Inova Diagnostics, Inc.

QUANTA-Lyser®

3000/4000

Operators Manual

IMPORTANT: Please read carefully before operating the QUANTA-Lyser instrument.

Inova Diagnostics

A Werfen Company

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Release Information

Inova Diagnostics reserves the right to make technical improvements to this equipment and documentation without prior notice as part of a continuous program of product development. Information in this document is subject to change without notice.

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CHAPTER 1: About

1.1 This Manual

This manual is intended to be a reference guide for trained operators and laboratory personnel. It provides detailed information about operation and maintenance of the QUANTA-Lyser instrument family.

The images used in this manual may not represent the specific instrument, component, or software/firmware version being used. Options and accessories may or may not be illustrated in each figure.

Illustrations based on CAD drawings may not show cables and tubing.

Carefully read all relevant chapters before use.

1.2 Policy Statement

It is the policy of Inova Diagnostics to improve products as new techniques and components become available. Inova reserves the right to change specifications at any time.

Inova Diagnostics is committed to providing customer with inventive, high quality products and services that are environmentally sound.

1.3 Symbols and Conventions

The following symbols are used on instruments, modules, and manuals.

Whenever these symbols appear on instruments or modules, please observe appropriate safety procedures.

Caution

Consult the manual for further information, proceed with caution

Caution

Consult the manual for further information, proceed with caution

Caution

High voltage, possibility of electric shock, proceed with caution

Caution

Risks associated with a laser beam

Caution

Touching this part while not properly grounded may cause damage due to electrostatic discharge (ESD)

Caution

Risks associated with biohazards

Caution

Risks associated with chemicals or biological materials

Caution

Risks associated with flammable materials

Caution

Risks associated with puncture hazard

Caution

Advice associated with the use of lubricants

Caution

Risks associated with heavy load

Caution

Do not walk or stand here

Note

Must be performed by certified engineers only

Note

Consult the manual, proceed with caution (label on instruments only)

Note

Advises special attention

Tip

Useful Hints

Note

RoHS aims at restricting hazardous substances in electrical and electronic equipment (EEE) so as to contribute to the protection of human health and the environmentally sound recovery and disposal of electrical and electronic equipment waste.

Note

WEEE Directive 212/19/EU: Waste Electrical and Electronic Equipment (WEEE) legislation lays down collection, recycling, and recovery targets for electrical goods.

Note

Environmental Protection Use Period – 25 years: The period during which toxic or hazardous substances or elements contained in electronic information products will not leak or mutate

Manufacturer

Indicates the manufacturer

Note

Catalogue or Part Number

Note

Batch Code

Note

Date of Manufacture

Note

European Authorized Representative

Note

European Conformity

Note

In Vitro Diagnostic Medical Device

Note

Consult Instructions for Use

1.4 Intended Use

The QUANTA-Lyser Operators Manual is designed to assist in training and operation of the QUANTA-Lyser instrument family.

QUANTA-Lyser instruments are fully automated benchtop processors for use in conjunction with certain reagents to measure a variety of analytes. QUANTA-Lyser is intended to automate slide and reagent barcode reading, sample dilution and distribution, reagent pipetting and dispensing, slide and plate washing, dispensing slide mounting medium in preparation for microscope analysis and photometric measurement of microwell plates.

QUANTA-Lyser systems provide flexible automation solutions for mid-to-high volume laboratories, a broad test menu, and fast turnaround time. The QUANTA-Lyser 4000 supports high volume Immunofluorescence Assay (IFA) processing. The QUANTA-Lyser 3000 is an Enzyme-linked Immunosorbent Assay (ELISA) and IFA assay processor.

For further information, please contact instrument supplier.

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CHAPTER 2: Preinstallation and Installation Procedures

2.1 Preinstallation Procedures

This chapter contains information for preinstallation and setup of the QUANTA-Lyser instrument.

Note

Installation must be performed by certified engineers only.

Before installing the QUANTA-Lyser, laboratory personnel, in tandem with authorized service personnel, should inspect the site to identify a desirable location and ensure that the environment meets installation requirements. The following checks should be made:

- Receiving area and transportation pathway
- Adequate access to loading dock
- Facilities to offload the crate from the truck
- Space available to uncrate
- Adequate doorway width
- Safe and adequate passage
- Working area
- Ambient conditions
- Electrical power requirements

2.2 Requirements for Personnel

This section covers general competence and training necessary for transportation, installation, use, maintenance, and servicing of QUANTA-Lyser instruments.

Type of Task	Personnel	Training and Experience
Transportation	No special requirements	No special requirements
Installation	Certified service engineers authorized and qualified to install and maintain the entire robotic system	Technically skilled, with a good knowledge of the application field
Routine Use (Running pre-programmed test sequences)	Laboratory technicians or equivalent	Appropriately trained and experienced personnel, familiar with use of computers and automation in general. Familiarity with MS Windows® environment
Programming and optimization of test sequences	Inova certified personnel only	High degree of knowledge of the relevant application field
Preventative Maintenance	Certified service engineers authorized and qualified to install and maintain the entire robotic system	Technically skilled with a basic understanding of the application
Servicing	Certified service engineers authorized and qualified to install and maintain the entire robotic instrument	Background and experience in electronics/mechanics with computer knowledge

2.3 Requirements for Installation

Caution

Do not install the power cable yet. To avoid potential electrical shock and/or damage to the instrument, do not install the power cable before a certified service engineer has completed the setup procedure.

Whenever the instrument is moved from a cold place (e.g. transport at temperature below freezing point) to room temperatures, there is a chance of condensation. Allow 48 hours after transport before the instrument is put into operation.

2.3.1 Site

The QUANTA-Lyser instrument must be placed on a sturdy workbench, preferably equipped with wheels and fixing brakes. For service and maintenance, the instrument must be accessible from all sides. A clearance of at least 1 m (3 feet) must be provided. The instrument dimensions listed in Chapter 4: Performance Characteristics and Specifications do not take into account handles used to lift the instrument. If an immobile work bench is used, there must be enough room for 4 movers to lift the instrument onto the counter (instrument may not be placed directly beside a wall).

The instrument must not be located near a heat souce, ventilation, air conditioner, or exposed to direct sunlight. Make certain that the waste container can be placed within 1.5 meters (5 feet) of the instrument. Note that the unit has a gravity-fed waste unit that must be placed somewhere underneath the instrument, not to one side. The instrument should be close to an AC power outlet. The power cord reach is 6 feet.

2.3.2 Mains Supply

The mains supply for the entire instrument should be voltage regulated, properly grounded and surge protected.

The QUANTA-Lyser instrument has a self-regulating power supply. See “Electrical and Communication” section for power supply specifications.

Caution

Please read carefully.

To protect operating personnel, the National Electrical Manufacturers’ Association (NEMA) recommends that the instrument is correctly grounded. This instrument is equipped with a 3 conductor power cable that, when connected to an appropriate AC power outlet, grounds the instrument. To ensure that this protection feature functions properly , do not operate the instrument from an AC power outlet that does not include a ground connection.

2.4 Installation

Note

Installation must be performed by certified engineers only.

The QUANTA-Lyser system is delivered as an integrated unit. The system is installed and assembled by trained engineers. Installation consists of the following steps:

- Remove packaging and check for damage
- Verify that all components against the component list supplied in the box
- Remove all foam blocks from the moveable parts (i.e. robotic arms)
- Raise the instrument from the base and install on the work table (bench)
- Verify that the electrical plug conforms to the electrical technical specifications
- Install the software and connect the USB dongle
- Proceed with setup, calibration, and verification of the deck and robotic arms

2.5 Customization and Training

Following installation, each system is customized and verified by an Inova field service representative or an international service specialist. On-site training is performed after installation.

2.6 Assay Menu

The menu of assay protocols supporting kits supplied by Inova is installed with QUANTA-Lyser software. The QUANTA-Lyser is an open system and is capable of running most commercial ELISA/EIA and IFA assays. These can also be programmed for the QUANTA-Lyser assay menu. Such assays should be confirmed and validated by the user.

2.7 Labeling and Orientation Precaution

To ensure correct barcode scanning, labels must be attached according to the specification below. Observe the orientation of tubes and bottles in the racks.

2.7.1 120 mL Becker Vial Labeling

For diluents, labels must be peeled off original reagent container and adhered to the 120 mL Becker vial at the position shown in the figures below. The distance between the vial bottom and label bottom must be 17 mm, which is equivalent to the 20 mL mark on the 120 mL Becker vial scaling.

Figure 2-1: Reagent Label & Diluent Bottle

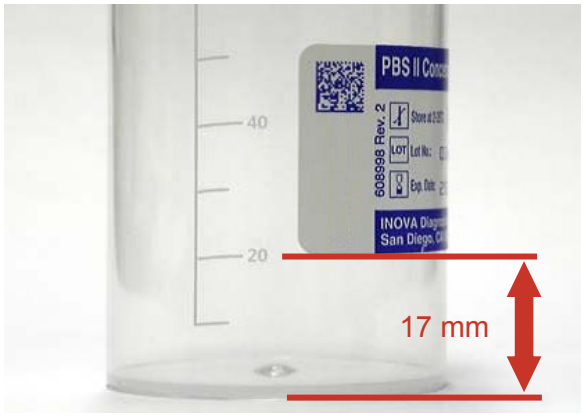

Figure 2-2: Correct Label Placement

2.7.2 Orientation of Bottles in Racks

The orientation of barcodes within the rack is very important. The barcode should be centered in its rack position. There is a notch in the rack to show the center point of that position.

Figure 2-3: Incorrect Bottle Orientation

Figure 2-4: Correct Bottle Orientation

2.8 System Requirements

2.8.1 Space Requirements

The QUANTA-Lyser system is comprised of the following components: a bench-top analyzer, computer, liquid supply unit (integrated on QUANTA-Lyser 4000 model), waste container and an uninterrupted power supply (UPS) unit. The liquid supply unit is positioned to the right of the instrument and holds system liquid and wash buffers. A 10 liter waste container is located underneath the instrument. If the instrument is placed on a bench rather than a moveable cart, be sure to provide ample space behind the instrument for repair and routine maintenance activities. Please see “Physical Attributes” section for model specific instrument dimensions.

2.8.2 Power Requirements

AC power cords are supplied with the instrument according to international standards. Appropriate AC power cords and plugs are included in the shipment inside the component boxes. Uninterrupted power supply (UPS) unit prevents problems due to power surges and is required. It is recommended that the instrument is shut down when not in use.

2.8.3 Water Supply, Waste, and Drainage

Depending on model, the system is equipped with either 5 or 9 L System Liquid bottle(s) and two or four 2 L wash buffer bottles. Deionized water is used to prepare System Liquid and Wash Buffers. Tip and plate/slide wash waste is collected in a 10 L waste container. The liquid waste container can be disconnected from the system and emptied manually. Alternatively, the waste can be connected through a drain line directly to the laboratory drain. Empty reagent vials, dilution tubes, microtiter plates and slide should be discarded appropriately according to laboratory procedures.

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CHAPTER 3: Principles of Operation

QUANTA-Lyser incorporates state of the art modern electronics, robotics, and computing components. The hardware and software components of QUANTA-Lyser are customized and configured to automate ELISA/EIA and IFA assays.

3.1 System Capabilities

3.1.1 Instrument Capabilities

QUANTA-Lyser hardware components provide barcode reading, pipetting, washing, mixing, incubation and detection methods in compliance with ELISA/EIA and IFA requirements:

- Automatic sample, reagent, and IFA slide barcode reading
- Preparation of sample dilution with flexible volume options
- Preparation of serial dilutions
- Sample distribution to various configurations of wells on glass slides and 96-well microtiter plates
- Reagent addition
- Microtiter plate washing
- IFA Slide well washing
- Mixing in microwell tubes and microtiter plates
- Liquid sensing in system wash containers
- Temperature controlled incubation
- Detection of optical densities utilizing single/dual wavelength options

3.1.2 Software and Applications

QUANTA-Lyser software controls all stages of the automatic processing phases. It provides a user interface for configuration of the instrument in the most effective mode and includes an extensive menu of assay definition options that allows single application optimization.

The flexibility of the QUANTA-Lyser provides advanced options for ELISA, EIA and IFA processing:

- Multiple assays combined onto a single plate frame
- Custom racks that fit Inova kit reagents
- Various bottles sizes can be used
- A variety of washing methods can be developed and programmed
- Multiple types of plates and slides are supported
- Various options to perform qualitative and quantitative data analyses are available
- Pipetting error handling and logging
- Connection to LIS

3.2 Hardware Components

The primary robotic components of QUANTA-Lyser are pipetting and tool arms, barcode reader, tip washing station, EIA plate washer module, EIA absorbance reader, deck (or workspace) with flexible sets of racks that configure the QUANTA-Lyser workspace layouts.

3.2.1 Hardware Devices

3.2.1.1 Pipetting Arm and Tips

The QUANTA-Lyser pipetting arm is configured with four pipetting and two aspiration tips (present on some models). Tips are aligned along the Y-axis of the pipetting arm and each tip has an individual Y- and Z- motor and liquid level detector. FlexiSpan refers to the independent Y-spacing of the tips. Tips can access nonconsecuitve wells or tubes in a column and simulateneously detects different levels in various containers.

Figure 3-1: Pipetting Tips

Liquid Detection (LD)

The QUANTA-Lyser detects liquid level by monitoring the change in capacitance (electrical charge) between each tip and instrument deck. Each tip assembly is equipped with a liquid sensor, which enables it to detect liquids (except non-polar substances) upon contact. The liquid level detector monitors changes in capacitance between pipette tip and deck. When the pipette tip touches a liquid surface, the sudden change in capacitance generates a detection signal.

The LD mechanism design minimizes influence from the surrounding environment. Liquid level sensors are programmed to detect insufficient amounts or total absence of sample and reagent liquid. The system will notify the user by alarm so that corrective steps can be taken.

Submerge Level

The liquid submerge depth of the pipette tip during sampling can be controlled to minimize cross-contamination (usually 1 – 2 mm).

Note

An error may occur if the tip touches the side of a vessel or air bubbles even if the contact is insufficient to cause capacitance change. Since the liquid level detector cannot identify what material causes a change in capacitance, it is imperative that the tips do not touch any surface except the liquid to be detected.

Poor water quality and the use of unproven additives in the system liquid can affect the performance of the liquid detection.

Pumps and Valves

Pipetting pumps (micro-annular gear pumps) are used to pipette samples, reagents, diluents, and wash buffers for IFA assays. Pumps in the robotic arm, reduce the need for syringe pumps and extended lengths of system liquid tubing. QUANTA-Lyser pumps operate on positive displacement and are programmed to dispense precise volumes ranging from a few microliters to 1mL.

A single pump is dedicated to one tip channel and controlled by the software. Valves are in line with the pump and controlled automatically by firmware.

Liquid flows in channels featuring multiple liquids such as system liquid and wash buffers. System liquid and buffers are controlled by Valve Unit 101 located on the back of the X-rail.

Liquid that will be removed through the aspiration tip is aspirated by the corresponding pump of the Pump Unit 101 located behind the rear rail of the instrument.

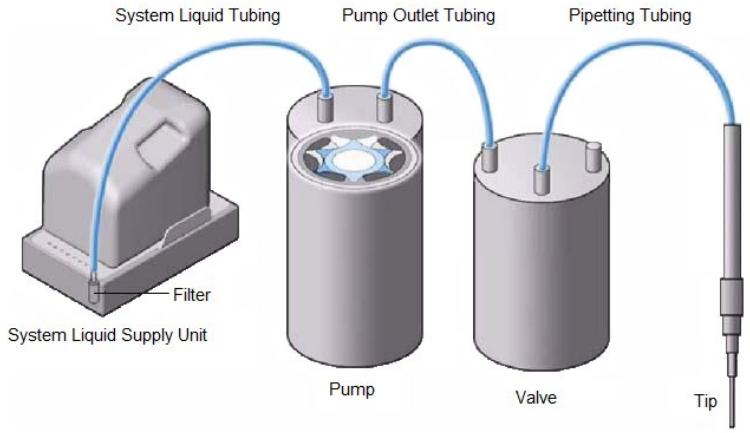

Figure 3-2: Pumps and Valves

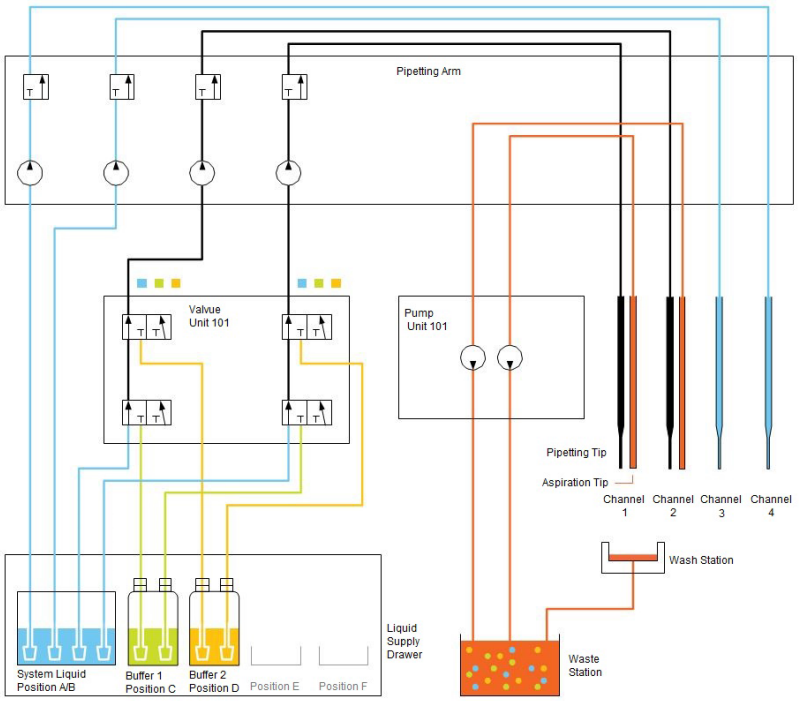

Figure 3-3: QUANTA-Lyser 4000 Hydraulic Diagram

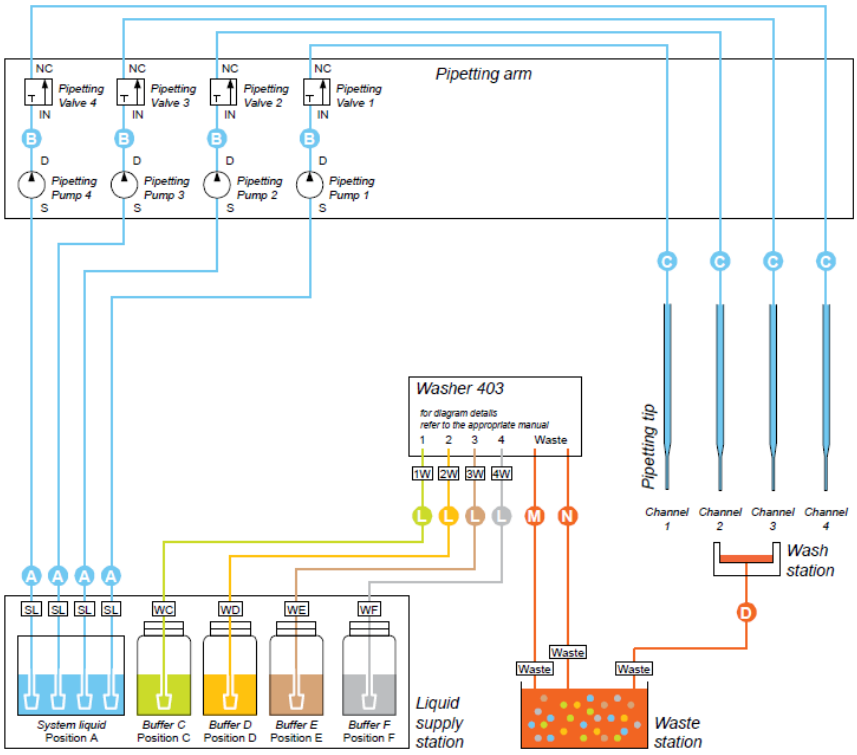

Figure 3-4: QUANTA-Lyser 3000 Hydraulic Diagram (Model Dependent)

3.2.1.2 Pipette Tips Wash Station and Waste Station

Pipette tips are thoroughly washed between steps with system liquid containing 0.4% Contrad 70 detergent solution in deionized water. Washable tips are rinsed under program control at the wash station. This module features a raised cup for each tip, into which the tip enters for washing.

System liquid uses distilled or deionized water with 0.4% Contrad 70 detergent agent. When the tips are positioned in the cups, system liquid is aspirated by the pump and forced through each tip.

The flow is activated by the conical shape of the cup and washes the outside of the tip in an upward motion before spilling into the moat and down the drain. Both inside and outside of each tip are thoroughly cleaned in a single step. A tube moves waste fluid from the drain to a waste station placed below the instrument.

In a second step, the pipetting tip dispenses system liquid while the aspiration tip aspirates to wash the internal channel.

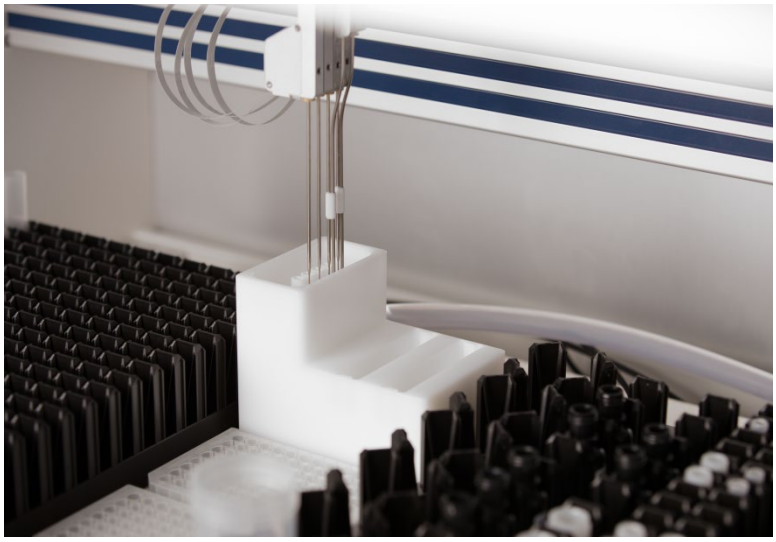

Figure 3-5: Pipette Tips Wash/Waste Station

3.2.1.3 Tool Arm and Handler (Gripper)

The QUANTA-Lyser instrument is equipped with an independent tool arm with a barcode reader (BCR) tool and handler tool, as well as gripper fingers, on certain models (QUANTA-Lyser 3000). The BCR can be swiveled by 90 degrees and rotated by 270 degrees to read 2D barcodes positioned horizontally or vertically. The handler transports microtiter plates between deck positions and modules. The handler is controlled by its own Y- and Z- motors, and can rotate. This function improves access to modules and accessories situated at any position in the rear or front of the instrument.

The tool arm and the BCR are controlled by their own X-, Y-, and Z-motors. This allows the BCR to read 2D barcodes on reagent bottles and slides.

Figure 3-6: QUANTA-Lyser 4000 Tool Arm

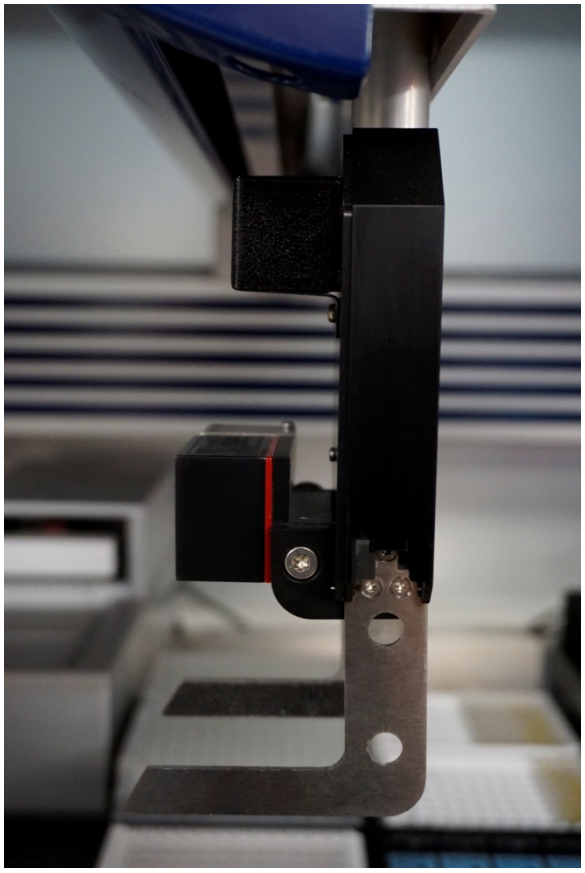

Figure 3-7: QUANTA-Lyser 3000 Tool Arm

Barcode Readers

An LED barcode reader is configured to read 1D barcode labels on sample tubes.

Figure 3-8: Sample Barcode Scanner

An additional barcode reader, a moveable camera to read 2D barcodes on IFA slides, diluent bottles, reagent bottles and standard/control bottles, is located on the tool arm (pictured above). The BCR tool is able to swivel down to read reagent barcodes from the side, and back up to read barcodes on slides located in slide trays seated on the decktray.

3.2.1.4 ELISA Plate Washer

The ELISA plate washer washes 8 wells simultaneously using 8 coaxial probes and 4 wash buffer lines in a 96 well plate format. The washing protocol and wash buffer lines can be defined and programmed, including number of wash cycles, volumes, and timing specifications.

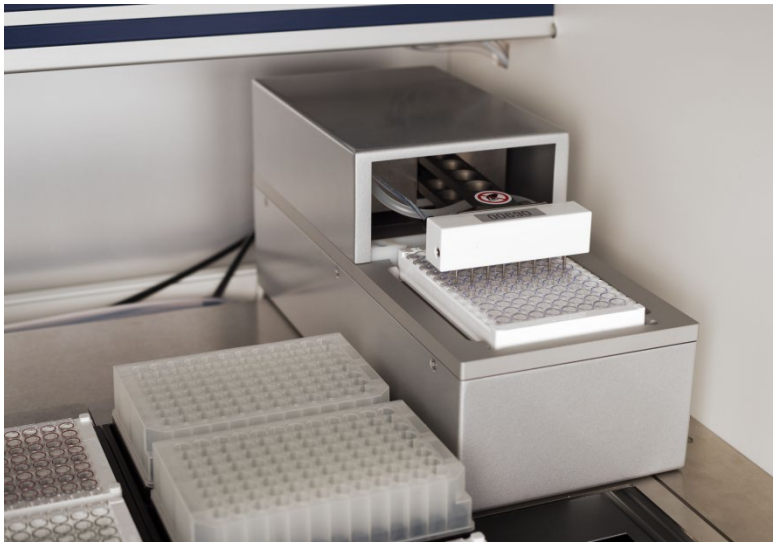

Figure 3-9: ELISA Plate Washer Module

Flat-bottom, C-bottom, U-bottom, and V-bottom microtiter plates can be accomodated. The vertical positions of the probes can be programmed to an accuracy of 0.1 mm. The wash head moves both vertically and horizontally, aspirating liquid from plates during the wash process.

3.2.1.5 Incubator

An optional four position incubator is available. The incubator incubates microtiter plates at 37°C without shaking. Incubation temperature and duration can be specified within the assay definition.

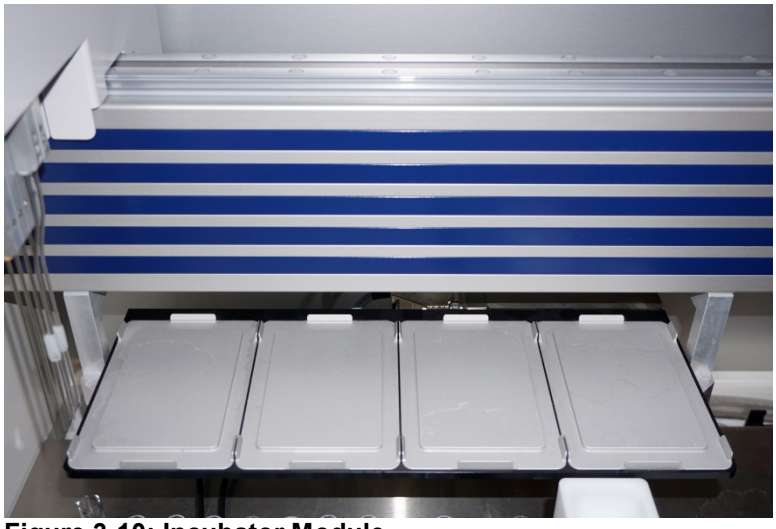

Figure 3-10: Incubator Module

3.2.1.6 Absorbance Reader

The absorbance reader module (mounted below the deck with an opening for top access) is configured with 5 wavelength filters (405 nm, 450 nm, 492 nm, 550nm, 620nm) and is suitable for the most common EIA assays.

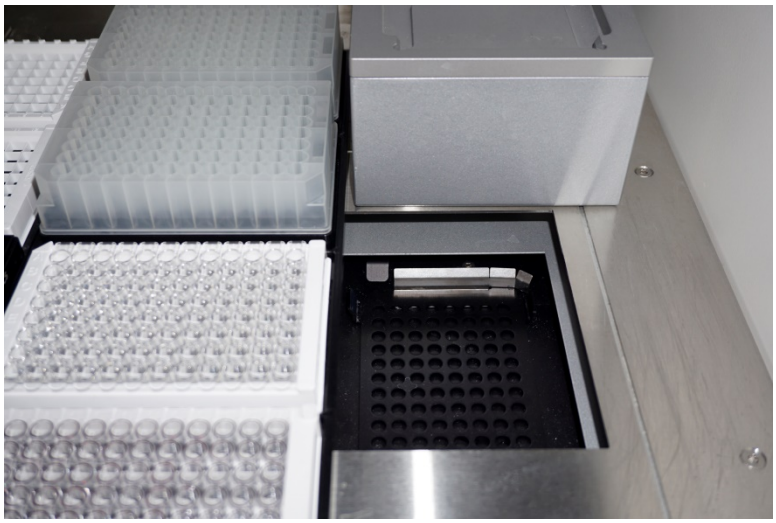

Figure 3-11: Absorbance Reader Module

3.2.1.7 System Liquid Detection Unit (QUANTA-Lyser 3000)

The liquid detection unit includes a capacitive level sensor that indicates the presence of fluid. It does not detect volume of fluid, only that some is present at the start of the run. It is the operator's responsibility to ensure sufficient wash volume is present. The software will not allow for a run to begin unless fluid is present.

Figure 3-12: QUANTA-Lyser 3000 System Liquid Detection Unit

3.2.1.8 Control and Liquid Supply Unit (QUANTA-Lyser 4000)

Figure 3-13: QUANTA-Lyser 4000 Control and Liquid Supply Unit

The liquid supply unit inlcudes a drawer where system liquid containers and buffer bottles are placed. The liquid level in each container and bottle is monitored by weight using a load cell under each container (weight measuring).

To prevent particles from entering the pump, a filter is installed on all system liquid and buffer tubing.

The computer, mounted above the liquid station drawer, is controlled by the height-adjustable touch screen monitor or an external keyboard and mouse situated in the keyboard drawer under the instrument.

3.2.1.9 QUANTA-Lyser Deck Workspace

QUANTA-Lyser holds patient sample tubes, reagents, standards, controls, and consumables on the deck workspace. Resa-trax sit on the deck and make up a portion of the deck workspace. Resa-Trax are tracks that are compatible with sample and reagent racks and allow for all liquid to remain secure as well as ensuring the precise location of each position. Sample tubes are placed in sample racks which are then loaded onto the Resa-trax 12S. Reagent bottles are loaded on the reagent racks which are then loaded onto Resa-Trax 601 or 901 (depending on instrument model). Deep-well dilution blocks are used to prepare single dilutions or multiple titers from patient samples and are placed onto specific deck locations as indicated by the software.

Resa-trax 12S

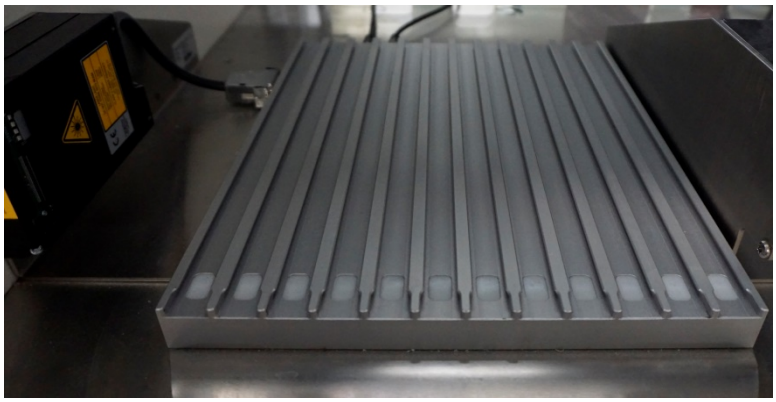

Figure 3-14: Resa-Trax 12S

Primary patient sample tubes are loaded onto a Resa-trax 12S. Resa-trax 12S is a semi-automated barcode reading system that uses 12 racks with 20 positions in each rack.

Sample tubes (outer diameter 12 – 16 mm) with barcodes are placed in racks, with barcodes facing the fix mounted barcode reader (BCR). Each rack is manually inserted into it's respective slot and sample barcodes are scanned as the sample tube passes the sample barcode reader. Most common laboratory barcodes can be read.

NOTE: QUANTA-Lyser 4000 has two Resa-trax 12S on its deck.

Resa-trax 601 (On QUANTA-Lyser 4000) and Resa-trax 901 (On QUANTA-Lyser 3000)

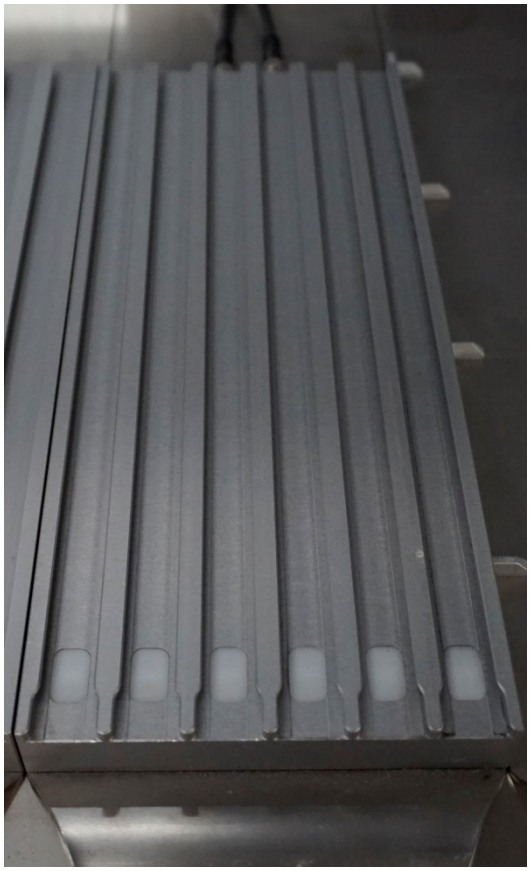

Figure 3-15: Resa-Trax 601

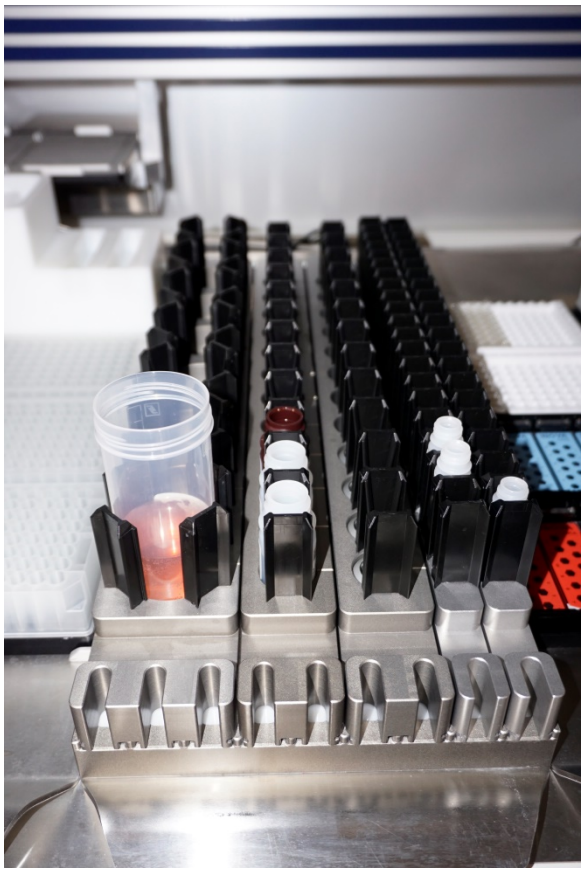

Figure 3-16: Resa-Trax 901

Resa-trax 601 provides 6 positions (slots; in terms of application = strip) featuring various rack sizes for tracking identification barcodes by the barcode reader tool (the Resa-trax itself does not have a reader). Resa-trax 901 is idential with the exception of having 9 positions.

Bottles and tubes with barcodes are placed in racks and manually inserted into a slot. Diluent Racks use 3 positions each, Reagent Racks use 2 positions each, and Control Racks use 1 position each. The barcode reader tool automatically starts reading as soon as the front shield is lowered.

3.2.1.10 Front Shield

The Front Shield encloses the workspace. The shield must be closed during operation. To open, lift the handle until fully open. The shield will remain in this position until it is closed. To close, push down on the handle until fully closed.

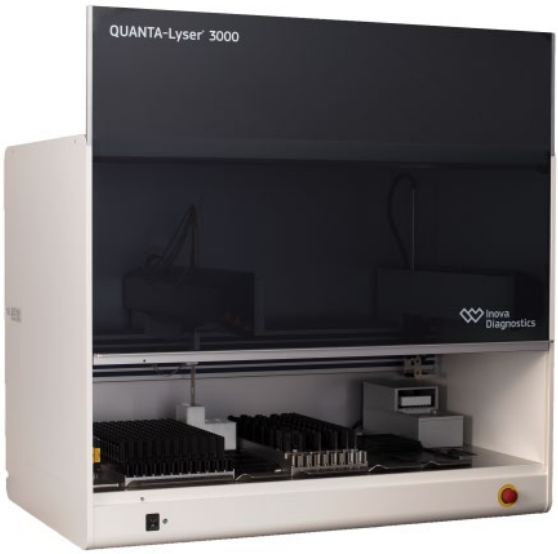

Figure 3-17: Front Shield

Caution

Pinching hazard. Be sure that your hands and fingers are clear when closing the front shield.

3.2.1.11 Controls and Connectors

Figure 3-18: QUANTA-Lyser 4000 Controls and Connectors

Figure 3-19: QUANTA-Lyser 3000 Controls and Connectors

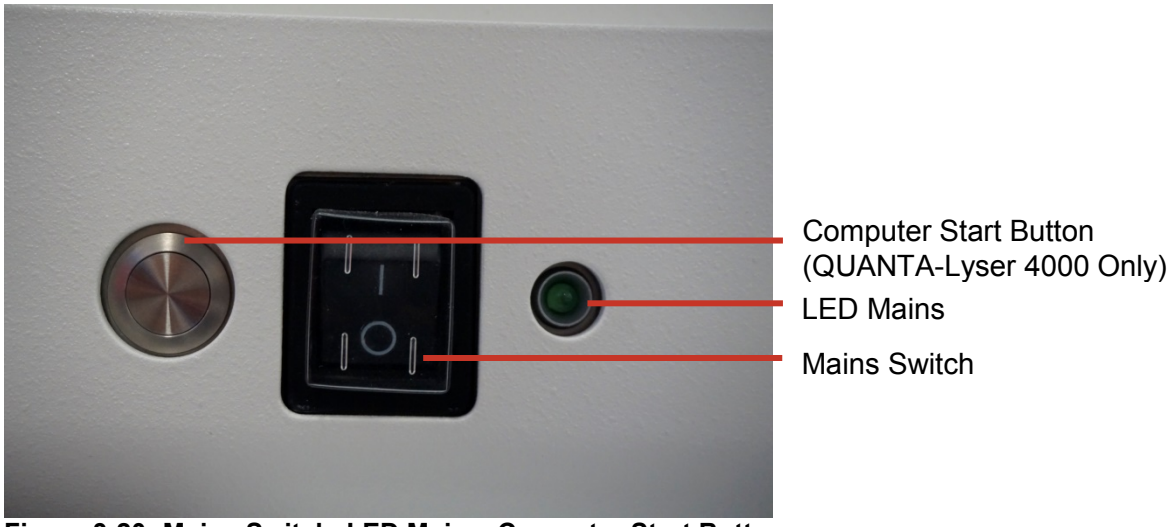

Figure 3-20: Mains Switch, LED Mains, Computer Start Button

Figure 3-21: Front USB (QUANTA-Lyser 4000 Only)

Mains Switch

Powers the robot on and off

LED Mains

Lit LED indicates instrument power is on

Computer Start Button (QL 4000 Only)

Power the computer on. To shut down the computer, use the Windows operating system

Front USB Ports (QL 4000 Only)

Two USB 2.0 connectors (e.g. to connect a memory stick, external hard disk, handheld barcode reader, etc.)

Figure 3-22: Emergency Button

Emergency Button

Switches robot off immediately (does not shut down computer on QL 4000, robot only)

Caution

Any work in progress will be lost after pushing the emergency button.

Rear Side

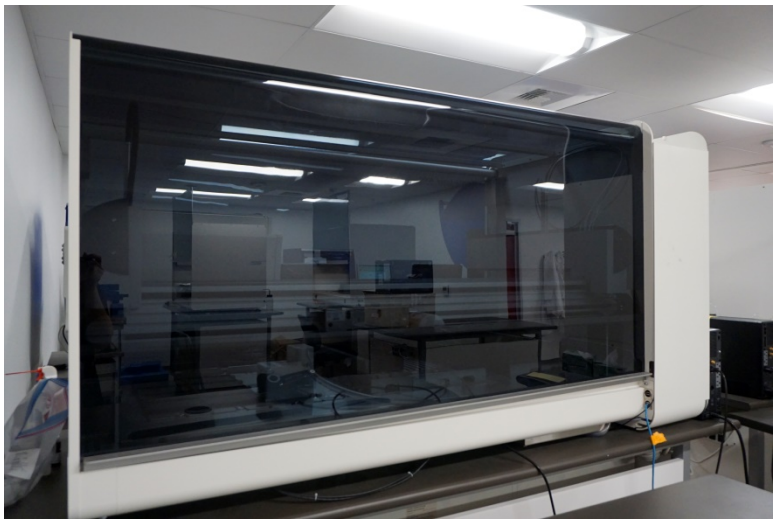

Figure 3-23: QUANTA-Lyser 4000 Rear View

Figure 3-24: QUANTA-Lyser 3000 Rear View

Figure 3-25: Mains Socket

Figure 3-26: Rear LAN Port and Rear USB (QUANTA-Lyser 4000 Only)

Mains Socket

Mains inlet, situated behind the rear rail

Rear LAN Port (QUANTA-Lyser 4000 only)

To connect the instrument to a local area network (LAN)

Rear USB (QUANTA-Lyser 4000 Only)

3.2.2 Monitor (QL 4000 Only)

The monitor is height-adjustable (range 200 mm / 8 inch) and can be tilted horizontally and vertically by approximately 30 degrees.

Figure 3-27: QUANTA-Lyser 4000 Monitor

Monitor Controls

The monitor controls are located on the rear, either vertically on the left hand side or horizontally on the top side (depending on monitor version):

Power:	Switches monitor on and off
LED:	Lit LED Indicates monitor is powered on
Menu:	Opens On Screen Display (OSD); used to confirm the selected setting
SL+:	To navigate up
SL-:	To navigate down
Auto:	Resets the monitor to factory settings

3.3 Software Features

QUANTA-Lyser software controls the QUANTA-Lyser ELISA/IFA processing system. The software provides the interface for system configuration, programming assay protocols, creating, scheduling and running an analytical session, interpretation of results, data storage, and reporting.

CHAPTER 4: Performance Characteristics and Specifications

4.1 Physical Attributes

4.1.1 Dimensions and Weights

The instrument's shipping crate physical dimensions and weight:

Instrument Model	Length	Depth	Height	Weight
QUANTA-Lyser 4000	81"	42"	51"	420 kg 926 lbs
QUANTA-Lyser 3000	59.1"	41.4"	47.6"	320 kg 705 lbs

The instrument's physical dimension and weight, uncrated, are:

Instrument Model	Width	Depth	Height (Hood Closed)	Height (Hood Open)	Weight
QUANTA-Lyser 4000	71.5"	39" (Including Monitor)	38"	53.5"	292 kg 644 lbs
QUANTA-Lyser 3000	45.3"	32"	36.6"	52"	210 kg 462 lbs

4.1.2 Environmental and Operating Conditions

Feature	Specification
Operating Conditions (Up to 2000 m above sea level)	Temperature: 15 - 30ºC / 60 - 85ºF Relative Humidity: 25 – 85% at 30ºC / 85ºF (non-condensing)
Storage Condition	Temperature: 10 - 40ºC / 50 - 104ºF Relative Humidity: 30 – 80% at 30ºC / 85ºF (non-condensing)
Transport Conditions	Temperature: 0 -60ºC / 32 - 140ºF Relative Humidity: 30 – 80% at 30ºC / 85ºF (non-condensing)
Noise	<85 dBA (QUANTA-Lyser 4000) / <80 dBA (QUANTA-Lyser 3000)
IP Code	20

4.1.3 Electrical and Communication

Feature	Specification
Mains Input	110 – 240 VAC 50 – 60 Hz 850 VA 220 VAC 60 Hz 850 VA
Mains Fuses	Mains Distribution Unit 101: F10 A / 250 V (2x, P, and N) PSU 208: F6.3 A / 250 V (2x, P, and N)
Output Fuses	Arm(s): F8 A / 250 V High Power: F8 A / 250 V (2x) CAN-bus Loop: F3.15 A / 250 V
Communication	CAN-bus (internal) Gigabit Ethernet (external)
Installation Category	II

4.1.4 Sample and Plate Format

Feature	Specification
Plate Size	SBS Format
Slides	75 x 25 x 1 mm (W x D x H)
Sample Tube Size	Minimum OD 12 mm Maximum OD 16 mm

4.1.5 BCR Tool

Feature	Specification
Reading Process	Manual rack load, automatic barcode reading
Barcode types	CODE39, ITF, Industrial2of5, COOP2of5, Codabar, CODE128, GS1128, GS1 DataBar, CODE93, EAN/UPC, Trioptic Code39
2D-Code Types	QR, MicroQR, DataMatrix, PDF417, MicroPDF, MaxiCode, GS1 Composite
Maximum Barcode Length	Depends on barcode type
Reading Distance	Barcode: 31 – 97 mmv(cell size 0.339 mm) 2D-code: 29 – 106 mm (minimum line width 0.339 mm)
Reading Resolution	0.127 mm

4.2 Performance Specifications

4.2.1 Capacity

QUANTA-Lyser 3000 can process batches of up to 240 samples, using EIA or IFA protocols.

QUANTA-Lyser 4000 can process batches of up to 480 samples, using IFA protocol only.

4.2.2 Quality Control

QUANTA-Lyser is capable of processing control material.

4.2.3 System Characteristics

Feature	Specification	
Volumes	Minimum sample/reagent volume: 5 µl Maximum sample/reagent volume: 1 ml (Sample), 2mL (Reagent) Minimum detectable volume: 150 µl	
Washable Pipetting Tips	4 (liquid channel 1 – 4)	
Aspiration Tips	2 (liquid channel 1 and 2) Available only on models with IFA capability.	
Dilutions, single and multistage	Yes	
	QUANTA-Lyser 3000	**QUANTA-Lyser 4000**
Sample Batch Size	240	480
	QUANTA-Lyser 3000	**QUANTA-Lyser 4000**
Maximum Number of IFA Slides	30	40
Number of Control Positions	40	20
Number of Reagent Positions	24	12

Feature	Specification	
Number of Diluent Positions	7	7
Number of Dilution Wells	480	672
Maximum Number of Wash Buffer Lines	ELISA: 4 IFA: 2	2

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CHAPTER 5: Operating Instructions

5.1 System Start-Up

- Switch the instrument on by pressing the mains switch.
- Double click QUANTA-Lyser Software Icon (

) to start the software.
  - Login screen is displayed.

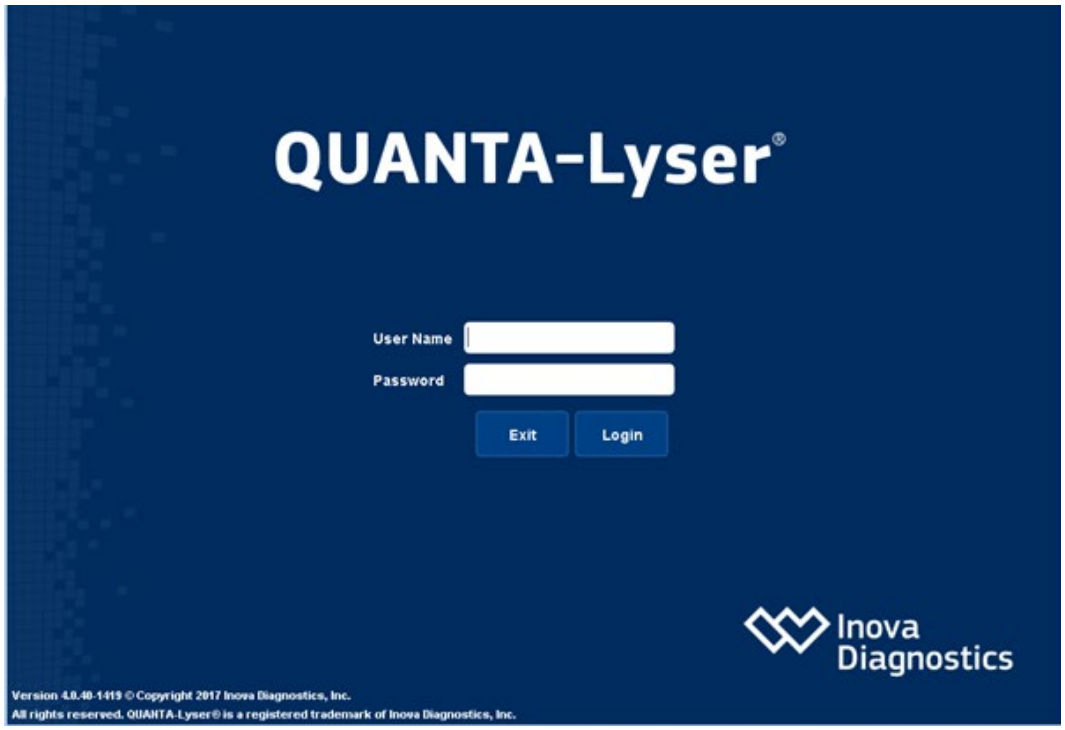


Figure 5-1: Login Screen

- Enter user name and password into text fields, then click Login to log into QUANTA-Lyser software.
  - The home screen will be displayed.

5.1.1 Common Buttons

There are a series of buttons at the top of the screen which are repeated on most other screens. These buttons are:

Button / Element	Description
	Returns to Worklist screen from any other window
	Returns to Timeline screen when a run is active

Button / Element	Description
	Returns to the Home screen
	Opens Maintenance screen
	Communications Icon – Indicates status of communications module (see below for details)

5.1.1.1 Communications Icon

The Communication Icon changes to a variety of colors to reflect different communication scenarios. Along with different colors, there may also be badge(s) present to reppresent messages or requests downloading. See below chart for details of the Communications Icon options.

Button / Element	Color Description	Badge Description
	Communications module not enabled	1 message waiting to be read
	Communications established	1 message waiting to be read
	Communications established	1 message waiting to be read 10 requests downloading (note that there may be multiple tests per request)
	Communications module enabled but not established	
	Communications module connecting	

5.1.2 Home Screen

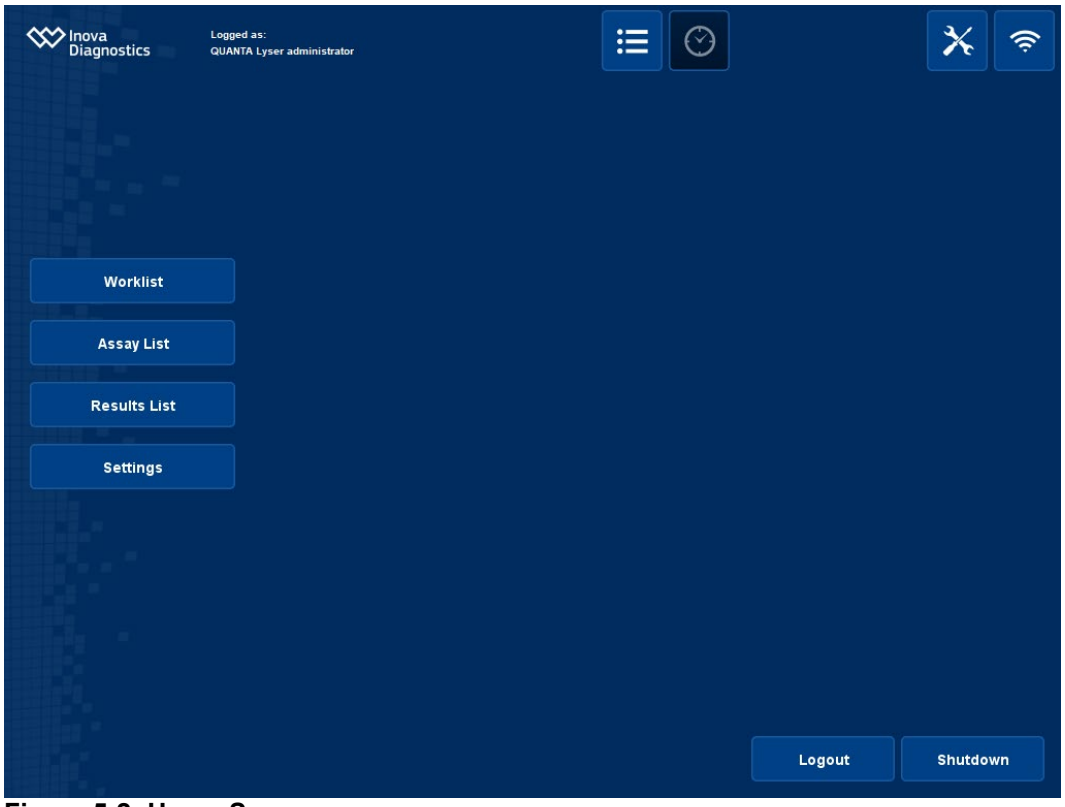


Figure 5-2: Home Screen

Note

If Laboratory Information System (LIS) is configured and available, the connection is established automatically.

The color of the communications icon indicates whether the connection is enabled or disabled and whether the connection has been established or not. See "Communications Icon" section for more detailed information.

Unique Elements of the Home Screen

Button / Element	Description
Worklist	Creates a new worklist (see "Creating a Worklist" section)
Assay List	Opens Assay List screen where all assays programmed on the system can be seen and edited (with appropriate permission level for user that is logged in)
Results List	Opens Results List screen where a list of completed sessions can be found and reviewed and reports can be generated and printed
Settings	Opens Settings screen where hardware and software settings are controlled
Logout	Logs current user out and returns to Login screen

Button / Element	Description
Shutdown	Shuts down QUANTA-Lyser software

5.2 Conditioning and Maintenance Actions

At startup, the liquid channels must be conditioned by filling the buffer lines (Prime), Decontaminate tips, as well as a flush with system liquid (Flush). Individual actions may be completed by clicking the corresponding button or all three functions can be performed by clicking Daily button.

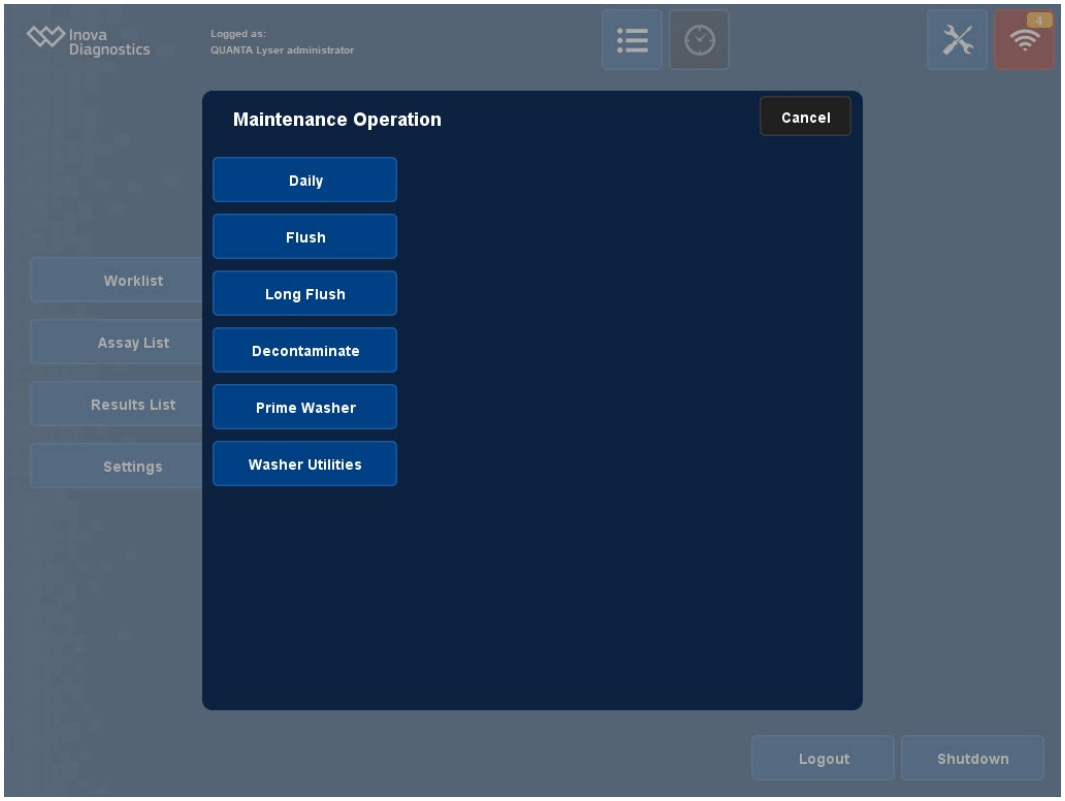


Figure 5-3: Maintenance Screen

Unique Elements of the Maintenance Screen

Button / Element	Description
Daily	Performs flush, decontaminate and prime procedures
Flush	Flushes system liquid channels thoroughly
Decontaminate	Performs decontamination procedure
Prime	Primes wash buffer lines

Button / Element	Description
Washer Utilities	Allows wash programs to be tested
Cancel	Closes the window

5.3 Performing an Analytical Session

5.3.1 Wash Buffer Assignment

Prior to setting up a worklist, the position(s) of the wash buffer(s) required for the a run must be established.

1. From the Home screen, click the Settings button to proceed to the settings menu.
2. Click on the Robot button from the menu on the left side of the screen.
3. Click on the Wash Buffers button to proceed to the Wash Buffers setup screen.

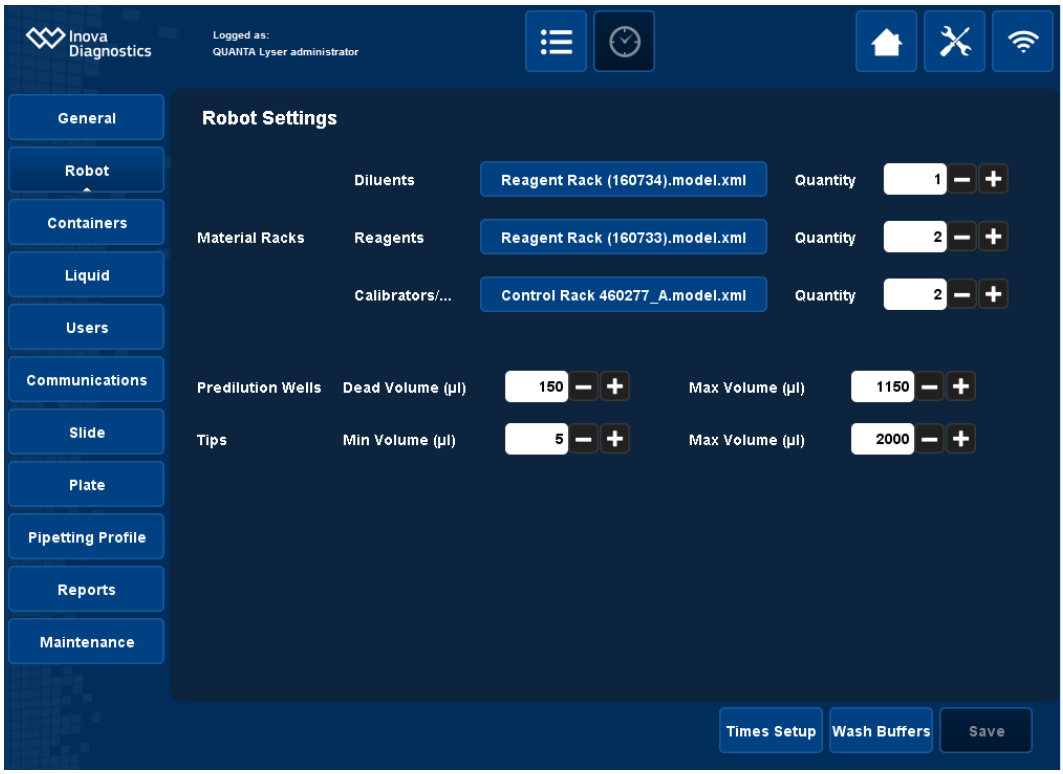


Figure 5-4: Robot Settings Screen

4. Once in the Wash Buffers screen, configure the wash buffer(s) to be used during the run being scheduled.

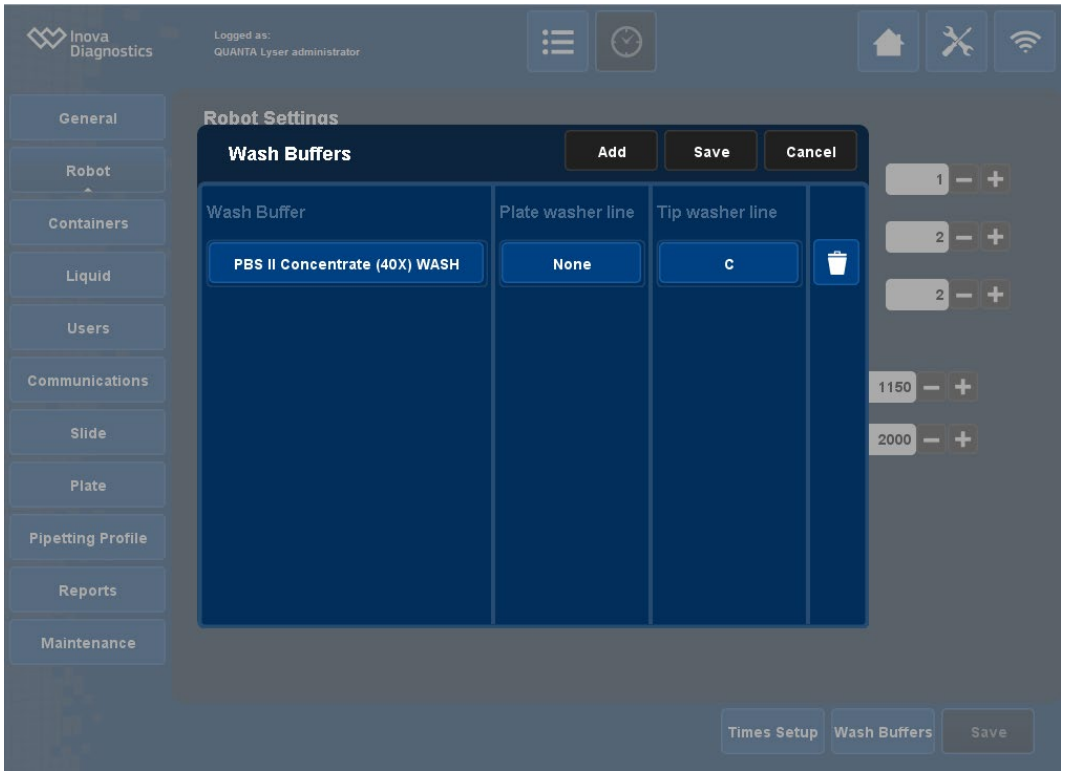


Figure 5-5: Wash Buffers Setup Screen

Wash Buffer can be selected from the liquids list and the wash line must be indicated. Note that IFA wash buffers must only be placed in bottles connected to buffer lines C and D, while ELISA buffer may be placed in any buffer bottle. Indicate the bottle location corresponding to the need for the buffer. For example, IFA wash buffer will only be used by Tip Washer as seen in the PBS II example in the image above. ELISA wash buffer is configured to use the plate washer line.

5.3.2 Creating a Worklist

From the Home screen, click the Worklist button to proceed to the Worklist screen.

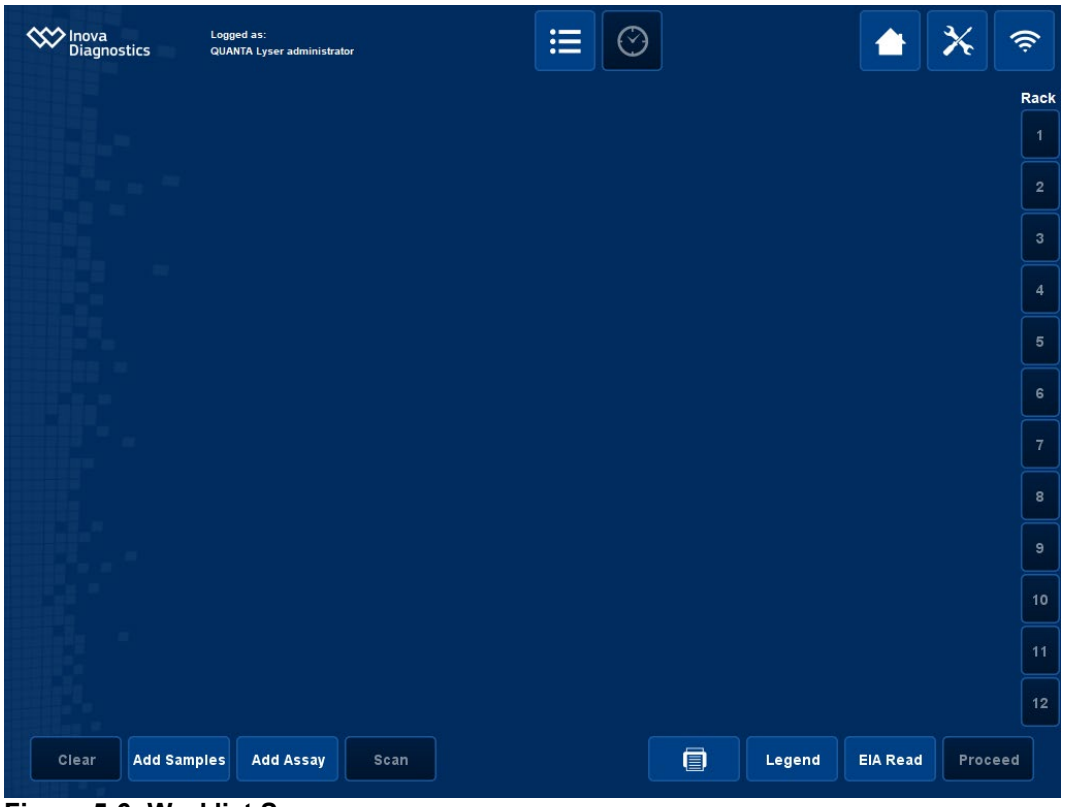


Figure 5-6: Worklist Screen

Unique Elements of the Worklist Screen

Button / Element	Description
Clear	Clears existing worklist
Add Samples	Adds samples to the worklist
Add Assay	Adds assays to the worklist
Scan	Allows sample barcodes to be scanned
1	Number buttons to the right correlate with sample racks
	Allows the worklist to be printed
Legend	Opens a window that displays a legend

Button / Element	Description
Preview	Proceeds to assay setup

1. From the worklist screen, click the Add Samples button.

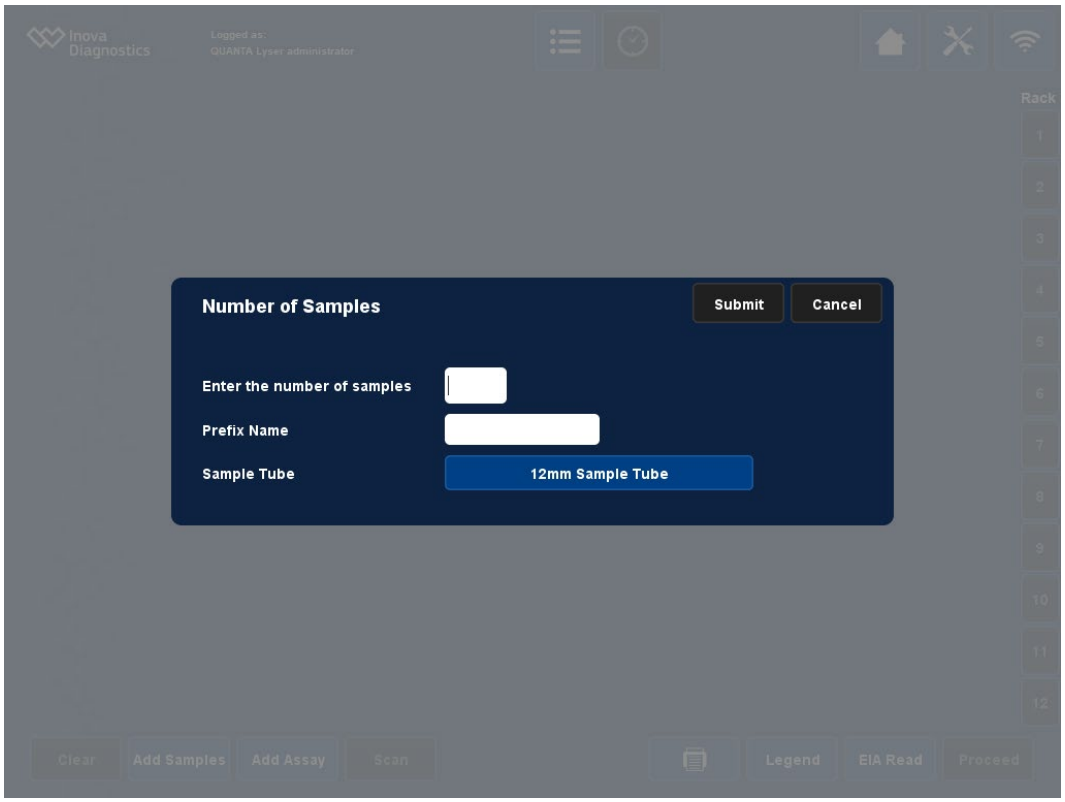


Figure 5-7: Adding Samples to Worklist

2. Enter the number of sample tubes to be scanned, enter a sample naming prefix (if running without barcodes), and verify sample tube size.
   a. Click the Submit button to return to Worklist screen.
3. If using barcoded samples, click the Scan button to open the Scan Racks window.
   a. For automatic barcode scanning, verify that all necessary sample racks are selected and click Automatic scan.

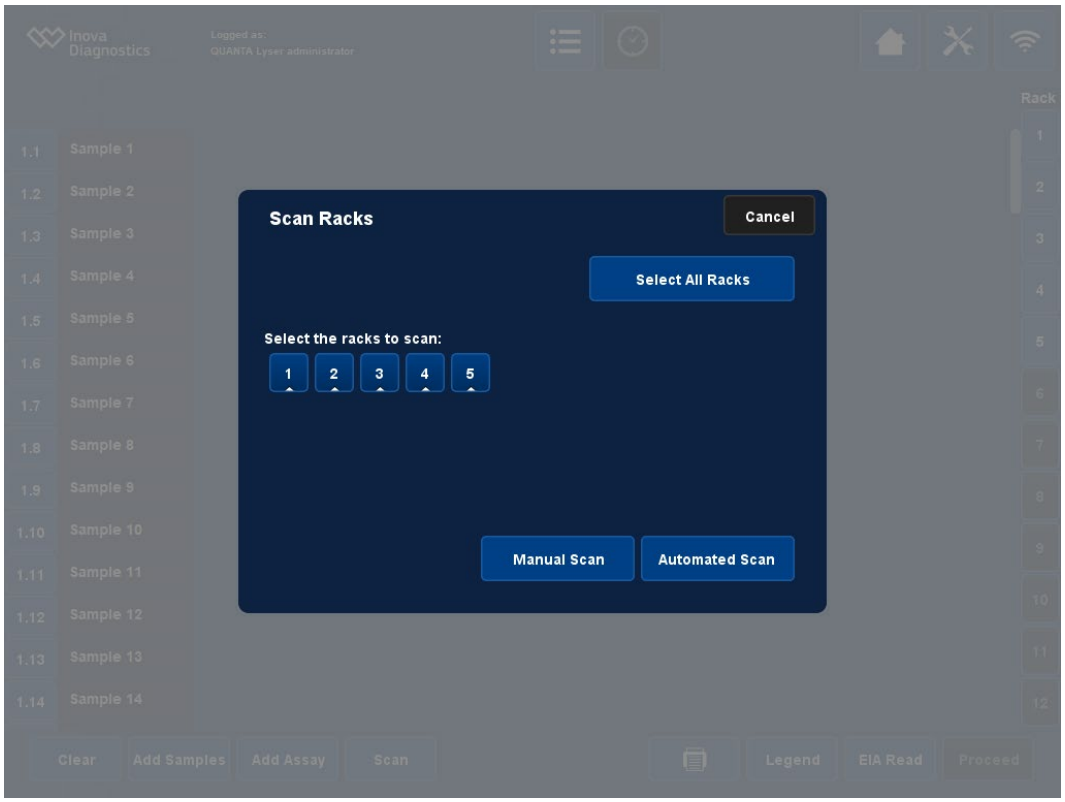


Figure 5-8: Scan Racks Window

b. Click the Automatic Scan button and follow the prompts to scan sample racks.

Figure 5-9: Scanning Sample Racks

c. If barcode IDs are to be entered manually, click the Manual Scan button to proceed to the Manual Sample Identification screen.

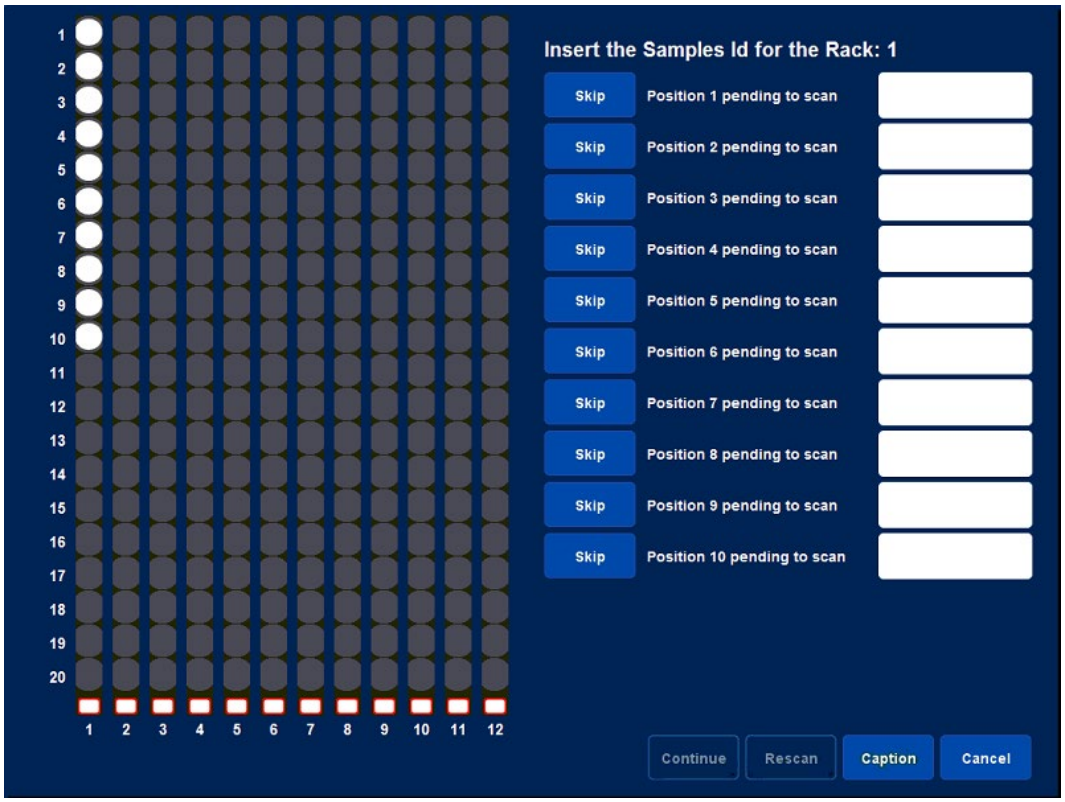


Figure 5-10: Manual Sample Identification Screen

d. In this screen, barcode IDs can be manually entered in the text boxes on the right of the screen or the Skip button may be selected for sample tubes to be skipped.

e. In the case of a duplicate barcode, the software will notify that duplicate barcodes have been detected and will give the option to select one of the duplicate barcode positions to be used.

Figure 5-11: Duplicate Sample Barcode Notification

f. Once a selection is made, a confirmation window will appear.

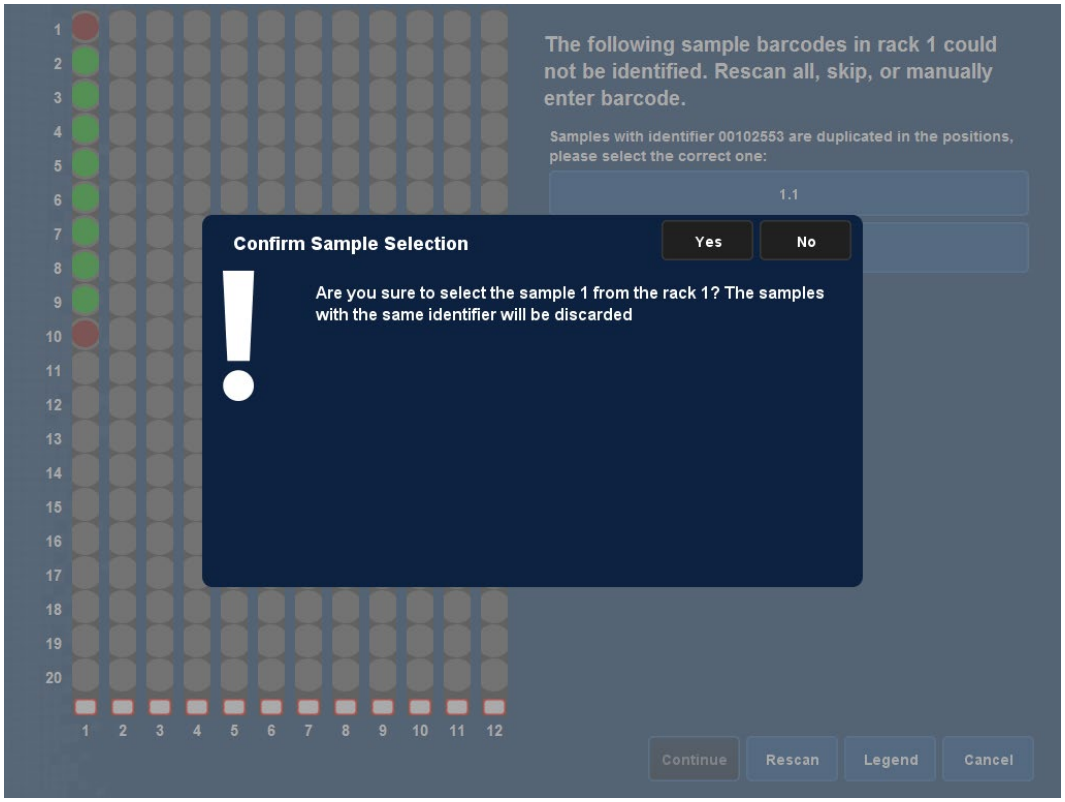


Figure 5-12: Duplicate Sample Selection Confirmation

g. Finally, the software will indicate that all errors have been resolved and the unused duplicate position must be skipped.

Figure 5-13: Duplicate Sample Selection Completion

h. Once returned to the worklist screen, all barcode IDs and locations will be listed, with the skipped duplicate position being blank.

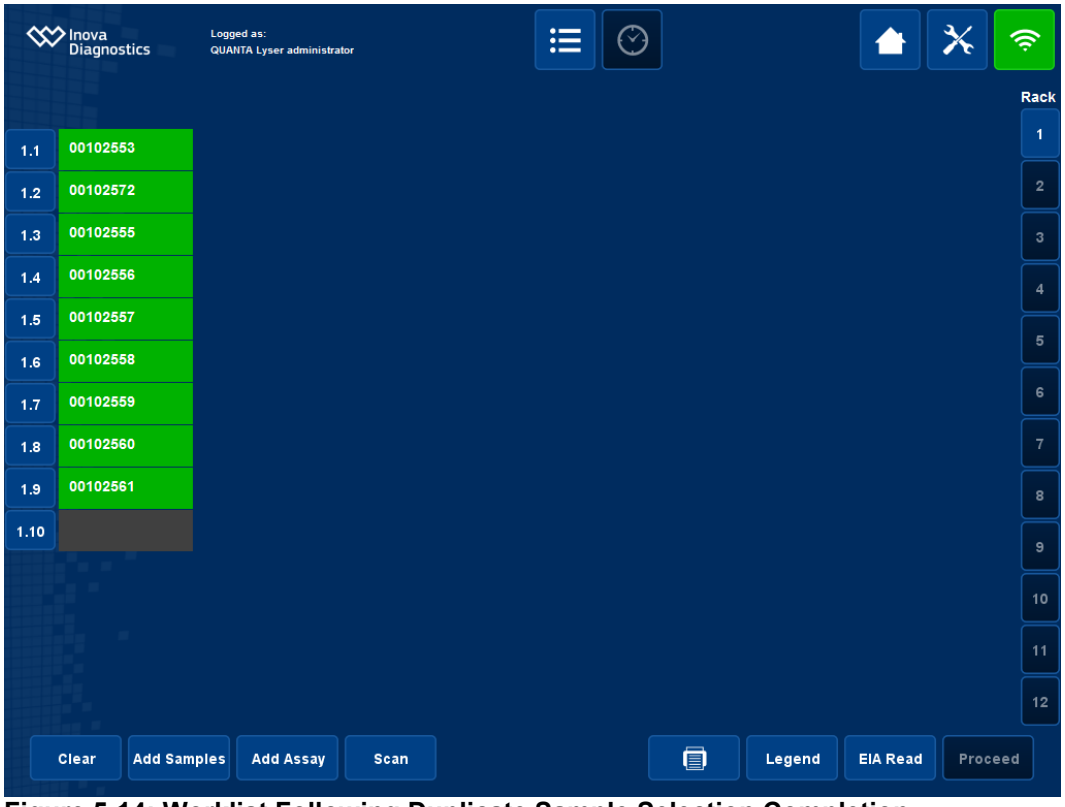


Figure 5-14: Worklist Following Duplicate Sample Selection Completion

i. If a barcode is unreadable, the following screen will appear, giving the opportunity to

manually enter the barcode ID, skip the sample, or Rescan.

Figure 5-15: Unread barcode

4. If connected to an LIS, the LIS will be queried as sample racks are scanned and the worklist will automatically be populated with assays and sample selections.

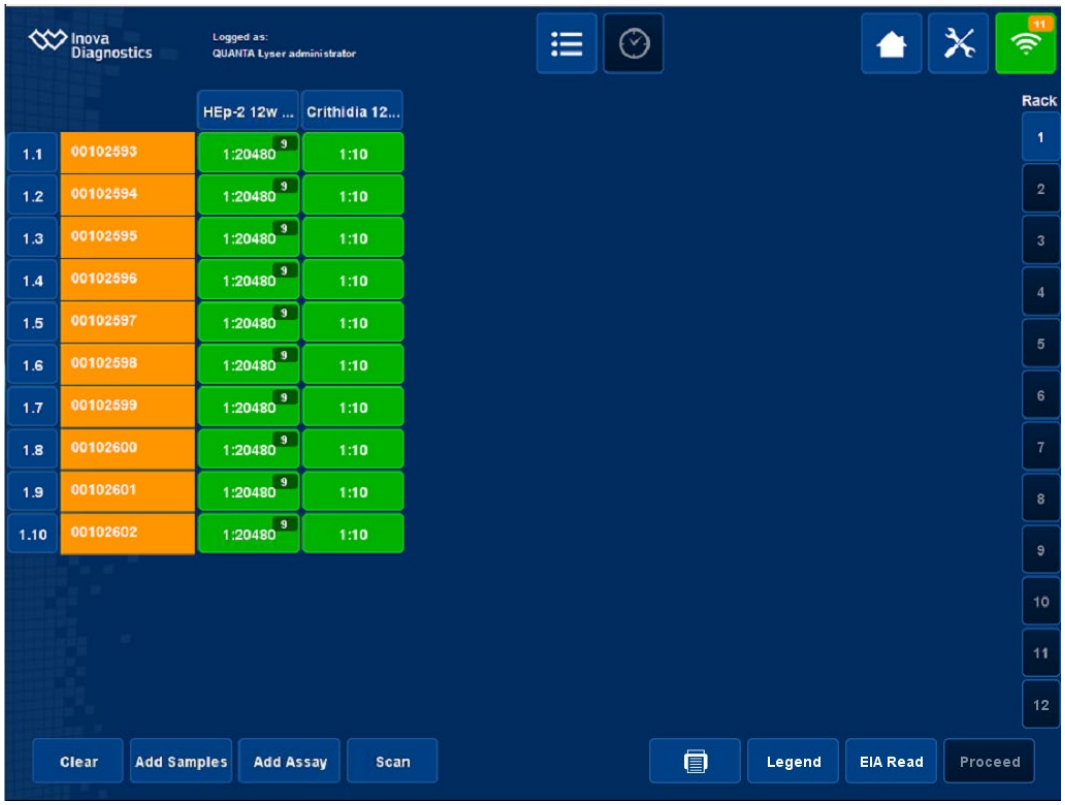


Figure 5-16: Worklist Screen After Sample Barcode Scanning

a. During test download, information may not appear on screen until all orders for all tests in the rack have been received in QUANTA-Lyser.

b. To see existing messages, select the communications icon ( )

Figure 5-17: Communications Log

c. To see the detail of the message, select the mouse ( ) icon.

Figure 5-18: Communications Log Details

5. If an LIS is not connected, assays and dilution information must be selected manually.
   a. Click the Add Assay button, select the assay(s) to be run, and click the Submit button.

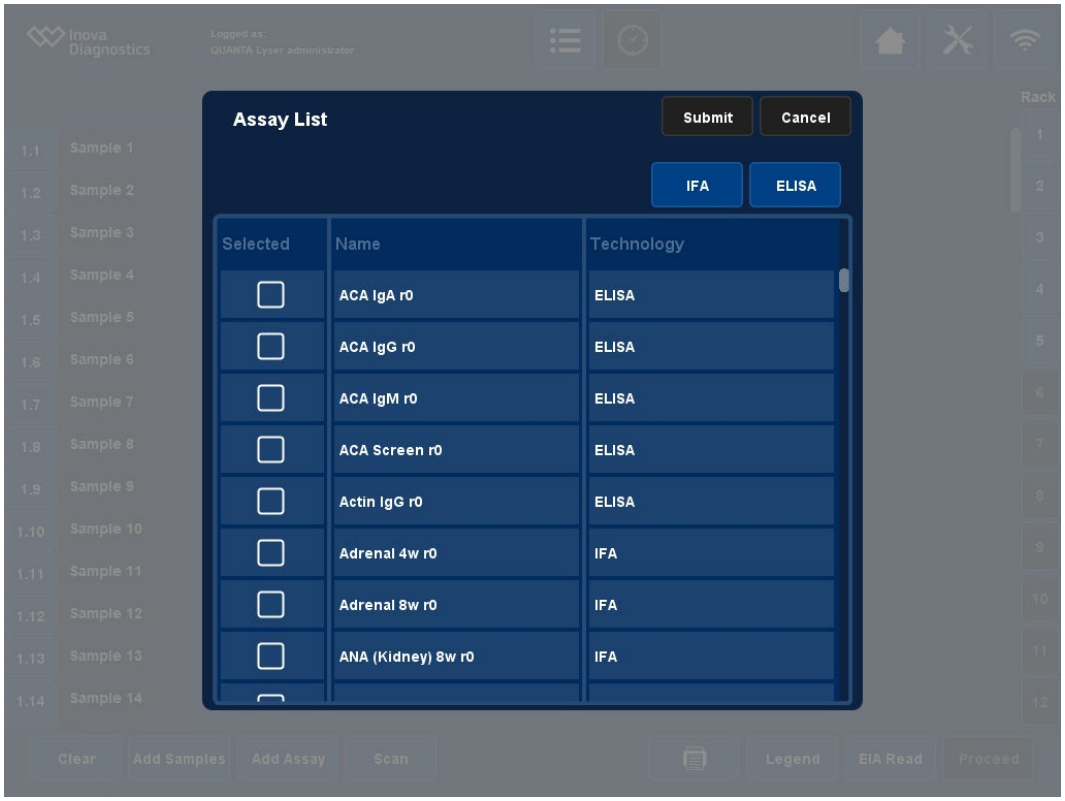


Figure 5-19: Assay List

   b. The worklist is updated to include the assay(s) that have been selected.

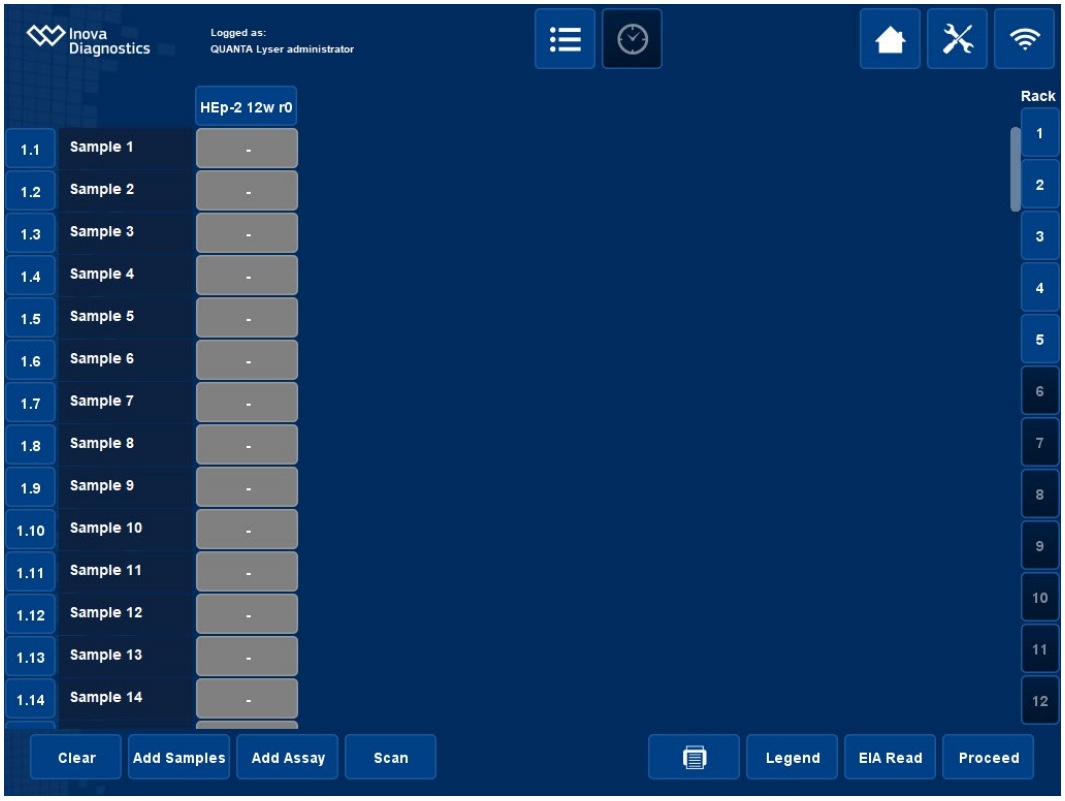


Figure 5-20: Worklist Following Assay Selection

c. Sample dilutions now must be selected. Click on each assay name at the top of the worklist screen to open the Dilution Selection window for that particular assay.

d. For IFA assays, depending on specific assay configuration, multiple dilution options may be available. Dilutions can be selected and applied to all samples by clicking the All Samples button or apply only to specific samples by clicking the Range button.

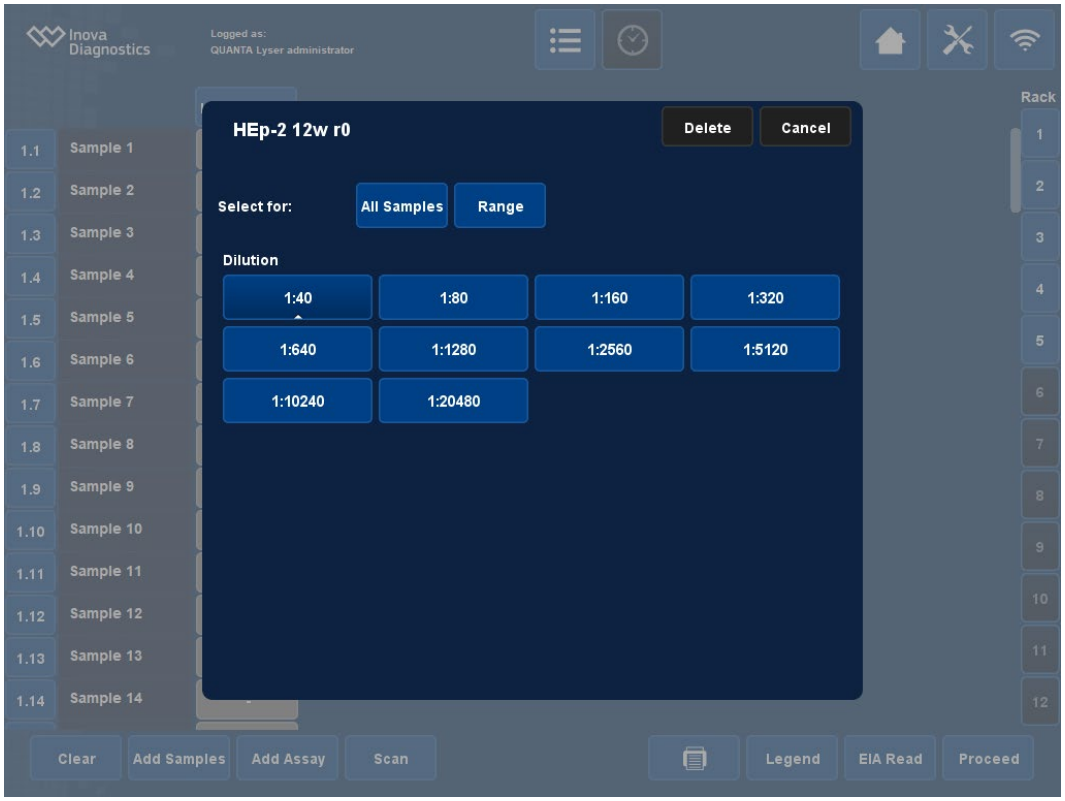


Figure 5-21: IFA Dilution and Sample Selection

e. For ELISA assays, the dilution factor is hard coded into each assay protocol so the only options are to select all samples in the worklist to be run on the assay in question or to select a range of samples.

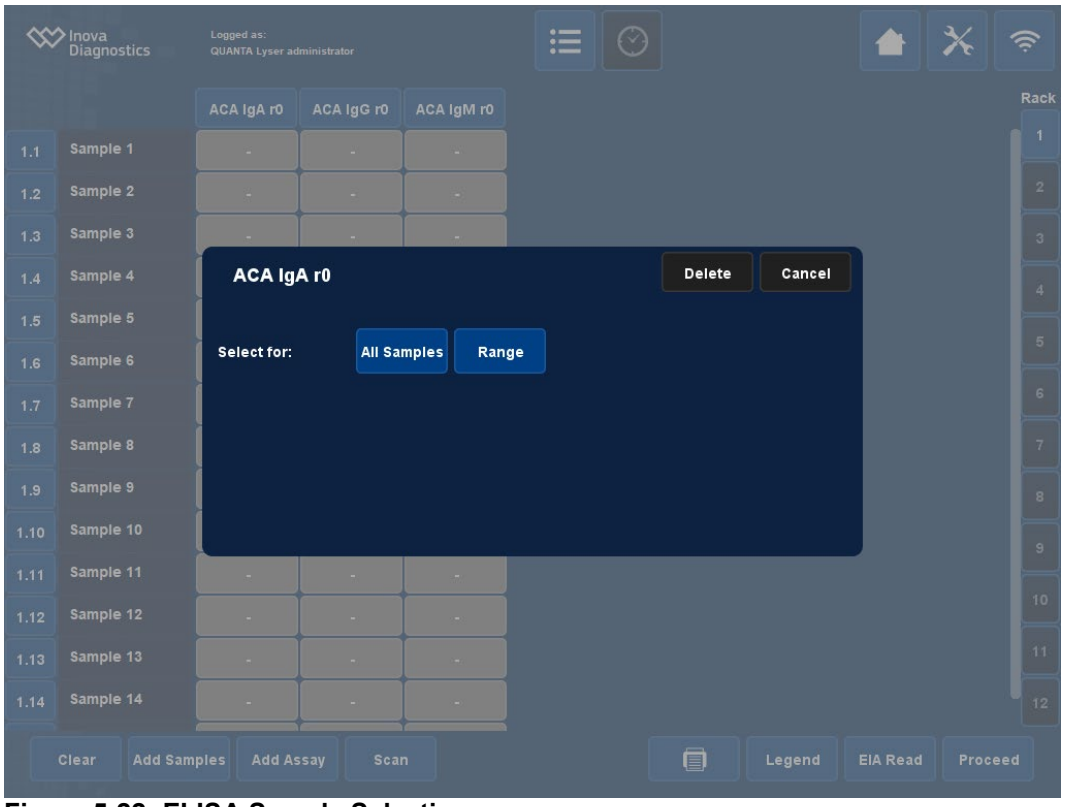


Figure 5-22: ELISA Sample Selection

f. A message will appear confirming that the selection is correct.

6. The worklist is now complete and ready for review.

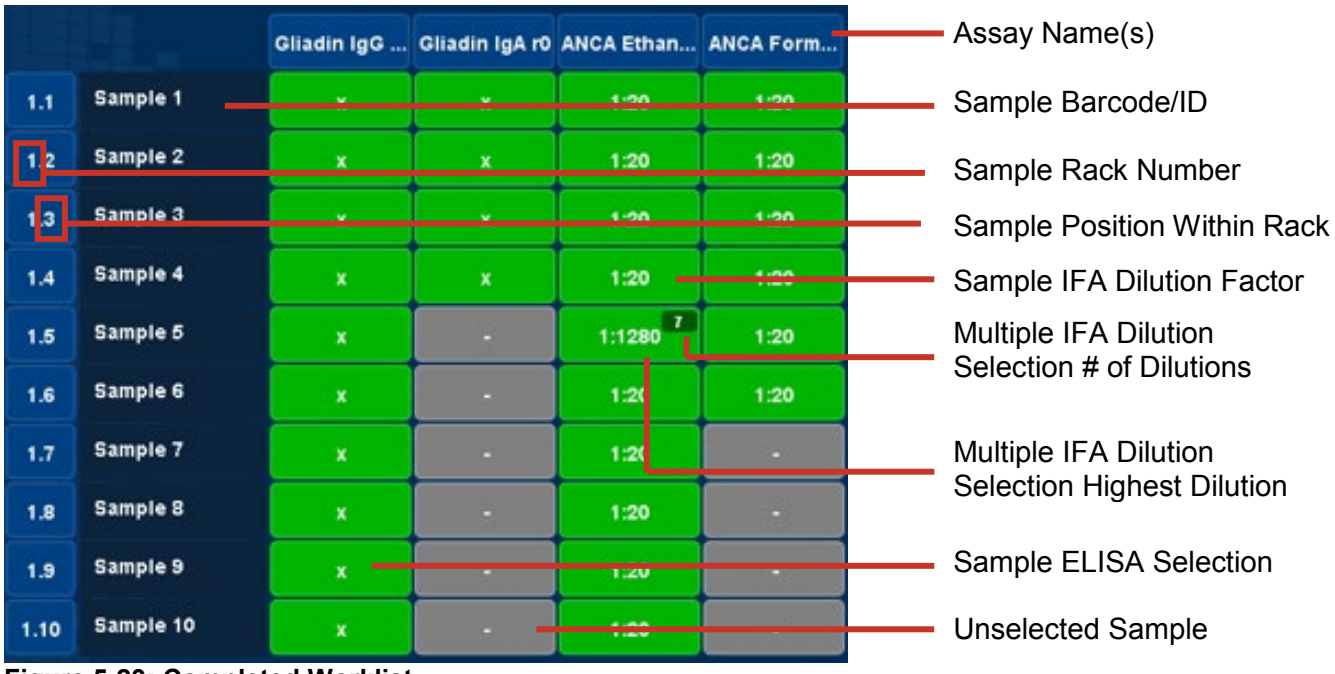
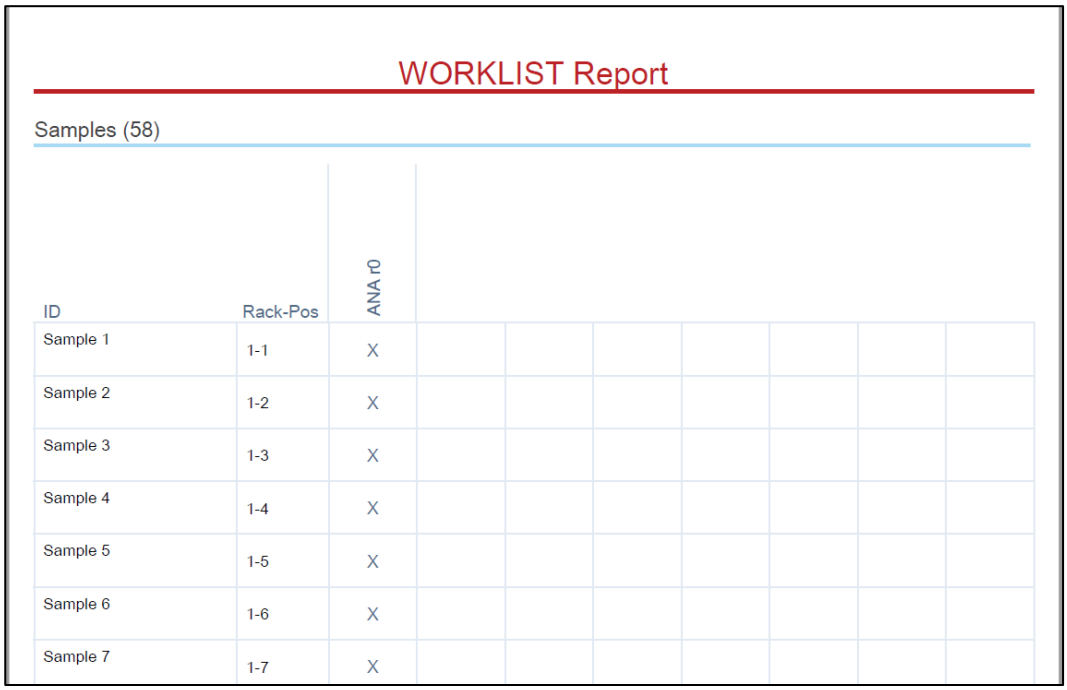


Figure 5-23: Completed Worklist

7. A Worklist Report may be printed, if desired, by clicking the Print icon in the Worklist screen.



WORKLIST Report

Samples (58)

ID	Rack-Pos	ANA r0
Sample 1	1-1	X
Sample 2	1-2	X
Sample 3	1-3	X
Sample 4	1-4	X
Sample 5	1-5	X
Sample 6	1-6	X
Sample 7	1-7	X

Figure 5-24: Worklist Report Example

8. Upon completion of the worklist, the Proceed button on the Worklist screen will become active to allow for reagent and consumable loading.

Figure 5-25: Proceeding After Worklist Completion

9. If assays in the worklist contain reagents that are configured to be lot specific, an additional window will pop up to allow the user to enter the expected lot number for each liquid that is configured to be lot specific.

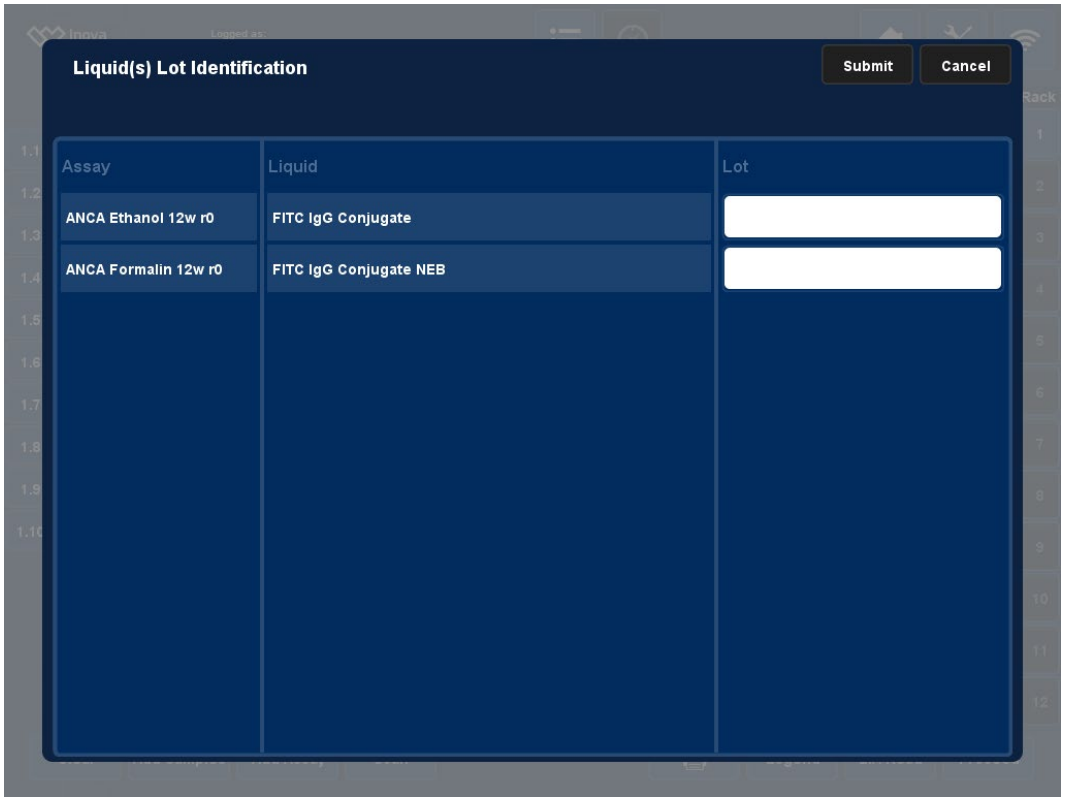


Figure 5-26: Liquid Lot Identification Window

5.3.3 Assay Setup

The Assay Setup screen has multiple tabs for different material that must be loaded to the instrument deck. Highlighted buttons indicate an action is required for that material before the run may be started.

There are a series of buttons that are common to most tabs and screens of the Assay Setup screen. Tabs which require action will have be highlighted in orange. The common buttons for the Assay Setup screen are:

Button / Element	Description
IFA Slides	IFA Slides Tab manages slide requirements, the triangle icon at the bottom of the button indicates this is the active tab
Predilutions	Predilutions Tab manages predilution block requirements
Liquids	Liquids Tab manages kit reagents requirements
Wash Buffers	Wash Buffers Tab manages wash buffer requirements
Close	When an alert is present, the Close button is active and may be clicked to remove the alert from view

Button / Element	Description
Back	Returns to Worklist screen
Schedule	Becomes active once all required components are loaded and will proceed to the timeline screen

5.3.3.1 IFA Slides Tab (Active only on IFA Runs)

The IFA Slides tab contains information about slide type and quantities required for the run. IFA Slides Tab also allows the user to scan slide barcodes using the automated barcode scanner or enter slide barcode or identifying information manually. The presence of an orange alert message at the top of the screen indicates either that slide barcodes have not been automatically scanned or, if automatic scan is not being used, the slide carrier has not been marked as loaded.

Information in this tab is used to place IFA slides into the appropriate slide tray and ensure those trays are placed in the appropriate position on instrument deck.

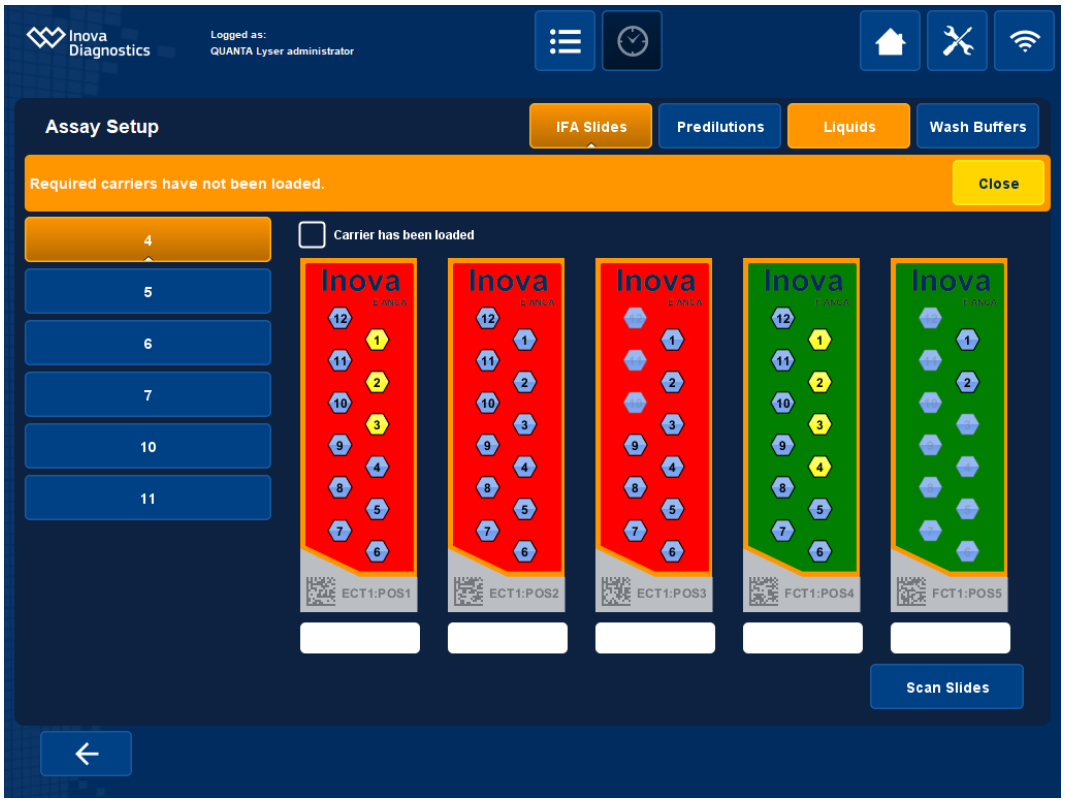


Figure 5-27: IFA Slides Tab

Unique Elements of the "IFA Slides" Tab

Button / Element	Description
4	Slide Tray number, if highlighted, it is required for current run; triangle icon at the bottom of the button indicates active selection

Button / Element	Description
5	Slide Trays that are not currently selected and not needed for current run
Scan Slides	Allows user to automatically scan barcodes for required slides

10. Slide barcode or other identifying information must be entered.
    a. If slides with 2D barcodes are being run, the automatic scan function may be used:
    b. Review the needed slides by clicking on each slide tray number. Review both slide type as well placement in the rack, place slides in rack(s) and place them in the appropriate position on the deck.
    c. Click the Scan Slides button. The Scan Slides window will appear.

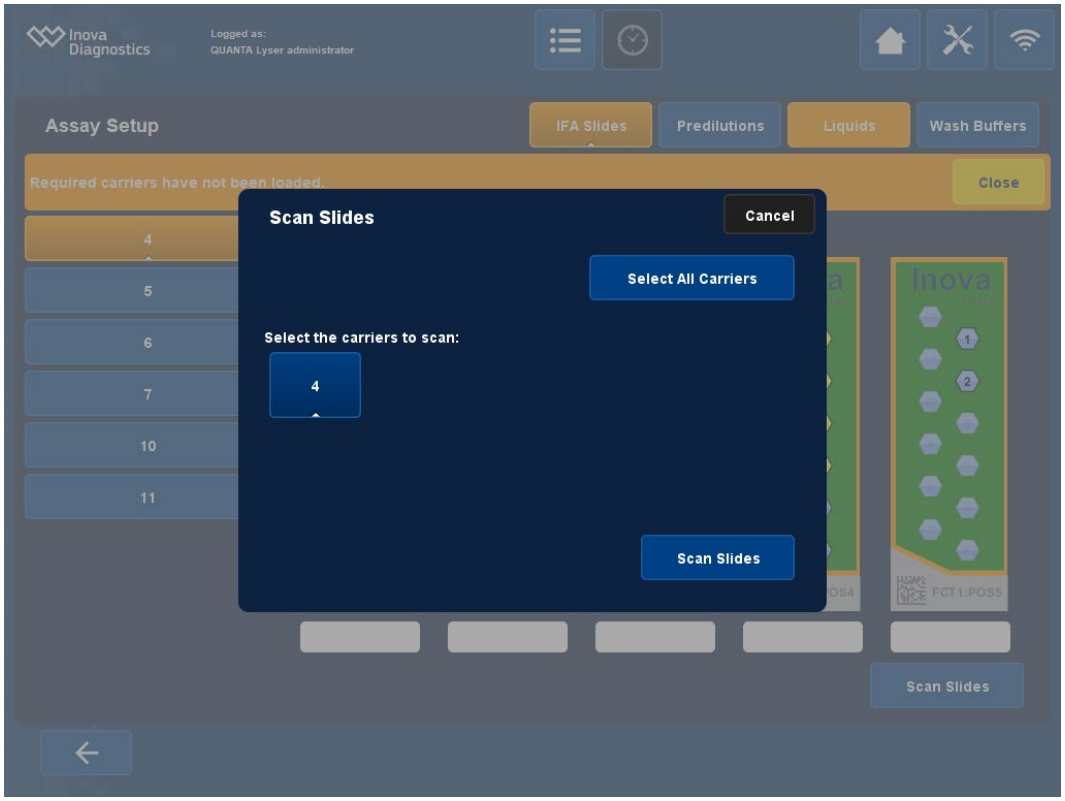
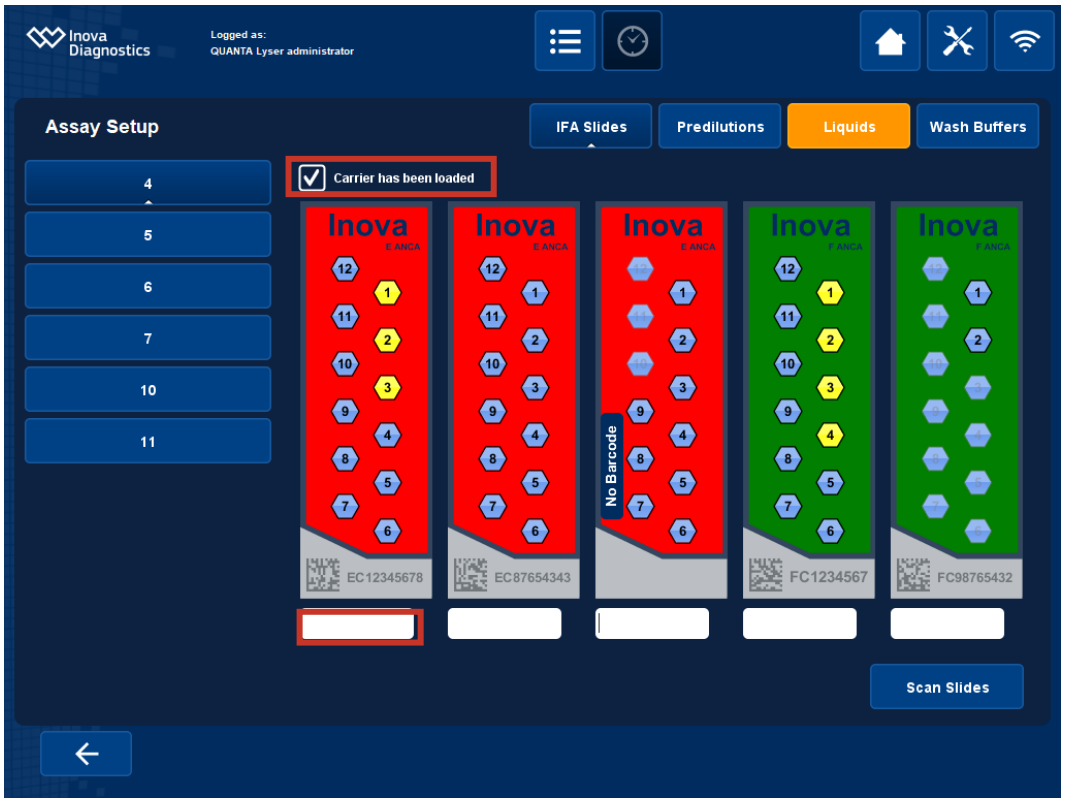


Figure 5-28: Scan Slides Window

    d. Select the slide tray/carrier to scan or click the Select all carriers button to select all.
    e. Click the Scan Slides button to begin the automatic barcode scanning process.
    f. Upon completion, the slides displayed in the IFA Slides tab will contain images of correct barcode numbers and the Carrier has been loaded check box will be automatically selected.
    g. If automatic scanning is not being used or if barcode or other slide identifier is being input manually:
    h. Slide barcode or other identifying information (i.e. slide number if writing manually on a

slide, etc.) can be entered in the text field below each slide. Enter information, then click enter to apply.



Select once slide tray has been loaded onto instrument deck

Slide barcode ID or other identifying information is entered here

Figure 5-29: Scan Slides Window Details

i. Once all slides have been identified, if desired, and slide tray is physically loaded onto the appropriate position on the instrument deck, click the Carrier has been loaded box, indicating that the slide tray has been placed on the deck.

j. Repeat for any other slide trays needed on the run.

k. If a slide barcode is duplicated, a notification will appear on the affected slides and the text field below will remain active to allow for a new barcode entry.

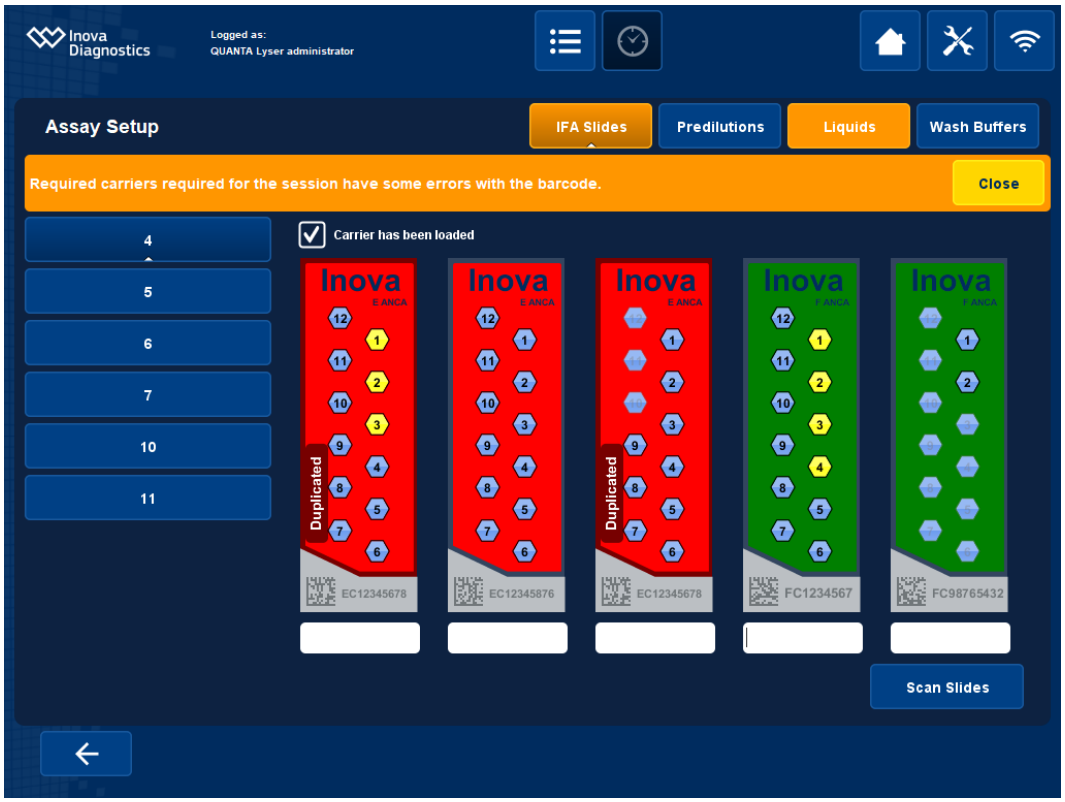


Figure 5-30: Duplicate Slide Barcodes

l. If a slide barcode is not recognized, a notification will appear, indicating there is no barcode assigned to the affected slide(s). The text field below the slide will remain active to allow for a new barcode entry.

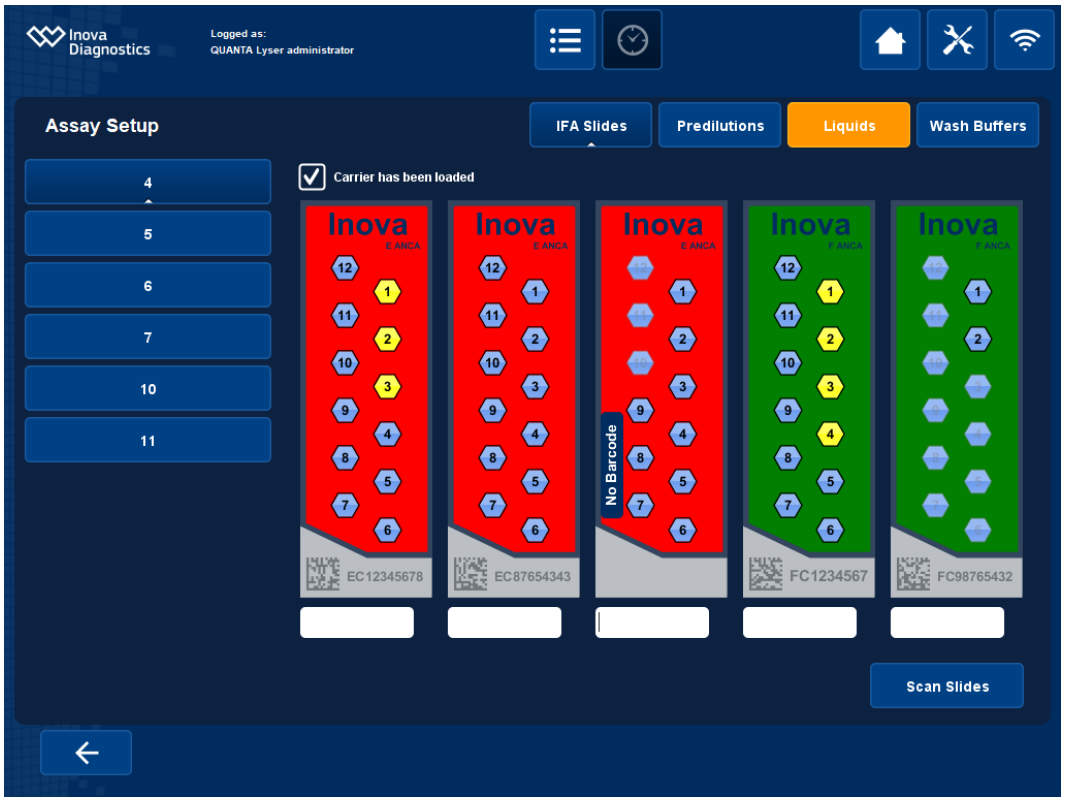


Figure 5-31: Unread Slide Barcode

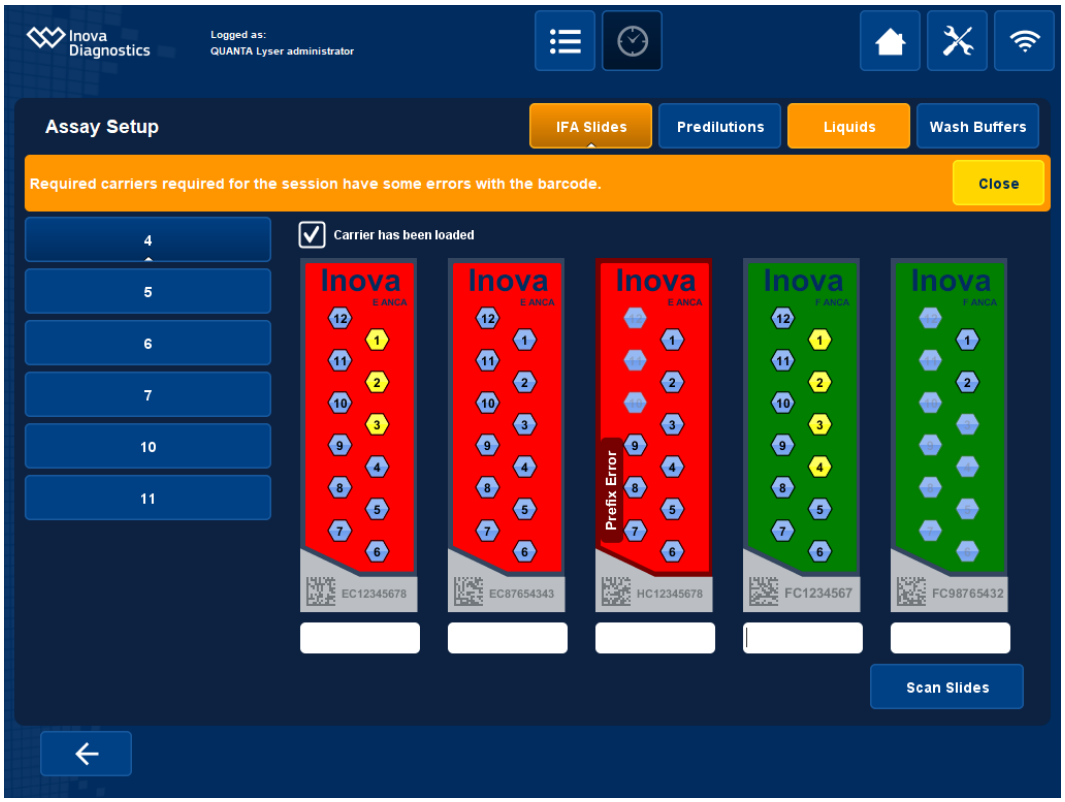


Figure 5-32: Incorrect Slide Type

m. If an incorrect slide barcode type is used (i.e. the system is expecting an HC barcode prefix for the selected assay and instead a slide with an EC barcode prefix is scanned), a Prefix Error label will appear on the affected slide(s). The text field below the slide will remain active to allow for a new barcode entry.

5.3.3.2 EIA Plates Tab (Active Only on ELISA Runs)

The EIA Plates tab contains information about the number and type of ELISA plate strips that are required for the run. Clicking on plate numbers using the buttons on the left will show the layout for each plate frame that is to be placed on the instrument deck as well as location of control vs. sample wells on the strips and assay name. Required plate type is also listed. Multiple ELISA assays may be combined onto one plate frame if they have identical assay steps, incubation times, and the same wash buffer.

Information in this tab is used to place ELISA plate strips into the appropriate plate frame and ensure those plates are placed in the appropriate position on instrument deck. Toggling back and forth from one plate number button on left side of the screen to another will display different plate (if multiple plates are required based on the scheduled worklist).

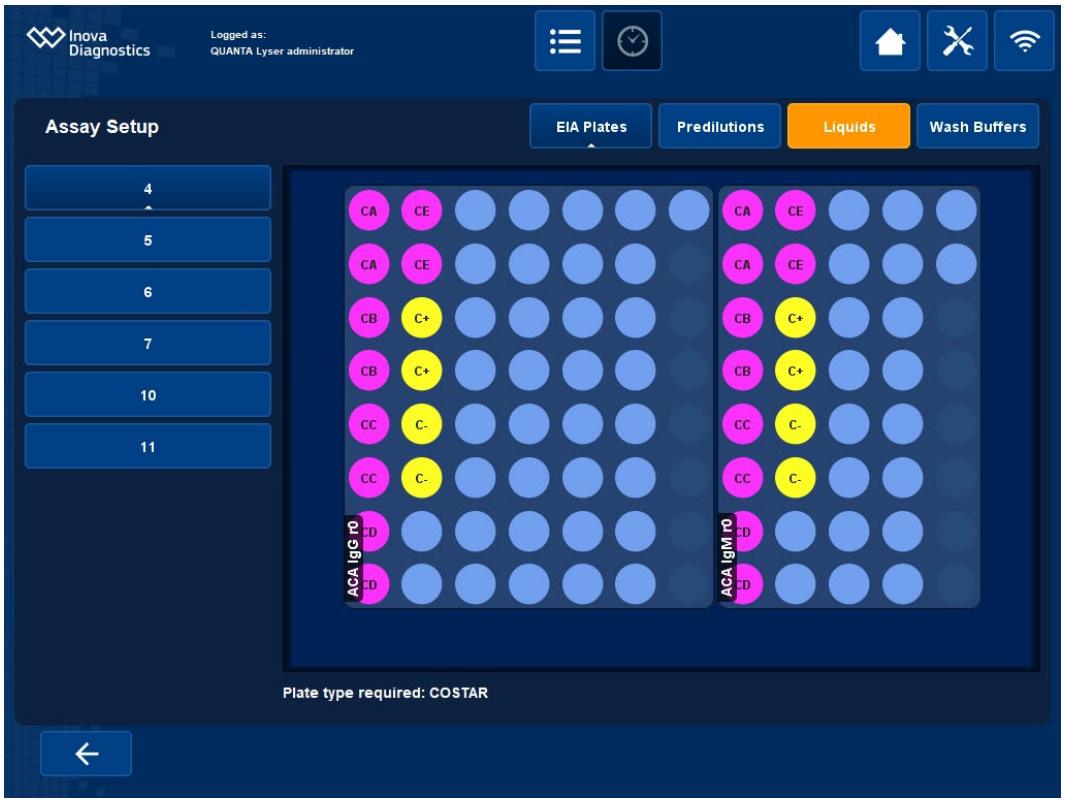
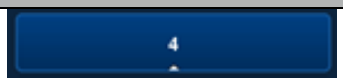


Figure 5-33: EIA Plates Tab

Unique Elements of the EIA Plates Tab

Button / Element	Description
	Plate number, triangle icon at the bottom of the button indicates active selection
	Plates that are not currently selected do not contain triangle icon

5.3.3.3 Predilutions Tab

The Predilutions tab contains information about the number and location of predilution blocks that are required for the run. Clicking on predilution block numbers using the buttons on the left will show which predilution racks and wells are scheduled to be used during the predilution step of the run.

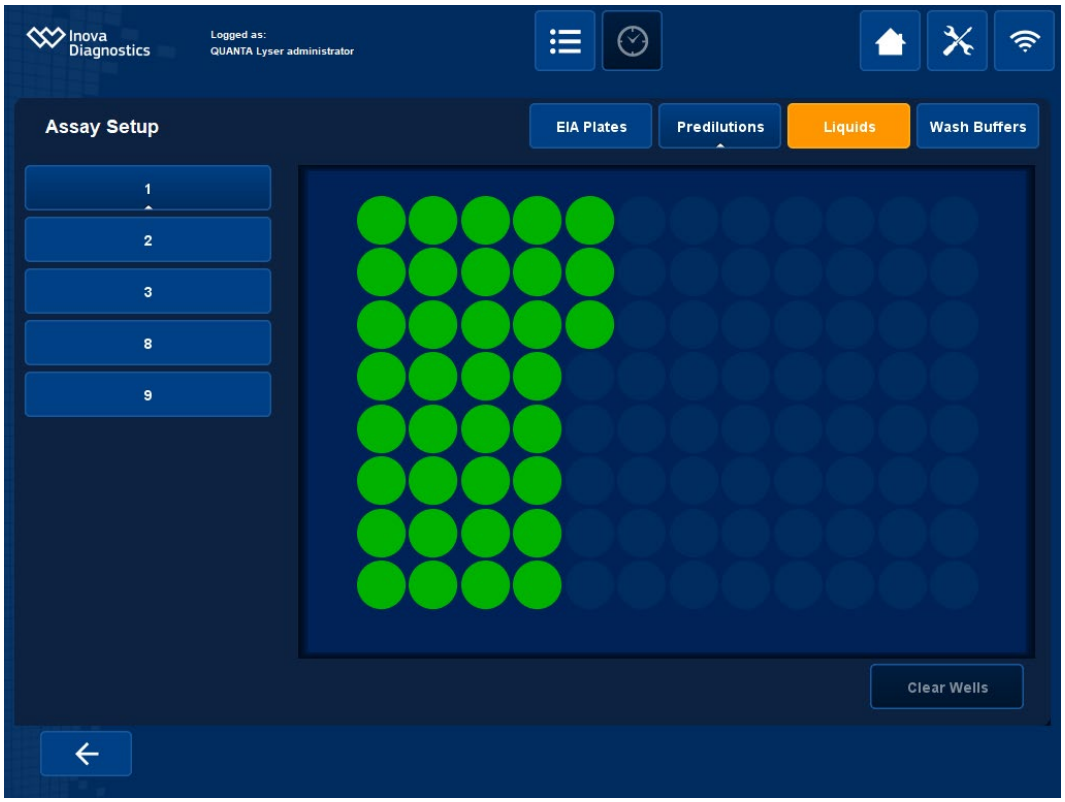


Figure 5-34: Predilutions Tab

Unique Elements of the Predilutions Tab

Button / Element	Description
1	Predilution block information, triangle icon at the bottom of the button indicates this is the active selection
2	Predilution blocks that are not currently selected do not contain triangle icon
Clear Wells	Resets predilution blocks, assumes user is discarding any partially used predilution blocks from the deck and is placing fresh blocks

5.3.3.4 Liquids Tab

The Liquids tab contains information about samples, diluents, controls, calibrators and reagents that are required for the currently scheduled worklist. Liquid type, liquid name, lot number (If a specific lot number is required due to a lot specific reagent) and volume needed for each liquid is listed in the table. To change which liquid types are being displayed, click the buttons above the table. A triangle icon at the bottom of a button indicates that liquid type is being displayed in the table.

Caution

Check bottles containing reagents and eliminate air bubbles on the liquid's surface to prevent liquid level sensing problems.

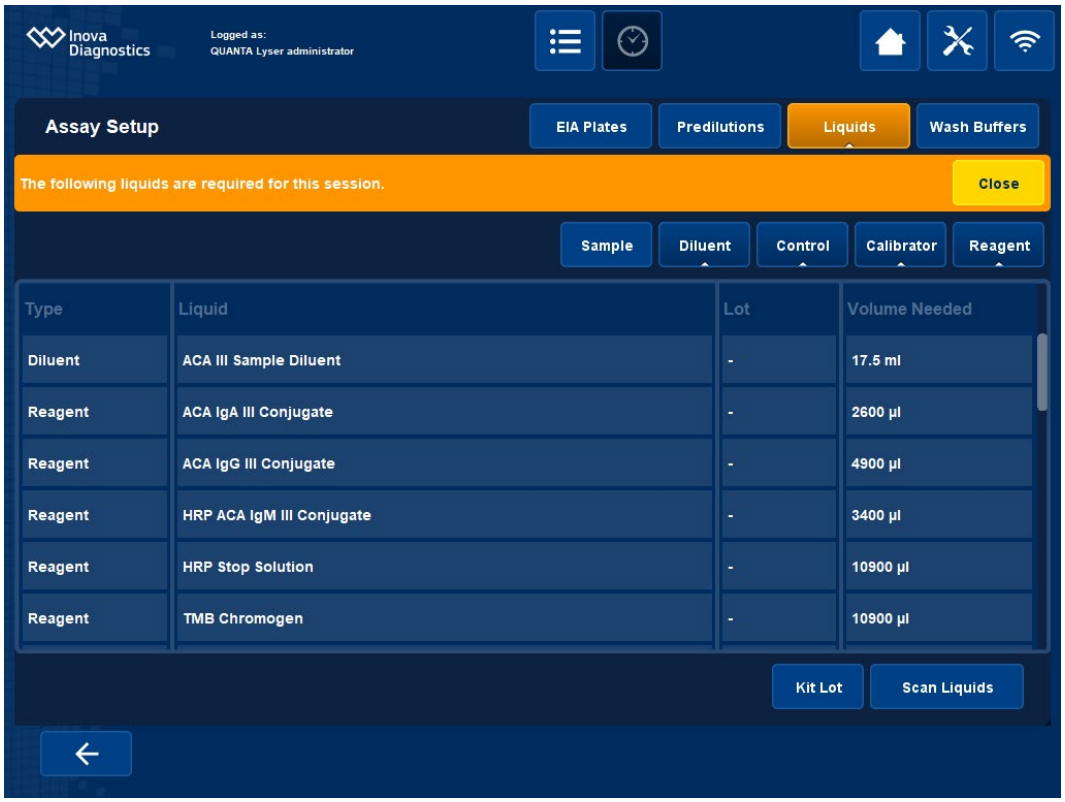


Figure 5-35: Liquids Tab

Unique Elements of the Liquids Tab

Button / Element	Description
Sample	Displays Sample information, a triangle icon at the bottom of the button indicates this fluid type is selected and is being displayed
Diluent	Displays required Diluent information, a triangle icon at the bottom of the button indicates this fluid type is selected and is being displayed
Control	Displays required Control information, a triangle icon at the bottom of the button indicates this fluid type is selected and is being displayed
Calibrator	Displays required Calibrator information, a triangle icon at the bottom of the button indicates this fluid type is selected and is being displayed
Reagent	Displays required Reagent information, a triangle icon at the bottom of the button indicates this fluid type is selected and is being displayed
Kit Lot	Allows user to enter kit lot number(s), if desired
Scan Liquids	Allows user to automatically scan reagent barcodes

1. Review the list of materials needed and load into appropriate reagent racks.
2. If desired, click the Kit Lot button to proceed to Kit Lot screen and record kit lot numbers to be included in results report.

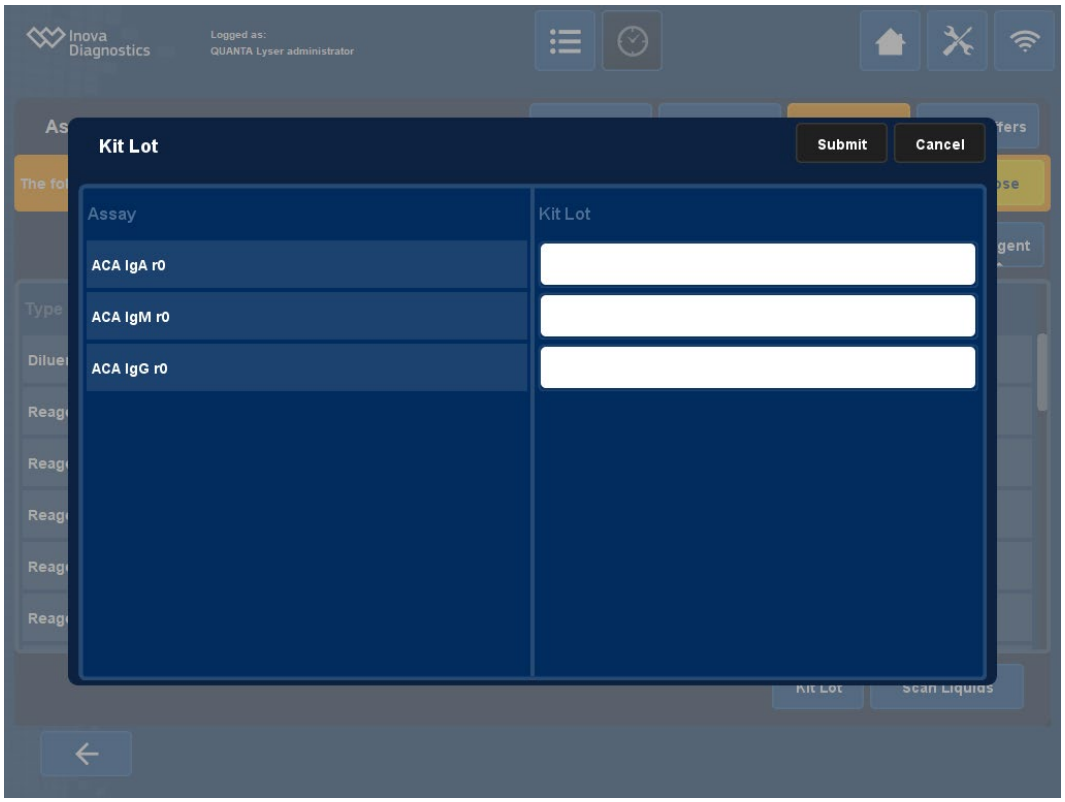


Figure 5-36: Kit Lot Window

3. Click the Scan Liquids button to proceed to automatic reagent barcode scanning window. The table lists all required liquids, required lot number (for lot specific reagents), volume needed and volume loaded onto the system. Make note the color of the fluid number on the left side of the table. Red highlighting indicates that there is an insufficient amount of that particular reagent or that the reagent hasn't been scanned or manually identified yet.

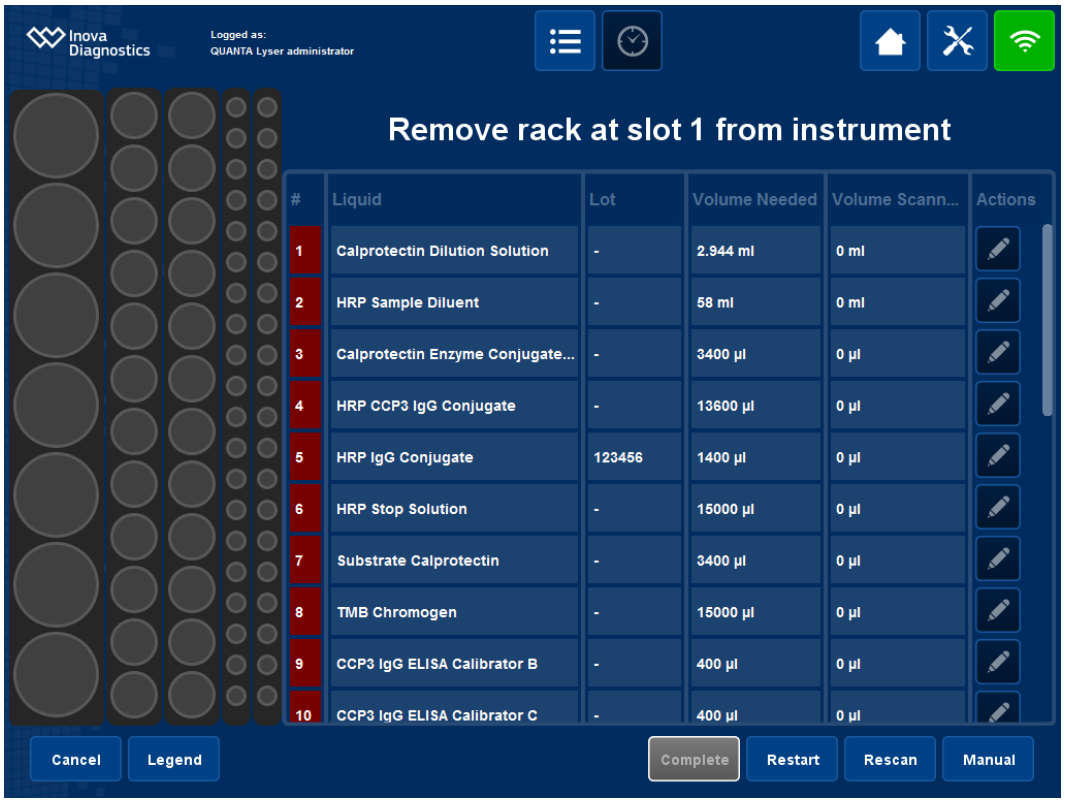


Figure 5-37: Automatic Reagent Scan Window

Unique Elements of the Automatic Reagent Barcode Scanning Window

Button / Element	Description
Cancel	Cancels the reagent scan process and returns to the previous screen
Legend	Opens a window that displays a legend
Complete	Becomes active upon completion of reagent scanning, returns to previous screen
Restart	Restarts the entire reagent scan process
Rescan	Rescans the last rack that was scanned
Manual	Allows for bottle position to be manually programmed rather than 2d barcodes being automatically scanned to identify positions

a. For automated barcode scanning, follow on-screen prompts to remove all reagent racks and load them one at a time, starting with the Diluent rack on the left, followed by the reagent racks and then standard/control racks.

b. It is important to load racks as indicated on the screen. Failure to load racks in the correct position or order could result in a hardware collision when the gripper arm with the barcode scanner moves over to the rack position to read the barcodes.

c. To manually identify the position of all diluents, reagent and control bottles within the racks, click the Manual button to proceed to the manual reagent identification screen.

d. Click on a rack position that corresponds to actual bottle placement to indicate the location of each bottle:

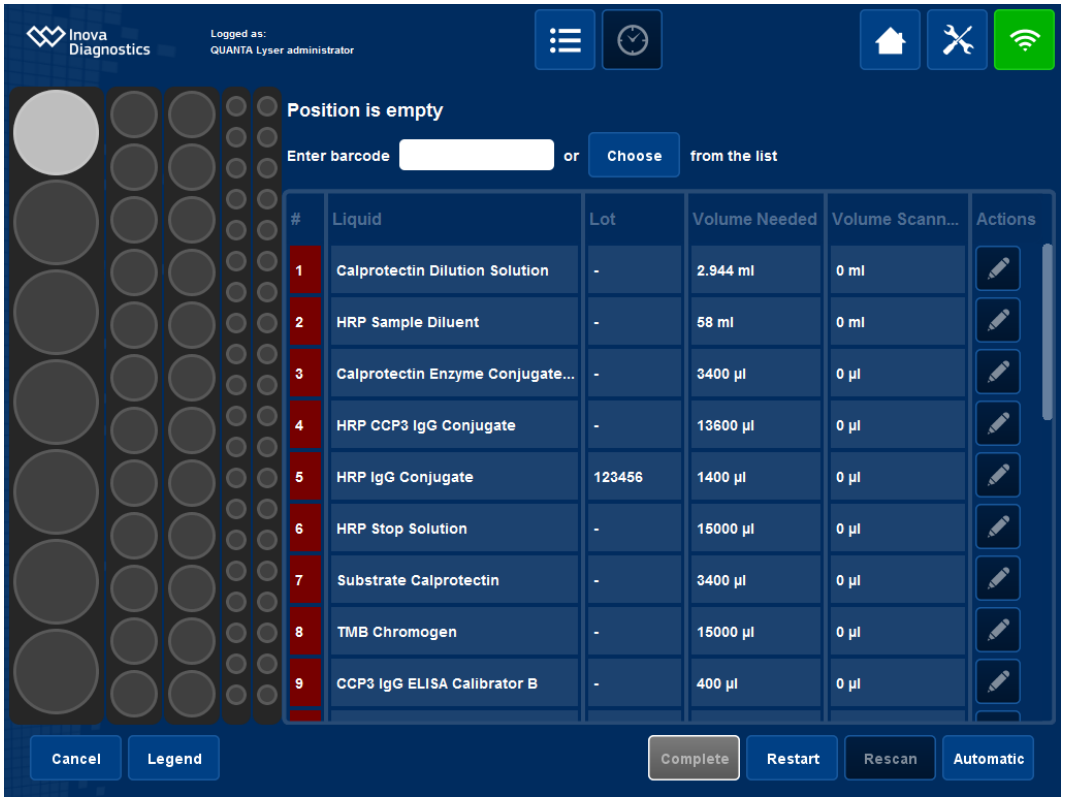


Figure 5-38: Manual Reagent Selection Window

e. Enter barcode (Full GTIN information) or click the Choose button to proceed to a pop up window containing information for each possible liquid associated with the currently scheduled worklist.

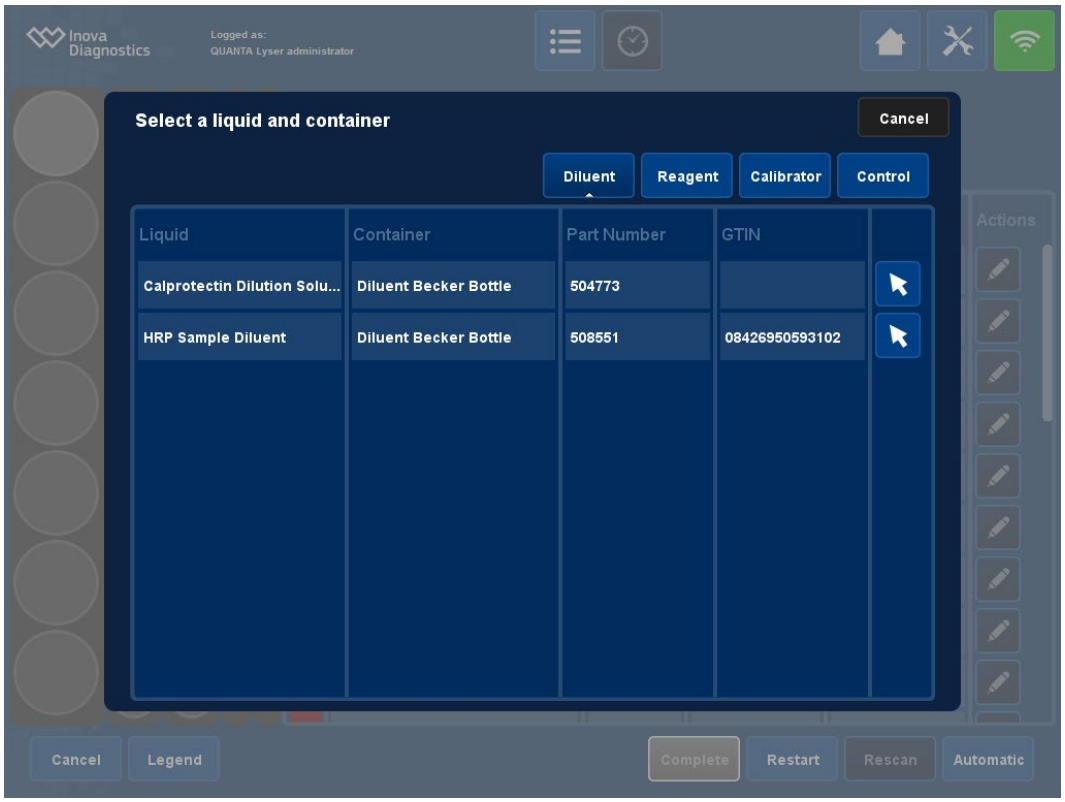


Figure 5-39: Liquid Selection Window

f. Click the arrow to the right of the desired selection to place that bottle in the selected position.

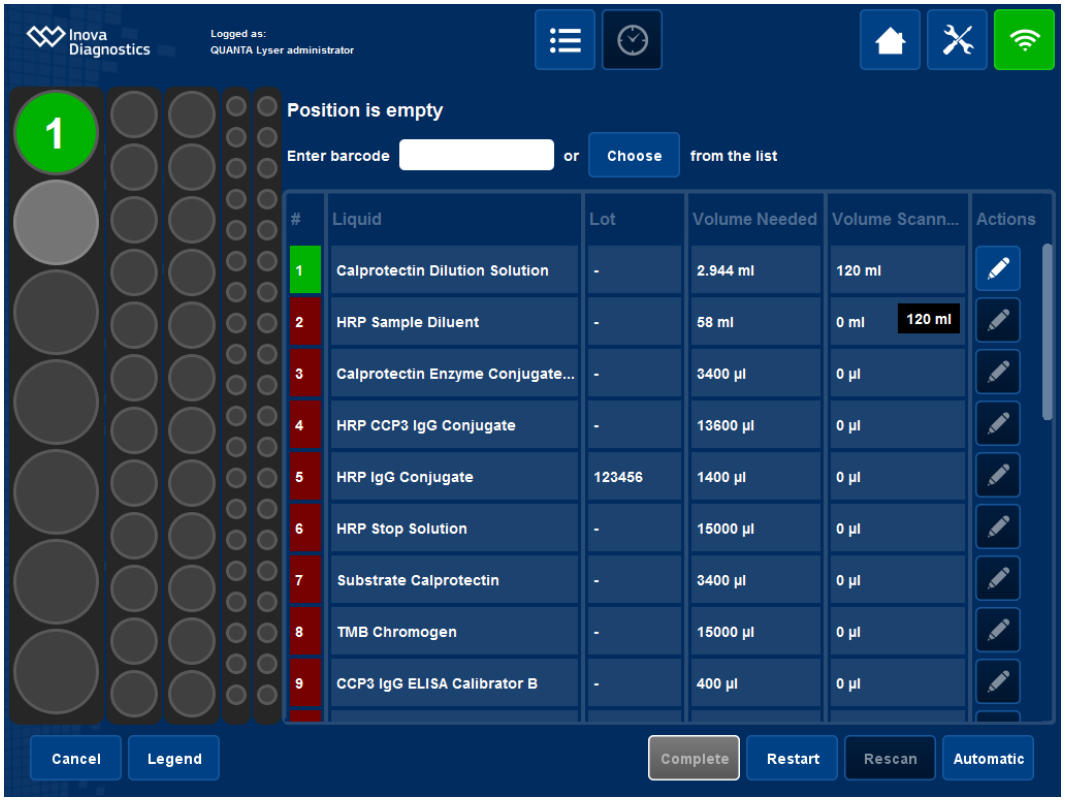


Figure 5-40: Liquid Following Manual Selection

g. Repeat for remaining liquids.

h. Click the edit ( ) button in the Actions column to edit the lot information for that particular liquid. Lot number and expiration date may be entered. Any information entered here will appear on the Results Report.

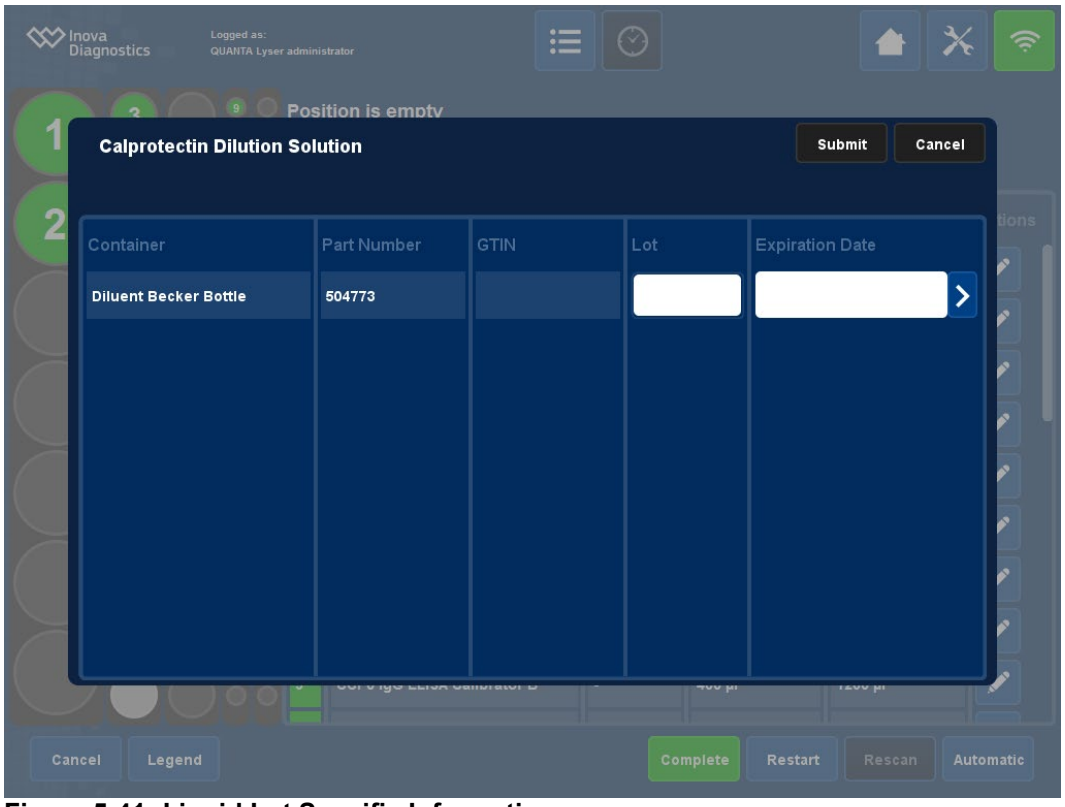


Figure 5-41: Liquid Lot Specific Information

4. Once all reagents have been automatically scanned or manually entered, the table in the liquid screen will list the volume scanned. This volume is determined according to the number of bottles that were identified and their recorded fill volumes. Green highlighting of reagent numbers indicates sufficient volume has been loaded. Red highlighting indicates additional bottles of that reagent are required.

Figure 5-42: Completed Liquid Identification

a. The edit buttons in the Actions column allow for additional reagent information (such as lot number or expiration date) to be added

b. Clicking on a reagent position in the diagram of the reagent racks will select that bottle. Information for the selected bottle is displayed above the table. Clicking the Empty button beside the bottle information will remove that bottle from display and assume the bottle has been physically removed from the rack.

c. The Legend button will open the Legend window explaining which statuses are possible to be seen in this window.

d. Once all needed reagents are placed, click the Complete button to proceed.

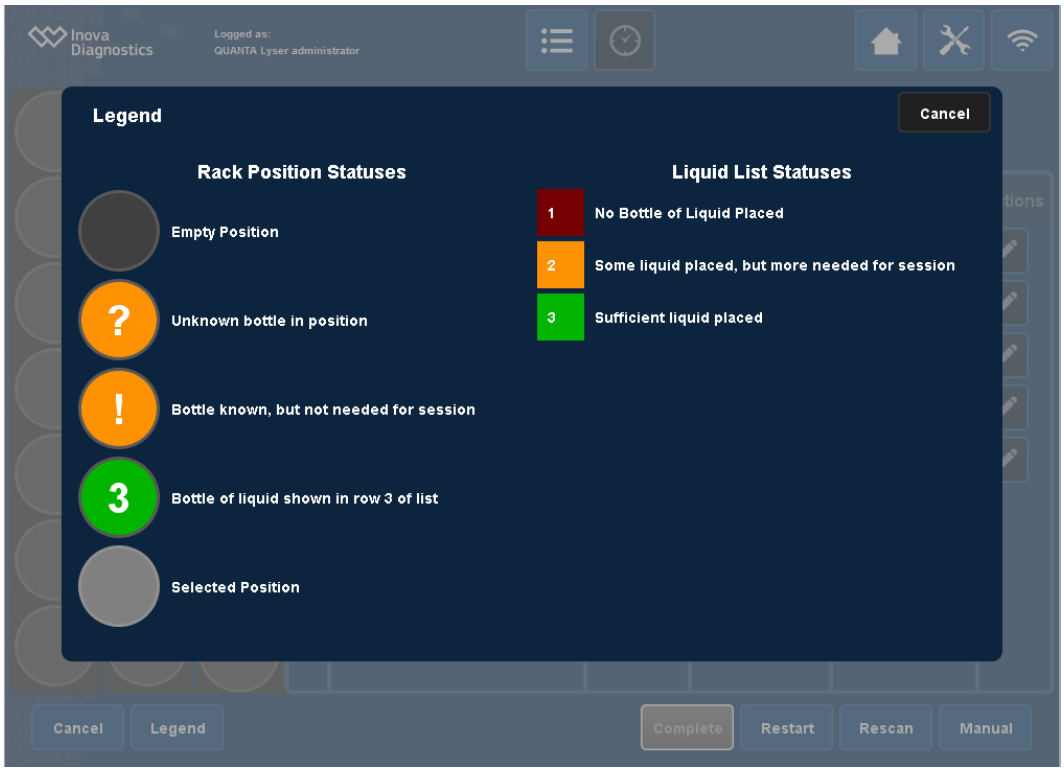


Figure 5-43: Liquids Tab Legend

5.3.3.5 Wash Buffers Tab

The Wash Buffers tab contains information about the wash buffers that are planned to be used for the currently scheduled worklist. The buffer description, assays in which it is used, assigned plate (for ELISA) or tip (for IFA) wash line, as well as the liquid identifier code, is listed in the table. The buffer bottles are placed into the appropriate position(s) in the liquid detection unit (see “Wash Buffer Assignment” section). The liquid detection unit includes a capacitive level sensor that indicates the presence of fluid. It does not detect volume of fluid, only that some is present at the start of the run. It is the operator’s responsibility to ensure sufficient wash volume is present.

If insufficient fluid is present, or necessary buffer has not be assigned during Wash Buffer Assignment procedures, an error will appear in the Wash Buffers tab.

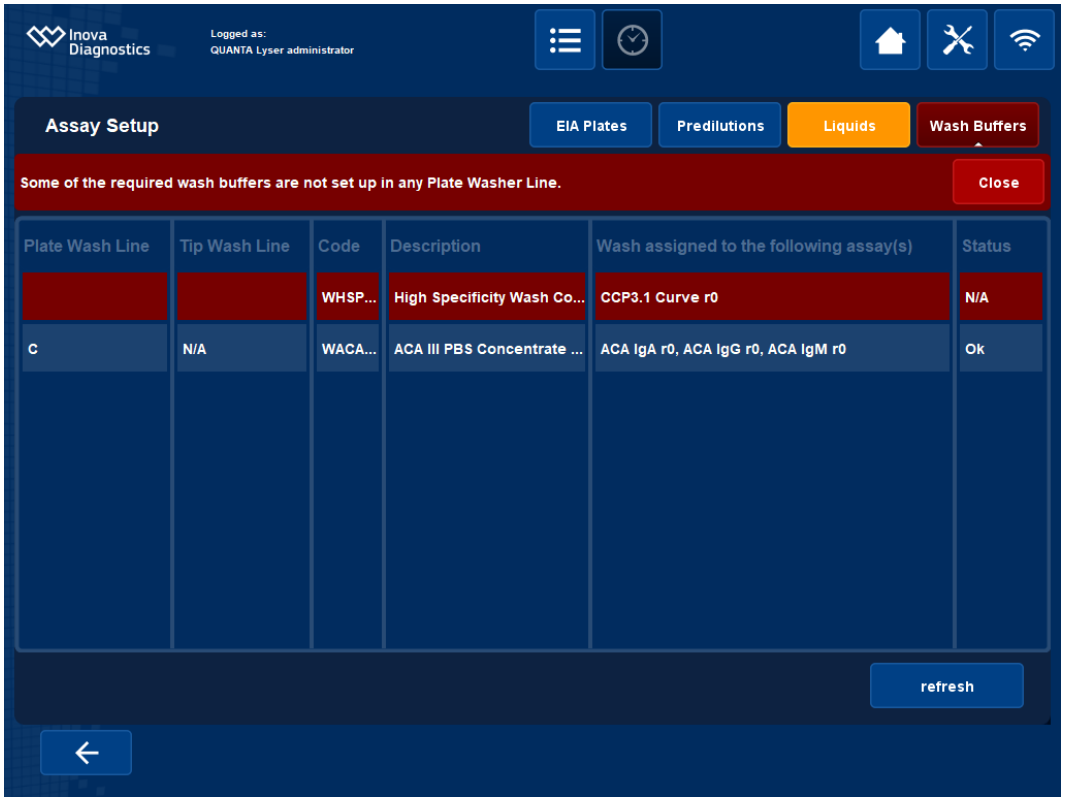


Figure 5-44: Wash Buffers Tab

Unique Elements of the Wash Buffers Tab

Button / Element	Description
refresh	Allows the instrument to recheck the signal from the sensor from the System Liquid Detection Unit

If all necessary wash buffers are present and liquid is found with the level sensor, no error will appear and the Wash Buffer tab will simply display the location and status of each buffer.

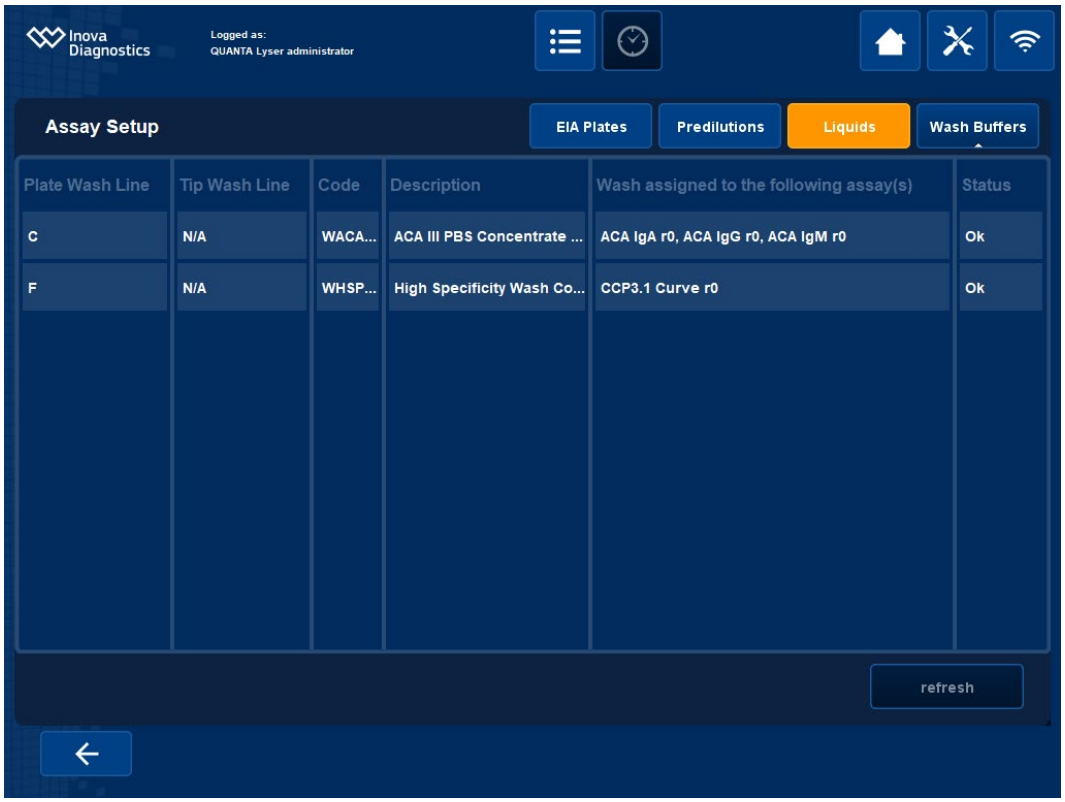


Figure 5-45: Wash Buffers Tab Without Errors

5.3.3.6 Timeline Screen

Once all required materials have been loaded onto the instrument and the timeline screen is active, the run is ready to be started. Timeline(s) can be reviewed, zoomed in or out or specific plates/carriers aborted. A list of steps is also available for review. When ready, click the Start Run button to begin.

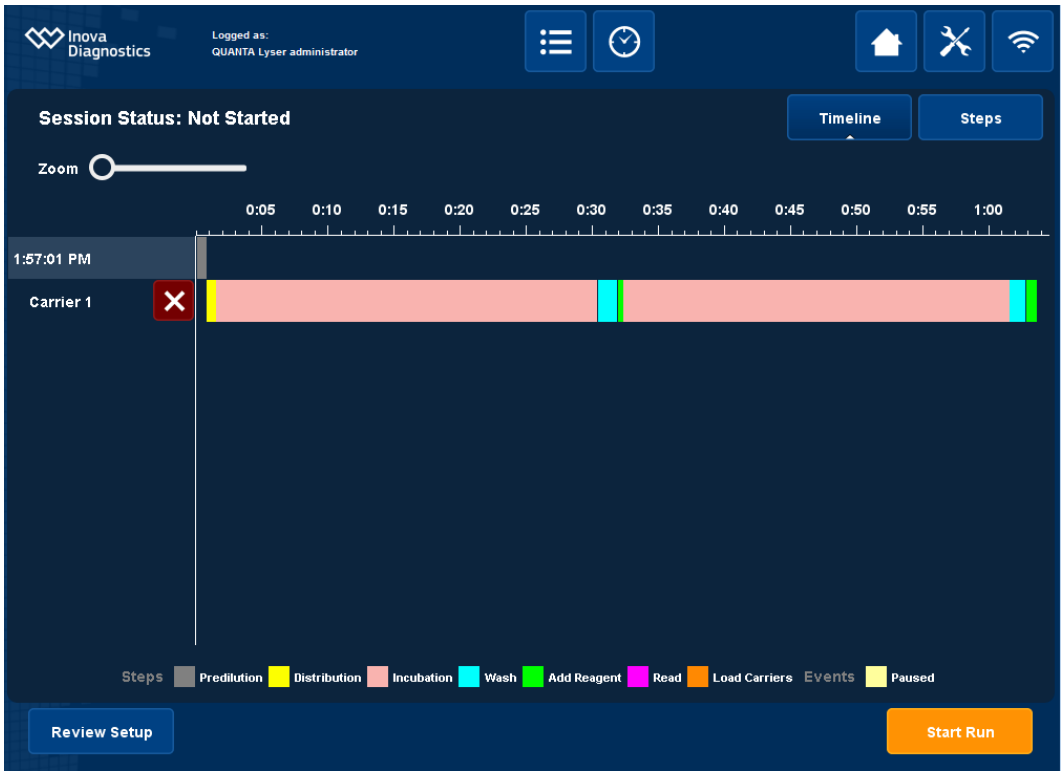


Figure 5-46: Timeline Screen Prior to Start of Run

Unique Elements of the Timeline Screen

Button / Element	Description
Zoom	The zoom sliding scale can be clicked and dragged to increase or decrease the zoom of the timeline
Timeline	Displays Timeline, triangle icon at bottom of button indicates an active selection
Steps	Displays run Steps, triangle icon at bottom of button indicates an active selection.
✕	Aborts the indicated ELISA plate or Slide Tray/Carrier
Review Setup	Returns to the Material Setup screen
Start run	Begins the run
Pause	Only active after session has begun; pauses the instrument

Once the run has begun, the Timeline screen will adjust slightly as the run proceeds, as needed, to reflect accurate timeline.

5.3.4 EIA Read

If it is necessary to re-read an ELISA plate, it is possible to perform a Read Only session that will perform a read step only to a plate that has already been processed. It is important to verify the plate had been processed correctly prior to setting up a Read Only session.

1. From the Worklist screen, click the EIA Read button.

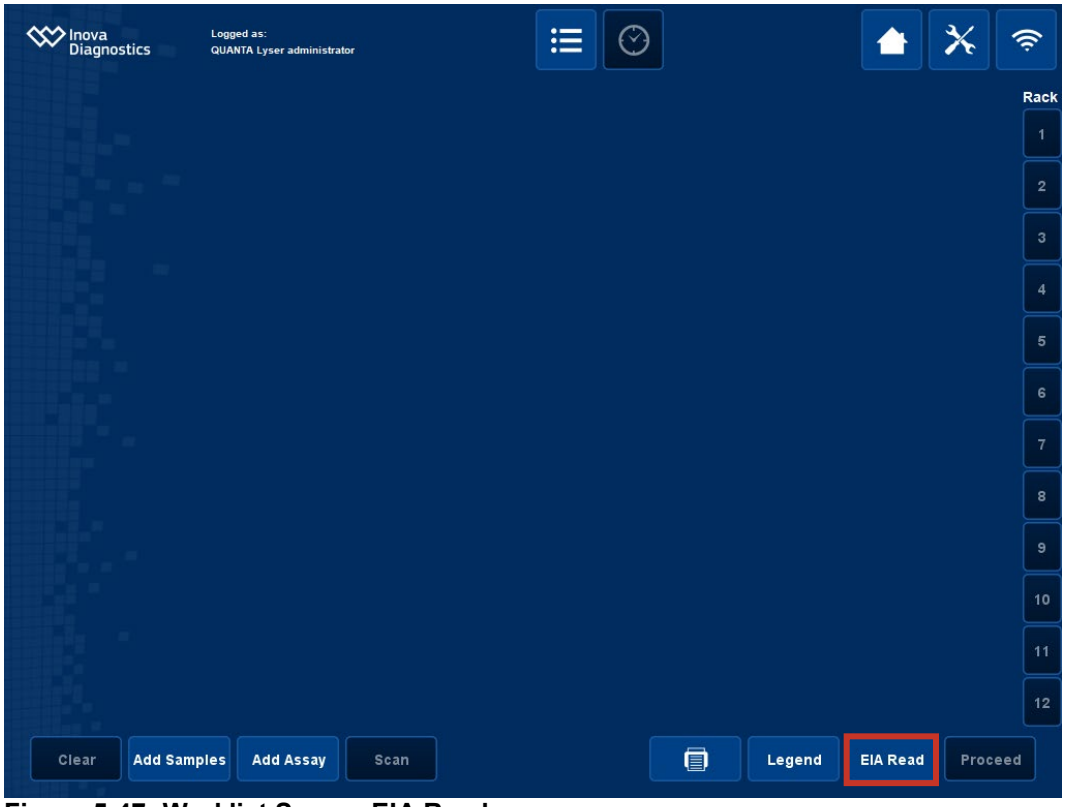


Figure 5-47: Worklist Screen EIA Read

2. A pop up window appears and will give options to use the Current Worklist or recently completed sessions that had been processed on that system.

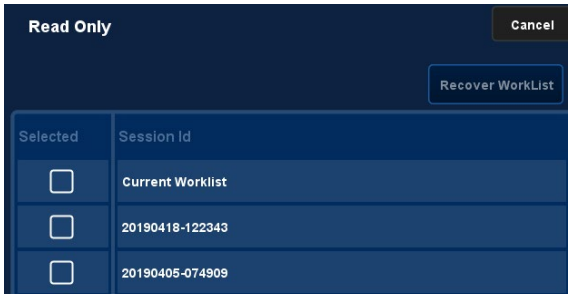


Figure 5-48: Read Only Screen

   a. Current Worklist will utilize the assay and sample selections present in the worklist screen.

   b. Choosing a recent session will assume all calibrator/control/sample locations from that particular session.

3. After making a selection, click the Recover Worklist button.

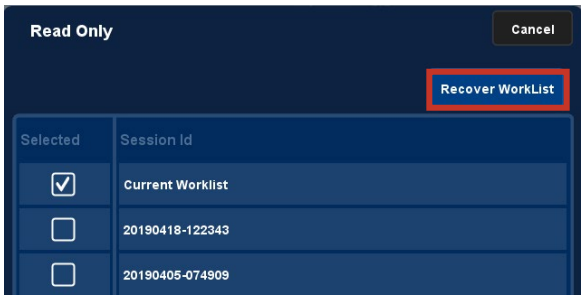


Figure 5-49: Recover Worklist

4. The Worklist screen will now have a Read Only button in place of the Proceed button. Click the Read Only button.

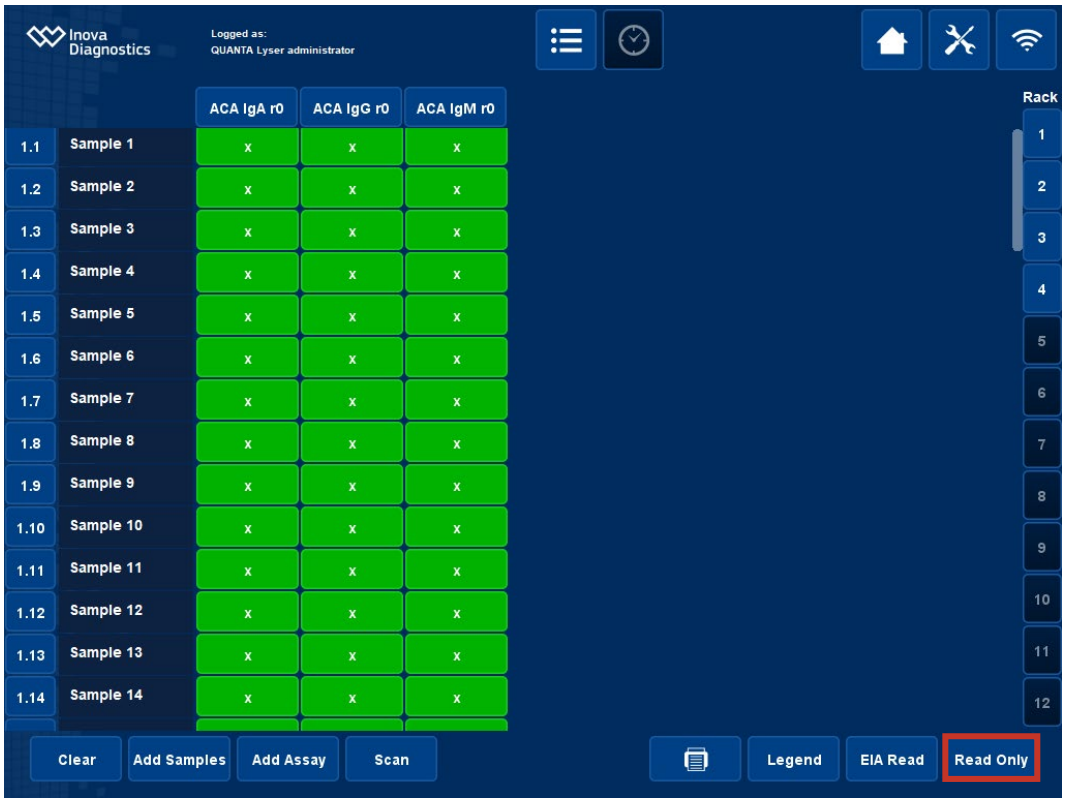


Figure 5-50: Read Only

5. The assay setup screen will appear. Confirm the EIA Plate placement on the instrument deck aligns with the information in the EIA Plates tab and click the Schedule button.

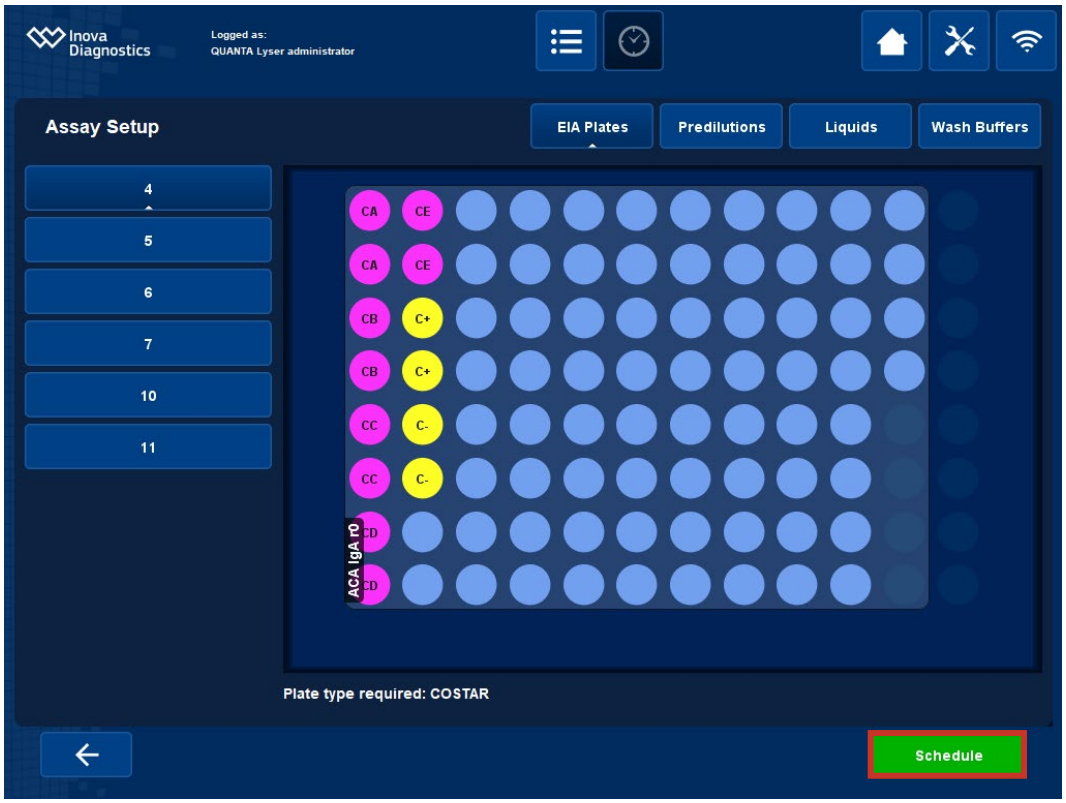


Figure 5-51: Schedule Read Only

6. All plates from the worklist will be present on the timeline screen. Abort any plates that do not need to be read by clicking the red X beside that plate number and proceed with the read by clicking the Start Run button.

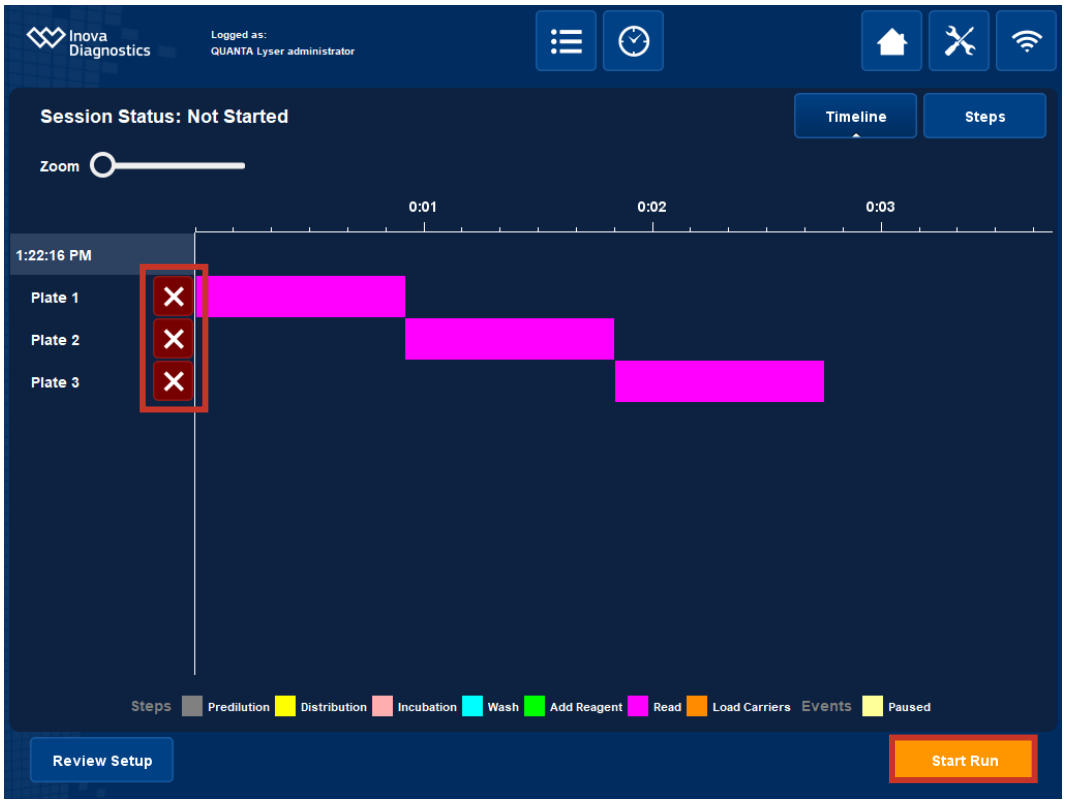


Figure 5-52: Read Only Timeline

7. A confirmation message will appear to confirm the plate(s) have been placed in the correct positions. Click Review Setup to return to the previous screen for additional review or Start Run to begin the session.

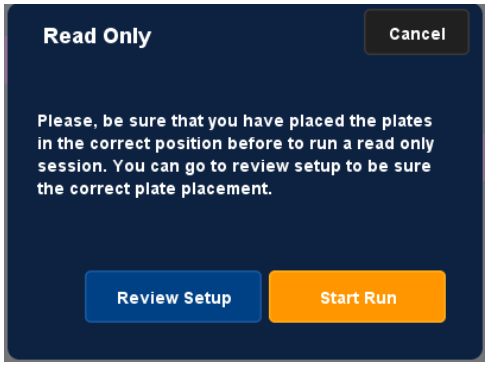


Figure 5-53: Read Only Confirmation

   a. Upon completion of setup review, if applicable, click the ← button to return to the Timeline screen.

8. After completion of the Read Only session, results can be accessed from the Results List. Please note that the Results Report will indicate that a Read Only session has been performed.

Figure 5-54: Timeline Screen Prior to Start of Run

Note

Original session results will remain in the Results List in addition to the Read Only session.

Any notes on samples from the original session, such as over incubation, manually done, etc. will not be carried over. The original session results should be referenced to check for any exceptions.

If a recent session was selected from the Read Only screen, any reagent/control/calibrator lot infromation from that session will carry over. If a Read Only session Is generated from a new worklist, no lot information will be captured.

If an assay's steps are modified in any way, any recent session containing that assay will be removed from the Read Only windows.

5.4 Pausing and Aborting a Session

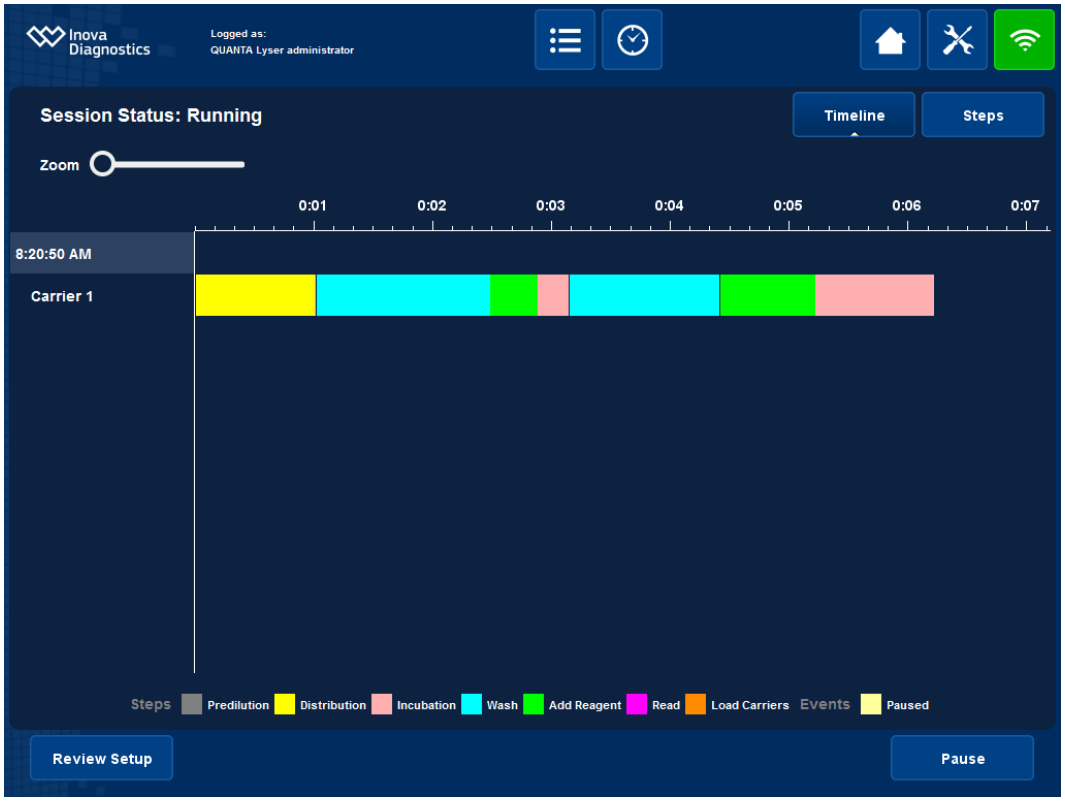


Figure 5-55: Pausing a Session

While a session is running the Pause button is active in the Timeline screen. In the case of an error, the system will automatically pause and automatically restart following the resolution of the error. If the operator chooses to pause, they may do so by clicking the Pause button.

Note

Upon clicking the Pause button, the system will wait for a suitable time to pause.

Once a suitable pause time is reached, the front cover will unlock.

Caution

Excess pause time may negatively impact any tests in process.

Figure 5-56: Session Paused

Once the system is in a paused state, the operator may select one of the following options:

-  : The buttons beside each row of the timeline will allow for that particular Slide Carrier/ELISA Plate to be aborted. Note that if multiple assays are shared on one slide tray or ELISA Plate, they would all be aborted. There is no way to abort individual assays on a shared tray/plate. A message will appear confirming that the operator wants to abort the slide carrier/plate. Upon completion of the abort action, the system returns to the Timeline screen and will remain paused until the operator chooses Resume.

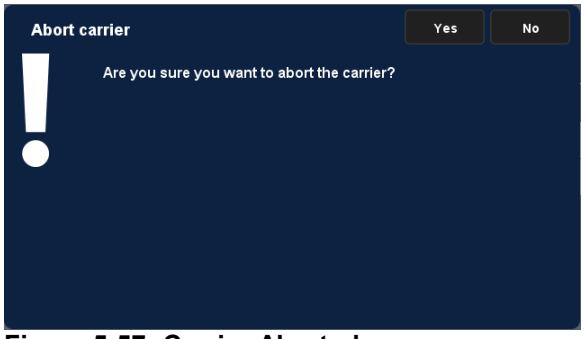


Figure 5-57: Carrier Aborted

Figure 5-58: Plate Aborted

- Abort: The entire session will be aborted if this option is chosen. A message will appear confirming that the operator wants to abort the session. Depending on the step in the process when the session is aborted, the probes may not be properly cleaned. If sample predilution or distribution steps were in process, it is recommended to perform Decontamination in the maintenance screen. If mounting medium was being dispensed, it is recommended to perform the Long Flush in the maintenance screen. If there is uncertainty

of the step in the process, it is recommended to run both the Decontamination and Long Flush prior to the Abort Session.

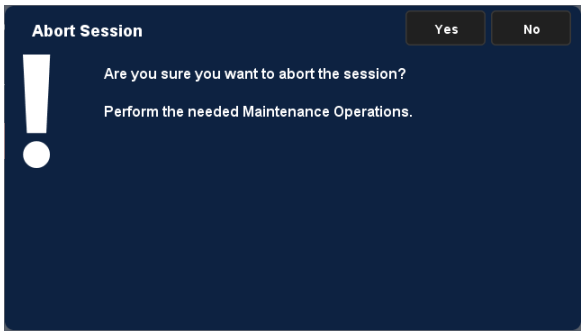


Figure 5-59: Abort Session Message

- Resume: Allows the session to immediately resume where it left off.

5.5 Low Liquid Errors

A number of errors may be present during a run for a number of reasons. It is important to note the error, preferably including a screen shot, when reaching out to your service provider for support.

One common error that may be seen if insuffient liquid volume is found and will be accompanied by an acoustic alarm, is a low liquid error.

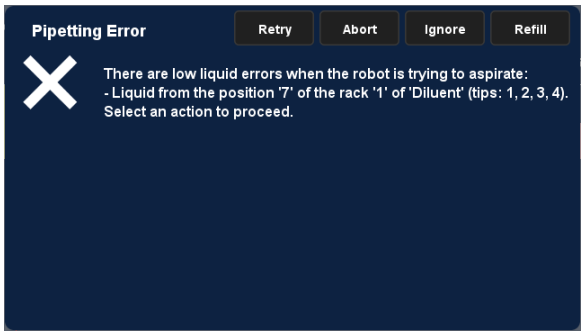


Figure 5-60: Low Liquid Error

The error message will indicate which tips were trying to aspirate the liquid as well as the position of the bottle. The operator may select one of the following options:

- Retry: The tip will attempt to detect the liquid level again and aspirate the liquid, if sufficient volume is now recognized.
- Abort: The abort option will abort the entire session.
- Ignore: The tip will move to the z-max (position programmed as the bottom of the container) position and aspirate without performing additional level sensing. If sufficient liquid is present, it will be aspirated. If no liquid is present, air will be aspirated.
- Refill: This option allows the operator to refill the bottle(s) in question. Upon choosing this option, the pipette tips will return to the wash station, the door will unlock, and the user will be allowed the refill the liquid in question.

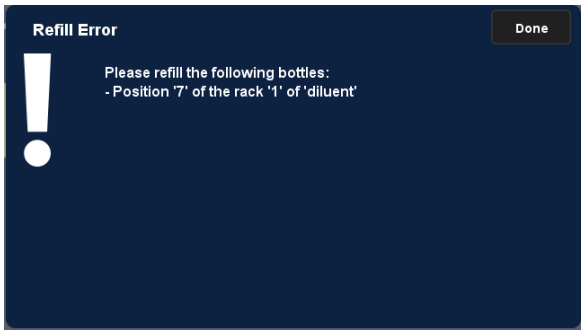


Figure 5-61: Refill Option

5.6 Short Sample Handling

In the case of a low liquid for samples, there are two possible scenarios for short sample handling. These options are defined in the instrument settings during instrument installation.

5.6.1 Basic Short Sample Handling

If Basic short sample handling is configured, a low liquid message will appear with each low liquid detection:

Figure 5-62: Basic Short Sample Handling

The operator may select one of the following options:

- Process Later: The system will continue to dilute the remaining samples. At the end of the Predilution step, another warning message will appear to allow the user to handle all short samples by either manually diluting or skipping the sample (see “Short Sample Processing” section for more details).
- Retry: The tip will attempt to detect the liquid level again and aspirate the liquid, if sufficient volume is now recognized.
- Abort: The abort option will abort the entire session.
- Ignore: The tip will move to the z-max (position programmed as the bottom of the container) position and aspirate without performing additional level sensing. If sufficient liquid is present, it will be aspirated. If no liquid is present, air will be aspirated.

5.6.2 Advanced Short Sample Handling

If Advanced short sample handling is configured, all sample predilutions will be completed. At the end of the predilultion process, the Low Liquid to process warning will appear (see “Short Sample Processing” section for further details).

5.6.3 Short Sample Processing

At the end of the predilution process, an alert will appear, indicating that there are low liquids which need to be processed.

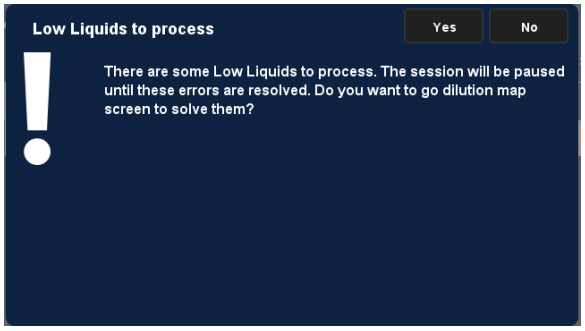


Figure 5-63: Low Liquids to Process

The operator may select one of the following options:

- No: The Timeline screen will appear and the system remains paused until the operator selects the Dilution Map button.

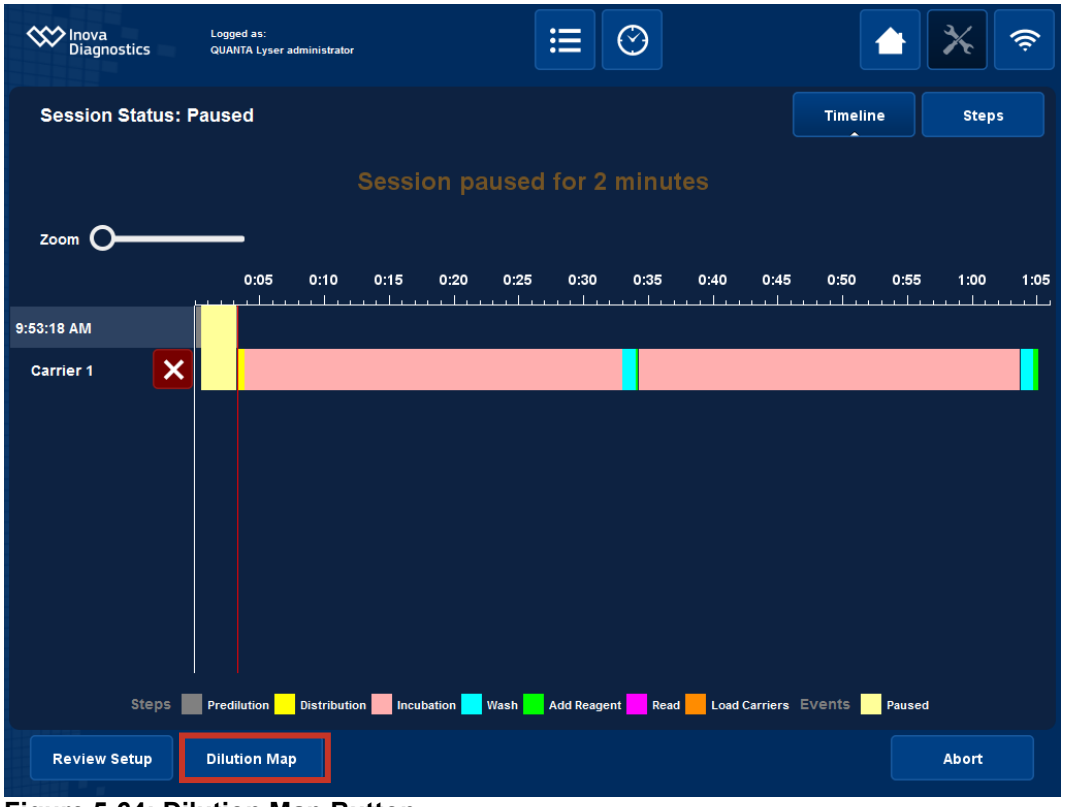


Figure 5-64: Dilution Map Button

- Yes: Advances to the Dilution Map screen.

5.6.3.1 Dilution Map Screen

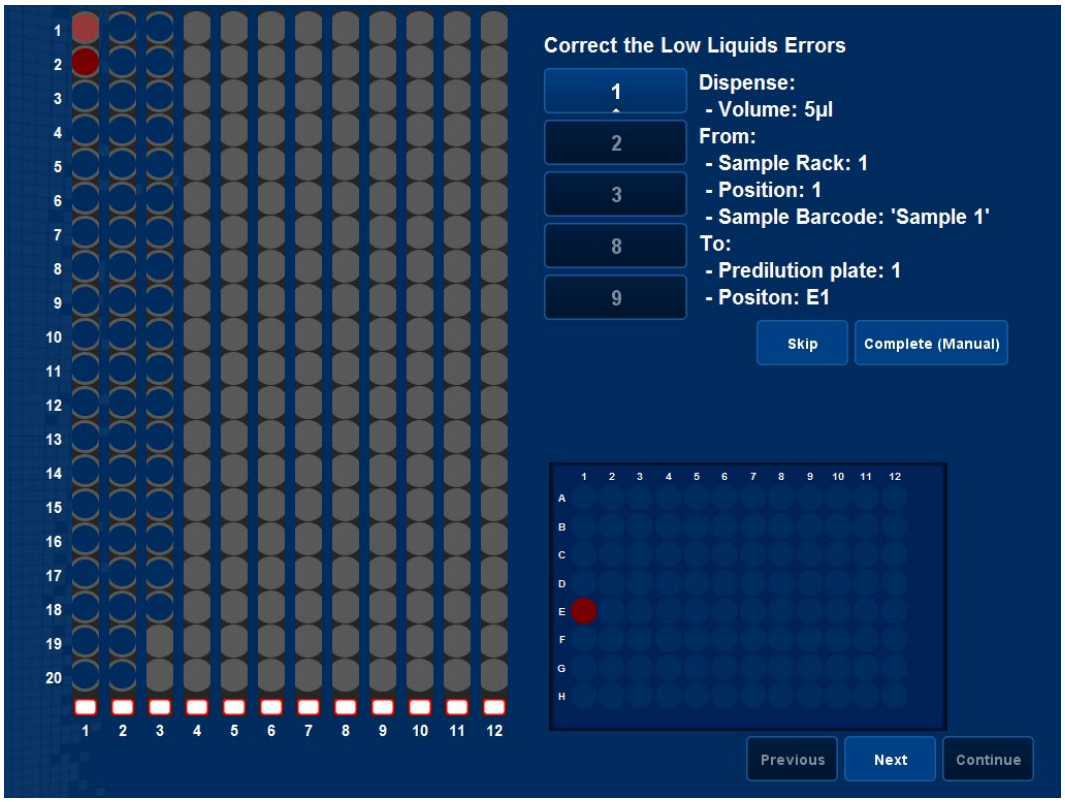


Figure 5-65: Dilution Map Screen

The Dilution Map screen allows for any short samples to either be completed manually or skipped. Low liquid samples are highlighted in red.

1. The user must choose for each low liquid sample whether to Skip or Complete(Manually). Once an action is selected, click Next to proceed.
    a. Skip: If Skip is selected, the screen will indicate such. All predilution operation regarding that sample will cease. The session will continue and skipped samples will be indicated as such in the Results and if it is to be run on an ELISA assay, no data reduction will be done for that sample.

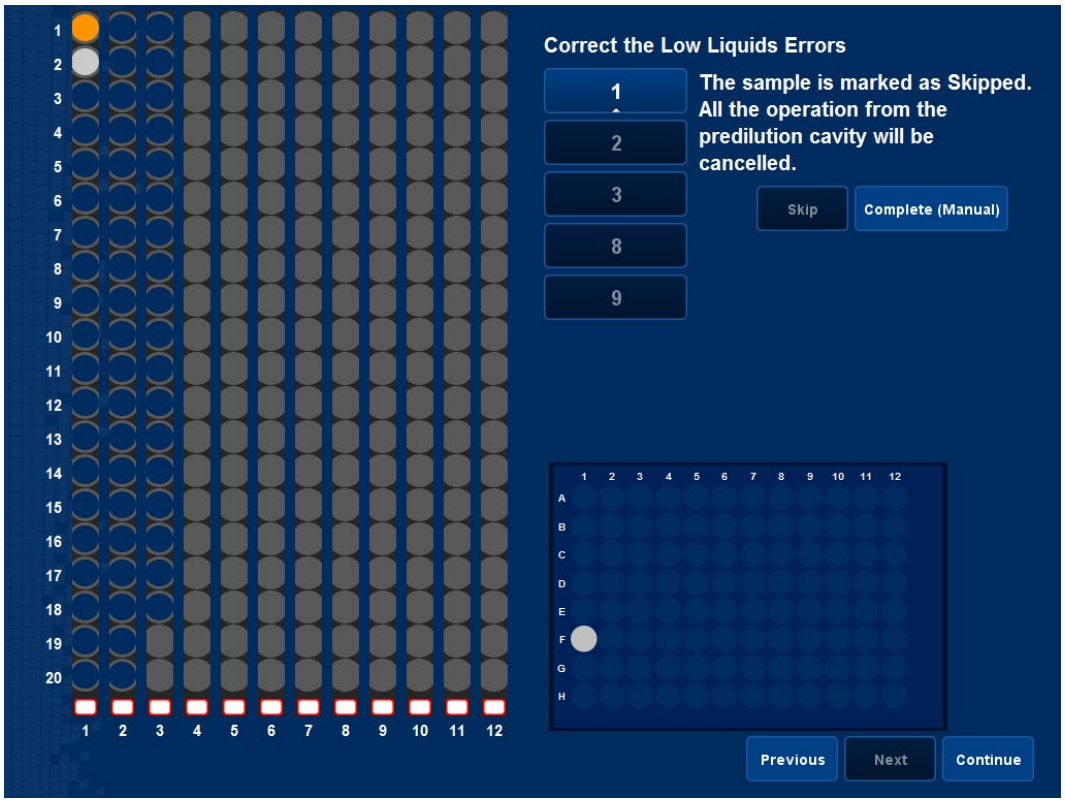


Figure 5-66: Skipped Sample

b. Complete (Manual): If the Complete(Manual) option is selected, instructions are given to indicate the volume of sample to be aspirated and where it should be dispensed, to allow the operator to perform the dilution manually. A remark will be added to the Results indicating that the sample was manually diluted.

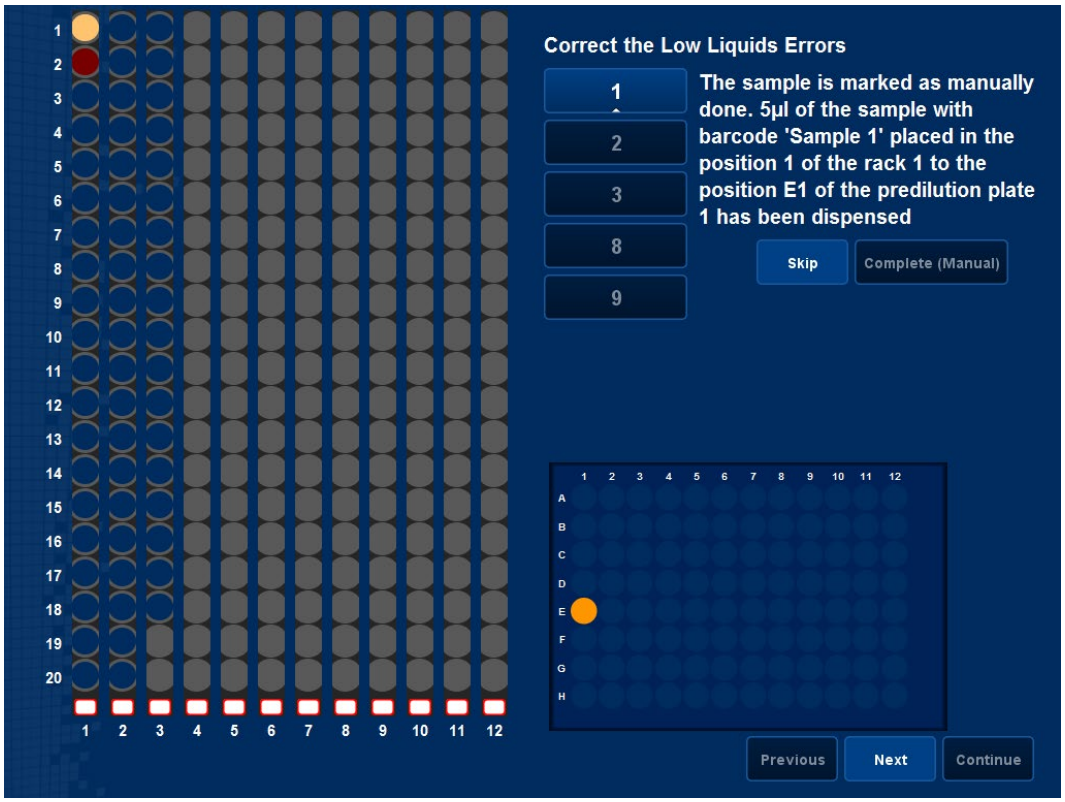


Figure 5-67: Complete (Manual) Sample

5.7 Working with Analytical Results and Reports

Final test results are automatically calculated (for ELISA) and available immediately upon completion of an analytical session. Analytical results can be released to the LIS system and printed. Quality Control requirements are checked and flagged in case of a failure. Pipetting problems that occurred during an analytical session that may impact results are documented in the run report.

5.7.1 Accessing Results

Following the completion of a run, a pop up window will allow the user to access run results. Alternatively, results may be accessed at any time by accessing the Results List from the Home screen.

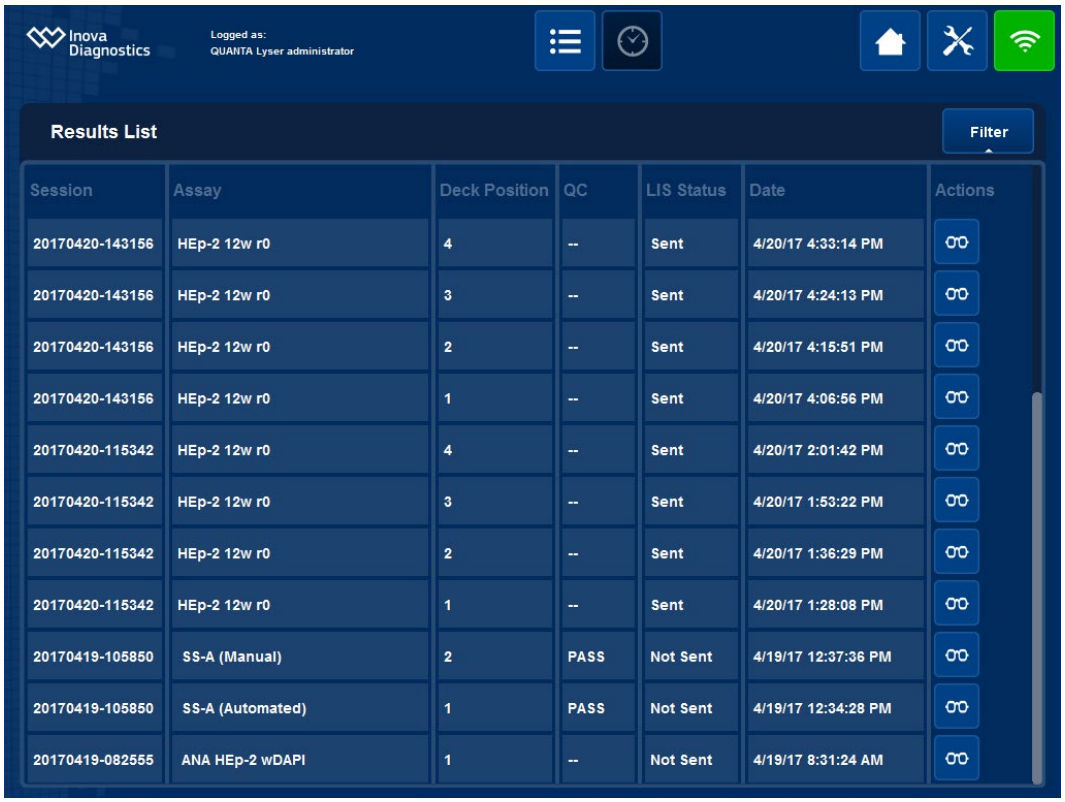


Figure 5-68: Results List

The Results List contains a list of all runs on the system. The list may be sorted by using the Filter button. Information about LIS status, and QC criteria pass or failure for ELISA results can be seen at a glance on the Results List. To view details about any run, click the  icon beside the desired session.

5.7.1.1 IFA Results

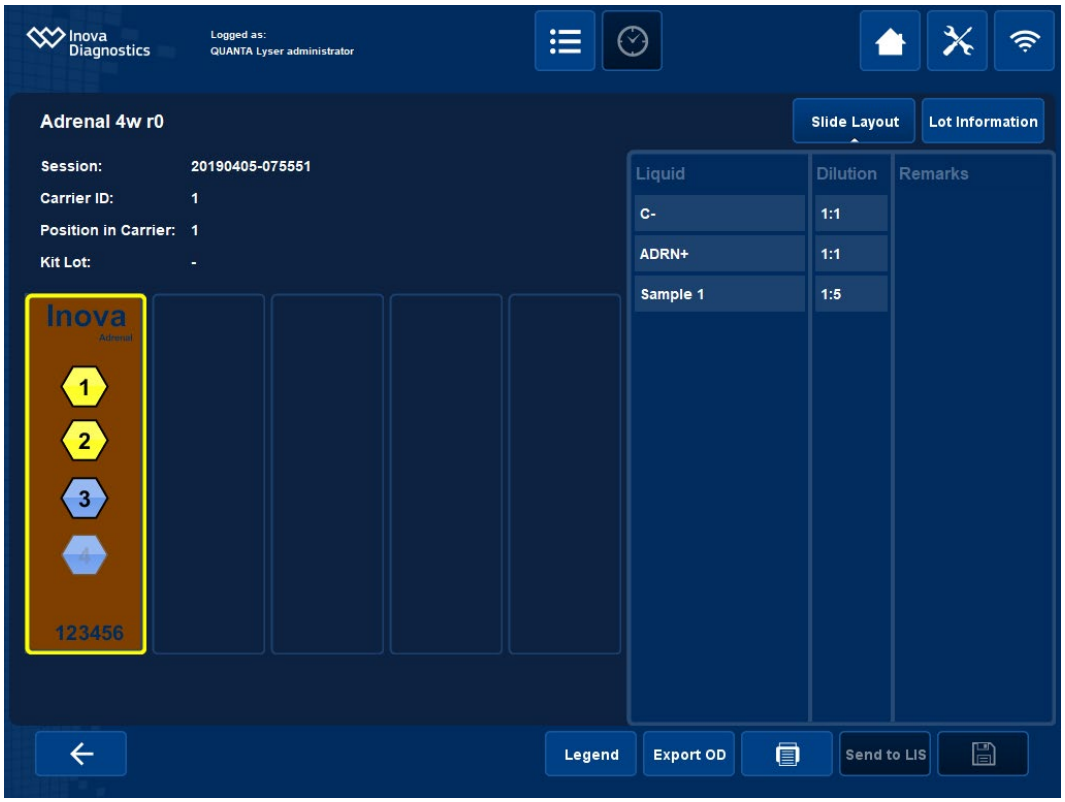


Figure 5-69: IFA Results : Slide Layout Tab

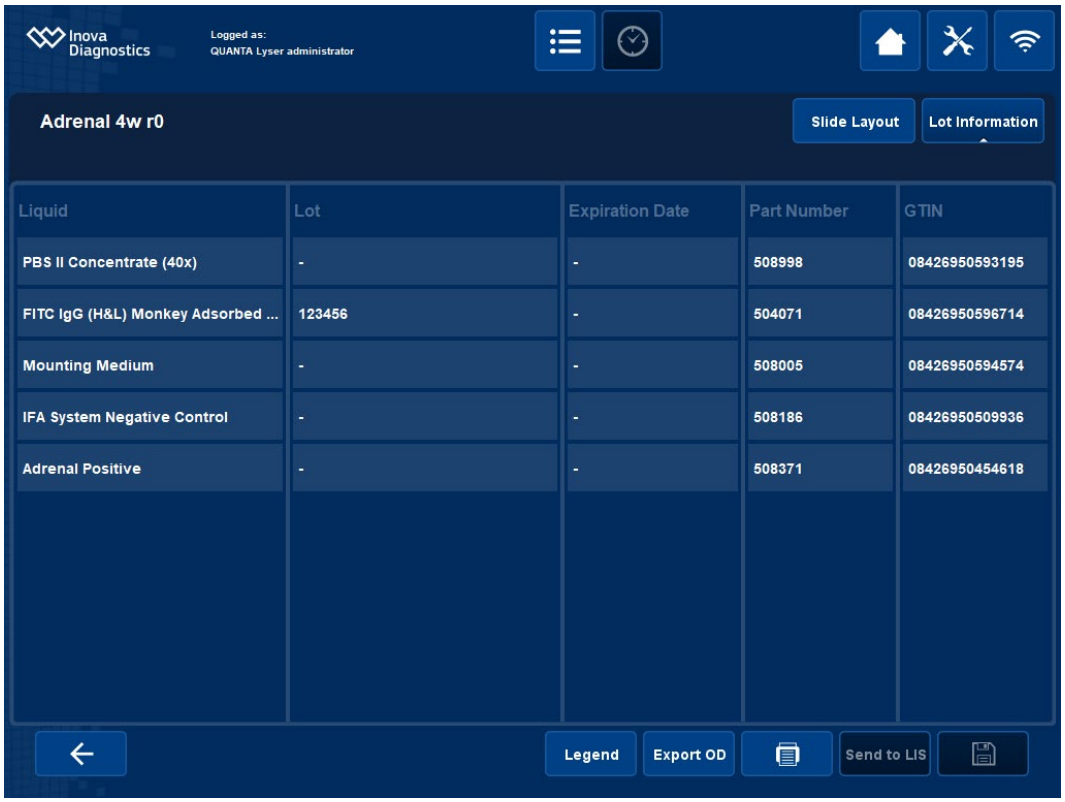


Figure 5-70: IFA Results : Lot Information Tab

Detailed information for an IFA session includes a graphical display of the slides, sample barcode ID, and dilution in the slide layout teb. Lot specific information about the controls and reagents used

during the run can be found in the Lot Information tab.

Clicking the Send to LIS button will send all information to the LIS, even if it has been previously sent.

5.7.1.2 ELISA Results

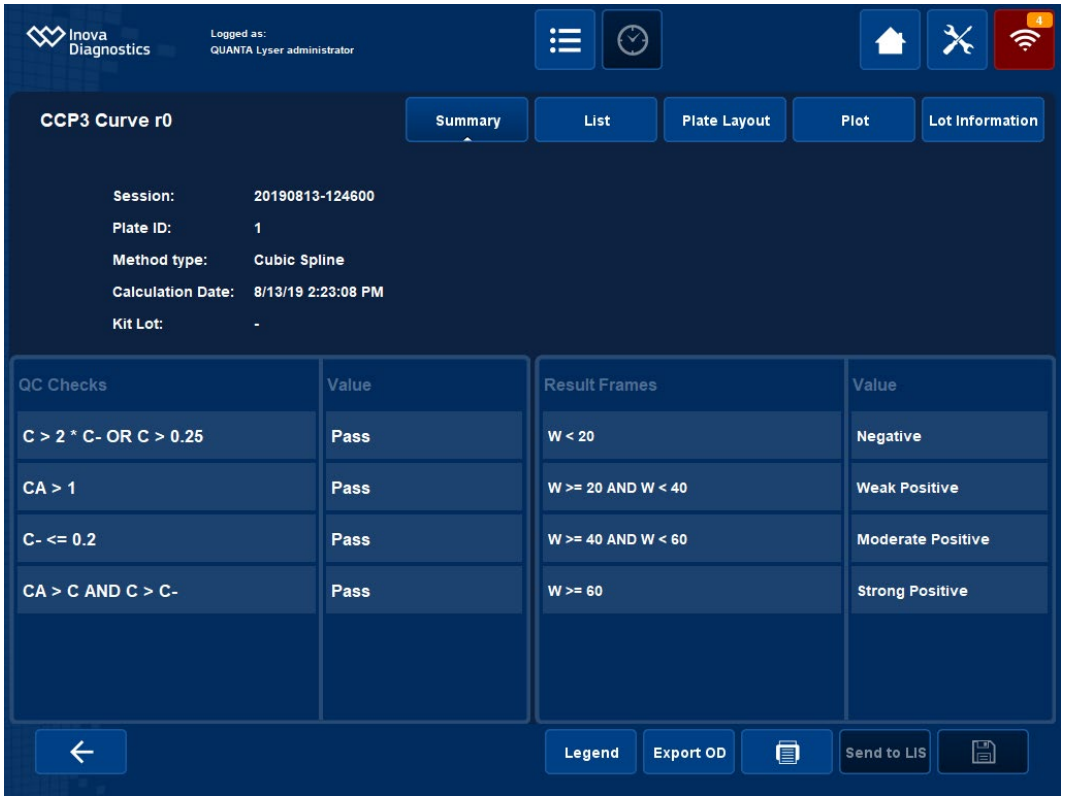


Figure 5-71: ELISA Results: Summary Tab

The Summary tab contains basic session information (dependent on data reduction type), data reduction formula, QC Checks, Mehtod type, calculation date, Units, Kit Lot number (if entered by user), and a list of the Result Frames used for interpretation of each sample result.

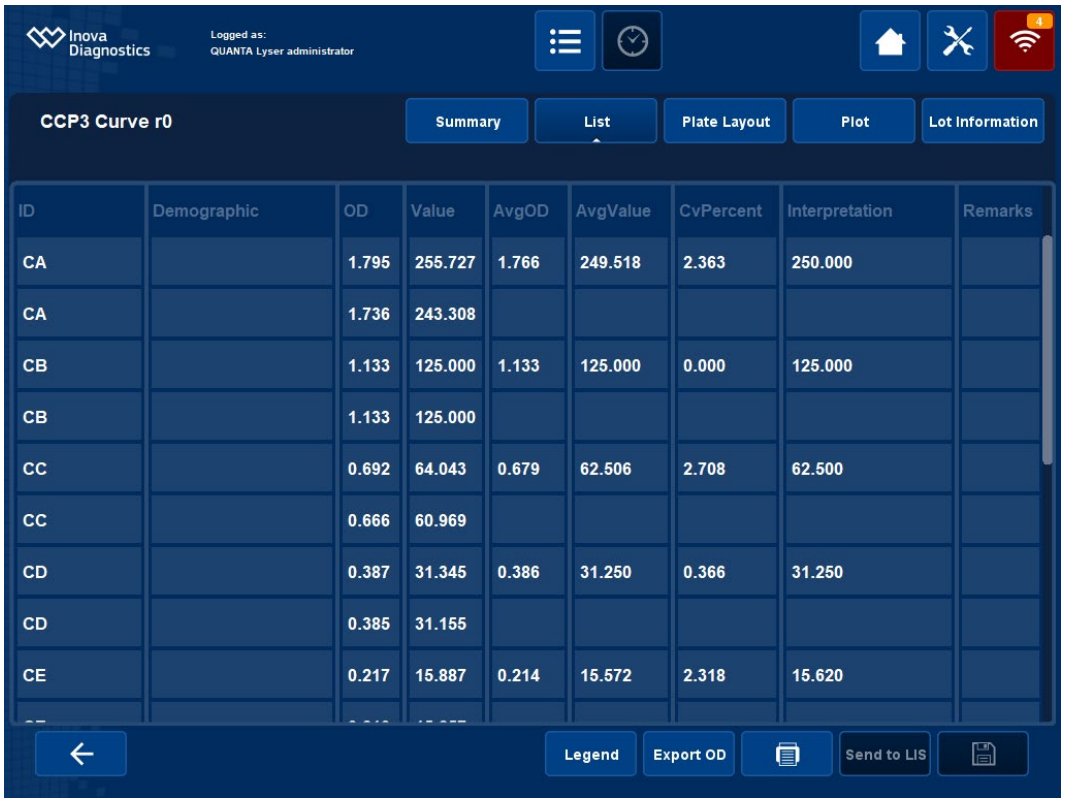


Figure 5-72: ELISA Results: List Tab

The List tab contains a table of results and includes the ID, OD, Value, Average OD, Average Value, CV %, Interpretation, and Remarks (includes notes about low liquid errors, extended pauses, etc).

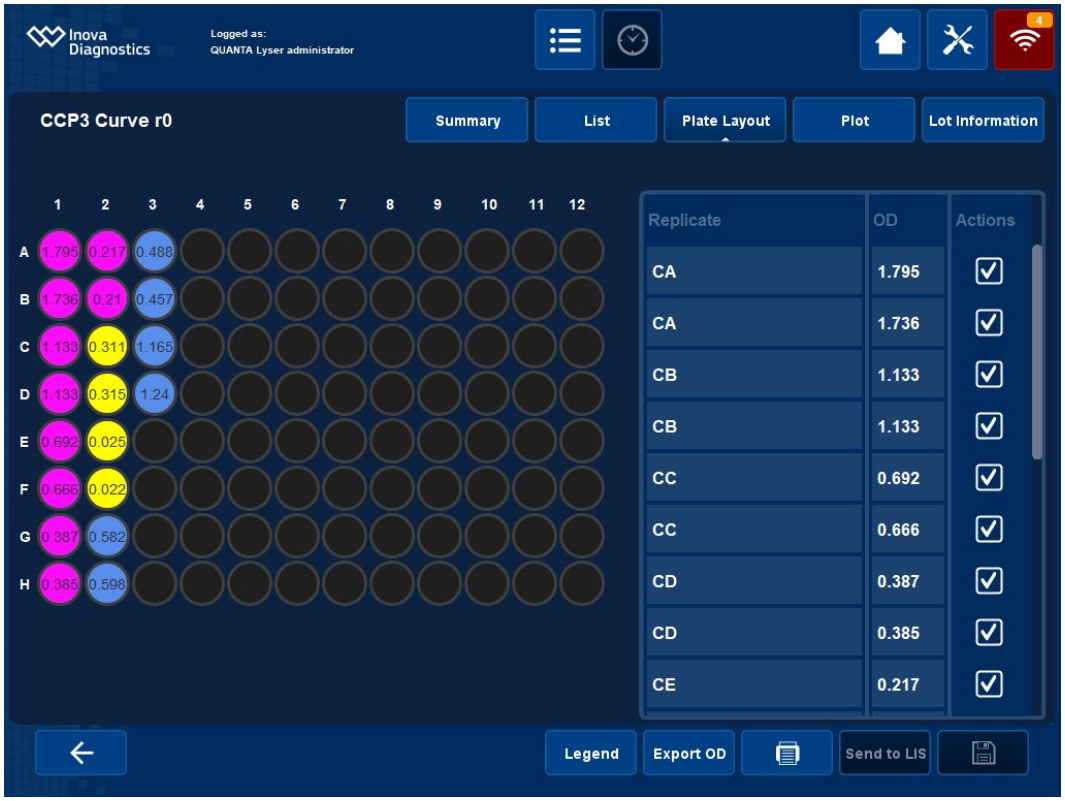


Figure 5-73: ELISA Results: Plate Layout Tab

The Plate Layout tab includes a graphical display of the plate as well as OD information. The Actions colum has a series of check boxes. This allows for an individual replicate to be disabled and the data recalculated. If a replicate is deselected (to disable), a warning message will appear to confirm the decision. The data reduction is recalculated upon confirmation.

Note

Modification to results will be flagged on the final report.

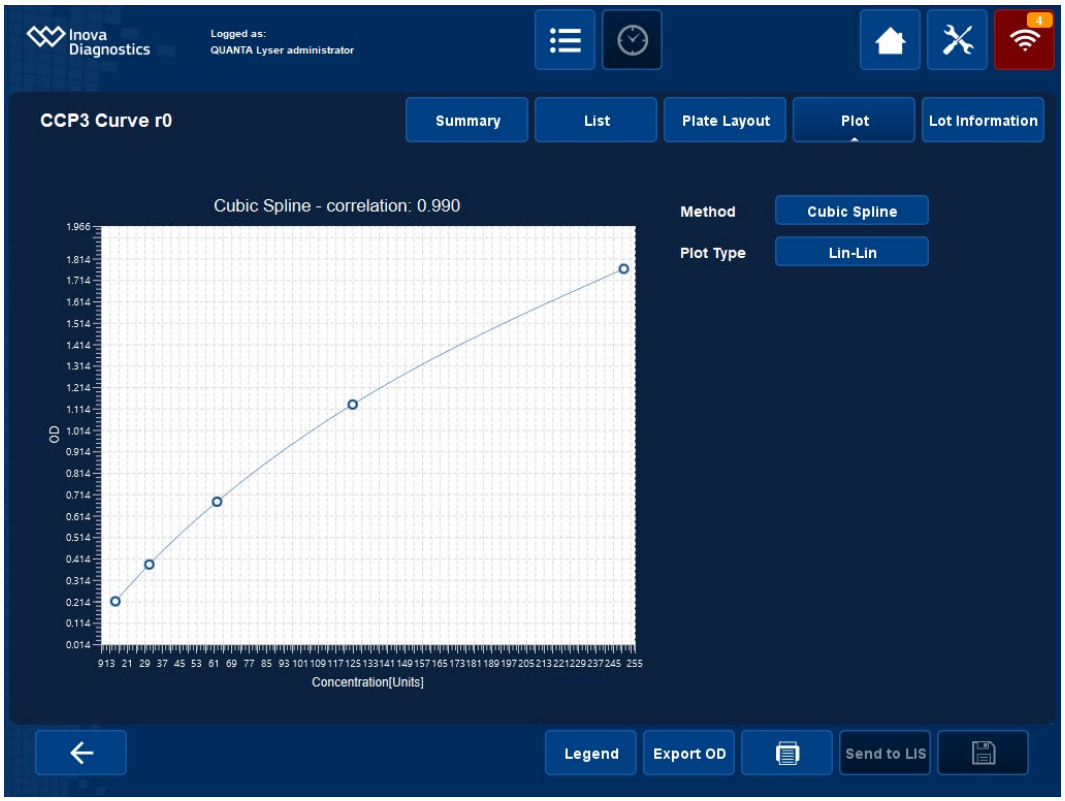


Figure 5-74: ELISA Results: Plot Tab

The Plot tab contains curve data for ELISA assays with curve data reduction type selected. The curve type (Method) as well as Plot Type (axis) can be adjusted, and will result in a recalcuation of the data. Upon changing either selection, a warning message will appear, confirming the decision to change. The data reduction is recalculated upon confirmation.

Note

Modification to results will be flagged on the final report.

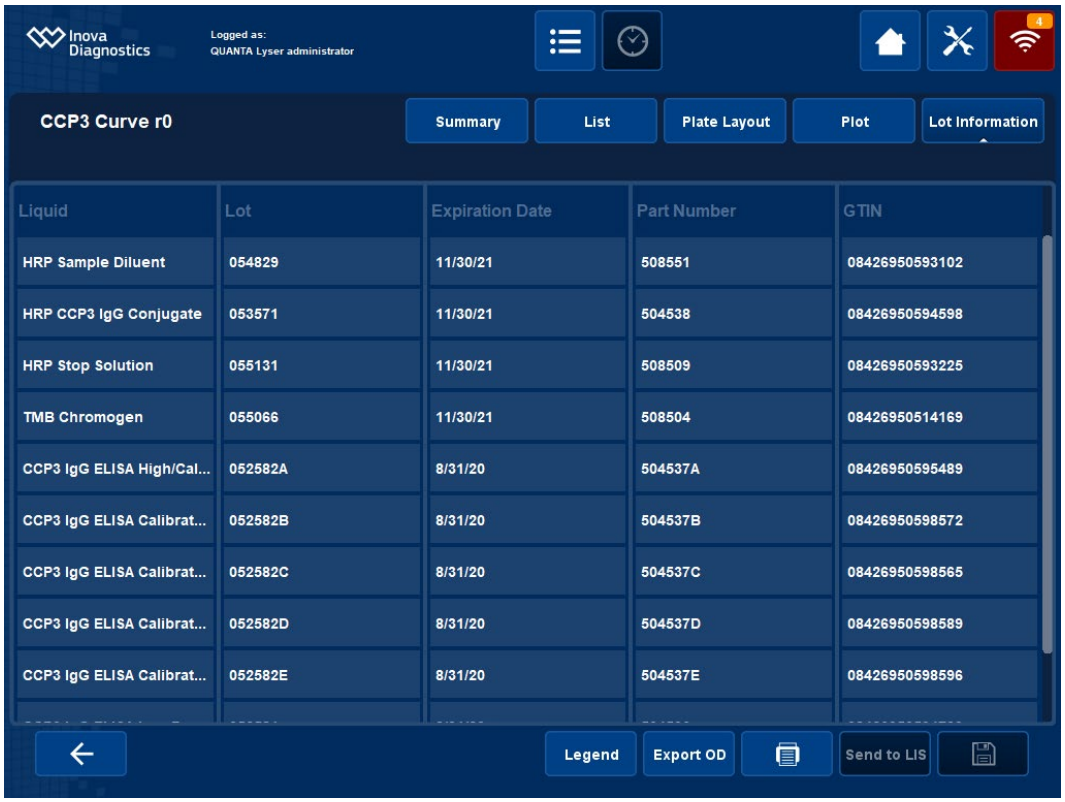


Figure 5-75: ELISA Results: Lot Information Tab

Lot specific information about the controls and reagents used during the run can be found in the Lot Information tab.

Clicking the Send to LIS button will send all information to the LIS, even if it has been previously sent.

5.7.1.3 Printing Results Report

To print the results report, simply click the printer icon at the bottom of the screen at any time while reviewing run results details. A message will appear, confirming the print:

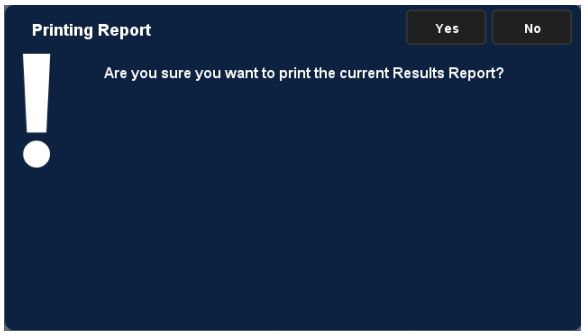


Figure 5-76: Printing Report

Upon confirmation of othe print request, a print preview screen will appear:

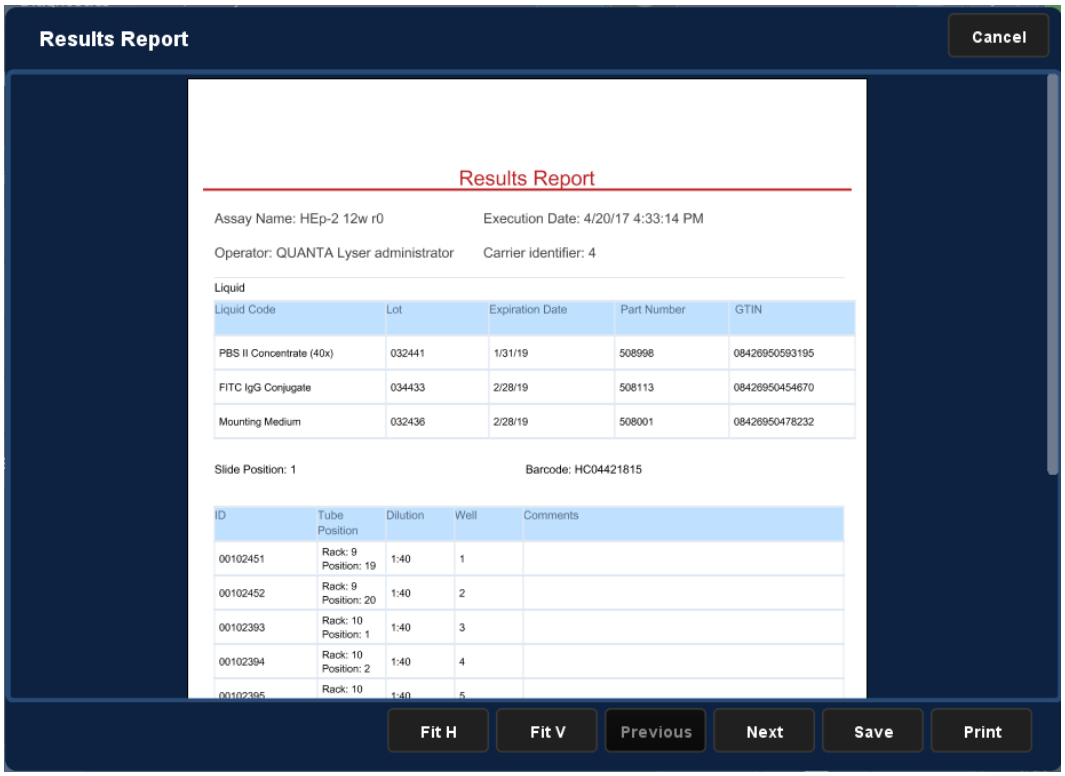


Figure 5-77: Results Report Screen

The Results Report screen is a print preview of the selected session results. Using the Fit H and Fit V button will zoom the preview. The Previous and Next buttons can be used to toggle from one page to another. The Save button will allow for the report to be saved as a PDF. The Print button will proceed to the Print Options window:

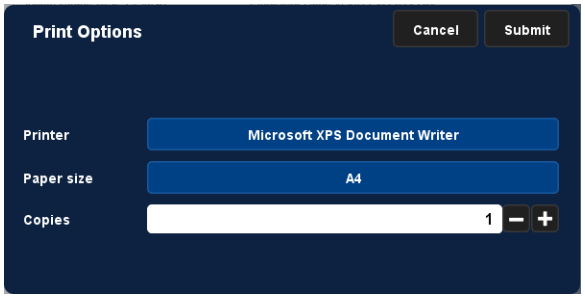


Figure 5-78: Print Options

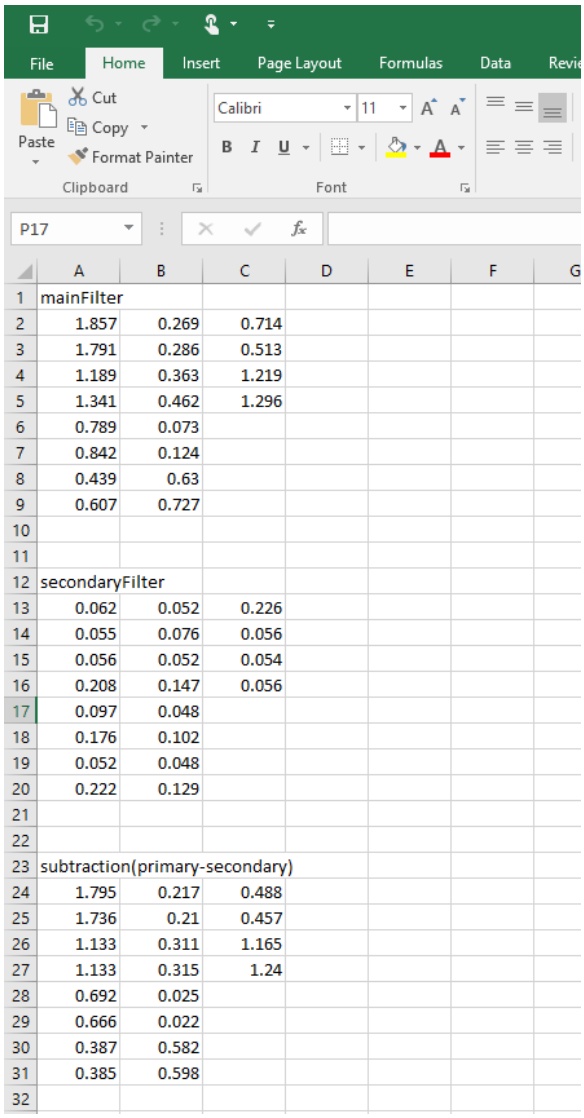
Simply select the desired printer, paper size and number of copies and click Submit to begin the printing process.

5.7.1.4 Export OD for ELISA Results

To export ODs of a given ELISA assay, click the Export OD button at the bottom of the screen at any time while reviewing run results details. A windows explorer window will appear, allowing the file name and location to be defined. A .csv file will be generated and saved in the selected location.

Upon opening the .csv file in Excel, raw ODs for primary, secondary (if used) and subtracted OD (if both filters are used) can be seen.

Note: Export OD functionality is only available for assays that have both data reduction and QC rules applied.



	A	B	C	D	E	F	G
1	mainFilter						
2	1.857	0.269	0.714				
3	1.791	0.286	0.513				
4	1.189	0.363	1.219				
5	1.341	0.462	1.296				
6	0.789	0.073					
7	0.842	0.124					
8	0.439	0.63					
9	0.607	0.727					
10							
11							
12	secondaryFilter						
13	0.062	0.052	0.226				
14	0.055	0.076	0.056				
15	0.056	0.052	0.054				
16	0.208	0.147	0.056				
17	0.097	0.048					
18	0.176	0.102					
19	0.052	0.048					
20	0.222	0.129					
21							
22							
23	subtraction(primary-secondary)						
24	1.795	0.217	0.488				
25	1.736	0.21	0.457				
26	1.133	0.311	1.165				
27	1.133	0.315	1.24				
28	0.692	0.025					
29	0.666	0.022					
30	0.387	0.582					
31	0.385	0.598					
32							

Figure 5-79: Example OD Export .csv

CHAPTER 6: Calibration Procedures

Note

QUANTA-Lyser calibration procedures are performed by certified service engineers. Calibration and functional tests verify the correct operation of the instrument after maintenance and service procedures and investigate suspected malfunctions of the instrument.

Calibration procedures are performed during installation, annual preventative maintenance and following repaired or replacementof parts and modules.

The procedure involves calibration of the instrument layout through the use of a two point deck calibration as well as the option to utilize offsets of individual racks or objects to ensure correct pipetting and/or gripper positioning.

If problems with calibration is observed, please contact Inova Technical Support or your local support provider.

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CHAPTER 7: Potential Hazards

7.1 Introduction

Additional safety measures and precautions are required if the instrument is used for applications involving infectious, toxic, explosive, flammable, and/or hazardous substance.

Such additional measures are the complete responsibility of the operator or the supplier of the reagent package.

For further information, please contact you instrument supplier.

Please read this section and the “Potential Safety Hazards” section before operating the instrument. Operators must be certified in general laboratory safety practices and the specific safety requirements of their QUANTA-Lyser instrument. If the equipment is used in a manner not specified by the manufacturer, protection provided by the equipment may be impaired.

QUANTA-Lyser is a robot that can be programmed to automatically perform chosen tasks. The open geometry of the system facilitates the loading of predilution blocks, samples, reagents, plate, and/or slides prior to commencement of the run and their off-loading after the run has been completed. Should user intervention be necessary during a run, the program should be interrupted strictly according to the instructions given in this manual and/or displayed on the screen of the PC.

7.2 Potential Safety Hazards

7.2.1 Mechanical

Caution

QUANTA-Lyser is a robotic device that operates under computer control. As with most robotic devices, there is a potential for injury and bodily harm from moving mechanical components whenever the instrument is in operation.

The hazard is minimized by the use of encoders on each movement axis, which immediately detects incorrect positioning when a power overload occurs due to a physical blockage.

The instrument is designed for automatic “hands-off” operation only. The housing prevents accidental contact with moving parts. The front shield must be closed whenever the instrument is running.

Never reach or lean into the instrument’s working area when the unit is in an operating mode, unless the system has paused and displays a dialog box indicating that user-intervention is required. Reaching onto the deck at any other time during a run may result in injury to the user and/or damage to the instrument and/or an aborted run.

Read the error warnings provided by the software in case of malfunction and choose the corrective action carefully.

Discontinue use if the instrument emits noise above normal levels.

7.2.2 Electrical

Caution

Standard electrical safety precaution should be applied.

Whenever the instrument is moved from a cold place (e.g. transport at temperature below freezing point) to a room temperature, there is a chance of condensation. Allow 48 hours after transport before the instrument is put into operation.

Do not operate the instrument from an AC power outlet that has no ground connection.

Do not touch the switches or outlets with wet hands.

Switch the instrument off before unplugging the power cable.

Unplug the instrument prior to cleaning up any major spills and prior to servicing any of the electrical or internal components.

Only qualified personnel should perform electrical servicing.

Do not connect any external devices to the power supply.

7.2.3 Precautions for Use

Caution

Please respect GLP (good laboratory practice) at all times.

Interruption of a run can adversely affect the assay in process.

All functions performed within the context of preparing, performing, and completing a run should be done with caution and care and with general respect both to the instrumentation and to associated chemicals, samples, and other devices.

Misuse of the robotic system is hazardous to the user.

Broken glass can result from accidental misuse (dropping bottles during service, etc.) or from instrument malfunction, e.g. an arm crash during faulty test sequence.

Never perform any manual tasks on the instrument deck while the instrument is operating.

Always make certain that the instrument is disabled before reaching into the work surface to add or replace items.

Never operate the instrument with the front shield open.

Take care not to splash or spill liquids when manually performs a task on the work surface. Immediately clean up accidental spills and/or splashes.

In case of a crash, immediately clean all related components if they came in contact with any liquids.

Defects in a motor or a power driver might cause uncontrolled XYZ-movements on the instrument, which could cause a crash and may harm the user.

The QUANTA-Lyser instrument is heavy. There is a risk of back injury if the device is moved.

(For QUANTA-Lyser 4000 model only) The monitor protrudes the instrument. Mind your head. Take care during transport (doorways).

Waste container may contain biohazardous liquid.

Avoid direct sight to the laser beam.

The robotic system is approved to handle substances with flash point above 70ºC, the instrument must be placed on a fire resistant surface with nonflammable material above it, and operated in a fire protected environment.

The instrument can cause injury, even if the instrument is not in operation.

There is risk of injury caused by reflex actions occurring due to unexpected movement or instrument malfunction.

The robotic arm can exert enough force to be a pinch hazard.

The pipette tips are sharp enough to be a puncture hazard.

Watch your fingers while closing front/rear door, lowering the front shield/rear panel, or sliding the monitor (QUANTA-Lyser 4000 model only). There is a risk of pinching.

7.2.4 Instrument Safety

Caution

It is important that the QUANTA-Lyser deck is setup in the exact manner describes and that no unnecessary items be present on the deck during operation.

The liquid waste container must be emptied at least once a day, or as it becomes full.

Ensure that the tubing extending from the instrument to the liquid waste container does not have any kinks and that there are no loops in the tubing path that would prevent the waste solution from flowing freely downwards.

Depending on the installation configuration, cut the waste tubing if it is too long to allow proper gravity drainage.

Ensure that the tubing from the system liquid container is free of kinks.

Ensure that the system liquid container is adequately filled prior to the start of each run.

The QUANTA-Lyser instrument should be connected to an uninterruptible power supply (UPS). This will allow a run to continue in the event of a power interruption and will prevent potential damage to the instrument due to loss of power during a run.

Inadequately tightened liquid connections might cause leaks.

Blocked tips or obstructed fluid lines might cause leaks.

In case the instrument is switched off (by the mains switch, emergency button, or power blackout) there is a chance that the BCR tool moves downward (Z-axis). Manually move the tool upwards before powering the instrument on.

Do not use a lifting device (e.g. crane trolley) to lift the instrument using its handles. Refer to the QUANTA-Lyser Service Manual.

An inaccurately programmed sequence on the instrument might cause a crash. Whenever programming a sequence, including single tests and scripts, do a mock run first.

Do not touch the tip, liquid level detector housing, Z-rack, or housing unless you are grounded properly. Electrostatic discharge may reset boards, which leads to the method being aborted.

Do not walk or stand on the balance pan.

Do not put a heavy load on the liquid station or keyboard drawer (both found on QUANTA-Lyser 4000 model only).

CHAPTER 8: Service and Maintenance

8.1 Introduction

The QUANTA-Lyser instrument is designed to require a minimal amount of maintenance by the user. However, to preserve the accuracy and reliability of the instrument, the following maintenance procedures must be performed on a regular basis according to the maintenance schedule below (Maintenance intervals are based on the assumption of 2 full instrument runs per day 250 days per year). Please note that instruments with higher throughput or use of some reagents may require more thorough or more frequent maintenance.

The Maintenance Operation window can be accessed by clicking on the Maintenance icon, which can be found in the upper right corner of most screens.

The Maintenance Operation window contains a series of different actions that can be performed.

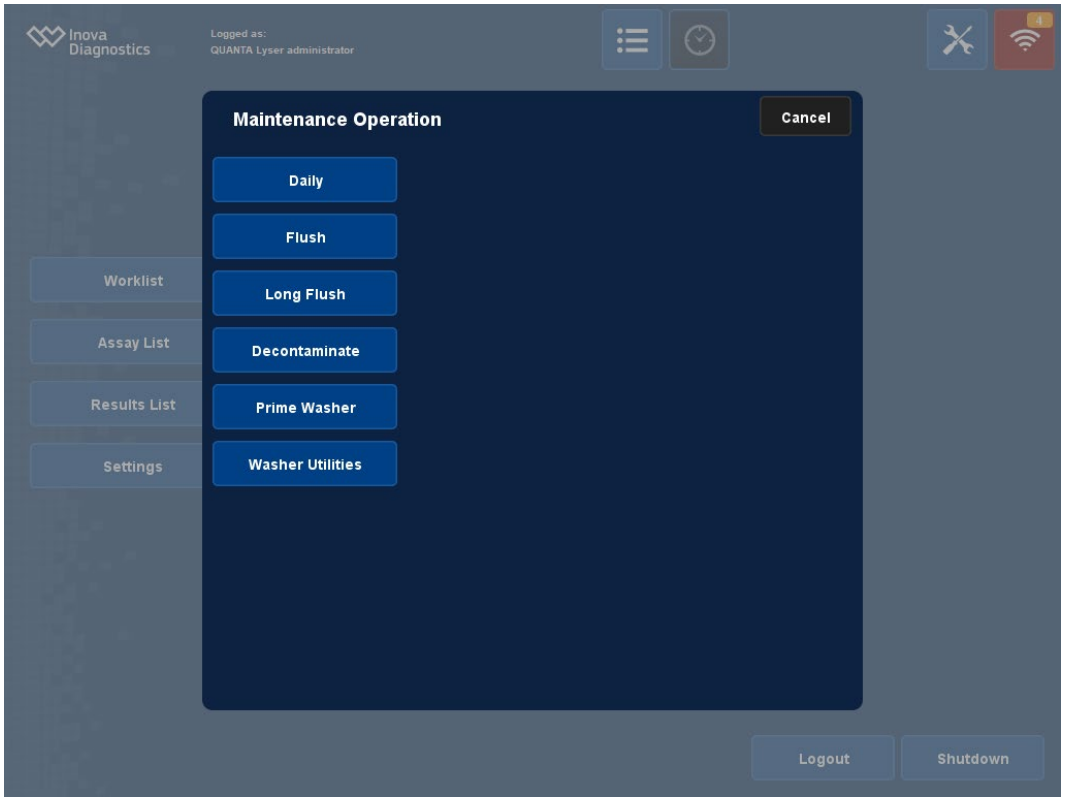

Figure 8-1: Maintenance Operation Window

Daily Maintenance

Daily maintenance is performed by the operator at the beginning and end of each day (or after 8 hours of operation, whichever comes first) and takes approximately 15 minutes.

Weekly Maintenance

Weekly maintenance is performed by the operator at the end of the week and takes approximately 30 minutes.

Preventative Maintenance 1 (Every 6 Months)

Preventative Maintenance 1 (PM1) is performed by the operator every 6 months and takes approximately 10 minutes.

Preventative Maintenance 2 (Annual)

Preventative Maintenance 2 (PM2) is performed by a certified service engineer every year and takes approximately 4-8 hours.

A maintenance record sheet is provided for verification of maintenance. Whenever maintenance actions are performed, the form should be updated.

It is important to maintain this record, as repairs necessitated by misuse, abuse, or negligence are not covered under the warranty or service contract.

Instrument data, including the run list, should be backed up at least weekly, or after modification of setup data.

Backups can be made on any storage media, using Windows Explorer to drag the relevant directory onto the corresponding drive. All data will be automatically copied.

For cleaning of the instrument (e.g. deck, tips, racks), use a 70% ethanol solution. Use lint-free tissues only.

For cleaning of system liquid related parts (e.g. container, reservoir, filter, wash station, waste tubing), use 70% ethanol solution or 0.05% ProClin 950 solution. Use lint-free tissues only.

Caution

Never use bleach to prime, flush, or clean the system tubing.

8.2 Daily Maintenance

Daily maintenance is performed by the operator daily and takes approximately 15 minutes.

Note

Whenever maintenance actions are performed, the maintenance record should be completed.

Caution

Take appropriate precautions if hazardous liquids are used.

Rinse with appropriate decontaminant and flush completely to minimize contamination before removing.

Wear protective clothing, gloves, and glasses.

8.2.1 Start Up Maintenance

1. Replacing the system liquid.
    a. Empty the system liquid container(s) and the system liquid reservoir (QUANTA-Lyser 4000 only - see “Draining the QUANTA-Lyser 4000 System Liquid Reservoir” section).
    b. Refill with fresh system liquid (0.4% Contrad 70 in DI water) (see “System Liquid Container” section).
2. Flush the system liquid.

a. Flushing the system is crucial to prevent growth of microorganisms or build-up of crystals or precipitates from reagents, which might affect assay precision and accuracy. It is also essential to flush the system liquid at the end of each shift. A flush must be executed at the beginning and end of each day.

b. Perform a flush by going to the Maintenance Operation screen and clicking the Flush button.

3. Perform tips decontamination.

   a. In the Maintenance Operation screen, click the Decontaminate button.

   b. Follow the on-screen instructions, placing 70% Ethanol or Isopropyl alcohol in the diluent position indicated on the screen and clicking the Start button.

4. Flush the wash buffer lines.

   a. In the Maintenance Operation screen, click the Prime button.

   b. Follow the on-screen instructions, placing all wash lines in their appropriate wash buffers or DI water if that wash buffer bottle will not be in use.

5. Alternatively, Steps 2-4 can be done in one step by clicking the Daily button and following the on-screen instructions. The flush, decontaminate, and prime will be done one after another without additional intervention.

6. Clean the end of the tip.

   a. Gently wipe the end of each tip with a 70% ethanol solution impregnated lint-free tissue to remove any accumulated serum or reagent.

   b. Replace tip if damage is seen for probes 3 or 4. If damage is seen on probe 1 or 2, schedule an engineer to replace the tip.

8.2.2 Shut Down Maintenance:

1. Flush the system liquid.

   a. Flushing the system is crucial to prevent growth of microorganisms or build-up of crystals or precipitates from reagents, which might affect assay precision and accuracy. It is also essential to flush the system liquid at the end of each shift. A flush must be executed at the beginning and end of each day.

   b. Perform a flush by going to the Maintenance Operation screen and clicking the Flush button.

2. Perform tips decontamination.

   a. In the Maintenance Operation screen, click the Decontaminate button.

   b. Follow the on-screen instructions, placing 70% Ethanol or Isopropyl alcohol in the diluent position indicated on the screen and clicking the Start button.

3. Flush the wash buffer lines

   a. In the Maintenance Operation screen, click the Prime button.

   b. Follow the on-screen instructions, placing all wash lines in DI water.

4. Alternatively, Steps 1-3 can be done in one step by clicking the Daily button and follow the on-

screen instructions. The flush, decontaminate, and prime will be done one after another without additional intervention.

5. Clean the end of the tip.
   a. Gently wipe the end of the tip with a 70% ethanol solution impregnated lint-free tissue to remove any accumulated serum or reagent.
   b. Replace tip if damage is seen for probes 3 or 4. If damage is seen on probe 1 or 2, schedule an engineer to replace the tip.
6. Clean the wash station.
   a. Clean wash station by pouring 70% Ethanol solution over the wash cups and leave in contact for 3 – 5 minutes. Rinse thoroughly with distilled or de-ionized water.
7. Clean the barcode reader (BCR) window(s).
   a. Clean the BCR window(s) with a lint-free tissue.

Caution

Never use alcohol or alcohol solutions to clean BCR windows.

8. Empty the waste container.
   a. Empty the waste container (see “Changing the Waste Container” section).
9. Clean the touch screen monitor.
   a. If required, clean touchscreen with a lint-free tissue.

Caution

Never use alcohol or alcohol solutions to clean touchscreen.

8.3 Weekly Maintenance

Weekly maintenance is performed by the operator at the end of the week and takes approximately 30 minutes.

Note

Whenever maintenance actions are performed, the maintenance record should be completed.

1. As needed, Back up instrument data.
   a. Back up “C:\QUANTA-Lyser\Nelson” folder and “C:\QUANTA-Lyser\quantalyser.h2” database file
2. Clean the system liquid channels.
   a. Clean the system liquid channels (see “Cleaning the System Liquid Channels” section).
3. Clean the liquid supply components applicable to particular model.
   a. Clean the system liquid container(s) and reservoir (as applicable) (see “Liquid Supply Cleaning” section).
   b. Clean the system liquid filter(s) and the buffer filter(s) (see “Liquid Supply Cleaning” section).

4. Clean the wash buffer bottles and lines.
    a. Prepare a solution of 0.05% ProClin 950 in DI water (i.e. 500µl ProClin into 1L of DI water).
    b. Place 0.05% ProClin 950 in the wash buffer bottles (see “Buffer Bottle 2L” section).
    c. Perform the Prime Washer action in the Maintenance Operation screen three times to flush all buffer lines thoroughly.
    d. Thoroughly rinse wash bottles with 0.05% ProClin 950, followed by DI water.
    e. Perform the Prime Washer action in the Maintenance Operation screen with DI water six times each to ensure all Proclin has been removed from the system.
5. Rinse the waste container.
    a. Rinse the waste container.
6. Clean the deck, modules, and accessories.
    a. Remove all racks.
    b. Clean deck, exterior of modules, and accessories (such as slide trays) with a damp cloth, then with 70% ethanol solution using a lint-free tissue.
    c. Clean Resa-trax and all racks with a lint free tissue moistened with a soft soap solution. Always remove soap solution with a lint free tissue moistened with de-ionized water.

8.4 Preventative Maintenance 1

Preventative maintenance 1 (PM1) is performed by the operator every 6 months. This procedure requires 10 minutes.

Required Material:

- System liquid filters and buffer filters. See below for quantities of each filter on different models. Note: Some filters come individually, others in packs of 4, 10, etc. Please note the packaging size when placing orders.

Filter Type	Photo	QUANTA-Lyser 4000	QUANTA-Lyser 3000 ELISA/IFA	QUANTA-Lyser 3000 IFA
Metal System Liquid Filters **066QL0031 (sold individually)**		4	N/A	N/A
Metal Buffer/System Liquid Filters **QL4000 – 066QL0338 (sold individually)** **QL3000 – 066QL0429 (pack of 4)**		4	8	8

Filter Type	Photo	QUANTA-Lyser 4000	QUANTA-Lyser 3000 ELISA/IFA	QUANTA-Lyser 3000 IFA
Plastic Buffer Filters **066QL0430** **(pack of 10)**		N/A	4	N/A

8.4.1 PM1 Procedure

1. Replace all system liquid and buffer filters.
   a. Replace the system liquid filters (see “Liquid Filters” section).
   b. Replace the buffer filters (see “Liquid Filters” section)

Note

Filter types vary slightly from model to model. Additionally, for the QUANTA-Lyser 3000 ELISA/IFA models, buffer bottles C and D have both plastic buffer filters used for ELISA wash lines that connect to the ELISA plate washer, as well as metal buffer/system liquid filters that are used for the system liquid lines as well as the 4 buffer lines that connect to the IFA tip washer.

Preventative Maintenance 2

Preventative maintenance 2 (PM2) is performed by a certified engineer annually.

8.5 System Liquid and Buffer Handling

8.5.1 Liquid Station

The liquid station contains system liquid containers and buffer bottles. Location varies depending on instrument model. For QUANTA-Lyser 4000, the system liquid and buffer bottles are contained within the liquid station drawer, while the QUANTA-Lyser 3000 model has a liquid station that is placed on the counter to the right of the instrument.

Caution

Do not put a heavy load on the liquid station drawer (present on QUANTA-Lyser 4000 model).

The level of the liquid container is monitored individually (using a load cell weight measuring for QUANTA-Lyser 4000, using capacitve level sensing for QUANTA-Lyser 3000). To prevent particles from entering the pump, a filter must be installed on each system liquid and buffer tube.

8.5.1.1 QUANTA-Lyser 4000 Liquid Station Drawer

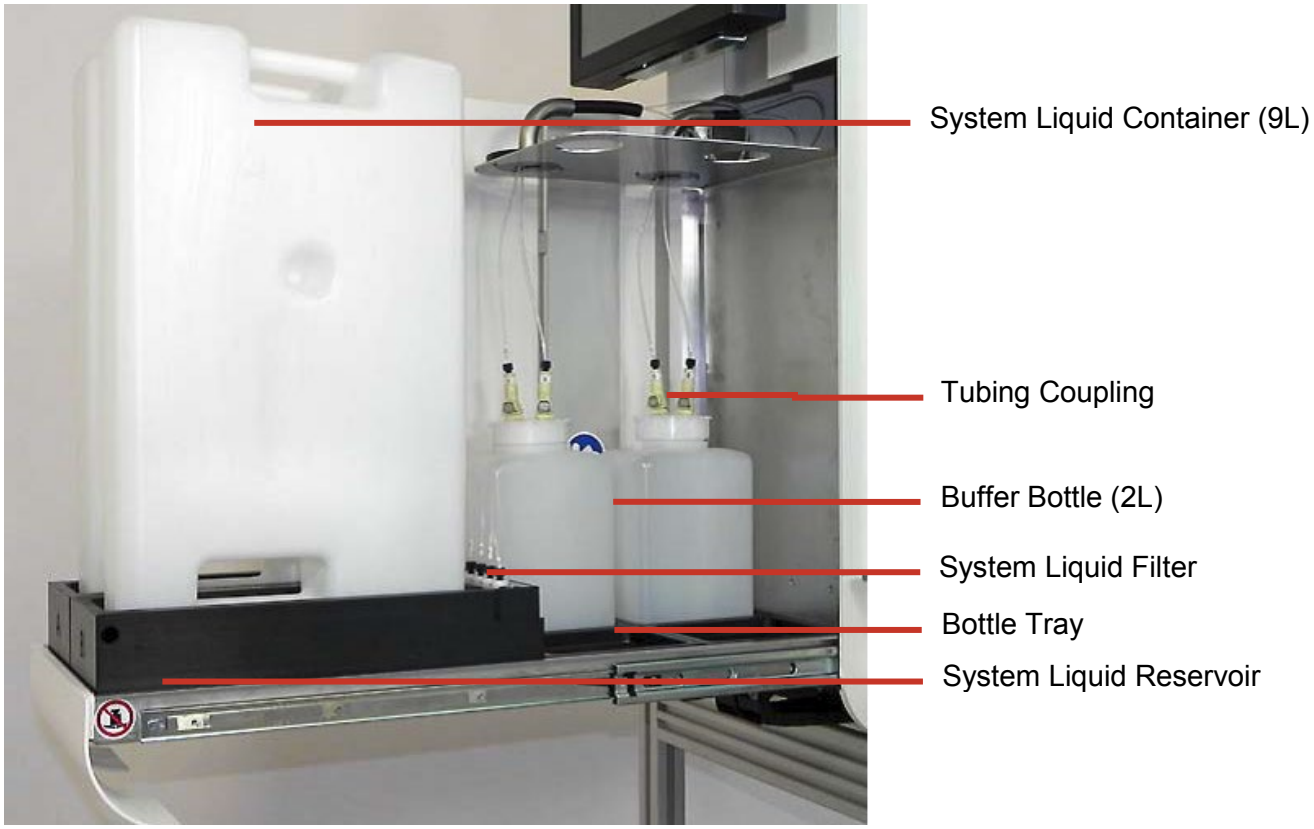

Figure 8-2: QUANTA-Lyser 4000 System Liquid Drawer

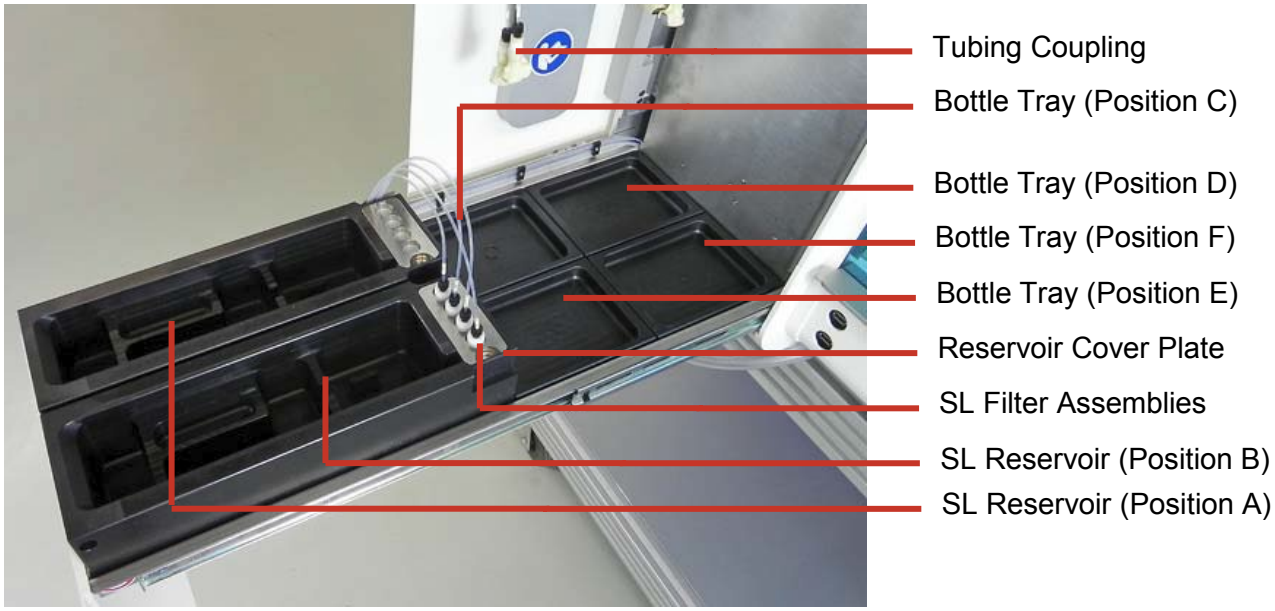

Figure 8-3: QUANTA-Lyser 4000 System Liquid Drawer Positions

8.5.1.2 QUANTA-Lyser 3000 Liquid Station

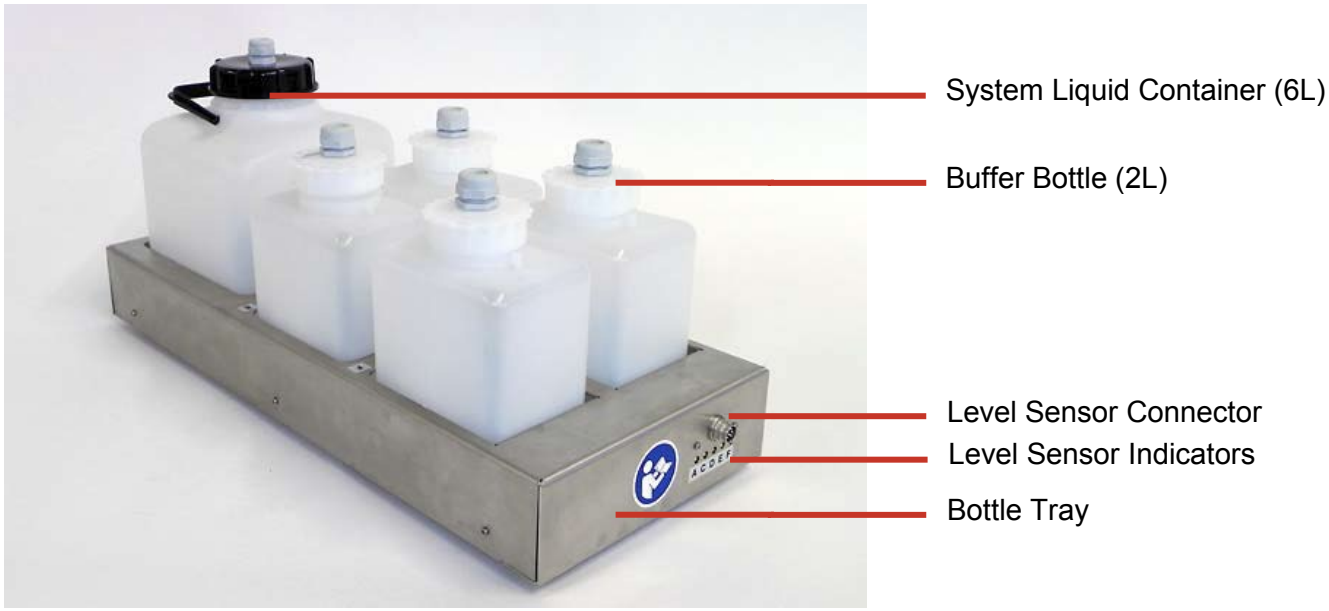

Figure 8-4: QUANTA-Lyser 3000 Liquid Station 501

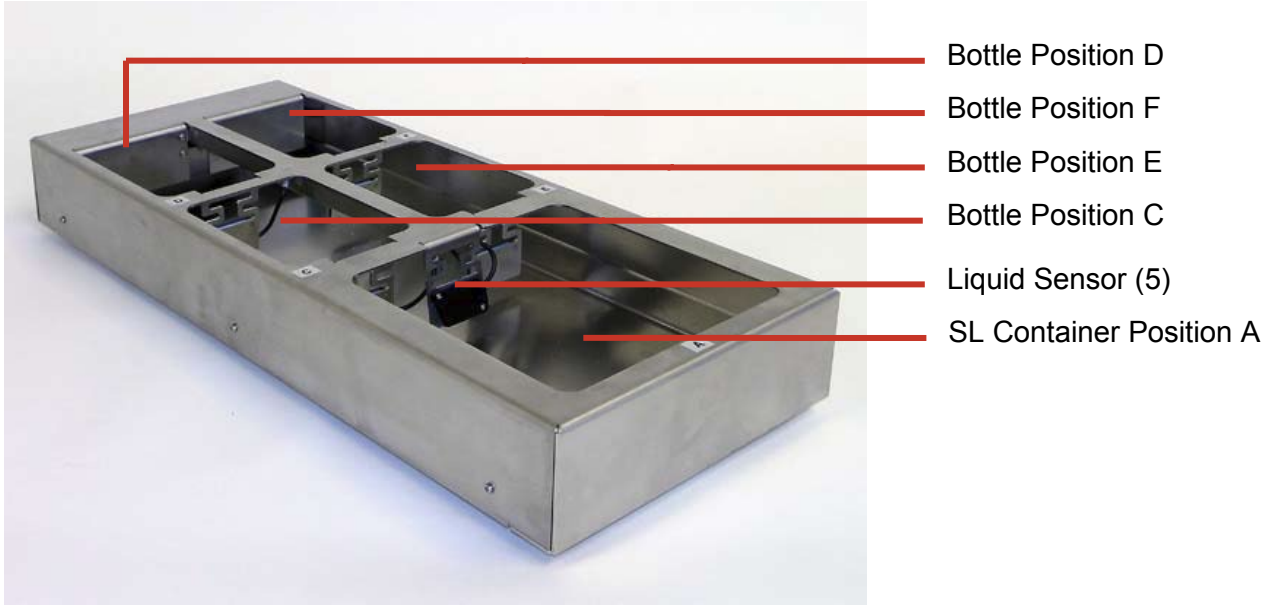

Figure 8-5: QUANTA-Lyser 3000 Liquid Station 501 Positions

8.5.2 System Liquid Container

8.5.2.1 QUANTA-Lyser 4000 System Liquid Container Installation

The liquid station provides two locations (position A and B) to place two liquid system containers, each with a capacity of 9 liters.

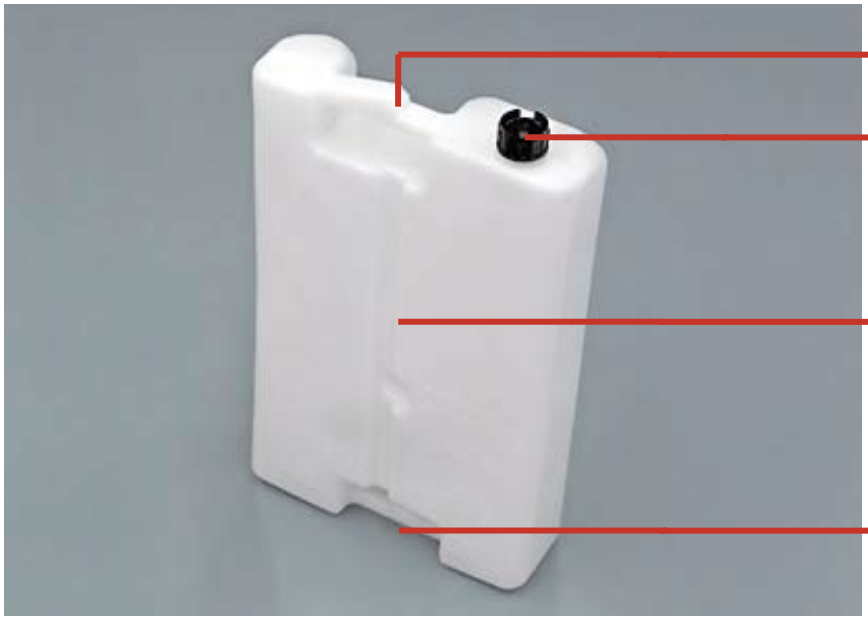

Figure 8-6: QUANTA-Lyser 4000 System Liquid Container

1. Open the front door and pull out the liquid station drawer. Lift out the system liquid container.
2. Remove the bottle cap and fill the container with the required system liquid.

Note

To prevent the contamination of the system liquid filter, 0.4% Contrad 70 is used. Never use bleach.

Caution

Observe the maximum filling quantity.

Install the container in the reservoir immediately after filling.

A full container is heavy. Be aware that there is a risk of back injury when carrying a full container if proper lifting techniques are not used.

3. Tighten the bottle cap well and check the function of the non-return valve by pressing and releasing the spring-loaded mechanism.

Figure 8-7: QUANTA-Lyser 4000 System Liquid Container Cap

Caution

For QUANTA-Lyser 4000, before inserting the liquid container, ensure that the reservoirs are emptied (see "QUANTA-Lyser 4000 System Liquid Reservoir" section) to avoid any overflow of the system liquid.

4. Insert the container upside down on the reservoir position A or B. Push the liquid station drawer back and close the front door.
5. Flush several times.

8.5.2.2 QUANTA-Lyser 3000 System Liquid Container Installation

The Liquid Station 501 provides space (at position A) to place a liquid system container with a capacity of 6 liters.

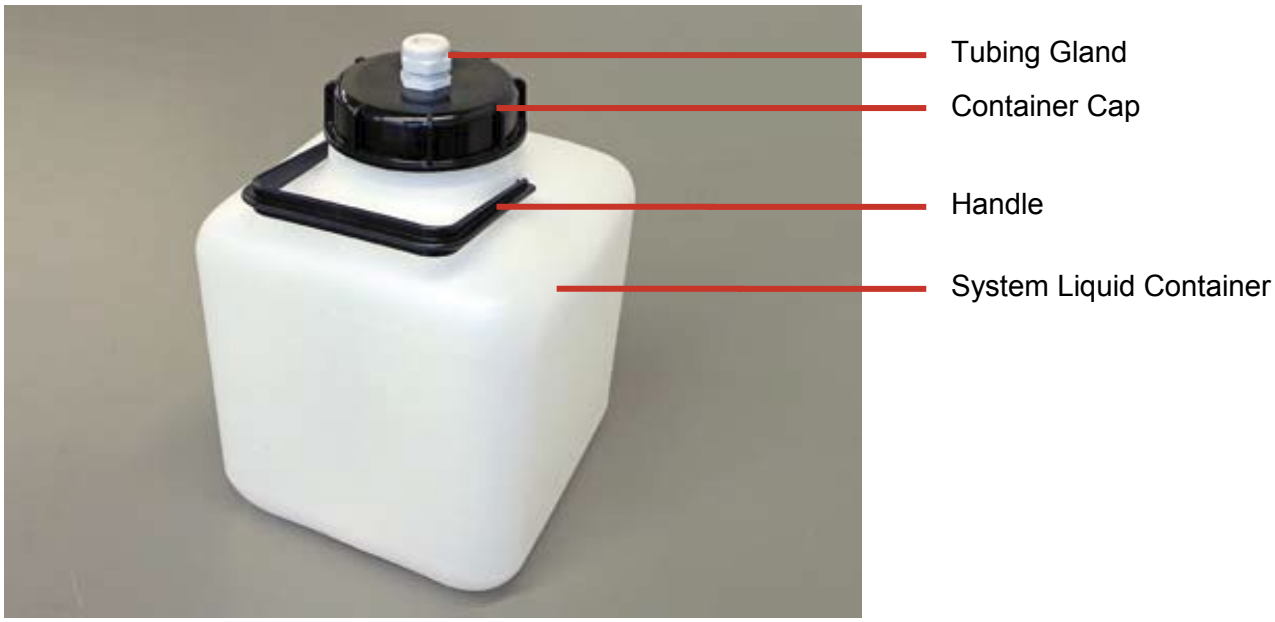

Figure 8-8: QUANTA-Lyser 3000 System Liquid Container

1. Hold the tubing gland while turning the container cap counter-clockwise.
2. Place the cap with the tubing on a lint-free tissue to avoid dripping.
3. Fill the container with the required system liquid.

Note

To prevent the contamination of the system liquid filter, 0.4% Contrad 70 is used. Never use bleach.

Caution

Observe the maximum filling quantity.

4. Place the container in its designated position (A).
5. Tighten the container cap well by turning the cap clockwise while holding the tubing gland.
6. Flush several times.

8.5.3 QUANTA Lyser 4000 System Liquid Reservoir

On the QUANTA-Lyser 4000 model, the system liquid reservoir consists of two individual reservoirs (A and B) connected by a connection tube to proveid equal liquid levels.

8.5.3.1 Draining the QUANTA-Lyser 4000 System Liquid Reservoir

1. Open the front door and pull out the liquid station drawer. Remove the two system liquid containers.
2. Disconnect all system liquid filter assemblies. Place filter assemblies on a lint free tissue to avoid any spillage.
3. Remove the reservoir cover plates from the reservoirs.
4. Lift the reservoirs joined together out of the drawer.

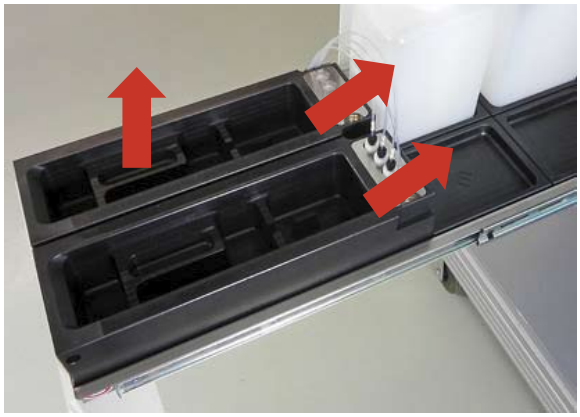

Figure 8-9: System Liquid Reservoir

Figure 8-10: System Liquid Drawer

5. Drain the residual system liquid into a sink.
6. Insert the reservoirs in the drawer.
7. Mount the reservoir cover plates and insert the system liquid filter assemblies (order is not important).
8. Insert the container upside down on the reservoir position A or B. Push the liquid station drawer back and close the front door.

Caution

Mind your fingers while pushing back the drawer. There is a risk of pinching. Push back the drawer smoothly to avoid spillage.

8.5.4 Liquid Filters

There are different types of liquid filters for buffers and system liquid on the various QUANTA-Lyser Models.

The QUANTA-Lyser 4000 instrument uses a System Liquid Filter Assembly for the 4 system liquid lines and stainless steel liquid filter for the 4 buffer lines that reside above bottle tray positions C and D.

QUANTA-Lyser 3000 uses the stainless steel liquid filters for the 4 system liquid lines as well as the 4 IFA buffer lines and a plastic liquid filter for the 4 ELISA wash buffer lines.

QUANTA-Lyser 3000 model has labels on the tubing that indicate where the tubing should go and also what type of filter is required.

Tubing	Label	Stainless Steel Filter	Plastic Filter
System Liquid	SL	X	
Buffer (Pipetting Tip for IFA Well Washing)	1C	X	
	2C	X	
	1D	X	
	2D	X	
Buffer (For ELISA Plate Washer	C		X
	D		X
	E		X
	F		X

Caution

Wear gloves while installing or removing the filter to avoid contamination.

Do not mix up filters and tubing when exchanging filters or tubing.

8.5.4.1 System Liquid Filter Assembly Installation, Removal, and Cleaning

The System Liquid Filter is used on QUANTA-Lyser 4000 models for the 4 system liquid lines.

Figure 8-11: System Liquid Filter Assembly

Installation

1. Slide nut over the tubing with the nut threads facing the connection end of the tubing.
2. Ensure the tubing ferrule is the appropriate size, then place it on the tubing, with the tapered portion of the ferrule facing the tubing nut.

Note

Make sure the tubing end protrudes from the tubing ferrule by approximately 0.5 mm.

Always replace the ferrule when you replace the filter tubing.

3. Insert the tubing in the filter holder and tighten the tubing nut finger-tight. Test the connection by pulling gently on the tubing while holding the filter holder.
4. Screw system liquid filter holder and tighten the filter finger tight.

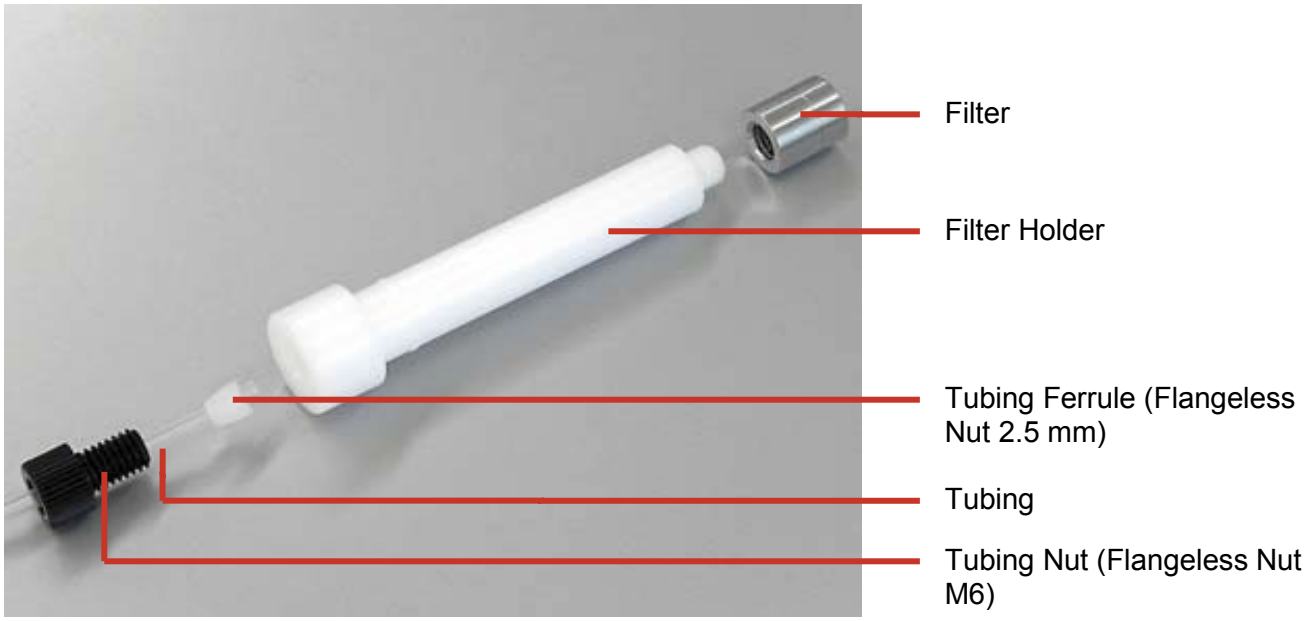

Figure 8-12: System Liquid Filter Assembly Components

5. Insert the system liquid filter assembly into the clamping ring of the reservoir cover plate until it snaps in with an audible click.

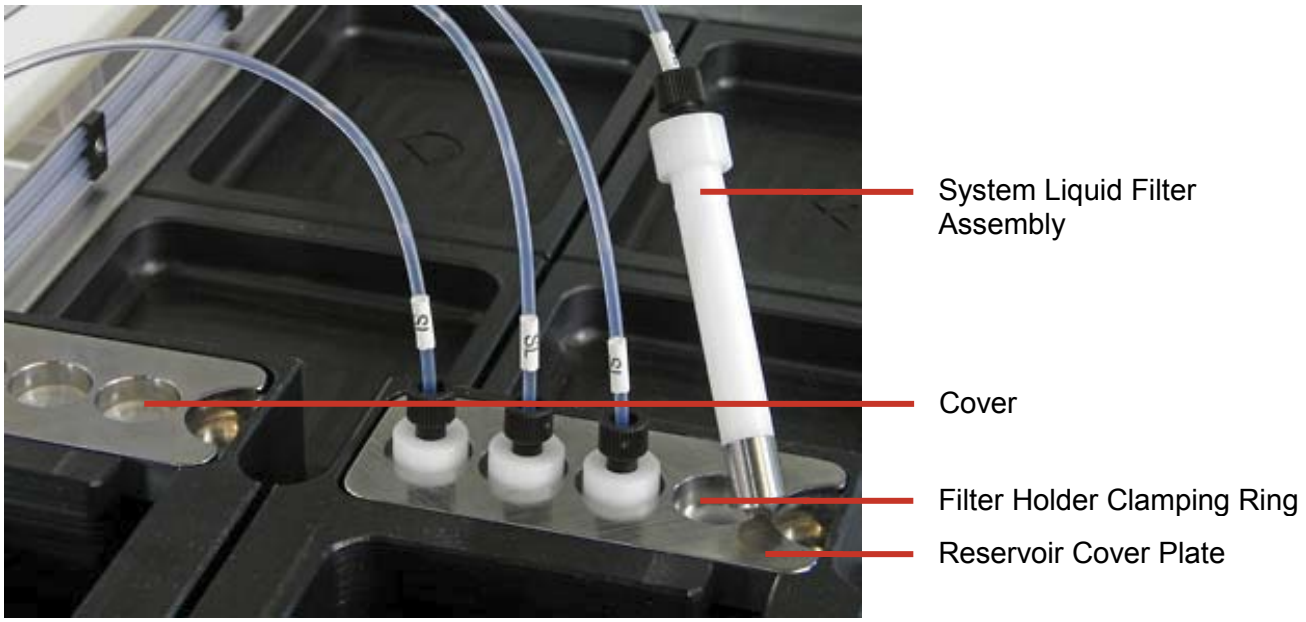

Figure 8-13: System Liquid Filter Holder

Note

Unused filter ports must be sealed with corresponding covers to prevent dust from contaminating the system liquid.

Removal

1. Hold the system liquid filter assembly by its holder and pull it straight out of the reservoir cover

plate.

Caution

Never try to remove the system liquid filter assembyl by pulling the tubing.

2. Unscrew the system liquid filter from the filter holder.
3. Unscrew the tubing nut from the filter holder.

Cleaning

1. Remove filters.
2. Put filters in a small ultrasonic bath and clean them with 70% ethanol solution or 0.05% ProClin® 950 solution for 10 minutes. Repeat procedure or replace filters if they are still dirty.

Caution

Do not clean filters with tools, such as cotton stick, etc.

3. Rinse filters carefully several times with distilled or de-ionized water.
4. Install liquid filters.

8.5.4.2 Liquid Filter Installation, Removal, and Cleaning

There are two different types of liquid filters, one being stainless steel that is used on QUANTA-Lyser 4000 buffer lines and QUANTA-Lyser 3000 system liquid as well as IFA buffer lines, the other is a plastic filter that is used for QUANTA-Lyser 3000 ELISA buffer lines.

Figure 8-14: Metal Liquid Filter

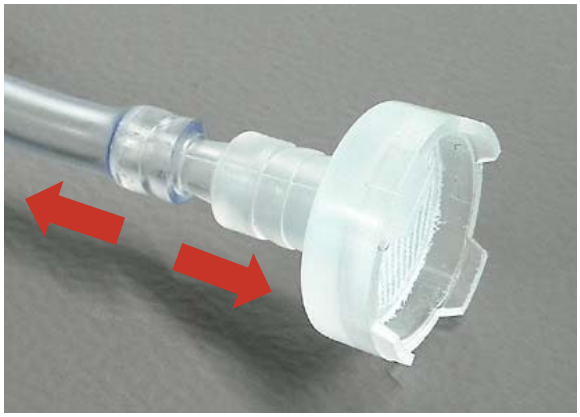

Figure 8-15: Plastic Liquid Filter

Installation

1. Fully attach filter to the tubing.
2. Tighten the container or bottle cap firmly.

Removal

1. Remove the container or bottle cap (For QUANTA-Lyser 4000, first disconnect tubing coupling from the buffer bottle by pressing the lock).
2. Pull filter from the tubing. Hold the tubing to avoid any force on the tubing gland.

Cleaning

1. Remove the liquid filters.

2. Put filters in a small ultrasonic bath and clean them with 70% ethanol solution or 0.05% ProClin 950 solution for 10 minutes. Repeat procedure or replace filters if the filters are still dirty.

Caution

Do not clean filters with tools, such as cotton stick, etc.

3. Rinse filters carefully several times with distilled or de-ionized water.
4. Install the liquid filters.

8.5.5 Buffer Bottle 2 L

8.5.5.1 QUANTA-Lyser 4000 Buffer Bottle 2 L

The liquid station provides space to place two buffer bottles (position C and D) each with a capacity of 2 liters.

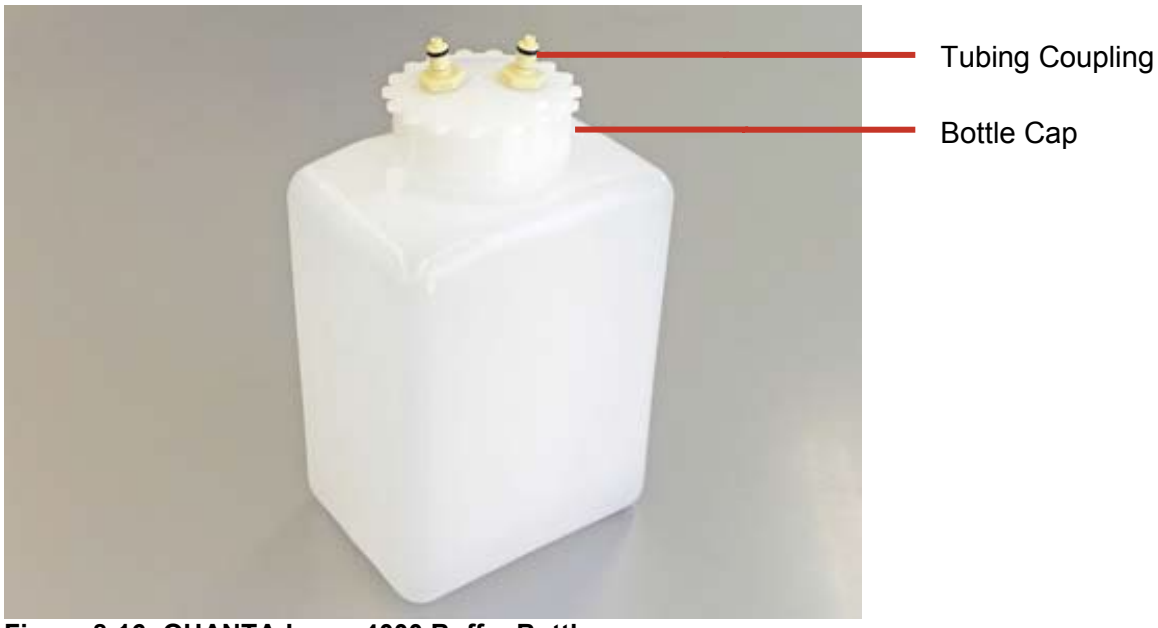

Figure 8-16: QUANTA-Lyser 4000 Buffer Bottle

Installation

1. Open the front door and pull out the liquid station drawer. Remove the system liquid containers.
2. Disconnect the tubing coupling from the buffer bottle by pressing the lock.
3. Remove the buffer bottle. Remove the bottle cap and fill with the required buffer.
4. Tighten the bottle cap well.
5. Place the buffer bottle in its designated position and connect the tubing coupling.
6. Insert the system liquid containers. Push the liquid system drawer back and close the front door.

8.5.5.2 QUANTA-Lyser 3000 Buffer Bottle 2 L

The Liquid Station 501 provides space (positions C – F) to place up to four buffer bottles with a capacity of 2 liters each.

Figure 8-17: QUANTA-Lyser 3000 Buffer Bottle

Installation

1. Hold the tubing gland while turning the bottle cap counter-clockwise.
2. Place the cap with tubing on a lint-free tissue to avoid dripping.
3. Fill the container with system liquid.
4. Place the buffer bottle in its designated position (C – F).
5. Tighten the bottle cap well by turning the cap clockwise while holding the tubing gland.

8.5.6 Cleaning the System Liquid Channels

1. Turn the instrument off.
2. Fill a beaker with approximately 0.5 liters of 0.05% ProClin 950 solution.
3. Remove system liquid containers.
4. Place the beaker close to system liquid filter assemblies. Pull them out and submerge in the solution.
5. Turn the instrument on.
6. Start QUANTA-Lyser software.
7. Go to the “Maintenance Operation” screen.
8. Click “Flush”.
9. Repeat flush procedure twice, for a total of three flush steps.
10. Remove beaker and replace with a beaker containing DI water.
11. Submerge system liquid filter assemblies in DI water.

12. Perform “Flush” maintenance item a total of six times.
13. Replace system liquid filter assemblies and system liquid containers.

8.5.7 Liquid Supply Cleaning

Note

It is recommended that the system liquid filters, the filter holder (QUANTA-Lyser 4000 only), and the buffer filters be cleaned weekly. Filters should be exchanged every 6 months.

Never use bleach.

Caution

Wear gloves while installing or removing filters to avoid contamination.

1. Remove system liquid containers and buffer bottles. Rinse thoroughly with distilled or deionized water before refilling.
2. Remove system liquid filter(s) and, if applicable, filter holder(s) (see “Liquid Filters” section).
3. Remove buffer filter(s) (see “Liquid Filters” section).
4. Soak filters with 0.05% ProClin 950 solution for 10 minutes. Repeat procedure or replace filter if the filters are still dirty.

Caution

Do not clean filters with tools, such as cotton stick, etc.

5. Rinse carefully several times with distilled or deionized water.
6. For QUANTA-Lyser 4000, drain system liquid reservoirs (see “Draining the QUANTA-Lyser 4000 System Liquid Reservoir” section) and clean them with 0.05% ProClin 950 solution. Rinse carefully with water and wipe the outside.

Caution

Do not clean system liquid reservoir in an autoclave or dishwasher.

7. Install system liquid filters and filter holders, if applicable (see “Liquid Filters” section).
8. Install buffer filter(s) (see “Liquid Filters” section).
9. Fill system liquid containers with system fluid (0.4% Contrad 70) and insert them in the reservoir (if applicable) (see “System Liquid Container” section).
10. Fill buffer bottles with distilled or deionized water.
11. Flush all liquid channels.

8.6 Waste Handling

The waste station houses the waste container with a capacity of 10 liters. On QUANTA-Lyser 4000 only, the liquid level is monitored by a load cell (weight measuring) generating an alert if the container is full.

Caution

The waste container may contain biohazardous or toxic material.

A full container is heavy. Be aware that there is a risk of back injury when carrying a full container. In case a full container is dropped accidentally on the balance pan, the load cell (if equipped) may be impaired.

To avoid an overflow of the container, the load cell must be checked by a certified service engineer.

Do not walk or stand on the balance pan.

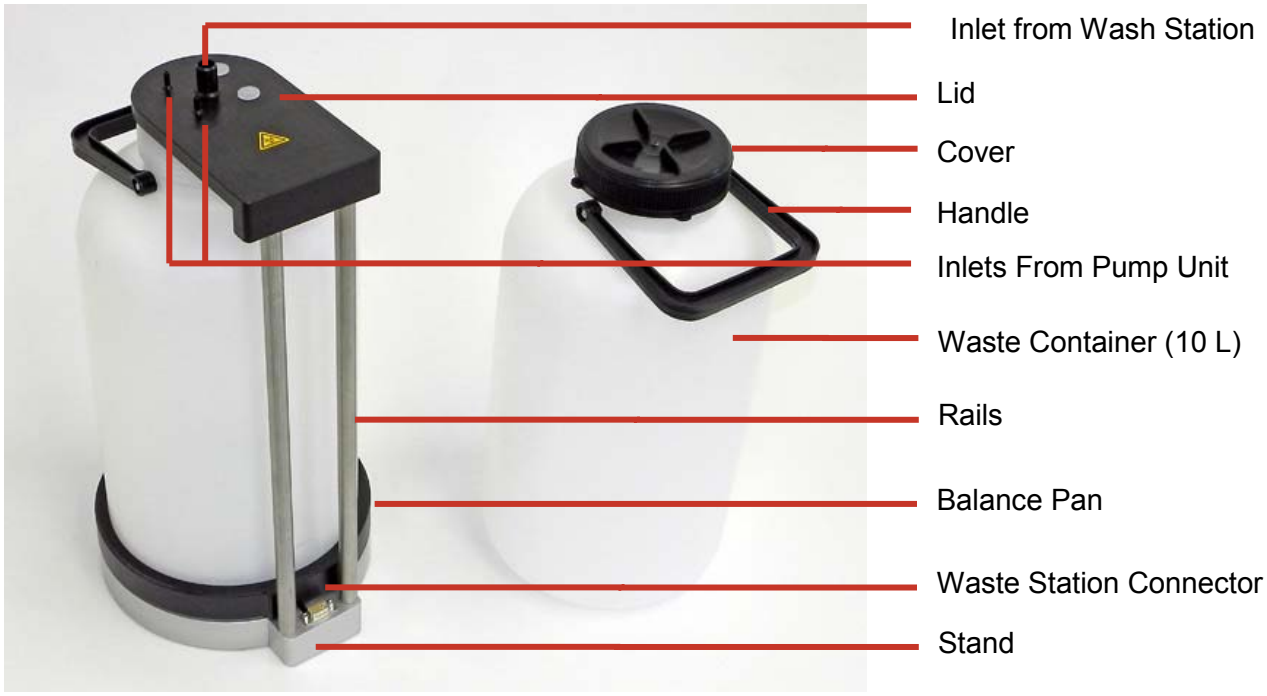

Figure 8-18: QUANTA-Lyser 4000 Waste Bottle

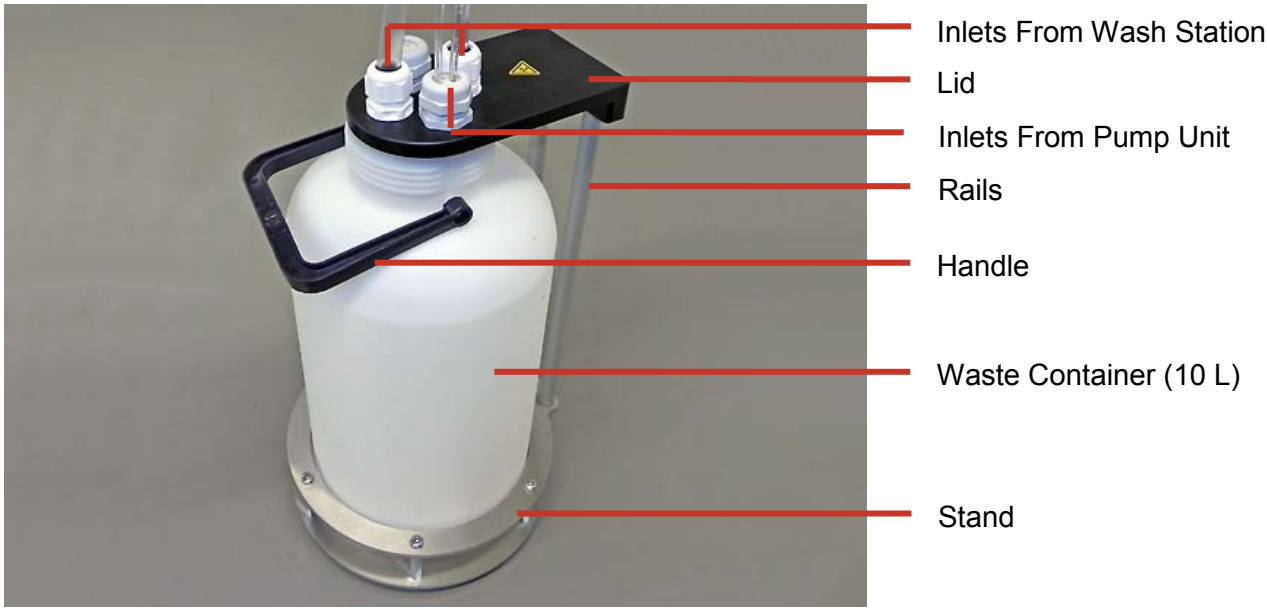

Figure 8-19: QUANTA-Lyser 3000 Waste Bottle

8.6.1 Changing Waste Container

1. Turn instrument off.

2. Place an empty container next to the waste station. Remove the container cover.
3. Lift the container lid and slightly shake it to avoid dripping. Place the lid in the empty container.
4. Firmly seal the full container with the cover and remove the container from the waste station. Use the handle to carry the container.

Figure 8-20: Waste Container Removal

5. Dispose of waste according to proper protocol.
6. Place the empty container on the waste station. Ensure the lid is properly inserted in the two rails and the container is properly sealed.

8.7 Opening the Front Shield Manually

A lock bolt is used to avoid an accidental elevation of the front shield. While the instrument is in operation, the lock bolt is controlled by the application software. When the instrument is turned off, the lock bolt must be released manually to elevate and lower the front shield. The lock bolt is located towards the bottom left side of the instrument.

In rare situations, it may be necessary to unlock the front shield manually. Note that it is not recommended to open the front shield manually while the system is in use. There is also a door sensor check performed by the software which will pause the run in the event the cover is found to be open.

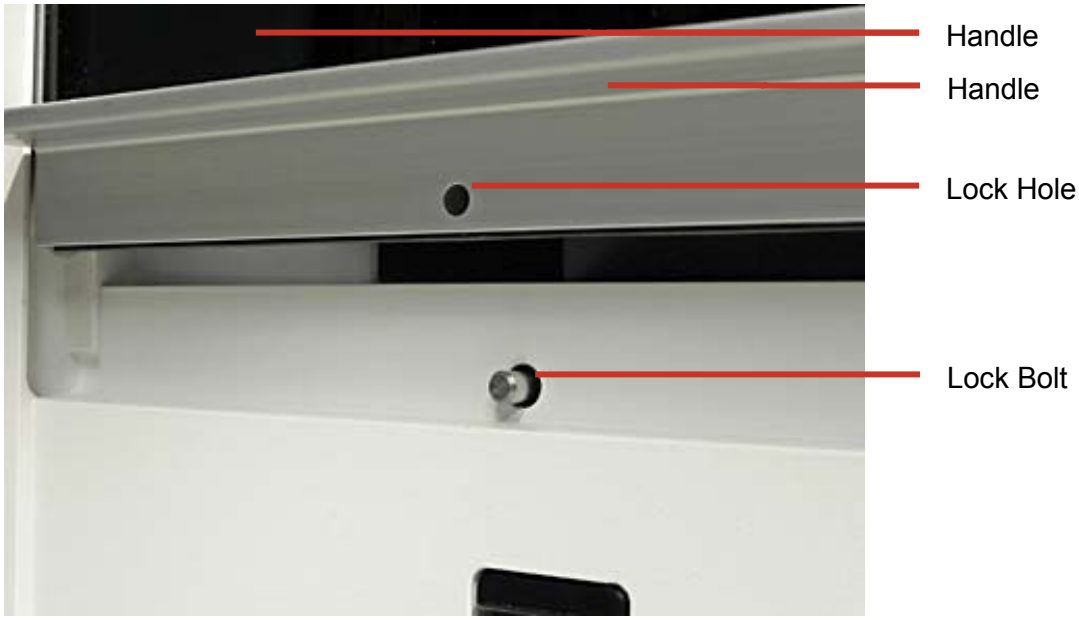

Figure 8-21: Front Cover Lock

8.7.1 Elevating and Lowering the Front Shield

Elevating the Front Shield

Insert a screwdriver or the like in the hole at the handle and carefully push the bolt back while elevating the front shield. Pull out screwdriver.

Lowering the Front Shield

Push back the lock bolt with a screwdriver or the like while carefully lowering the front shield. Pull out the screwdriver to fully close the front shield.

Caution

Do not try to close the front shield without pushing back the lock bolt.

Mind your fingers while lowering the front shield. There is a risk of pinching

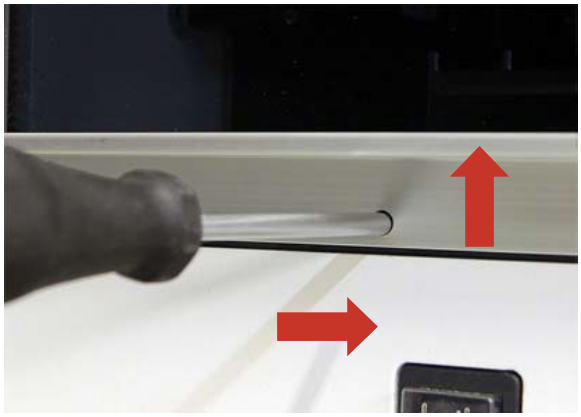

Figure 8-22: Unlocking the Front Cover

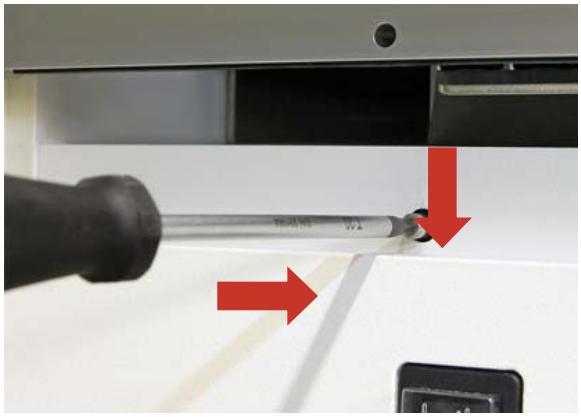

Figure 8-23: Locking the Front Cover

8.7.2 Cleaning the Housing

When necessary, arcylic panels of the housing can be cleaned either with a dry lint-free tissue or a lint-free tissue moistened with diluted dish detergent. Alternatively, an anti-static acrylic cleaner can be used (read instructions provided with the cleaner).

Caution

Never use cleaners containing organic solvents, such as ethanol, acetone, etc.

8.8 Exchanging Tips

8.8.1 Pipetting Tip

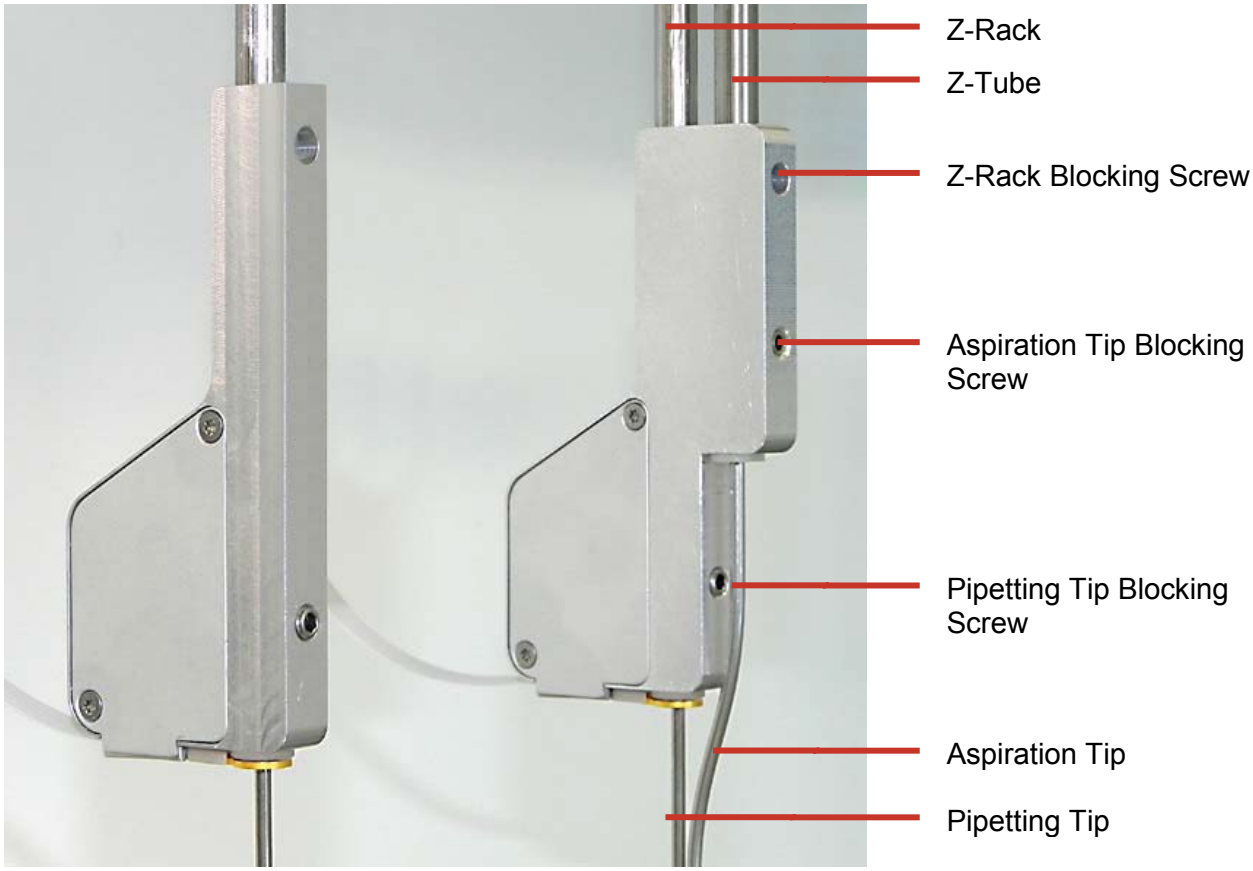

Figure 8-24: Pipette Tips

Caution

Handle tip with care to avoid damage to the outer coating.

The tip is sharp enough ot be a puncture hazard.

Required Tools

- Allen wrench 2 mm
- Try square
- Piece of a rubber liner or Parafilm

8.8.1.1 Dispense Tip Removal

Note

Probes 1 and 2 have an aspirate probe attached to the dispense probe. The aspirate probe must be removed before the pipetting tip can be removed. That process requires assistance from a service provider. Please contact your service provide in case probe 1 or 2 needs to be replaced.

Use a piece of rubber liner or Parafilm to get a better grip while removing and installing the tubing.

1. To avoid damage due to liquid dripping while removing the tip, cover the deck underneath the tips with absorbent tissues.
2. Turn the instrument off and unplug the power cable.
3. Elevate the front shield.
4. Loosen the z-rack blocking screw.
5. Loosen the tip blocking screw.
6. Hold the z-rack while carefully pushing the liquid level detector housing up by approximately 20 mm.
7. Disconnect the pipetting tip from the tubing.

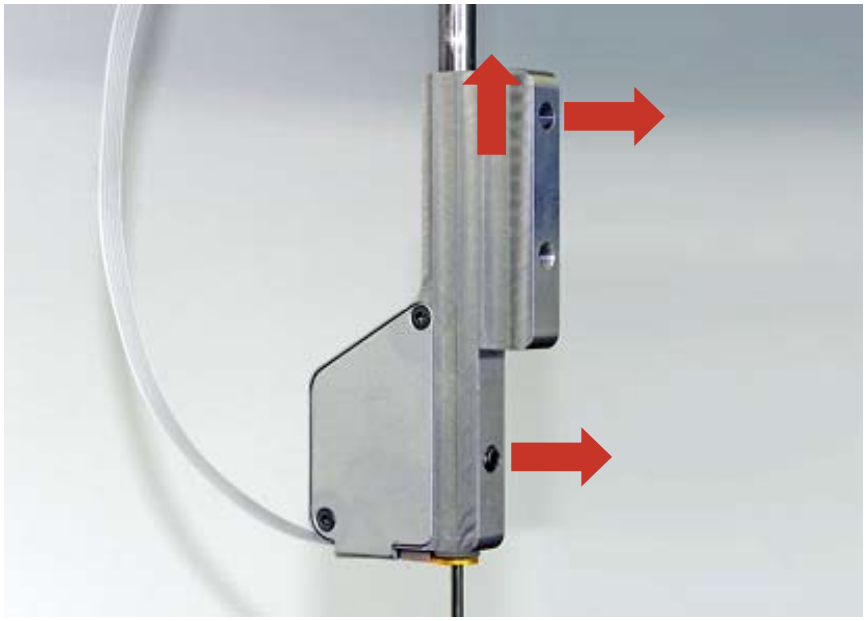

Figure 8-25: Disconnecting Dispense Tip

Tip

Rotating the tip while pulling down aids in disconnecting the tubing.

8.8.1.2 Dispense Tip Installation

Note

Probes 1 and 2 have an aspirate probe attached to the dispense probe. The aspirate probe must be installed before the pipetting tip can be installed. That process requires

assistance from a service provider. Please contact your service provider in case probe 1 or 2 needs to be replaced.

Use a piece of rubber liner or Parafilm to get a better grip while removing and installing the tubing.

1. Ensure that the instrument is switched off and the power cable is unplugged.
2. Ensure the contact of the pipetting tip touches the terminal at the liquid level detector housing and then connect the tip to the tubing.
3. Move the pipetting tip upwards until the terminal contact fits into the recess on the liquid level detector terminal.

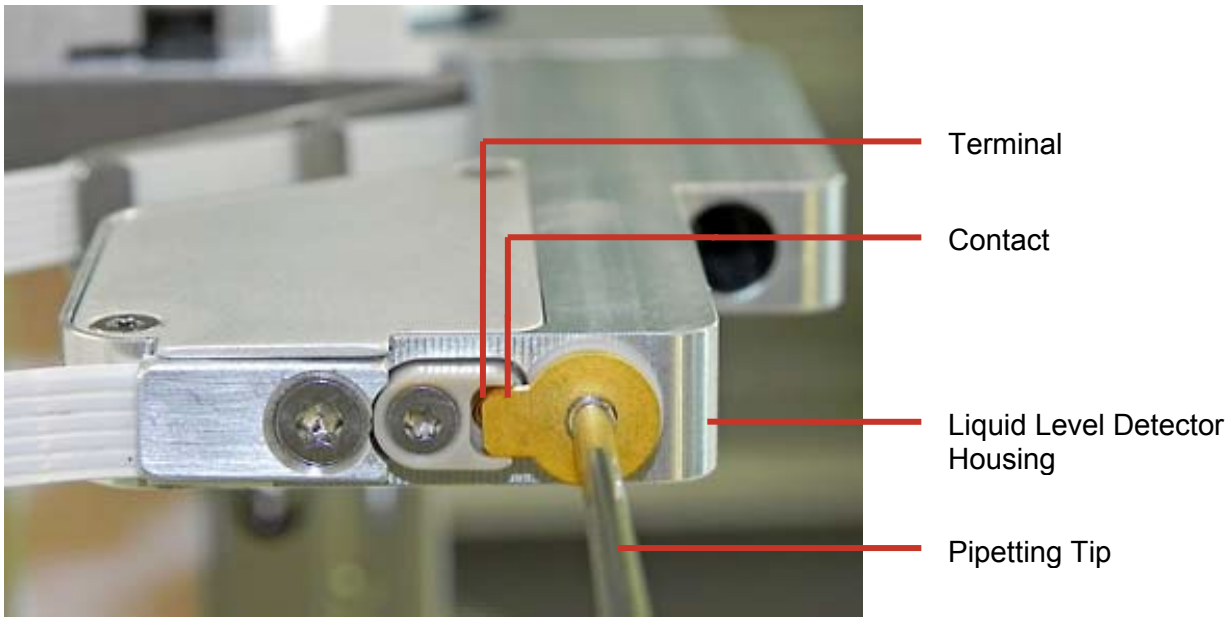

Figure 8-26: Dispense Tip Installation

4. Tighten the tip blocking screw.
5. Put a try square on the deck and check the X-tilt along the left-hand side of the tip. Parallelism must be within 0.2 mm on a length of 100 mm. If out of range, either try to bend the tip carefully in position or replace it.
6. Turn the try square by 90° and check Y-tilt along the front side of the tip. Parallelism must be within 02 mm on a length of 100 mm. If out of range, either try to bend the tip carefully in position or replace it.

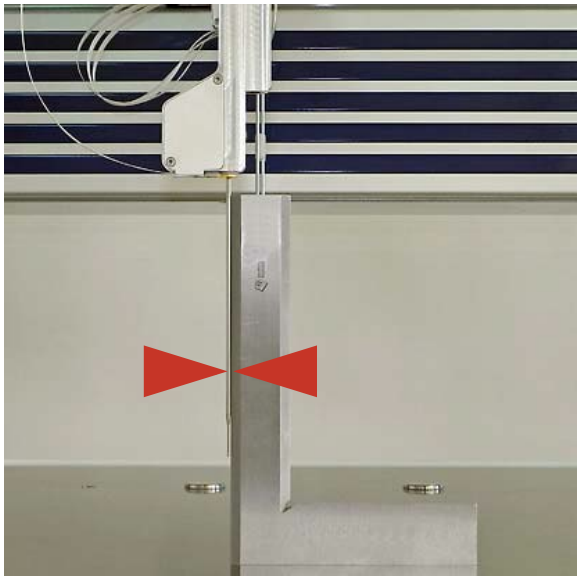

Figure 8-27: Dispense Tip Parallelism Left/Right

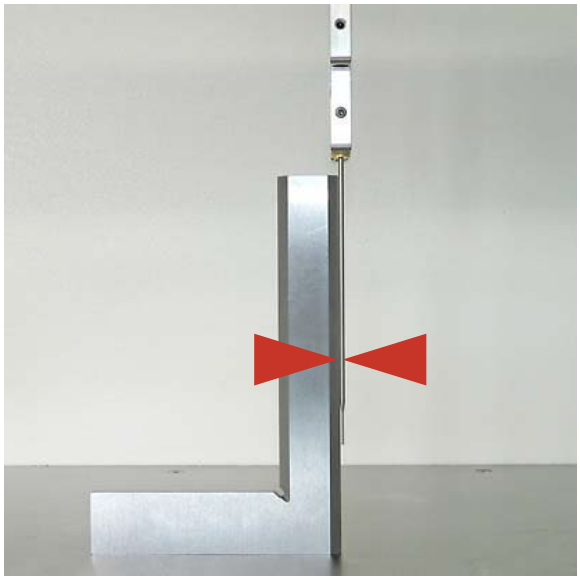

Figure 8-28: Dispense Tip Parallelism Front/Back

7. Plug in the power cable and turn the instrument on.
8. Flush the appropriate liquid channel.

8.8.2 Aspiration Tip

Caution

Handle the tip with care to avoid damage to the outer coating.

The tip is sharp enough ot be a puncture hazard.

The aspiration tip, located on probes 1 and 2, requires additional assistance to remove or install. Please contact your service provider for further assistance.

8.9 Handling Instrument Data

The instrument data containing instrument specific data should be backed up at regular intervals (once a week, according to the maintenance schedule), or as needed.

8.9.1 Backup Procedure

Locate the “C:\QUANTA-Lyser\Nelson” folder and the “quantalyser.h2” file (in C:\QUANTA-Lyser) and save a copy of both to an external location, either an external hard drive or flash drive. It is advised to change to a unique name (such as quantalyserDDMMYYYY) in order to be able to store multiple backups in the same location.

QUANTA-Lyser® Maintenance Record

QUANTA-Lyser Model _____SN _____ Month_____ Year_____

Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Start Up																															
Replace System Liquid																															
Flush System Liquid																															
Perform Tips Decontamination																															
Flush Wash Buffer Lines																															
Wipe Tips With Alcohol																															
Shut Down																															
Flush System Liquid																															
Perform Tips Decontamination																															
Flush Wash Buffer Lines																															
Wipe Tips With Alcohol																															
Clean Tips Wash Station																															
Clean Barcode Reader Windows																															
Empty Waste Container																															
Clean Monitor																															
Weekly Maintenance																															
Back Up Instrument Data																															
Clean System Liquid Channels																															
Clean Liquid Supply Components																															
Clean Buffer Bottles and Lines																															
Rinse Waste Container																															
Clean Deck and Modules																															
PM1 – 6-Month Maintenance																															
Filters Replacement																															
PM2 – Annual Maintenance																															
Professional PM																															
Initials																															

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CHAPTER 9: Troubleshooting

The following section describes some potential errors and gives some assistance locating the cause and possible remedy. If the recommended action does not solve the issue, please contact your service provider for further assistance.

Issue Description	Possible Cause	Recommended Action
Problems Related to Liquid Handling		
Drop at the end of the tip	• Leaky tubing • Bubbles in tubing • Tip collision	• Flush system liquid channels to remove bubbles • If a tip has crashed, is bent, or has a damaged coating, exchange the tip • Clean tip with a 70% ethanol solution moistened lint-free tissue
Liquid detection problems	• Bubbles in tubing • Tubing not fully connected	• Flush system liquid channels • Check connection between tip and terminal
Missing volume in some dispensed wells	• Foam/bubbles in sample or reagent containers	• Remove foam manually
Poor pipetting precision	• Foam/bubbles in sample or reagent containers • Bubbles in tubing • Clogged/dirty system liquid filter	• Remove foam manually • Flush system liquid channels • Clean and/or replace system liquid filters
Problems Related to Liquid Handling		
BCR tool fails to read	• Barcodes not positioned correctly • Barcodes not clean or clear • Barcodes too glossy	• Adjust label so that barcode is positioned correctly • Clean labels or replace them with clean ones • Try reprinting barcodes with a higher print quality • Replace glossy barcodes with matte ones

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