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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?

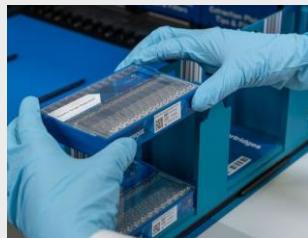
- A liquid-handling instrument with touchscreen computer, accessories, reagents, and consumables

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

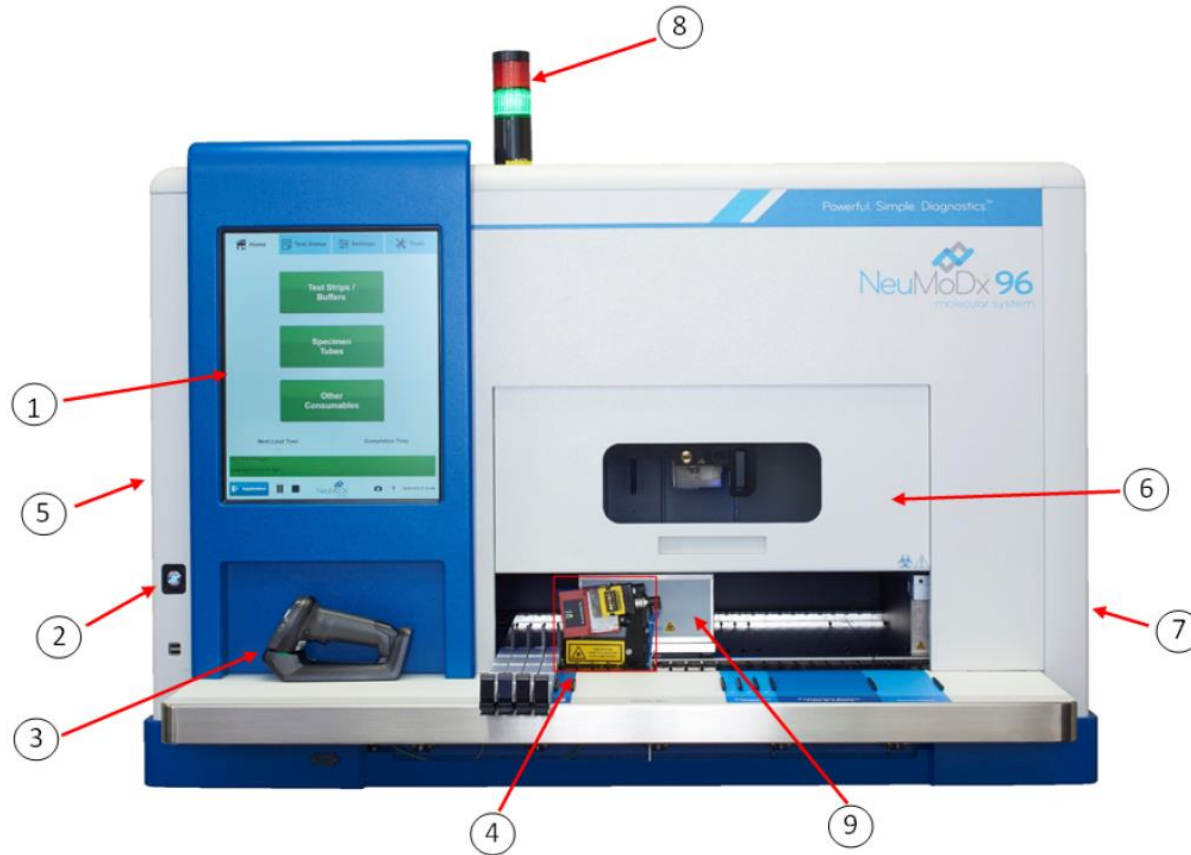
STEP 3



Touch 'Load' button

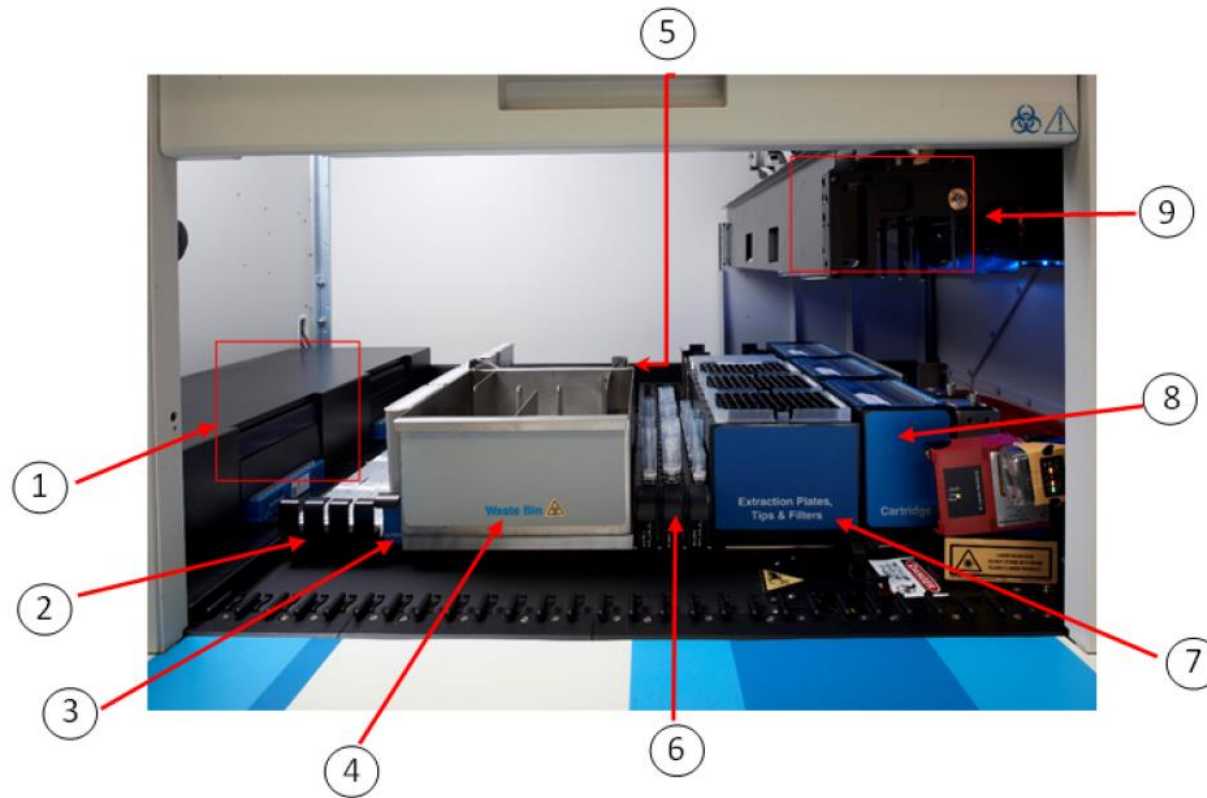
*Step 1 is not necessary if system has sufficient consumables, reagents and tests to complete the desired testing. If insufficient, the system will prompt the operator to load the required product(s).

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



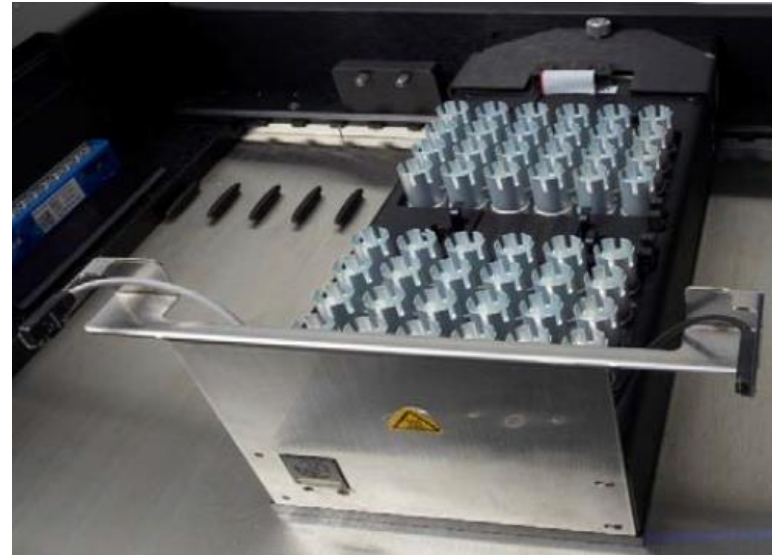
②

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

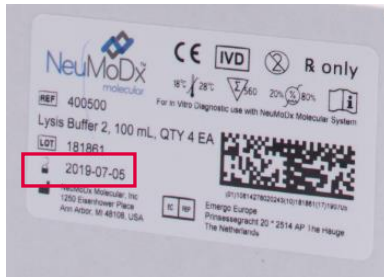


The background of the slide is a close-up, slightly blurred image of a microfluidic chip. The chip is a rectangular, light-colored substrate with a grid of small, rectangular wells. The wells are arranged in rows and columns, and the image shows the perspective of looking down at the chip. The lighting is soft, highlighting the texture of the chip.

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

- NeuMoDx™ Extraction Plate
 - NeuMoDx™ Test Strip
 - NeuMoDx™ Lysis Buffer
- } **Worktable Reagents**
- NeuMoDx™ Wash Reagent
 - NeuMoDx™ Release Reagent
- } **Bulk Reagents**
- NeuMoDx™ Tip Tray (reusable)
 - CO-RE Tips 1000 µL with Filters (1000 µL tips)
 - CO-RE Tips 300 µL with Filters (300 µL tips)
 - NeuMoDx™ Cartridge
- } **Consumables**
- NeuMoDx™ Priming Waste Bottle (reusable)
 - Biohazardous Waste Containers
 - NeuMoDx™ Biohazardous Waste Bag
- } **Waste Containers**

Reagents & Consumables

For your information: NeuMoDx™ Reagents & Consumables

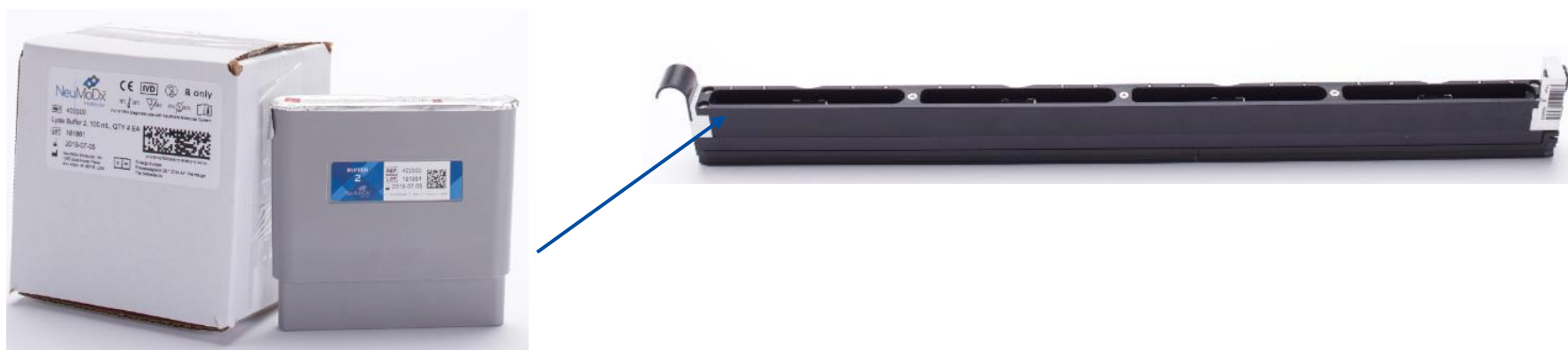
Item	Tests per Item	# Items per Box
NeuMoDx™ Test Strip	16 per test strip	6 strips per box
NeuMoDx™ Lysis Buffer	80mL per Container	4 Containers per box
NeuMoDx™ Extraction Plate	24 per plate	16 plates per box
NeuMoDx™ Cartridge	12 per cartridge	48 cartridges per box
NeuMoDx™ Wash Reagent	2L per bottle	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)

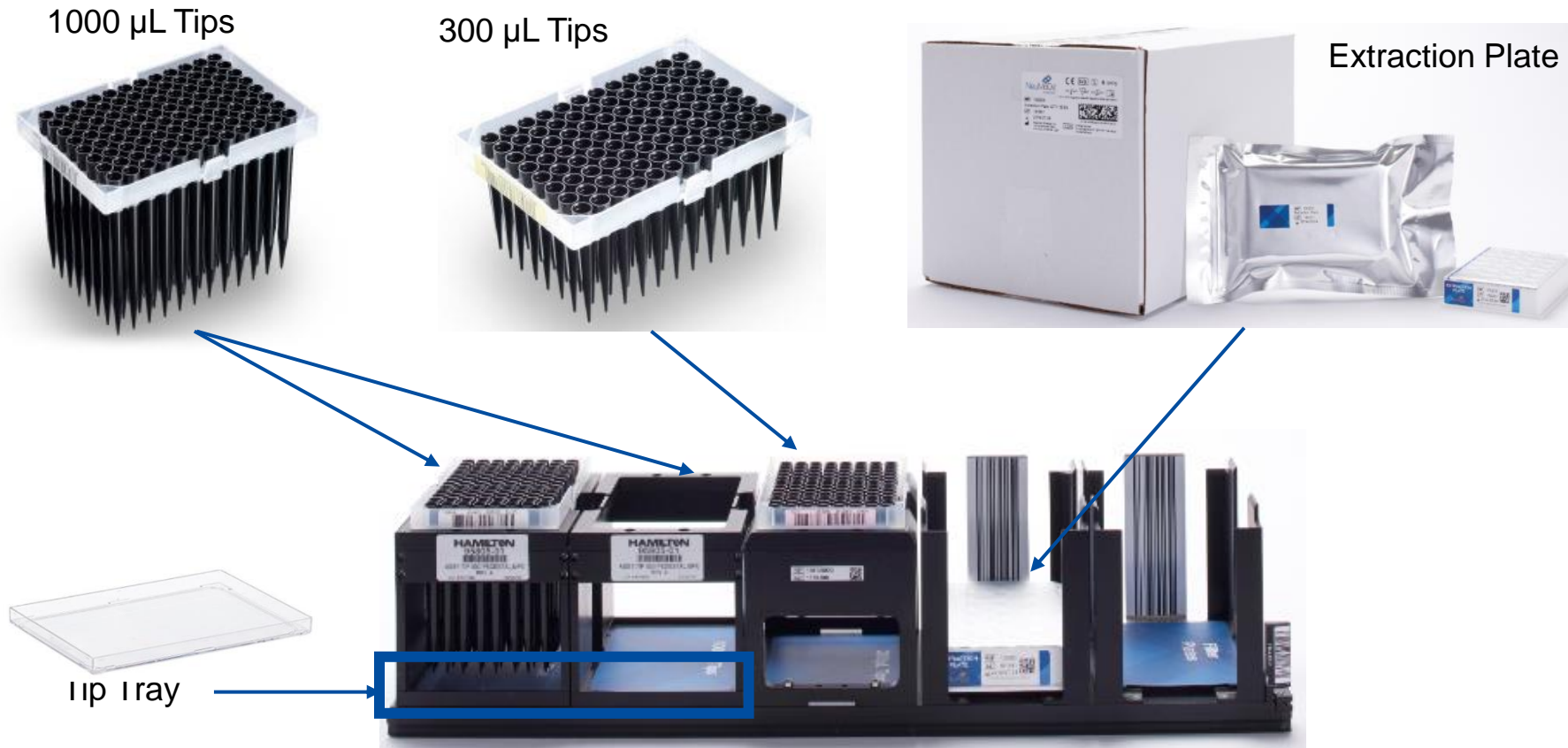


- NeuMoDx Lysis Buffer goes in the Buffer Carrier (up to 4 per carrier)
NOTE: remove the foil before loading into carrier



Reagents & Consumables

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



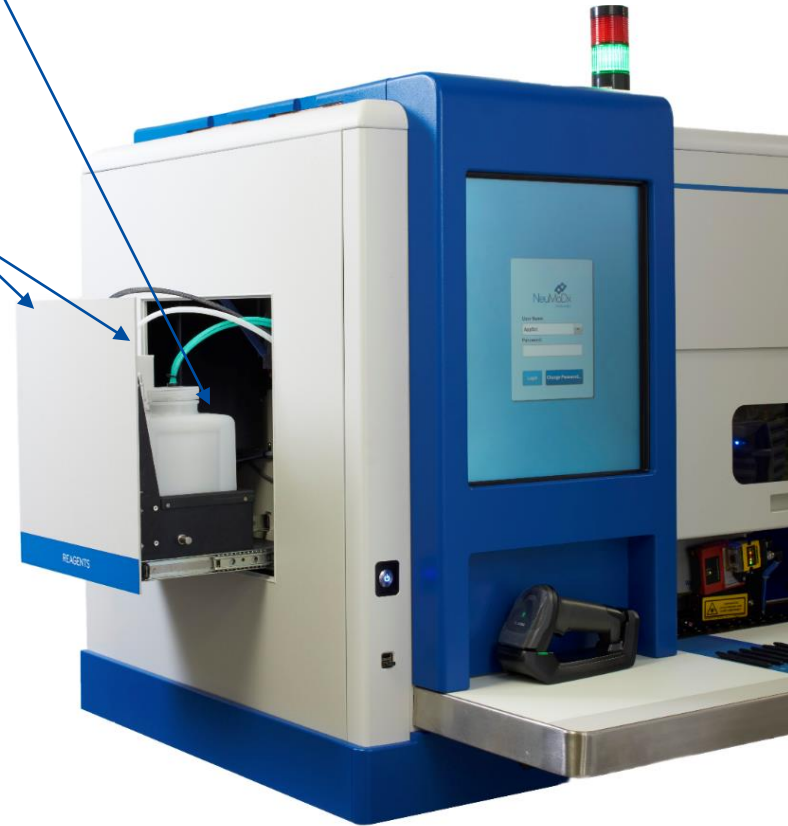
Reagents & Consumables

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

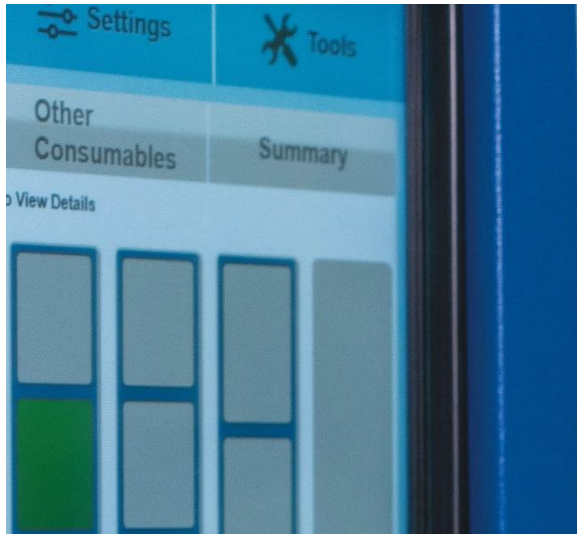


Reagents & Consumables

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



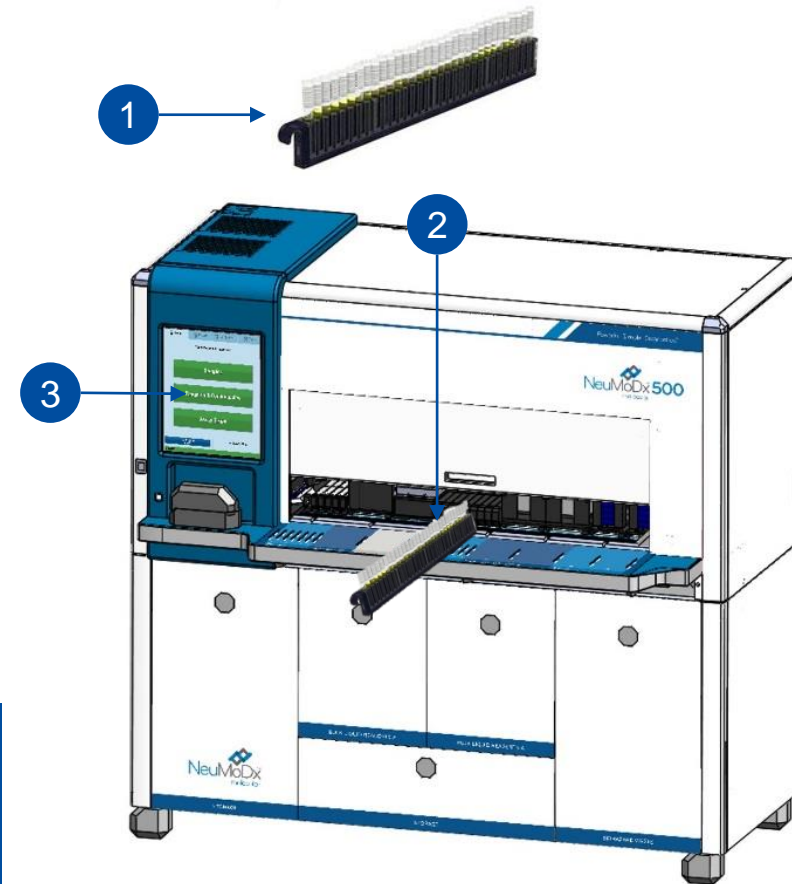
N96



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.*

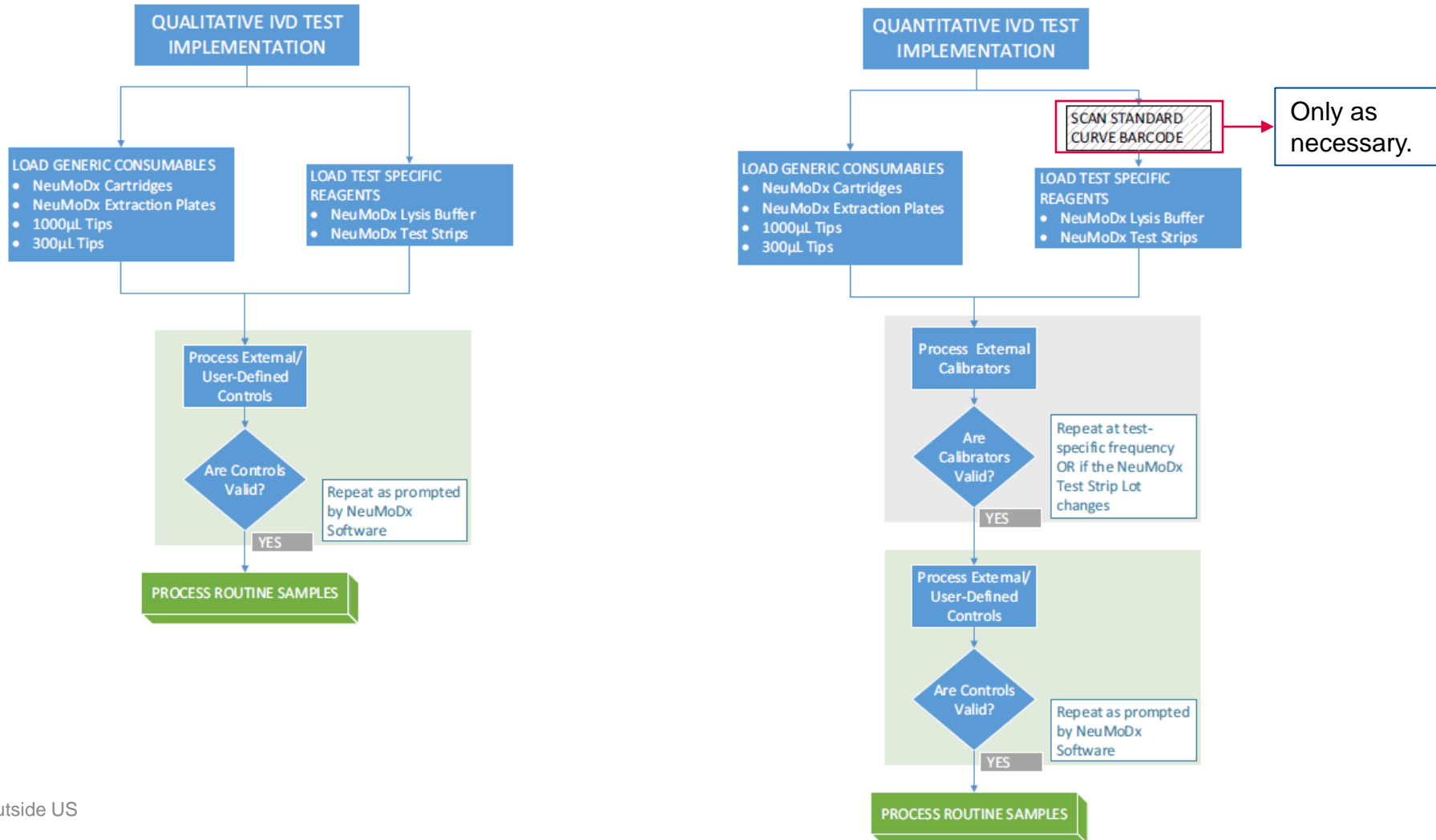


So long as the system has sufficient consumables to complete the testing, the results will be available without further operator interaction.

NOTE: Instrument shown is N288, but overall operation is the same.

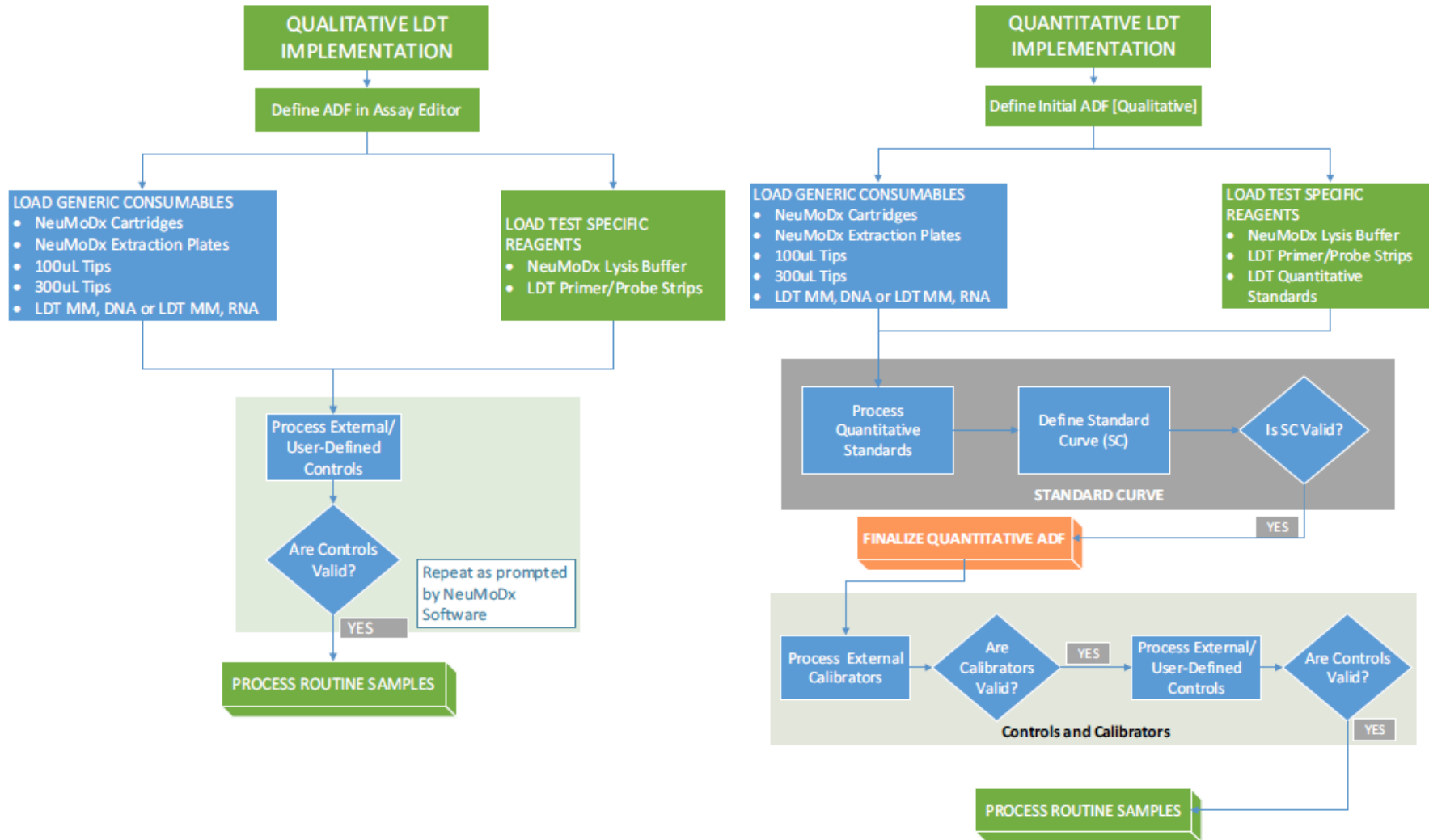
*Specimen tubes can be assigned to specific tests before or during sending in the specimen tube carrier

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

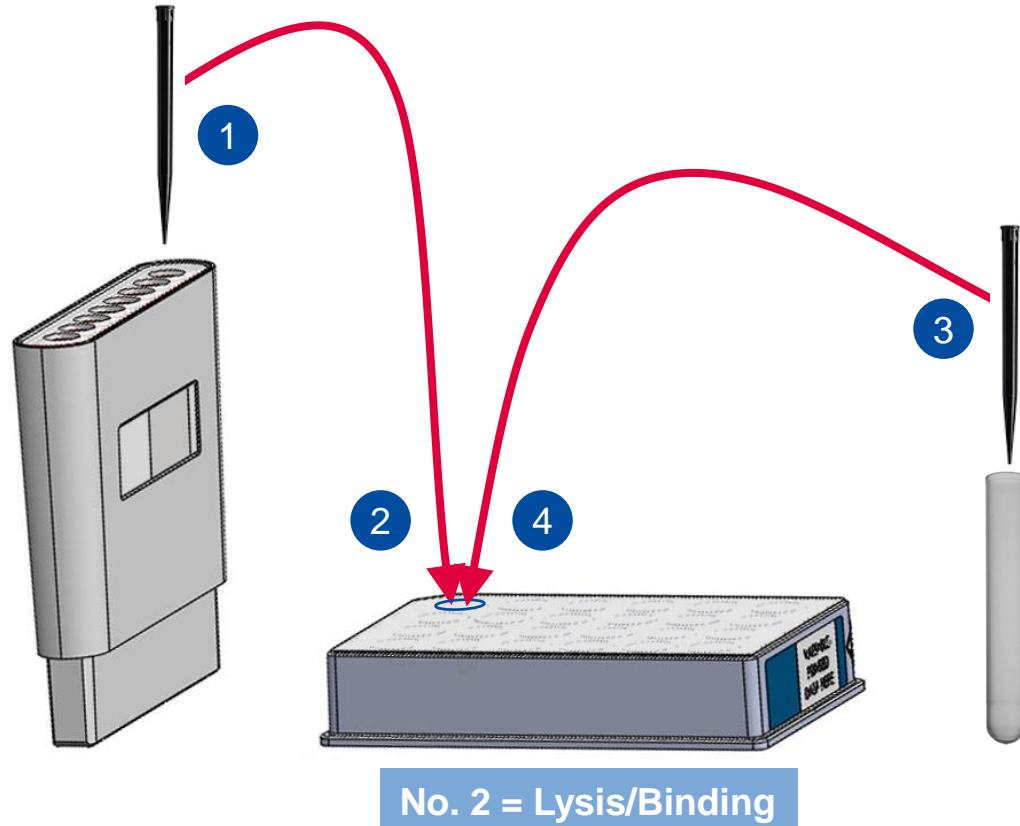
- Two main components of patented technology fuels the sample-to-result system
- (1) NeuDry™ Chemistry
 - Room-temperature stable, dried reagents require no re-hydration by the operator
- (2) Microfluidic Cartridge
 - All extraction and PCR is executed within the Microfluidic Cartridge
 - Not batched, 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

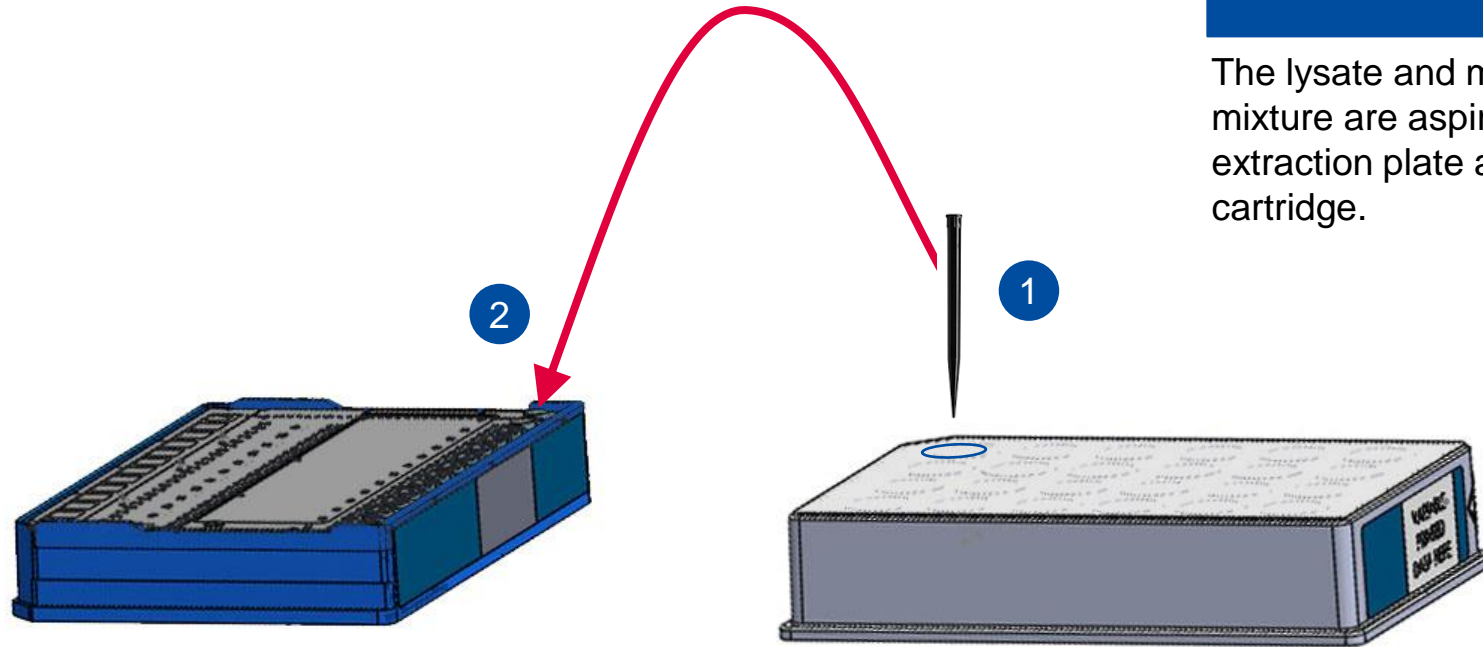


LHPA

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



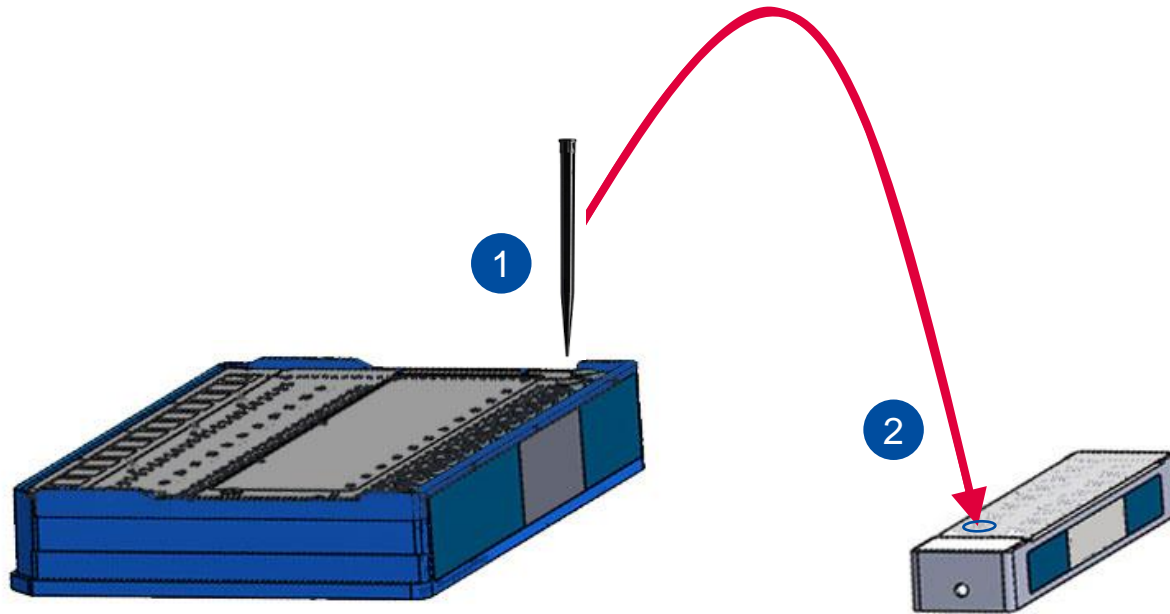
No. 3 = LHPB

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

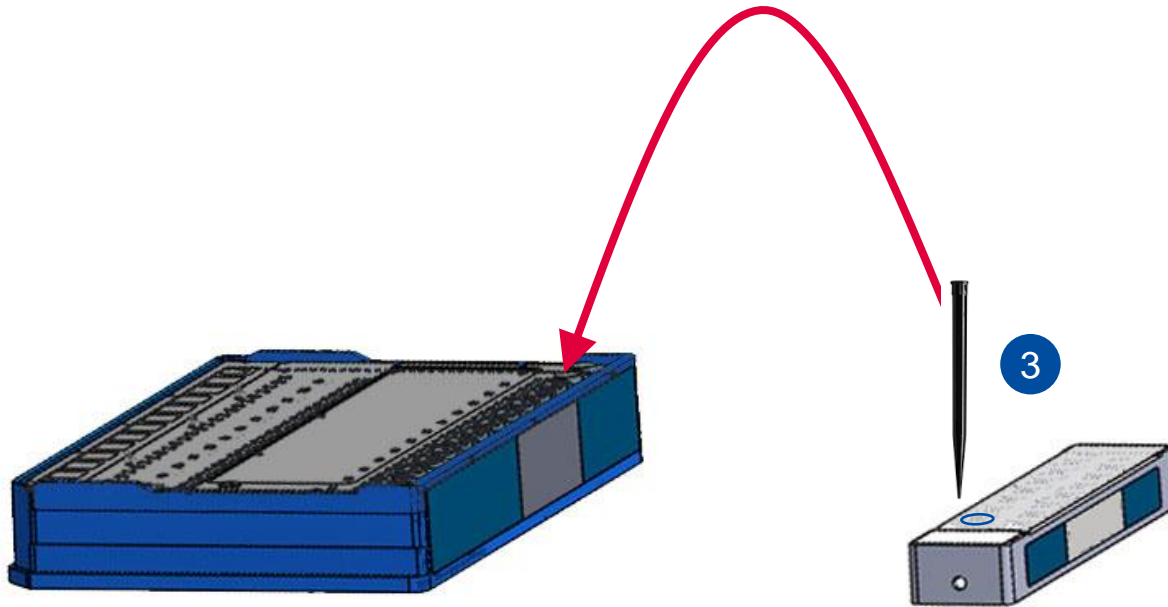
Liquid Classes in blue

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



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.

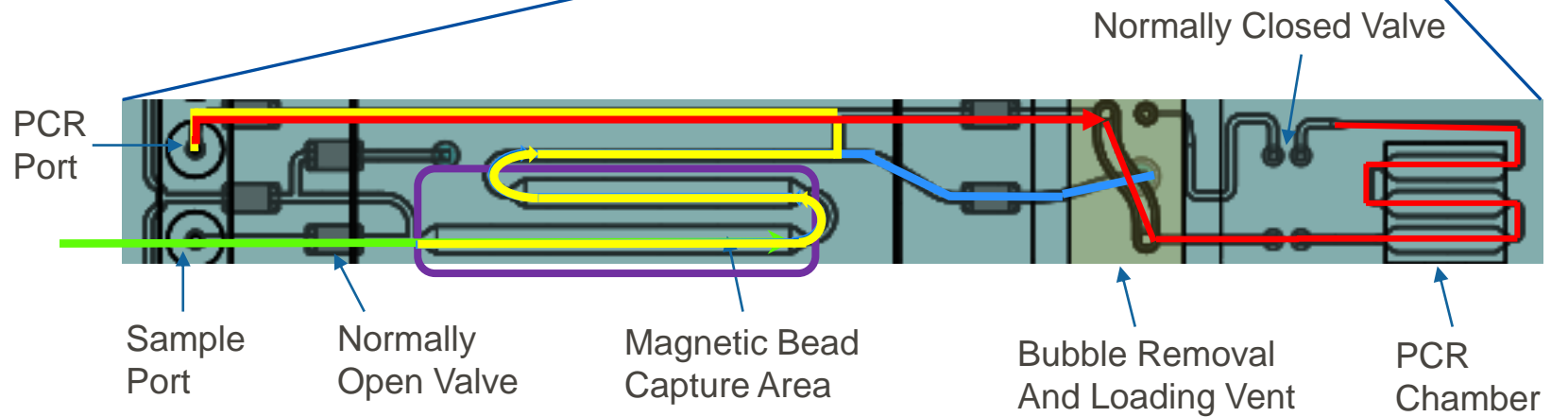
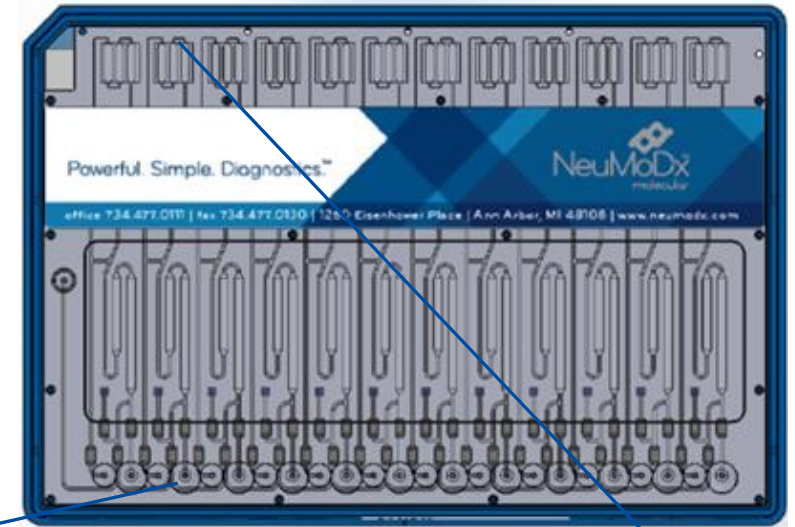
No. 6 = PCR/Real-time PCR

Liquid Classes in blue

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

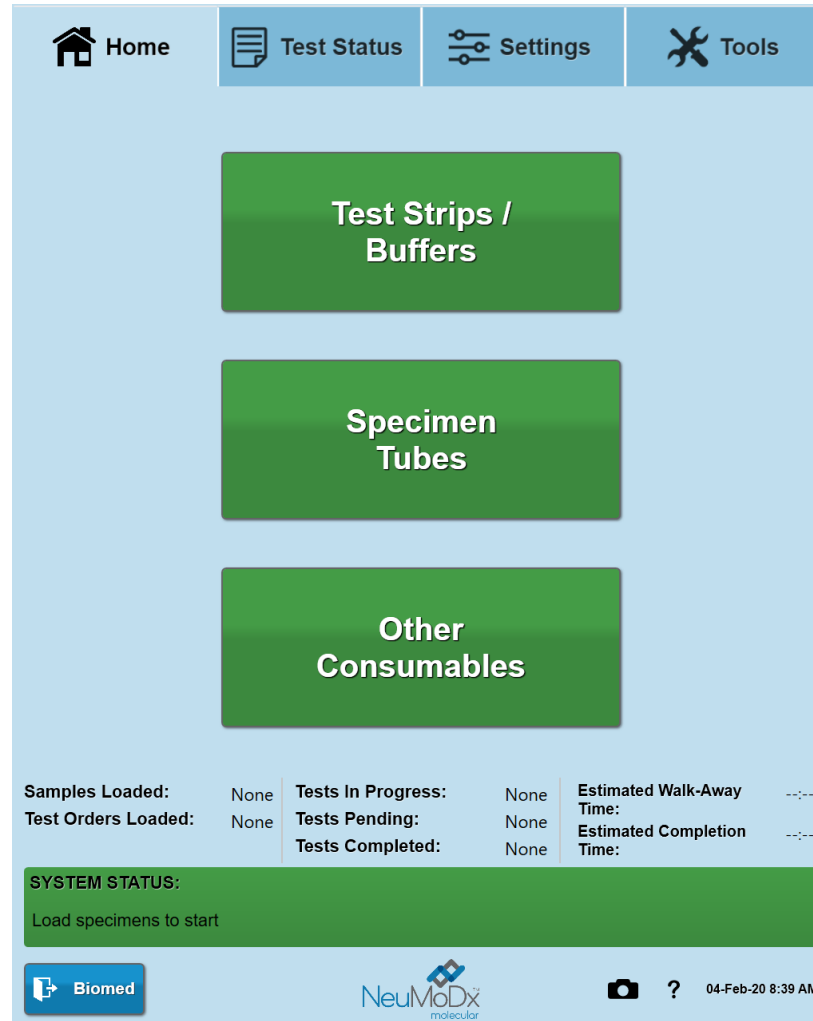
NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

BioMed Level User



Home Test Status Settings Tools

Test Strips / Buffers

Specimen Tubes

Other Consumables

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed NeuMoDx molecular 04-Feb-20 8:39 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

Touch Carrier to View Details

<div style="display: flex; flex-direction: column; align-items: center;"> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; color: white; margin-bottom: 2px;">CTNG</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; color: white; margin-bottom: 2px;">CTNG</div> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; font-weight: bold; margin-top: 5px;"> Test Strips 1 </div>	Not Loaded	Not Loaded	Not Loaded	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #ccc; margin-bottom: 2px;">Test Strip</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; color: white; margin-bottom: 2px;">HCV</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; font-weight: bold; margin-top: 5px;"> Test Strips 5 </div>	Not Loaded	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 4</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 1</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 1</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 2</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; font-weight: bold; margin-top: 5px;"> Buffers 1 </div>	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 3</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 4</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 2</div> <div style="width: 100%; height: 20px; background-color: #4CAF50; margin-bottom: 2px;">Lysis Buffer 4</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; font-weight: bold; margin-top: 5px;"> Buffers 2 </div>
↓	↑	↑	↑	↓	↑	↓	↓

Samples Loaded:	None	Tests In Progress:	2
Test Orders Loaded:	None	Tests Pending:	None
		Tests Completed:	None

SYSTEM STATUS:
Weekly Maintenance is required

Biomed
03/19/2020 2:26 PM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

Test Strips 1 Carrier Details

	Available	Serial #	Lot #	Expiration Date	Open-Life
Test Strip					
Test Strip					
CTNG	9	00059	103152	03/30/2021	13 Day(s)
CTNG	0	00475	191901	07/09/2020	
Test Strip					

Carrier ID: SR160465

↓
OK

Load Time: 07/07/2020 12:11 PM

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:
 Weekly Maintenance is required

Biomed

📷
?
07/07/2020 3:12 PM

NeuMoDx 96 Software Screen

BioMed Level User

The screenshot displays the software interface for a BioMed Level User. At the top, there is a navigation bar with icons for Home, Test Status, Settings, and Tools. Below this is a secondary menu with 'Test Strips / Buffers', 'Specimen Tubes', 'Other Consumables', and 'Summary'. The 'Specimen Tubes' section is active, showing three vertical bars representing tubes 1, 2, and 3. Tube 1 is blue and labeled 'Specimen(s) Loaded' with a '1' at the bottom and a downward arrow. Tubes 2 and 3 are grey and labeled 'Not Loaded' with '2' and '3' at the bottom and upward arrows. A status bar at the bottom provides system metrics: Samples Loaded: 24, Test Orders Loaded: 24, Tests In Progress: None, Tests Pending: 24, Tests Completed: None, Estimated Walk-Away Time: --:--, and Estimated Completion Time: 10:30 AM. A green 'SYSTEM STATUS' bar indicates 'Samples are processing'. The footer includes a 'Biomed' button, the 'NeuMoDx molecular' logo, a warning icon, a camera icon, a help icon, and the date/time '06-Feb-20 9:11 AM'.

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

Touch Carrier to View Details

Reagents

Filter Plate

Extraction Plate

300uL Tips

1000uL Tips

1000uL Tips

Tips Extraction Filter Plates 1

Cartridge

Cartridge

Cartridge

Cartridges 1

Biohazard Tip Waste Bin

Module Consumables

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed
⚠️ 📷 ? 19-Mar-20 3:03 PM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers

Specimen Tubes

Other Consumables

Summary

Est. Tests Remaining	Serial #	Lot #	Expiration Date	Open-Life	
Drawer A					
1457	N/A	N/A	N/A	N/A	
747	00009	105024	06/25/2021	28 Day(s)	<div style="display: flex; justify-content: space-between;"> <div>Replace Prime</div> <div>Bottle Set Primes</div> </div>
172	00018	101719	01/16/2022	53 Day(s)	<div style="display: flex; justify-content: space-between;"> <div>Replace Prime</div> <div>Full Prime</div> </div>
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;"> <p>Priming Waste</p> <p>Release</p> <p>Wash</p> <p>Reagents</p> <p>↓</p> </div> <div style="text-align: center;"> <p>OK</p> </div> </div>					

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:

Weekly Maintenance is required

Biomed
07/07/2020 3:13 PM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers	Specimen Tubes	Other Consumables	Summary
		Remaining Tests	Last Emptied
 Biohazard Waste Bin	Extraction Plates	24	07/06/2020 12:27 PM
 Biohazard Waste Bin	Cartridges	120	
 Biohazard Tip Waste Bin	Tips	206	07/02/2020 5:29 PM
<div style="border: 1px solid #ccc; display: inline-block; padding: 5px 15px; background-color: #007bff; color: white; border-radius: 5px;">OK</div>			

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
 Weekly Maintenance is required

Biomed
07/07/2020 3:13 PM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

	#	Available	Serial #	Lot #	Expiration Date	Open-Life	Load Time
Cartridges in XPCR Modules	1	4	00335	102303	18-Feb-22	N/A	19-Mar-20 8:01 AM
	2	12	00342	102303	18-Feb-22	N/A	19-Mar-20 3:23 PM
Extraction Plates in Modules	1	24	00115	102460	16-Mar-22	27 Day(s)	19-Mar-20 3:22 PM
	2	16	00142	102272	25-Feb-22	27 Day(s)	19-Mar-20 8:02 AM

OK

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:
Load specimens to start

Biomed

⚠️ 📷 ?
19-Mar-20 3:27 PM

NeuMoDx 96 Software Screen

BioMed Level User

Inventory Summary (Units of Tests)

Test Strips	Needed	Remaining	Consumables	Needed	Remaining
Test - Sentinel BKV	0	0	Extraction Plates	0	0
BKV	0	0	Tips 300uL	0	73
CMV	0	0	Tips 1000uL	0	143
CT NG	0	0	Cartridges	0	0
CTNG	0	9	Filters	0	0
EBV	0	0	Liquid Reagents		
FLU A-B-RSV	0	0	Wash	172	
GBS	0	0	Release	747	
HBV	0	0	Priming Waste	1457	
.....			Waste		
			Tips	0	206
			Extraction Plates	0	24
			Cartridges	0	120

Buffers	Needed	Remaining
Lysis Buffer 1	0	0
Lysis Buffer 2	0	49
Lysis Buffer 3	0	0
Lysis Buffer 4	0	0

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
Weekly Maintenance is required

Biomed | NeuMoDx molecular | 07/07/2020 3:13 PM

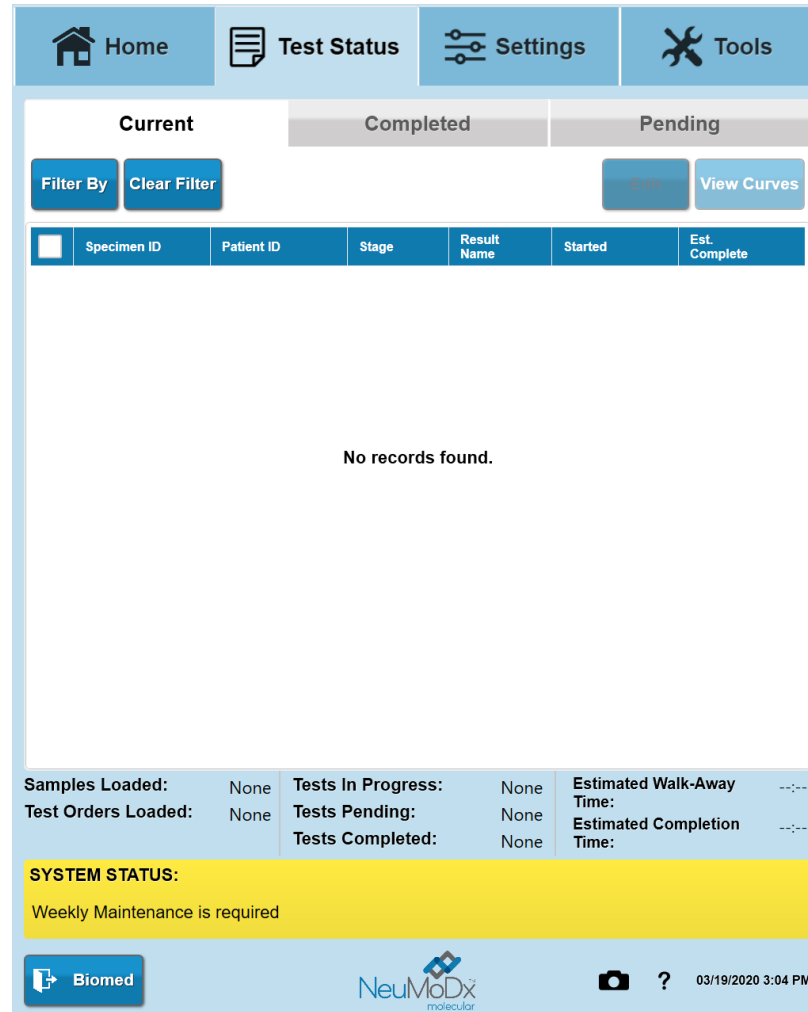
one 300 μ L tips/test but

2 tips/test; ~71 tests

Lysis Buffers are in mL

NeuMoDx 96 Software Screen

BioMed Level User



The screenshot displays the 'Test Status' interface for a BioMed Level User. The top navigation bar includes 'Home', 'Test Status', 'Settings', and 'Tools'. Below this, there are tabs for 'Current', 'Completed', and 'Pending', with 'Current' selected. Filter options include 'Filter By', 'Clear Filter', 'Print', and 'View Curves'. A table with columns for 'Specimen ID', 'Patient ID', 'Stage', 'Result Name', 'Started', and 'Est. Complete' is shown, but it contains no data, displaying 'No records found.' Below the table, a summary section shows 'Samples Loaded: None', 'Test Orders Loaded: None', 'Tests In Progress: None', 'Tests Pending: None', and 'Tests Completed: None'. It also displays 'Estimated Walk-Away Time: ---:--' and 'Estimated Completion Time: ---:--'. A yellow banner indicates 'SYSTEM STATUS: Weekly Maintenance is required'. The footer includes a 'Biomed' button, the 'NeuMoDx molecular' logo, a camera icon, a help icon, and the date/time '03/19/2020 3:04 PM'.

NeuMoDx 96 Software Screen

BioMed Level User

Home | Test Status | Settings | Tools

Current
Completed
Pending

Filter
Report
Import
Export
View Curves

Filter By
Clear Filter

Selected: 0 of 19

<input type="checkbox"/>	Specimen ID	Patient ID	Sample Type	Result Name	Started
<input type="checkbox"/>	N130001084		Patient	GBS	01/29/2020 5:48 PM
<input type="checkbox"/>	N130001062		Patient	GBS	01/29/2020 4:48 PM
<input type="checkbox"/>	N130001041		Patient	GBS	01/29/2020 4:04 PM
<input type="checkbox"/>	N130001033		Patient	GBS	01/29/2020 3:49 PM
<input type="checkbox"/>	N130001032		Patient	GBS	01/29/2020 3:49 PM
<input type="checkbox"/>	N130001031		Patient	GBS	01/29/2020 3:49 PM
<input type="checkbox"/>	N130001030		Patient	GBS	01/29/2020 3:49 PM
<input type="checkbox"/>	N130001029		Patient	GBS	01/29/2020 3:49 PM
<input type="checkbox"/>	N130001028		Patient	GBS	01/29/2020 3:49 PM

Samples Loaded: 96

Test Orders Loaded: 96

Tests In Progress: 24

Tests Pending: None

Tests Completed: 72

Estimated Walk-Away Time: ---:--

Estimated Completion Time: 8:25 PM

SYSTEM STATUS:
Weekly Maintenance is required

Application
||
■
01/29/2020 8:00 PM

NeuMoDx 96 Software Screen

BioMed Level User

Filter By

Select Date Range:
Date Range Type: **Custom**

Start Filter Date: **01/29/2020** End Filter Date: **01/29/2020**
Start Filter Time: **12:00 AM** End Filter Time: **11:59 PM**

Specimen ID: Enter Specimen ID Operator: Select Operator

Patient ID: Enter Patient ID Test Strip Lot Number: Enter Test Strip Lot

Assay Name: Select Assay Name XPCR Module Serial Number: Enter Serial Number

Result Name: Select Result Name XPCR Lane: Enter XPCR Lane

Sample Type: Select Sample Type Extraction Plate Module Serial Number: Enter Serial Number

Result: Select Result Heater Well: Enter Heater Well

Standard Curve Name: Select Standard Curve Name

Extraction Only

OK Cancel

01/29/2020 1:12 PM

NeuMoDx 96 Software Screen

BioMed Level User

The screenshot displays the 'Test Status' section of the NeuMoDx 96 software. The 'Pending' tab is active, showing a table with columns for Specimen ID, Result Name, Patient ID, Created, Specimen, and Tube Type. The table is currently empty, displaying 'No records found.'. Above the table are buttons for 'Filter By', 'Clear Filter', 'Import', 'Download', 'Create', and 'Delete'. Callouts on the right side of the screen point to these buttons:

- Create individual test order**: Points to the 'Create' button.
- Download from:**
 - LIS
- Import excel from:**
 - USB
 - Network

At the bottom of the screen, there is a summary section with the following data:

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

Below this is a yellow 'SYSTEM STATUS' banner that reads: 'Weekly Maintenance is required'. The footer includes a 'Biomed' button, the 'NeuMoDx molecular' logo, a camera icon, a help icon, and the date/time '03/19/2020 3:04 PM'.

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:
 Device Info... Upgrades...

Instrument Name:

Lab Name:

Lab Address:

Volume Level

Volume (%): 50

Virtual Keyboard

Samples Loaded:	1	Tests In Progress:	1	Estimated Walk-Away Time:	----
Test Orders Loaded:	1	Tests Pending:	None	Estimated Completion Time:	12:04 PM
		Tests Completed:	None		

Home | Test Status | Settings | Tools

General | Report | Network | Assay | Controls | Users | LIS

Site
Localization
Workflow

Apply Cancel

Localization

Language:

Date Format:

Time Format:

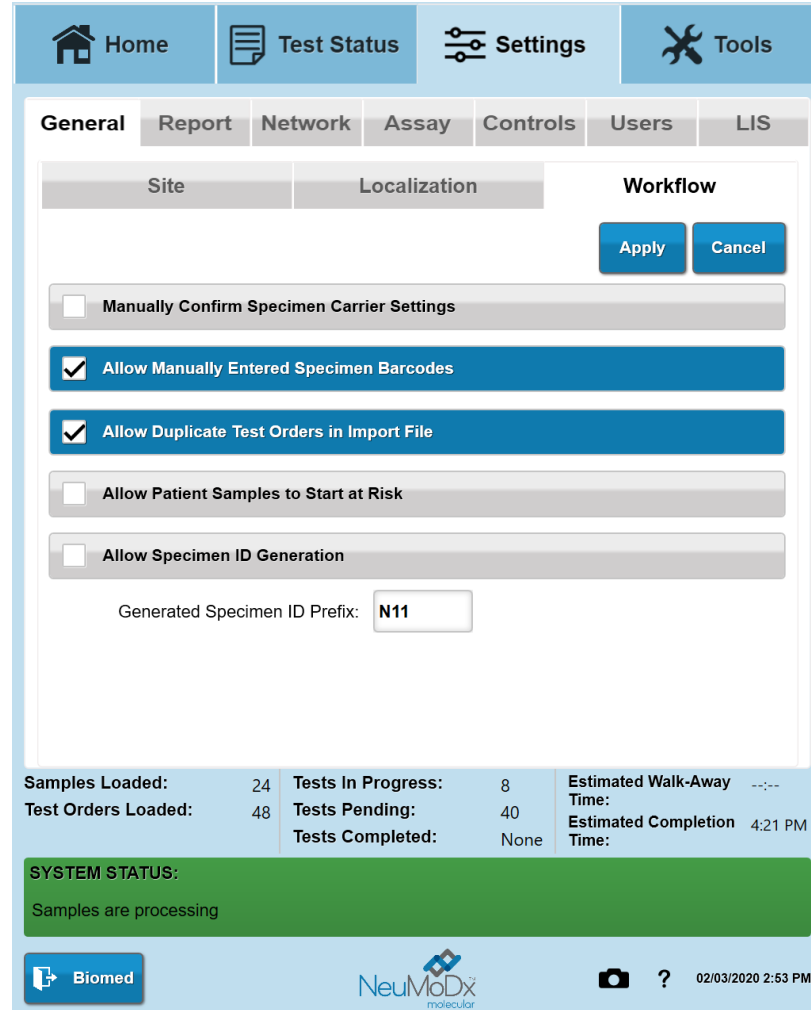
Market:

Set Date/Time

Samples Loaded:	24	Tests In Progress:	8	Estimated Walk-Away Time:	----
Test Orders Loaded:	48	Tests Pending:	40	Estimated Completion Time:	4:21 PM
		Tests Completed:	None		

NeuMoDx 96 Software Screen

BioMed Level User



Home Test Status Settings Tools

General Report Network Assay Controls Users LIS

Site Localization Workflow

Apply Cancel

Manually Confirm Specimen Carrier Settings

Allow Manually Entered Specimen Barcodes

Allow Duplicate Test Orders in Import File

Allow Patient Samples to Start at Risk

Allow Specimen ID Generation

Generated Specimen ID Prefix:

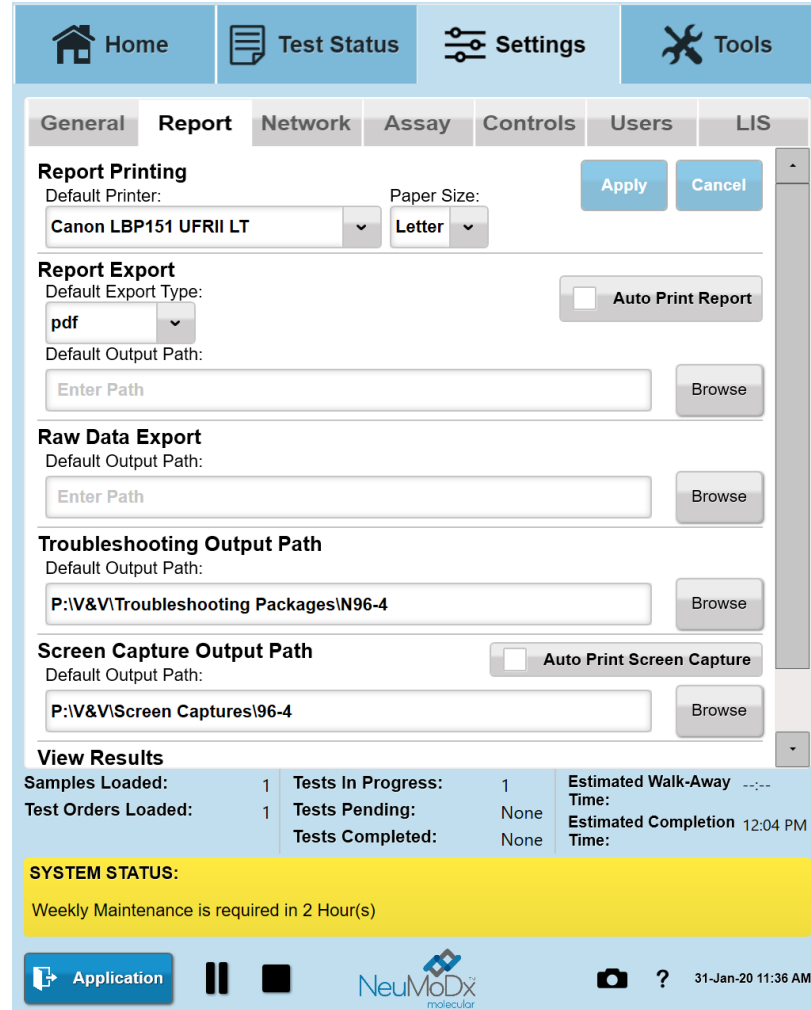
Samples Loaded:	24	Tests In Progress:	8	Estimated Walk-Away Time:	---
Test Orders Loaded:	48	Tests Pending:	40	Estimated Completion Time:	4:21 PM
		Tests Completed:	None		

SYSTEM STATUS:
Samples are processing

Biomed NeuMoDx molecular 02/03/2020 2:53 PM

NeuMoDx 96 Software Screen

BioMed Level User



The screenshot shows the 'Settings' menu with the 'Report' tab selected. The interface includes a top navigation bar with 'Home', 'Test Status', 'Settings', and 'Tools'. Below this is a sub-menu with 'General', 'Report', 'Network', 'Assay', 'Controls', 'Users', and 'LIS'. The 'Report' section contains several configuration options:

- Report Printing:** Default Printer: Canon LBP151 UFR II LT; Paper Size: Letter. Includes 'Apply' and 'Cancel' buttons.
- Report Export:** Default Export Type: pdf; Default Output Path: Enter Path. Includes an 'Auto Print Report' checkbox and a 'Browse' button.
- Raw Data Export:** Default Output Path: Enter Path. Includes a 'Browse' button.
- Troubleshooting Output Path:** Default Output Path: P:\V&V\Troubleshooting Packages\N96-4. Includes a 'Browse' button.
- Screen Capture Output Path:** Default Output Path: P:\V&V\Screen Captures\96-4. Includes an 'Auto Print Screen Capture' checkbox and a 'Browse' button.

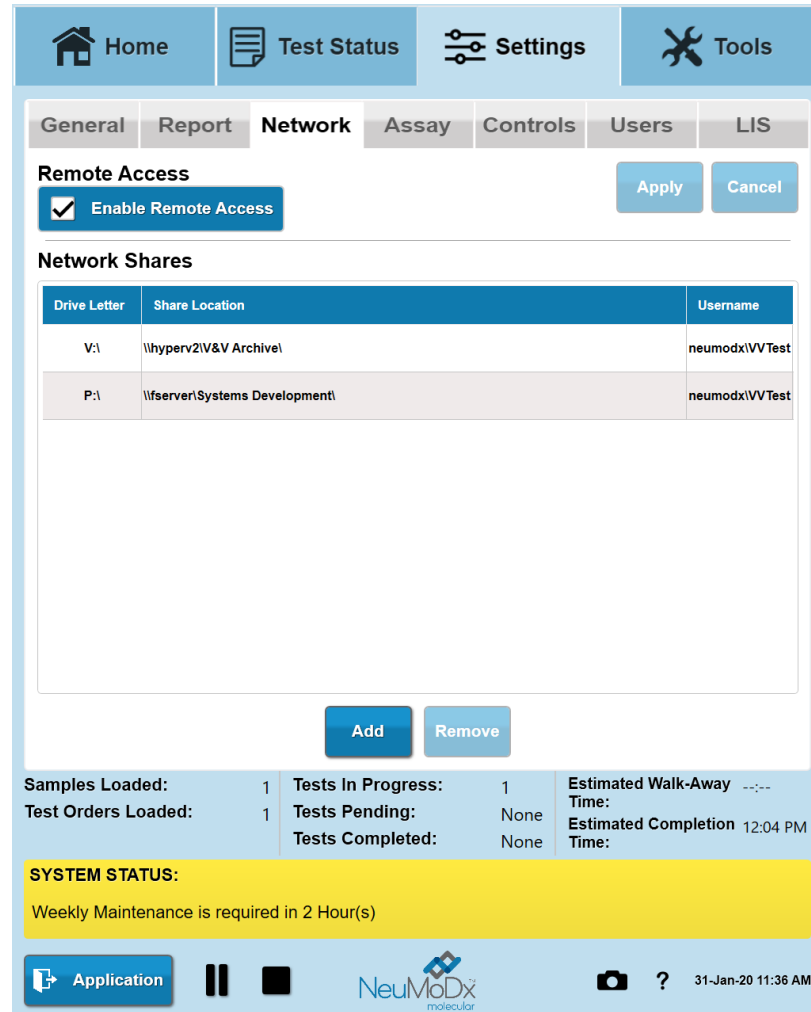
At the bottom, there is a 'View Results' section with a summary table:

Samples Loaded:	1	Tests In Progress:	1	Estimated Walk-Away Time:	---
Test Orders Loaded:	1	Tests Pending:	None	Estimated Completion Time:	12:04 PM
		Tests Completed:	None		

Below the table is a yellow 'SYSTEM STATUS' banner: 'Weekly Maintenance is required in 2 Hour(s)'. The bottom status bar shows 'Application', system icons, the 'NeuMoDx molecular' logo, a camera icon, a help icon, and the date/time '31-Jan-20 11:36 AM'.

NeuMoDx 96 Software Screen

BioMed Level User



The screenshot displays the NeuMoDx 96 software interface. At the top, there is a navigation bar with icons for Home, Test Status, Settings, and Tools. Below this is a sub-menu with tabs for General, Report, Network, Assay, Controls, Users, and LIS. The 'Network' tab is currently selected.

Under the 'Network' tab, there is a 'Remote Access' section with a checked checkbox for 'Enable Remote Access' and 'Apply' and 'Cancel' buttons. Below this is a 'Network Shares' section containing a table with two entries:

Drive Letter	Share Location	Username
V:\	\\hyperv2\IV&V Archive\	neumodx\IVTest
P:\	\\server1\System\Development\	neumodx\IVTest

Below the table are 'Add' and 'Remove' buttons. At the bottom of the interface, there is a status bar showing:

- 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

A yellow banner at the bottom indicates 'SYSTEM STATUS: Weekly Maintenance is required in 2 Hour(s)'. The bottom-most bar includes an 'Application' button, system icons, the NeuMoDx molecular logo, a camera icon, a help icon, and the date/time '31-Jan-20 11:36 AM'.

NeuMoDx 96 Software Screen

BioMed Level User

The screenshot displays the NeuMoDx 96 Software interface for a BioMed Level User. The top navigation bar includes Home, Test Status, Settings, and Tools. The Assay settings page is active, showing tabs for General, Report, Network, Assay, Controls, Users, and LIS. Under the Assay tab, there are buttons for Reflex Settings, Standard Curves, and Import... Below these are filters for Active Only, Current, and Archived. A table lists various assays with their versions, default status, enabled features, and an edit button.

Name	Version	Default	Enabled Features	Settings
CMV	4.1.1	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
CTNG	9.0.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
EBV	4.0.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
GBS	4.1.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
HBV	4.1.1	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
HPV16/18/31	4.0.1	<input type="checkbox"/>	Include Graphs, Include Ct	Edit

Summary statistics:

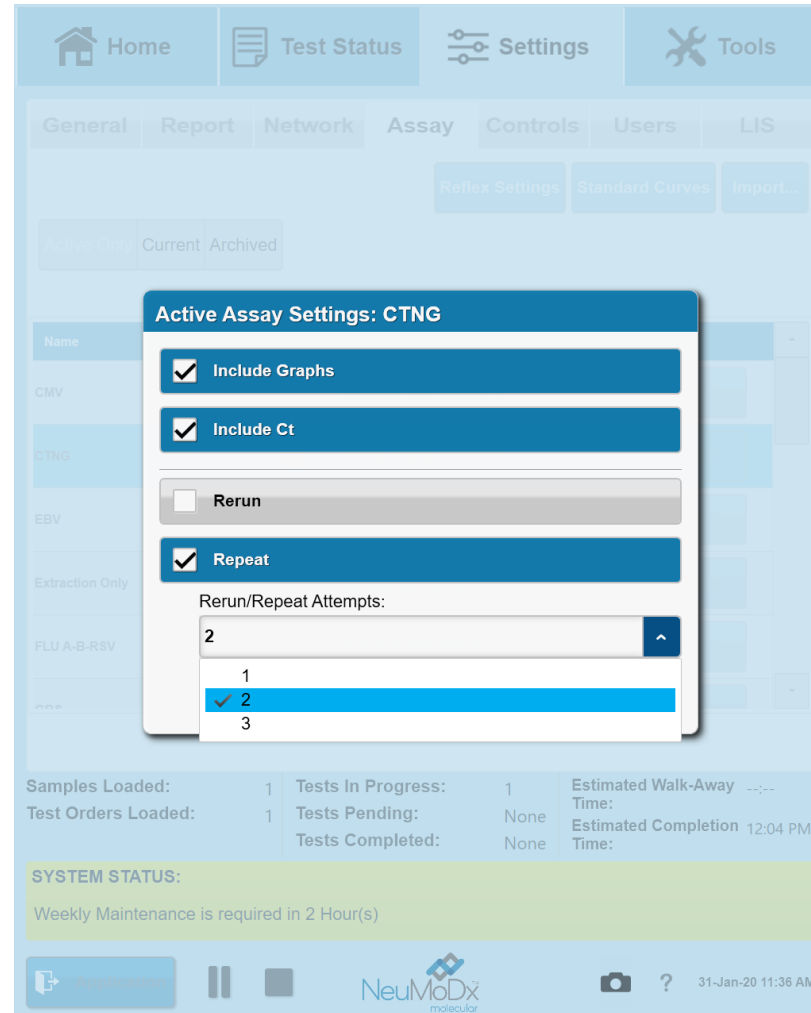
- Samples Loaded: None
- Test Orders Loaded: None
- Tests In Progress: None
- Tests Pending: None
- Tests Completed: None
- Estimated Walk-Away Time: ---:--
- Estimated Completion Time: ---:--

SYSTEM STATUS: Load specimens to start

Application | NeuMoDx molecular | 03-Feb-20 2:55 PM

NeuMoDx 96 Software Screen

BioMed Level User



The screenshot displays the NeuMoDx 96 Software interface. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these are sub-tabs: General, Report, Network, Assay, Controls, Users, and LIS. A secondary row of buttons includes Reflex Settings, Standard Curves, and Import... Below this is a filter section with 'Active Only', 'Current', and 'Archived' options. A table lists assay types: Name, CMV, CTNG, EBV, Extraction Only, and FLU A-B-RSV. A dialog box titled 'Active Assay Settings: CTNG' is open, showing settings for 'Include Graphs' (checked), 'Include Ct' (checked), 'Rerun' (unchecked), and 'Repeat' (checked). A dropdown menu for 'Rerun/Repeat Attempts' is open, showing options 1, 2 (selected), and 3. At the bottom, a status summary shows: Samples Loaded: 1, Test Orders Loaded: 1, Tests In Progress: 1, Tests Pending: None, Tests Completed: None, Estimated Walk-Away Time: ---, and Estimated Completion Time: 12:04 PM. A green banner indicates 'SYSTEM STATUS: Weekly Maintenance is required in 2 Hour(s)'. The bottom bar contains a 'Report' button, a pause icon, a stop icon, the NeuMoDx molecular logo, a camera icon, a help icon, and the date/time: 31-Jan-20 11:36 AM.

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

General
Report
Network
Assay
Controls
Users
LIS

Import Mappings
QC Report

Select Assay: SARS COV-2

User-Defined Controls Settings

Apply
Cancel

Require Lot Frequency

Require Run Frequency Days:

Qualitative Controls

User-Defined Controls
External Controls

View By Lot
 Show Active Only

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	COVPC, COVPC-TM	Transport Medium, User-Specified 1	--	Needs Controls	<input checked="" type="checkbox"/>
SARS CoV 2 Negative	COVNC, COVNC-TM	Transport Medium, User-Specified 1	--	Needs Controls	<input checked="" type="checkbox"/>

Add
Edit

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

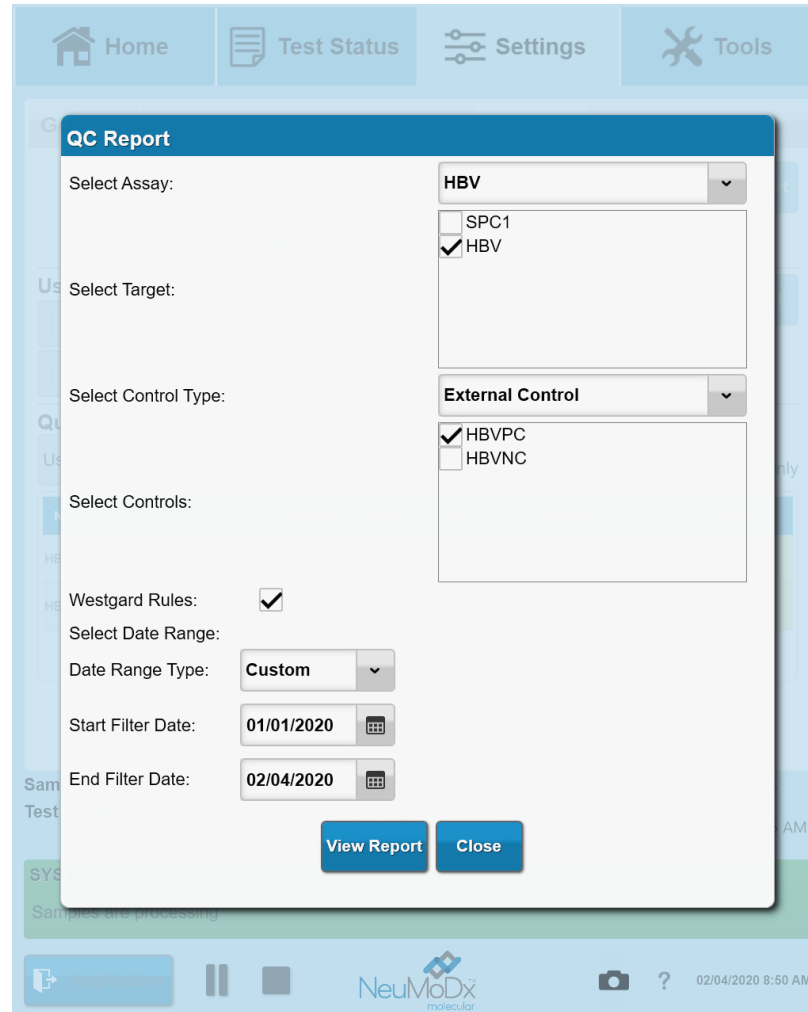
SYSTEM STATUS:
Load specimens to start

Biomed

04-Feb-20 8:42 AM

NeuMoDx 96 Software Screen

BioMed Level User



NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

General
Report
Network
Assay
Controls
Users
LIS

Apply
Cancel

User Related Settings

Password Expiration (Days):
 Password Warning (Days):
 Inactivity Timeout (Minutes):

User Management

All Users
Active Only
Manage My Account

User Name	First Name	Last Name	Role	Active
Application	Application	Scientist	App Scientist	<input checked="" type="checkbox"/>
Biomed	Biomed	User	Biomed	<input checked="" type="checkbox"/>
Operator	Operator	User	Operator	<input checked="" type="checkbox"/>
Service	Service	Technician	Service	<input checked="" type="checkbox"/>
Supervisor	Supervisor	User	Supervisor	<input checked="" type="checkbox"/>

Add
Edit

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

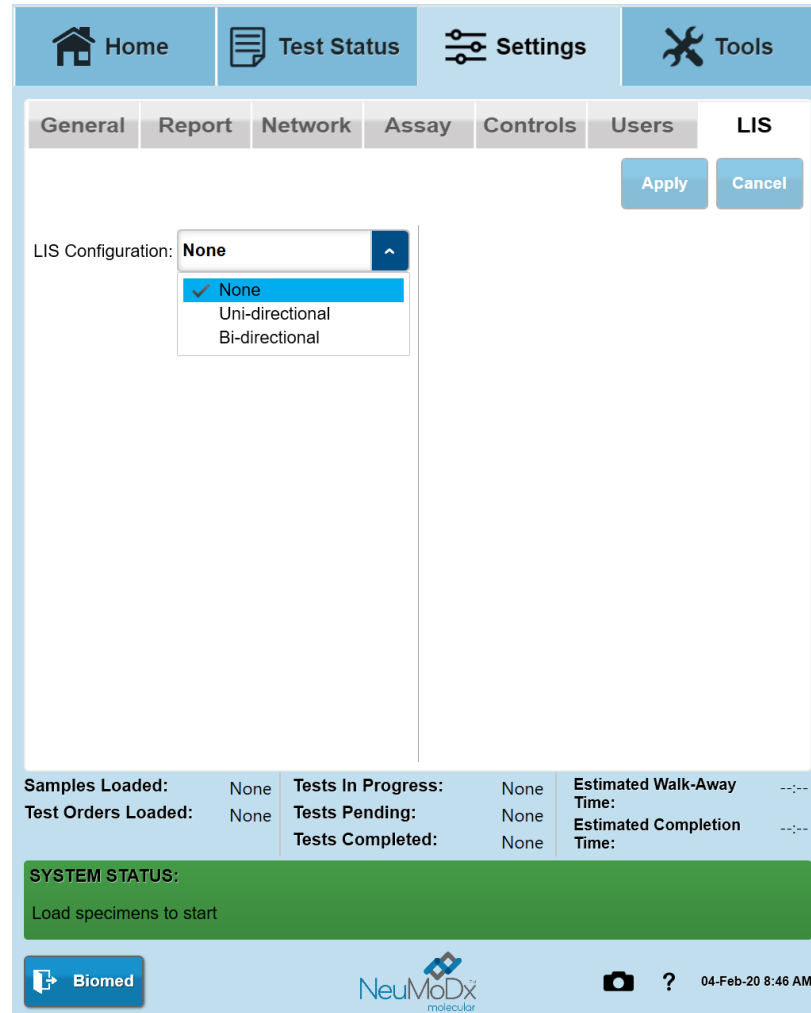
SYSTEM STATUS:

Weekly Maintenance is required in 2 Hour(s)

Application
||
■
31-Jan-20 11:37 AM

NeuMoDx 96 Software Screen

BioMed Level User



Home Test Status Settings Tools

General Report Network Assay Controls Users LIS

Apply Cancel

LIS Configuration: **None**

- None
- Uni-directional
- Bi-directional

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed NeuMoDx molecular 04-Feb-20 8:46 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

System Events
Maintenance
Database
Support
Assay

Filter By
Clear Filter
View Report

Date/Time	Code	Type	Severity	User	Description
03-Feb-20 10:14 AM	4095	Alert	Information	System	Anti-Virus Message Received Message: An animalware scan was completed Severity: Informational
03-Feb-20 10:09 AM	4062	Alert	Warning	System	The following HBV external controls have expired: HBVPC:Plasma, HBVNC:Plasma.
03-Feb-20 10:09 AM	4062	Alert	Warning	System	The following CMV external controls have expired: CMV Positive Control:Plasma, CMV Negative Control:Plasma.
03-Feb-20 10:09 AM	4062	Alert	Warning	System	The following HBV QUANT LDT external controls have expired: Pos Control:Plasma, Neg Control:Plasma.
03-Feb-20 10:09 AM	4095	Alert	Information	System	Anti-Virus Message Received Message: An animalware scan was started Severity: Informational
03-Feb-20 10:09 AM	4020	Alert	Warning	System	The instrument was not able to connect to backup UPS power.
03-Feb-20 10:09 AM	4002	Alert	Information	System	The configured Automatic Database Backup Directory is not accessible.
03-Feb-20 10:09 AM	4002	Alert	Information	System	The configured Troubleshooting Export Path is not accessible.
03-Feb-20 10:09 AM	4002	Alert	Information	System	The configured Screen Capture Output Path is not accessible.
03-Feb-20 9:33 AM	4062	Alert	Warning	System	The following HBV external controls have expired: HBVPC:Plasma, HBVNC:Plasma.

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:

Load specimens to start

Biomed
04-Feb-20 8:39 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home **Test Status** **Settings** **Tools**

System Events **Maintenance** **Database** **Support** **Assay**

General **XPCR Modules** **Extraction Plate Modules**

Instrument Serial #: 96000004 Hamilton Serial #: C629

Daily Upkeep Time: 12:00 AM

Weekly Maintenance **Weekly Maintenance**

Required for Sample Processing
Last Performed: 31-Jan-20 2:30 PM

Access Service Door **Access Service Door**

Instrument Maintenance **Instrument Maintenance**

Last Performed: 04-Feb-20 12:02 AM

Preventative Maintenance **Log Maintenance**

Last Performed: 13-Jan-20 3:39 PM
Next Due: 31-Jul-20 3:39 PM

Prepare System For Long Term Storage **Long Term Storage**

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed 04-Feb-20 8:40 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

System Events
Maintenance
Database
Support
Assay

General
XPCR Modules
Extraction Plate Modules

#	Serial #	PCR FW Version	Actuator FW Version	Status	Available Lanes	Service
1	V120	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	Service
2	V85	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	Service
3	V92	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	Service
4	V102	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	Service

[Housekeeping](#)
[Update Firmware](#)
[Perform Calibration](#)

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:
Weekly Maintenance is required

Biomed

03/20/2020 9:15 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

System Events
Maintenance
Database
Support
Assay
Test Tool

General
XPCR Modules
Extraction Plate Modules

#	Serial #	Firmware Version	Status	Available Wells	Service
1	C8	App: 0.15.2, Bolo: 1.9.0	Ready	24	Service
2	C8	App: 0.15.2, Bolo: 1.9.0	Ready	24	Service
3	C9	App: 0.15.2, Bolo: 1.9.0	Ready	24	Service
4	C9	App: 0.15.2, Bolo: 1.9.0	Ready	24	Service

[Housekeeping](#)
[Update Firmware](#)

Samples Loaded: 5

Test Orders Loaded: 5

Tests In Progress: 5

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: 9:51 AM

SYSTEM STATUS:
Weekly Maintenance is required

[Application](#)
⏸
⏹📷 ? 01/29/2020 9:11 AM

NeuMoDx 96 Software Screen

BioMed Level User

Home
Test Status
Settings
Tools

System Events
Maintenance
Database
Support
Assay

Automatic Database Backup: Apply Cancel

Frequency: Time of the Day: Day of the Week:

Location: Browse

Database Utilities

Backup Backup

Last Backup Performed On: 03/20/2020 7:58 AM

Purge 03/20/2020 Purge

Last Purge Performed On: 05/07/2019 7:28 AM

Restore

Restore Database File Path: Browse Restore

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

SYSTEM STATUS:

Weekly Maintenance is required

Biomed
03/20/2020 9:24 AM

NeuMoDx 96 Software Screen

BioMed Level User

The screenshot displays the 'Troubleshooting Package' configuration screen in the NeuMoDx 96 software. The interface includes a top navigation bar with 'Home', 'Test Status', 'Settings', and 'Tools'. Below this is a secondary menu with 'System Events', 'Maintenance', 'Database', 'Support', and 'Assay'. The 'Support' menu is active, showing 'Troubleshoot' and 'Reports' options. The 'Troubleshooting Package' section features a 'Create Package' button and configuration options for date ranges and package contents. The date range is set to 'Today' from 03/20/2020 to 03/20/2020. The package options include Application Logs, Database Backup, Instrument Logs, Screen Capture Files, Sample Results Reports (unchecked), System Events Reports, and Raw Data Export (all checked). A status bar at the bottom shows 'Samples Loaded: None', 'Test Orders Loaded: None', 'Tests In Progress: None', 'Tests Pending: None', and 'Tests Completed: None'. A yellow warning banner indicates 'SYSTEM STATUS: Weekly Maintenance is required'. The bottom right corner shows the user 'Supervisor', the NeuMoDx molecular logo, a camera icon, a help icon, and the timestamp '03/20/2020 9:29 AM'.

NeuMoDx 96 Software Screen

BioMed Level User

Home
 Test Status
 Settings
 Tools

System Events
Maintenance
Database
Support
Assay

Assay Editor Wizard

Select "Create New" to create a new Assay from defaults. Select "Create From Template" and an Assay to use as a basis for a new Assay. Press "Next" to continue.

Create New

Create From Template

Summary:

Name	Version	Description
HBV LDT	9.0.0	PRO-6037 - Test Case 1 HBV LDT Qual/Quant
PLASMA DNA QUAL	0.1.1	Qualitative Plasma DNA LDT Template

Active
Current
Archive

Next

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

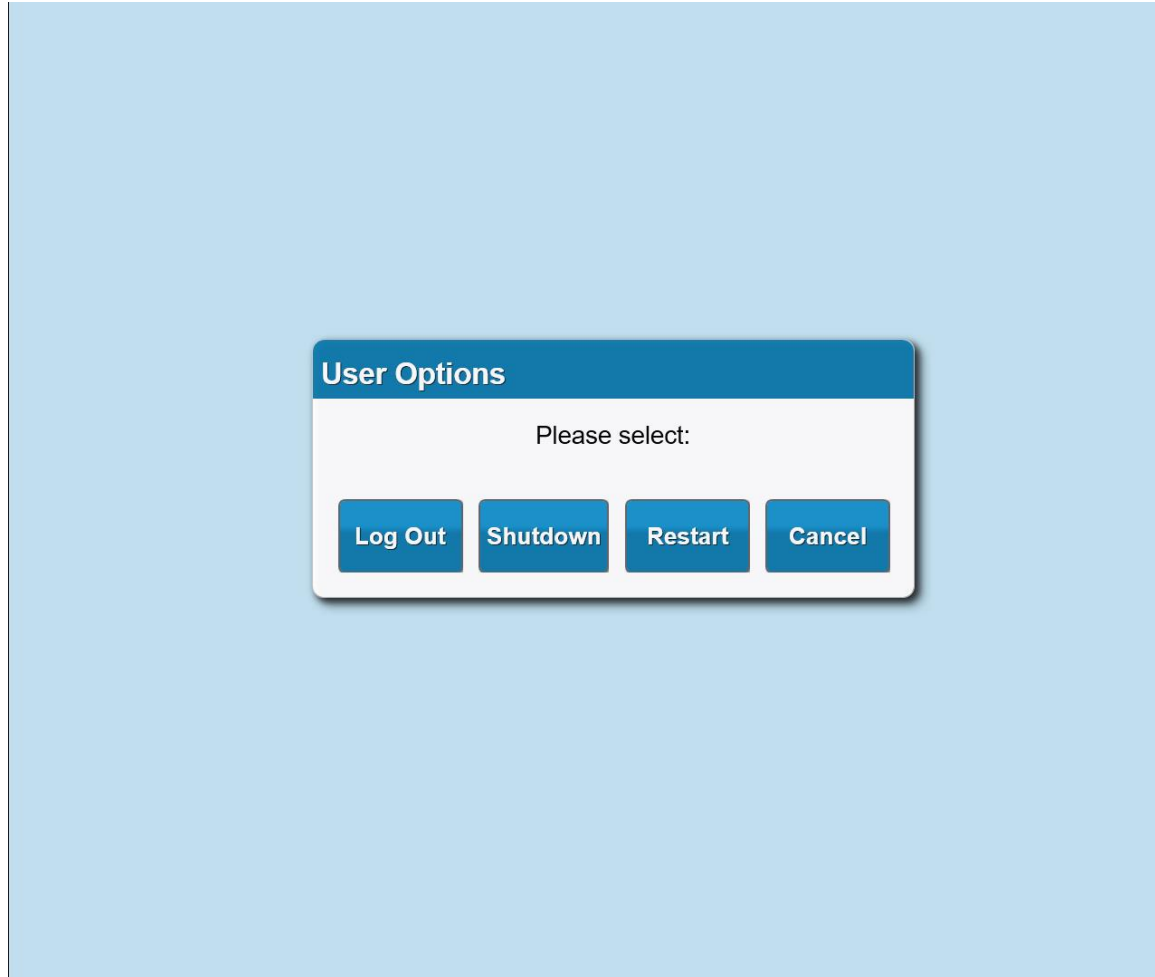
SYSTEM STATUS:
Weekly Maintenance is required

 Biomed

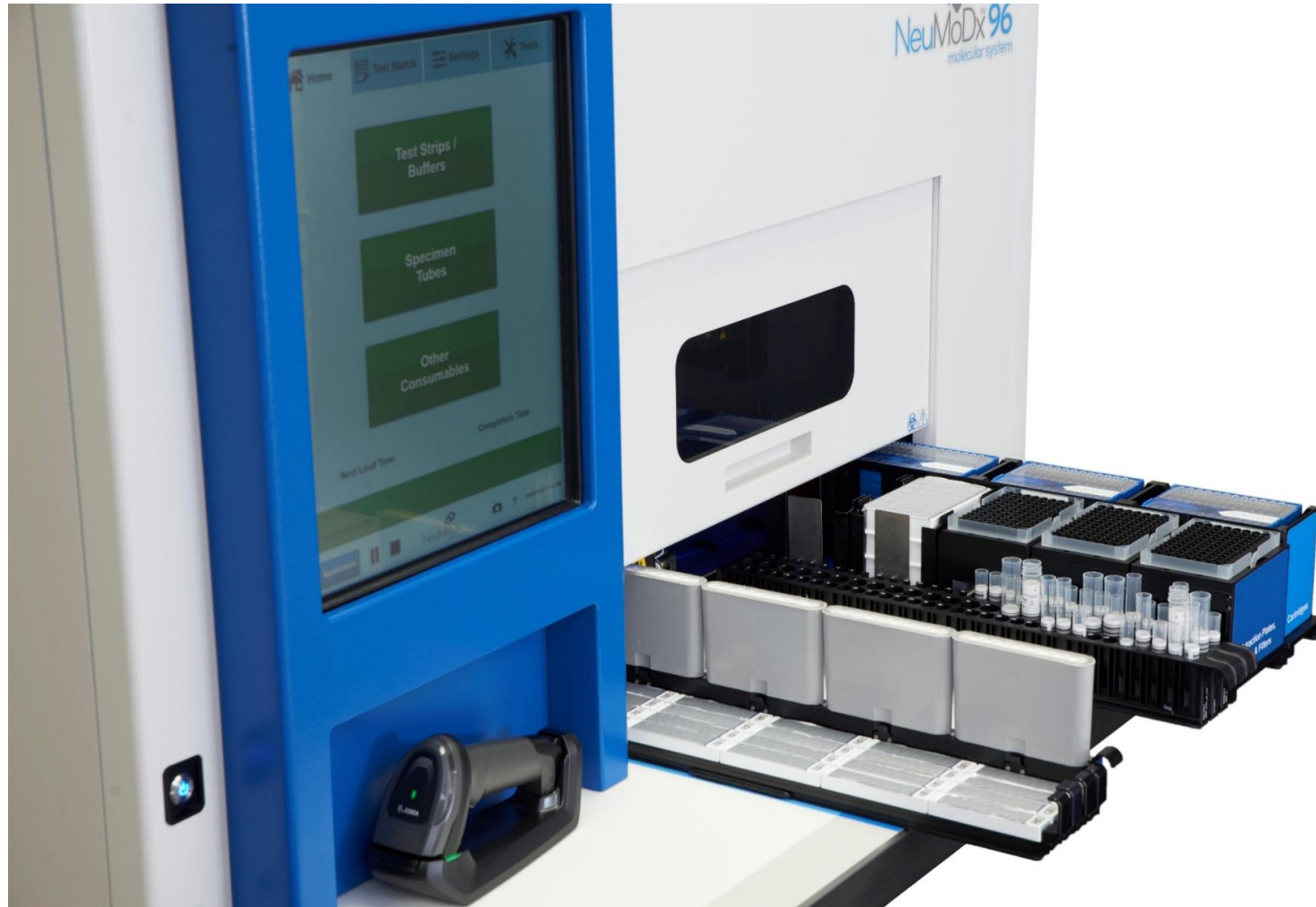
?
03/20/2020 8:24 AM

NeuMoDx 96 Software Screen

BioMed Level User

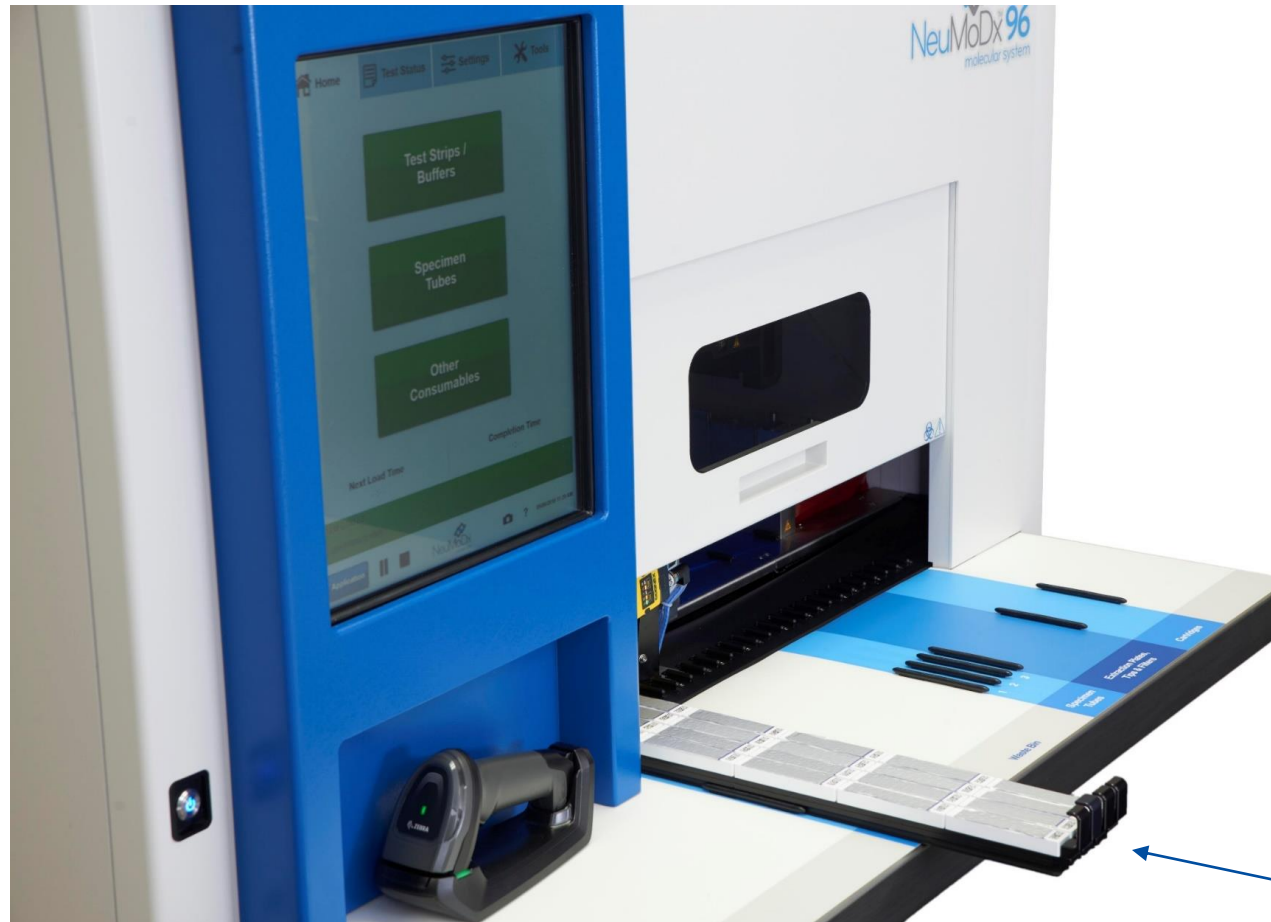


Loading Consumables



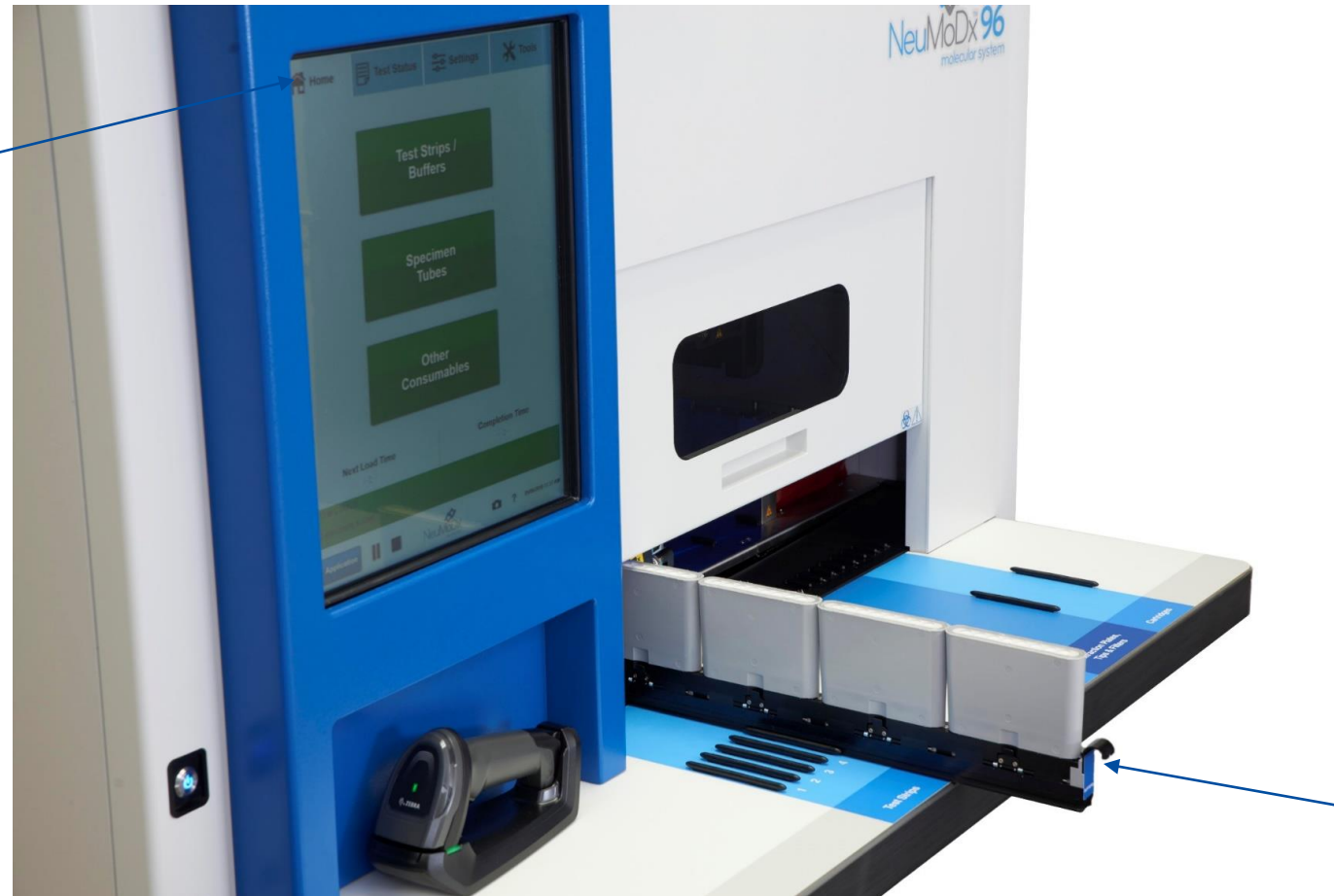
Loading Consumables

Test Strips and/or Buffers



Loading Consumables

Test Strips and/or Buffers



Loading Consumables

Test Strips and/or Buffers

Touch Carrier to View Details

Test Strips 1 Test Strips 2 Test Strips 3 Test Strips 4 Buffers 1

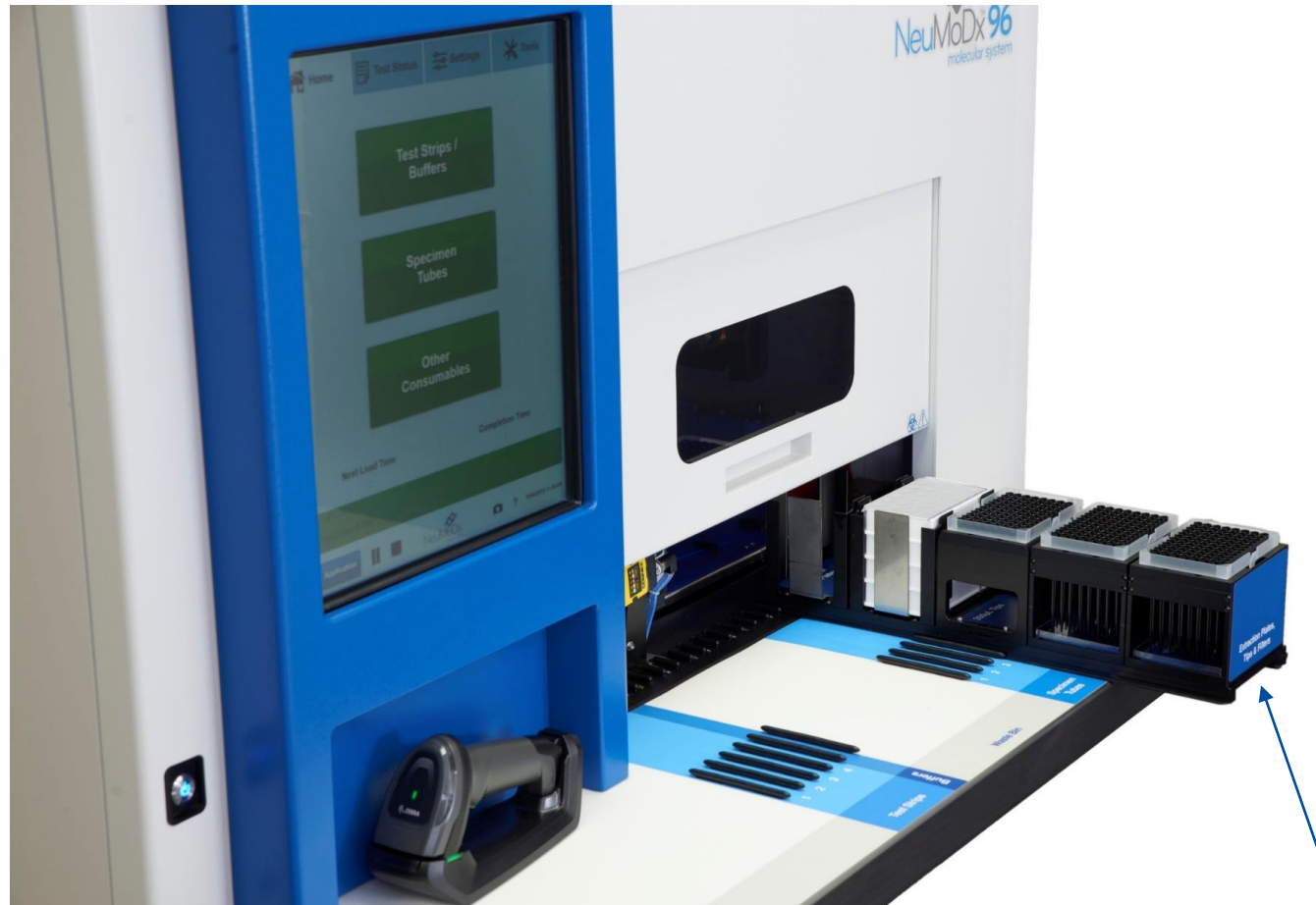
Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed NeuMoDx molecular 03/24/2020 6:44 PM

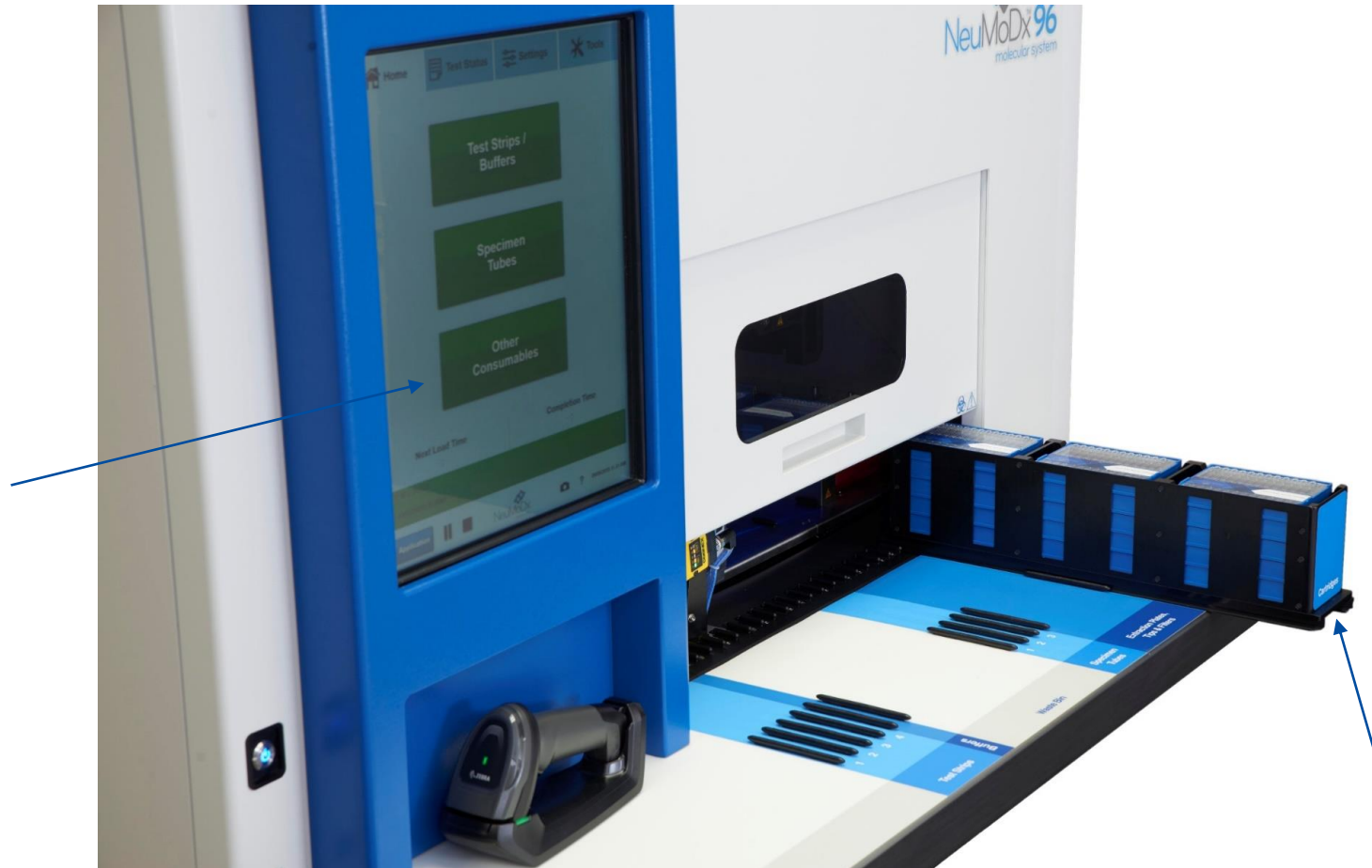
Loading Consumables

“Other Consumables”



Loading Consumables

“Other Consumables”



Loading Consumables

“Other Consumables”

Touch Carrier to View Details

Reagents

Biohazard Waste Bin

Loading

Loading

Tips Extraction Filter Plates 1

Cartridges 1

Biohazard Tip Waste Bin

Module Consumables

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

Biomed

NeuMoDx molecular

03/24/2020 6:44 PM

Loading Consumables

“Other Consumables”

Touch Carrier to View Details

 Reagents 	 Biohazard Waste Bin 	 Filter Plate Extraction Plate 300uL Tips 1000uL Tips 1000uL Tips Tips Extraction Filter Plates 1 	 Cartridge Cartridge Cartridge Cartridges 1 	 Biohazard Tip Waste Bin 	 Module Consumables
-------------------------	------------------------------------	---	---	--	-----------------------------------

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---:--
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

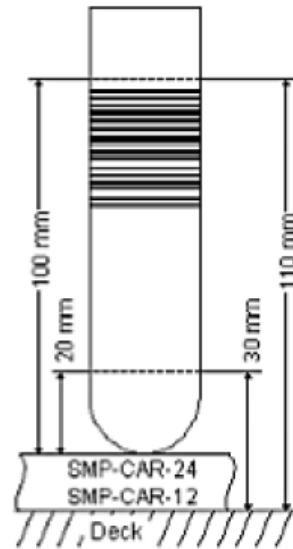
Biomed | NeuMoDx molecular | 03/24/2020 6:47 PM

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

The screenshot displays the user interface of the NeuMoDx 96 Molecular System. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these are sub-tabs for Test Strips / Buffers, Specimen Tubes (which is active), Other Consumables, and Summary. The main area shows three vertical blue bars representing specimen tubes, each labeled 'Loading' and numbered 1, 2, and 3. Below each tube is a small blue icon with a white dot pattern, which is highlighted by a red rectangular box. A text prompt 'Touch Carrier to View Details' is positioned above the tubes. At the bottom of the interface, there is a status summary section with the following data:

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

Below the summary is a green 'SYSTEM STATUS' bar with the text 'Load specimens to start'. The bottom of the screen features a 'Biomed' button, the 'NeuMoDx molecular' logo, a warning icon, a camera icon, a help icon, and the date/time '03/24/2020 6:44 PM'.

Loading Samples

The screenshot displays the 'Specimen Tubes' section of the system interface. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these are sub-tabs: Test Strips / Buffers, Specimen Tubes (selected), Other Consumables, and Summary. The main area shows three vertical bars representing specimen tubes, numbered 1, 2, and 3. Tube 1 is black and labeled 'Processing'. Tubes 2 and 3 are blue and labeled 'Specimen(s) Loaded'. Below each bar is a control button: a lock icon for tube 1, and downward arrows for tubes 2 and 3. A status bar at the bottom provides a summary of the system's state.

Samples Loaded:	3	Tests In Progress:	1	Estimated Walk-Away Time:	---
Test Orders Loaded:	3	Tests Pending:	2	Estimated Completion Time:	8:17 PM
		Tests Completed:	None		

SYSTEM STATUS:
Samples are processing

Biomed | NeuMoDx molecular | 03/24/2020 6:49 PM

Viewing Current Samples

Home
Test Status
Settings
Tools

Current
Completed
Pending

Filter By
Clear Filter
Sub
View Curves

Selected: 0 of 20

<input type="checkbox"/>	Specimen ID	Patient ID	Stage	Result Name	Started	Est. Complete
<input type="checkbox"/>	N130001244		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001243		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001245		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001240		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001239		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001241		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001242		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input checked="" type="checkbox"/>	N130001246		LhpC	GBS	02/06/2020 9:57 AM	02/06/2020 11:05 AM
<input type="checkbox"/>	N130001252		XPCR Extraction	GBS	02/06/2020 10:01 AM	02/06/2020 11:07 AM
<input type="checkbox"/>	N130001251		XPCR Extraction	GBS	02/06/2020 10:01 AM	02/06/2020 11:07 AM

Samples Loaded: 20

Test Orders Loaded: 20

Tests In Progress: 20

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---

Estimated Completion Time: 11:12 AM

- 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

The screenshot shows the 'Other Consumables' section of the system interface. It features a grid of consumable items with dropdown arrows. A red box highlights the arrow for 'Reagents'. Below the grid is a status summary table and a system status bar.

Test Strips / Buffers		Specimen Tubes		Other Consumables		Summary				
Filter Plate	Extraction Plate	300uL Tips	1000uL Tips	1000uL Tips	Tips Extraction Filter Plates 1	Cartridge	Cartridge	Cartridge	Biohazard Tip Waste Bin	Module Consumables
↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

SYSTEM STATUS:
Load specimens to start

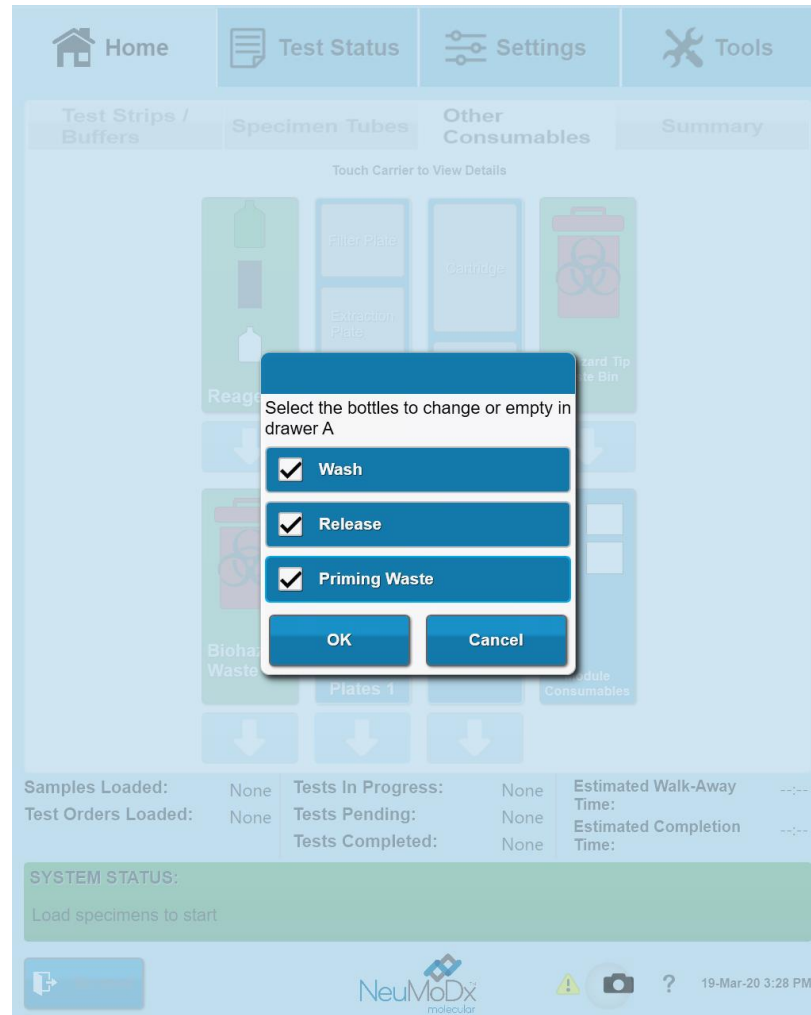
Biomed | NeuMoDx molecular | 19-Mar-20 3:22 PM

Changing Wash & Release

The screenshot shows the main interface of the NeuMoDx molecular system. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these are sections for Test Strips / Buffers, Specimen Tubes, Other Consumables, and Summary. A central table displays inventory data for two drawers, A and B. A modal dialog box is open, prompting the user to select bottles to change or empty in drawer B. The dialog has three options: Wash, Release, and Priming Waste, each with an unchecked checkbox. At the bottom of the dialog are OK and Cancel buttons. The background interface shows system status information, including 'Samples Loaded: None', 'Tests In Progress: 2', and 'Estimated Walk-Away Time: ---'. A green banner at the bottom indicates 'SYSTEM STATUS: Weekly Maintenance is required'. The footer includes the NeuMoDx molecular logo, a camera icon, a help icon, and the date/time '03/19/2020 2:43 PM'.

Est. Tests Remaining	Serial #	Lot #	Expiration Date	Open-Life
3441	N/A	N/A	N/A	N/A
1041	00018	101650	06/13/2020	20 Day(s)
836	00			
2191	N			
367	00			
328	00			

Changing Wash & Release



Changing Wash & Release



Changing Wash & Release



Home
Test Status
Settings
Tools

Test Strips / Bu
Specimen Tubes
Other
Summary

Replace Wash Reagent Bottle

1. Open Liquid Reagent Drawer A. Confirm
2. **Scan the barcode of the new Wash reagent bottle.**
 010081427802021510LLLLLLX21SSSSX17YYMMDD
3. *Remove and discard the temporary cap from the new Wash reagent bottle.* Confirm
4. *Without setting the tubing on any surface, disconnect the cap with affixed White tubing from the old Wash reagent bottle.* Confirm
5. *Immediately place cap with affixed tubing on the new Wash reagent bottle. Turn cap to tighten.* Confirm
6. *Discard old Wash reagent bottle.* Confirm
7. *Close Liquid Reagent Drawer A with all liquid reagents in place.* Confirm

Close
Cancel

Changing Wash & Release



Home
Test Status
Settings
Tools

Test Strips /
Specimen Tubes
Other
Summary

Replace Release Reagent Box

1. Open Liquid Reagent Drawer A.
 Confirm
- Scan the barcode of the new Release reagent box.

2.
3. Remove and discard the temporary cap from the new Release reagent box.
 Confirm
4. Without setting the tubing on any surface, disconnect the cap with affixed Black tubing from the old Release reagent box.
 Confirm
5. Immediately place cap with affixed tubing on the new Release reagent box. Turn cap to tighten.
 Confirm
6. Discard old Release reagent box.
 Confirm
7. Close Liquid Reagent Drawer A with all liquid reagents in place.
 Confirm


Close
Cancel

SYSTEM
Load specimens to start

NeuMoDx molecular
19-Mar-20 3:30 PM

Changing Wash & Release

Empty Priming Waste Reagent Bottle



1. Open Bulk Reagent Drawer A.

 Confirm
2.
Unscrew and remove the cap with affixed green-tagged tubing from the Priming Waste Bottle.

 Confirm
3.
Place the cap with affixed green-tagged tubing into the tubing holder for storage during Priming Waste disposal.

 Confirm
4.
Properly dispose of the Priming Waste.

 Confirm
5.
Place the Priming Waste Bottle back into the original position.

 Confirm
6.
Securely screw the cap with affixed tubing on the Priming Waste Bottle.

 Confirm
7.
Close Drawer A with all bottles in place.

 Confirm

Next Load Time

Close
Cancel

Completion Time

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

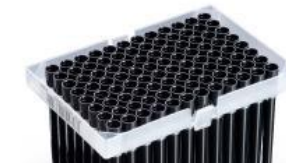
- The following reagents/consumables after usage are considered **biohazardous** and should be discarded in **appropriate biohazard waste**:

- 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



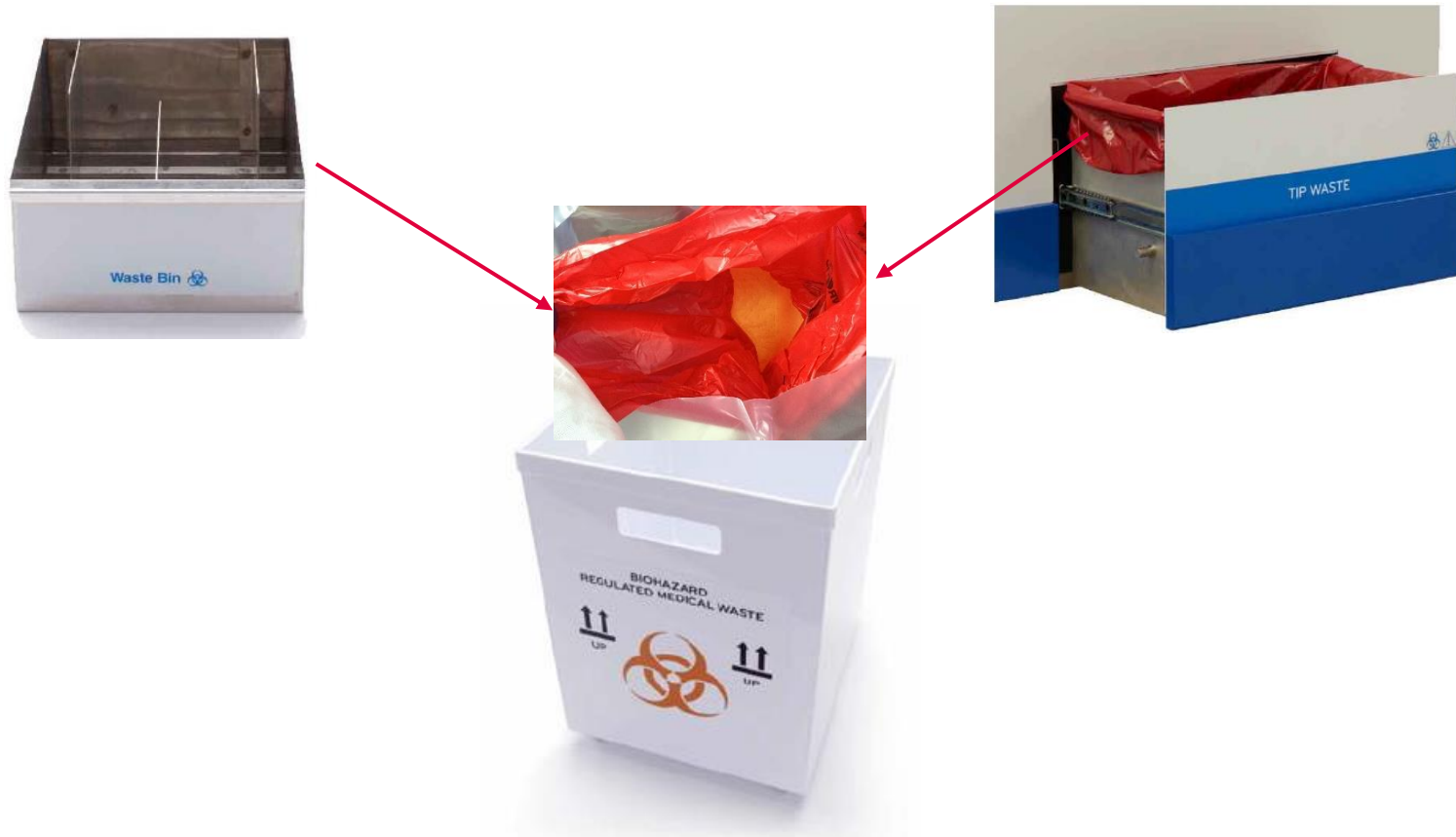
- The NeuMoDx Biohazard Tip Waste Bin is at the rear for automated disposal of tips
- Has red biohazard waste bag lining



NeuMoDx 96 Molecular System

Biohazard Waste Handling

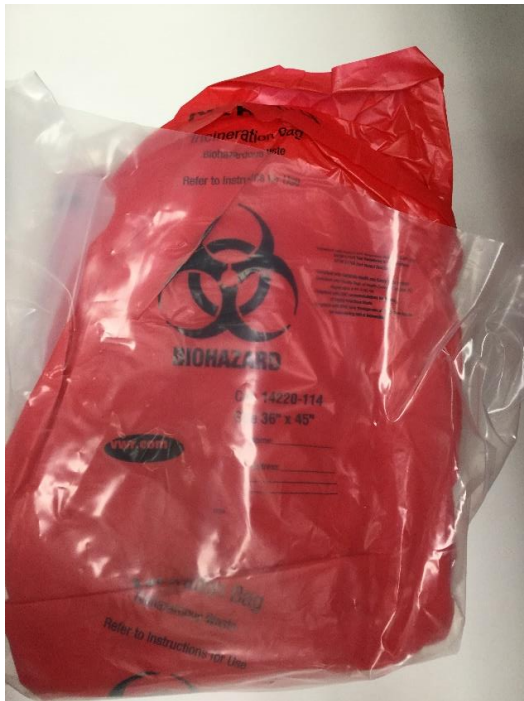
- When either waste bin is **full as prompted by the Software**, the waste should be emptied into a NeuMoDx Biohazard Waste Container lined with the NeuMoDx Biohazard Waste Bag



NeuMoDx 96 Molecular System

NeuMoDx™ Biohazard Waste Bag

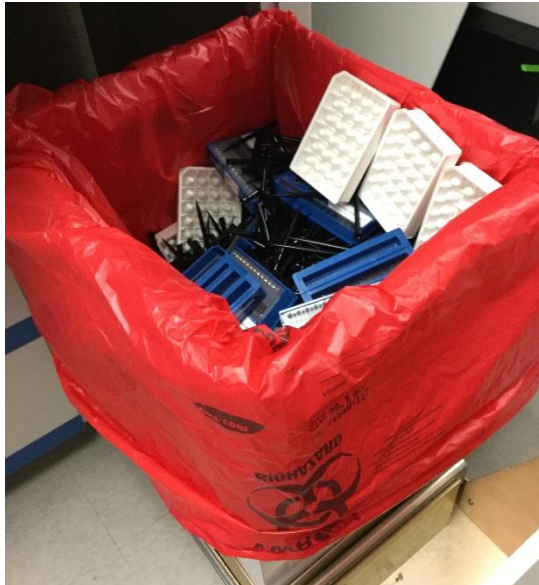
- It is imperative that NeuMoDx™ consumables (namely the NeuMoDx™ Extraction Plates and NeuMoDx™ Cartridges) are disposed in the NeuMoDx™ Biohazard Waste Bag



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

System Events	Maintenance	Database	Support	Test	Test Tool
General		XPCR Modules		Extraction Plate Modules	
Instrument Serial #: N000010		Hamilton Serial #: B735			
Daily Upkeep Time: 12:00 AM					
Weekly Maintenance				Weekly Maintenance	
<input type="checkbox"/> Required for Sample Processing					
Last Performed: 03/20/2020 10:48 AM					

Weekly Cleaning & Weekly Shutdown

Weekly Maintenance

CAUTION: Do not use any decontamination or cleaning agents that could cause a hazard as a result of a reaction with parts of the equipment, or with material contained in it.

CAUTION: Do not use Microcide SQ, DECONEX Solarsept, alcohol, or any decontamination or cleaning agents to clean the touchscreen.

Do not spray or pour any decontamination or cleaning solutions directly on surfaces. Consult NeuMoDx Technical Support to determine the compatibility of any decontamination or cleaning agents not listed in the manual.

1. Unlock the Service Door.

Confirm

2. *Open the Service Door*

Confirm

3. *Carefully wipe the 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.*

Confirm

4. *Wipe off all system parts that came into contact with Microcide SQ or DECONEX Solarsept with a lint-free cloth dampened with water.*

Confirm

5. *Clean the touchscreen with the provided glass cleaner wipes or apply a NeuMoDx-approved window or glass cleaner to a clean, lint-free cloth and wipe the touchscreen. In the event of biological contamination on the touchscreen, wipe the screen with wipe soaked in a 10% dilution of household bleach, followed by deionized water. Dry the touchscreen with a soft cloth*

Confirm

6. *Close the Service Door*

Confirm

Close

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

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

SYSTEM STATUS:
These carriers have loading errors requiring user intervention: Test Strips 1

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

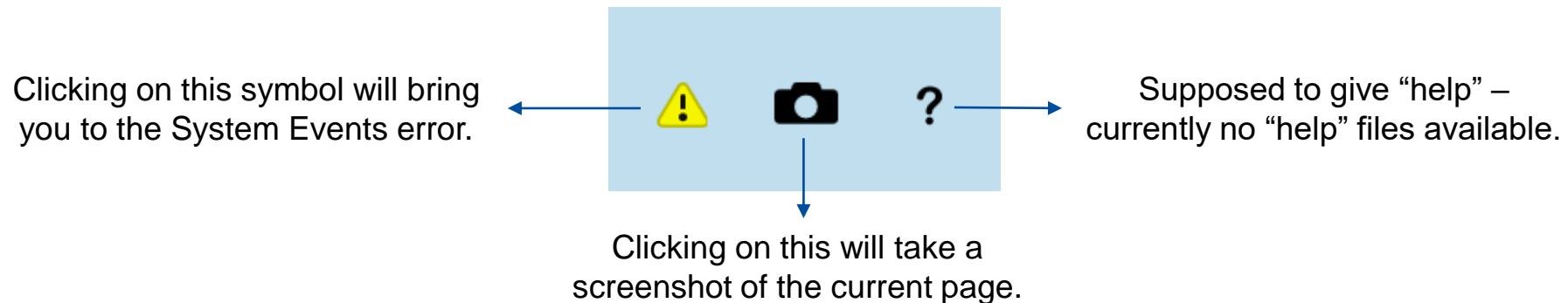
Yellow – system or consumable is ready to be used but may require user intervention for optimal performance


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.



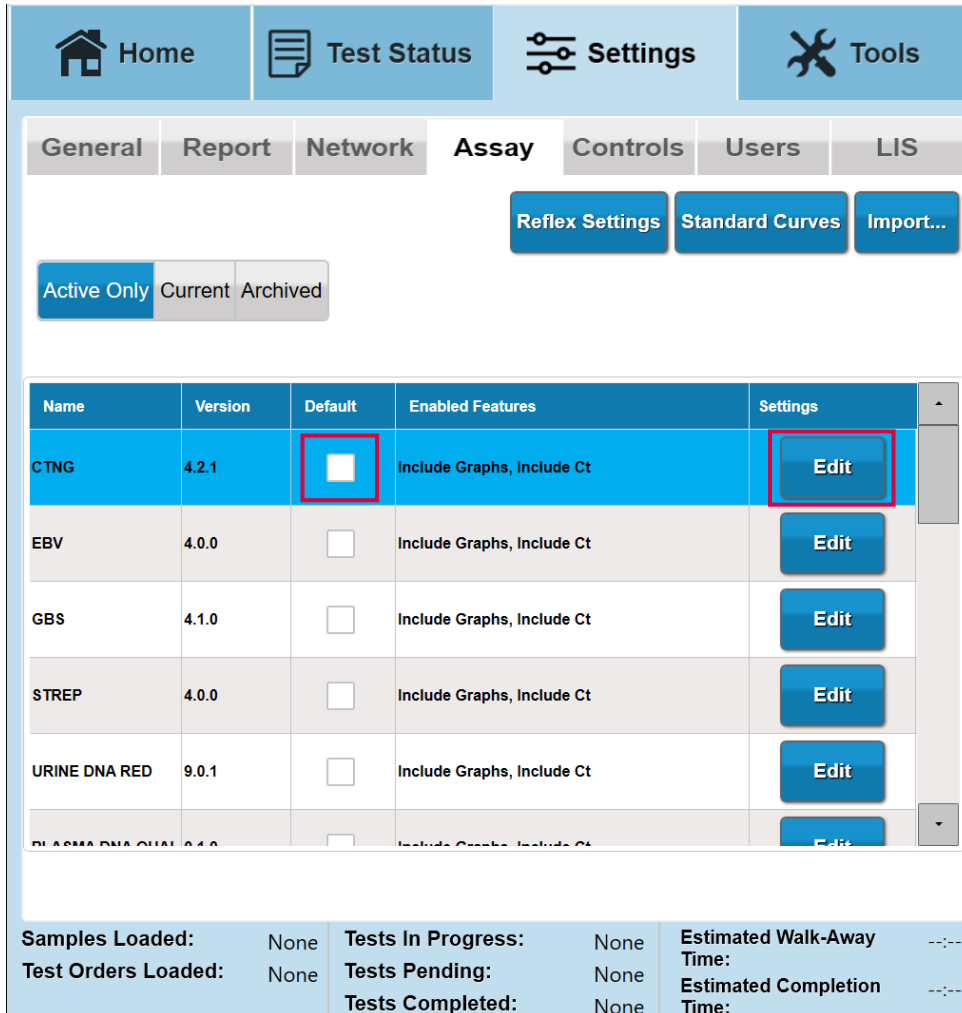


Part IV
NeuMoDx
More Information



Setting Up an Assay

Assay Settings



Name	Version	Default	Enabled Features	Settings
CTNG	4.2.1	<input checked="" type="checkbox"/>	Include Graphs, Include Ct	Edit
EBV	4.0.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
GBS	4.1.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
STREP	4.0.0	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
URINE DNA RED	9.0.1	<input type="checkbox"/>	Include Graphs, Include Ct	Edit
PLASMA DNA QIA...	...	<input type="checkbox"/>	Include Graphs, Include Ct	Edit

Samples Loaded: None **Tests In Progress:** None **Estimated Walk-Away Time:** ---:--
Test Orders Loaded: None **Tests Pending:** None **Estimated Completion Time:** ---:--
Tests Completed: None

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

Active Assay Settings: CTNG

Include Graphs

Include Ct

Rerun

Repeat

Rerun/Repeat Attempts:

2
▼

OK

Cancel

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



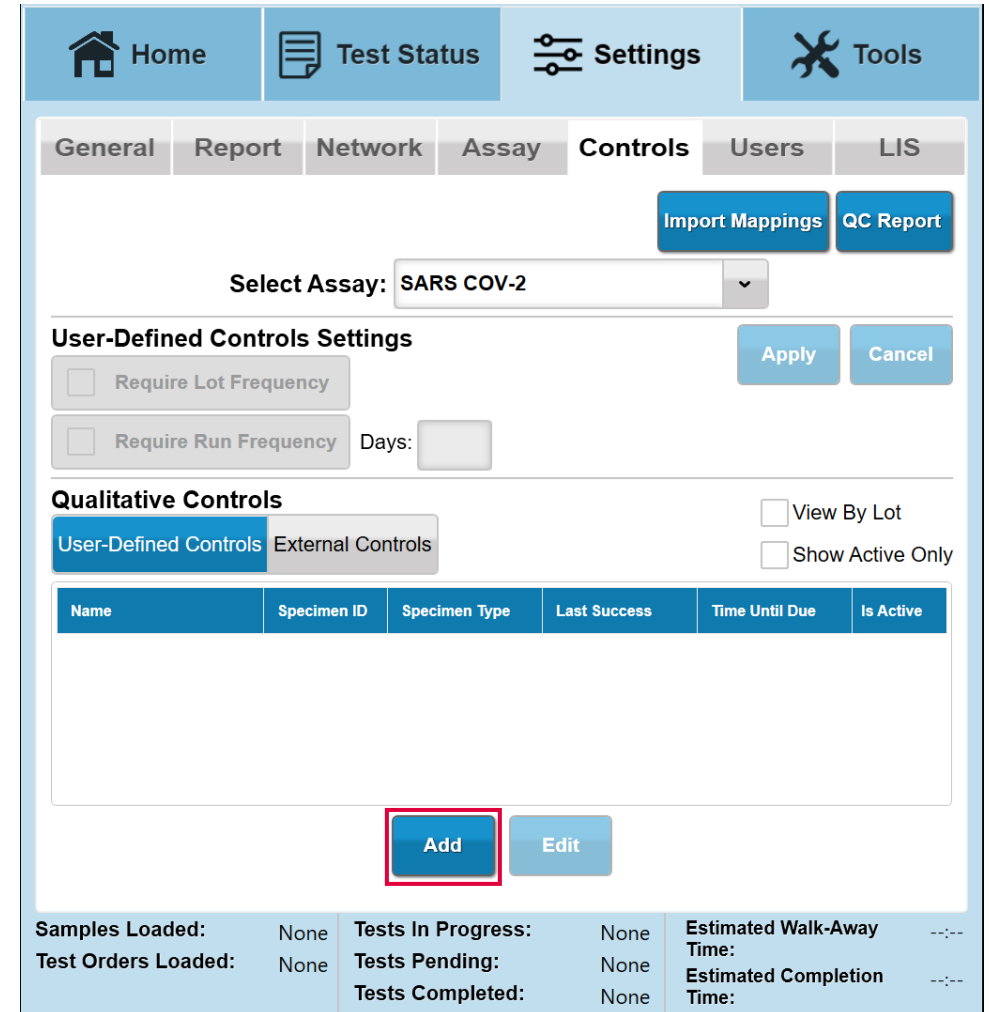
Defining User-Defined Controls

- 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



The screenshot shows the 'Settings' menu with 'Controls' selected. The 'Assay' dropdown is set to 'SARS COV-2'. Under 'User-Defined Controls Settings', there are checkboxes for 'Require Lot Frequency' and 'Require Run Frequency' (with a 'Days' input field). The 'Qualitative Controls' section has tabs for 'User-Defined Controls' (selected) and 'External Controls', along with checkboxes for 'View By Lot' and 'Show Active Only'. A table below lists controls with columns: Name, Specimen ID, Specimen Type, Last Success, Time Until Due, and Is Active. The 'Add' button is highlighted with a red box. At the bottom, there are status indicators for Samples Loaded, Test Orders Loaded, Tests In Progress, Tests Pending, Tests Completed, Estimated Walk-Away Time, and Estimated Completion Time.

Defining User-Defined Controls

Specify User-Defined Control for SARS COV-2

Control Name:

Supported Specimen Type(s):

- Transport Medium
- User-Specified 1

Click to Close Target Data

Target	Select Result
Nsp2 gene	Select Result
N gene	Select Result

Is Active

A Supported Specimen Type must be selected.
A result must be selected for target Nsp2 gene.

Specify User-Defined Control for SARS COV-2

Control Name:

Supported Specimen Type(s):

- Transport Medium
- User-Specified 1

Click to Close Target Data

Target	Select Result
Nsp2 gene	Target Not Amplified
N gene	Target Amplified

Is Active

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

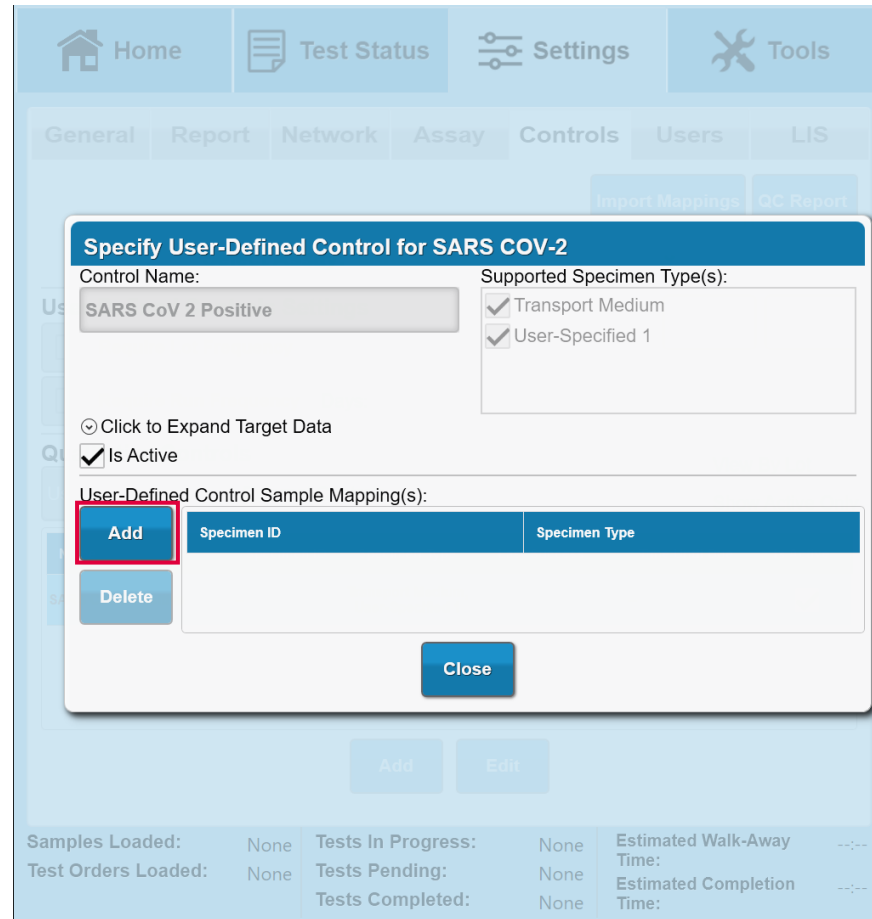
Mapping User-Defined Controls

The screenshot shows the 'Settings' page with the 'Controls' tab selected. The 'Select Assay' dropdown is set to 'SARS COV-2'. Under 'User-Defined Controls Settings', there are checkboxes for 'Require Lot Frequency' and 'Require Run Frequency' (with a 'Days' input field). Under 'Qualitative Controls', there are checkboxes for 'View By Lot' and 'Show Active Only'. A table lists the controls, with one entry 'SARS CoV 2 Positive' highlighted in blue. Below the table are 'Add' and 'Edit' buttons, with the 'Edit' button circled in red. At the bottom, there is a summary section for 'Samples Loaded', 'Test Orders Loaded', 'Tests In Progress', 'Tests Pending', and 'Tests Completed', along with 'Estimated Walk-Away Time' and 'Estimated Completion Time'.

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	--	Transport Medium, User-Specified 1	--	--	<input checked="" type="checkbox"/>

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

Mapping User-Defined Controls



Specify User-Defined Control for SARS COV-2

Control Name: SARS CoV 2 Positive

Supported Specimen Type(s):
 Transport Medium
 User-Specified 1

Click to Expand Target Data
 Is Active

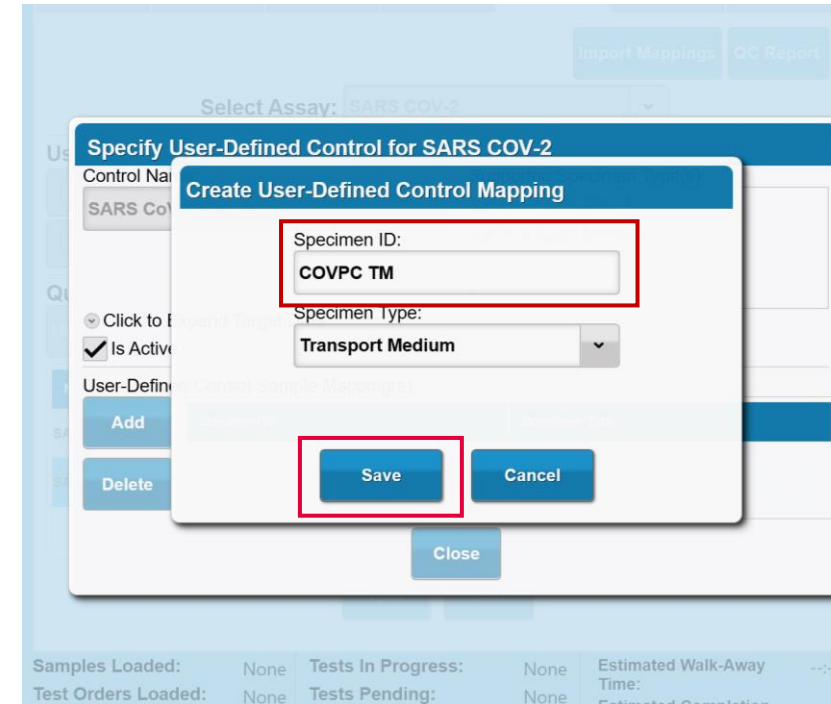
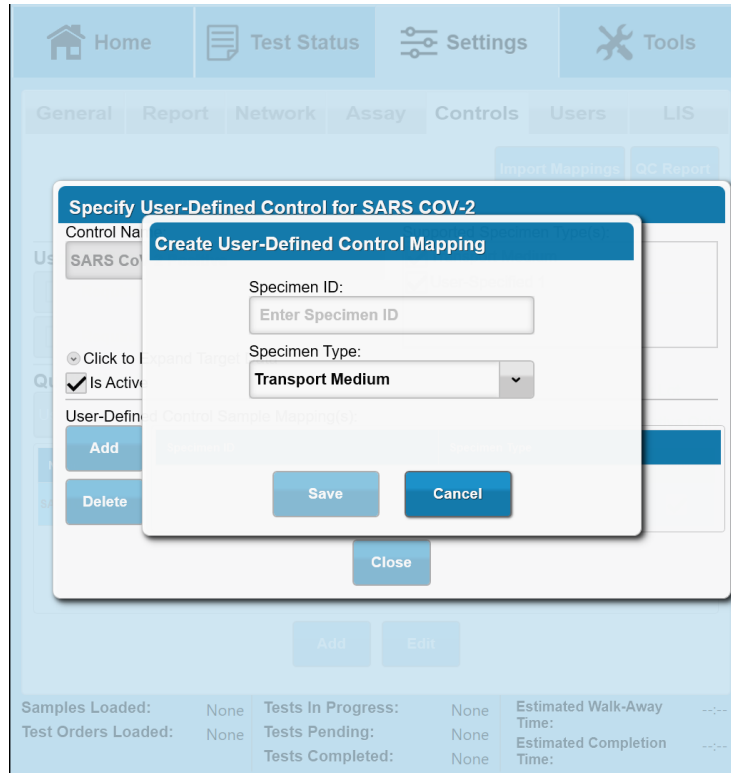
User-Defined Control Sample Mapping(s):

Specimen ID	Specimen Type

Buttons: Add (highlighted), Delete, Close

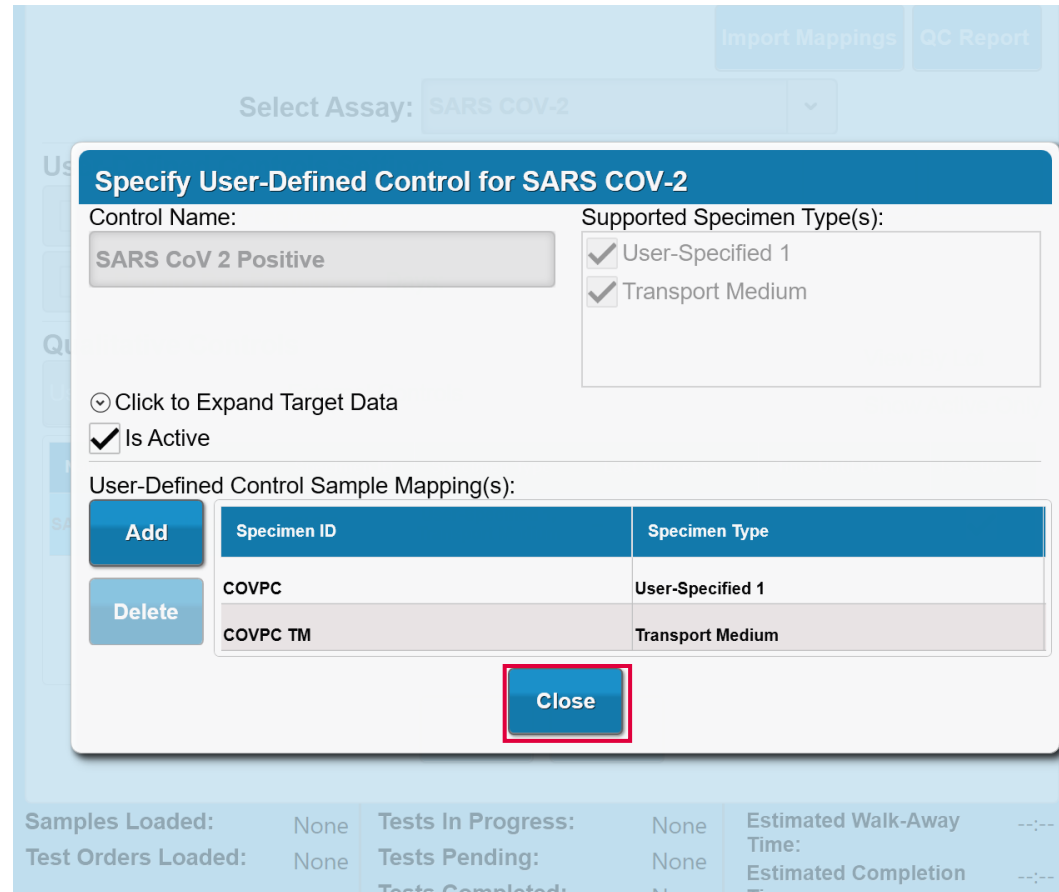
Select "Add" to add a "mapping" (specimen ID) to the control

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 Assay: SARS COV-2

Specify User-Defined Control for SARS COV-2

Control Name: SARS CoV 2 Positive

Supported Specimen Type(s):
 User-Specified 1
 Transport Medium

Click to Expand Target Data
 Is Active

User-Defined Control Sample Mapping(s):

Specimen ID	Specimen Type
COVPC	User-Specified 1
COVPC TM	Transport Medium

Close

Samples Loaded: None Tests In Progress: None Estimated Walk-Away Time: --:--
 Test Orders Loaded: None Tests Pending: None Estimated Completion Time: --:--

Select "Close" to return to the Controls tab

Defining User-Defined Controls

Home | Test Status | Settings | Tools

General | Report | Network | Assay | **Controls** | Users | LIS

Import Mappings | QC Report

Select Assay: SARS COV-2

User-Defined Controls Settings

Require Lot Frequency

Require Run Frequency Days:

Apply | Cancel

Qualitative Controls

View By Lot

Show Active Only

User-Defined Controls | External Controls

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	COVPC, COVPC TM	User-Specified 1, Transport Medium	--	--	<input checked="" type="checkbox"/>
SARS CoV 2 Negative	--	User-Specified 1, Transport Medium	--	--	<input checked="" type="checkbox"/>

Add | Edit

Samples Loaded: None | Tests In Progress: None | Estimated Walk-Away Time: --:--

Test Orders Loaded: None | Tests Pending: None | Estimated Completion Time: --:--

Tests Completed: None

Home | Test Status | Settings | Tools

General | Report | Network | Assay | **Controls** | Users | LIS

Import Mappings | QC Report

Select Assay: SARS COV-2

User-Defined Controls Settings

Require Lot Frequency

Require Run Frequency Days:

Apply | Cancel

Qualitative Controls

View By Lot

Show Active Only

User-Defined Controls | External Controls

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	COVPC, COVPC TM	User-Specified 1, Transport Medium	--	--	<input checked="" type="checkbox"/>
SARS CoV 2 Negative	COVNC, COVNC TM	User-Specified 1, Transport Medium	--	--	<input checked="" type="checkbox"/>

Add | Edit

Samples Loaded: None | Tests In Progress: None | Estimated Walk-Away Time: --:--

Test Orders Loaded: None | Tests Pending: None | Estimated Completion Time: --:--

Tests Completed: None

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

Defining User-Defined Controls

Specify User-Defined Control for SARS COV-2

Control Name: Supported Specimen Type(s):
 User-Specified 1
 Transport Medium

Click to Close Target Data

Target	Select Result
Nsp2 gene	Target Amplified
N gene	Target Amplified

Is Active

Home | Test Status | Settings | Tools

General | Report | Network | Assay | **Controls** | Users | LIS

Select Assay: SARS COV-2

User-Defined Controls Settings

Require Lot Frequency

Require Run Frequency Days:

Qualitative Controls View By Lot Show Active Only

User-Defined Controls | External Controls

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Pos T	COVPC	User-Specified 1	--	--	<input checked="" type="checkbox"/>
SARS CoV 2 Neg	COVNC	User-Specified 1	--	--	<input checked="" type="checkbox"/>

Samples Loaded: None | Tests In Progress: None | Estimated Walk-Away Time: --:--:--
 Test Orders Loaded: None | Tests Pending: None | Estimated Completion Time: --:--:--
 Tests Completed: None | Tests Completed: None

Controls can also be defined for only one specimen type

Requiring User-Defined Controls

The image displays two screenshots of the 'Settings' page for the 'SARS COV-2' assay. The left screenshot shows the 'User-Defined Controls Settings' section where the 'Require Run Frequency' checkbox is checked and the 'Days' field is set to 1. The 'Apply' button is highlighted with a red box. The right screenshot shows the 'Qualitative Controls' table with the 'Needs Controls' status highlighted in yellow for both 'SARS CoV 2 Positive' and 'SARS CoV 2 Negative' entries.

User-Defined Controls Settings

Require Lot Frequency

Require Run Frequency Days: 1

View By Lot

Show Active Only

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	COVPC, COVPC-TM	Transport Medium, User-Specified 1	--	--	<input checked="" type="checkbox"/>
SARS CoV 2 Negative	COVNC, COVNC-TM	Transport Medium, User-Specified 1	--	--	<input checked="" type="checkbox"/>

Qualitative Controls

Name	Specimen ID	Specimen Type	Last Success	Time Until Due	Is Active
SARS CoV 2 Positive	COVPC, COVPC-TM	Transport Medium, User-Specified 1	--	Needs Controls	<input checked="" type="checkbox"/>
SARS CoV 2 Negative	COVNC, COVNC-TM	Transport Medium, User-Specified 1	--	Needs Controls	<input checked="" type="checkbox"/>

Summary:

Samples Loaded: None Tests In Progress: None Estimated Walk-Away Time: ---
 Test Orders Loaded: None Tests Pending: None Estimated Completion Time: ---
 Tests Completed: None

- 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

The interface shows a navigation bar with Home, Test Status, Settings, and Tools. Under Test Status, there are tabs for Current, Completed, and Pending. Below the tabs are buttons for Filter By, Clear Filter, Import, Download, Create, and Delete. The Download button is highlighted with a red box in the left screenshot.

The table in the right screenshot contains the following data:

Specimen ID	Result Name	Patient ID	Created	Specimen	Tube Type
A00004	SARS COV-2	0004	04/03/2020 4:42 PM	Transport Medium	Unspecified
A00005	SARS COV-2	0005	04/03/2020 4:42 PM	Transport Medium	Unspecified
A00006	SARS COV-2	0006	04/03/2020 4:42 PM	Transport Medium	Unspecified
A00007	SARS COV-2	0007	04/03/2020 4:42 PM	Transport Medium	Unspecified
A00008	SARS COV-2	0008	04/03/2020 4:42 PM	Transport Medium	Unspecified
A00009	SARS COV-2	0009	04/03/2020 4:42 PM	User-Specified 1	Unspecified
A00010	SARS COV-2	0010	04/03/2020 4:42 PM	User-Specified 1	Unspecified
A00011	SARS COV-2	0011	04/03/2020 4:42 PM	User-Specified 1	Unspecified
A00012	SARS COV-2	0012	04/03/2020 4:42 PM	User-Specified 1	Unspecified
A00013	SARS COV-2	0013	04/03/2020 4:42 PM	User-Specified 1	Unspecified

Summary statistics at the bottom of both screenshots:

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

- 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.xlsx 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

The image shows two side-by-side screenshots of a software interface. The left screenshot shows the 'Pending' section with the 'Import' button highlighted by a red box. The right screenshot shows the same interface but with a table of records displayed below the 'Import' button. The table has columns for Specimen ID, Result Name, Patient ID, Created, Specimen, and Tube Type. The 'Import' button is also highlighted in the right screenshot.

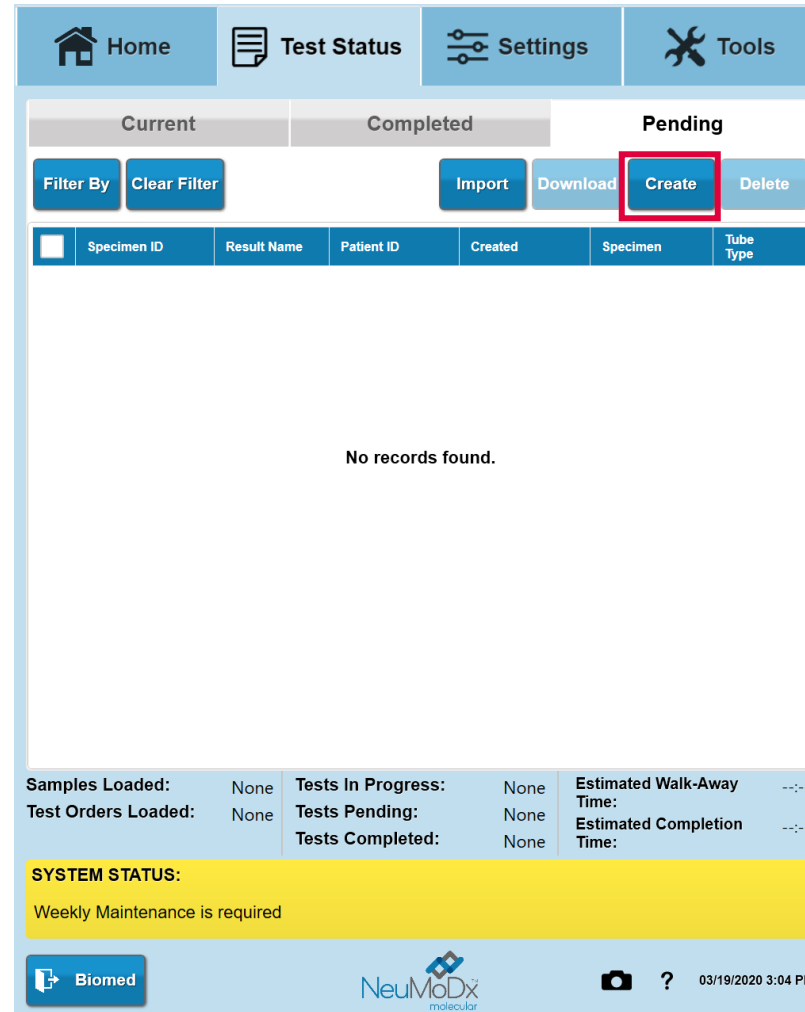
Specimen ID	Result Name	Patient ID	Created	Specimen	Tube Type
A00035	SARS COV-2	0035	04/03/2020 5:18 PM	Transport Medium	Transport Medium 16x100 mm
A00036	SARS COV-2	0036	04/03/2020 5:18 PM	Transport Medium	Transport Medium 16x100 mm
A00037	SARS COV-2	0037	04/03/2020 5:18 PM	Transport Medium	Transport Medium 16x100 mm
A00038	SARS COV-2	0038	04/03/2020 5:18 PM	Transport Medium	Transport Medium 16x100 mm
A00039	SARS COV-2	0039	04/03/2020 5:18 PM	Transport Medium	Transport Medium 16x100 mm
A00040	SARS COV-2	0040	04/03/2020 5:18 PM	User-Specified 1	Unspecified
A00041	SARS COV-2	0041	04/03/2020 5:18 PM	User-Specified 1	Unspecified
A00042	SARS COV-2	0042	04/03/2020 5:18 PM	User-Specified 1	Unspecified
A00043	SARS COV-2	0043	04/03/2020 5:18 PM	User-Specified 1	Unspecified
A00044	SARS COV-2	0044	04/03/2020 5:18 PM	User-Specified 1	Unspecified

- 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”



The screenshot shows the NeuMoDx Molecular System interface. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these, there are three main tabs: Current, Completed, and Pending. The Pending tab is selected. In the Pending tab, there are buttons for Filter By, Clear Filter, Import, Download, Create (highlighted with a red box), and Delete. Below the buttons is a table with columns: Specimen ID, Result Name, Patient ID, Created, Specimen, and Tube Type. The table is currently empty, displaying "No records found." At the bottom of the interface, there is a summary section with the following data:

Samples Loaded:	None	Tests In Progress:	None	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	--:--
		Tests Completed:	None		

Below the summary section, there is a yellow banner with the text "SYSTEM STATUS: Weekly Maintenance is required". At the bottom of the interface, there is a Biomed logo, the NeuMoDx molecular logo, a camera icon, a question mark icon, and the date and time "03/19/2020 3:04 PM".

NeuMoDx Molecular System

Assigning a Test

The 'Enter Test Orders' dialog box contains the following fields:

- Specimen ID: Enter Specimen ID
- Patient ID: Enter Patient ID
- Sample Specimen Type: Select Specimen Type
- Specimen Tube Type: Unspecified
- Specimen Tube Size: Select Tube Size
- Assay: Select Assay
- Result Name: Select Result Name
- Test Specimen Type: Select Test Specimen Type

Buttons: Add, Remove, Save & New, Save & Close, Cancel

Assay Name	Result Name	STAT
------------	-------------	------

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

The screenshot displays the 'Specimen Tubes' section of the NeuMoDx Molecular System interface. At the top, there is a navigation bar with 'Home', 'Test Status', 'Settings', and 'Tools'. Below this is a sub-menu with 'Test Strips / Buffers', 'Specimen Tubes' (selected), 'Other Consumables', and 'Summary'. The main area shows three vertical tubes, each labeled 'Not Loaded' and numbered 1, 2, and 3. Below each tube is a blue arrow pointing up. A status bar at the bottom provides system metrics: Samples Loaded: None, Test Orders Loaded: None, Tests In Progress: None, Tests Pending: None, Tests Completed: None, Estimated Walk-Away Time: ---, and Estimated Completion Time: ---. A red banner indicates 'SYSTEM STATUS: An anti-virus scan is in progress. The system will have limited functionality until the scan completes.' The bottom of the screen features a 'MirandaApp' button, system icons, the 'NeuMoDx molecular' logo, a camera icon, a help icon, and the date/time '03/02/2020 10:56 AM'.

NeuMoDx Molecular System

Assigning a Test

The screenshot displays the 'Specimen Tubes' section of the NeuMoDx Molecular System interface. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these are sub-tabs: Test Strips / Buffers, Specimen Tubes (selected), Other Consumables, and Summary. The main area shows three specimen tubes labeled 1, 2, and 3. Tube 1 is red and labeled 'Error', while tubes 2 and 3 are grey and labeled 'Not Loaded'. Below each tube is a blue arrow button pointing up or down. A status bar at the bottom provides summary statistics:

Samples Loaded:	16	Tests In Progress:	None	Estimated Walk-Away Time:	---
Test Orders Loaded:	None	Tests Pending:	None	Estimated Completion Time:	---
		Tests Completed:	None		

SYSTEM STATUS:
These carriers have loading errors requiring user intervention: Specimens 1

At the bottom of the interface, there is a 'Biomed' button, the NeuMoDx molecular logo, a warning icon, a camera icon, a help icon, and the date/time: 19-Mar-20 4:51 PM.

NeuMoDx Molecular System

Assigning a Test

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

Specimens 1 Carrier Details

Touch Patient Specimen to View Details

Specimen ID	Patient ID	Test Order(s)	Sample Type	Specimen	Specimen Tube	Open Life	Errors
1	9640000245		Patient	Unknown	Secondary Tube 13x75 mm		!
2	9640000246		Patient	Unknown	Secondary Tube 13x75 mm		!
3	9640000247		Patient	Unknown	Secondary Tube 13x75 mm		!
4	9640000248		Patient	Unknown	Secondary Tube 13x75 mm		!
5	9640000249		Patient	Unknown	Secondary Tube 13x75 mm		!
6	9640000250		Patient	Unknown	Secondary Tube 13x75 mm		!
7	9640000251		Patient	Unknown	Secondary Tube 13x75 mm		!
8	9640000252		Patient	Unknown	Secondary Tube 13x75 mm		!
9	9640000253		Patient	Unknown	Secondary Tube 13x75 mm		!
10	9640000254		Patient	Unknown	Secondary Tube 13x75 mm		!
11	9640000255		Patient	Unknown	Secondary Tube 13x75 mm		!
12	9640000256		Patient	Unknown	Secondary Tube 13x75 mm		!
13	9640000257		Patient	Unknown	Secondary Tube 13x75 mm		!
14	9640000258		Patient	Unknown	Secondary Tube 13x75 mm		!

Carrier ID: 50205854 Load Time: 05-Feb-20 10:59 AM

- Empty Position
- Specimen Loaded
- Specimen Processing
- Specimen Processed

- Specimen Halted
- Specimen Error
- Specimen Warning
- Specimen Querying LIS

- Reflex
- Rerun
- Repeat

Set Tubes
Carrier Errors: !
↓
Close

Samples Loaded: 32

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---:--

Estimated Completion Time: ---:--

SYSTEM STATUS:
 These carriers have loading errors requiring user intervention: Specimens 1

Application
⏸
⏹⚠
📷
?
05-Feb-20 10:59 AM

NeuMoDx Molecular System

Assigning a Test

Edit Specimen : Position 1

Specimen ID: Patient ID:

Sample Specimen Type: Sample Type: Dilution Factor:

Specimen Tube Type: Specimen Tube Size:

Assay:

Result Name:






Test Specimen Type:

Result Name	Owner	STAT	Comments	Cancel

Specimen Comments

Status: No test order assigned

Tests for this sample will not start processing until changes are applied.






03/02/2020 10:23 AM

NeuMoDx Molecular System

Assigning a Test

Edit Specimen : Position 1

Specimen ID: Patient ID:

Sample Specimen Type: Sample Type: Dilution Factor:

Specimen Tube Type: Specimen Tube Size:

Assay:

Result Name:

Test Specimen Type:

Result Name	Owner	STAT	Comments	Cancel
CMV (Plasma)	MirandaApp	<input type="checkbox"/>	<input type="button" value="Comments"/>	<input type="button" value="X"/>

Specimen Comments

Enter Comments

Status: Specimen(s) Loaded

Tests for this sample will not start processing until changes are applied.

NeuMoDx molecular
03/02/2020 10:23 AM

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

Home | Test Status | Settings | Tools

General | Report | Network | Assay | Controls | Users | LIS

Site | Localization | Workflow

Apply | Cancel

- Manually Confirm Specimen Carrier Settings
- Allow Manually Entered Specimen Barcodes
- Allow Duplicate Test Orders in Import File
- Allow Patient Samples to Start at Risk
- Allow Specimen ID Generation

Samples Loaded: None | Tests In Progress: None | Estimated Walk-Away Time: ---

Test Orders Loaded: None | Tests Pending: None | Estimated Completion Time: ---

Tests Completed: None

Home | Test Status | Settings | Tools

Test Strips / Buffers | Specimen Tubes | Other Consumables | Summary

Touch Carrier to View Details

1 Pending Confirmation | 2 Not Loaded | 3 Not Loaded | 4 Not Loaded | 5 Not Loaded | 6 Not Loaded | 7 Not Loaded | 8 Not Loaded | 9 Not Loaded

Samples Loaded: 32 | Tests In Progress: None | Estimated Walk-Away Time: Now

Test Orders Loaded: 32 | Tests Pending: 32 | Estimated Completion Time: ---

Tests Completed: None

- 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

Define Tube Types for Specimens 8

<input type="checkbox"/>	Pos	Specimen ID	Tube Type
<input type="checkbox"/>	1	AUTO001884	Secondary Tube 13x75 mm
<input type="checkbox"/>	2	AUTO001885	Secondary Tube 13x75 mm
<input type="checkbox"/>	3	AUTO001886	Secondary Tube 13x75 mm
<input type="checkbox"/>	4	AUTO001887	Secondary Tube 13x75 mm
<input type="checkbox"/>	5	AUTO001888	Secondary Tube 13x75 mm
<input type="checkbox"/>	6	AUTO001889	Secondary Tube 13x75 mm
<input type="checkbox"/>	7	AUTO001890	Secondary Tube 13x75 mm
<input type="checkbox"/>	8	AUTO001891	Secondary Tube 13x75 mm
<input type="checkbox"/>	9	AUTO001892	Secondary Tube 13x75 mm
<input type="checkbox"/>	10	AUTO001893	Secondary Tube 13x75 mm
<input type="checkbox"/>	11	AUTO001894	Secondary Tube 13x75 mm
<input type="checkbox"/>	12	AUTO001895	Secondary Tube 13x75 mm
<input type="checkbox"/>	13	N/A	N/A
<input type="checkbox"/>	14	N/A	N/A

Instructions:

1. Select the specimens to change on the left
2. Select the Tube Type
3. Select the Tube Size
4. Click on Apply to change the specimens
5. Repeat as necessary
6. Click Save below to make the changes and return to carrier view, otherwise click Cancel

Total samples selected for change: 0

Tube Type:
Plasma/Serum Tube ▼

Tube Size:
13x75 mm ▼

Apply

Confirming Sample Processing

Home
Test Status
Settings
Tools

Test Strips / Buffers
Specimen Tubes
Other Consumables
Summary

Specimens 1 Carrier Details

Touch Patient Specimen to View Details

Specimen ID	Patient ID	Test Order(s)	Sample Type	Specimen	Specimen Tube	Open Life	Errors
1	00000000000000000001	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
2	00000000000000000002	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
3	00000000000000000003	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
4	00000000000000000004	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
5	00000000000000000005	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
6	00000000000000000006	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
7	00000000000000000007	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
8	00000000000000000008	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
9	00000000000000000009	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
10	00000000000000000010	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
11	00000000000000000011	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
12	00000000000000000012	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
13	00000000000000000013	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
14	00000000000000000014	GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	

Carrier ID: S02000001 Load Time: 04/10/2020 1:43 PM

- Empty Position
- Specimen Loaded
- Specimen Processing
- Specimen Processed

- Specimen Halted
- Specimen Error
- Specimen Warning
- Specimen Querying LIS

- Reflex
- Rerun
- Repeat

Set Tubes

 Continue

Close

Samples Loaded:	32	Tests In Progress:	None	Estimated Walk-Away Time:	Now
Test Orders Loaded:	32	Tests Pending:	32	Estimated Completion Time:	---
		Tests Completed:	None		

Select "Continue" to begin processing the samples

Viewing and Exporting Reports



Filtering Samples

The screenshot shows the 'Completed' tab in the 'Test Status' section. The 'Filter By' button is highlighted with a red box. Below the filter buttons is a table with the following columns: Specimen ID, Patient ID, Sample Type, Result Name, Started, and Released. The table is currently empty, displaying 'No records found.'

Specimen ID	Patient ID	Sample Type	Result Name	Started	Released
No records found.					

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

Viewing Sample Results Reports

Home Test Status Settings Tools

Current Completed Pending

Filter **Report** Import Export View Curves Send to LIS

View Report Summary Report Extraction Mapping

Selected: 2 of 179

<input type="checkbox"/>	Specimen ID	Patient ID	Sample Type	Result Name	Started	Released
<input checked="" type="checkbox"/>	B91922		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	A10314		Patient	HCV	02/14/2020 3:18 PM	
<input type="checkbox"/>	C10093		Patient	HCV	02/14/2020 3:19 PM	
<input type="checkbox"/>	B91923		Patient	HCV	02/14/2020 3:19 PM	
<input type="checkbox"/>	A10315		Patient	HCV	02/14/2020 3:19 PM	
<input type="checkbox"/>	B91924		Patient	HCV	02/14/2020 3:19 PM	
<input type="checkbox"/>	A10316		Patient	HCV	02/14/2020 3:19 PM	
<input type="checkbox"/>	C10094		Patient	HCV	02/14/2020 3:19 PM	

Samples Loaded: None Tests In Progress: None Estimated Walk-Away Time: ---
 Test Orders Loaded: None Tests Pending: None Estimated Completion Time: ---
 Tests Completed: None

Sample Results Report

Specimen: B91922 02/14/2020 3:19 PM

NeuMoDx
 Sample Results Report (B91922)
 NMDX-VV
 1250 Eisenhower Pl Ann Arbor, MI

Specimen ID: B91922 Patient ID: --
 Instrument Name: N13 Instrument SN: ND00013
 Specimen Type: Plasma Software Version: 1.8.1.3
 Sample Type: Patient Specimen Tube Type: Secondary Tube 13x75 mm
 Specimen Comment: --

Overall Result Summary

Result Name	Run Reason	Overall Result	Target Results
HCV	Normal	Positive	HCV Positive

04/03/2020 7:16 PM CONFIDENTIAL Research Use Only Page 1 of 4

Send to LIS Print Export Export As Close

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

Viewing Summary Reports

Home Test Status Settings Tools

Current Completed Pending

Filter Report Import Export View Curves Send to LIS

View Report Summary Report Extraction Mapping

Selected: 8 of 179

<input type="checkbox"/>	Specimen ID	Patient ID	Sample Type	Result Name	Started	Released
<input checked="" type="checkbox"/>	B91922		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	A10314		Patient	HCV	02/14/2020 3:18 PM	
<input checked="" type="checkbox"/>	C10093		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	B91923		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	A10315		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	B91924		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	A10316		Patient	HCV	02/14/2020 3:19 PM	
<input checked="" type="checkbox"/>	C10094		Patient	HCV	02/14/2020 3:19 PM	

Samples Loaded: None Tests In Progress: None Estimated Walk-Away Time: ---:--
 Test Orders Loaded: None Tests Pending: None Estimated Completion Time: ---:--
 Tests Completed: None

Results Summary Report

NeuMoDx
NMDX-VV 1250 Eisenhower Pl Ann Arbor, MI

Instrument Name: N13 Software Version: 1.8.2.2
 Instrument SN: N00013

Filters Applied

Start Filter Date: 02/14/2020 12:00 AM End Filter Date: 06/03/2020 11:59 PM
 Assay Name: HCV Result: Positive

Results Summary

Specimen ID	Sample Type	Result Name	Started	Overall Result	Target Result	Ct	Flags
A10314	Patient	HCV	02/14/2020 3:18 PM	Positive	HCV Positive	36.18	--
B91922	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	35.21	--
C10093	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	37.51	1018
A10315	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	35.81	--
B91923	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	37.47	1018
C10094	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	37.05	1018
A10316	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	33.96	--
B91924	Patient	HCV	02/14/2020 3:19 PM	Positive	HCV Positive	36.25	--

06/03/2020 7:05 PM CONFIDENTIAL Page 1 of 1

Send to LIS Print Export Export As Export Raw Data Close

- 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



SAFETY DATA SHEET

REF 100200

SECTION 1: Identification

1.1	Product Name Product Code	NeuMoDx™ Extraction Plate 100200
1.2.	Relevant identified use	For <i>In Vitro</i> 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).

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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 probes) 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 <i>Dried magnetic affinity microspheres, lytic enzymes, and sample process controls</i>
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.

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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

Customer Care email: customercare-us@qiagen.com

Technical Services:

Phone: +1-800-362-7737

Email: techservice-na@qiagen.com

Questions?

