

Part I



# NeuMoDx 96 Molecular System – Operator Training

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Powerful. Simple. Diagnostics.™



# 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<sup>™</sup> 96 Molecular System



NeuMoDx<sup>™</sup> 288 Molecular System

# Visit Objectives

- Be able to successfully place reagents and consumables in correct carriers and locations on both instruments
- Navigate NeuMoDx<sup>™</sup> 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

# 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

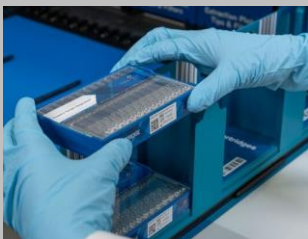
# The Concept

- 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

# NeuMoDx Molecular Systems offer Industry Best Workflow

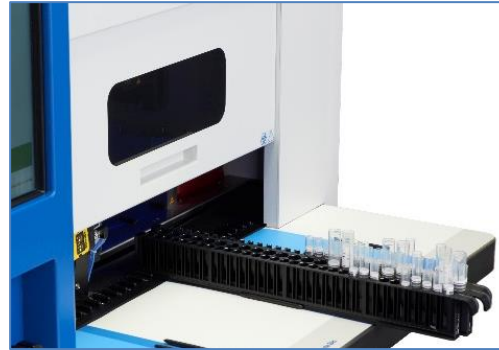
## STEP 1\*

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).*

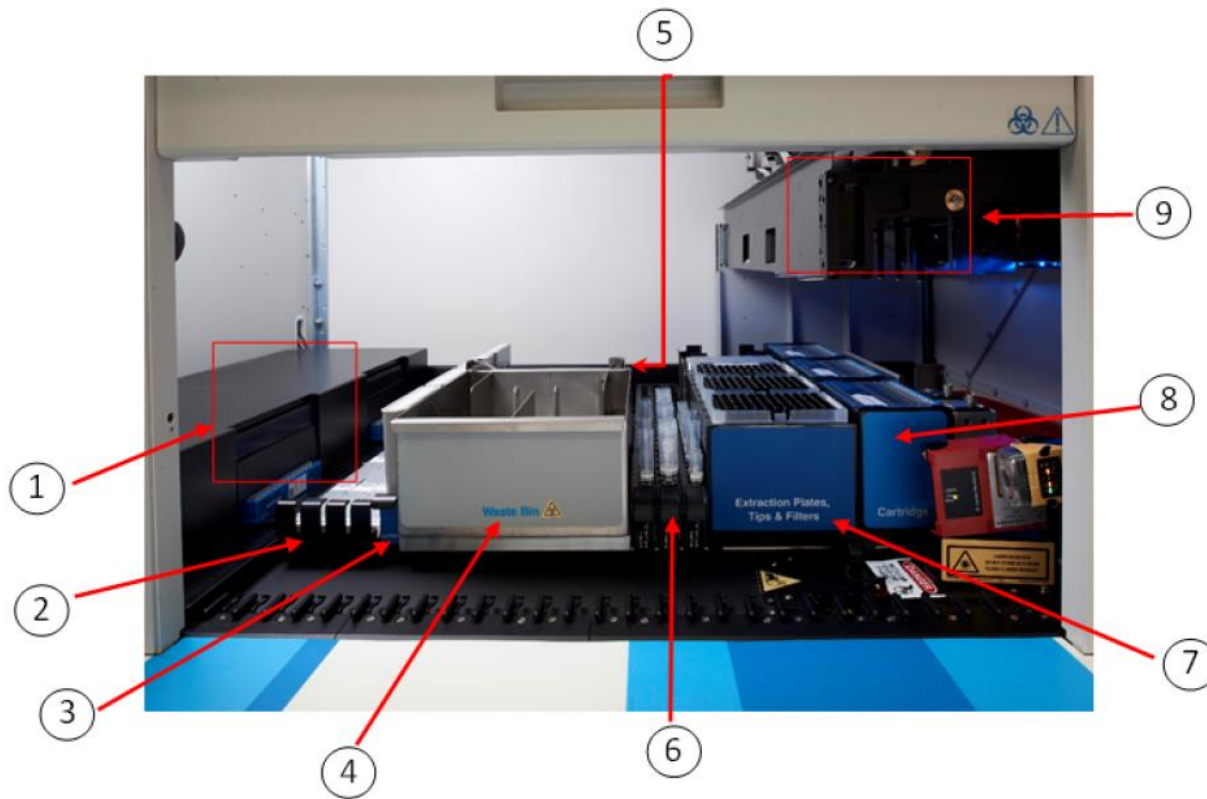


# NeuMoDx™ 96 Molecular System - instrument description



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

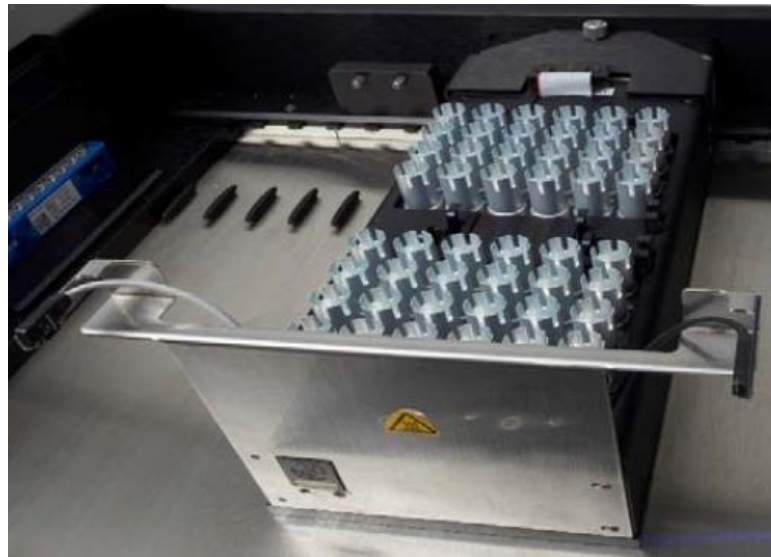


②

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



- Fully automated steps
  - Operator interacts with specimen and NeuMoDx Software (GUI)
  - Instrument does automated:
    - Sample pickup from specimens
    - Combination with lysis buffer for lysis step
    - Extraction and purification of nucleic acids
    - Real-Time PCR and results
    - On-board reagent and consumable inventory
- Sample process control (Internal Control) is co-extracted with every extraction
  - It is part of the *extraction plate*
  - SPC1 for DNA and SPC2 for RNA specimens

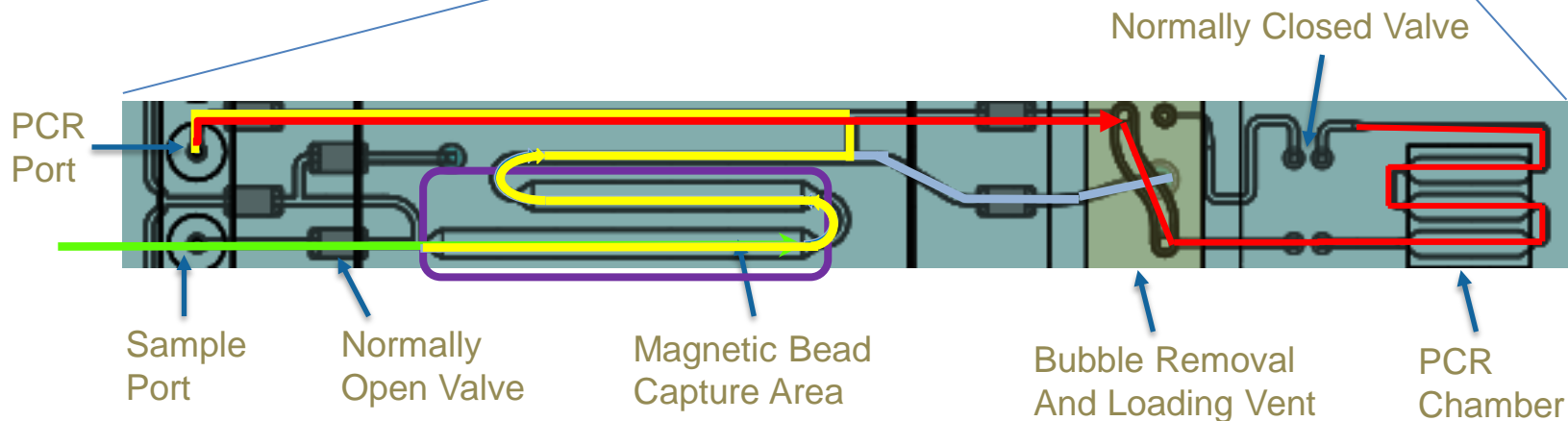
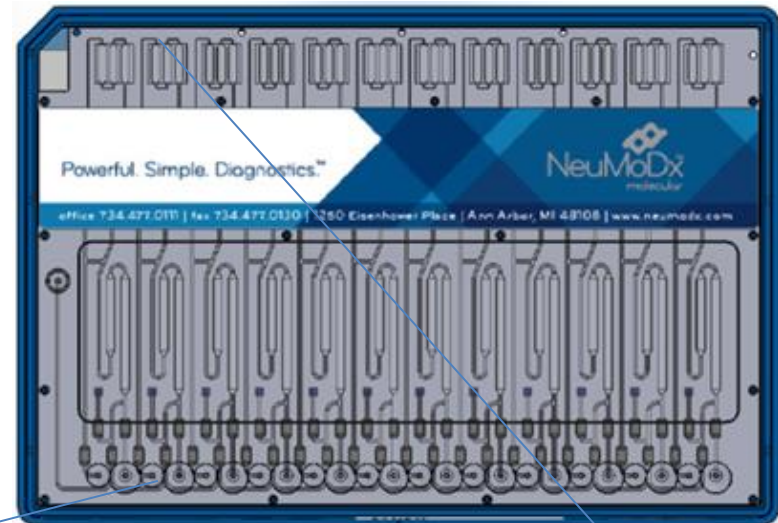
- Two main components of patented technology fuels the sample-to-result system
- (1) NeuDry<sup>™</sup> Chemistry
  - Room-temperature stable, dried reagents require no re-hydration by the operator
- (2) Microfluidic Cartridge
  - All extraction and PCR is executed within the Microfluidic Cartridge
  - Not batched, so each lane can process a different sample



# 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



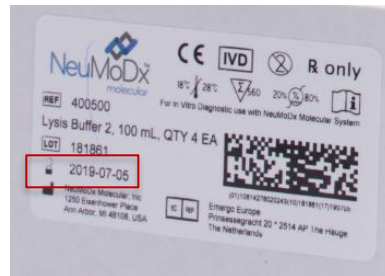
Part II



# 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  $\mu$ L with Filters (1000  $\mu$ L tips)
- CO-RE Tips 300  $\mu$ L with Filters (300  $\mu$ L tips)
- NeuMoDx™ Cartridge

Consumables

- NeuMoDx™ Priming Waste Bottle (reusable)
- Biohazardous Waste Containers
- NeuMoDx™ Biohazardous Waste Bag
- NeuMoDx™ 96 Biohazard Tip Waste Bag

Waste Containers

# Reagents & Consumables

## For your information



Powerful. Simple. Diagnostics.™

### 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™ 96 Biohazard Tip Waste Bag	1050 tips per bag	25 bags per box
NeuMoDx™ Tip Tray	N/A	12 per box

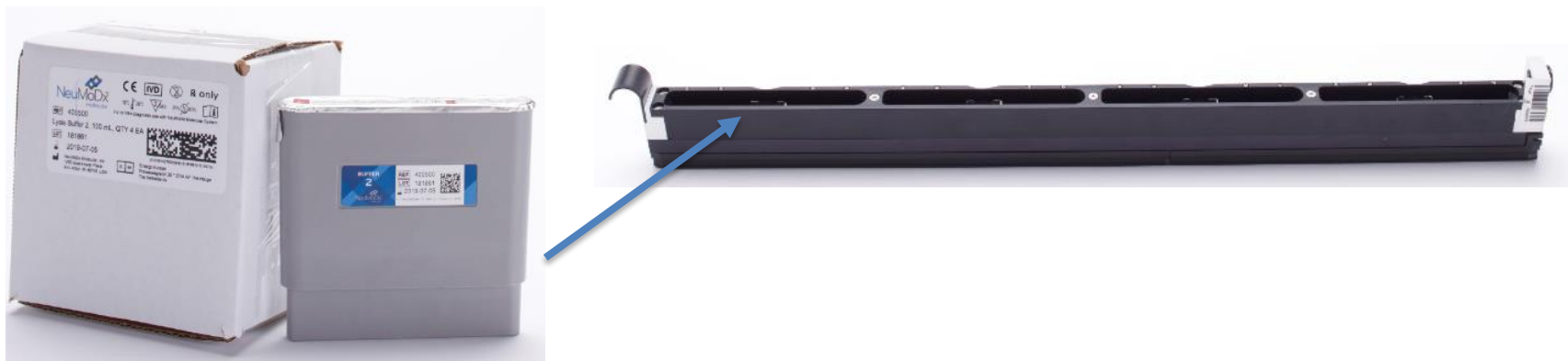
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# Reagents & Consumables

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

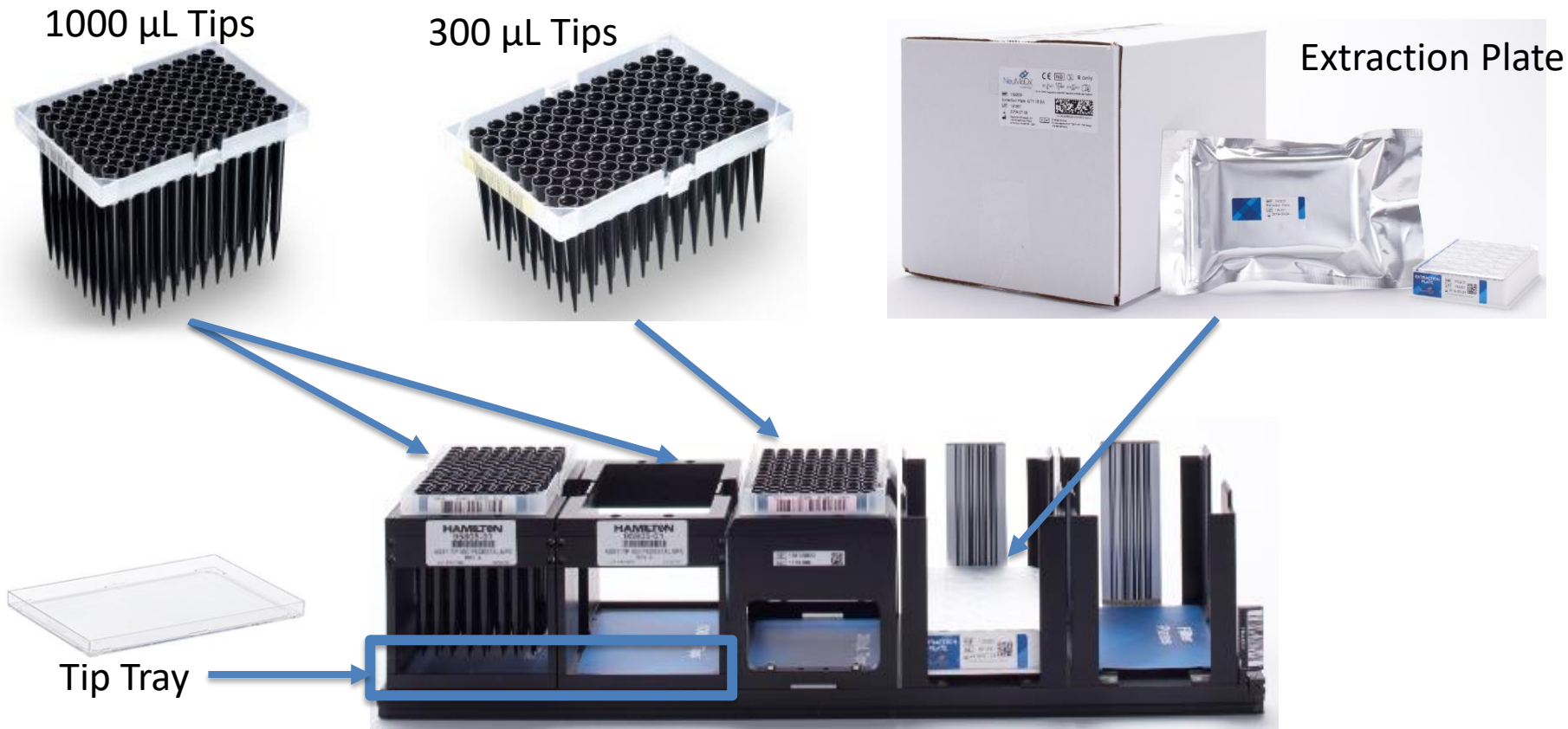


- NeuMoDx Lysis Buffer goes in the Buffer Carrier (up to 4 per carrier)  
***NOTE: remove the foil before loading into carrier***



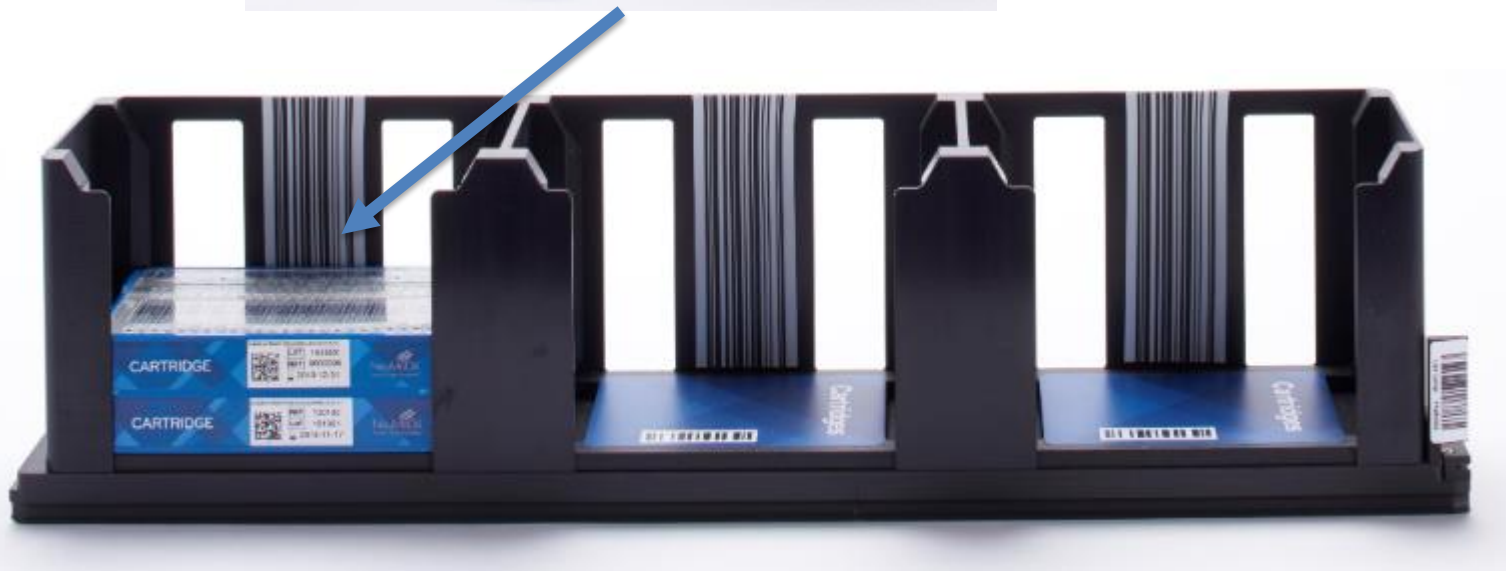
# Reagents & Consumables

- NeuMoDx Extraction Plate (up to 4 per carrier), CO-RE Tips 1000  $\mu$ L Tips (2 racks per carrier), 300  $\mu$ 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

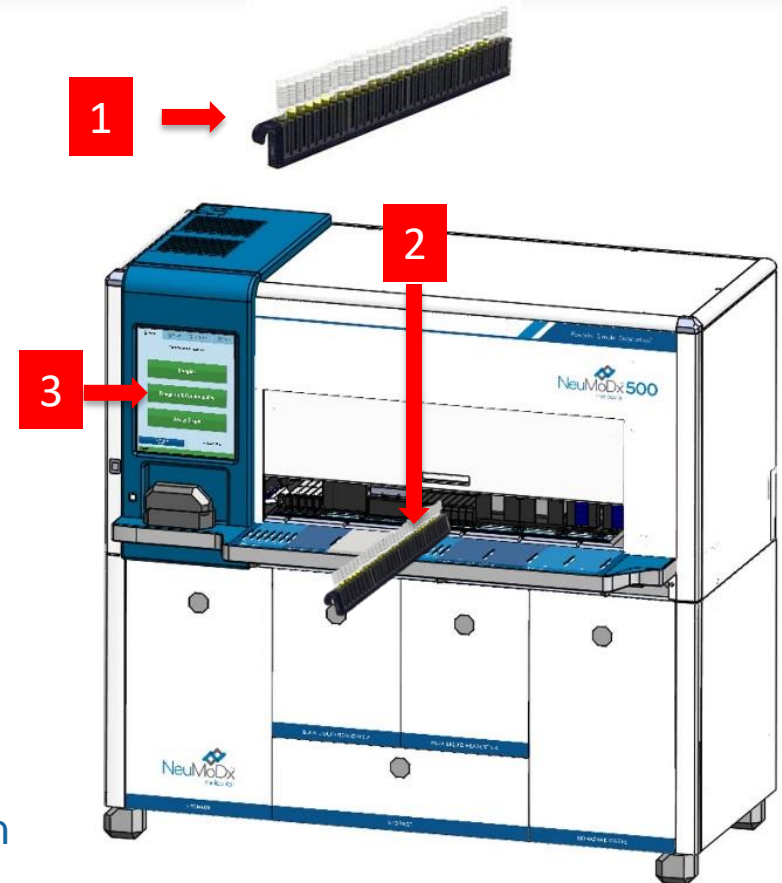


# System Operation & Workflow

# 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.\*

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

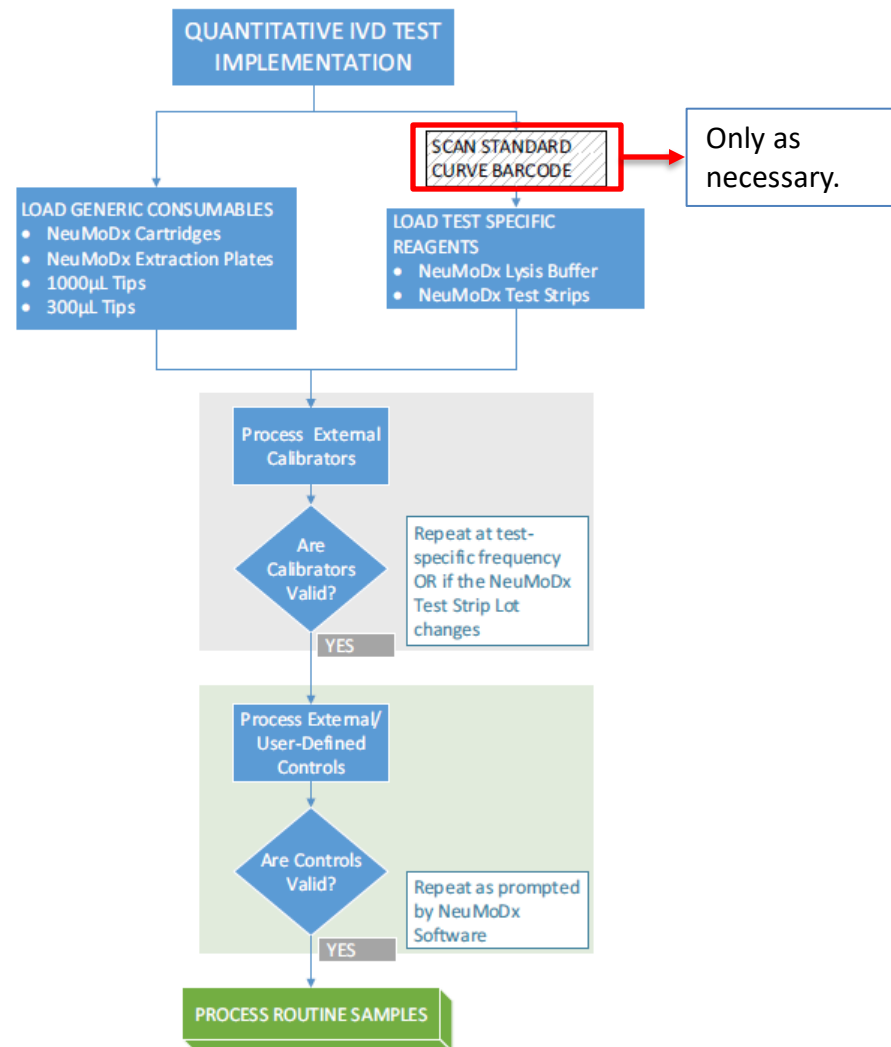
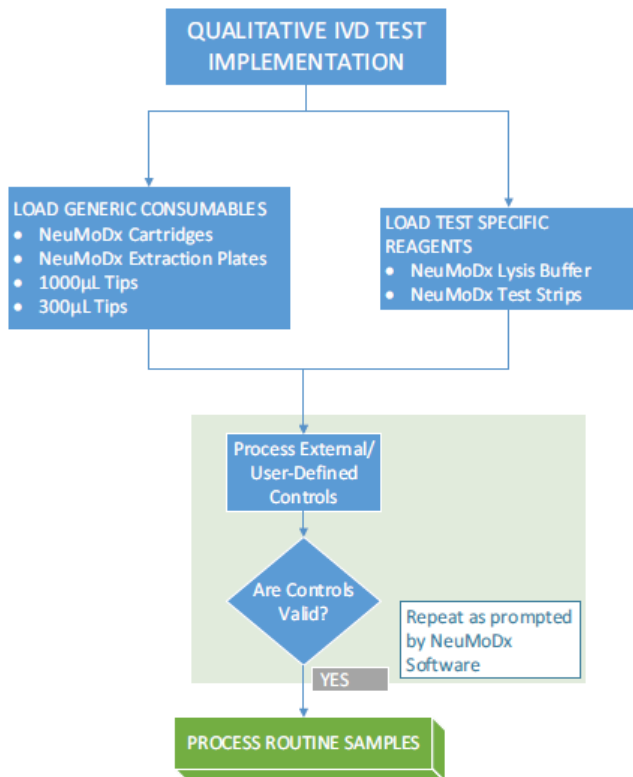


So long as the system has sufficient consumables to complete the testing, the results will be available without further operator interaction.

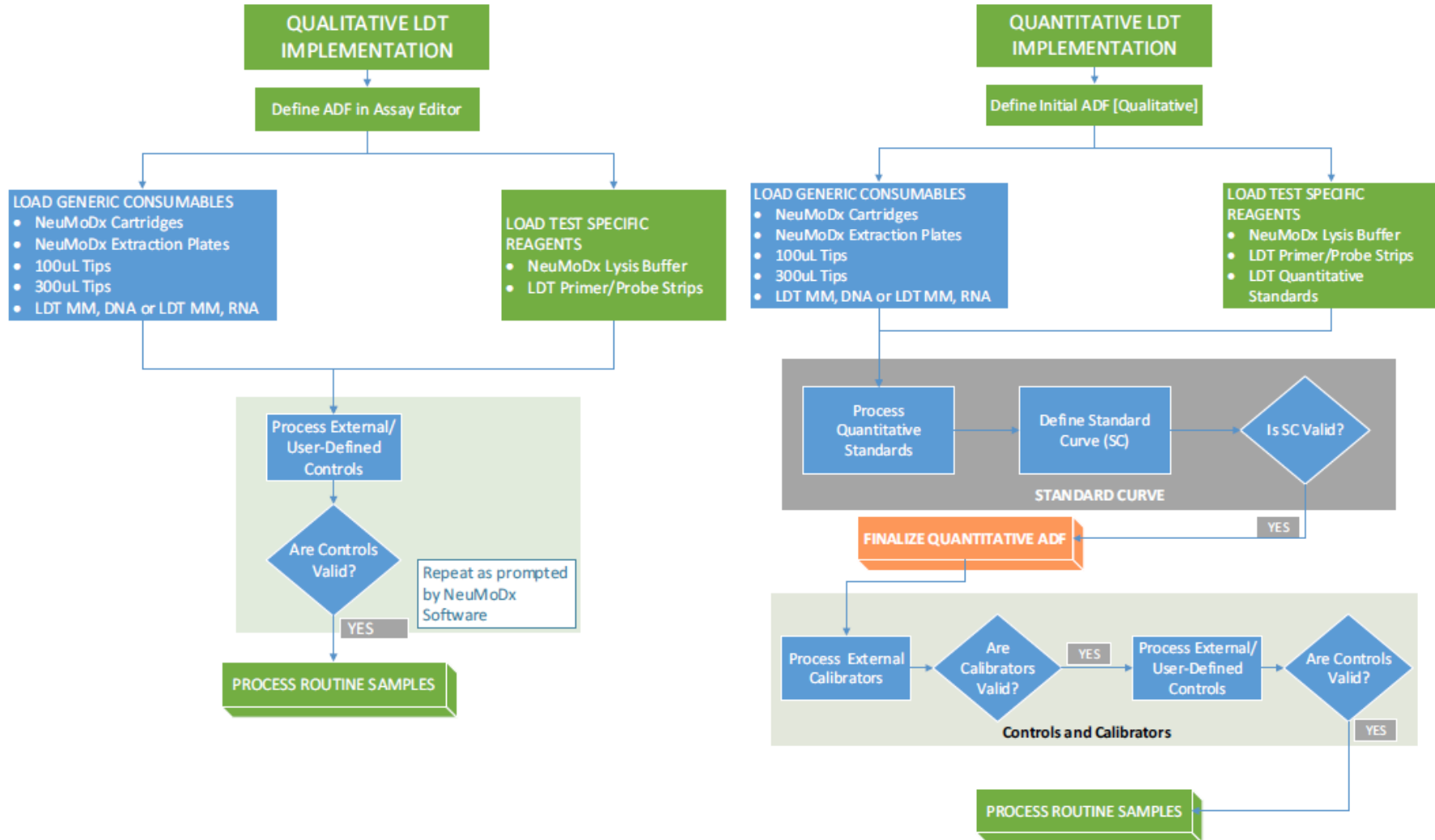
NOTE: Instrument shown is N288, but overall operation is the same.

# IVD Workflow

\*Note: Mostly applicable to outside US



# LDT Workflow



# Assay Definition Files

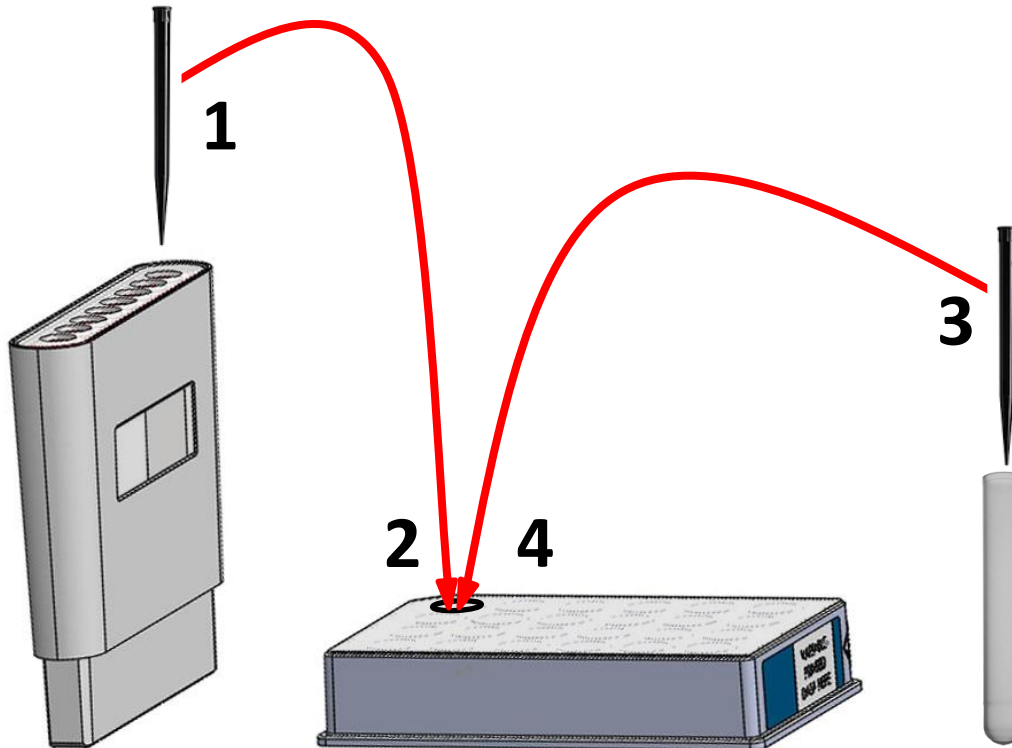
- Assay Definition Files (ADFs) for IVD tests are provided and controlled by NeuMoDx
- Some LDT templates are available as a starting point for laboratories interested in LDT applications
- Contains all the Assay-specific extraction, PCR, and results processing parameters
  - Can be qualitative or quantitative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

# 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 control occurs in the PCR regions of the cartridge.

# Key Processing Steps LHPA



## No. 1 = LHPA

**Samples are mixed with buffer in the Extraction Plate**

1. Aspirate Buffer from Buffer Carrier.  
This tip is placed back into the tip 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.

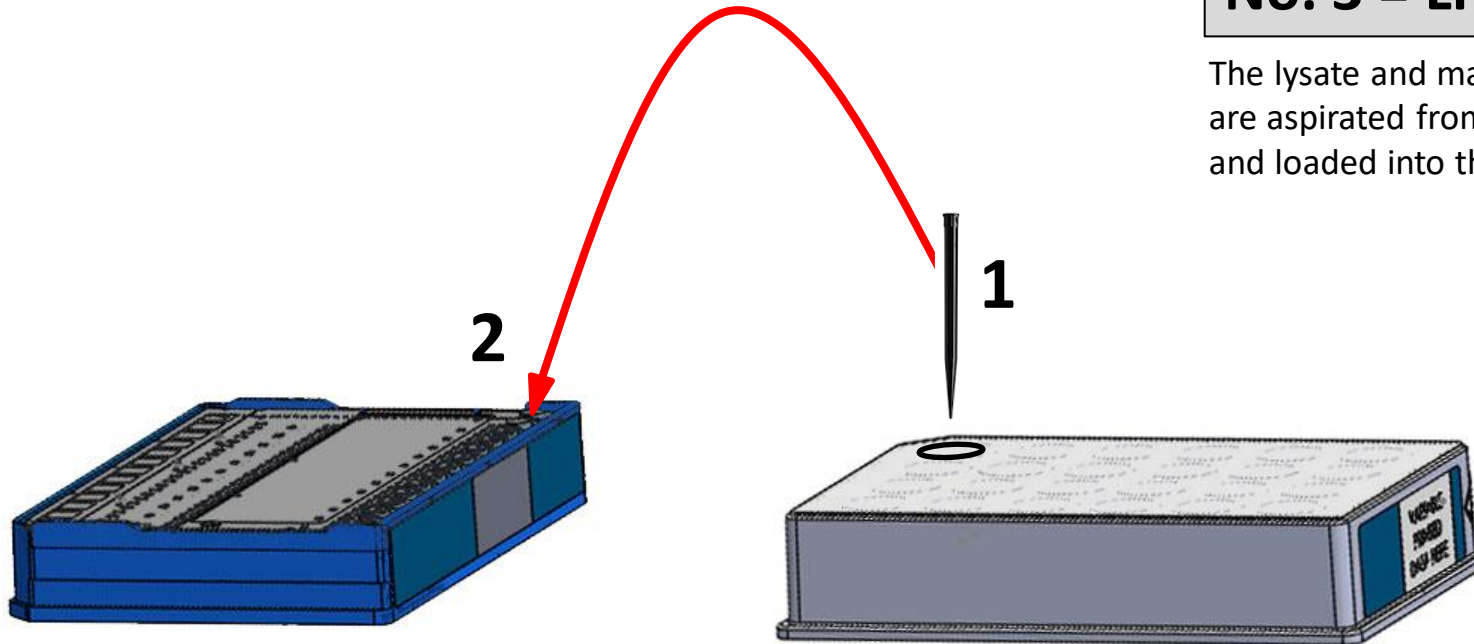
## No. 2 = Lysis/Binding



# 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

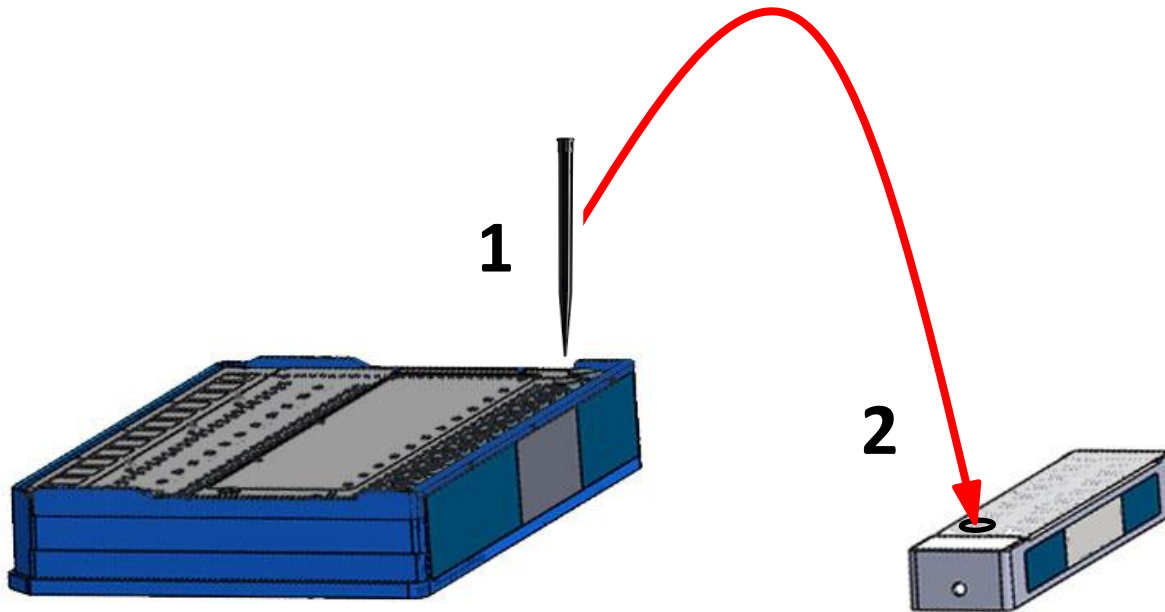
1. Aspirate sample from Extraction Plate with the tip that was used for aspirating buffer.
2. Dispense sample into Cartridge.  
Tip is discarded, XPCR Extraction begins.

# Key Processing Steps LHPC

## No. 5 = LHPC

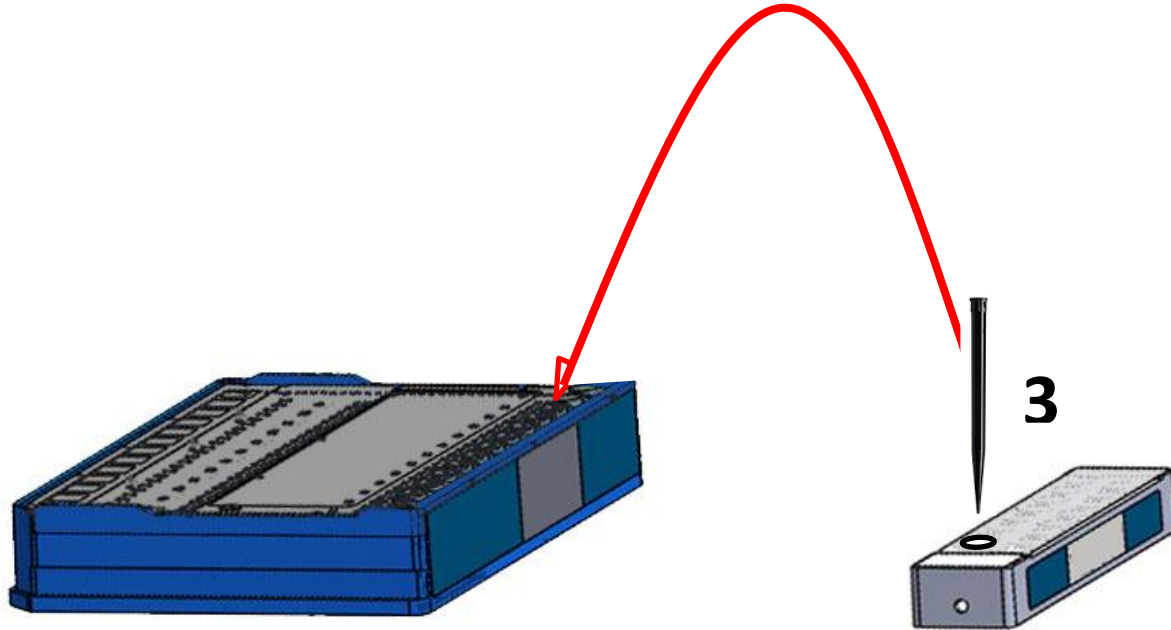
Eluate is mixed with dried PCR reagents in the test strip, then transferred back to the cartridge.

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

# 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


- 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

Part III



# NeuMoDx Software Guide

NeuMoDx 96 Software Screen  
BioMed Level User



User Name:

BioMed

Password:

Login Change Password...

NeuMoDx 96 Software Screen  
BioMed Level User

Test Strips /  
Buffers

Specimen  
Tubes

Other  
Consumables

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

**SYSTEM STATUS:**

Load specimens to start

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

Test Strip	Test Strip	Not Loaded	Not Loaded	Empty
Test Strip	Test Strip			Lysis Buffer 2
CTNG	Test Strip			Empty
CTNG	Test Strip			Empty
Test Strip	Test Strip			Empty
<b>Test Strips 1</b>	<b>Test Strips 2</b>	<b>Test Strips 3</b>	<b>Test Strips 4</b>	<b>Buffers 1</b>
↓	↓	↑	↑	↓

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

**SYSTEM STATUS:**

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User



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
- CTNG
- Test Strip

9	00059	103152	03/30/2021	13 Day(s)
0	00475	191901	07/09/2020	

Carrier ID: SR160465



Load Time: 07/07/2020 12:11 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		

SYSTEM STATUS:

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

Not Loaded

Not Loaded

Not Loaded

1

2

3



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

NeuMoDx 96 Software Screen  
BioMed Level User

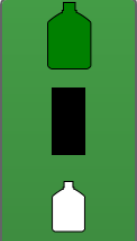





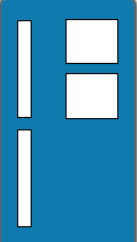
Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

 <p><b>Reagents</b></p> 	<p>Filter Plate</p> <p>Extraction Plate</p> <p>300uL Tips</p> <p>1000uL Tips</p> <p>1000uL Tips</p> <p><b>Tips Extraction Filter Plates 1</b></p> 	<p>Cartridge</p> <p>Cartridge</p> <p>Cartridge</p> <p><b>Cartridges 1</b></p> 	 <p><b>Biohazard Tip Waste Bin</b></p>   <p><b>Module Consumables</b></p>
--	--	---	--

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

**SYSTEM STATUS:**

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User

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)	Replace Prime
172	00018	101719	01/16/2022	53 Day(s)	Replace Prime

 Priming Waste  
 Release  
 Wash  
**Reagents**

Bottle Set Primes

Full Prime

Daily Prime



OK

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

NeuMoDx 96 Software Screen  
BioMed Level User

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Remaining Tests

Last Emptied



Extraction Plates

24

07/06/2020 12:27 PM



Tips

206

07/02/2020 5:29 PM



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:

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

	#	Available	Serial #	Lot #	Expiration Date	Open-Life	Load Time
Cartridges in XPCR Modules	1	0	01221	100061	10/16/2021	N/A	07/07/2020 12:15 PM
	2	0	01228	100061	10/16/2021	N/A	07/07/2020 12:14 PM

Extraction Plates in Modules	1	0	--	--	--	--	
	2	0	--	--	--	--	

OK

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

NeuMoDx 96 Software Screen  
BioMed Level User

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

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			
FLU A-B-RSV	0	0	<b>Liquid Reagents</b>	<b>A</b>	
GBS	0	0	Wash	✓ 172	
HBV	0	0	Release	✓ 747	
.....			Priming Waste	✓ 1457	
			<b>Waste</b>	<b>Needed</b>	<b>Remaining</b>
<b>Buffers</b>	<b>Needed</b>	<b>Remaining</b>	Tips	0	206
Lysis Buffer 1	0	0	Extraction Plates	0	24
Lysis Buffer 2	0	49	Cartridges	0	120
Lysis Buffer 3	0	0			
Lysis Buffer 4	0	0			

NeuMoDx 96 Software Screen  
BioMed Level User

Lysis Buffers are in mL

2 tips/test; ~71 tests

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

SYSTEM STATUS:

Weekly Maintenance is required

Current

Completed

Pending

Filter By

Clear Filter

Edit

View Curves

<input type="checkbox"/>	Specimen ID	Patient ID	Stage	Result Name	Started	Est. Complete
--------------------------	-------------	------------	-------	-------------	---------	---------------

No records found.

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

NeuMoDx 96 Software Screen  
BioMed Level User



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    Tests In Progress: 24    Estimated Walk-Away Time: ---  
 Test Orders Loaded: 96    Tests Pending: None    Estimated Completion Time: 8:25 PM  
 Tests Completed: 72

SYSTEM STATUS:

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User

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

Current

Completed

Pending

Filter By

Clear Filter

Import

Download

Create

Delete

<input type="checkbox"/>	Specimen ID	Result Name	Patient ID	Created	Specimen	Tube Type
--------------------------	-------------	-------------	------------	---------	----------	-----------

No records found.

Create individual test order

Download from:  
- LIS

Import excel from:  
- USB  
- Network

NeuMoDx 96 Software Screen  
BioMed Level User

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

**Site**      Localization      Workflow

**Site Information**
Apply   Cancel

Version: 1.8.1.1      Install Date: 29-Jan-20

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		

**Site**      Localization      Workflow

Apply   Cancel

**Localization**

Language:

Date Format:

Time Format:

Market:

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		



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:

N11

Samples Loaded:

24

Tests In Progress:

8

Estimated Walk-Away

--:--

Test Orders Loaded:

48

Tests Pending:

40

Estimated Completion

4:21 PM

Tests Completed:

None

Time:

SYSTEM STATUS:

Samples are processing



Biomed



NeuMoDx 96 Software Screen  
BioMed Level User



Home



Test Status



Settings



Tools



Powerful. Simple. Diagnostics.™

General

Report

Network

Assay

Controls

Users

LIS

### Report Printing

Default Printer:

Canon LBP151 UFR II LT

Paper Size:

Letter

Apply

Cancel

### Report Export

Default Export Type:

pdf

Auto Print Report

Default Output Path:

Enter Path

Browse

### Raw Data Export

Default Output Path:

Enter Path

Browse

### Troubleshooting Output Path

Default Output Path:

P:\V&V\Troubleshooting Packages\N96-4

Browse

### Screen Capture Output Path

Default Output Path:

P:\V&V\Screen Captures\96-4

Auto Print Screen Capture

Browse

### View Results

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		

### SYSTEM STATUS:

Weekly Maintenance is required in 2 Hour(s)

NeuMoDx 96 Software Screen  
BioMed Level User

Application



31-Jan-20 11:36 AM

CONFIDENTIAL

General

Report

Network

Assay

Controls

Users

LIS

Remote Access

Enable Remote Access

Apply

Cancel

Network Shares

Drive Letter	Share Location	Username
V:\	\\hyperv2\IV&V Archive\	neumodx\VVTest
P:\	\\fserver\Systems Development\	neumodx\VVTest

Add

Remove

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		

SYSTEM STATUS:

Weekly Maintenance is required in 2 Hour(s)

NeuMoDx 96 Software Screen  
BioMed Level User

General

Report

Network

Assay

Controls

Users

LIS

Reflex Settings

Standard Curves

Import...

Active Only

Current

Archived

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
HPV16/18/31/33/35/39/45	4.0.1	<input type="checkbox"/>	Include Graphs, Include Ct	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

Application



NeuMoDx 96 Software Screen  
BioMed Level User



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 these are filters for Active Only, Current, and Archived. A central modal window titled "Active Assay Settings: CTNG" is open, showing the following settings:

- Include Graphs
- Include Ct
- Rerun
- Repeat

Below the Repeat setting, there is a dropdown menu for "Rerun/Repeat Attempts:" with the value "2" selected. The dropdown list shows options 1, 2 (selected), and 3.

At the bottom of the interface, there is 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 "SYSTEM STATUS:" section with a green background, indicating "Weekly Maintenance is required in 2 Hour(s)".

The bottom of the screen shows a mobile-style navigation bar with an Application icon, a NeuMoDx molecular logo, a camera icon, a question mark icon, and the date/time "31-Jan-20 11:36 AM".

Import Mappings

QC Report

Select Assay: SARS COV-2

User-Defined Controls Settings

Apply

Cancel

Require Lot Frequency

Require Run Frequency Days: 1

Qualitative Controls

View By Lot

User-Defined Controls External Controls

Show Active Only

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

SYSTEM STATUS:

Load specimens to start

NeuMoDx 96 Software Screen  
BioMed Level User

NeuMoDx 96 Software Screen  
BioMed Level User

### QC Report

Select Assay:

HBV

SPC1

HBV

Select Target:

Select Control Type:

External Control

HBVPC

HBVNC

Select Controls:

Westgard Rules:



Select Date Range:

Date Range Type:

Custom

Start Filter Date:

01/01/2020

End Filter Date:

02/04/2020

View Report

Close

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

SYSTEM STATUS:

Weekly Maintenance is required in 2 Hour(s)

NeuMoDx 96 Software Screen  
BioMed Level User

Apply

Cancel

LIS Configuration:

None

- ✓ None
- Uni-directional
- Bi-directional

NeuMoDx 96 Software Screen  
BioMed Level User

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



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 antimalware 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 antimalware 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	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 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

Required for Sample Processing

Last Performed: 31-Jan-20 2:30 PM

Weekly Maintenance

### Access Service Door

Access Service Door

### Instrument Maintenance

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

Instrument Maintenance

### Preventative Maintenance

Last Performed: 13-Jan-20 3:39 PM

Next Due: 31-Jul-20 3:39 PM

Log Maintenance

### 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



NeuMoDx 96 Software Screen  
BioMed Level User

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	<a href="#">Service</a>
2	V85	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	<a href="#">Service</a>
3	V92	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	<a href="#">Service</a>
4	V102	App: 0.35.3, Bolo: 1.9.0	App: 0.57.1, Bolo: 1.9.0	Ready	12	<a href="#">Service</a>

[Housekeeping](#)

[Update Firmware](#)

[Perform Calibration](#)

NeuMoDx 96 Software Screen  
BioMed Level User

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





Home



Test Status



Settings



Tools



Powerful. Simple. Diagnostics.™

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	<a href="#">Service</a>
2	C8	App: 0.15.2, Bolo: 1.9.0	Ready	24	<a href="#">Service</a>
3	C9	App: 0.15.2, Bolo: 1.9.0	Ready	24	<a href="#">Service</a>
4	C9	App: 0.15.2, Bolo: 1.9.0	Ready	24	<a href="#">Service</a>

[Housekeeping](#)

[Update Firmware](#)

NeuMoDx 96 Software Screen  
BioMed Level User

Samples Loaded:	5	Tests In Progress:	5	Estimated Walk-Away Time:	--:--
Test Orders Loaded:	5	Tests Pending:	None	Estimated Completion Time:	9:51 AM
		Tests Completed:	None		

**SYSTEM STATUS:**

Weekly Maintenance is required



Application



01/29/2020 9:11 AM

CONFIDENTIAL

System Events

Maintenance

Database

Support

Assay

Automatic Database Backup:

Apply Cancel

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

Location:

Database Utilities

Backup

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

Backup

Purge

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

Purge

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

NeuMoDx 96 Software Screen  
BioMed Level User

Troubleshoot

Reports

Troubleshooting Package

Create Package

Select Date Range:

Date Range Type: Today

Start Filter Date: 03/20/2020

End Filter Date: 03/20/2020

Select Troubleshooting Package Options:

Data Export

Application Logs

Database Backup

Instrument Logs

Screen Capture Files

Sample Results Reports

System Events Reports

Raw Data Export

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

Supervisor

NeuMoDx 96 Software Screen  
BioMed Level User

### 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

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

#### Summary:

Next

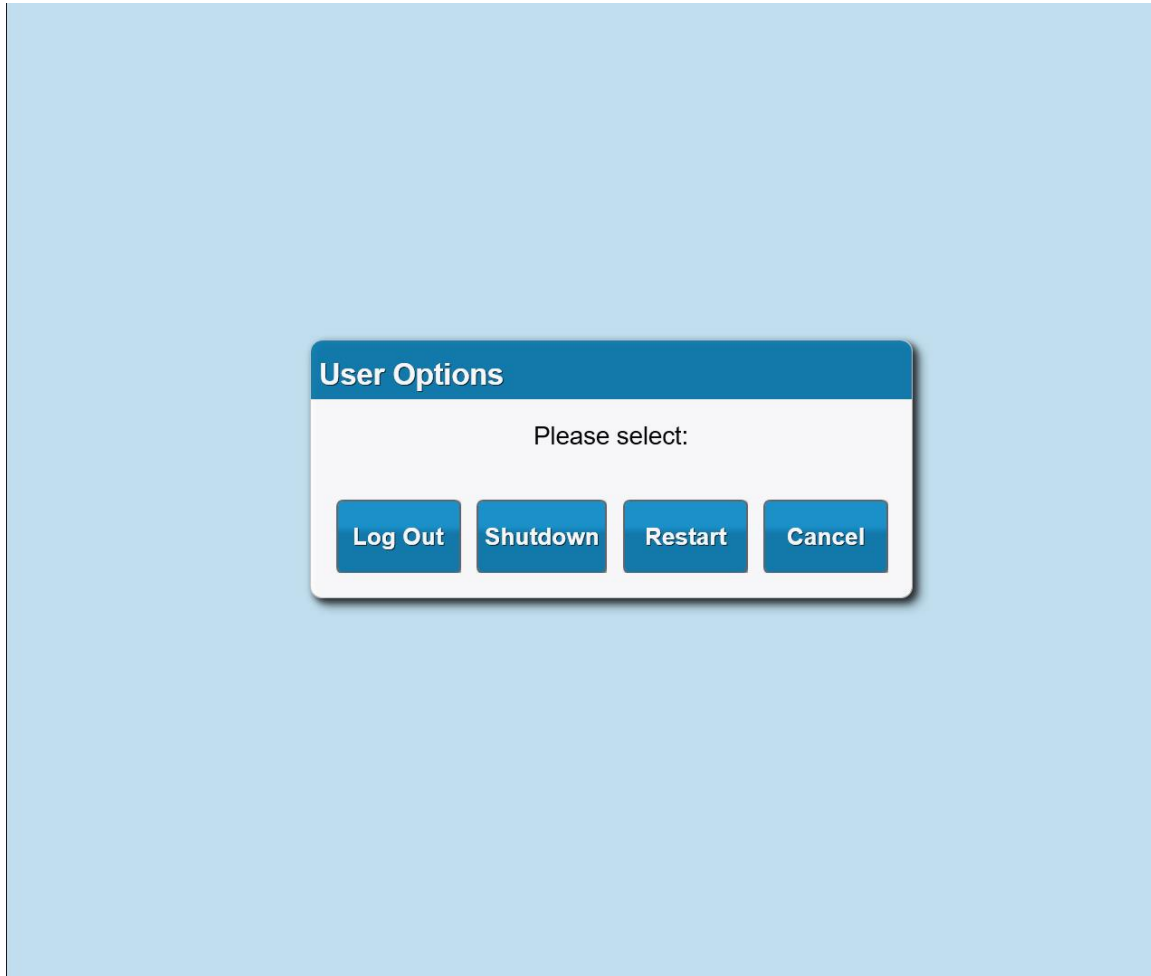
<b>Samples Loaded:</b>	None	<b>Tests In Progress:</b>	None	<b>Estimated Walk-Away Time:</b>	---
<b>Test Orders Loaded:</b>	None	<b>Tests Pending:</b>	None	<b>Estimated Completion Time:</b>	---
		<b>Tests Completed:</b>	None		

#### SYSTEM STATUS:

Weekly Maintenance is required

NeuMoDx 96 Software Screen  
BioMed Level User

NeuMoDx 96 Software Screen  
BioMed Level User



# 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



Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

The interface displays four vertical columns of consumables:

- Reagents:** Contains icons for a green bottle, a black strip, and a white bottle. Below these is a blue button with a white downward arrow, which is highlighted with a red border.
- Biohazard Waste Bin:** Contains a red biohazard waste bin icon. Below it is a blue button with a white downward arrow.
- Tips Extraction Filter Plates 1:** Contains three green boxes labeled "Filter Plate", "Extraction Plate", and "300uL Tips", followed by two more green boxes labeled "1000uL Tips". Below these is a blue button with a white downward arrow.
- Cartridges 1:** Contains three grey boxes labeled "Cartridge". Below these is a blue button with a white downward arrow.
- Module Consumables:** Contains a blue icon representing a module. Below it is a blue button with a white downward arrow.

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

**SYSTEM STATUS:**

Load specimens to start

Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

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

Select the bottles to change or empty in drawer B

Wash

Release

Priming Waste

Samples Loaded: None    Tests In Progress: 2    Estimated Walk-Away Time: ---  
 Test Orders Loaded: None    Tests Pending: None    Estimated Completion Time: 3:01 PM  
 Tests Completed: None

SYSTEM STATUS:

Weekly Maintenance is required



Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

Select the bottles to change or empty in drawer A



Wash



Release



Priming Waste

OK

Cancel

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

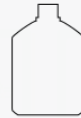
SYSTEM STATUS:

Load specimens to start





### Replace Wash Reagent Bottle



1. Open Liquid Reagent Drawer A.

Confirm

**Scan the barcode of the new Wash reagent bottle.**

2.

010081427802021510LLLLLLX21SSSSSX17YYMMDD

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



Samples

Test Ord

SYSTEM

Load specimens to start



### 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

Samples

Test Ord

SYSTEM

Load specimens to start



### 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

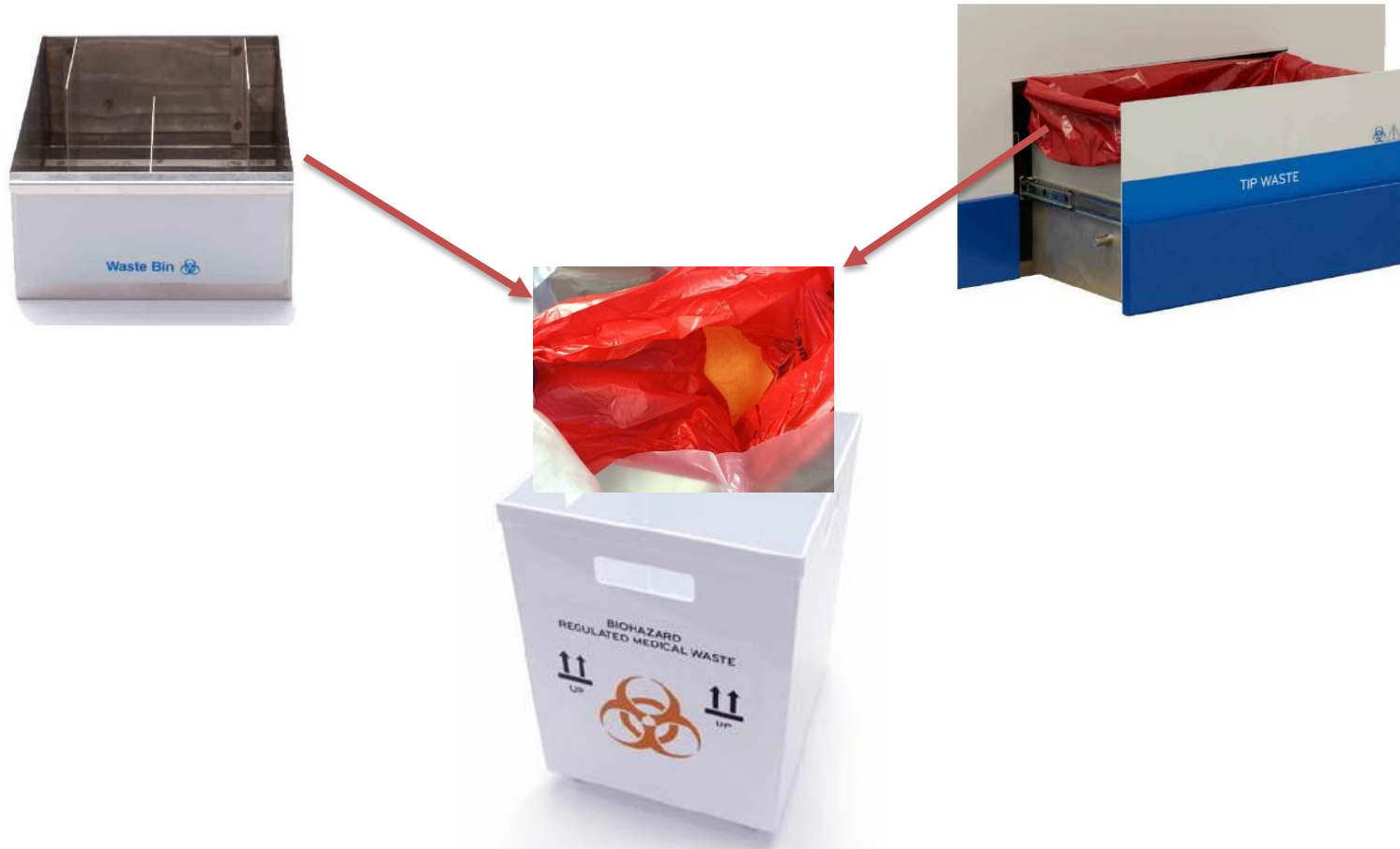


- The NeuMoDx Biohazard Tip Waste Bin is at the rear for automated disposal of tips
- Has red biohazard waste bag lining



# NeuMoDx 96 Molecular System Biohazard Waste Handling

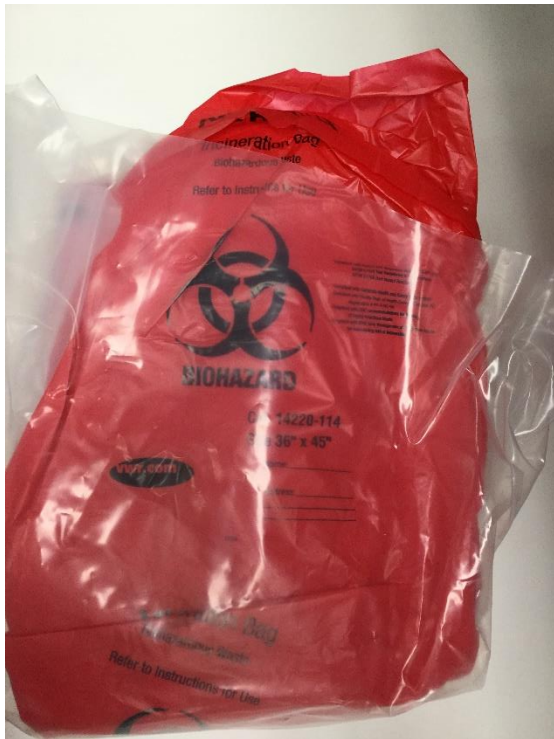
- When either waste bin is **full** as prompted by the **Software**, the waste should be emptied into a NeuMoDx Biohazard Waste Container lined with the NeuMoDx Biohazard Waste Bag



# NeuMoDx 96 Molecular System

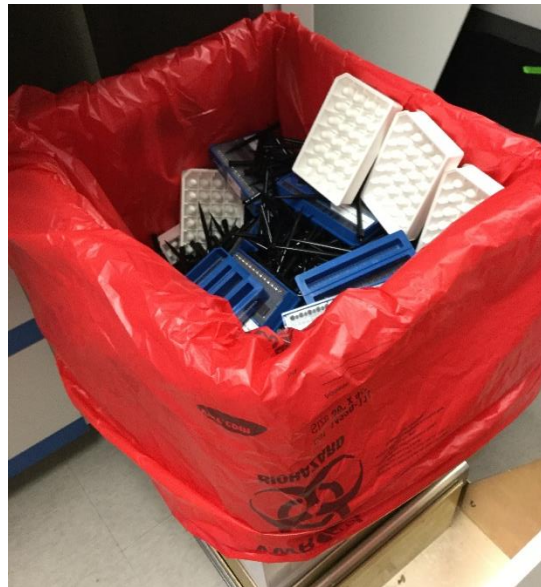
## NeuMoDx™ Biohazard Waste Bag

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

**Alert!** Software bug in v 1.8.2.4 requires a full system shutdown every 3-5 days.

## 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, 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.

Optional Press the Unload button to have the system unload all carriers on the deck. Do not manually unload the carriers.

Unload

### 1. Unlock the Service Door.

Confirm

2. *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.*

Confirm

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

Confirm

4. *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

5. *Shutdown the system*

Confirm

**Lock Service Door**

Close

Completion Time

# Weekly Cleaning & Weekly Shutdown

## Weekly Cleaning & Weekly Shutdown

Remove all carriers that are on deck with the touchscreen.

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



# Weekly Cleaning & Weekly Shutdown



2) Carefully wipe specimen tube carriers and accessible external work surfaces of the NeuMoDx Molecular Systems with a lint-free cloth saturated with **Microcide SQ**.

3) Follow the Microcide SQ cleaning with a lint-free cloth dampened with water. Set cleaned carriers aside on separate bench.





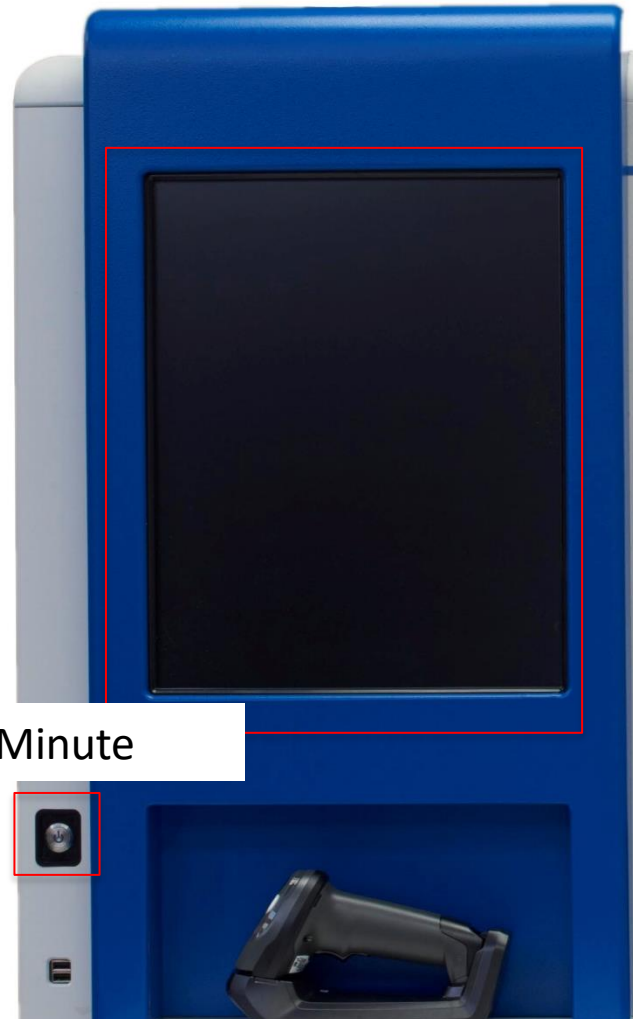
# Weekly Cleaning & Weekly Shutdown

## Weekly Cleaning & Weekly Shutdown

4) Clean the touchscreen by wiping with provided glass cleaner wipes.  
5) Shutdown the System  
Wait 1 minute after the system is shut down, then press the power button on the instrument to turn it back on.

\*Make sure to tug down firmly on the service door until you hear a click\*

Wait 1 Minute



# 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

Part IV



# NeuMoDx More Information

# 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

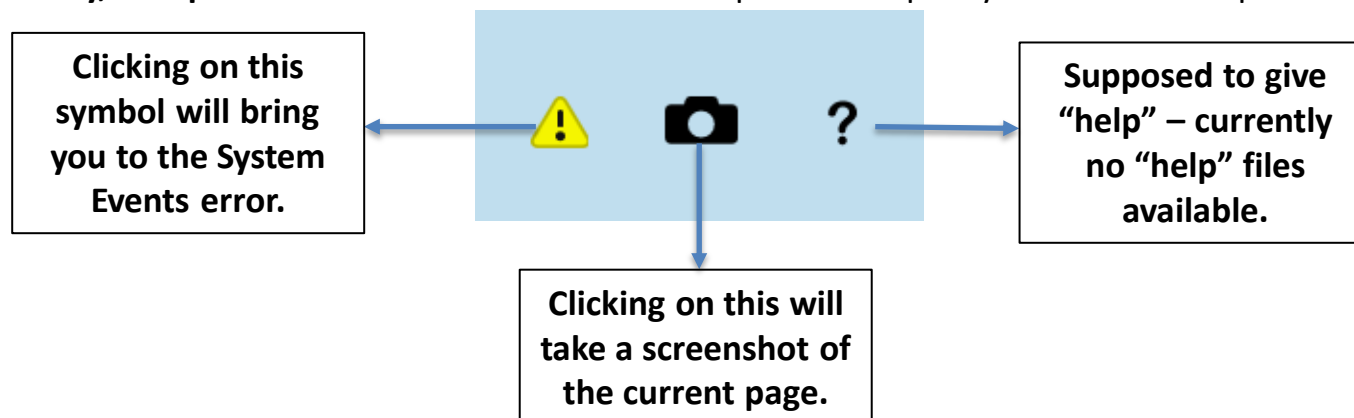
**Yellow** – system or consumable is ready to be used but may require user intervention for optimal performance

**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.

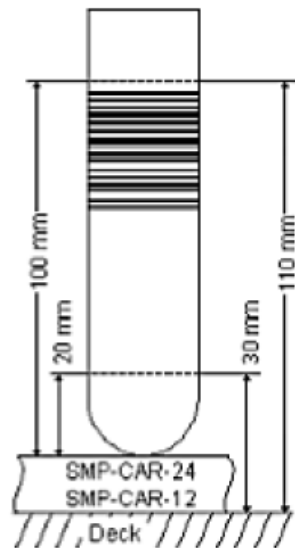




# Loading and Assigning Tests

# 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



24-Sample Carrier



32-Sample Carrier

Also a 32-Sample Carrier for Low Volume Tubes (not shown)



# 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.



- Tests may be assigned multiple ways to every sample (match barcode to the test)
  - These are instructions before the System is integrated with LIMs
- May be assigned before the sending in sample rack in with a test order, or individually after sending the sample rack in

# NeuMoDx Molecular System Assigning a Test

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

The screenshot displays the NeuMoDx Molecular System interface. At the top, there are navigation tabs: Home, Test Status, Settings, and Tools. Below these, there are three main sections: Current, Completed, and Pending. The Pending section is active, and the 'Create' button is highlighted with a red box. Below the buttons, there 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, 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, there is a yellow banner with the text: **SYSTEM STATUS:**  
Weekly Maintenance is required

At the bottom of the interface, there is a footer with the Biomed logo, the NeuMoDx molecular logo, a camera icon, a question mark, and the date/time: 03/19/2020 3:04 PM.



### Enter Test Orders

Specimen ID:

Patient ID:

Sample Specimen Type:

Specimen Tube Type:

Specimen Tube Size:

Assay:

Result Name:

Test Specimen Type:

Assay Name	Result Name	STAT

Samples  
Test Order

SYSTEM  
Weekly M



Current

Completed

Pending

Filter By

Clear Filter

Import

Download

Create

Delete

<input type="checkbox"/>	Specimen ID	Result Name	Patient ID	Created	Specimen	Tube Type
--------------------------	-------------	-------------	------------	---------	----------	-----------

No records found.

Import excel from:

- USB
- Network

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

**SYSTEM STATUS:**

Weekly Maintenance is required

# NeuMoDx Molecular System

## Assigning a Test

Home Test Status Settings Tools

### Select Test Order Import File

P:\V&V.csv Files for Interspersed Runs

Name
02.24.20 HCV 30 IU Test N11 200.90
02.24.20 HCV 30 IU Test N11.xlsx
02.24.20 HCV 30 IU Test on 96-8-LB
02.24.20 HCV 30 IU Test on N13.xlsx
02.24.20 HCV 30 IU Test on N13-LB
02.24.20 HCV 30 IU Test on N96-8.xl
02.25.20 200IUpermL EBV Evaluatio
02.25.20 200IUpermL EBV Evaluatio
02.25.20 TVMG Evaluation 96-4 Offs
02.25.20 TVMG Evaluation 96-4.xlsx

File Name: **02.24.20 HCV 30 IU Test on 96-8-LB** Excel Import file

OK Cancel

# NeuMoDx Molecular System

## Assigning a Test

- Upload test order with the “Pending Tab”
- Use the .xls Test Order template provided by NeuMoDx
  - Must have Sample ID (barcode), Test LIS code, and Specimen type filled out
  - All other entries are optional

	A	B	C	D	E	F
1	Specimen ID	Result Code	Specimen Type	Patient ID	Comment	Specimen Tube Type
2	A11111	LDT	Plasma	100	Comment1	PPTSST13x75
3	A11112	LDT	Plasma	101		PPS13x100
4	A11113	LDT	Plasma	102		PPS16x100
5	B11111	LDT2	Urine	200		
6	B11112	LDT3	Urine	201		SDT13x100
7	B11113	LDT4	Urine			LVT1
8						

# 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

# NeuMoDx Molecular System

## Assigning a Test



Powerful. Simple. Diagnostics.™

- 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






Test Strips /  
Buffers

Specimen Tubes

Other  
Consumables

Summary

Touch Carrier to View Details

Error	Not Loaded	Not Loaded
1	2	3
		

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

**SYSTEM STATUS:**

These carriers have loading errors requiring user intervention: Specimens 1

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	964000245		Patient	Unknown	Secondary Tube 13x75 mm		!
2	964000246		Patient	Unknown	Secondary Tube 13x75 mm		!
3	964000247		Patient	Unknown	Secondary Tube 13x75 mm		!
4	964000248		Patient	Unknown	Secondary Tube 13x75 mm		!
5	964000249		Patient	Unknown	Secondary Tube 13x75 mm		!
6	964000250		Patient	Unknown	Secondary Tube 13x75 mm		!
7	964000251		Patient	Unknown	Secondary Tube 13x75 mm		!
8	964000252		Patient	Unknown	Secondary Tube 13x75 mm		!
9	964000253		Patient	Unknown	Secondary Tube 13x75 mm		!
10	964000254		Patient	Unknown	Secondary Tube 13x75 mm		!
11	964000255		Patient	Unknown	Secondary Tube 13x75 mm		!
12	964000256		Patient	Unknown	Secondary Tube 13x75 mm		!
13	964000257		Patient	Unknown	Secondary Tube 13x75 mm		!
14	964000258		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



## Edit Specimen : Position 1

Specimen ID:

P12

Patient ID:

Enter Patient ID

Sample Specimen Type:

Plasma

Sample Type:

Patient

Dilution Factor:

None

Specimen Tube Type:

Secondary Tube

Specimen Tube Size:

13x75 mm

Assay:

CMV

Result Name:

CMV

Test Specimen Type:

Plasma

Add Test Order

Result Name	Owner	STAT	Comments	Cancel
-------------	-------	------	----------	--------

Specimen Comments

Enter Comments

Status: **No test order assigned**

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

Define As ...

Apply

Cancel

## Edit Specimen : Position 1

Specimen ID:

P12

Patient ID:

Enter Patient ID

Sample Specimen Type:

Plasma

Sample Type:

Patient

Dilution Factor:

None

Specimen Tube Type:

Secondary Tube

Specimen Tube Size:

13x75 mm

Assay:

CMV

Result Name:

CMV

Test Specimen Type:

Plasma

Add Test Order

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

Specimen Comments

Enter Comments





Status: **Specimen(s) Loaded**

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

Apply

Cancel

# NeuMoDx Molecular System Default Test

 Home
 Test Status
 Settings
 Tools

General
Report
Network
Assay
Controls
Users
LIS

Reflex Settings
Standard Curves
Import...

Active Only
Current
Archived

Name	Version	Default	Enabled Features	Settings
PLASMA DNA QUAL	0.1.1	<input type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>
SARS COV-2	3.0.1	<input checked="" type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>
CSF CMV QUAL	1.0.1	<input type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>
TB v2 LDT	9.0.5	<input type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>
STREP	4.0.1	<input type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>
TMC	4.0	<input type="checkbox"/>	Repeat, Include Graphs, Include Ct	<span style="background-color: #4a86e8; color: white; padding: 5px 10px; border-radius: 3px;">Edit</span>

Samples Loaded: None

Test Orders Loaded: None

Tests In Progress: None

Tests Pending: None

Tests Completed: None

Estimated Walk-Away Time: ---

Estimated Completion Time: ---

Check Default Test for specific ADF and every sample loaded will be automatically processed using this ADF

*Cons: Other Assays would also be processed using the default ADF unless pre-assigned beforehand*



# Running Primary Tubes

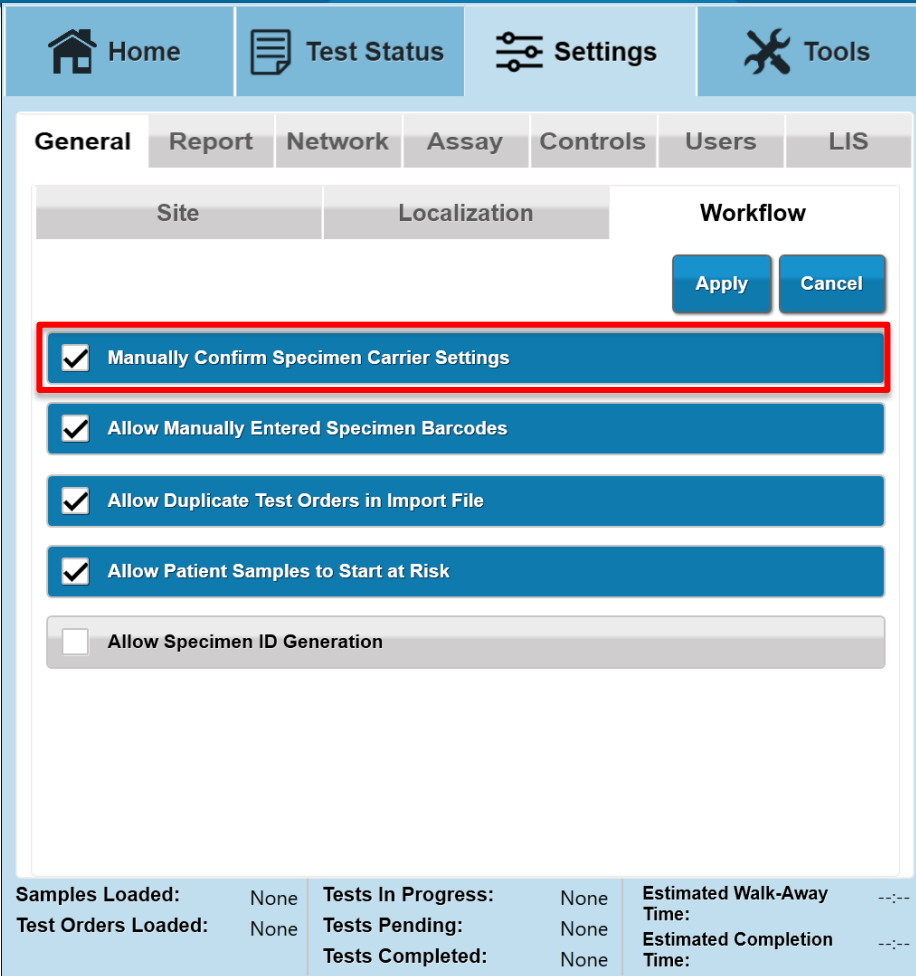
# NeuMoDx Molecular System Primary Tubes

- 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 <sup>™</sup> /SST <sup>™</sup> 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

- Must have “Manually Confirm Specimen Carrier Settings” option checked for appropriate function

# 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

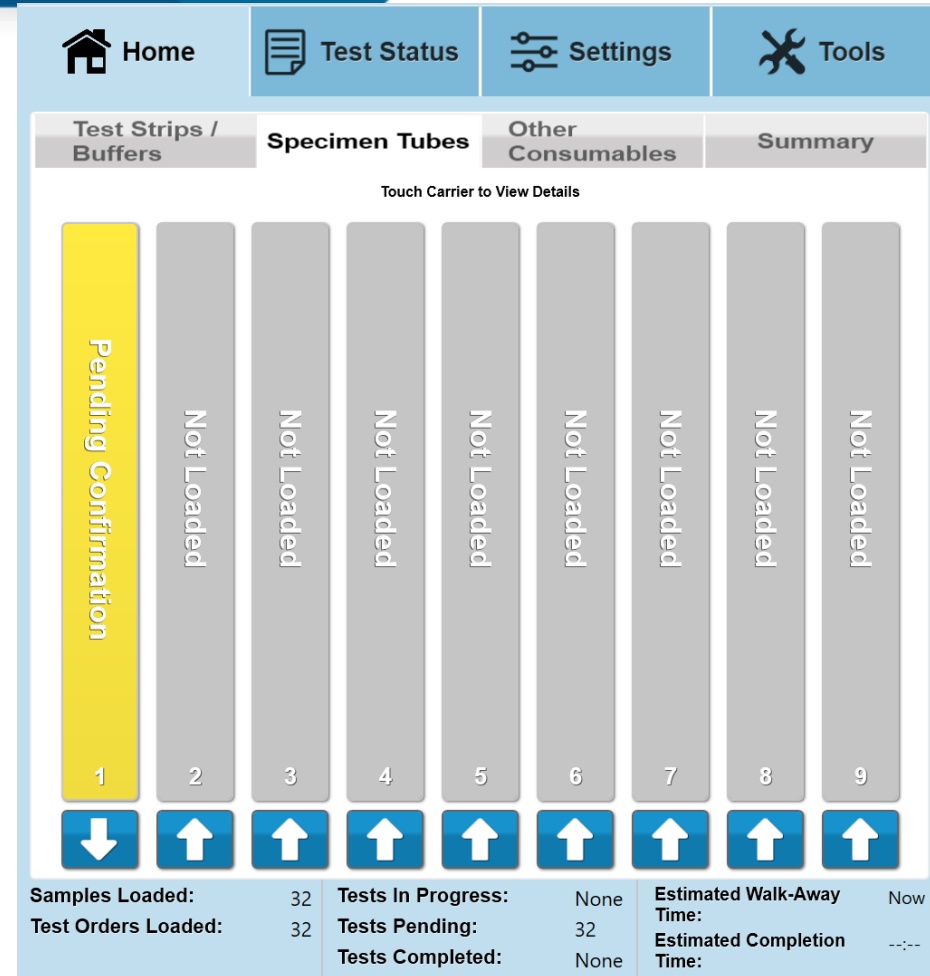
Allow Manually Entered Specimen Barcodes

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

Pending Confirmation

Not Loaded

Not Loaded

Not Loaded

Not Loaded

Not Loaded

Not Loaded

Not Loaded

Not Loaded

Not Loaded

1 2 3 4 5 6 7 8 9

↓ ↑ ↑ ↑ ↑ ↑ ↑ ↑ ↑

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



# 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 000000000000000000000001		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
2 000000000000000000000002		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
3 000000000000000000000003		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
4 000000000000000000000004		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
5 000000000000000000000005		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
6 000000000000000000000006		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
7 000000000000000000000007		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
8 000000000000000000000008		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
9 000000000000000000000009		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
10 000000000000000000000010		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
11 000000000000000000000011		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
12 000000000000000000000012		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
13 000000000000000000000013		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	
14 000000000000000000000014		GBS	Patient	Transport Medium	Secondary Tube 13x75 mm	23 Hour(s)	

Carrier ID: 502000001    Load Time: 04/10/2020 1:43 PM

- Empty Position
- Specimen Halted
- ⚡ Reflex
- Specimen Loaded
- Specimen Error
- ↺ Rerun
- Specimen Processing
- Specimen Warning
- ↺ Repeat
- Specimen Processed
- Specimen Querying LIS

Set Tubes
Continue
Close

Samples Loaded: 32

Test Orders Loaded: 32

Tests In Progress: None

Tests Pending: 32

Tests Completed: None

Estimated Walk-Away Time: Now

Estimated Completion Time: --:--

Select "Continue" to begin processing the samples

# Defining Primary Tubes

## Specimens 8 Carrier Details

Touch Patient Specimen to View Details

Specimen ID	Patient ID	Test(s)	Sample Type	Specimen	Specimen Tube	Open Life	Errors
1 AUTO001884		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
2 AUTO001885		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
3 AUTO001886		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
4 AUTO001887		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
5 AUTO001888		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
6 AUTO001889		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
7 AUTO001890		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
8 AUTO001891		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
9 AUTO001892		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
10 AUTO001893		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
11 AUTO001894		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
12 AUTO001895		HCV	Patient	Plasma	Secondary Tube 13x75 mm	Expired	!
13 EMPTY POSITION							
14 EMPTY POSITION							
15 EMPTY POSITION							

Carrier ID: S0295384  
Load Time: 03/24/2020 1:24 PM

- Empty Position
- Specimen Halted
- ⚡ Reflex
- Specimen Loaded
- Specimen Error
- 🔄 Rerun
- Specimen Processing
- Specimen Warning
- 🔄 Repeat
- Specimen Processed
- Specimen Querying LIS

Set Tubes



Continue

Close

## 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

### Summary

#### 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



# Results Interpretation

# NeuMoDx Molecular System Results Interpretation

- NeuMoDx processing algorithm will assign one of five results
- Valid results can be either Positive or Negative
- Invalid results can be either Unresolved, Indeterminate, or No Result (no internal control amplified)
  - Unresolved is typically associated with sample inhibition
    - Re-Run will re-process the sample
  - Indeterminate will have some system error flag, associated with system issue
    - Repeat will re-process the sample
  - No Result means there was an issue with the results processing algorithm in obtaining a valid result
    - Repeat will re-process the sample
  - All can be automatically re-processed *provided enough sample volume is still onboard the instrument and Re-Run & Repeat are selected*

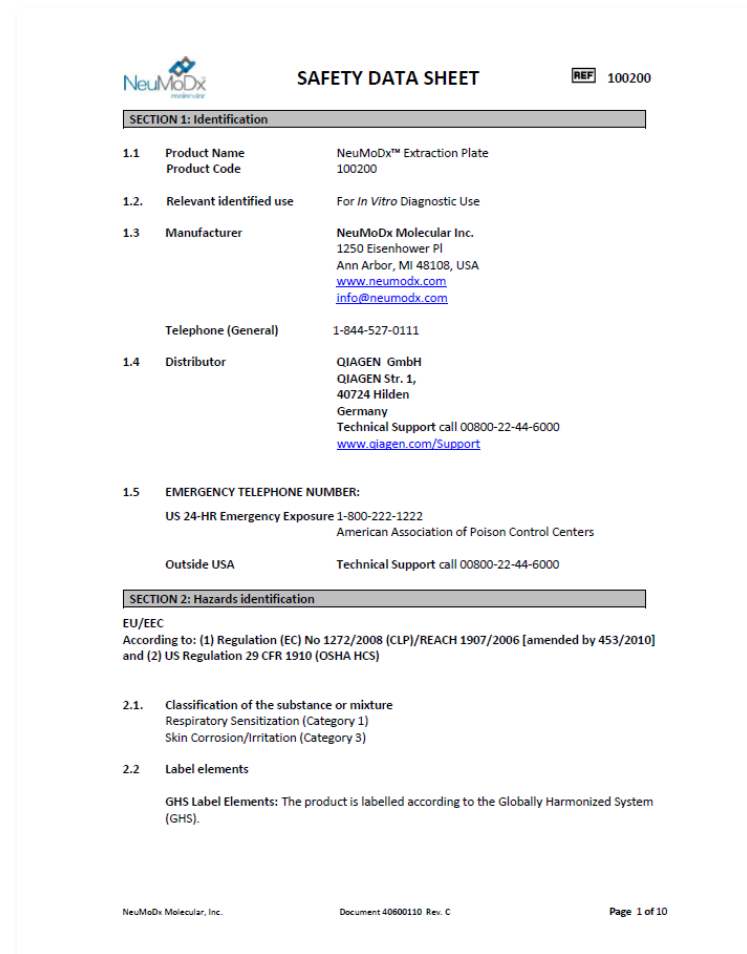



# Informational Resources & Safety Information

- 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](http://www.neumodx.com/client-resources)



 SAFETY DATA SHEET **REF** 100200

**SECTION 1: Identification**

1.1	Product Name Product Code	NeuMoDx <sup>™</sup> 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 <a href="http://www.neumodx.com">www.neumodx.com</a> <a href="mailto:info@neumodx.com">info@neumodx.com</a>
	Telephone (General)	1-844-527-0111
1.4	Distributor	QIAGEN GmbH QIAGEN Str. 1, 40724 Hilden Germany Technical Support call 00800-22-44-6000 <a href="http://www.qiagen.com/Support">www.qiagen.com/Support</a>
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](http://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 VPCR modules of the NeuMoDx System. The NeuMoDx Cartridge also incorporates a chamber to contain all the liquid waste generated in the course of processing the samples.

### PRINCIPLES OF THE PROCEDURE

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

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

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



### REAGENTS / CONSUMABLES

#### Material Provided

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

#### NeuMoDx™ Reagents and Consumables Required But Not Provided

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

#### Other Equipment and Materials Required But Not Provided

NeuMoDx™ 288 Molecular System (REF 500100) OR NeuMoDx™ 96 Molecular System (REF 500200)

# 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

- If additional assistance is required or a question arises, which is not answered in the operator manual, contact NeuMoDx<sup>™</sup> technical support:  
[techsupport@NeuMoDx.com](mailto:techsupport@NeuMoDx.com)  
Phone: 888-301-NMDX (6639)
- When contacting NeuMoDx<sup>™</sup>, have the following information available:
  - Product name, part number, and serial number
  - Troubleshooting Package
  - Details surrounding event

# Questions?

