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NOTICE of CHANGE dated 29/06/2021

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITe InGenius®»
Ref. INT030-K

In the Instruction for Use Manual (IFU), ELITe InGenius INT030-K, the update of the windows operating system from OS7 to OS10 is introduced.

PLEASE NOTE

	LA REVISIONE DI QUESTO IFU NON E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVIEW OF THIS IFU IS NOT COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	CET IFU MIS A JOUR ANNULE ET REMPLACE ET N'EST PLUS COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT
	LA REVISIÓN DE ESTE IFU ES NO COMPATIBLE CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU NÃO É COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIE REVIEW VON DIESER IFU IST NICHT KOMPATIBLE MIT DER VORIGE VERSION VON DEM KIT

ELITe InGenius

FOR BEST RESULTS, THIS DOCUMENT MUST BE PRINTED IN COLOR

ELITe InGenius®

Operator's Manual

(Software version 1.3)

REF **INT030-K**

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EMPOWERING IVD

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CE IVD

Table of Contents

1 Introduction

This Operator's Manual pertains to the ELITe InGenius® functions required for operations with ELITechGroup-validated in vitro diagnostic tests only.

This instrument has been cleared/approved by the Food and Drug Administration (FDA) to run only FDA-approved/cleared assays.

1.1 Intended use

The ELITe InGenius® system is an in vitro diagnostic (IVD) platform that performs nucleic acid based tests. The ELITe InGenius system is a fully automated device integrating extraction and purification of nucleic acids from multiple sample types, amplification and detection of the target sequence by real-time Polymerase Chain Reaction (PCR), and result interpretation.

1.2 System Overview

The ELITe InGenius system is a bench top instrument integrating all required hardware, reagent and software components to perform nucleic acid sample preparation and real-time PCR operations including:

- Extraction modules, liquid handling pipettors, PCR units
- Nucleic acid extraction and real-time PCR reagents
- Interactive system/run setup and result analysis software controlled via an integrated touch screen and interfacing bi-directionally with the Laboratory Informatics System (LIS).

The ELITe InGenius system can process from 1 to 12 samples in 12 parallel tracks, and samples may be loaded in primary tubes. The system utilizes a universal, cassette-based process for sample extraction and allows for multiple and independent PCRs to be performed from a single nucleic acid eluate enabling laboratories to develop custom testing panels for their specific needs. The unused eluates can be saved for future retesting or archiving.

The system can operate in three different modes: nucleic acid extraction only, PCR amplification only, or nucleic acid extraction with PCR amplification.

1.2.1 Instrument

The ELITe InGenius instrument can automatically perform the following operations:

- Barcode verification of extraction and PCR cassettes
- Liquid handling operations including sample and reagent dispensation
- Magnetic bead-based nucleic acid extraction with optional ultra-sonication capability
- PCR-based target amplification with real-time fluorescence detection

The ELITe InGenius instrument is comprised of the following components:

Single nozzle pipettor

- Moves along the X-Y-Z axis
- Reads barcodes on the extraction and PCR cassettes
- Transfers sample from the primary tube to the secondary tube, performs nucleic acid and PCR reagent dispensation
- Dispenses volume ranges from 5 to 300 µL using 300 µL filter tips

Twelve nozzle pipettor

- Moves along the Y-Z axis and performs various tasks:
  - Fluorescence detection
  - Magnetic particle capture for extraction
  - PCR cap closing
  - Liquid handling operations during extraction and extracted nucleic acid elution
- Dispenses volume ranges from 10 to 1000 µL

Both single and twelve nozzle pipettors are equipped with liquid sensors to detect sample and reagent liquid levels, clots, tips and liquid leakage.

Twelve extraction modules

- Each equipped with a heat block
- Ultra-sonication available for any combination of samples (this function is not available / active for IVD assays)
- Three elution volumes available: 50 µL, 100 µL, 200 µL

Twelve PCR units

- Independent temperature control allows parallel, diverse PCR thermal profiles
- Peltier block
- Reaction volume range from 20µL to 50µL
- Melt curve analysis capability (this function is not available / active for IVD assays)
- Six fluorescent channels are available for each PCR with the following specifications:

Channel	ELITechGroup Dyes	Excitation filter (nm)	Detection filter (nm)
1	FAM	470	510
2	AquaPhluor® 525	530	560
3	AquaPhluor 559	560	590
4	AquaPhluor 593	590	630
5	AquaPhluor 642	630	670
6	AquaPhluor 680	670	710

Table 1-1: Specification of fluorescent channels

Reagents and consumables are loaded in dedicated ELITe InGenius racks.

Figure 1.1: ELITe InGenius instrument – Exterior view

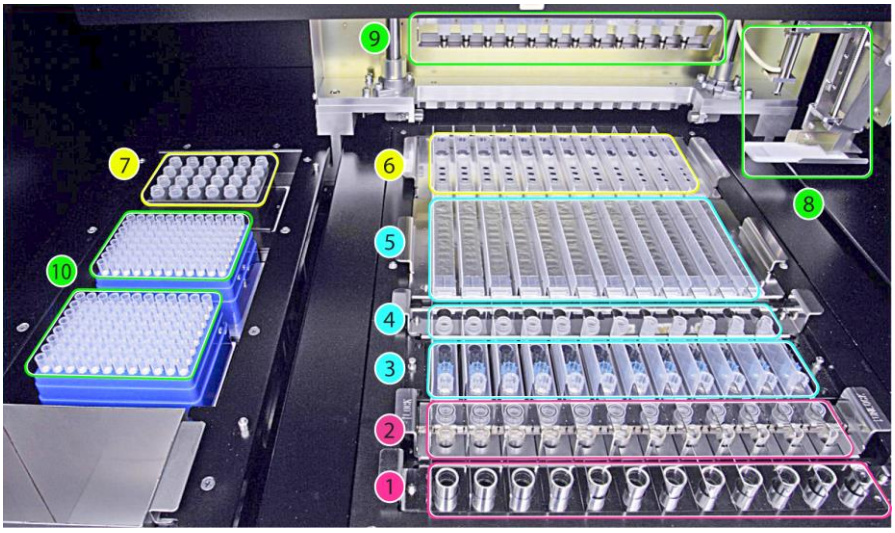


Figure 1.2: ELITe InGenius instrument – Working Area view

1. Primary sample tubes
2. Sonication tubes & sonication caps
3. Extraction Tip cassettes
4. Nucleic acid storage tubes
5. Extraction cassette
6. Universal PCR vessel and caps
7. Inventory reagent manager area
8. Single nozzle pipettor arm
9. Twelve nozzles pipettor head
10. Filter tips racks (300 µL)

1.2.2 Reagents and Consumables

Table 1-2 summarizes the reagents and consumables required for nucleic acid extraction and amplification. Further details are provided below.

Name	Part Number	Description	Required for Process
ELITe InGenius SP 200 Extraction Reagent	INT032SP200	Extraction cartridges	Extraction
ELITe InGenius SP 200 Consumable Set	INT032CS	Tip packages, tubes and caps	Extraction
ELITe InGenius PCR Cassette	INT035PCR	PCR vessel with cap	PCR
Filter Tips	M100294	300 µL filter tips in racks	Extraction and PCR
Sample Tubes	-	Primary tubes, supplied by outside vendors	Optional source vessel for samples to be tested
Monoreagent	-	PCR reagents in single tube format	PCR
Internal Control	-	Extraction process control in a separate tube	Extraction and PCR

Table 1-2: Reagents and consumables required

ELITe InGenius SP 200

- 8-well prefilled cassette sealed with aluminum foil containing all the necessary reagents for cell lysis, extraction and purification including the magnetic beads
- Universal cassette suitable for human, bacterial DNA and viral genomic DNA/RNA which has been validated on a range of sample matrices (Figure 1-3)

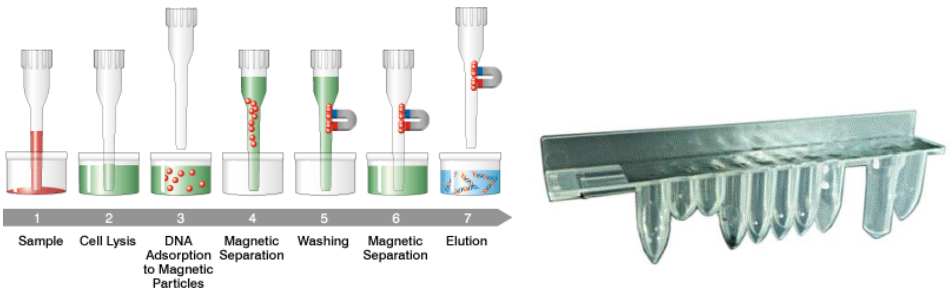


Figure 1.3: Nucleic acid extraction principle and ELITe InGenius SP 200 extraction cassette

ELITe InGenius SP 200 Consumable Set containing all necessary consumables for extraction with ELITe InGenius SP 200:

- Sonication tubes and caps
- Tip cassettes, each of which contain one piercing tip (Ref PP75) for automated extraction cassette piercing and one pipetting tip (Ref DN100N) for sample processing
- Nucleic acid storage tube and screw caps

ELITe InGenius PCR cassette: universal PCR vessel and caps for IVD and user defined assay protocol (Figure 1.4: ELITe InGenius - PCR cassette)

Figure 1.4: Universal PCR vessel for PCR

Filter tips (300 µL) – Axygen

The following Reagents are necessary for RT-PCR amplification with ELITe InGenius system

Sample Tubes

- Samples may be manually transferred into a sonication tube (included in the Consumable Set)
- Primary tube sampling is supported by loading the tube directly in the Primary Tube Rack and uncapping
- Primary tubes compatible with the ELITe InGenius system are listed below (Table 1-3); other tubes may be compatible, please refer to Customer Support

Primary Sample Tubes	Manufacturer	Position	Minimum Volume	Processed Volume	Dead Volume
13 x 75 mm, U-bottom tube	BD 3.0 mL Vacutainer, P/N 368856	Short Rack	2.2 mL	0.2 mL	2 mL
13 x 75 mm, U-bottom tube,	BD 4.0 mL Vacutainer P/N 368861				
13 x 100 mm, U-bottom tube BD 6.0 mL	Vacutainer, P/N 367864	Tall Rack	4.2 mL	0.2 mL	4 mL

Table 1-3: Primary tubes compatible with the ELITe InGenius

Monoreagent

Monoreagent is an assay-specific, ready-to-use formulation of PCR reagents (including enzymes, probes, primers, dNTPs and buffer components) that require addition of nucleic acid sample to complete PCR setup. Monoreagent for an IVD assay is a component of an FDA-cleared assay kit.

Internal Control

Internal Control is a ready-to-use formulation of a nucleic acid source that is first extracted and then amplified during PCR using Internal Control-specific primers. The IC is added to the lysis buffer to monitor the extraction process. Internal Control for an IVD assay is a component of an FDA-cleared assay kit.

1.2.3 Software

The ELITe InGenius system is piloted with an intuitive software performing the following tasks:

Settings

- Configure the system
- Manage user access
- Manage assay database

Operation

- Select pre-defined assay protocol or test template
- Perform a run
- Analyze and interpret the results
- Generate reports

Management

- Manage sample and reagent traceability
- Archive, retrieve and export data
- Calibrate and maintain the system
- Generate quality control charts

The ELITe InGenius home screen (Figure 1-5 below) enables direct access to these main functionalities.

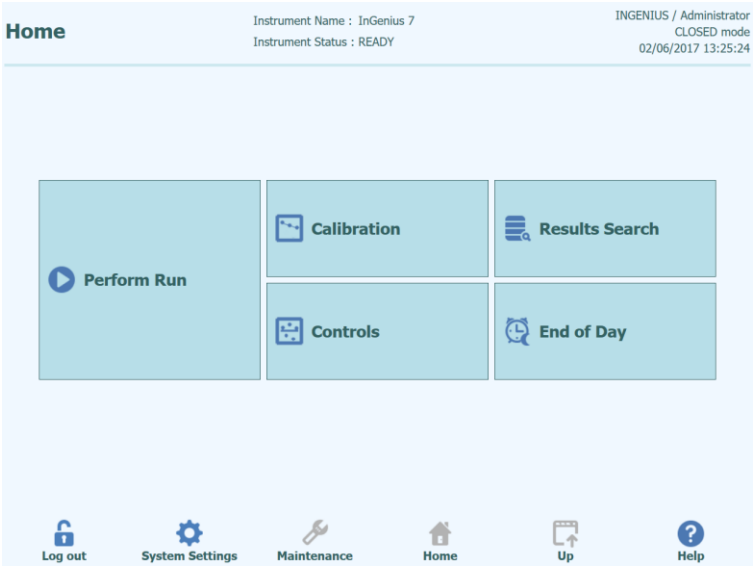


Figure 1-5: ELITe InGenius home screen

NOTE NO Calibration functionalities are described in this document since NO quantitative IVD assays have been validated on the ELITe InGenius instrument

1.3 Workflow Overview

The ELITe InGenius system can operate in CLOSED or OPEN mode. Operation of the system with in vitro diagnostic (IVD) assays, which can only be use in the CLOSED mode, is described in this publication.

ELITe InGenius workflow:

1. Start the ELITe InGenius system
2. Login with the CLOSED mode
3. Select the extraction elution volume
4. Query the LIS to import the sample work list, if applicable
5. Configure Run (see Section **Errore. L'origine riferimento non è stata trovata.**~~5.4.2~~)
6. Load ELITe InGenius extraction reagents and consumables
7. Load amplification reagents
8. Load the samples
9. Start the run
10. Approve the results (with optional data upload to LIS)

Assay calibration and control validation may be required for each PCR reagent lot and set to periodic expiry.

1.4 Customer Support

In case of questions related to the ELITe InGenius system, please contact Customer Support.

For customer/technical support:

Telephone: 1.800.453.2725
Fax: 1.425.482.5550
E-mail: mdx@elitechgroup.com
Website: www.elitechgroup.com

1.5 Proprietary Statement

The software programs and system documentation for the ELITe InGenius instrument are protected by intellectual property laws, including copyright laws, and all rights are reserved.

The ELITe InGenius instrument and accessories are manufactured for ELITechGroup by PSS (Precision System Science Co., Ltd) and include patent-protected technology. For more information, please visit http://www.pss.co.jp/english/

1.6 Notes and Symbols

The warnings, notes and symbols described hereafter are used in the current manual, on the instrument and its packaging.

1.6.1 Display of Warning and Notes

DANGER

The signal word "Danger" and relating symbol points to imminent dangers.

Avoiding a “Danger” warning can result in death or at least serious injuries. Damage to the system or an adverse effect on the system function may also occur.

WARNING

The signal word "Warning" and relating symbol points to potential dangers.

Avoiding a “Warning” instruction can result in death or at least serious injuries. Damage to the system or an adverse effect on the system function may also occur.

CAUTION

The signal word "Caution" and relating symbol points to potential dangers/problems.

Avoiding of “Caution” instructions can result in minor injuries. Damage to the system or an adverse effect on the system functionmay also occur.

NOTE

The signal word "Note" points to potential problems.

Avoiding of “Note” instructions can result in damage to the system or an adverse effect on the system function.

1.6.2 Warning Symbols

Symbol	Description
	Indicates the manual should be consulted for further information and to proceed with appropriate caution
	Indicates potentially infectious materials. Safety measures must be followed according to local regulation when performing the described task
	Indicates the presence of an electrical shock hazard and to proceed with appropriate caution
	Indicates the presence of a UV light inside the instrument and to proceed with appropriate caution
	Indicates the presence of a heated component inside the instrument and to proceed with appropriate caution
	Indicates the presence of a laser inside the instrument and to proceed with appropriate caution
	Indicates the presence of moving parts and to proceed with appropriate caution
	Indicates that protective measures have to be used in order to prevent electronic component from electrostatic discharge during handling
	Indicates that protective gloves must be worn
	Indicates that a protective lab coat must be worn
	Indicates that protective goggles must be worn
	Do not operate personal mobile terminals, cellphones, two-way radios or other radio equipment (WiFi, Bluetooth and ZigBee included) next to a running system, since this may impair the correct function of the system.

1.6.3 Other Symbols

Symbol	Description
	**Manufacturer**
	**Date of manufacture**
IVD	**In-Vitro Diagnostic device**
	**Disposal of Electrical and Electronic Equipment** In the European Union, electrical and electronic equipment must not be disposed with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in your country.
REF	**Part number**
SN	**Serial number**
	**TUV mark** TUV mark indicates the instrument has been tested by TUV SUD for regulatory compliance.
	**Consult Operator Manual**
	**Fuse**

2 Safety instructions

The following safety instructions must be observed at all times; both before and during operation and maintenance. Please read and completely understand the following explanations before using the ELITe InGenius system.

The ELITe InGenius system was designed and manufactured with a risk management system to eliminate or reduce risks to the user as much as possible. Using this instrument in a manner not specified by ELITechGroup may compromise the safety protection designed into the equipment.

Therefore:

- The user must carefully read the instructions about appropriate use of the system.

Only items supplied by ELITechGroup or representative should be used. The use of unapproved items may affect the safe operation of the system or cause damage to the system.

WARNING

2.1 Handling of the Operator's Manual

The Instructions for Use is provided for your safety and provides important instructions for the handling of the system described.

- Read all instructions.
- Keep the Operator's Manual near the system.
- The Operator's Manual must be accessible to the user always.

The ***ELITe InGenius*** instrument is designed and manufactured in accordance with the safety requirements for electronic and medical systems. It is the operator's responsibility to comply with local and national laws, regulations, and laboratory procedures for installation and operation of the instrument.

The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The instruments are tested by the manufacturer and are supplied in a condition that allows safe and reliable operation.

Non-Observance of Safety Instructions

The non-observance of safety instructions may result in serious personal injuries and material damages.

- Follow all safety instructions included in the Operator's Manual.
- Heed all warnings marked on the instrument.

WARNING

2.2 Use of the System according to Intended Use only

Improper use of the system can produce erroneous results, produce damage to the system, and/or cause personal injuries.

- The handling and maintenance of the system must be performed only by trained and authorized personnel.
- Before operating the system, the Operator's Manual must be completely read and understood.
- The instrument must only be used in accordance with the Intended Use as described in this manual.
- Use only the approved consumables and accessories described herein (e.g. disposable tips, disposable sheaths, extraction and PCR cassettes, etc.).
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

CAUTION

Use of personal mobile terminals/ cellphones.

Do not operate personal mobile terminals, cellphones, two way radios or other radio equipment (WiFi, Bluetooth and ZigBee included) next to a running system, since this may impair the correct function of the system.

Changes to the Instrument

Any changes to the instrument that are not authorised by the manufacturer may invalidate the conformity to the applicable regulations the manufacturer has declared. In this case, the customer is responsible for the fulfilment of the applicable regulations.

2.3 Electrical Safety

DANGER

Electrocution/Fire Hazard

Avoiding rules and regulations can cause serious personal injuries with deadly consequences and material damages.

- National rules and legal regulations for the safe electrical operation of the system must be observed.

DANGER

Electrocution/Fire Hazard

Improper connection of the system and the peripheral devices to mains supply can cause serious personal injuries with deadly consequences and material damages (e.g. fire).

- Use only extension cables with a protective earth conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- Never interrupt the grounding contacts.
- Grounding of the system and its peripheral devices to the same protective earth potential must be ensured.
- The use of a power strip is not allowed.

DANGER

Electrocution/Fire Hazard

Damaged connecting cables can cause serious personal injuries with deadly consequences and material damaged (e.g. fire).

- Damaged connecting cables must be replaced immediately!
- No objects may be placed on the connecting cables.
- Connecting cables must be arranged so that they cannot be squeezed or damaged.
- Connecting cables must be arranged so that they do not lay in accessible or drivable areas.

DANGER

Electrocution/Fire Hazard!

Defective systems can result in serious injuries with deadly consequences and material damages (e.g. fire).

- Separate immediately the defective system from the mains supply, if safe usage is no longer possible.
- Secure the defective system against reconnection.
- Label the defective system clearly as being defective.

DANGER

Electrocution!

Working with electrical devices on wet floors can cause serious injuries with deadly consequences and material damages due to electrocution.

- Surfaces (floors, work table) must be dry when working with the system.

DANGER

Emergency

In case of an emergency use the mains switch or the mains plug to switch off the instrument or separate the instrument from the mains supply.

WARNING

Danger due to Improper positioning during Installation

Improper site location during installation of the system can cause accidents with serious injuries with deadly consequences, fire or serious system damage if the system cannot be switched off or be separated from the mains supply.

- Ensure that the power supply and mains switch are easily accessible in the system installation location.

CAUTION

Electrostatic Discharge

During handling, electrostatic discharge can damage components of electronic circuit boards.

- Use protective measures against electrostatic discharge.

NOTE

This instrument has been tested to and complies with the following standards:

- UL 61010-1 (ed. 03), “Safety Requirements for Electrical Equipment for Laboratory Use, Part 1: General Requirements.”
- CAN/CSA C22.2 No. 61010-1-12 (ed.03) “Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- IEC 61010-1 (ed. 03) “Safety Requirements for Electrical Equipment for Laboratory Use, Part 1: General Requirements”
- IEC 61010-2-010 (ed. 02) “Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory use. Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of materials”
- IEC 61010-2-081 (ed. 02) “Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use. Part 2-081: Particular Requirements for Automatic and Semi-automatic Laboratory Equipment for Analysis and Other Purposes”
- IEC 61010-2-101 (ed. 02) “Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

2.4 Laser and UV-Light Safety

Eye Injuries due to Laser Radiation

WARNING

a) Laser radiation cause eye irritation when you look directly into the laser beam. During operation of laser, inform all people around the instrument to avoid watching the laser beam.

- Never look directly into the laser beam.
- Do not use optical devices (e.g. mirrors).
- Take off watches and mirroring jewellery before operating the laser.
- Note that the wrong usage of operating elements, adjustments, or the non-observance of processes can cause a dangerous emission of laser radiation.

WARNING

Conjunctivitis and Skin Burns due to UV-Light

The radiation of the UV-Lamps causes conjunctivitis and skin burns within minutes.

- Never look directly into the UV-Lamp!
- Protect your eyes and skin from direct radiation.
- Keep the instrument door closed during UV sterilization.

2.5 Mechanical Safety

WARNING

Danger of Electrocution or Mechanical Injuries by Missing or Open Protective Covers

To avoid serious injuries with deadly consequences due to electrocution or injuries by the system (e.g. contusion, cuts etc.), protective covers may only be opened, by-passed, or removed for certain maintenance procedures and with the highest level of caution by authorized and trained personnel.

- Only perform maintenance procedures described in this manual.
- Make sure that no one is working on the system and that all covers are attached and closed before reconnecting the system to the mains supply.
- Make sure that all covers are attached before switching on the instrument.
- Switch off the system, separate it from the mains supply and protect the system against restarting, if protective coversor gear is missing.
- Make sure that the motion of the pipettor has stopped before opening covers and/or accessing the working area of the instrument.
- Avoid touching the pipettor and other moving parts while the system is in operation.
- Perform all maintenance procedures with the highest level of caution.
- Do not wear clothes or accessories which can be caught by the system.
- System malfunction or unexpected movement can cause injury. Keep away, shut down and remove power supply in such cases.

2.6 Heat Hazards

WARNING

Improper placement during installation of the system may cause fire or serious system damage due to overheating.

- Select the place of installation of the system so that the ventilation airducts are not blocked or covered.
- Select the location where the system is to be installed, so that air can circulate freely.
- Do not touch the hot collar or PCR block during or immediately after PCR process. To minimize the risk for the users the system automatically decreases the temperature after PCR completion.
- Pay attention to heated areas accessible to user during removal/placement of consumables.

2.7 Biological Hazard

DANGER

Risk of infection

Biological samples used in association with the ***ELITe InGenius*** system have the potential to transmit infectious diseases. Follow all applicable national and international laboratory safety regulations.

There are biological hazards during the following user activities:

- Sample handling
- Eluate handling
- Waste disposal (fluids and consumables)
- Maintenance and cleaning

The following guidance must be observed:

a) Observe local and national provisions, legislation and laboratory regulations.
b) Use appropriate gloves
c) Use an appropriate lab coat!
d) Use appropriate eye protection (e.g. goggles)
e) Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
f) Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.
g) In case of spills of reagent or samples, wash and clean by using 70% alcohol and dispose treating cleaning material as potentially infectious.
h) Do not use broken or chipped tubes or bottles.
i) Observe the instructions in the package inserts for correct use of reagents.
j) Observe the legal regulations for the handling of infectious material.
k) Never use bio-hazardous liquids for testing the instrument!
l) Do not drink or eat eat in laboratories.

2.8 Chemical Hazards or Safety

There is possibility of exposure to hazardous chemicals through handling of reagents, calibrators or controls. The following precautions should be observed to minimize the risk of accidental spilling of chemical agents (in the sample loading sample area, cooling block area, consumable areas …) when handling of reagents, calibrators or controls

a) Carefully read and follow the Safety Data Sheet (SDS) for each assay.
b) Wear recommended protection such as disposable gloves, lab coat, eye protection to prevent exposure to hazardous reagents and infectious samples.
c) In case of exposure, follow the guidance on the SDS.

d) Follow all applicable national and international laboratory safety regulations.

2.9 Electromagnetic Interference

Maintain a compatible electromagnetic environment to ensure the device performs as intended.

- Only use instrument and cables supplied by ELITechGroup to maintain compliance.
- Installation should be done only by trained service staff approved by ELITechGroup or representative.
- Do not use the instrument near a source of electromagnetic radiation, such as an instrument without appropriate shield, or an instrument or equipment without appropriate EMC certification.

This instrument has been tested to and complies with the following standards:

- IEC/EN 61326-1:2012 “Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- IEC/EN 61326-2-6:2012 “Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: particular requirements – In vitro diagnostic (IVD) medical equipment.

2.10 Residual Risks for User Safety

This section explains potential residual risks to the user after certain safety measures have been taken. The user should carefully read and understand these residual risks and follow guidance in order to use the ELITe InGenius system in a safe manner.

2.10.1 Design and Manufacturing Process for Safety

The ELITe InGenius system was designed and manufactured with a risk management system to eliminate or reduce risks to the user as much as possible. Using this instrument in a manner not specified by ELITechGroup S.p.A. may compromise the safety protection designed into the equipment.

The user must carefully read the instructions about appropriate use of the system. Only items supplied by ELITechGroup S.p.A. or representative should be used. The use of non-approved items may affect the safe operation of the system or cause damage to the system.

2.10.2 Ergonomics

Ergonomic principles were considered in the design of the ELITe InGenius system to reduce discomfort, fatigue, and physical stress to the user.

The instrument touch screen is adjustable to allow individuals to find their most comfortable working position

2.10.3 Power Supply Interruption

If power is interrupted during use of the ELITe InGenius, the system will not automatically restart. The system will need to be manually restarted by the user.

2.10.4 Protection Against Mechanical Hazards

Care was taken in the design of the ELITe InGenius to protect the user from sharp edges and rough surfaces. There are also safety systems in place to stop the operation of the instrument if the door is opened. It is strictly prohibited to remove the door, covers, or alter the built-in safety mechanisms in any manner.

2.10.5 Protection Against Biological Hazards

Always observe local and national provisions, legislation, and laboratory regulations and standard practices to minimize biological hazard.

a) Do not operate the ELITe InGenius system or handle consumables or potentially contaminated items without wearing appropriate personal protective equipment (PPE). Consult the appropriate SDS for requirements.
b) Do not handle sample specimens without wearing appropriate personal protective equipment.

2.10.6 Protection Against CyberSecurity Hazards

To safeguard the ELITe InGenius system against CyberSecurity hazards the following instructions shall be noted

WARNING

It is recommended to use virus-free USB memory sticks to avoid and prevent the automatic start up, through the Windows auto-run mechanism, of any malware applications prior to use with the ELITe InGenius System.

WARNING

If it is necessary to connect the ELITe InGenius system to a network (Ethernet), this connection should always be directly protected against cyber-attacks using a hardware firewall device (possibly equipped with antivirus). The hardware firewall should block all network addresses that are not necessary for the operation of the ELITe InGenius system. Please contact your ELITechGroup technical service support partner for further firewall hardware and configuration recommendations.

NOTE

Only ELITechGroup approved software updates shall be installed to the ELITe InGenius system. These shall only be installed by ELITechGroup trained and approved personnel.

NOTE

The use of the ELITe InGenius system should be monitored by the system administrator for unusual patterns of use and/or suspicious behavior by regularly inspecting the System Logs (see section **Errore. L'origine riferimento non è stata trovata.**~~6.4.7~~ for further details).

Suspicious events should be reported to ELITechGroup support staff immediately and the system should not be used until checked by ELITechGroup.

NOTE

An external keyboard and mouse shall not be connected to the ELITe InGenius system unless specifically indicated by your ELITechGroup technical service support partner.

2.10.7 Protection Against Electrical Hazards

The ELITe InGenius system was designed and produced to prevent electrical shock or electrostatic hazards. A fuse is installed for overcurrent protection. Strictly follow local and national regulations for safety.

The ELITe InGenius system was designed for indoor laboratory use only. Do not operate the instrument in an explosive environment or atmosphere. End user is responsible for safe use:

a) Do not interrupt the electrical ground contact
b) Do not connect other electric devices to the same plug or electrical outlet (unless authorized by ELITechGroup or trained representative).
c) Do not use damaged wiring.
d) If safe use is impossible, disconnect the system from mains power supply. Do not use damaged instrument.
e) Do not open the locked cover during operation.
f) Do not attempt internal repairs. Refer servicing to qualified service personnel.

2.10.8 Protection Against High Temperature Hazards

A hot collar is installed in the system to prevent condensation during PCR. There is a Caution Hot Surface label near the hot collar. Handle with care.

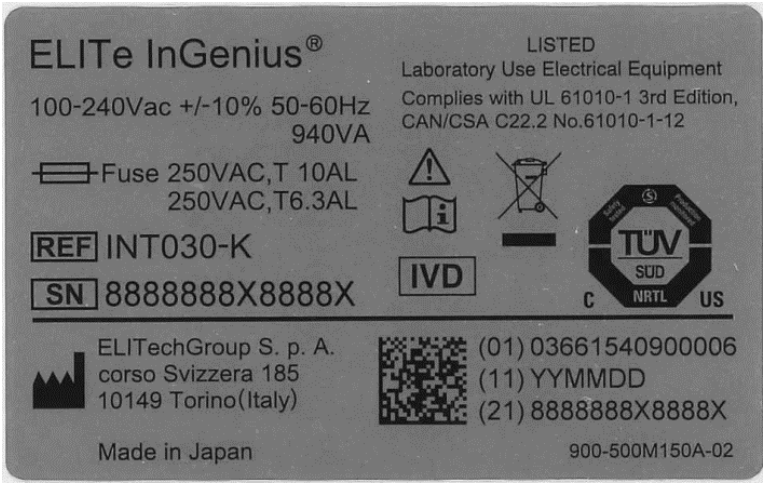
2.10.9 Protection Against Noise Hazards

The instrument is designed and produced to keep the A-weighted emission sound to be less than 70dB at distances at least 1 meter away.

3 Safety labels / Instrument labelling

3.1 Instrument Nameplate

Nameplate with model and serial number can be found on the right side of the instrument as shown in the example below.



3.2 Power Switch

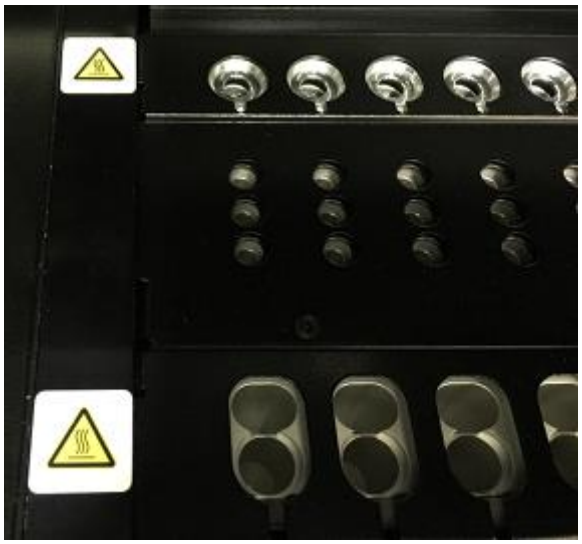
The main power switch is located on the right side of the instrument.

In case of emergency, the user can shutdown the instrument by switching this switch to the OFF position.

3.3 Hot Surface Label

A Caution Hot Surface label is located near the hot collar and heating block. Handle with care.

CAUTION



3.4 Mechanical Hazard Label

The ELITe InGenius system has many moving parts inside. The door is equipped with a locking mechanism to prevent opening during use. The system is also designed to shut down if the door is opened during use. However, a Caution Mechanical Hazard label is located inside the instrument. Handle with care.

CAUTION

3.5 Biohazard Label

A Biohazard warning label is attached inside the instrument. There is a potential biohazard risk if the user does not adhere to good laboratory practices and follow all local and national regulations for safety. Operator must wear all recommended PPE.

CAUTION

4 Operational precautions and limitations

In order to safely obtain reliable results from the instrument, users must strictly adhere to this manual. Using the instrument in a manner not specified by ELITechGroup S.p.A. is prohibited and may impair the safety protection designed into the equipment, lead to injury, and affect results.

4.1 General requirement

a) Keep away from heat generating sources.
b) Keep out of direct sunlight.
c) Operate the instrument only within the defined operating temperature range.
d) Maintain the defined minimum space on all sides of the instrument at all times..

This is important for:

i) Maintaining reliable temperature control
ii) Preventing overheating of the system and/or serious system damage
iii) Maintaining functionality of electrical and detection systems
iv) Preserving instrument life
v) Providing sufficient access for maintenance

4.2 Minimum Sample Volumes

The procedure of the **ELITe InGenius** is optimized for the isolation of DNA and RNA from 200 µL samples.

Primary Sample Tubes	Manufacturer	Position	Minimum Volume	Processed Volume	Dead Volume
13 x 75 mm, U-bottom tube	BD 3.0 mL Vacutainer, P/N 368856	Short Rack	2.2 mL	0.2 mL	2 mL
13 x 75 mm, U-bottom tube,	BD 4.0 mL Vacutainer P/N 368861				
13 x 100 mm, U-bottom tube BD 6.0 mL	Vacutainer, P/N 367864	Tall Rack	4.2 mL	0.2 mL	4 mL

Minimum volume of samples in primary tubes

Depending on sample tube type, a minimum sample volume is needed to prevent pipetting errors. The minimum volumes of sample required for primary tubes are shown in the table above.

NOTE: If the **ELITe InGenius System** detects a low sample volume, it skips the sample and makes a note in the Result Report.

Minimum volume of samples in the sonication tubes

All sample types may be directly loaded into the system using the sonication tube included in the **ELITe InGenius SP 200 Consumable Set (**part number INT032CS).

The volume required when using sonication tubes is 200 µL.

4.3 System Installation

Installation Policy

The ELITe InGenius system is installed by authorized ELITechGroup service representatives, who will perform all checks required on the system. Attempts should not be made to unpack, lift, move or install the system unless under the supervision of an authorized ELITechGroup service representative.

Installation Site Location

The instrument should be installed in an area that allows for good air circulation, and is free from undue vibration, high humidity, dust, temperature extremes, and corrosive or explosive vapors or gases.

If this equipment is used for detection of potentially hazardous substances, it should be installed in an area intended for handling these substances.

- Input voltage and power requirements: 100-240 VAC (+/- 10%), 50-60 Hz, 940 VA.
- Use of a UPS is recommended.
- System must be placed at least 3 inches (7.5 cm) from the right wall to allow access to the power cord.
- Room temperature (operational) must be between 15.0°– 30.0° C.
- Relative humidity (RH, operational) must be between 20% and 80% (non-condensing).
- Altitude 0 to 2000m
- Minimum space around instrument for air circulation: 6” / 15 cm
- Do not place the system in direct sunlight.

Environments which exceed these limits could adversely affect the performance of the instrument components.

4.4 Removal of the system

If the instrument needs to be relocated to another installation site or returned for repair or service, only an ELITechGroup or trained service representative is authorized to do so.

5 System Operation

The ELITe InGenius instrument is supplied with a built-in user interface that runs the ELITe InGenius software. IVD Assay Programs can only be performed in CLOSED mode. Changes to the system in CLOSED mode are limited to protect assay integrity.

CAUTION

Use of Approved Software

Use only approved ELITe InGenius instrument software to operate the instrument and to generate assay results.

The following chapters describe the basic process of starting up the instrument, setting up and executing a run, approving the run results and shutting down the instrument.

Most of the basic functions of the ELITe InGenius software are described in this chapter.

Some additional basic functions and more advanced functions are described in chapter 6.

Maintenance functions are described in chapter 8.

5.1 Starting the Instrument

CAUTION

To avoid injury due to moving parts, the instrument initialization cannot be performed when the door is open. During startup, the system requires the user to confirm the door is closed.

1. Close Door
2. Turn on the power switch which is located on the right side of the instrument.
3. The ELITe InGenius software starts automatically on the integrated PC. The system displays the start-up screen (see **Errore. L'origine riferimento non è stata trovata.**~~Figure 5-1~~) while the start-up checks are being performed.

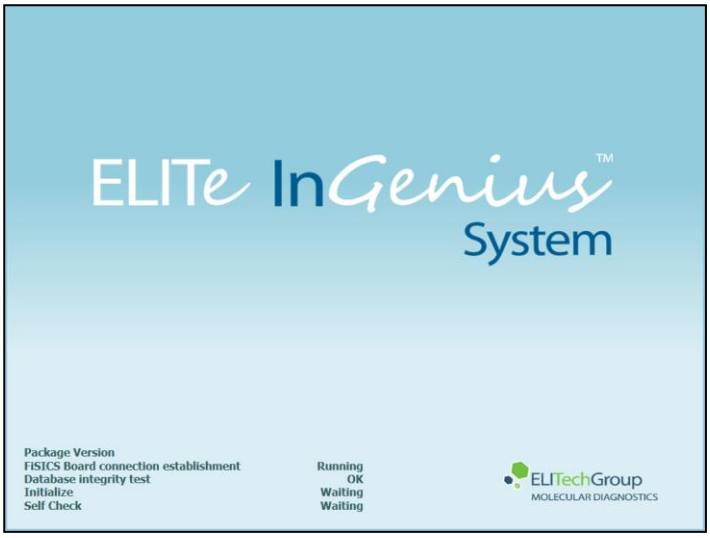


Figure 5-1: Software Initialization.

CAUTION

If an error is detected during the system start-up checks, the running of assays will be locked out until the problem is resolved.

Please consult Technical Service (See Section 1.4) if an error occurs.

4. After the system start-up checks are complete, the ELITe InGenius software shows the login screen:

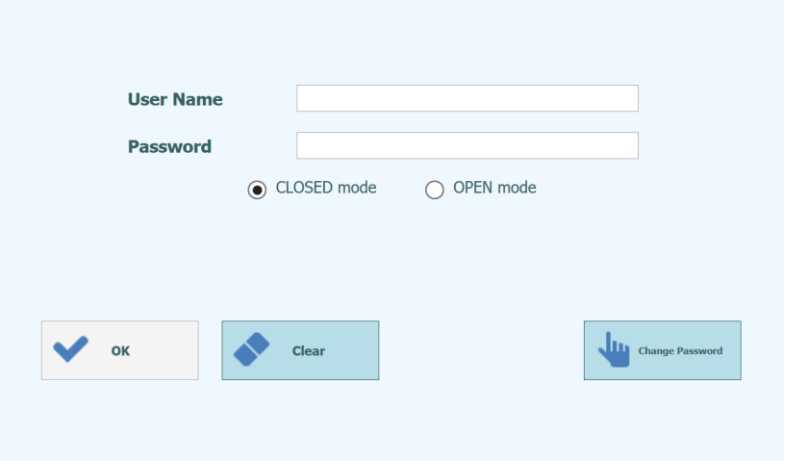


Figure 5-2 : Login display.

Description of Login Display:

User Name: Field/input box to enter the user name.

Password: Field/input box to enter the password.

CLOSED mode and OPEN mode: Radio buttons to select operation mode.

5. Touch the “User Name” field/input box and enter your user name with the on-screen keyboard (case-sensitive).
6. Touch the “Password” field/input box and enter your password with the on-screen keyboard (case-sensitive).
7. Choose “CLOSED mode” by touching the radio button
8. Touch “OK”.
9. If the username and password is authenticated, the Home Screen display will be shown.

NOTE

The ELITe InGenius instrument implements an access model that restricts access to certain functions in the software by associating a User Role to each account when the account is setup (see 6.3~~6.3~~).

Processes	Operator	Analyst	Administrator
Run assays	●	●	●
Approve assay results		●	●
Approve a run that has assays with expired or missing calibrators and/or controls			●
Export Data from Runs			●
Change system settings			●

NOTE

The first time a user logs on to their account, they will be prompted to change the temporary password that was assigned to the account (see Chapter 6.3.2~~6.3.2~~ Changing Password).

5.2 The Home Screen

The Home Screen is the main screen of application software and is used to access the main features of the ELITe InGenius software.

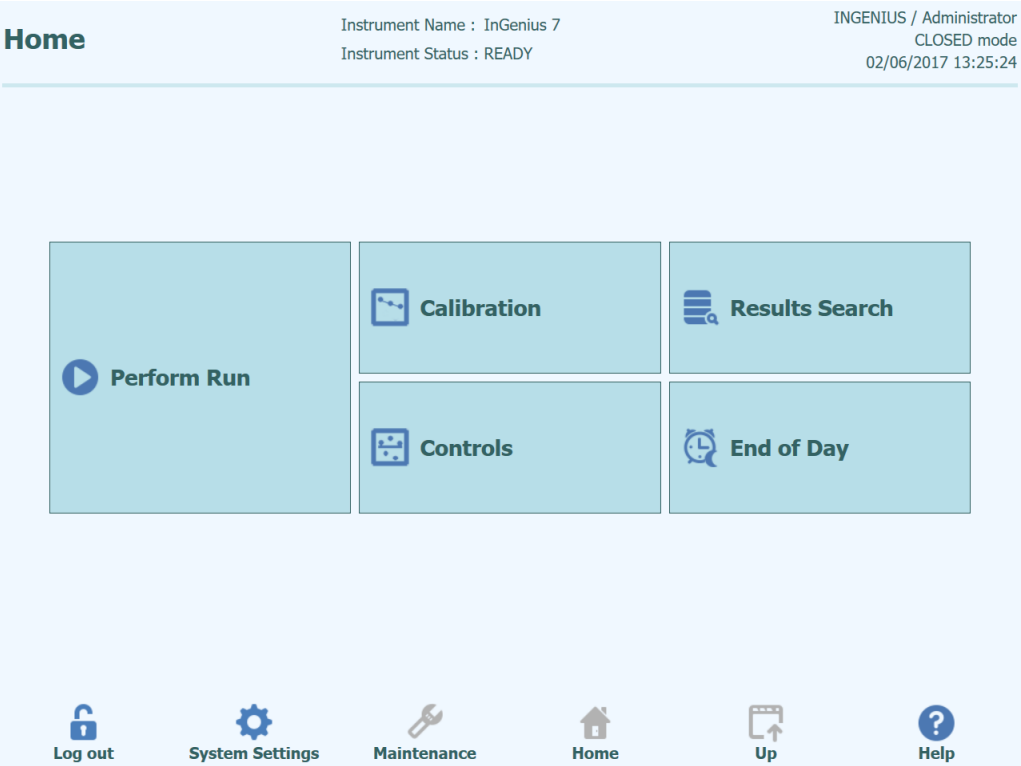


Figure 5-3 : Home Screen display

The following table summarizes the main functions that can be accessed from the Home Screen:

Perform Run

Used for setting up and accessing the details for a run while it is in progress.

Depending on the progress of the run, selecting the Perform Run icon will display one of three different screens as follows:

RUN progress	Destination screen
Run not started	Setup Run Screen
Run in progress	Run Status Screen
Run completed	Run Result Screen

End of Day

Used for Shutting down the system at the end of the day. If a run is in progress, this button is disabled until the run has completed.

Results Search

Used to access the database of completed Run Results.

Calibration

Displays Calibration Manager screen.

NOTE NO Calibration functionalities are described in this document since NO quantitative IVD assays have been validated on the ELITe InGenius instrument

Controls

Displays Controls Manager screen.

At the bottom of the screen there are additional buttons for for configuring and managing the instrument.

Logout

Logs the current user out.

System Settings

Displays the System Settings Screen (Administrator and Service Users only).

Maintenance

Displays the Maintenance software (Service User only).

Home

Shortcut back to the Home Screen.

Up

Navigate to previously viewed screen.

Help

Displays instructions for accessing this user manual on the ElitechGroup website: https://www.elitechgroup.com/north-america/documentation/ifu

5.3 Runs, Assays and Controls

The term “RUN” is used to refer to a group of between one and twelve assays that are processed during a single sample-to-answer cycle on the twelve tracks of the instrument. Between 1 and 12 tracks may be included in a run with any configuration of tracks.

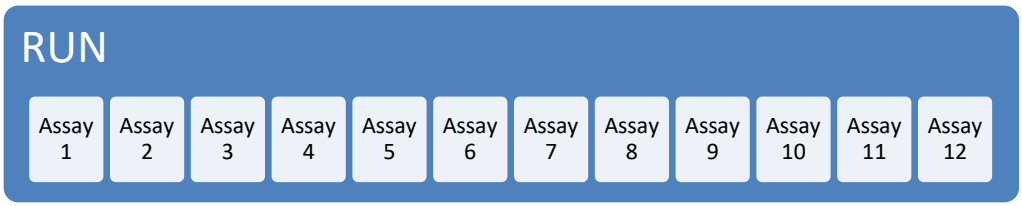


Figure 5-4: A Twelve Assay Run

Assay protocols are the settings used to instruct the system how to process each sample on the instrument. There are two types of assays:

- Sample Assays
- Control Assays

Sample Assays may be run as Extract Only, Extract + PCR or PCR only.

An assay will yield either a Qualitative result per the Assay protocol settings. A post-PCR Melt analysis may also be conducted after completing PCR amplification. Assay protocols may be configured to perform no result interpretation and report only C_t and T_m results.

To approve the results of a run with a Qualitative Sample Assay, the ELITe InGenius Software requires an approved one or more approved Control results stored in its database.

To generate Control results, Control Assays are run with Positive and Negative controls. The Control results are required in Qualitative Sample assays for Sample result approval.

The results of Control Assays are stored within the ELITe InGenius database and remain valid for a user-defined period, negating the need for a new Control in every run.

For efficiency, it is possible to generate a Control results and perform Sample Assays within the same run. In this case, it is necessary to approve the Control Results, and finally the Sample Results.

To set up a Run on your ELITe InGenius system, it must be configured with the following configuration information:

- Assay protocols (Sample, Control as required)
- Control Details

If the required configuration is not available on your system, refer to sections 6.5 and 6.6 for instructions how to import Assay protocols.

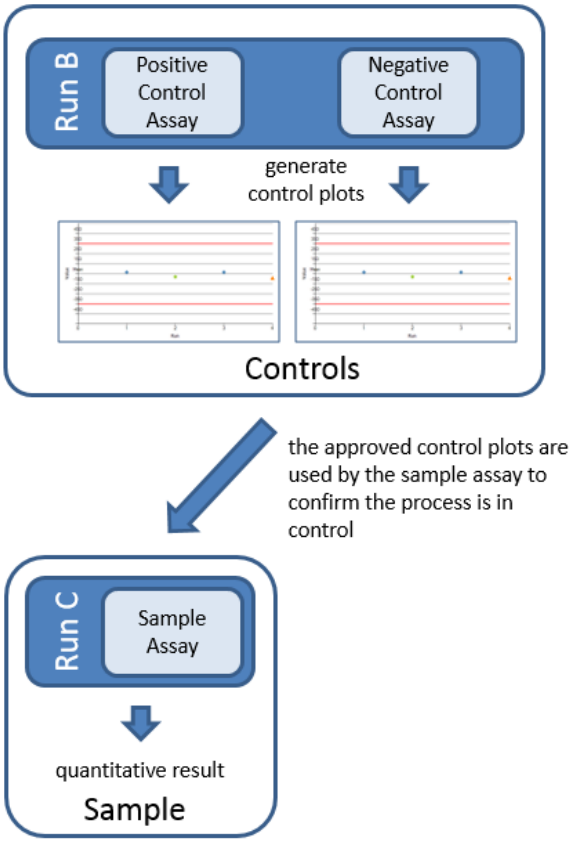


Figure 5-5: Relationship between Control and Sample Assays.

NOTE

It is possible to run Control and Sample Assays in the same run (e.g., to combine Run B and Run C in **Errore. L'origine riferimento non è stata trovata.**~~Figure 5-5~~) and use Sequential Approval to approve the results.

5.4 Performing a Run

To perform a Run, the following sequence of activities should be followed:

1. Check and Control Status
2. Configure the Run
3. Load / Unload Inventory in Reagent Cold Block
4. Load Consumables and Samples
5. Monitor Run Progress
6. Review Results and Approve
7. Unload used consumables at end of Run

5.4.1 Step 1: Check Calibration and Control Status

5.4.1.1 Check Status of Controls

Display the “Control” screen by touching the “Controls” button on the Screen.

Figure 5-6: Controls screen.

This Control screen may be used to:

- View the details and status of each control plot stored on the system
  - monoreagent lot number used to generate each control Run
  - traceability information for the Calibration reagents used to generate each control Run
  - expiry date for the control Run
  - status (Need to Run, Approval Pending, Approved, Expired)
- View the Control Plots stored on the system
- View the process settings and number of levels for the Controls
- Register new Control
- Remove Control Runs from the database

NOTE When running an Assay, it is necessary to use the same lot number of monoreagent as was used to generate the Control Result. If you wish to use multiple lots of monoreagent, then it is necessary to generate a Control Result for each lot number.

Control Details

Touching the “Details” button, shows the settings for the Controls in the following screens, shown on two tabs (General Settings and Level Settings):

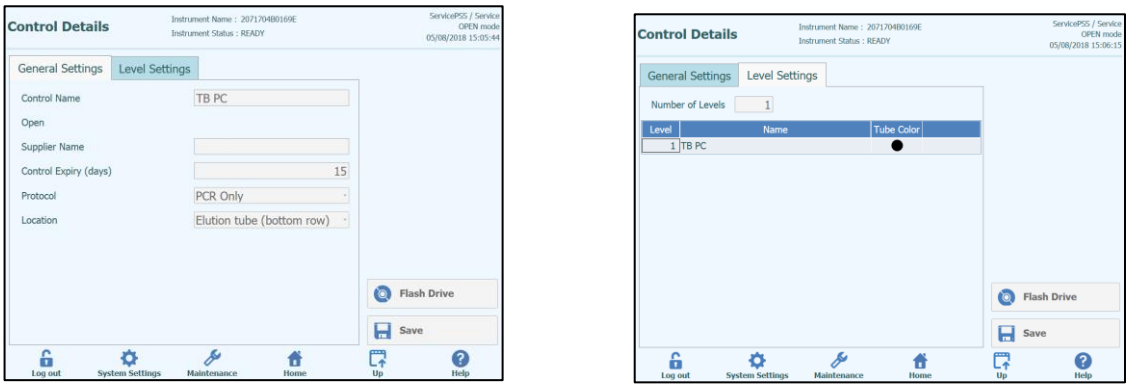


Figure 5-7: Controls Details – General Settings and – Level Settings screens.

These settings are usually provided by the Assay Developer and are registered in the database when loading the Assay settings onto the system.

It is also possible to add new Controls settings independently from the loading of Assays by pressing the “Add New” button in the Control Manager Screen and then using the “Barcode Scan” or “Flash Drive” buttons in this screen.

NOTE

It is possible to specify the tube color for each level that will be shown in the run setup screen. This is intended to help guide the user and thus reduce the risk of loading control fluids to the wrong tracks.

NOTE

The software will not allow control settings to be deleted or modified if there are test results in the database that depend on these data.

Control Plots

If a Control Run has been performed for a Control, the “View Chart” button will be activated in the Control Manager screen. By clicking on this button, it is possible to view the Control Results and Control Curve as in the example below:

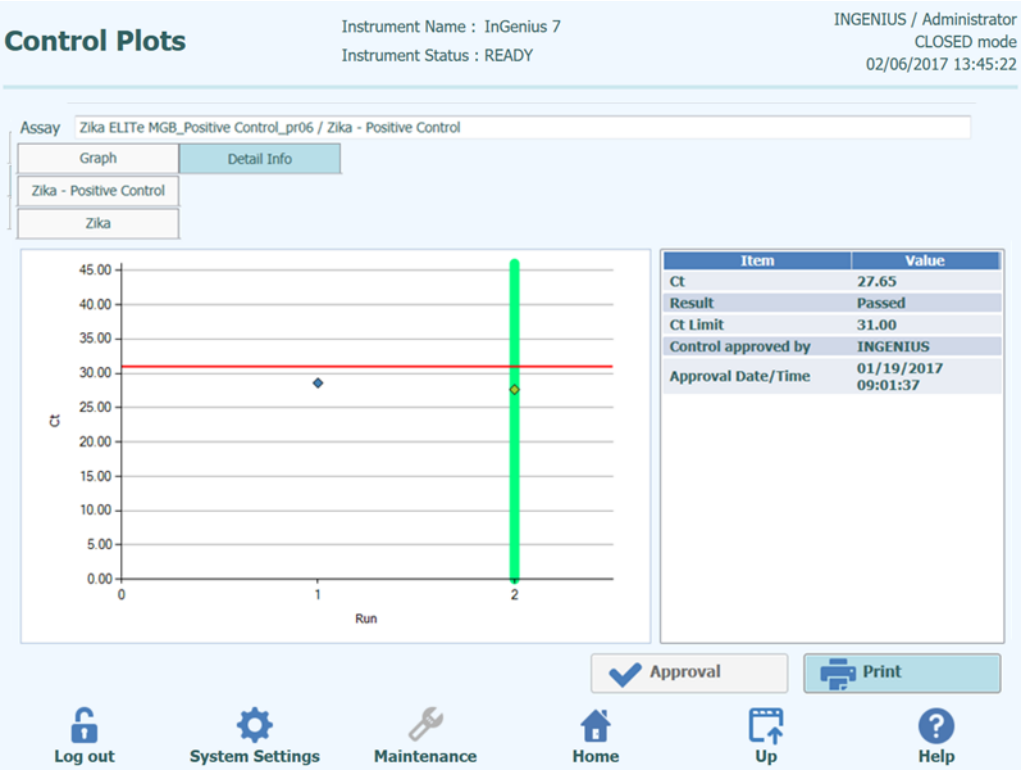


Figure 5-8 : Control Plot – Plot screen.

This screen will show a summary of recent Control Runs for each Control. Runs using different lot numbers for the monoreagents are shown with different markers in the plot. Touching a single point on the plot will show the Lot numbers used to generate the specific point.

Style of plot varies by the conditions below (Table 5-1). Color varies by lot number of control.

Run	Non-approved		Approved	
	Passed	Failed	Passed	Failed
latest	▲	▲	◆ ◆ ◆ (*)	-
past	▲	■	◆ ◆ ◆ (*)	-

Table 5-1: Style of plot

The green vertical bar (**Errore. L'origine riferimento non è stata trovata.**~~Figure 5-8~~) indicates the run for which the numerical data is shown in the panel on the right side of the screen.

It is possible for an Administrator or Service user to Approve Control Plots in this screen.

It is also possible to generate a printed or .pdf format report by clicking the “PRINT” button from this screen.

The Detailed Info tab of this screen shows further information about the Run that was used to generate the latest run in the Control Plot, including the results from each reaction as well as the lot numbers and expiry dates for each reagent and control fluid that was used in the run.

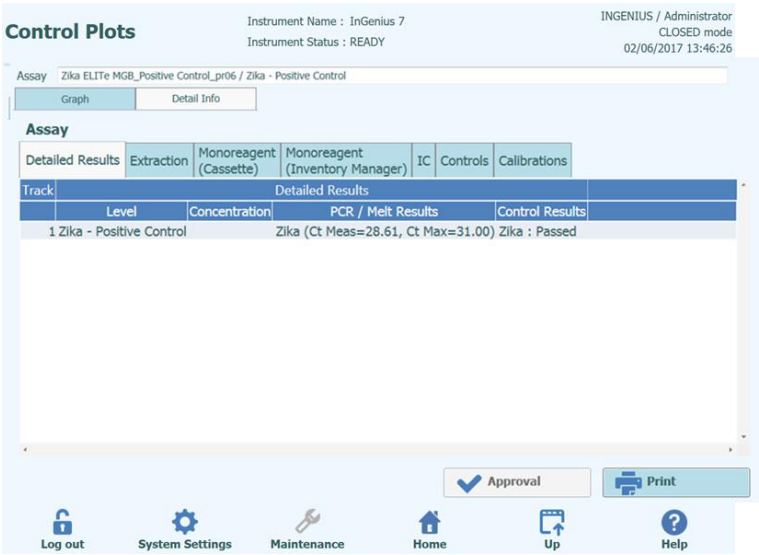


Figure 5-~~89~~: Control Plots – Run Details screen.

Controls History

By clicking on the “Show Runs” button in the Control Manager screen, it is possible to view the Control Results and Control Plots for previous control runs as shown in the example below:

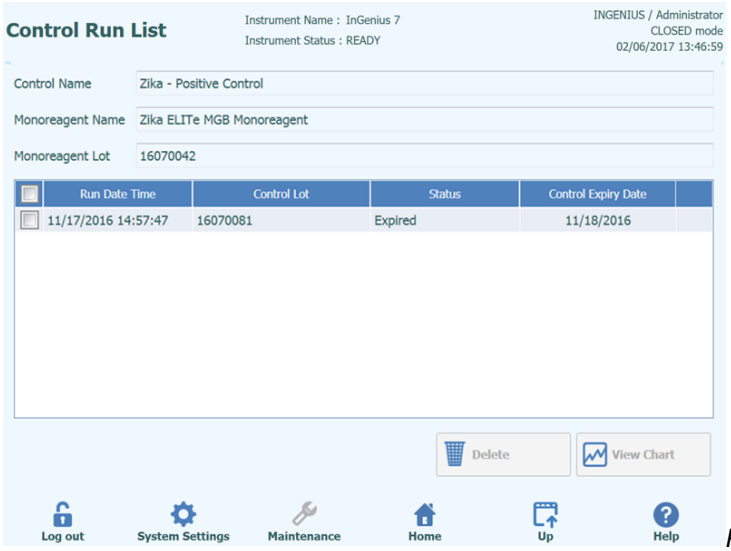


Figure 5-~~910~~: Control Plots – Control Run List screen.

In this screen, the “View Chart” button can be used to access historical data as required, and “Delete” will remove the information from the system.

5.4.2 Step 2: Configure the Run

Touch the “Perform Run” button on the Screen to display the Perform Run screen used for Run Setup:

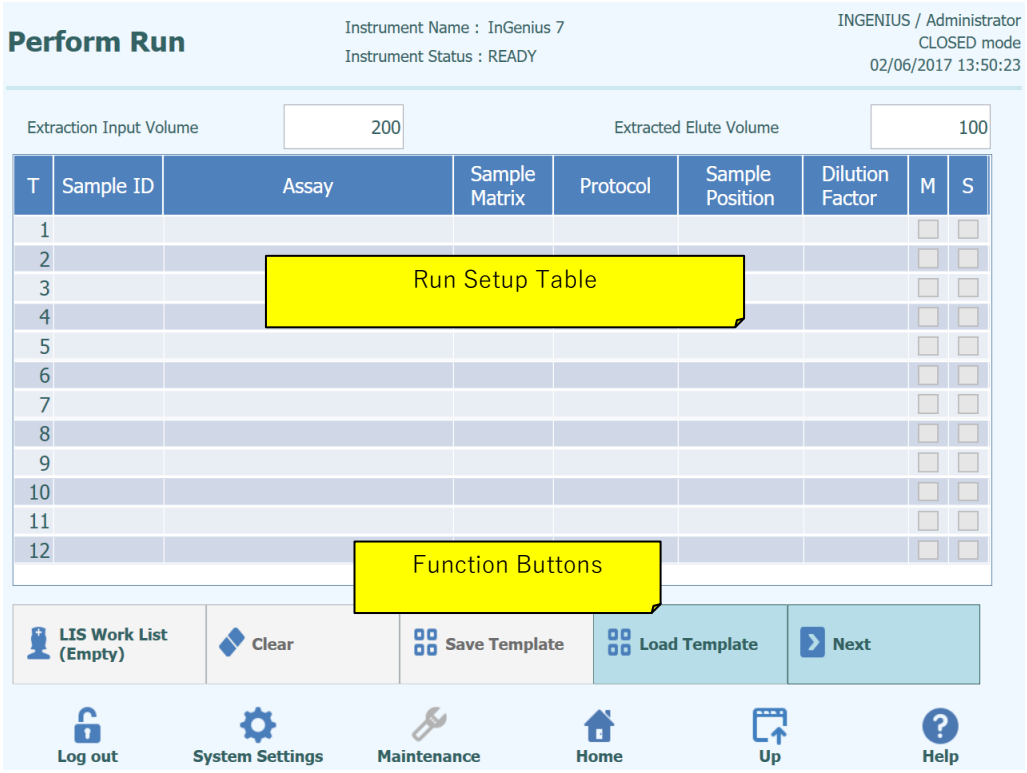


Figure 5-1011: Perform Run Screen.

5.4.2.1 Configuring Assays to be Run

Select the “Extraction Input Volume” and “Extracted Eluate Volume” by touching on the corresponding fields above the main grid. The ELITe InGenius Software uses these settings to filter the list of Assays to ensure that all tracks have the same Input and Output volume settings.

NOTE Put the Sample Tubes on the rack in the same order indicated in grid table. The position in the Sample Carrier of the Sample Tubes is very important for the traceability of results. Place the sample tubes without caps.

Each row in the grid corresponds to a single track on the instrument working area.

For each track in turn:

- Enter the Sample ID (SID) for Patient Samples.
    - If the sample tube does not have a barcode, it is necessary to enter the Sample ID (SID) manually. Click on the SampleID cell for the track to be setup and enter the SID manually using the on-screen keyboard.
    - If the sample tube has a bar code, click on the SampleID cell and then use the Handheld Barcode to load the SID into the system.

- Choose the Assay to be run in the track by clicking in the "Assay" cell for the track to be setup and selecting the required Assay from the list that is presented.

  The list of Assays can be filtered by adding text in the box at the top of the Assay Selection List. The list can also be re-ordered by touching on the column headings (Name, Type, Matrix).

NOTE If an Assay is absent in the list that you would expect to see, check the Extraction Input Volume and Extracted Eluate Volume settings in case these are causing the Assay to be filtered out from the list.

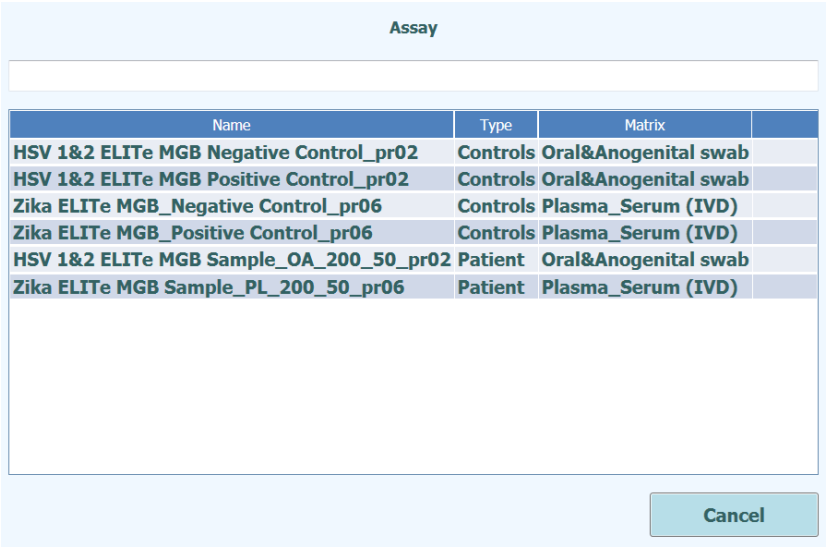


Figure 5-1112: Assay Selection List.

NOTE Only IVD Assay protocols are displayed and may be selected in CLOSED mode;

- Once you have selected the Assay, the columns for Sample Matrix, Protocol, Sample Position, Dilution Factor, will be filled automatically based on the process settings for the Assay.
- Choose the Protocol you wish to run for the Assay by touching the “Protocol” cell for the track and choose from the popup list
    - **Extract Only**
      Nucleic acid will be extracted but not amplified in this track, thus not giving an interpreted result.
      If the eluate is used for PCR in another track in the same Run, this is known as the “source track” and its track number is used as the Sample Position.

    - **Extract + PCR**
      Full sample-to-answer process.
      If the eluate is used for PCR in another track in the same Run, this is known as the “source track” and its track number is used as the Sample Position.

    - **PCR Only**
      This process performs PCR on a previously extracted eluate or other sample to give a result. The eluate may be loaded on the track from a previous Run, or may be sourced from a different track in the same Run.

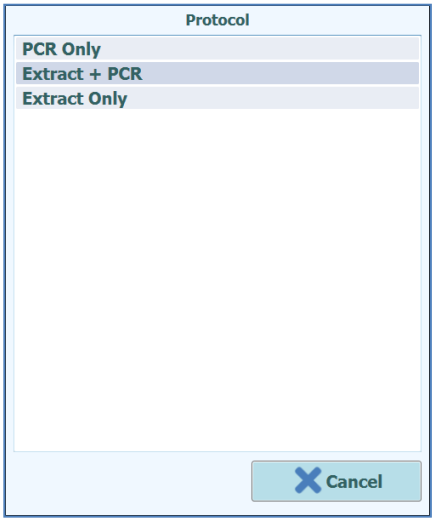


Figure 5-1213: Protocol Selection List.

NOTE It is possible to combine different protocols in the same Run. e.g. Track 1 may perform Extract Only, Track 2 may perform Extract+PCR and Track 3 may perform PCR only

- Choose the Sample Position for the Assay to direct the system where to find the sample.
    - **Primary Tube** (Extract Only or Extract + PCR)
      When Sample is in the Primary Tube
    - **Sonicator Tube** (Extract Only or Extract + PCR)
      When Sample is in the Sonicator Tube
    - **ExtraTube (Position1)** (PCR Only)
      When Eluate is in the Extra Tube rack (bottom position) in the same track
    - **Track 1...12** (PCR Only)
      When Eluate is to be shared from another track

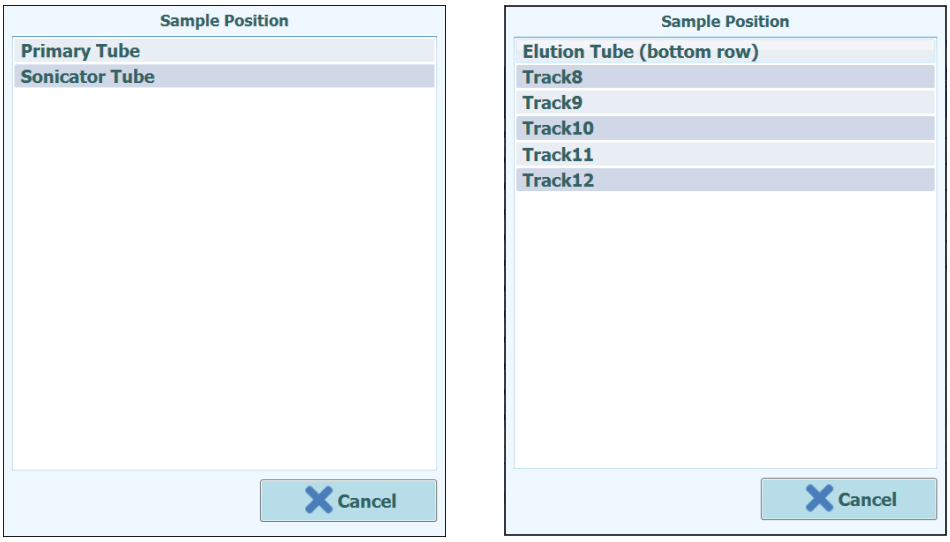


Figure 5-1314: Sample Position Selection Lists.

NOTE

If the source track is performing an extraction step, the system will check that sufficient Eluate will be output from the extraction step to meet the needs of all the tracks sharing the Eluate.

If the source track is performing PCR only, it is not possible for the SW to check the volume of Eluate placed in the source track, so cannot check that sufficient Eluate is available for all the tracks sharing the Eluate.

- Once all Assay settings have been entered, touch the “Next” button to continue the next step (Load Consumables and Samples)

NOTE

When the “Next” button is touched, the ELITe InGenius Software will check the Run setup information for problems and give error and warning messages if any settings need to be corrected.

5.4.2.2 LIS Work list

The “LIS Work List” button at the bottom of the Run Setup screen is used to obtain Test Orders from an external Lab Information System (LIS). If test orders are already present in the “Pending” work list, the number of items will be shown on the button.

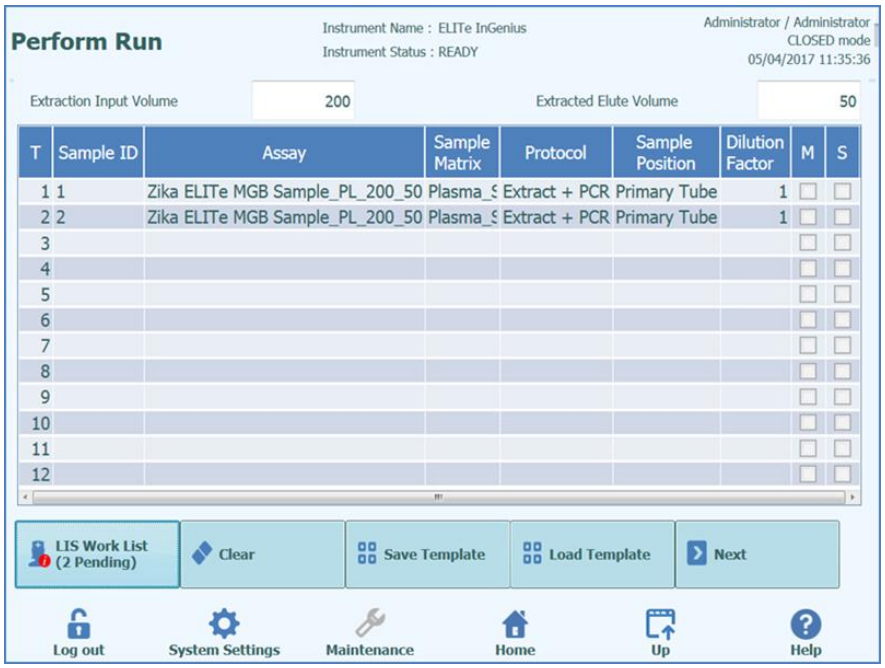


Figure 5-~~14~~15: Run Setup Table after LIS query.

To check for Test Orders, first open the LIS Work List by pressing on the “LIS Work List” Button in the Perform Run screen.

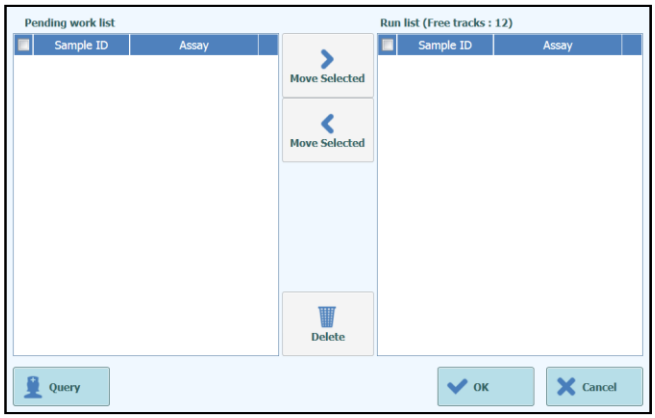


Figure 5-16 : LIS Work List

Now click on the “Query” button. At this point, the behaviour of the ELITe InGenius System, depends on the setting in LIS page (see 1.1.2 paragraph):

- If “Starting Range SampleID All=Yes” ELITe InGenius System send a query ALL message to the LIS to receive all the samples that are possible analyse.
- If “Starting Range SampleID All=No” the operator must enter SIDs of interest into the dialogue box, then ELITe InGenius System send a query message to the LIS for the SIDs typed.

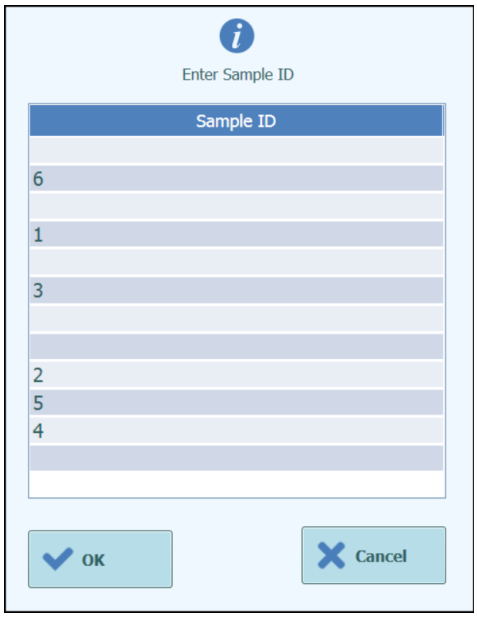


Figure 5-17 : LIS Query Sample ID dialogue.

Click “OK” and the ELITe InGenius System will then query the external LIS system to obtain a list of Test Orders for each of the Sample ID’s

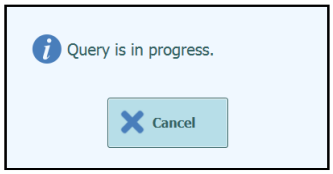


Figure 5-18 : LIS Query In Progress.

On completing the LIS Query, the ELITe InGenius System will show a list of all Test Orders found on the LIS for the Patient Samples for which there are matching Assays available on the ELITe InGenius System.
Sample list from Query to Perform run, following the order provided by LIS.

If there are several different Assays with the same pathogen name will be listed all the possible Assays. Choose the Assay program from the list for the Patient Sample Type actually available at the instrument.

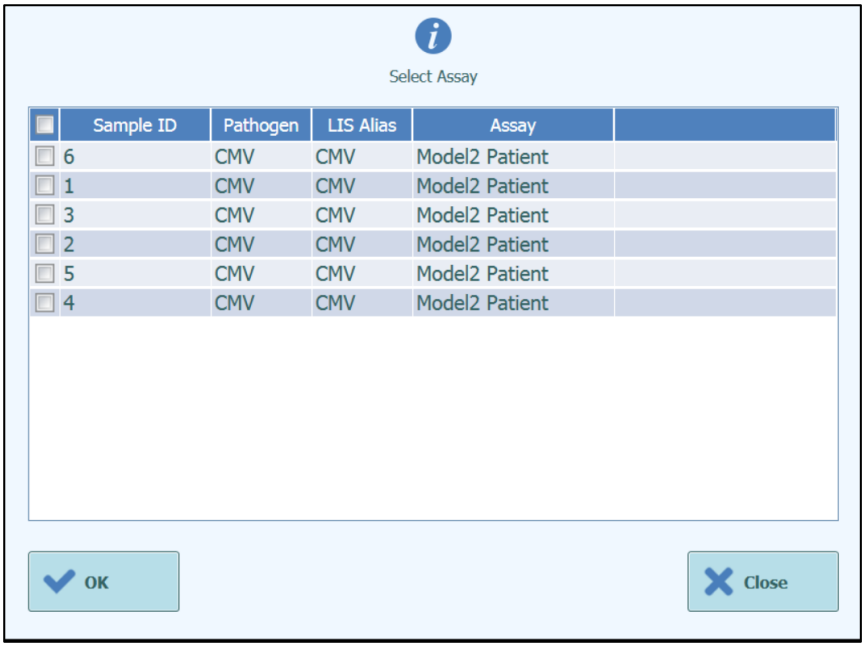


Figure 5-19 : LIS Query Results.

Test orders that are ticked in the LIS Query Results will be added to the “Run List” on the right pane of the LIS Work List. These test orders will then be loaded to the Perform Run screen when the LIS Work List dialogue is closed.

Test orders that are NOT ticked will be added to the “Pending Work List” .”(**Errore. L'origine riferimento non è stata trovata.**~~Figure 5-20~~).

Test orders can be moved between the “Pending Work List” and the “Run List” at any time using the Left and Right Arrow buttons or deleted from the queues (see the example below **Errore. L'origine riferimento non è stata trovata.**~~Figure 5-20~~).

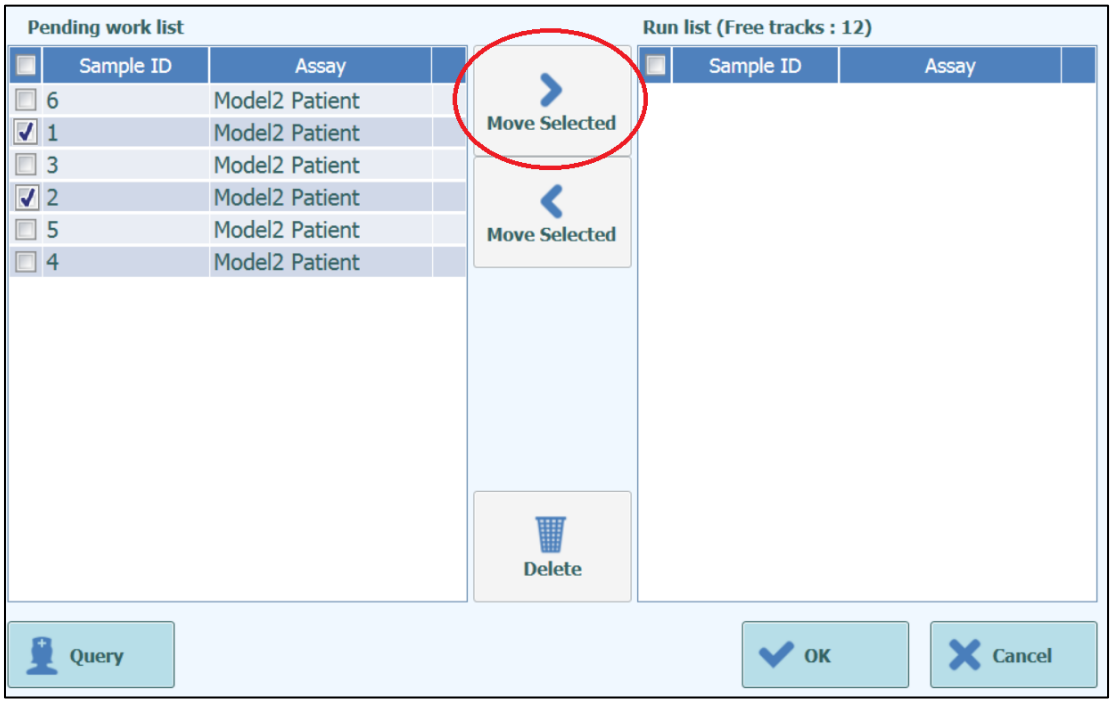


Figure 5-20: Example of LIS Work List after a query

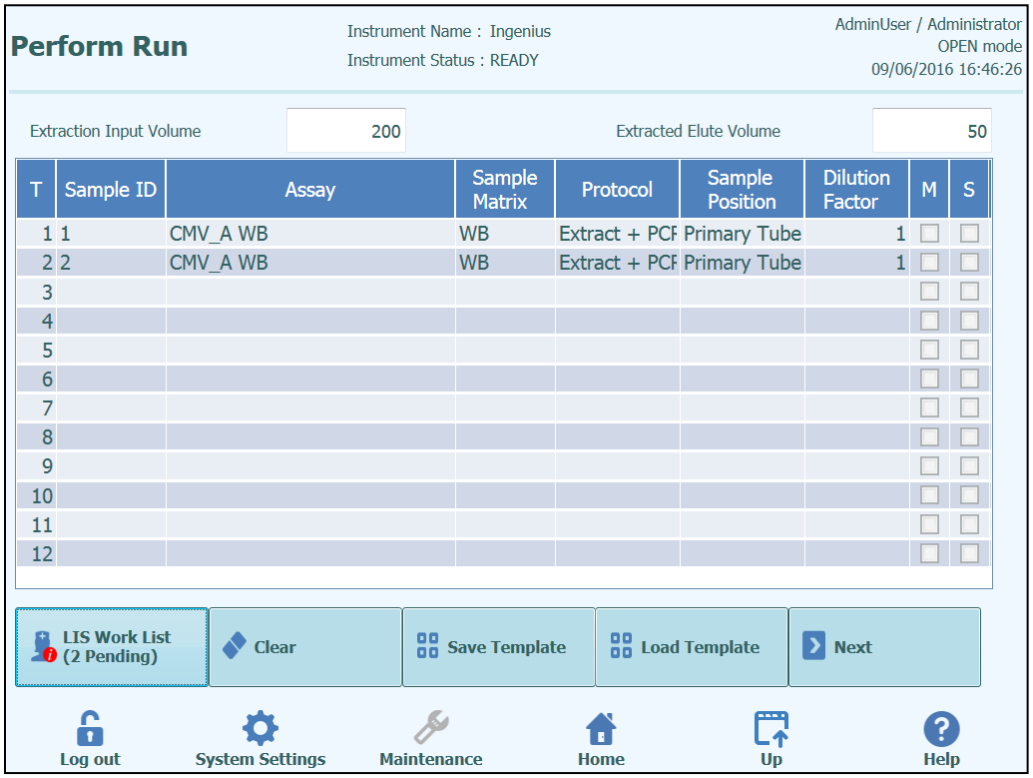


Figure 5-21 : Run Setup after LIS query

In order to complete the Perform Run setup with all the information required, it will be necessary to select the correct work protocol and sample position, then press Next button.

5.4.2.3 "Clear" button

The "Clear" button is used to clear the Run settings from one or more of the Tracks in the Run Setup grid.

Press the "Clear" button to show the Clear Tracks dialogue.

Click on each of the tracks in the dialogue box that are to be cleared.

Tracks selected for clearing will be highlighted in blue and have a tick mark.

The "Select All" tick box can be used to toggle the selection of all tracks.

Press the "OK" button and information will be cleared from the Run Setup Grid.

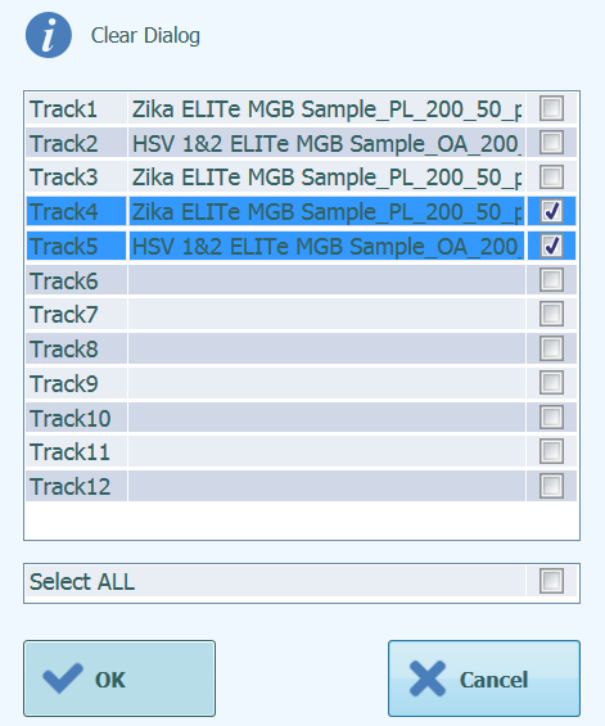


Figure 5-15~~22~~ : Selection of Tracks to be cleared.

NOTE Controls which use more than one track are cleared as an entire group.

5.4.2.4 "Save Template" button

Groups of Assays may be saved to the ELITe InGenius System Template Database (see section 6.10) from the Perform Run Screen and recalled later to streamline Run setup.

To create a Template, complete the Assay, Sample Matrix, Protocol, Sample Position, Dilution factor, M (melting) and S (sonication) settings in the Perform Run Screen, then touch the "Save Template" button at the bottom of the Perform Run Screen to display the following popup.

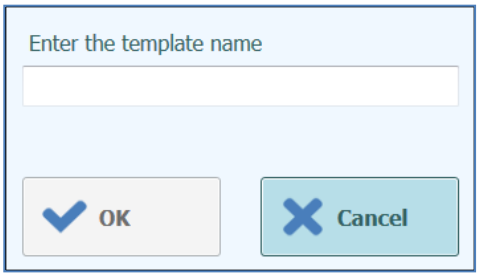


Figure 5-16~~23~~ : Save Template Dialogue.

Enter the name for the Template and press "OK" button to confirm.

All settings from the Run Setup screen are saved to the ELITe InGenius System Template Database with the exception of any Patient Sample ID's.

If a Template already exists with the same name as the one specified, a warning will be issued and it is possible to then choose whether to overwrite the existing template, or to cancel the creation of the new Template.

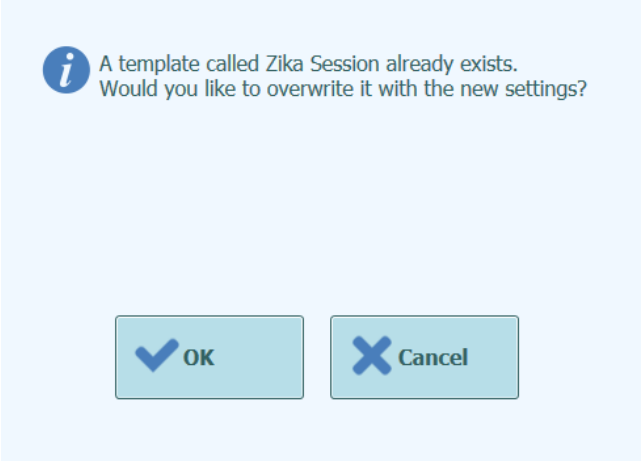


Figure 5-17~~24~~ : "Template Already Exists" Warning.

5.4.2.5 “Load Template” button

To load a previously created Template from the ELITe InGenius System Template Database, click the “Load Template” button at the bottom of the Run Setup screen to display the Load Template Selection Dialogue:

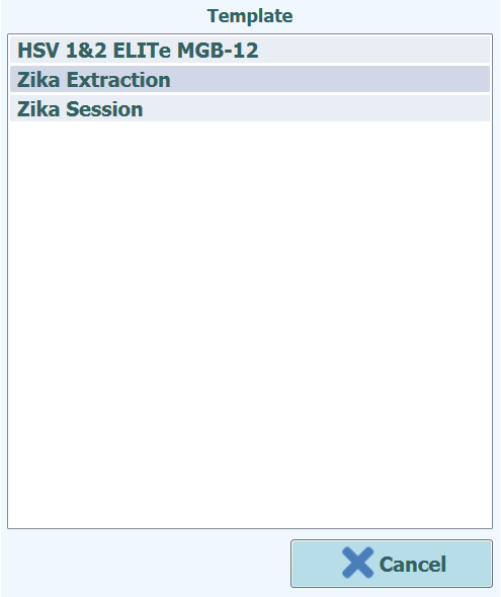


Figure 5-18~~25~~ : Load Template Selection Dialogue.

When you click on a “Template” name in the list then the dialogue box will be closed and the Run Setup for the selected template will be automatically loaded to the Run Setup Screen.

When loading a Template, all settings in the Run Setup screen are loaded from the ELITe InGenius System Template Database with the exception of any Patient Sample ID’s. These must be entered after loading the Template.

5.4.2.6 Example Run Settings for Patient Samples

In the Run Setup Screen, a Patient Sample Assay is selected in the same way as any other Assay from the Assay Selection List. In this example Patient Sample Assays can be identified using the “Type” column on the Assay Selection screen where “Patient” is shown next to the Assay Name.

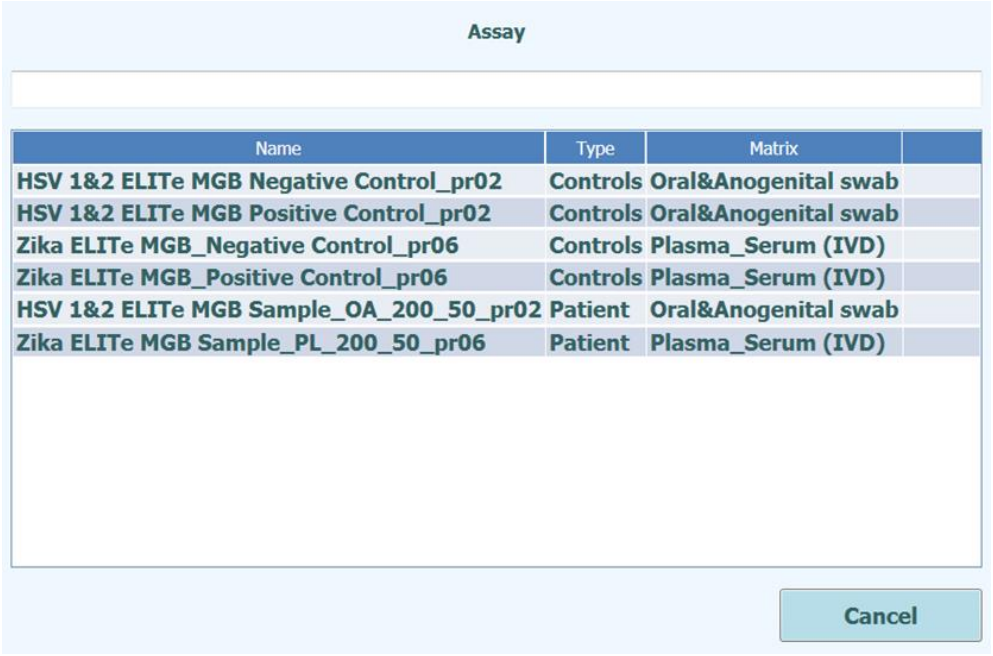


Figure 5-26 : Assay Selection List

If a Sample Assay is selected, a popup message will be shown that indicates which monoreagent Lot Numbers may be used to Run the Assay. Lot numbers will be displayed based on the availability of monoreagent lots with valid Controls.

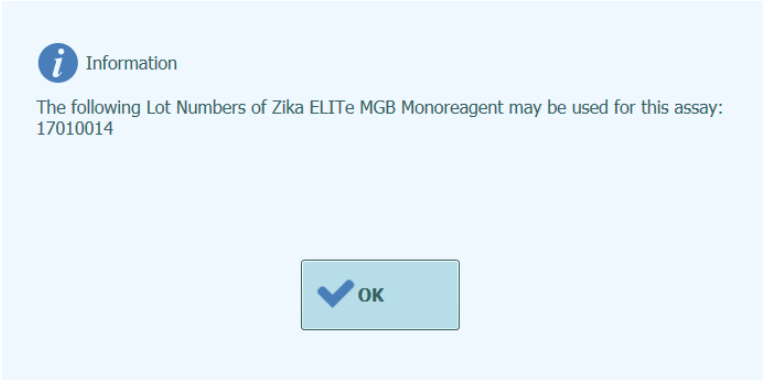


Figure 5-27 : Monoreagent Lot Number advisory message

If the required Approved Controls for the Assay cannot be found in the database, a warning message will be given, for example:

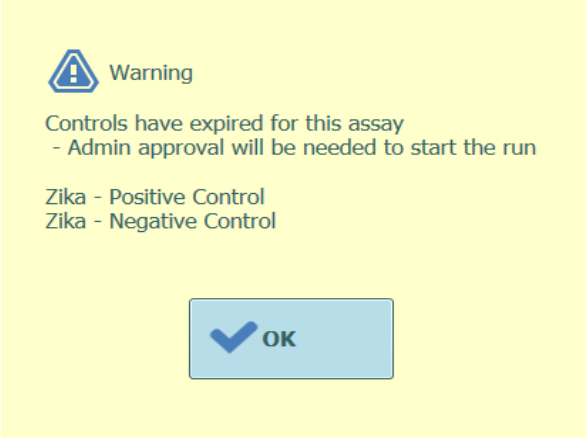


Figure 5-28 : Missing Controls/Calibrators message.

The following Run setup shows various Sample Assay settings:

- Track 1 is setup to perform Extract + PCR on a sample in the Primary Tube with SID1
- Track 2 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 1
- Track 3 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 1
- Track 4 is setup to perform Extract + PCR on a sample in the Primary Tube with SID2
- Track 5 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 4
- Track 6 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 4
- Track 7 is setup to perform Extract + PCR on a sample in the Primary Tube with SID3
- Track 8 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 7
- Track 9 is setup to perform Extract + PCR on a sample in the Primary Tube with SID4
- Track 10 is setup to run a PCR only protocol on the Eluate generated by the Extraction step in Track 9

When setting up several Assays that share Eluate from one track to another, the Sample IDs and Dilution Factors in the Run Setup Table are copied from the source track to the destination track automatically. These values may only be changed by editing the field for the source track.

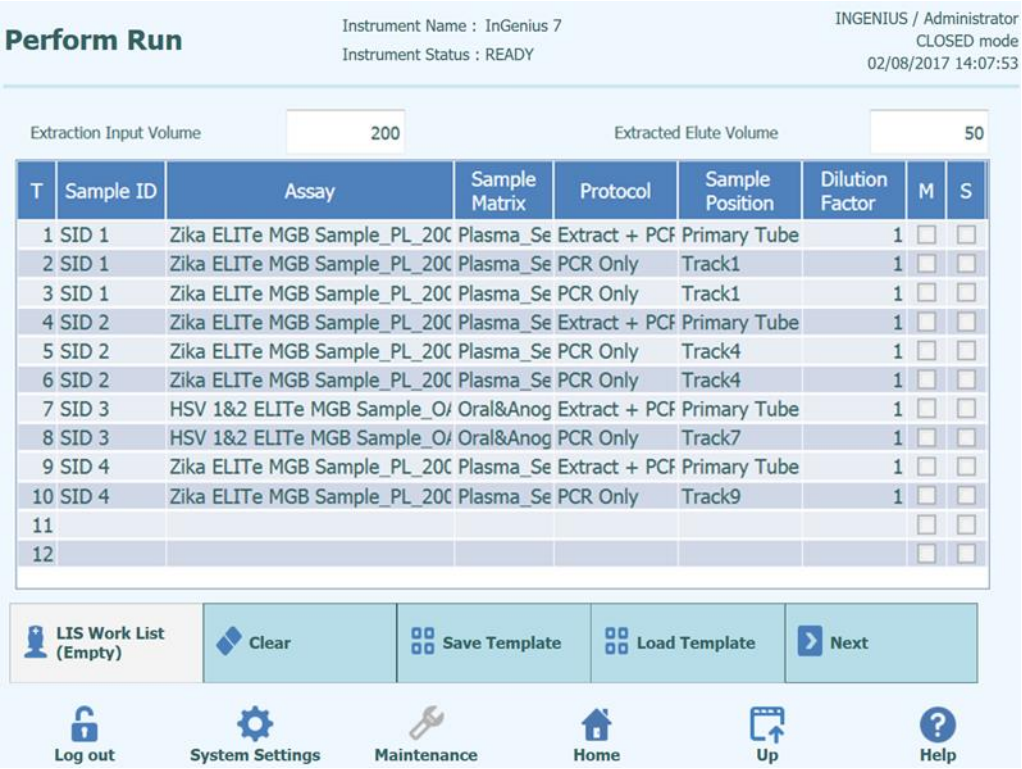


Figure 5-29: Example of a filled in Perform Run Screen

NOTE

Before performing a PCR Run with samples, approved Control (required) results should be available for result approval. Refer to Sections **Errore. L'origine riferimento non è stata trovata.**~~5.3~~ and 6.7.

DANGER

Risk of infection: The instrument must be treated as potentially infectious. Improper handling of infectious materials and contaminated instrument parts can cause skin irritations or lead to illnesses and possible death.

NOTE

In the working area of the instrument, two different types of rack are provided

- Sample rack
- Sonicator Rack

The Sample Rack holds 12 positions that can each hold a Primary Tube. Track numbers are counted from the left to right, with Track 1 being the leftmost Track.

Alternatively Patient Samples may be loaded directly to the Sonicator Rack.

5.4.2.7 Example Run Settings for a Control Assay

Positive and Negative controls are required for an Assay, each with their own assay protocol. A Control Assay requires at least one reference material; for a Control with several levels, more than one reference material will need to be run.

Results of each Control run will be recorded in the database. Results which pass criteria in the Assay Parameters may be approved. The historical data for each Control will be plotted in Control Plots, with approval status indicated by markers (Section **Errore. L'origine riferimento non è stata trovata.**~~5.4.1.1~~).

In the Perform Run Screen, a Control Assay is selected from the Assay Selection List. In this example (**Errore. L'origine riferimento non è stata trovata.**~~Figure 5-29~~), two Control Assays can be identified using the "Type" column on the Assay Selection screen where "Controls" is shown next to the Assay Name.

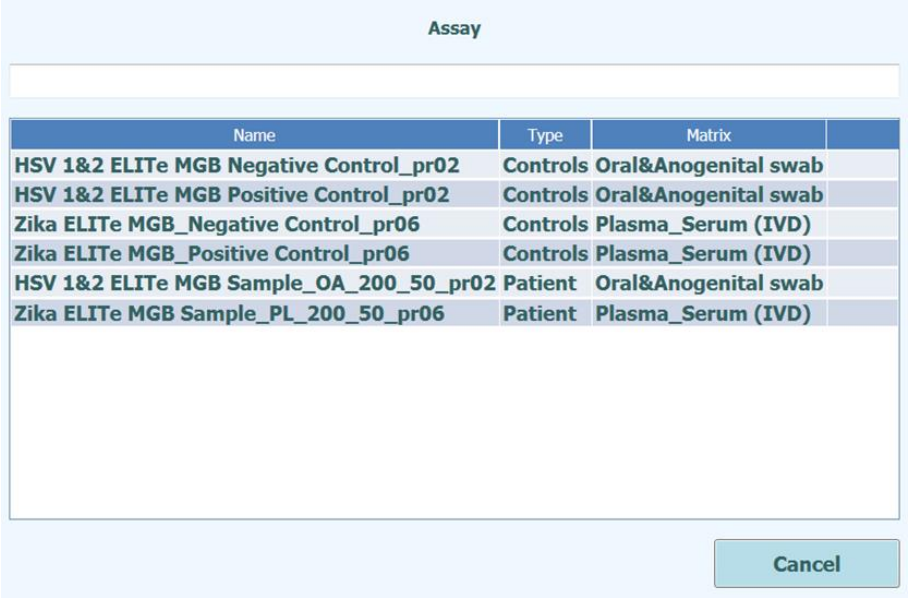


Figure 5-~~19~~~~30~~ : Assay Selection List

If a Control Assay is selected, a popup message will then be shown that indicates which monoreagent lot numbers may be used to run the Assay. (Note that when running a new lot of monoreagent with Control Assays in the same Run, the "valid lot number" popup can be ignored.)

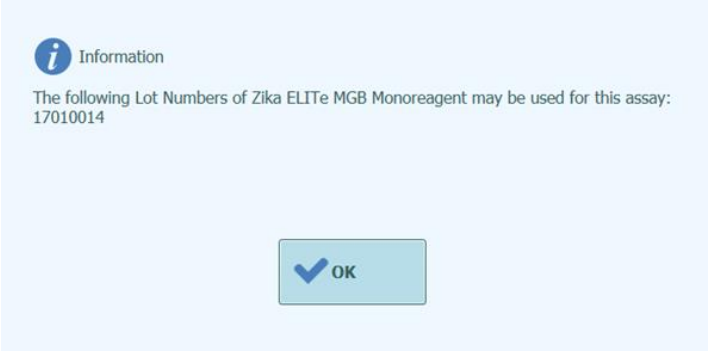


Figure 5-2031 : Monoreagent Lot Number advisory message

The Control Registration Dialogue is then displayed.

Enter the Lot Number and Expiry Date for the Control Fluids by clicking on the data entry fields and using the on-screen keyboard.

Touch “OK” to confirm the values, and the Control details will be filled in on the Perform Run Screen.

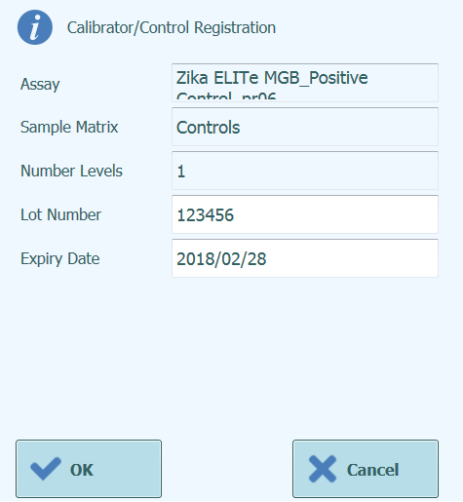


Figure 5-2132 : Control Registration Dialogue.

On confirming the selections, the Run Setup screen will then be completed with the full details for the Control tracks.

The ELITe InGenius Software will automatically setup the details for the number of tracks needed by the Control in the Run Setup grid. If insufficient tracks are available to run all the Control levels, the system will report an error.

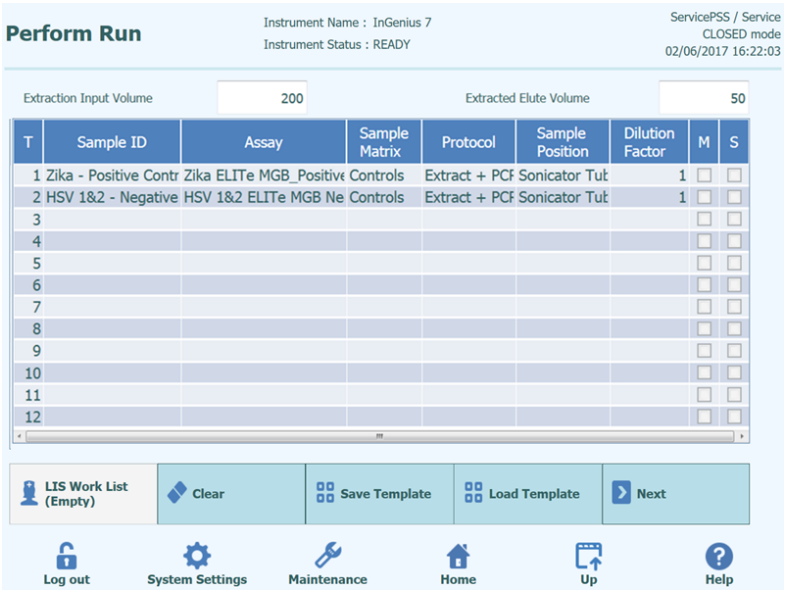


Figure 5-33: Example of a Run Setup Table for Two-level Positive Control and Single Level Negative Control.

NOTE For a Control Assay, the Sample ID field will be automatically populated to show the Control names for each track. The other Assay settings (e.g., Protocol and Sample Position) will also hold fixed values as defined in the Control Details.

5.4.3 Step 3: Load Reagents, Consumables & Samples

The next step in preparing the ELITe InGenius to run assays is to setup the Inventory Manager.

The Inventory Manager is a cooled block used to hold PCR Monoreagent and Internal Control fluids, as well as an area for storing the Single Tips used that are used for moving the fluids to the 12 tracks.

The ELITe InGenius Software supports up to ten different block configurations that can be recalled at will. This feature allows the definition of a number of different configurations to support the most commonly used Assay Panels.

The ELITe InGenius Software maintains traceability and usage information for each reagent loaded in each block:

- Reagent name
- Reagent expiry date
- Reagent lot number
- Number of tests remaining in tube

5.4.3.1 Warnings

DANGER

Risk of infection: The instrument must be treated as potentially infectious. Improper handling of infectious parts can cause skin irritations, illnesses and possible death.

- Observe local and national provisions, legislation and laboratory regulations.
- Use appropriate gloves!
- Use an appropriate lab coat!
- Use appropriate eye protection (e.g. goggles)!
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.
- Do not use broken or chipped tubes or cassettes.
- Observe the instructions in the package inserts for the correct use of reagents.
- Observe the legal regulations for the handling of infectious material.
- Never use bio-hazardous liquids for testing the instrument!

WARNING

Eye Injuries due to Laser Radiation: Laser radiation cause eye irritations when you look directly into the laser beam for a long period of time.

- Never look directly into the laser beam!
- Do not use optical devices (e.g. mirrors).
- Take off watches and mirroring jewellery before operating the laser.
- Be careful during operation and testing the laser of the bar code scanner. A class 2 laser is used.
- Note that the wrong usage of operating elements or of adjustments or the non-observance of processes can cause a dangerous emission of laser radiation.

WARNING

Incorrect loading of Reagents, Consumables, Samples, etc:

Improperly loaded reagent Cassettes or samples can produce erroneous results.

- Ensure that the Sample IDs entered in the Run Setup screen match what is actually setup on the instrument working area.
- Do not swap positions of sample or reagent tubes after they have been loaded. This could result in incorrect test results.
- Ensure that there is no foam on the surface of the liquid. Note that foam may cause pipetting problems.
- Avoid forming Air bubbles or clotting of the samples during the loading process as these may affect the liquid detection functionality and lead to incorrect test results.
- Do not overfill tubes or other liquid containers.
- Remove all caps from the sample tubes and reagent tubes.
- Do not mix tip sizes in the same tip box.
- Tips must be loaded in the tip racks as they are provided in the original packaging.

WARNING

Use only Approved Disposables.

Extraction cassettes, Sample tubes, PCR cassettes etc.

CAUTION

Internal Controls

Use Internal Controls to check the accuracy of the extraction process. See also extraction kit and amplification product specific manuals for details.

5.4.3.2 Step 3a: Load Waste Container

After pressing “NEXT” in the Run Setup screen, the Inventory Manager screen is displayed. It is possible to return to the Perform Run screen by pressing the “UP” button at the bottom of the screen.

In figure below, the indicated position on the instrument working area is the metal container; line this with an empty plastic Waste Box. Ensure the metal waste box is locked in by sliding towards the rear of the instrument.

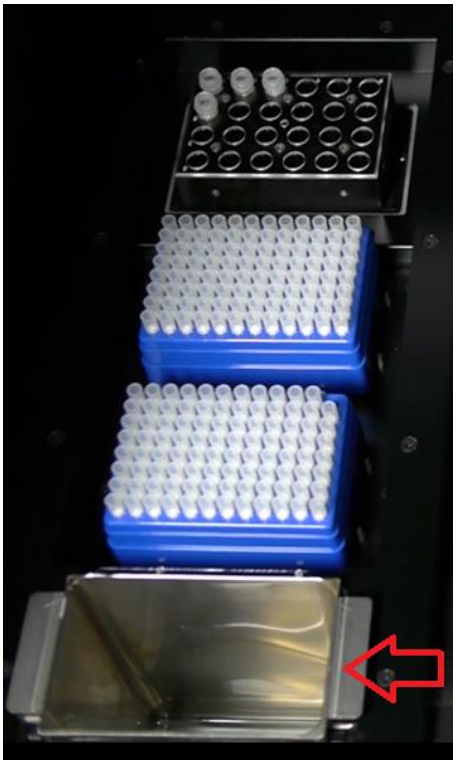


Figure 5-34: Waste container placement on the Instrument.

5.4.3.3 Step 3b: Load Reagents

The Load/Unload Inventory screen is used to record which PCR Monoreagent and Internal Control (IC) reagents are present in reagent cold blocks, and which reagent cold block is currently loaded on the instrument.

Loading reagent cold block details saves information to the Inventory Manager.

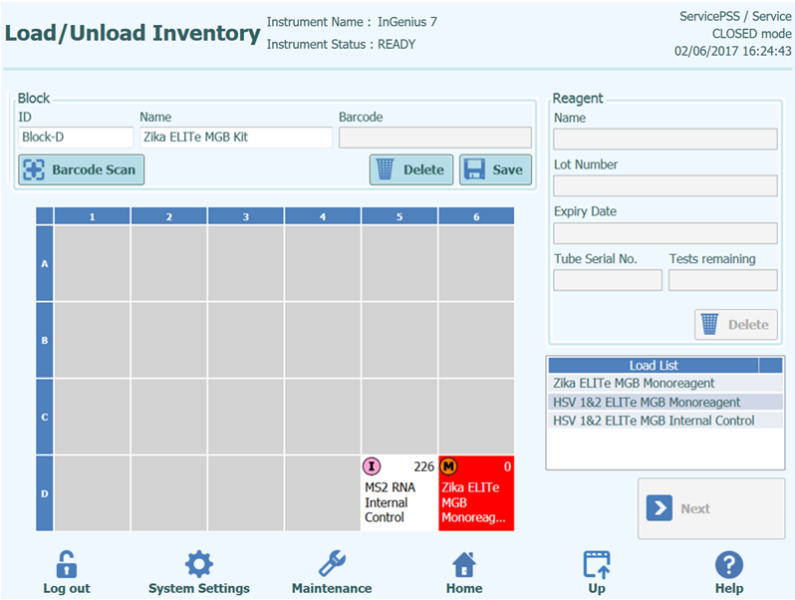


Figure 5-35: Load / Unload Inventory screen.

Load a block with the required reagents to the Instrument working area

CAUTION All reagent tubes used in the current Run must have caps removed before starting the Run.

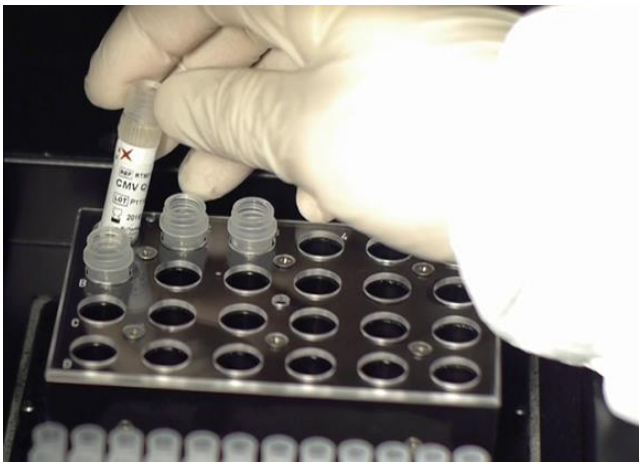


Figure 5-36: Loading / Unloading Inventory on the Instrument.

Select the corresponding Block ID in the inventory manager screen (or scan the block barcode if this has been programmed on the instrument) and check that the actual reagents loaded in the physical block match the configuration that is displayed on the screen and that the “Tests Remaining“ count for each reagent is sufficient for the tests about to be run.

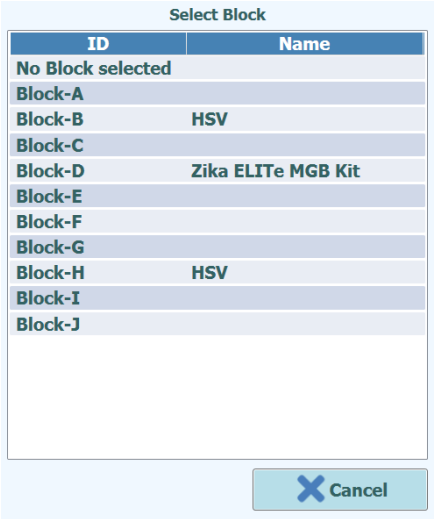


Figure 5-37: Inventory Manager Block Selection List.

It is possible to give each block a User Defined Block Name by clicking on the “Block Name” field to bring up the on-screen keyboard and entering a Name for the Block.

Block Barcoding

It is possible to link individual blocks with a bar code ID (to save manually selecting the block ID each time the block is loaded to the instrument)

To setup this feature, press the “Barcode scan” button and scan the bar code to be used for identifying the currently selected block. If this is the first time that the bar code has been recognised by the ELITe InGenius Software, the following confirmation message will be shown. Click OK and then press the “SAVE” button to link the bar code to the block ID.

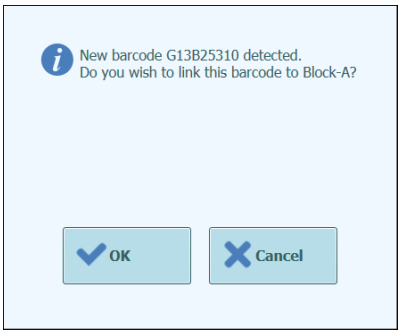


Figure 5-38: Inventory Manager Block Barcode Pairing Confirmation.

The next time the “Barcode scan” button is pressed and the memorised barcode ID is scanned, the details for the paired block will be automatically loaded to the Inventory Manager Screen.

Checking / Loading Reagent Details

Once an Inventory Manager Block has been selected, the next step is to load the block with reagents.

For a block that has already been setup, it is possible to view or change the Reagent details for that block.

Any changes that are made must be saved by pressing the “SAVE” button on the left side of the screen.

The type and expiry status of each reagent loaded to the Inventory Manager block is indicated by the icon displayed in each grid position as detailed in 5.4.3.

Description	Icon	Notes
MonoReagent		
Internal Control (IC)		
Reagent expiry date has passed		Use of expired reagents requires Administrator approval and will be noted in the report

Table 5-2 : Description of Icons in Inventory Manager Screen.

To load or view the reagent details (reagent name, expiry date, lot number and number of tests remaining) for a tube in the block, click on the corresponding tube location on the grid.

The reagent details for the selected position are shown in the fields on the right side of the screen. You can check the number of tests remaining for each reagent before starting a run using this screen.

To add a new reagent to the block, select an empty position on the grid and then either scan the barcode on the reagent tube to auto-complete the reagent details, or enter the details manually by clicking on the data fields.

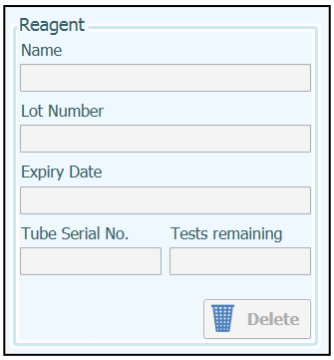


Figure 5-39: Inventory Manager Reagent Details.

Entering Reagent details manually

If the “Reagent Name” field is clicked, it is possible to choose a Reagent from the list of all the Reagents registered in the ELITe InGenius Database to be loaded to the selected locations in the Inventory Manager Block.

Figure 5-40 : Reagent Selection (Red text indicates a reagent intended for IVD use).

Enter the Lot number, the number of tests remaining and the expiry date for the

selected reagent by clicking on the corresponding fields and using the on screen keyboard to enter the required information.

To keep track of the number of tests remaining for each reagent tube, the system requires a unique 9 digit tube serial number. Once this has been entered, the reagent details are locked and cannot be changed on the instrument.

Entering Reagent details using Barcode reader

ELITech reagent details for the selected tube location may also be entered using the Handheld Barcode Reader instead of the on-screen keyboard. Simply select the location to be loaded and scan the 2D barcodes supplied in the reagent kit.

NOTE A Handheld Barcode Reader needs to be connected to the InGenius system via the USB connector to use this function.

WARNING

When operating the Handheld Barcode Reader, avoid looking directly at the laser light.

NOTE It is possible to load more than one tube of the same Reagent to an Inventory Manager block to increase the maximum number of tests that can be run from one block, however all locations for each different Reagent must be configured with the same expiry date and lot number.

NOTE When a tube of Monoreagent has Run out, it is recommended to replace it with a new one with the same Lot number.

When a different Lot number is used, Control Assays need to be re-run and approved.

NOTE The “Load List” shows which reagents still need to be loaded to the Inventory Manager area in order to be able to run all of the Assays specified in the Run Setup screen.

Reagents are listed in the “Load List” either if they are not configured in the currently loaded Block, or if their “Tests Remaining” count is insufficient to cover the requirements of the Assays in the Run Setup screen.

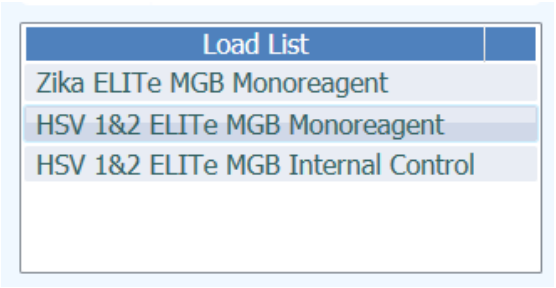


Figure 5-2241: Reagent Load List

Click the “Save” button to save the Inventory Manager. The first pop up messages will allow you to confirm you wish to save the Block settings with a second pop-up confirming that the save was successfully completed.

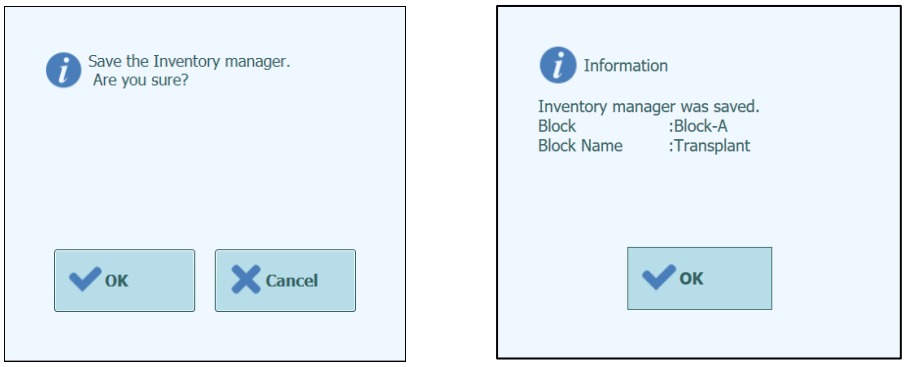


Figure 5-42: Inventory Manager Save Confirmation.

Removing Reagent Details

To remove a reagent from the Inventory Manager Block, select the required positions and then click on the “DELETE” button in the Reagent Details box on the right side of the screen.

Click OK in the confirmation pop-up window to complete the removal of the chosen Reagent from the block.

Figure 5-43: Inventory Manager Reagent Removal Confirmation.

Click the “Save” button to save the Inventory Manager. The first pop up messages will allow you to confirm you wish to save the Block settings with a second pop-up confirming that the save was successfully completed.

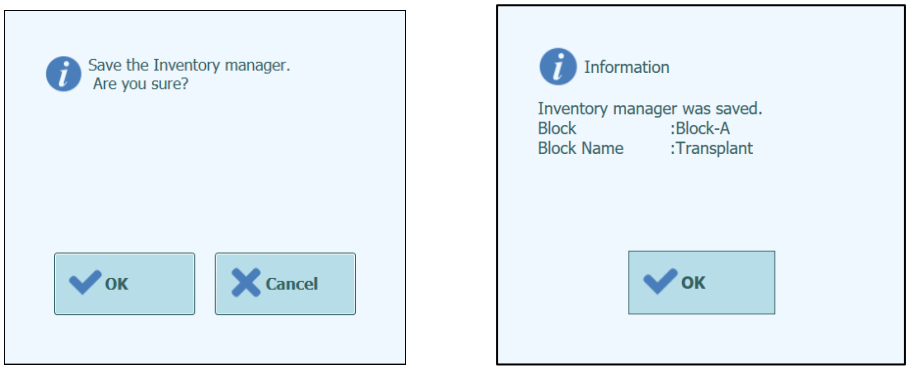


Figure 5-44: Inventory Manager Save Confirmation.

To completely reset all the Reagent details for the selected Inventory Manager Block, ensure the correct Block ID is loaded on the screen and then click on the “Delete” button in the Block Details box at the top of the screen.

Click OK in the confirmation pop-up window to complete the removal of the chosen Reagents from the block.

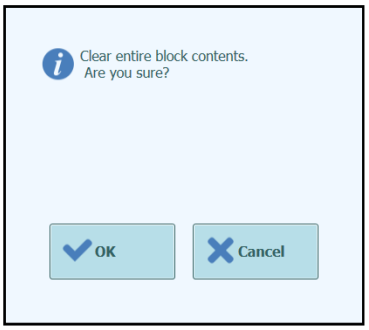


Figure 5-45: Inventory Manager Reset Block Confirmation.

5.4.3.4 Step 3c: Reagent Loading Completed

When the Inventory Manager Configuration and Loading has been completed, press the “Next>“ button to move to the next step.

Before showing the next screen, the ELITe InGenius Software will perform some final checks to ensure that each reagent has sufficient “Tests Remaining” and that the reagents have not passed their expiry date.

If there are insufficient “Tests Remaining” for the needs of the run setup, the following message is displayed:

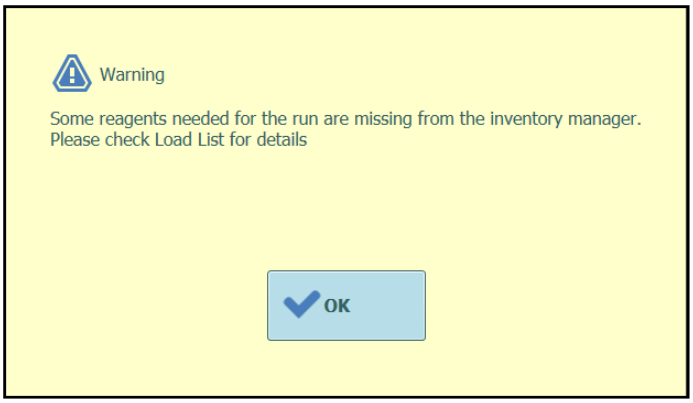


Figure 5-46: Insufficient Reagents in Inventory Manager

If there are reagents which have passed their expiry dates, then an error message will be shown giving details of which reagents are expired e.g.

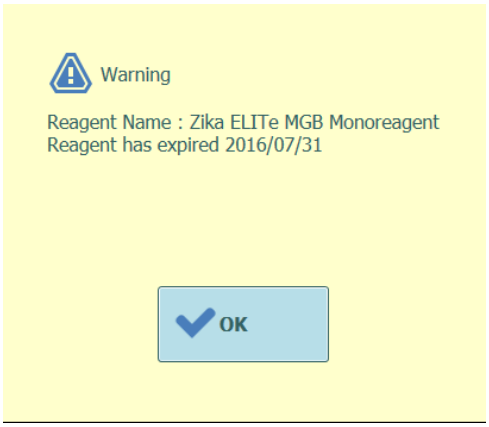


Figure 5-47: Expired Reagents in Inventory Manager

If the required Approved Controls cannot be found in the database, then a warning message will be shown e.g.

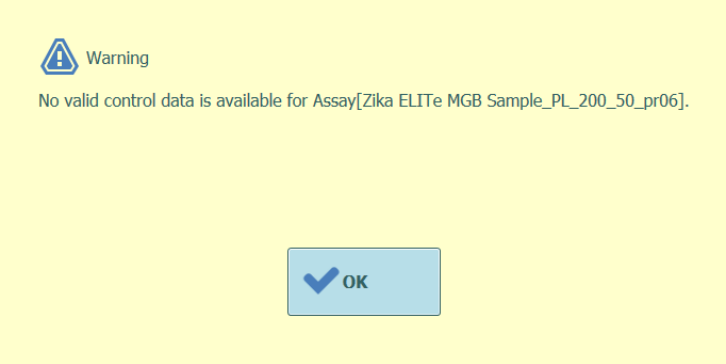


Figure 5-48 : Example of missing Control for Assay

If the logged in user is already an Administrator then it will be possible to proceed with the Run, even if the reagents have expired or the required Approved Calibrators or Controls are unavailable. However if the logged in user is an Operator or Analyst, then the system will request an Administrator or Service User to enter their User name and password to allow the run to proceed and use the expired fluids

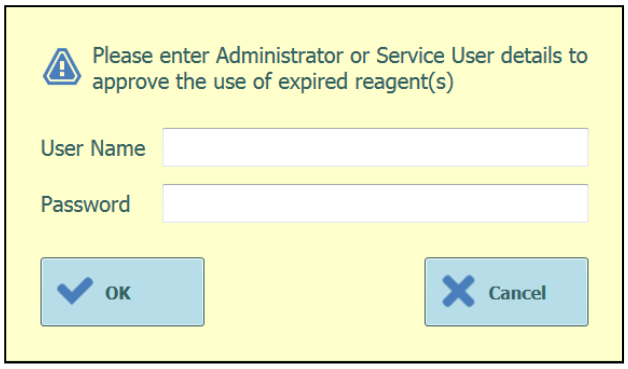


Figure 5-49 : Administrator Override for Expired Reagents

5.4.3.5 Step 3d: Configure Single Tips

The ELITe InGenius System has space to load two Tip Racks, each of which holds 96 Single Tips.

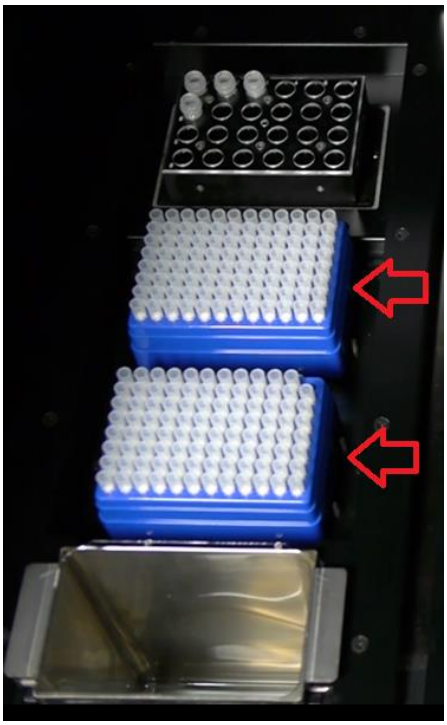


Figure 5-50: Inventory Manager Single Tips placement on the Instrument.

CAUTION

Tip Placement

Make sure the tip boxes are seated correctly with no space left between the box and the base of tip box position. Some tip boxes are not symmetric and may require that the orientation be flipped for them to be properly seated.

WARNING

Contamination and Biohazard Risk

Please wear gloves while changing the tip racks.

The Inventory Manager Tip Loading Screen is shown once the Inventory Manager Reagents have been confirmed in Step 3c.

Check that there are sufficient tips available for the Assays you are planning to Run.

If there are insufficient tips available in the Inventory Manager, replace the tip racks with full racks and reset the software using the “Replace Tip Rack” buttons.

Press the “Next” button once you have confirmed the tip settings to move to the next step.

The “Next” button is disabled when there are insufficient tips for the run.

You can go back to the Inventory Manager screen by pressing the “Up” button at the bottom of the screen.

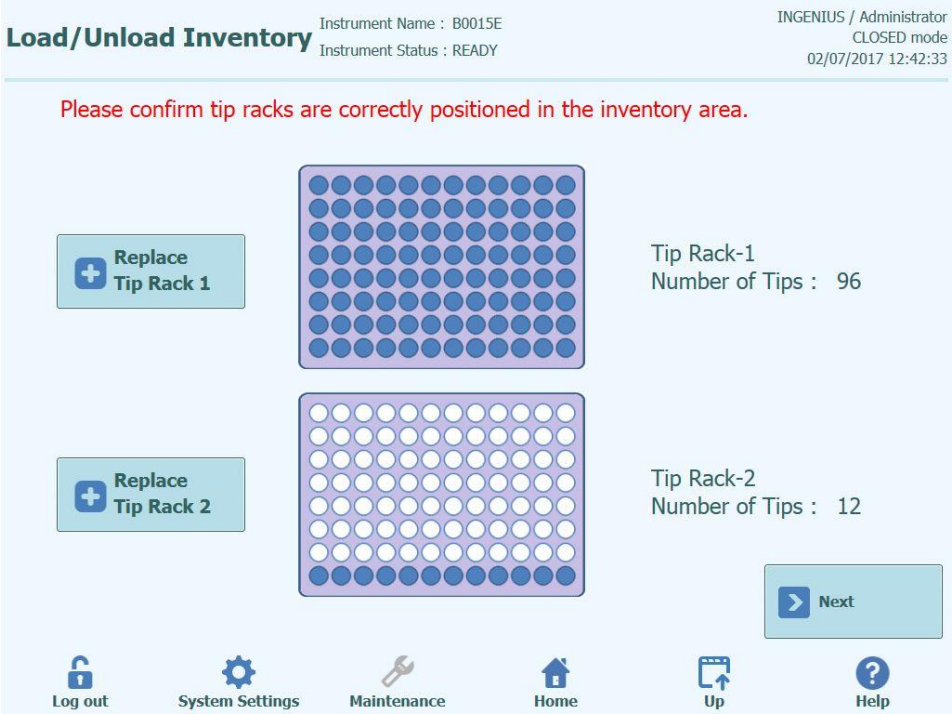


Figure 5-51 : Tip Rack Screen.

The ELITe InGenius Software counts the number of tips it has used for each run and updates the information on this screen to show the number of tips remaining in each rack. The presence of a single tip in each location is displayed using the following icons:

- when the position is empty;
- when the position is occupied;

If you wish to replenish either one or both of the tip racks, open the instrument front door and remove the empty tip box from left hand side of the instrument working area and replace with a new tip box. It is important to replenish the box with a new box containing all 96 tips.

Click on either “Replace Tip Rack 1” or “Replace Tip Rack 2” depending on the rack position you have replenished. Confirm the action in the popup message that follows.

Figure 5-52 : Confirmation of Tip Rack Replacement

The number of Tips for the block is reset to 96 following the above confirmation.

NOTE During Assay execution, the Single Tip racks cannot be replaced although it is still possible to check the number of tips remaining in this screen.

5.4.3.6 Step 3e: Load PCR Cassette Rack

After loading the Inventory Manager, the next step is to load the PCR Cassette Rack and disposables.

The ELITe InGenius software shows the following PCR Cassette loading display to guide the placement of the disposables to be loaded in this step.

PCR Cassettes are needed for any tracks configured as PCR Only or Extract + PCR.

NOTE

The information on the right hand side of the screen lists which tracks need to be loaded with PCR Reaction Cassettes.

The Tube Rack Graphic shows pictorially where the cassettes should be loaded.

The Assay selected for each track is shown below the tube rack graphic.

Once you have loaded the PCR Cassettes and Rack, press the “Next” button to continue to the next step.

NOTE

If only “Extraction Only” Assays are configured in the Run Setup, there will be no PCR Reaction Cassettes to load at this step, so simply press the “Next” button to continue.

In the following example, tracks 1 through 10 are running a PCR and require a PCR Cassette to be loaded as shown in the picture.

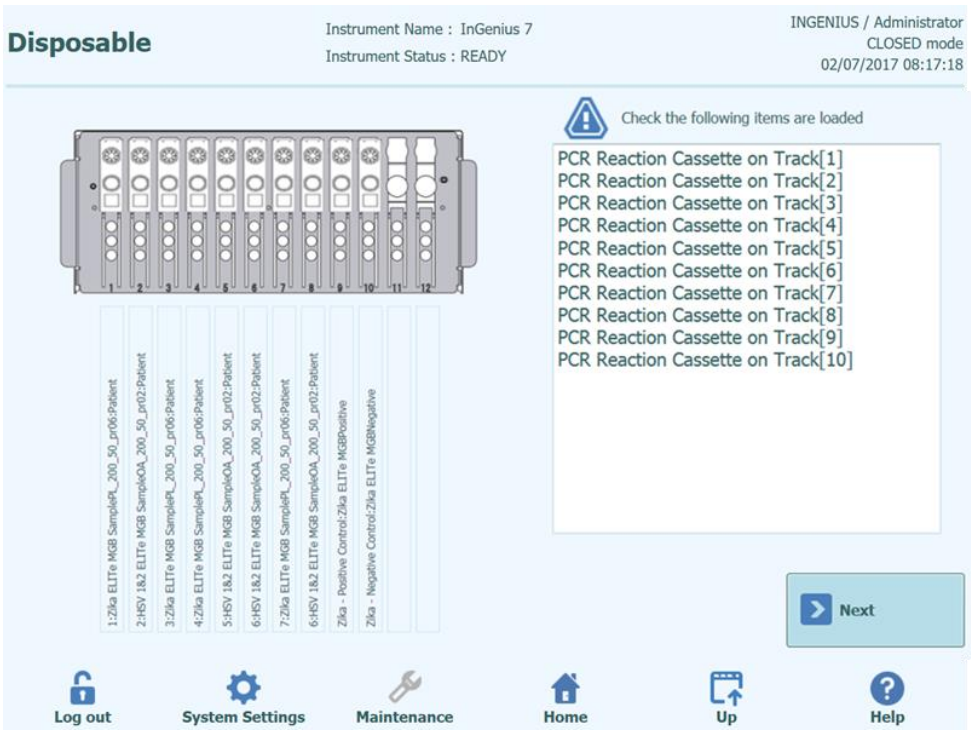
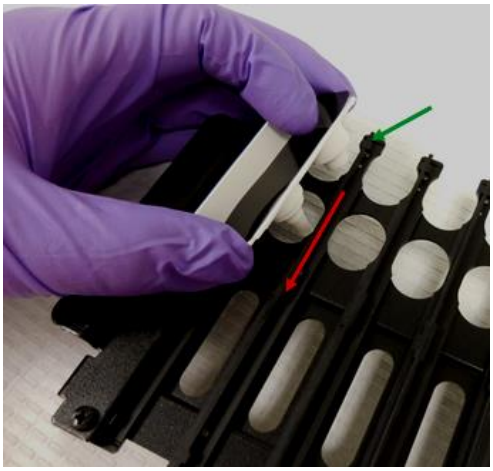


Figure 5-53 : PCR cassette loading guidance.

NOTE

To load PCR Cassettes into the rack, insert the cassette oriented as shown below; there are notches (green arrow) which need to be aligned to seat the cassette in the rack, and then the cassette needs to be locked by sliding in the direction of the red arrow.

Remove the black dust cover as shown below before placing rack in the instrument.



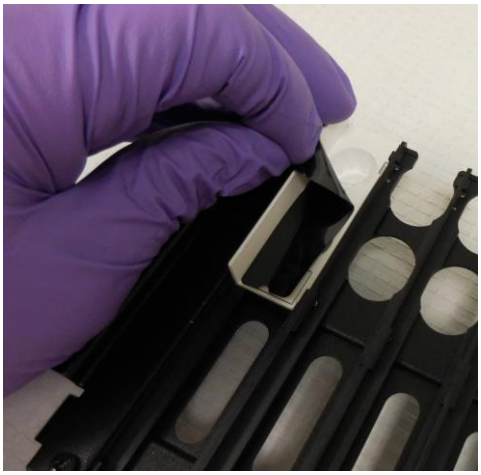


Figure 5-54 : Loading PCR cassette rack on the instrument

5.4.3.7 Step 3f: Load Extraction Rack

After loading the PCR Cassette Rack, the next step is to load the Extraction Cassette Rack and disposables.

The ELITe InGenius software shows the following Extraction Cassette loading display to guide the placement of the disposables to be loaded in this step.

Extraction Cassettes are needed for any runs that are configured as Extract Only or Extract + PCR.

NOTE

The information on the right hand side of the screen lists which tracks need to be loaded with Extraction Cassettes.

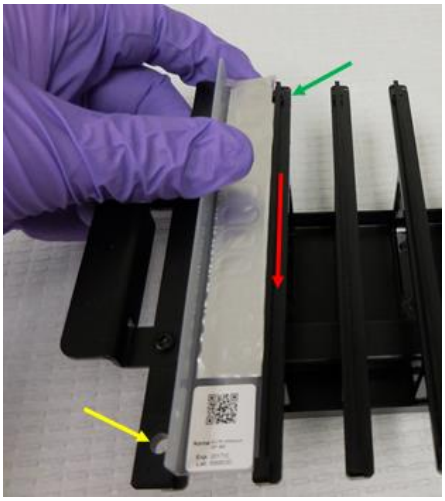
The Tube Rack Graphic shows pictorially where the cassettes should be loaded.

The Assay selected for each track is shown below the tube rack graphic.

Once you have loaded the Extraction Cassettes and Rack, press the “Next” button to continue to the next step.

NOTE

To load Extraction Cassettes into the rack, insert the cassette oriented as shown below with the barcode by the alignment hole (yellow arrow); there are notches (green arrow) which need to be aligned to seat the cassette in the rack, and then the cassette needs to be locked by sliding in the direction of the red arrow.



NOTE

If only “PCR Only” Assays are configured in the Run Setup, there will be no Extraction Cassettes to load at this step, so simply press the “Next” button to continue.

In the following example, tracks 1 and 3 are running Extraction step so require an Extraction Cassette to be loaded as shown in the picture, while track 3 is running “PCR Only”, and does not require an Extraction Cassette.

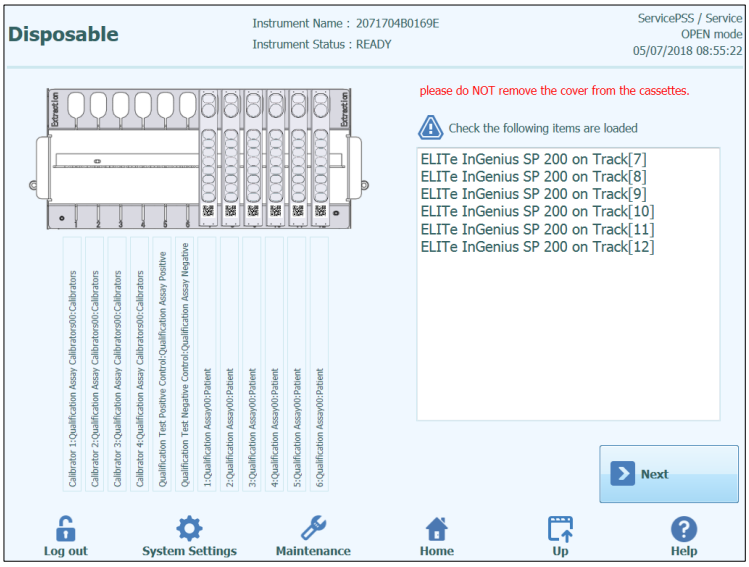


Figure 5-55 : Extraction cassette loading guidance.

Figure 5-56 : Loading Extraction cassette rack on the instrument.

5.4.3.8 Step 3g: Load Elution Tube Rack

After loading the Extraction Cassette Rack, the next step is to load the Elution Tube Rack and disposables.

The ELITe InGenius software shows the following Elution Tube Rack loading display to guide the placement of the disposables to be loaded in this step.

Elution Tubes are needed for all tracks that are configured to run assays.

NOTE When running Controls (Positive Control or Negative Control), the Control Fluids and Elution Tube should be loaded in Position 1 of the Elution Tube rack.

NOTE When running an Assay with Extraction, load an empty Elution Tube in Position 1 of the Elution Tube rack.

When running an extracted sample from a previous run, load the Elution Tube and Eluate directly to Position 1 of the Elution Tube rack.

NOTE The information on the right hand side of the screen lists which tracks need to be loaded with Elution Tubes. If a Sample or other fluid needs to be loaded, the text will also indicate the Sample ID or Fluid Name (including calibrator or control level) for each position.

The Tube Rack Graphic shows pictorially where the tubes should be loaded.

The Assay selected for each track is shown below the tube rack graphic.

NOTE The ELITe InGenius software will indicate the position in the Elution Tube rack marked by color depending of the type of sample or control/calibrator fluid to be loaded.

CAUTION Do NOT fit caps to the tubes loaded to the Elution Tube Rack.

Once you have loaded the Elution Tubes and Rack, press the “Next” button to continue to the next step.

In the following example

- tracks 1, 2, 3, 5, 6, and 7 are running an extraction and require an empty eluate tube.
- track 9 is running a positive control (color coded as per control details).
- track 10 is running a negative control (color coded as per control details).

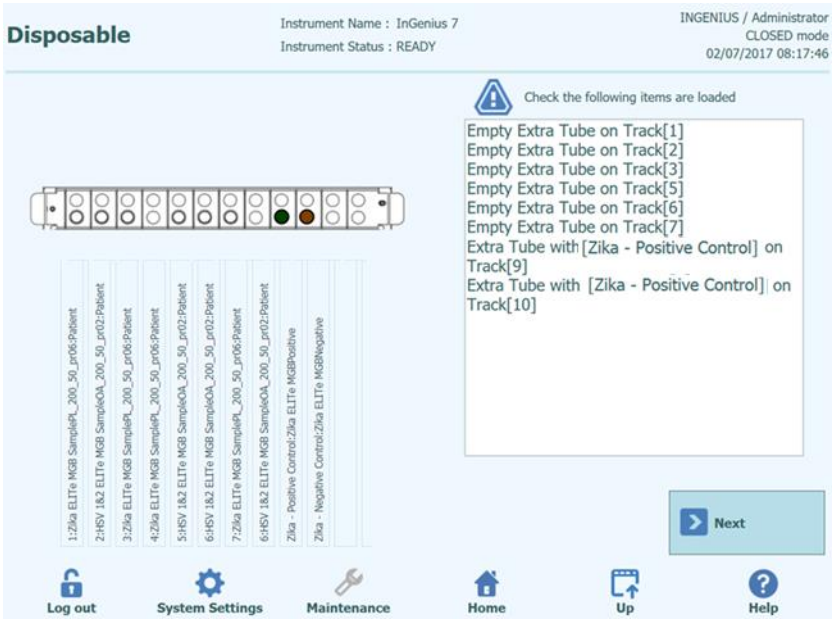


Figure 5-57 : Elution Tube (position 1) loading guidance.

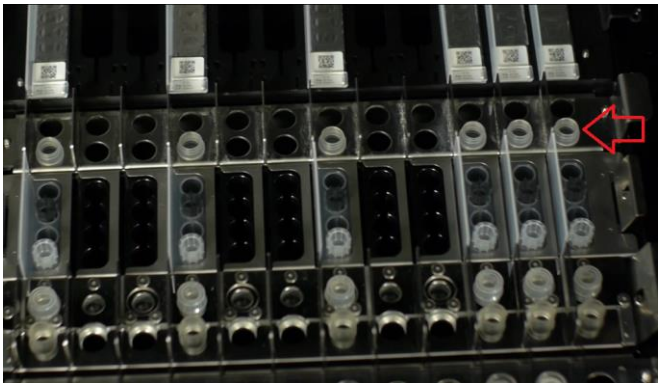


Figure 5-58: Loading Elution Tube Rack on the instrument. Elution tubes are placed in position 1, which is the closest to the front of the instrument

5.4.3.9 Step 3h: Load Tip Rack

After loading the Elution Tube Rack, the next step is to load the Tip Rack and disposables.

The ELITe InGenius software shows the following Tip Rack loading display to guide the placement of the disposables to be loaded in this step.

Tips are needed for all tracks that are configured to run Extraction.

NOTE

The information on the right hand side of the screen lists which tracks need to be loaded with Tips.

The Tip Rack Graphic shows pictorially where the tips should be loaded.

The Assay selected for each track is shown below the tip rack graphic.

Once you have loaded the Tips and Rack, press the “Next” button to continue to the next step.

NOTE

If only “PCR Only” Assays are configured in the Run Setup, there will be no Tips to load at this step, so simply press the “Next” button to continue.

In the following example, tracks 1, 2, 3, 5, 6, and 7 are running Extraction and require Tip Packages to be loaded as shown in the picture.

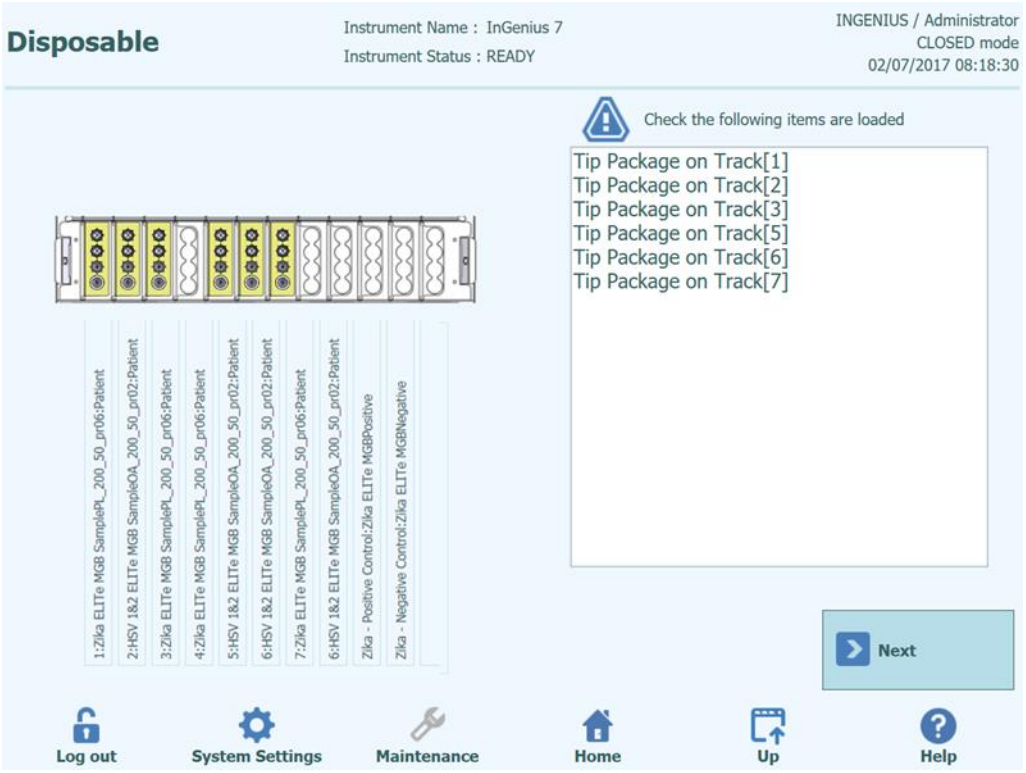


Figure 5-59: Tip loading guidance.

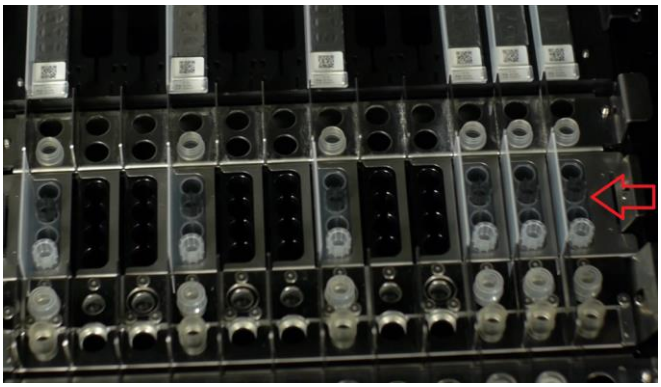


Figure 5-60: Loading Tips on the instrument

5.4.3.10 Step 3i: Load Sonication Rack

After loading the Tips Rack, the next step is to load the Sonication Rack and disposables.

The ELITe InGenius software shows the following Sonication Tube and Cap loading display to guide the placement of the disposables to be loaded in this step.

Tubes and Caps are needed for all tracks that are configured to run Extraction.

NOTE

To remove the Sonication Rack from the ELITe InGenius system, push the tabs on each ends towards the center and lift the rack.

Figure 5-61: Removing Sonication Rack

NOTE

The information on the right hand side of the screen lists which tracks need to be loaded with Sonication Tubes and Caps. If the Patient Sample is to be loaded to the Sonication Tube, the Sample ID will be shown in this window.

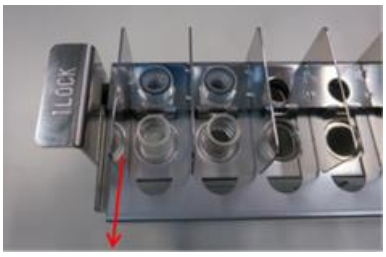
The Sonication Tube and Cap Graphic shows pictorially where the disposables should be loaded.

The Assay selected for each track is shown below the disposables graphic.

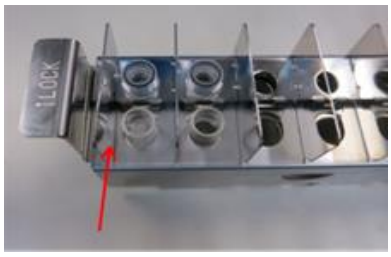
Load the Sonication Tubes and Caps into the Rack and lock the Tubes and Caps in place.

NOTE

Tubes are released and locked into the Rack by sliding the mechanism in the direction of the arrows as shown below:



Releasing Tube Lock from Rack



Locking Tube Lock

CAUTION

Sonication Tube Placement

Make sure Sonication Tubes are correctly locked into the rack. If the tubes are not locked, the resulting position of the tube will be higher with risk of contact between extraction tip and the bottom of sonication tube during extraction process.

Load the Sonication Rack onto the Instrument working area.

Once you have loaded the Sonication Tubes and Caps, press the “Next” button to continue to the next step.

NOTE

If only “PCR Only” Assays are configured in the Run Setup, there will be no Sonication Tubes or Caps to load at this step, so simply press the “Next” button to continue.

CAUTION

Take care not to pinch fingers when locking and unlocking the Sonicator Rack, or when loading and unloading the rack from the instrument.

In the following example, tracks 1, 2, 3, 5, 6, and 7 are running Extraction and require empty Sonicator Tubes without Caps to be loaded as shown in the picture. Track 9 has a positive control loaded in the Sonication Tube, while Track 10 has a negative controls in the sonication tubes.

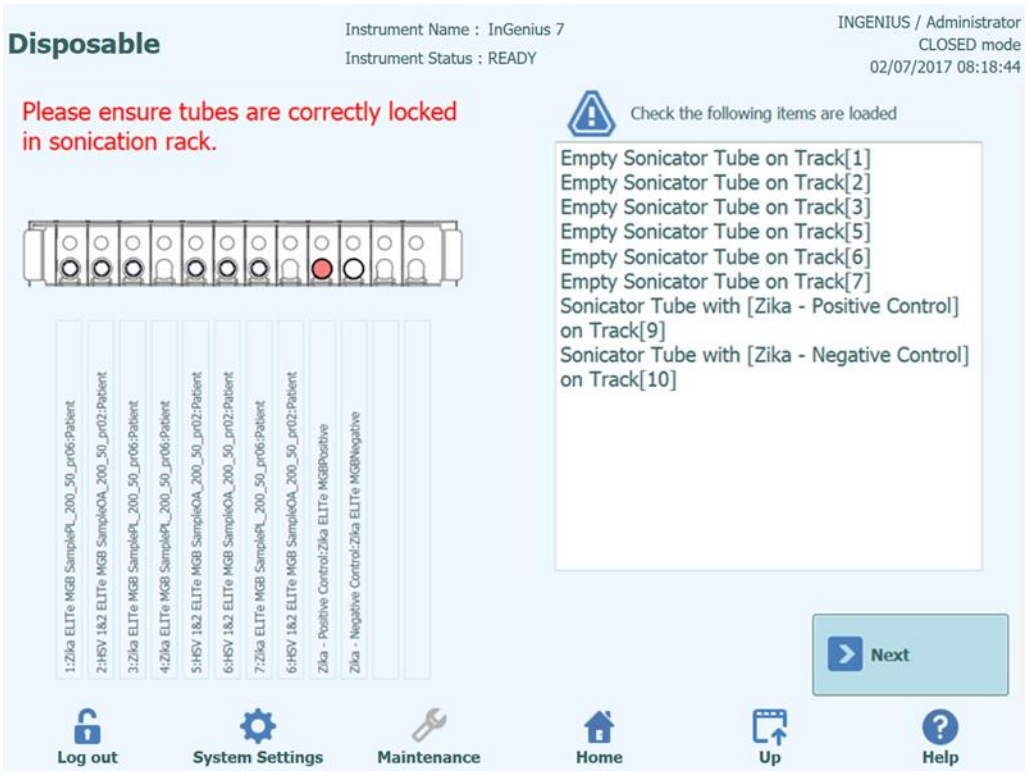


Figure 5-62: Sonication Tube and Cap loading guidance

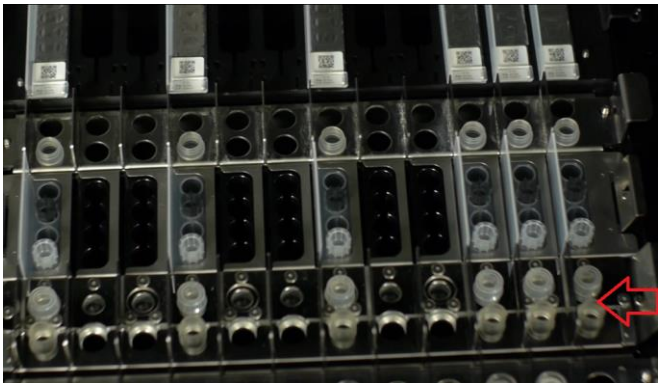


Figure 5-63: Example of Sonication Tube (bottom) and Cap (top) placement on the instrument

5.4.3.11 Step 3j: Load Primary Sample Tubes

After loading the Sonication Rack, the final step is to load the Primary Tubes and samples.

The ELITe InGenius software shows the following Primary Tube loading display to guide the placement of the disposables to be loaded in this step.

Tubes and Samples are needed for all tracks that are configured to run Extraction with the Sample Position set to “Primary Tube”.

NOTE

The information on the right hand side of the screen lists which tracks need to be loaded with Primary Tubes and Samples.

The Primary Tube Graphic shows pictorially where the tubes should be loaded.

The Assay selected for each track is shown below the tube rack graphic.

Once you have loaded the Primary Tubes and Samples into the rack, load the rack onto the instrument working area.

NOTE

If only “PCR Only” Assays are configured in the Run Setup or the sample location for all Extraction Assays is set to “Sonication Tube”, there will be no Primary Tubes to load at this step, so simply press the “Start” button to continue.

CAUTION

Do NOT place caps on the Primary Tubes when loading into the instrument.

In the following example (**Errore. L'origine riferimento non è stata trovata.**~~Figure 5-64~~), tracks 1, 2, 3, 5, 6, and 7 are setup to be run with Sample Extraction from the Primary Tube Rack and require Primary Tubes and Samples.

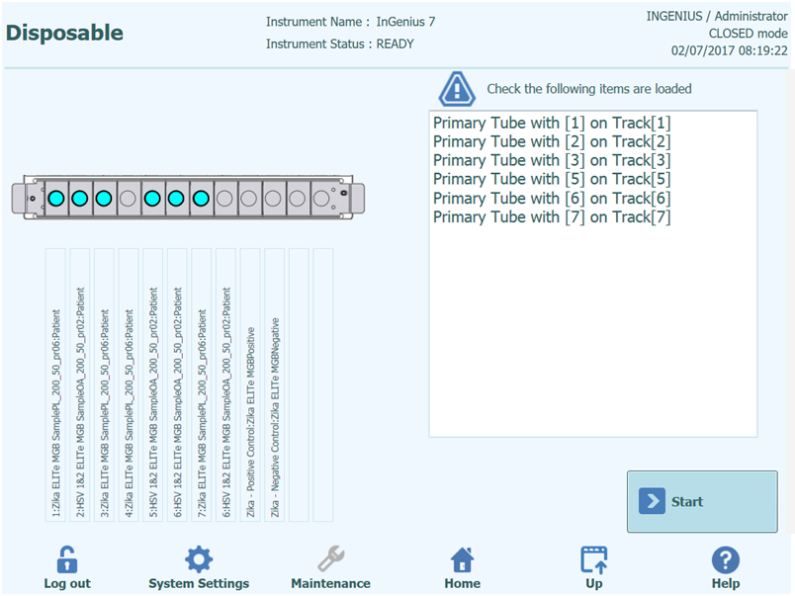


Figure 5-64: Primary Tube and Sample loading guidance.

Figure 5-65: Example of Primary Tube loading on the instrument.

5.4.3.12 Step 3k: Start Run

Before starting the run, carry out one final check that all consumables have been loaded in accordance with the run configuration including waste box container.

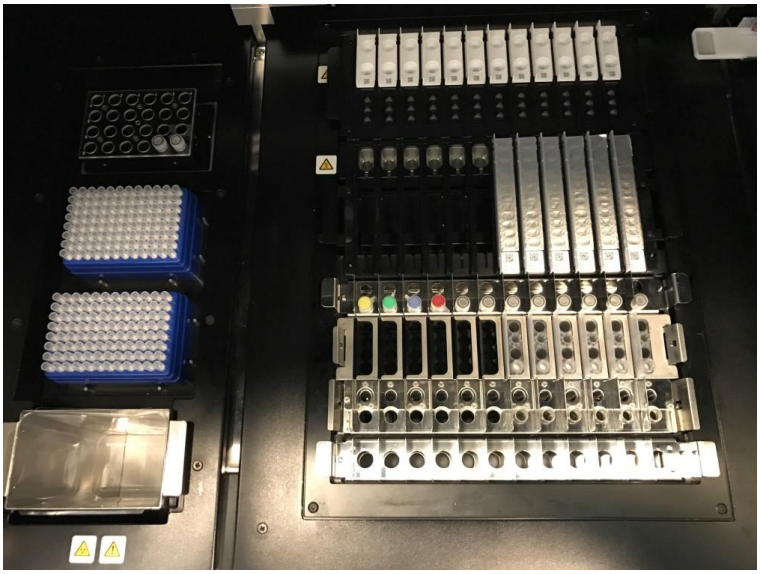
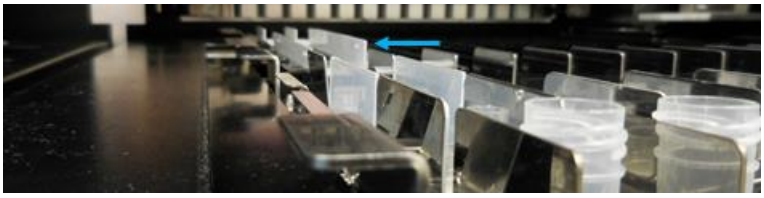


Figure 5-66: Example of final instrument configuration. In this picture it is represented a run configuration that includes: 5 primary samples, 5 extraction cassettes, 12 amplification cassettes.

NOTE

To ensure proper operation of the instrument, verify all materials are seated properly by viewing from the level of the Working Area. In the example below, an extraction cassette is not seated correctly (blue arrow) and needs to be corrected or the instrument will produce an error.



To start the run, press the “Start>” button on the Primary Sample Tube Loading Screen.

The ELITe InGenius System will ask you to confirm that you wish to proceed with the run. Ensure the instrument door is closed before clicking the OK button.

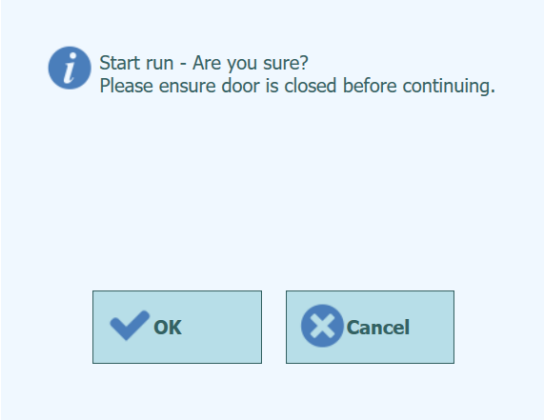


Figure 5-67: Start Run confirmation message.

Once “OK” is touched, the door will lock and the Run will start.

NOTE

Once a Run has been started, the front door is locked to prevent injury from moving parts. The instrument door cannot be opened until either the run is aborted, or it has completed normally.

5.4.4 Step 5: Monitoring Run Progress

Once the Run has been started, the following screen is displayed which shows the progress of the Run through the various process steps.

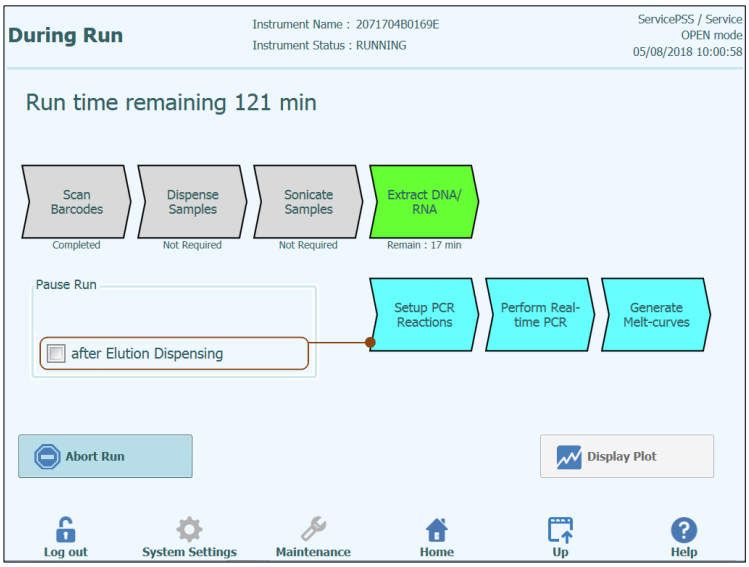


Figure 5-68: "During Run" display.

Execution Process	Description
Scan Barcodes	Process of reading QR bar codes from the consumables loaded to the instrument to check correct placement and prevent accidental.
Dispense Samples	Process to dispense patient samples
Sonicate Samples	Process to destruct cell-wall of patient samples using ultrasonic agitation
Extract DNA/RNA	Process to extract nucleic acids
Setup PCR Reactions	Process to dispense reagents
Perform Real-time PCR	Process to amplify nucleic acid
Generate Melt-Curves	Process to generate Melt curves

Table 5-3 : Process Steps

	Process that is not needed or has been completed
	Process that is scheduled to be run
	The currently executing process

Table 5-4 : Process Status Symbols

While a run is in progress, it is possible to press the “Up” button to return to the Home Screen and carry out other operations. To return to the During Run screen, press the “Perform Run” button on the Home Screen.

5.4.4.1 Aborting the RUN

If you wish to stop the run before it has completed, press the “Abort Run” button in the “During Run” display. A pop-up confirmation box is show to avoid stopping the run accidentally. Press “Yes” to stop the run or “No” allow the run to continue.

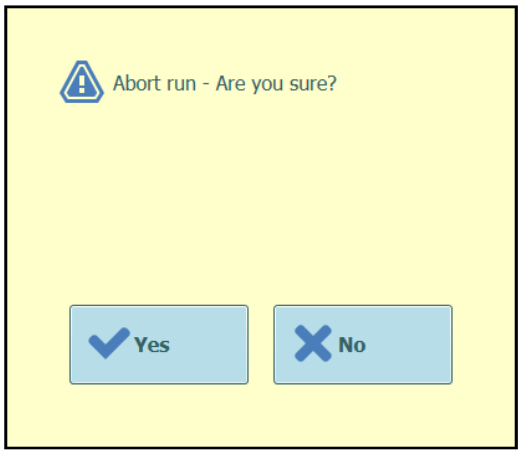


Figure 5-69: Abort run confirmation.

After a run is aborted, the Results display will be shown.

NOTE

If the run is aborted, results for some Assays may not be reported if not all the needed processes have been completed.

The Run Results screen will show that the Run was aborted.

After Aborting a run, the front door will remain locked until the temperature of the PCR and Extraction units have cooled down to a safe temperature.

5.4.4.2 Displaying Fluorescence Plots During Run

If you wish to view the fluorescence curves during PCR Amplification or Melting, press the “Display Plot” button in the During Run Screen.

The Display Plots Screen has three tabs that can be used to view

- Amplification Curves
- Melt Curves
- Detailed Information about run (includes details of calibrators, controls, samples etc)

The curves in the Display Plots screen are updated in real time as the run progresses.

The buttons and check boxes on the right hand side of the screen can be used to choose which curves should be displayed on the graph.

- Line Colour by Track Number
  The fluorescence curves for all channels in a track are plotted using the same colour. A different colour is used for each track.

- Line Colour by Channel Number
  The fluorescence curves for each channel regardless of track are plotted using the same colour. A different colour is used for each channel.

- Display Tracks
  Used to select which tracks are included to the display

- Display Channel
  Used to select which channels are included to the display

To return to the During Run Screen, press the “Up” button at the bottom of the screen.

Figure 5-70: Display Plots During Run: Amplification Curves

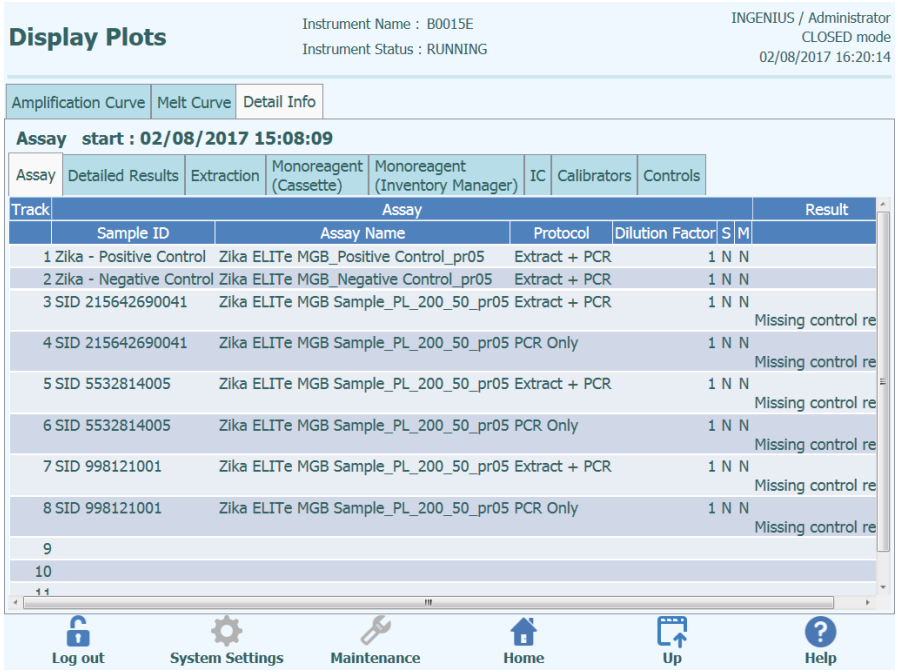


Figure 5-~~2371~~ : Display Plots During Run: Detail Info

5.4.5 Step 6: Results Review and Approval

Once all the processes have been completed for a Run, the “Result Display” screen is displayed automatically.

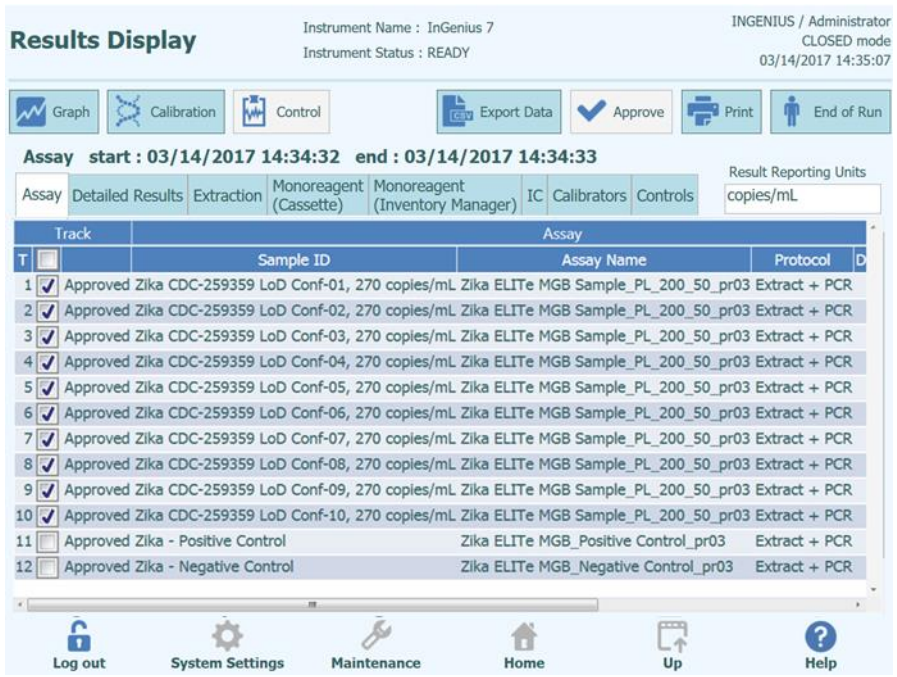


Figure 5-72: Example of Results Display.

The Results Screen provides a number of different data views that may be accessed by clicking on the tabs above the table of results.

- Assay Tab
  Shows a summary of the assay settings for each track together with the interpreted results for the track and approval status for each track.

- Detailed Results Tab
  Shows further details of the result interpretation for patient samples, calibrators and controls

- Extraction Tab
  Shows traceability information for each extraction cassette used in the run (Name, Lot Number, Expiry Date)

- Monoreagent (Cassette) Tab
  Shows traceability information for each Reagent Cassette based Monoreagent that was used in the run (Name, Lot Number, Expiry Date)

- Monoreagent (Inventory Manager) Tab
  Shows traceability information for each Inventory Manager based Monoreagent that was used in the run (Name, Lot Number, Expiry Date)

- IC Tab
  Shows traceability information for each Inventory Manager based Internal Control that was used in the run (Name, Lot Number, Expiry Date)

- Calibrators Tab
  Shows details of the calibration curve that was used to calculate the viral load in each track (Calibrator fluid Lot Number and Expiry Date, Calibration Curve Approval Status and Expiry Date).

NOTE NO Calibration functionalities are described in this document since NO quantitative IVD assays have been validated on the ELITe InGenius instrument

- Controls Tab
  Shows details of the Control plots that were used to validate the result in each track (Control fluid Lot Number and Expiry Date, Control Approval Status and Expiry Date)

NOTE It is possible to resize the columns in the results table by dragging the separators in the column headings. It is also possible to scroll left/right and up/down if the results do not fit on the screen

In addition to the results table, the Run Results screen also provides buttons to access graphical views:

- **Graph** Button: View PCR amplification and Melting Curves
- **Calibration** Button: View and Approve Calibration Curves
- **Controls** Button: View and Approve Control Plots
- **Export Data** Button: Export data to CSV (Administrator users only)

NOTE The “Calibrator” and “Control” buttons are only displayed if the Run includes Calibrator or Control Assays.

5.4.5.1 Viewing PCR Amplification and Melt Curve Results

This screen is accessed by pressing the “Graph” button in the Result Display screen.

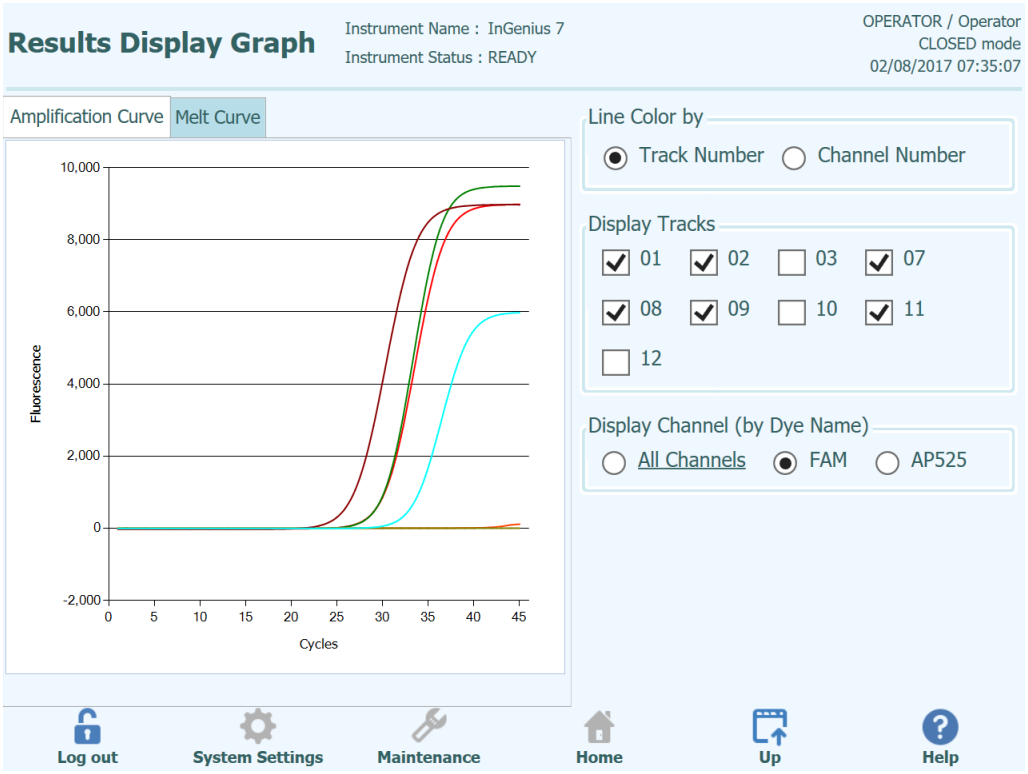


Figure 5-73 : Results Display Graph.

The Results Display Graphs Screen has two tabs that can be used to view

- Amplification Curves
- Melt Curves

The curves in the Results Display Graphs screen show the processed data used to calculate C_t and T_m values.

The buttons and check boxes on the right hand side of the screen can be used to choose which curves should be displayed on the graph

- Line Colour by Track Number
  The fluorescence curves for all channels in a track are plotted using the same colour. A different colour is used for each track.

- Line Colour by Channel Number
  The fluorescence curves for each channel regardless of track are plotted using the same colour. A different colour is used for each channel.

- Display Tracks
  Used to select which tracks are included to the display

- Display Channel
  Used to select which channels are included to the display

To return to the Run Results Screen, press the “Up” button at the bottom of the screen.

5.4.5.2 Approving Patient Sample Results

To approve Patient Sample Results, select each track to be approved using the tick boxes on the left hand side of the Results Display.

NOTE Only users with an Analyst, Administrator or Service account are able to Approve assay results.

Figure 5-74 : Approving Patient Results

When at least one Patient Sample Result is selected, the “Approve” button at the top of the screen will be activated.

Press the “Approve” button to approve the results.

The ELITe InGenius System will then ask for confirmation of the Approval action for the selected tracks. Click “Yes” if you wish to proceed with the Approval.

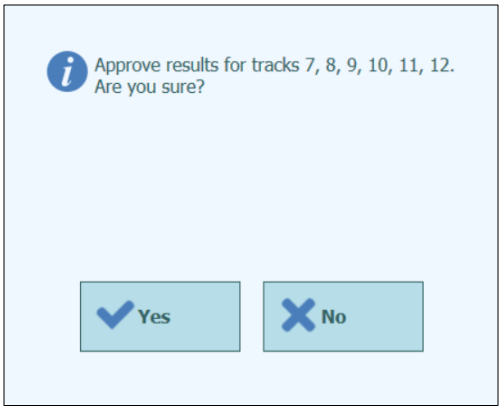


Figure 5-75: Confirmation of tracks to be approved

If the person approving the results has only an Operator account, the ELITe InGenius System will request that the credentials for an Analyst, Administrator or Service User to allow the Approval to be given. If the person approving the results has the necessary role, this step will be skipped.

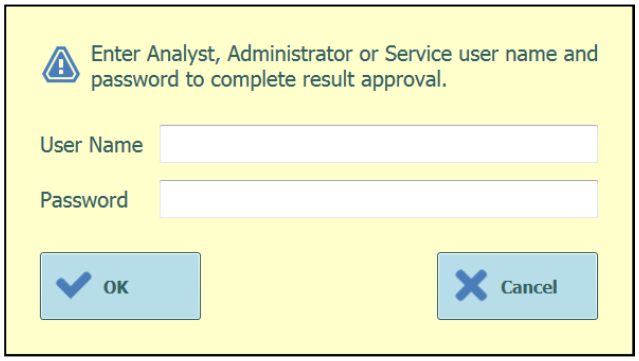


Figure 5-76: Authorisation of Result Approval

If the ELITe InGenius System is configured to perform upload of results to an LIS system, this will be attempted once the results are approved.

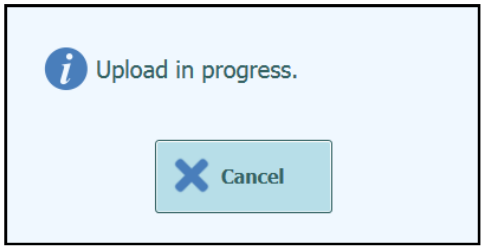


Figure 5-77: Uploading Results to LIS

The ELITe InGenius System will timeout the LIS Upload operation if it does not complete within a predefined time.

Once the Results have been uploaded to the LIS successfully, the Approval Status will be shown as “Approved, Uploaded”.
If the LIS upload fails, the Approval Status will be shown as “Approved, Upload failed”. It is possible to request the system to retry the upload by pressing the “Approve” button again when the required tracks are selected in the Results Display.

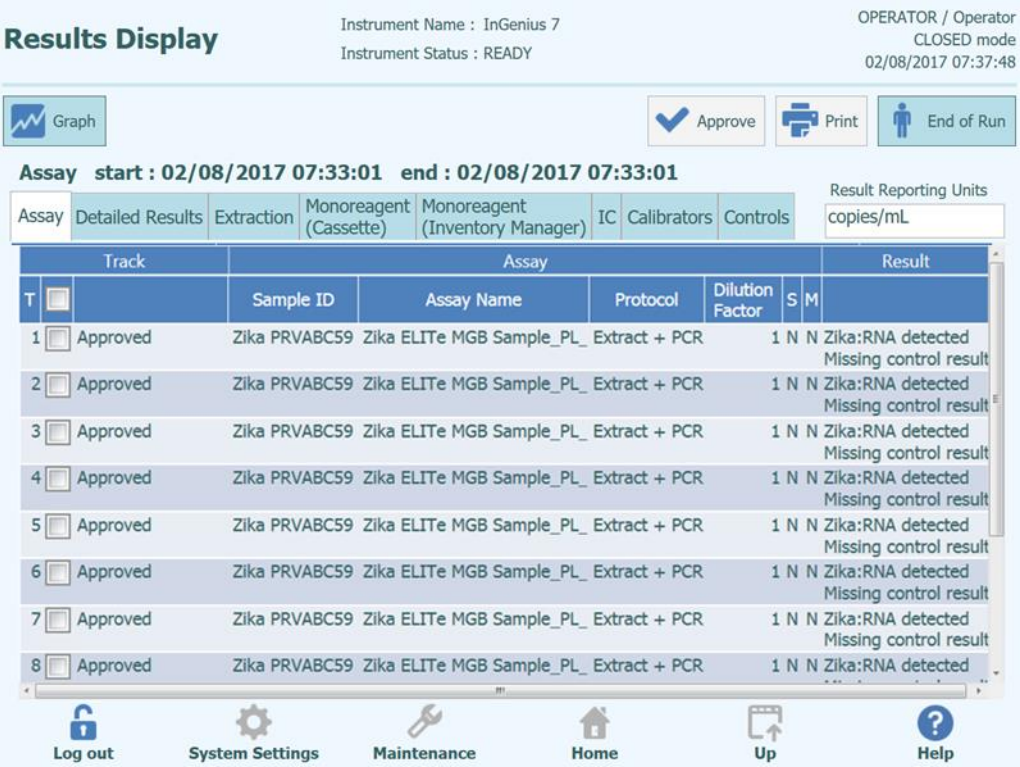
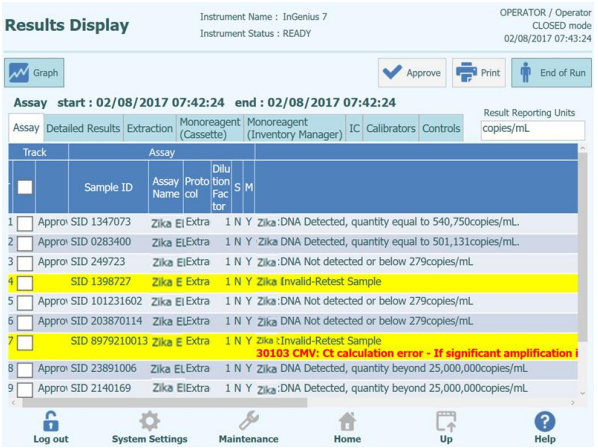


Figure 5-78: Example of Approved Results

NOTE

If the result for a track cannot be determined (e.g., if sample is invalid because C_ts are undetermined for both IC and target or if an error occurred during the run), the track is highlighted in yellow as demonstrated in the example here:



In the case of invalid samples or tracks which experienced an error, the result cannot be approved.

For tracks that have PCR Only results, the ELITe InGenius System allows the results to be reported in different units.

This function is controlled using the setting in the box highlighted below.

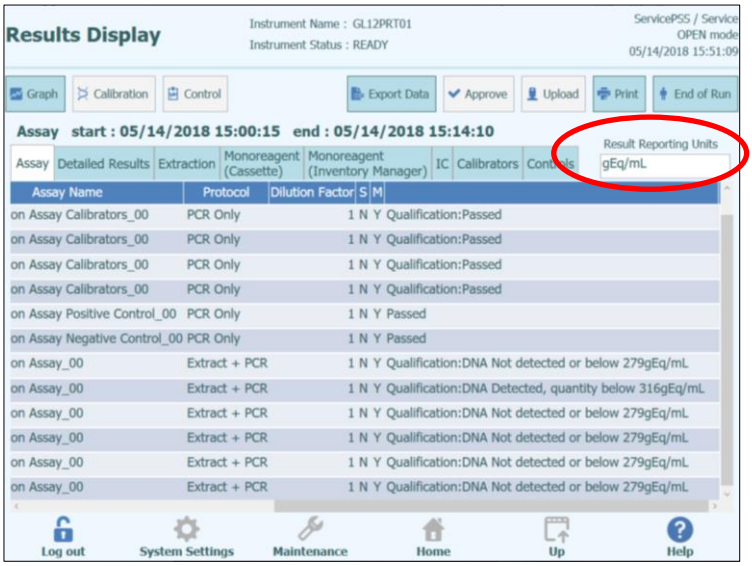


Figure 5-79: Result reporting units for PCR only assays

NOTE

It is not possible to change the results reporting units for assays run with an Extract+PCR process.

A conversion factor for converting from copies/mL to IU/mL must be specified in the Assay Program before test results can be reported in IU/mL.

5.4.5.3 Printing Track and Patient Sample Reports

The ELITe InGenius System supports two styles of output reports for the track results. These reports can be exported to a PDF file or printed. Note that only tracks with the checkboxes checked will be reported.

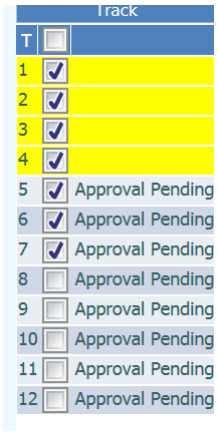
NOTE Sample and Track Reports are marked “IVD” for all IVD assays.

- **Sample Report**
  This report has the following structure. It is intended to allow paper copies of the report to be separated by Sample ID for inclusion to different patient files.
  - Summary page showing the Assay results and approvals for 1st Sample ID
    - Detailed pages for 1st Assay for 1st Sample ID
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - Detailed pages for 2nd Assay for 1st Sample ID
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - etc
  - Summary page showing the Assay results and approvals for 2nd Sample ID
    - Detailed pages for 1st Assay for 2nd Sample ID
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - Detailed pages for 2nd Assay for 2nd Sample ID
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - etc
  - etc

- **Track Report**
  This report has the following structure.
  - Summary page showing the Assay results and approvals for each of the selected tracks in the run
    - Detailed pages for track 1 Assay
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - Detailed pages for track 2 Assay
      - Assay Parameters
      - PCR and Melt plots and Ct/Tm results
    - etc

To generate either of these reports,

- Select the tracks / samples you wish to include in the report by clicking on the check boxes on the left hand side of the Run Results Screen



- Press the “Print” button at the top of the Run Results Screen
- Select the report style from the pop-up list. Based on end user need it is possible to select Track Reports or Sample Reports, a Summary only Report, select or deselect graphs

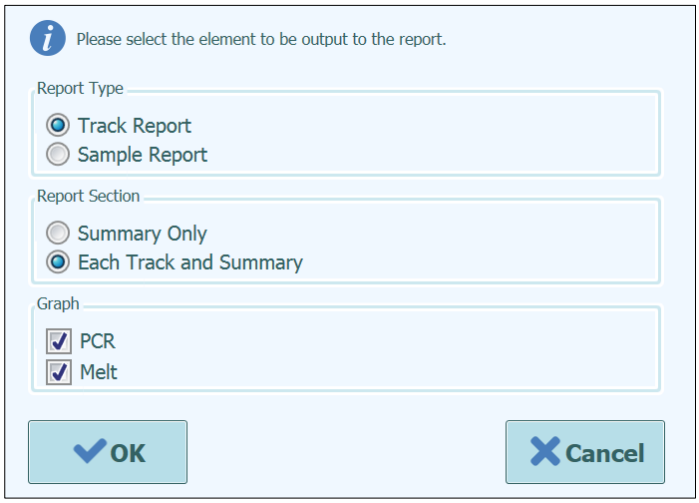


Figure 5-80: Report Style Selection.

The report viewer tool can be used to preview the report on the screen and step between pages in the report.

Press the “Print” button to send the report to the printer.
Press the “Export as PDF file” button to specify a PDF output.
Press the “Close” button once you have finished with the report.

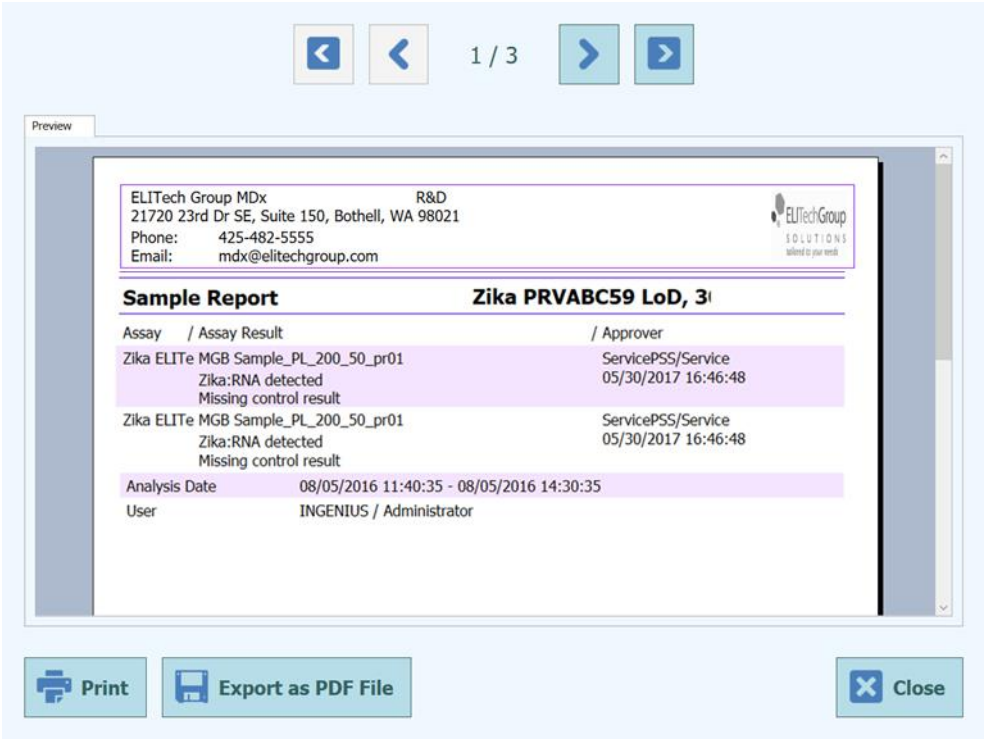


Figure 5-81: Example of Sample Report

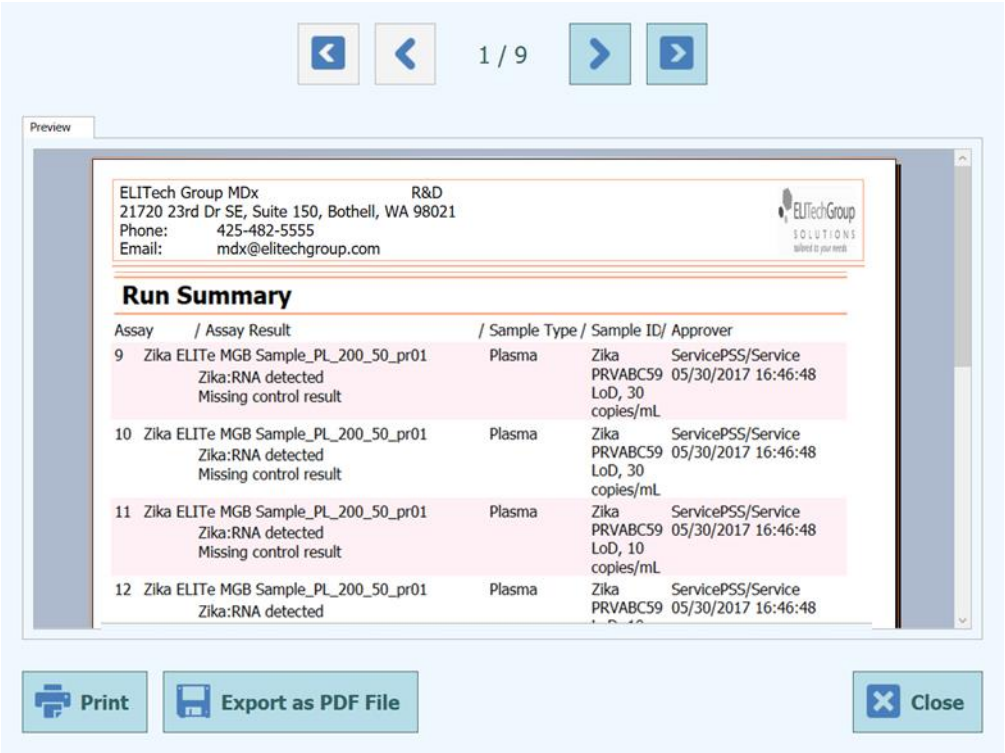


Figure 5-82: Example of Track Report

5.4.5.4 Viewing Control Results

When a Run includes a Control Set, the Run Results screen will show whether each individual track was amplified correctly or not (see “Result” column in example below).

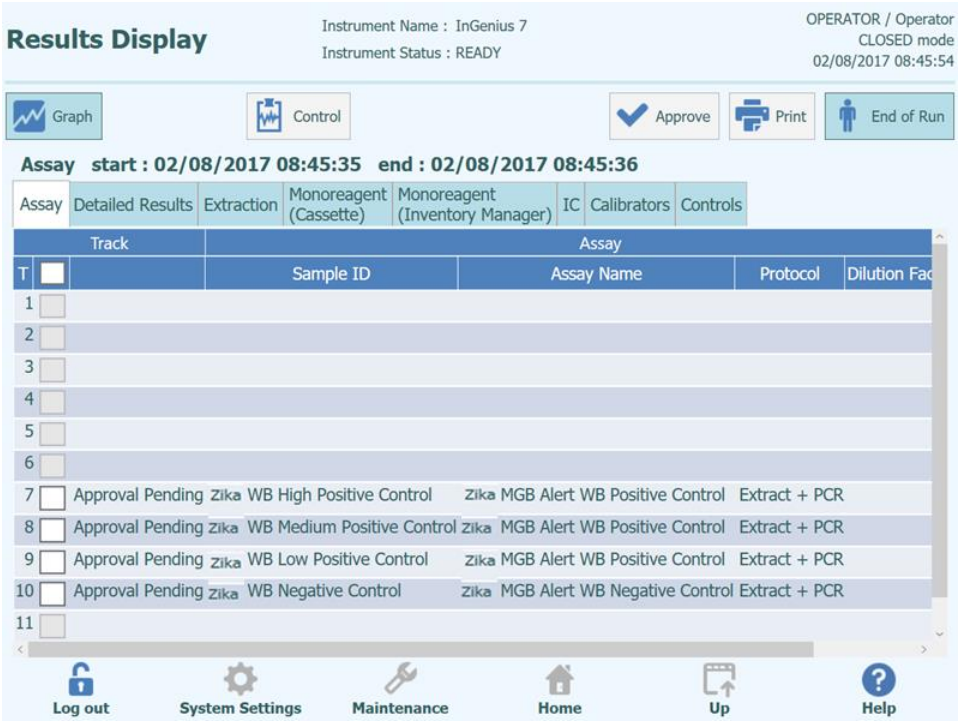


Figure 5-83: Example of Run Results for a Control Set

NOTE

The “Approve” button on the Results Display Screen is NOT used for Approving Controls. A reminder message will be displayed if the Approve Button is pressed when a Control Set is selected in the Results Display Screen.

To View and Approve the Control Plots, click on the tick box for any of the tracks in the Control Set. All other tracks in the Control Set will be automatically selected.

Click on the “Control” button in the top right corner of the screen to display the Control screen.

To return to the Run Results Screen, press the “Up” button at the bottom of the screen.

For Positive Qualitative Controls, the software verifies the calculated C_t is below the Pass/Fail threshold to allow the result to be Approved, while for a Negative Qualitative Control, the software checks that the calculated C_t is above the Pass/Fail threshold before allowing result Approval.

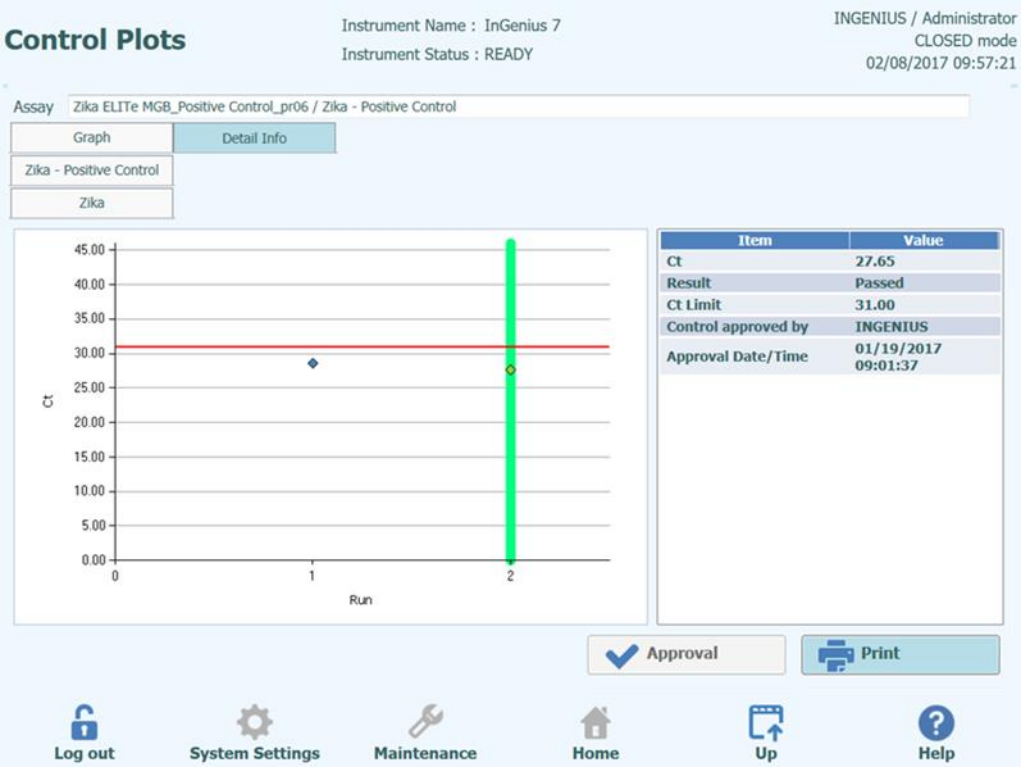


Figure 5-84: Control Screen – Statistics Plot

The text box on the right side of the Control Screen provides further details.

Above the Control Plot, the tabs are used to select between the different levels and different targets (if applicable) within the Control Set.

By touching the “Detail Info” tab in the Control Screen, detailed info about the control run can be displayed. The Detail Info tab has further sub-tabs that can be touched to show similar information to the Run Results screen, but specific to the selected control tracks.

Style of plot varies by conditions below. Color varies by lot number of control.

Run	Non-approved		Approved	
	Passed	Failed	Passed	Failed
latest	▲	▲	◆ ◆ ◆ (*)	-
past	▲	■	◆ ◆ ◆ (*)	-

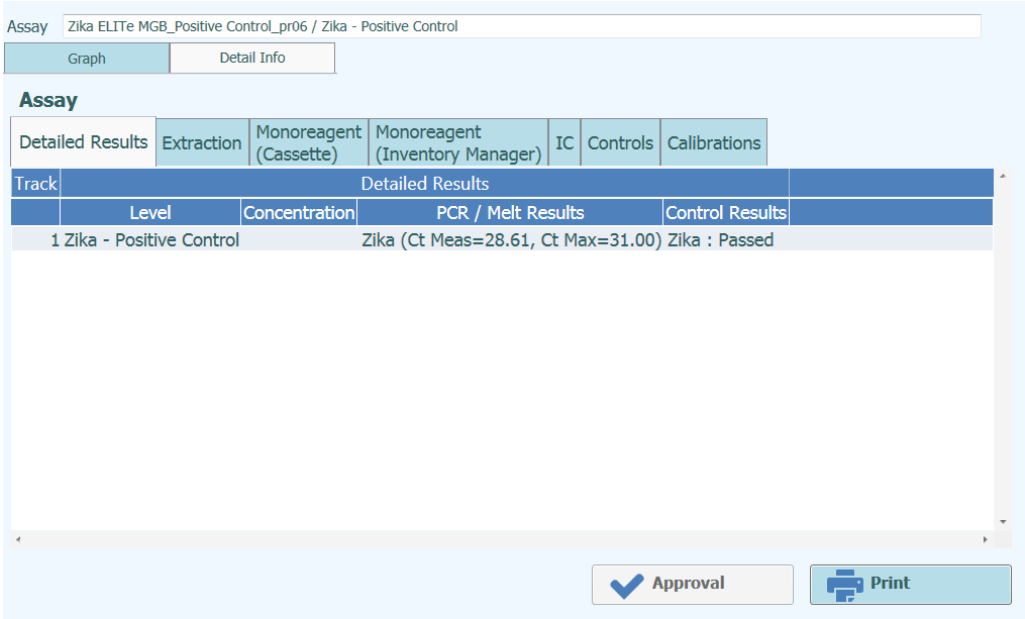


Figure 5-85: Control Screen – Detailed information

5.4.5.5 Approving Controls Results

If the all of the levels and targets contained within the Control Set yield acceptable results (i.e. All tracks amplify satisfactorily and the C_t / SD validations pass), the "Approval" button will be enabled in the Control Screen.

Click the "Approval" button on the Control Screen to approve the Control Plots so that they will be available for validating results in other related Assays.

If the person approving the results has only an Operator account, the ELITe InGenius System will request that the credentials for an Analyst, Administrator or Service User to allow the Approval to be given. If the person approving the results has the necessary role, this step will be skipped.

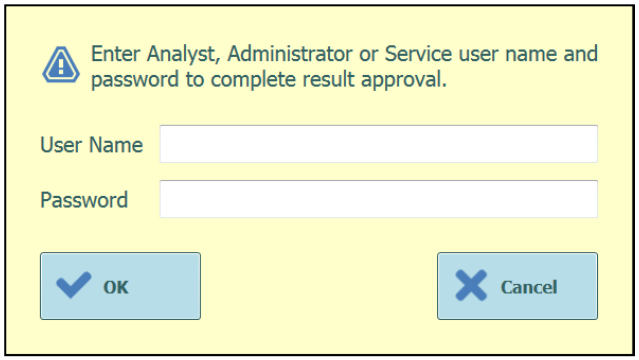


Figure 5-86: Authorisation of Result Approval

5.4.5.6 Printing Controls Report

Press the “Print” button in the Controls Screen to generate a report that can be exported to a .PDF file or sent to a printer.

You can use the buttons on the screen to preview the report.

Press the “Print” button to send the report to the printer.
Press the “Export as PDF file” button to specify a PDF output.
Press the “Close” button once you have finished with the report.

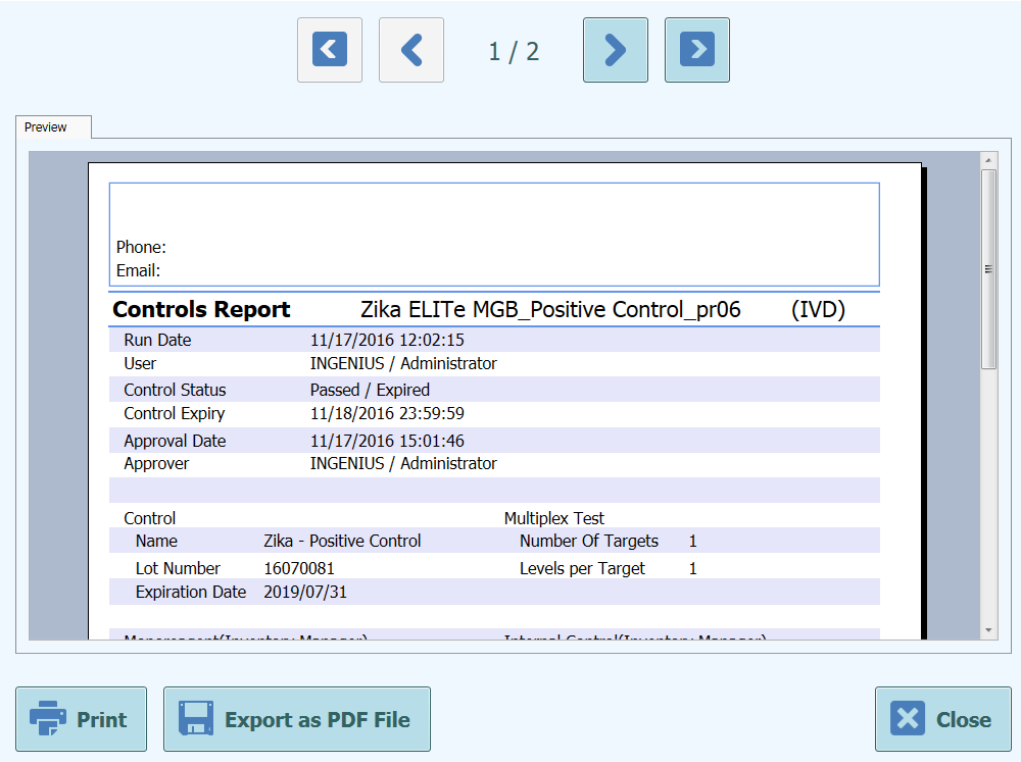


Figure 5-87: Printing Controls Report

To return to the Run Results Screen, touch the “Up” button at the bottom of the screen.

NOTE An IVD mark will appear in Controls Report at the top of the first page for all controls associated with IVD assays.

5.4.5.7 Exporting Run Data

When the logged in user is an Administrator or Service User, it is possible to export run data from the ELITe InGenius System for offline analysis.

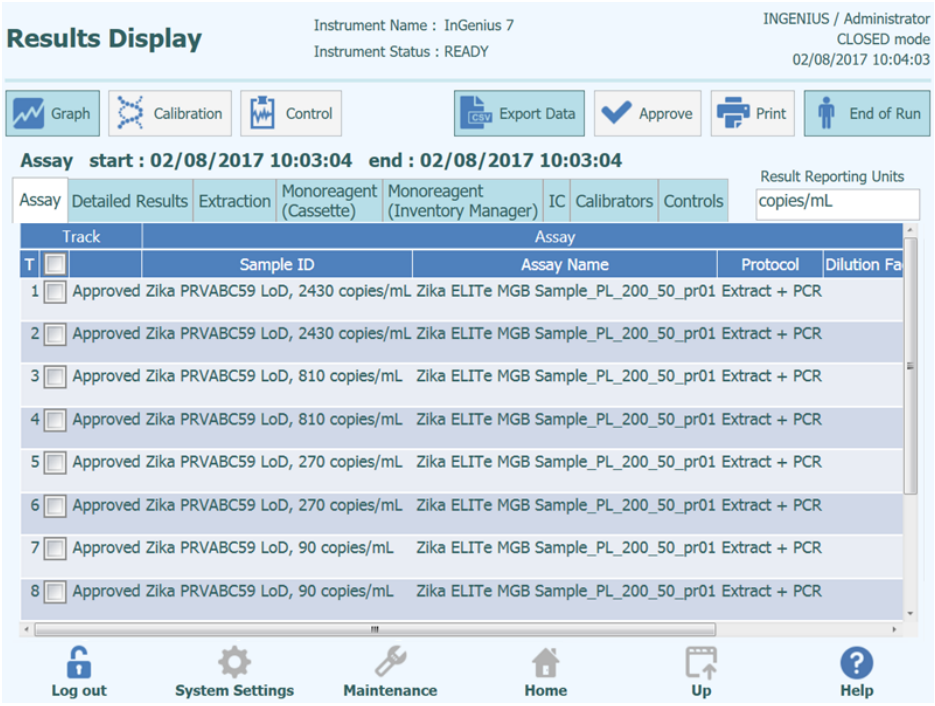


Figure 5-88: Exporting Run Data

To save the run data to an external USB memory stick or folder on the ELITe InGenius System, click on the “Export Data” button at the top of the Results Display Screen.

NOTE The “Export Data” button is not displayed for an Operator or Analyst user.

Choose a destination folder for the data to be exported to using the folder dialog and click on “OK” to output the data.

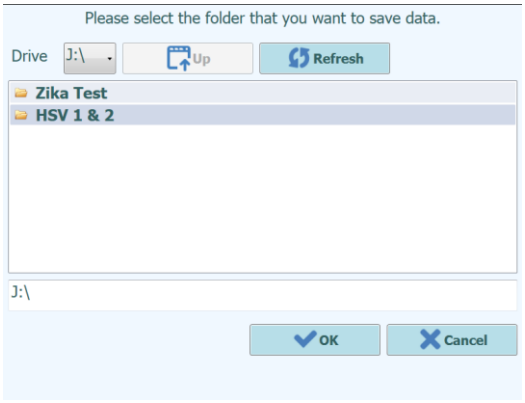


Figure 5-89 : Data Export Folder Selection

The data is created in a number of .csv and .ini files, with filenames that are defined by the ELITe InGenius System.

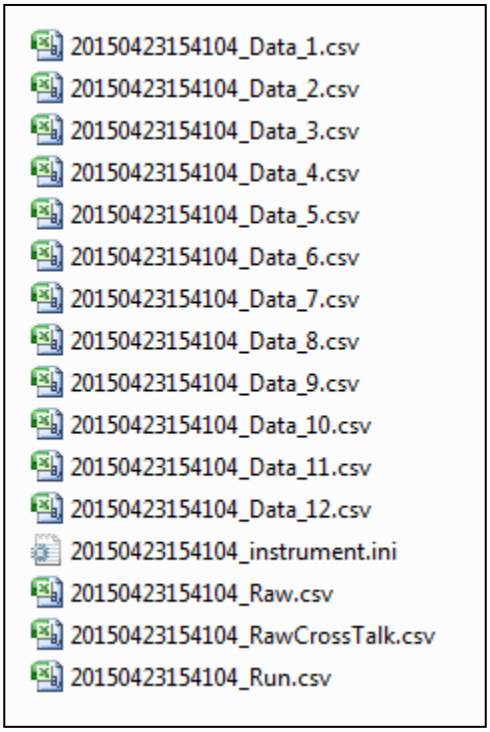


Figure 5-90: Example of Files Generated by Data Export

5.4.5.8 Completing the Run

Once you have completed the review and approval of the Run Results, press the “End Of Run” button in the top right corner of the Results Display Screen.

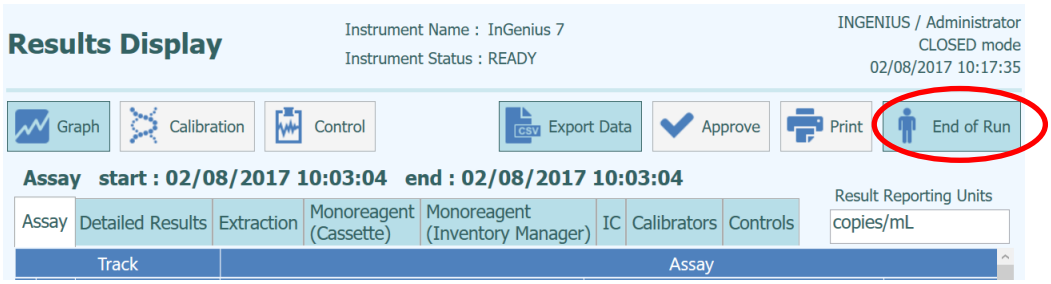


Figure 5-91: End of Run Button

If there are still results with Approvals pending, a warning message will be shown. Select “Yes” to proceed with the run completion, or “No” to return to the Run Results Screen to Approve the remaining test results.

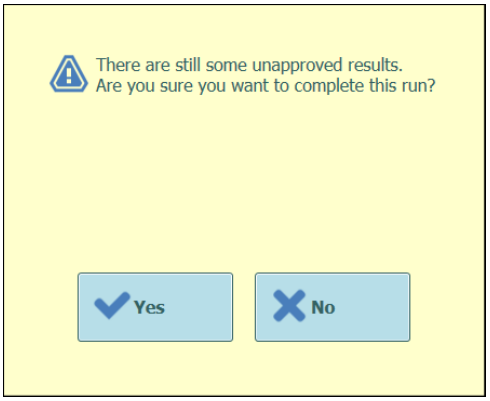


Figure 5-92: Reminder for unapproved results

NOTE After completing a run, it is still possible to retrospectively approve results after the run has been completed by accessing the Results Search function.

5.4.6 Step 7: Unloading Consumables and Fluids after Run

After the Run Results have been reviewed and approved, the final step of the Run is to unload the consumables and fluids from the instrument.

The End of Run Screen provides instructions on unloading, storing or discarding the samples, materials and reagents. Please carry out these actions immediately.

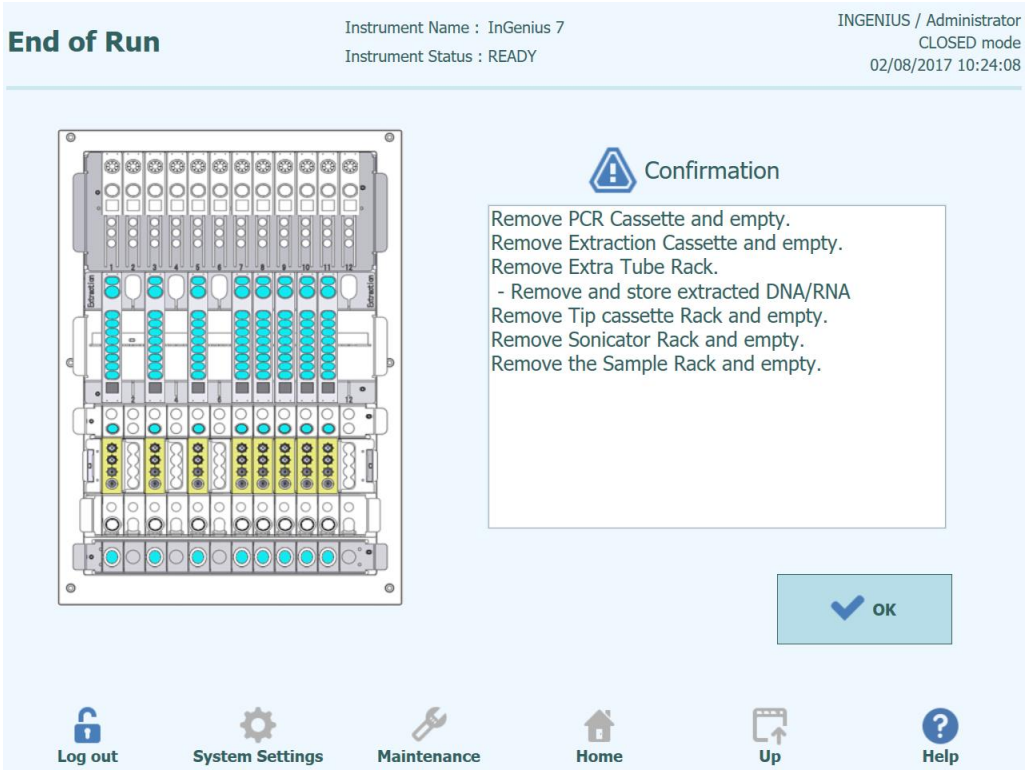


Figure 5-93: End Of Run Screen

DANGER

Risk of infection!

The instrument must be treated as potentially infectious. Improper handling of infectious parts can cause skin irritations, illnesses and possible death.

Observe local and national provisions, legislation and laboratory regulations.

Use appropriate gloves!

Use an appropriate lab coat!

Use appropriate eye protection (e.g. goggles)!

Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.

Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.

Observe the legal regulations for the handling of infectious material.

Never use bio-hazardous liquids for testing the instrument!

WARNING

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed of according to the local and national provisions, legislation and laboratory procedures.

NOTE

After completing a run, the OK button will be greyed out and the user will be unable to press it and the front door will remain locked until the temperature of the PCR and Extraction units have cooled down to a safe temperature. Once the system has reached a safe temperature the user will then be able to press OK which will unlock the door enabling it to be opened so the system can be unloaded.

Press OK, the Home page will be displayed ready to start the next run or perform other operations.

Open the front door.

Close the cap of the Mono Reagent and Internal Control tubes located in the Inventory Manager Block.

NOTE

Take care to follow the storage instructions for the Mono Reagent and Internal Controls products as specified in their Instructions For Use.

Discard the waste box.

Remove and discard the PCR Cassettes from the PCR Rack.

Remove and discard the Extraction Cassettes from the Extraction Rack.

Fit caps to the Elution tubes, Control tubes or Calibrators tubes, remove them from the Elution Tube Rack and store.

NOTE

Take care to follow the storage instructions for the Calibrators and Control products as specified in their Instructions For Use.

Remove and discard the Tip Cassette from Tip Rack.

Remove, close off and discard the Sonication tubes from the Sonication Rack if loaded.

Remove and close off the Primary tubes from Sample Rack if loaded.

Close off the Primary tubes using the correct caps and store them as described in the Instructions for Use for the “ELITe InGenius® SP 200” extraction kit.

5.5 Result Search

The Results Search function is used to access the results from previous runs that are stored in the ELITe InGenius System database.

Click the “Results Search” button on the Home Screen to access the search screen.

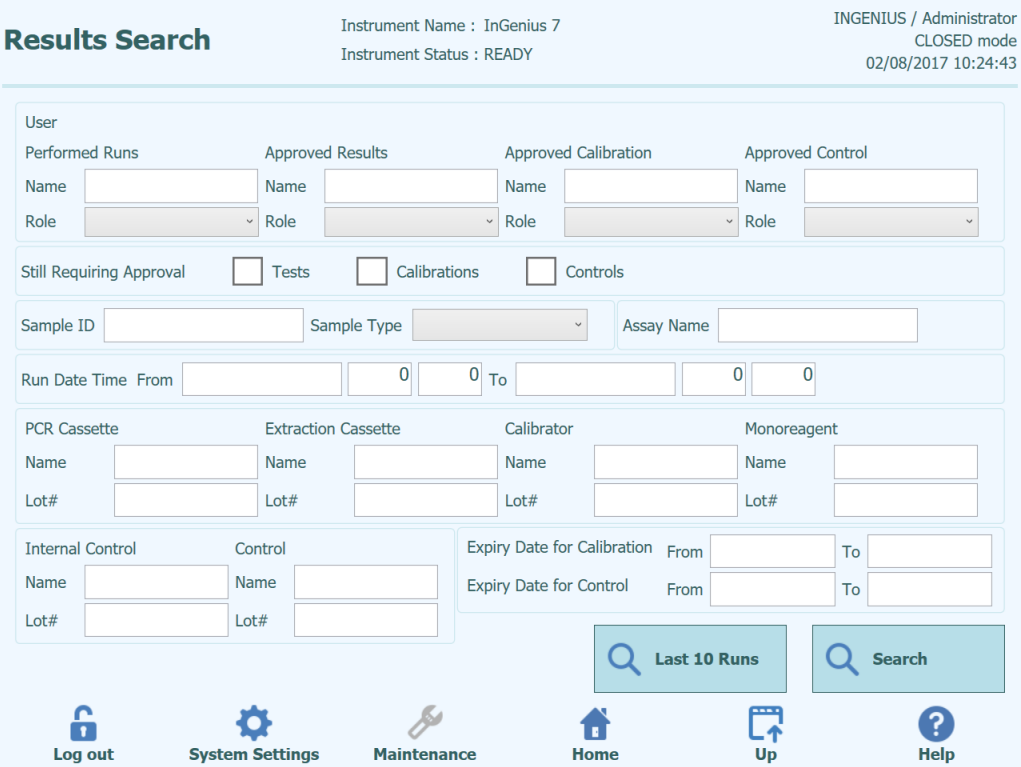


Figure 5-94: Results Search screen

In this screen, you can narrow the search by filling out the fields to specify parameters that will be used to filter the results returned from the database.

Fields that are left blank will be matched to any value in the database (i.e. behave as a wildcard).

Press the “Search” button to perform the search.

The “Last 10 Runs” button provides a shortcut to access the most recent runs in the database.

Once the database search has completed, matching Runs are listed in the Search Results screen.

Each row in the Search Results represents a single Run. Each row includes a summary of the assays that were run in each of the tracks within the Run.

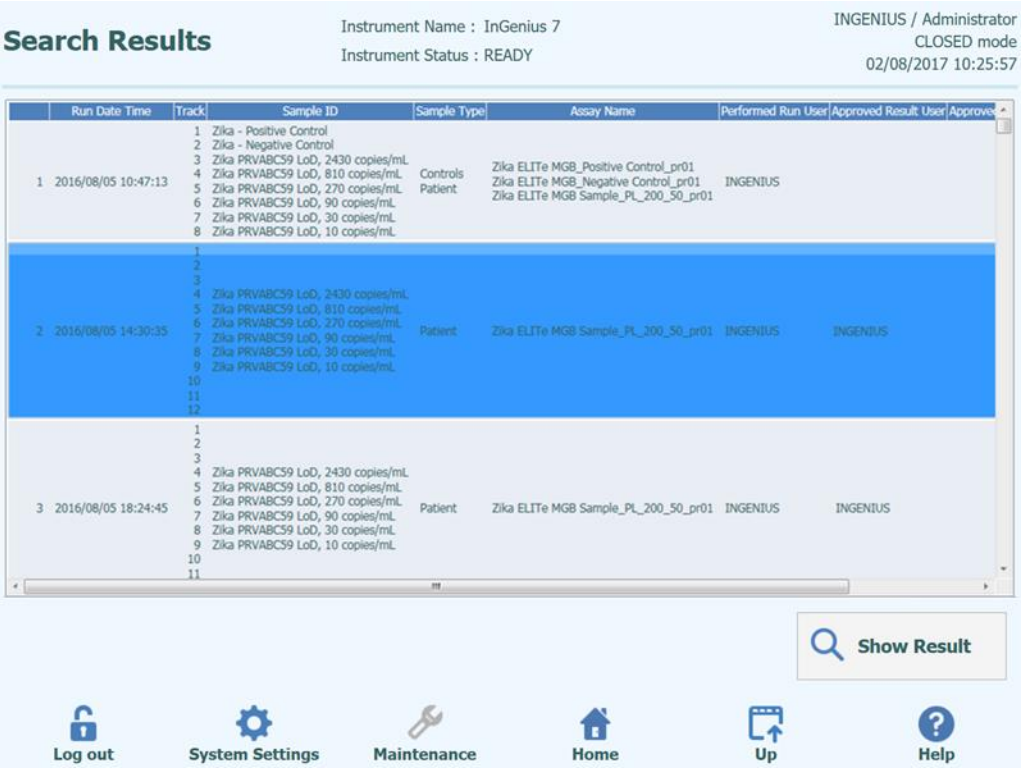


Figure 5-95: Search Results screen.

To view the results for a specific run, click on the row in the Search Results screen that is showing the run you wish to view, and click the “Show Result” button.

The same level of information will be displayed as when the Run was actually run. See section 5.4.5 for further details on how to view the detailed results for the run.

This screen may be used to Approve previously unapproved results or to re-attempt the upload of results to the LIS if this had failed previously.

5.6 Shutting Down the Instrument at End of Day

At the end of each day you should perform the following steps to shut down the system. The ELITe InGenius software will guide you through this procedure when you select the “End of Day” option from the Home Screen. If a Run is currently in progress, you will need to wait until the Run completes before you will be able to select the “End of Day” option.

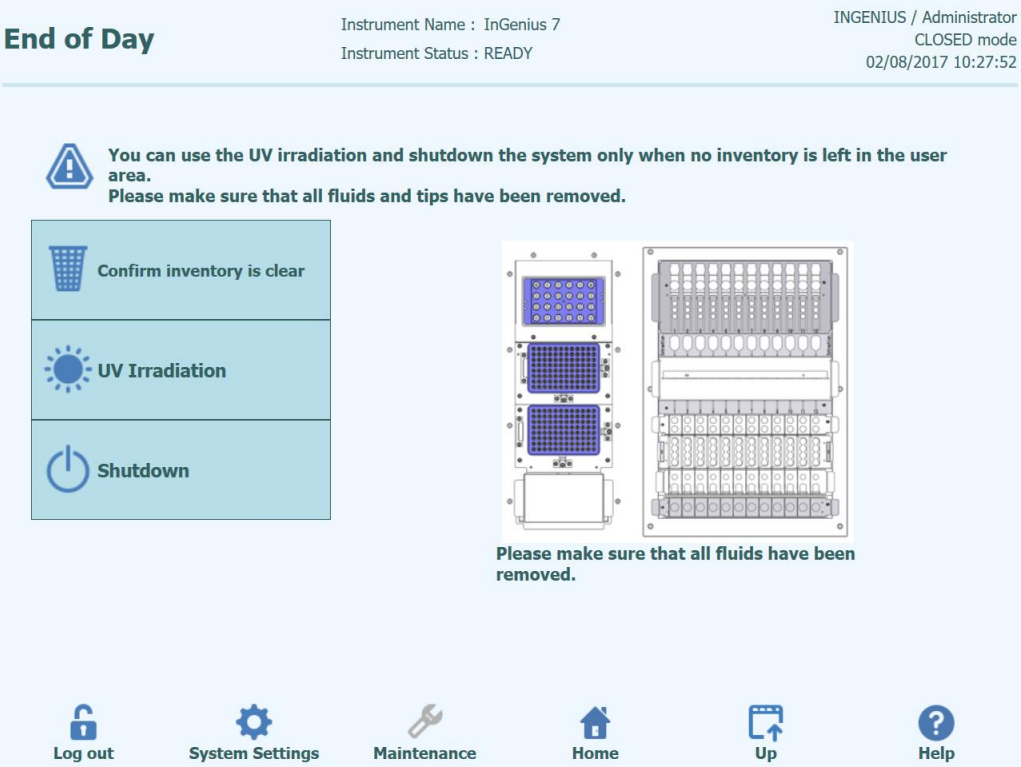


Figure 5-96: End of Day screen.

Open the front door.

Remove the block from the Inventory Area and store it in the refrigerator.

NOTE The instrument should not left with reagents in the Inventory Area since the cooling block will be switched off once the instrument is shut down

Press the “Confirm Inventory is Clear” button.

Press the “Shutdown” button

NOTE It is also possible to perform a UV sterilisation cycle before you shut down the instrument. See section 5.6.1 for details.

Once the system has completed its shut down, you should turn off the power switch at the side of the instrument.

You may then perform any additional cleaning processes once the instrument is switched off.

WARNING

Carry out cleaning of the instrument only after switching off the instrument power.

NOTE

Do not use disinfecting materials which contain hypochlorite or bleaching fluids. Only use cleaning, disinfecting and decontaminating fluid in accordance with manufacturer's instructions (see "Maintenance", Chapter 0).

5.6.1 UV Sterilisation

The instrument working area may be sterilised using the built-in UV lamp. You must select the sterilisation function manually by clicking on the "UV Irradiation" button prior to shutting down the instrument. The UV sterilisation process is an optional step of the shut down process.

WARNING

Conjunctivitis and Skin Burns due to UV-Light

The radiation of the UV-Lamp may cause conjunctivitis and skin burns within minutes.

Never look directly into the UV-Lamp!

Protect your eyes and skin from direct radiation!

Keep the instrument door closed during UV sterilization!

NOTE

The UV sterilisation function not enabled until you have confirmed that the Inventory Area has been cleared using the "Confirm Inventory is Clear" button.

Close the front door.

Click on the "UV Irradiation" button to start the UV sterilisation procedure and click OK on the following pop-up box to confirm that the Instrument Door is closed.

The following popup will be displayed to confirm whether you want to run automatic shutdown after the UV radiation or not.

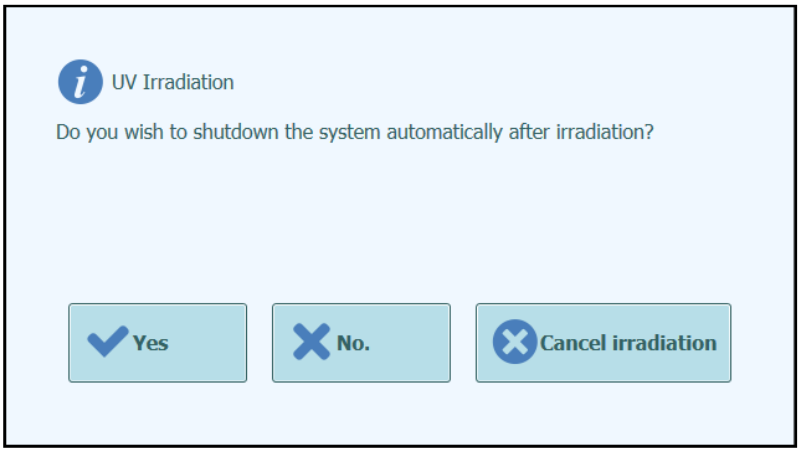


Figure 5-97: Selecting shutdown options for after UV sterilisation completes.

You should normally choose to shutdown the system on completion of the UV sterilisation procedure (Yes).

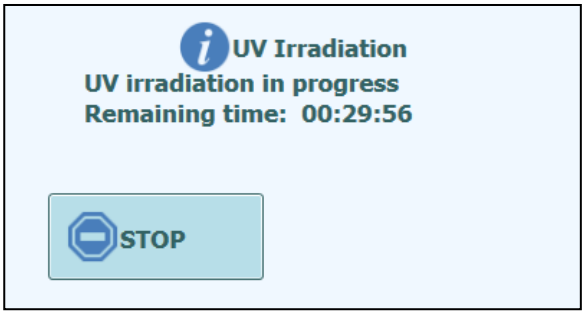


Figure 5-98: UV irradiation in progress popup

After the UV sterilisation has completed, the door lock is unlocked and the system software is shutdown automatically.

Once the system has completed its shutdown, you should turn off the power switch at the side of the instrument.

6 Advanced Functions

The following functions are only accessible from an Administrator or Service user account. It is not possible to access these functions using an Operator or Analyst user account.

6.1 System Settings

Before using the system, it is advisable to configure some initial settings and user accounts. A default Administrator account is provided to provide access to the System Settings on first use of the system.

The “System Settings” menu is accessed by selecting the “System Settings” icon at the bottom of the Home screen. This icon will be greyed out and disabled if you are logged in as an Operator or Analyst.

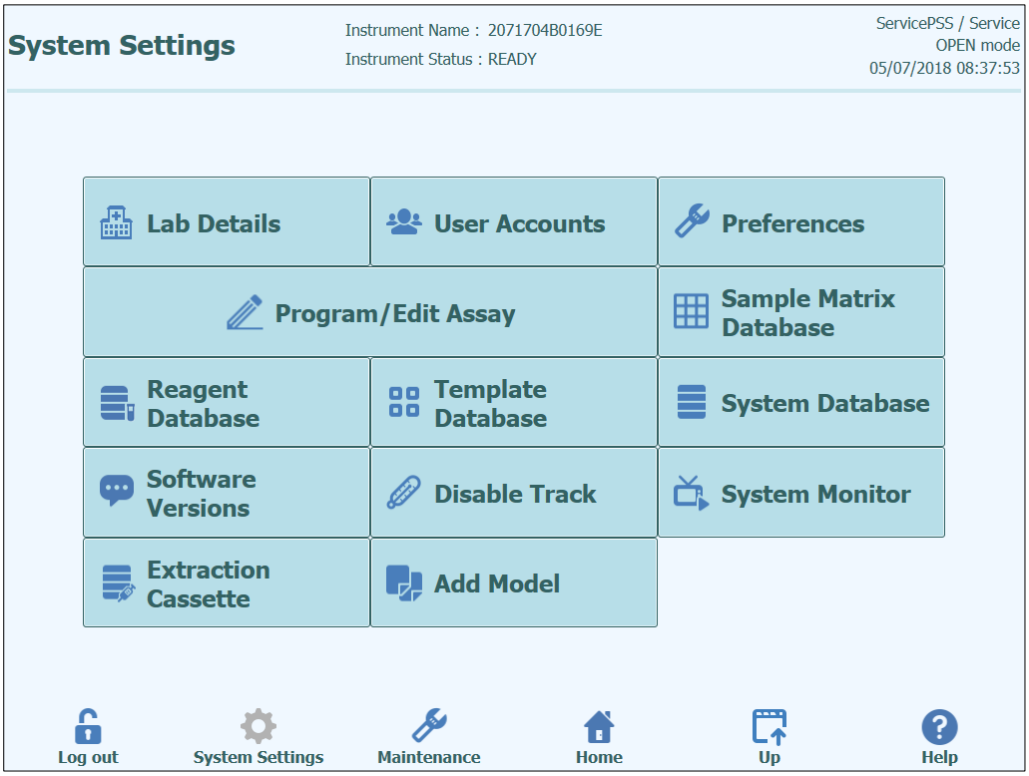


Figure 6-1 : System Settings screen.

6.2 Lab Details

This screen allows you to configure the contact details and logo for your institution or laboratory. These details are included on all printed reports that are generated by the system.

This screen also allows you to define the “Instrument Name” that is shown on the user interface and printed reports.

It is not mandatory to provide the information in this screen. Running of assays and generation of reports are possible even if some or all of the fields in this screen are not completed.

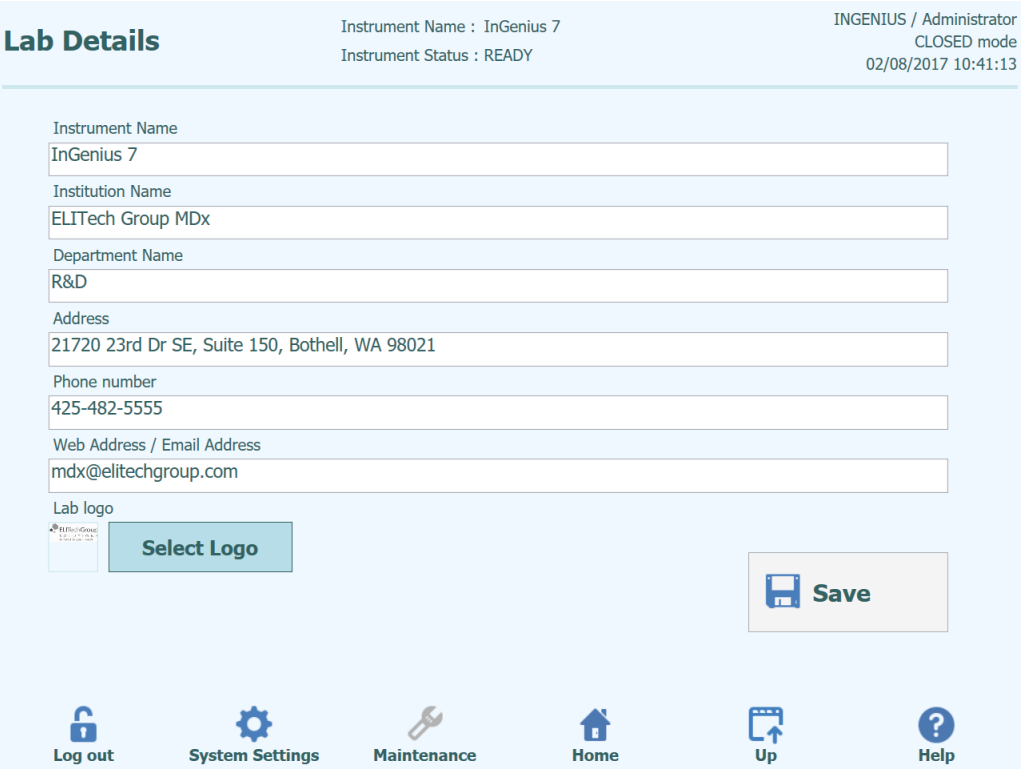


Figure 6-2 : Lab Details screen.

1. Access the “Lab Details” screen by selecting the “Lab Details” button on the System Settings menu.
2. Input your institution information.
3. Touch “Save” button.
4. Information is saved in the system.

6.3 User Accounts

This screen is used to manage the login details for users of the system. On this screen, accounts can be created and deleted or the passwords reset It is also possible to unlock a locked account (e.g. when an incorrect password has been entered repeatedly) and to control the password expiry feature (requires users to change password on a regular basis).

This screen can be accessed by pressing the “User Accounts” button in the System Settings screen.

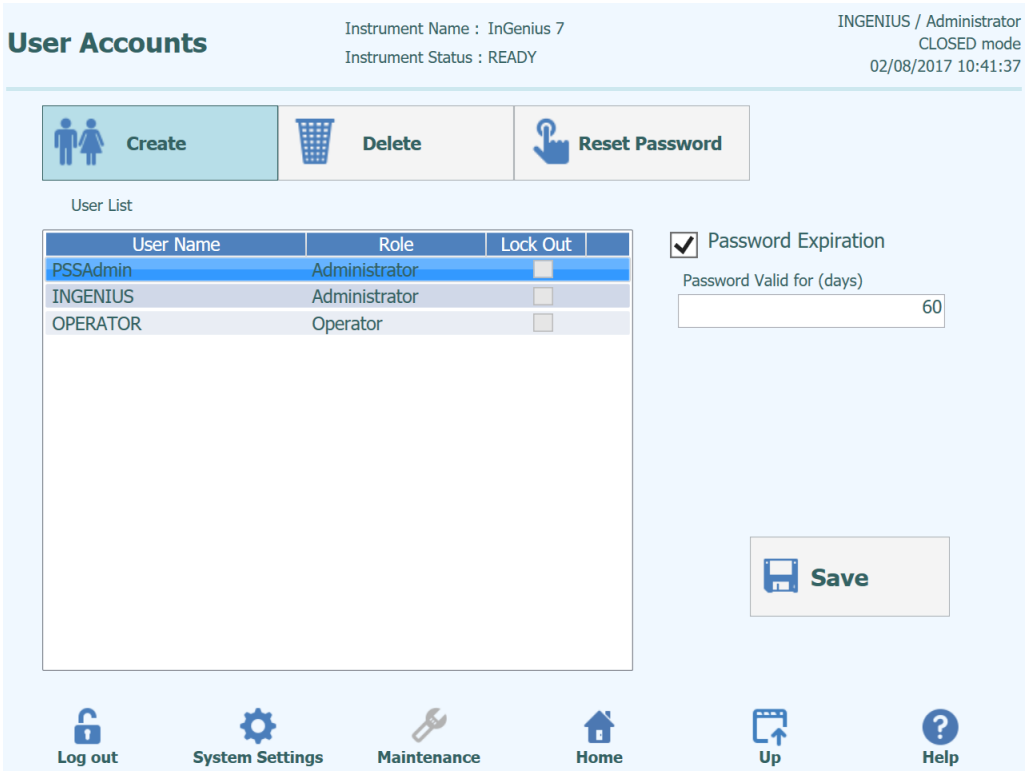


Figure 6-3 : User Account screen.

6.3.1 Creating a new User Account

To create a new User Account:

1. Touch the “Create” button and the following dialog box is displayed:

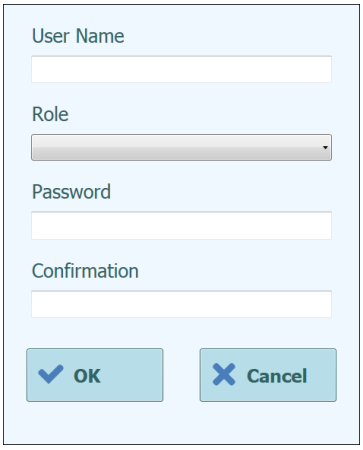


Figure 6-4 : Enter new account details.

1. Enter a User Name for the account (must contain at least 8 characters).
2. Select the Role for the account.
3. Enter a temporary Password for the account (must contain at least 8 characters).
4. Re-enter the temporary Password in the Confirmation box.
5. Touch “OK” button to create the new user account.
6. Check that the added user account is listed in User List and touch “Save” button.

NOTE The Role is used to determine what functionality the user will be able to access on the instrument.

	Operator	Analyst	Administrator
Run assays	●	●	●
Approve assay results		●	●
Approve a run that has assays with expired or missing calibrators or controls			●
Export data from runs			●
Change system settings			●

NOTE When the user logs in to the new account for the first time, they will be asked to change the temporary password that was set when creating the account.

NOTE User IDs and passwords are case-sensitive.

6.3.2 Changing Password

On first login to a newly created user account, or if your password has been reset by an Administrator or Service user, the system will prompt for the temporary password to be changed to a new password.

After the first login has been completed, Users may also change their passwords on-demand by clicking on the “Change Password” button on the login screen.

Administrator or Service users may reset the password for any user from the User Account Screen (see section 6.3~~6.3~~).

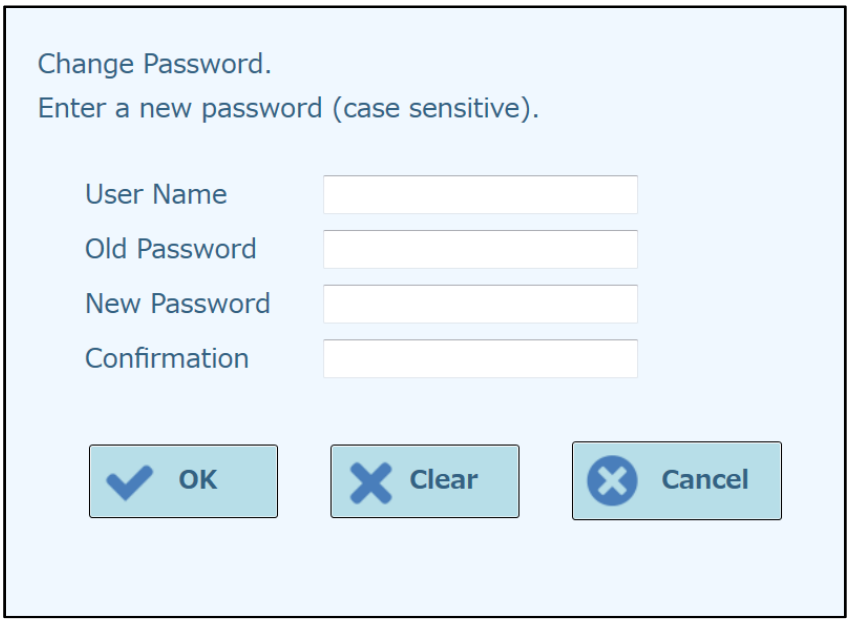


Figure 6-5 : Change Password dialog box.

Changing the password for a user account is achieved by providing the following information:

1. Input User Name.
2. Input Old Password.
3. Input New Password.
4. Confirm New Password in the Confirmation box.

Press “OK” button.

NOTE Access to account information should be controlled according to your laboratory security policy.

6.4 Preferences

The Preferences Screen is used to configure a number of different configuration settings for the software.

This screen can be accessed by pressing the “Preferences” button in the System Settings screen.

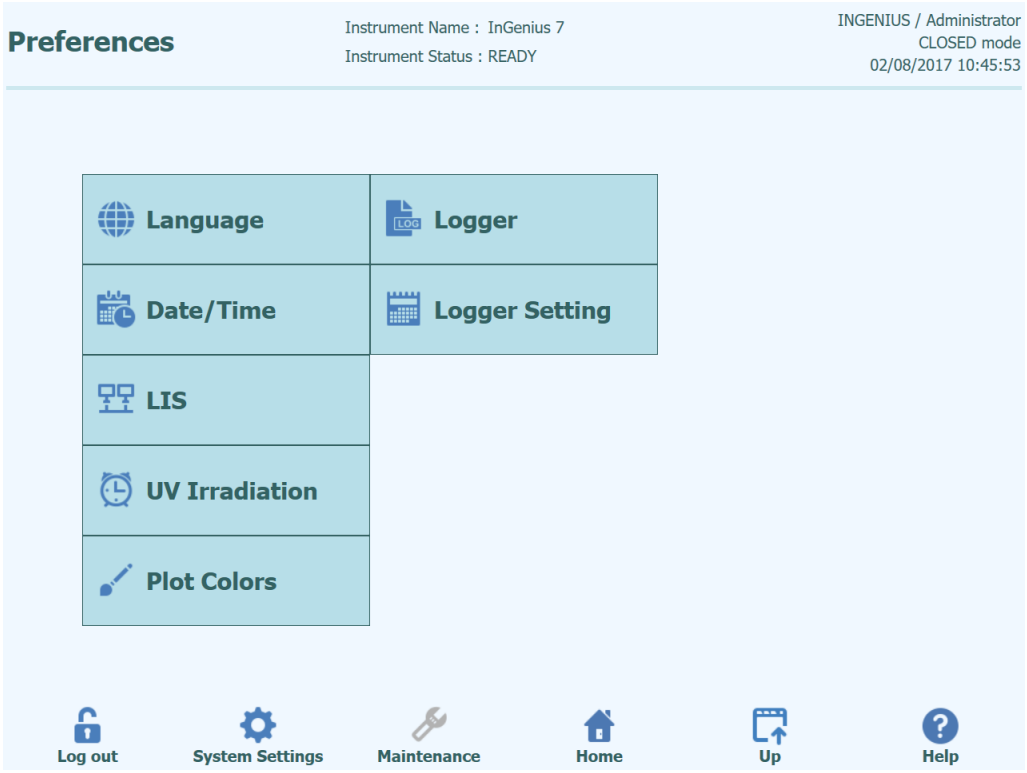


Figure 6-6 : Preferences Screen.

6.4.1 Language

This screen is used to select the language for the user interface and report generator.

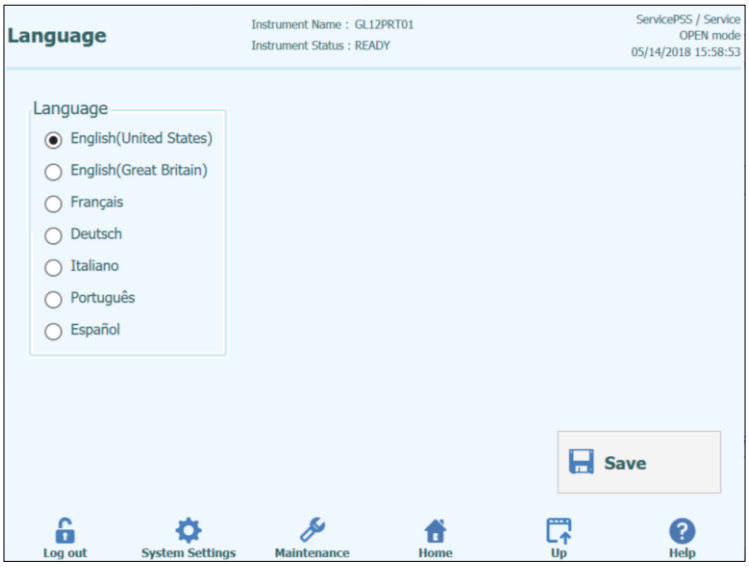


Figure 6-7 : Language Settings

6.4.2 Date/Time

This screen is used to set the system date and time.

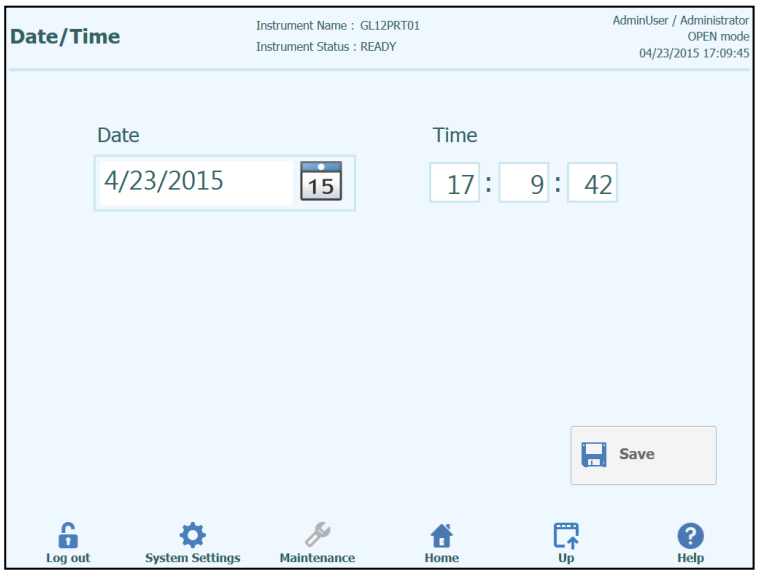


Figure 6-8 : Date and Time Settings

6.4.3 LIS

This screen is used to configure the preferences for the LIS interface.

Please consult your LIS Administrator for details on what settings are necessary for your LIS installation.

Use the tick boxes to enable the

- LIS Query during assay setup
- Upload of Approved test results to LIS

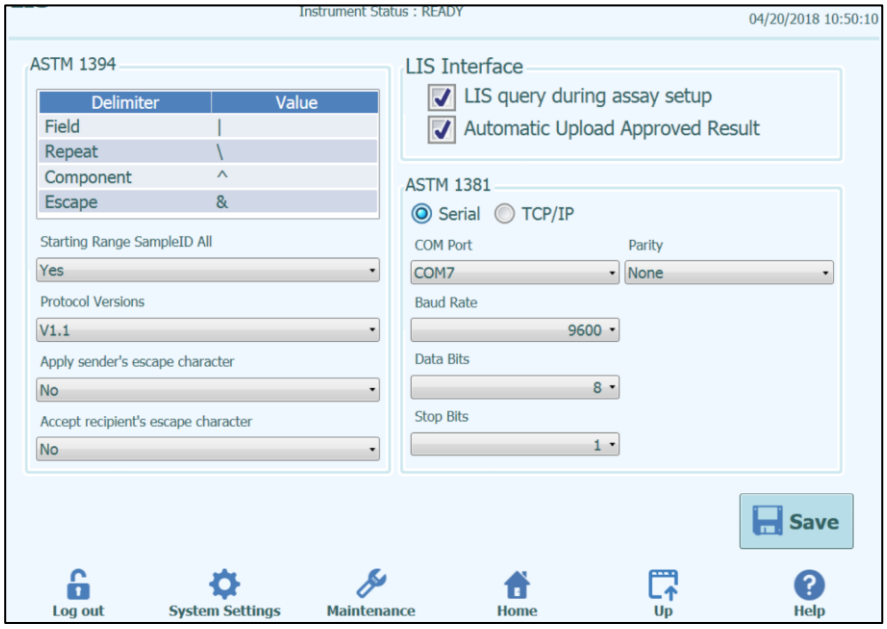


Figure 6-9 : LIS Configuration Settings

This screen can also be used to configure the followings options for ASTM 1394:

- Starting Range SempleID All:
  Yes = Enable Query ALL to LIS system (ELITe InGenius System will receive all the samples that are possible analyse).
  No = Enable Query for SID to LIS system (ELITe InGenius System will send a query message to the LIS only for the SIDs typed).

- Protocol Versions:
  V1.0 = not used
  V1.0.1 = protocol LIS that guarantees back compatibility with previous software version: ELITe InGenius System SW 1.2 (for detail see LIS specification)
  V1.1 = new protocol LIS (for detail see LIS specification)

- Apply sender's escape character and Accept recipient's escape character:
  Yes = ELITe InGenius System and LIS can manage special character normally used by ASTM protocol, like: ^, &, \, |.
  No = Escape character are not managed

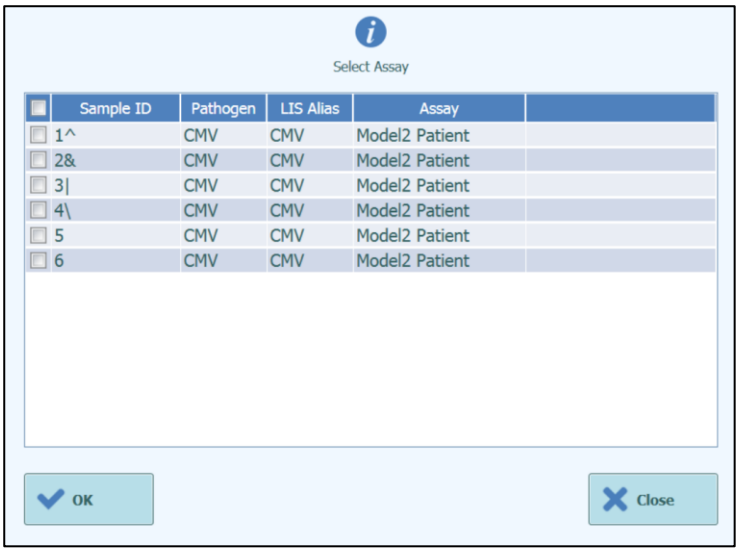


Figure 6-10 : Apply sender's escape character and Accept recipient's escape character

- Option for ASTM 1381 (ways for physical connection):
  Serial: set the correct serial parameters for communication (COM port, Parity, Baud Rate, Data Bits, Stop Bits). Port settings must to match the requirements of the LIS.
  TCP/IP: LAN Connection, PC LIS must have a static IP Address. ELITe InGenius System works always in client mode on a specific destination port. The destination port number and the IP LIS PC can be defined in field Destination IP Address and Destination Port Number [0 – 65535].

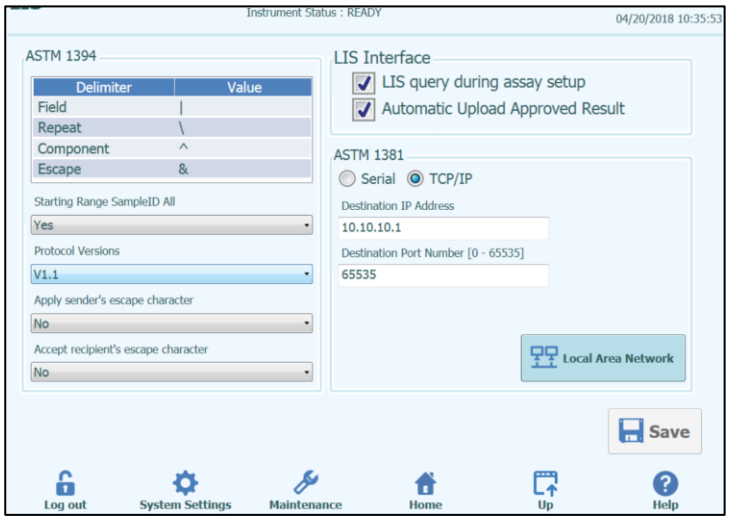


Figure 6-11 : TCP/IP configuration

6.4.4 UV Irradiation

This screen is used to configure the duration of the UV sterilisation that is run as part of the End-Of-Day shutdown process.

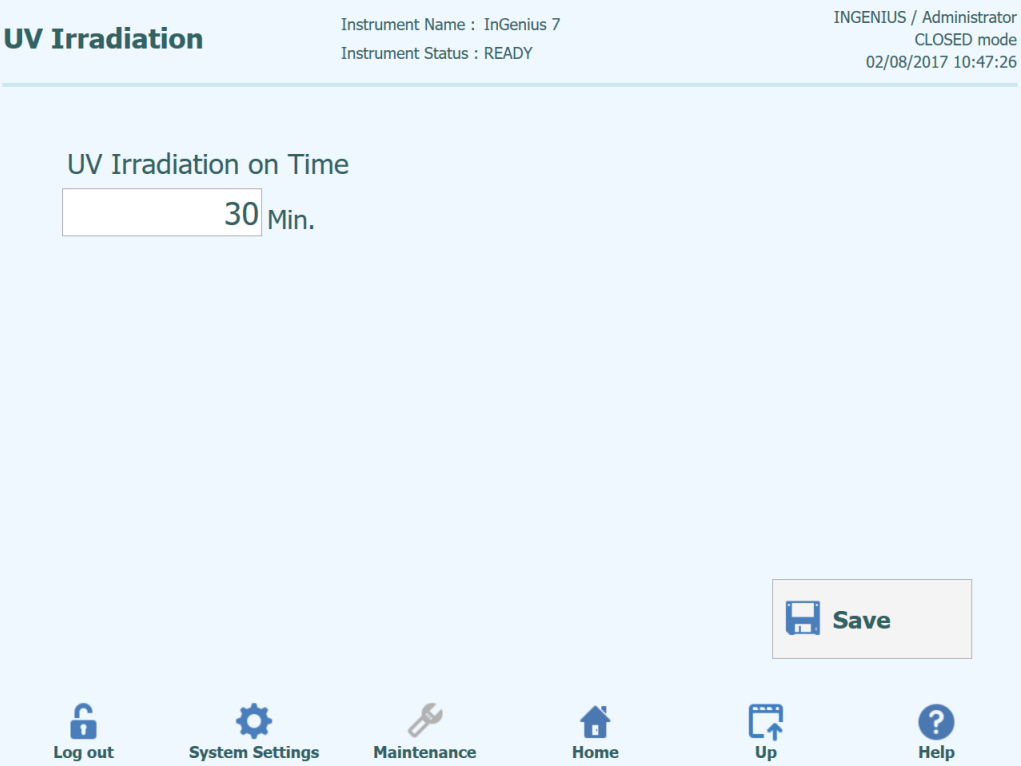


Figure 6-10 : UV Irradiation Configuration Settings

6.4.5 Plot Colours

This screen is used to configure the line styles for the PCR Amplification and Melt Analysis plots.

The software supports up to 12 different line styles (for a maximum of 12 tracks or 6 channels).

The RESET button can be used to reset the plot styles to their default settings.

Figure 6-11 : Plot Color Settings

6.4.6 Logger Setting

This screen is used to configure the logging function of the ELITe InGenius System.

The settings in this screen allow you to configure the policy used for managing the various log files that are generated as the system is used.

If Auto-delete is enabled, log files are deleted from the system after the number of days specified by the Auto Delete Period.

If Auto-delete is disabled, log files remain on the system indefinitely.

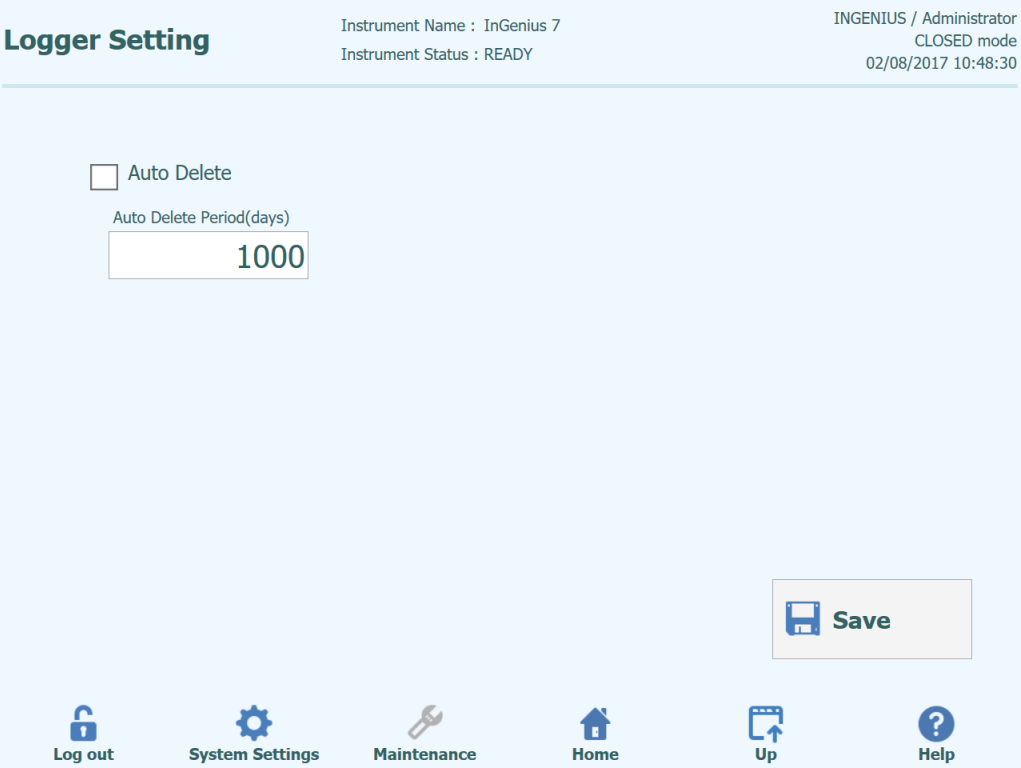


Figure 6-12 : Logger Settings

6.4.7 Logger

This screen is used to view the various log files that are generated by the ELITe InGenius System.

Log files are segregated according to the following functional areas:

- System
- Debug
- Fisics
- Operation
- Astm

The “Log” pulldown list allows switching of the display between the different types of log.

Separate log files are created for each day. The “Date” picker allows the switching between historical logs.

Press the “Delete” button to clear the log that is currently displayed.

Copies of the logs may be requested by your service partner partner for troubleshooting.

Press the “Export Log” button to Export the Log data to an external file suitable for sharing with your service partner.

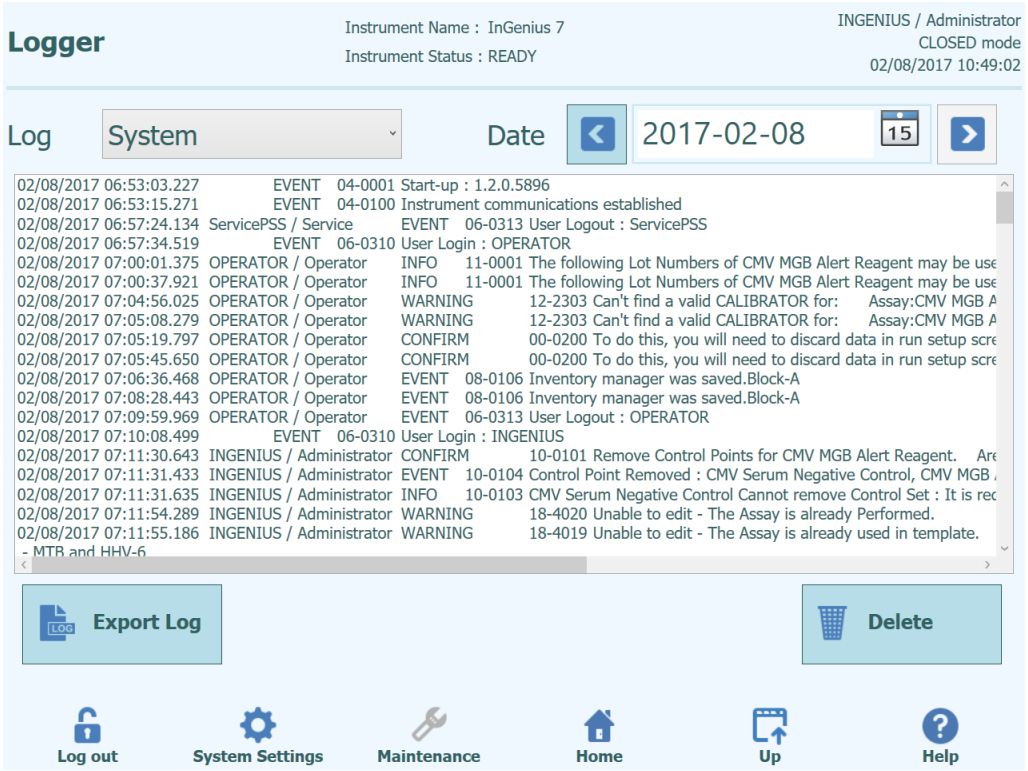
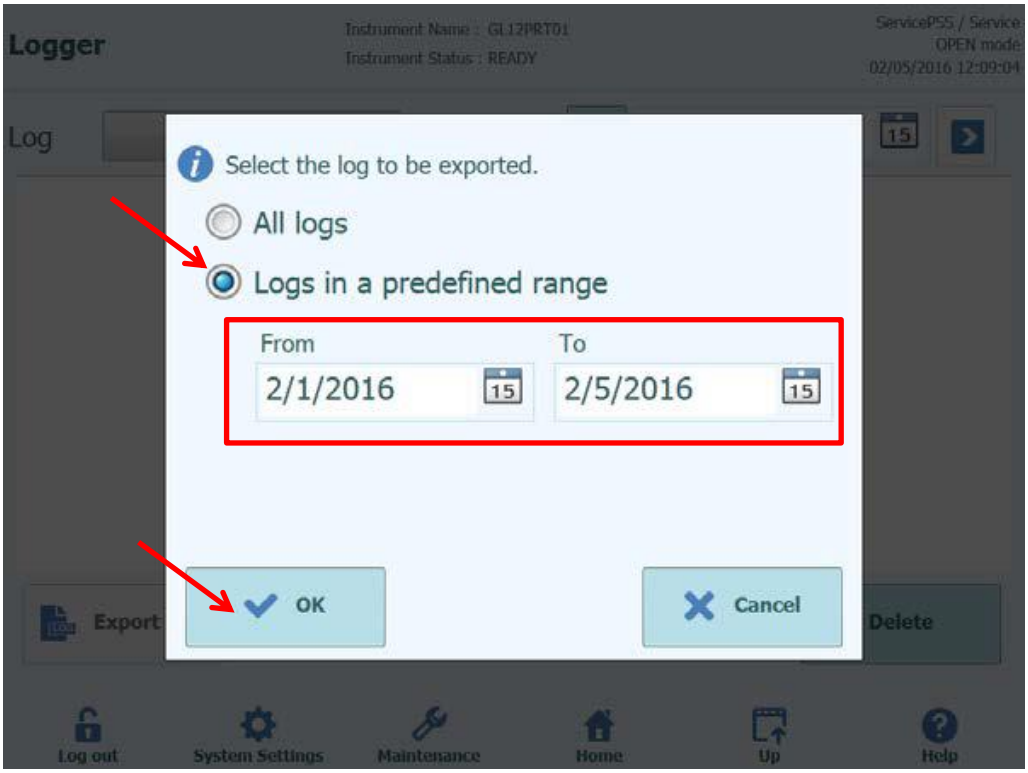


Figure 6-13 : Logger Screen

In details, from the “Logger” screen, select “Export Log”. Then, in the “Select the log to be exported” window choose the option for “Logs in a predefined range” and choose the appropriate date range in the “From” and “To” boxes.
Afterwards, press the OK button and in the folder menu select the USB flash drive you inserted as the location to save the data.
Press again the OK button and then you will see a “Log Successfully exported” message when the download is complete.
After pressing the last OK, remove the USB flash drive from the instrument. In this way, Log files will be in a compressed (zip) format and will have a date code as the file name as follows: ExportLog_yyyymmdd_hhmmss.zip. There is no need to extract the file before sending to ELITechGroup Technical Support for review.



6.5 Loading Assay Programs

Assay Programs are loaded onto the system through the “Program Assay” screen.

This screen can be accessed by pressing the “Program Assay” button in the System Settings screen.

Assay Information can then be loaded onto the system from a USB memory stick (“Flash Drive”).

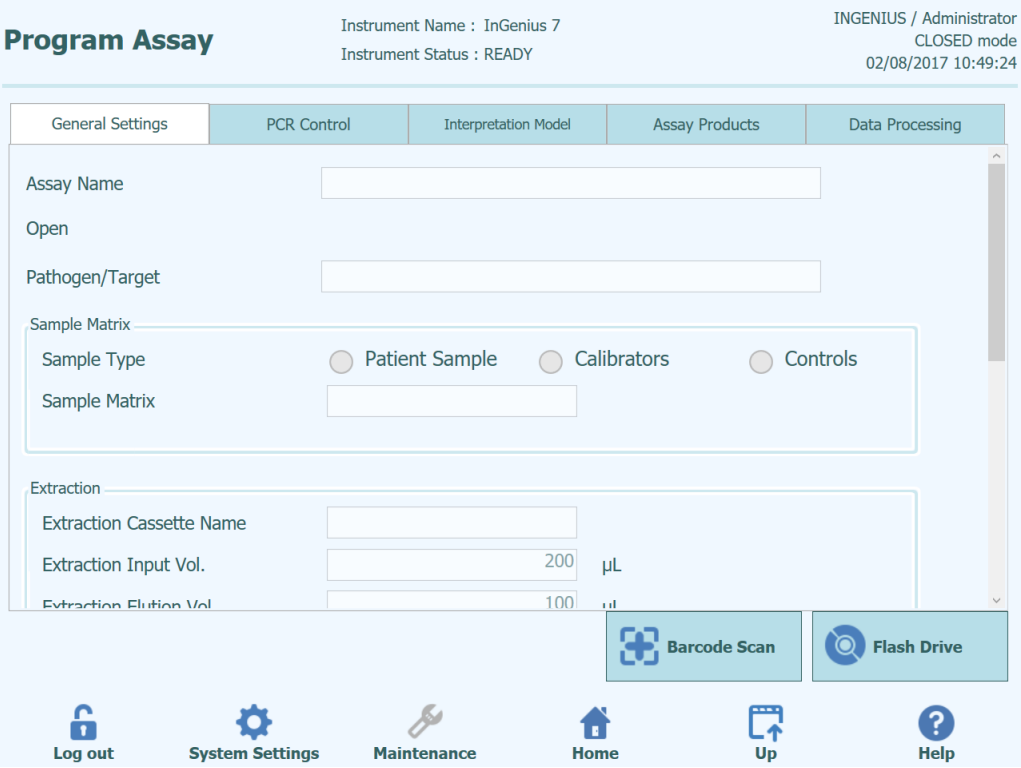


Figure 6-14 : Program assay screen.

6.5.1 Loading from Flash Drive

NOTE An external USB memory stick needs to be connected to the InGenius system via the USB connector to use this function.

WARNING

It is recommended to scan USB memory sticks for viruses using third-party anti-virus software prior to attaching them to the InGenius System.

1. Insert a USB memory stick containing the Assay protocol files into the USB port of the ELITe InGenius System.
2. Touch the "Flash Drive" button.
3. Navigate to the Assay protocol file on the USB memory stick using the on-screen dialog.
4. Touch the “OK” button to load the selected Assay protocol file.
5. Once the information has been read from the USB memory stick, the Assay Information is displayed on the screen.

NOTE As well as loading the Assay program itself, the system will also attempt to load any additional configuration data it needs to run the assay such as settings for Calibrators, Controls, Reagents, Sample Matrix etc. These additional settings will only be loaded if they are not already registered in the ELITe InGenius system.

6.6 Viewing and Deleting Assay protocols

Viewing and deleting IVD assay protocols is accomplished via the Edit Assay screen.

The “Edit Assay” screen is used to:

- View Assay protocols
- Remove unused Assay protocols from the system

This screen can be accessed by touching the “Edit Assay” button in the System Settings screen.

NOTE IVD Assay protocols are read-only on the ELITe InGenius system; no changes are possible without loss of IVD status for the modified assay.

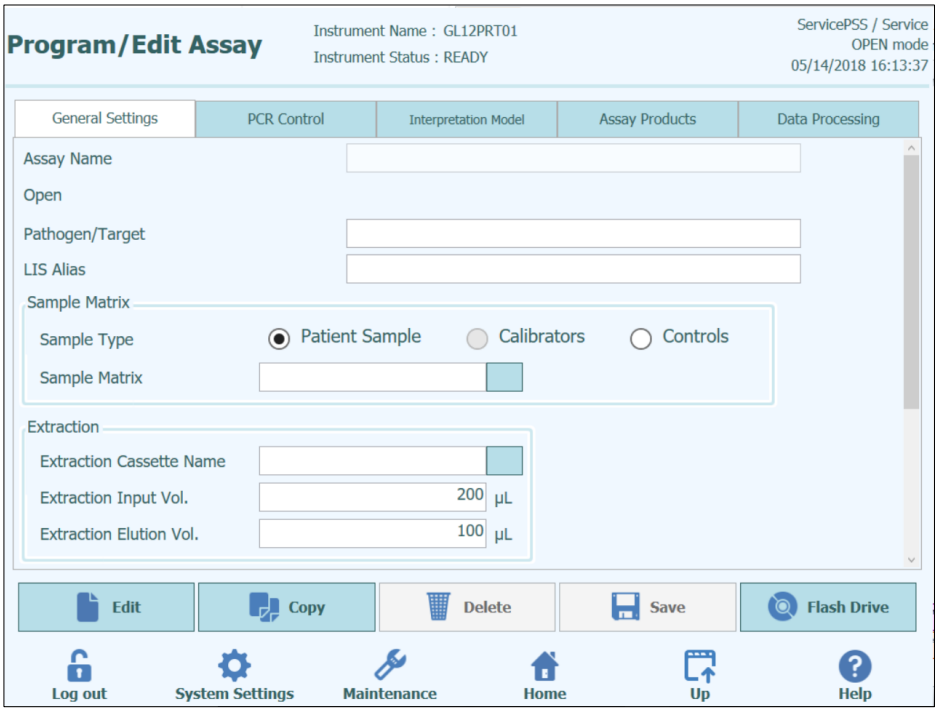


Figure 6-15 : Edit Assay Screen.

6.6.1 View an Assay protocol

IVD Assay protocols are read-only on the ELITe InGenius system, but the Edit function can be used to view the assay parameters. Press the “Edit” button and then select the assay that you wish to view from the list presented.

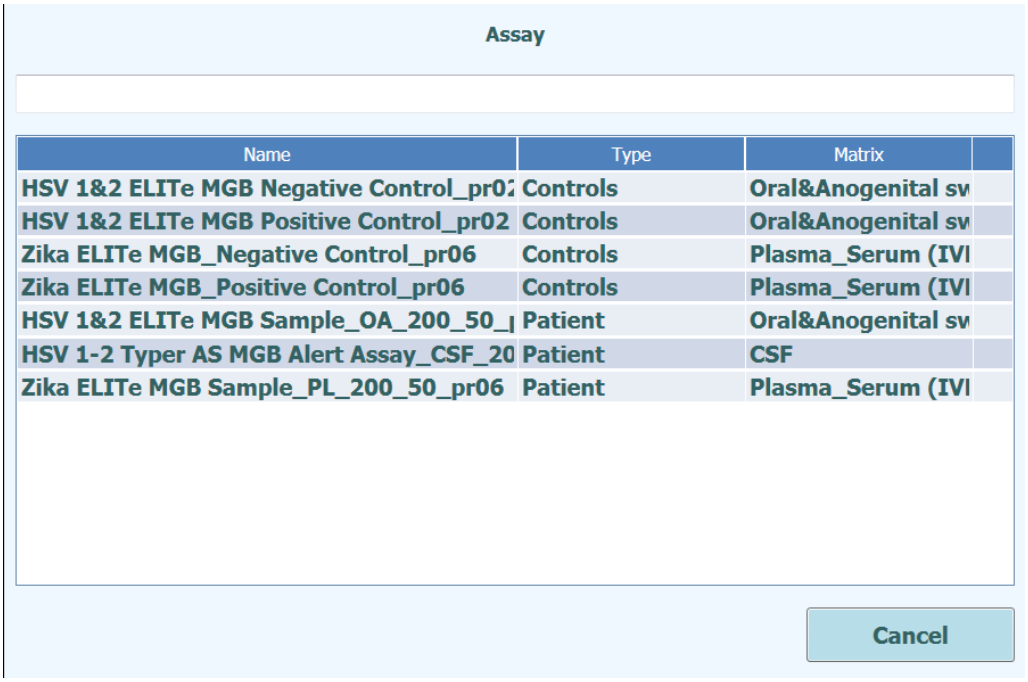


Figure 6-16 : Assay selection list

When an Assay protocol is selected, its parameters will be displayed as detailed in section 6.7.

6.6.2 Delete an Assay Program

To delete an existing Assay protocol, touch the “Edit” button and select the assay that you wish to delete from the list presented.

You can then delete the Assay protocol by touching the “Delete” Button.

6.7 Assay Parameters and Interpretation Models

The Edit Assay screen has several tabs that contain the settings (Assay Parameters) loaded into the system as described in section **Errore. L'origine riferimento non è stata trovata.**~~6.5~~ and used by the ELITe InGenius system to control run execution as well as results interpretation once the run has completed.

Assays Parameters that are available through the tabs on the Edit Assay Screen for IVD assays intended for viewing purposes only. Any editing and saving will result in loss of IVD status for the modified assay.

6.7.1 Edit Assay: General Settings Tab

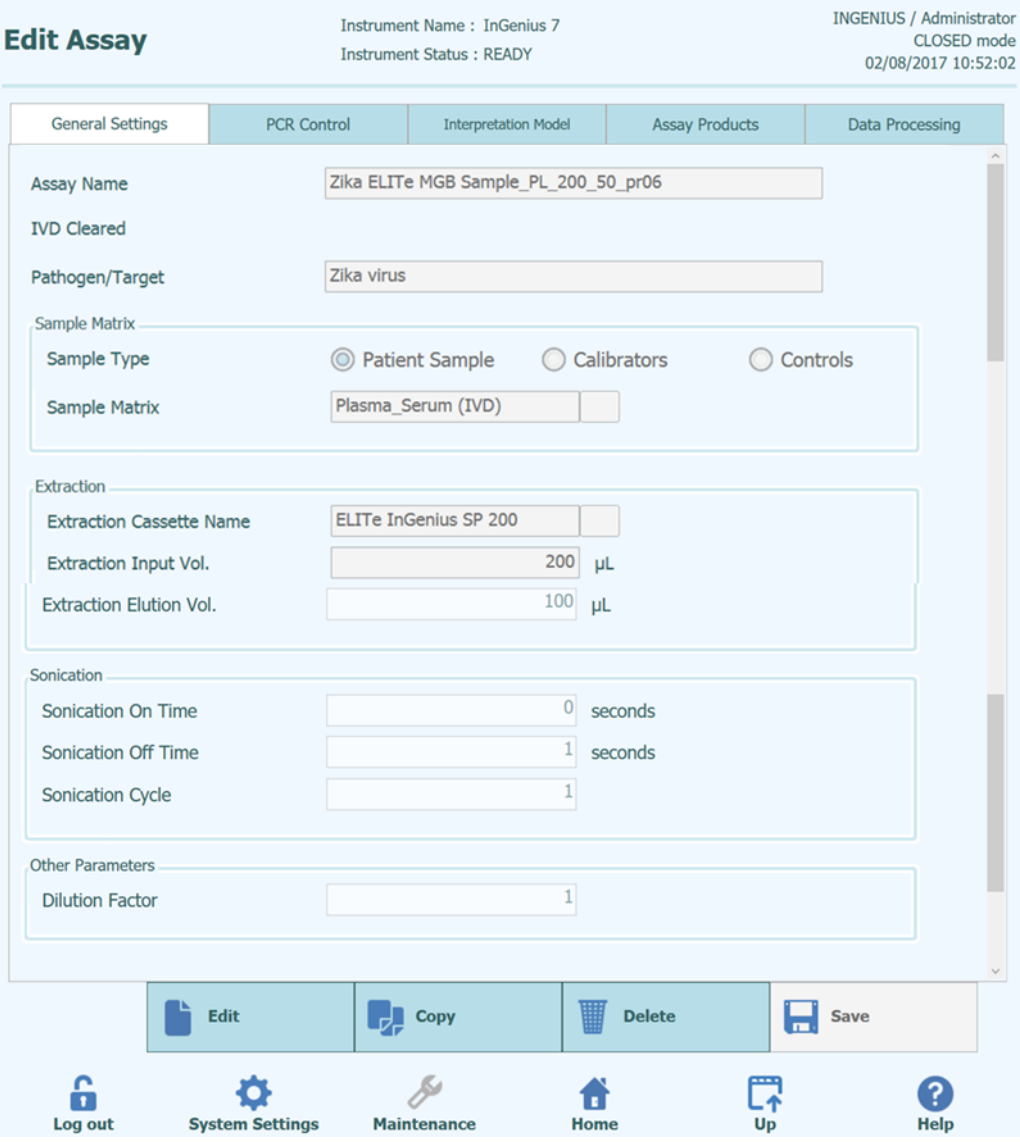


Figure 6-17 : Edit Assay General Settings Tab

The General Setting Tab allows viewing the following parameters for a specified IVD assay:

- Assay Name
  This is the unique name that is used in the Perform Run Screen to select the assay.

- Pathogen/Target
  This field is used to group several assays together. For example, several assay protocols may exist for a common target, each with a different Sample Matrix (e.g., serum, plasma).

- Sample Type
  This field defines whether the Assay protocol is for a sample, calibrators, or controls.

- Sample Matrix
  This field defines which Sample matrix is used for the Assay. Sample Matrices are linked to the Sample Matrix Database (see section 6.8).

- Extraction Cassette Name
  This field defines which Extraction Cassette is used for the assay.

- Extraction Input Vol.
  This field shows the input volume expected by the Extraction Cassette specified in the previous field.

- Extraction Elution Vol.
  This field specifies the Eluate volume produced by the extraction process.

- Sonication Off Time / On Time / Cycle
  These three fields define the sonication parameters. Sonication On Time is zero for no sonication.

- Dilution Factor
  This specifies the sample dilution factor used for quantitative

6.7.2 Edit Assay: PCR Control Tab

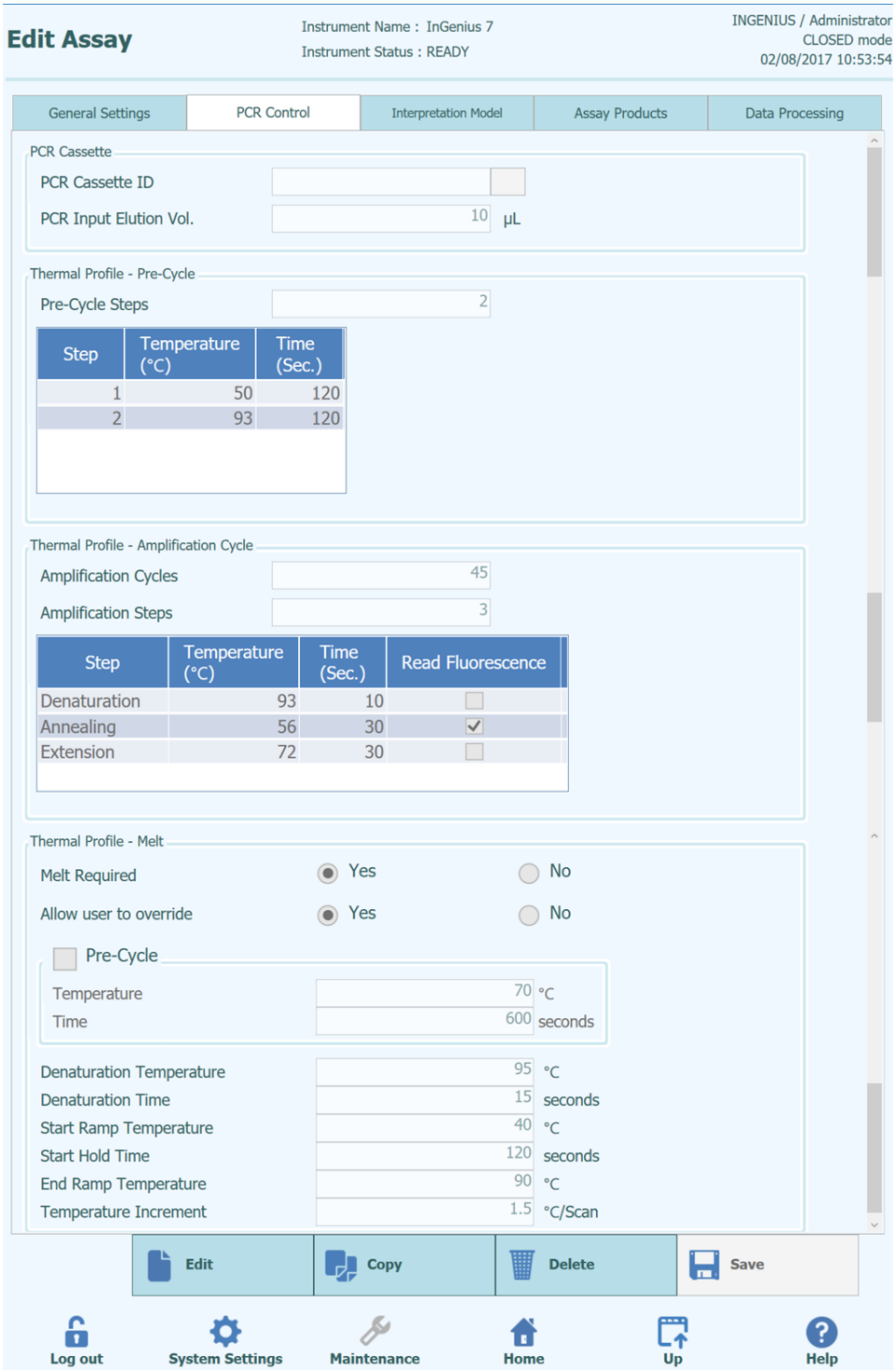


Figure 6-18: Edit Assay PCR Control Tab

The PCR Control Tab allows viewing PCR parameters in a specified IVD assay:

- PCR Cassette ID
  Inactive field.
- PCR Input Elution Vol.
  This field specifies the volume of eluate, calibrator, or control used for setting up a PCR.

The following fields specify the characteristics for the PCR thermal profile. Pre-Cycle conditions are conducted once, then the specified number of repeated PCR cycles, and finally a Melt temperature ramp; Melt may be optional or required, depending on the Interpretation Model.

- Thermal Profile – Pre-Cycle
- Thermal Profile – Amplification Cycle
- Thermal Profile – Melt

6.7.3 Edit Assay: Interpretation Model Tab

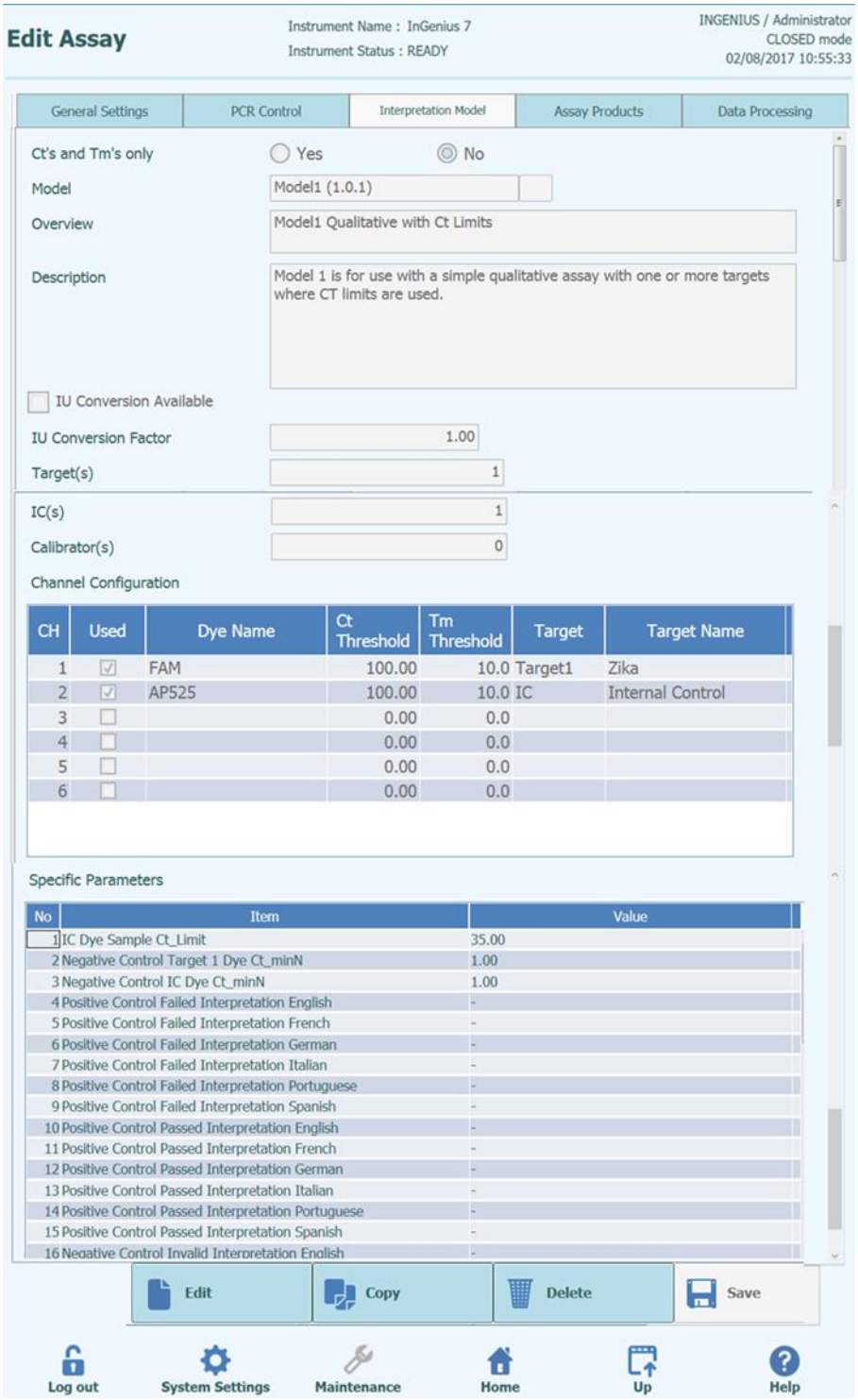


Figure 6-19 : Edit Assay Interpretation Model Tab

The Assay Interpretation Tab allows viewing the following parameters in a specified IVD assay:

- Ct's and Tm's Only
  Assays that only generate C_ts and T_ms without results interpretation.

- Model
  This specifies which result interpretation model is used for generating results. Interpretation logic for each model is available from Customer Support on request.

- Version/Description
  These fields provide further information about the selected interpretation model.

- Target(s)
  This field specifies how many targets are detected within a multiplexed Assay. Since the ELITe InGenius system provides detection of up to six wavelengths, it is capable of supporting assays with up to five multiplexed targets plus an Internal Control.

- IC(s)
  This setting is determined by the selected interpretation model.

- Channel Configuration
  - Used
  - Dye Name
  - C_t Threshold
  - T_m Threshold
  - Target
  - Target Name

  These settings define which optical channels are used by the Assay, and how these are mapped to the different targets and internal controls used by the interpretation models. This links the target specific settings (C_t limits, etc) in the models to the specific channels used by the assay.

- Specific Parameters
  For each interpretation model, there are several settings used by the model to process results of calibrators, controls, and samples. The text results at the end of a run are specified. Further details about these settings can be provided by Customer Support.

6.7.4 Edit Assay: Assay Products Tab

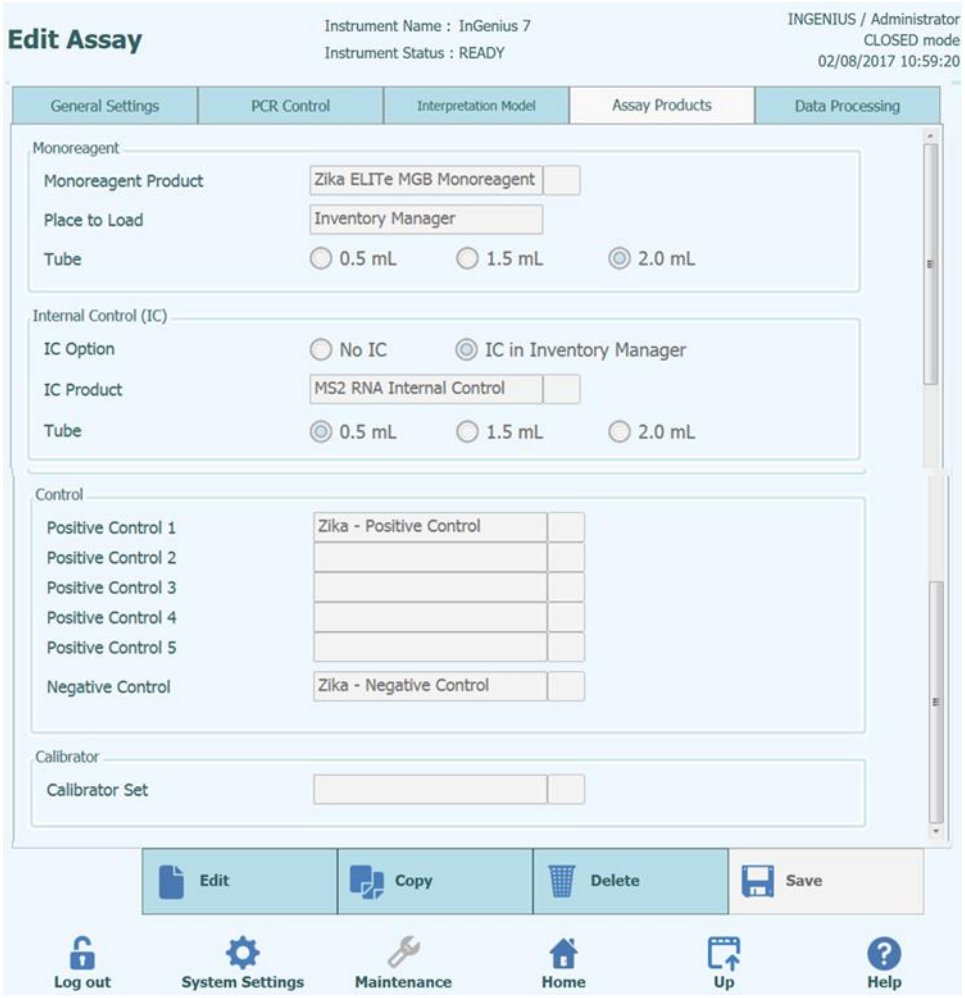


Figure 6-20: Edit Assay Assay Products Tab

The Assay Product Tab allows viewing the following information for a specified IVD assay:

- Monoreagent
  This specifies the Monoreagent and its tube size.

- IC
  This specifies the Internal Control and its tube size.

- Control
  Specifies the control sets used to monitor the process quality for the Assay.

- Calibrator
  Specifies the calibrator sets used to generate the standard curves for a quantitative Assay.

NOTE NO Calibration functionalities are described in this document since NO quantitative IVD assays have been validated on the ELITe InGenius instrument

6.7.5 Edit Assay: Data Processing Tab

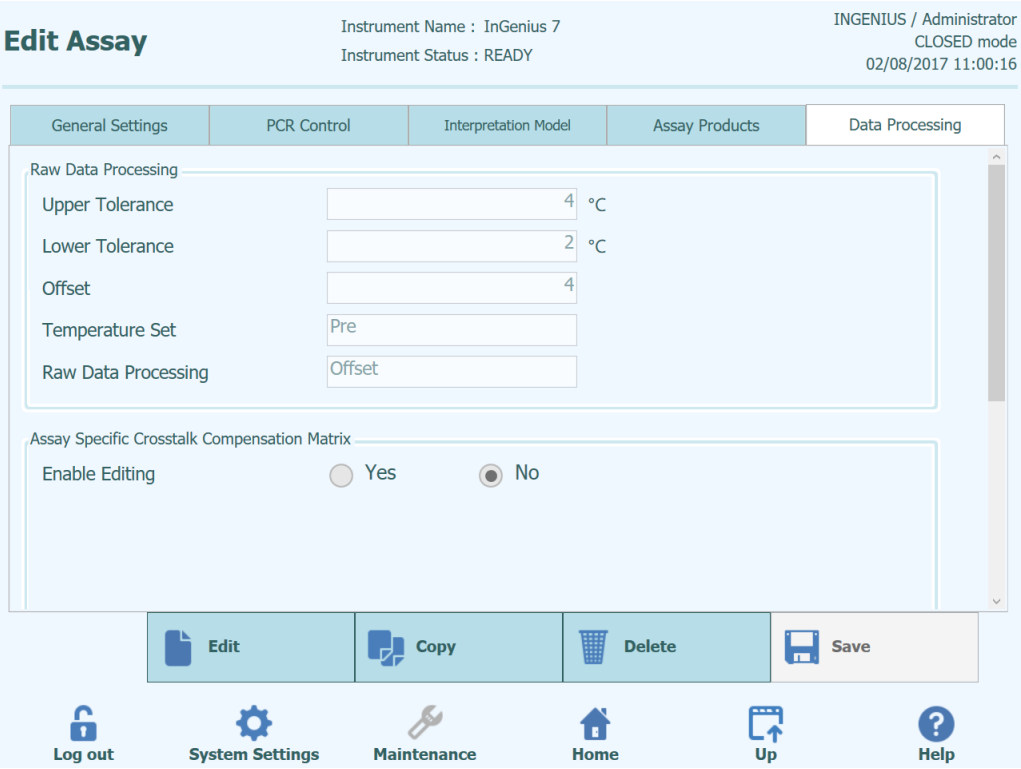


Figure 6-21: Edit Assay Data Processing Tab

The Data Processing Tab allows viewing the settings that are used in a specified IVD assay to process raw fluorescence data from the instrument. Further details can be obtained by contacting Customer Support.

6.8 Sample Matrix Database

The Sample Matrix Database contains details for the Sample Matrices loaded on the ELITe InGenius system.

An Administrator or Service user can add or remove entries in the Sample Matrix database.

This screen can be accessed by touching the “Sample Matrix Database” button in the System Settings screen.

Sample Matrix settings can be loaded onto the system using either:

- Barcode Scanner
- USB Flash Drive

The Delete button is used to delete a Sample Matrix. A Sample Matrix may not be deleted if an Assay protocol uses it. A warning will be given by the software if you try to delete a Sample Matrix that is still in use by the system.

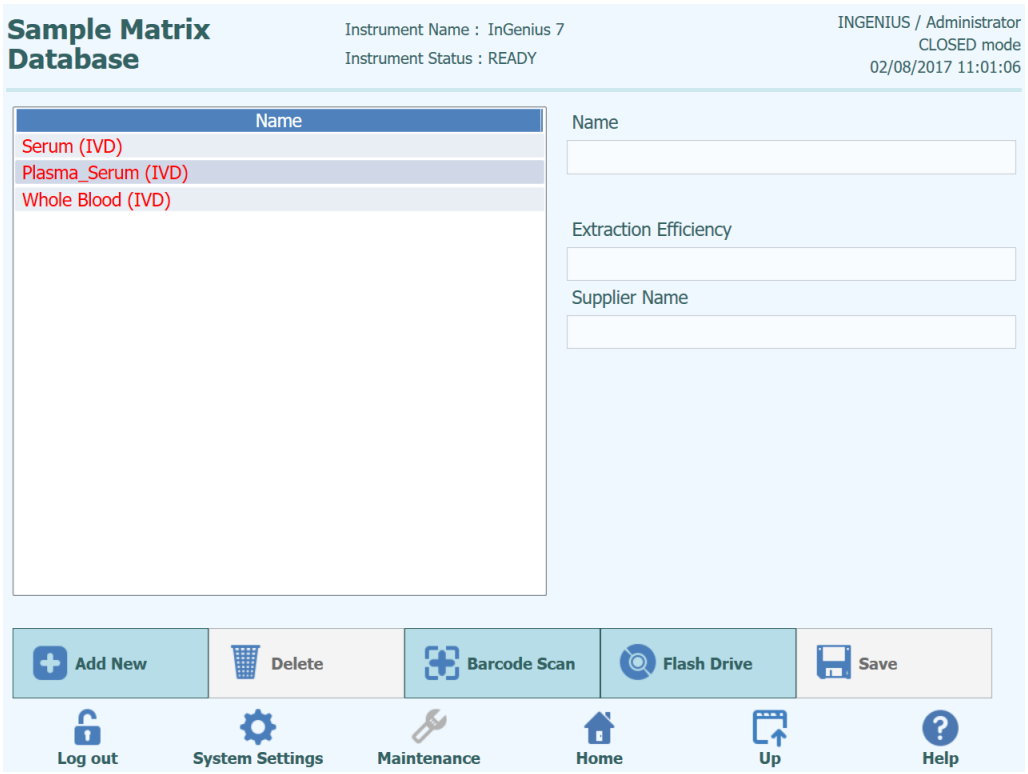


Figure 6-22: Sample Matrix Database screen

6.9 Reagent Database

The Reagent Database contains details for PCR monoreagents and Internal Controls loaded on the ELITe InGenius system.

The Administrator or Service user can add or remove entries in the Reagent database.

This screen can be accessed by touching the “Reagent Database” button in the System Settings screen.

Reagent settings can be loaded onto the system using any of the following:

- Barcode Scanner
- USB Flash Drive

The Delete button is used to delete a reagent. A Reagent may not be deleted if an Assay protocol uses it. A warning will be given by the software if you try to delete a Reagent that is still in use by the system.

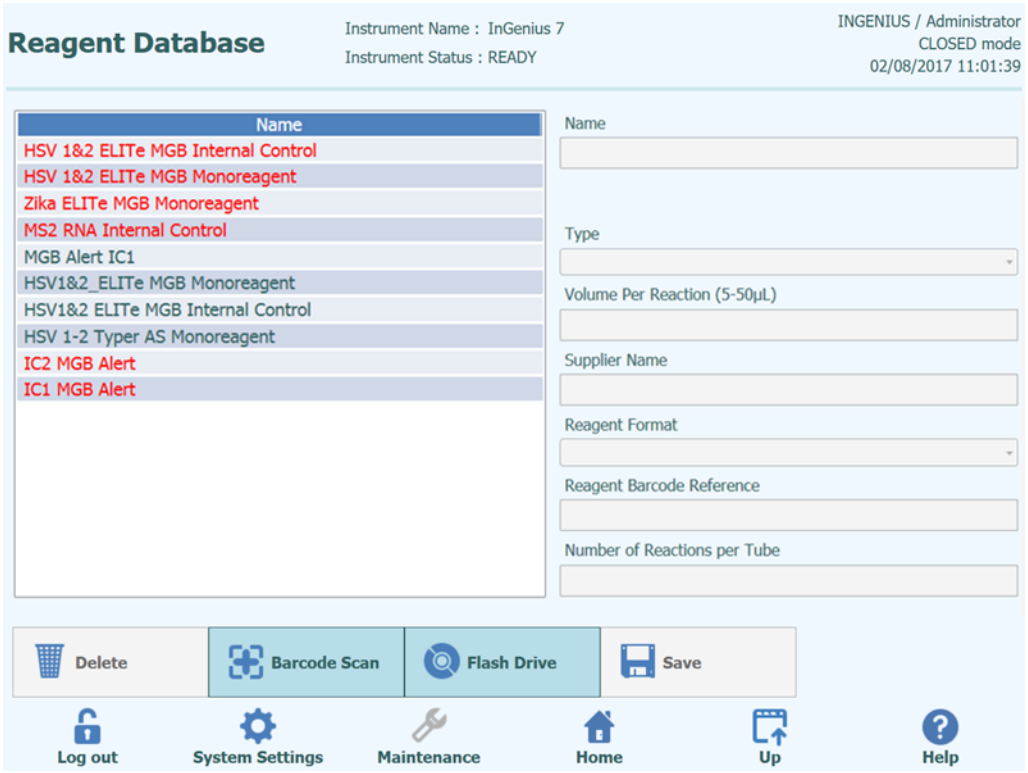


Figure 6-23: Reagent Database screen (Red text indicates a reagent intended for IVD use).

6.10 Templates Database

This screen is used to manage the database of Templates that are created and used in the Run Setup Screen (see sections 5.4.2.4 and 5.4.2.5).

This screen can be accessed by pressing the “Templates Database” button in the System Settings screen.

The Administrator or Service user can view or remove entries in the Templates database.

You can view the Assay details for each Template and also delete Template definitions from the database should this be necessary.

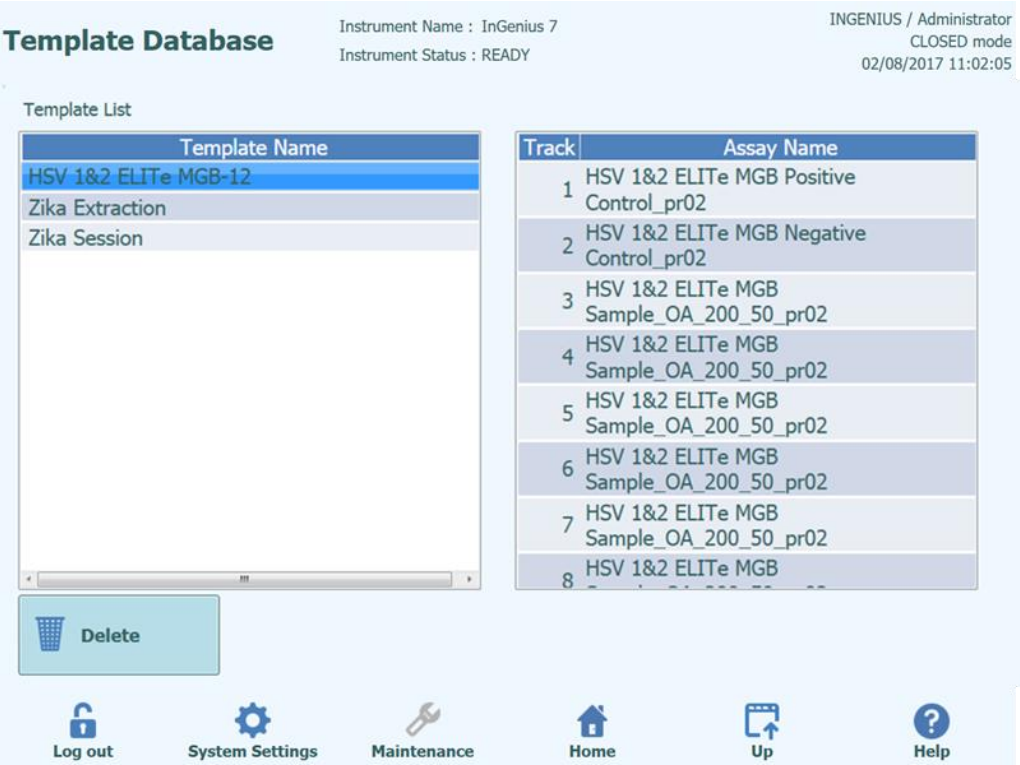


Figure 6-24: Templates Database screen.

6.11 System Database Management

This screen is used to manage the main system database.

This screen can be accessed by pressing the “System Database” button in the System Settings screen.

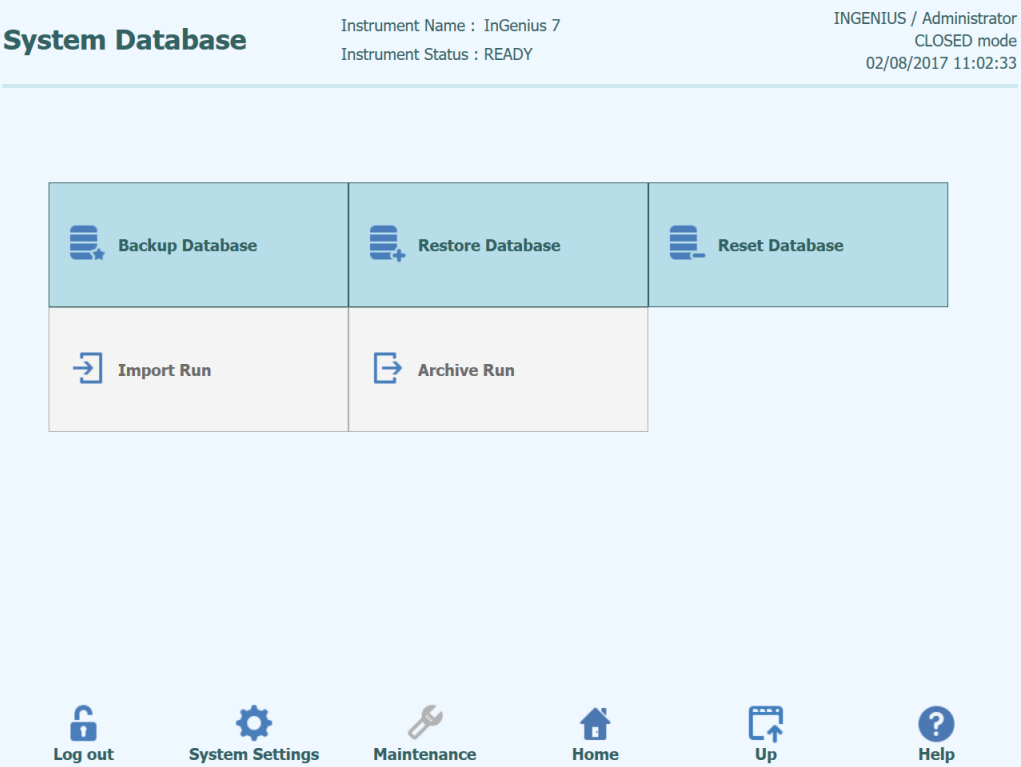


Figure 6-25: System Database Screen.

Functions accessed from this screen are

- Backup Database
- Restore Database
- Reset Database

WARNING

These operations operate on ALL data stored in the system database, so extreme care must be taken to avoid loss of important data.

- Test Results
- Assay Programs
- Reagent Registration
- Calibrator Registrations
- Control Registrations
- Calibration Curves
- Control Plots
- User Accounts
- All system preference settings
- Etc

6.11.1 Backup Database

Selecting the “Backup Database” button will show a dialogue where the destination folder and name should be entered (e.g. external FLASH drive)

Press “Ok” to backup the database to the chosen location.

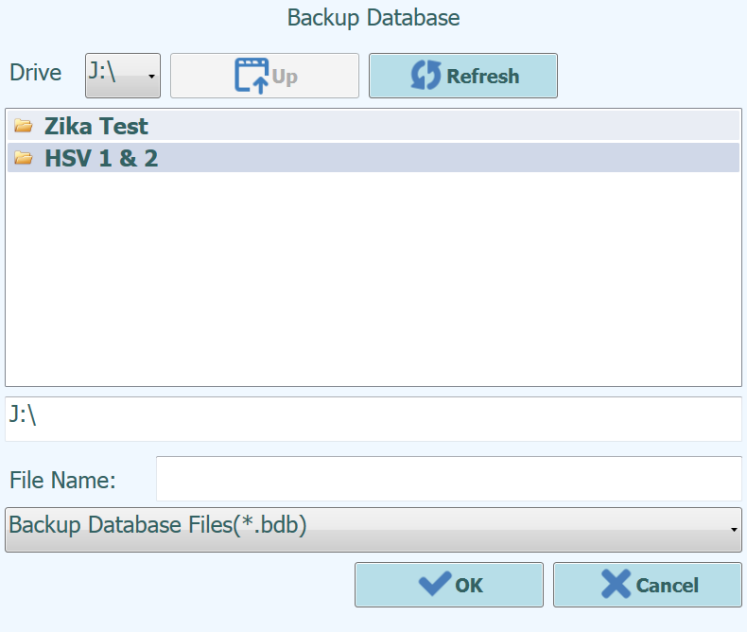


Figure 6-26: Backup Database Destination Selection

6.11.2 Restore Database

Selecting the “Restore Database” button will show a dialogue where the source folder and name should be entered (e.g. external FLASH drive)

Press “Ok” to restore the database from the chosen location.

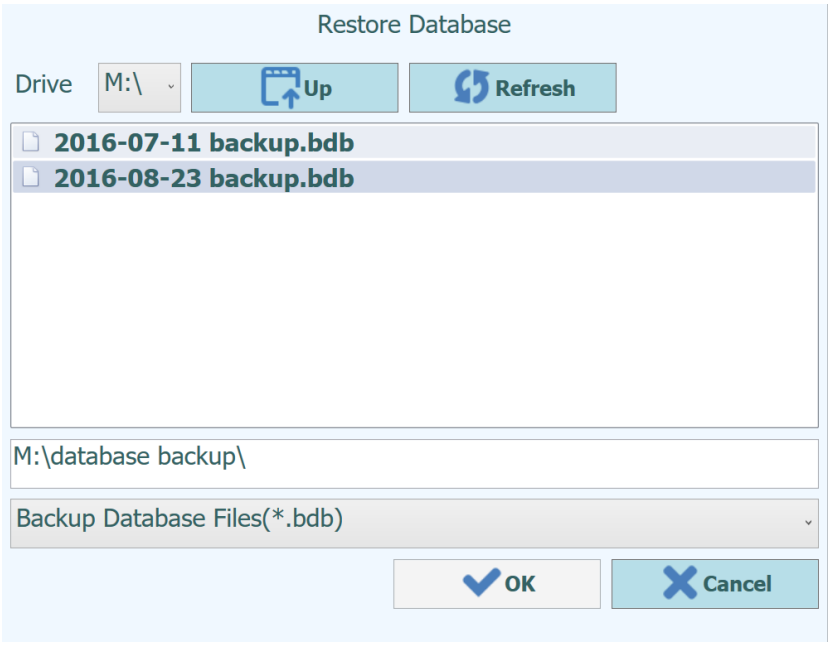


Figure 6-27: Restore Database Source Selection

WARNING

This operation will overwrite all data and settings in the system database, so use extreme caution when using this function

6.11.3 Reset Database

Selecting the “Reset Database” button will show a confirmation box to check you really wish to proceed with this operation.

Press “Ok” to reset the system database.

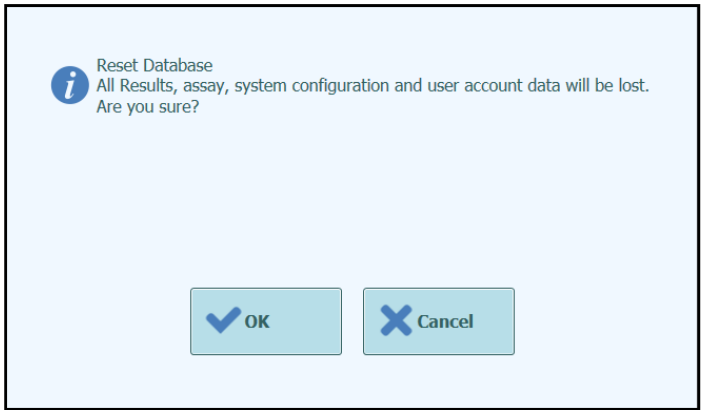


Figure 6-28: Reset Database Confirmation

WARNING

This operation will clear all data and settings in the system database, so use extreme caution when using this function

6.11.4 Import Run

This function is not supported in this release of software.

6.11.5 Archive Run

This function is not supported in this release of software.

6.12 Software Version

The Software versions screen displays information about the various software elements installed on the ELITe InGenius system.

This screen can be accessed by pressing the “Software Versions” button in the System Settings screen.

To generate a .pdf or to print a paper report containing the Software version information, press the “PRINT” button on this screen.

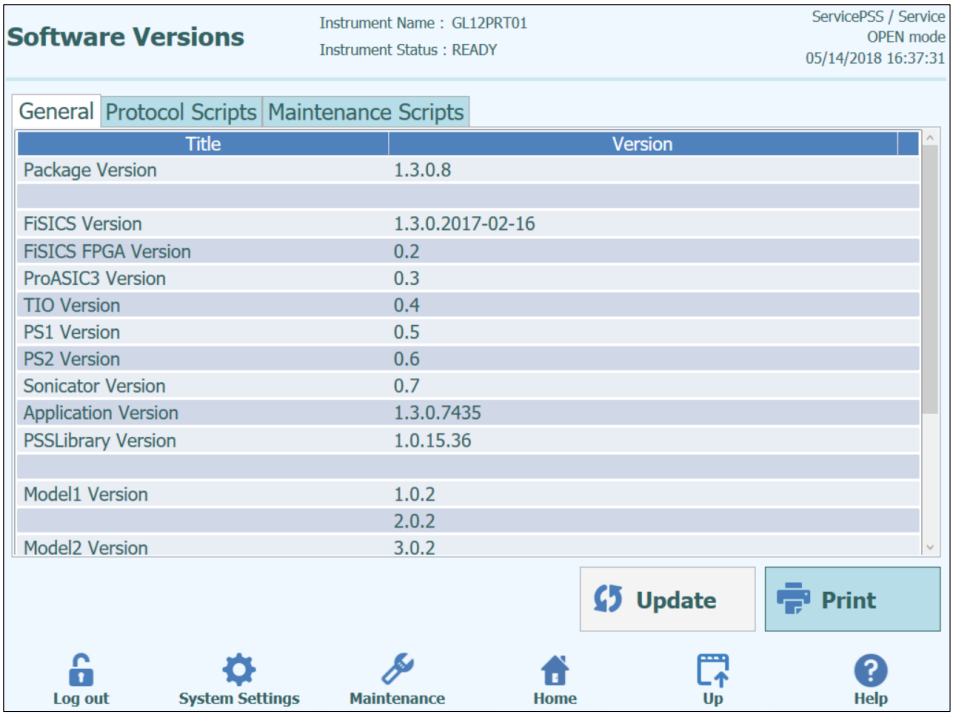


Figure 6-29: Software Versions screen

6.13 Disable tracks

In the Disable track screen an Administrator or Service User can disable a track and mark it as unavailable for performing runs (e.g. for failed/intermittent hardware).

This screen can be accessed by pressing the “Disable Track” button in the System Settings screen.

To toggle a track between the disabled and enabled state.

- Click on the icon corresponding to the track you wish to enable or disable
- Click on the “SAVE“ button

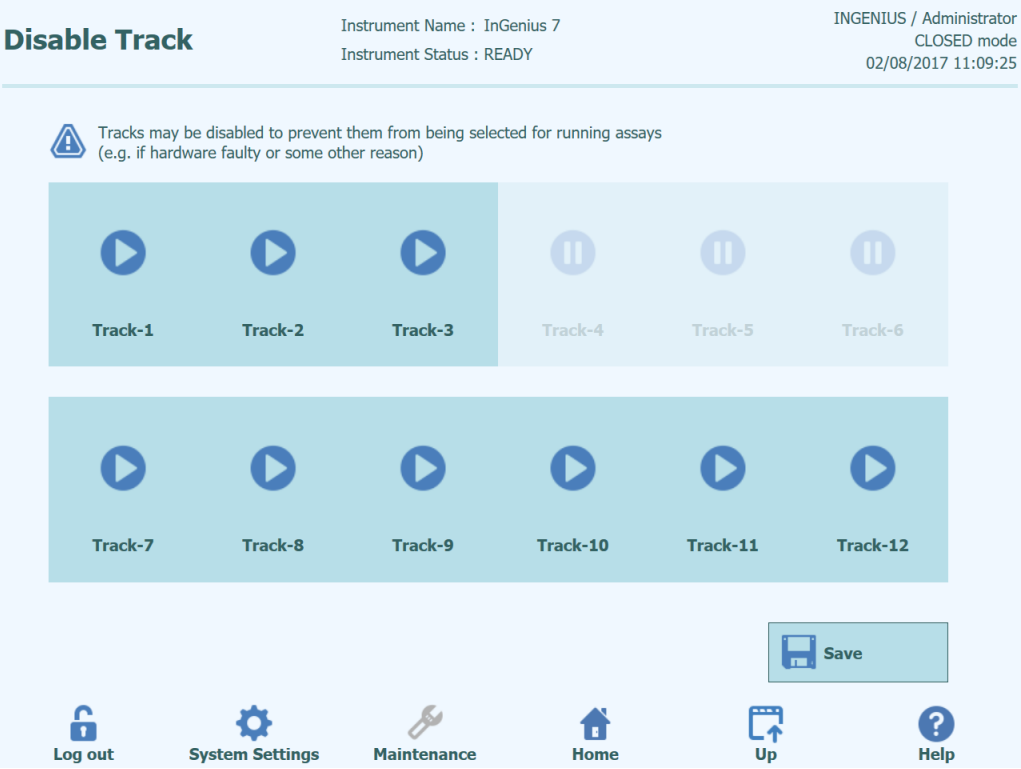


Figure 6-30: Disable Track screen

6.14 System Monitor

In the System Monitor screen an Administrator or Service User can view the temperature of the PCR blocks for each track and also monitor the positioning of each of the motorised axes.

This screen can be accessed by pressing the “System Monitor” button in the System Settings screen. The following functions may be run by clicking on the corresponding button:

a) Axis Initialize: initializes the motor axes of the system
b) Clear Error : resets system error conditions
c) Self Check : verifies the system is working correctly
d) Initialize: performs a full system hardware initialization

WARNING

The functions provided by the System Monitor should only be used by experienced operators of the system. These functions are primarily provided to allow a service user to diagnose faults in the system.

Figure 6-31: System Monitor screen

6.15 Control Management

Control management includes importing Control Details into the Controls Databaset and deleting Controls which are no longer used.

Control Details are supplied on a Flash Drive or Barcode by ELITechGroup. Contact customer support for more details. To import Control Details, access the Controls screen by clicking the Controls button on the Home screen, then click the “Add New” button.

Figure 6-32: Controls Screen.

The following Control Details screen is displayed after touching “Add New” button. Control Details may be imported by “Barcode Scan” or “Flash Drive” buttons.

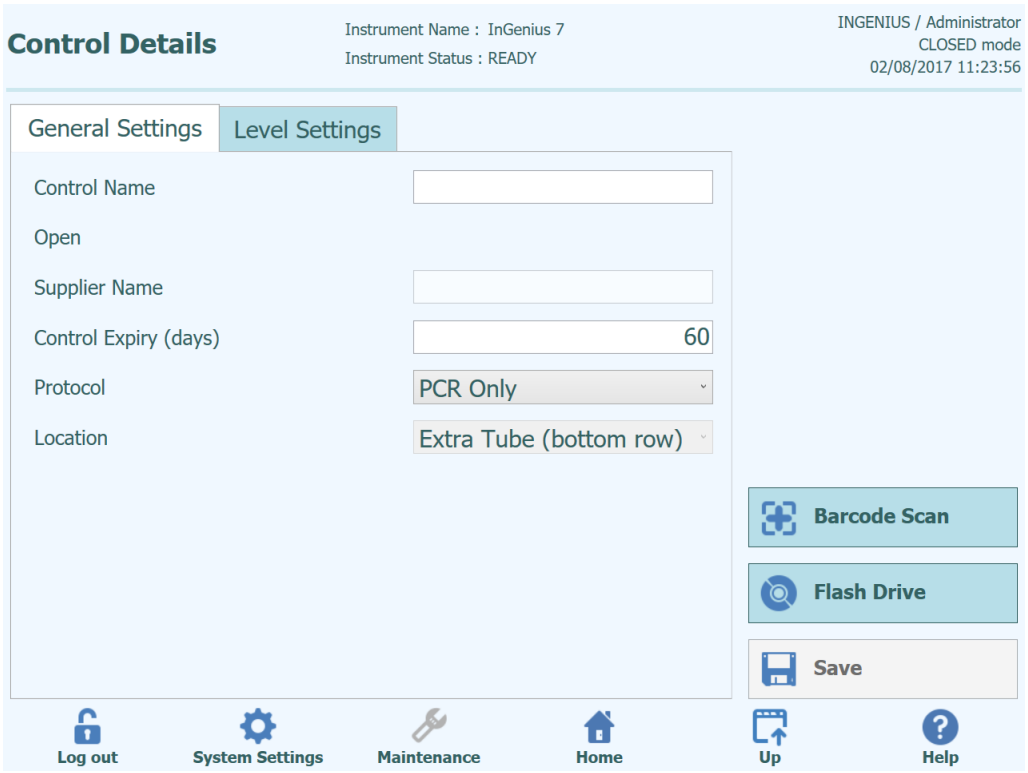


Figure 6-33: Add New Control Details.

To view Control Details, select a Control on the Controls screen and touch the "Details" button.

To delete Control Details, select the Control on the Controls screen and touch the "Delete" button. The system will not allow deletion of a Control which is required for a currently loaded Assay protocol—the Assay protocol needs to be deleted first.

7 Error Handling and Troubleshooting

In case of errors during the process, different responses can be provided by the instrument. When possible the instrument automatically handles the error. In other cases, in order to avoid aborting the session, operator intervention is required.

When operator intervention is required, in order to recover manually the session from errors, the ELITe InGenius shows an Error window with error description, instrument component involved and some recovery option buttons with different actions.

7.1 List of Main Error Codes

The errors generated will be traced in the report files. The error code IDs are useful for traceability and technical service. Some examples are shown in the following Table 7.1; for other error codes, please contact Customer Support.

Error Code	Error Description	Possible Mitigation
20031	Monoreagent Liquid level detection	Monoreagents should be in 2 mL tubes for best results
20008/ 20009	Single Nozzle Aspiration	Ensure reagent volumes are adequate
20060	Leakage of DN100N during head movement	Please contact the ELITechGroup service representative
30103	Ct calculation error	Sample may be too concentrated to calculate a Ct and should be diluted and reanalyzed

Table 7.1: List of Main Error Codes

Barcode Reading Error

When an error occurs during the Barcode Reading process, the run is paused and the Barcode Read Error screen appears where a description of the errors is presented. The following conditions may prompt a barcode read error:

- Extraction or PCR Cassette barcode illegible
- Extraction or PCR Cassette present in unexpected position, or absent in expected position
- ID of Extraction or PCR Cassette does not match the designation in Assay Parameters
- Detection of used cassette

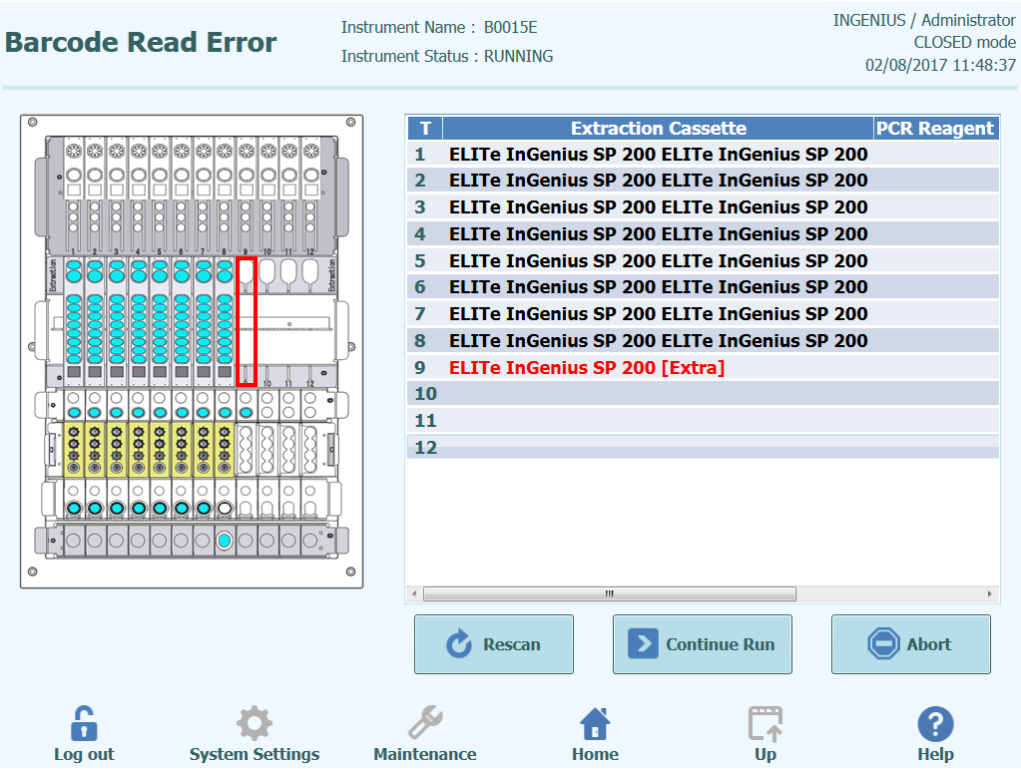


Figure 7-1: Barcode read error screen

To retry the barcode scanning:

1. The instrument unlocks the door automatically.
2. The user opens the door and replaces the highlighted cassette(s) with appropriate replacements.
3. The user closes the door and touches the “Rescan” button.

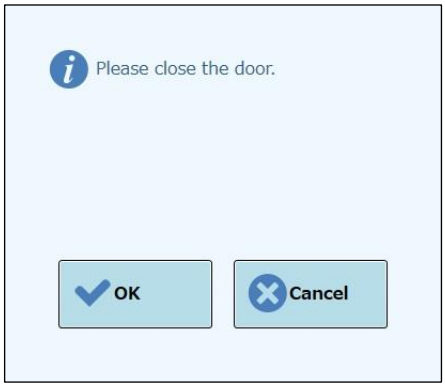


Figure 7-2: Popup message about to confirm that the front door is closed

The popup appears to confirm that the front door is closed.

Press “OK” button and the Barcode Reading process is retried.

Nucleic Acid Extraction Troubleshooting

Problem	Probable Cause	Comments and Suggestions
Low yield of extraction or NA purity	Sample status	Verify that the sample storage condition is appropriate as reported in the sample and controls section. Use only fresh sample or sample stored under appropriate conditions. Extraction yield can vary from fresh or previously frozen sample.
	Reagent status	Verify that the extraction reagent cartridge storage condition is appropriate. In case the extraction reagent has been refrigerated, allow reagents to come to room temperature prior use. Do not freeze the reagents and avoid storage locations subject to vibration.
	Solid items residues	Sample with solid residues may cause tip obstruction, and the mixing process may not function properly. The sample should be a clear solution for smooth handling by the 200 µL pipet. Do not use solids in samples to be extracted.
	Contamination	Clean all instrument parts well after use, including all surfaces by using 70 % ethanol.
	Issues with automation system	Refer to the error code displayed in the instrument operator's manual.
RNA is degraded	Sample concentration too high	If the sample concentration is excessive the RNase cannot be inactivated. Dilute sample before loading
	Elution storage	Tighten cap of elution tube as soon as possible, and keep samples at -20 °C.
	External RNAase contamination	After use, clean all parts on the instrument surface carefully by using RNase removal agents.

Detection of Used Cassette

A cassette may be recorded as used if scanned in a previous run. If the run was aborted before the cassette was used, the "Continue" button may be used to proceed with the run. If the cassette was used in a previous run, replace it with a new cassette and touch "Rescan."

Discard used cassettes per proper regulatory requirements.
Wear gloves when handling cassettes.

8 System Calibration

The ELITe InGenius system is calibrated on-site as part of the installation procedure, as well as during annual preventive maintenance, offered with a service contract.

9 Maintenance

9.1 Periodic maintenance by ELITech Group

Periodic maintenance by ELITech Group is necessary for the InGenius system to keep appropriate performance. ELITech Group service staff will provide appropriate maintenance and inspection on an annual basis with purchase of a service contract or instrument reagent rental.

9.2 Periodic maintenance by user

Regular Maintenance

In case of spills of reagent or samples, wash and clean by using 70% alcohol and dispose, treating cleaning material as potentially infectious.

Empty and replace the waste box liner at the end of each run.

Also at the end of each run:

- Remove and discard any PCR Cassettes from the PCR Rack and any extraction cassettes from the extraction rack.
- Remove and discard any extraction Tip Packages, and any Sonication tubes from the Sonication Rack
- Fit caps to the Elution tubes, Control tubes or Calibrators tubes should be removed from the Extra Tube Rack and stored or discarded.

Daily Maintenance

- **UV Decontamination**

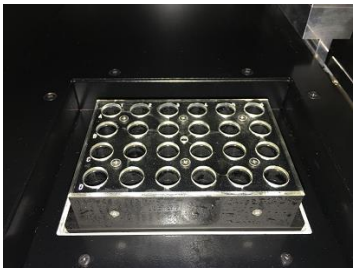
Every day at the end or beginning of routine perform a UV decontamination.
Refer to Daily end-of-day processing in section 5.6.

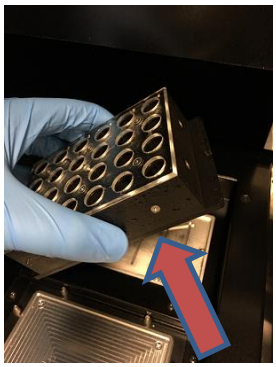
- **Cold Block**

As this unit is temperature controlled, condensation may form on the surface of the Cold Block (EXT) and the worksurface itself. The following procedure describes how to clean the block and remove the condensation.
This procedure can be also performed before starting a run.

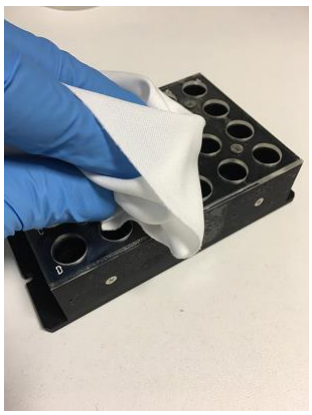
Proceed by:

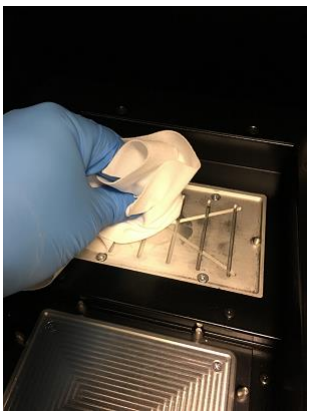
1) Extracting the Cold Block (EXT).



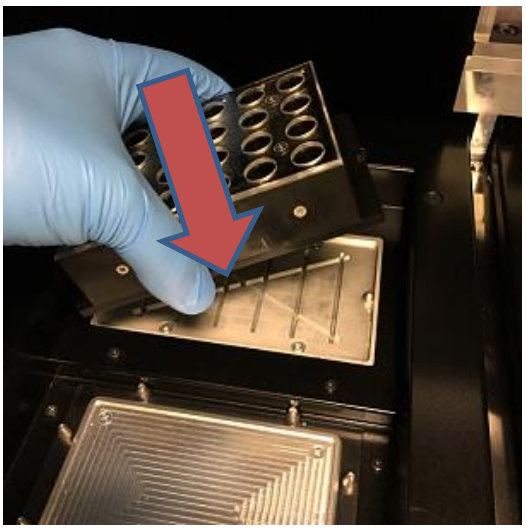


2) Using a Cloth or a paper towel dry the Cold Block all around, aswell as the worksurface as shown below.





3) After cleaning and drying the Cold Block (EXT) and the worksurface reinstall the Cold Block as shown below.



Weekly Maintenance

Every week wipe all interior and exterior surfaces of the instrument using a lint free cloth dampened in less than 6% hypochloryde or 70% Ethanol 30% Purified water solution. Rinse well with water to remove any residuals.

10Remote Diagnostics

In order to troubleshoot your system, it may be helpful that your support partner is able to access your system. This can be done using one software with remote access feature or asking IT staff a VPN connection. Please follow instructions provided by your support partner.

10.1 Terms and conditions

By sharing your ID and password you will allow your support partner to access your system. During this session your support partner cannot change results or associated data.

Please check the privacy regulations in your laboratory before granting access. The support partner is responsible to ensure that no private information that may be obtained during troubleshooting is maintained. You will be able to end a session at any time. ELITech cannot be held liable in the event local privacy regulations are breached using this remote control feature.

10.2 Using the ELITech Remote Access feature

ELITe InGenius may be accessed remotely using TeamViewer. To use TeamViewer, follow these steps:

1) Connect a USB keyboard and simultaneously press the Windows key and the “d” character to display the desktop.

2) Double-click (tap twice) the TeamViewer icon on the desktop. The ELITechGroup Remote Access/TeamViewer window opens.

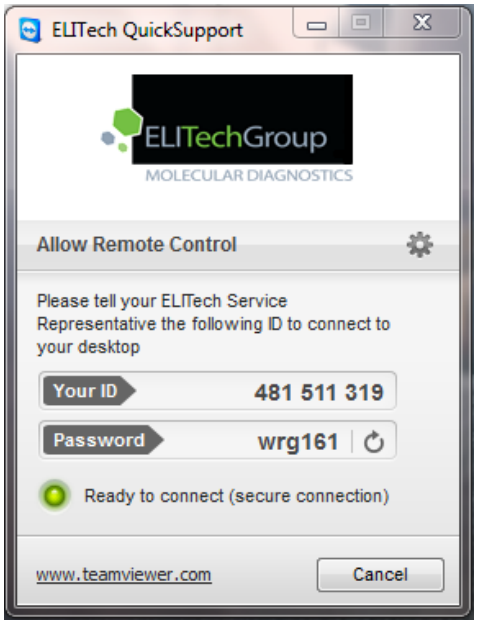


Figure 10-1: ELITechGroup Remote Access window and TeamViewer window.

3) Provide your ELITechGroup technical service support partner your ID and Password. Your support partner can now connect to your computer. A TeamViewer window is shown in the bottom left section of the screen.

4) To close the connection, tap the “x” button in the TeamViewer window.

Note: The ID is generated automatically the first time the software is started.

A new random temporary password is generated every time the software is started.

11 Technical Specification

11.1 Instrument dimensions

Unpacked instrument:

- WEIGHT: 189 Kg
- SIZE: L = 100 cm (39.4 in), D = 75 cm (29.5), H = 85 cm (33.5 in) with closed door and H= 102 cm (40.2 in) with open door.

Packed instrument:

- WEIGHT: 230.5 Kg
- SIZE: W = 110 cm (43.3 in), D = 86cm (33.9 in), H = 133 cm (52.4 in)

11.2 Operating environment conditions

Operation temperature shall be within +15 to 30°C.

Operation humidity shall be within 20 to 80 RH% under no condensation.

System operation shall be done within 0 to 2000m in altitude.

11.3 Noise levels

The instrument is designed and produced to keep the emission sound less than 70 dB at distances at least 1 meter away.

11.4 HEPA filter unit specifications

Maximum flow: more than 0.7 m^3/min

Pressure loss: less than 160 Pa

Particle size retention: at least 99.99% at 0.3 µm

11.5 UV light specifications

Wavelength: 254 nm

Power consumption: over 5W

UV intensity: more than 10 µW/cm^2 (at 1m distance from center of fluorescent tube)

11.6 Pipetting performance

Pipetting range:

Single-nozzle pipettor: 5 - 300 µL

12-nozzle pipettor: 10 - 1000 µL

11.6.1 Single-nozzle Pipettor unit

Volume	Accuracy	Precision (%CV)
5 to <20 µL	±5%	5.0%
20 to <50 µL	±5%	2.5% (*3.5%)
50 to <150 µL	±3%	2.0%
150 to 300µL	±2%	1.0%

* Precision criteria 3.5% CV when using one tip with multiple aspirate / dispense operations (PCR Mmix only) with target volume of 20 µL

11.6.2 12-nozzle Pipettor unit

When using DN100N tips:

Volume	Accuracy	Precision (%CV)
≥25 to <100 µL	±5%	5%
≥100 to <200 µL	±3%	2%
≥200 to ≤1000 µL	±3%	1.5%

11.7 Automatic sensing managed by the system

- Automatic liquid level detection (Samples + Eluate+ Reagents)
- Automatic pressure monitoring inside the tips
- Automatic leak detection
- Automatic clot detection
- Check presence of secondary tubes
- Check presence of sonication caps
- Check presence of PCR caps
- Check presence of tip/filter: 12-nozzle
- Check presence of tip/filter: single-nozzle
- Check presence of extraction cassettes (via barcode)
- Check presence of PCR cassettes (via barcode)

11.8 Sonication specifications

Oscillation voltage of ultrasonic transducer within 350 - 450V (Pk-Pk).

Frequency of ultrasonic emission between 39 - 40 kHz.

Processing time of sonication programmable from 1 - 20 sec with control resolution of 0.1 sec

11.9 Extraction specifications

Extraction heat block:

- Temperature control range: 65 - 80°C
- Temperature control accuracy: ±1.5°C

Extraction tube:

- for Internal Control and Eluted DNA: Micro Tube 0.5 mL (Sarsted, code 72.730.005)

11.10PCR specifications

Reaction volume of PCR between 20 - 50µL.

Temperature control range of PCR block between 40 - 98°C

Temperature accuracy of PCR block for the PCR tube:

- ±0.5°C for 40 - 60°C and
- ±0.3°C for 61 - 98°C

Temperature ramp performances of PCR block:

- 3.4°C/sec ± 0.2 °C/sec
- Hot Collar Unit temperature control 120°C ± 2°C

Melting analysis temperature range of PCR block: 40 - 98°C.

Melting analysis max resolution: 0.2 °C/step. It is possible to reduce resolution to improve TAT (e.g. 0.5 °C/step).

Reagent tube:

- for Master Mix: Micro Tube 2 mL (Sarsted, code 72.694.005)
- for Standards and Controls: Micro Tube 0.5 mL (Sarsted, code 72.730.005)

11.11Optics specifications

The optics group has six channel fluorescence detection. The optics were optimized with ELITechGroup's proprietary dyes. There are six LEDs with filters for excitation and six photodiodes with filters for detection. Excitation and emission filters are compatible with many other commercial fluorescent dyes.

Channel	ELITechGroup Dyes	Compatible dyes	Excitation filter (nm)	Detection filter (nm)
1	FAM	FAM, SYBR green, Alexa Fluor 488	470	510
2	AP525	JOE, HEX, VIC	530	560
3	AP559	TAMRA, Alexa Flour 555, NED	560	590
4	AP593	Rox , Texas red	590	630
5	AP642	Cy5, Alexa Flour 647	630	670
6	AP680	Cy5.5, Alexa Flour 680, Quasar 705	670	710

11.12 Cool block (Inventory Manager) specifications

Temperature control accuracy: ± 4°C (at 8°C).

11.13 Operating system

Windows Embedded 10, 64 Bit.

11.14 LIS Interface

Connectivity: 9 pin RS-232 Serial Port (via USB adapter and standard serial cable)

TCP/IP via LAN connection (ELITe InGenius System works always in client mode on a specific destination port)

Protocols: Industry Standard ASTM E-1394-97 and ASTM 1381-02

Modes: Host Query

Orders & Results

11.15 Barcodes compatibility

A broad range of barcode are accepted

1D Bar Codes:

UPC/EAN/JAN (A, E, 13, 8); UPC/EAN/JAN (including P2 /P5); UPC/EAN/JAN (including; ISBN /Bookland & ISSN); UPC/EAN Coupons; Code 39 (including full ASCII); Code 39 Trioptic; Code39 CIP (French Pharmaceutical); LOGMARS (Code 39 w/ standard check digit enabled); Danish PPT; Code 32 (Italian Pharmacode 39); Code 128; Code 128 ISBT; Interleaved 2 of 5 ; Standard 2 of 5; Interleaved 2 of 5 CIP (HR); Industrial 2 of 5; Discrete 2 of 5; Matrix 2 of 5; IATA 2of5 Air cargo code; Code 11; Codabar; Codabar (NW7); ABC Codabar; EAN 128; Code 93 ; MSI; PZN; Plessey; Anker Plessey; GS1 DataBar Omnidirectional; GS1 DataBar Limited; GS1 DataBar Expanded; GS1 DataBar Truncated; DATABAR Expanded Coupon.

2D / Stacked Codes:

Datamatrix; Inverse Datamatrix; Datamatrix is configurable for the following parameters: Normal or Inverted; Square or Rectangular Style; Data length (1 - 3600 characters); Maxicode; QR Codes (QR, Micro QR and Multiple QR Codes); Aztec; Postal Codes - (Australian Post; Japanese Post; KIX Post; Planet Code; Postnet; Royal Mail Code (RM45CC); Intelligent Mail Barcode (IMB); Sweden Post; Portugal Post); LaPoste A/R 39; PDF-417; MacroPDF; Micro PDF417; GS1 Composites (1 - 12); French CIP13a; GS1 DataBar Stacked; GS1 DataBar Stacked Omnidirectional; GS1 DataBar Expanded Stacked; GSI Databar Composites; Chinese Sensible Code; Inverted 2D codesb .