Part I

NeuMoDx 96 Molecular System – Operator Training

Huilin Lee, M.S.
Applications Scientist

Welcome & Introduction

NeuMoDx™ molecular

NeuMoDx Molecular Systems Address All Key Customer Desires

NeuMoDx™ molecular
Powerful. Simple. Diagnostics.™

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

NeuMoDx™ molecular

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- 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

NeuMoDx™ molecular

General Overview

NeuMoDx™ molecular

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- 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

NeuMoDx™ molecular
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- 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

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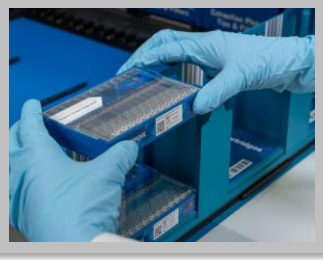
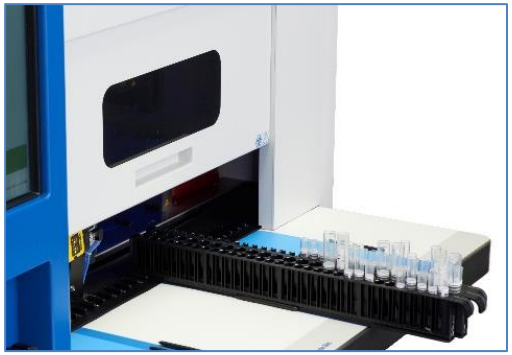
STEP 1*

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

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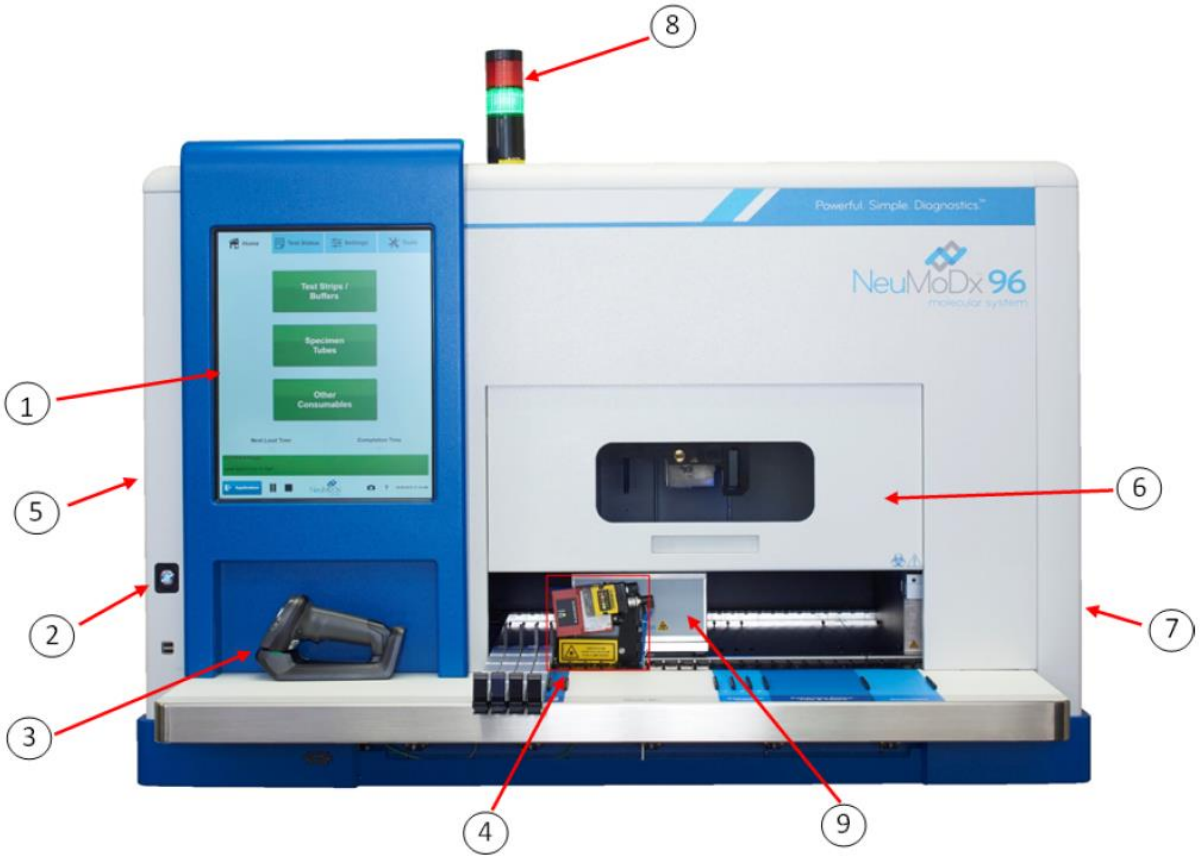

Area	
1	Touchscreen computer
2	On/Standby button
3	Handheld barcode scanner
4	Autoloader & Autoloader shelf
5	Reagent Drawer
6	Service Door
7	Biohazard Tip Waste Bin
8	Status light
9	Biohazard Waste Bin

NeuMoDx™ 96 Molecular System - System Worktable

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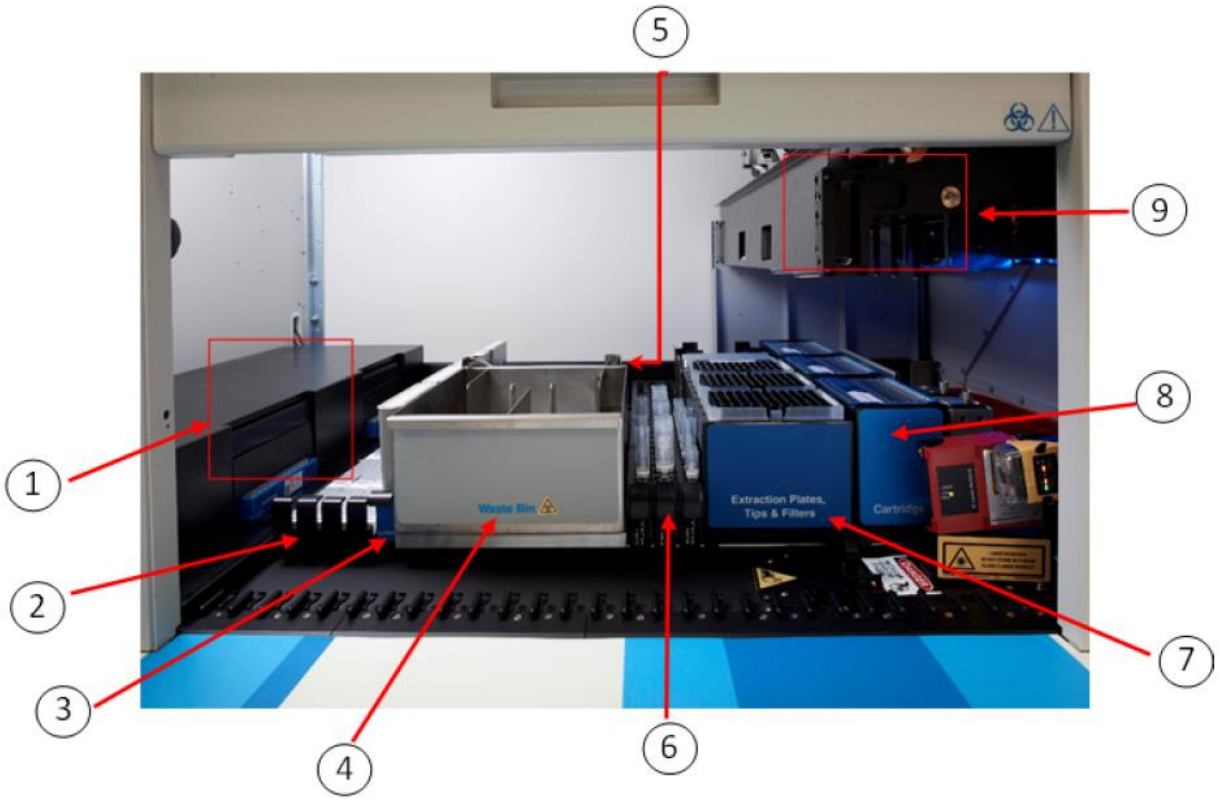

Area	
1	XPCR Modules
2	Test strips
3	Buffer carrier
4	Biohazard Waste Bin
5	Extraction plate heaters (not shown; located behind Biohazard Waste Bin)
6	Specimen tube carriers
7	Tips, Extraction Plates, and Filters carrier
8	Cartridge carrier
9	Liquid handling robot (LHR)

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

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1

2

Area	
1	Tip Waste Drawer
2	Bulk Liquid Reagent Drawer

NeuMoDx™ 96 Molecular System Extraction Heater Modules

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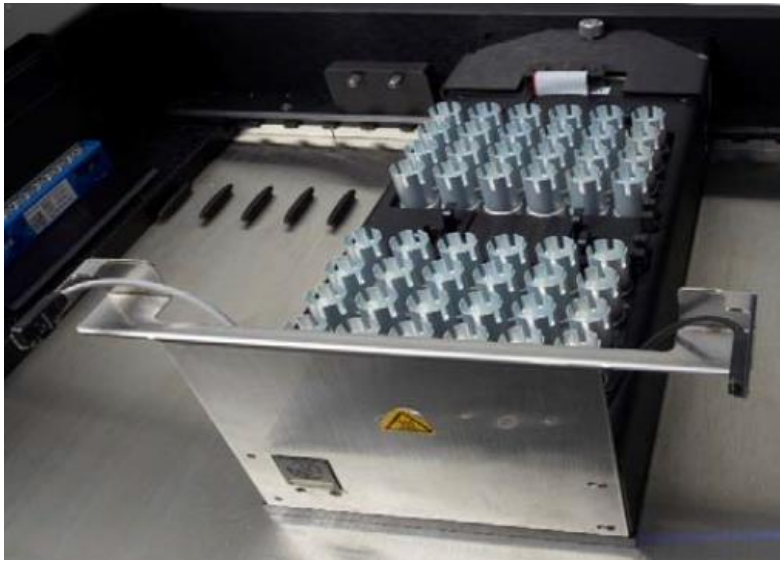
- Extraction Plate Heater Modules
  - N96 has one Extraction Heater Module
- Independently controlled heater lysis wells
- Performs the Lysis Heating Step of extraction



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

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- 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

Principles of Operation

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- 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

Principles of Procedure

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- 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

Proprietary chemistry & microfluidics

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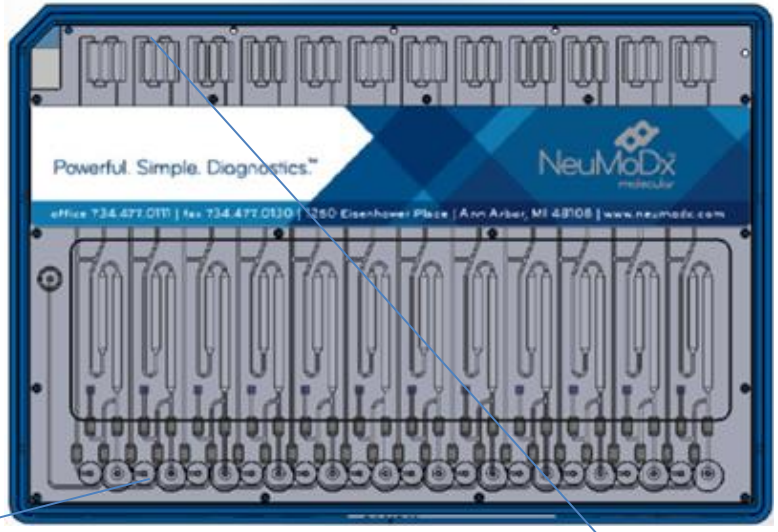
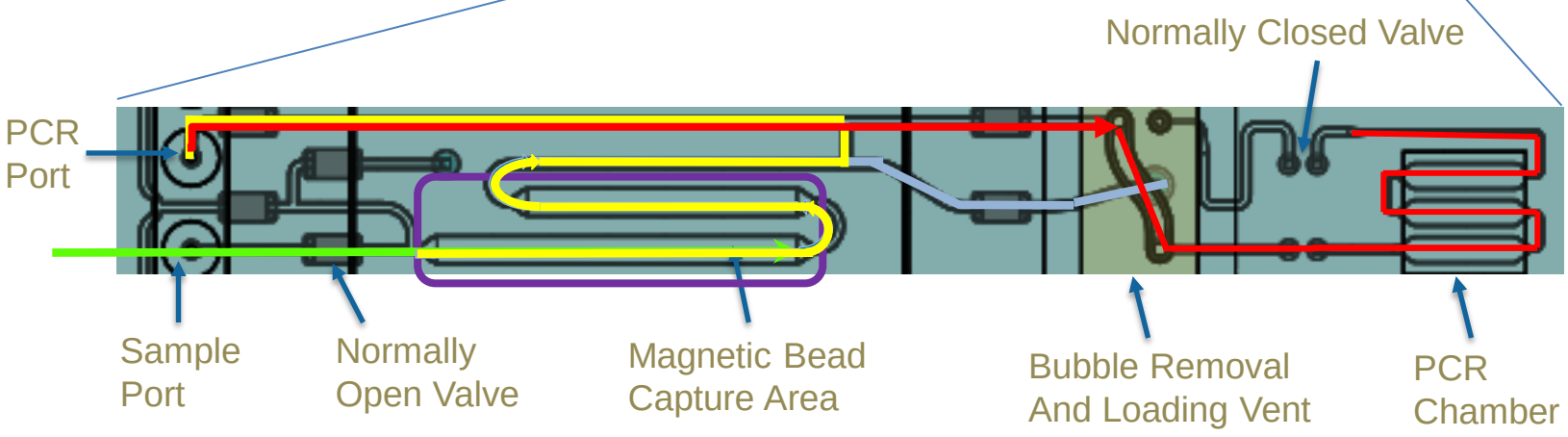
Performs the following operations for a single sample:

- 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

NeuMoDx™ molecular

Brief Information

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- 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

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- 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
- NeuMoDx™ 96 Biohazard Tip Waste Bag

Waste Containers

Reagents & Consumables
For your information

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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

Reagents & Consumables

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- 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

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

1000 µL Tips

300 µL Tips

Extraction Plate

Tip Tray

Reagents & Consumables

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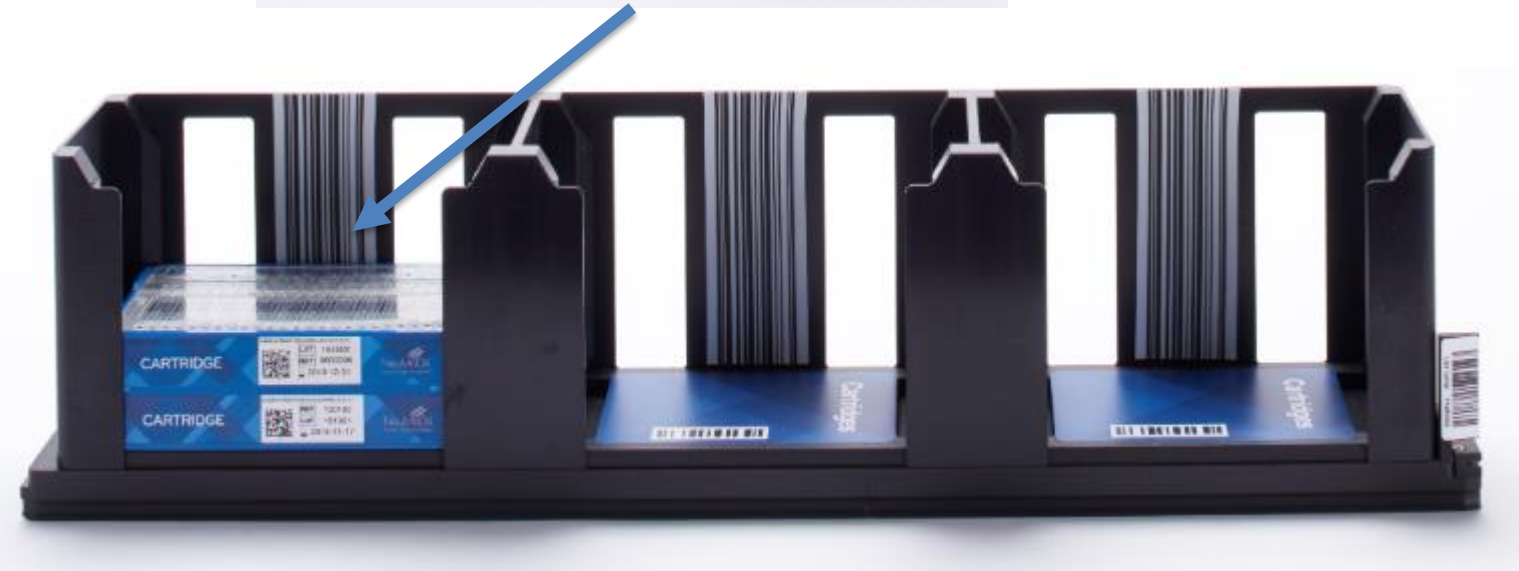
- Cartridges go into the cartridge carrier (up to 5 per slot, 15 total per carrier)



Reagents & Consumables

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

N96

System Operation & Workflow

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System Operation

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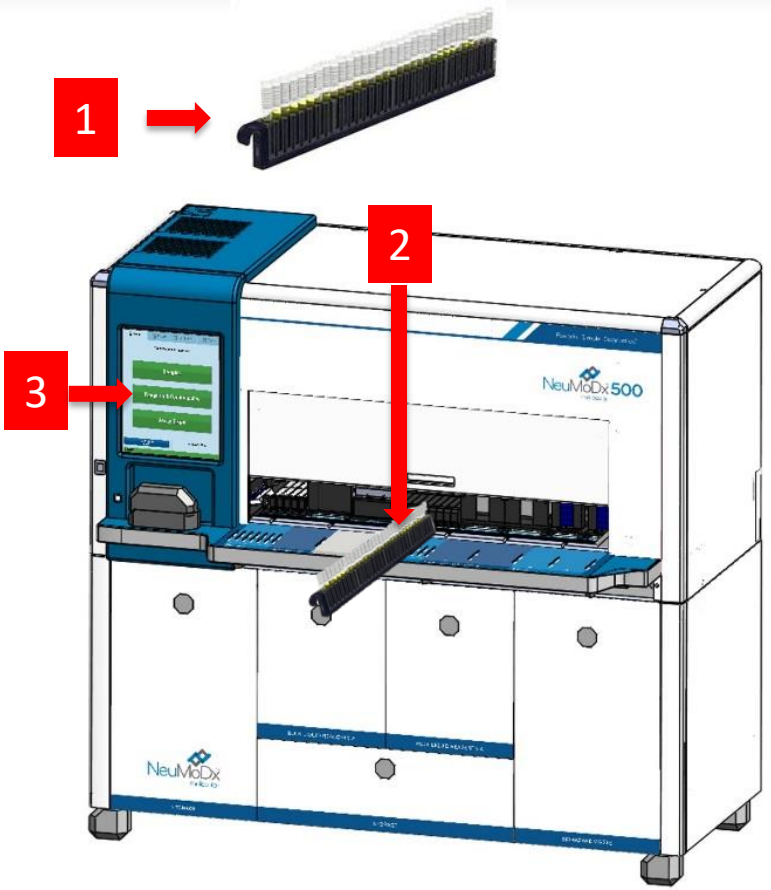
1. Operator loads specimen tube in Specimen Tube Carrier;
2. Operator places Specimen Tube Carrier on Autoloader Shelf;
3. Operator touches ‘load’ arrow on touchscreen user interface; and
4. Operator walks away.*

*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

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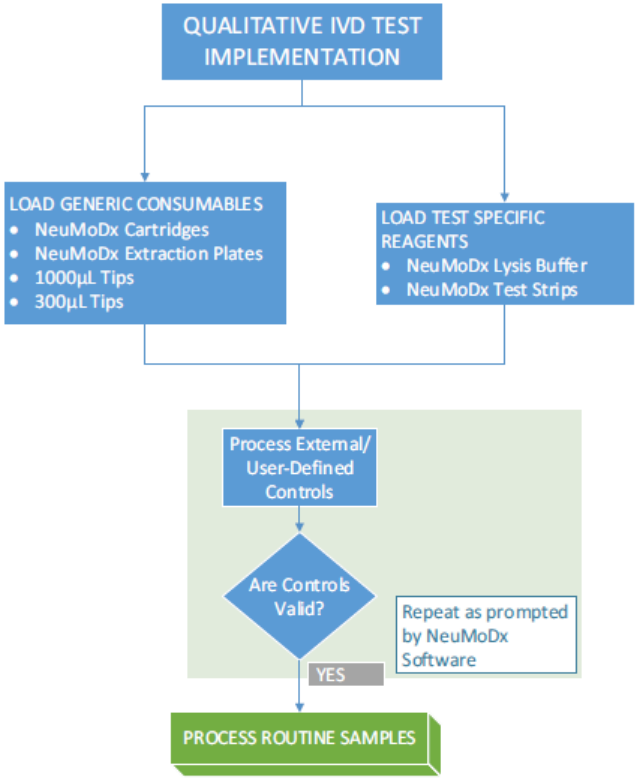

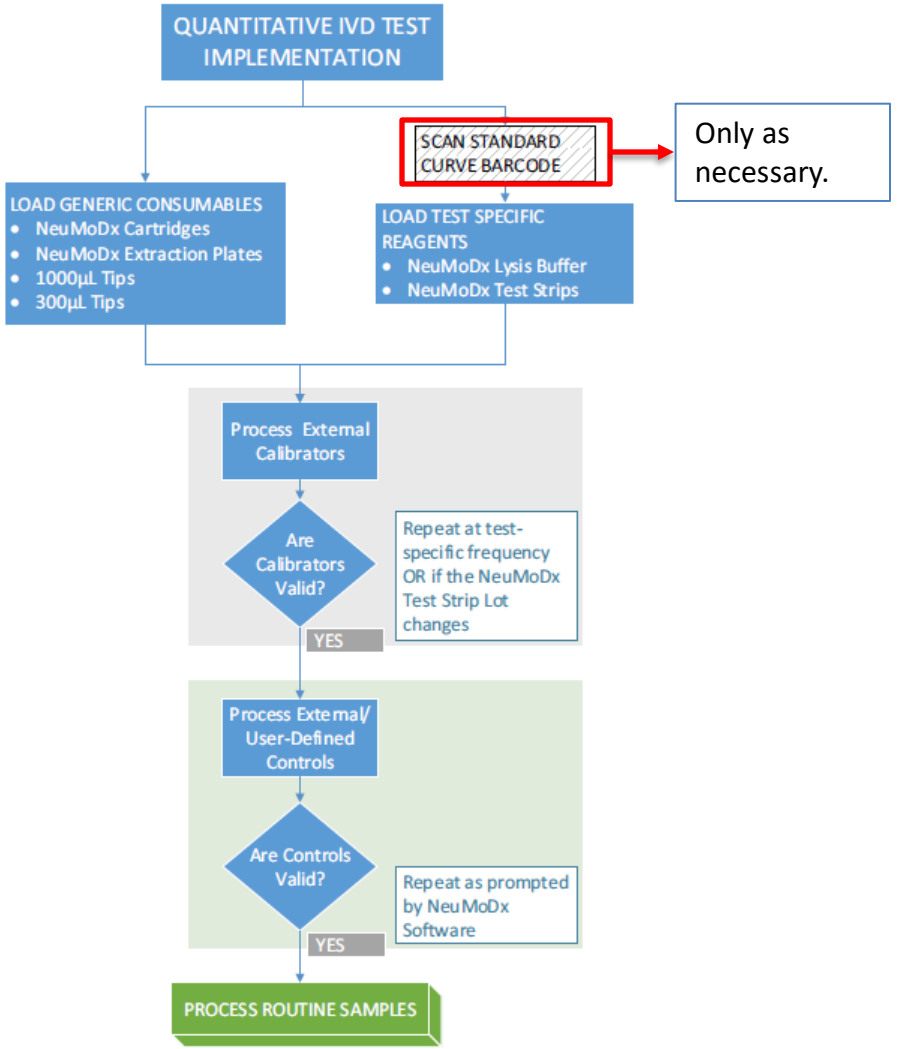

LDT Workflow

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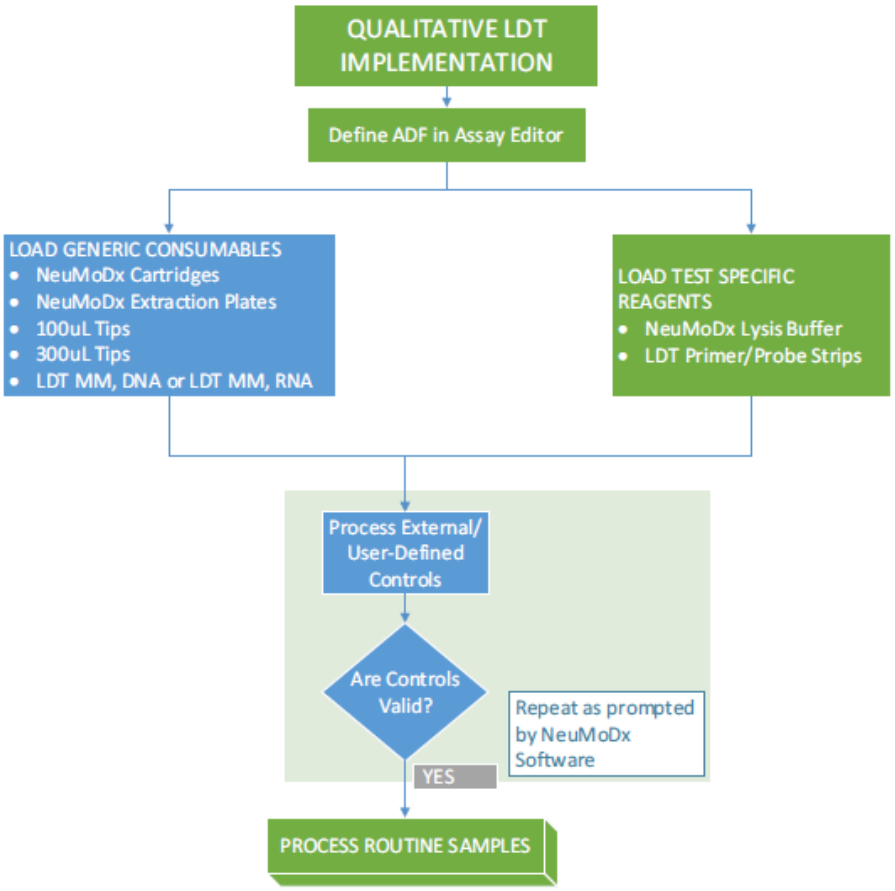

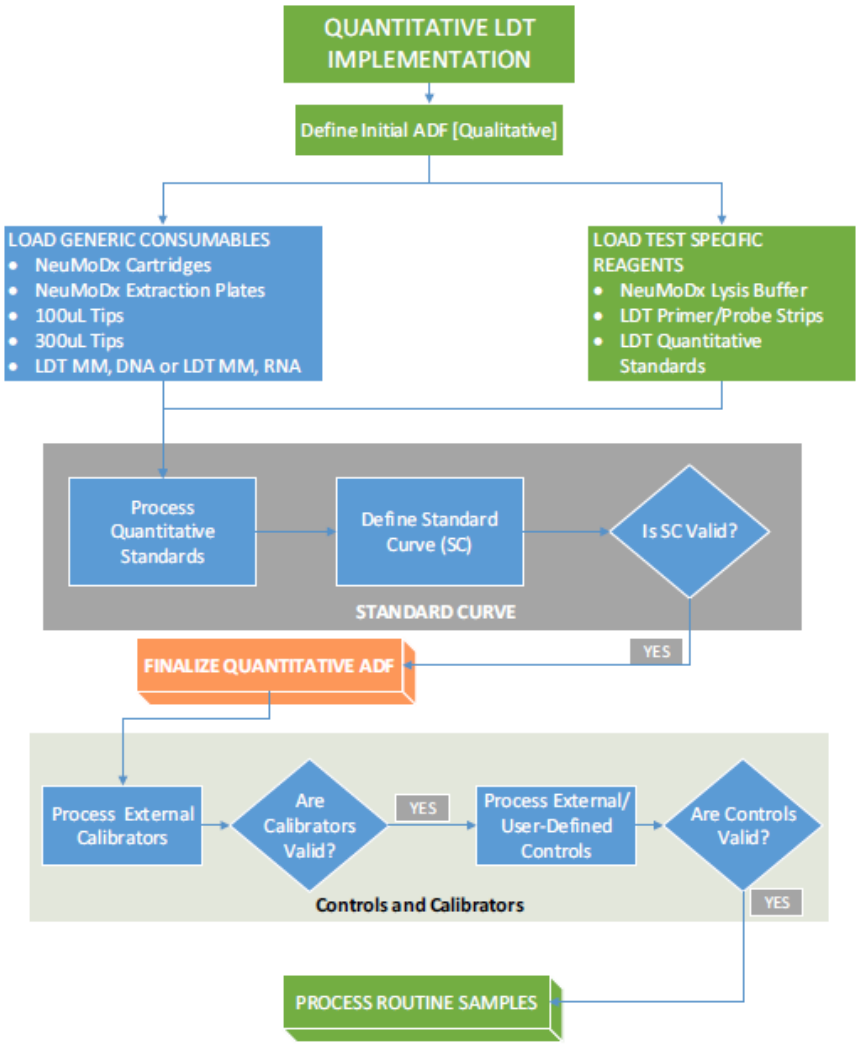

Assay Definition Files

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- 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

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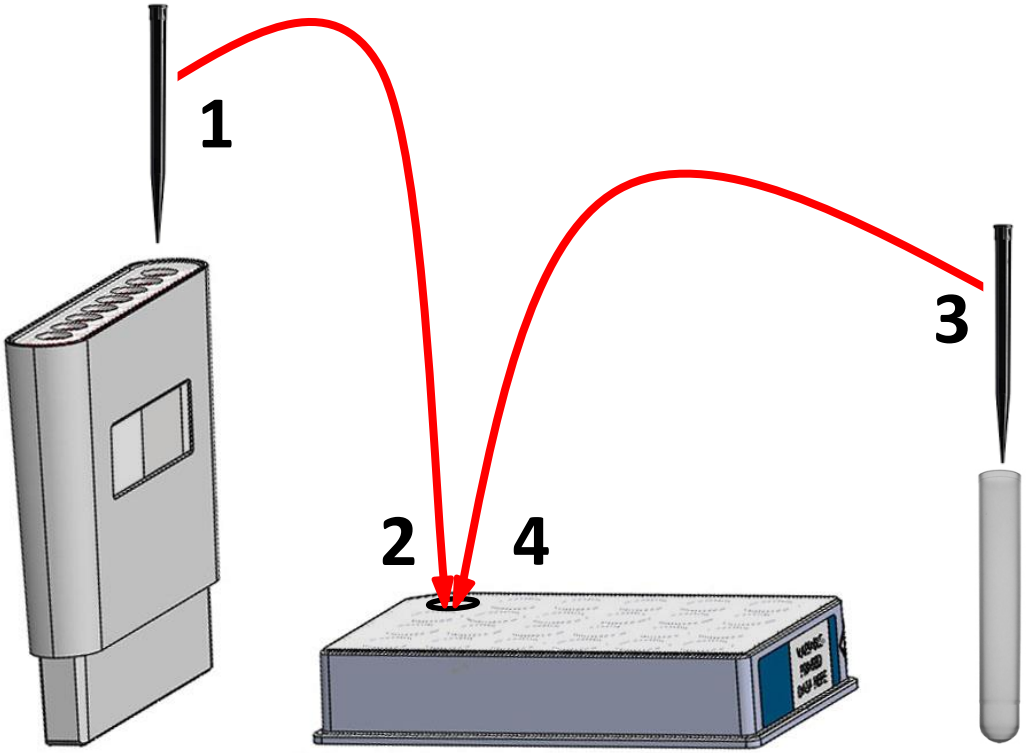
- As specimen tubes are loaded, sample processing is initiated as follows:

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.
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

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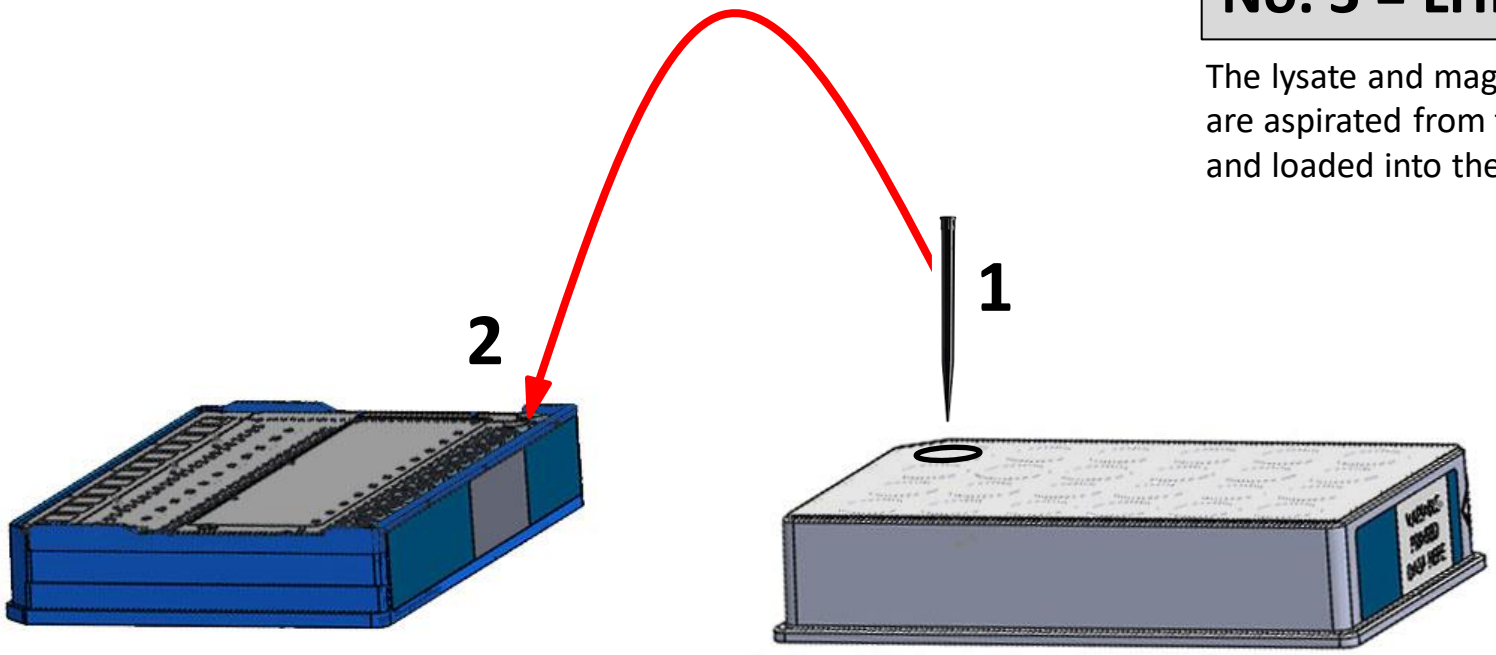
No. 3 = LHPB

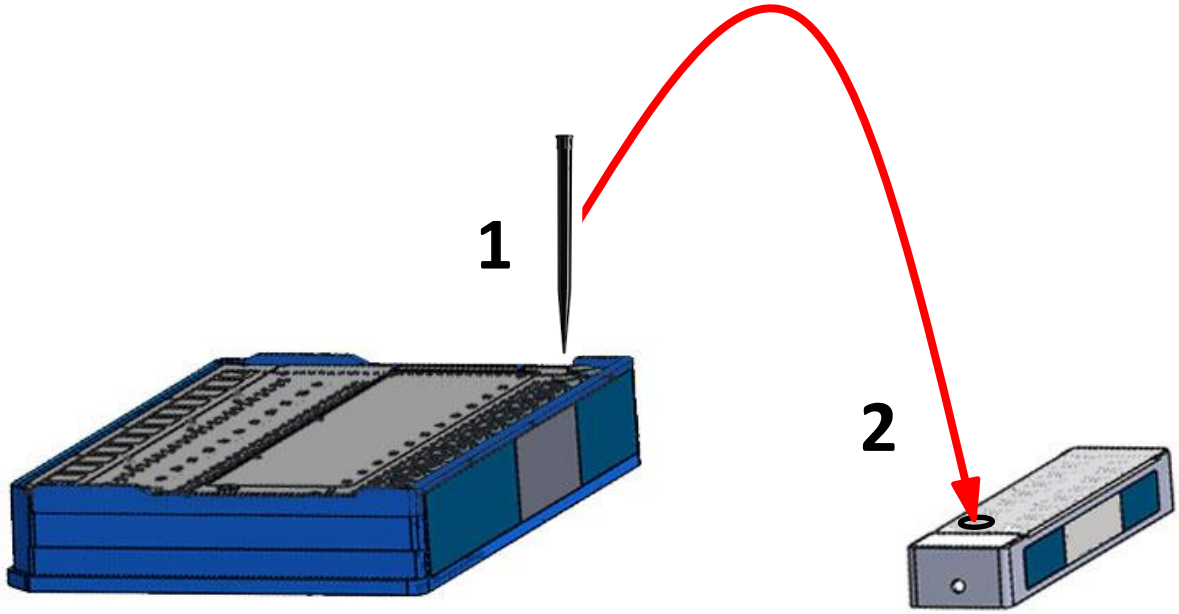
The lysate and magnetic bead mixture are aspirated from the extraction plate and loaded into the cartridge.



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



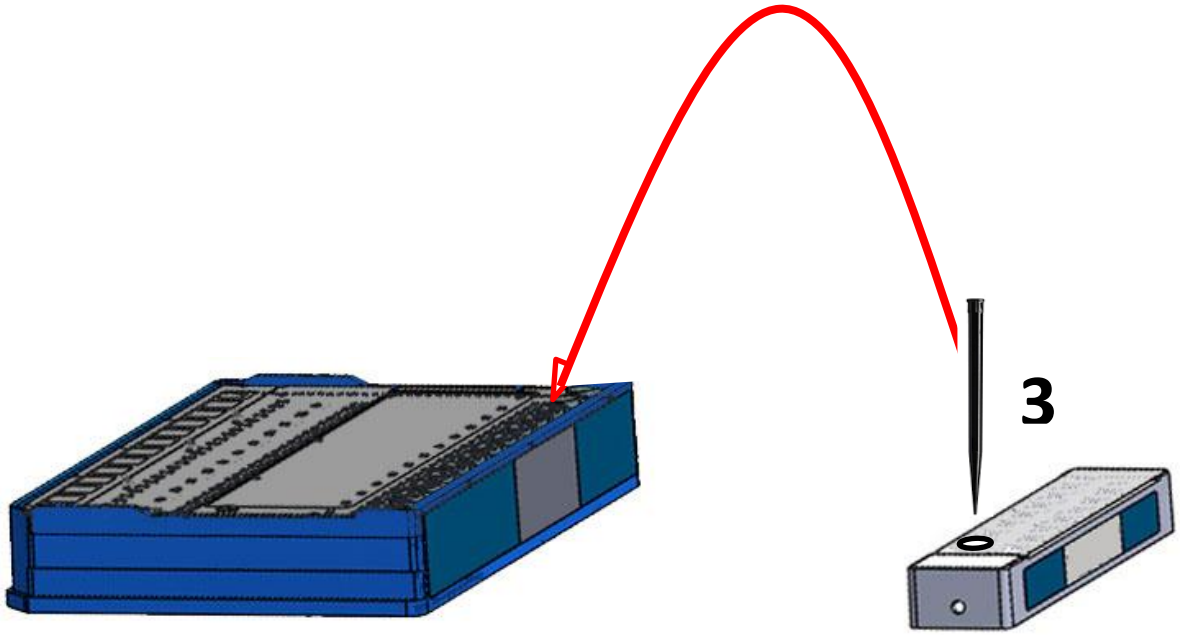
No. 5 = LHPC

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



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No. 6 = PCR/Real-time PCR

Process Control

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- 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™ molecular

NeuMoDx 96 Software Screen
BioMed Level User

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NeuMoDx 96 Software Screen
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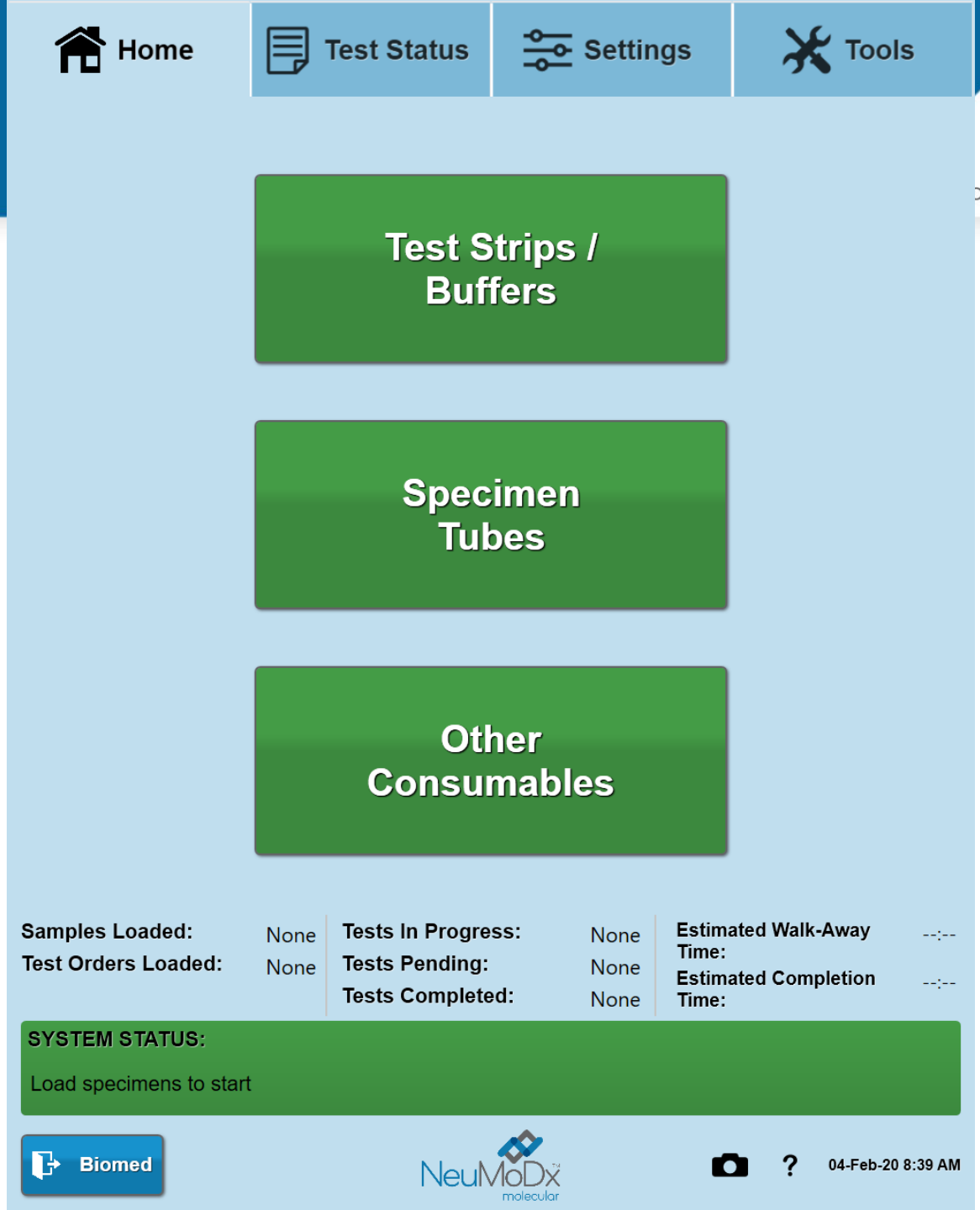
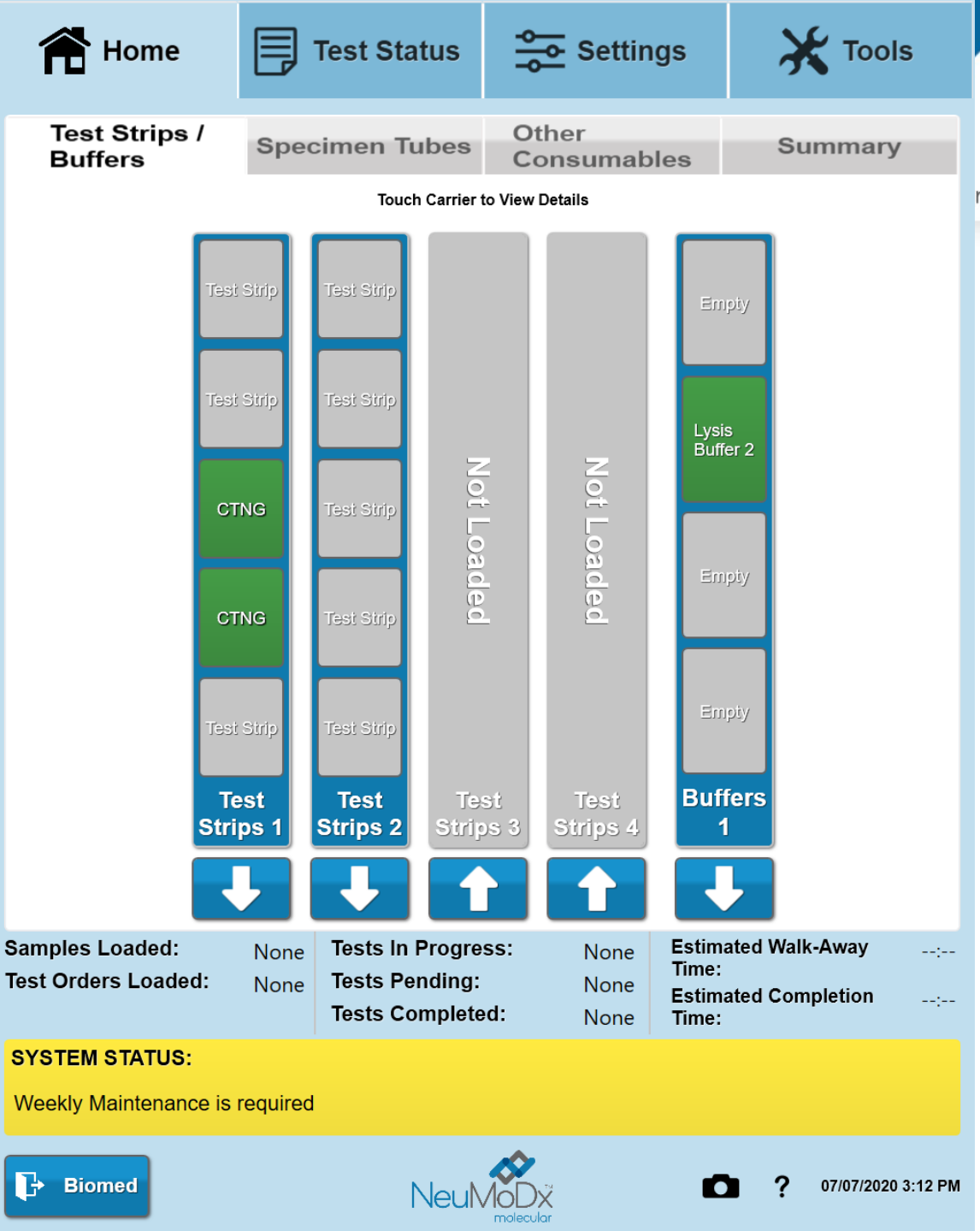


NeuMoDx 96 Software Screen
BioMed Level User



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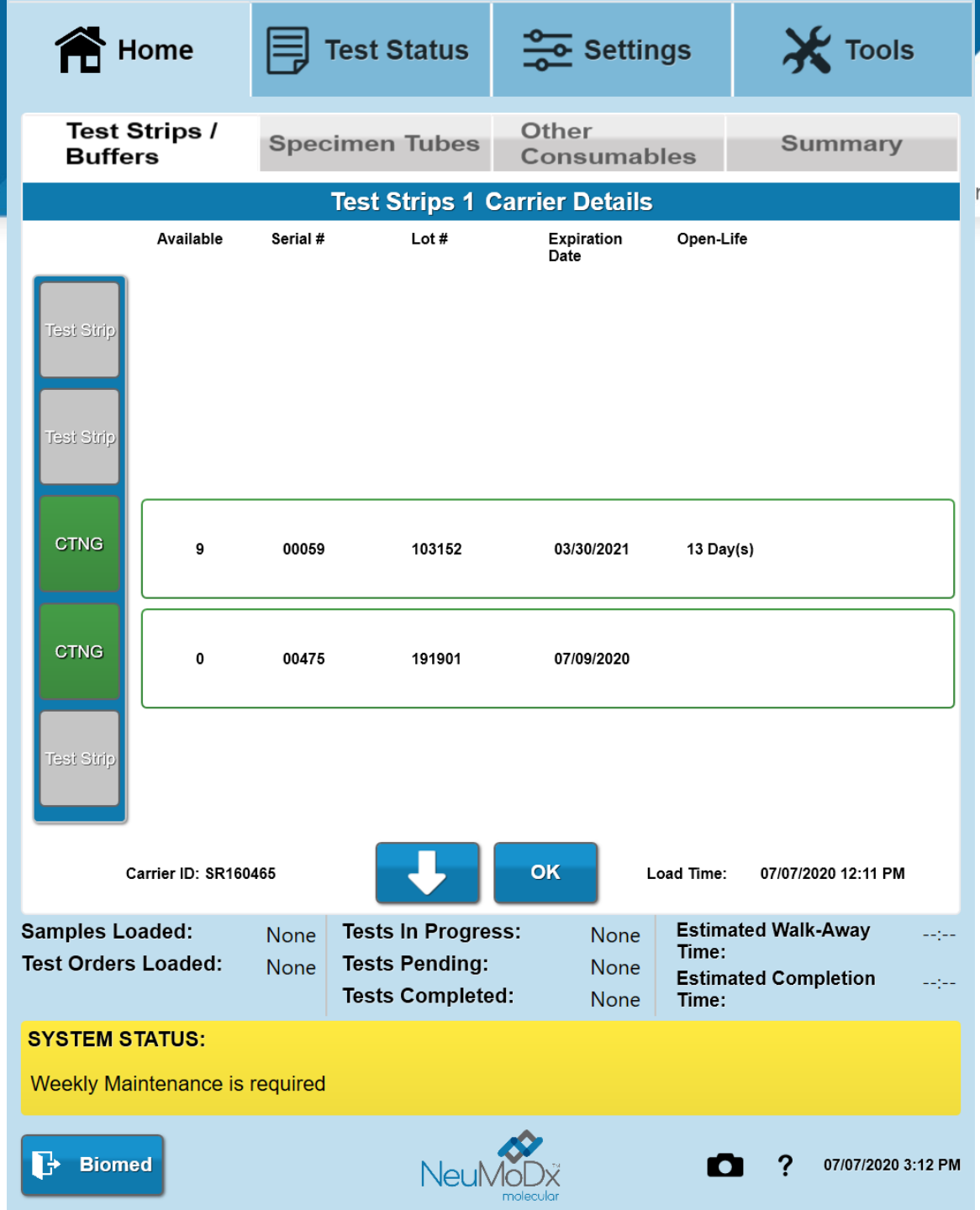

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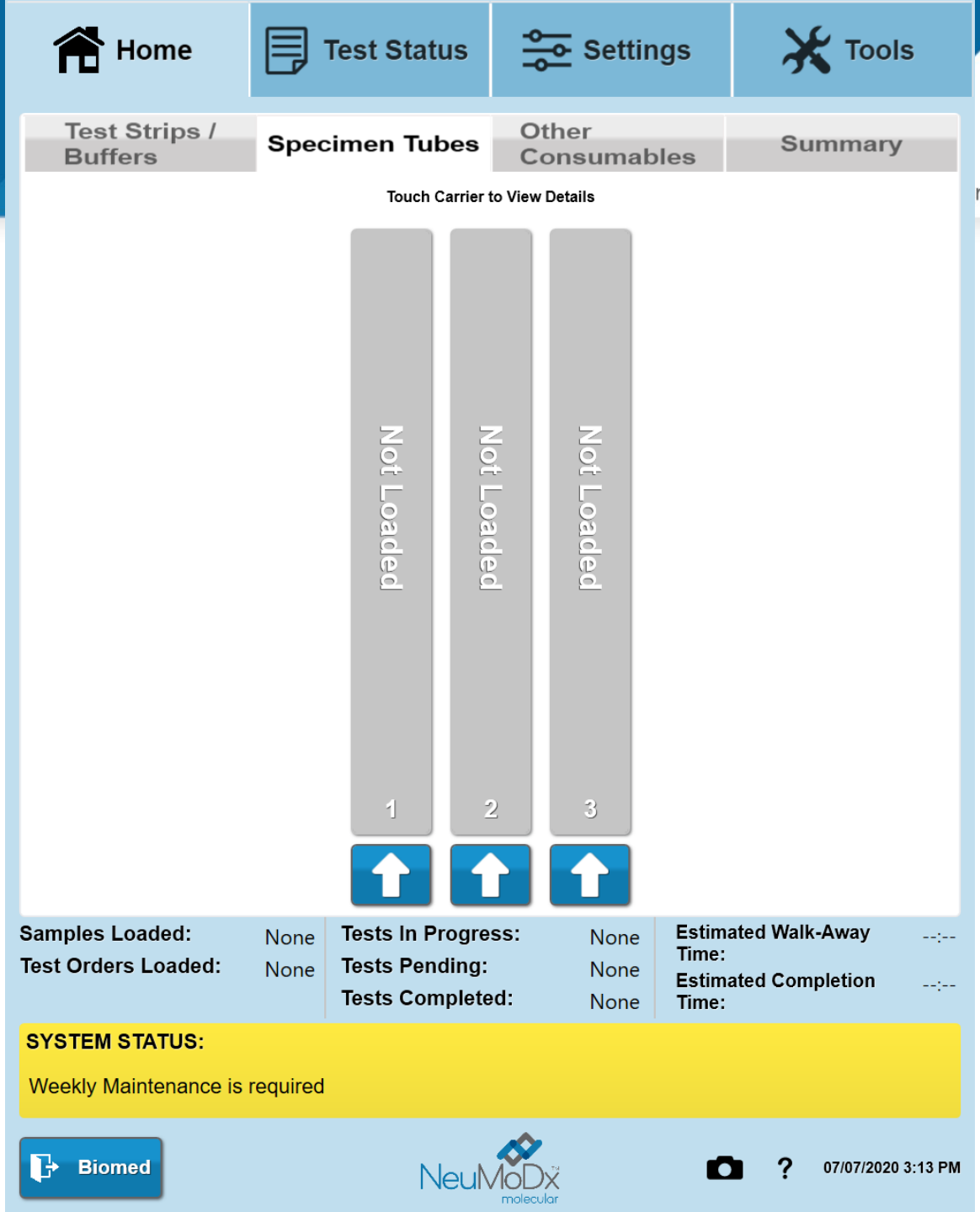

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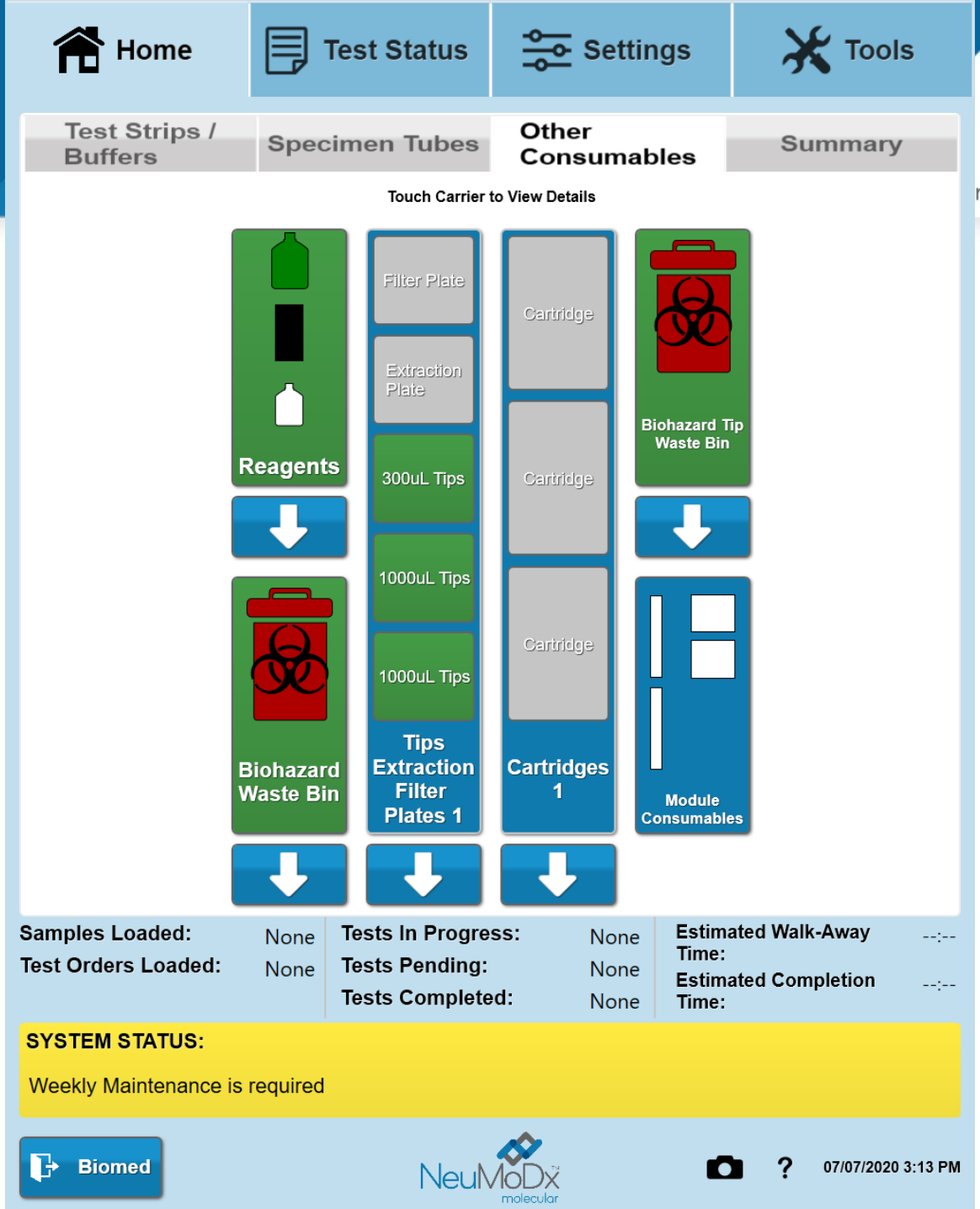

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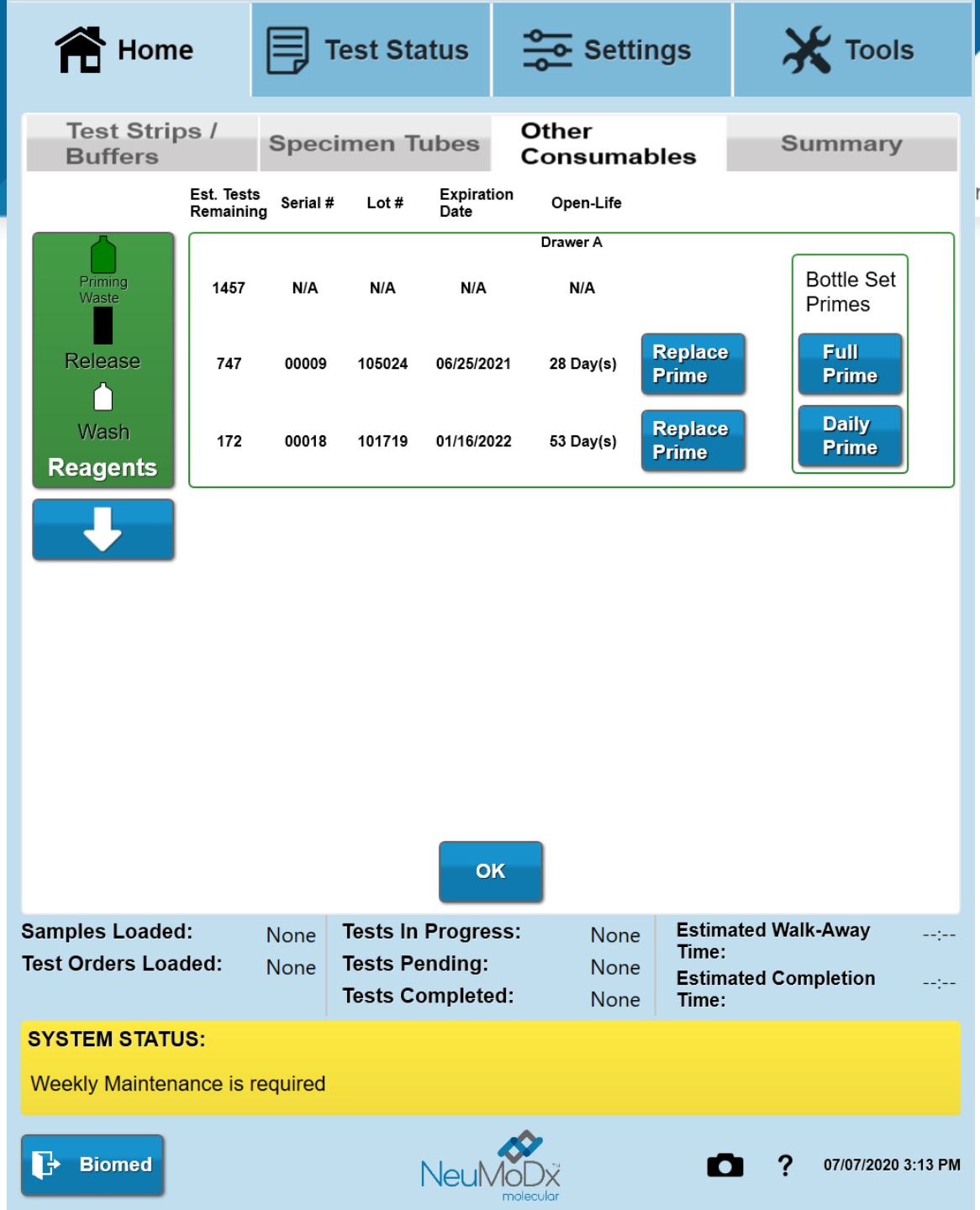

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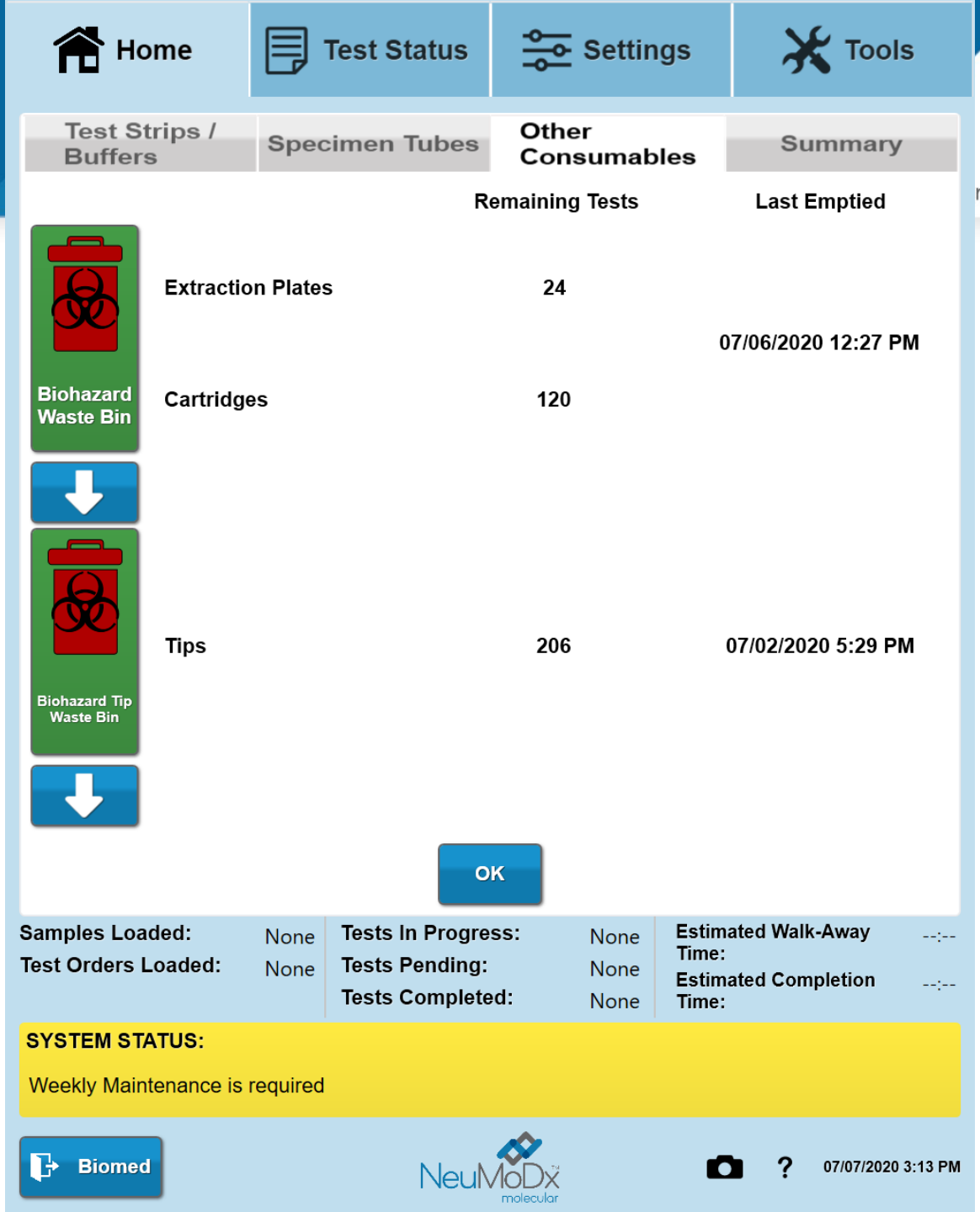

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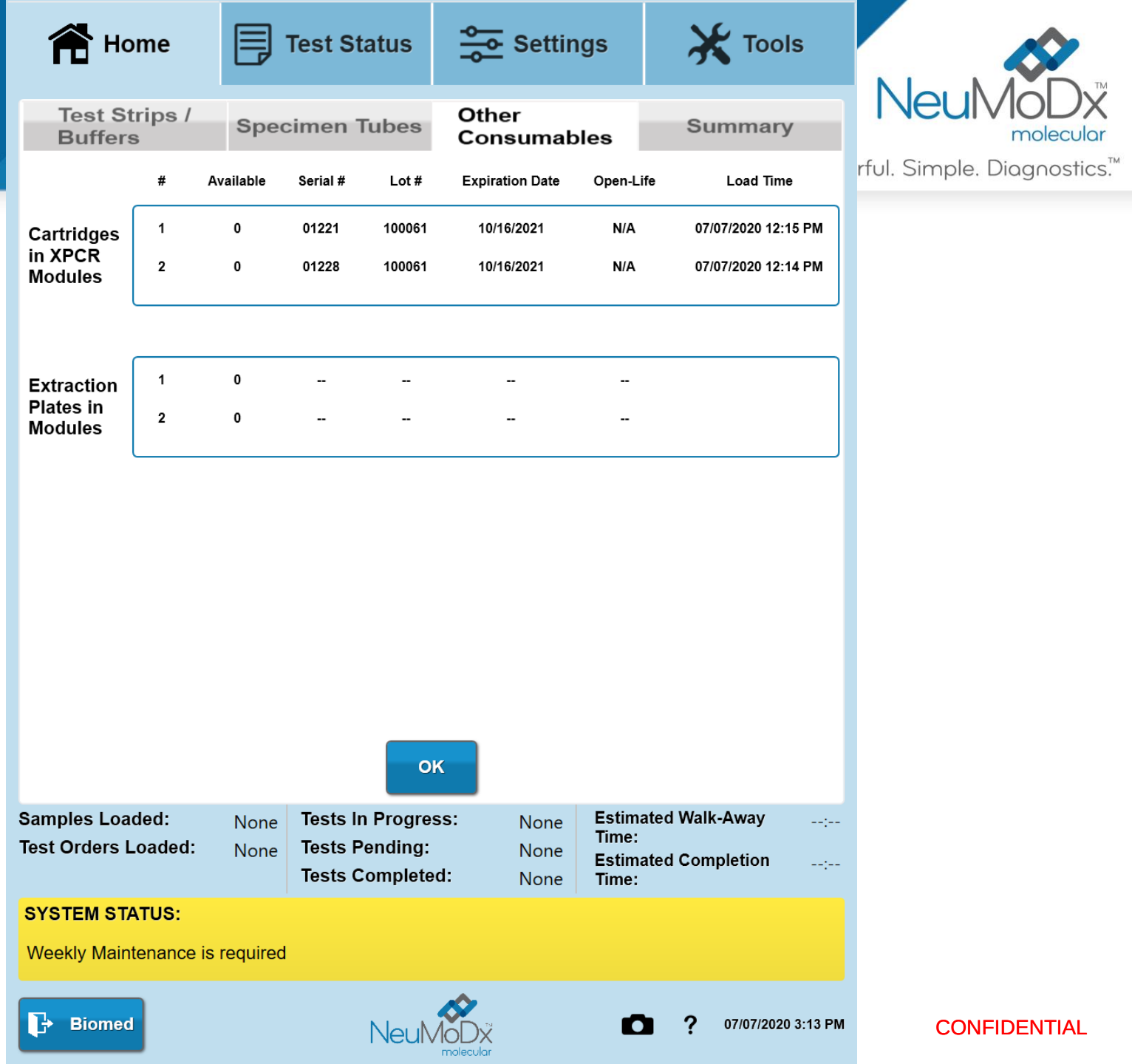

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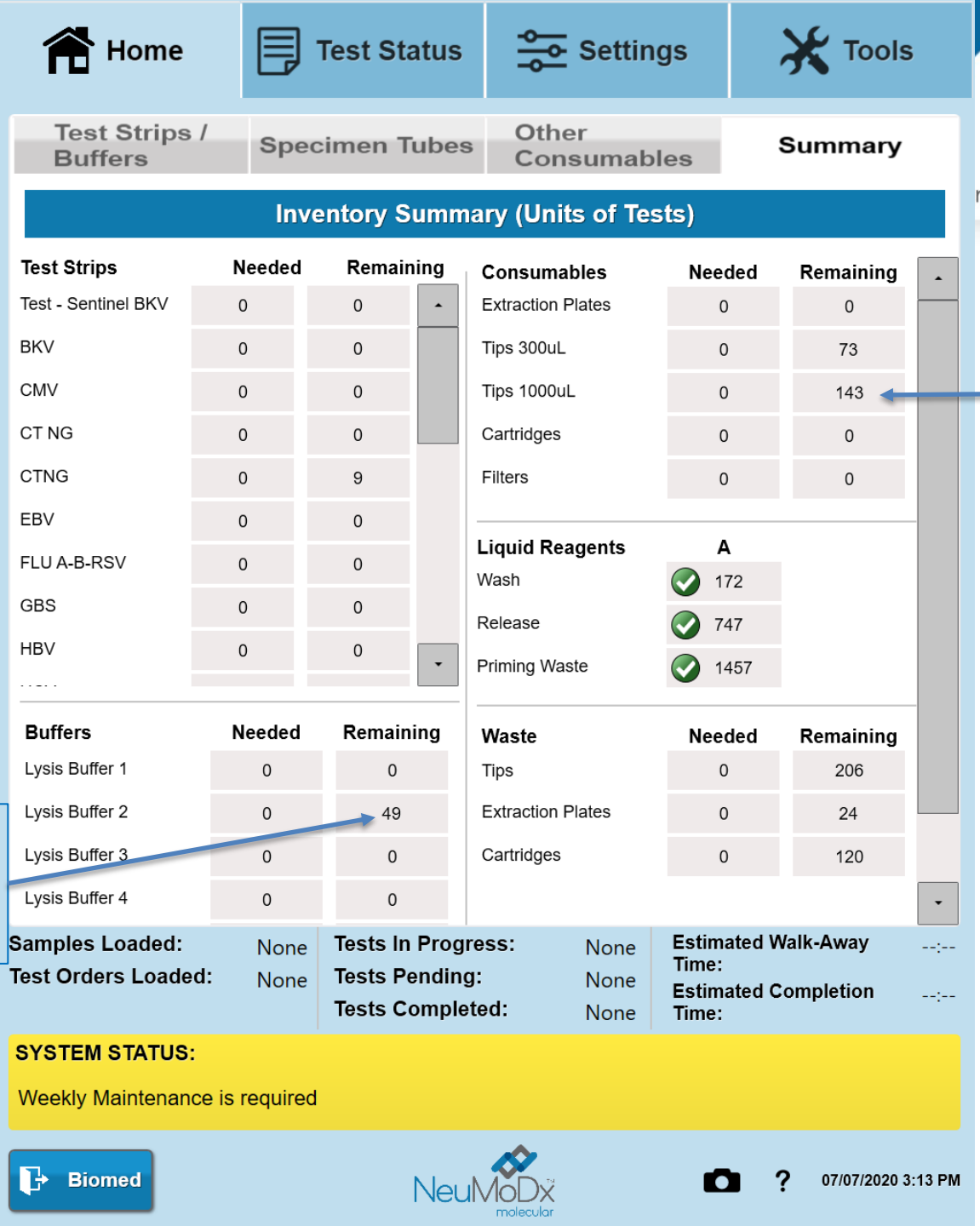

2 tips/test; ~71 tests

Lysis Buffers are in mL

NeuMoDx 96 Software Screen
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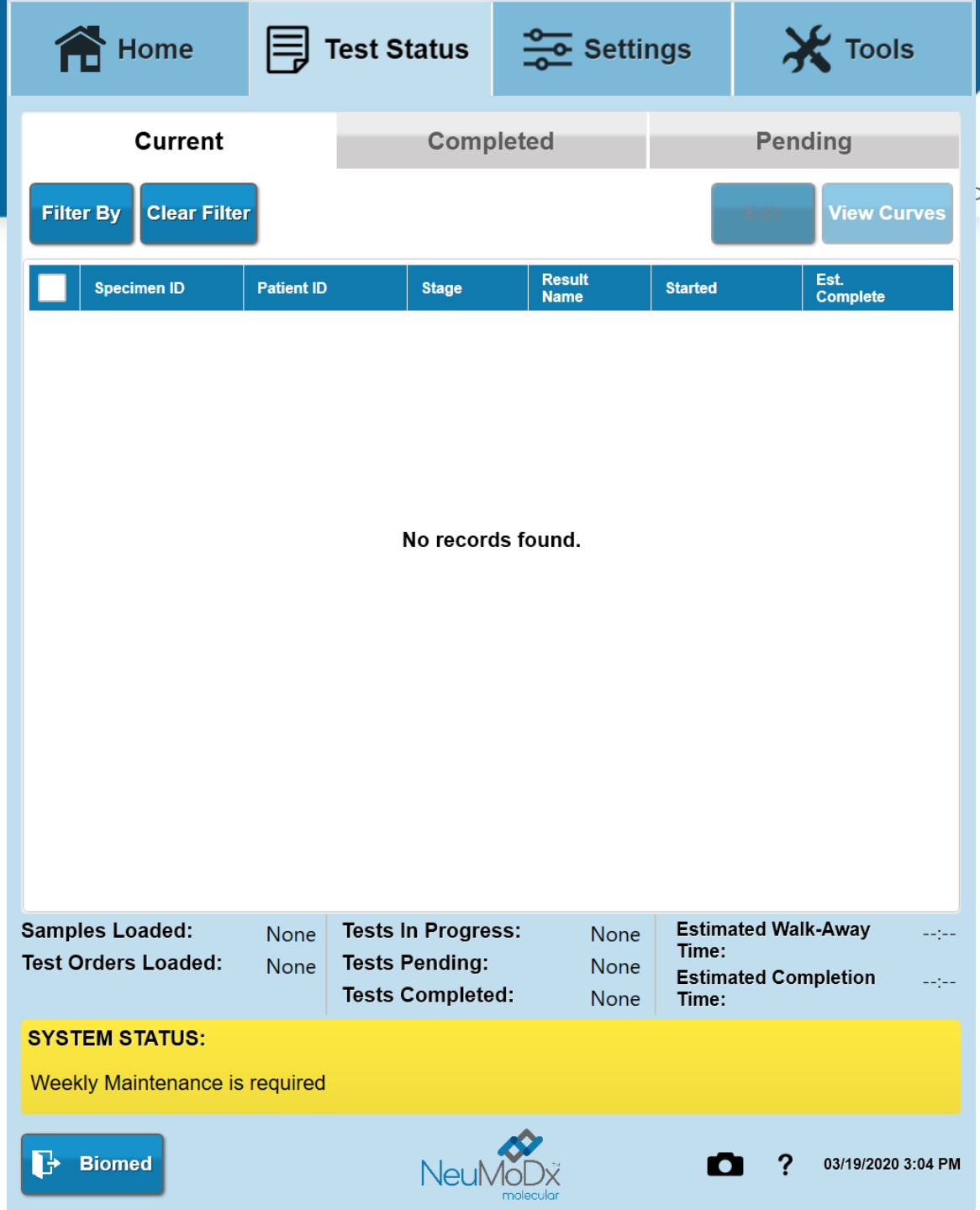

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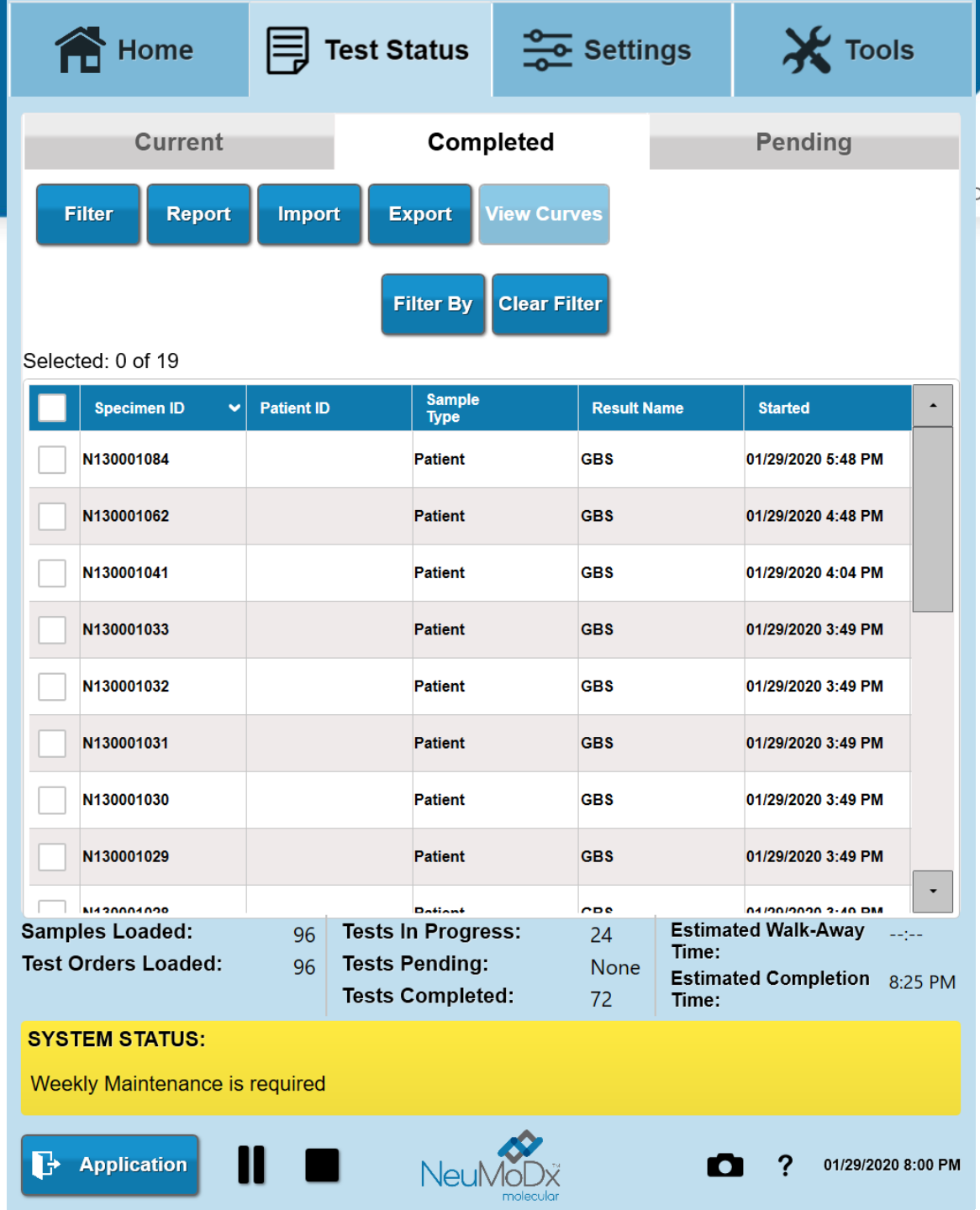

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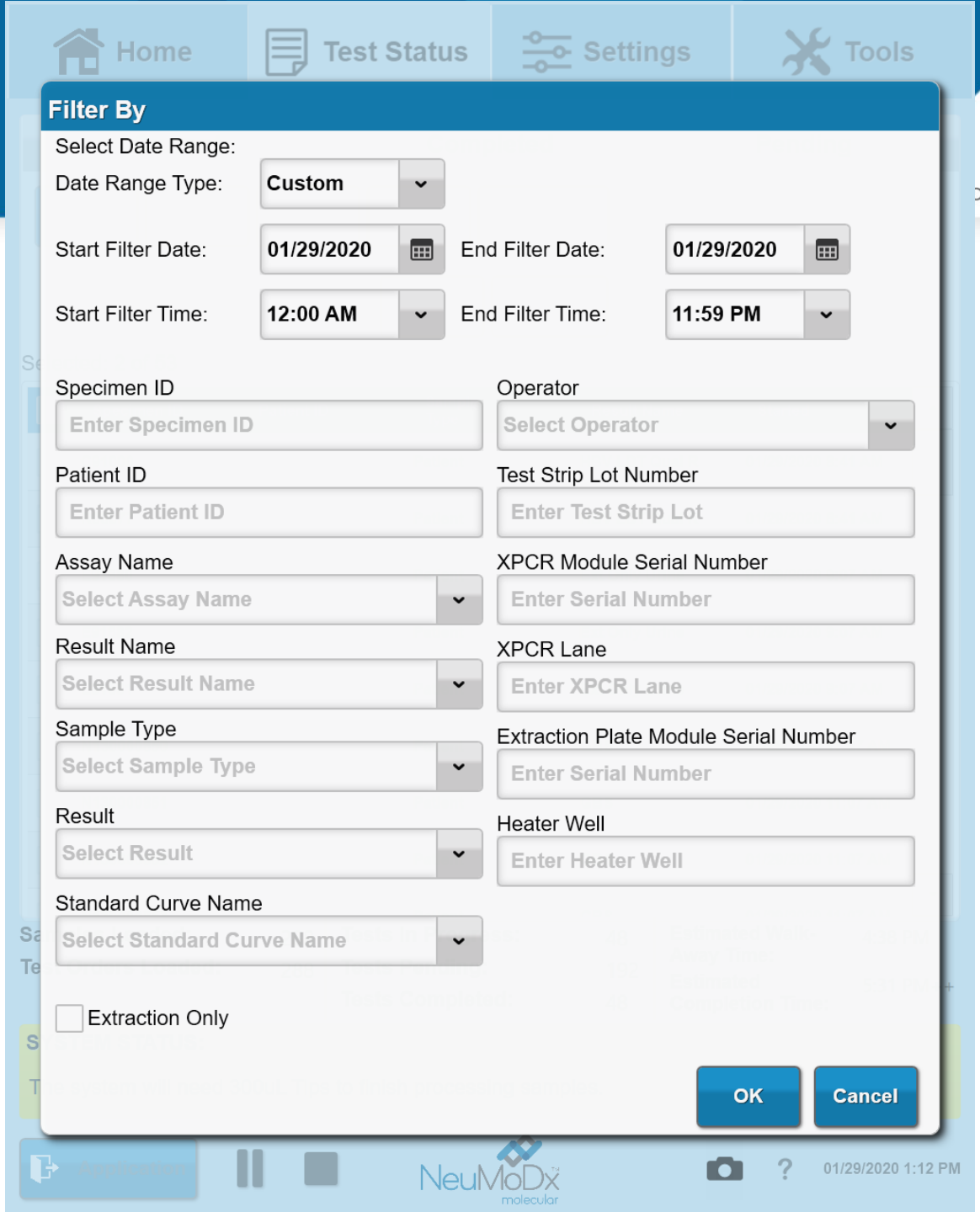

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NeuMoDx 96 Software Screen
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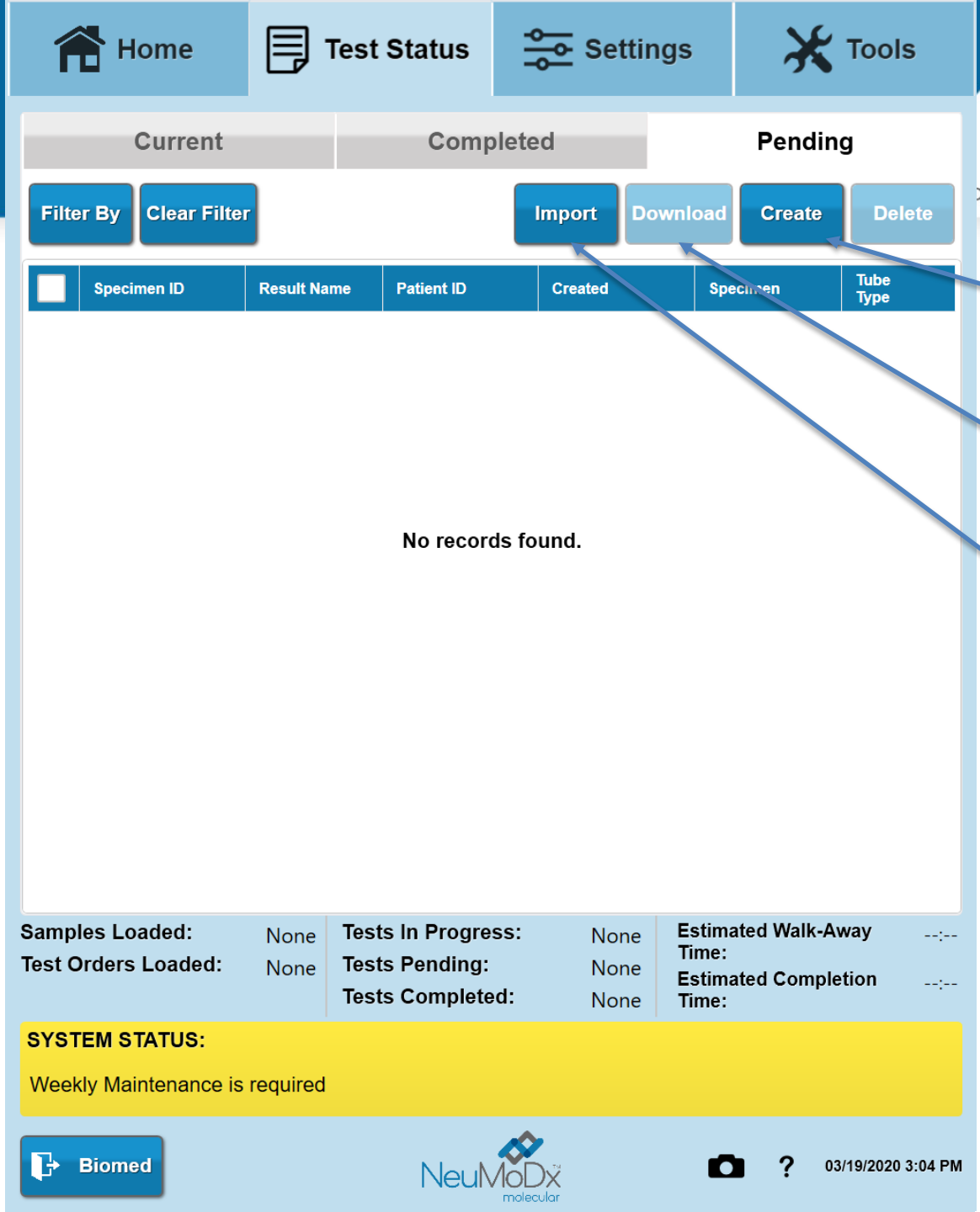

NeuMoDx molecular

Create individual test order

Download from:
- LIS

Import excel from:
- USB
- Network

NeuMoDx™ molecular

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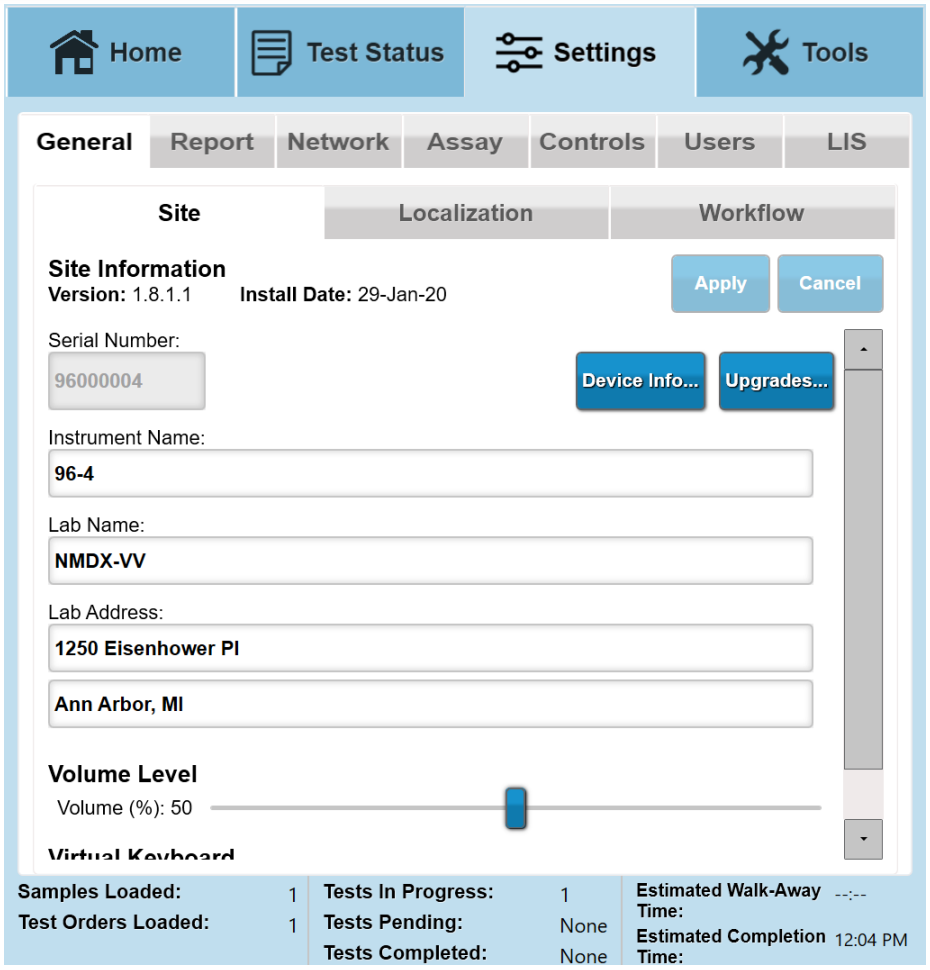
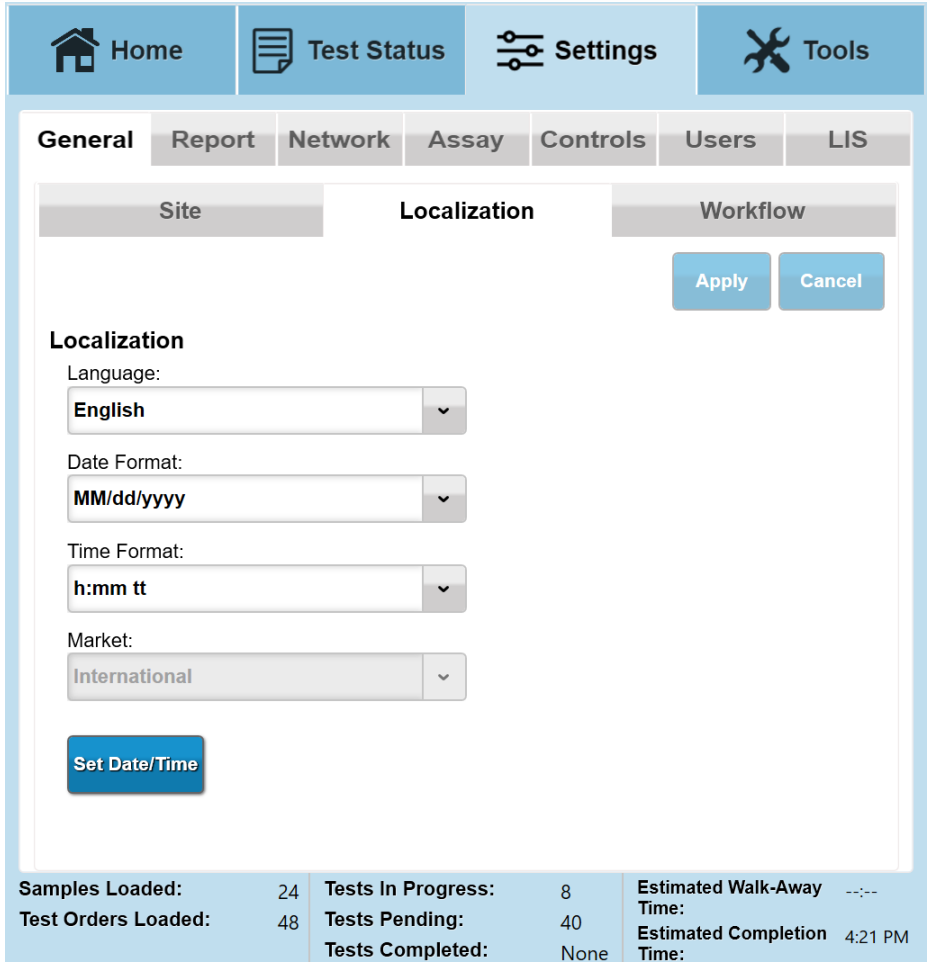
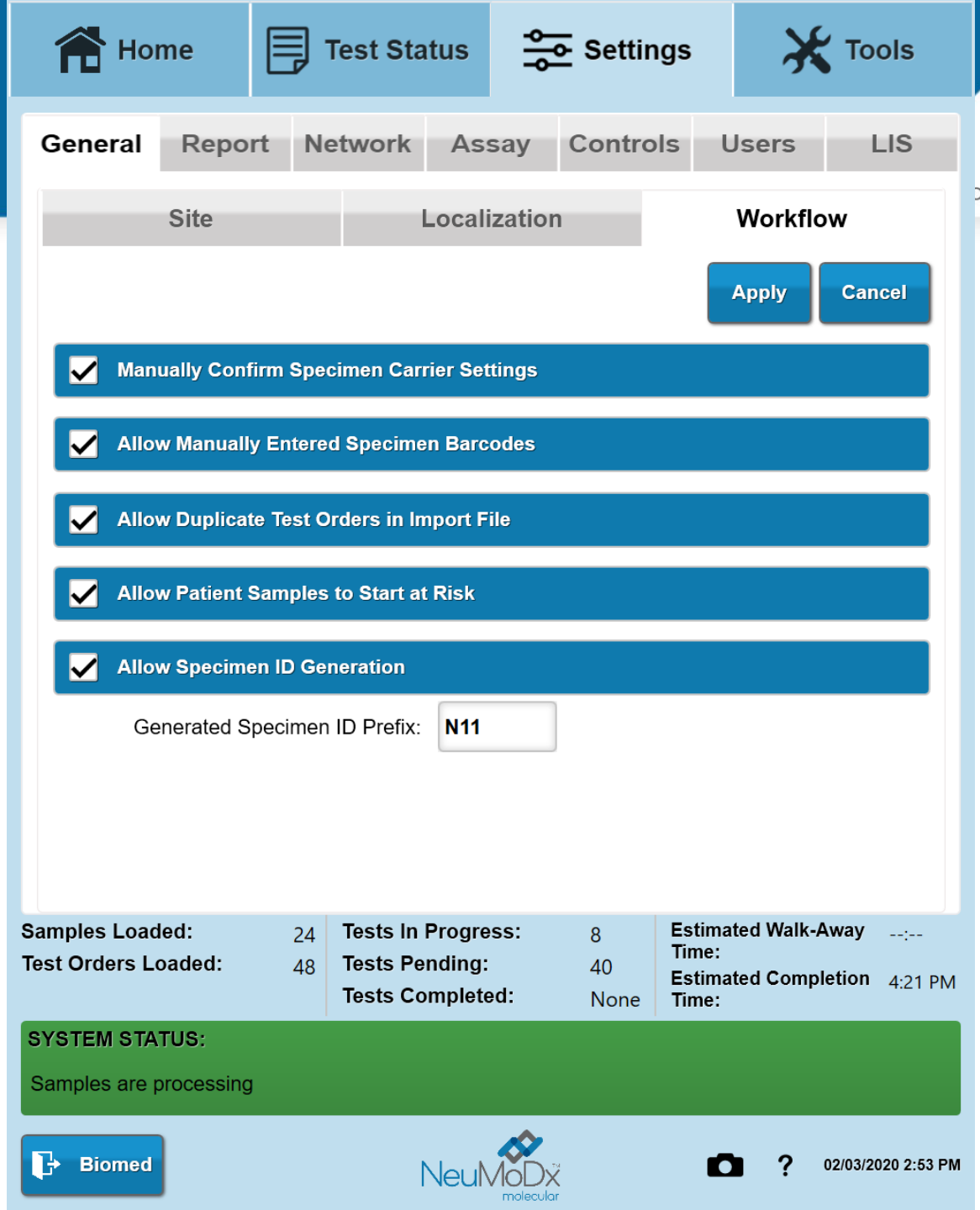




NeuMoDx 96 Software Screen
BioMed Level User



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NeuMoDx 96 Software Screen
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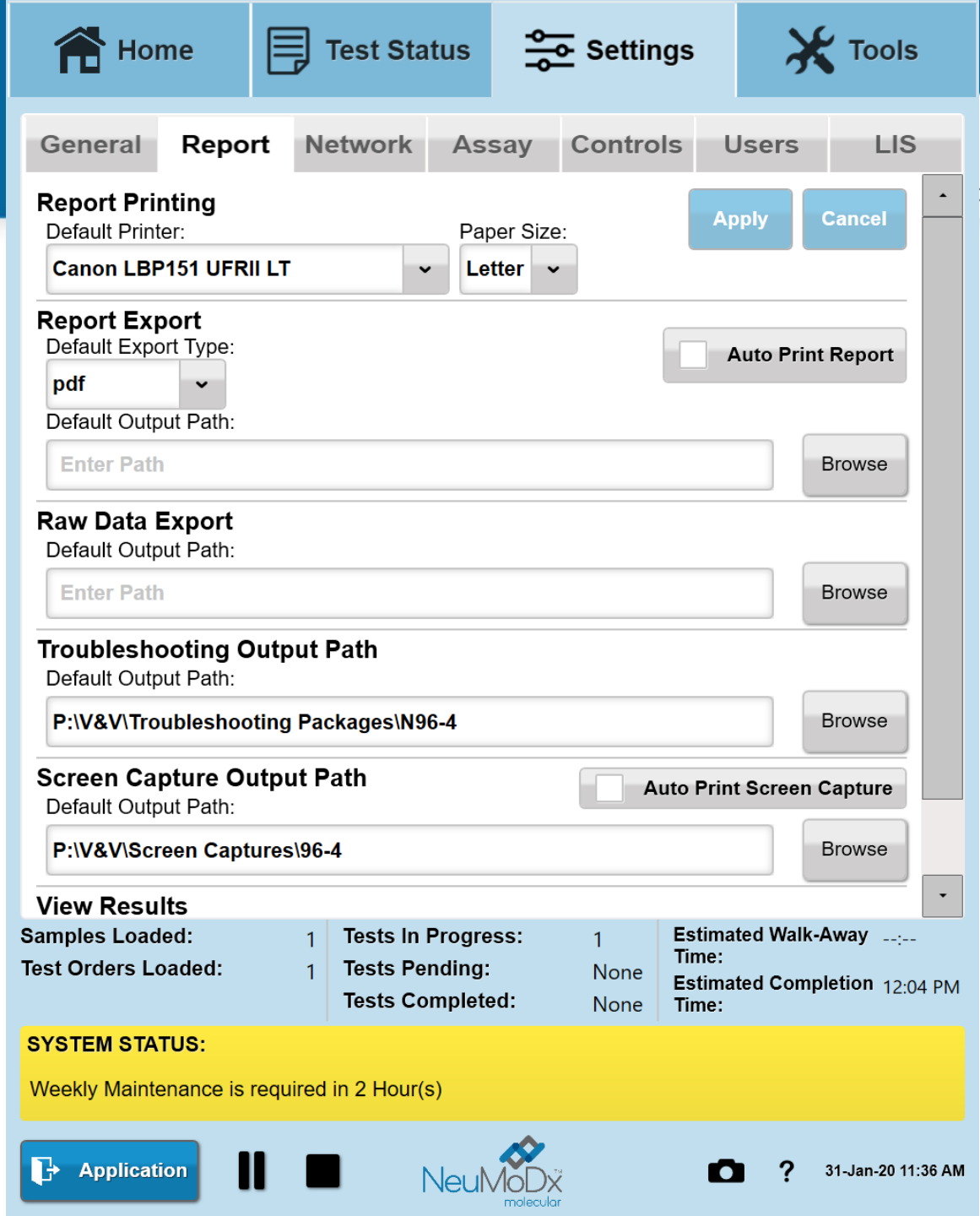

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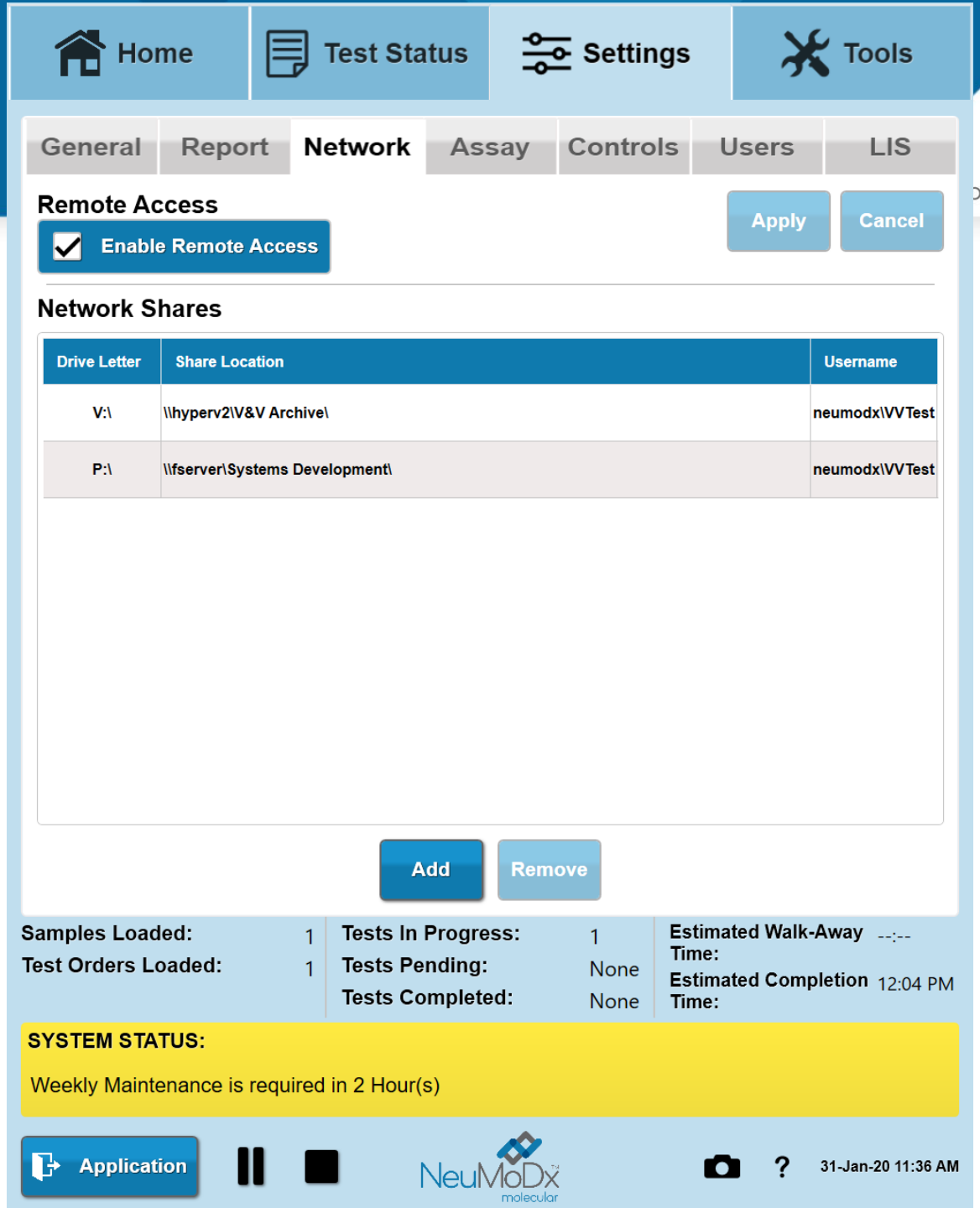

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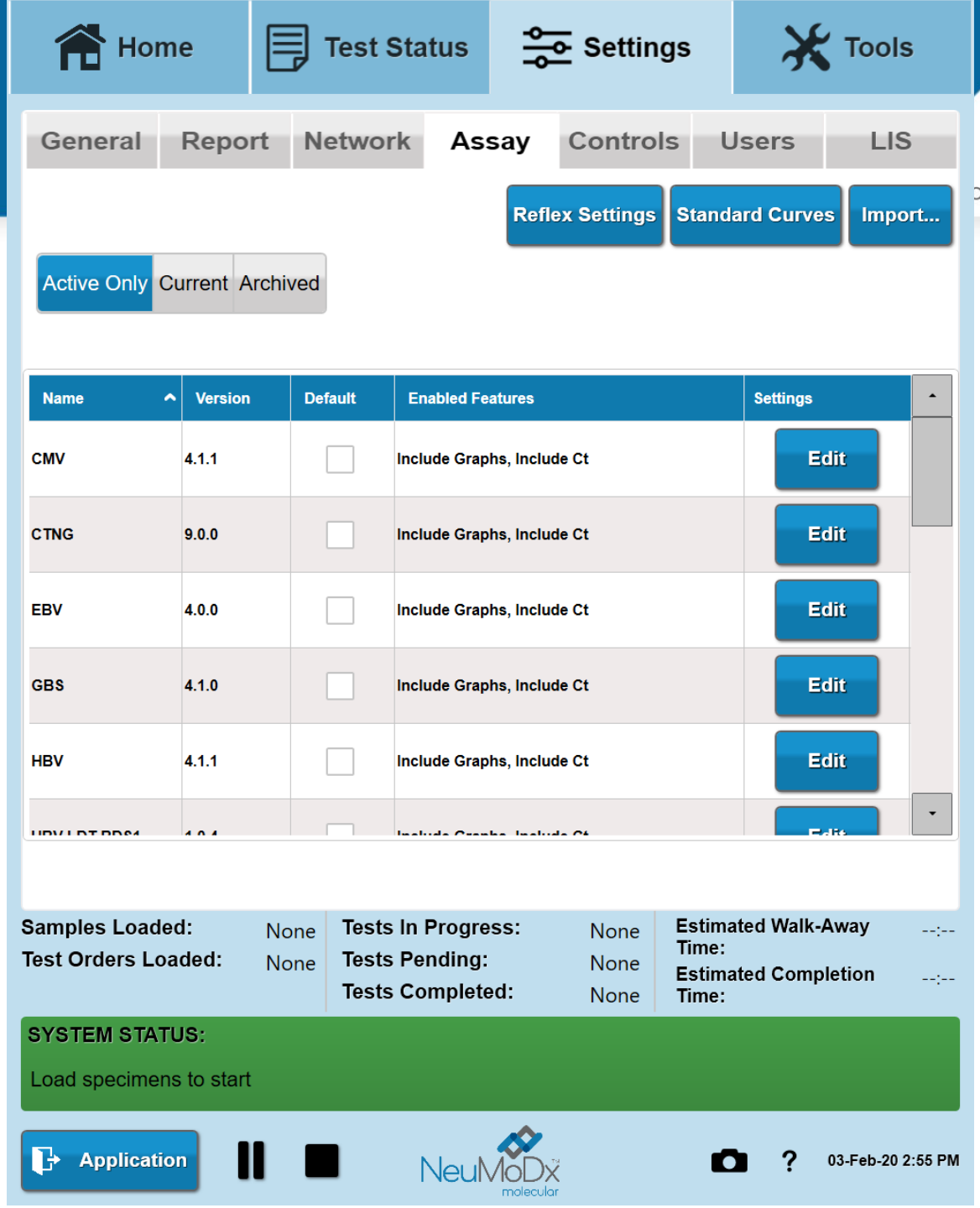
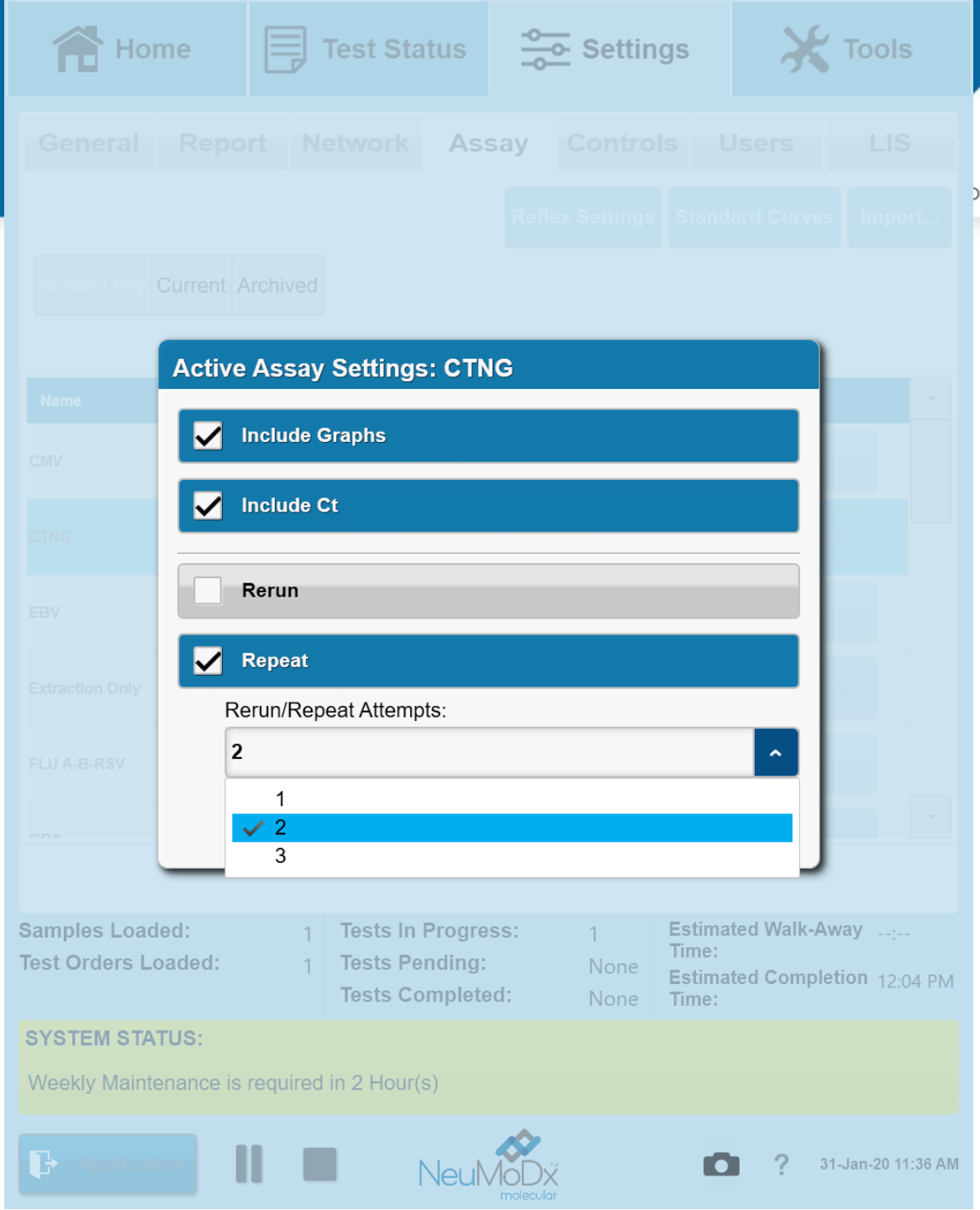


NeuMoDx 96 Software Screen
BioMed Level User



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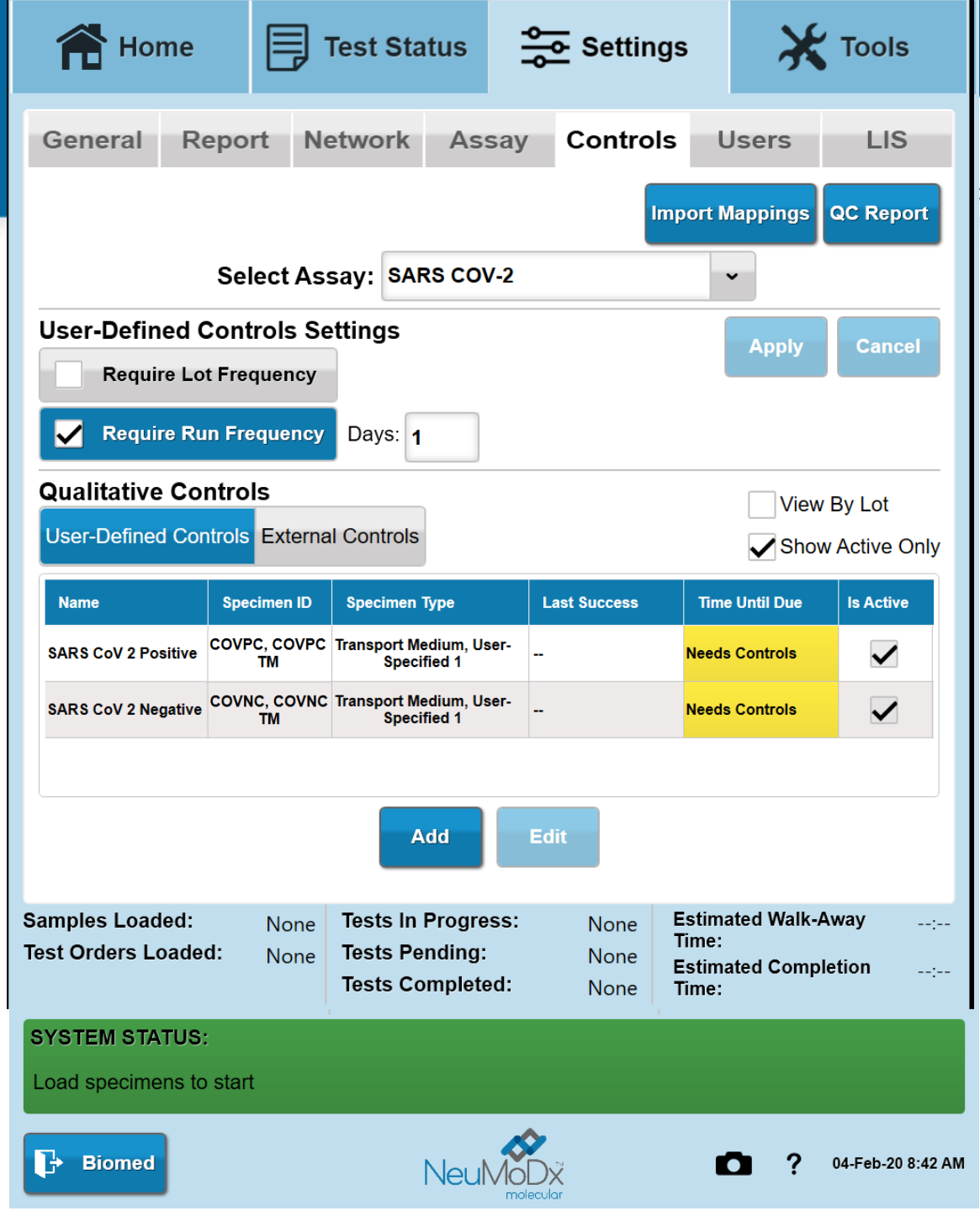
BioMed Level User



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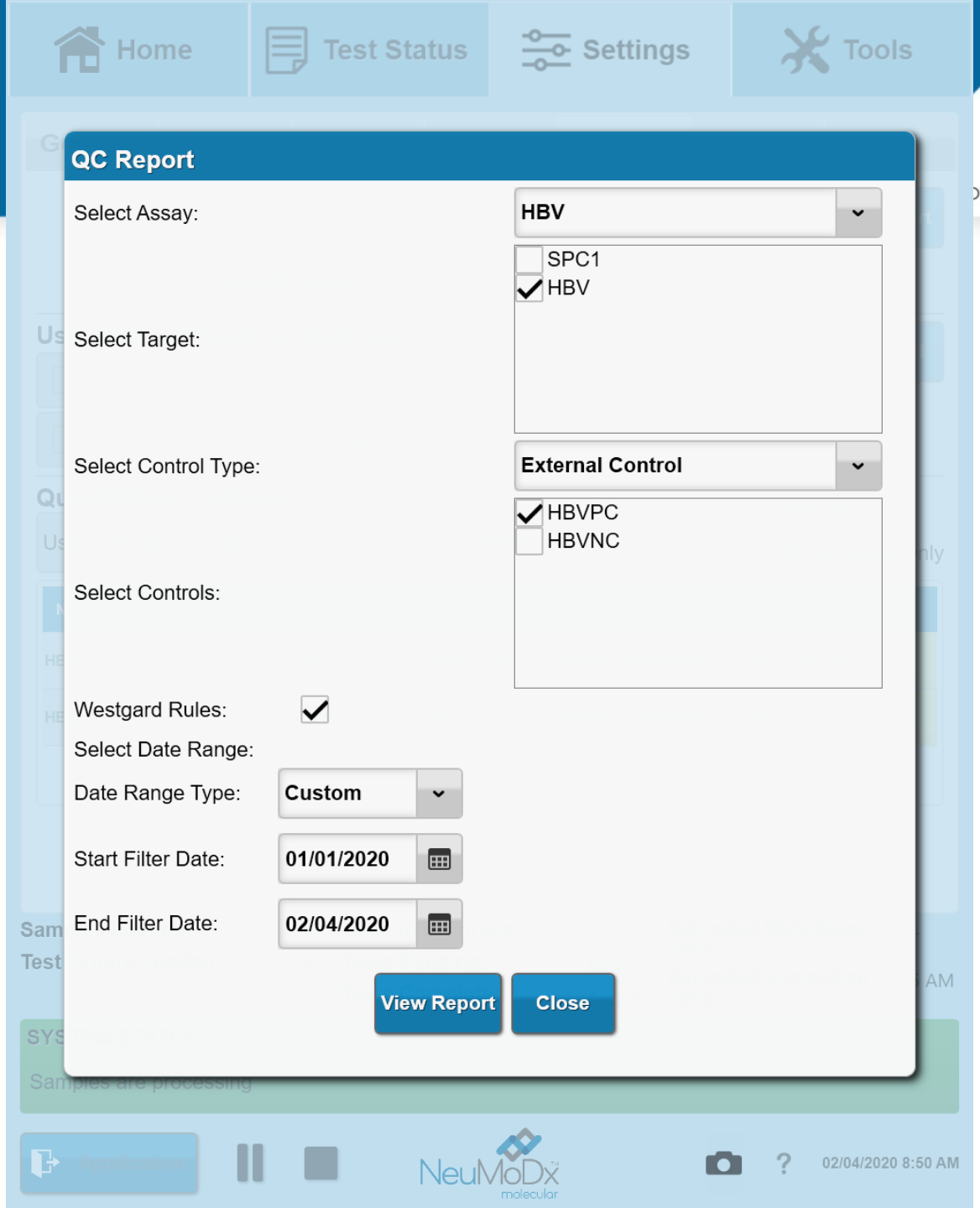
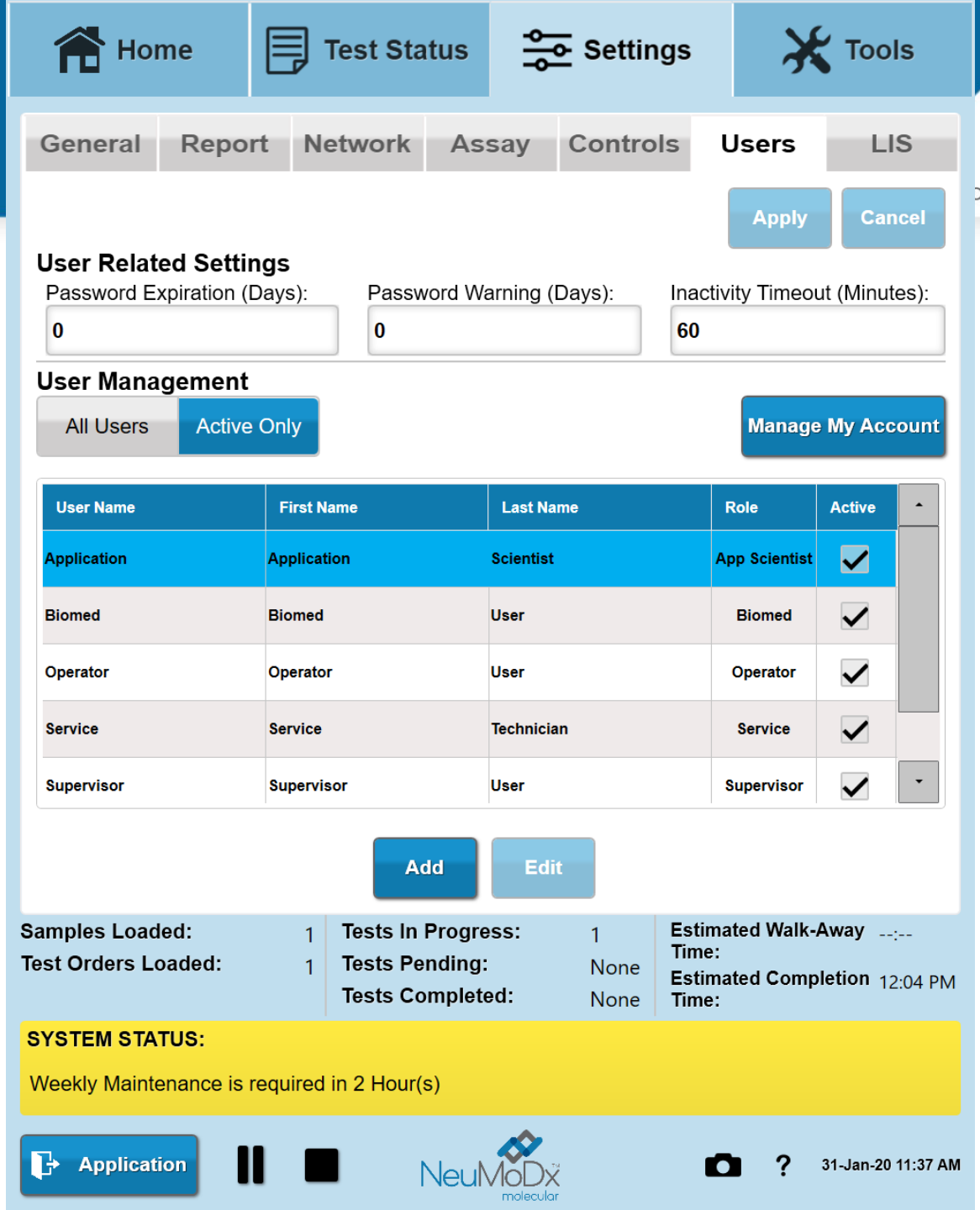
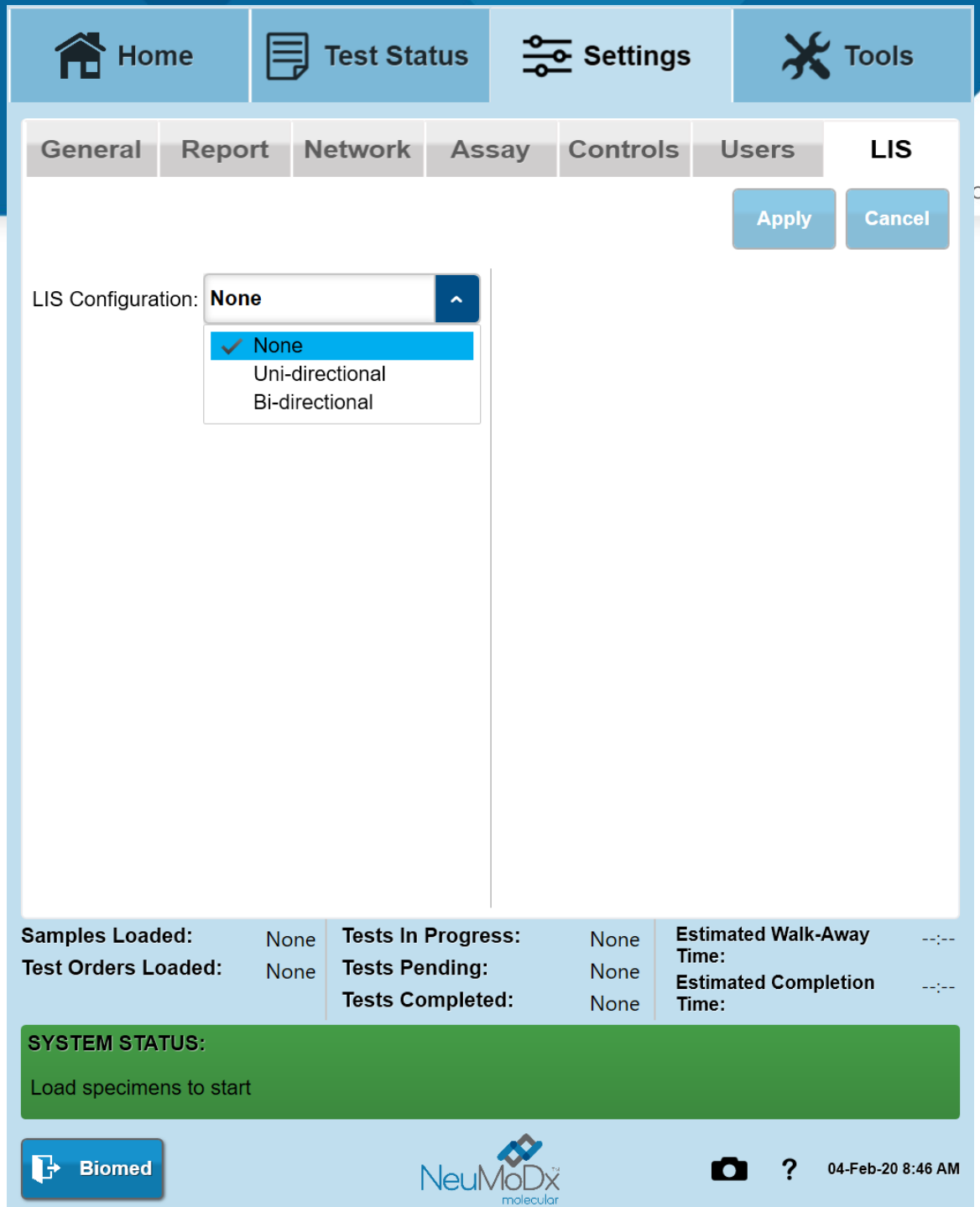


NeuMoDx 96 Software Screen
BioMed Level User



NeuMoDx 96 Software Screen
BioMed Level User



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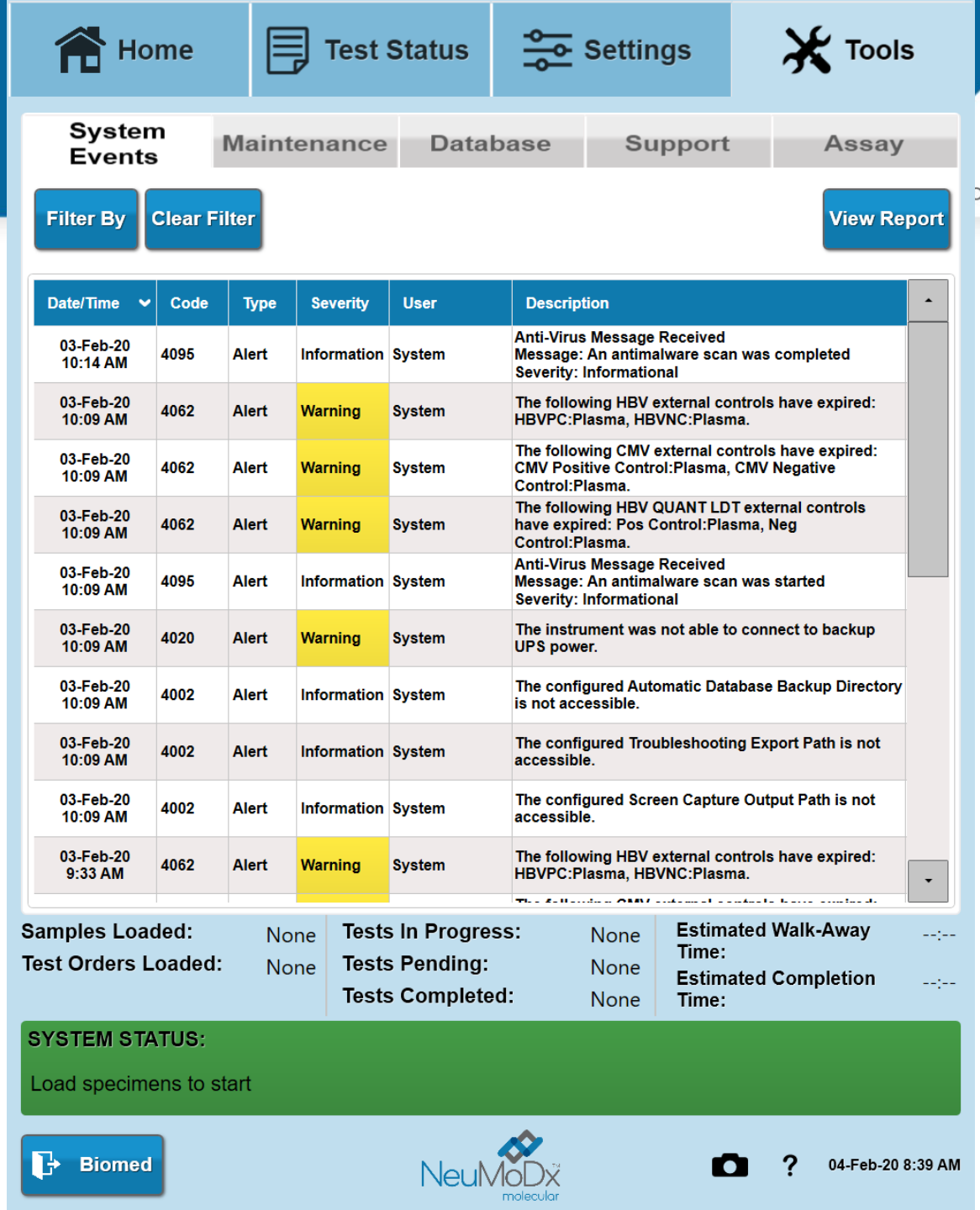

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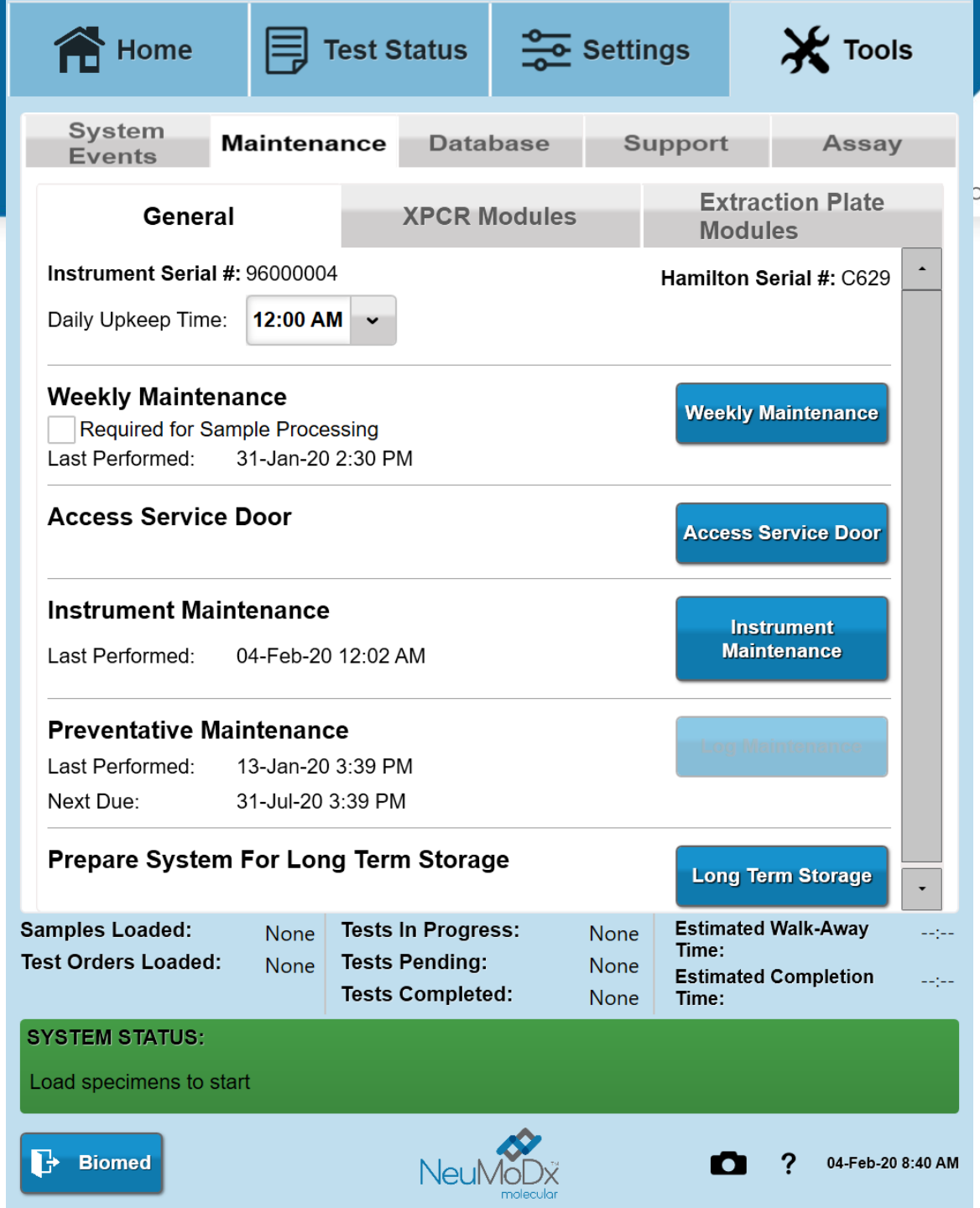
BioMed Level User



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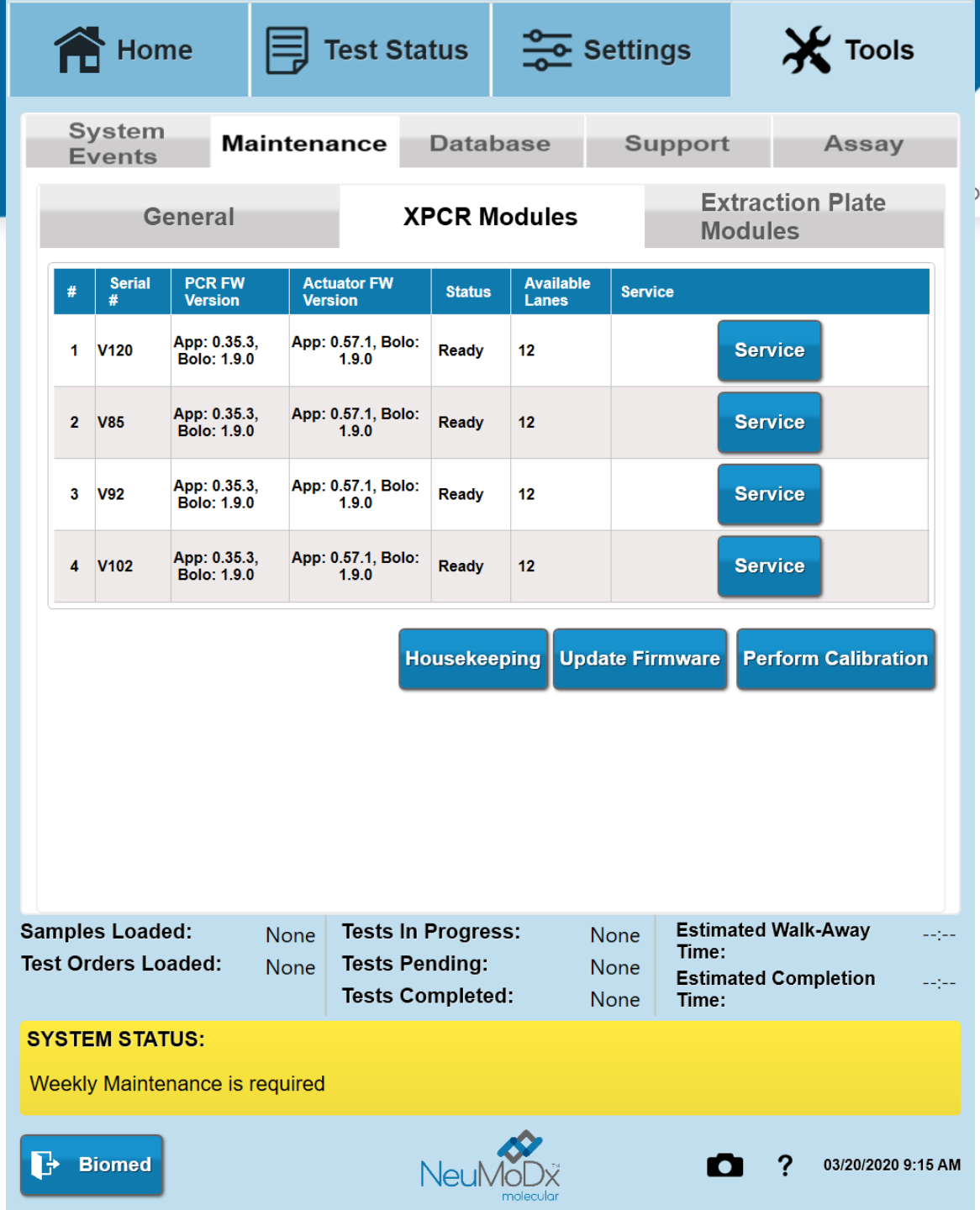
BioMed Level User



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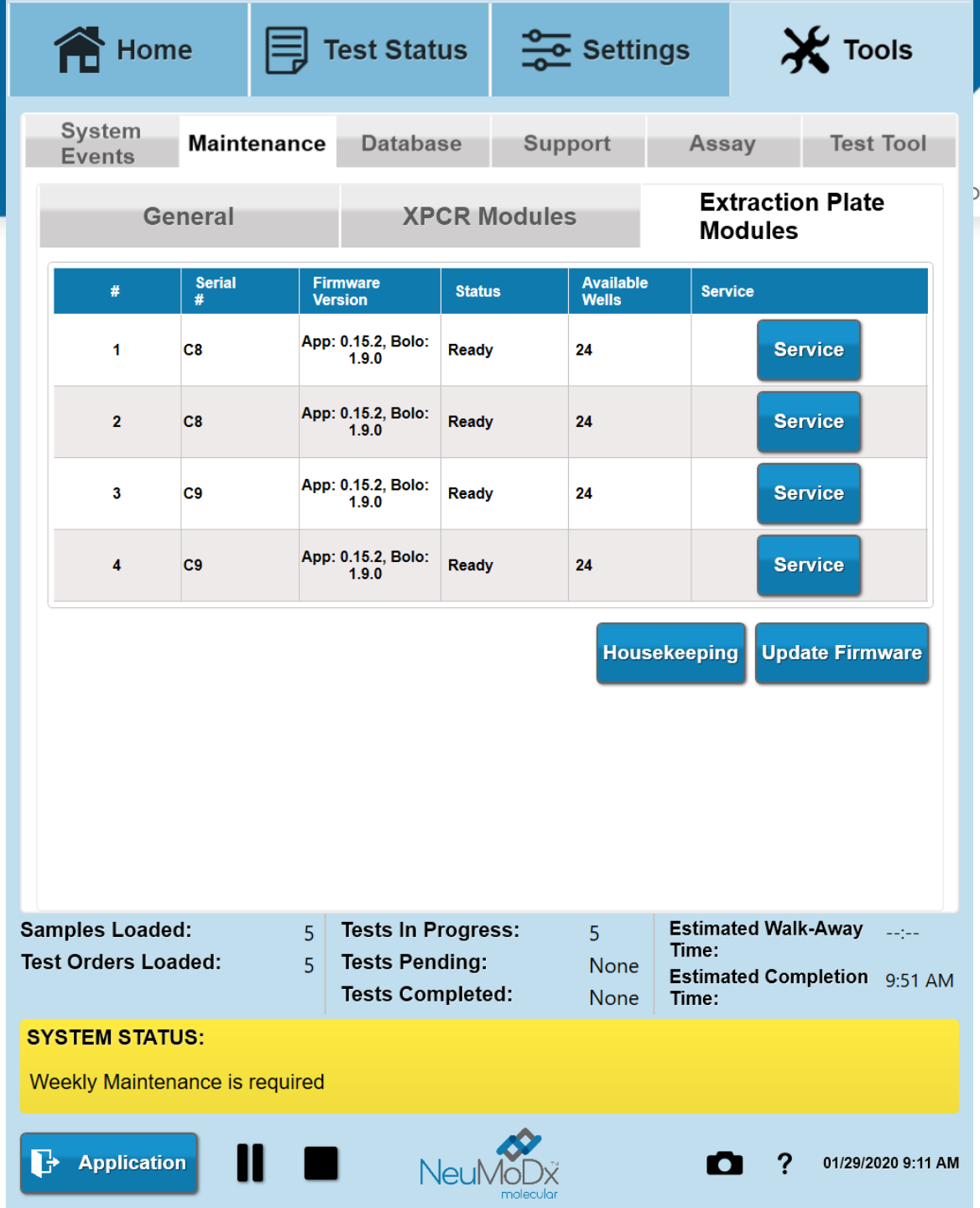
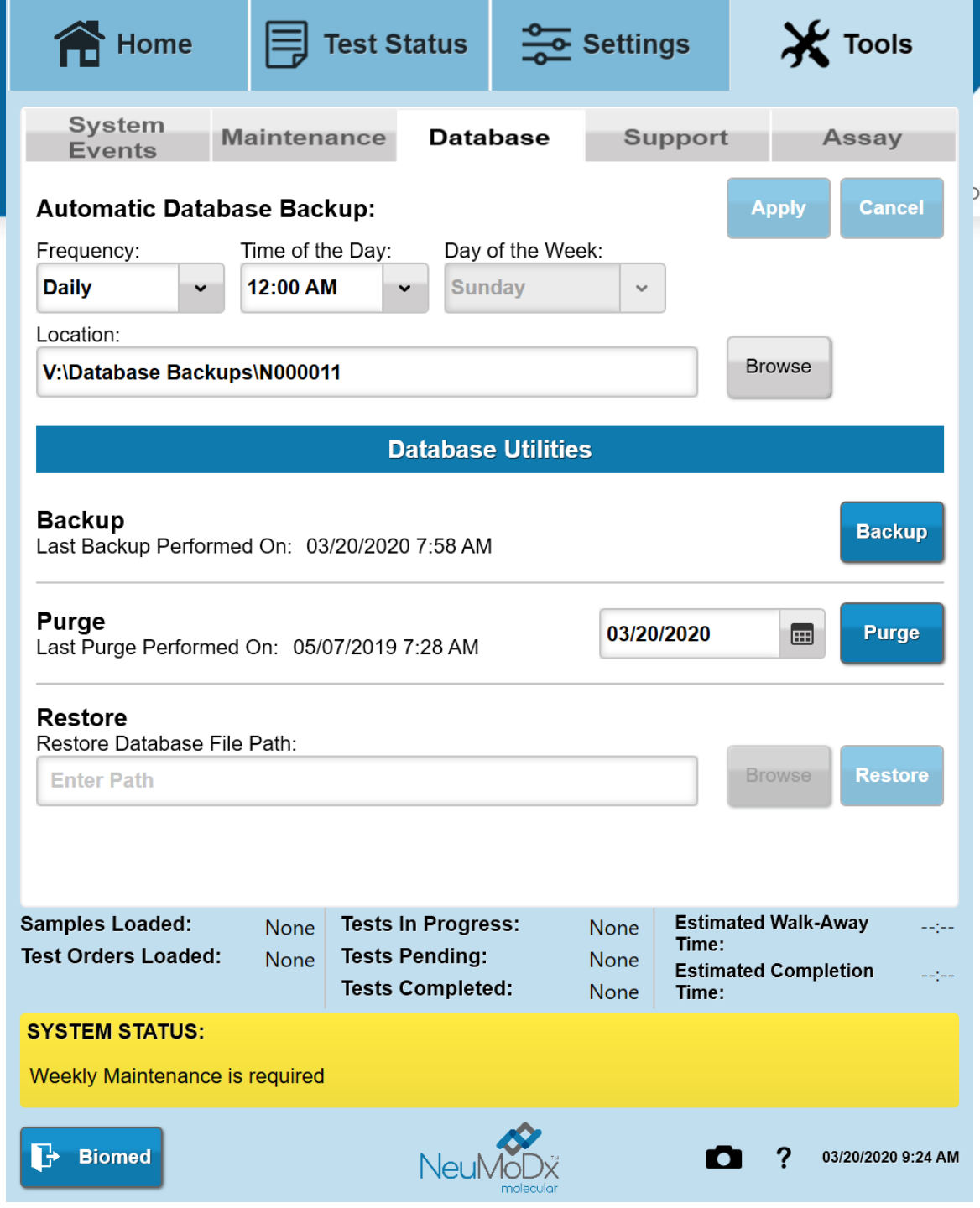
NeuMoDx 96 Software Screen
BioMed Level User



NeuMoDx 96 Software Screen
BioMed Level User



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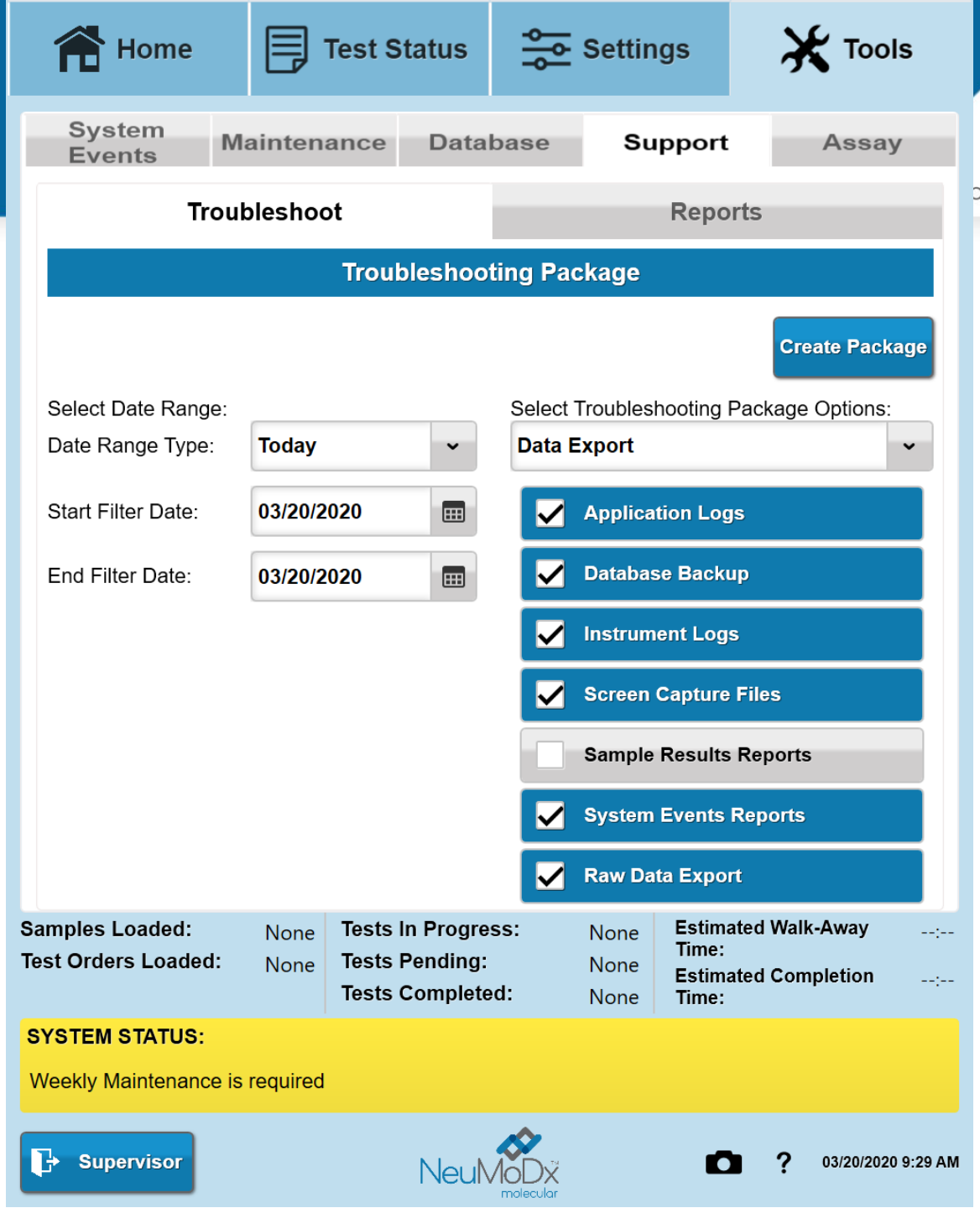
NeuMoDx 96 Software Screen
BioMed Level User



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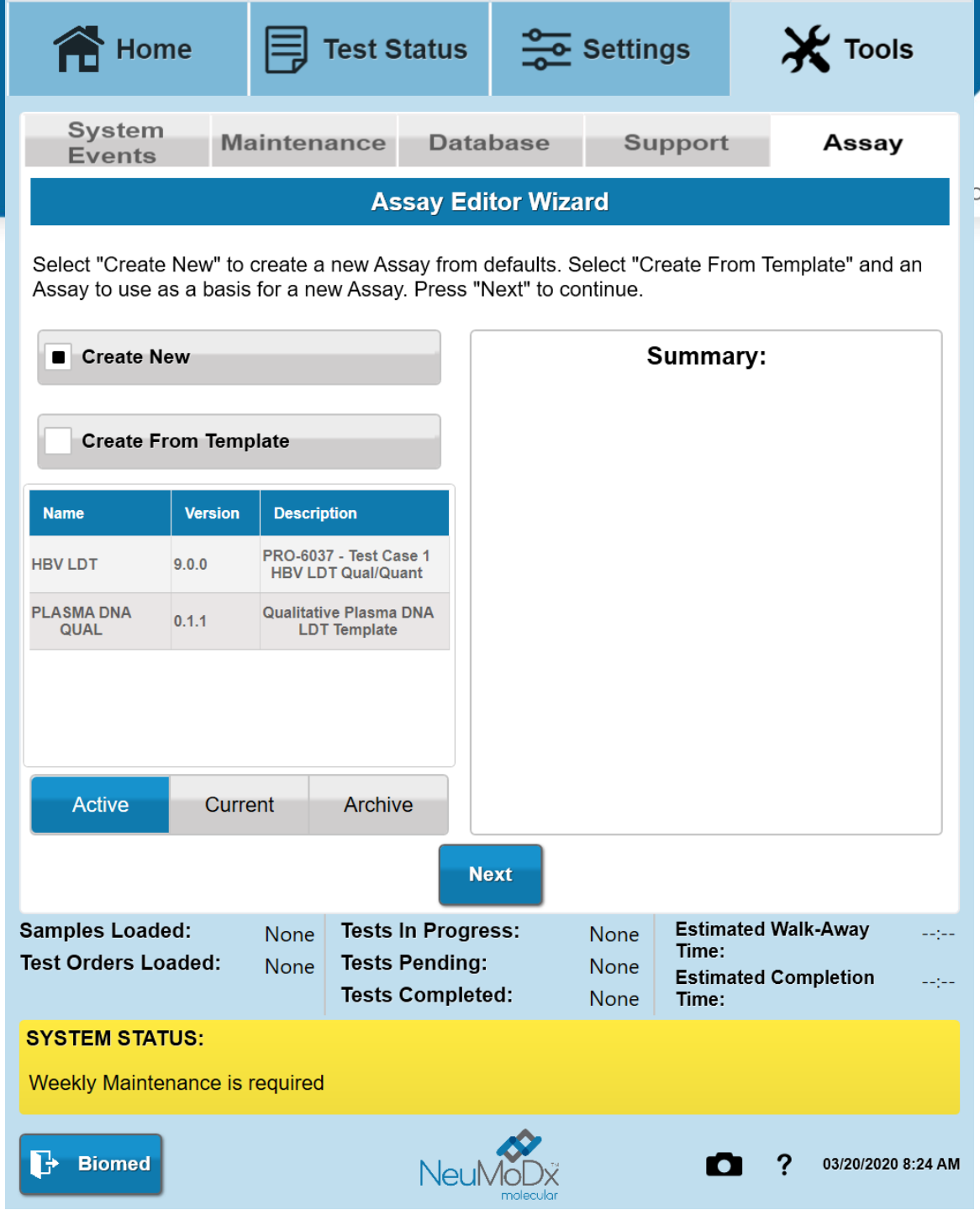
NeuMoDx 96 Software Screen
BioMed Level User



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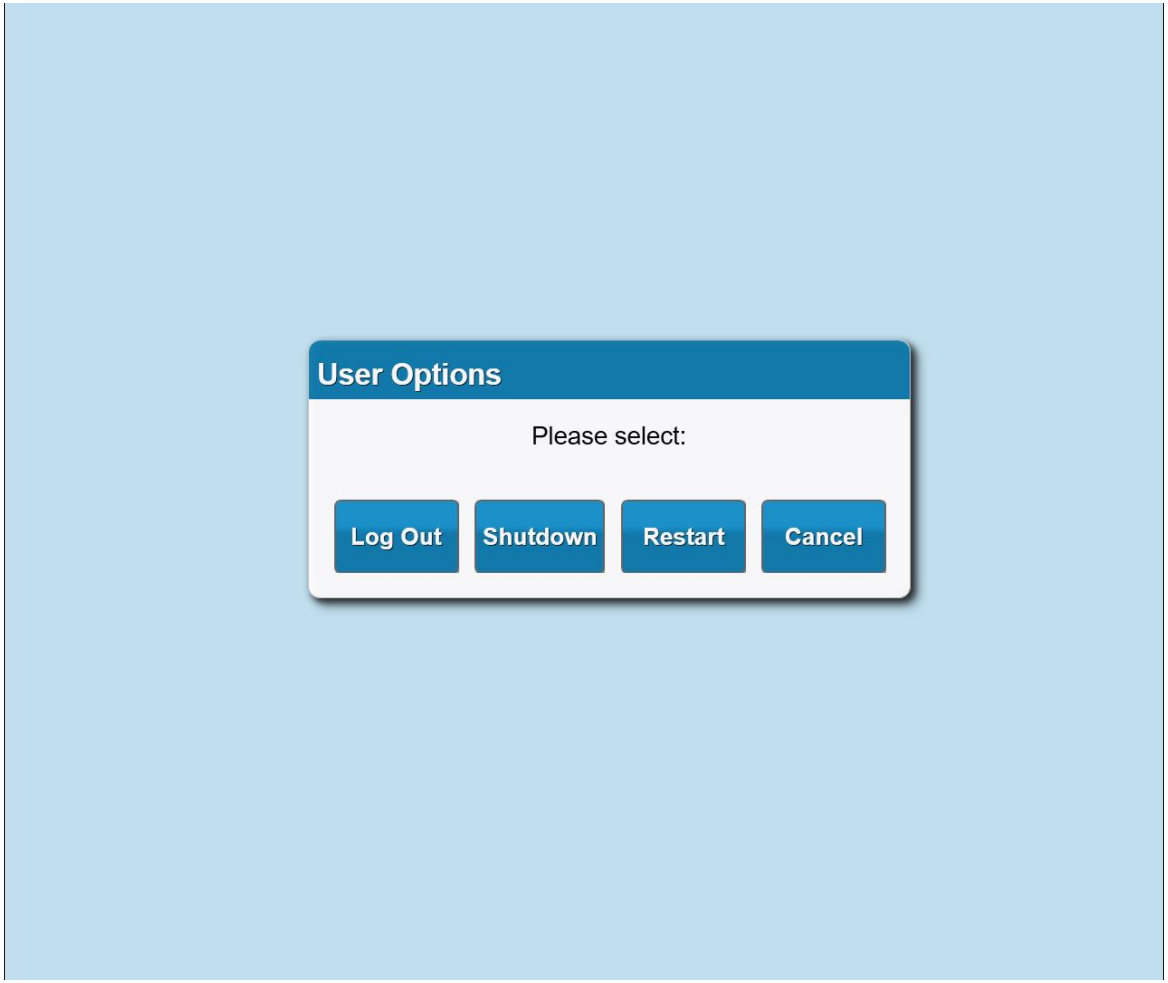
NeuMoDx 96 Software Screen
BioMed Level User



Changing Wash & Release, and Emptying Priming Waste

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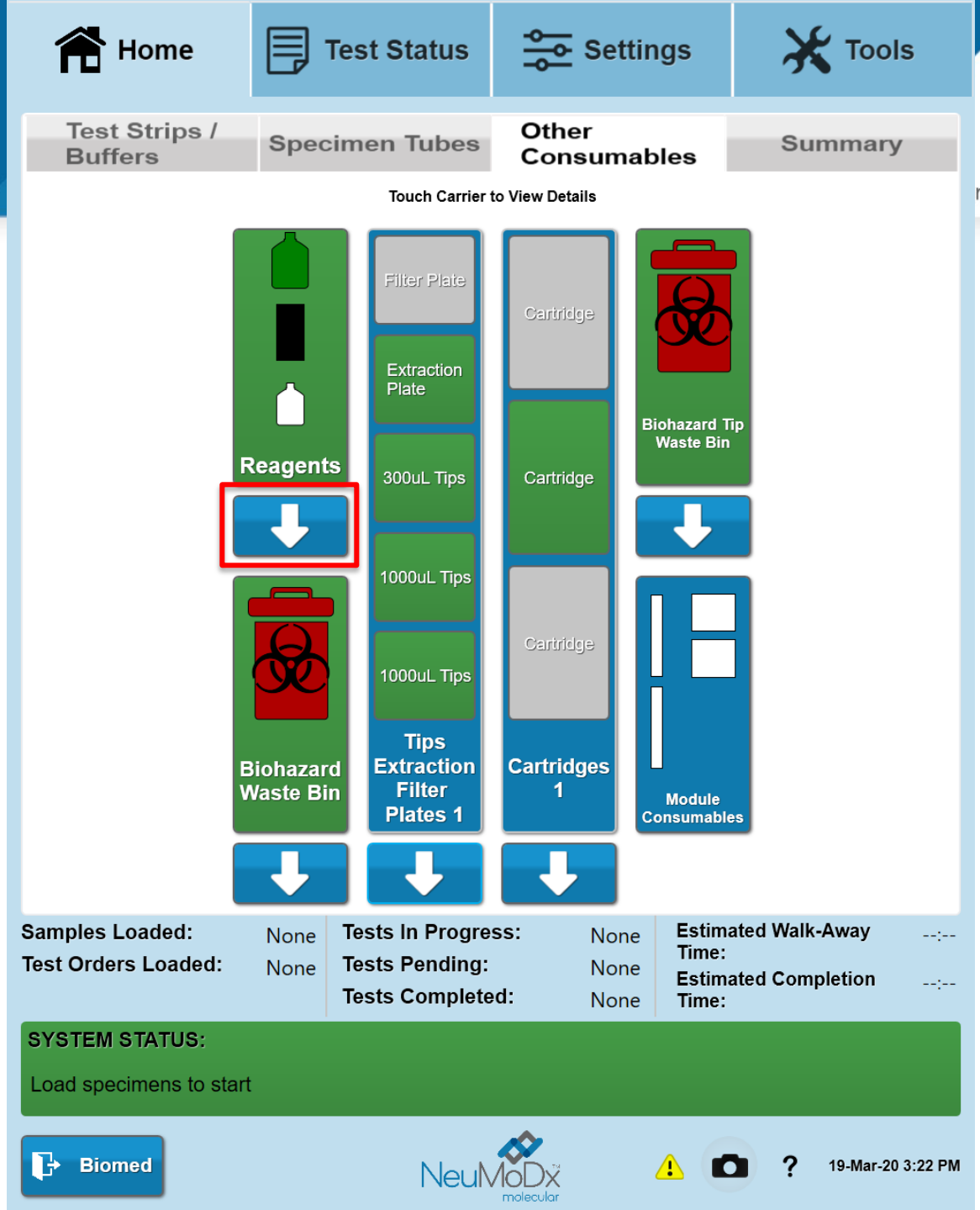
Follow the prompts on the GUI to:

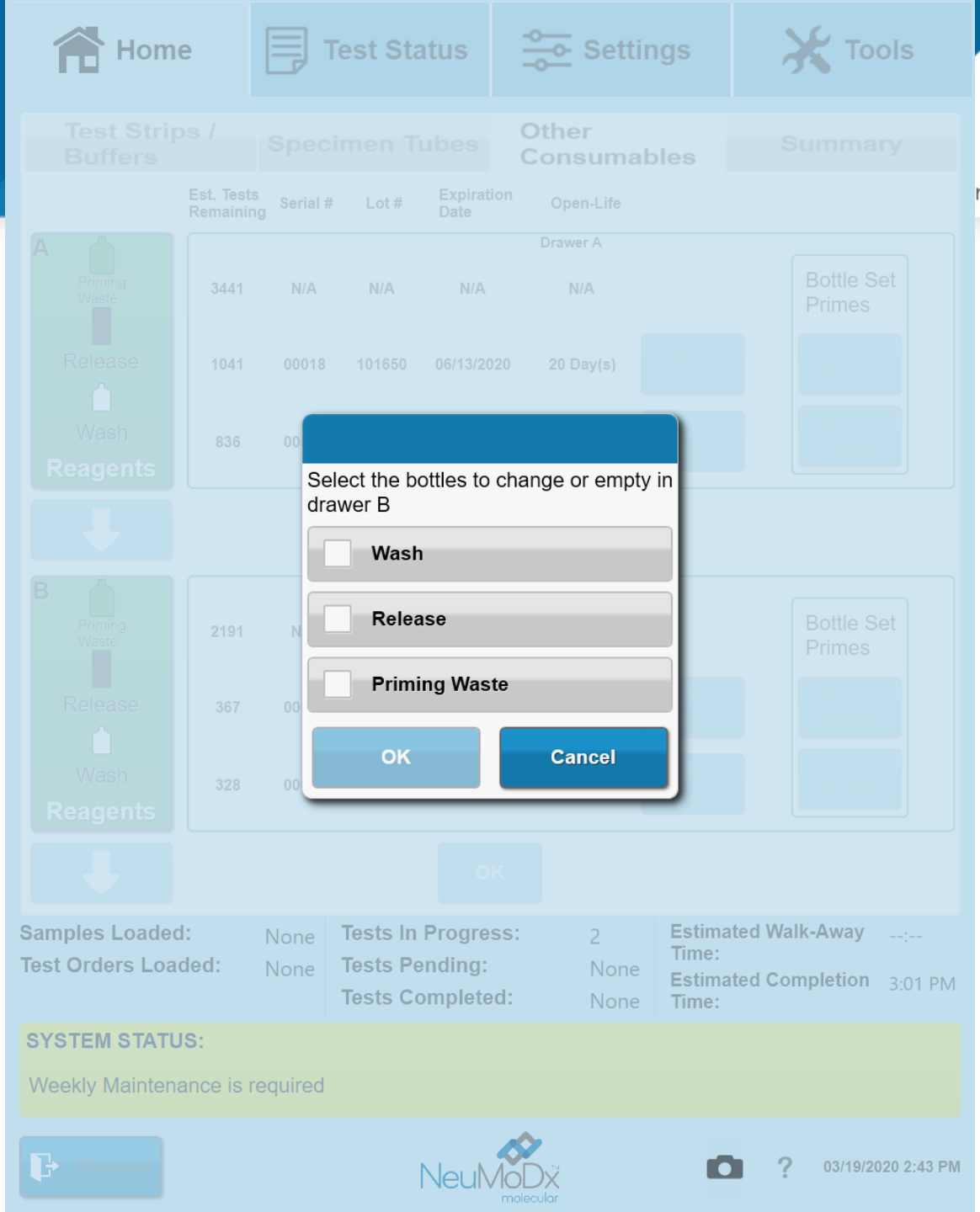
- Change Wash & Release
- Empty Priming Waste

0.02% Sodium Azide

<1% Sodium Hydroxide

Combination of Wash and Release





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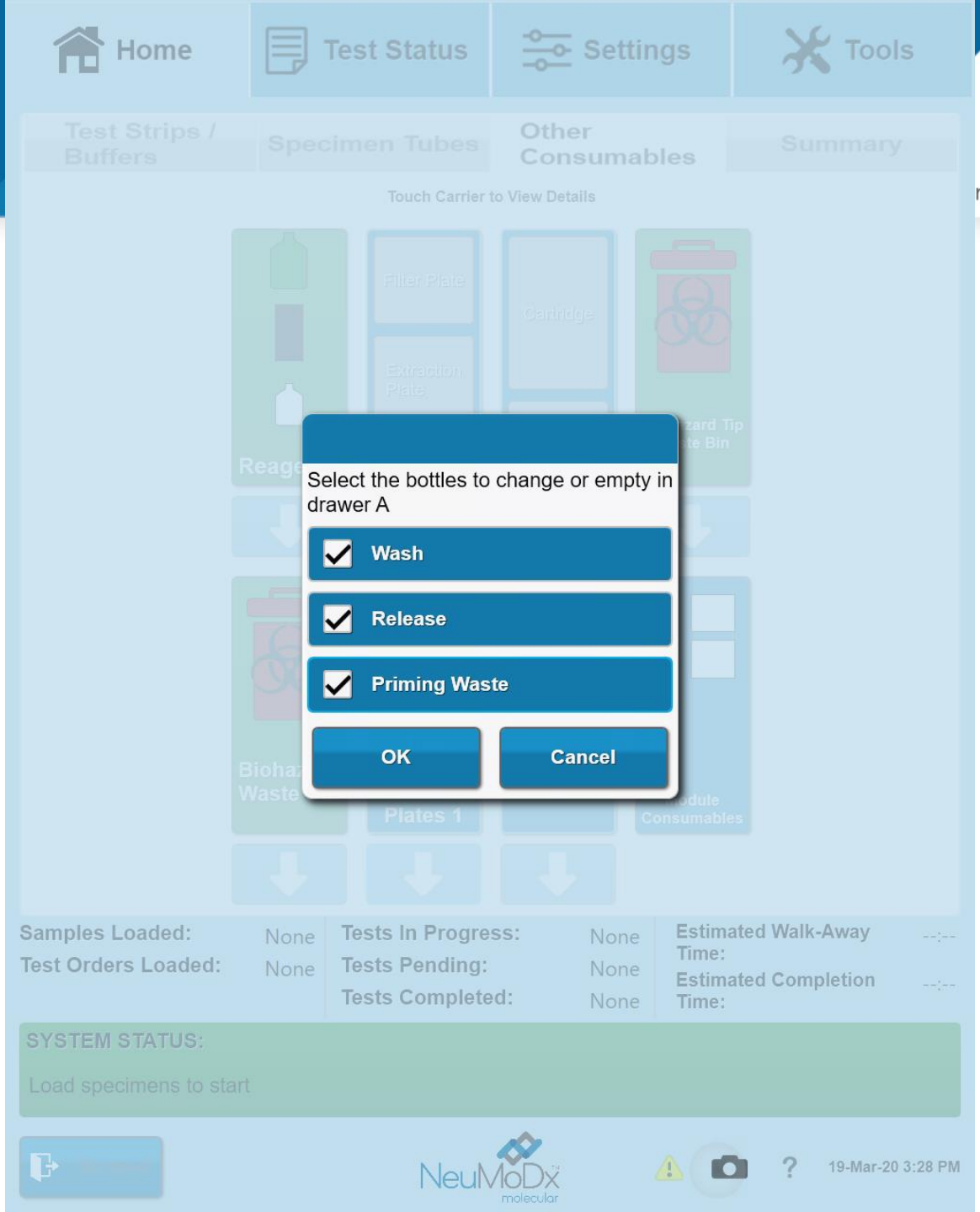

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Home | Test Status | Settings | Tools

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Replace Wash Reagent Bottle

1. Open Liquid Reagent Drawer A. — Confirm

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

SYSTE

Load specimens to start

Biomed

NeuMoDx molecular

19-Mar-20 3:28 PM

Home | Test Status | Settings | Tools

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Replace Release Reagent Box

1.	Open Liquid Reagent Drawer A.	Confirm ☑
2.	**Scan the barcode of the new Release reagent box.** 0100814278020222 10LLLLLLX21SSSSSX17YYMMDD	☐
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

Load specimens to start

19-Mar-20 3:30 PM

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

Close Cancel

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

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- 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

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- 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

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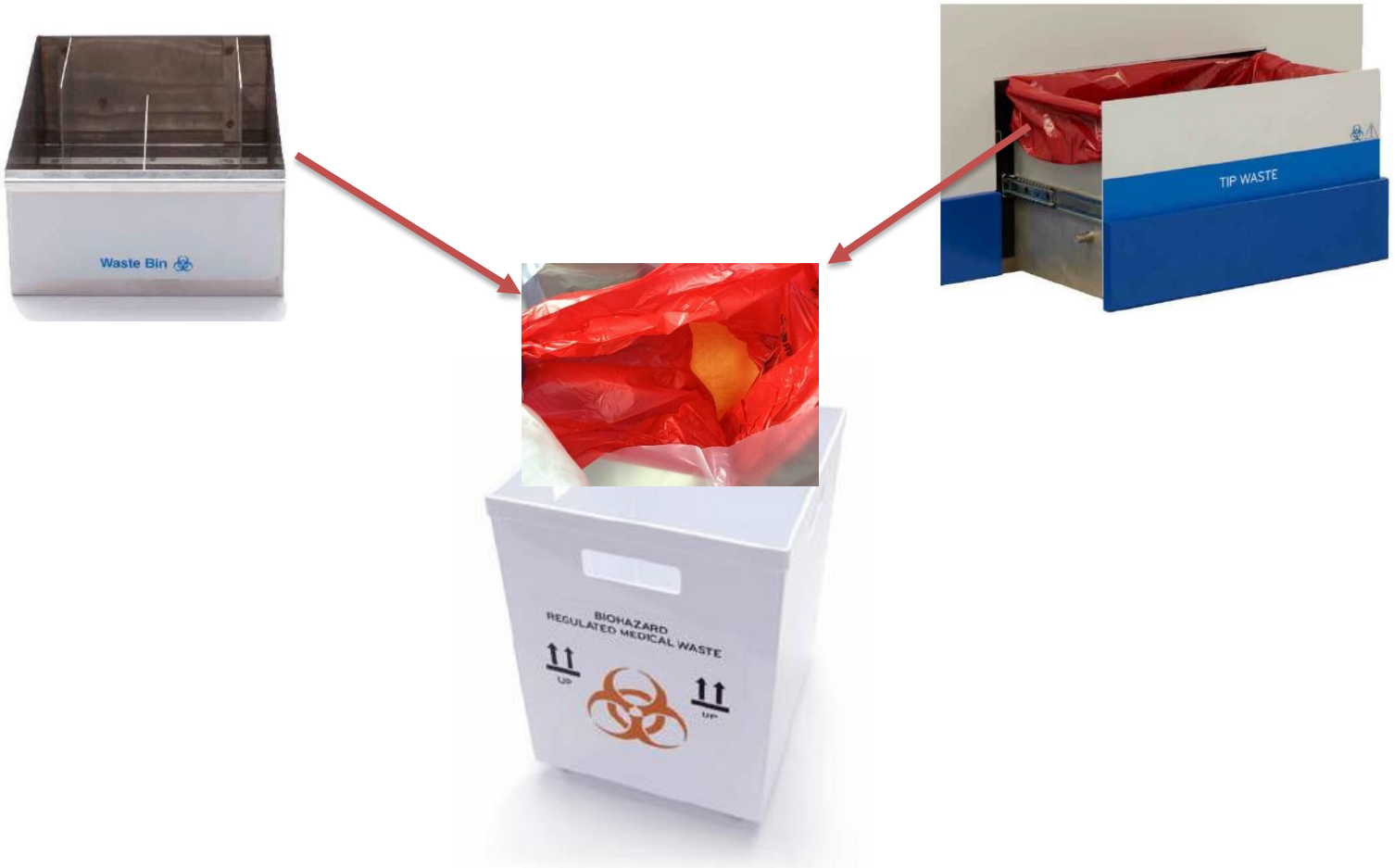
- When either waste bin is **full as prompted by the Software**, the waste should be emptied into a NeuMoDx Biohazard Waste Container lined with the NeuMoDx Biohazard Waste Bag



NeuMoDx 96 Molecular System
NeuMoDx™ Biohazard Waste Bag

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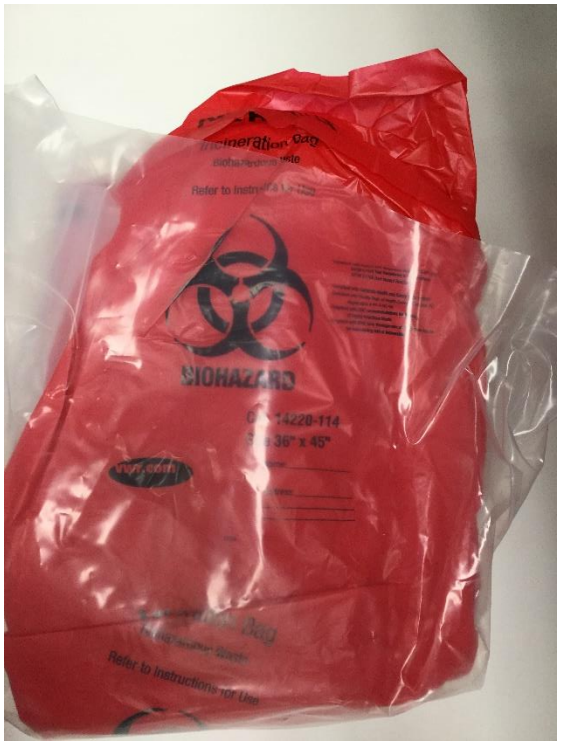
- It is imperative that NeuMoDx™ consumables (namely the NeuMoDx™ Extraction Plates and NeuMoDx™ Cartridges) are disposed in the NeuMoDx™ Biohazard Waste Bag



NeuMoDx Biohazard Waste Bag Handling once full

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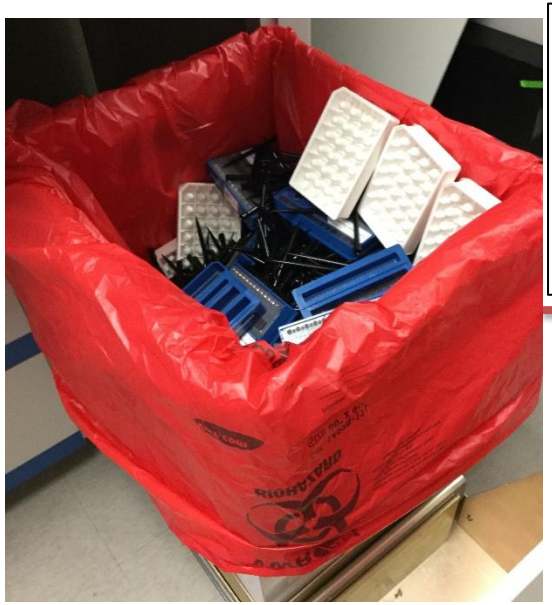
- Once the external Biohazard Waste Bag associated with the NeuMoDx 96 is full (confirm visually, should not be overflowing), follow these instructions:



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

Weekly Cleaning & Weekly Shutdown

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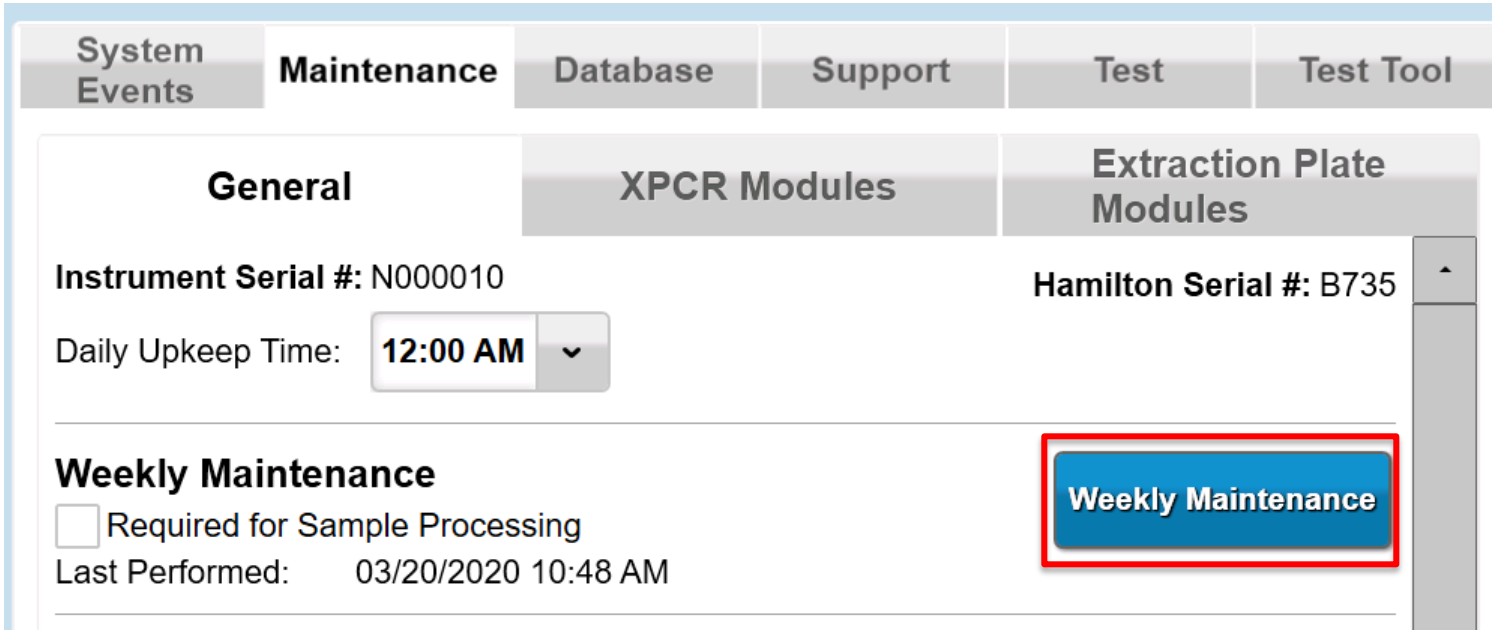

Alert! Software bug in v 1.8.2.4 requires a full system shutdown every 3-5 days.

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

Weekly Cleaning & Weekly Shutdown

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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

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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

Weekly Cleaning & Weekly Shutdown
Some Cautions

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- 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

NeuMoDx™ molecular

User Accounts / Permissions

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	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

NeuMoDx™ molecular

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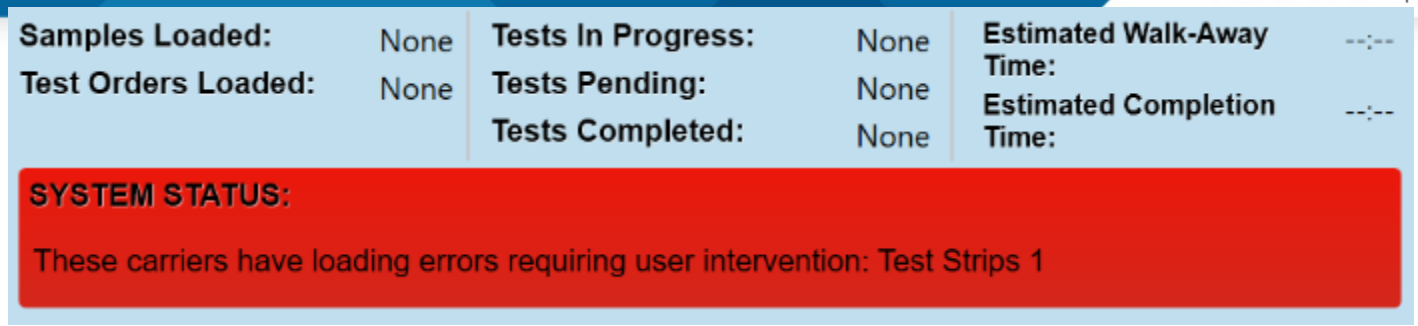


Status Bar: Can be Green, Yellow, or Red. Clicking on the status bar will bring you to the page that requires attention.

Green – system or consumable status is ready to be used, no issues

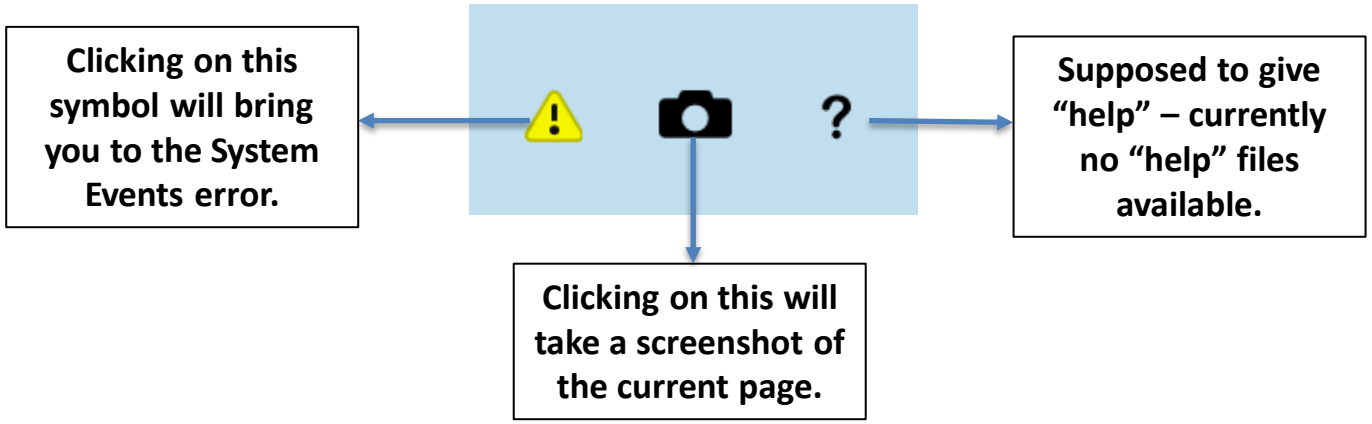
Yellow – system or consumable is ready to be used but may require user intervention for optimal performance

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

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Placing Barcodes on Samples

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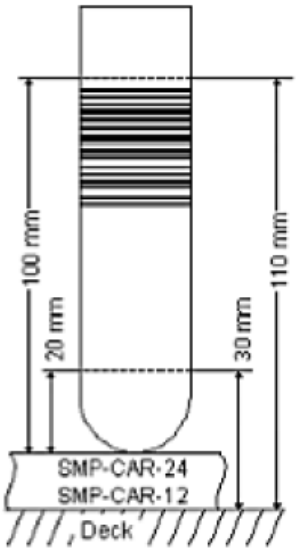
- Barcodes should be placed between 20 mm and 100 mm from the bottom of the tube
- Place the tubes in a 32-tube or 24-tube carrier with the barcodes facing outwards



24-Sample Carrier

32-Sample Carrier

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

Loading Samples
Sample Tube Dimensions & Volumes

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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.

NeuMoDx Molecular System
Assigning a Test

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- 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

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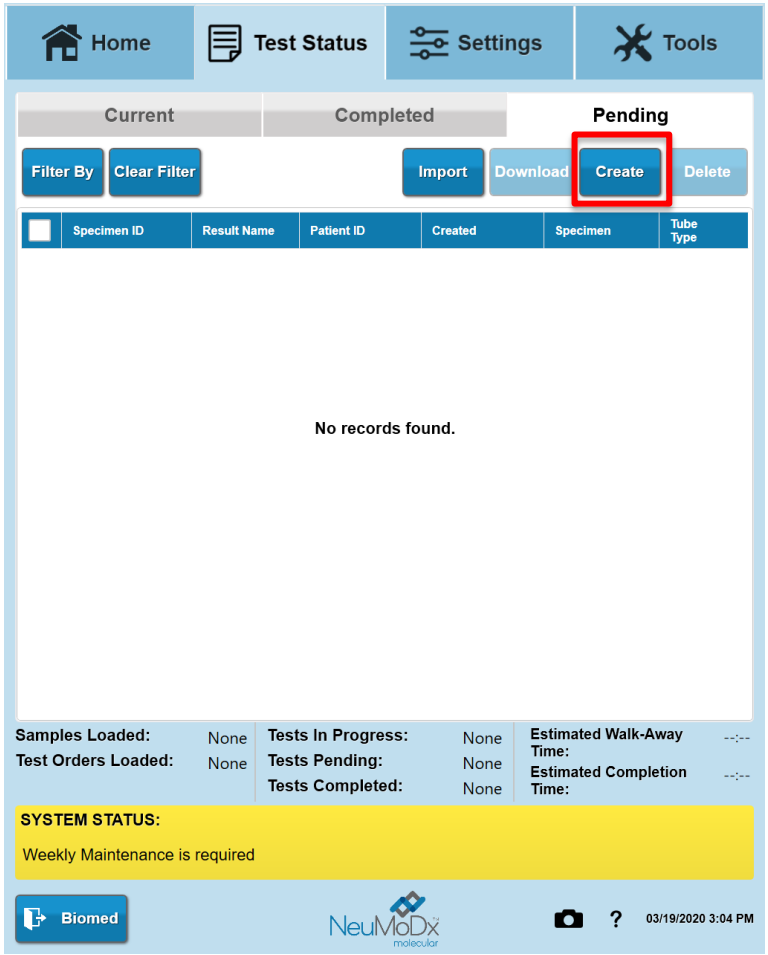
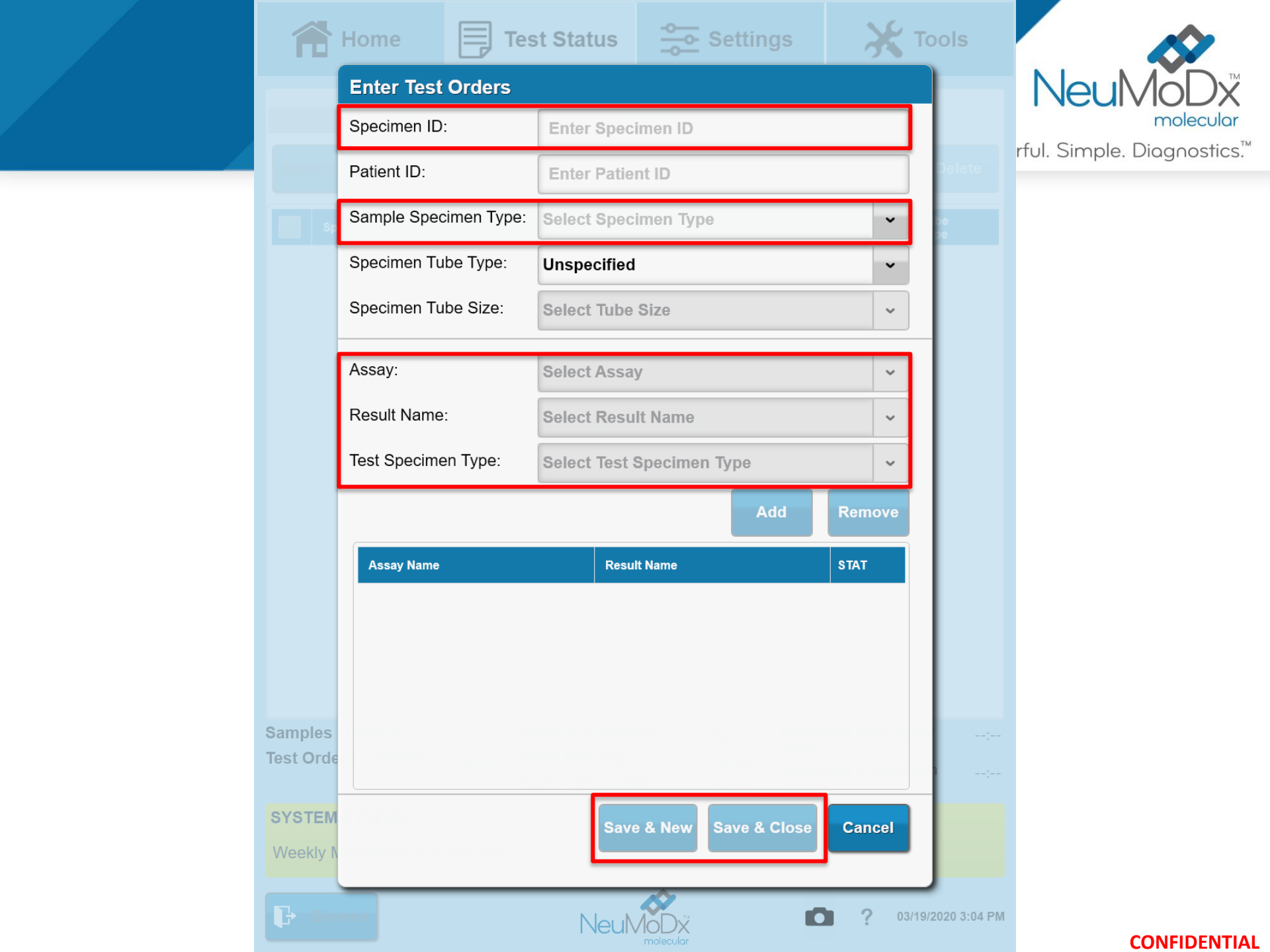
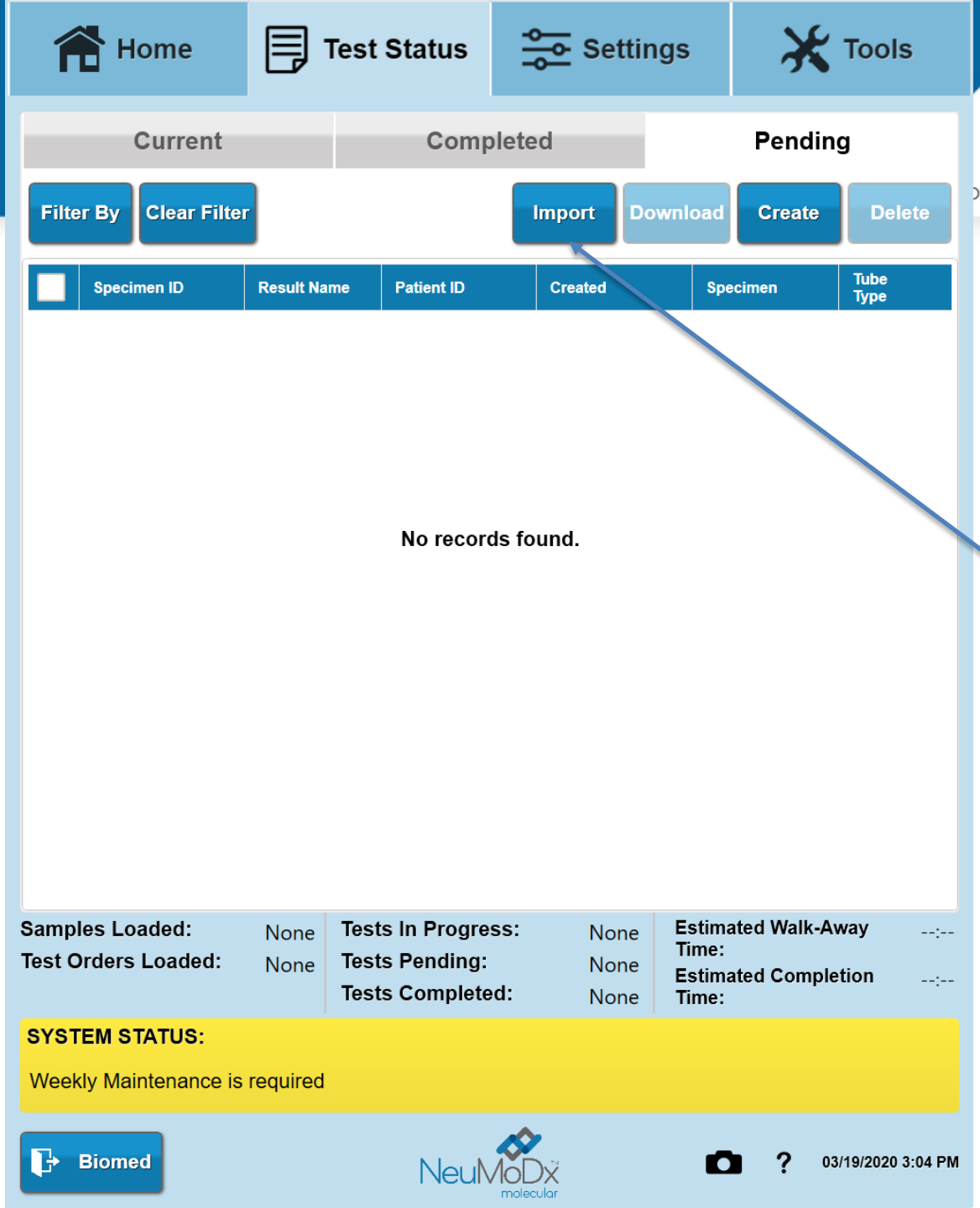
- Pre-assign test order manually with the "Pending Tab"







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Import excel from:
- USB
- Network

NeuMoDx Molecular System
Assigning a Test

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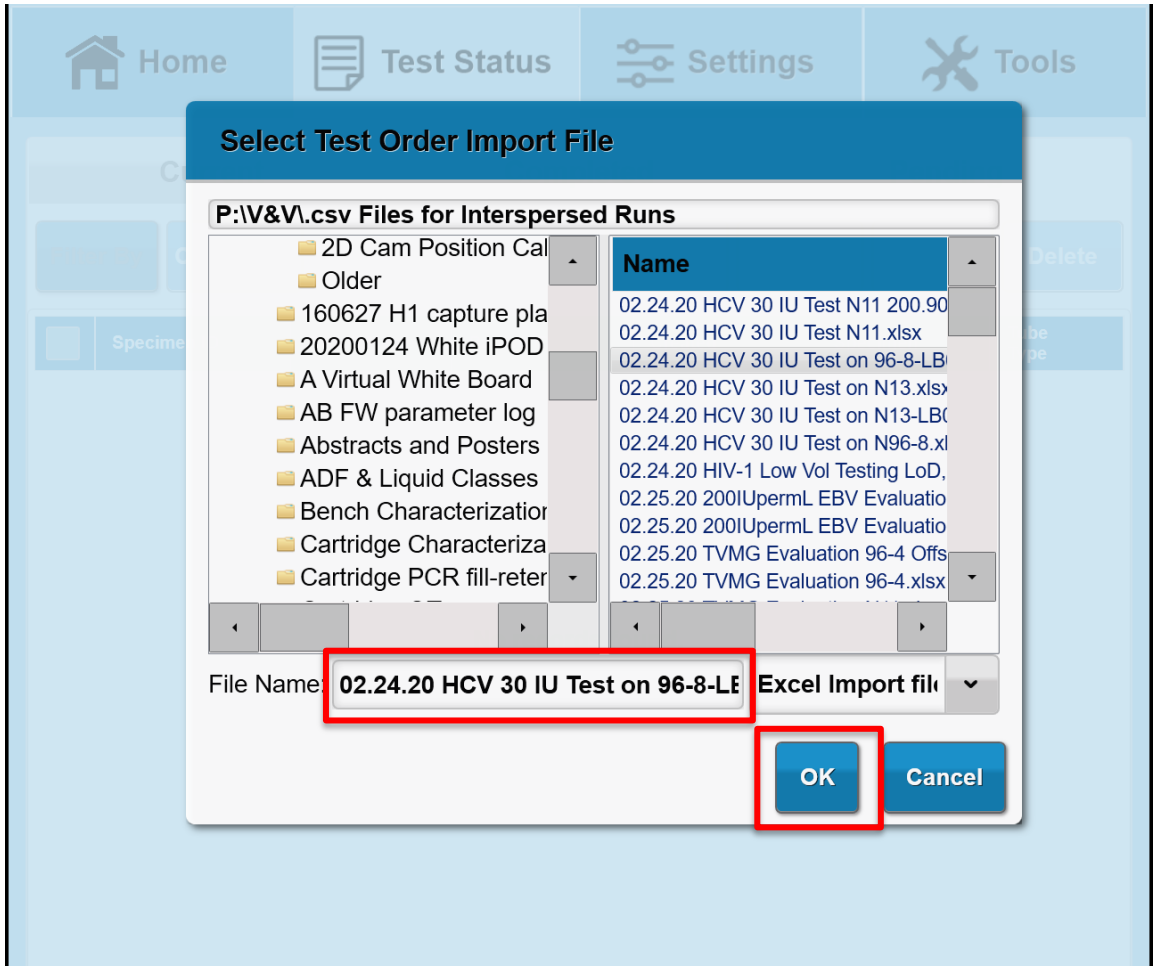

NeuMoDx Molecular System
Assigning a Test

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- 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

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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

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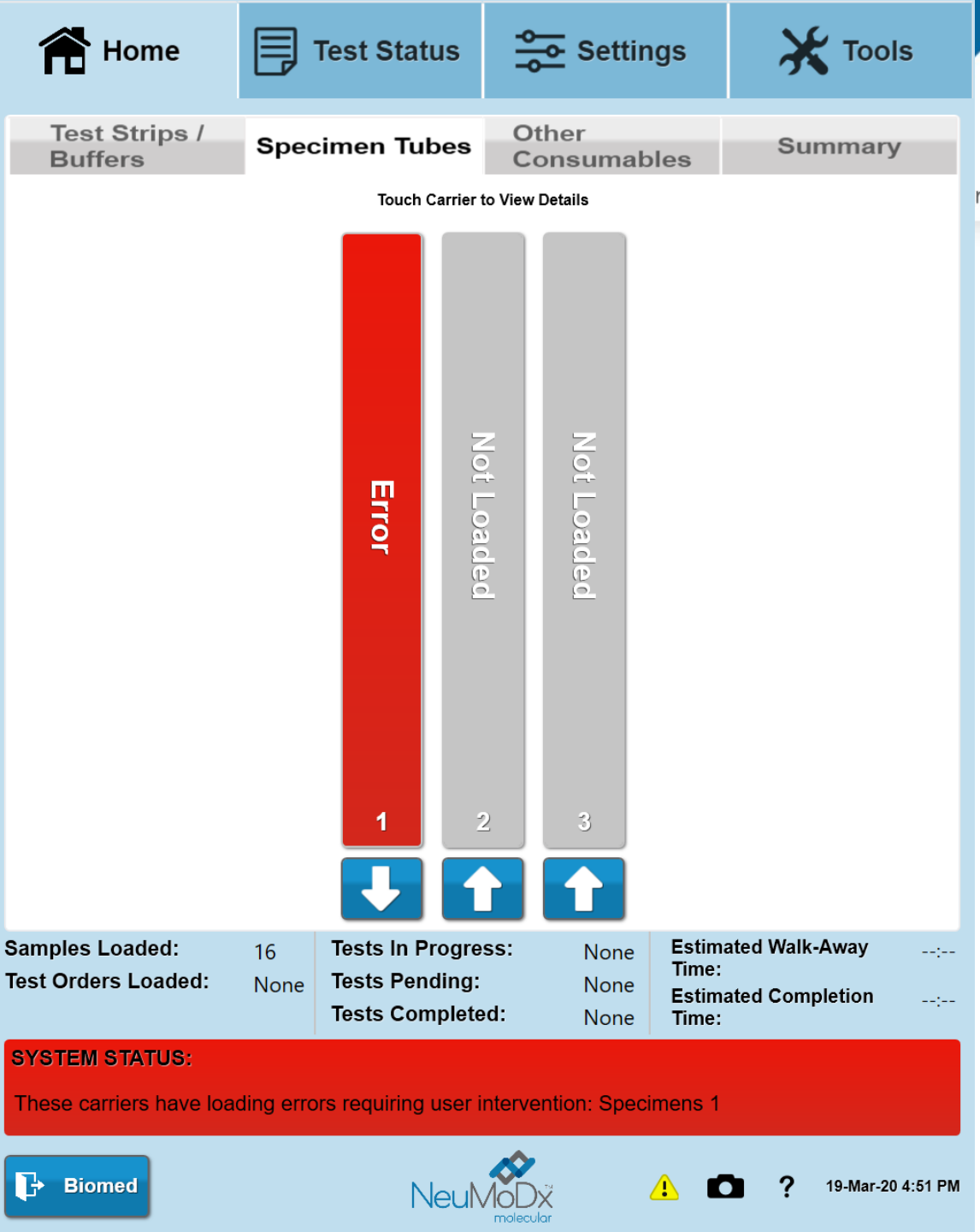
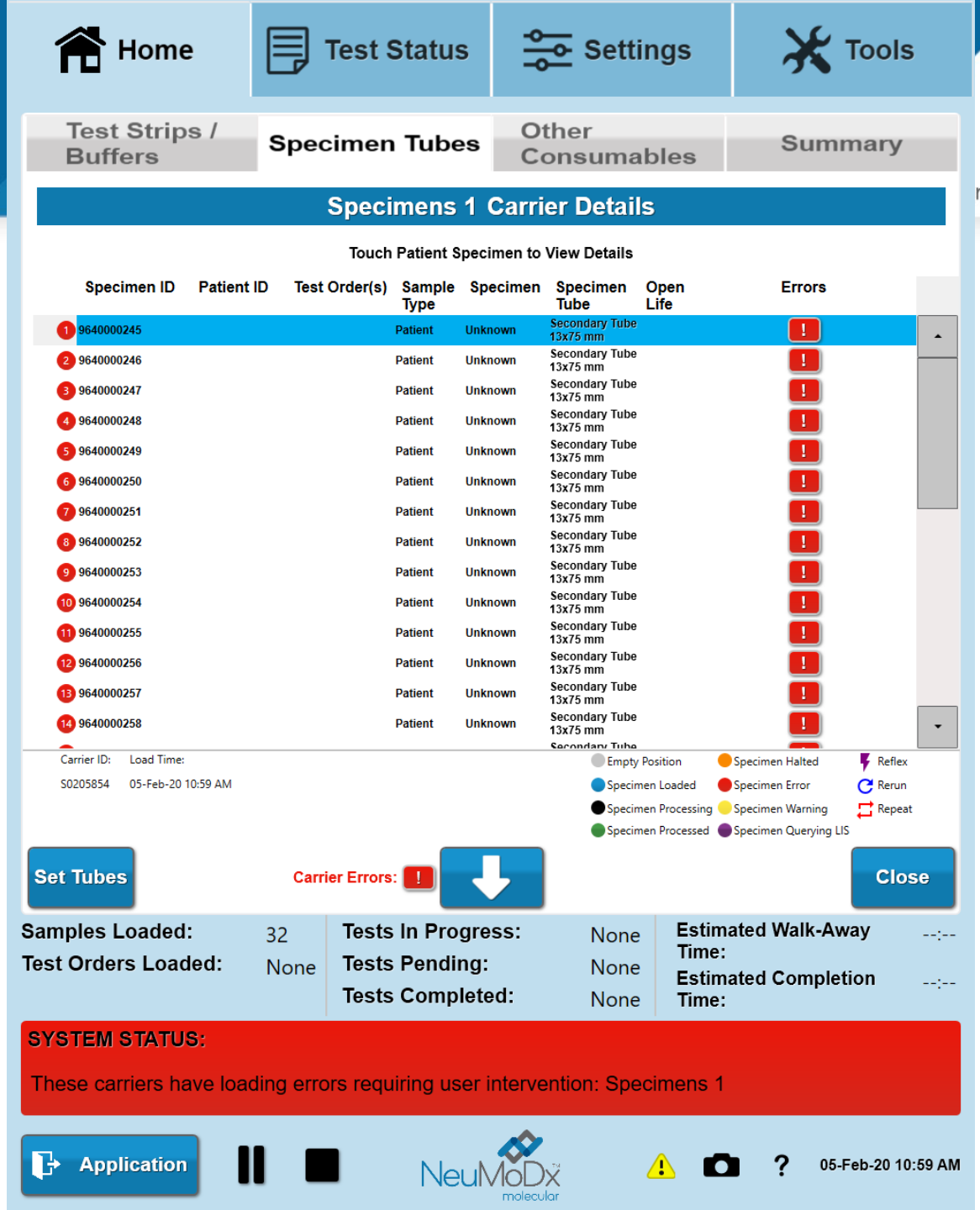
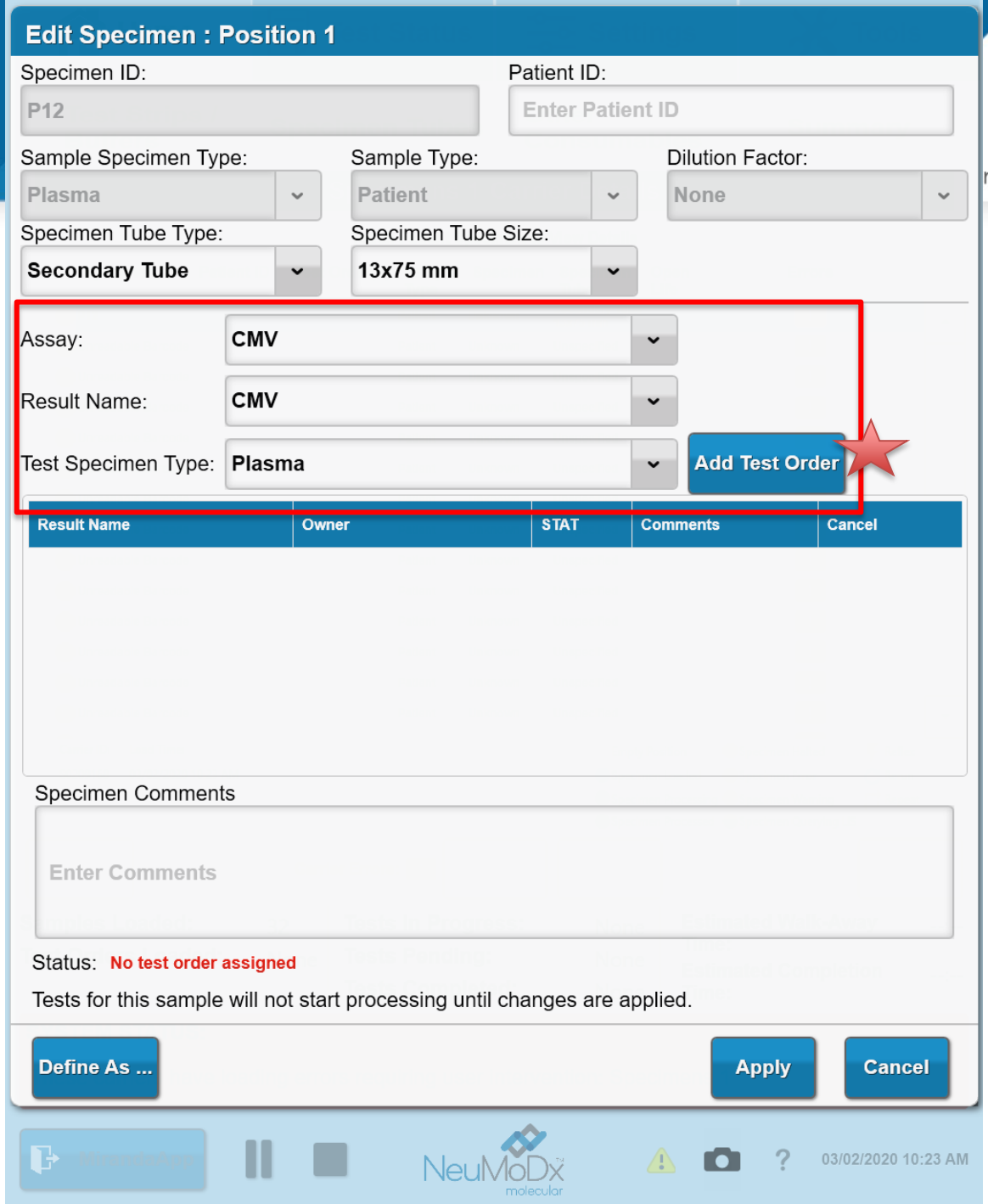
- Send in Sample Rack, assign each specimen individually and manually
  - Software will throw an error saying “No Test assigned” unless there has been a test defaulted







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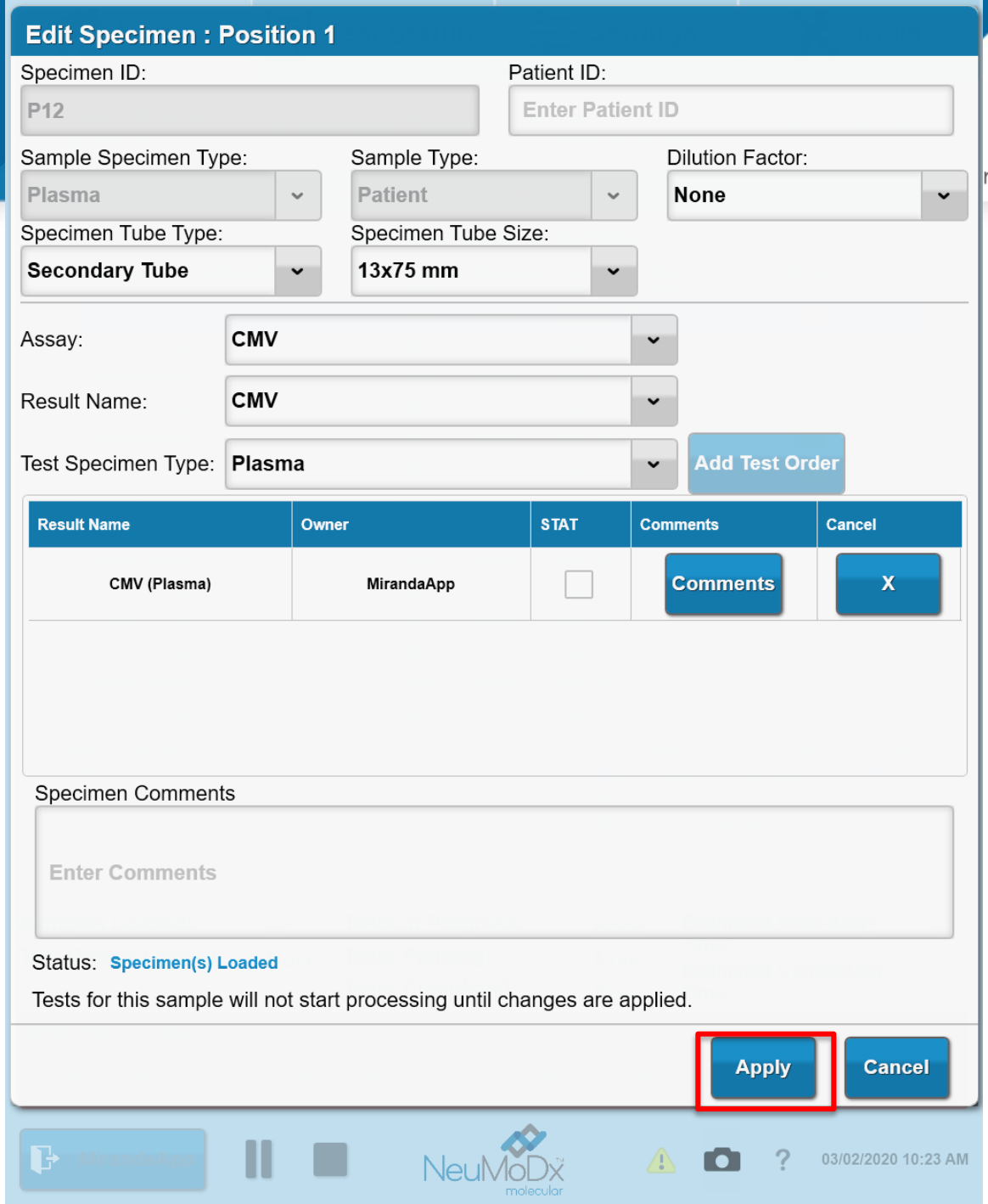

NeuMoDx Molecular System Default Test

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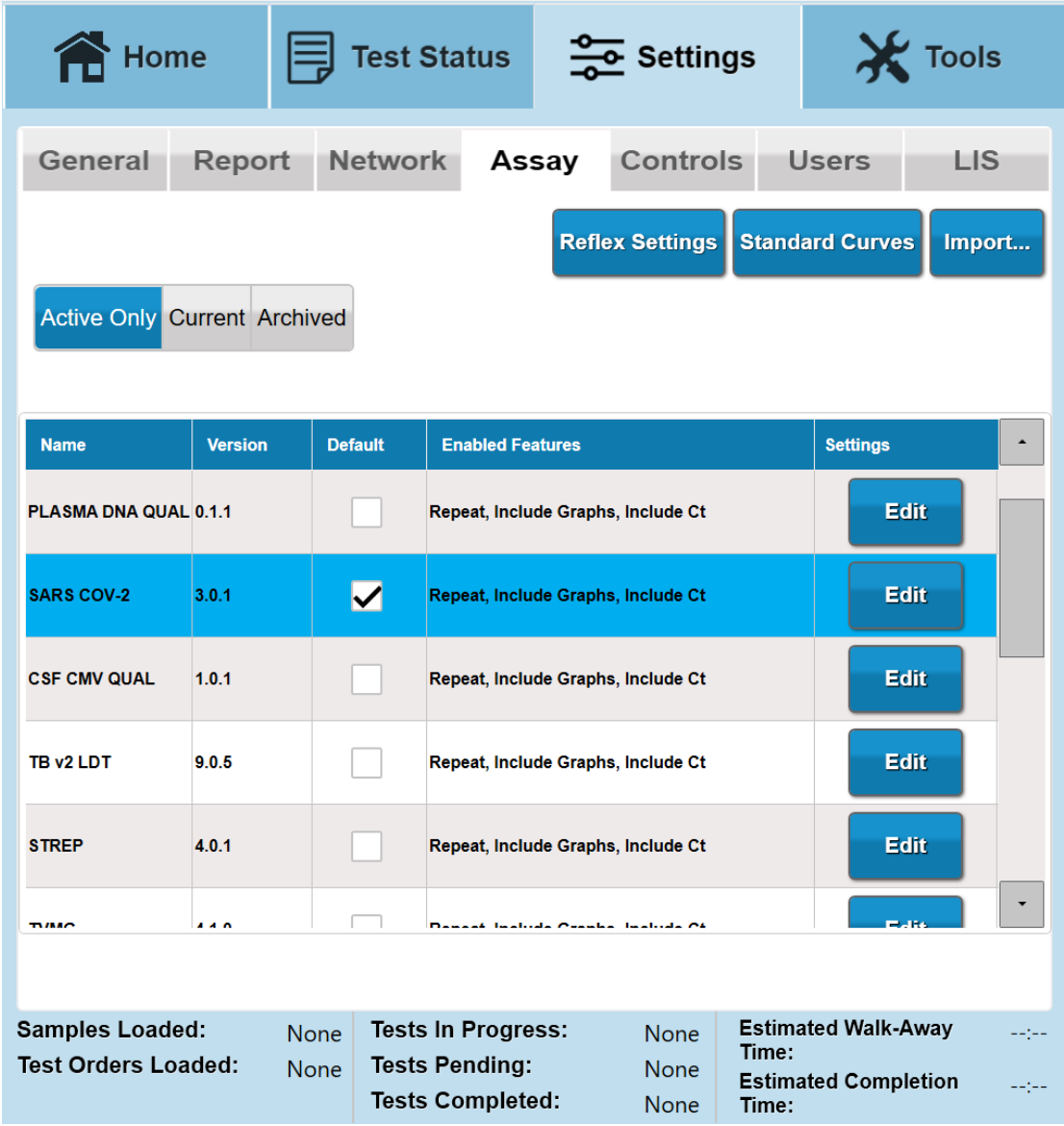
Check Default Test for specific ADF and every sample loaded will be automatically processed using this ADF

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



Running Primary Tubes

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NeuMoDx Molecular System Primary Tubes

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- 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

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

Confirming Sample Processing

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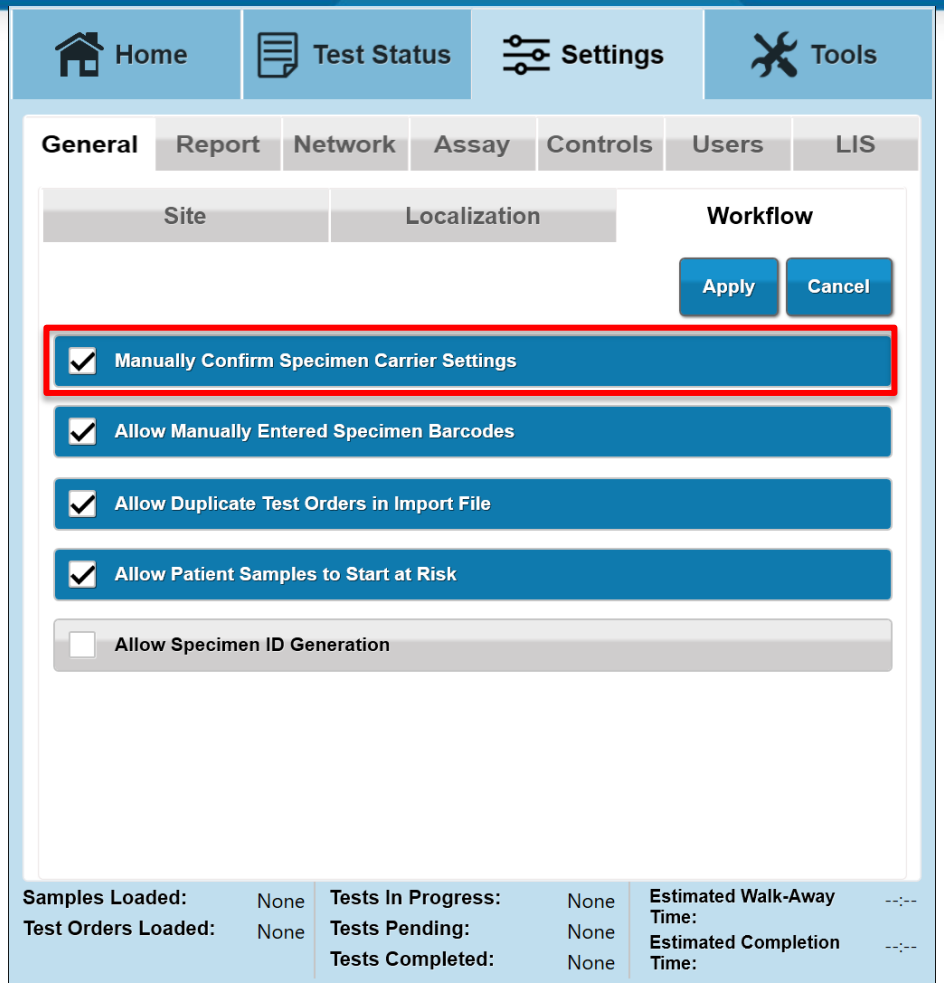

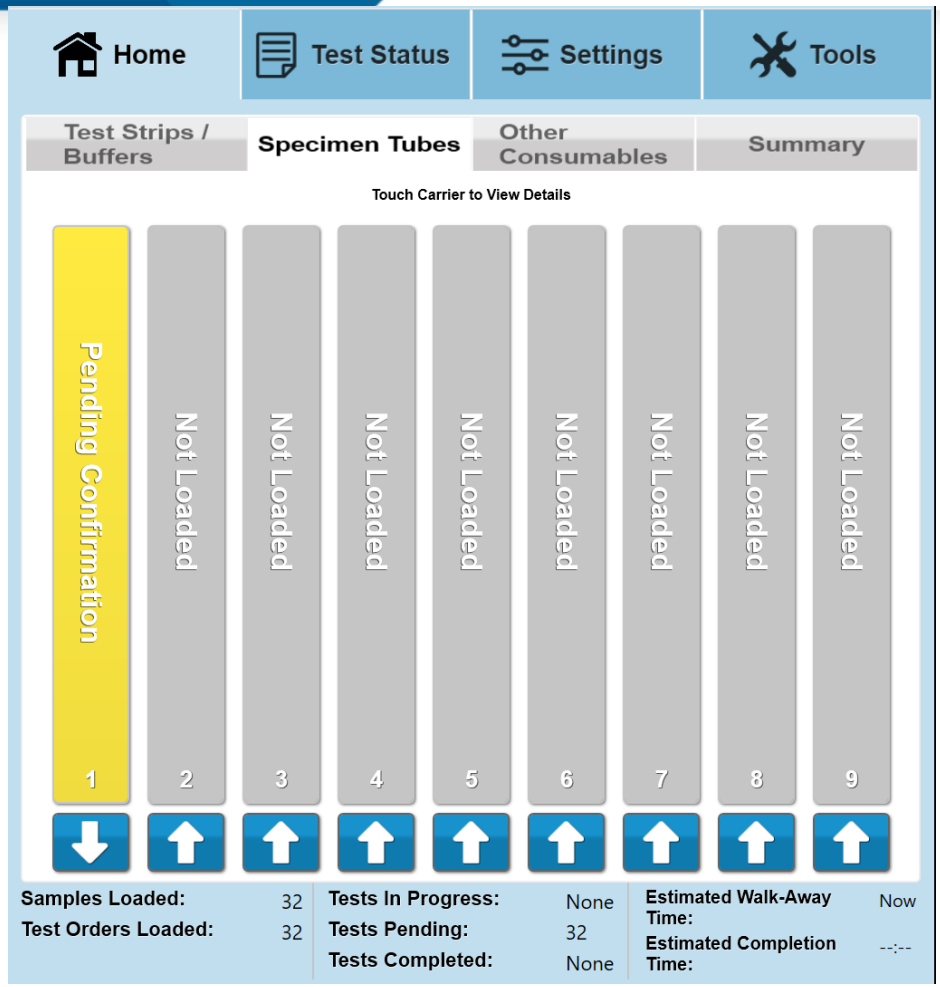

- If “Manually Confirm Specimen Carrier Settings” is selected in the General Workflow Settings tab and samples are then loaded, the carrier will say “Pending Confirmation”
- Select the carrier to display the Specimen Carrier screen

Confirming Sample Processing

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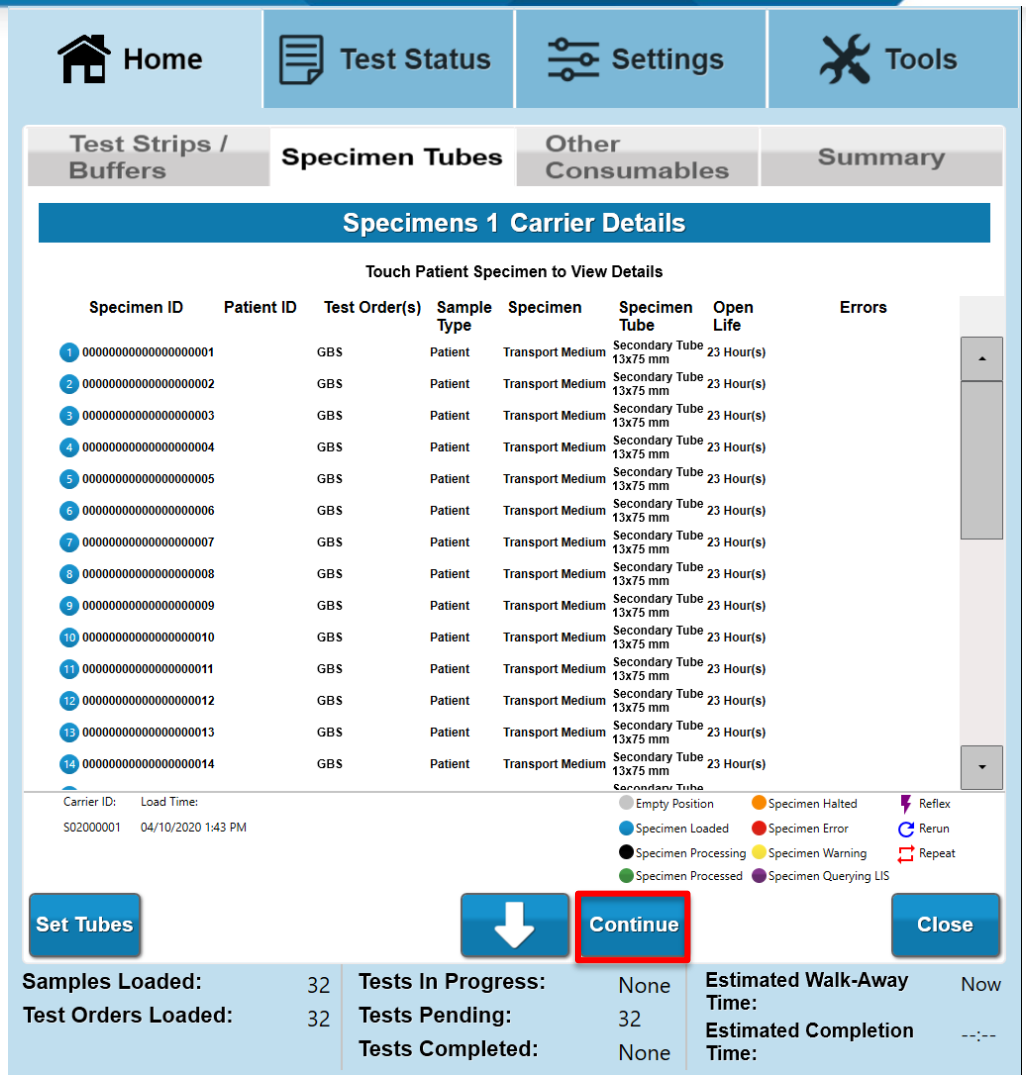

Select “Continue” to begin processing the samples

Defining Primary Tubes

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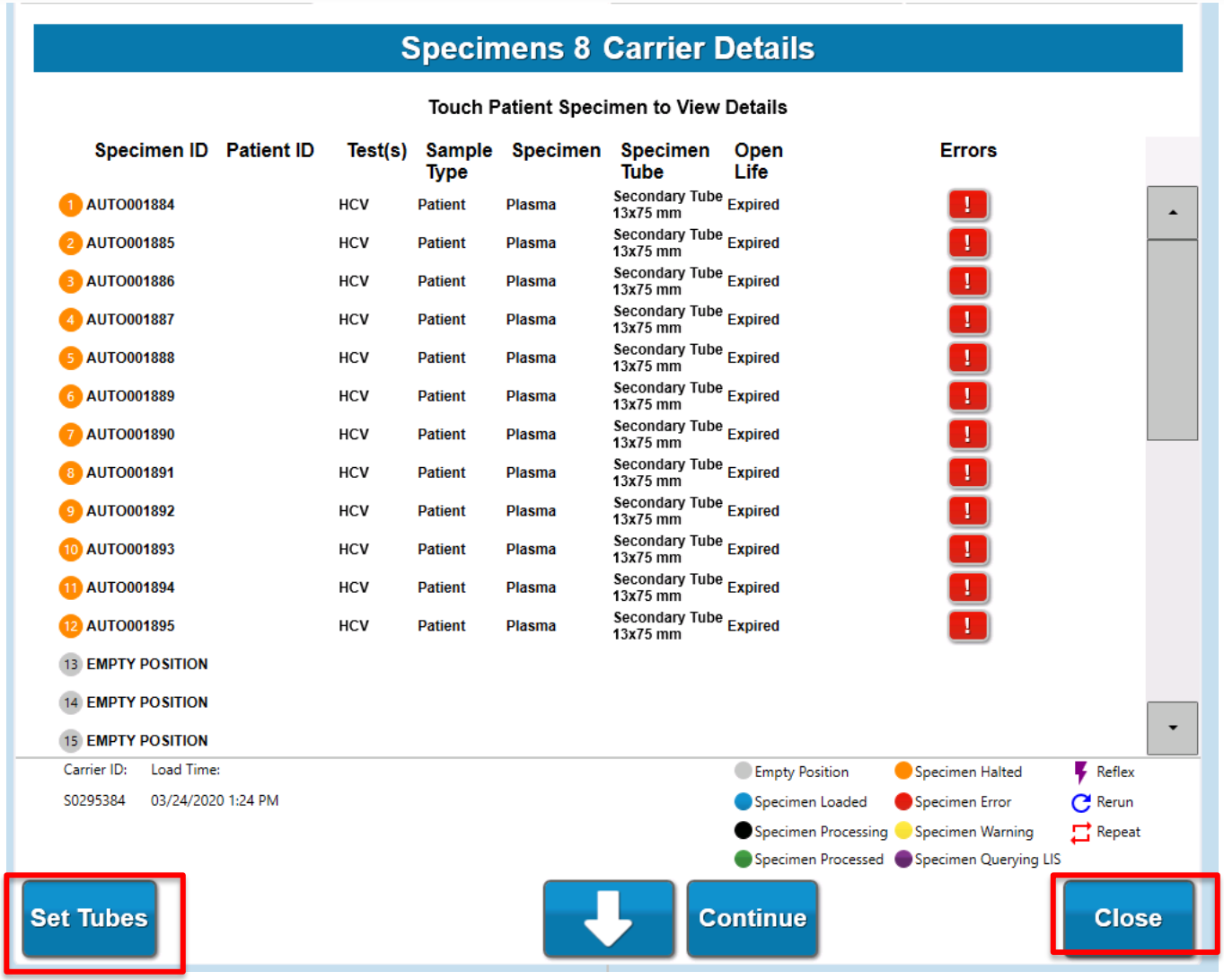

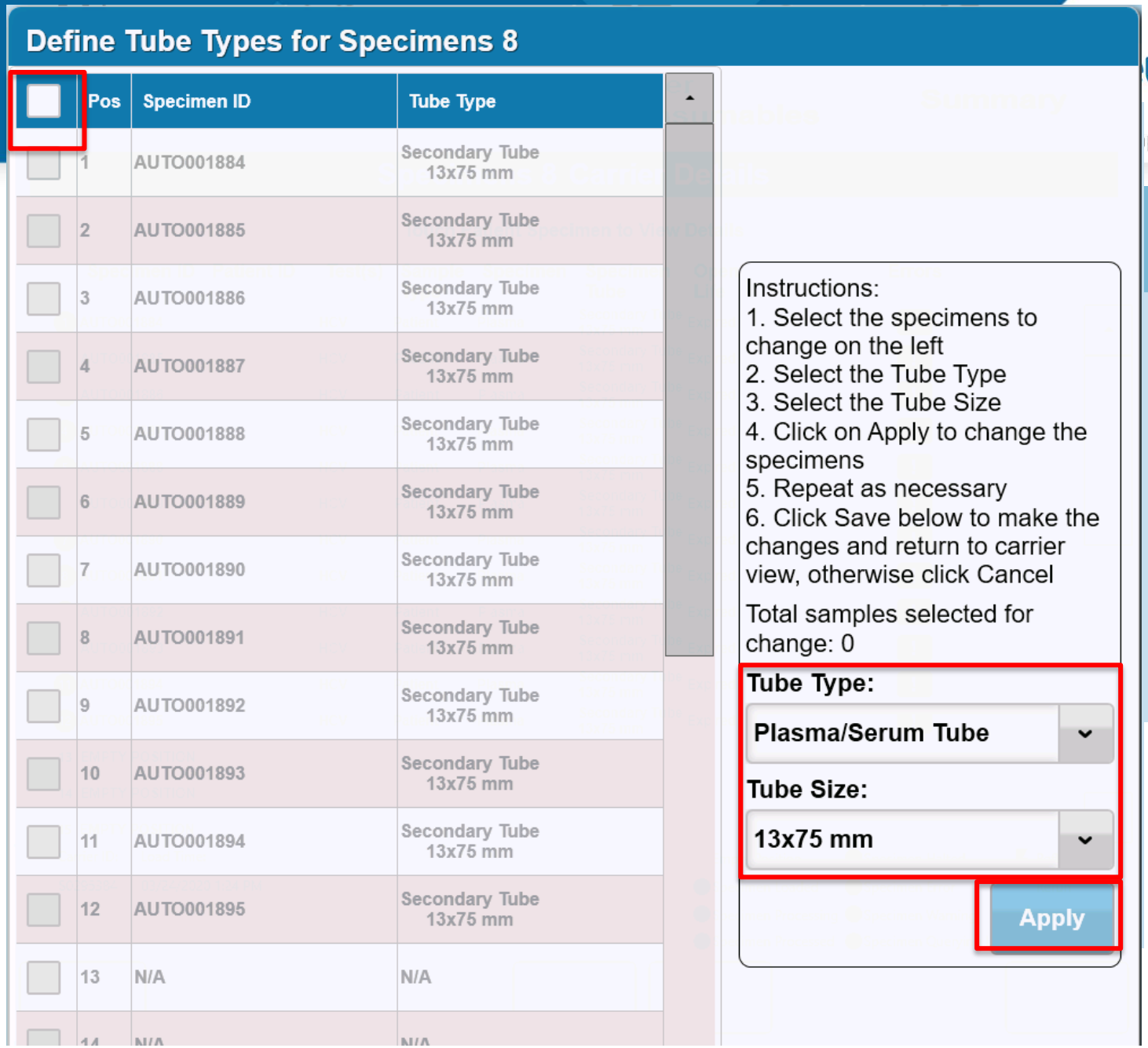

Results Interpretation

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NeuMoDx Molecular System Results Interpretation

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- 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

Useful Documents

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- 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)

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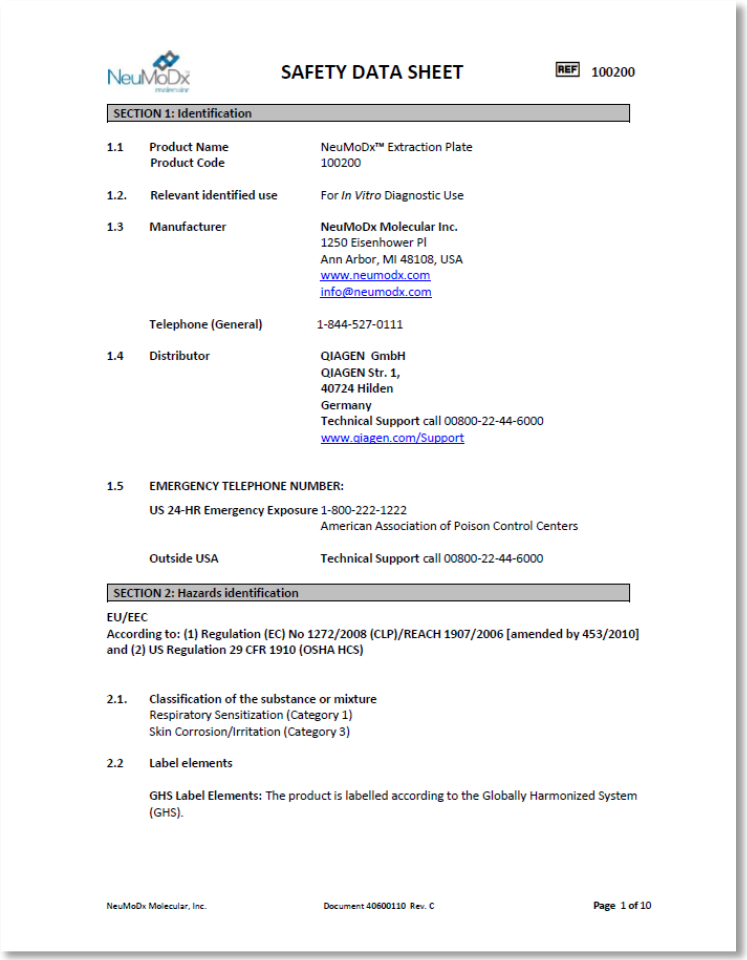
To access Safety Data Sheets (SDS), please visit www.neumodx.com/client-resources



NeuMoDx

SAFETY DATA SHEET REF 100200

SECTION 1: Identification

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

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

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

Telephone (General) 1-844-527-0111

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

1.5 **EMERGENCY TELEPHONE NUMBER:**

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

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

SECTION 2: Hazards identification

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

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

2.2 **Label elements**

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

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

Instructions for Use (IFU)

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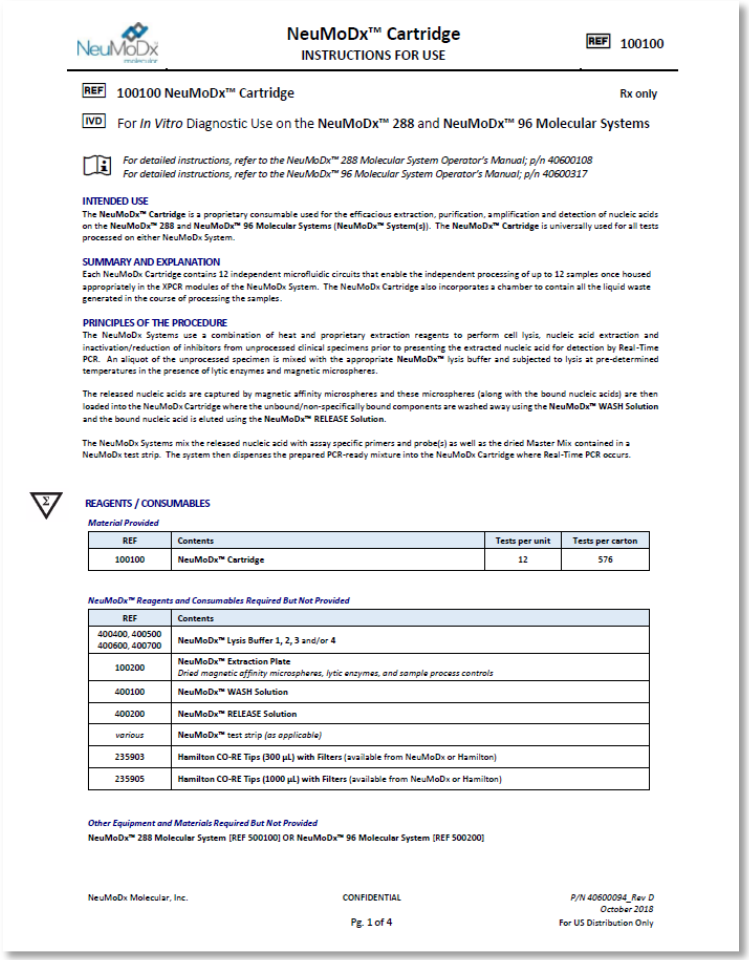
To access Instructions for Use (IFU), please visit www.neumodx.com/client-resources



NeuMoDx

NeuMoDx™ Cartridge
INSTRUCTIONS FOR USE

REF 100100

REF **100100 NeuMoDx™ Cartridge** Rx only

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

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

INTENDED USE

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

SUMMARY AND EXPLANATION

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

PRINCIPLES OF THE PROCEDURE

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

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

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

Σ **REAGENTS / CONSUMABLES**

Material Provided

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

NeuMoDx™ Reagents and Consumables Required But Not Provided

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

Other Equipment and Materials Required But Not Provided

NeuMoDx™ 288 Molecular System [REF 500100] OR NeuMoDx™ 96 Molecular System [REF 500200]

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

System Safety Information
Some tips:

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- 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™ technical support:
  techsupport@NeuMoDx.com
  Phone: 888-301-NMDX (6639)
- When contacting NeuMoDx™, have the following information available:
  - Product name, part number, and serial number
  - Troubleshooting Package
  - Details surrounding event

Questions?

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