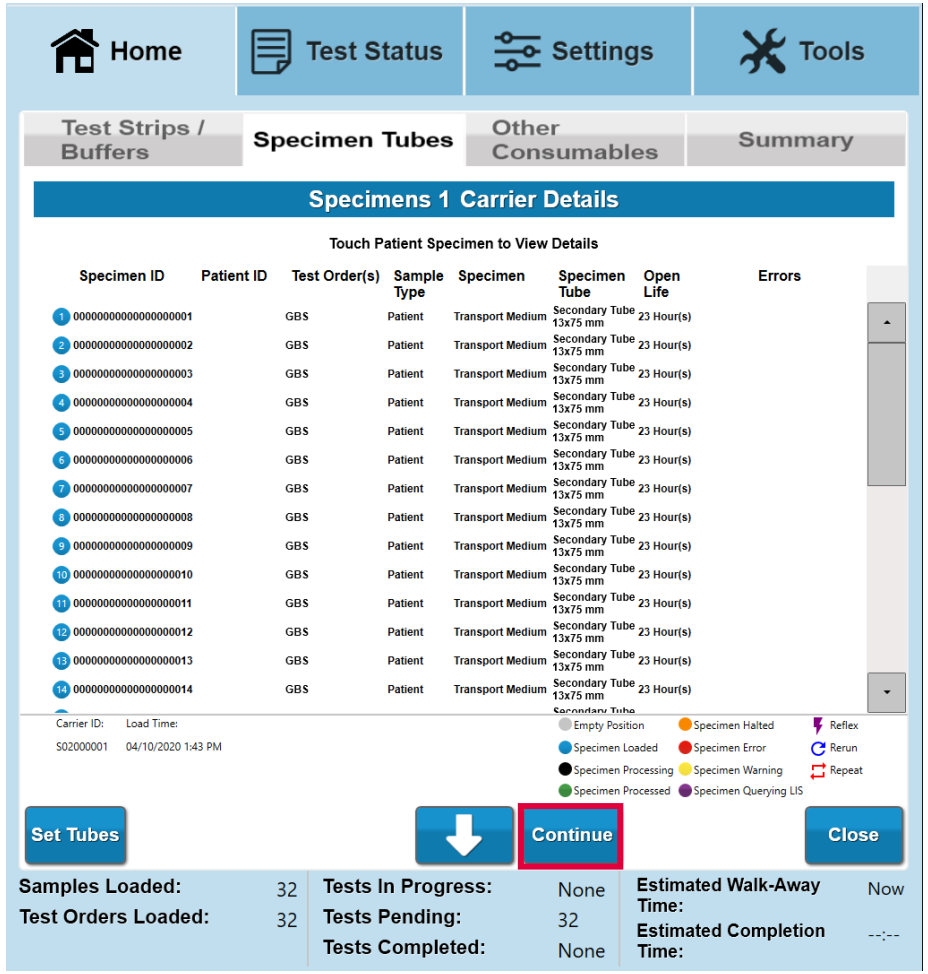


- If “Manually Confirm Specimen Carrier Settings” is selected in the General Workflow Settings tab and samples are then loaded, the carrier will say “Pending Confirmation”
- Select the carrier to display the Specimen Carrier screen

Defining Primary Tubes



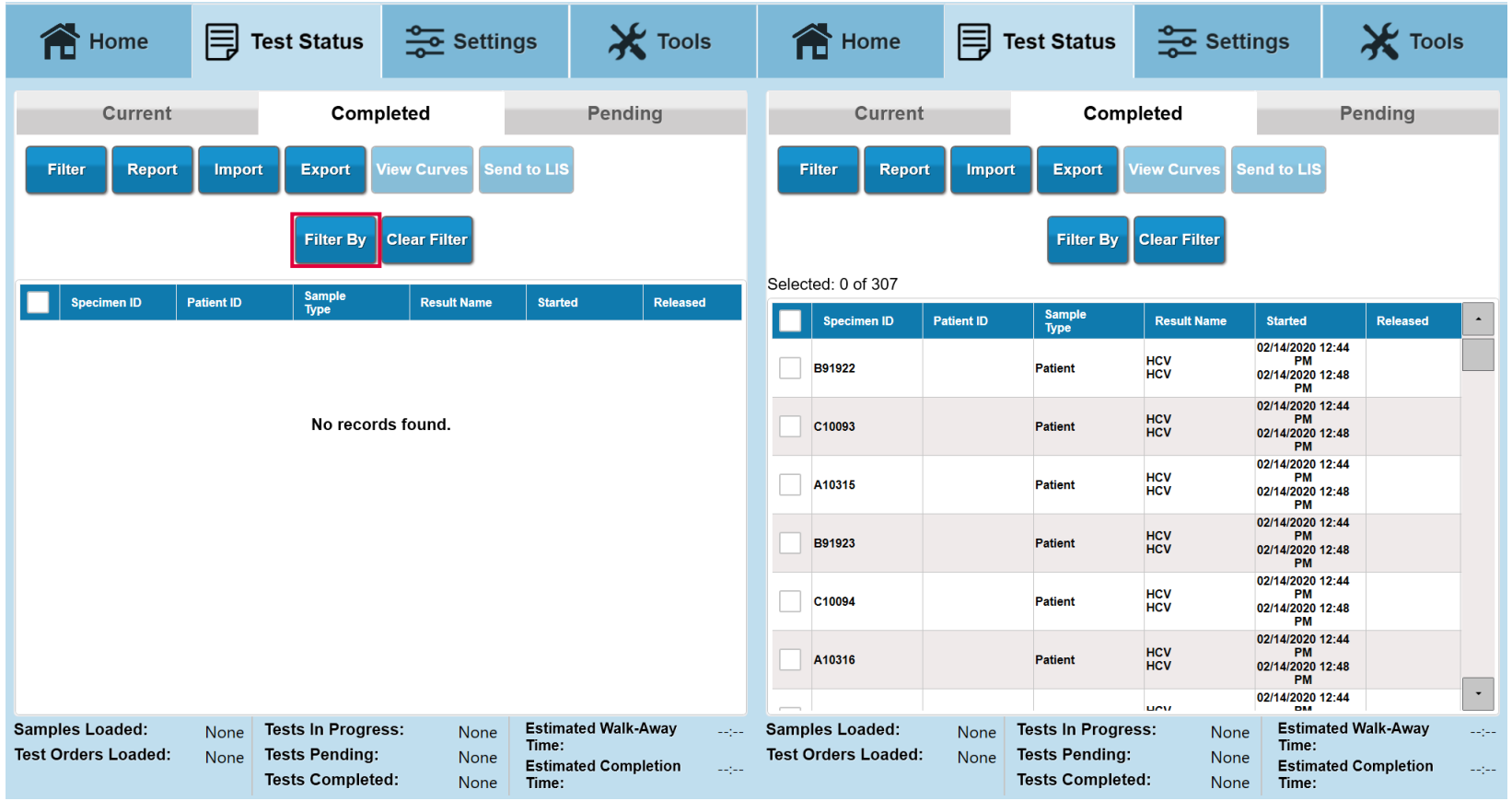
Confirming Sample Processing



Select “Continue” to begin processing the samples

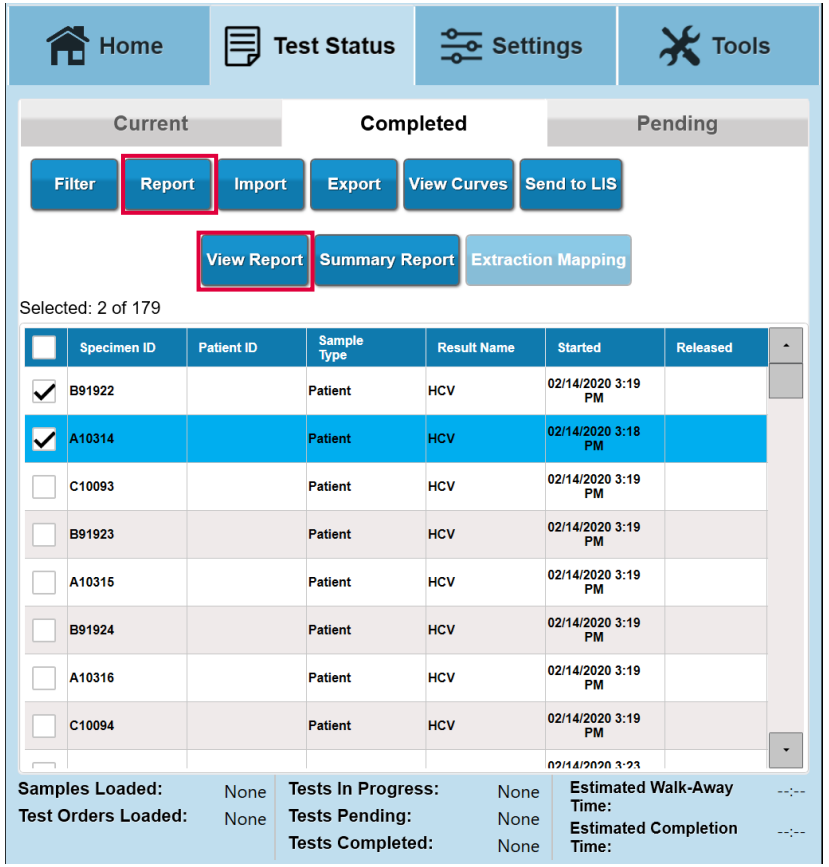
Viewing and Exporting Reports

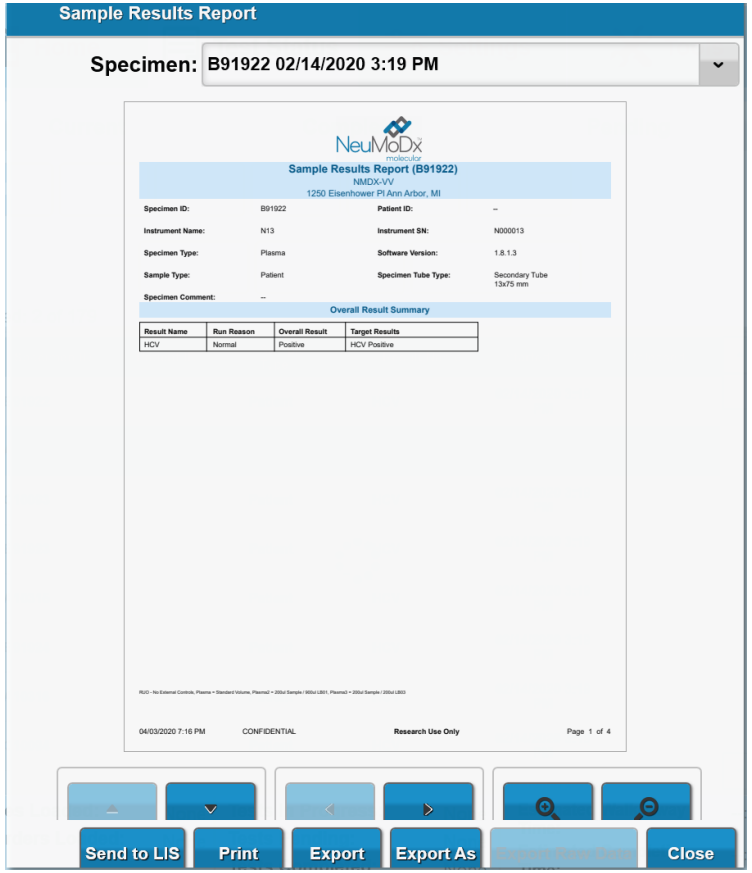
Filtering Samples



- Navigate to Test Status, then Completed
- Select Filter and apply the appropriate filters to find your samples

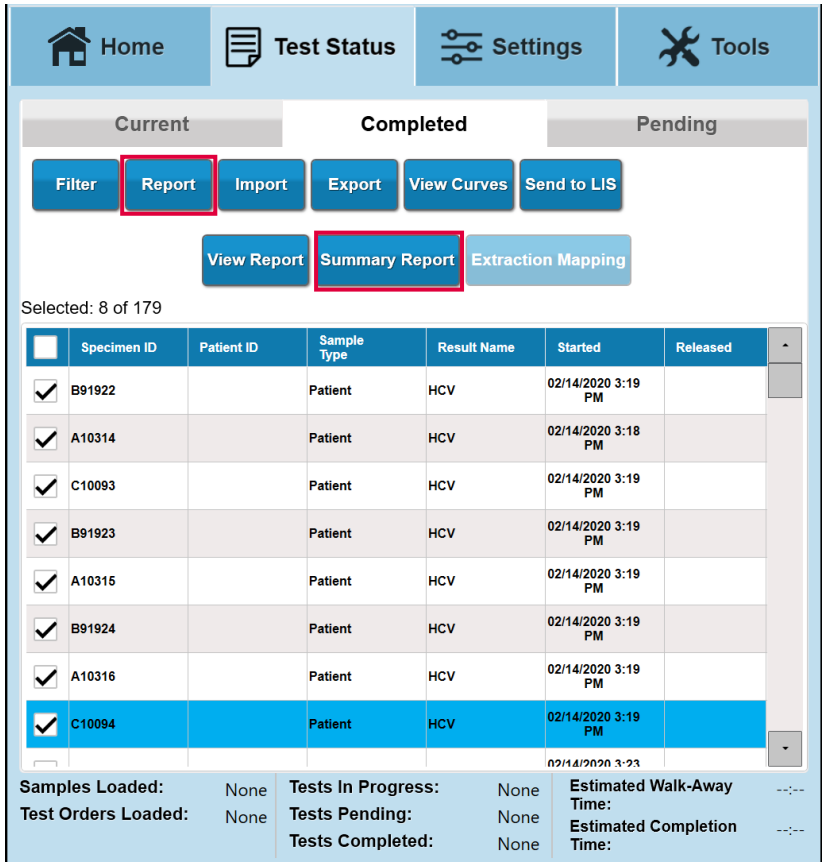
Viewing Sample Results Reports





- Select Report, then View Report
- The reports for all selected samples will display

Viewing Summary Reports



- Select Report, then Summary Report
- The reports for all selected samples will display

Reports Controls

- Up and Down Arrows: Navigate between pages within a report
- Left and Right Arrows: Navigate through reports if more than one sample was selected
- “Plus” Magnifying Glass: Zoom in
- “Minus” Magnifying Glass: Zoom out
- Send to LIS: Sends the results to the LIS
- Print: Prints the report if the system is attached to a printer
- Export: Exports the report to a selected file location as the default document type (set up in the Settings, Reports tab)
- Export As: Allows the user to choose the file type (PDF or CSV) and save the report to a selected file location
- Close: Closes the window

Results Interpretation

User-Defined Control Results Interpretation

Overall Result	Positive Control	Negative Control	Interpretation
Valid	Amplified **AND** No System Errors Present	Not Amplified **AND** No System Errors Present	All of the set conditions for the control have been met
Invalid	Not Amplified **OR** Relevant System Errors Present **OR** Both	Amplified **OR** Relevant System Errors Present **OR** Both	Any of the conditions for the control have not been met

- The System automatically reruns/repeats controls with an IND/UNR regardless of whether “repeat” and/or “rerun” are enabled for the assay

Results Interpretation

- Indeterminate Results
  - Accompanied by relevant flags
  - May be caused by:
    - General system failures or system errors (see “Troubleshooting” in the appropriate Operator’s Manual)
    - Failure of the PCR region of the cartridge to fill with PCR mix
- Unresolved Results
  - Not accompanied by relevant flags
  - May be caused by:
    - Test inhibition
    - Other processing or system error
- Aborted Results
  - Accompanied by relevant flags
  - Not accompanied by data
  - Caused by the user choosing to abort the test
- No Results
  - Not accompanied by relevant flags
  - Caused by general system failures or system errors (see “Troubleshooting” in the appropriate Operator’s Manual) that occur in the pre-analytical stages of sample processing

Informational Resources & Safety Information

Useful Documents

For further help, refer to the following documents:

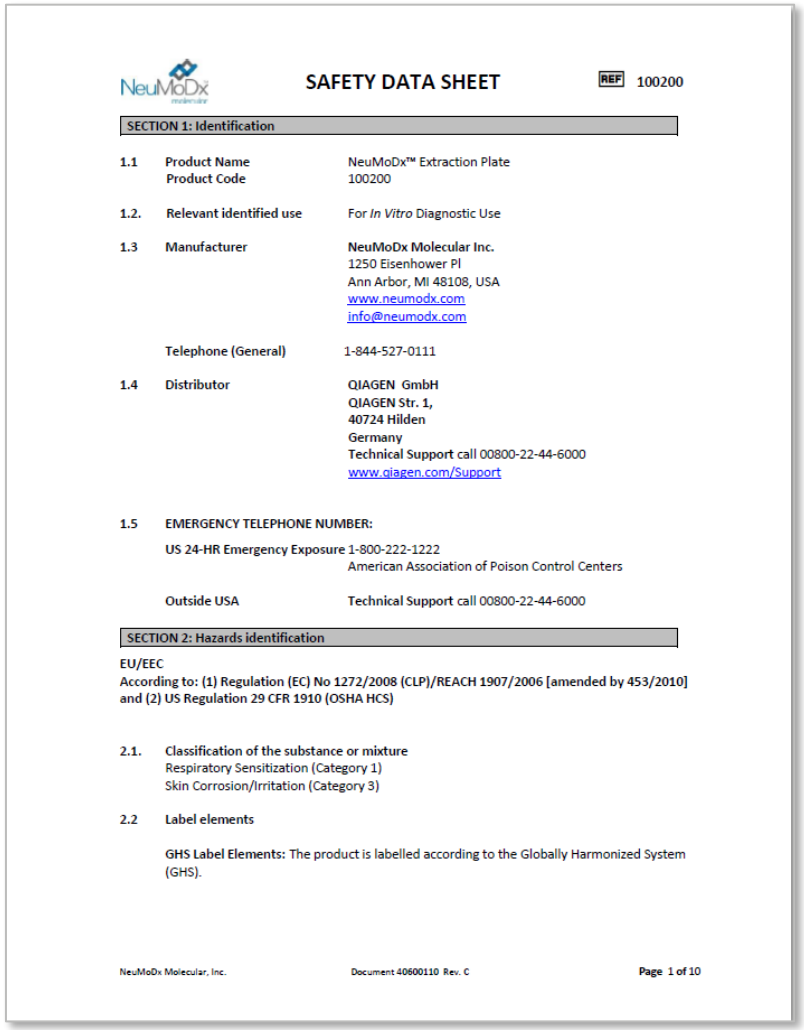
- NeuMoDx 96 System Operator’s Manual
- NeuMoDx LDT Supplement (if applicable)

- NeuMoDx Cartridge Instructions For Use
- NeuMoDx Extraction Plate Instructions For Use
- NeuMoDx Wash Solution Instructions For Use
- NeuMoDx Release Solution Instructions For Use
- Biohazardous Waste Bag Instructions For Use

- NeuMoDx Test Strip Instructions For Use – Assay Specific
- NeuMoDx Calibrators Instructions For Use – Assay Specific
- NeuMoDx External Controls Instructions For Use – Assay Specific

Safety Data Sheets (SDS)

To access Safety Data Sheets (SDS), please visit
www.neumodx.com/client-resources



NeuMoDx molecular

SAFETY DATA SHEET REF 100200

SECTION 1: Identification

1.1 **Product Name** NeuMoDx™ Extraction Plate
Product Code 100200

1.2. **Relevant identified use** For *In Vitro* Diagnostic Use

1.3 **Manufacturer** **NeuMoDx Molecular Inc.**
1250 Eisenhower Pl
Ann Arbor, MI 48108, USA
www.neumodx.com
info@neumodx.com

Telephone (General) 1-844-527-0111

1.4 **Distributor** **QIAGEN GmbH**
QIAGEN Str. 1,
40724 Hilden
Germany
Technical Support call 00800-22-44-6000
www.qiagen.com/Support

1.5 **EMERGENCY TELEPHONE NUMBER:**

US 24-HR Emergency Exposure 1-800-222-1222
American Association of Poison Control Centers

Outside USA **Technical Support** call 00800-22-44-6000

SECTION 2: Hazards identification

EU/EEC
According to: (1) Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010] and (2) US Regulation 29 CFR 1910 (OSHA HCS)

2.1. **Classification of the substance or mixture**
Respiratory Sensitization (Category 1)
Skin Corrosion/Irritation (Category 3)

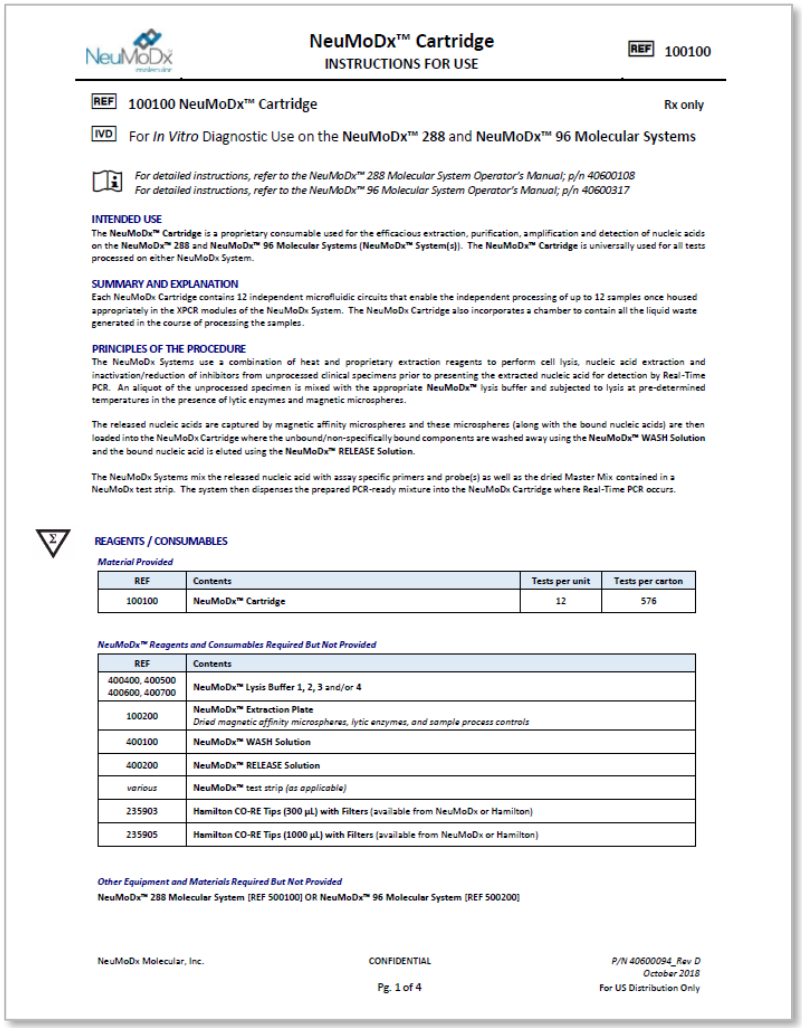
2.2 **Label elements**

GHS Label Elements: The product is labelled according to the Globally Harmonized System (GHS).

NeuMoDx Molecular, Inc. Document 40600110 Rev. C **Page 1 of 10**

Instructions for Use (IFU)

To access Instructions for Use (IFU), please visit
www.neumodx.com/client-resources



NeuMoDx™ Cartridge
INSTRUCTIONS FOR USE
REF 100100

REF 100100 NeuMoDx™ Cartridge Rx only

IVD For *In Vitro* Diagnostic Use on the **NeuMoDx™ 288** and **NeuMoDx™ 96 Molecular Systems**

For detailed instructions, refer to the NeuMoDx™ 288 Molecular System Operator's Manual; p/n 40600108
For detailed instructions, refer to the NeuMoDx™ 96 Molecular System Operator's Manual; p/n 40600317

INTENDED USE
The **NeuMoDx™ Cartridge** is a proprietary consumable used for the efficacious extraction, purification, amplification and detection of nucleic acids on the **NeuMoDx™ 288** and **NeuMoDx™ 96 Molecular Systems (NeuMoDx™ System(s))**. The **NeuMoDx™ Cartridge** is universally used for all tests processed on either NeuMoDx System.

SUMMARY AND EXPLANATION
Each NeuMoDx Cartridge contains 12 independent microfluidic circuits that enable the independent processing of up to 12 samples once housed appropriately in the XPCR modules of the NeuMoDx System. The NeuMoDx Cartridge also incorporates a chamber to contain all the liquid waste generated in the course of processing the samples.

PRINCIPLES OF THE PROCEDURE
The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by Real-Time PCR. An aliquot of the unprocessed specimen is mixed with the appropriate **NeuMoDx™** lysis buffer and subjected to lysis at pre-determined temperatures in the presence of lytic enzymes and magnetic microspheres.

The released nucleic acids are captured by magnetic affinity microspheres and these microspheres (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the **NeuMoDx™ WASH Solution** and the bound nucleic acid is eluted using the **NeuMoDx™ RELEASE Solution**.

The NeuMoDx Systems mix the released nucleic acid with assay specific primers and probe(s) as well as the dried Master Mix contained in a NeuMoDx test strip. The system then dispenses the prepared PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.

REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit	Tests per carton
100100	**NeuMoDx™ Cartridge**	12	576

NeuMoDx™ Reagents and Consumables Required But Not Provided

REF	Contents
400400, 400500 400600, 400700	**NeuMoDx™ Lysis Buffer 1, 2, 3 and/or 4**
100200	**NeuMoDx™ Extraction Plate** *Dried magnetic affinity microspheres, lytic enzymes, and sample process controls*
400100	**NeuMoDx™ WASH Solution**
400200	**NeuMoDx™ RELEASE Solution**
various	**NeuMoDx™** test strip *(as applicable)*
235903	**Hamilton CO-RE Tips (300 µL) with Filters** (available from NeuMoDx or Hamilton)
235905	**Hamilton CO-RE Tips (1000 µL) with Filters** (available from NeuMoDx or Hamilton)

Other Equipment and Materials Required But Not Provided
NeuMoDx™ 288 Molecular System [REF 500100] OR **NeuMoDx™ 96 Molecular System** [REF 500200]

NeuMoDx Molecular, Inc. CONFIDENTIAL *P/N 40600094_Rev D*
October 2018
Pg. 1 of 4 For US Distribution Only

System Safety Information

Some tips:

- Refer to the **operator's manual** for the operation you are performing – refer to table of contents or index to locate the information.
- Follow the instructions and do not do any "off-label" practices.
- Always use powderless, disposable, nitrile gloves when handling consumables, reagents, and specimens. Be sure to change gloves between interactions with potentially infectious material and new consumables.
  - Avoid touching the top surfaces of cartridges, extraction plates, lysis buffers, tips, and test strips
- Do not reach inside the instrument.
- Do not manually insert or manually remove any carriers.
- If any errors appear on screen, follow all prompts exactly as written.
- Do not lean on the Autoloader shelf.
- Clean the instrument with only a lint-free cloth and Microcide SQ.
- Follow Good Laboratory Practice (GLP) and always wear proper Personal Protective Equipment (PPE) when interacting with the NeuMoDx Molecular System(s) and patient specimens.

Contacting NeuMoDx for Tech Support

- If additional assistance is required or a question arises, which is not answered in the operator manual, contact NeuMoDx™ Technical Services:

  Email: techservice-na@qiagen.com

  Phone: +1-800-362-7737

- When contacting NeuMoDx™, have the following information available:
  - Product name, part number, and serial number
  - Desired email(s) to receive link to upload Troubleshooting Package
  - Details surrounding event
    - Videos or photos if helpful

Order From:

QIAGEN LLC

19300 Germantown Rd.

Germantown, MD 20874

Orders: orders-us@qiagen.com

Customer Care Order Fax: 617 227 2489

Customer Care

Phone: 800 426 8157 option 1

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