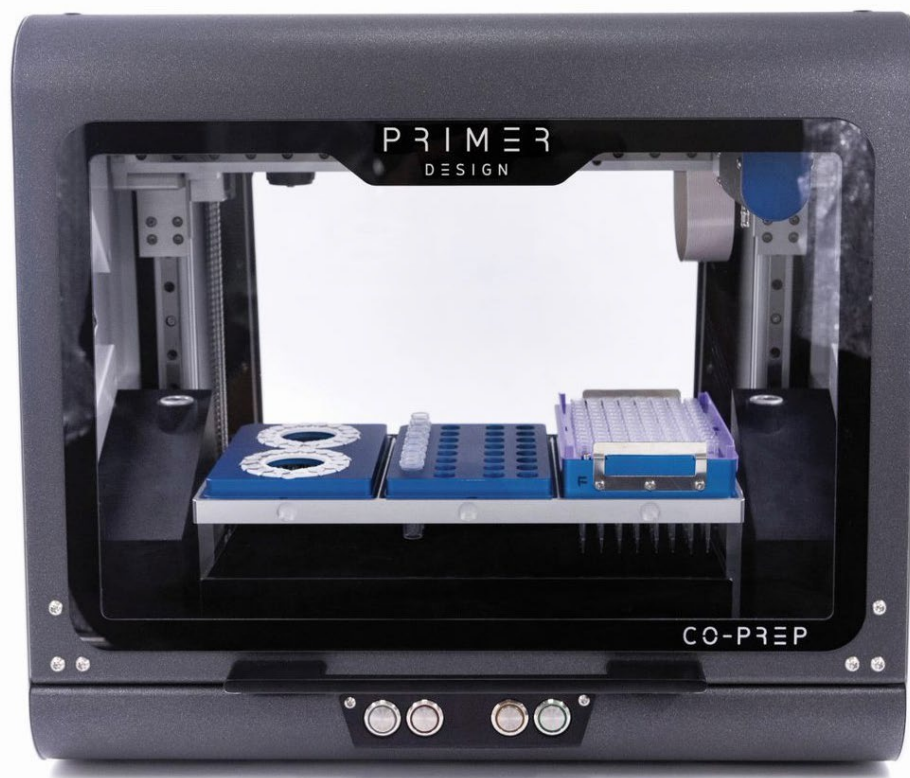


CO-PRÉP

User Manual

CO-Prep™ Automated Liquid Handling System

M00050



Advena Ltd,
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Notices

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Trademarks

The CO-Prep logo is a registered trademark of Novacyt.

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Safety Notices

Detailed safety information is provided in the Safety section. Laboratory users must strictly adhere to the safety guidelines, warnings and notes of caution.

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Introduction

1. Introduction

Please read this user manual carefully before using the CO-Prep™.

The CO-Prep must be operated and maintained using the instructions detailed in this user manual.

About this user manual

This manual provides detailed instructions and procedures that must be followed for the safe and correct operation and maintenance of the CO-Prep. The manual contains the following sections:

[1. Introduction](#)

[2. General description](#)

[3. Safety](#)

[4. Installation](#)

[5. Product overview](#)

[6. Software](#)

[7. Using the CO-Prep](#)

[8. PROmate COVID-19 product range](#)

[9. Accessories](#)

[10. Maintenance](#)

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[Appendices](#)










1.1 Important safety advice

Good Laboratory Practice should be followed at all times using the relevant local and national guidelines.

- ❖ Shock hazards or unsafe practices are dangerous as they can cause severe personal injury, fire or death.
- ❖ DO NOT use combustible substances near hot objects.
- ❖ DO NOT use the equipment in hazardous atmospheres.
- ❖ DO NOT operate or handle any part of the product with wet hands or use on surfaces that may become flooded.
- ❖ NEVER move the product while still connected to the power supply.
- ❖ HIGH TEMPERATURES ARE DANGEROUS as they can cause serious burns to operators and ignite combustible material.
- ❖ Users are responsible for wearing appropriate personal protective equipment to protect themselves against hazardous agents. Gloves, made of the appropriate material, should be used to avoid injury from direct contact with hazardous materials (biological and chemical hazards)
- ❖ NEVER lift or carry the instrument until it has been switched off.
- ❖ DO NOT position the unit so that it is difficult to disconnect from the mains supply using the mains plug.
- ❖ The mains socket used should be located close to the equipment and readily identifiable and accessible to users.
- ❖ The unit should be carried using both hands, and any risk of personal injury must be avoided by following the appropriate Manual Handling procedures.
- ❖ Do not interfere with the safety interlocks.

1.2 Symbols on the CO-Prep

The warning symbols alert the user to important information about using the instrument.

Symbol	Location	Details
	Front of the instrument	This instrument uses a UV light source. Do not look directly at the light source
	Front of the instrument	Caution must be taken when using and maintaining the instrument
	Back of the instrument	Service only Disconnect the UV light source. Do not remove the covers unless you are a qualified service representative. Disconnecting the UV source is a service engineer task only.
	Back of the instrument	Caution must be taken when using and maintaining the instrument
	Back of the instrument	FCC mark of the United States Federal Communications Commission
	Back of the instrument	Waste Electrical and Electronic Equipment (WEEE)
	Back of the instrument	Consult user manual
	Back of the instrument	CE mark for European Conformity
	Back of the instrument	UK Conformity Assessed (UK CA)



Back of the
instrument

Serial Number



Back of the
instrument

Part Number / Catalog Number



Back of the
instrument

In vitro Diagnostic Medical Device

Other labels

The Serial Number label can be found on the machine.

1.3 Symbols used throughout the manual



Warning



UV radiation hazard



EU Authorized Representative

A chassis number can be found on the base plate (back right of the instrument)

The main power control board (PCB) number (top left)

1.4 Technical assistance

Novacyt is dedicated to providing the highest quality support to all customers that use our products. Our technical experts can advise and solve technical issues that may arise. Our technical support team can be contacted by email (techsupport@primerdesign.co.uk) and by telephone [+44(0) 2380 748 830].

1.5 CO-Prep user requirements

The CO-Prep must only be operated by trained personnel. Personnel must already be trained in potential laboratory risks and hazards. Depending on the sample type used with the CO-Prep, the appropriate laboratory hazard training must have been carried out prior to using the CO-Prep. Personnel must also be trained to use computerised equipment and automated devices.

Only a person who is qualified and aware of the hazards involved should be responsible for any adjustments, maintenance, and repair of the CO-Prep.

Both operating and service personnel must employ a safe system of work at all times, follow the detailed instructions specified in this manual.

1.6 Policy statement

Primerdesign, part of Novacyt, reserves the right to change specifications at any time.

1.7 Warranty policy information

The CO-Prep has a 12-month manufacturer warranty.

Other than for those items defined in the maintenance procedures herein, there are no user-serviceable items in this instrument. Removal of covers and attempted adjustment or service by unqualified personnel will invalidate the warranty and may incur additional charges for repair.

In warranty conditions

For any instrument repairs, the following is covered:

1. All parts and labour are covered for any in warranty claims, except for the following conditions:

- a) The instrument has been abused by the customer, such as fluid spillages, misuse, or extreme neglect.
 - b) Any unauthorised service intervention or tampering of the instrument prior to any claim without the explicit instruction by the manufacturer.
 - c) The above exceptions may incur additional charges, and the customer/distributor will be notified before any repairs are carried out.
2. The customer/distributor will be responsible for shipping costs to Novacyt, and any return shipping will be at the cost of Novacyt.
 3. Instruments repaired under original warranty will be covered under a Repair Warranty that will expire on the later of:
 - a) Three months from the shipment of the repaired instrument, or,
 - b) The original warranty expiration date.
 4. If the customer wishes to not proceed with any repairs after any additional charges have been incurred, a processing fee will be charged to cover our investigation and diagnostic costs up to that point.

Out of warranty conditions

For any instrument repairs, the following is covered:

1. Instruments repaired out of original warranty will be covered under a Repair Warranty that will expire on the later of:
 - a) 12 months from the shipment of the repaired instrument, for the subsystem repaired, and,
 - b) Three months from the shipment of the repaired instrument, for all other parts.
 - c) If an instrument comes back for repair which has been tampered with or misused, additional charges may be incurred, the customer/distributor will be notified of any charges and must be agreed prior to any repairs being carried out.
 - d) If the customer/distributor wishes to not proceed with any repairs, a processing fee will be charged to cover our investigation and diagnostic costs up to that point.

2. Shipping costs will be responsible by the customer/distributor to Novacyt for the repair and return costs unless agreed prior to any work being carried out or predetermined agreements in place.

1.8 Intended use of the CO-Prep

CO-Prep is an automated liquid handling platform which is intended to be used to automate the pipetting stage required when using the PROmate® COVID-19 assays for the genesig® q16 or genesig® q32 qPCR instrument platforms. It will transfer 5 µl of sample from a 2 ml tube into a 0.1 ml vial. The product will also be able to track the sample identification from sample barcodes through to the handover to the genesig® software.

The CO-Prep is to be used with trained healthcare/public health professionals (i.e., one of the ten health and social care professional bodies that are overseen by the professional standards authority) and suitably trained and assessed as competent lab technicians or scientists in a healthcare or medical laboratory setting.

General description

2. General description

This section contains the following topics:

- [2.1 Instrument description](#)
- [2.2 CO-Prep instrument specifications and functional parameters](#)
- [2.3 Pipette module specification](#)

2.1 Instrument description

The CO-Prep Automated Liquid Handling System is a liquid handling system with a single pipetting channel, full X,Y and Z encoded movement with three deck positions. The CO-Prep has been optimised for use with PROmate® COVID-19 assays.

The CO-Prep liquid handling system utilises a 5 µl fixed volume pipetting module. The CO-Prep is only compatible with specific robotic pipette tips.

CO-Prep is controlled via a standalone Windows tablet or laptop with dedicated software(s) and applications.

This equipment is designed to operate under the following conditions:

- ❖ For indoor use only
- ❖ Use in a well-ventilated area
- ❖ Ambient temperature range 5°C to 40°C (41°F to 104°F)
- ❖ Altitude to 2000 m (6500 ft)
- ❖ Relative humidity not exceeding 80%
- ❖ Mains supply fluctuations not exceeding 10% of nominal
- ❖ Overvoltage category II IEC60364-4-443
- ❖ Pollution degree 2 IEC664
- ❖ Use with a minimum distance all round of 200 mm (8 inches) from walls or other items

2.2 CO-Prep instrument specifications and functional parameters

Drive Design	Stepper motor-driven linear actuator with a high-resolution optical encoder for step loss detection
Compatible Chemistries	<ul style="list-style-type: none"> • PROmate® COVID-19 (1 gene) (catalogue no: D00068) used with genesig® q16 instrument (catalogue no: Z-genesig-q16) • PROmate® COVID-19 (1 gene) (Catalogue no: D00070) used with genesig® q32 instrument (catalogue no: Z-genesig-q32)
Run Time	Approximate values
Automated setup of 14 samples and negative control per q16 magazine	Less than 6 mins
Automated setup of 30 samples and negative control per q32 magazine	Less than 12 mins
Physical Characteristics	
Weight	16 kg (without accessories)
Dimensions	Width 421 mm (452 mm with tip waste containers) Depth 405 mm (includes a front handle at 30 mm) Height 365 mm (door closed) Height 598 mm (door open)
Power Requirements	Supply voltage/frequency: 100–240 V AC at 50 to 60 Hz 3 Amps External Power supply: 24 V DC, 6.75 A
Connectivity	Network (Ethernet port or Wi-Fi)

Direct standalone mode (Wi-Fi)

Software

genesig Software Compatibility genesig q16 version 2.10 or higher
or
genesig q32 software version 1.5 or higher

Requirements for device required OS Windows 10 Home/Professional
to operate the CO-Prep

Memory 4 GB Ram

Storage 60 GB SSD

Processor Intel® Core™ m3 or above

2.3 Pipette Module Specification

Specifications and Functional Parameters

Drive Design	Stepper motor-driven linear actuator with a high-resolution optical encoder for step loss detection
Dispense speed	Pump volume 5 µl: 100 µl/second
Volume Resolution	Pump volume 5 µl: 0.0047 µl per microstep
Operating Noise	< 60 dBA
Operating Temperature	15°C to 40°C (59°F to 104°F)
Operating Humidity	20 to 95% RH at 40°C (104°F)
Media Temperature	15°C to 40°C (59°F to 104°F)
Pipette Tips	Tecan 50 µl filter tips, which can be ordered via Novacyt (No. A00551 CO-Prep Validated filter tips) Thermo Fisher Scientific 50 µl filter tips (Fisher Scientific UK Product Code 16495939)
Pipetting Volume	Fixed 5 µl
Systematic Error	+/- 0.125 µl
Random Error	+/- 0.075 µl

Safety information

3. Safety information

Please read this information carefully before installing, using this equipment or performing any maintenance procedure on the CO-Prep.

1. The unit described in this manual is designed to be operated only by trained personnel. Any adjustments, maintenance, and repair must be carried out as defined in this manual by a person qualified to be aware of the hazards involved.

2. It is essential that both operating and service personnel employ a safe system of work, in addition to the detailed instructions specified in this manual.

3. Other than for those items defined in the maintenance procedures herein, there are no user-serviceable items in this instrument. Removal of covers and attempted adjustment or service by unqualified personnel will invalidate the warranty and may incur additional charges for repair.

4. References should always be made to the Health and Safety data supplied with any chemicals used. Generally accepted laboratory procedures for the safe handling of chemicals should be employed. Do not use hazardous or flammable substances in the instrument.

5. If it is suspected that safety protection has been impaired in any way, the unit must be made inoperative and secured against any intended operation. The fault condition should immediately be reported to the appropriate servicing authority.

6. The warning symbol alerts the user to important information about using the instrument. Read and follow the associated instructions carefully.



7. This instrument uses a UV light source. Do not look directly at the light source.



8. **WARNING:** If the equipment is not used in the manner specified, the protection provided by the equipment may be impaired.

9. Do not replace the detachable mains leads with inadequately rated leads.
10. Do not exchange the external 24 V DC power supply unit for an alternative or similarly rated power supply unit.
11. Do not use Network Cables or USB cables longer than 3 meters in length.
12. The CO-Prep contains moving parts. Guidance from the Provision and Use of Work Equipment Regulations 1998 (PUWER) must be followed.

Installation

4. Installation

This section contains the following topics:

- [4.1 Unpacking the machine](#)
- [4.2 Installation](#)

4.1 Unpacking the machine

Remove all packaging from the CO-Prep.

Note The instrument weighs 16 kg.

Ensure the following items are included:

1. 1 x CO-Prep Automated Liquid Handling System
2. 1 x 24 V 6.75 A external power supply unit
3. 1 x Mains Power leads UK
4. USB drive containing the software application and the user manual
5. 1 x Left Hand Tip Waste Container and Lid
6. 1 x Right Hand Tip Waste Container and Lid
7. 1 x Calibrated Pipette Module (5 µl pipette)
8. 1 x Robotic Tip Adapter (fitted to pipette module)
9. 1 x Setup plate for q16
10. 1 x Setup plate for q32
11. 1 x Target plate for q16
12. 1 x Target plate for q32
13. 1 x Cradle for use with Setup plate and Robotic Tip Rack Adapter
14. 1 x Robotic Tip Rack Adapter
15. 1 x Calibration Tool (for service use only)
16. 1 x Tip Adapter Tool (for service use only)

Please contact Novacyt if any item components are missing.

4.2 Installation

The CO-Prep is supplied ready to use.

The unit should be placed on a clean flat surface that is free from draughts and vibrations. The AC plug is the electrical safety disconnect device and should be easily accessible, easily recognisable and identifiable. Do not position the unit so that it is difficult to access the mains ON/OFF switch.

Do not position the product so that it is difficult to disconnect from the mains supply using the mains plug.

The mains socket used should be located close to the unit and be readily identifiable and accessible to users.

The unit and its power supply are not intended for use in environments outside of the specified conditions.

The unit should only be used in an environment with a temperature range of 5 to 40°C and maximum relative humidity 0 to 80% for temperatures up to 31°C, decreasing linearly to 50% at 40°C. When the instrument is used for the first time or moved to a different environmental temperature, it is important to allow the instrument to equalise to the ambient temperature. Therefore, allow the unit to stand for 2 hours before switching it on.

The supplied AC/DC external power supply unit is designed for operation on 100 V AC to 240 V AC input at 50 to 60 Hz and outputs 24 V DC 6.75 A. Select the power lead and attach it to the power supply unit. Connect the power supply unit to the power inlet socket on the rear panel of the instrument and connect to the mains socket. The AC Supply should have an earth connection.

Ensure that the sample deck is empty before turning the power on at the mains and switching the instrument on using the power switch on the rear of the instrument. A central blue LED will illuminate on power-up. The instrument will perform several power-on tests and calibration before displaying solid white status LED.

WARNING: Leaving a tip on the pipette module or objects in the sample deck could result in failure of the power-on tests.



Product overview

5. Product overview

This section contains the following topics:

- [5.1 Rear panel](#)
- [5.2 Front panel](#)
- [5.3 Powering up, running and shutting down the instrument](#)
- [5.4 Tip waste](#)
- [5.5 Pipette module](#)
- [5.6 Front door](#)
- [5.7 Deck](#)
- [5.8 Gantry](#)
- [5.9 Illumination](#)
- [5.10 UV light](#)
- [5.11 Replacing the UV Source \(only included with the service\)](#)

5.1 Rear panel

Figure 5.1 shows the rear panel on the instrument:

- Network Port, \geq Cat 5 network cable, \leq 3 m in length
- Dual USB port allows connection to USB devices or peripherals. This connection is not currently used in this configuration, but any USB cable used must be \leq 3 m in length
- Rocker Switch allows the unit to be powered on or off. Powering off requires initial shutdown on the front of the instrument
- Power in socket connection for external AC/DC power supply unit
- Instrument serial plate

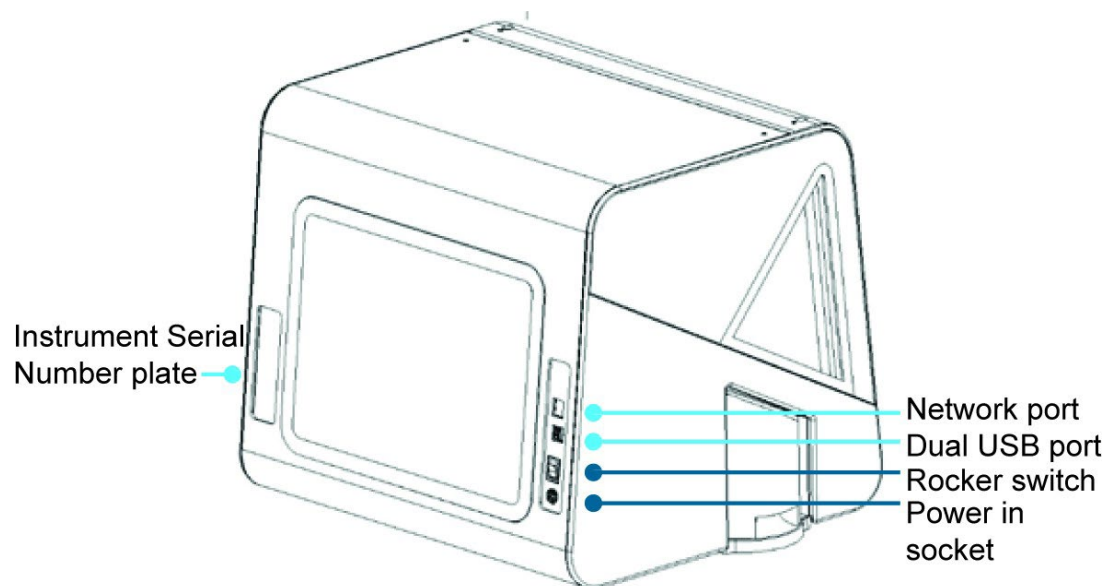


Figure 5.1 Rear panel of the CO-Prep

5.2 Front panel

Figure 5.2 shows the front panel of the instrument:

- White Status LED/Button
- Red Alarm LED/Button
- Blue Power Status LED
- Amber Pause LED/Button
- Green Resume LED/Button
- Door (vertical travel)
- Door handle
- Tip Waste Compartment (one either side)

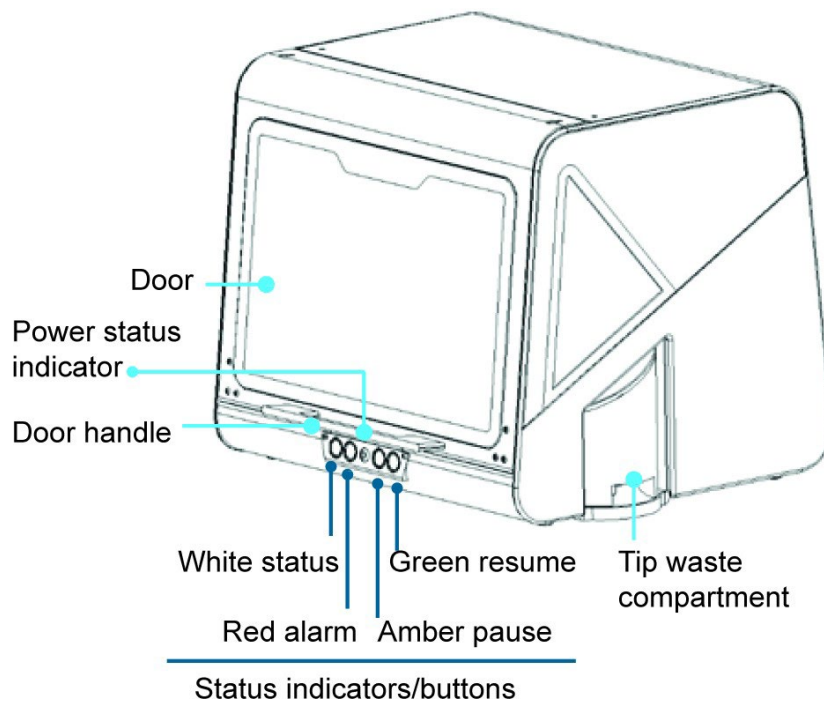
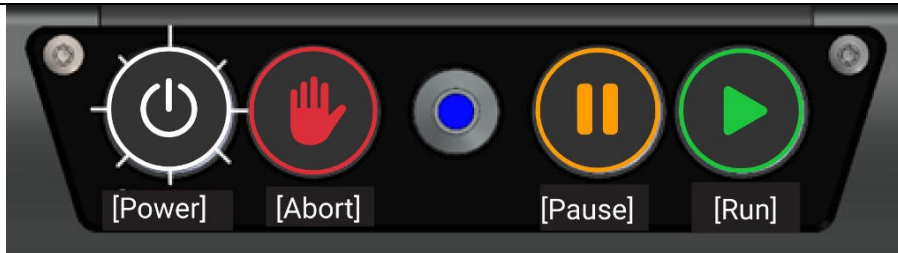


Figure 5.2 Front panel of the CO-Prep

5.3 Powering-up, running and shutting down the CO-Prep

To switch on the instrument, press the power switch located at the rear panel of the instrument (see Figure 5.1).

Instrument power-up – initialising and self-checks



- Blue LED illuminated – denotes power at all times
- All buttons are off for 30 sec during initial power-up
- White button flashes, and internal white light will also flash

Running the instrument



Once initialisation is complete, all lights will be illuminated

Shutting down the instrument

- Press and release shutdown button. White light (both button and internal light in instrument) will start to flash, then extinguishes when shut down is complete
- Blue LED will stay illuminated, switch off the instrument completely using the Rocker Switch, located at the back left of the instrument. When fully switched off, no lights are illuminated.

5.3.1 Home screen

The CO-Prep cannot function without first installing software. See [section 6](#) for details.

The home screen on the software (Figure 5.3) provides access to:

- Sample queuing and sample set up
- Running samples (tasks)
- Change pipette module
- Load the deck
- View run history
- UV light function
- System settings

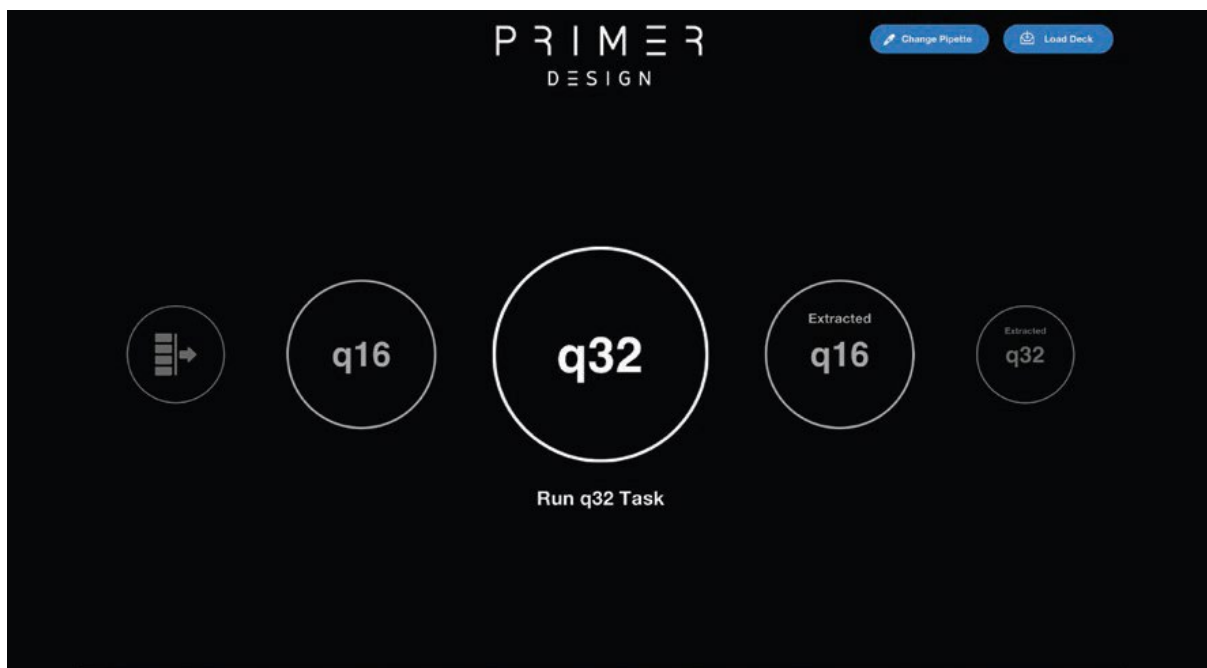


Figure 5.3 Home screen

5.3.2 Settings screen

From the "Settings" the connection to the device can be established (Figure 5.4).

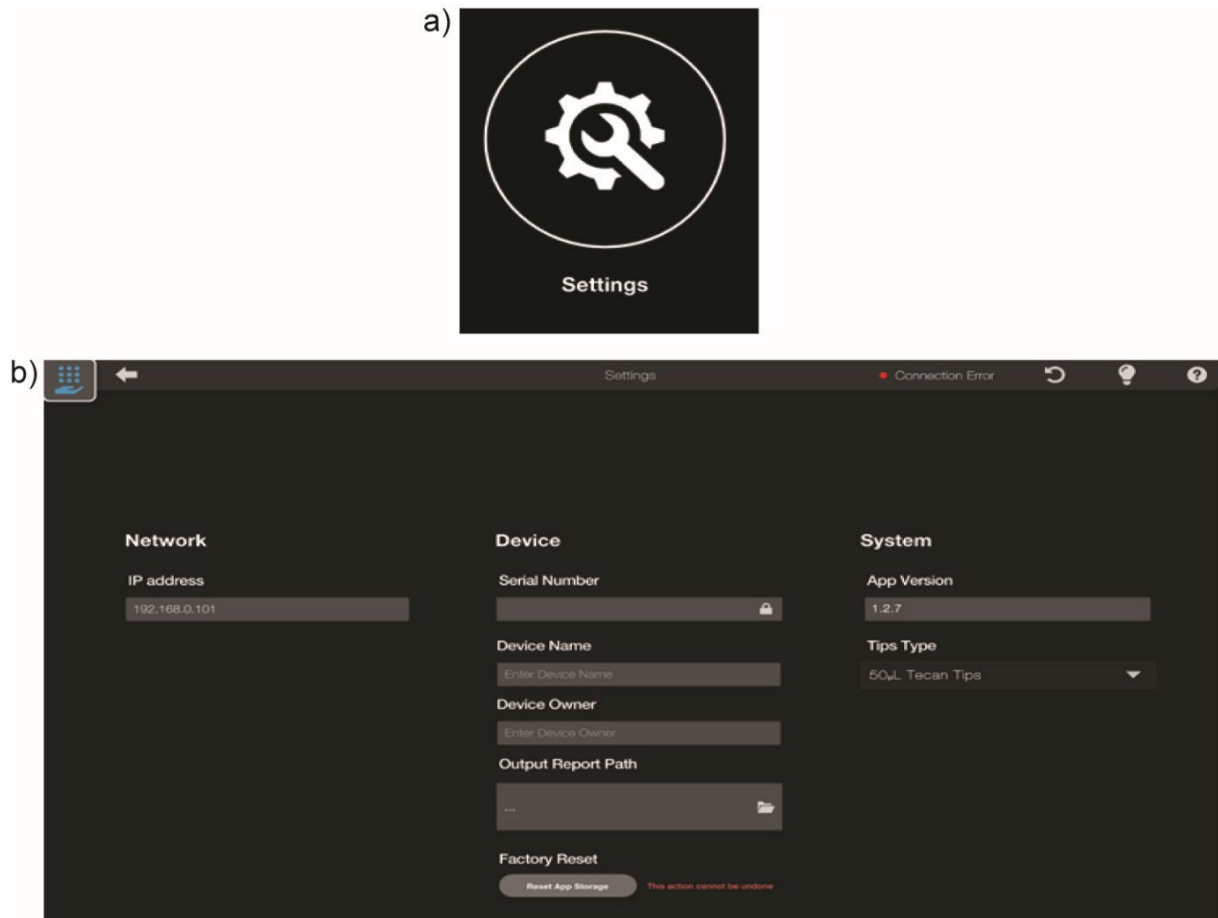




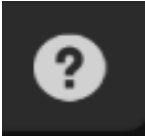
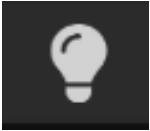
Figure 5.4 Settings screen

a) Settings icon b) Screen for CO-Prep device and software details

WARNING: The "Settings" screen also has a factory reset button. This reset option cannot be undone when this option is selected, and the run history cannot be restored.



5.3.3 Other icons on the screen

Icon	Function
	Return to home screen icon:
	Return to the previous screen
	Help function
	Switch ON/OFF the white light source

5.3.4 Run history

Details of previous runs can be viewed in History (Figure 5.5a). This contains information (Figure 5.5.b) on:

- Run history – date and time of the run
- Sample plate ID
- Target plate (magazine ID) with a unique run ID number and details (number of samples in the run).
- Any UV light cycles performed during the lifetime of the instrument
- Reports can be generated by selecting files located on the individual rows in the "Run History". The files can then be exported and saved as text files.

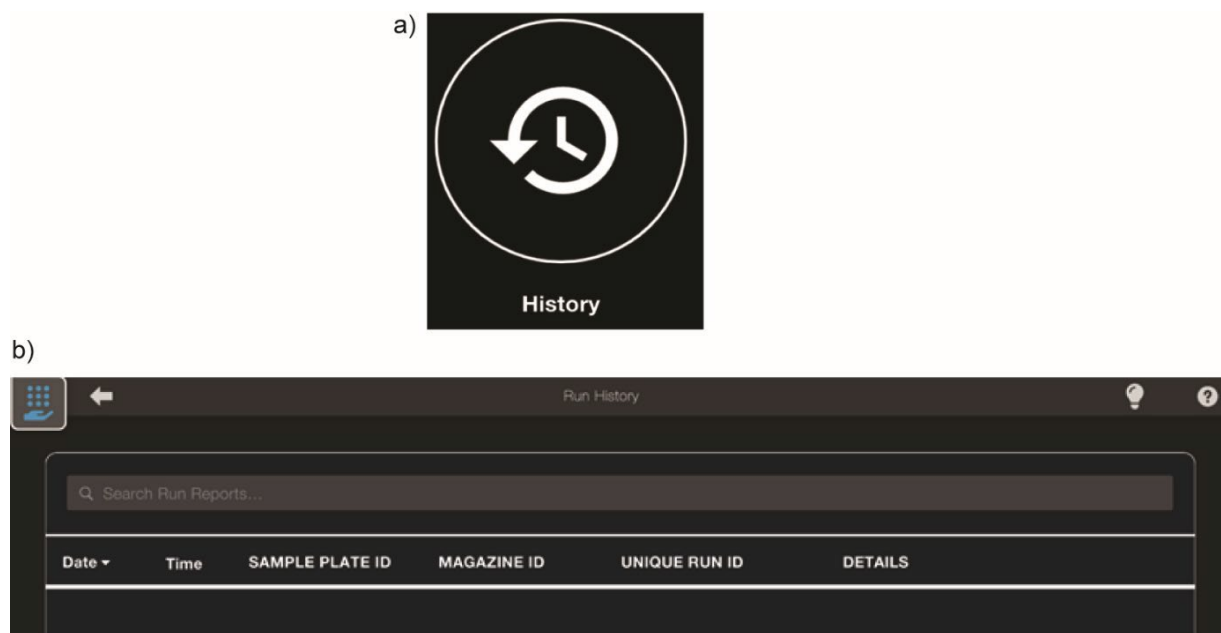


Figure 5.5 Run history

a) History icon b) Run history screen used to enter sample details

5.4 Tip waste

The instrument contains two tip waste compartments (Figure 5.6). The default tip waste compartment is on the left-hand (LH) side. The right-hand (RH) side is a mirror part/assembly, not used in the current PROmate workflow.

Both the LH and RH tip waste containers must be engaged at all times.

Insert a disposable liner if required. Secure the tip waste lid on the top of the tip container. Insert the container into the corresponding tip waste aperture on the side of the instrument.

The system does not have a physical level monitoring feature. Therefore, tip waste container must be inspected. The tip waste container should always be emptied before it reaches its maximum capacity. We recommend emptying after every run of 28-30 samples.

The tip waste container is a potential biological or chemical hazard. Caution must be exercised when emptying the liquid and tips waste. Follow local and national guidelines for the appropriate disposal of potential biological or chemical hazards.



The tip waste container and lid can be cleaned with soapy water. It must then be treated with 10% bleach (minimum of 5 minute contact time), rinsed with water and dried before placing back into the instrument.

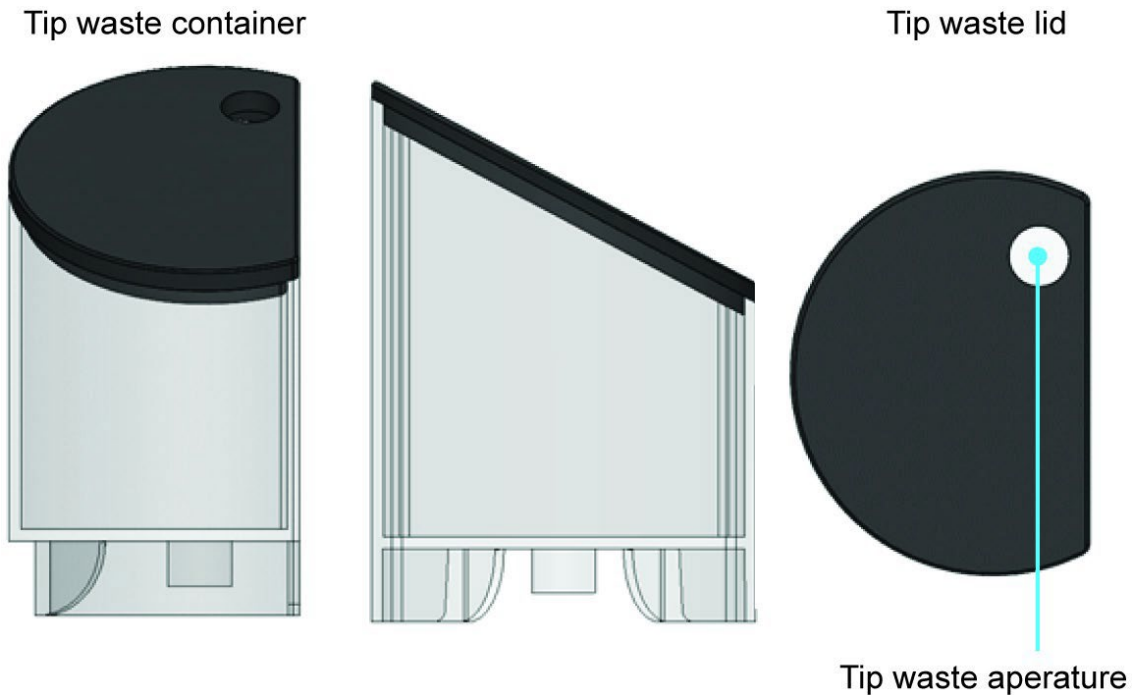


Figure 5.6 Tip waste

5.5 Pipette module (first time set up only)

The instrument utilises one pipette module (Figure 5.7). The pipette module is demountable for servicing and simply slides into the pipette bracket on the gantry. When fully inserted, the pipette module engages with the electrical system to provide power and communications.

The CO-Prep contains a fixed 5 µl pipette module, which is not installed when the unit is shipped. Please unpack and slide it into place before first use.

The pipette module cannot be tampered with, should not be altered in any way and should not be taken apart.



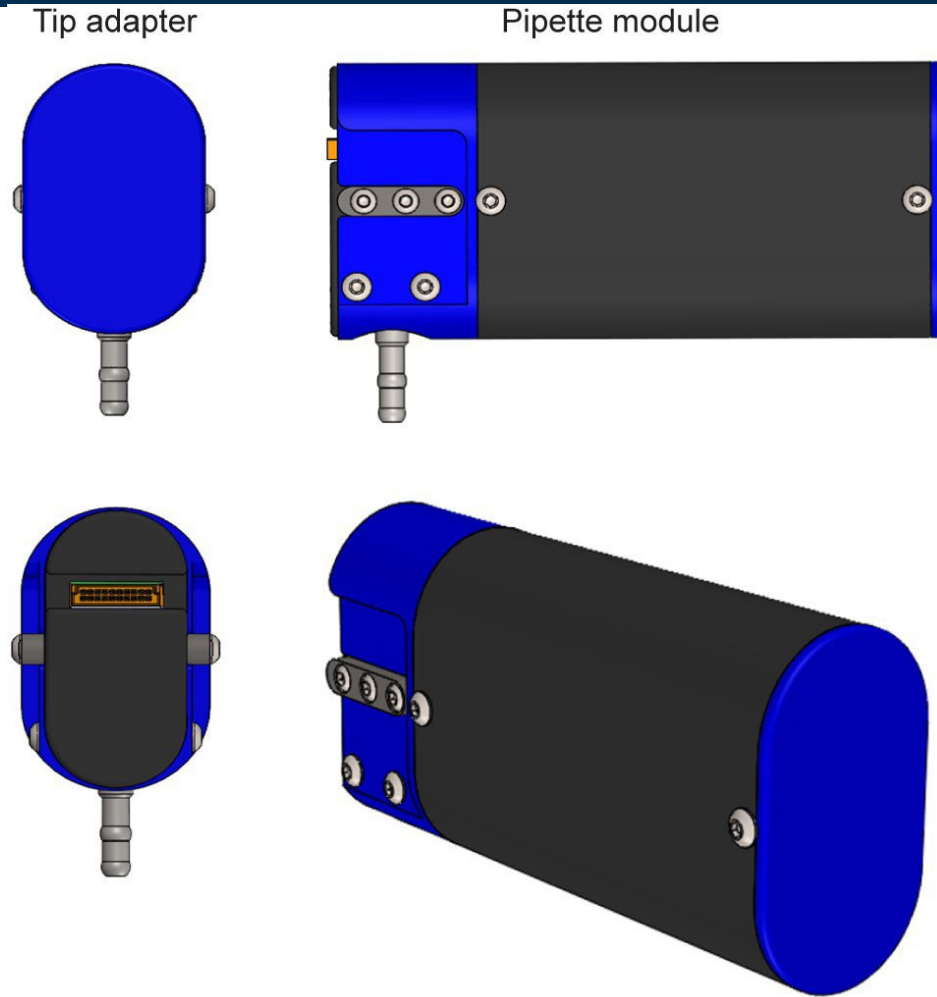


Figure 5.7 Pipette module

5.6 Front Door

The door (Figure 5.8) utilises both a logic level switch and an electrical interlock switch. These should not be tampered with, removed or adjusted in any way. The logic level switch is an active component in managing the deck status on standby and during a task. Opening the door during the run will pause the run, which will resume upon closure of the door. When a task is not running, opening the door brings the deck forward, and the deck will return to the default position when the door is closed again.

The electrical safety interlock is linked to the UV light function and disconnects the power to the UV light source in the event that the door is opened during UV light cycle.

The door moves vertically and is hand operated. Hold the handle centrally and simply lift or lower the door. There are magnetic catches that hold the door securely in either position. The door is free to move between the magnetic catches but has no holding position. The door can only be left up or down, and it must be down to run a task or to perform UV light function (Figure 5.6).

The door is open and fully engaged on the top magnetic catches. When the door is lifted, it immediately disengages the logic level and interlock switches.

WARNING: To avoid personal injury or damage to the instrument, the user must exercise caution when opening and closing the door.

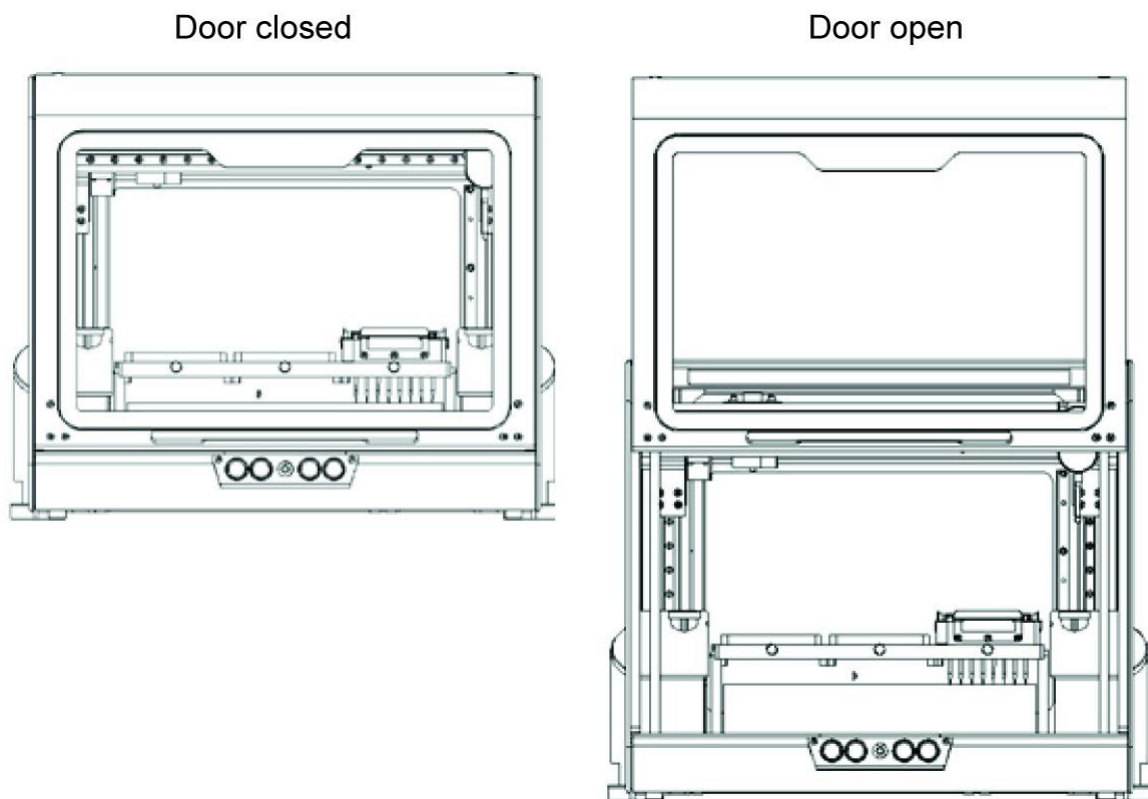


Figure 5.8 Open and closed-door configurations

5.7 Deck

The deck (Figure 5.9) is a moving linear stage (x-axis) within the system that traverses forwards and backwards. The deck will automatically present itself forward for access when the door is opened.

It will return to the last known position when the door is closed.

Whilst the door is open, the deck has force feedback to allow an operator to load and unload objects within the deck. Once the door is closed, the XYZ system will re-home and initialise each axis.

The deck comprises of three zones (zone 1, zone 2 and zone 3). The zones are numbered as labelled in Figure 5.9.

A magnetic slider is positioned at the rear of each zone and produces a force that pushes any object into the opposing front corner of the zone for optimal object positioning. Simply insert an object to the zone by pushing back against the slider; the slider will then push the object forward, securing it in place.

The deck works with the gantry and pipette transblock to provide the full X, Y and Z movement.

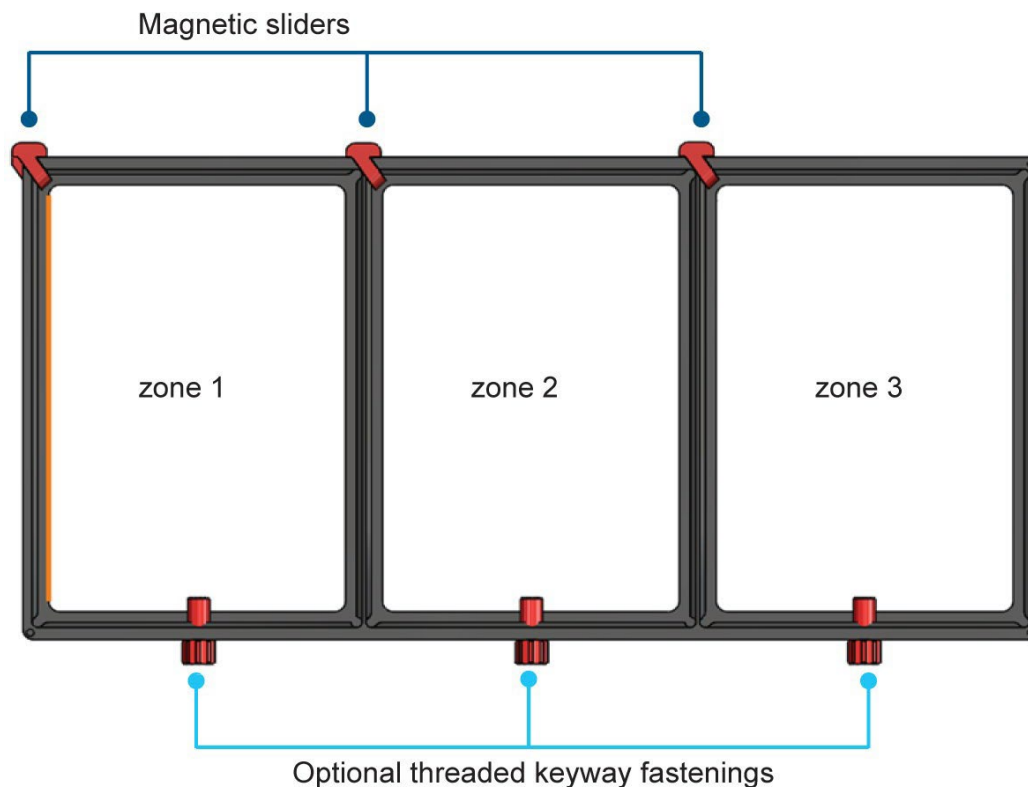


Figure 5.9 Deck

5.8 Gantry

The gantry is a moving linear stage (z-axis) within the system that traverses up and down, as shown in Figure 5.10.

The pipette transblock (y-axis) is positioned on the front of the gantry and traverses left to right.

The gantry and pipette transblock will automatically position itself to provide unobstructed access to the deck when the door is opened. It will return to the last known position when the door is closed.

The gantry and pipette transblock work with the deck to provide the full X, Y and Z movement.

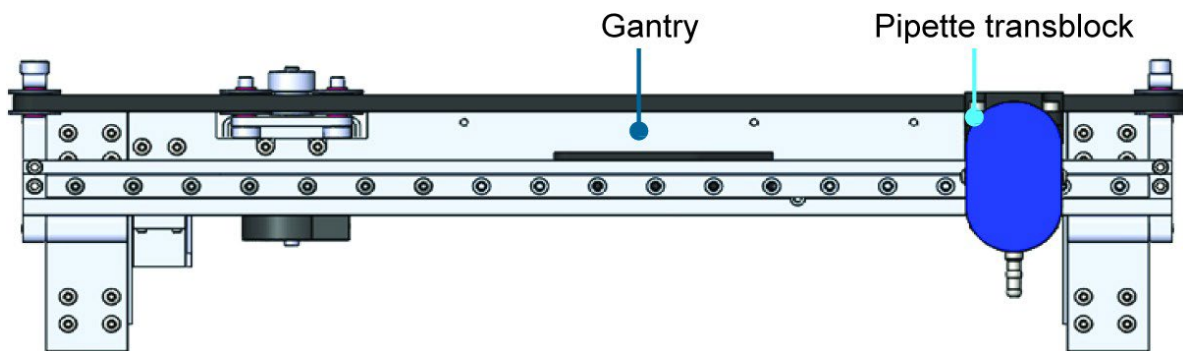


Figure 5.10 Gantry (top view)

5.9 Illumination

This system is equipped with a white light source to illuminate the deck compartment. The white light is on by default following start up, and can be toggled on and off from the software to suit the operators' requirements. Click the "light bulb" icon to toggle.

The white light source will stay on if the door is opened.

CAUTION: As with any white light, the blue light spectrum could cause damage. Do not look directly at any light source.



5.10 UV light

UV Light Safety Information

UV sources produce UV Radiation that will cause rapid, permanent damage to unprotected eyes and skin. Before operating any unit, be sure that all personnel in the area are properly protected. The enclosure is manufactured from a material impermeable to UV light. Safety switches on the doors will instantly turn off the UV sources when the door is opened.



UV light is not a substitute for cleaning the instrument. Please follow the [daily maintenance guidance \(section 10.2\)](#) for cleaning the instrument prior to using UV light as an aid to decontamination. UV radiation is useful in decontamination because of its ability to inactivate biological molecules. The system is equipped with a UV light source that can be used to treat the instrument's interior with UV light to help with decontamination after cleaning. **Note** UV treatment is not a substitute for cleaning. Using the UV lamp treatment alone may not provide sufficient decontamination. Please follow the advice on [daily maintenance tasks](#) in Section 11.2 and check the system for any spillages after every run.

The UV light can be configured to run between 5 seconds–300 minutes 55 seconds. To configure the UV light, navigate to the [UV section](#) in the software. Ensure the deck is clear of all objects, tips and samples. Select the irradiation exposure duration in minutes – press “Run”. The system will automatically complete the process and switch off the UV source at the end. The UV light cycle will be logged in the history for future reference.

If a UV light cycle is interrupted by opening the door, the cycle will be aborted, and the UV source will be switched off. As the deck compartment may have been compromised, a new UV light cycle will have to be initiated.

Note The UV light function should not be activated unless the door is closed and both tip waste containers are fully engaged (left and right side). The UV light function can be operated with the pipette module mounted or demounted.

Also, check deck is clear of all objects before starting the UV light function.

5.10.1 Running UV light function

1. Ensure the CO-Prep instrument is connected ("Ready" will be displayed at the top right of the screen)
2. Ensure the deck is clear of all objects and the door is closed
3. Click on "UV Sterilisation" icon (Figure 5.11)
4. The user can select between 5 seconds and 300 minutes 55 seconds and press "run" to start the UV light process. ((Figure 5.11b).
5. A timer will display. Opening the door will switch off the UV source and pause the timer. This can be resumed after closing the door, but due to the potential for contamination following the opening, we recommend fully restarting the UV decontamination cycle

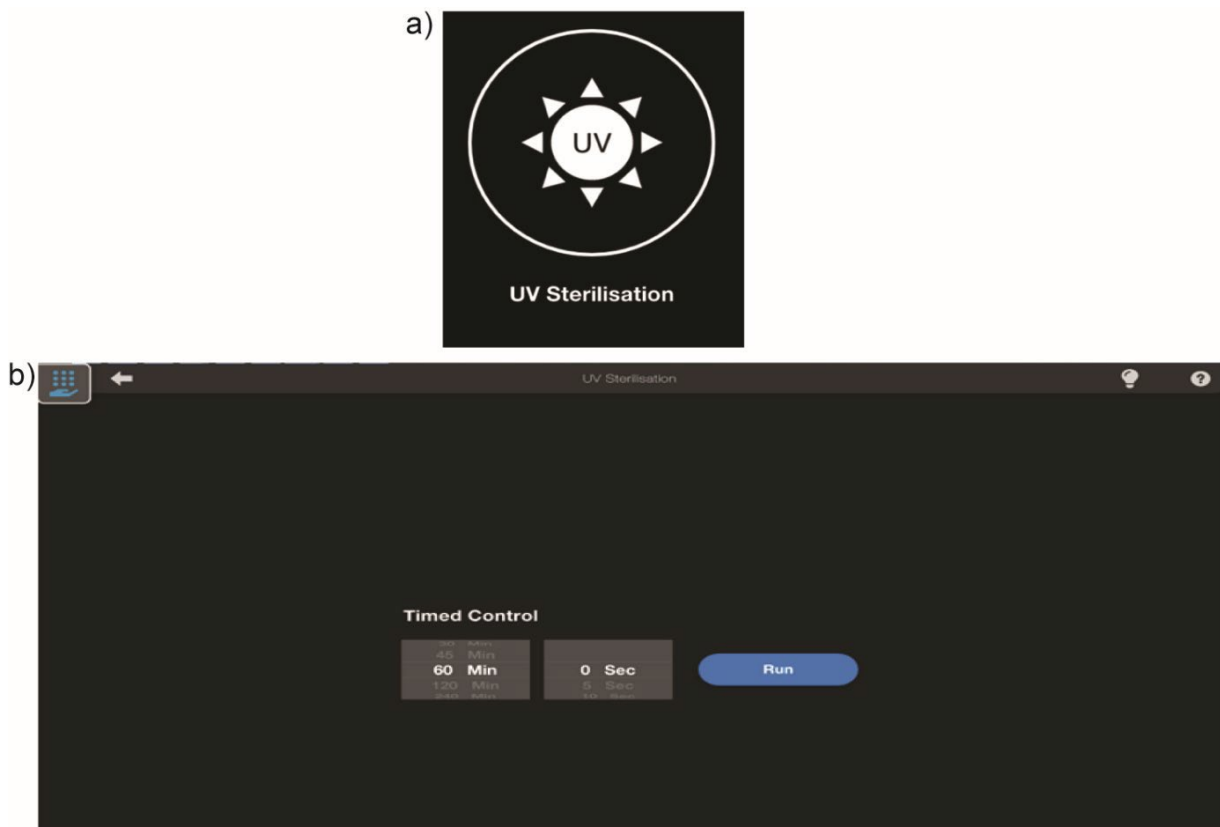


Figure 5.11 UV light function

a) UV icon

b) Screen for light timing the length of UV exposure

5.11 Replacing the UV Source (only included with the service)

Over time, the UV source will diminish in output. It is therefore recommended that the UV source be checked for performance and efficiency. Please use a qualified safety engineer to replace and check the operation of the UV source. The UV source will last the lifetime of the instrument.

CAUTION: The UV source can become hot during use. Ensure that the UV source has cooled down before removing it to prevent injury.



This assembly is designated a service change component by authorised service personnel only. Please email technical support for further details (techsupport@primerdesign.co.uk).

Software

6. Software and applications

This section contains the following topics:

- [6.1 Software installation](#)
- [6.2 Connecting the CO-Prep software output to the genesig software input](#)
- [6.3 Connecting a Bar code scanner \(Zebra DS8108\)](#)

6.1 Software installation

For further advice on software installation, removal and user instructions, please contact technical support (techsupport@primerdesign.co.uk).

Following software download, please install security certificates manually using the following steps:

- Right click on the .cer file that is located with supplied build (example Promate iPrep_0.10.2.0_x64_Master.cer)
- Press “Install Certificate”
- Set Store Location to Local Machine
- Select Place all certificates in the following store
- Browse and select Trusted Root Certification Authorities
- Press “Next”
- Press “Finish”
- Then you can install the app from Novacyt COPREP_1.2.7.0_x64_Master.appxbundle

The CO-Prep is controlled from a touch-driven Windows tablet or Windows laptop running the CO-Prep software. These UI (User Interfaces) enable control of the CO-Prep system. This unlocks the convenience of controlling the CO-Prep whilst sitting or standing at the bench but also allows the CO-Prep to be used within a laminar flow hood.

6.1.1 Webserver Network Configuration and Device Connection

The CO-Prep App can connect to the device in multiple ways.

1. Direct Wi-Fi connection through access point using Device standalone mode (not connected to a network).
2. Connection to a network via LAN cable
3. Connection to a network via Wi-Fi

Note Options 2 and 3 may require knowledge of the network configuration and support from a network administrator to setup.

Options 1 and 2 are recommended.

6.1.2 Connecting on a Network using LAN or Wi-Fi

Connect a LAN cable to the device. The network should assign an IP address to the device using DHCP.

Connect the computer with the CO-Prep App to the same network as the device. Go to the "Setting" page in the App and either directly enter the device's IP address (if known) or press the "Search" button (Figure 6.1).

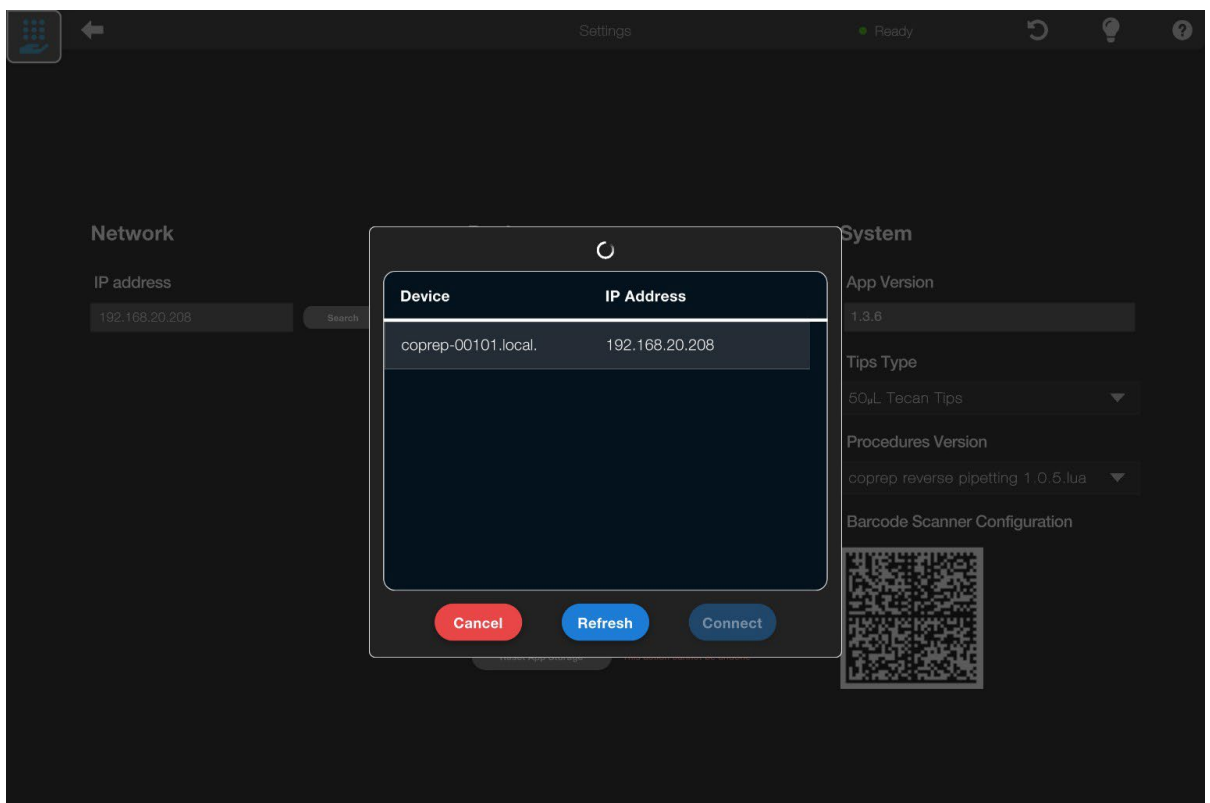


Figure 6.1 Device IP address

Identify the desired CO-Prep by means of its serial number and select it from the list. Press "Connect" to establish a connection to the device. Ensure that connection is established by means of the "Ready" status and green indicator in the menu bar (Figure 6.2).

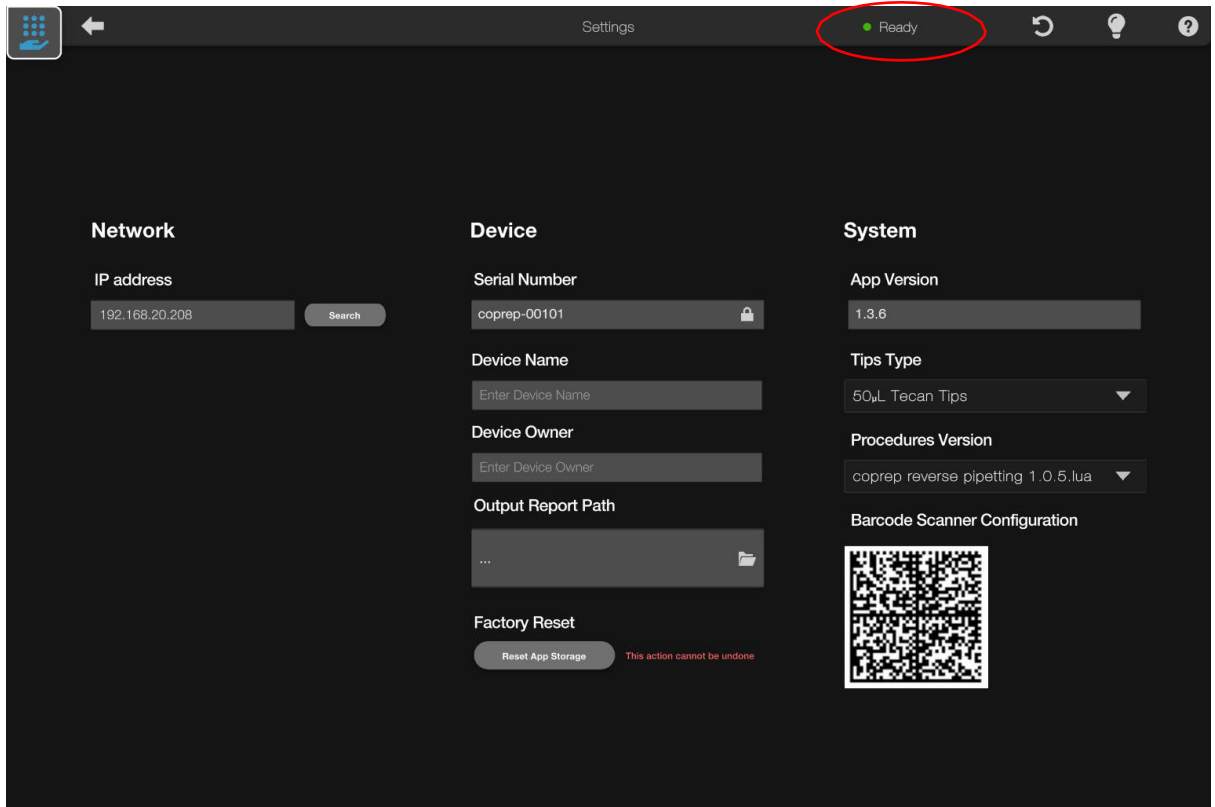


Figure 6.2 Connection verification

The process for connecting to the device via a network using Wi-Fi is identical, although before a connection can be established from the App, the network Wi-Fi setting should be entered from the web server, and standalone mode should be disabled. Refer to the subsequent section for instructions on connecting a network using Wi-Fi.

If, for any reason, the device does not connect to the network, contact the network administrator to ensure the connection is permitted, and the device is not being blocked by network security settings.

6.1.3 Connecting to the device using Standalone Mode and Description of Webserver Settings

CO-Prep devices are shipped with the default Standalone mode to aid initial setup.

When in Standalone mode, the device will broadcast its network SSID and shown in the Wi-Fi list (Figure 6.3).

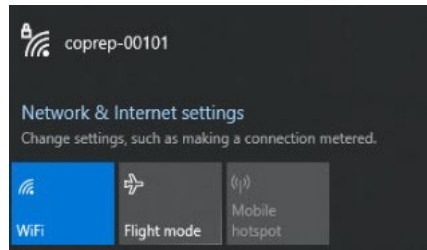


Figure 6.3. Network SSID of the device will appear in the Wi-Fi list

6.1.4 Connecting to the device Wi-Fi

If Wi-Fi is not shown in the list, the device is not in Standalone mode. Standalone mode can be initiated by holding down the amber button on the keypad during device start-up. The Amber button must be held down until the internal illumination LED's start to flash (approximately 30 seconds). Once in Standalone mode, subsequent power cycles of the device will always initiate standalone mode until Standalone mode is disabled from the webserver.

Once connected to the device Wi-Fi, a connection can be established from the App for normal operation, and the webserver can be accessed for configuration. To connect from the App, when in standalone mode, navigate to the settings page and manually enter the following hostname in the IP address field "my.coprep" and press "Enter".

6.1.5 Accessing the webserver

Once connected to the device Wi-Fi, open a web browser, and enter the URL <http://my.coprep:11015>, which opens the device webserver (Figure 6.4).

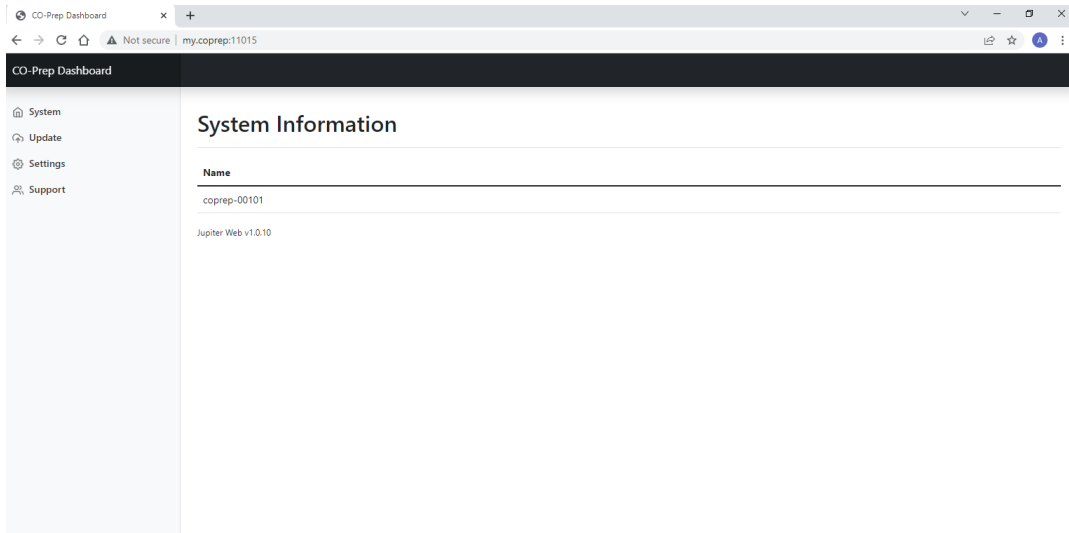


Figure 6.4 System information

The system tab shows the device serial number and web server software version (Figure 6.5). Update tab allows firmware updates – should only be used under manufacturer instruction.

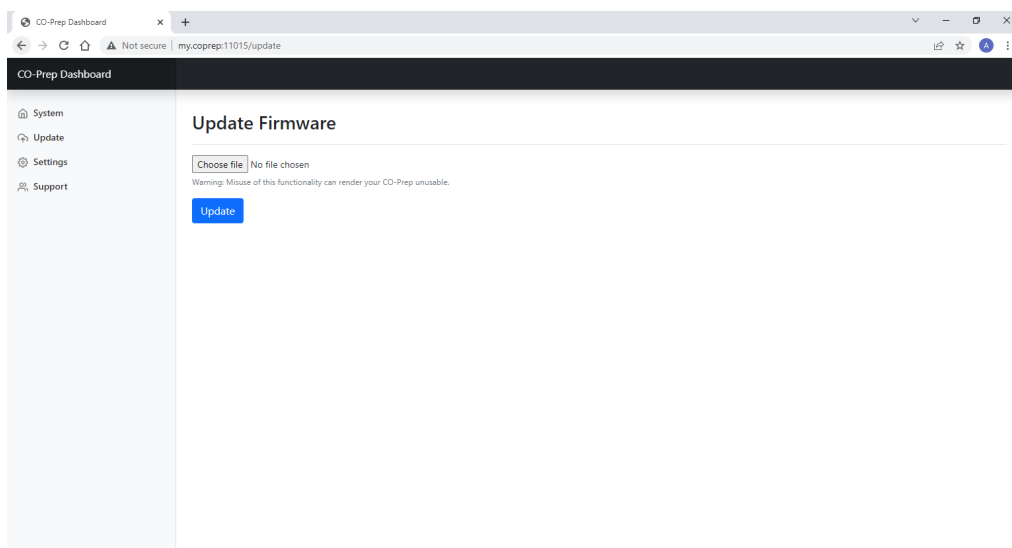


Figure 6.5 Firmware updates

The Settings tab provides the following functions

Wi-Fi connection to network:

To connect the device onto a network using Wi-Fi, enter the network SSID and password, then disable standalone mode. If the network is accessible from the device on the next power cycle, the device will automatically attempt to connect to the network using Wi-Fi. **Note** The standalone mode must be disabled to allow a Wi-Fi connection to a network (Figure 6.6).

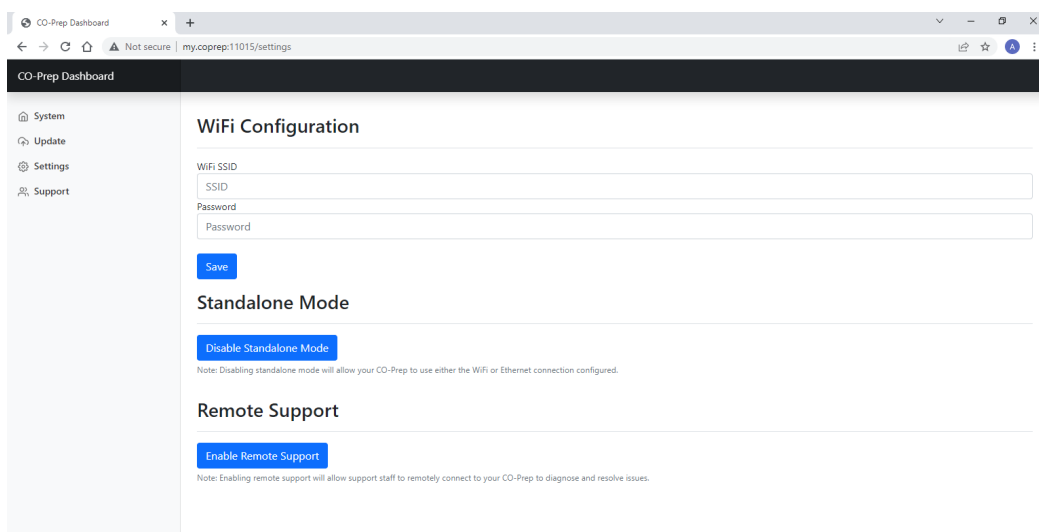


Figure 6.6 Wi-Fi configuration

Disable standalone mode:

Disabling standalone prevents the device from broadcasting its Wi-Fi signal on start up. This mode should only be disabled if the device is connected to a network.

Remote Support:

It is possible for the manufacturer to establish a remote connection to the device to allow the support team to perform diagnostics on the device. This requires the device to be connected to a network with internet access via LAN. Only use this feature when instructed by the manufacturer.

Please email technical support if you require any further assistance with the topics covered in this section (techsupport@primerdesign.co.uk).

The Support tab only contains features required for technical support (Figure 6.7).

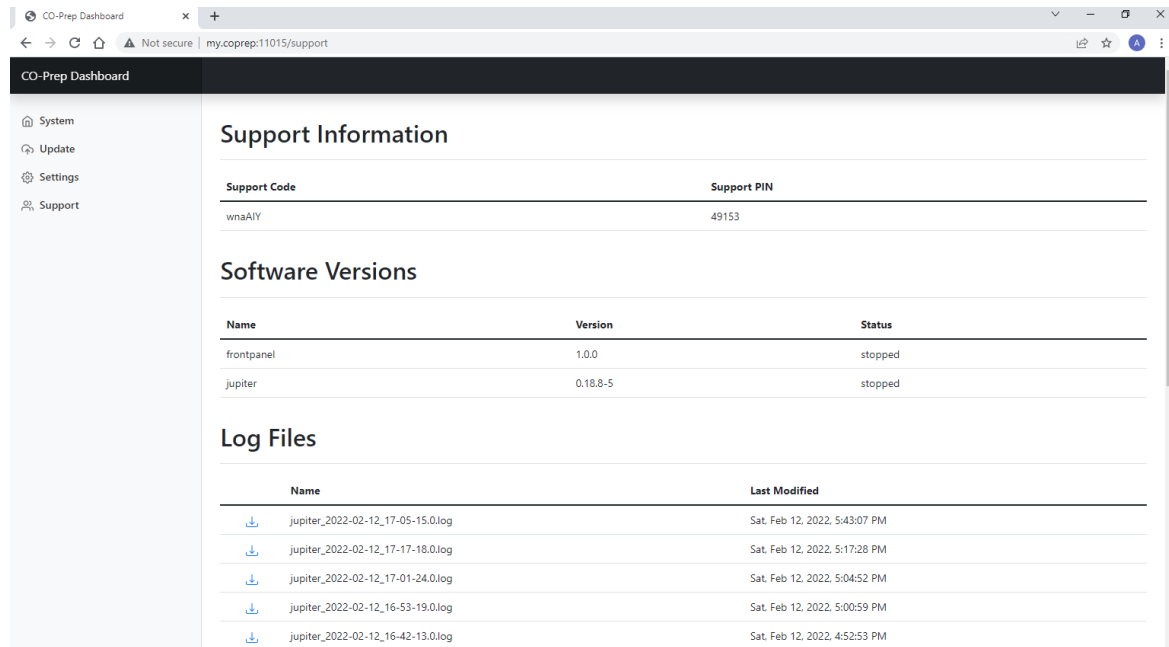


Figure 6.7 Support information

6.2 Connecting the CO-Prep software output to the genesig software input

In order to begin successful setup of the CO-Prep the following software must be installed on the same system as the CO-Prep software:

- genesig q16 PCR software (Version 2.12 or later)
- genesig q32 PCR software (Version 1.5 or later)
- q16-sample-queue

The q16-sample-queue app allows you to create templates with sample IDs ready for genesig q16 software, but in this context the same software creates the workflow for CO-Prep sample processing. An output report from the CO-Prep can be read by the genesig q16 or q32 software in order to populate the run file with sample and plate IDs through a .JSON format data exchange.

Once the q16 sample queue app is installed it will automatically create a ". pecan" folder which will have a "sample-data-queue" folder within it. This will be the location where all the templates run files will be stored, and must be linked to the CO-Prep software:

In the CO-Prep software in the settings screen click on "Output Report Path", click on the folder icon and navigate to the following directory for the file c:\Users\USERNAME\.pecan/sample-data-queue (where USERNAME is replaced with the computer or users ID) and "Select folder". This filepath will then be displayed (Figure 6.8).

The JSON formatted data run files (.samples file extension) can be accessed by the genesig q16 or q32 software. They will be recognised by either rescanning the QR code on the magazine or inputting the plate ID if doing manual input while using the genesig software (see "Setting up the PCR run" in section 7.5). This data file is separate from the .txt file that can be generated following a run (see section 7.4)

The "Device Name" and "Device Owner" sections can be populated by the user.

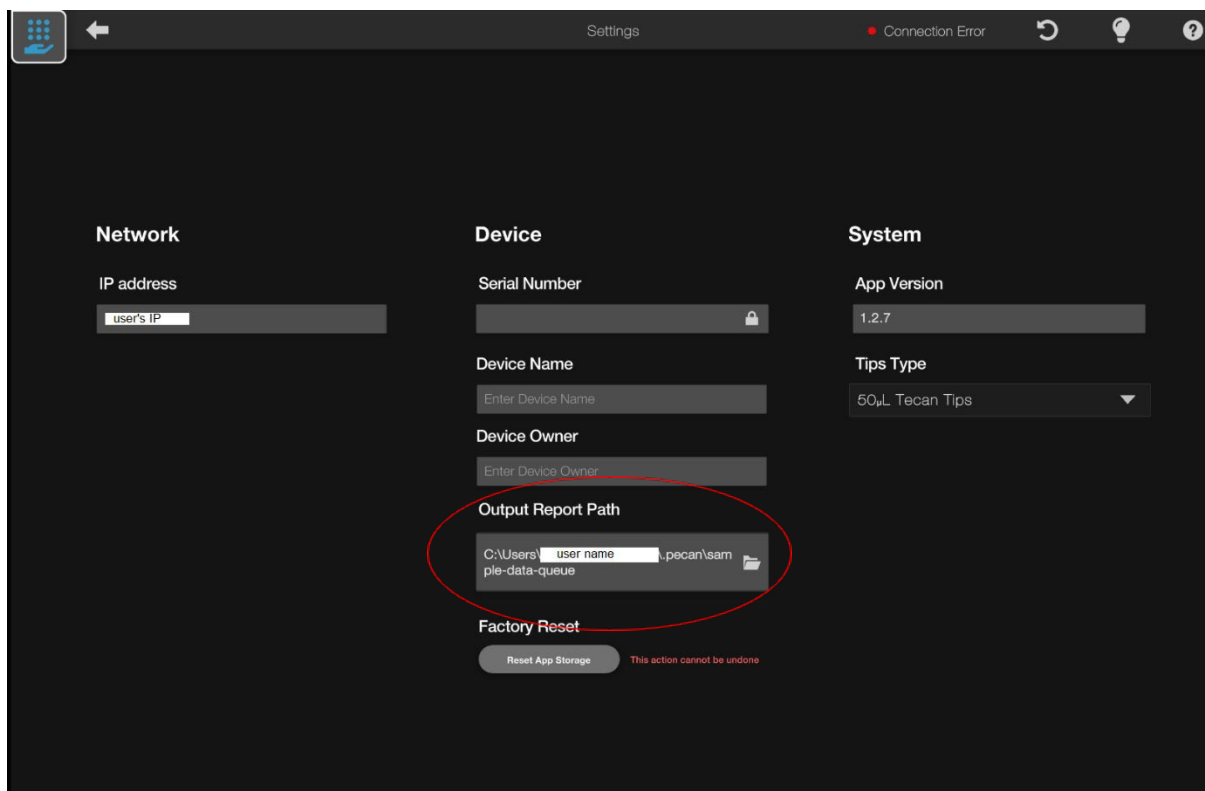


Figure 6.8 Output path

6.3 Connecting a Bar Code Scanner (Zebra DS8108)

To configure the Bar Code Scanner, plug the Bar Code Scanner into a spare USB port and allow it to enumerate.

From the software, open the "Settings" page and select "Bar Code Scanner"

Scan the displayed bar code on the screen. This will automatically update the bar code scanner configuration. The bar code scanner will reboot and then be ready for use.

Using the CO-Prep

7. Using the CO-Prep

This section contains the following topics:

- [7.1 Setting up the deck and workflow flow overview](#)
- [7.2 Setting up the plate and sample IDs \(Direct PROMate workflow\)](#)
- [7.3 Running the CO-Prep tasks](#)
- [7.4 Importing CO-Prep run data into genesig software](#)

7.1 Setting up the deck and workflow overview

7.1.1 Setting up the deck

The CO-Prep is a pipetting platform. A pipette module with the desired volume range is inserted into the pipette transblock. Zone 1 must be loaded with the Target Plate (the qPCR reaction magazine). Zone 2 must be loaded with the Set Up Plate (the inactivated patient samples). Zone 3 must be loaded with the desired pipette tips.

The door needs to be closed for the instrument to operate.

The software provides the interface to program a task or sequence of tasks. These instructions are relayed to the CO-Prep, which will then move a pipette module and tip to a given X, Y and Z position to aspirate a liquid and then move to another X, Y and Z position to dispense or aliquot that liquid with relative precision. The PROmate workflow moves 5 µl of patient sample from the Sample Preparation Buffer tube to the corresponding position on the qPCR magazine. Subsequently, the tip is discarded in the tip waste bin located on the left-hand side of the instrument. Once all patient samples have been processed, the system moves 5 µl of the negative control buffer into the corresponding position on the qPCR magazine.

An optional audible sound informs the operator that a particular task requires the operator to perform an action or that a task is completed. Once a task is complete, the operator can open the door and remove the objects that have been processed by the desired task.

Note: The CO-Prep software has the functionality to work with an extracted workflow from the NC-15 Rapid Automated Extraction System. Separate instructions are provided for use by those labs working to validate the NC-15 workflow.

7.1.2 Workflow overview

The workflow for preparing samples using the CO-Prep and running the samples using the q16/q32 instrument is depicted in Figure 7.1.

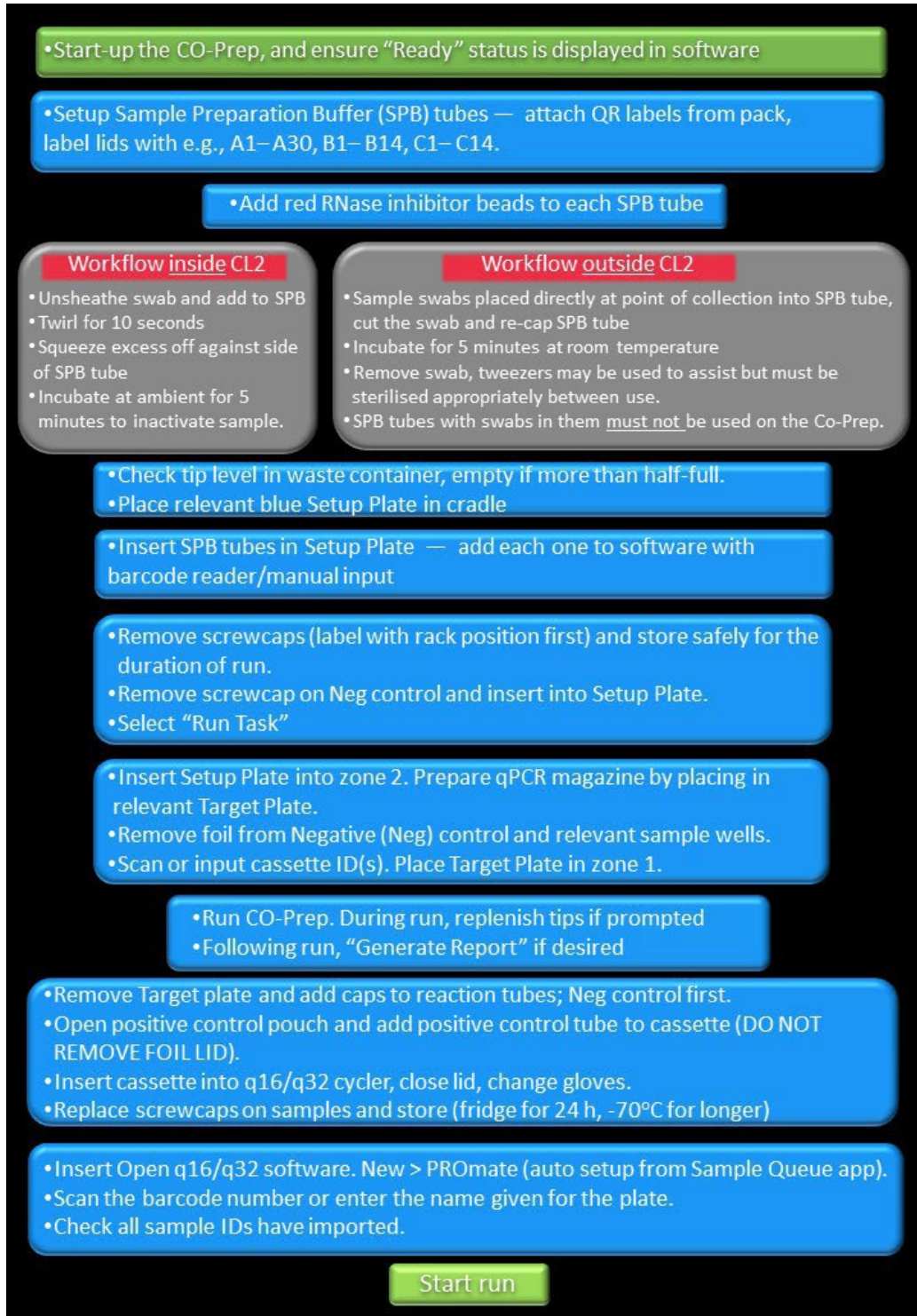


Figure 7.1 Workflow overview

7.1.3 Assay Procedure

A detailed description of the different workflows follows. Users are advised to read the relevant workflow in full before using any consumables and rehearse the workflow in the local setting.

Sections in red text are particularly time-dependent or describe a point in the workflow where there is a risk to the integrity of the samples or controls.

7.2 Setting up the plate and sample IDs (Direct PROmate workflow)

7.2.1. Setting up the plate ID

To start compiling patient samples into a plate layout, select the appropriate workflow using the relevant circular icon (Figure 7.2). Another way to start is within the "Queue" screen, by clicking "+ Add Task to Queue". The user must select the format of the samples (Figure 7.3, Figure 7.4 and Figure 7.5).

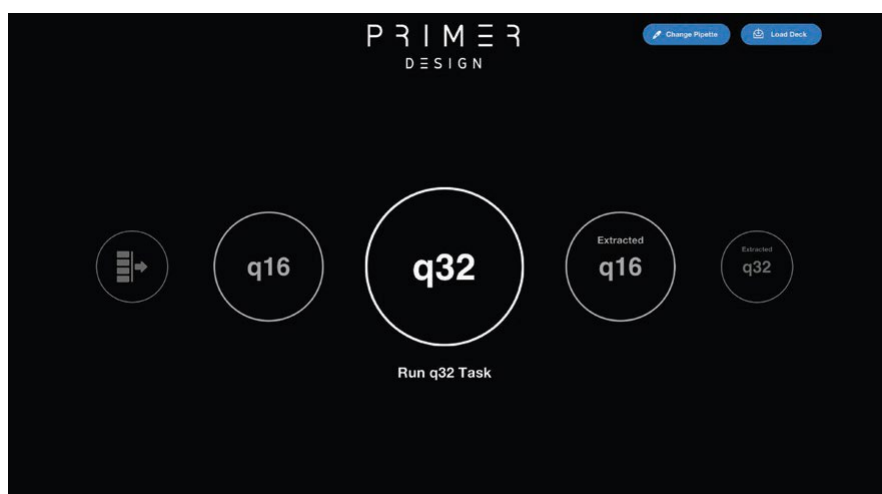


Figure 7.2 Home screen selection of tasks

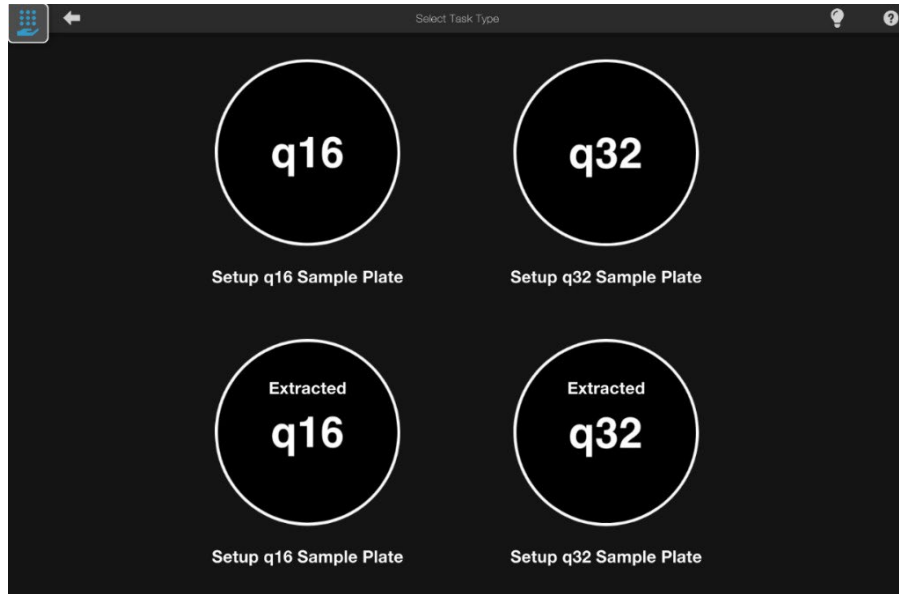


Figure 7.3 Selecting the format of the samples from the Task Queue

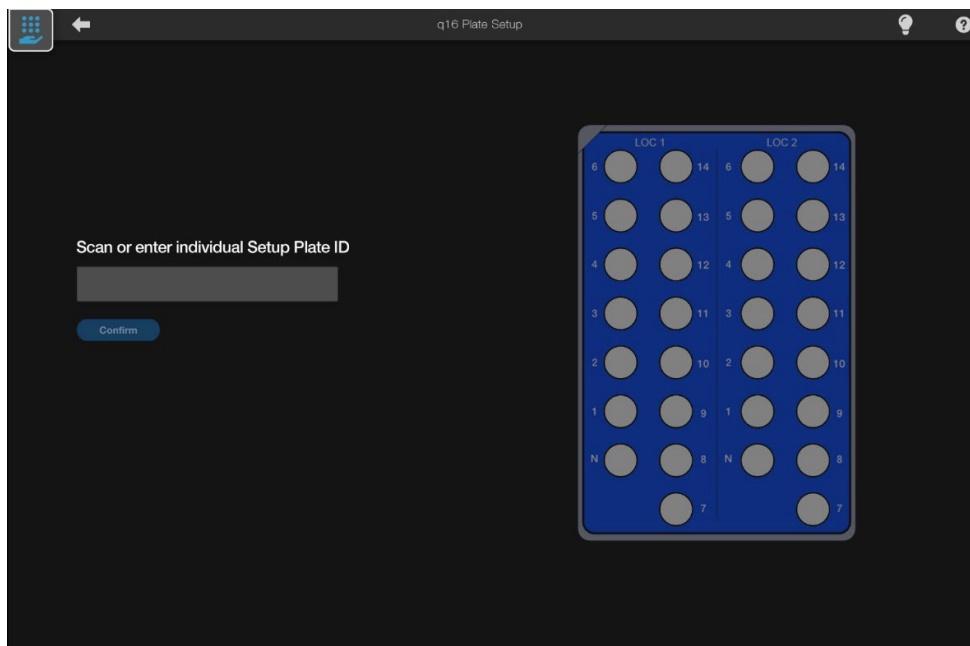


Figure 7.4 q16 plate setup

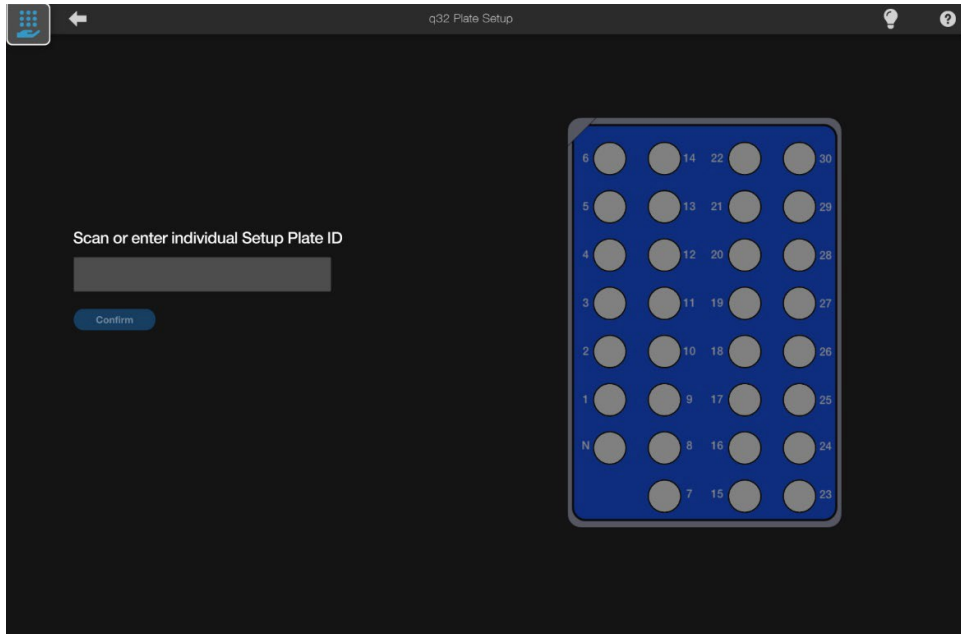


Figure 7.5 q32 plate setup

Once the setup is selected the user can either:

- manually enter a setup plate ID
- or
- use the barcode scanner to scan the QR code on the q16/q32 setup plate,
- A green tick icon will appear to confirm ID accepted.
- Click "Confirm" again to progress with setting up the sample plate (Figure 7.6).

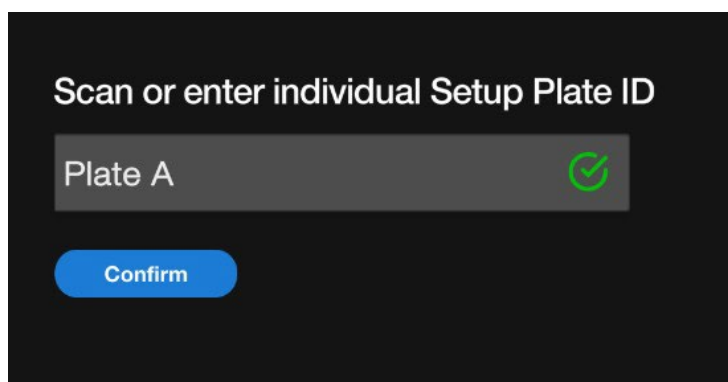


Figure 7.6 Confirmation of plate setup

A warning symbol and explanation will be displayed if a duplicate setup plate ID exists in the Task Queue or if a setup plate is scanned, which is mismatched to the selected workflow. In these cases, the ID will not be accepted (Figure 7.7).

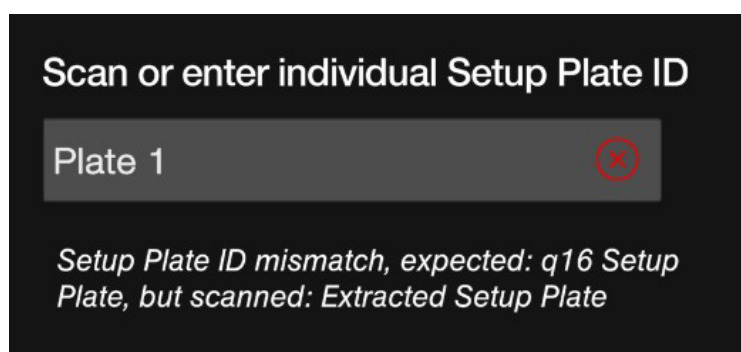


Figure 7.7 Duplicate setup plate warning

7.2.2. Setting up sample IDs

An initial screen will be displayed (Figure 7.8a). **Note** The setup plate on the RHS will change slightly depending on if it is a q16 or q32 task being set up:

- Click "Add Sample" or click on well 1 in the plate to enter the first sample ID (Figure 7.8a).
- Manually enter a unique ID without repeating IDs or use the barcode scanner to scan in the sample ID (Figure 7.8b). Click OK to confirm or cancel to return to the setup screen.
- You cannot leave the sample ID field blank.
- Upon clicking "OK", the user needs to manually confirm that this sample ID is in e.g., position 1 in the LOC 1 side of the plate (Figure 7.9a) and manually place the sample preparation buffer tube into this position in the setup plate.
- **Note** The setup plate should be in the cradle to help insert the Sample Preparation Buffer tubes in the setup plate. Please ensure the tubes are fully inserted, with the collar of the tube meeting the setup plate. Do not force a tube into the plate. If the tube will not fit, it could cause a clash with the pipette tip, so should be replaced by pipetting the sample into an alternative tube. Contact technical support if you have a batch of tubes that do not fit.
- Confirm by clicking on the icon with the green tick (Figure 7.9b)
- The sample position is now confirmed.

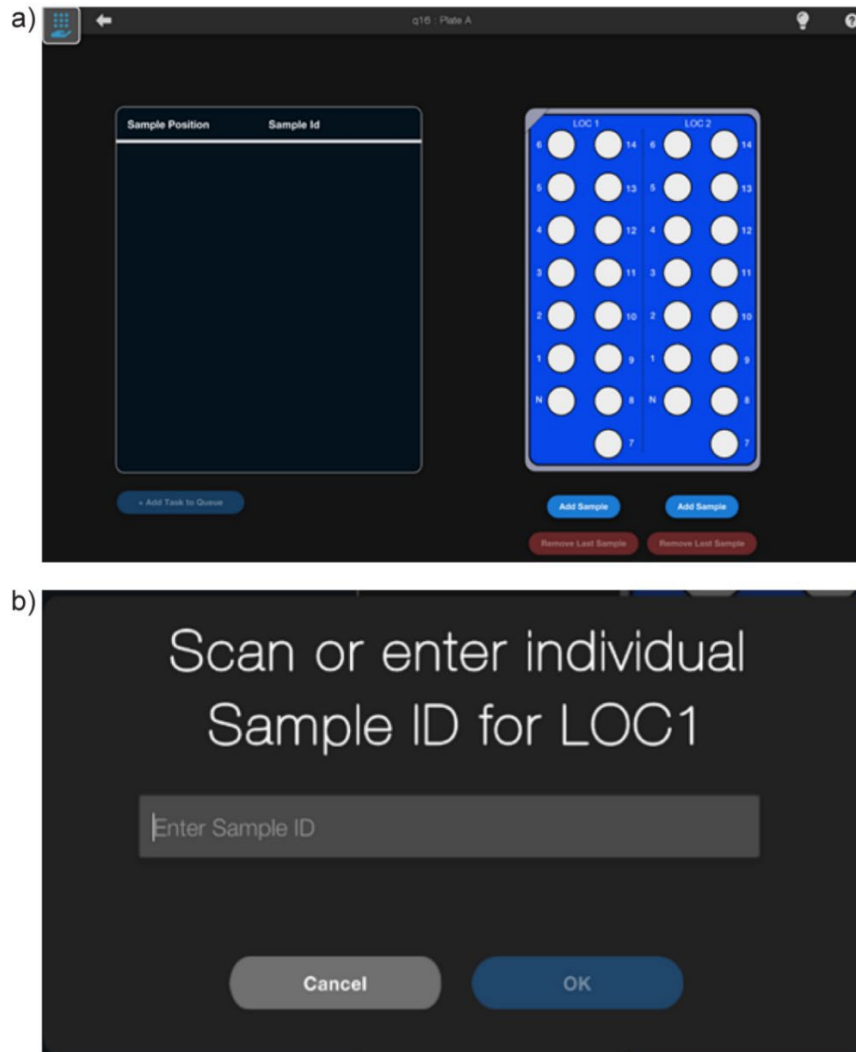


Figure 7.8 Adding sample and entering sample identification

a) Screen for adding in samples.

b) Adding the sample ID.

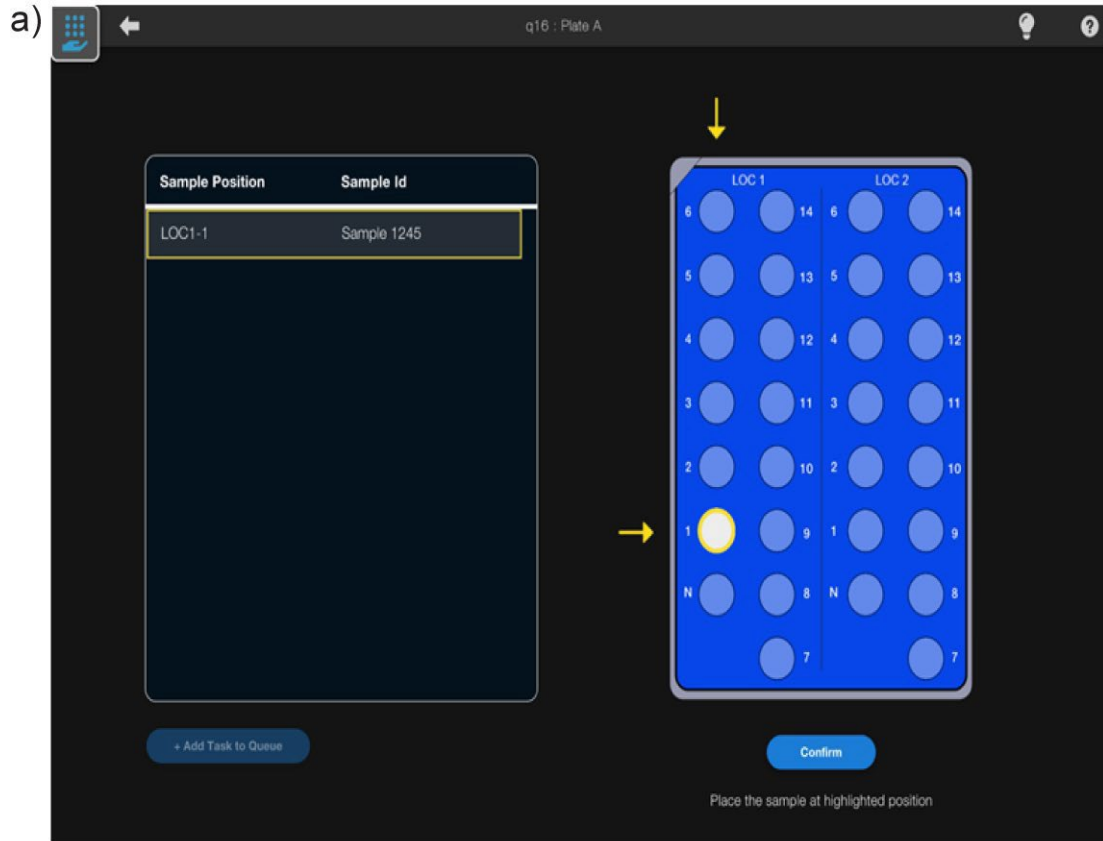


Figure 7.9 Adding sample location

a) Choosing the sample position

b) Confirming the location

7.2.3 Duplicated or incorrect samples

If a duplicate sample ID is entered (Figure 7.10), the following warning will be displayed. Click "OK" to clear the warning message, check the sample IDs and proceed to add the next sample.

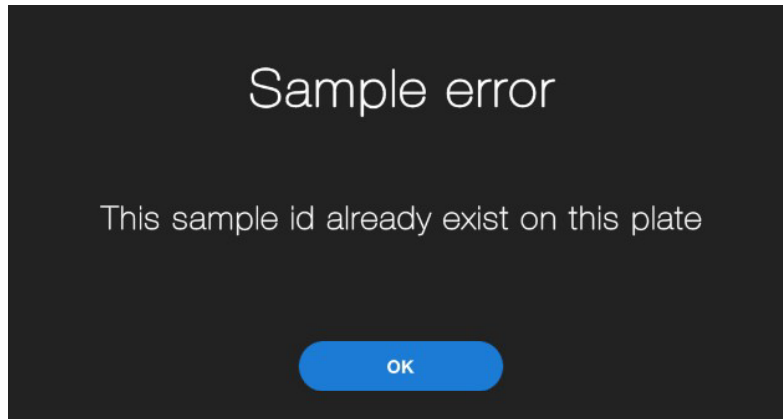


Figure 7.10 Sample duplication error message To

remove incorrect samples:

- If an incorrect sample is entered, click "Remove Last Sample" to remove or exclude that specific sample. This will bring up the screen in Figure 7.11
- Click "Cancel" to return to the sample setup screen
- Click "Remove" to remove the last sample entered
- Once the Sample ID has been inputted, it cannot be edited, only removed.
- Once a well has been excluded, it cannot be overwritten. Instead, it can only be reincluded.

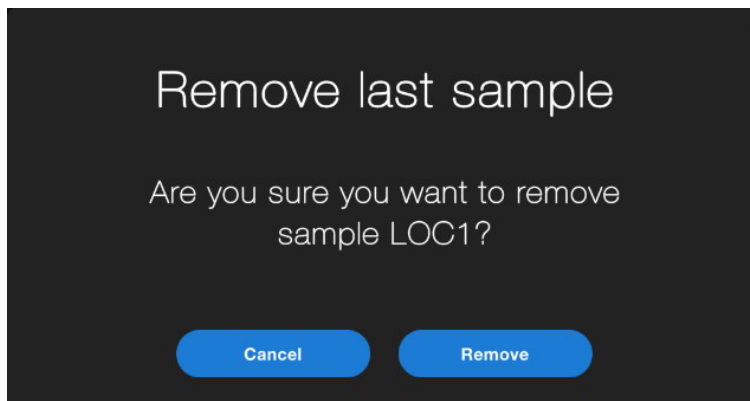


Figure 7.11 Removing samples from plate

7.2.4 Completing the plate setup

To add the completed sample setup to the queue:

- Check that all the required sample IDs have been entered correctly (Figure 7.12)
- Click "+Add Task to Queue" or "Next step" depending on if the setup screen was entered from the Task Queue or directly from the home screen.
- **At this point, the screw cap tubes from each sample can be removed, and the negative control can be inserted into the relevant position(s) in the setup plate, again with the screwcap removed. Insert the plate into zone 2 of the deck, with the negative controls to the left/front of the instrument.**
- **Immediately proceed to section 7.4 of the manual**

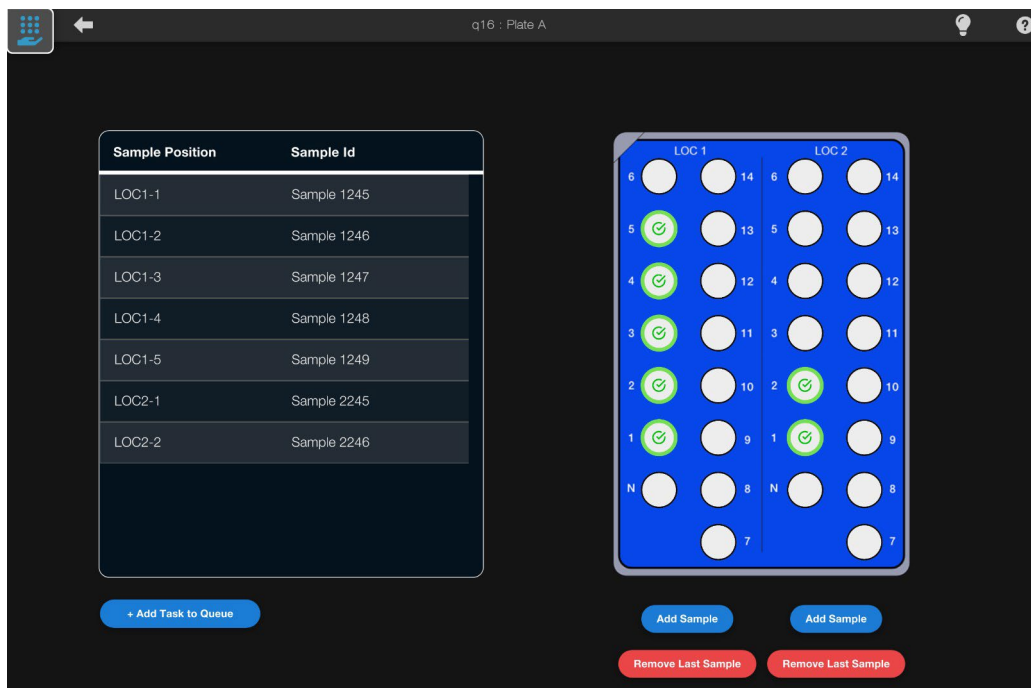


Figure 7.12 A populated sample screen

7.2.5 Deleting a sample plate

To delete an entire sample plate from the Task Queue:

- Select "Next Step" or "+Add task to Queue"
- Select the option "Delete Sample Plate" (Figure 7.13). This will delete all the entered samples and plate from the task queue
- If you click on "Delete Sample Plate", a warning message will be displayed (Figure 7.14)
- Click Cancel to return to the previous screen. Click Delete to confirm deletion of the sample plate, and it will be removed from the task queue.

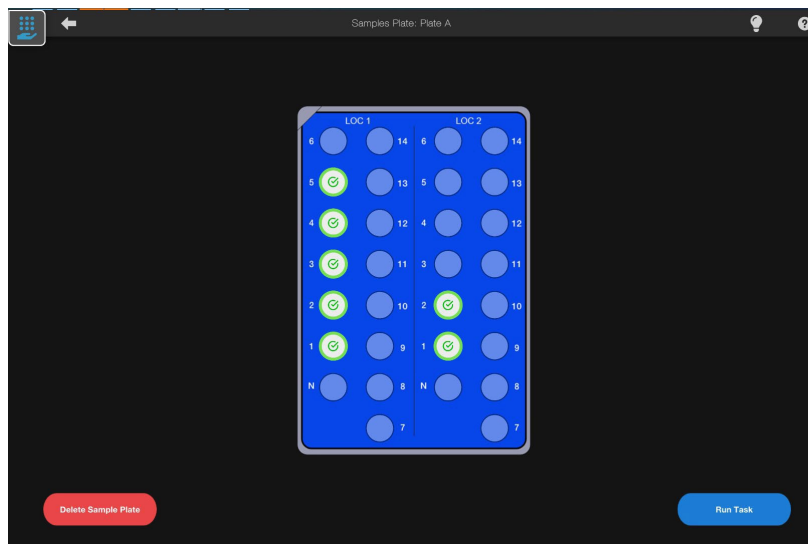


Figure 7.13 Deleting a sample plate

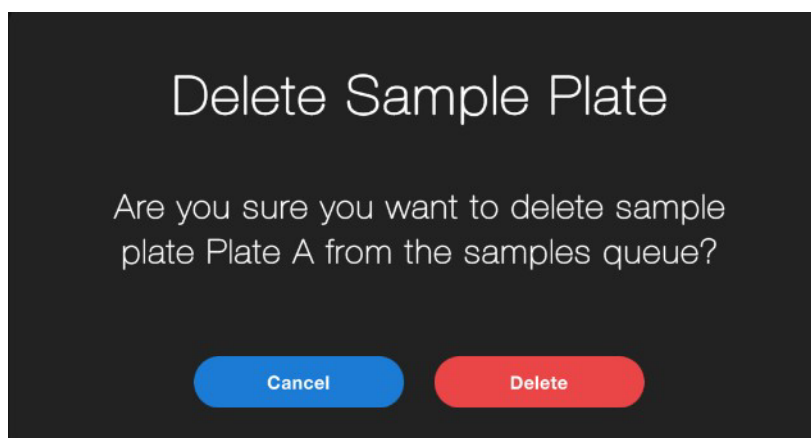


Figure 7.14 Warning message for the confirmation of sample deletion.

7.3 Running the CO-Prep tasks

7.3.1 Running tasks

CO-Prep tasks can be run directly following the completion of the plate setup (by pressing “Run Task”) or by selecting the task from the Task Queue list.

At this point, you will be prompted to enter the Plate ID as established in section 7.2.1 (Figure 7.15 and Figure 7.16). This has to be the same information entered previously, or you will receive an error message (Figure 7.17).

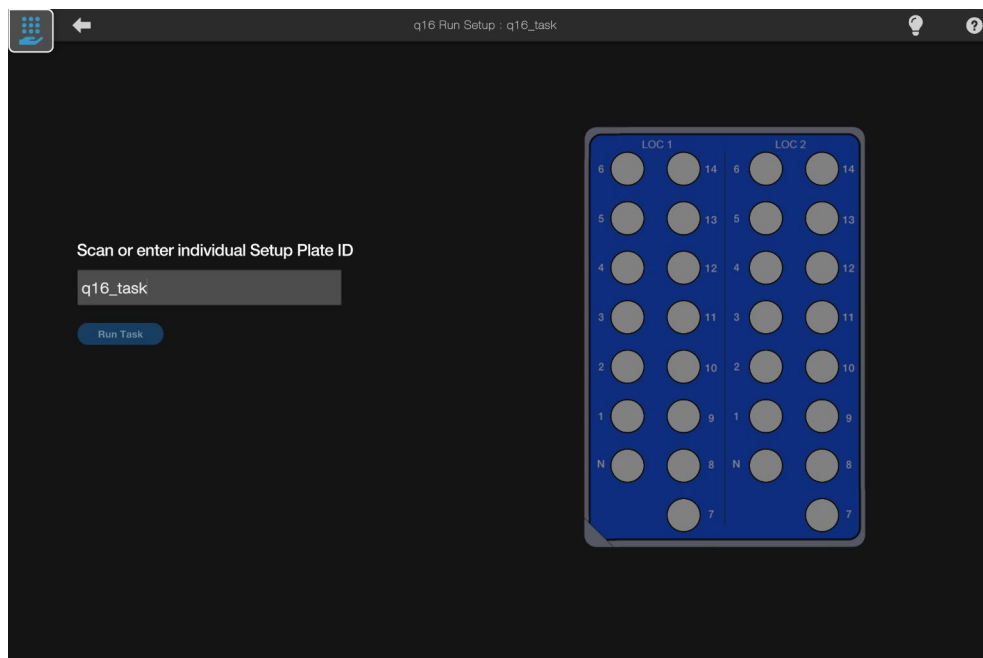


Figure 7.15 Entering the plate ID details

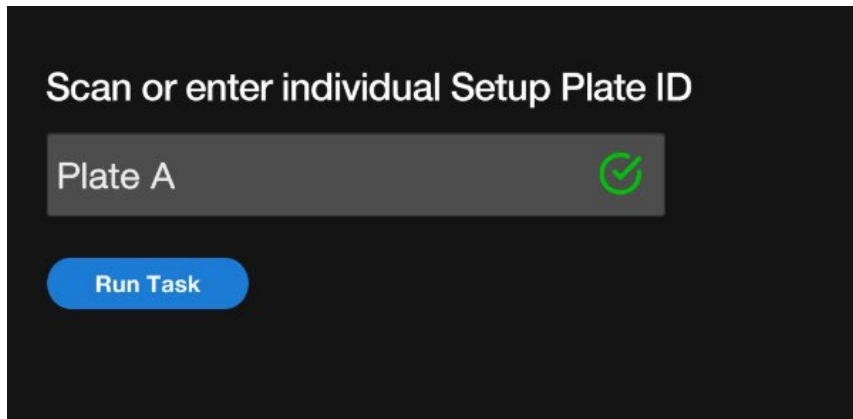


Figure 7.16 Re-enter plate ID details

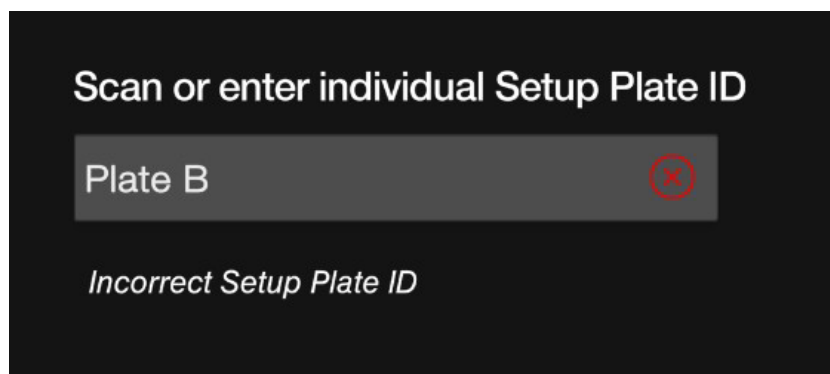


Figure 7.17 Error message if incorrect Plate ID is entered

The instrument will then search for the first available tip in zone 3, but this can be bypassed by simply clicking on the relevant position. The software will then prompt the user to scan magazine barcode(s) (Figure 7.18). Either use the barcode scanner or input an ID for the plate, ensuring that for q16 plates with both magazines in place that the codes for LOC1 and LOC2 are assigned correctly.

Note Some of these steps will be bypassed if going directly from sample set up, without coming from e.g., the task queue, or if the software has established the location of the first available tip.

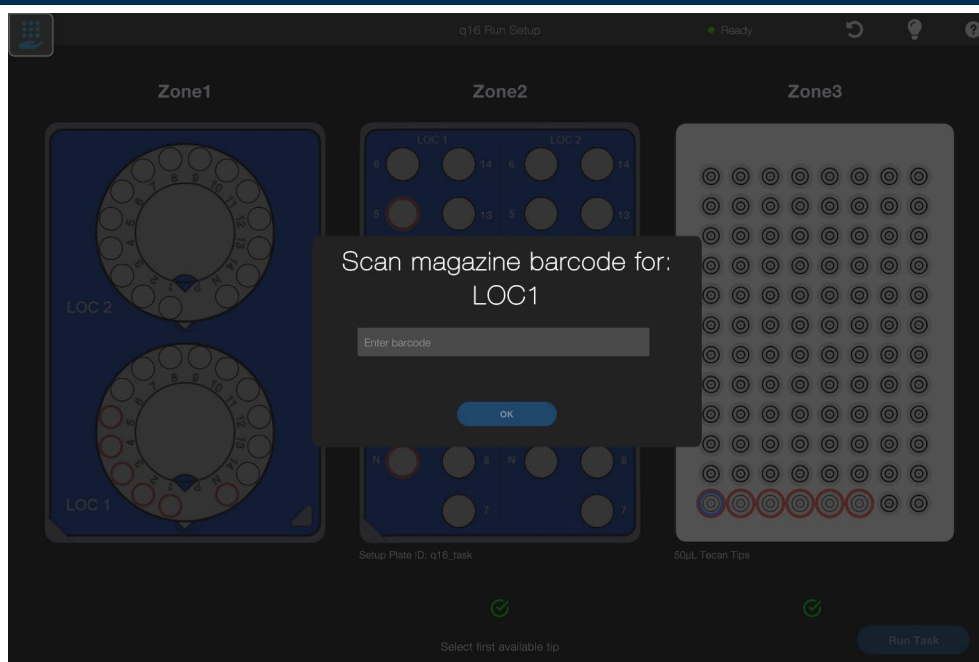


Figure 7.18 Scanning PROmate magazine barcode

At this point, ensure that the foils on the lids of all the necessary PROmate tubes have been removed, including the negative control, and place the target plate in zone 1. Ensure a q16 target plate has LOC1 to the front of the instrument, and that the magazine in the q32 target plate has the negative control position to the left and front of the target plate/instrument.

7.3.2 Final checks

The Run Setup screen shown in Figure 7.19 gives an example of the q16 Direct PROmate workflow when the run is ready to start with all information input. Zone 1 and zone 2 will be illustrated differently depending on the workflow used.

In the screen, there are several visual cues: every position in zone 1 and zone 2 with a sample present will be ringed in red. The pipette tips to be used will also be ringed in red, with the tip in the first position to be used also highlighted in blue. The bottom left hand of the screen shows the magazine ID(s).

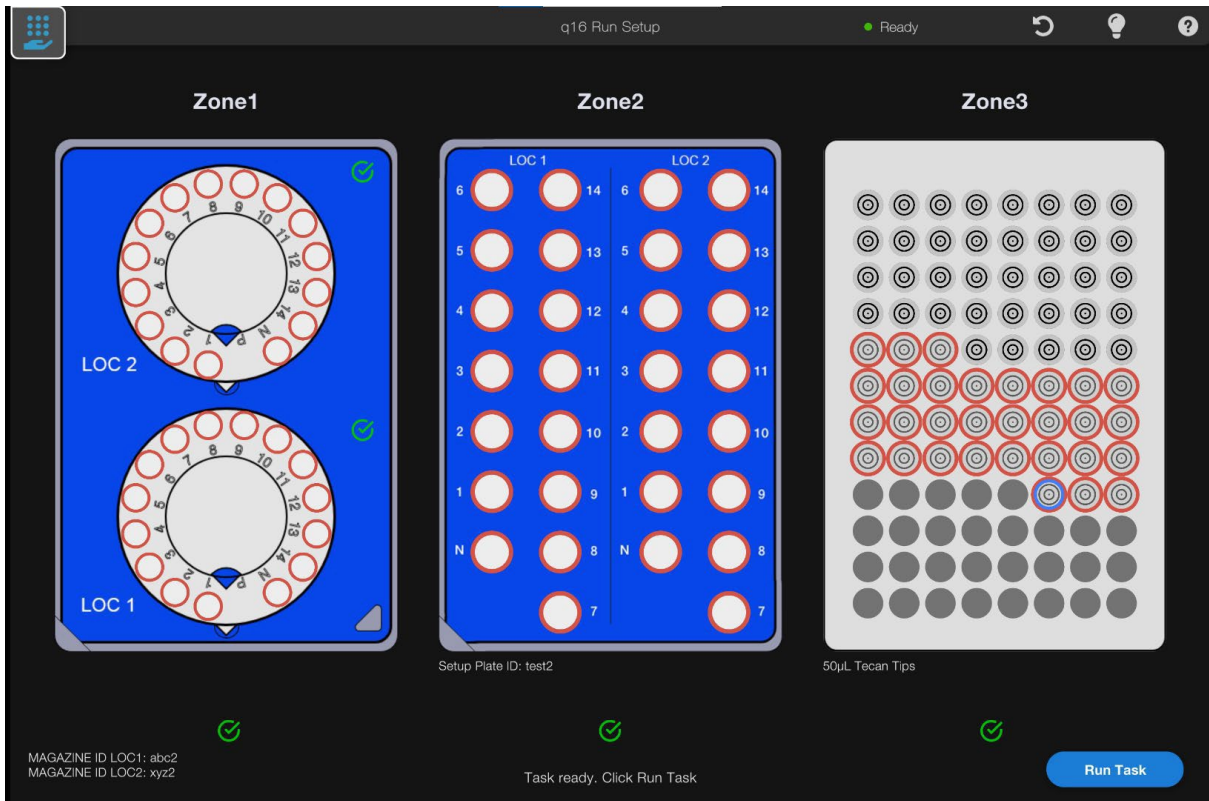


Figure 7.19 Run Setup screen

Click “Run Task”, the software will display a “You want to run” screen (Figure 7.20), showing the number of samples and the negative control. “Confirm” if all information is correct.

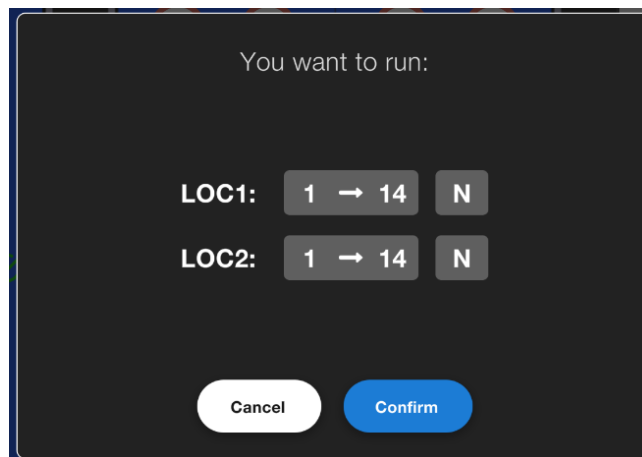


Figure 7.20 Screen confirming the number of samples and controls to be run

The software will display a final check screen (Figure 7.21), so at this point double check everything is set up correctly in zones 1 and 2, and that the tip waste pot is not more than half full. Once all these checks are completed, click Confirm to start the run.

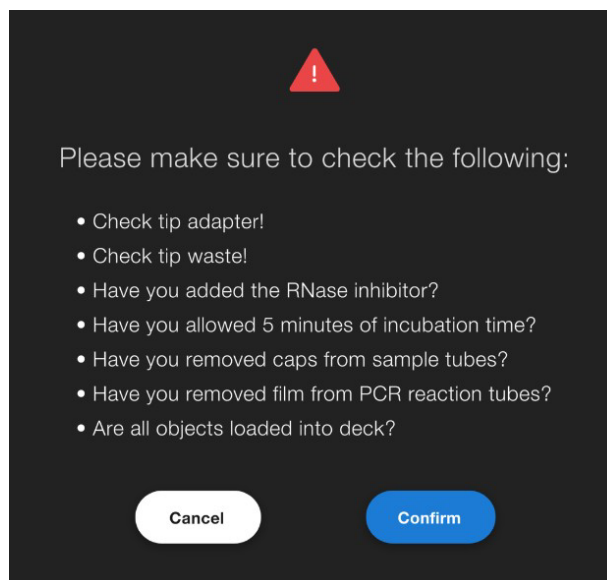


Figure 7.21. A final check to prompt the user to check all aspects of the instrument

7.3.3 During the run

The software displays a screen which counts up the time elapsed, and gives an indication of progress (Figure 7.22). At this point the user can pause or abort the run using the relevant buttons, and also change the alarm status – selecting “Audio” “Visual” or “Both” from the drop down menu.

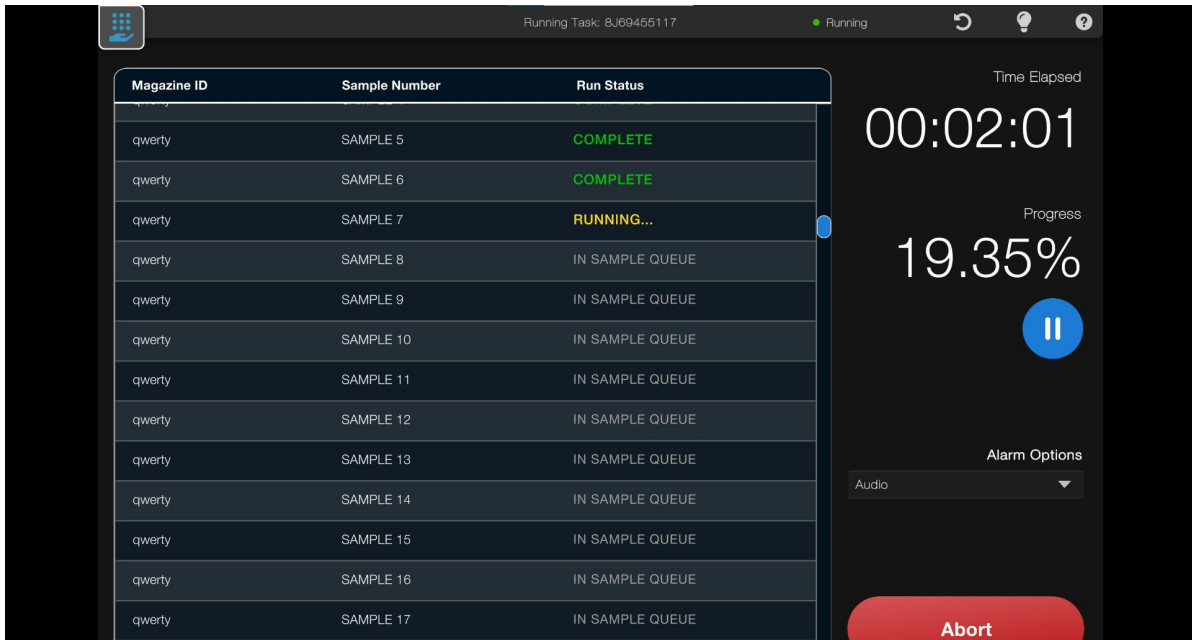


Figure 7.22. Run status screen

7.3.4 Replenishing tips during a run

The CO-Prep software does not require that the correct number of tips is present in zone 3 at the beginning of the run, and instead allows the tip rack to be replenished during the run.

When the final tip is used up, the software will display a warning screen (Figure 7.23) and give an audible alarm.

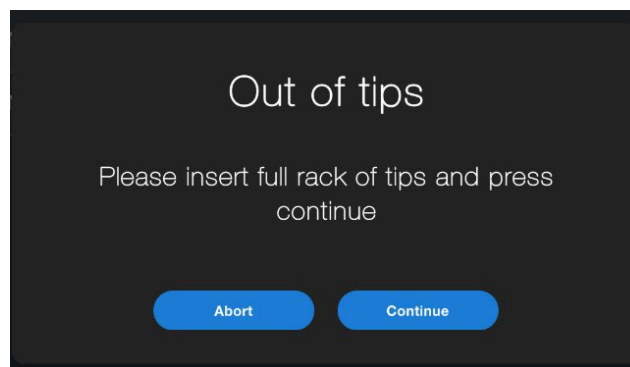


Figure 7.23 Error message warning that the CO-Prep needs further tips

To replace the tips, open the door and place the empty Robotic Tip Rack Adapter into the cradle. **It is essential that you do this to ensure that the ends of the new tips remain suspended, and do not touch the lab bench.**

Remove the pipette tip rack by gently pushing the metal clip at one end. Unwrap a fresh rack of tips, and make sure the notch in the tip rack marries up to the short metal post in the Robotic Tip Rack Adapter. Click both metal clips onto the tip rack.

Replace the Robotic Tip Rack Adapter into zone 3, taking care that the ends of the tips do not touch the deck. Check that the Robotic Tip Rack Adapter is fully engaged into zone 3 and orientated with the short metal post in the Adapter towards the front of the instrument. Press “Continue” to allow the run to proceed.

7.3.5 Completing the run

At the end of the run, once the pipette has returned to the final position, a “Run Completed” screen will be displayed (Figure 7.24). Click on Review to display the “Run Report” screen (Figure 7.25).

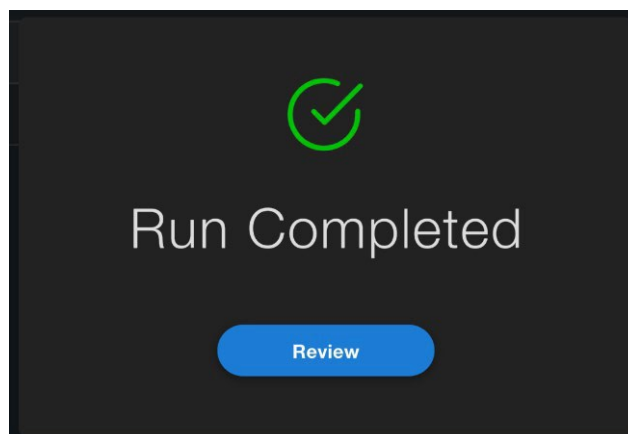


Figure 7.24 Run completed message

Date	Time	Magazine ID	Sample Number	Run Status
22/02/2022	01:17:01	abc2	LOC1-1	COMPLETE
22/02/2022	01:17:19	abc2	LOC1-2	COMPLETE
22/02/2022	01:17:36	abc2	LOC1-3	COMPLETE
22/02/2022	01:17:53	abc2	LOC1-4	COMPLETE
22/02/2022	01:18:10	abc2	LOC1-5	COMPLETE
22/02/2022	01:18:28	abc2	LOC1-6	COMPLETE
22/02/2022	01:18:45	abc2	LOC1-7	COMPLETE
22/02/2022	01:19:03	abc2	LOC1-8	COMPLETE
22/02/2022	01:19:21	abc2	LOC1-9	COMPLETE
22/02/2022	01:19:39	abc2	LOC1-10	COMPLETE
22/02/2022	01:19:56	abc2	LOC1-11	COMPLETE
22/02/2022	01:20:13	abc2	LOC1-12	COMPLETE
22/02/2022	01:20:30	abc2	LOC1-13	COMPLETE
22/02/2022	01:20:48	abc2	LOC1-14	COMPLETE

Unique Run ID: 1B9B600709

Total Run Time: 00:09:01

Generate Report

Figure 7.25 Run Report Screen

It is essential that the PCR magazine is dealt with first, so the user should remove the target plate from zone 1 and cap all the wells as soon as possible, starting with the negative control. Samples in the setup plate in zone 2 should have their screwcaps replaced, ensuring that they are returned to the correct sample to prevent cross-contamination.

The positive control can now be placed in the PCR magazine, remembering to take care that the positive control pouch or tube is not compromised. The magazine should be placed in the PCR instrument as soon as possible after this point, and the user's gloves changed to minimise any contamination risk following handling of the positive control.

At this point, the CO-Prep will have generated a file that is machine-readable by the genesig software (Section 7.5), but the user can also use the "Generate Report" button to produce a .txt file which records information from the run. The user will be prompted to save the file to a folder of their choice, and can change the filename from the default, which is the Unique Run ID generated by the CO-Prep software. The task will now appear in the "History" section of the software and have been removed from the "Task Queue".

7.3.6 Closing down software

If the user wishes to close the CO-Prep down, you must right click on the software on the taskbar and then close the window.

7.4 Importing CO-Prep run data into genesig software

Please ensure the instructions in section 6.2 have been completed to link the CO- Prep output to the genesig software.

To import the CO-Prep run data into the genesig software open up the q16 or q32 software and select New, then select the PROmate auto setup from sample Queue app (Figure 7.26).

Either scan the QR code on the q16 or q32 magazine, or type in the magazine ID if using manual input (Figure 7.27). This will load up your CO-Prep file ready to be run (Figure 7.28).

To proceed, simply select “Start run”.

For further information on working with the genesig run file and selecting the correct PCR instrument, please refer to the instrument manual. For interpretation of run data, please refer to the IFU of the PROmate kit.

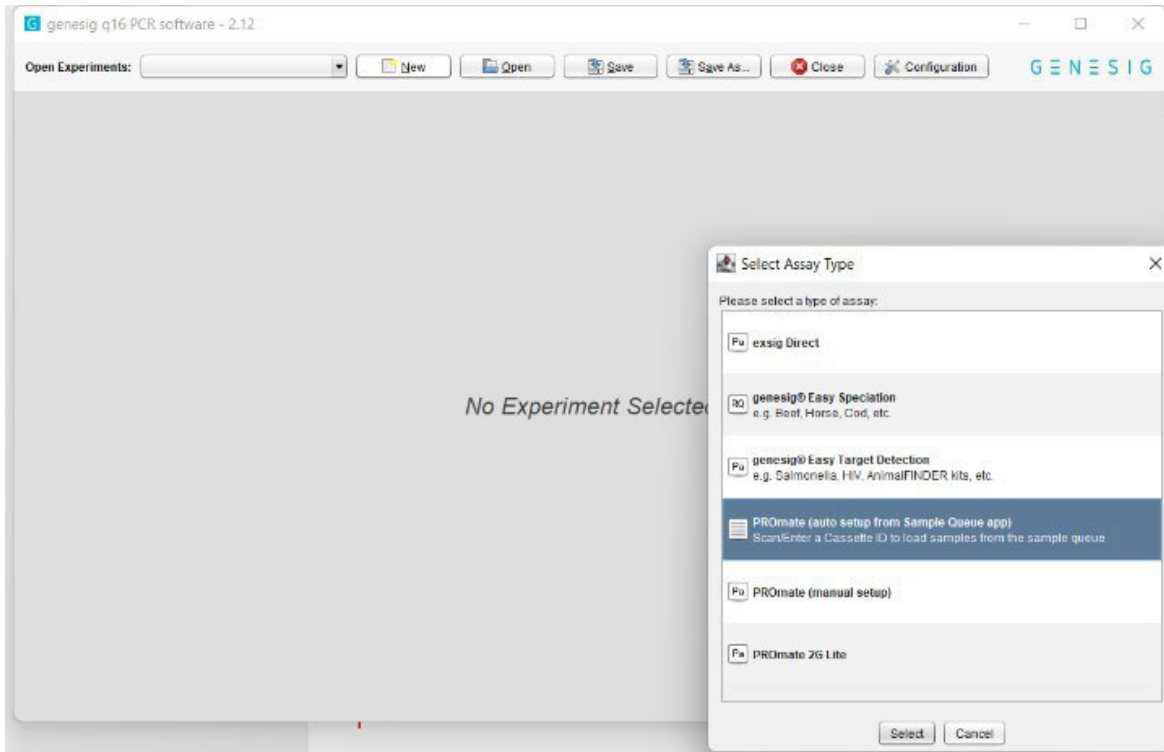


Figure 7.26 q16 CO-Prep setup

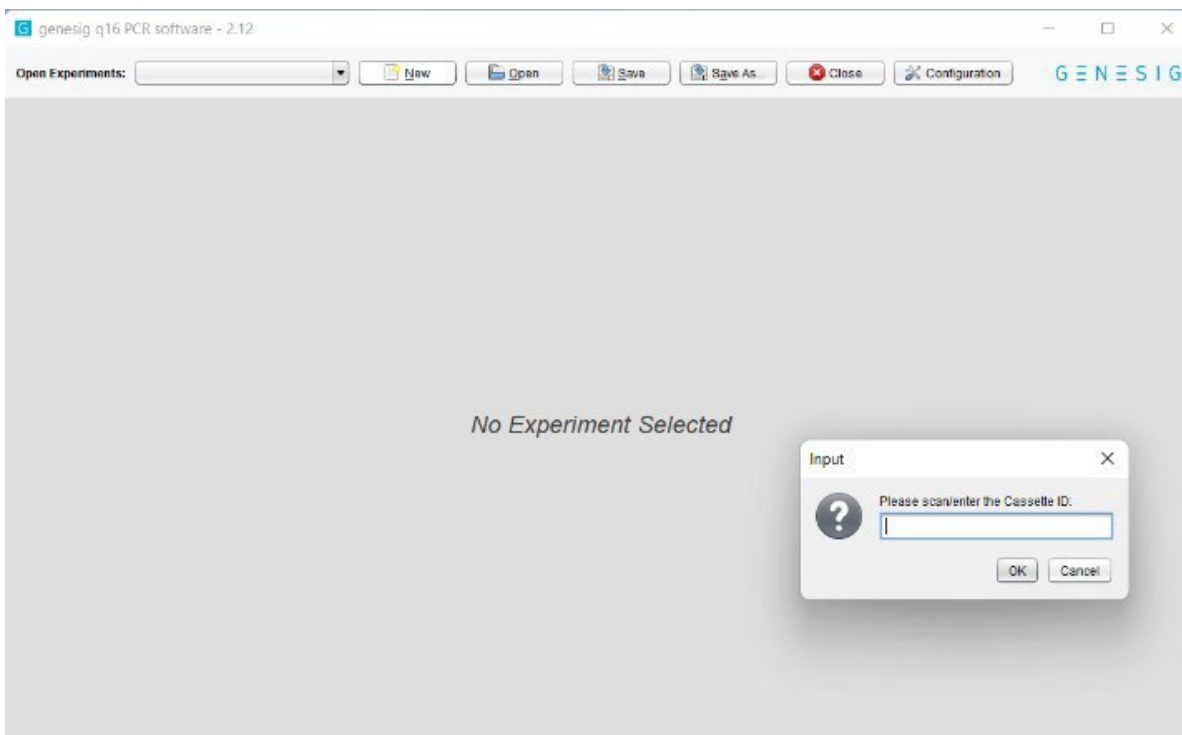


Figure 7.27 Locating the pre-made template

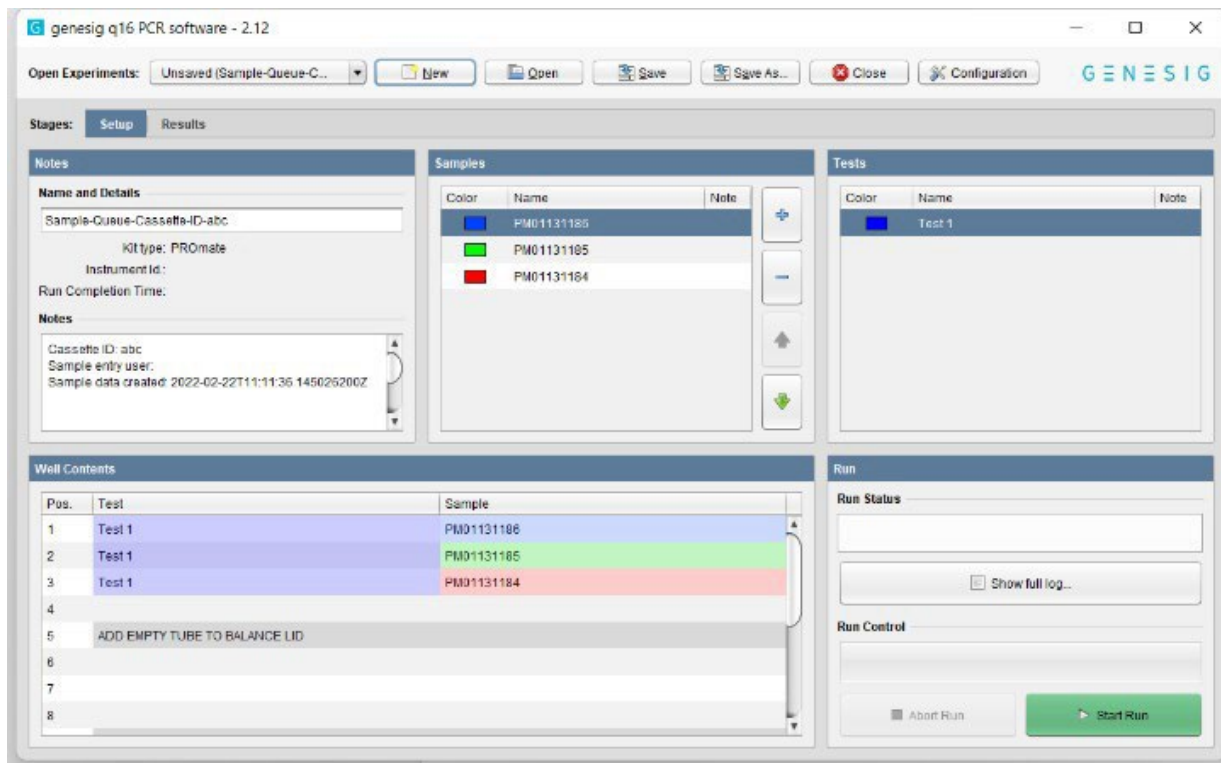


Figure 7.28 An example of data imported for the q16 instrument.

PROmate COVID-19 product range

8. PROmate COVID-19 product range

This section refers to the performance of the PROmate product range using the CO-Prep.

8.1 Compatible PROmate kits

The CO-Prep is compatible with:

- PROmate COVID-19 (1 gene) for q16 (Catalogue no: D00068) and q32 (D00070).
- PROmate 2G for q32 (Catalogue number: D00074)
- Validation testing used the genesig q16 instrument (catalogue no: Z-genesig-q16) and the genesig q32 instrument (catalogue no: Z-genesig-q32) for qPCR amplification and analysis for the PROmate COVID-19 (1 gene). Validation testing used genesig q32 instrument (catalogue no: Z-genesig-q32) for qPCR amplification and analysis for the PROmate COVID-19 2G.

Please refer to the relevant product's Instructions For Use (IFU) for the detailed methods. Please use the QR code located on the instrument to verify the most recent version of the IFU. It is the user's responsibility to prevent contamination of samples, from the user or other samples, by following the applicable clinical and laboratory standards when preparing reagents and handling samples.

The lids/caps of the samples need to be replaced when the CO-Prep run is complete to avoid cross-contamination between samples. Samples must not be left without a lid for extended periods to avoid evaporation of the sample contents. Likewise, the PCR magazine should only be prepared immediately prior to the CO-Prep run to prevent evaporation of the mastermix and potential contamination from the laboratory environment and caps used to seal the PCR tubes as soon as possible after the completion of the CO-Prep pipetting steps. Follow the relevant workflow in Section 7 to ensure that the kit is prepared and handled correctly.

WARNING: Please refer to the assay's IFU for the relevant hazards and precaution notices related to chemical and environmental risks. A risk assessment of any experimentation involving the CO-Prep must be performed prior to using the CO-Prep. It is the user's responsibility to follow the guidance of the assay's IFU in addition to local and national guidance policies.



8.2 Analytical validation of CO-Prep performance

8.2.1 PROmate COVID-19 (1 gene) assay: Limit of Detection testing

The PROmate COVID-19 (1 gene) assay is a CE-IVD marked assay for the detection of the SARS-CoV-2 virus using dry anterior nasal swabs. The instructions for use (IFU) have previously established the limit of detection (LoD) of the assay as being 0.96 copies/ μ l in the PCR reaction. The limit of detection is the level of viral material that can be reliably detected with >95% confidence.

We assessed whether the performance of the assay was equivalent when magazines were prepared via manual pipetting or via the CO-Prep instrument. A synthetic SARS-CoV-2 RNA (control 48, which is of the Omicron B.1.1.529, BA.1 lineage) was obtained from Twist Bioscience. This material was used to contrive dry anterior nasal swab samples collected from negative donors with a known amount of viral genome copies. Twenty replicates of the contrived anterior nasal samples at three different concentrations were tested, and the positive call rates for each concentration were recorded. Table 1 shows the results for the samples analysed using the genesis q16 Real-time PCR q16 instrument. Table 2 shows the results for samples analysed using the genesis q32 Real-time PCR q16 instrument.

Table 1. q16 instrument

Concentration (copies/ μ l in the reaction)	Call Rate	
	Manual	CO-Prep
0.72	95%	95%
0.60	100%	100%
0.48	100%	65%

Table 2. q32 instrument

Concentration (copies/μl in the reaction)	Call Rate	
	Manual	CO-Prep
0.72	95%	95%
0.60	85%	75%
0.48	95%	75%

In summary, both manual preparation and the automated preparation of samples using the CO-Prep instrument were capable of detecting 95% of samples contrived at a level below the previously established LoD of the PROmate COVID-19 (1 gene) assay. The LoD was confirmed using both the genesig q16 Real-time PCR q16 and q32 instruments.

8.2.2 PROmate COVID-19 (1 gene) assay: Testing for potential cross-contamination of samples

To confirm that the CO-Prep workflow did not introduce contamination either inter- or intra-run, PROmate COVID-19 (1 gene) magazines were contrived with a synthetic SARS-CoV-2 RNA (control 48, which is of the Omicron B.1.1.529, BA.1 lineage), obtained from Twist Bioscience. Dry anterior nasal swab samples collected from negative donors were either left uncontrived or contrived with the equivalent of 2145 viral genome copies (107.25 copies/μl in the reaction). This would ensure that anything above 1% carryover (equivalent to 0.05 μl) would be detected in a negative sample/control, given the limit of detection of the kit.

The contrived positive and negative samples were arranged in alternate wells in the setup plates for q16 or q32 magazines, and negative controls pipetted as per their respective CO-Prep workflows. Following thermal cycling, the instrument has automatic calling software that calculates the results and presents this to the user in the form of a simple interpretation: Neg produces a FAM Cq>37.66; Pos for positive samples and PCT produces a Cq of between 14-25 in the FAM channel. Table 3

shows the automatic calling software results for the q16 magazines. Table 4 shows the automatic calling software results for the q32 magazines.

Table 3. Automatic calling software results for the q16 magazines

Magazine LOC1	1	2	3	4	5	6	7	8
A	Pass (PTC)	Pass (NTC)	Pos	Neg	Pos	Neg	Pos	Neg
B	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos

Magazine LOC2	1	2	3	4	5	6	7	8
A	Pass (PTC)	Pass (NTC)	Neg	Pos	Neg	Pos	Neg	Pos
B	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg

Table 4. Automatic calling software results for the q32 magazines

	1	2	3	4	5	6	7	8
A	Pass (PTC)	Pass (NTC)	Pos	Neg	Pos	Neg	Pos	Neg
B	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
C	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
D	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos

	1	2	3	4	5	6	7	8
A	Pass (PTC)	Pass (NTC)	Neg	Pos	Neg	Pos	Neg	Pos
B	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
C	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
D	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg

8.2.3 PROMate COVID-19 2G assay: Limit of Detection testing

The PROMate COVID-19 2G assay is an assay used to detect the SARS-CoV-2 virus using dry anterior nasal swabs. The instructions for use (IFU) have previously established the limit of detection (LoD) of the assay as being 0.4 copies/ μ l in the PCR reaction. The limit of detection is the level of viral material that can be reliably detected with >95% confidence.

We assessed whether the performance of the assay was equivalent when magazines were prepared via manual pipetting or via the automated CO-Prep Liquid handling workflow. A synthetic SARS-CoV-2 RNA (control 48, which is of the Omicron B.1.1.529, BA.1 lineage) was obtained from Twist Bioscience. This material was used to contrive anterior nasal swab samples collected from negative donors with a known amount of viral genome copies. Tentative LoD was initially established by running 20 replicates of contrived anterior nasal samples in sample preparation buffer (SPB) at the tentative LoD concentration (data not shown). A further 20 replicates of the contrived anterior nasal samples were run at tentative LoD (20%) and a level below tentative LoD (20%). The LoD was defined as the lowest concentration of analyte that was reliably detected at a 95% (19/20) call rate. Table 5 shows the call rate (positive PCR reactions) from the verification of LoD using the genesig q32 Real-time PCR instrument.

Table 5. Call rate for verification of LoD using the q32 instrument (n=20)

Concentration (copies/ μ l in the SPB tube)	Concentration (copies/ μ l in the PCR reaction)	Call Rate	
		Manual	CO-Prep
320	0.08	100%	100%*
240	0.06	100%	100%
160	0.04	100%	95%

*One inconclusive sample, however, 19/19 sample amplified making the call rate 100%.

In summary, both manual preparation and the automated preparation of samples using the CO-Prep instrument were capable of detecting 95% of samples contrived at a level below the previously established LoD of the PROmate COVID-19 2G assay.

The LoD was validated using the genesig q32 instrument.

8.2.2 PROmate COVID-19 2G assay: Testing for potential cross-contamination of samples

To confirm that the CO-Prep workflow did not introduce contamination either inter- or intra-run, PROmate COVID-19 2G magazines were contrived with a synthetic SARS-CoV-2 RNA (control 48, which is of the Omicron B.1.1.529, BA.1 lineage), obtained from Twist Bioscience. Alternating negative “blank” samples and positive spiked “samples” were analysed using the genesig PROmate COVID-19 2G. The contrivance material used was prepared by diluting neat TwistBio synthetic SARS- CoV2 RNA (Control 48) in a 1:100 dilution (4290 copies/μl) using Template Preparation Buffer (TPB). Any contamination was identified by positive amplification in the FAM and Cy5 channels of blank wells.

The contrived positive and negative samples were arranged in alternate wells in the setup plates for the q32 magazines, and negative controls pipetted as per their respective CO-Prep workflows. Following thermal cycling, the instrument has automatic calling software that calculates the results and presents this to the user in the form of a simple interpretation: Neg produces a FAM Cq>38.14; Pos for positive samples and PCT produces a Cq of between 14-25 in the FAM and Cy5 channels.

Table 6 shows the results from the contamination run for the q32 magazines.

Table 6. FAM Cq values of both q32 contamination runs prepared with CO-Prep (PCT= positive control template, NTC= negative control template)

Run 1	1	2	3	4	5	6	7	8
A (FAM Cq)	PTC	NTC	29.48	N/A	29.84	N/A	30.22	N/A
A (Cy5 Cq)			28.54	N/A	28.87	N/A	29.29	N/A
B (FAM Cq)	N/A	29.78	N/A	29.99	N/A	29.79	N/A	30.15
B (Cy5 Cq)	N/A	28.76	N/A	29.07	N/A	28.76	N/A	29.18
C (FAM Cq)	30	N/A	30.28	N/A	29.85	N/A	29.89	N/A
C (Cy5 Cq)	28.88	N/A	29.23	N/A	29.23	N/A	28.91	N/A
D (FAM Cq)	N/A	30.01	N/A	30.04	N/A	29.8	N/A	29.5
D (Cy5 Cq)	N/A	28.96	N/A	29.2	N/A	28.96	N/A	28.58

Run 2	1	2	3	4	5	6	7	8
A (FAM Cq)	PTC	NTC	N/A	29.87	N/A	29.35	N/A	29.28
A (Cy5 Cq)			N/A	28.96	N/A	28.51	N/A	28.44
B (FAM Cq)	29.95	N/A	29.41	N/A	29.64	N/A	29.37	N/A
B (Cy5 Cq)	29.11	N/A	28.53	N/A	28.77	N/A	28.59	N/A
C (FAM Cq)	N/A	29.54	N/A	30	N/A	29.46	N/A	29.4
C (Cy5 Cq)	N/A	28.62	N/A	29.24	N/A	28.55	N/A	28.45
D (FAM Cq)	29.2	N/A	29.64	N/A	29.69	N/A	29.88	N/A
D (Cy5 Cq)	28.58	N/A	28.86	N/A	2881	N/A	29	N/A

In summary, there was no observed inter or intra-run sample contamination when samples were prepared on the CO-Prep instrument and analysed using the q32 instrument.

Accessories

9. Accessories

Part Number	Product Name
A00551	CO-Prep validated filter tips (pack)
A00552	CO-Prep calibrated pipette module
A00553	CO-Prep q16 target plate
A00554	CO-Prep q32 target plate
A00555	CO-Prep q16 setup plate
A00556	CO-Prep q32 setup plate
A00557	Magnetic extraction adapter plate
A00558	CO-Prep tip rack adapter (standard)
A00559	CO-Prep tip rack adapter (extraction)
A00561	CO-Prep universal DC power supply with a UK plug
A00085	USB C to USB 3.1 adapter
A00080	Corded Barcode scanner

Maintenance

10. Maintenance

This section contains the following topics:

- [10.1 CO-Prep maintenance](#)
- [10.2 Daily maintenance](#)
- [10.3 Additional operator maintenance procedures](#)
- [10.4 CO-Prep Pipette Module Maintenance](#)
- [10.5 CO-Prep Repair Services and Service Contract](#)
- [10.6 CO-Prep Pipette Module Calibration](#)
- [10.7 CO-Prep Pipette Module Exchange Service](#)

10.1 CO-Prep Maintenance

There are no internal operator serviceable parts in this unit. If the power should fail, the unit must be inspected or returned to the authorised distributor for service support.



Electrical System: do not remove any covers unless you are a qualified service representative.

The system contains a UV source that is hazardous to health. Do not remove the covers unless you are a qualified service representative. Disconnecting the UV source is a service engineer task only.



10.2 Daily maintenance checks

The tip waste container must be inspected. The tip waste container should always be emptied before it reaches its maximum capacity, and ideally should be emptied after every run of a single q32 magazine or two q16 magazines. Instructions for cleaning the tip waste container can be found in section 5.4.

The UV light cycle, which is used as an aid to decontamination, is recommended between runs using the appropriate UV conditions (Meechan & Wilson, 2006), for at least 15 minutes, and certainly should be performed at the end of each working day for 30 minutes. See section 5.10 on using the UV light function of the software.

Check the acrylic tray at the bottom of the instrument for signs of liquid spillage. To clean, first soak up the spillage with paper towels. Then lift the tray out of the CO-Prep instrument and decontaminate with Distel (Tristel Solutions Ltd, 2020) or similar disinfectant, or 10% bleach, rinsing with distilled water afterwards. Please make sure the tray is completely dry before reinsertion.

The deck must be checked for spillages and cleaned as detailed above. The target and setup plates should also be cleaned with Distel or similar disinfectant, or 10% bleach, rinsing with distilled water afterwards. Please be aware that some cleaning agents/disinfectants can discolour the anodised surface of the target and setup plates.

10.3 Additional operator maintenance procedures

Beyond keeping the system in a clean, usable condition for optimum performance and operational up-time, the system would benefit from operator preventative maintenance. The system consists of three moving axes, known as an "X, Y and Z platform". The operator can perform simple operator preventative maintenance by wiping down the stainless steel linear rails with a dry tissue and applying some light lubricant to the linear rails using a cotton bud or equivalent. Wipe away any excess oil with a dry tissue.

This function can be performed at any time when the instrument is in a standby/ready state and not actively running a task. Simply open the door and perform the simple operator preventative maintenance as described.

10.4 CO-Prep Pipette Module Maintenance

There are no internal operator serviceable parts in this unit. If the power should fail, the unit must be inspected or returned to the authorised distributor for service support.

All Pipette Modules being returned for maintenance or calibration require an RMA ticket number. This is the reference number attached to the returned item, which is linked to a customer account.

Any Pipette module being returned for calibration will also require a completed 'Decontamination Certificate' supplied with the module. This can be obtained by contacting technical support by email (techsupport@primerdesign.co.uk).

10.5 CO-Prep Repair Services and Service Contract

A full repair and service solution is available from your authorised distributor. Please contact your local authorised distributor or contact Novacyt to establish your nearest authorised distributor or 'back to base' service solution.

10.6 CO-Prep Pipette Module Calibration

The pipette module requires annual calibration to remain certified for use. An annual pipette calibration service is available on a 'back to base' basis. The pipette calibration frequency is based on the end-user standard operating procedures and may, therefore, be needed every six months. Pipette calibration can be arranged through your local authorised distributor.

A manufacturer calibration includes a full module test, adjustment and repair as required, then calibrated against ISO 8655.

10.6.1 Mounting a pipette module

The instrument must be initialised and ready for operation to mount a pipette module. Within the software or application, navigate to the Pipette settings. Within pipette settings, you can mount a pipette module. Once selected, this places the hardware in an accessible position to mount or demount the pipette module. Open the door, then mount a pipette module by fully engaging the module against the backstop. Once installed, close the door. The system will automatically re-home all axes and initialise the pipette module. The pipette module status can be seen in the software or application.

10.6.2 Demounting a pipette module

The instrument must be initialised and ready for operation to demount a pipette module. Within the software or application, navigate to the Pipette settings. Within pipette settings, you can demount a pipette module. Once selected, this places the hardware in an accessible position to mount or demount the pipette module. Open the door, then demount a pipette module by pulling the module towards you. Once removed, close the door. The system will automatically re-home all axes. The pipette module status can be seen in the software or application. Without a pipette module, the system will not be able to perform any tasks or liquid transfers.

10.6.3 Exchanging a pipette module

The instrument must be initialised and ready for operation to exchange a pipette module. Within the software or application, navigate to the Pipette settings. Within pipette settings, you can demount a pipette module. Once selected, this places the hardware in an accessible position to mount or demount the pipette module. Open the door, then demount the first pipette module by pulling the module towards you. Take the second pipette module and mount the pipette module by fully engaging the module against the backstop. Once installed, close the door. The system will automatically re-home all axes and initialise the pipette module. The pipette module status can be seen in the software or application.

The pipette module engages with a pipette tip by means of a stainless steel tip adapter. This is screwed into a threaded port on the bottom of the pipette module. **Note** The black O-ring functions as a seal between the pipette module and tip adapter. The tip adapter is tightened/untightened using the tip adapter tool. Finger tight force is adequate to secure the tip adapter with the tool.

The system requires a pipette module to be engaged and connected to perform any liquid transfers.

The pipette module can be wiped down with a damp cloth using 10% bleach and water. Please be careful to not wet the electrical interface.

10.7 CO-Prep Pipette Module Exchange Service

Novacyt operates an exchange program that enables a fast turnaround of pipette module calibration or repair. Ask your local Authorised Distributor for further information.

References

- Meechan, P. J., & Wilson, C. (2006). UV Effects on Biological Molecules and Microorganisms. *Applied Biosafety*, 11(4), 222–227.
<https://doi.org/https://doi.org/10.1016/B978-1-4831-9716-6.50013-6>
- Tristel Solutions Ltd. (2020). *DOSING SYSTEM*. <https://Tristel.Com/Wp-Content/Uploads/2020/12/CCH-DISTEL-003-4-DISTEL-User-Guide.Pdf>.
www.tristel.com

Appendices

Appendices

Appendix 1

A1.1 Technical data

Primerdesign, part of Novacyt, reserves the right to change specifications at any time.

A1.2 Declaration of Conformity

This product meets the applicable harmonised standards for radio frequency interference and may be expected not to interfere with, or be affected by, other equipment with similar qualifications. We cannot be sure that other equipment used in its vicinity will meet these standards, and so we cannot guarantee that interference will not occur in practice. Where there is a possibility that injury, damage, or loss might occur if equipment malfunctions due to radio frequency interference, or for general advice before use, contact the manufacturer.

Name and address of the legal manufacturer:

Primerdesign Ltd

York House

School Lane

Chandlers Ford

SO53 4DG

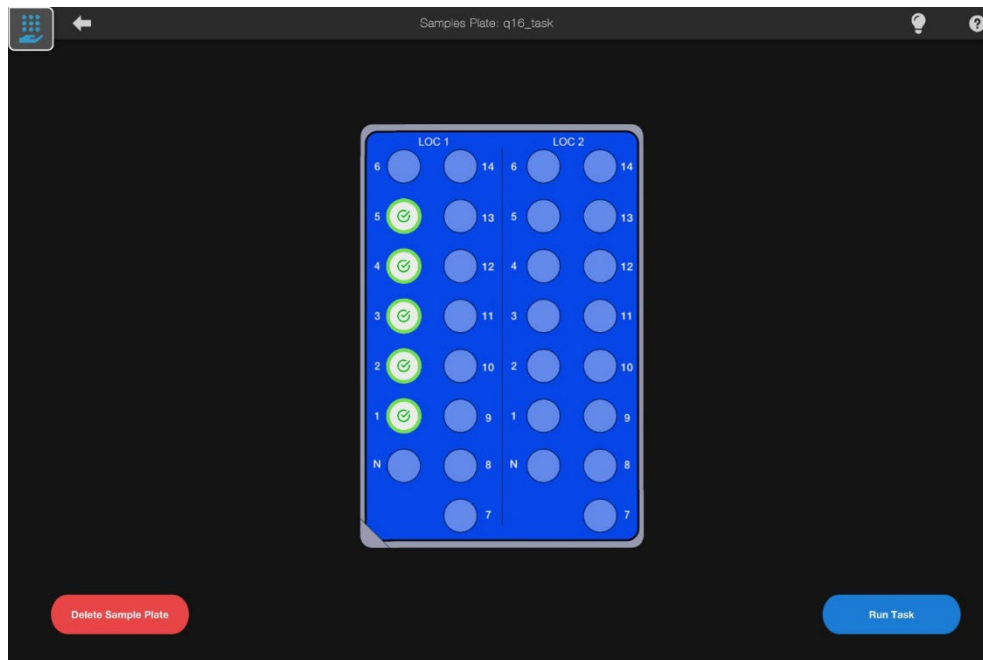
United Kingdom

An up-to-date declaration of conformity can be requested from Primerdesign Technical Services (techsupport@primerdesign.co.uk).

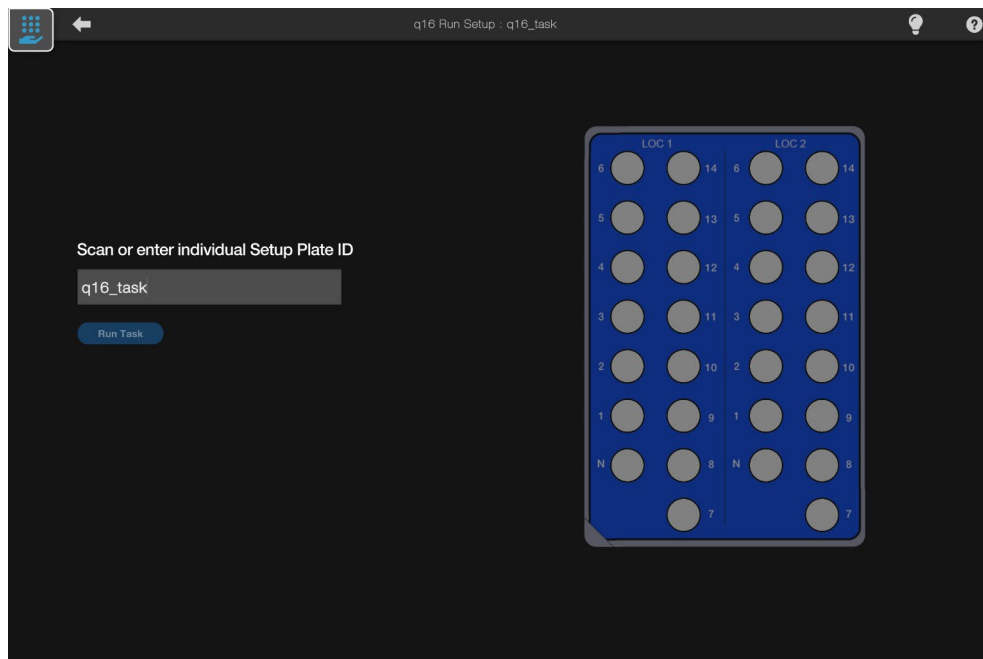
Appendix 2. Screenshots of workflows from Run Task to Completed Task

A2.1 q16 workflow

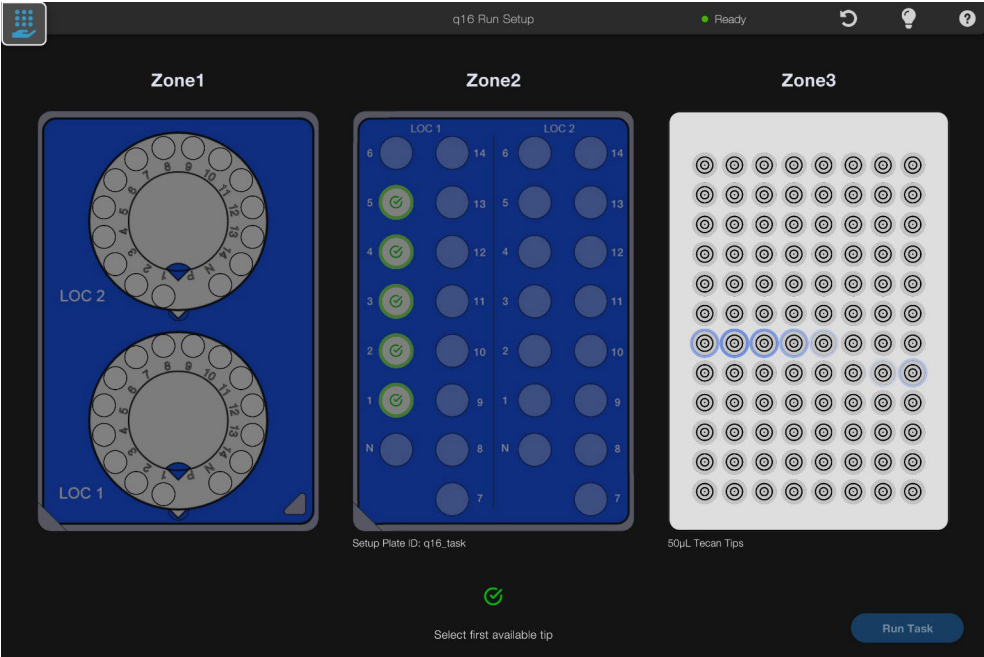
Step 1



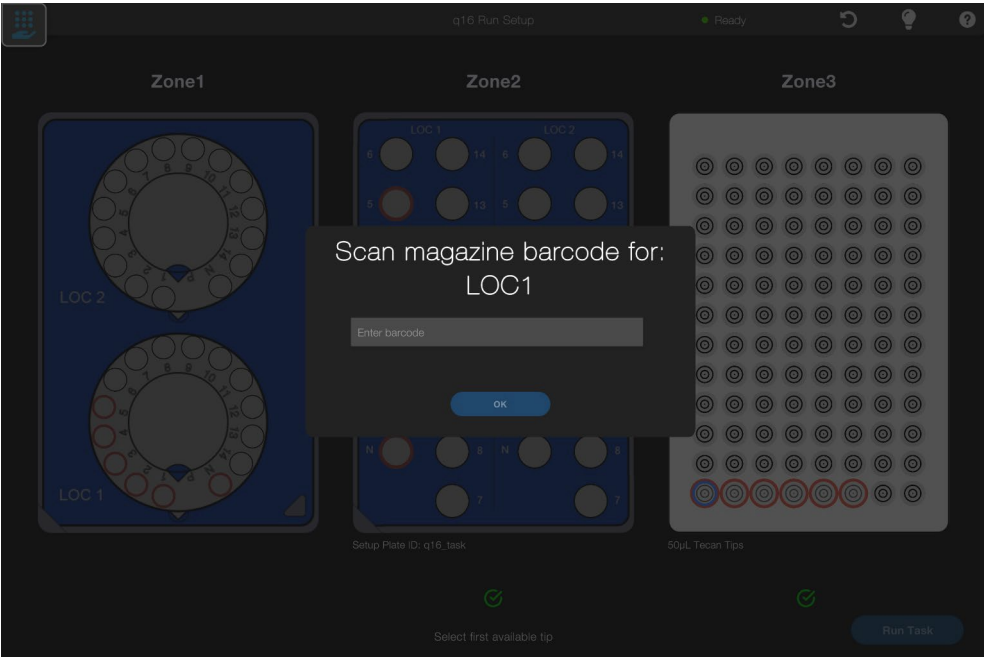
Step 2



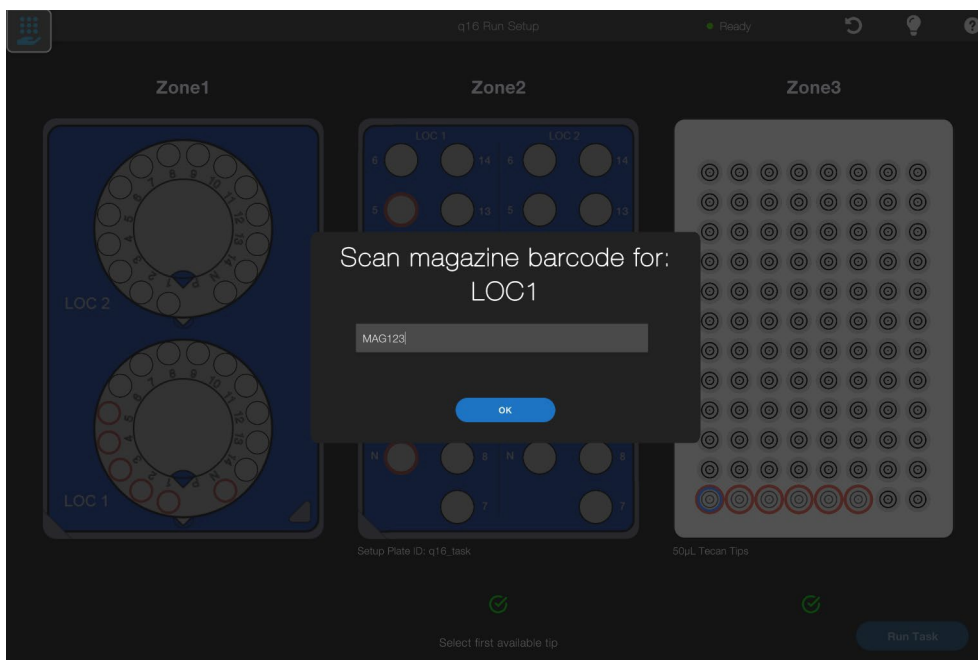
Step 3



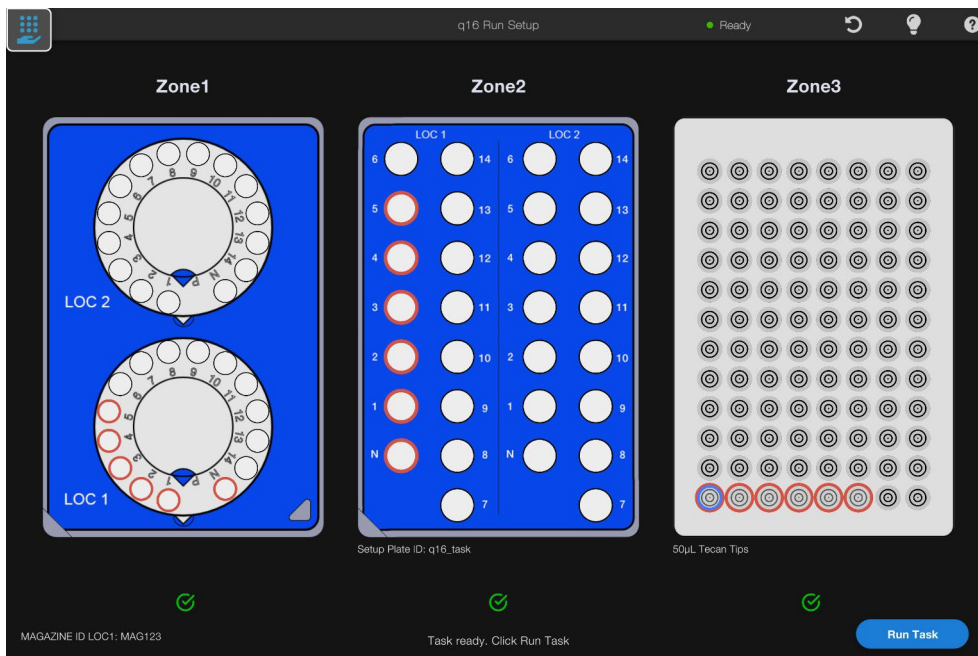
Step 4 (Tip selected)



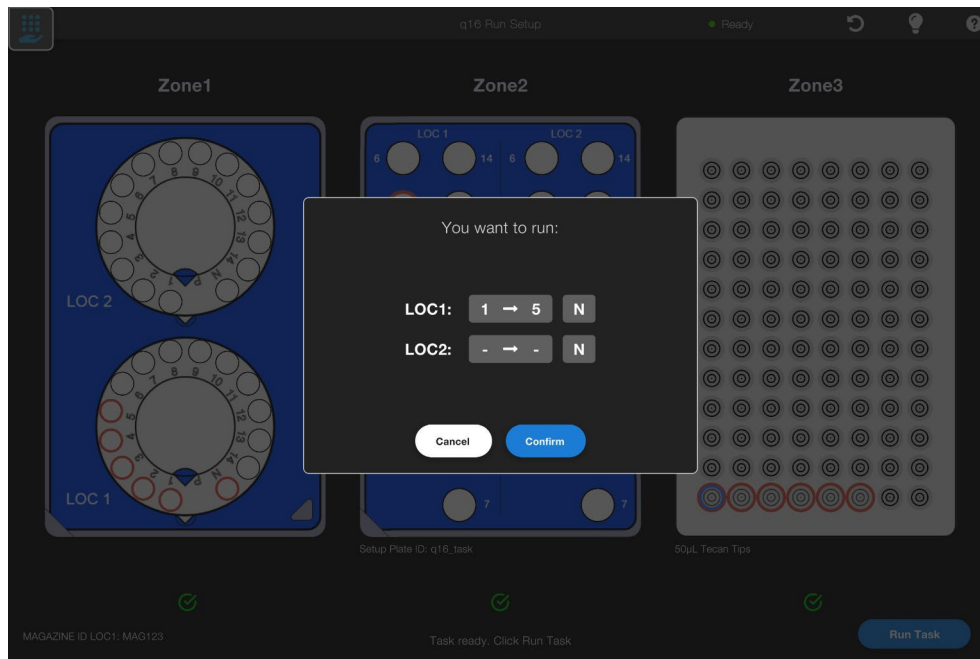
Step 5



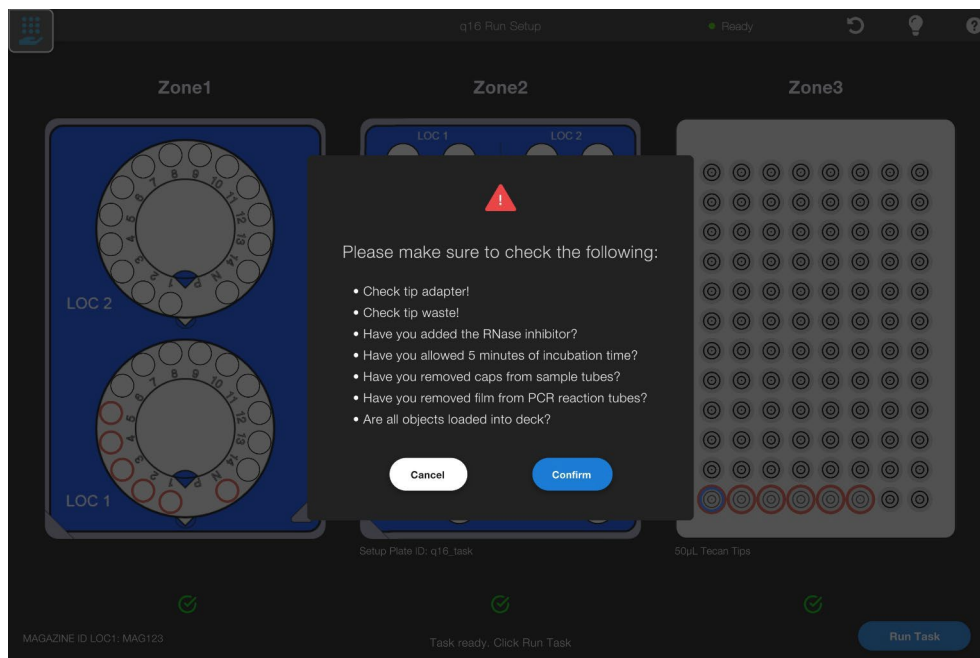
Step 6



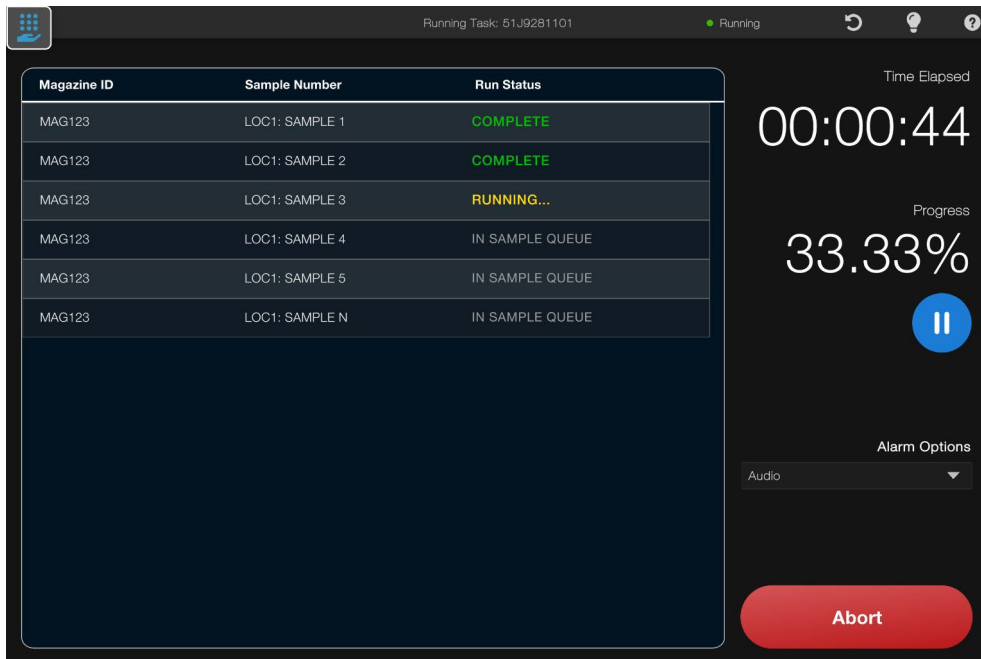
Step 7 (Click run task)



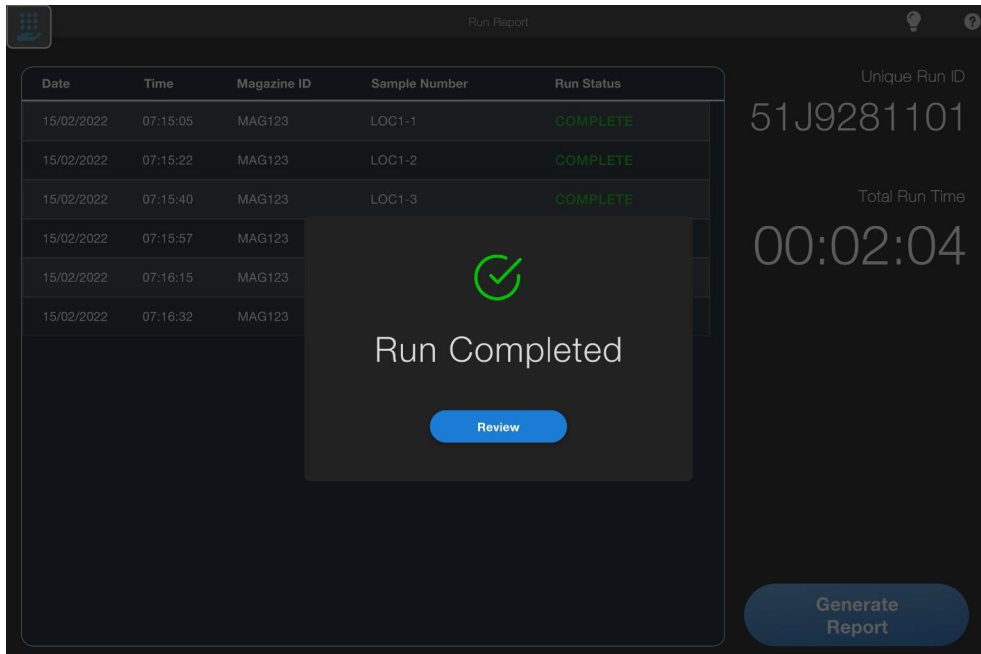
Step 8 (Confirm)



Step 9 (Confirm and upload tasks)



Step 10



Step 11

The screenshot shows a 'Run Report' window with a dark theme. On the left is a table with the following data:

Date	Time	Magazine ID	Sample Number	Run Status
15/02/2022	07:15:05	MAG123	LOC1-1	COMPLETE
15/02/2022	07:15:22	MAG123	LOC1-2	COMPLETE
15/02/2022	07:15:40	MAG123	LOC1-3	COMPLETE
15/02/2022	07:15:57	MAG123	LOC1-4	COMPLETE
15/02/2022	07:16:15	MAG123	LOC1-5	COMPLETE
15/02/2022	07:16:32	MAG123	LOC1-N	COMPLETE

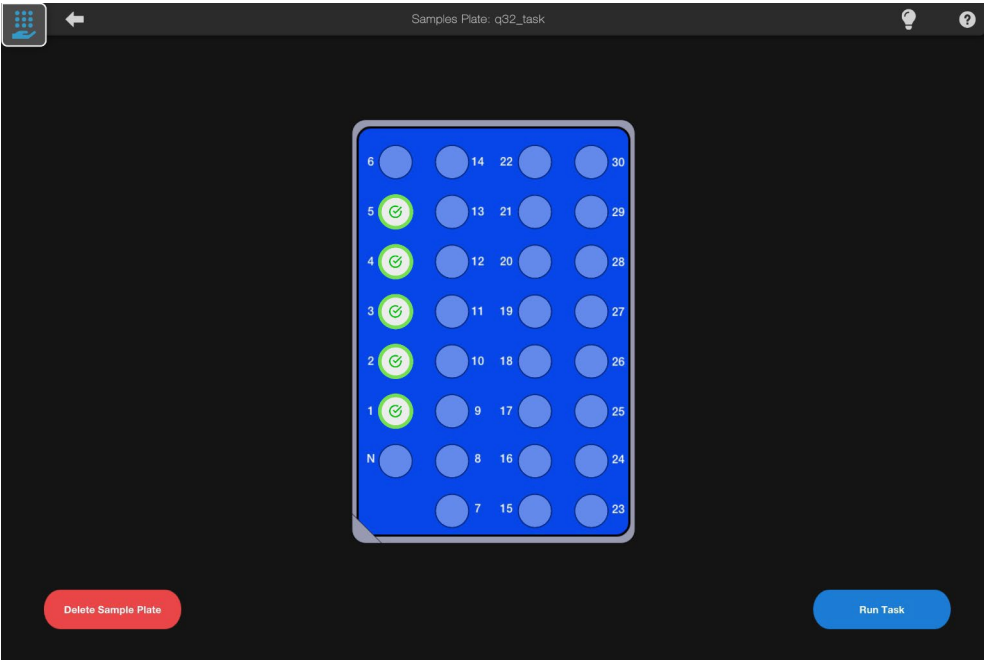
On the right side of the interface, there are summary statistics:

- Unique Run ID: 51J9281101
- Total Run Time: 00:02:04

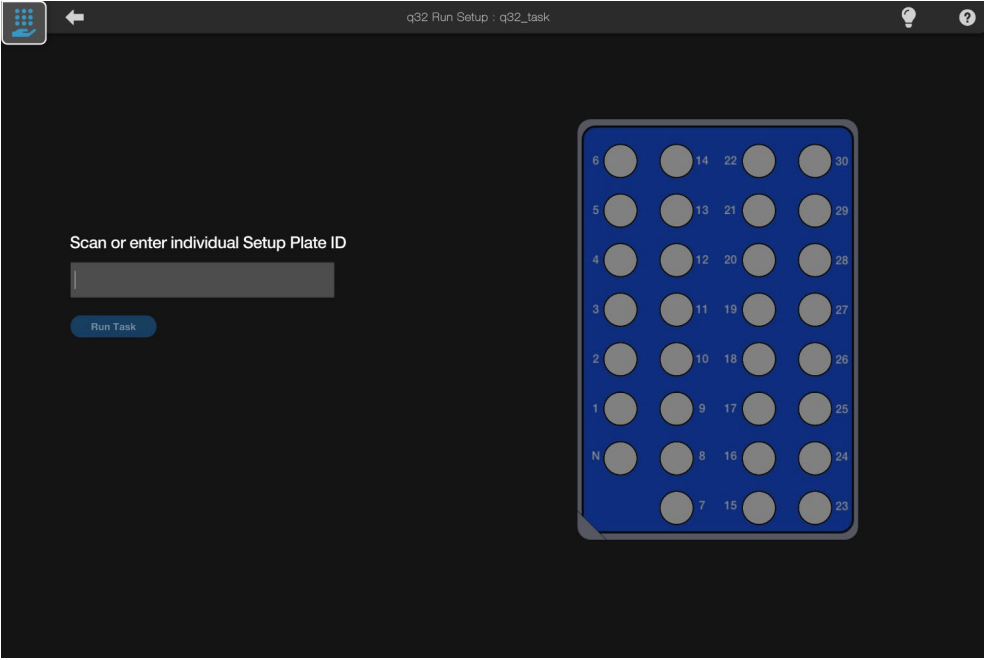
At the bottom right, there is a blue button labeled 'Generate Report'.

A2.2 q32 workflow

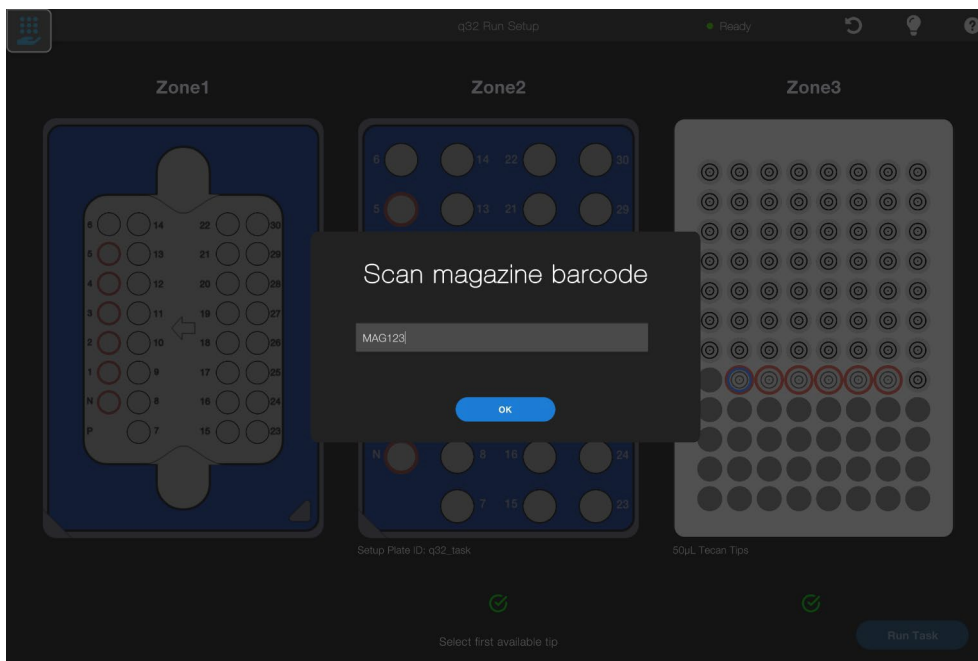
Step 1



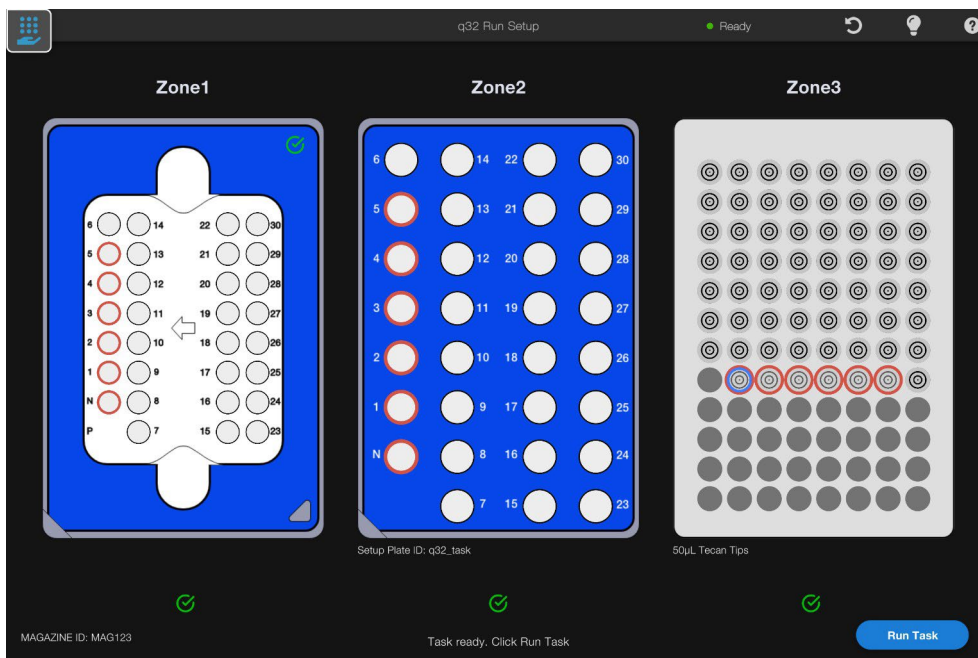
Step 2



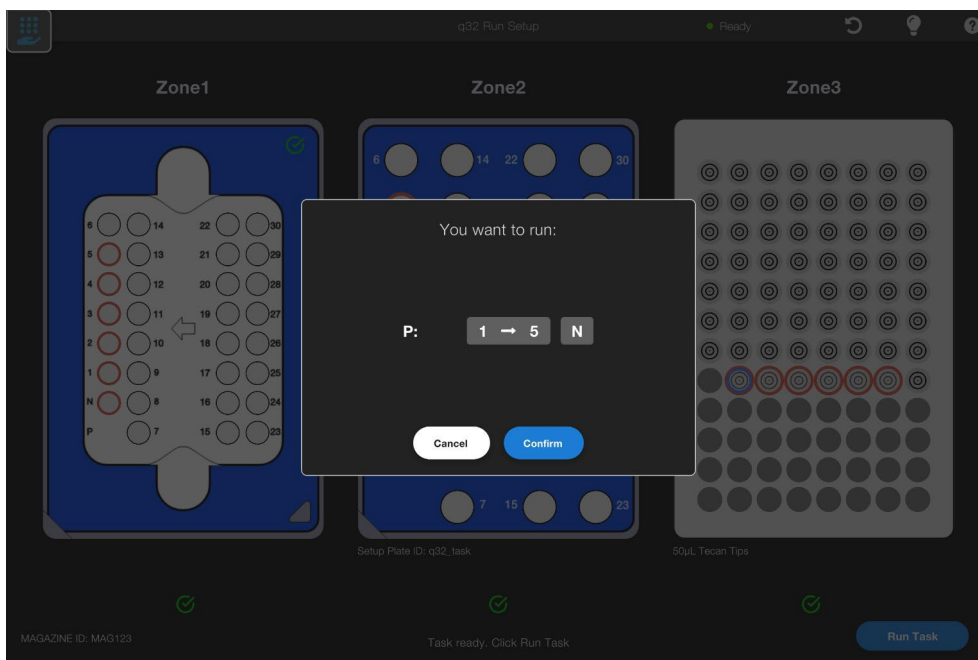
Step 3



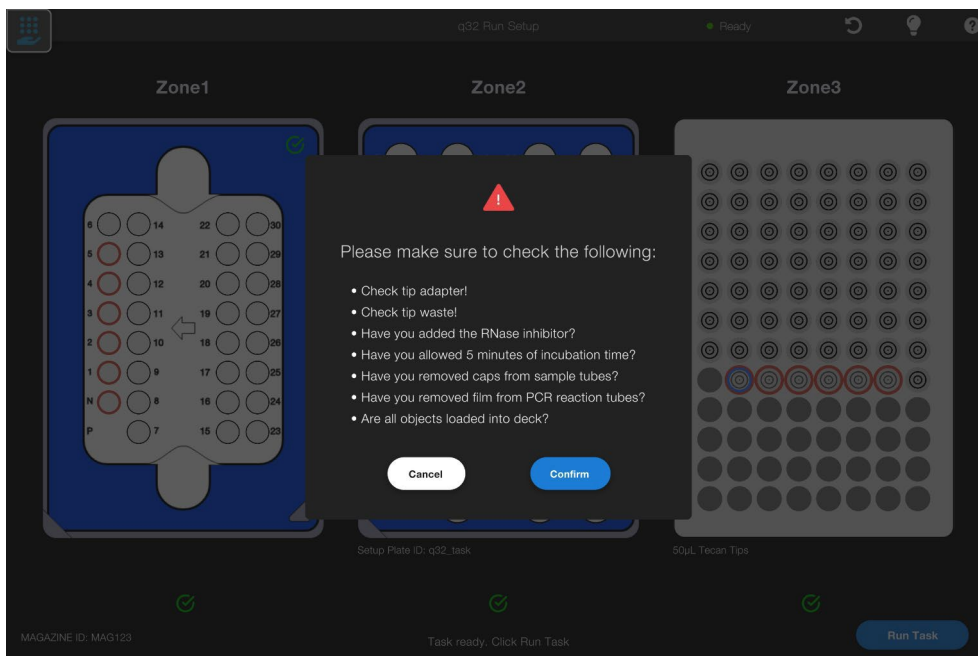
Step 4



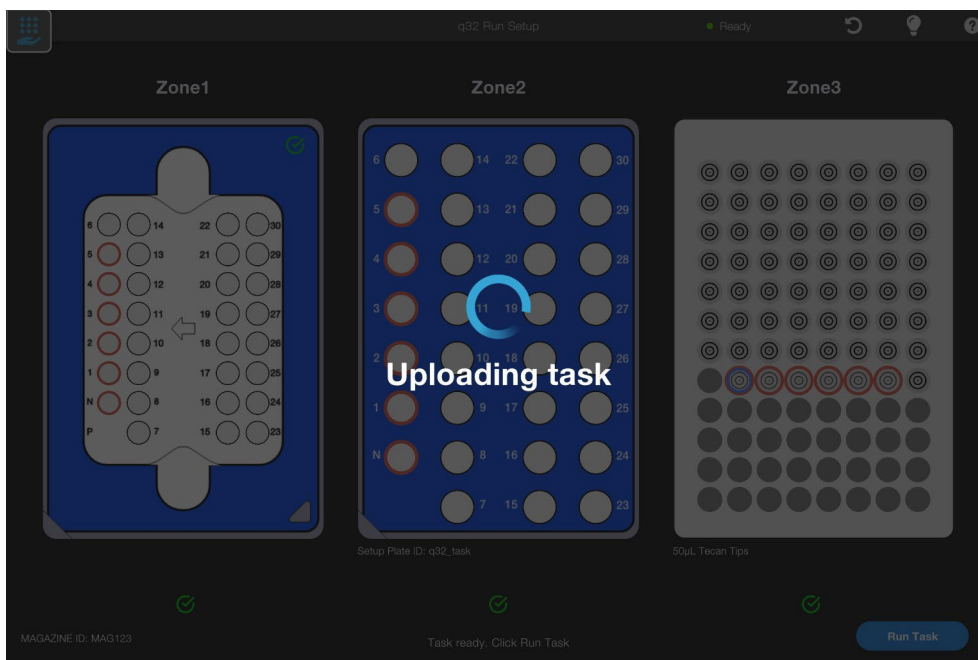
Step 5



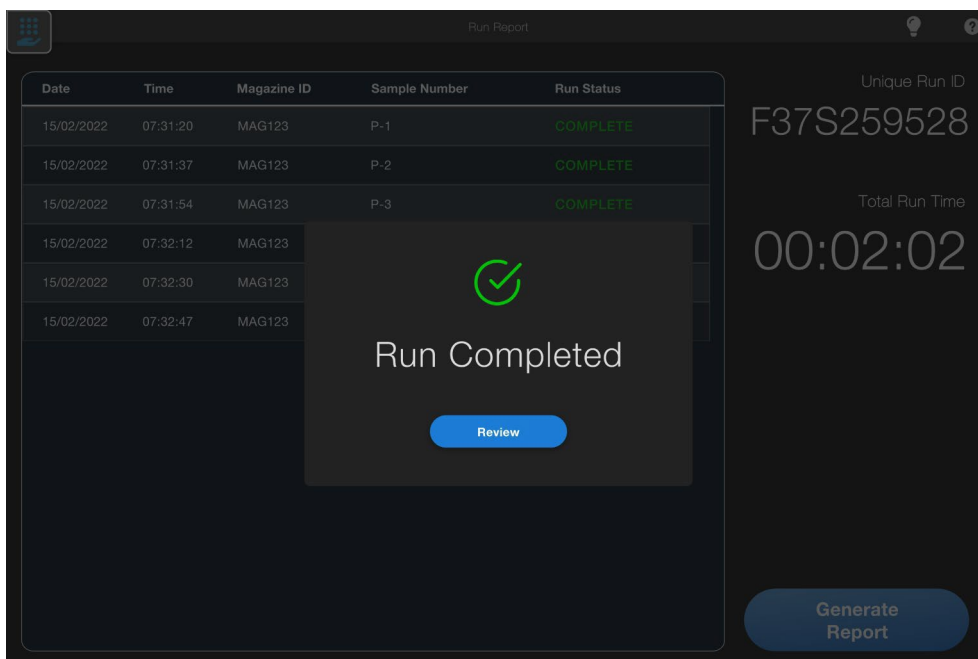
Step 6



Step 7



Step 8



Step 9

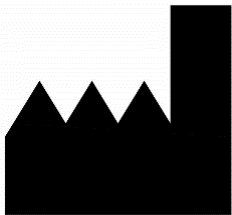
The screenshot displays a 'Run Report' interface. On the left, a table lists individual runs with columns for Date, Time, Magazine ID, Sample Number, and Run Status. All runs are marked as 'COMPLETE'. On the right, summary statistics are shown: 'Unique Run ID' is F37S259528 and 'Total Run Time' is 00:02:02. A blue 'Generate Report' button is located at the bottom right.

Date	Time	Magazine ID	Sample Number	Run Status
15/02/2022	07:31:20	MAG123	P-1	COMPLETE
15/02/2022	07:31:37	MAG123	P-2	COMPLETE
15/02/2022	07:31:54	MAG123	P-3	COMPLETE
15/02/2022	07:32:12	MAG123	P-4	COMPLETE
15/02/2022	07:32:30	MAG123	P-5	COMPLETE
15/02/2022	07:32:47	MAG123	P-N	COMPLETE

Unique Run ID
F37S259528

Total Run Time
00:02:02

Generate Report



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