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NOTICE of CHANGE dated 16/09/2025

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITe InGenius®»
Ref. INT030

This new revision of the Instruction for Use (IFU) contains the following changes:

- New paragraphs: "Personal data processing", “Calorific value and power consumption”, “Battery information”
- Typo correction at paragraph 1.2
- Addition of reference codes for reagents and consumables
- Update of the paragraph 5.1: better definition of different Assay Protocol types

ELITe InGenius

ELITe InGenius®

Instructions for use

(Software version 1.3)

REF **INT030**

ELITechGroup
A BRUKER COMPANY

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CE IVD

UDI **03661540900013**

PLEASE NOTE

Questo manuale è aggiornato per la **versione 1.3 del Software ELITe InGenius**.
Per richiedere il manuale per una versione precedente di Software, si prega di contattare il personale di ELITechGroup al seguente indirizzo email: emd.ifu@elitechgroup.com

This manual is updated for **version 1.3 of the ELITe InGenius Software.**
Please contact the ELITechGroup staff at the following email address: emd.ifu@elitechgroup.com, to request the manual for a previous version of the Software.

Ce manuel est mis à jour pour la **version 1.3 du Software ELITe InGenius**.
Pour demander le manuel pour une version précédente du Software, veuillez contacter le personnel d'ELITechGroup à l'adresse électronique suivante: emd.ifu@elitechgroup.com

Este manual se actualiza para la **versión 1.3 del software ELITe InGenius**.
Para solicitar el manual relacionado a una versión anterior de el Software, póngase en contacto con el personal de ELITechGroup a el siguiente correo electrónico: emd.ifu@elitechgroup.com

Este manual é atualizado para a **versão 1.3 do software ELITe InGenius.**
Para solicitar o manual de uma versão anterior do Software, entre em contato com a equipe do ELITechGroup no seguinte endereço de e-mail: emd.ifu@elitechgroup.com

Dieses Handbuch wurde für **Version 1.3 der ELITe InGenius Software** aktualisiert.
Um das Handbuch für eine frühere Version der Software anzufordern, wenden Sie sich bitte an die Mitarbeiter der ELITechGroup unter der folgenden E-Mail-Adresse: emd.ifu@elitechgroup.com

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1 Introduction

1.1 Intended use

The ELITe InGenius® system is a fully automated device integrating the following tasks: extraction and purification of nucleic acids, amplification and detection of the target sequence by Real-Time Polymerase Chain Reaction (RT-PCR) and result interpretation. The system is suitable with multiple sample types for qualitative and quantitative in vitro diagnostics applications.

The ELITe InGenius® system shall be operated by healthcare professionals and properly trained molecular biology technicians and can be used in combination with proprietary extraction and amplification reagents as well as custom amplification reagents.

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.

- extraction modules, liquid handling pipettors, RT-PCR units
- nucleic acid extraction and RT-PCR reagents
- dedicated software piloted with an integrated touch screen, interfacing bi-directionally with the Laboratory Informatics System (LIS).

The ELITe InGenius system can process from 1 to 12 samples in 12 parallel tracks. It features primary tube loading capability, a universal extraction process combined with multiple and independent PCR's from one or several extracted sample(s) enabling laboratories to develop custom test panels according to their specific needs.

The extracted nucleic acid can be stored for retesting or archiving.

Several operational modes are available: nucleic acid extraction only, RT-PCR amplification only, or nucleic acid extraction, RT-PCR amplification and result analysis.

Instrument

The ELITe InGenius is able to automatically perform the following operations:

- Nucleic acid extraction and purification based on magnetic beads technology with optional ultra-sonication capabilities.
- Amplification and detection by RT-PCR of the target sequence
- Liquid handling operations including sample & reagent dispensing
- Barcode reading with an integrated barcode reader for extraction cassette and PCR cassette, or with a hand-held barcode reader for samples and RT PCR reagents

The ELITe InGenius instrument features the following components

Single Nozzle Pipettor

- operates the SX, SZ, SP axis.
- sample transfer from the primary tube to the secondary tube, nucleic acid and RT-PCR reagents dispensing
- dispensed volume ranges from 5 to 300 µL, using 300 µL filter tips

Twelve Nozzle Axis

- operates in the Y-Z-P axis and performed various tasks:
- magnetic particle capture for extraction
- liquid handling operations during extraction and extracted nucleic acid elution
- dispensed volume ranges from 10 to 1000 µL

Both Single Nozzle and Twelve Nozzle Axis are equipped with liquid sensors to detect sample and reagent liquid levels, clots, tips and liquid leakage.

Detection Nozzle Axis

- Real Time Fluorescence Detection.
- PCR well capping.

M - Axis

- Assists extraction using magnetic extraction.

Twelve Extraction Modules

- each equipped with a heat block
- ultra-sonication available for any combination of samples
- three elution volumes available: 50 µL, 100 µL, 200 µL

Twelve RT-PCR units

- independent temperature control allows parallel diverse PCR thermal-profiles.
- Peltier block 1 peltier element for every well
- Reaction volume range from 20µL to 50µL
- Melt curve analysis capability
- Six fluorescent channels are available for each RT-PCR with the following specifications:

Channel	ELITechGroup Dyes	Excitation filter (nm)	Detection filter (nm)
1	FAM	470	510
2	AP525	530	560
3	AP559	560	590
4	AP593	590	630
5	AP642	630	670
6	AP680	670	710

The ELITe InGenius is organized in 12 parallel **Tracks** enabling to process in parallel and independently 12 samples processed from extraction to amplification.
The loading of the reagents and consumables is performed in dedicated ELITe InGenius racks.

Figure 1.1: ELITe InGenius instrument – Exterior view

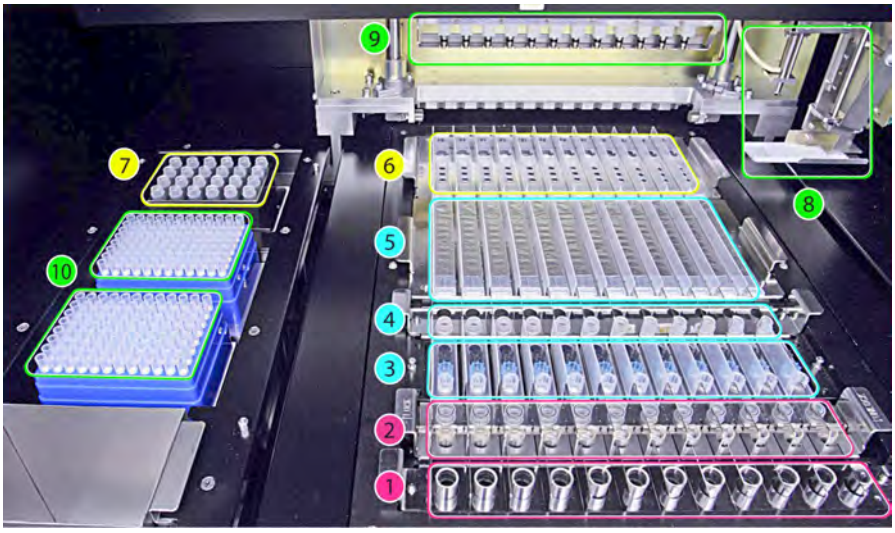


Figure 1.2: ELITe InGenius instrument – Working Area view

1. Primary sample tubes
2. Sonication tubes & sonication caps or extraction tubes
3. Extraction Tip cassettes
4. Nucleic acid storage tubes and DNase tubes and adaptors
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)

Reagents and Consumables

The following ELITe InGenius reagents are necessary for nucleic acid extraction in open and closed mode.

ELITe InGenius SP 200 (code **INT032SP200**)

- 8-wells prefilled, unitary 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 genomic DNA and viral DNA/RNA and validated on a very large range of sample matrices.
- The reagent set has been optimized for the isolation of nucleic acids from 200 µL samples(Figure 1.3: ELITe InGenius – SP200 Extraction cassette and extraction principle).

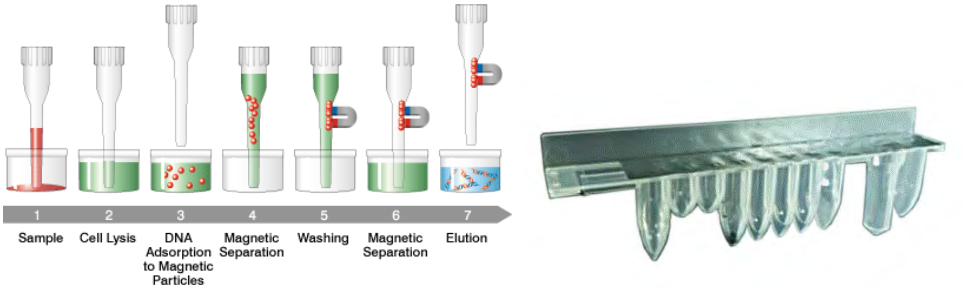


Figure 1.3: Nucleic acid extraction principle and ELITe InGenius SP 200 extraction cassette

Additional Extraction kits, using similar configurations, can be used on the System to expand clinical applications. Each extraction kit will use the corresponding method present in the software.

ELITe InGenius SP 1000 (code **INT033SP1000**)

- 8-wells prefilled, unitary 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 genomic DNA and viral DNA/RNA and validated on a very large range of sample matrices.
- The reagent set has been optimized for the isolation of nucleic acids from up to 1 mL of samples. (Figure 1.4: ELITe InGenius – SP1000 Extraction cassette and extraction principle).

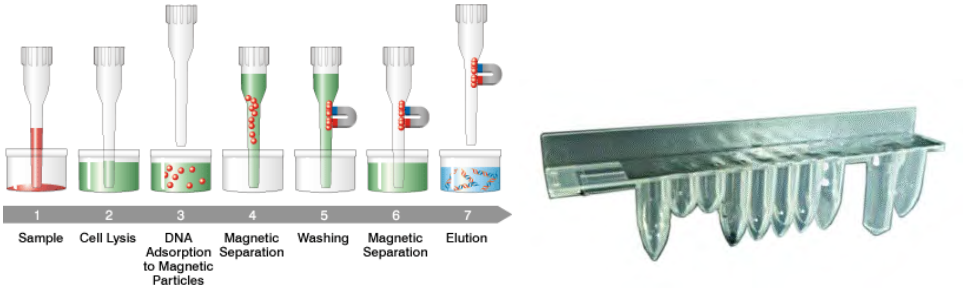


Figure 1.4: Nucleic acid extraction principle and ELITe InGenius SP 1000 extraction cassette

Additional Extraction kits, using similar configurations, can be used on the System to expand clinical applications. Each extraction kit will use the corresponding method present in the software.

ELITe InGenius SP RNA (code **INT034SPRNA**)

- 8-wells prefilled, unitary cassette sealed with aluminum foil containing all the necessary reagents for cell lysis, extraction and purification including the magnetic beads.
- Universal cassette suitable for RNA extraction and purification from lympho-monocyte suspensions and leukocyte suspensions from clinical samples of peripheral blood.
- The reagent set has been optimized for the isolation of nucleic acids from 0.2 mL samples. (Figure 1.5: ELITe InGenius – SP RNA Extraction cassette and extraction principle).

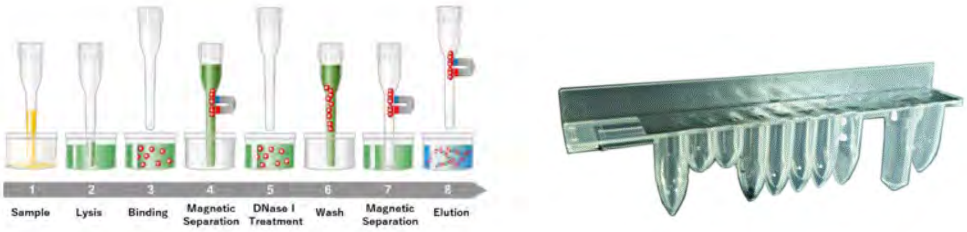


Figure 1.5: RNA extraction principle and ELITe InGenius SP RNA extraction cassette

Additional Extraction kits, using similar configurations, can be used on the System to expand clinical applications. Each extraction kit will use the corresponding method present in the software.

ELITe InGenius DNase I (code **INT034DNASE**) containing a lyophilized endonuclease, aliquoted into 48 ready-to-use test tubes. The DNase I tubes must be used with the ELITe InGenius DNase I tube adapter.

ELITe InGenius DNase tube adapter kit (code **G6431-000**) containing 12 DNase I tube adapter and an uncapped tool.

ELITe InGenius SP 200 Consumable Set (code **INT032CS**) containing all necessary consumables for extraction along with the extraction kit:

- extraction tubes
- tips cassettes, including one piercing tip for automated extraction cassette piercing and one pipetting tip for sample processing
- nucleic acid storage tube and screw caps.

The following ELITe InGenius consumables are necessary for RT-PCR amplification in open and closed mode.

ELITe InGenius PCR cassette (code **INT035PCR**): universal PCR vessel and caps for IVD and user defined assay protocol (Figure 1.6: ELITe InGenius - PCR cassette)

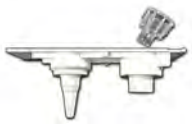


Figure 1.6: Universal PCR vessel for PCR

ELITe InGenius® Waste Box (code **F2102-000**), Disposable plastic boxes for tip waste.

Filter tips (300 µL) – Axygen (code TF-350-L-R-S)

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

ELITe MGB® line: target–specific RT-PCR assays in monoreagent format including probes, primers and enzyme for qualitative and quantitative IVD applications.

Software

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

Settings

- configure the system
- manage user's access
- manage assay database

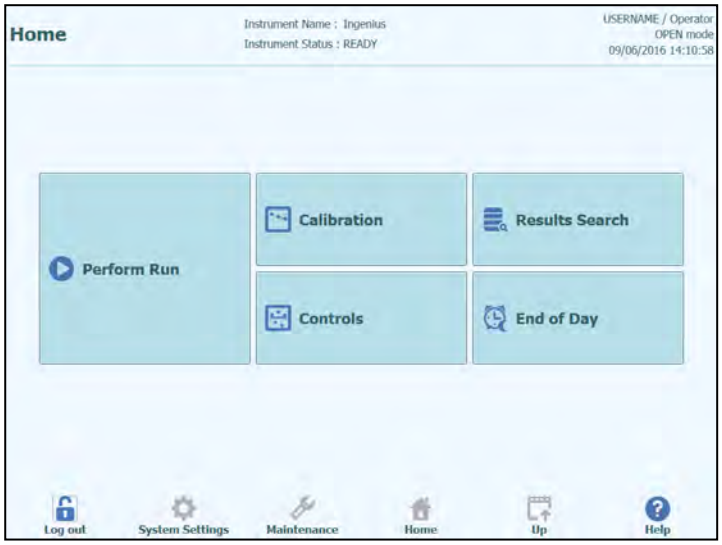
Operation

- select pre-defined assay protocol or test panels
- perform a run
- measure the target nucleic acid
- analyze and interpret the results
- generate customized report

Management

- manage sample & reagent traceability
- archive, retrieve and export data
- calibrate and maintain the system
- generate quality control chart

This ELITe InGenius home screen enables direct access to these main functionalities.



1.3 Workflow

The ELITe InGenius system operates in CLOSED or OPEN mode.

The CLOSED mode enables the user to run only IVD assay protocols. The CLOSED mode is also considered as a depository including all the IVD validated assay protocol according to the IFUs of the ELITe MGB assays in use. Modification of assay protocols or creation of a new assay protocol are not allowed in the CLOSED mode.

The OPEN mode enables the user to run also additional non-IVD user-defined assay protocols developed by the laboratory to fit their specific needs.

ELITe InGenius workflow with IVD assay protocol

1. Start the ELITe InGenius system
2. Select the CLOSED mode
3. Select the extraction elution volume
4. Query the LIS to import the sample work list
5. Select IVD assay protocol or testing panel for each sample
6. Load ELITe InGenius extraction reagents & consumables
7. Load ELITe InGenius amplification reagents
8. Load the scanned samples
9. Start the run
10. Approve result
11. Upload data to the LIS

ELITe InGenius workflow with EGSPA protocol & user-defined and user-validated protocol

1. Start the ELITe InGenius system
2. Select the OPEN mode
3. Select the extraction elution volume
4. If needed, query the LIS to import the sample work list*
5. Select user-defined assay protocol or panel for each sample and/or EGSPA assay protocol previously imported without modification from the CLOSE mode*
6. Load ELITe InGenius extraction reagents & consumables
7. Load user-defined amplification reagents (and/or ELITe MGB® RT-PCR reagents)
8. Load the scanned samples
9. Start the run
10. During run, optional pause after dispensation from primary tubes to the secondary and after the PCR set up can be selected in order to unload primary tubes or eluates from the system
11. Approve result*

Upload data to the LIS (if needed)
*see NOTE below

Assay controls is recommended once every two weeks for each parameter running one positive and one negative control.

One assay calibration per PCR reagent batch is mandatory running one positive and one negative control.

NOTE

Any analytical result obtained through OPEN mode assay is under complete responsibility of users.

1.4 Customer support

If there are any questions about ELITe InGenius, please contact your local customer support representative.

1.5 Proprietary statement

The ELITe InGenius software programs and system documentation are protected by copyright laws, all rights are reserved.

The software and manual are dedicated to the ELITe InGenius for in vitro diagnostic applications.

The documentation may include technical inaccuracies or typographical errors. ELITechGroup reserves the right to make additions or modifications to the documentation at any time without any prior notification.

1.6 Personal data processing

This device is designed to operate in compliance with current legislation on the protection of personal data, in particular Regulation (EU) 2016/679 (GDPR). The system is designed for the identification of samples by anonymous barcodes or by manual entry of alphanumeric identifiers, generated and processed by the controller.

Before insert the sample and start the work session, the operator must enter the patient's data into the instrument in a pseudonymised form (e.g. by anonymous barcodes or alphanumeric identifiers).

CAUTION

The manual insert of identification data (e.g. name and surname of the patient) is a non-compliant and a non- authorized use of the device, in violation of the principles of the GDPR, as per Article 32.

The customer is an independent controller and, therefore, is responsible for the correct configuration and use of the device, as well as for the training of the personnel involved, in accordance with the Articles 24 and 32 of the GDPR.

The manufacturer of the instrument is not responsible for any unlawful personal data processing resulting from an improper use of the device by the user.

The manufacturer of the instrument:

- is not the controller or the processor of the personal data inserted by the user
- disclaims any liability for any breach of data protection legislation arising from improper use of the device
- recommends the controller to adopt appropriate technical and organizational measures to ensure the complaint use of the device by the authorized users

The use of the device in a manner that differs from the instructions contained in this manual indemnifies the manufacturer from any civil, administrative or criminal liability with regard to the processing of personal data.

1.7 Notes and Symbols

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

1.7.1 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.

1.7.2 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.

1.7.3 Other Symbols

Symbol	Description
CE	**Conformité Européenne** – CE mark This symbol indicates conformity with European Regulation
	Manufacturer
	Date of manufacture
CC	**Country 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	**Catalogue number**
SN	**Serial number**
TÜV	**TUV mark**
	Consult Instructions for Use
	Fuse
UDI	Unique Device Identification

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 not approved items may affect the safe operation of the system or cause damage to the system.

WARNING

2.1 Handling of the Instructions for Use

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

- o Read all instructions.
- o Keep the Instructions for Use near the system.
- o The Instructions for Use must be accessible to the user at all times.

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.

- o Follow all safety instructions included in the Instructions for Use.
- o 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 Instructions for Use 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.

NOTE

Laboratory Equipment

The ***ELITe InGenius*** instrument has been designed and developed as laboratory equipment in accordance to the requirements of the Regulation (EU) 2017/746 (Regulation (Eu) 2017/746 Of The European Parliament And Of The Council Of 5 April 2017). In order to assure compliance, applicable standards recorded in the list of standards harmonised for the IVD Regulation were observed. The application of this product for in vitro diagnostics purposes requires a separate conformity assessment according to the Regulation (EU) 2017/746 for the complete system into which it will be incorporated and/or has to be used in combination with (e.g. reagent).

NOTE

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

Transient Emissions and Interference Resistance

This instrument meets all requirements described in standard IEC 61326-2-6 on transient emissions and interference resistance.

- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference
- The electromagnetic environment shall be evaluated before setup and operation of the instrument,
- Do not use the instrument in the proximity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) as these could interfere with the proper operation of the instrument.

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 personell.

- Only perform maintenance procedures described in this manual or dedicated TSB's.
- 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 place of installation of the system 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. Observe the following 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 SDS for each assay.
b) Wear recommended protection such as disposable gloves / lab coat / eye protection to prevent exposure.
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

ELITe InGenius is designed and manufactured in compliance with applicable EMC standards. For current information about applicable standards, please refer to the CE Declaration of Conformity for this instrument.

The user must ensure that a compatible electromagnetic environment for this instrument is maintained in order to ensure the device will perform as intended.

- Only use instrument and cables supplied by ELITechGroup S.p.A. to maintain compliance.
- Installation should be done only by trained service staff approved by ELITechGroup S.p.A. 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.

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.

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 immunized 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 **could 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 local 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, if connected to the laboratory / hospital computer network, can be monitored to identify any anomalies or suspicious behavior by the network administrator.

Any anomalies that could compromise the correct functioning of the instrument shall 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.

NOTE

The ELITe InGenius system can be connected remotely to allow technical assistance activities. The remote assistance service to be used is the one validated and issued by ELITechGroup and which allows to guarantee effective, safe and integrated support, significantly reducing the time to solve problems without the need to install any software on the remote stations and in compliance with the current GDPR regulation (EU Reg. 2016/679 and subsequent transposition into national legislation Legislative Decree 101/2018).

The solution used by ELITechGroup is a Cloud solution that uses data centers that have obtained the ISO / IEC 27001 certification of their information security management systems. In addition, all data centers completed the following exams: SOC II Type 1, SSAE 16, SOC 1 Type II and SOC 2 Type II.

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 S.p.A. 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

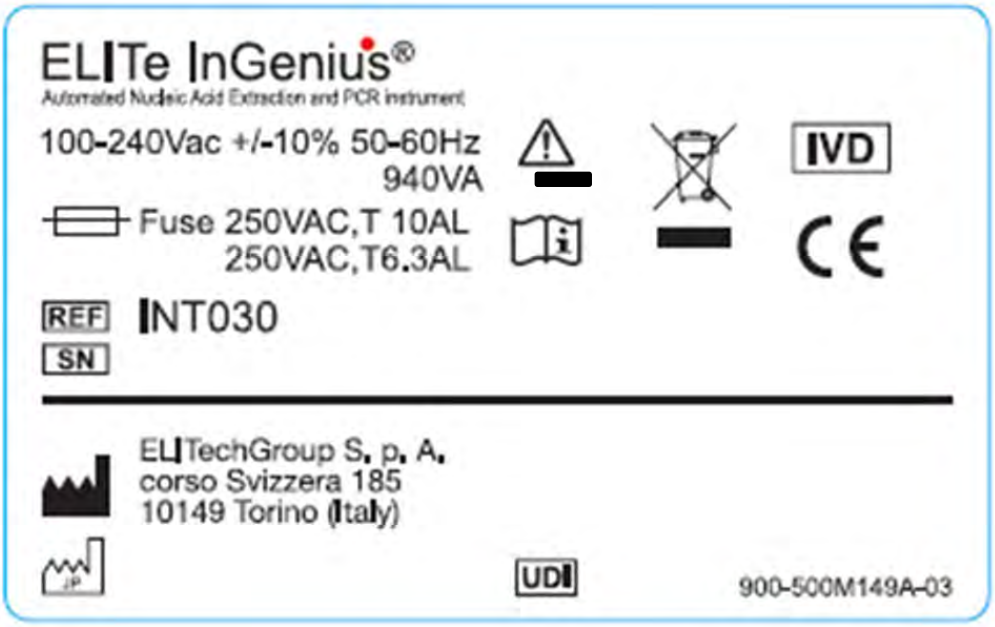
The instrument is designed and produced to keep the A-weighted emission sound to be less than 70dB at distances at least 1 meter away.

3 Safety labels / Instrument labelling

3.1 Instrument Type Plate

Serial Number LabelInstrument REF and serial number can be found on the right side of the instrument on the serial number label.

The serial number is unique for each instrument.



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

Minimum useful lifecycle of the ELITe InGenius system is five (5) years, providing the system is maintained by qualified personell.

4.2 Installation of the system

The ELITe InGenius system installation may only be performed by ELITechGroup S.p.A. or trained representative service staff. The ELITe InGenius system must be connected to ground.

4.3 Removal of the system

If the instrument will be move from where installed now, be sure to contact the manufacturer.

If the instrument will be relocated to another installation site or must be returned for repair or service, only an ELITechGroup S.p.A. or trained 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.

CAUTION

Use of Approved Software

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

The following chapters describes 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 chapters 5.

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

Maintenance functions are described in chapter 0.

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 instrument starts the ELITe InGenius software on the integrated PC. The system displays the start-up screen 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.

Refer to Chapter 7 “Error Handling and Troubleshooting” to resolve the problem.

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.

Select login mode: Select the login mode as shown in the following table

Mode Name	Outline
CLOSED Mode	Mode that allows execution of IVD assays only
OPEN Mode	Mode that allows execution of Open assays

5. Press the User name field/input box and enter your user name with the on-screen keyboard.
6. Press the Password field/input box and enter your password with the on-screen keyboard.
7. Choose either CLOSED mode or OPEN mode
8. Press OK button.
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).

	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 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.

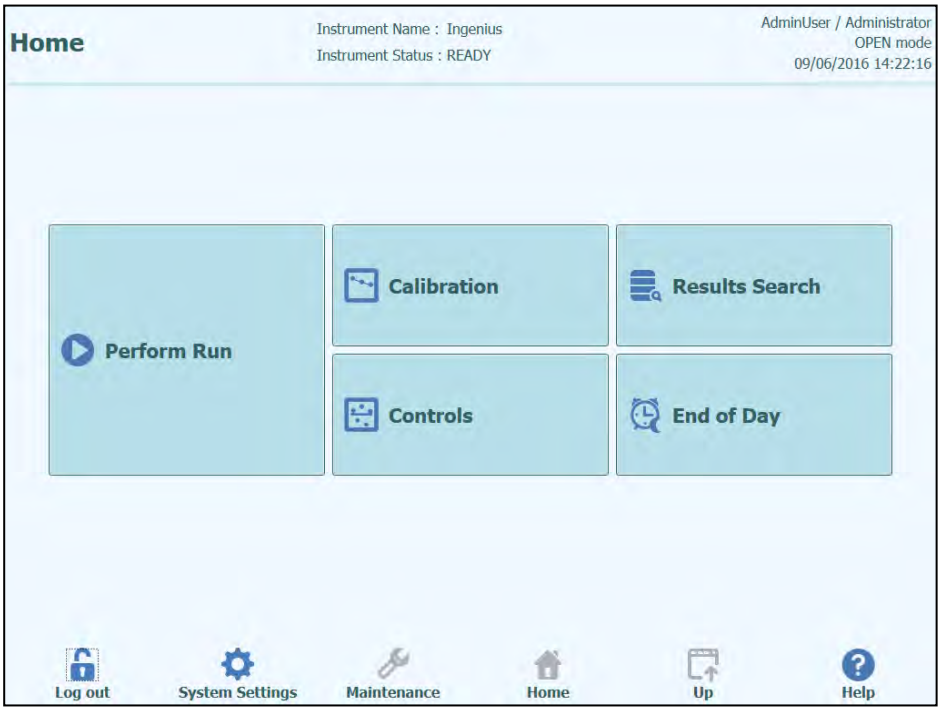


Figure 5-3: Home Screen display

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.

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: http://www.elitechgroup.com/corporate/ifu-emd.

5.3 Runs, Assays, Controls and Calibrators

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.

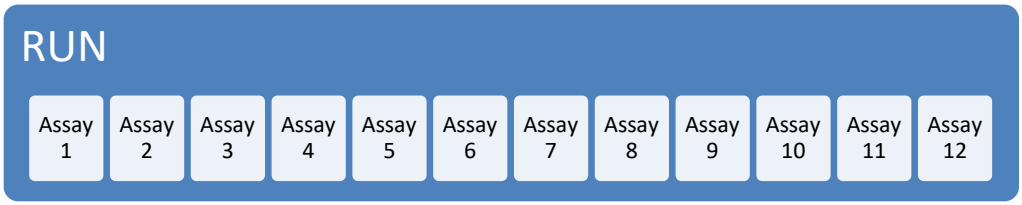


Figure 5-4: A Twelve Assay Run

Assay Programs are the settings used to instruct the ELITe InGenius system on how to analyse each sample on the tracks of the instrument. Each assay may be one of three types

- Patient Sample Assays
- Calibration Assays
- Control Assays

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

An assay will yield either a Quantitative or Qualitative result according to the setup by the Assay developer. An optional Melt analysis may also be specified to be run after completing the PCR amplification. It is also possible for an Assay developer to configure assays that carry out no result interpretation and to report only C_t and T_m results.

Typically, to give a diagnostic result for a Quantitative Patient Sample Assay, the ELITe InGenius Software will need to have an approved Calibration Curve and one or more approved Control results stored in its database. For a Qualitative Patient Sample Assay, only the approved Control results will be needed.

A Calibration (Standard) Curve is generated by the software by running a special type of Assay called a “Calibration Assay”. Typically, the Calibration Assay will be setup to run a series of reactions with a set of Calibrator fluids (e.g. 10^5 copies, 10^4 copies, 10^3 copies, 10^2 copies). The software will then automatically calculate the Standard curve parameters that may then be used to determine the DNA titer for Patient Sample Assays.

A Control result is generated by the software by running a “Control Assay”. Control Assays are typically used for running Positive and Negative controls that are then used to validate the results generated by Patient Sample Assays.

The results of running Calibration Assays and Control Assays are stored within the ELITe InGenius database and may remain valid for several weeks, removing the need to run a new Calibrator or Control with every Patient Sample (e.g. 60 days for Calibrators and 30 days for Controls, according to Assay Protocol settings)

For efficiency, it is possible to create Calibration curves and Control results *in the same run* as Patient samples, or in a separate run. If you do choose to run Calibration or Control Assays in the same run as your patient samples, you will need gain approval first for the Calibration Assay Results, then the Control Results and finally the patient Sample Results. This is known as sequential approval and is necessary to ensure that the Patient Sample Results are calculated on the most recent Calibration curves.

To setup a Run- on your ELITe InGenius system, it should have been configured with at least the following configuration information:

- Assay Programs (Patient Sample, Control, Calibrator as required)
- Calibrator Details (for quantitative assays)
- Control Details

If the required configuration is not available on your system, refer to sections 6.5 and 6.6, for further details on how to setup your system.

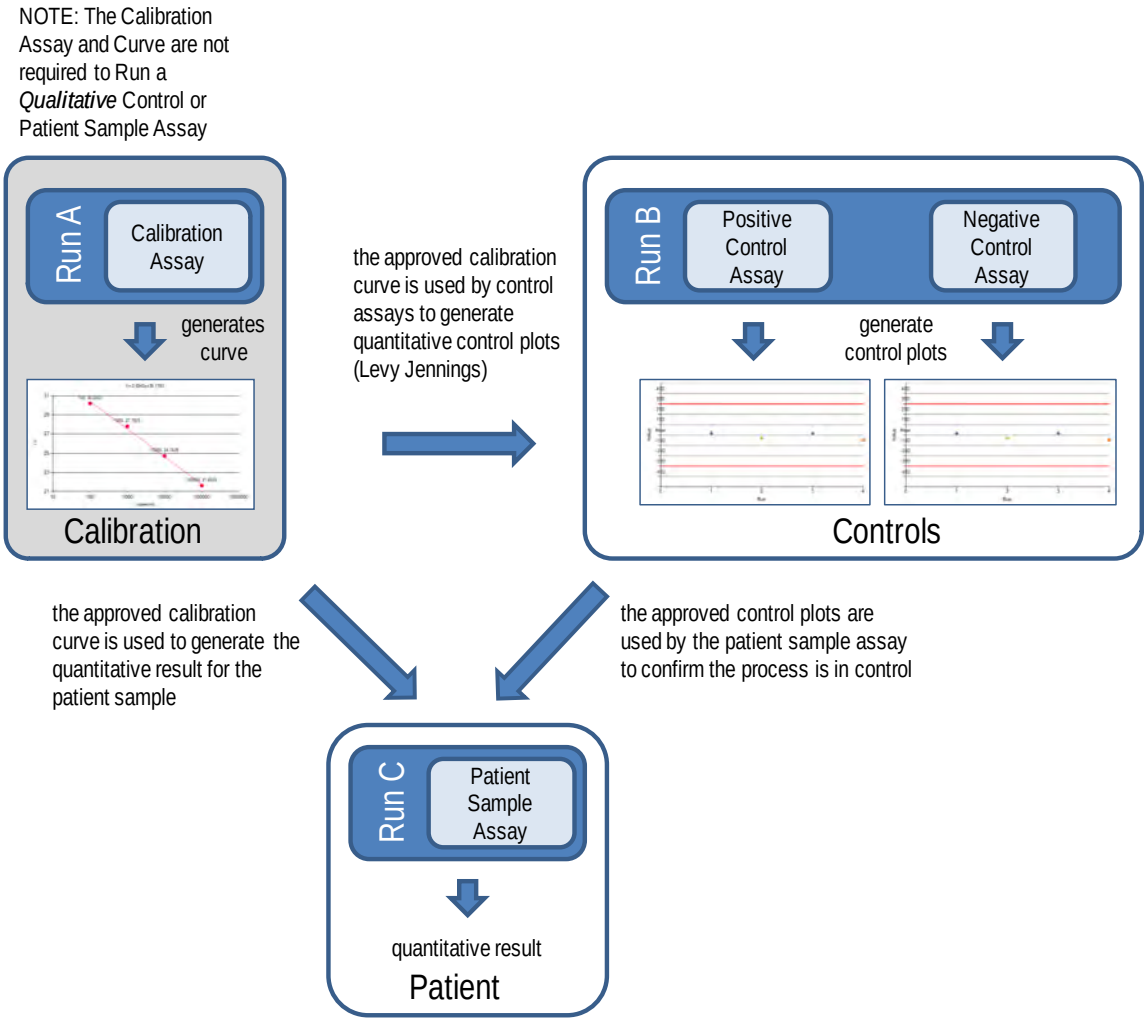


Figure 5-5: Relationship between Calibrator, Control and Patient Sample Assays

NOTE It is possible to run Calibrator, Control and Patient Sample Assays in the same run (e.g. to combine Run A, Run B and Run C in 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 Calibration and Control Status
2. Configure the Run
3. Setup Inventory Manager
4. Load Consumables and Samples
5. Monitor Run Progress
6. Review Results and Approve
7. Unload at end of run

5.4.1 Step 1: Check Calibration and Control Status

5.4.1.1 Check Status of Calibration

If you wish to run an Assay that gives a Quantitative result (this might be either a Patient Sample Assay, or a Quantitative Control Assay) then before setting up the run it is advised to check that an Approved Calibration (Standard) Curve is available in the database.

NOTE If you only wish to run Qualitative assays, the Calibration Status check can be skipped

Display the “Calibration” screen by pressing the “Calibration” button on the Home Screen.

This screen may be used to:

- View the details and status of each calibration curve stored on the system
  - lot number of the Mono-mix used to generate each calibration curve
  - traceability information for the Calibration fluids used to generate each calibration curve
  - expiry date for the calibration curve
  - status (Need to run, Approval Pending, Approved, Expired)
- View the actual Calibration Curves stored on the system
- View the process settings and number of levels for the Calibrators
- Register New Calibrators
- Remove Calibration Curves from the database

NOTE When running a Quantitative Assay, it is necessary to use the same Lot number of Mono-reagent as was used to create the Calibration Curve. If you wish to use multiple lots of Mono-reagent, then it is necessary to create a Calibration Curve for each lot number.

Figure 5-6: Calibration Manager screen.

Calibrator Details

Pressing “Details” button, shows the process settings for the Calibrators in the following screen. The details are held on two tabs (General Settings and Level Settings).

Figure 5-7: Calibrator Details screen.

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 Calibrator settings independently from the loading of Assays by pressing the “Add New” button in the Calibration Manager Screen and then using the “Barcode Scan” or “Flash Drive” buttons in this screen.

NOTE It is possible to define a different number of replicates for each calibrator level as well as to specify the tube color that will be shown in the run setup screen. This is intended to help guide the user and thus reduce the risk of loading calibrator fluids to the wrong tracks.

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

Calibration (Standard) Curves

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

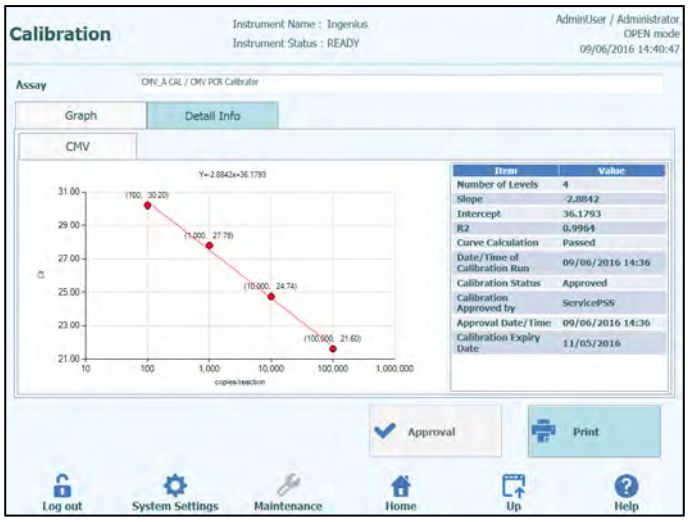


Figure 5-8: Calibration Curve - Graph screen.

This screen will show the most recent Calibration Curve for each Calibrator / Mono-mix.

It is possible for an Administrator or Service user to Approve Calibration Curves in this screen.

In case of calibration levels replicates, it is possible to exclude outliers and recalculate values when needed.

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 Calibration Curve, including the results from each reaction as well as the lot numbers and expiry dates for each reagent and calibrator fluid that was used in the run.

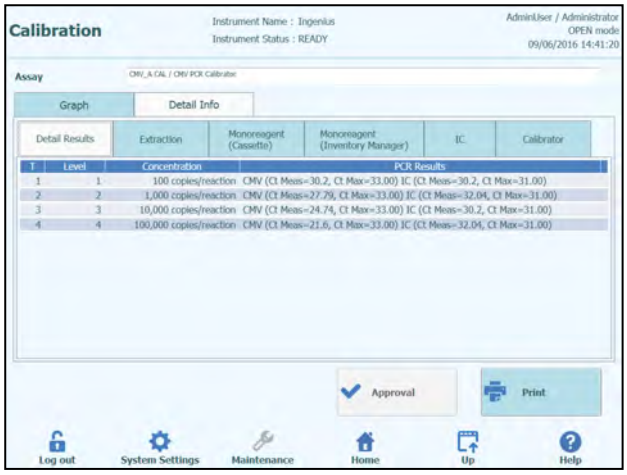


Figure 5-9: Calibration Curve – Run Details screen.

Calibration History

By clicking on the “Show Runs” button in the Calibration Manager screen, it is possible to view the Calibration Results and Calibration Curves for previous calibrations as shown in the example below:

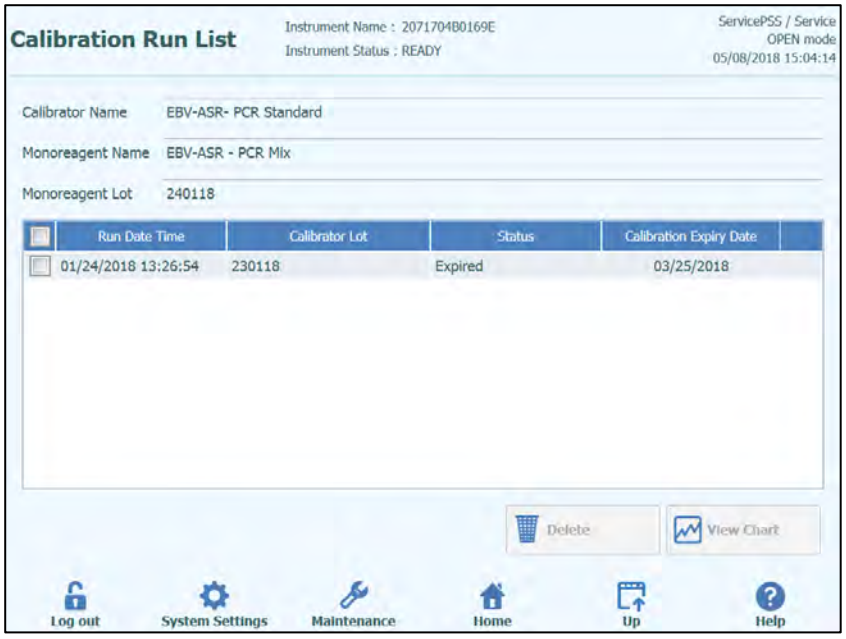


Figure 5-10: Calibration Curve – Run List screen.

In this screen, the “View Chart” and “Delete” buttons can be used to access historical data as required.

5.4.1.2 Check Status of Controls

Display the “Control Manager” screen by pressing the “Controls” button on the Home Screen.

This screen may be used to:

- View the details and status of each control plot stored on the system
  - lot number of the Mono-mix used to generate each control run
  - traceability information for the Calibration fluids used to generate each control run
  - expiry date for the control run
  - status (Need to run, Approval Pending, Approved, Expired)
- View the actual 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 Mono-reagent as was used to create the Control Plot. If you wish to use multiple lots of Mono-reagent, then it is necessary to create a Control Result for each lot number.

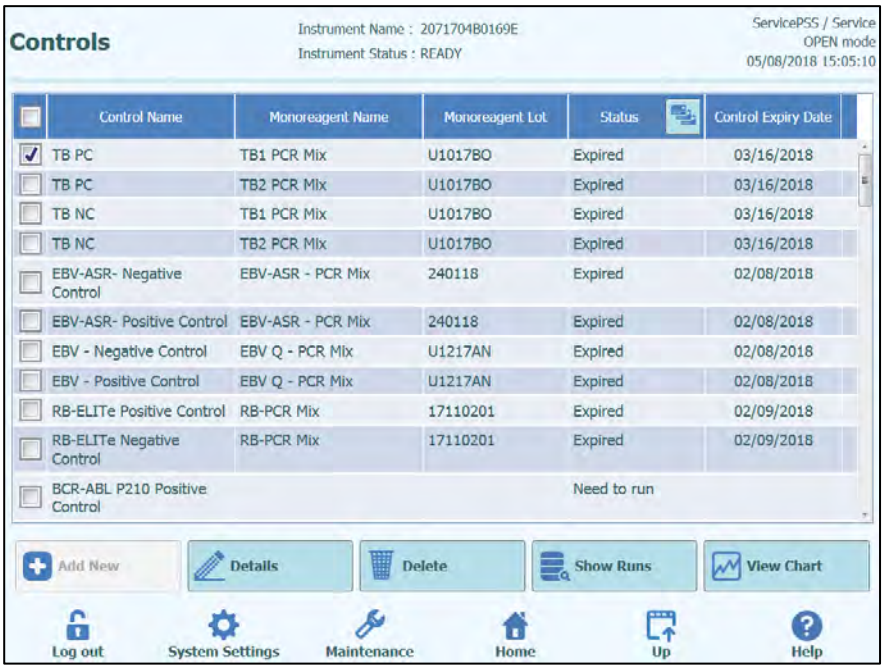


Figure 5-11: Control Manager screen.

Control Details

Pressing “Details” button, shows the process settings for the Controls in the following screen. The details are held on two tabs (General Settings and Level Settings):

Figure 5-122: Controls Details screen.

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 this 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 5-13: Control Plot – Plot screen.

This screen will show a summary of the last few Control Runs for each Control. Runs using different Lot numbers for the Mono-mix are shown with different markers in the Plot. For a Quantitative Control, the plot is shown as a Levy Jennings plot. Clicking on a single point on the plot will show the Lot numbers used to generate the specific point.

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

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

The green vertical bar 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.

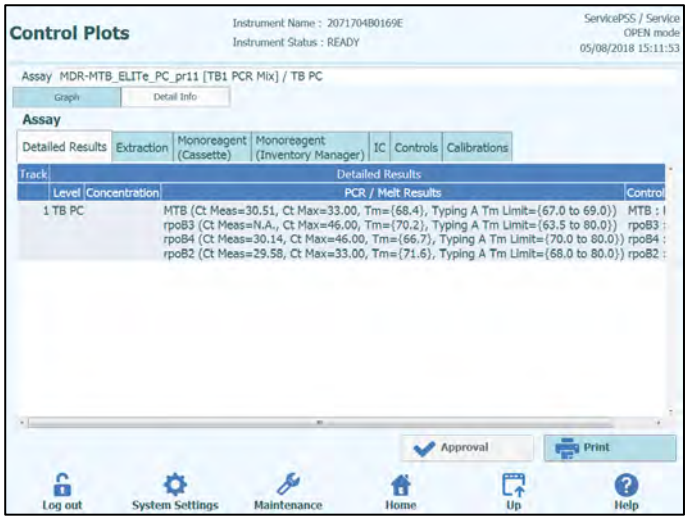


Figure 5-14: Control Plot – Run Details screen.

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:

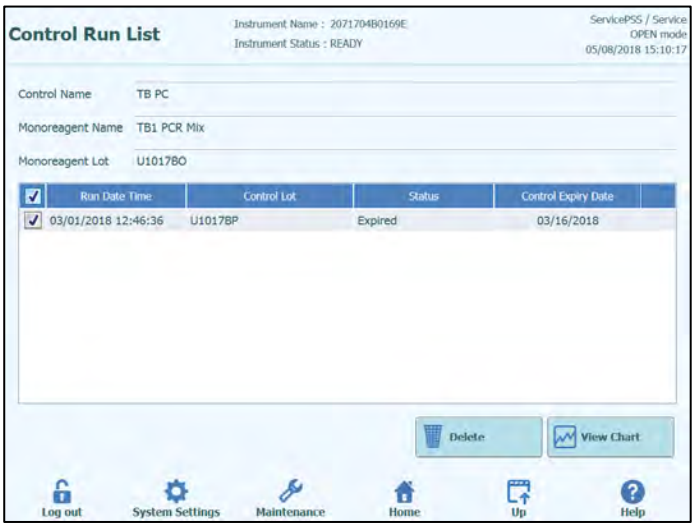


Figure 5-15: Control Plot – Run List screen.

In this screen, the “View Chart” and “Delete” buttons can be used to access historical data as required.

5.4.2 Step 2: Configure the Run

Once you have configured the Inventory Manager and confirmed the availability of all necessary Calibrations and Controls, press the “Perform Run” button on the Home Screen to display the Run Setup Screen:

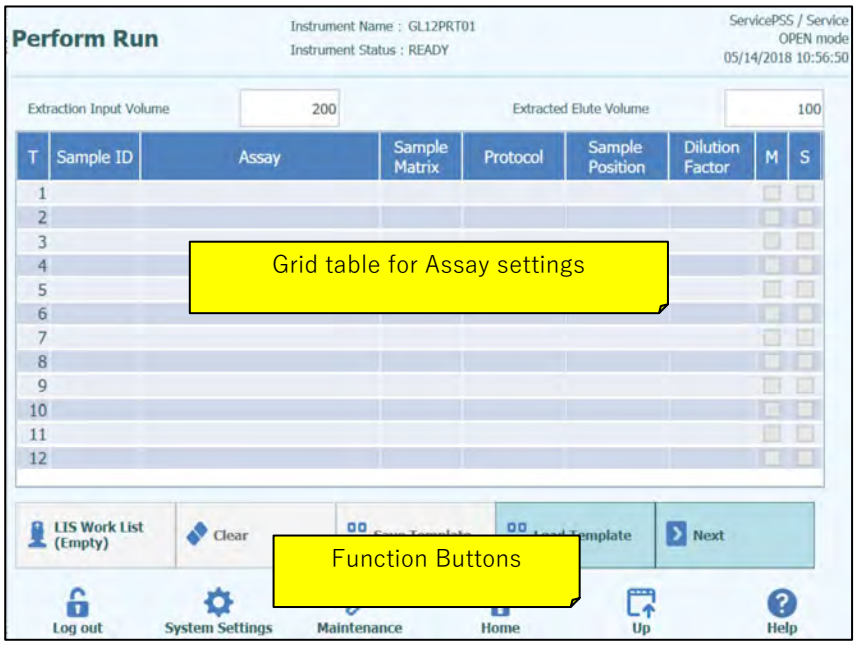


Figure 5-16: Run Setup Screen.

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.

NOTE

It is possible to perform Quantitative and Qualitative Assays in the same Run as long as all the Assays you wish to run have the same Extraction Input Volume and Extracted Eluate Volume requirements.

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).

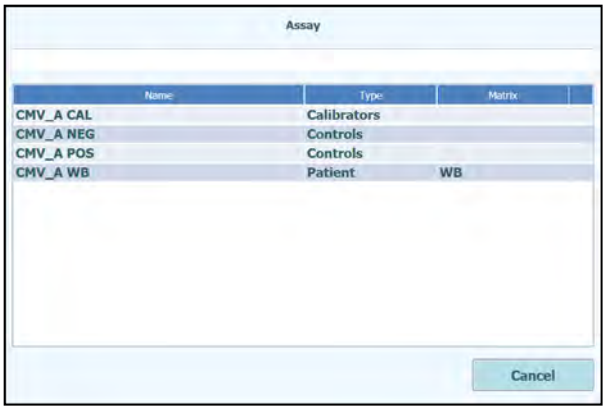


Figure 5-17: Assay Selection List

NOTE If you cannot find an Assay 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.

- Once you have selected the Assay, the columns for Sample Matrix, Protocol, Sample Position, Dilution Factor, M (Melting), S (Sonication) will be automatically completed based on the process settings for the Assay.

- Choose the Protocol you wish to run for the Assay by clicking on the “Protocol” cell for the track and choose from the pop up list.
    - **Extract Only**
      The sample will be processed to extract DNA but processing will not proceed to PCR step, so no diagnostic result will be output.

    - **Extract + PCR**
      Full sample-to-answer process.

    - **PCR Only**
      This process performs PCR amplification on previously extracted eluate to give a diagnostic result. Eluate may be loaded to the track from a previous run, or may be shared from a different track in the same run.

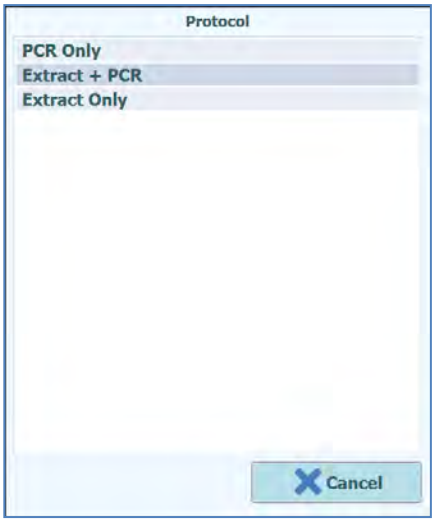


Figure 5-18: Protocol Selection List

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. This tells the system where the input sample can be found for each track.
    - **Primary Tube** (Extraction only or Extraction + PCR)
      When Sample is to be found in the Primary Tube
    - **Extraction Tube** (Extraction only or Extraction + PCR)
      When Sample is to be found in the Extraction tube
    - **Elution Tube (Position1)** (PCR Only)
      When Eluate is to be found in the Elution Tube rack (position 1)
    - **Track 1..12** (PCR Only)
      When Eluate is to be shared from another track.

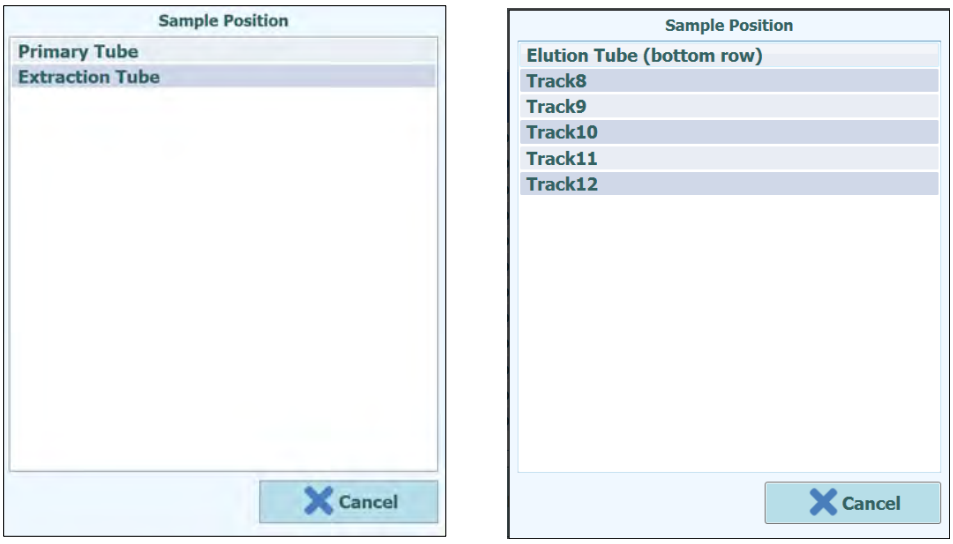


Figure 5-19: Sample Position Selection Lists

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.

- If you have logged in to “OPEN” mode, it is possible to modify the Dilution factor setting for tracks that are running Patient Samples. The Dilution Factor is used to inform the system if the Sample has already been diluted before loading to the instrument and is used to adjust the reported Quantities. Dilutions of up to x10000 may be configured.
- Once all the Assay settings have been entered, press the “Next>” button to move to Step 4 (Load Consumables and Samples)

NOTE

When the “NEXT>” button is pressed, 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.

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

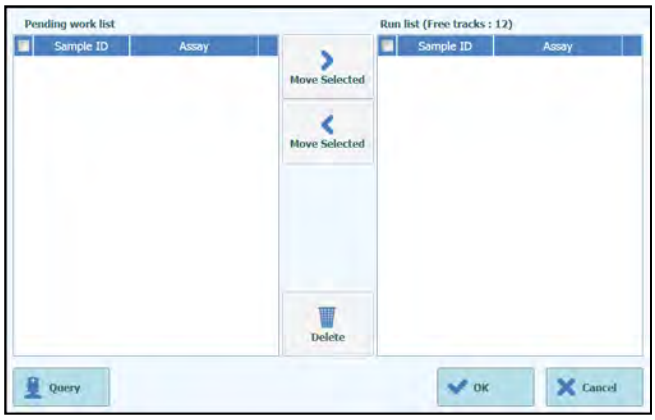


Figure 5-20: LIS Work List

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.

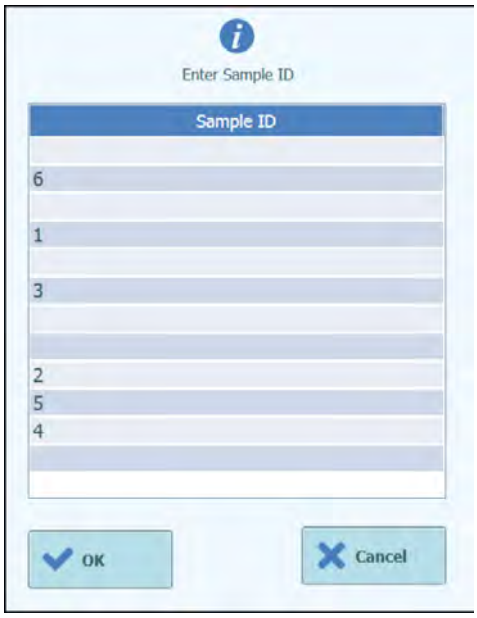


Figure 5-21: LIS Query Sample ID dialogue.

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

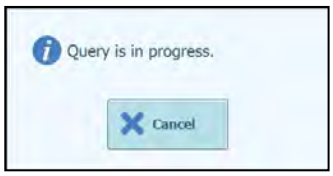


Figure 5-22: LIS Query In Progress.

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.

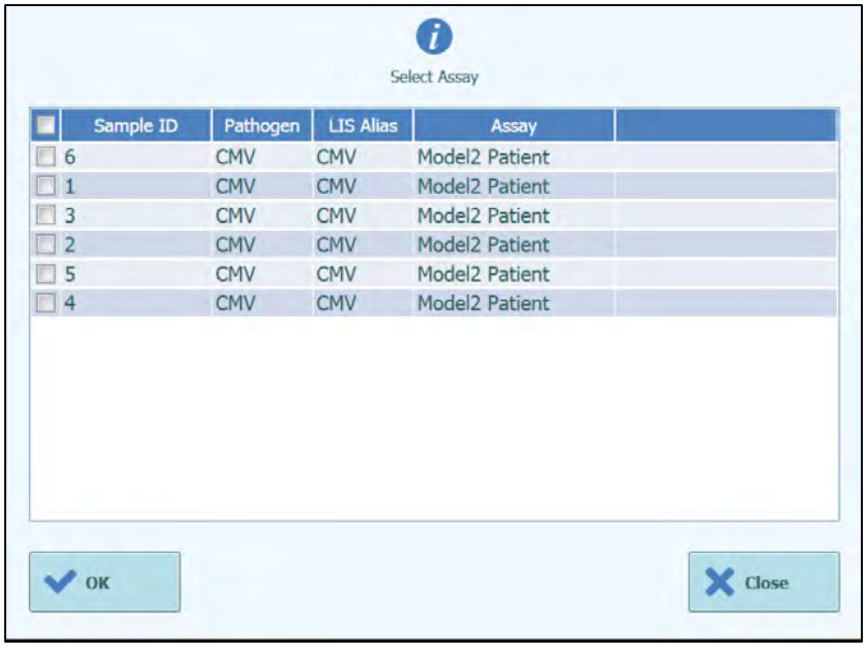


Figure 5-23: LIS Query Results.

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".

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.

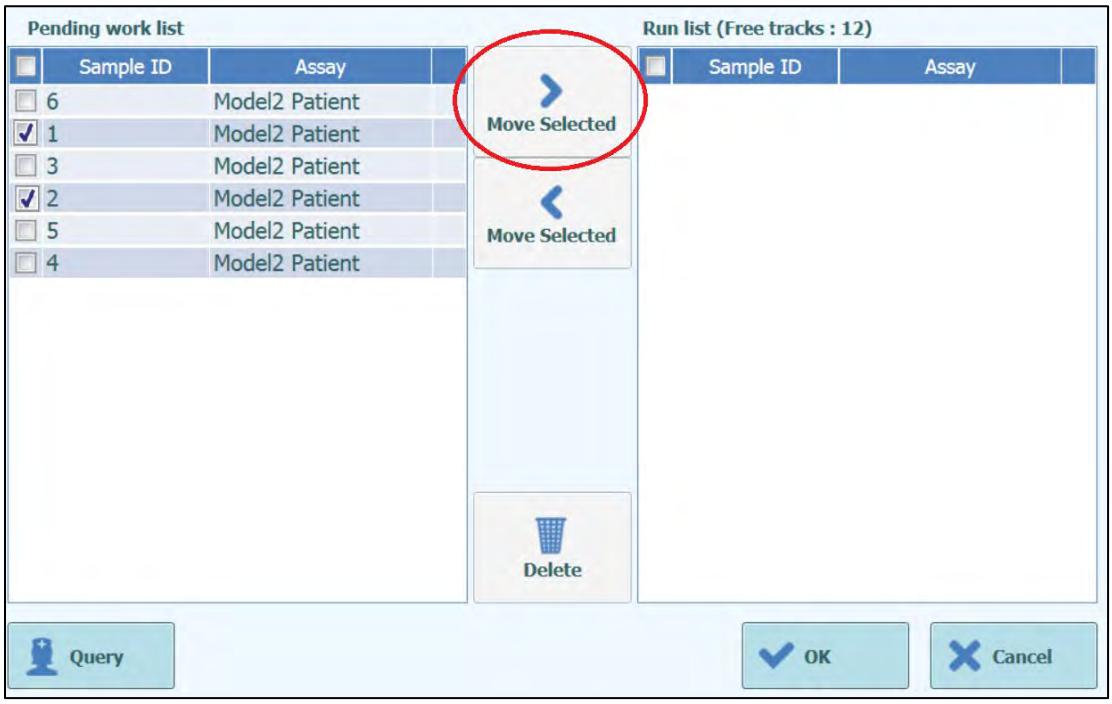


Figure 5-24: LIS Work List after a query

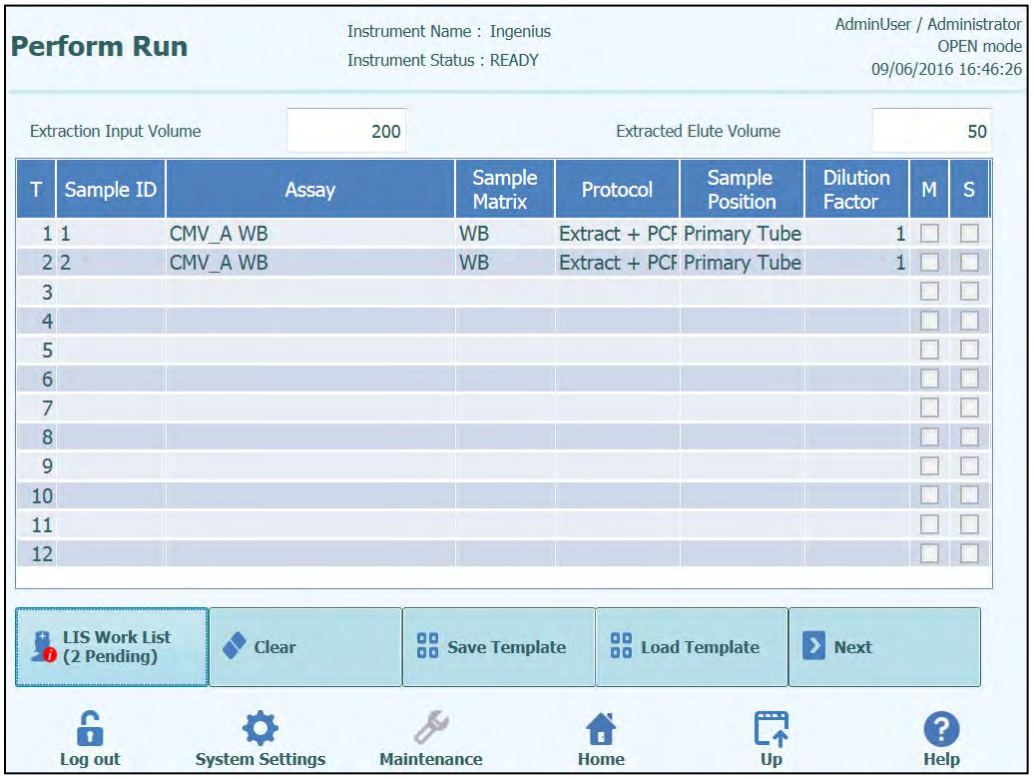


Figure 5-25: Run Setup after LIS query

In order to complete the Perform Run setup with all the information required, it will be necessary 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.

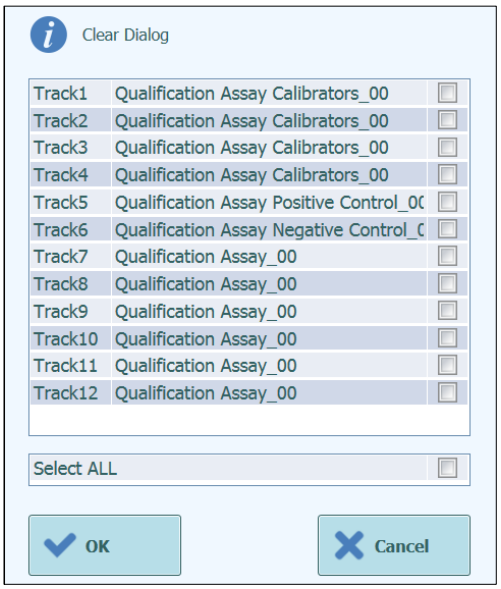


Figure 5-26: Selection of Tracks to be cleared.

NOTE Multiple level Calibrators and Controls (that use more than one track) are cleared as an entire group.

5.4.2.4 “Save Template” button

Groups of commonly used Assays may be saved to the ELITe InGenius System Template Database (see section 6.10) from the Run Setup Screen and recalled later to speed up the setting up of runs.

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

Figure 5-27: 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.

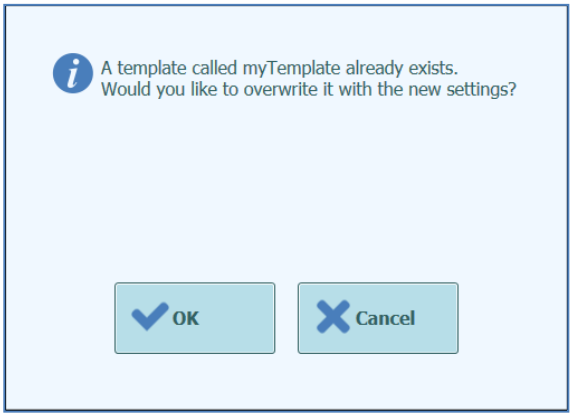


Figure 5-28: “Template Already Exists” Warning.

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:

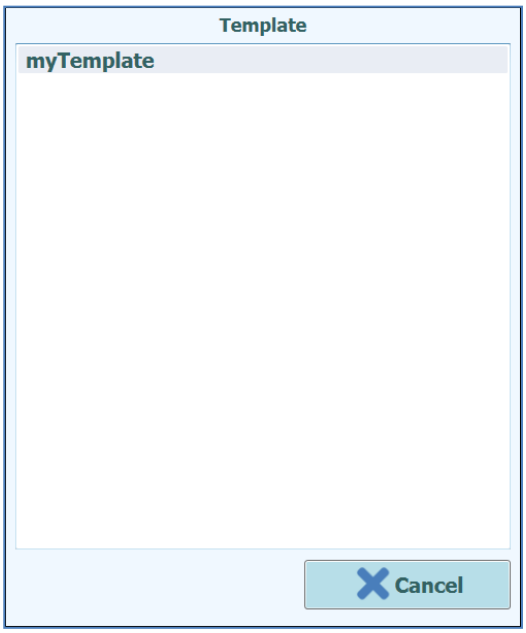


Figure 5-29: Load Template Selection Dialogue.

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.

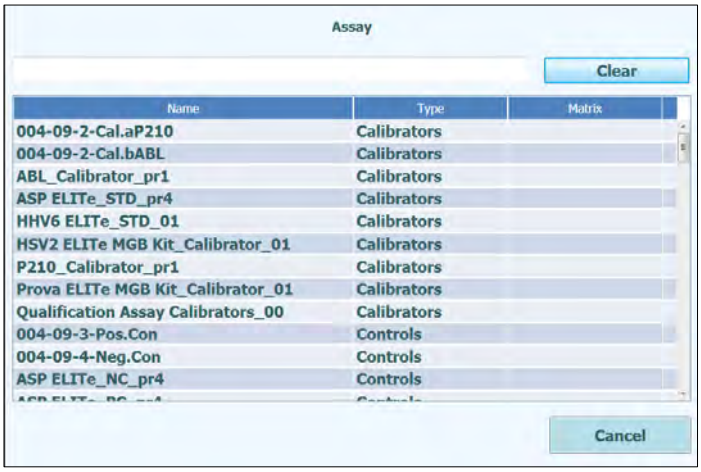


Figure 5-30: Assay Selection List

If a Patient Sample Assay is selected, a pop-up message will then be shown that indicates which Mono-reagent Lot Numbers may be used to run the Assay. Lot numbers will be offered based on the availability of Calibration Curves and Control Plots that were created and approved with the same Lot of Mono-reagent.

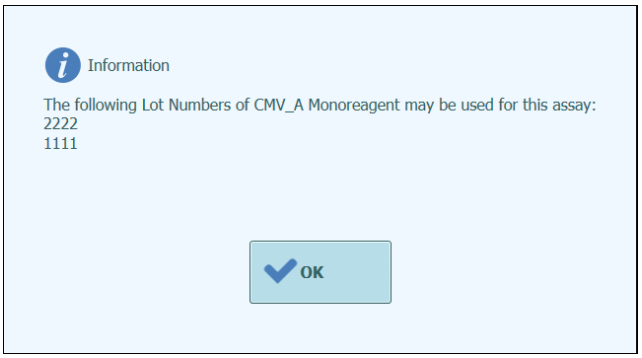


Figure 5-31: Mono-reagent Lot Number advisory message

If the required Approved Calibrator or Controls for the Assay cannot be found in the database, a warning message will be given: e.g.

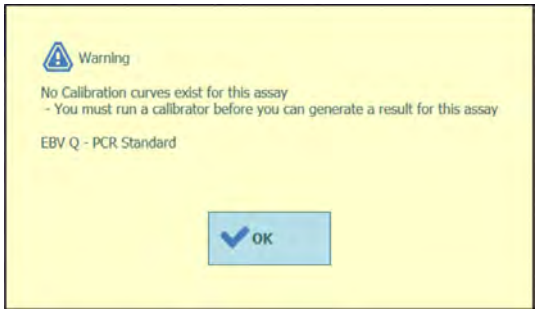


Figure 5-32: Missing Controls/Calibrators message.

It is possible to continue with the Run Setup process even with missing Calibrators or Controls, however an Administrator user will need enter their login credentials before it will be possible to start executing the run after loading the Inventory Manager (see section 0)

The following Run Setup shows a number of different Patient Sample Assay settings:

- Track 1 is setup to carry out Extract Only protocol on a sample in the Primary Tube with SID1
- Track 2 is setup to carry out Extract+PCR protocol on a sample in the Primary Tube with SID1
- Track 3 is setup to carry out a PCR only protocol on a sample in the Elution Tube with SID3
- Track 4 is setup to run a replicate of the Sample SID1 by performing a PCR only protocol on the Eluate generated by the Extraction step in Track 1
- Track 5 is setup to run a replicate of the Sample SID2 by performing a PCR only protocol on the Eluate generated by the Extraction step in Track 2
- Track 6 is setup to run a replicate of the Sample SID3 by performing a PCR only protocol on the Eluate loaded manually in Track 3 Elution Tube

When setting up several Assays that share Eluate from one track to another, the SampleID's and Dilution Factors in the Run Setup grid are copied from the source track to the destination track automatically. These values may only be changed by touching the fields for the source track.

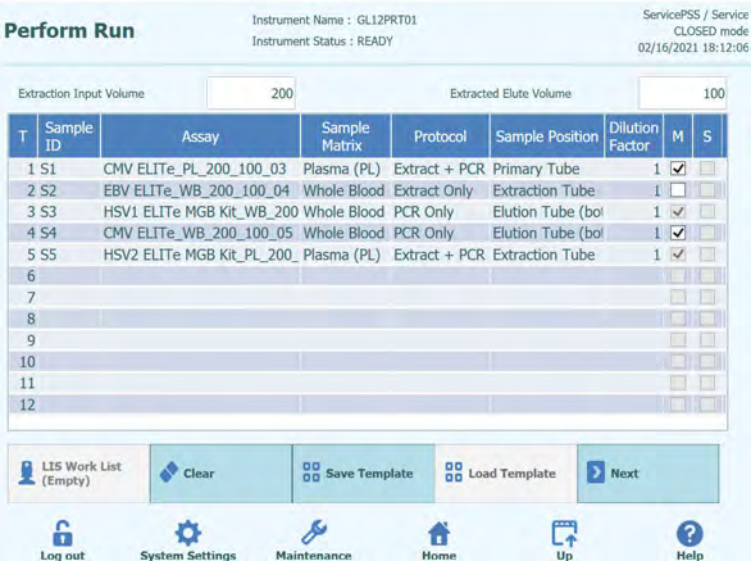


Figure 5-33: Example of Patient Sample Run Setup screen

NOTE

Before performing a PCR run with patient samples, approved Calibration and Control results should be available for validating the diagnostic result for the Patient Sample. Refer to Sections 5.3 and 6,7.

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.

NOTE

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

- Sample rack
- Extraction Tube 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 Extraction Tube Rack.

For the Assays that require Sonication process, the Sonication rack has to be ordered separately. The Sonication rack is not provided as instrument accessory.

5.4.2.7 Example Run Settings for a Calibration Assay

A Calibration Assay will typically require several different concentration reference fluids to be run. The results from this run will be used by the ELITe InGenius Software to calculate a Calibration (Standard) Curve that may be used by other Assays to convert from C_t results to actual DNA concentration values (copies/mL, gEq/mL, IU/mL or user defined units).

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

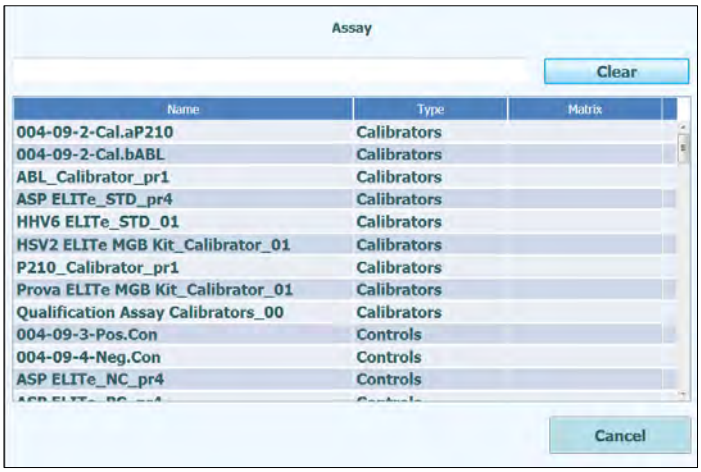


Figure 5-34: Assay Selection List

On selecting a Calibration Assay, the Calibrator Registration Dialogue is displayed.

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

Click OK to confirm the values.

Figure 5-35: Calibrator Registration Dialogue.

On confirming the values, the Run Setup screen will then be filled by the ELITe InGenius Software with the full details for the Calibrator tracks.

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

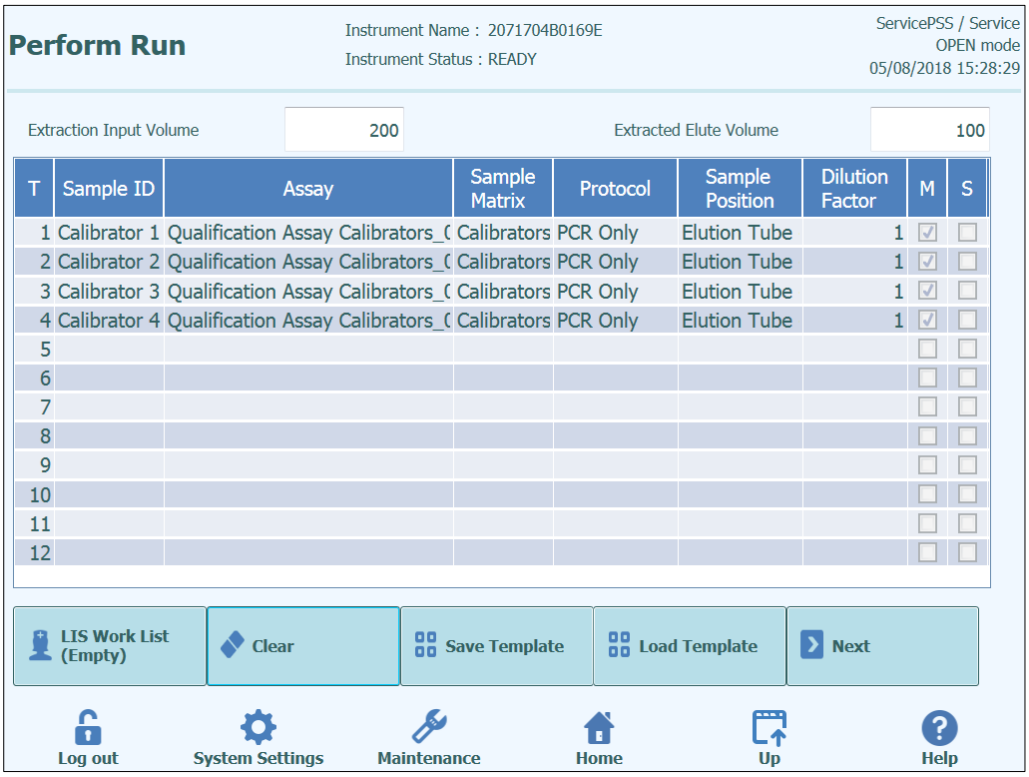


Figure 5-36: Example Run Setup for Four-level Calibrator

NOTE

For a Calibrator Assay, the Sample ID field will be automatically completed to show the Calibrator Level for each track. The other Assay settings (e.g. Protocol and Sample Position) will also hold fixed values as defined by the Assay developer.

NOTE

The ELITe InGenius Software can be configured by the Assay developer to use replicates during calibration.

5.4.2.8 Example Run Settings for a Control Assay

A Control Assay will require at least one reference fluid to be run. In the case of a Control with several levels, more than one fluid will need to be run.

The results from a Control run will be used by the ELITe InGenius Software to generate one or more Control Plot that may be Approved as showing statistically valid results. The Control Approval will then be used by other Assays to determine if a valid result may be reported.

It is normal to run at least a Positive and a Negative control for an Assay, each with their own assay program.

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

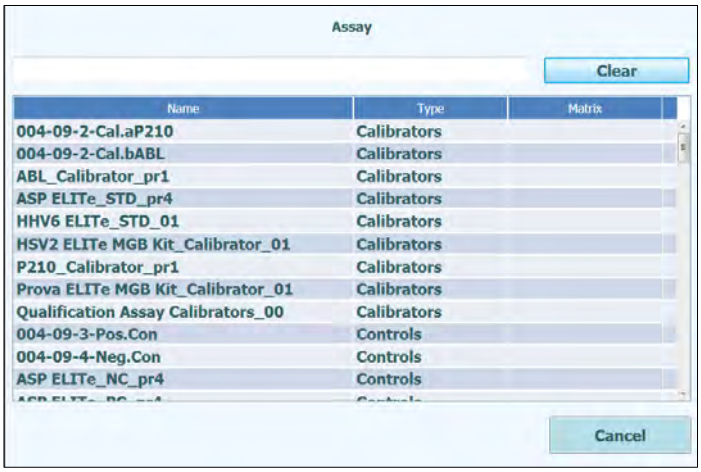


Figure 5-37: Assay Selection List

If a Quantitative Control Assay is selected, a pop-up message will then be shown that indicates which Mono-reagent Lot Numbers may be used to run the Assay. Lot numbers will be offered based on the availability of Calibration Curves that were created and approved with the same Lot of Mono-reagent.

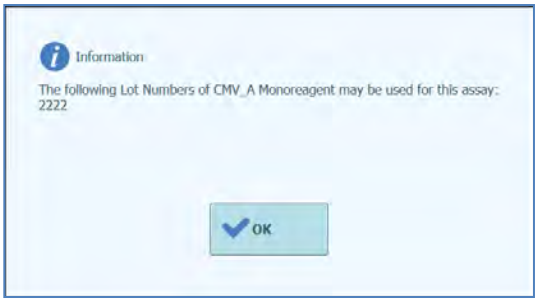


Figure 5-38: Mono-reagent Lot Number advisory message

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.

Click OK to confirm the values.

Figure 5-39: 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.

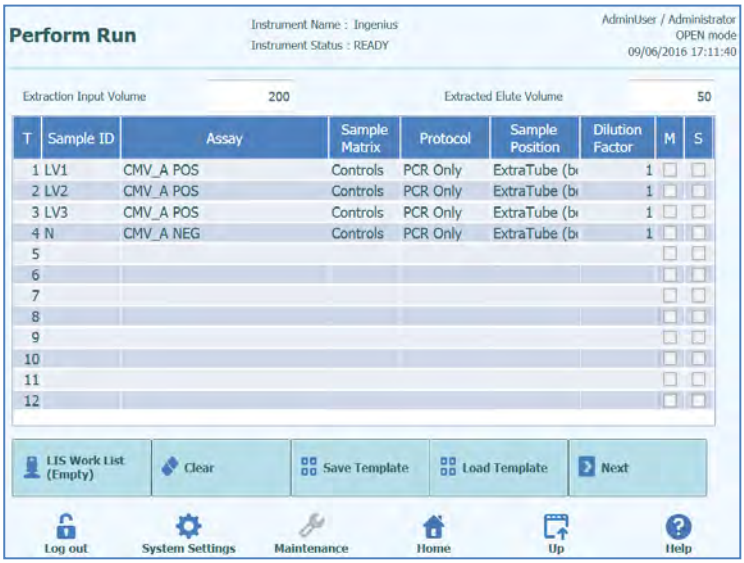


Figure 5-40: Example Run Setup for Three-level Positive Control and Single Level Negative Control

NOTE

For a Control Assay, the Sample ID field will be automatically completed to show the Control Name/Level for each track. The other Assay settings (e.g. Protocol and Sample Position) will also hold fixed values as defined by the Assay developer.

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 Mono-reagent 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.

Load an empty Solid Waste Container in the correct position on the instrument working area.

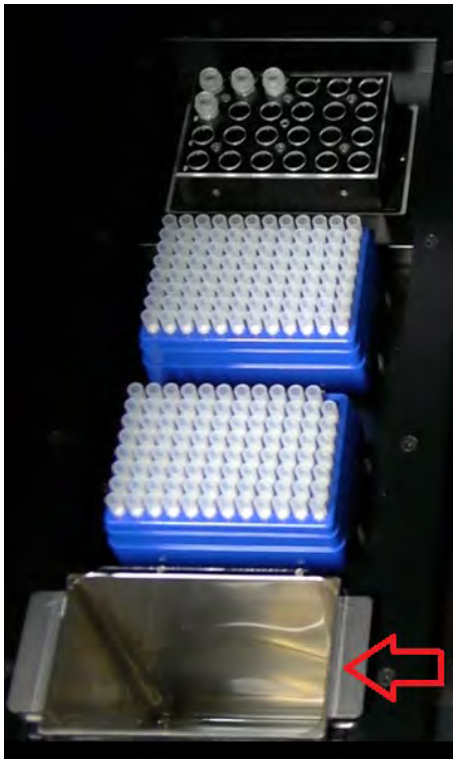


Figure 5-41: Waste container placement on the Instrument.

5.4.3.3 Step 3b: Load Reagents

This screen is used to inform the ELITe InGenius Software as to which PCR Mono-reagent and Internal Control (IC) are present in each 24 tube Inventory Manager block, and which Inventory Manager block is actually loaded on the instrument.

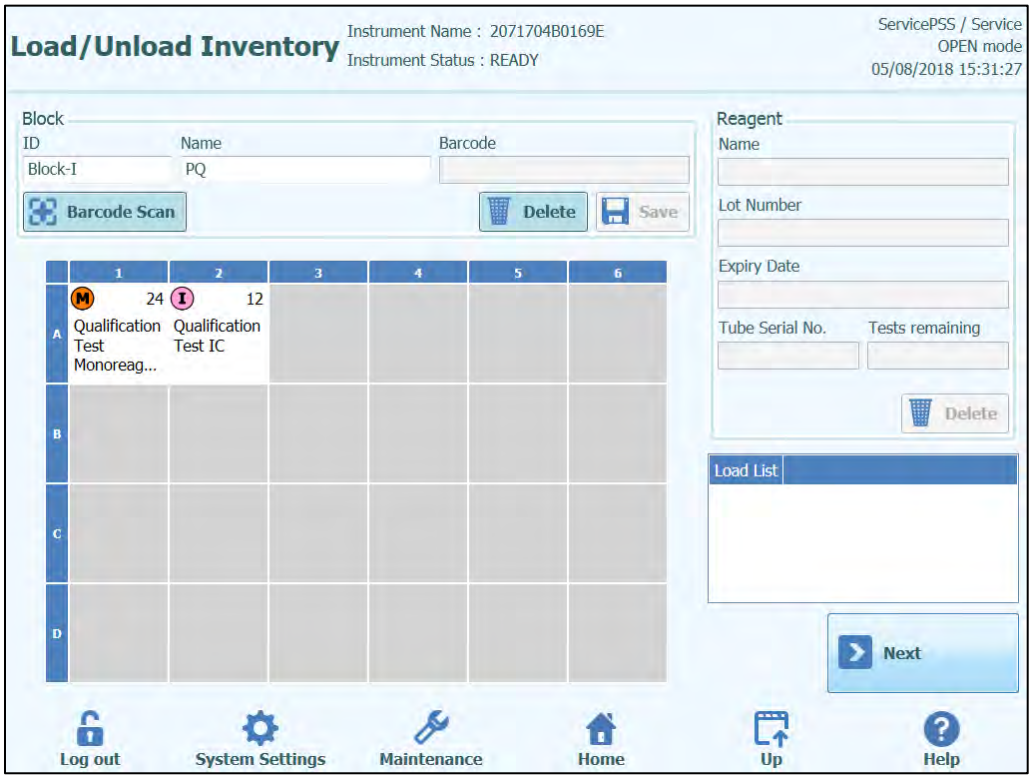


Figure 5-42: Load / Unload Inventory screen.

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

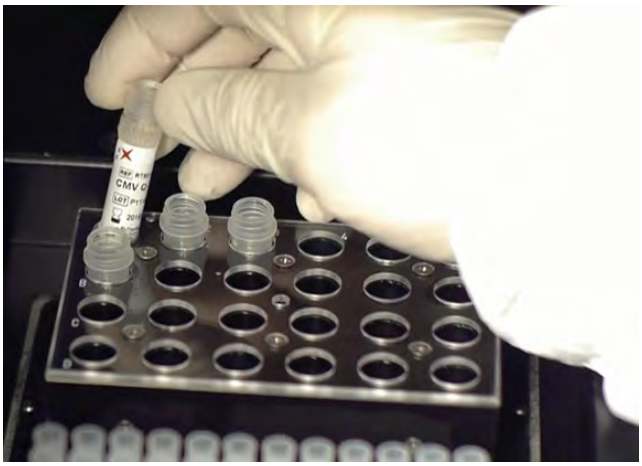


Figure 5-43: Loading / Unloading Inventory on the Instrument.

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.

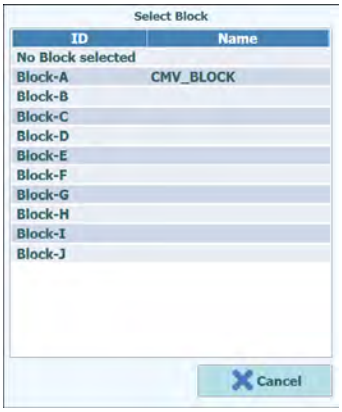


Figure 5-44: Inventory Manager Block Selection List.

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 Bar-coding

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.

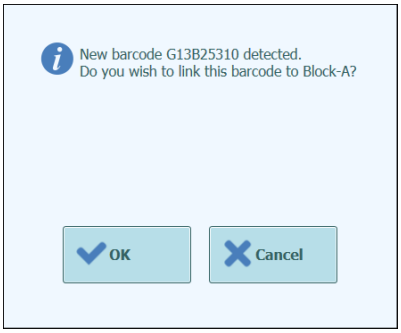


Figure 5-45: Inventory Manager Block Barcode Pairing Confirmation.

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
Mono-Reagent		
Internal Control (IC)		
Reagent expiry date has passed		Reagent should be used for running assays

Table 5-1 : 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 hand 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 5-46: 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 5-47: Reagent Selection.

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

It is also possible to complete the reagent details for the selected tube locations using the Handheld Barcode Reader instead of the on-screen keyboard. Simply select the locations 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

Most tubes of Mono-reagent supplied by Elitech will contain sufficient reagent for 25 tests.

NOTE

When a tube of Mono-reagent has run out, it is important to replace it with a new one with the same Lot number.

A different Lot number may be used however this will require any Calibrators and Control Assays to be re-run and approved before any Patient Sample results can be calculated.

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.

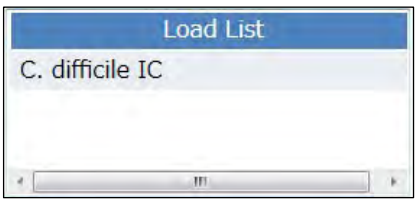


Figure 5-48: Reagent Load List

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.

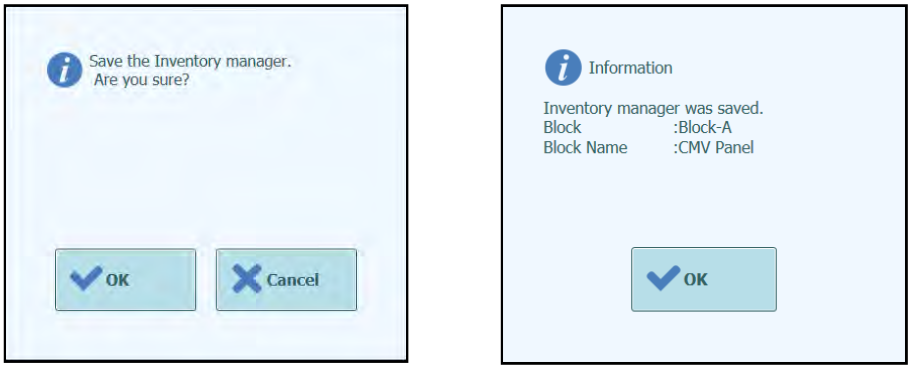


Figure 5-49: Inventory Manager Save Confirmation.

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 5-50: 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.

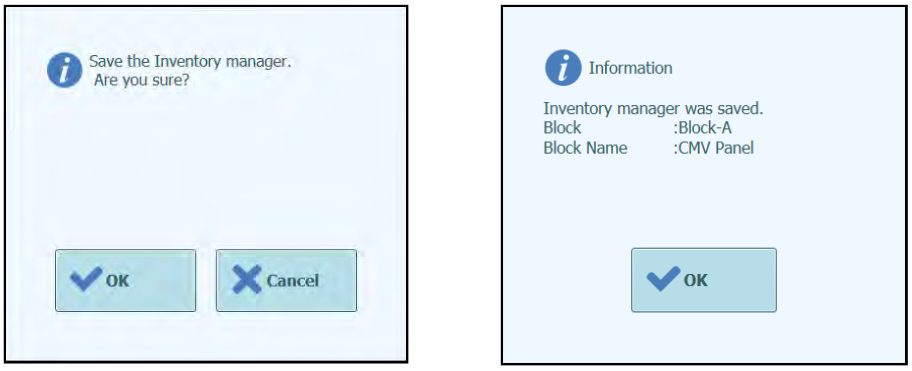


Figure 5-51: Inventory Manager Save Confirmation.

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.

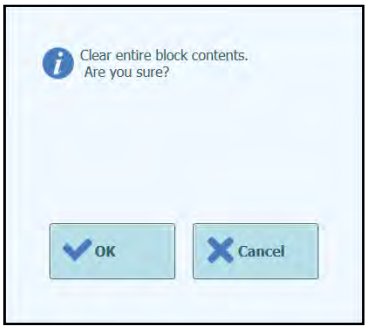


Figure 5-52: Inventory Manager Reset Block Confirmation.

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:

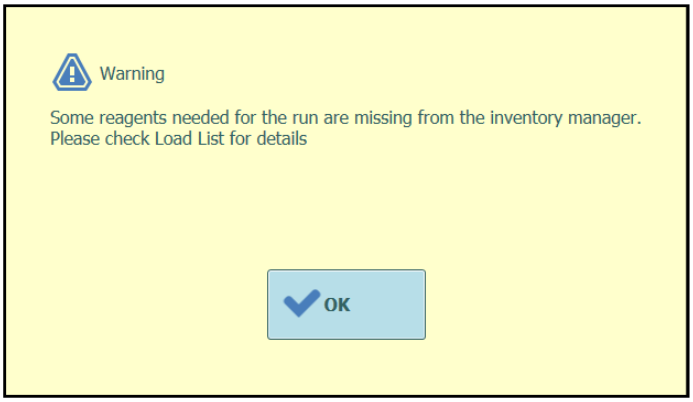


Figure 5-53: Insufficient Reagents in Inventory Manager

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.

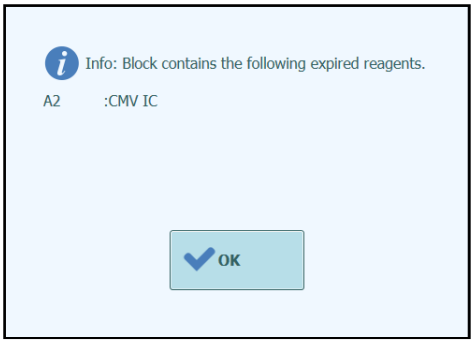


Figure 5-54: Expired Reagents in Inventory Manager

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

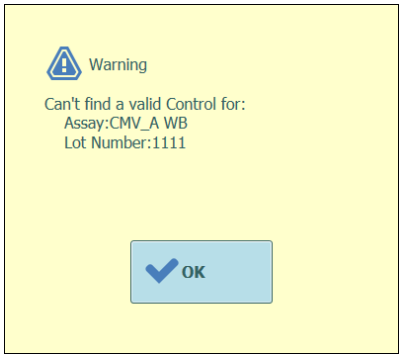


Figure 5-55: Example of missing Control for Assay

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

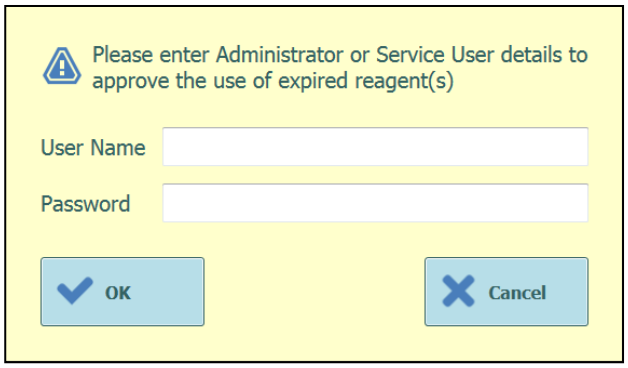


Figure 5-56: Administrator Override for Expired Reagents

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.

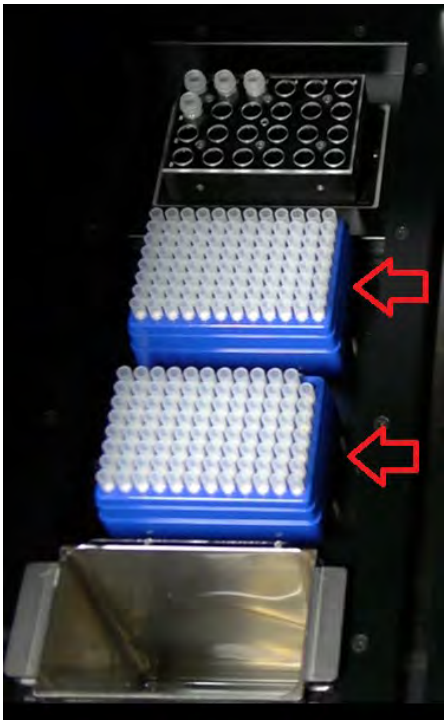


Figure 5-57: Inventory Manager Single Tips placement on the Instrument.

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.

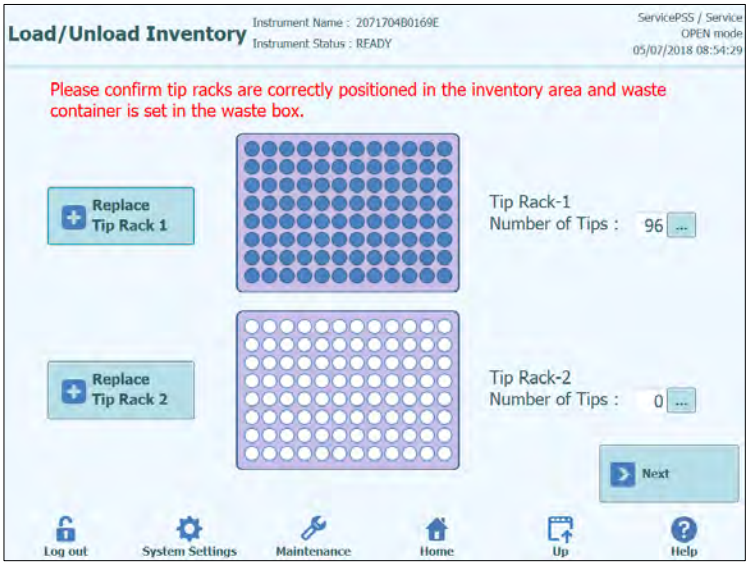


Figure 5-58: Tip Rack Screen.

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.

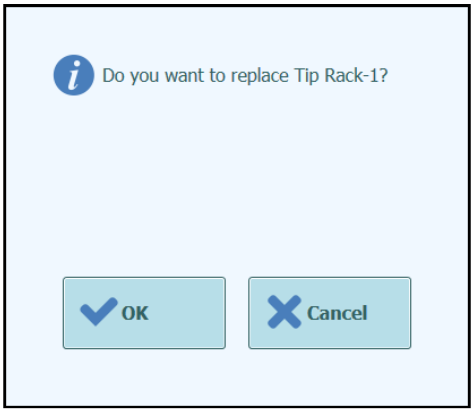


Figure 5-59: Confirmation of Tip Rack Replacement

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 Reaction Cassettes are needed for any runs that are configured as “PCR Only” or “Extraction with 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 and 2 are running a PCR step so require a PCR Reaction Cassette to be loaded as shown in the picture, while track 3 is running “Extraction Only”, and does not require a PCR Reaction Cassette.

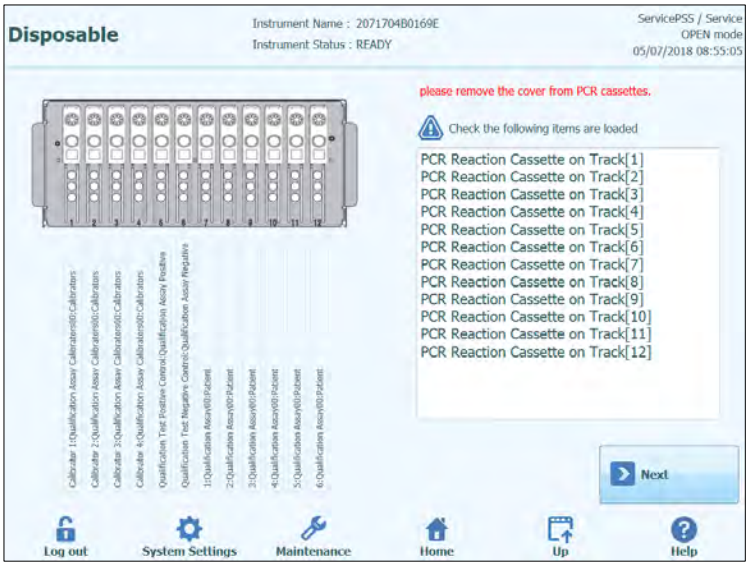


Figure 5-60: PCR cassette loading guidance.

Figure 5-61: 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 “Extraction Only” or “Extraction with 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

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.

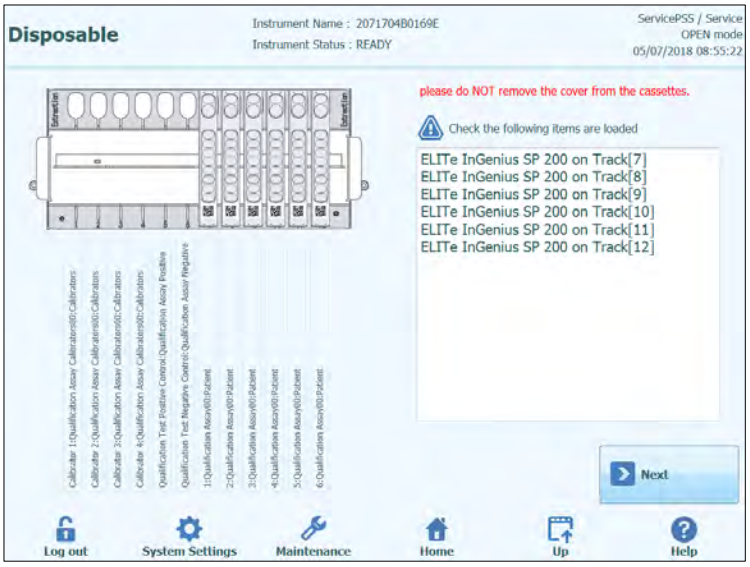


Figure 5-62: Extraction cassette loading guidance.

Figure 5-63: Loading Extraction cassette rack on the instrument.

5.4.3.8 Step 3g: Load DNAse I reagent Rack (only for RNA extraction cassette)

After loading the Extraction Cassette Rack, in case the run involves the RNA extraction cassette, the additional DNAse I reagent tube loading is required. The reagent tube has to be loaded into position 2 of Elution Tube Rack (position 2 is the farest to the front of the instrument)

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.

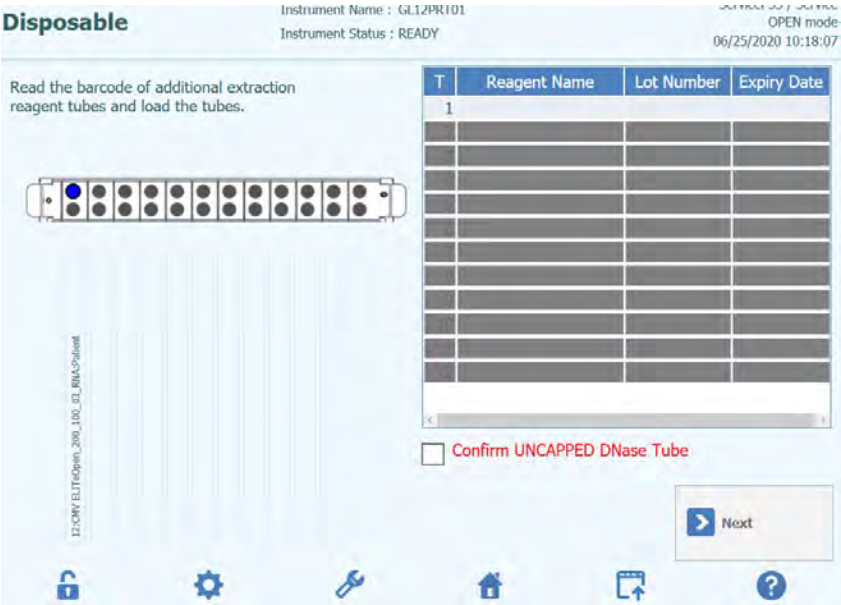


Figure 5-64: DNAse I loading guidance

The information about DNAse I tube can be registered into the software by scanning the QR code placed on the consumable bag via external barcode reader.

To scan the reagent barcode, press the Track number (column ‘T’) and the following window is shown

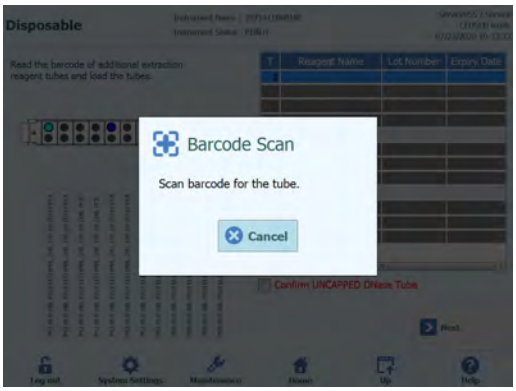


Figure 5-65: Scan window

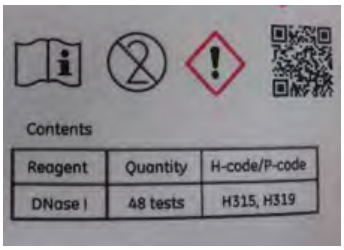


Figure 5-66: DNAse QR code example

By scanning the QR barcode, all information of Reagent Name, lot number and expiry date are properly inserted.

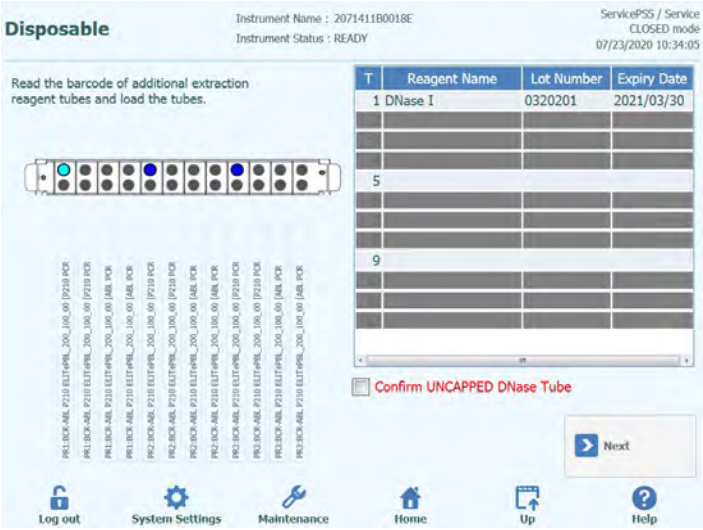


Figure 5-67: DNAse I loading guidance after scanning

To proceed with the routine, the checkbox ‘Confirm UNCAPPED Dnase Tube’ must be checked to confirm that all the DNase I tube are loaded without the caps.

5.4.3.9 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 Calibrators, the Calibrator Fluids and Elution Tubes 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 or reagent DNAse I 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 to 4 are running a 4 level calibrator. The colour coding can be used to identify which Calibrator fluids should be loaded to each track.
- tracks 5 to 7 are running a 3 level control. (colour coded as per control details).
- track 8 is running a 1 level negative control (colour coded as per control details).
- track 9 is running an Extract+PCR assay so needs an empty elution tube.
- track 10 is running a PCR only patient sample so requires an eluate sample to be loaded at the indicated position.

Figure 5-68: Elution Tube (position 1) loading guidance.

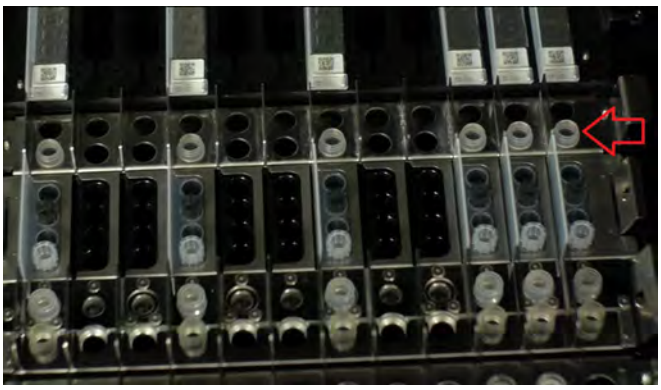


Figure 5-69: Loading Elution Tube Rack on the instrument. Elution tubes are placed in position 1, which is the closest to the front of the instrument

5.4.3.10 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 and 3 are running Extraction step so require Tips to be loaded as shown in the picture, while track 3 is running “PCR Only”, and does not require Tips.

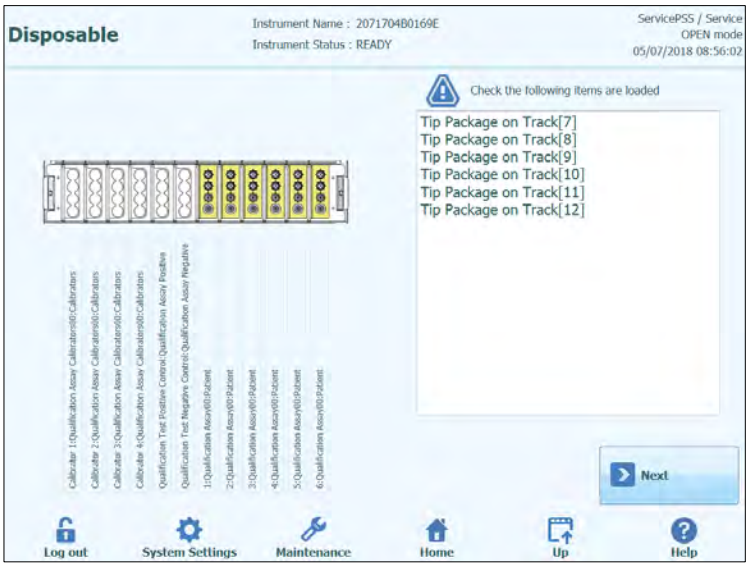


Figure 5-70: Tip loading guidance.

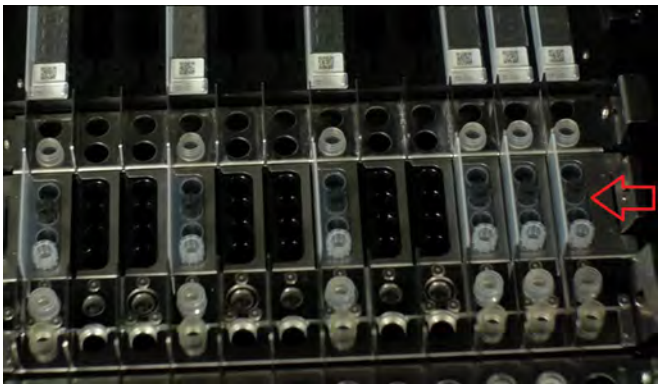


Figure 5-71: Loading Tips on the instrument

5.4.3.11 Step 3i: Load Extraction/Sonication Rack

After loading the Tips Rack, the next step is to load the Extraction or Sonication Rack and disposables:

- Load Sonication Rack with Sonication Tube and Cap if the Assay requires Sonication process;
- Load Extraction Rack with Extraction Tube <u>without Cap</u> if the Assay does not require Sonication process;

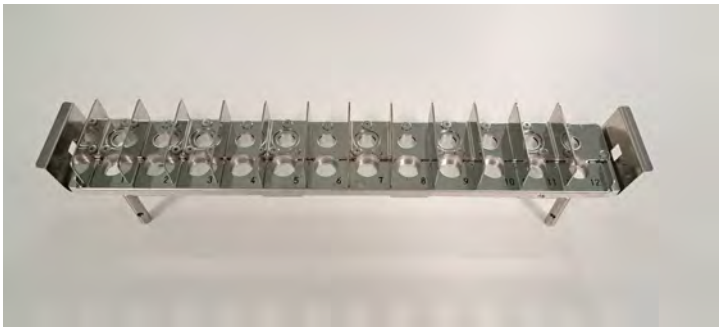


Figure 5-72: Sonication Rack.

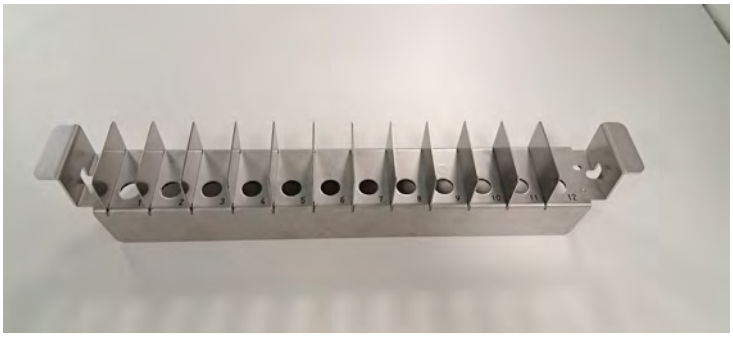


Figure 5-73: Extraction Rack.

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

Sonication Tubes and Caps or Extraction Tube are needed for all tracks that are configured to run Extraction: in case of extraction processes that includes sonication process, load Sonication Tube and Cap in the proper Sonication rack; in all the other cases, load Extraction Tube in the proper Extraction rack.

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 5-74: 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 or Extraction Tube. If the Patient Sample is to be loaded to the SonicationTube or Extraction Tube, the Sample ID will be shown in this window.

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

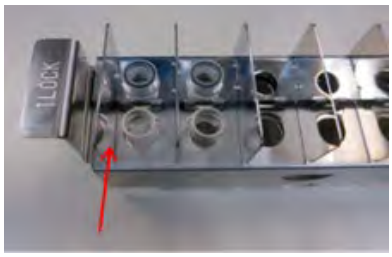
The Assay selected for each track is shown below the disposables graphic.

Load the Sonication Tubes and Caps or the Extraction Tube into the Rack. In case of Sonication Rack, lock the Tubes and Caps in place.

NOTE

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

Releasing Sonication Tube Lock from Rack



Locking Sonication Tube

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 or Extraction Rack onto the Instrument working area.

Once loaded, 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/Extraction 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 6 and 7 are running Extraction step so require Extraction Tubes to be loaded as shown in the picture, while track 8 is running “PCR Only”, and does not require a Tube.

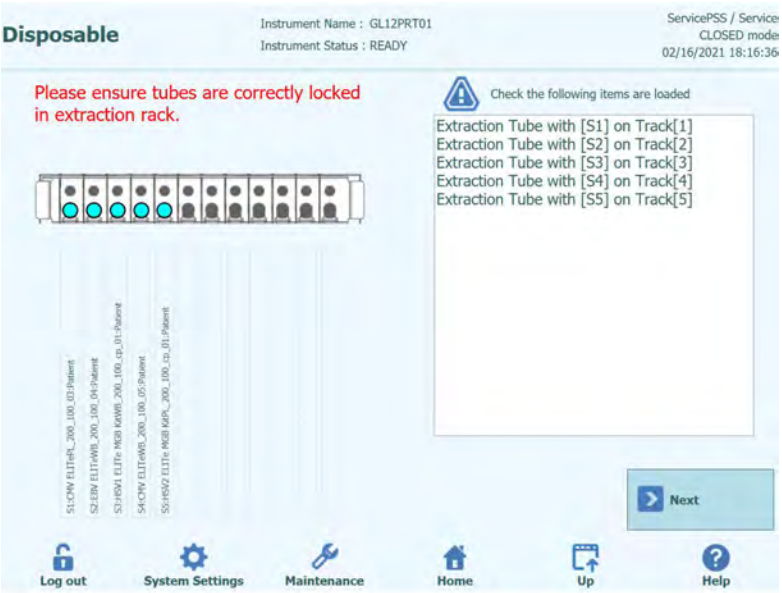


Figure 5-75: Extraction Tube loading guidance

Figure 5-76: Example of Extraction Tube placement in the Extraction Tube Rack.

5.4.3.12 Step 3j: Load Primary Sample Tubes

After loading the Sonication or Extraction 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 “Extraction 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, tracks 1 and 3 are running Extraction step, with Sample Position = “Primary Tube” so require a Tube and Sample to be loaded as shown in the picture, while track 3 is running “PCR Only”, and does not require a Primary Tube.

Figure 5-77: Primary Tube and Sample loading guidance.

Figure 5-78: Example of Primary Tube loading on the instrument.

5.4.3.13 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.

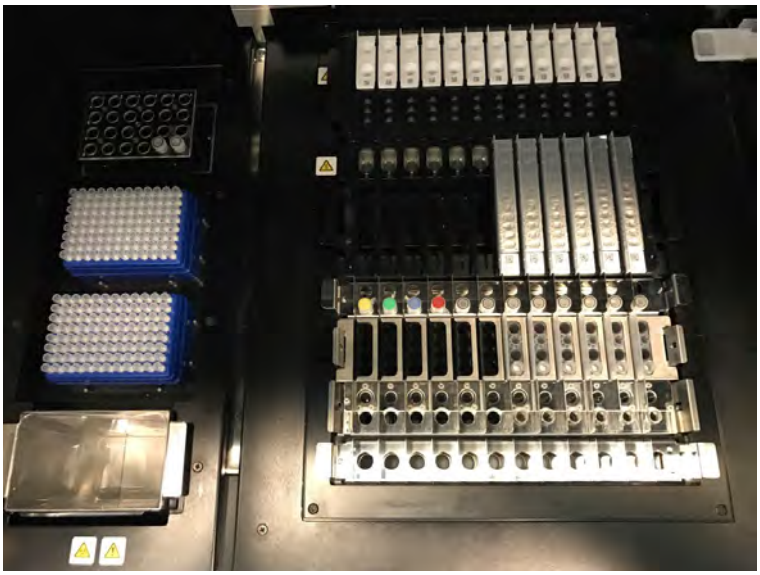


Figure 5-79: Example of final instrument configuration. In this picture it is represented a run configuration that includes: 5 primary samples, 5 extraction cassettes, 12 amplification cassettes.

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.

5.4.3.14 Step 3l: Optional Pauses – Primary tube dispensing (OPEN MODE)

In OPEN MODE, it is possible to select optional pause after dispensation from primary to the secondary tube in order to unload primary tubes samples from the system.

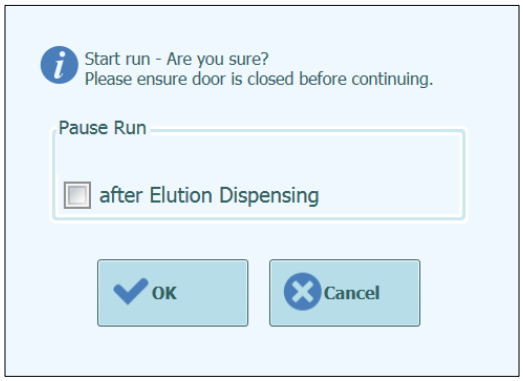


Figure 5-80A: Start Run confirmation message and selection of optional pause

Once OK is clicked, the Door will be locked and the Run will be started.

5.4.3.15 Step 3M: Optional Pauses – PCR set-up dispensing (OPEN MODE)

In OPEN MODE, it is also possible to select optional pause after PCR set-up in order to unload eluates from the system.

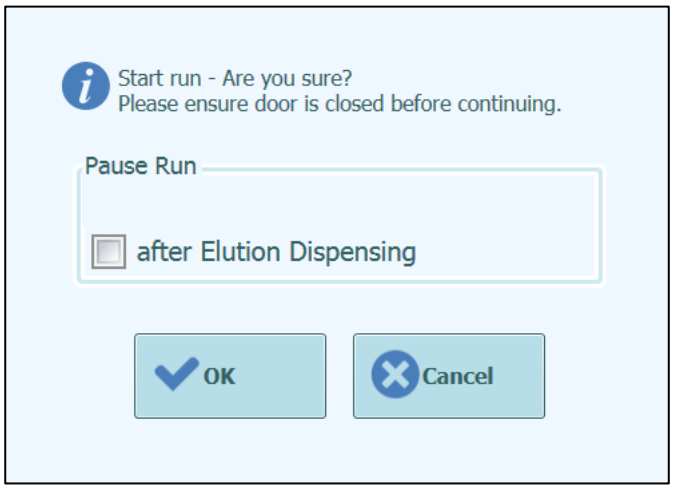


Figure 5-80B: Start Run confirmation message and selection of optional pause

NOTE	When a Run is in progress, it is possible to return to the Inventory Manager screen to view the Inventory Manager configuration, tests remaining etc. It is not however possible to make any changes to the Inventory Manager settings during a Run.
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 paused, aborted, or it has completed normally.

5.4.4 Step 4: 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.

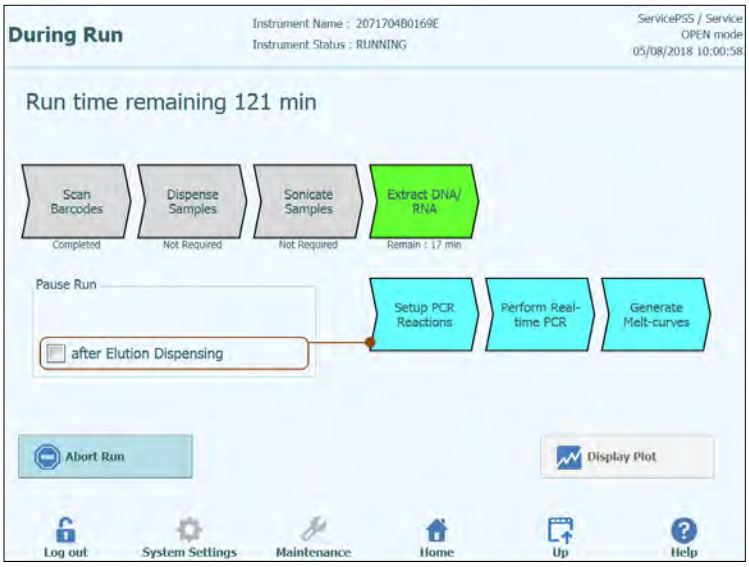


Figure 5-81: "During Run" display.

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 5-2 : Process Steps

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

Table 5-3 : 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 showed to avoid stopping the run accidentally. Press “Yes” to stop the run or “No” allow the run to continue.

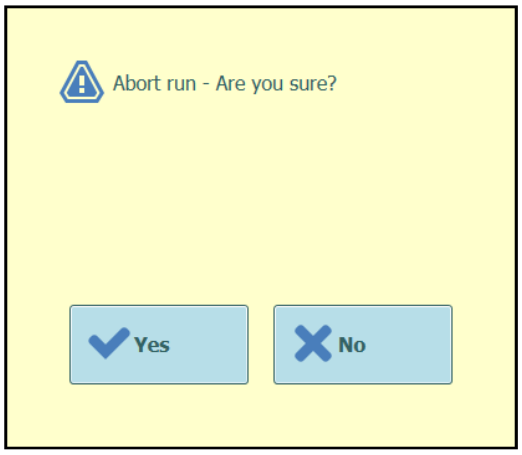


Figure 5-82: Abort run confirmation.

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.

NOTE 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.

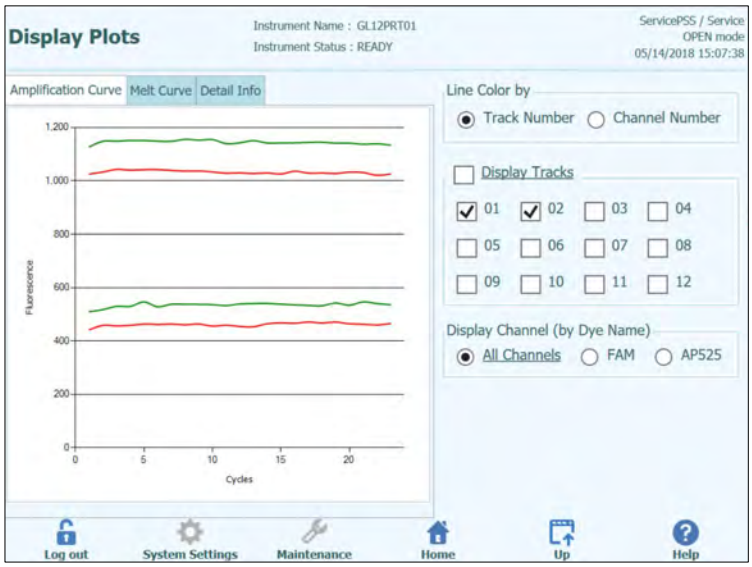


Figure 5-83: Display Plots During Run: Amplification Curves

Figure 5-84 : Display Plots During Run: Detail Info

5.4.5 Step 5: Results Review and Approval

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

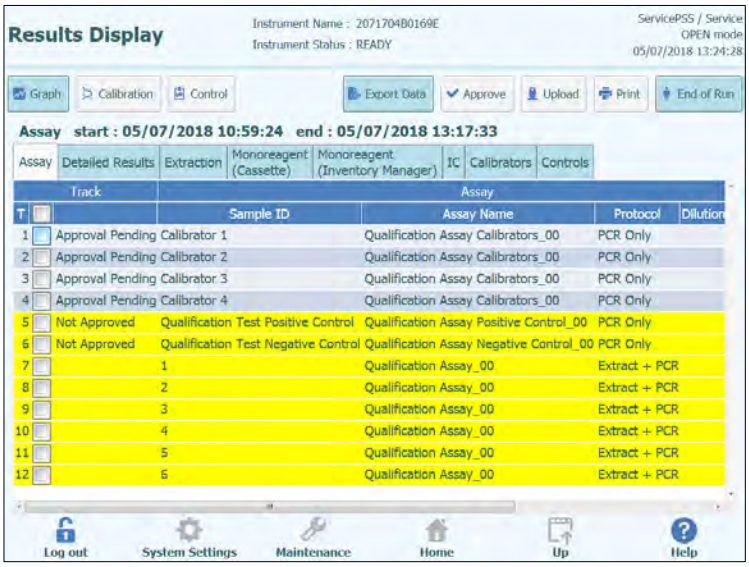


Figure 5-85: Example of Results Display.

NOTE The approval of Results (Patient Samples, Calibrators and Controls) should be performed only when the instrument is not performing a run.

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).
- 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.

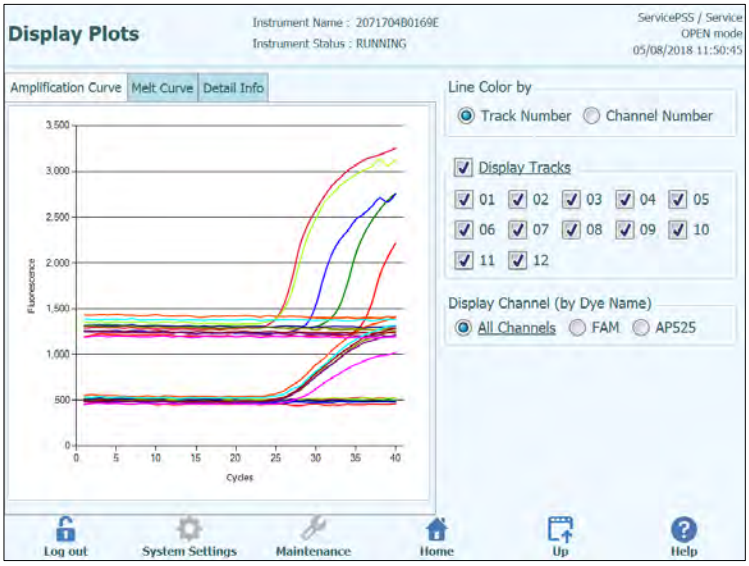


Figure 5-85: Results Display Graph.

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.

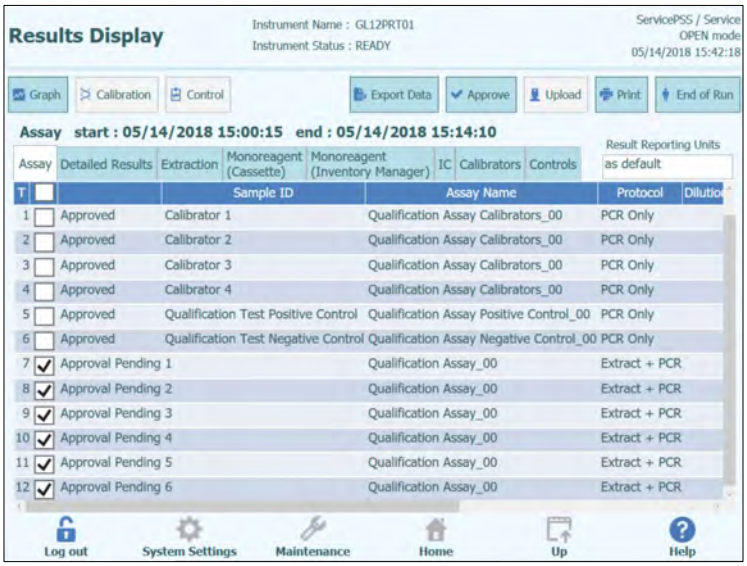


Figure 5-86: Approving Patient Results

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 5-88: 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.

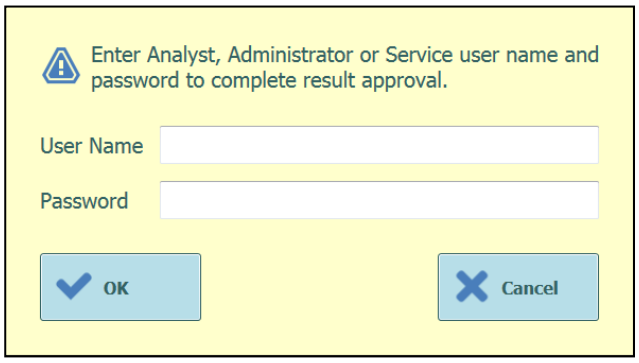


Figure 5-89: Authorisation of Result Approval

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.

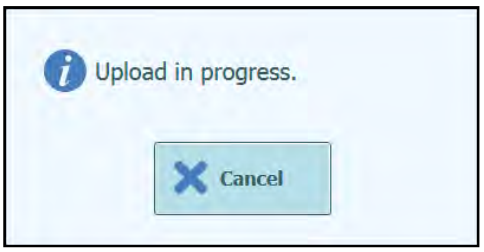


Figure 5-90: Uploading Results to LIS

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.

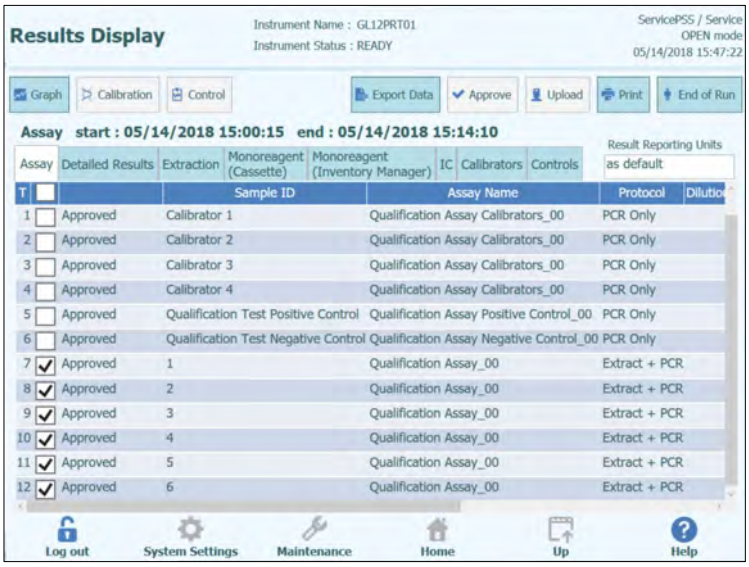
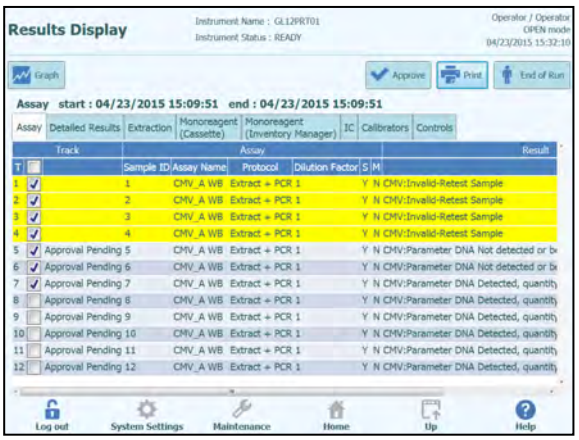


Figure 5-91: Example of Approved Results

NOTE

If the result for a track cannot be determined (e.g. if Ct cannot be determined), the track is highlighted in Yellow as demonstrated in the example here:



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

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

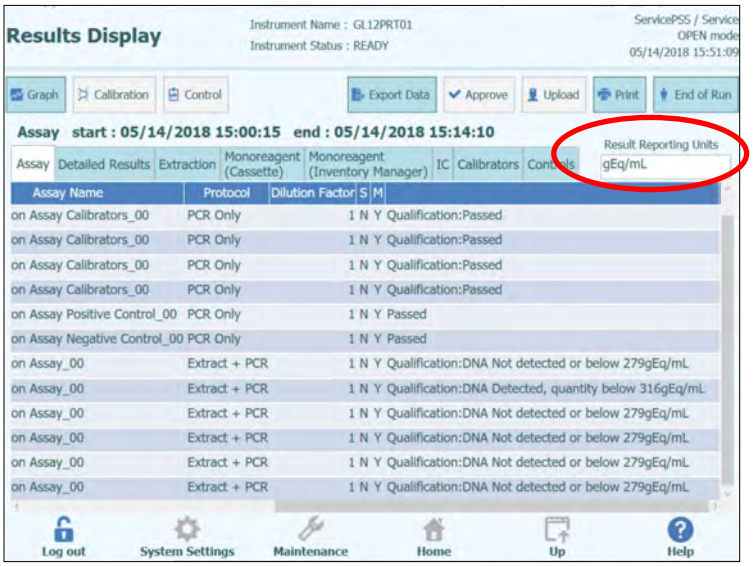


Figure 5-92: Result reporting units for PCR only assays

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 Manual approval for undetermined sample results and for sample with 3010X errors

The manual approval is possible for:

- undetermined samples but having Tm and
- in case of sample with errors 3010X (30103-30107 and 30108).

For all these cases, the sample results will be highlighted in pink.

➢ In case of undetermined samples having Tm, select each track to be approved using the tick boxes on the left hand side of the Results Display.

NOTE The manual approval for undetermined samples having Tm is possible only for Model 1 and Model 2.

Figure 5-93: Example of undetermined sample highlighted in pink.

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.

A pop – up will open with the target to approve highlighted in green.

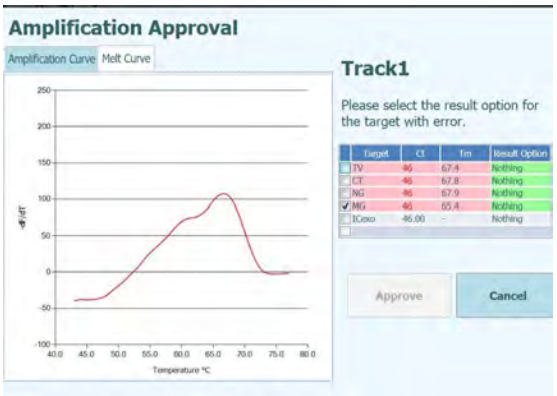


Figure 5-94: Targets highlighted in green.

Clicking on the green string, a pop-up with the results option (Detected and Not Detected) will open.

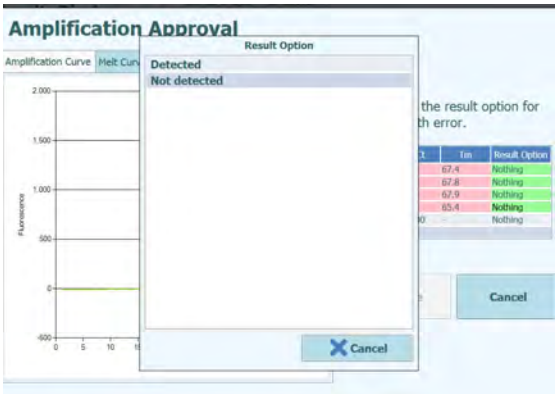


Figure 5-95: Result options.

After clicking on “Detected” or “Not Detected” press the button “Approve” to approve the results.

Figure 5-96: Approve button after the manual approval.

In the Run Summary the samples approved manually report “Result manually confirmed”.

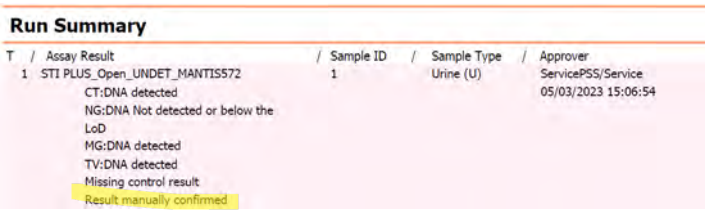


Figure 5-97: Run Summary for a sample manually approved.

In the Track Report, the samples manually approved reporting Ct = 0.

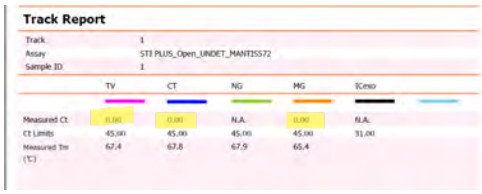


Figure 5-98: Ct = 0 for samples manually approved.

- In case of error 30103 select each track to be approved using the tick boxes on the left hand side of the Results Display.

NOTE The manual approval for samples with error 30103 is possible for all models except for model 3.

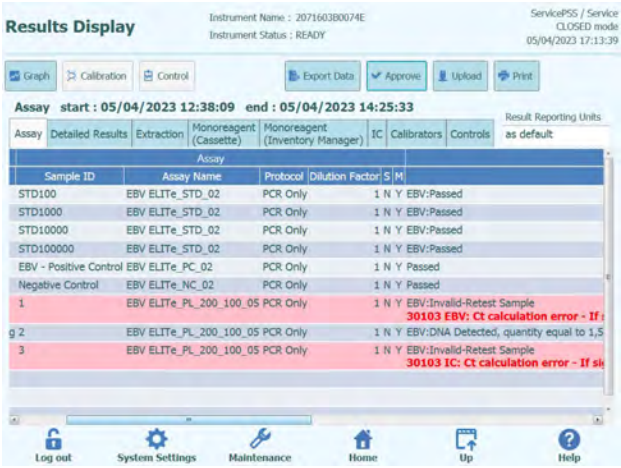


Figure 5-99: Example of 30103 error sample highlighted in pink.

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.

A pop – up will open with the target to approve highlighted in green.

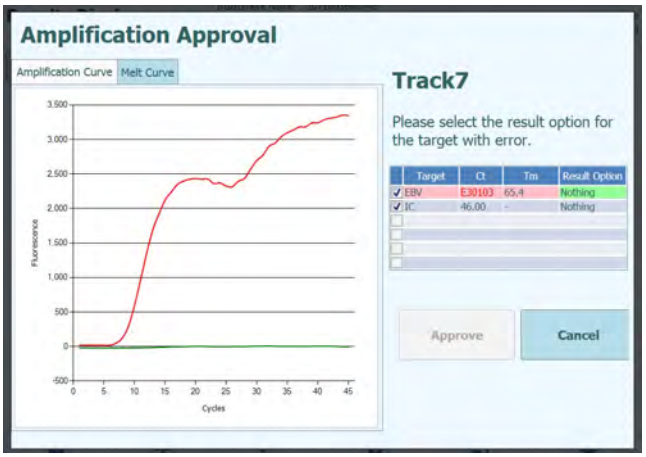


Figure 5-100: Targets highlighted in green.

Clicking on the green string, a pop-up with the results option (Detected and Not Detected) will open.

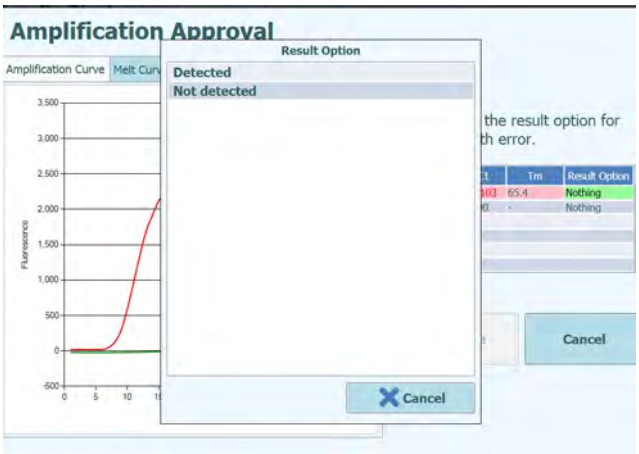


Figure 5-101: Results options.

After clicking on “Detected” or “Not Detected” press the button “Approve” to approve the results.

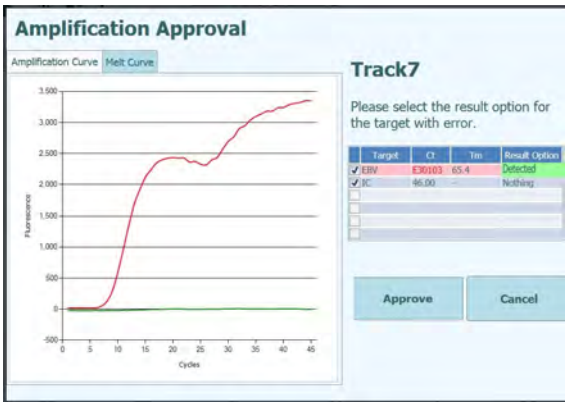


Figure 5-102: Approve button after the manual approval.

In case of a “Detected” result for quantitative model, the ULoQ will be reported on the GUI, Run Summary and Track Report.

Figure 5-103: The sample manually approved as “Detected”reporting the ULoQ value.

In the Run Summary the samples approved manually report “Result manually confirmed”.

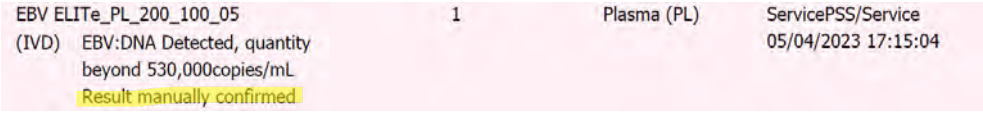


Figure 5-104: Run Summary for a sample manually approved.

In the Track Report, the samples manually approved reporting Ct = 7.

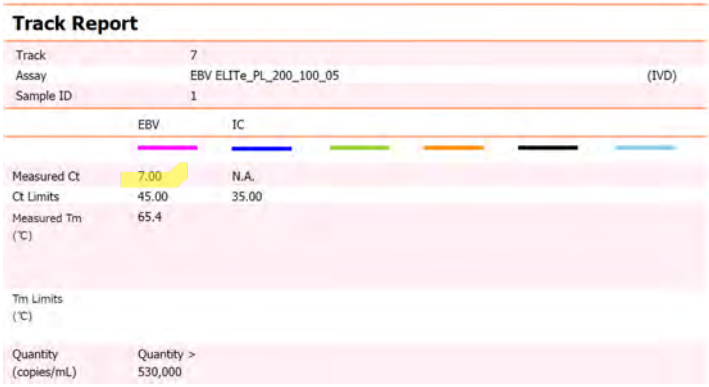


Figure 5-105: The sample manually approved reported Ct = 7.

The manual approval for errors 3010X (30107 and 30108) follow the rules described for the error 30103.

The manual approval for errors 3010X ((30107 and 30108) is possible for all the models except for model 3 and model 9.

In the track report, the samples manually approved, reported Ct = 0

NOTE The manual approval for samples with errors 3010X with model 2 and model 14, display only qualitative results.

5.4.5.4 Printing Track and Patient Sample Reports

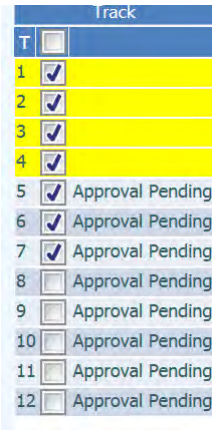
The ELITe InGenius System supports two styles of output reports for the track results. These reports can be exported to a .PDF file or sent to a printer.

- **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 5-106: 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.

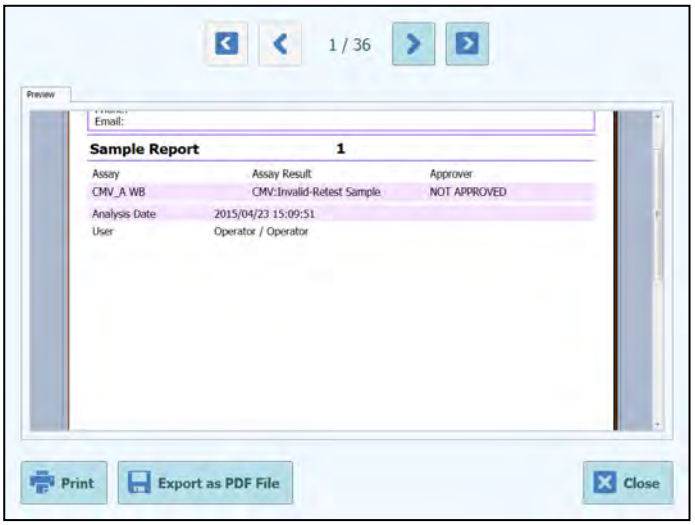


Figure 5-107: Example of Sample Report

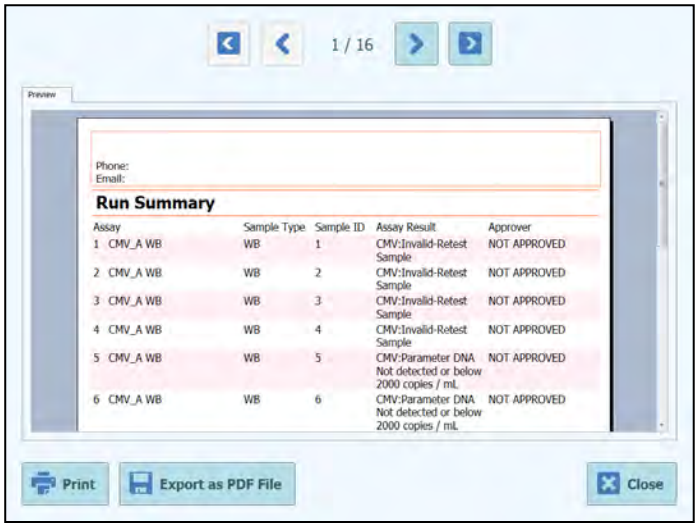


Figure 5-108: Example of Track Report

5.4.5.5 Viewing Calibration Results

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

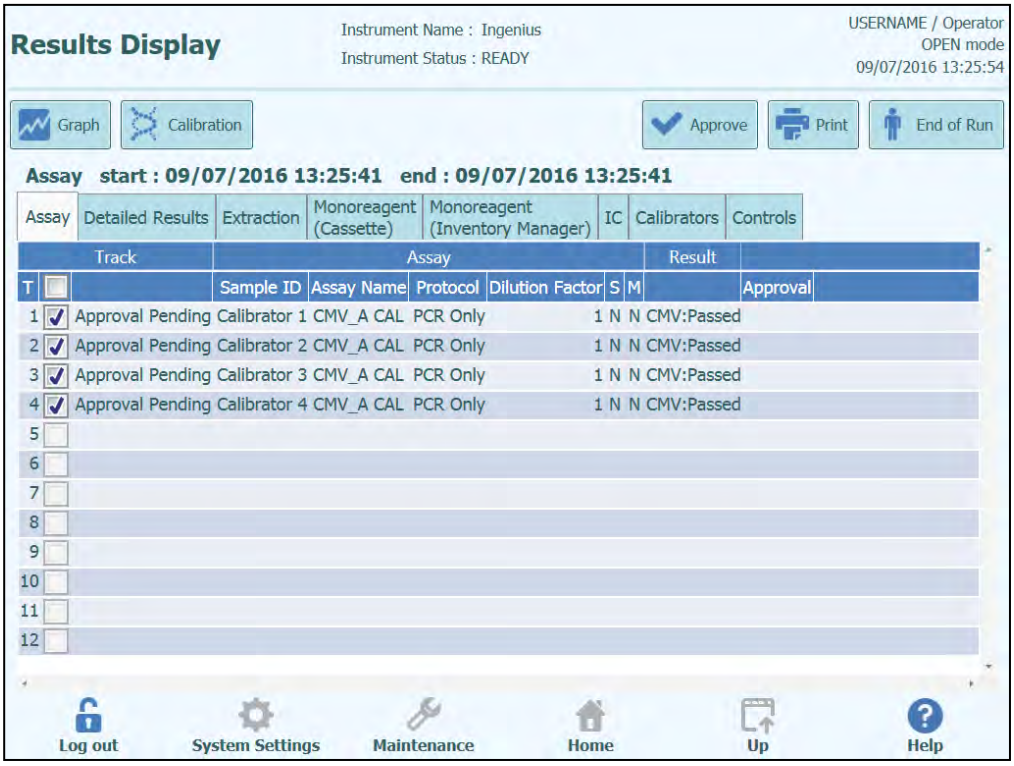


Figure 5-109: Example of Run Results for a Calibrator Set

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

To View and Approve the Calibration (Standard) Curve, click on the tick box for any of the tracks in the Calibrator Set. All other tracks in the Calibrator Set will be automatically selected.

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

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

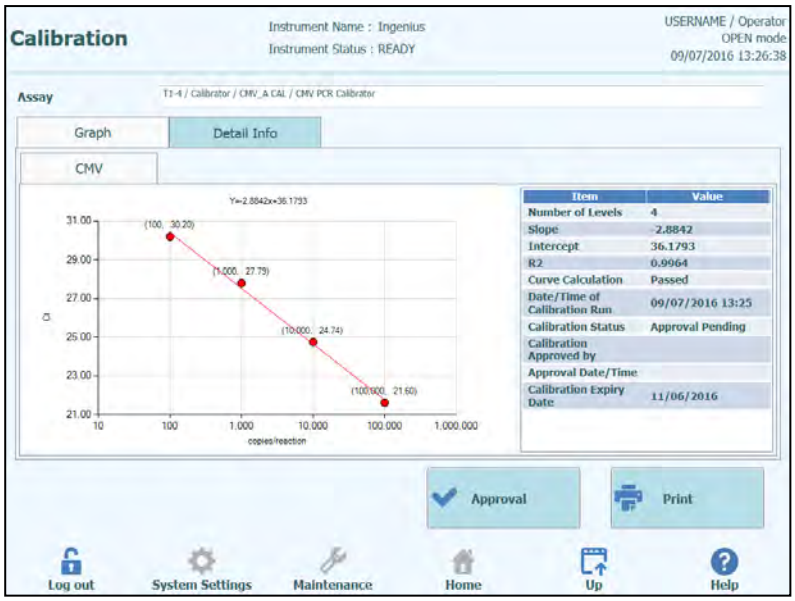


Figure 5-110: Calibration Screen – Standard Curve

On the left hand side of the Calibration Screen, the C_t results from each calibrator level are plotted together with the best-fit line calculated by the ELITe InGenius System. On the right hand side of the Calibration Screen, further details are given about the Calibration in the text box.

By clicking on the “Detail Info” tab in the Calibration Screen, detailed info about the calibration run can be displayed. The Detail Info tab has further sub-tabs that can be clicked to show similar information to the Run Results screen, but specific to the selected calibrator tracks.

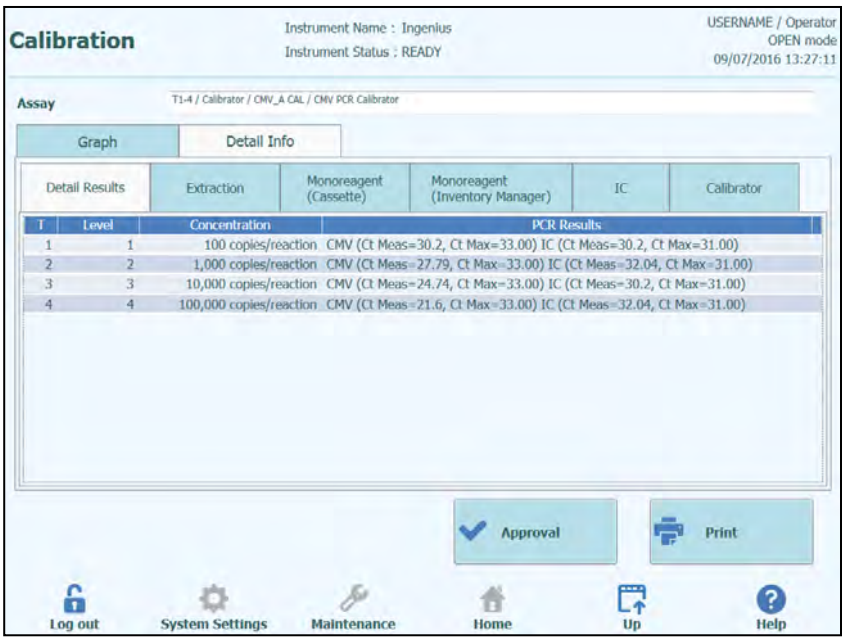


Figure 5-111: Calibration Screen – Detailed information

When running calibration with Replicates, the standard curve plot will show multiple points for each calibrator level. The following example shows the output for a 4 level calibrator, with 3 replicates for each level (12 tracks in total)

Figure 5-112: Calibration Screen – Standard Curve with Replicates

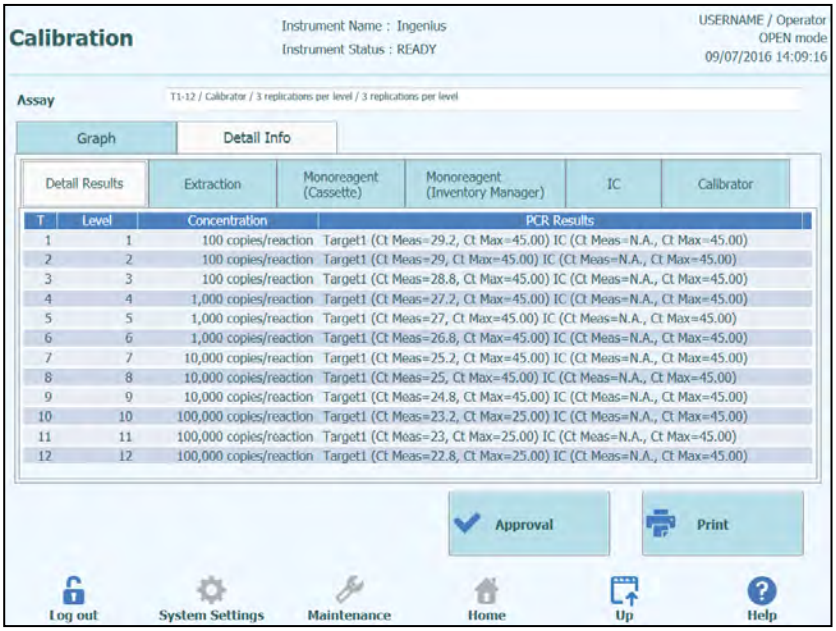


Figure 5-113: Calibration Screen – Detailed information with Replicates

5.4.5.6 Approving Calibration Curves

If the Calibration Curve calculated by the ELITe InGenius System is within acceptable limits, the “Approval” button will be enabled in the Calibration Screen.

In case of calibrator level replicates, it is possible to exclude outliers and to recalculate the curve before approval. Change will be recorder in the Software for traceability.

Click the “Approval” button on the Calibration Screen to approve the Calibration Curve so that it will be available for calculating 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.

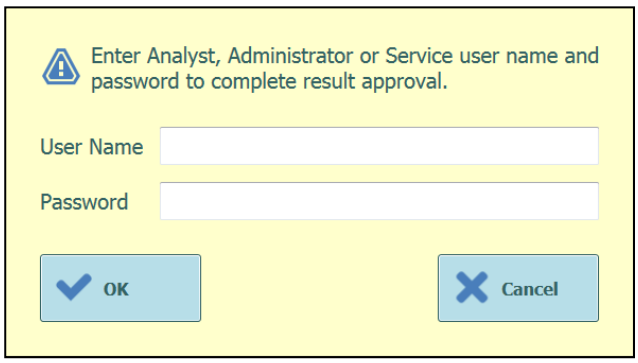


Figure 5-114: Authorisation of Result Approval

5.4.5.7 Printing Calibration Report

Press the “Print” button in the Calibration 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 5-115: Printing Calibration Report

5.4.5.8 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).

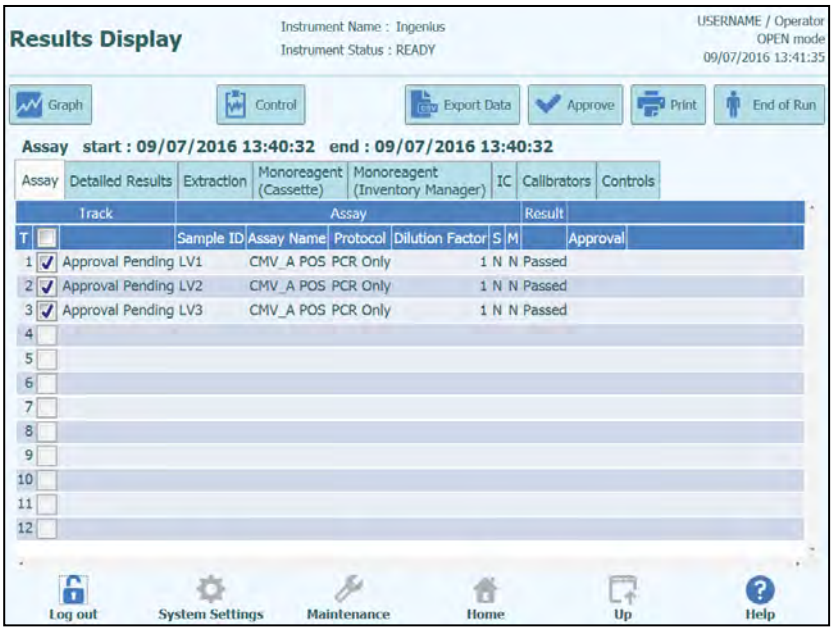


Figure 5-116: Example of Run Results for a Control Set

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.

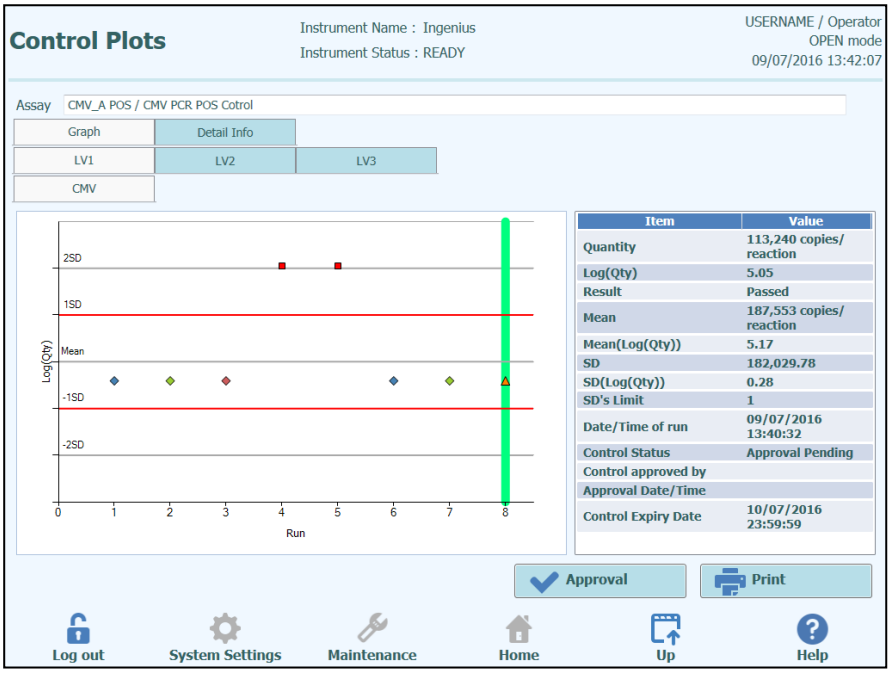


Figure 5-117: Control Screen – Statistics Plot

On the left hand side of the Control Screen, the results from each control level are plotted.

The X axis of the plot shows the number of times each control has been run

The Y axis behaves differently, depending on whether the control is Quantitative or Qualitative.

For a Quantitative Control, the Y axis shows the calculated Log(Quantity). When sufficient control runs have been completed, the Y axis is scaled to show +/-3 standard deviations relative to the calculated mean for the approved results. The red marker lines are plotted on the graph to show the Approval Pass/Fail SD threshold as programmed by the Assay developer.

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

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

NOTE For a Quantitative Control, the Standard Deviation calculation and validation is disabled until at least four control runs have been approved.

For a Qualitative Control the Y axis shows the C_t for the track. A red marker line shows the Approval Pass/Fail C_t threshold as programmed by the Assay developer.

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

For assays that utilize Melting Controls, a further plot for Tm's is also generated in addition to the Ct plots. This can be viewed by selecting the Tm radio button on the right side of the screen. In some cases, more than one Tm point is expected for a give channel; the pass/fail range is indicated on the graph by the pale blue horizontal areas (if the point is within the blue bar, it's a pass; if it's outside the bar, it's a fail)

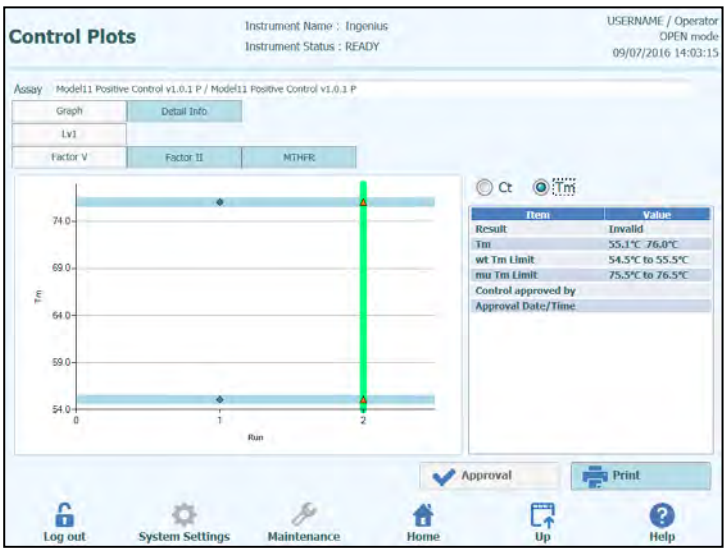


Figure 5-118: Control Screen – Melting Control Plot

On the right hand side of the Control Screen, further details are given about the Controls in the text box.

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

By clicking on 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 clicked to show similar information to the Run Results screen, but specific to the selected control tracks.

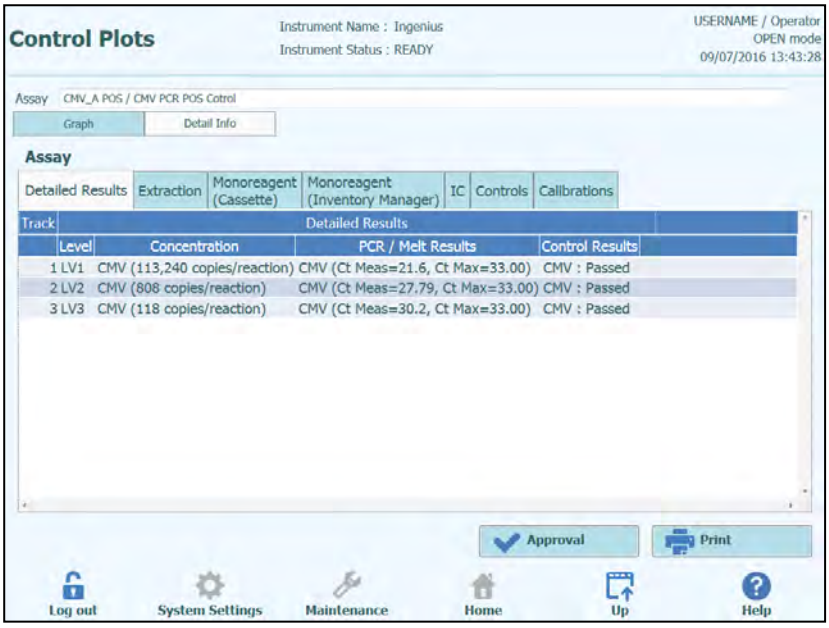


Figure 5-119: Control Screen – Detailed information

5.4.5.9 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.

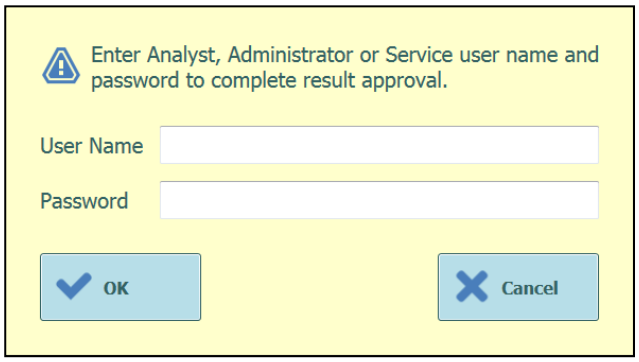


Figure 5-120: Authorisation of Result Approval

5.4.5.10 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.

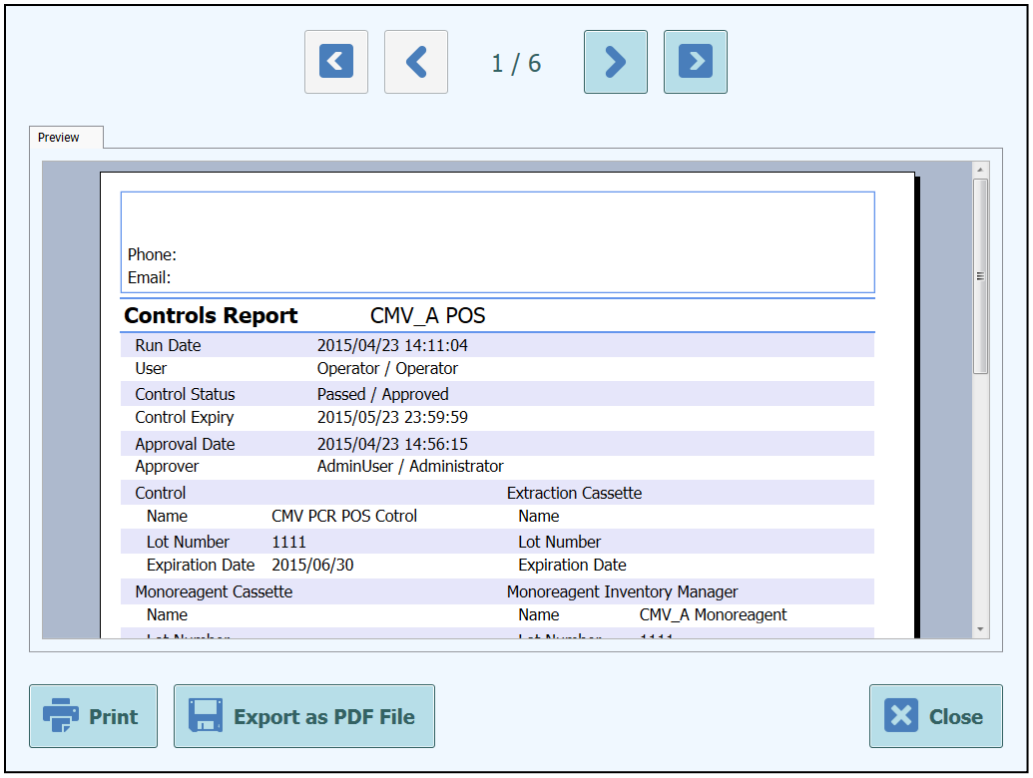


Figure 5-121: Printing Controls Report

5.4.5.11 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.

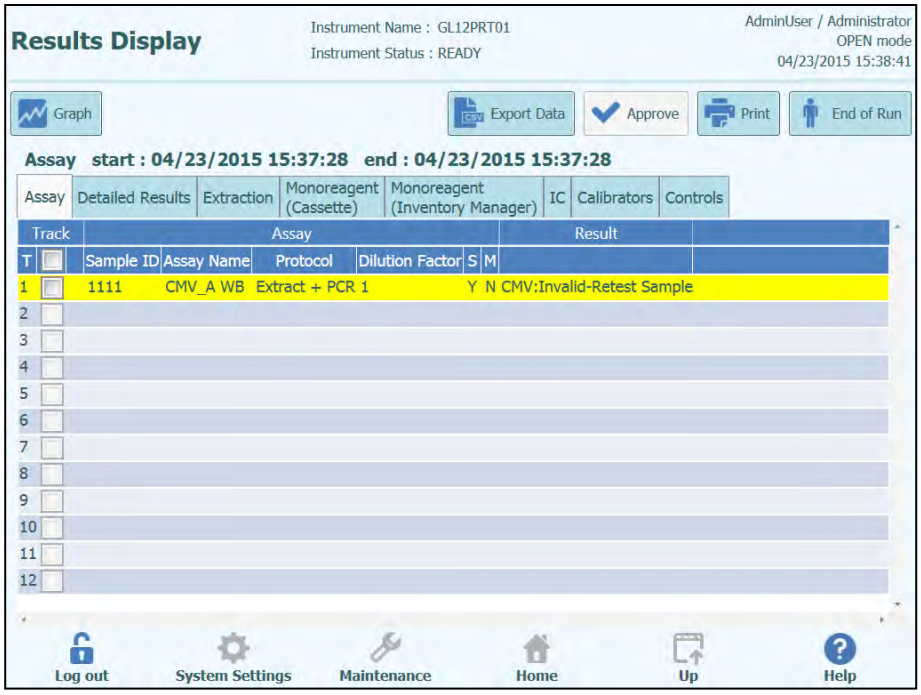


Figure 5-122: Exporting Run Data

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.

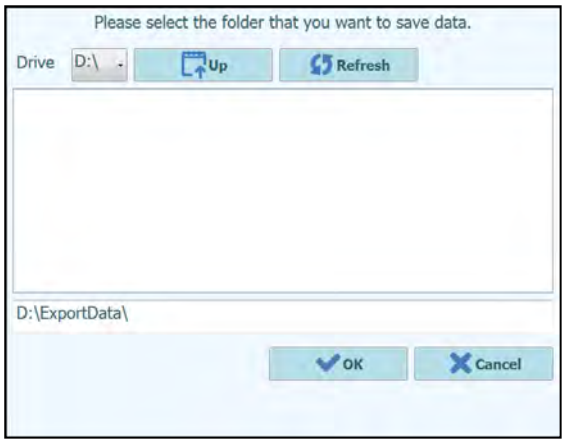


Figure 5-87: Data Export Folder Selection

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

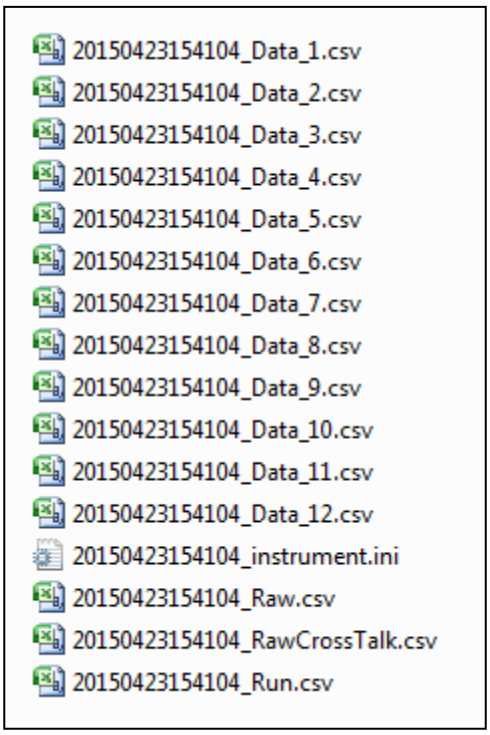


Figure 5-124: Example of Files Generated by Data Export

5.4.5.12 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.

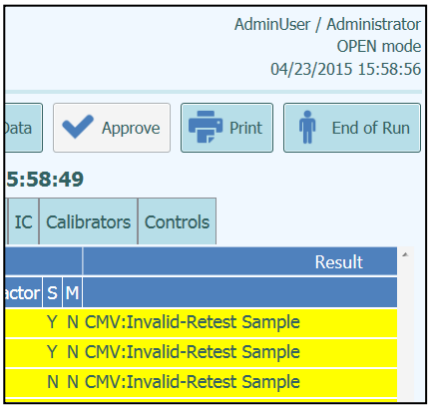


Figure 5-125: End of Run Button

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.

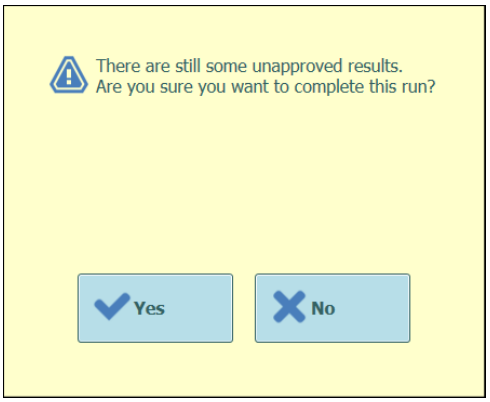


Figure 5-12688: Reminder for unapproved results

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 6: 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.

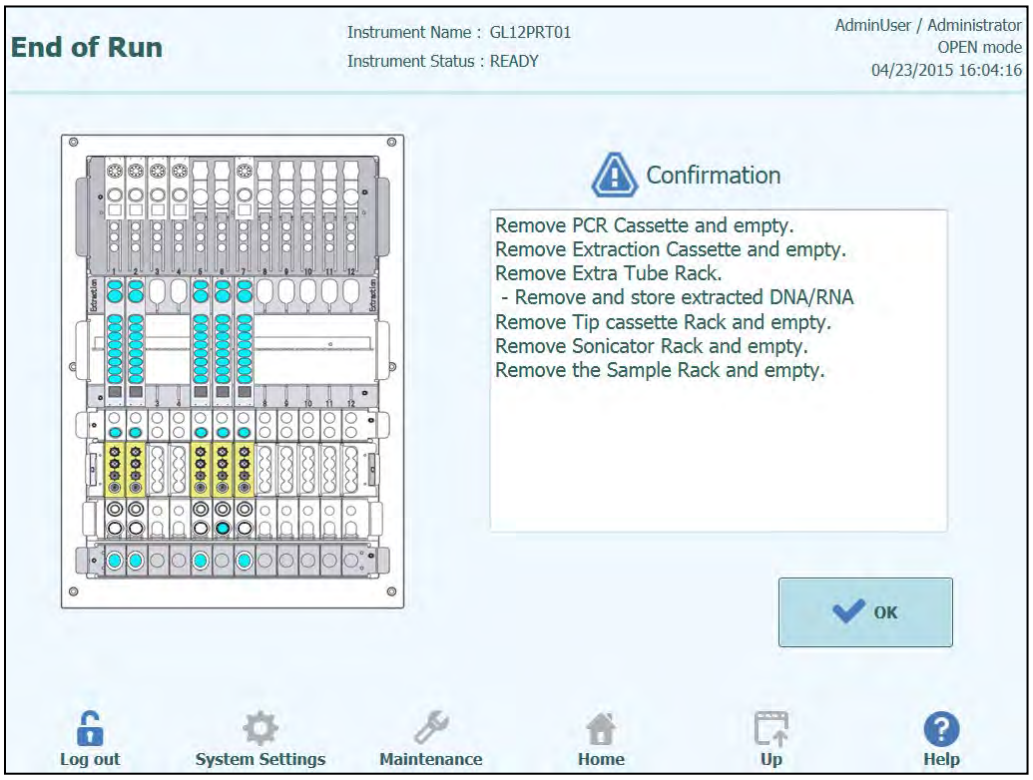


Figure 5-127: End Of Run Screen

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.

NOTE

The Elution tube contains eluted samples. The extracted DNA or RNA may be stored at -20 °C for a maximum of thirty days or at -70 °C for longer periods. Freeze/thawing cycles of extracted DNA or RNA must be limited to five times in order to avoid titre loss.

Remove and discard the Tip Cassette from Tip Rack.

Remove, close off and discard the Sonication tubes or the Extraction tubes from the proper 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.

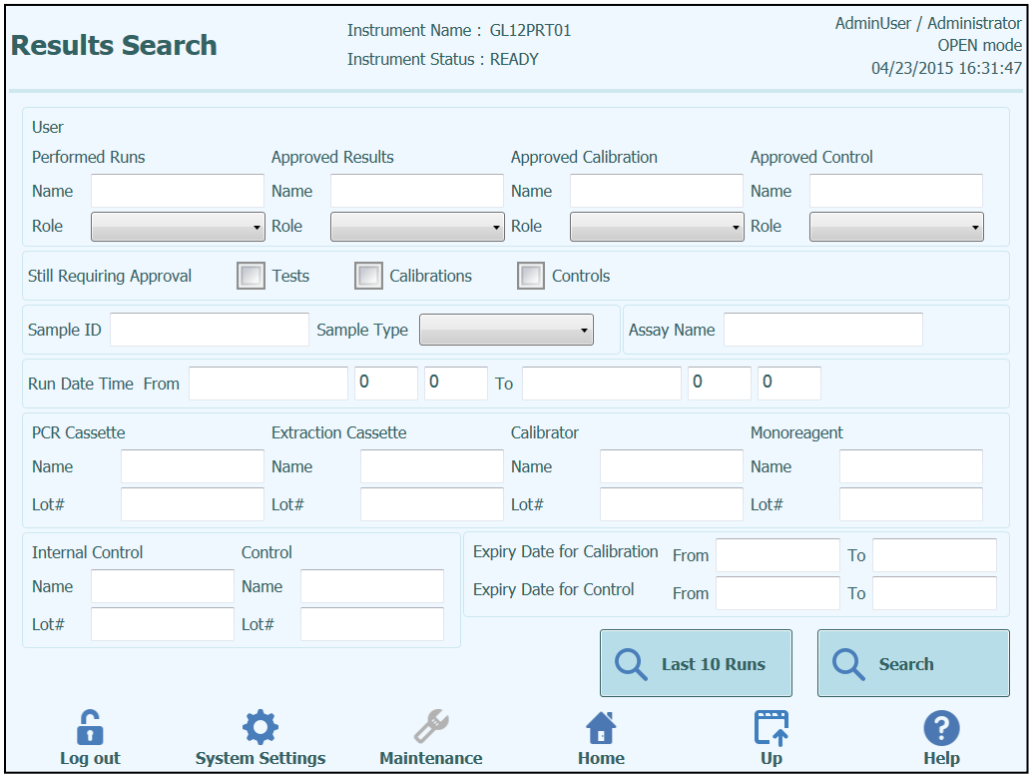


Figure 5-128: Results Search screen

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.

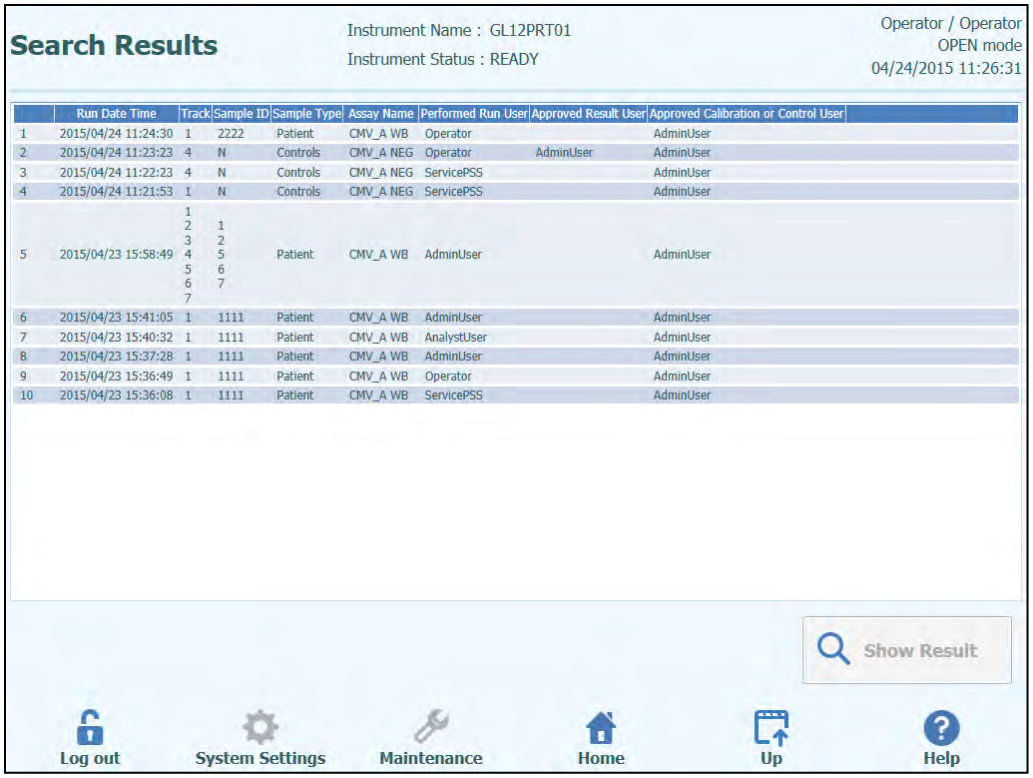
Fields that are left blank will be matched to any value in the database (i.e. behave as a wildcard).

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.



	Run Date Time	Track	Sample ID	Sample Type	Assay Name	Performed Run User	Approved Result User	Approved Calibration or Control User
1	2015/04/24 11:24:30	1	2222	Patient	CMV_A WB	Operator		AdminUser
2	2015/04/24 11:23:23	4	N	Controls	CMV_A NEG	Operator	AdminUser	AdminUser
3	2015/04/24 11:22:23	4	N	Controls	CMV_A NEG	ServicePSS		AdminUser
4	2015/04/24 11:21:53	1	N	Controls	CMV_A NEG	ServicePSS		AdminUser
5	2015/04/23 15:58:49	1 2 3 4 5 6 7	1 2 5 6 7	Patient	CMV_A WB	AdminUser		AdminUser
6	2015/04/23 15:41:05	1	1111	Patient	CMV_A WB	AdminUser		AdminUser
7	2015/04/23 15:40:32	1	1111	Patient	CMV_A WB	AnalystUser		AdminUser
8	2015/04/23 15:37:28	1	1111	Patient	CMV_A WB	AdminUser		AdminUser
9	2015/04/23 15:36:49	1	1111	Patient	CMV_A WB	Operator		AdminUser
10	2015/04/23 15:36:08	1	1111	Patient	CMV_A WB	ServicePSS		AdminUser

Figure 5-89: 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.

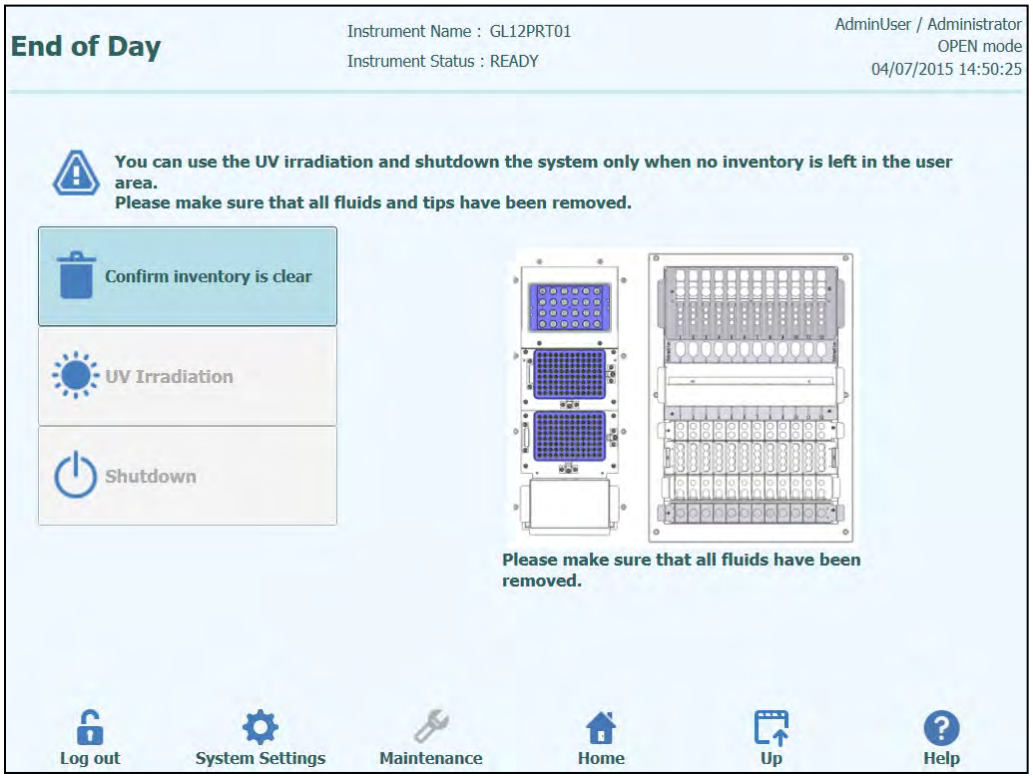


Figure 5-130: End of Day screen.

Open the front door.

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

NOTE The instrument should not leave 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.

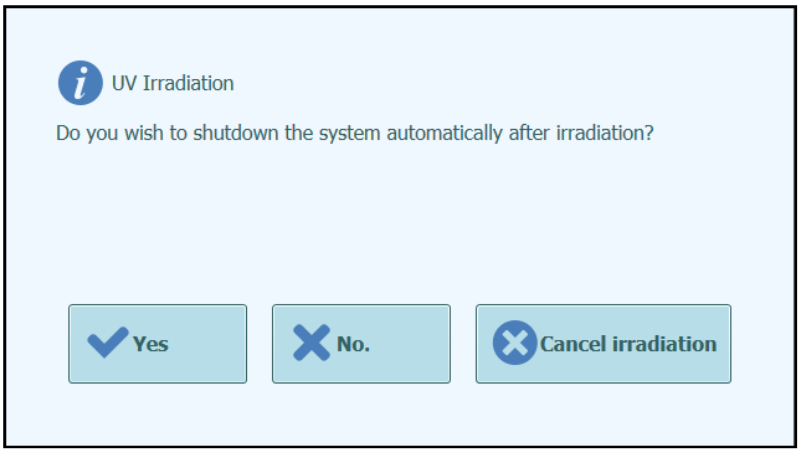


Figure 5-90: Selecting shutdown options for after UV sterilisation completes.

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

Figure 5-132: 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.

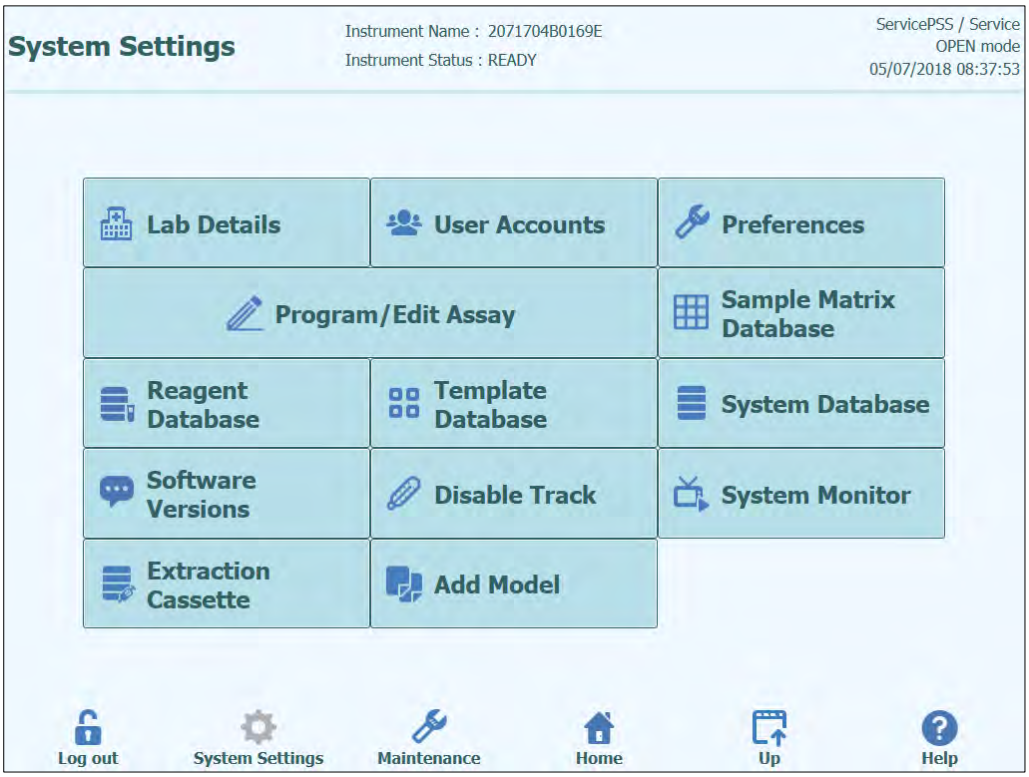


Figure 6-1: System Settings screen.

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.

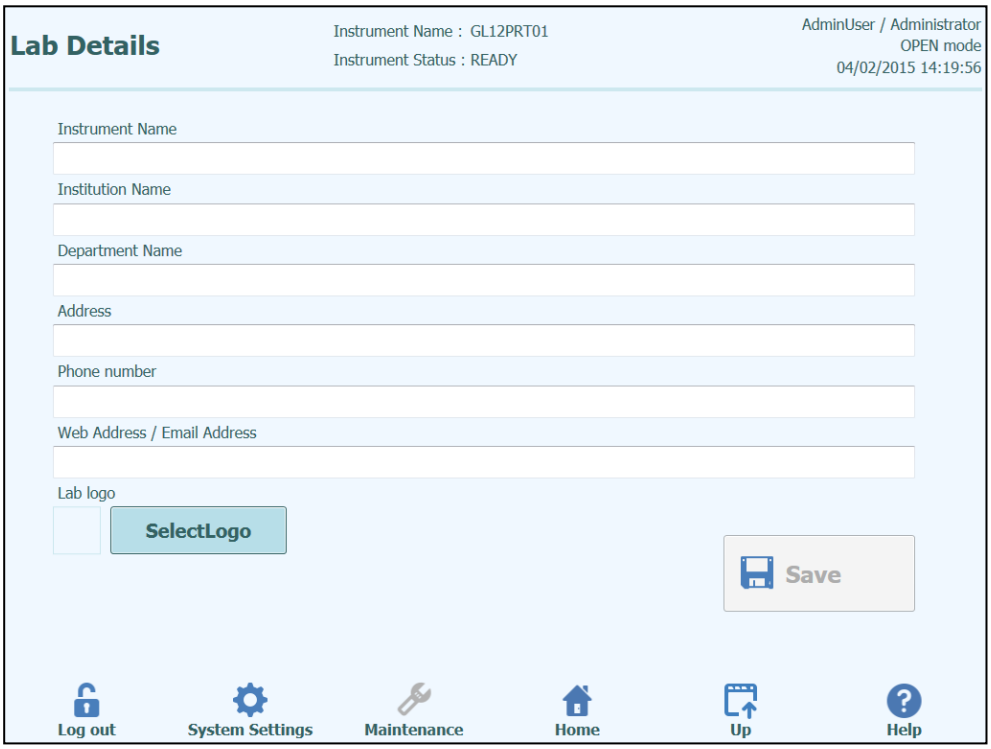


Figure 6-2: Lab Details screen.

1. Access the “Lab Details” screen by selecting the “Lab Details” button on the “System Settings” menu
2. Input your institution information
3. Press “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 (after 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.

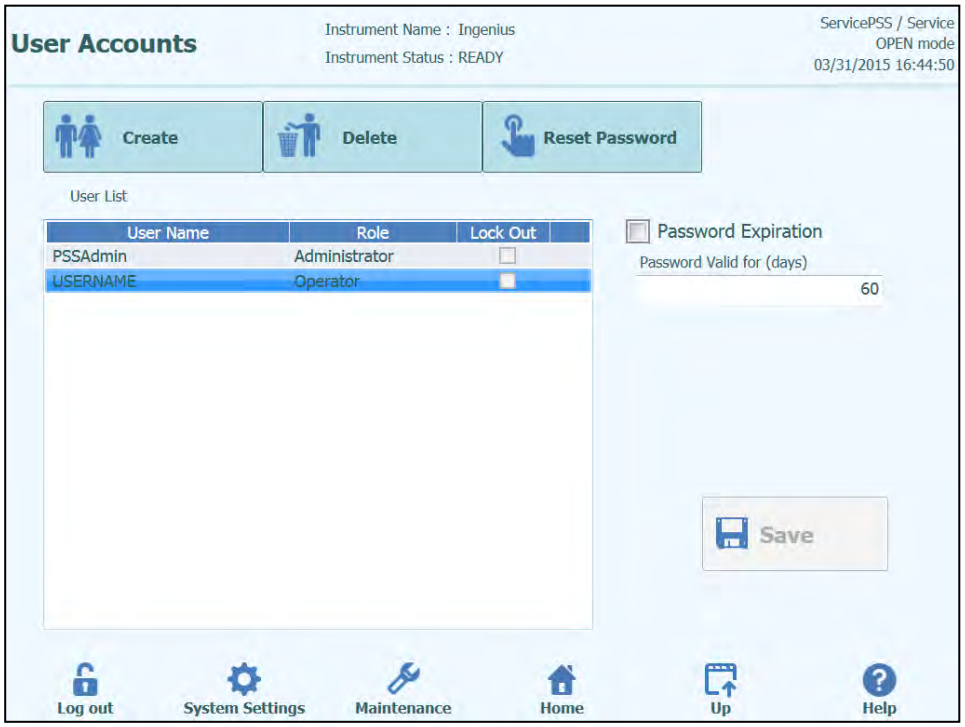


Figure 6-3: User Account screen.

6.3.1 Creating a new User Account

To create a new User Account:

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

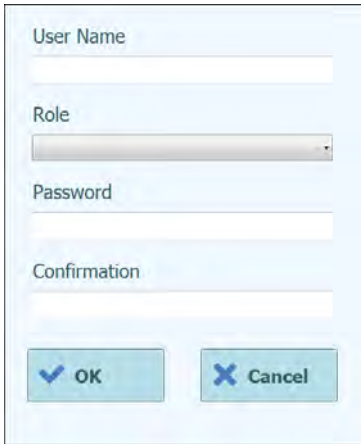


Figure 6-4: Enter new account details.

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

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).

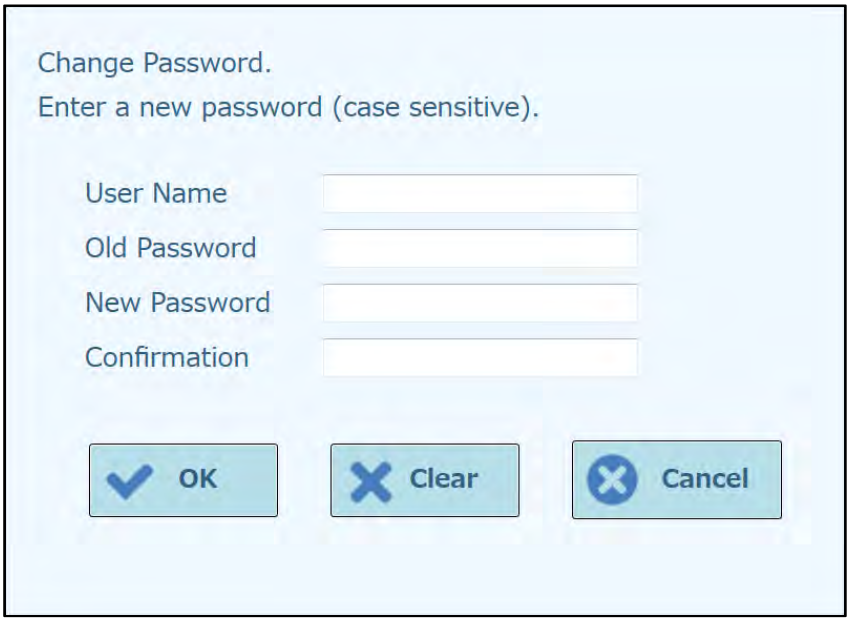


Figure 6-5: Change Password dialog box.

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.

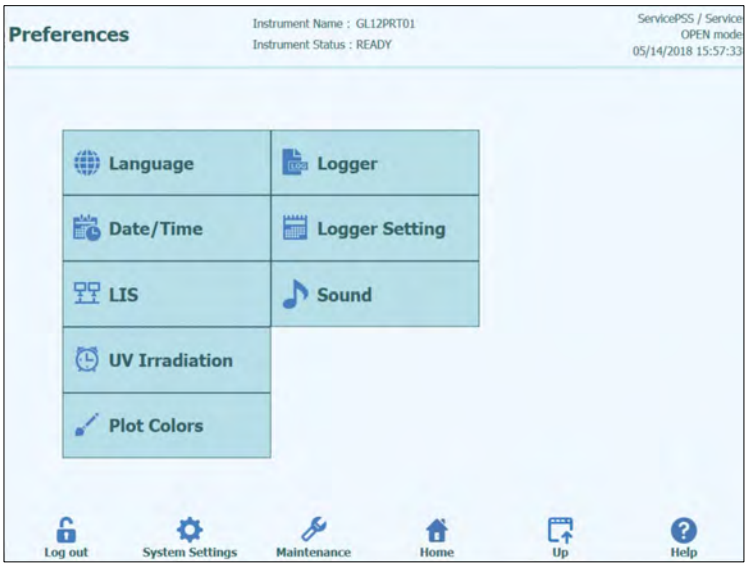


Figure 6-6: Preferences Screen.

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.

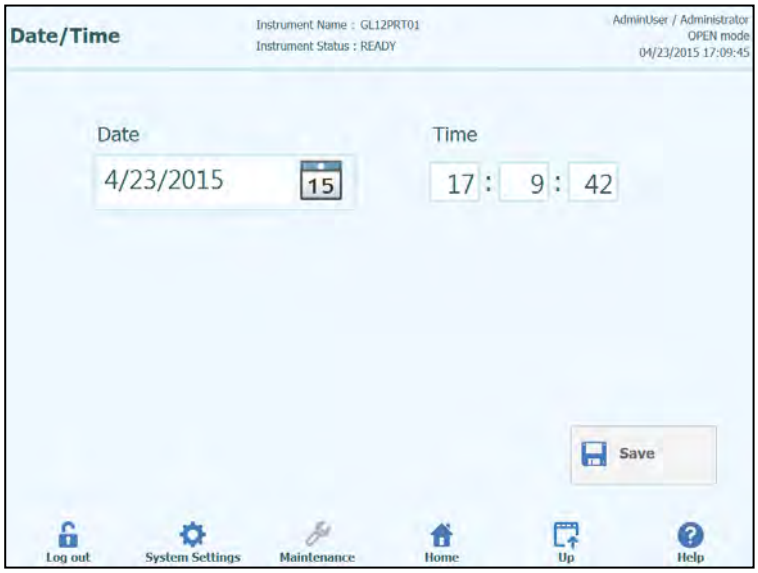


Figure 6-8: Date and Time Settings

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

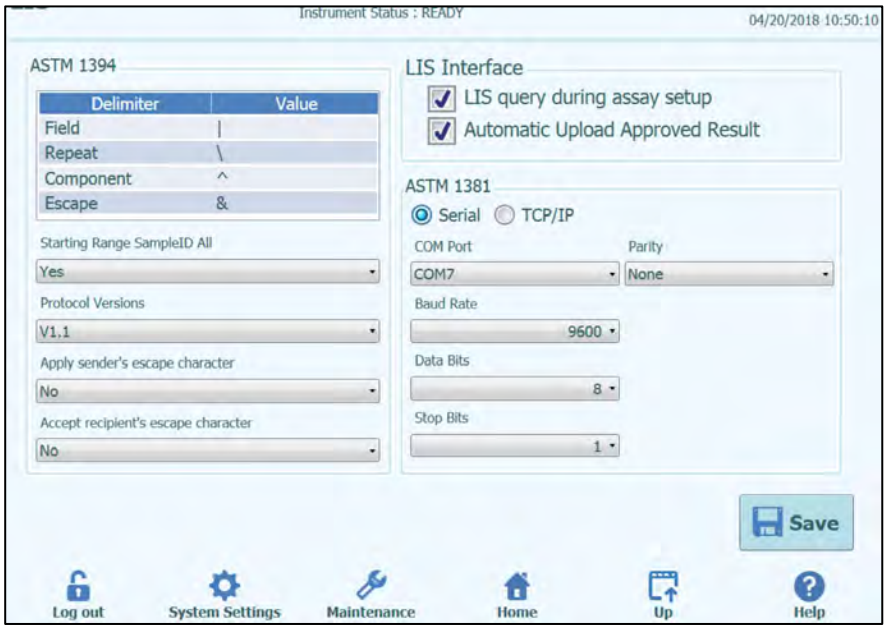


Figure 6-9: LIS Configuration Settings

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

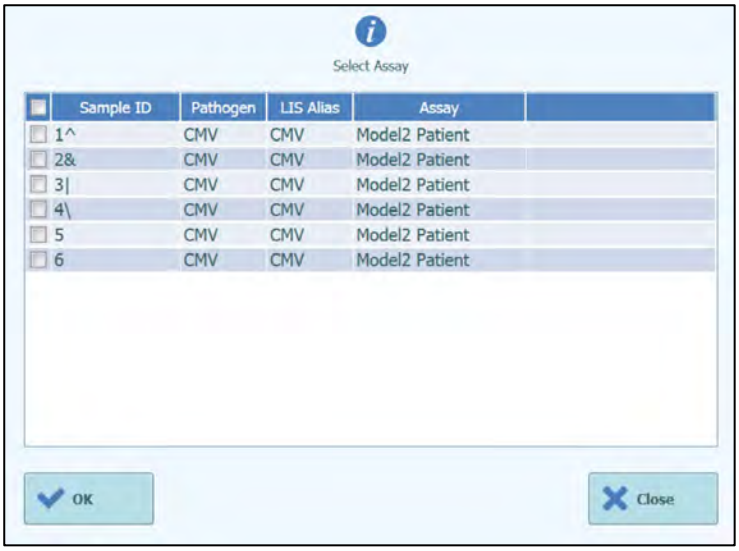


Figure 6-10: Apply sender's escape character and Accept recipient's escape character

- 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 6-12: 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.

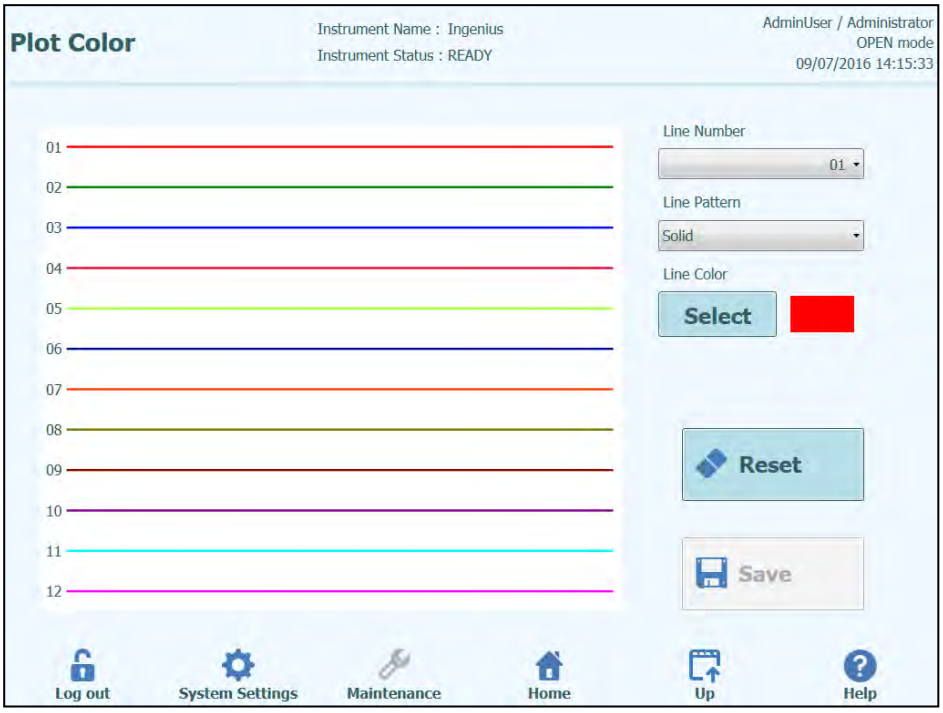


Figure 6-13: Plot Color Settings

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.

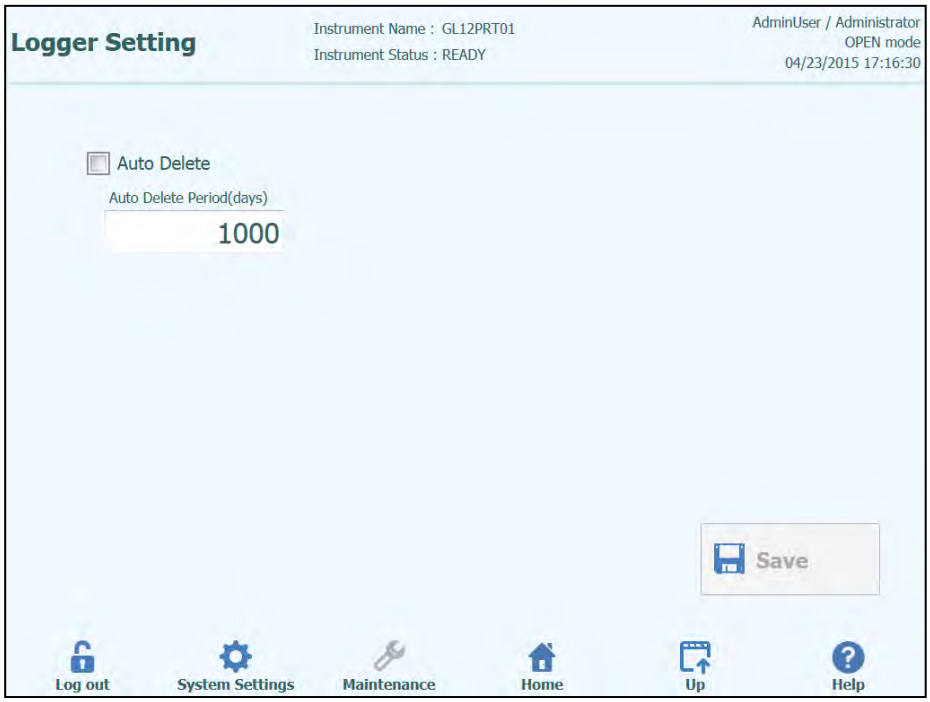


Figure 6-14: Logger Settings

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.

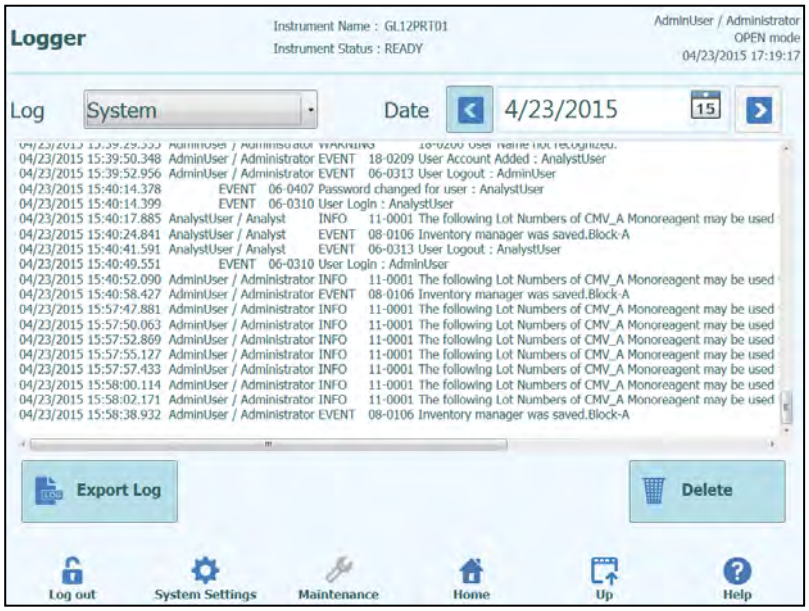
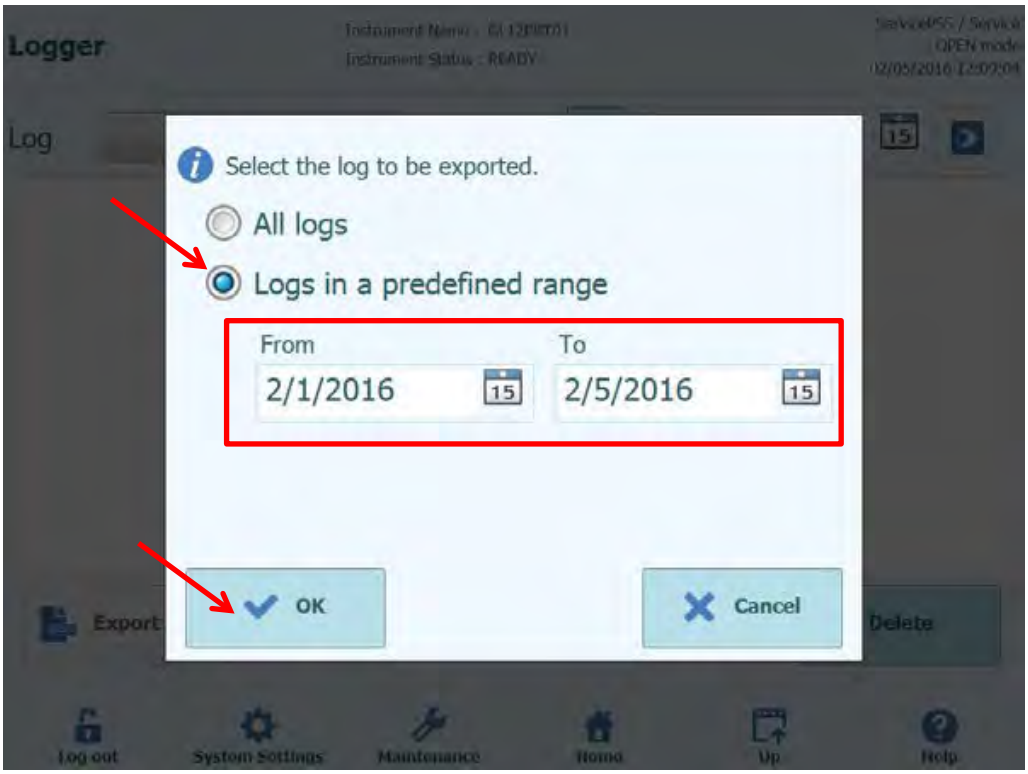


Figure 6-15: Logger Screen

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”).

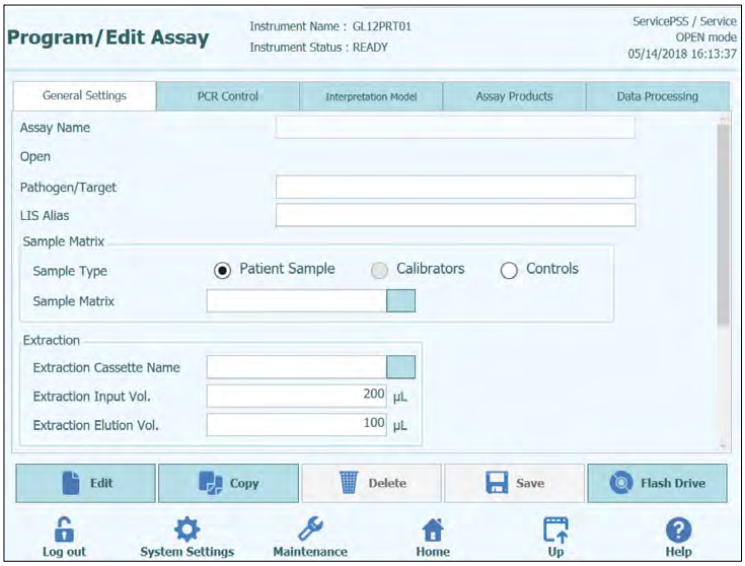


Figure 6-16: Program assay screen.

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 Program files into the USB port of the InGenius System.
2. Press "Flash Drive" button.
3. Navigate to the Assay Program file on the USB memory stick using the on-screen dialogue.
4. Press “OK” button to load the selected Assay Program 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 Creating, Editing, Copying and Deleting Assay Programs

The “Edit Assay” screen is used to:

- to create new Assay Programs.
- to edit existing “Open” Assay Programs
- to remove unused Assay Programs from the system
- to copy/rename existing “IVD Cleared” or “Open” assay programs on the system

This section describes the basic operations required to manage the Assay Programs stored on the system. Detailed information about the individual Assay Parameters and Results Interpretation Models can be found in section 6.7.

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

NOTE

CLOSED Assay Protocol: is an IVD Cleared Assay Protocol, which has been approved and validated by ELITechGroup SpA for IVD purpose, used for the detection/quantification of a specific analyte in association with a specific sample matrix. In order to ensure the system uses this assay in exactly the same way as it was validated and approved (on-label use), the system does not allow to edit any of the parameters of the Assay Protocol.

OPEN IVD-Cleared Assay Protocol: is a version of a CLOSED Assay Protocol which can be in used in OPEN mode. Creation and availability of this kind of Assay Protocols is to enhance ELITe BeGenius flexibility, allowing contemporary use of Closed and Open Assay Protocols. Installation of both CLOSED and OPEN IVD-Cleared Assay Protocol on ELITe BeGenius systems can be performed only by ELITechGroup qualified staff.

OPEN IVD-Cleared Assay Protocol provides results for IVD purposes as long as their parameters are NOT modified after release and installation. If the OPEN IVD-Cleared Assay Protocols are used UNCHANGED, they maintain all parameters validated during the clinical studies of the related ELITe MGB Kits performed by the ELITechGroup SpA, therefore they can be used for producing results with diagnostic value.

WARNING

OPEN Assay Protocol: any Assay Protocol which has not been approved for IVD purposes. It may be created during development of new assays or for lab customizations of a CE-IVD assay (off-label use) or for Laboratory Developed Tests or for any other tests of interest. Results with diagnostic value can be produced ONLY after a proper validation process.

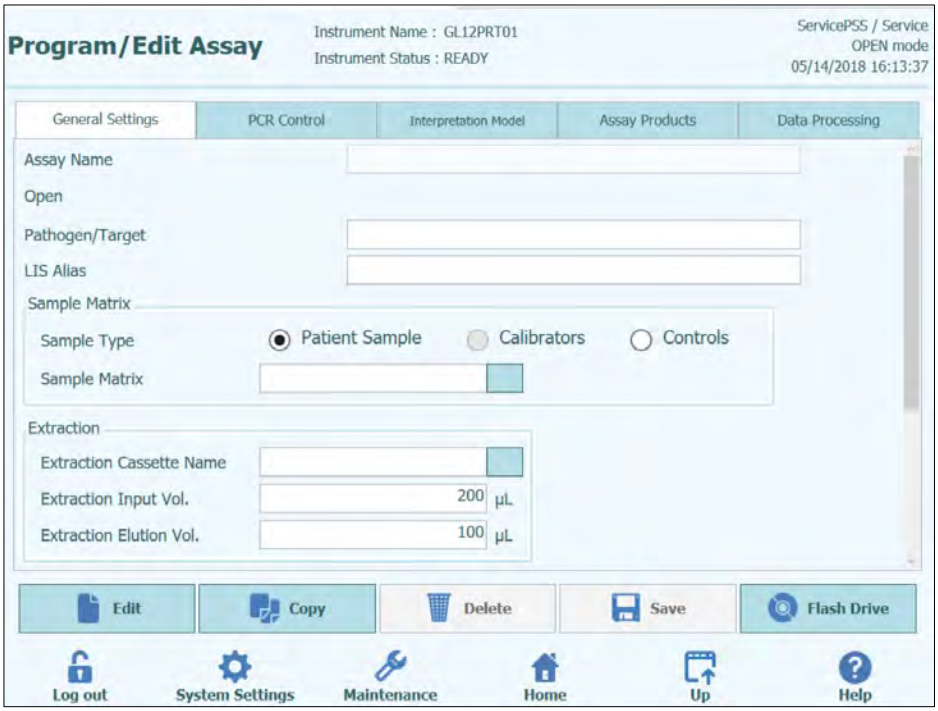


Figure 6-10: Edit Assay Screen.

6.6.1 Create a new Assay Program

To create a brand new Assay Program, simply start filling out the fields on the screen to configure the assay parameters.

Once you have completed the Assay Program, press the **SAVE** button.

The system will check that all the necessary parameters have been specified then ask you to provide a name for the Assay Program.

6.6.2 Edit an existing Assay Program

To edit an existing Assay Program, press the Edit button and then select the assay that you wish to edit from the list that is presented.

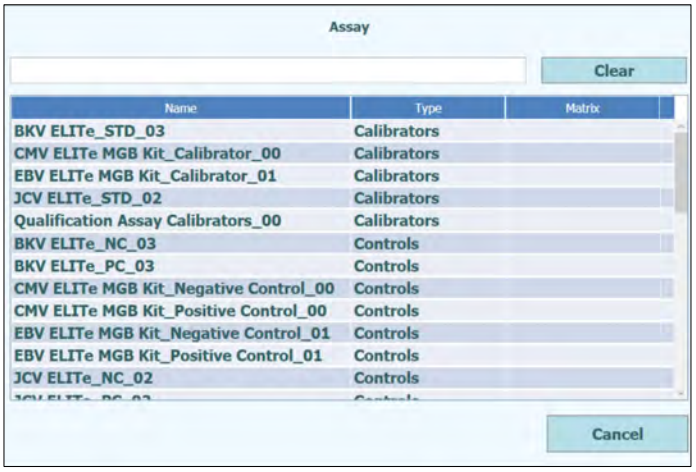


Figure 6-18: Assay selection list

When you select one of the Assay Programs from the list, its parameters will be loaded to the Edit Assay screen and if the Assay Program is an Open Assay, you will then be able to save your changes to the Assay Program using the Save Button. If the Assay Program is IVD Cleared, you will only be able to view the parameters.

When saving a changed Assay Program, you will be asked to confirm the name for the Assay Program before the Save operation is completed. It is possible to change the name used for the Assay Program at this stage.

6.6.3 Delete an existing Assay Program

To delete an existing Assay Program, press the Edit button and then select the assay that you wish to delete from the list that is presented (see Figure 6-)

When you select one of the Assay Programs from the list, its parameters will be loaded to the Edit Assay screen

You will then be able to delete the Assay Program by pressing the **Delete** Button.

6.6.4 Copy an existing Assay Program

To make a copy of an existing Assay Program, press the Copy button and then select the assay that you wish to copy from the list that is presented (see Figure 6-).

When you select one of the Assay Programs from the list, its parameters will be loaded to the Edit Assay screen and you may edit the Assay Parameters as required.

Assay Programs created using the Copy function will always be marked as Open Assays, regardless of whether the original was IVD Cleared.

After making any changes, you will then be able to save the Assay Program using the **Save** Button.

When saving a changed Assay Program, you will be asked to enter the name for the Assay Program before the Save operation is completed.

6.7 Assay Parameters and Interpretation Models

The Edit Assay screen contains several tabs that contain the settings that are used by the ELITe InGenius system to control the execution of a run and the results interpretation once the run has completed.

The ELITe InGenius system supports both IVD Cleared (Read Only) assays and Open (Editable, RUO) assays. IVD Cleared assays may be viewed in the “Edit Assay” screens but it is not possible to change any of the settings.

6.7.1 Edit Assay: General Settings Tab

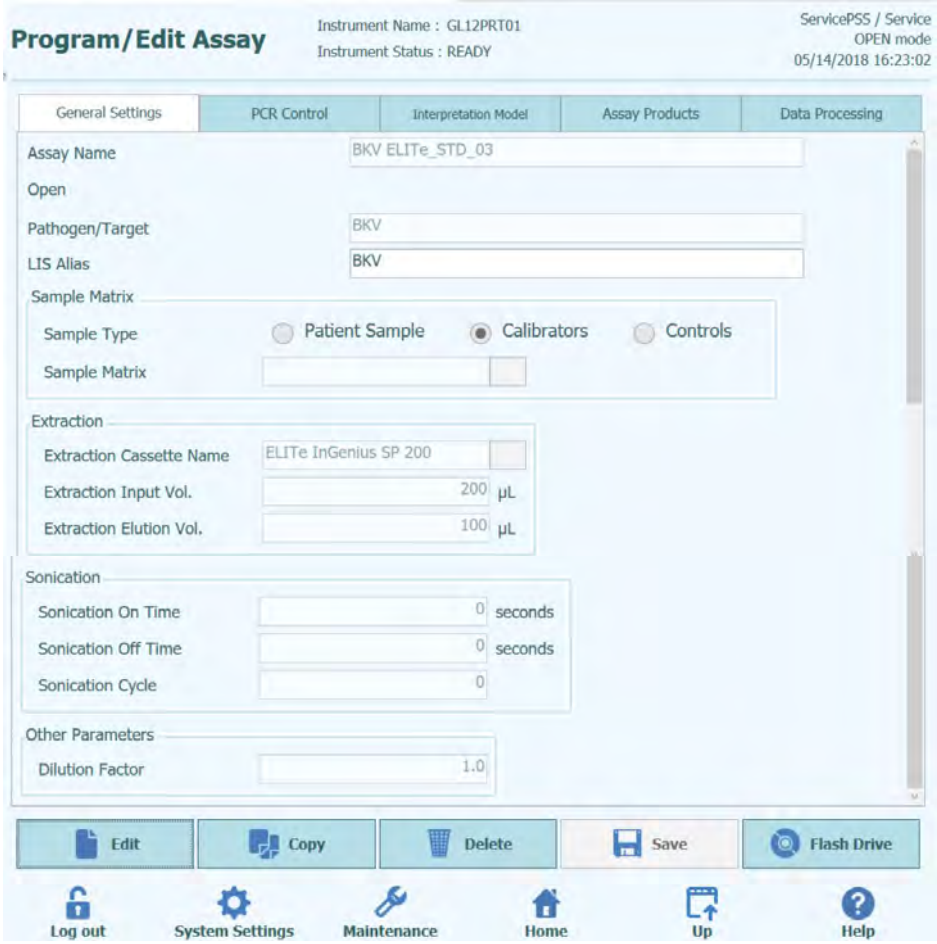


Figure 6-19: Edit Assay General Settings Tab

- Assay Name
  This is the name that is used in the Run Setup screen to select the assay. It should uniquely identify the assay. The name can only be edited when saving the complete Assay settings by pressing the SAVE button. The Assay Name cannot be modified by editing the entry directly on the screen

- Pathogen/Target
  This field is a short text string that is used to group a number of assays together. For example, several assay programs may be created for a common target, each with a different Sample Matrix (e.g. “WB“, “Plasma“, “Urine“)

- Sample Type
  This field is used to define if the Assay program is used to update the stored calibrations or controls on the system or to generate a result for a patient sample. Different results interpretation behavior is defined in the interpretation models based on the Sample Type being processed. Separate Assay programs are required to generate control results, calibration curves and patient sample results for each pathogen (e.g. CMV CAL Assay, CMV POS CTL Assay, CMV NEG CTL Assay, CMV WB Assay)

- Sample Matrix
  This field is used to choose which Sample matrix is used for the Assay. The Sample Matrix values available here are taken from the Sample Matrix Database (see section 6.8)

- Extraction Cassette Name
  This field is used to choose which Extraction Cassette will be used for the assay

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

- Extraction Elution Vol.
  This field specifies the Eluate volume that you wish to generate from the extraction process. A pop up menu allows the selection of eluate volumes that may be generated.

- Sonication Off Time / On Time / Cycle
  These three fields allow the sonication parameters to be specified for the Assay. If no Sonication is needed, then set the Sonication On Time to Zero.

- Dilution Factor
  This specifies the primary sample dilution factor that is to be used for the assay. It is used when calculating results for quantitative assays.

6.7.2 Edit Assay: PCR Control Tab

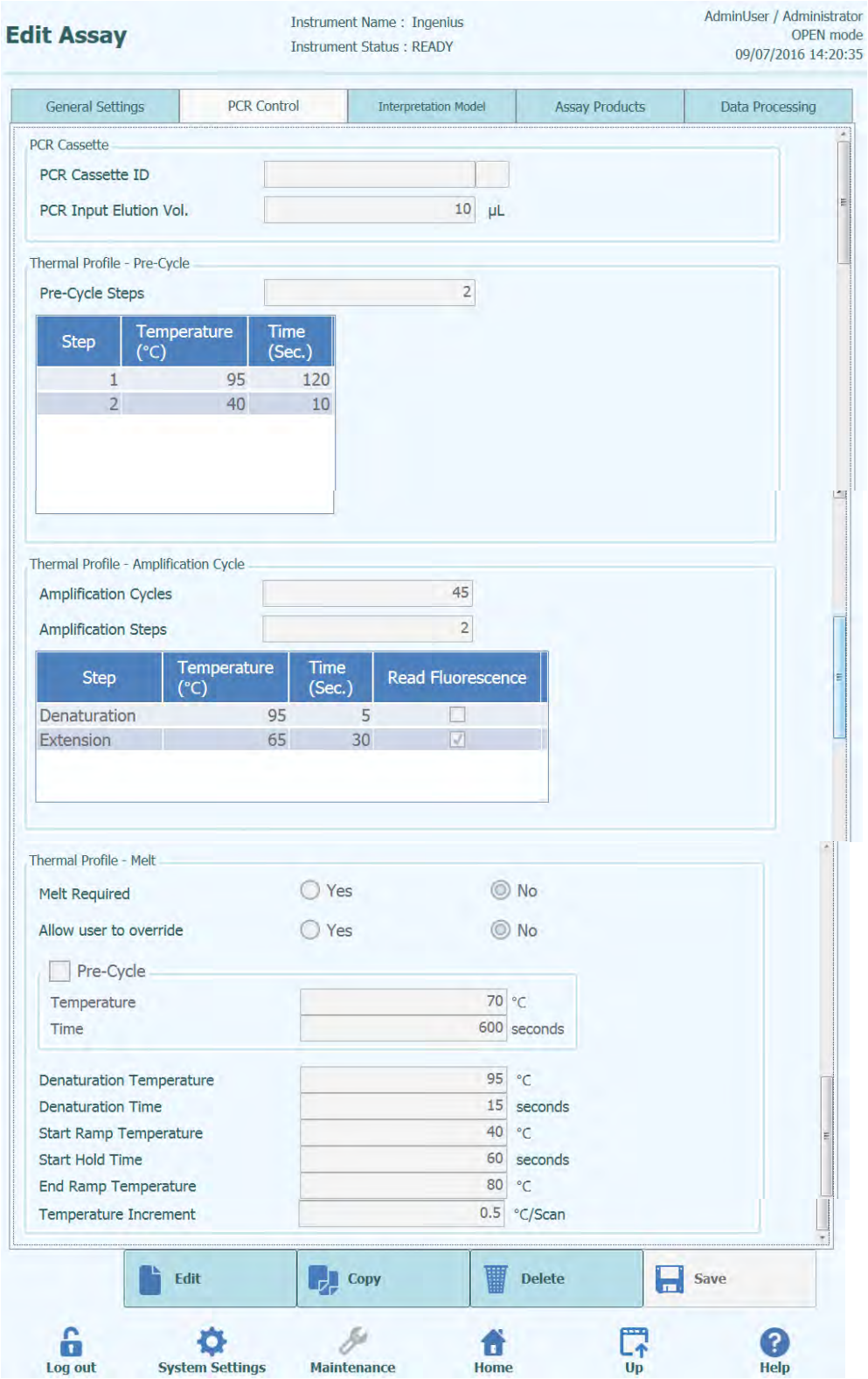


Figure 6-20: Edit Assay PCR Control Tab

This tab allows the parameters to be defined for the PCR step in the processing.

- PCR Cassette ID
  In future releases, this will be used to specify a particular PCR Reagent Cassette to be used for the Assay. This should be left blank if no PCR Reagent Cassette is required.
- PCR Input Elution Vol.
  This field specifies the volume of eluate that is to be used for the PCR reaction.
- Thermal Profile – Pre-Cycle
- Thermal Profile – Amplification Cycle
- Thermal Profile – Melt
  These fields specify the characteristics for the PCR thermal profile. Pre-Cycle conditions are conducted once, then a number of repeated PCR cycles, and finally a Melt temperature ramp may be optional, depending on the Interpretation Model selected.

6.7.3 Edit Assay: Interpretation Model Tab

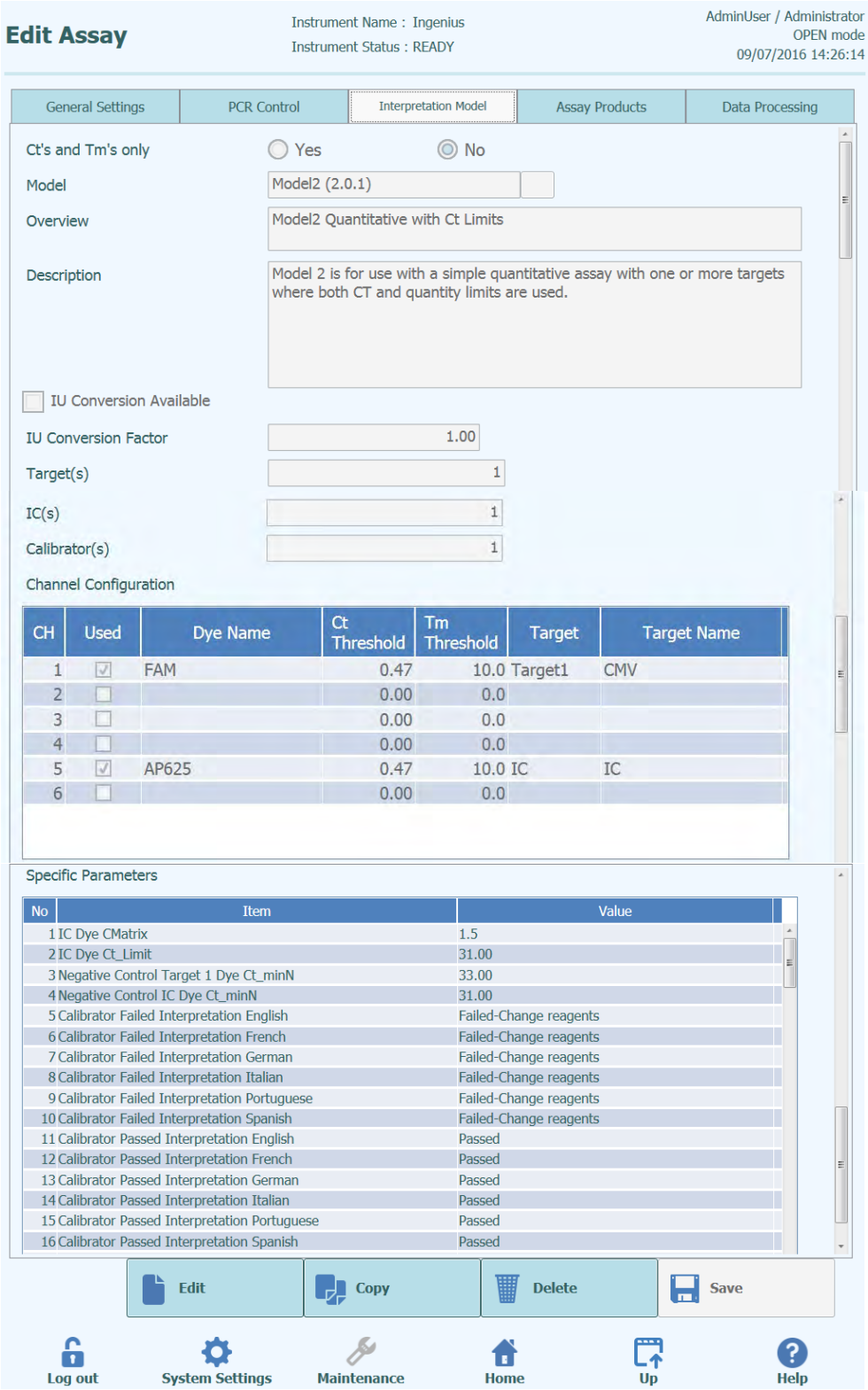


Figure 6-21: Edit Assay Interpretation Model Tab

- Ct's and Tm's Only
  This setting can be set for Assays that only need to generate Ct's and Tm's only, and do not need to perform any further results interpretation. If Ct's and Tm's is selected, then only the Channel Configuration table needs to be completed (all other fields on this tab are disabled)

- Model
  This specifies which result interpretation model should be used for generating results for this assay. See below for further information on the different interpretation models that are available.

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

- Result Reporting Units / Conversion Factor IU
  If the selected interpretation model provides a quantitative result, this field can be used to specify if results should be reported in copies/mL, gEq/mL or IU/mL. If the reporting units are set to IU/mL, you must also specify the factor for converting from copies/mL to IU/mL

- Target(s)
  This field specifies how many targets are to be 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. Not all interpretation models support more than one target; contact an Elitech Product Support representative for more details.

- IC(s)
  This setting is determined by the selected interpretation model. Usually only one internal control is used for each assay.

- Calibrator(s)
  This setting is determined by the selected interpretation model. The current version of software only supports a single calibrator for each assay even if the assay is multiplexed. In the future it is planned to allow specify different calibrators for each of the multiplexed channels in a future software release.

- Channel Configuration
  - Used
  - Dye Name
  - Ct Threshold
  - Tm Threshold
  - Target
  - Target Name

  These settings are used to configure 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 (Ct limits etc) in the models to the specific dyes used by the assay.

- Specific Parameters
  For each interpretation model there are a number of settings used by the model to validate calibrations, controls, and patient sample results. It is also possible to customise the text messages that are output from the models when displaying the results at the end of a run. Further details about these settings can be obtained by contacting your Elitech Product Support representative.

6.7.3.1 Model 1 - Qualitative with Ct Limits

This model is for use with a simple qualitative assay with one Internal Control where Ct limits are used to validate the result (e.g. Toxoplasma). This model also uses a positive control and a negative control to provide an additional level of validation for the results.

Three Assay programs must be configured for model 1:

- A Positive control assay
- A Negative control assay
- A Patient sample assay

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 2 assays.

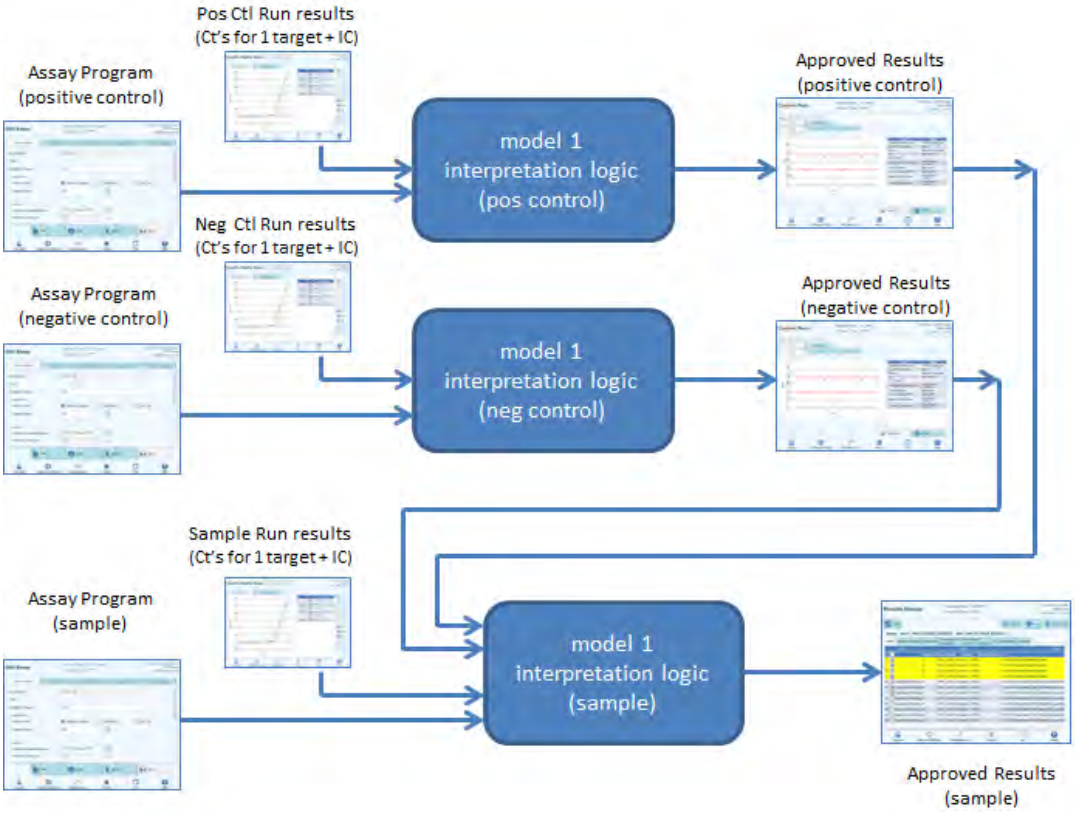


Figure 6-22: Model 1 Overview

For Model 1 v2.0.2, patient sample results are generated using the following decision table:

Target Dye Channel Ct	IC Dye Channel Ct	Other Target Dye Channel Ct	Sample Result	Result Interpretation
Target Dye Ct > Target Dye Ct_Limit	IC Dye Ct > IC Dye Ct_Limit	All other TargetN Dye Ct > TargetN Dye Ct_Limit	Invalid	Invalid Interpretation Text
	IC Dye Ct > IC Dye Ct_Limit	At least one other TargetN Dye Ct ≤ TargetN Dye Ct_Limit	Valid, Negative	Valid Negative Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Ignored	Valid, Negative	Valid Negative Interpretation Text
Target Dye Ct ≤ Target Dye Ct_Limit	IC Dye Ct > IC Dye Ct_Limit	Ignored	Valid, Positive	Valid Positive Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	ignored	Valid, Positive	Valid Positive Interpretation Text

Table 6-1 : Model 1 Patient Sample Interpretation Logic

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target Dye Ct_Limit
- IC Dye Ct_Limit
- Invalid Interpretation text
- Valid Negative Interpretation text
- Valid Positive Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

6.7.3.2 Model 2 - Quantitative with Ct Limits

This model is for use with a simple quantitative assay with one target and one Internal Control where both Ct limits and quantity limits are used to validate the result (e.g. CMV). This model requires a calibration curve to convert Cts to quantities and also uses a positive control and a negative control to provide an additional level of validation for the results.

Four Assay programs must be configured for model 2:

- A Calibrator Assay Program
- A Positive Control Assay Program
- A Negative Control Assay Program
- A Patient Sample Assay Program

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 2 assays.

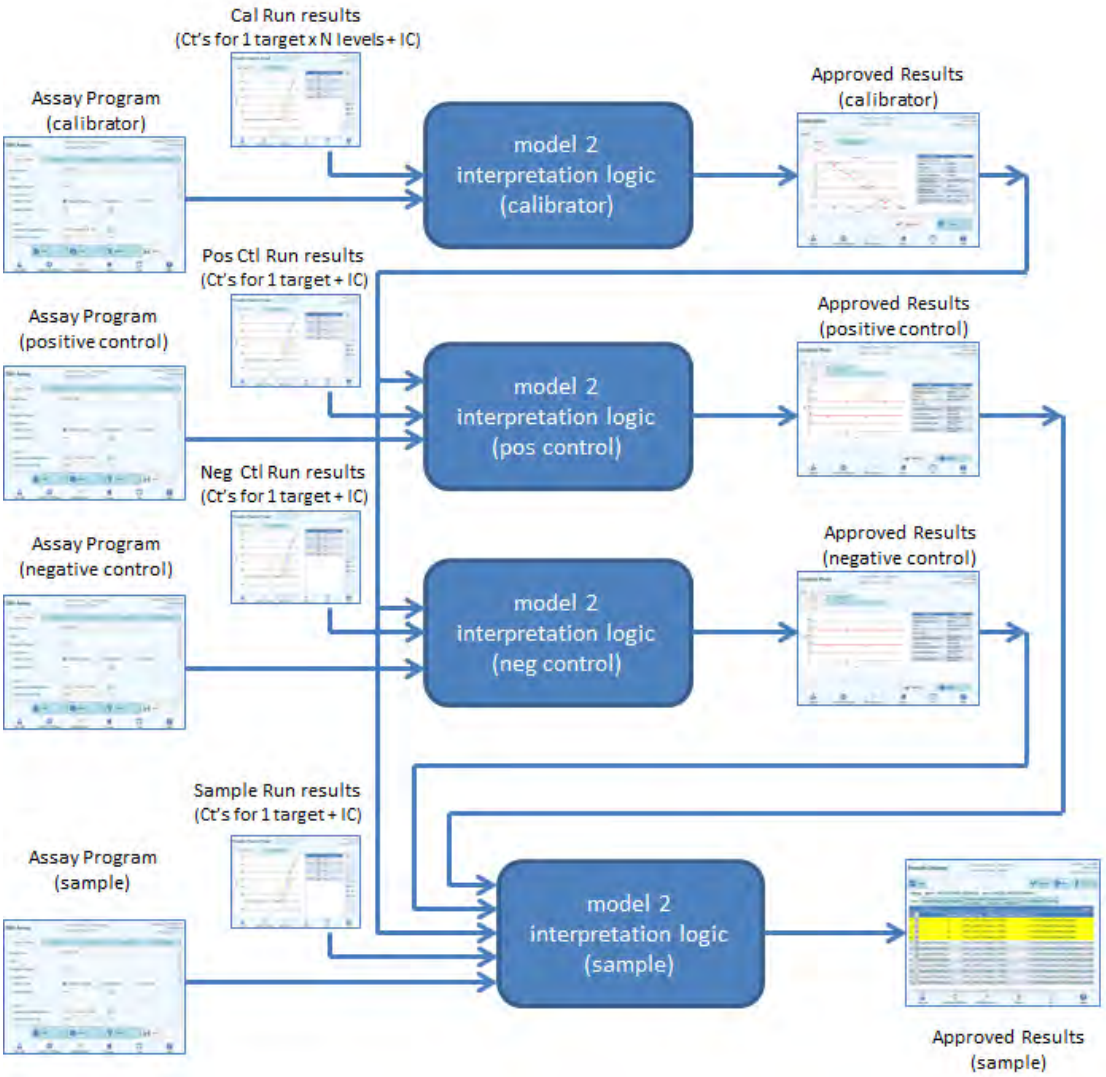


Figure 6-23: Model 2 Overview

For Model 2, patient sample results are validated using the following decision table:

Target Dye Channel Ct	IC Dye Channel Ct	Sample Result	Qualitative Result Interpretation
Target Dye Ct > Target Dye Ct_Limit	IC Dye Ct > IC Dye Ct_Limit	Invalid	Invalid Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Valid, Negative	Valid Negative Interpretation Text
Target Dye Ct ≤ Target Dye Ct_Limit	IC Dye Ct > IC Dye Ct_Limit	Valid, Positive	Valid Positive Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Valid, Positive	Valid Positive Interpretation Text

Table 6-2 : Model 2 Patient Sample Interpretation Logic

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target Dye Ct_Limit
- IC Dye Ct_Limit
- Invalid Interpretation text
- Valid Negative Interpretation text
- Valid Positive Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

The Target concentration is calculated using the following algorithm

$$\text{Target Concentration} = \frac{\text{Quantity} \times \text{Ve} \times \text{Cf} \times \text{Df}}{\text{Vi} \times \text{Va} \times \text{Ep}}$$

Where:

- Target concentration is the initial Target titer in the Sample in Target copies / mL, gEq / mL or IU / mL (depending on user request and related Cf value used)
- Quantity is the Target copies / reaction calculated by software from Target Ct and PCR only Calibration Curve: Quantity (copies / rxn) = f(Calibration Curve, Ct)
- Ve is the elution volume (volume added to beads) in uL as defined in the Assay Program
- Cf is the Conversion Factor, as defined in Assay program
  - for Target copies / mL Cf = 1
  - for Target gEq / mL Cf = 1 gEq / copy
  - for Target IU / mL Cf = 0.1 to 10 IU / copy
- Df is the dilution factor (1 to 10), defined in Assay program or during Run setup
- Vi is the extraction input volume in mL (0.2 or 1.0), defined in Assay program
- Va is the elution volume (extraction output volume) transferred into the amplification reaction in uL / reaction (5 to 50), defined in Assay program

- Ep is the Efficiency of procedure (0.1 to 1.0), defined in Assay program and Matrices Table
- ElutionLoss is the volume of eluate that is wasted when moving from extraction cassette to the eluate tube

6.7.3.3 Model 3 - Two targets, Ct differential with interpreted results

This model is for use with a qualitative assay with two targets and one Internal Control where both Ct limits and the difference between the Ct of the two targets are used to validate the result (e.g. MRSA/SA). This model also uses a positive control and a negative control to provide an additional level of validation for the results.

Three Assay programs must be configured for model 3:

- A Positive Control Assay Program
- A Negative Control Assay Program
- A Patient Sample Assay Program

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 3 assays.

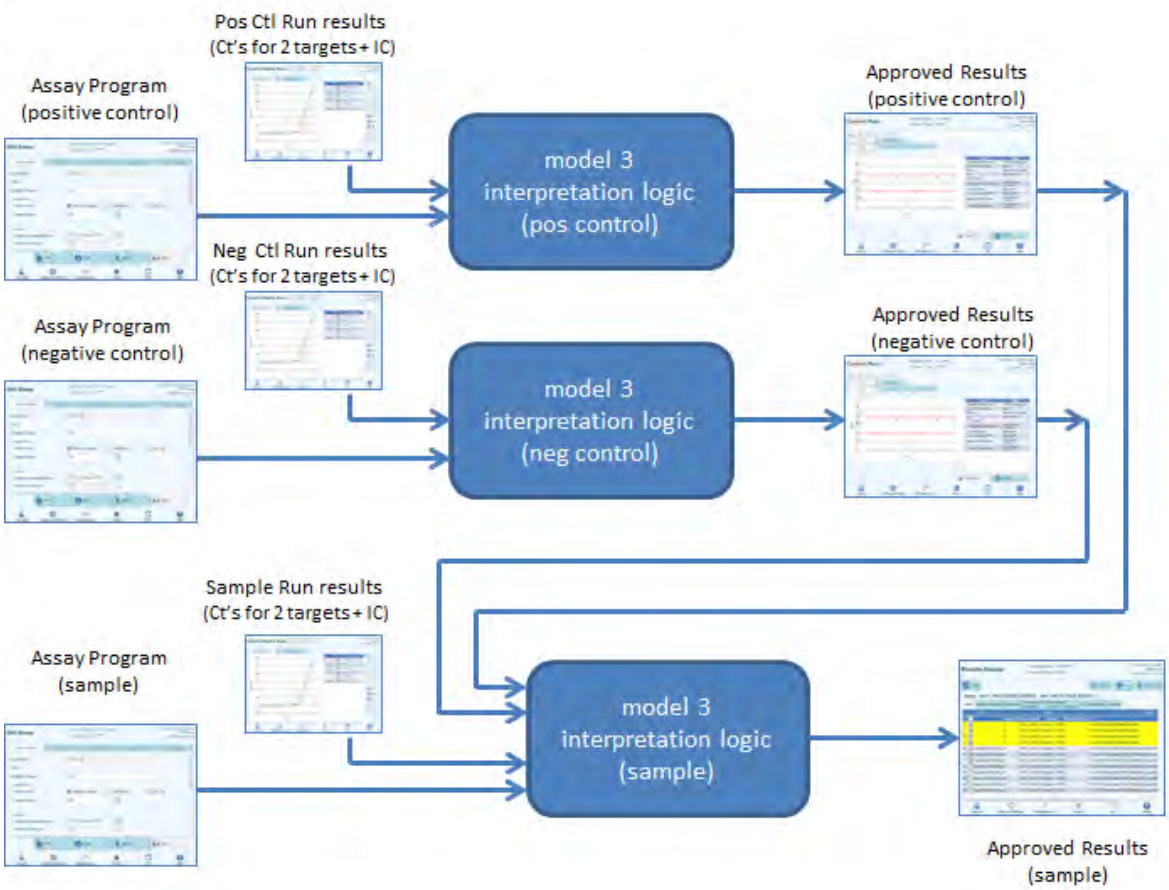


Figure 6-24: Model 3 Overview

For Model 3, patient sample results are validated using the following decision table:

Target1 Dye Channel (Ct1)	Target2 Dye Channel (Ct2)	Δ Ct = |Ct1-Ct2| IF (Ct1 < Ct2) THEN dCtLimit = dCtLimit1 ELSE dCtLimit = dCtLimit2	IC Dye Channel Ct	Sample Result Result A	Sample Result Result B	Result Interpretation
Target1 Dye Ct > Target1 Dye Ct_Limit	Target2 Dye Ct > Target2 Dye Ct_Limit	Δ Ct ignored	IC Dye Ct ≥ IC Dye Ct_Limit	Invalid	Invalid	Invalid Interpretation Text
			IC Dye Ct < IC Dye Ct_Limit	Valid, Negative	Valid, Negative	Valid Negative Interpretation Text
	Target2 Dye Ct ≤ Target2 Dye Ct_Limit	Δ Ct ignored	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Negative	Valid, Negative	Valid Negative Interpretation Text
			IC Dye Ct < IC Dye Ct_Limit	Valid, Negative	Valid, Negative	Valid Negative Interpretation Text
Target1 Dye Ct ≤ Target1 Dye Ct_Limit	Target2 Dye Ct > Target2 Dye Ct_Limit	Δ Ct ignored	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive A Interpretation Text
			IC Dye Ct < IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive A Interpretation Text
	Target2 Dye Ct ≤ Target2 Dye Ct_Limit	Δ Ct ≥ Delta Ct Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive A Interpretation Text
			IC Dye Ct < IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive A Interpretation Text
		Δ Ct < Delta Ct Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Positive	Valid, Positive	Valid Positive B Interpretation Text
			IC Dye Ct < IC Dye Ct_Limit	Valid, Positive	Valid, Positive	Valid Positive B Interpretation Text

Table 6-3 : Model 3 Patient Sample Interpretation Logic

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target1 Dye Ct_Limit
- Target2 Dye Ct_Limit
- Delta Ct_Limit1 / Ct_Limit2 (Asymmetric limits supported)
- IC Dye Ct_Limit
- Invalid Interpretation text
- Valid Negative Interpretation text
- Valid Positive A Interpretation text
- Valid Positive B Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

6.7.3.4 Model 4 - Two targets with Interpretation

This model is for use with a simple qualitative assay with two targets and one Internal Control where Ct limits are used to validate the result (e.g. C diff). This model also uses a positive control and a negative control to provide an additional level of validation for the results.

At least three Assay programs must be configured for model 4:

- A Positive Control Assay Program
- A Negative Control Assay Program
- A Patient Sample Assay Program

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 4 assays.

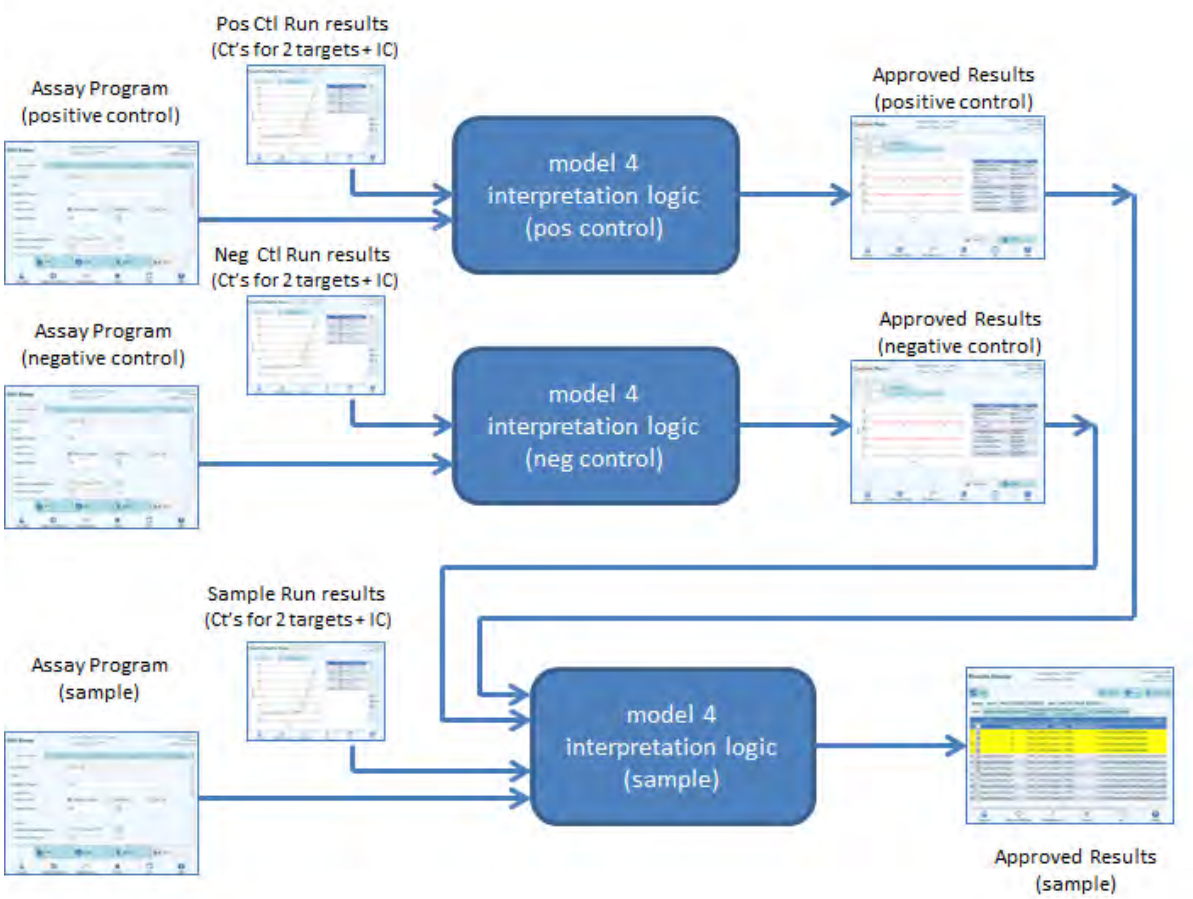


Figure 6-25: Model 4 Overview

For Model 4, patient sample results are validated using the following decision table:

Target1 Dye Channel (Ct1)	Target2 Dye Channel (Ct2)	IC Dye Channel Ct	Sample Result		Result Interpretation
			Result A	Result B	
Target1 Dye Ct ≥ Target1 Dye Ct_Limit	Target2 Dye Ct ≥ Target2 Dye Ct_Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Invalid	Invalid	Invalid Interpretation Text
		IC Dye Ct < IC Dye Ct_Limit	Valid, Negative	Valid, Negative	Valid Negative Interpretation Text
	Target2 Dye Ct < Target2 Dye Ct_Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Negative	Valid, Positive	Valid Positive Interpretation Text
		IC Dye Ct < IC Dye Ct_Limit	Valid, Negative	Valid, Positive	Valid Positive Interpretation Text
Target1 Dye Ct < Target1 Dye Ct_Limit	Target2 Dye Ct ≥ Target2 Dye Ct_Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive Interpretation Text
		IC Dye Ct < IC Dye Ct_Limit	Valid, Positive	Valid, Negative	Valid Positive Interpretation Text
	Target2 Dye Ct < Target2 Dye Ct_Limit	IC Dye Ct ≥ IC Dye Ct_Limit	Valid, Positive	Valid, Positive	Valid Positive Interpretation Text
		IC Dye Ct < IC Dye Ct_Limit	Valid, Positive	Valid, Positive	Valid Positive Interpretation Text

Table 6-4 : Model 4 Patient Sample Interpretation Logic

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target1 Dye Ct_Limit
- Target2 Dye Ct_Limit
- IC Dye Ct_Limit
- Invalid Interpretation text
- Valid Negative Interpretation text
- Valid Positive Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

6.7.3.5 Model 7 - Qualitative Results with Target identification using melting curve

This model is for use with a qualitative assay with one or more targets and one Internal Control where Ct limits are used to validate the result and then a melting analysis is used to determine which target(s) are present (e.g. Influenza A&B / RSV).

Model 7 can discriminate up to a maximum of three different target melting temperature windows per wavelength.

This model also uses a positive control and a negative control to provide an additional level of validation for the results.

At least three Assay programs must be configured for model 7:

- A Positive Control Assay Program
- A Negative Control Assay Program
- A Patient Sample Assay Program

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 7 assays.

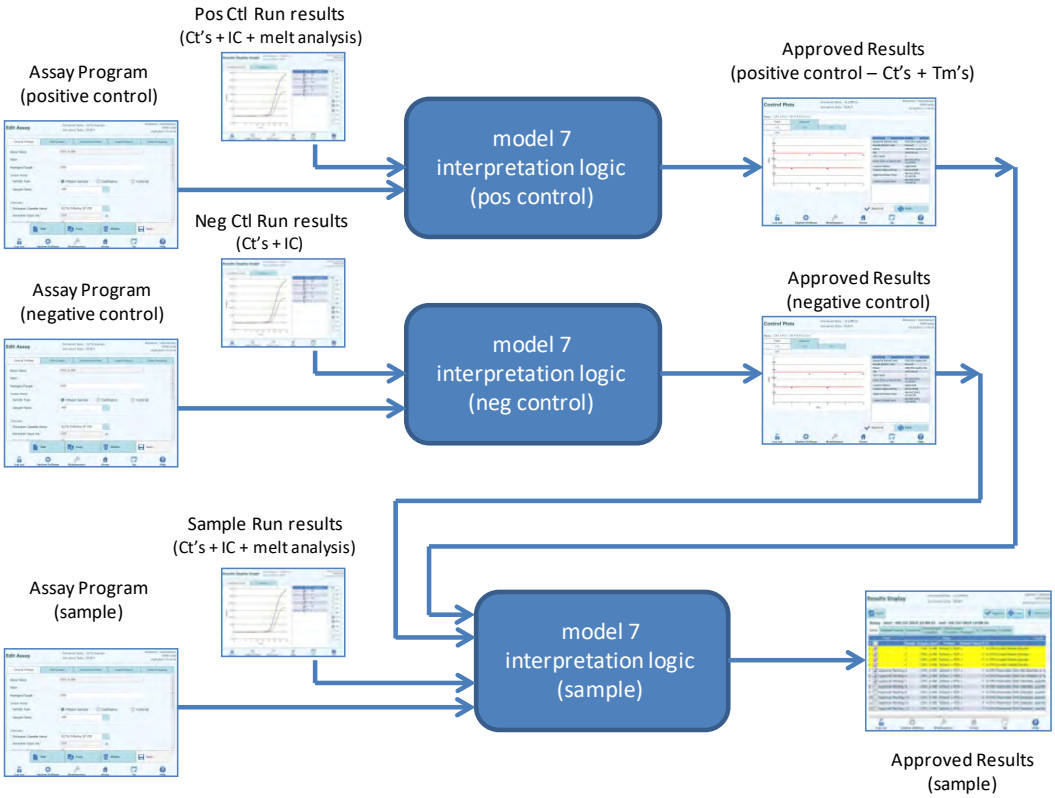


Figure 6-26: Model 7 Overview

For Model 7, patient sample results are validated using the following decision table:

Target Dye Channel Ct	IC Dye Channel Ct	Sample Result	Result Interpretation
Target Dye Ct = Undet	IC Dye Ct > IC Dye Ct_Limit	Invalid	Invalid Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Valid, Negative	Valid Negative Interpretation Text
Target Dye Ct_Limit ≤ Target Dye Ct < Undet	IC Dye Ct > IC Dye Ct_Limit	Inconclusive	Inconclusive Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Inconclusive	Inconclusive Interpretation Text
Target Dye Ct < Target Dye Ct_Limit	IC Dye Ct > IC Dye Ct_Limit	Valid, Positive	Valid Positive Interpretation Text
	IC Dye Ct ≤ IC Dye Ct_Limit	Valid, Positive	Valid Positive Interpretation Text

If a Valid Positive result is determined, the software then checks the Tm's from the melt analysis to determine which of up to three targets may be present using the following logic

Target Dye Tm1	Pathogen Typing Result Interpretation
TargetA Tm Lower Limit ≤ Target Dye Tm1 ≤ TargetA Tm Upper Limit	TargetA Pathogen Typing Interpretation Text

Target Dye Tm2	Pathogen Typing Result Interpretation
TargetB Tm Lower Limit ≤ Target Dye Tm2 ≤ TargetB Tm Upper Limit	TargetB Pathogen Typing Interpretation Text

Target Dye Tm3	Pathogen Typing Result Interpretation
TargetC Tm Lower Limit ≤ Target Dye Tm3 ≤ TargetC Tm Upper Limit	TargetC Pathogen Typing Interpretation Text

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target Dye Ct_Limit
- IC Dye Ct_Limit
- Tm Upper and Lower Limits for 3 targets
- Invalid Interpretation text
- Valid Negative Interpretation text
- Valid Positive Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

6.7.3.6 Model 9 - Two tubes, one or more targets, Ct and quantity with interpreted results, no IC

This model is used for simple quantitative assays with two tubes (e.g. PCR Mix 1 and PCR Mix 2) with one or more targets (different genes) with one or more types (type A with quantity limits, type B with quantity limits), where the Ct and/or quantity is used to interpret results.

Model 9 does not requires Internal Control.

Model 9 shall always be constrained to run one or more targets in two tracks, each with its own dedicated dye. The IC is not needed.

When Model 9 is selected, the software shall check that the Assay Programmer has configured the following products:

- Two PCR Mixes
- Two Standard Curves
- One Positive Control Set
- One Negative Control Set

6.7.3.7 Model 11 - Multiple targets, Tm with interpreted results, no IC

This model is for use with allelic discrimination assays with one or more targets (different genes) with two forms (wild-type, wt, and mutant, mu), where the Tm of two forms (Tm of wt, Tm of mu, single Tm for homozygous sample or both Tm for heterozygous sample) is used to interpret results. (e.g. Coagulation Allelic Discrimination).

Model 11 does not require an Internal Control to be present for results interpretation.

This model also uses a positive control and a negative control to provide an additional level of validation for the results.

At least three Assay programs must be configured for model 11:

- A Positive Control Assay Program
- A Negative Control Assay Program
- A Patient Sample Assay Program

The following diagram shows the relationships between the interpretation model logic and the Assay Programs, Run Results and Approvals in the database for model 11 assays.

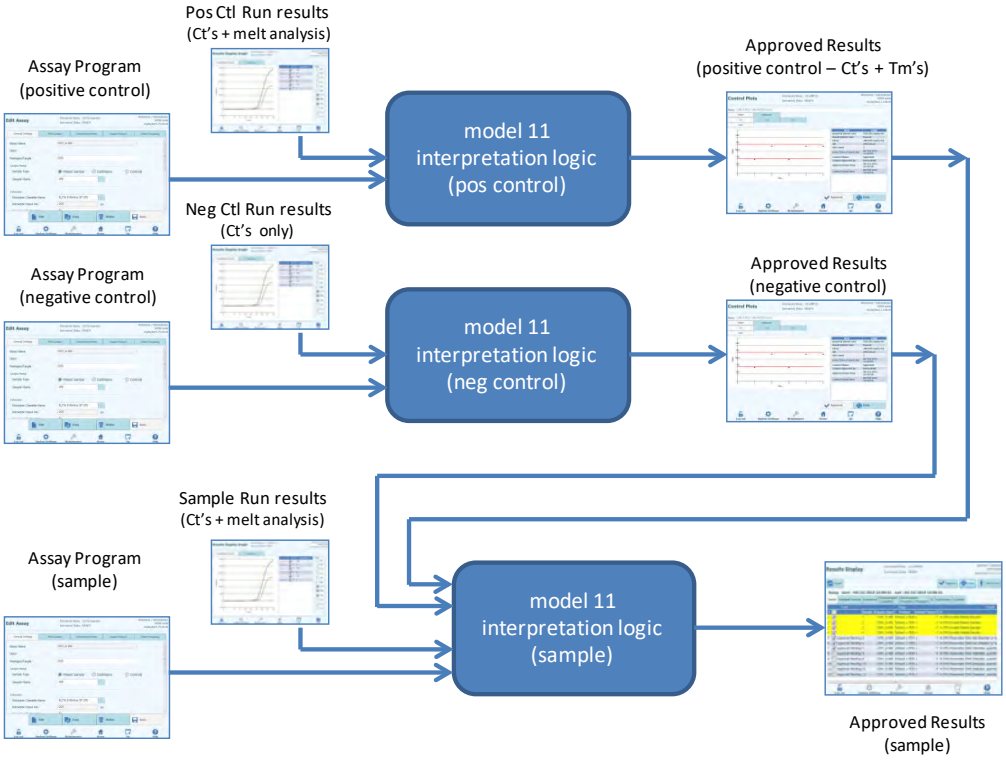


Figure 6-27: Model 11 Overview

For Model 11, patient sample results are validated using the following decision table:

Target Dye Channel (Ct)	Target Dye Tm (none, one or both Tm1 and Tm2 may be detected)		Sample Result	Result Interpretation
Ct > Target Dye Ct_Limit For one or more targets	ignored		Invalid	Target Invalid Interpretation Text
Ct ≤ Target Dye Ct_Limit For all targets	Target Dye wt Tm Lower Limit ≤ Tm1 ≤ Target Dye wt Tm Upper Limit	Target Dye mu Tm Lower Limit ≤ Tm2 ≤ Target Dye mu Tm Upper Limit	Heterozygous	Target Heterozygous Interpretation Text
	Target Dye wt Tm Lower Limit ≤ Tm1 ≤ Target Dye wt Tm Upper Limit	Tm2 < Target Dye mu Tm Lower Limit or Tm2 > Target Dye mu Tm Upper Limit	Wild-type	Target Wild-type Interpretation Text
	Tm1 < Target Dye wt Tm Lower Limit or Tm1 > Target Dye wt Tm Upper Limit	Target Dye mu Tm Lower Limit ≤ Tm2 ≤ Target Dye mu Tm Upper Limit	Homozygous	Target Homozygous Interpretation Text
	Tm1 < Target Dye wt Tm Lower Limit or Tm1 > Target Dye wt Tm Upper Limit	Tm2 < Target Dye mu Tm Lower Limit or Tm2 > Target Dye mu Tm Upper Limit	Inconclusive	Target Inconclusive Interpretation Text

The following customisable parameters are all defined in the Edit Assay, Interpretation Model Tab, Specific Parameters section of the Assay Program:

- Target Dye Ct_Limit
- Target wt Tm Upper and Lower limits
- Target mu Tm Upper and Lower limits
- Invalid Interpretation text
- Valid Heterozygous Interpretation text
- Valid Wild-Type Interpretation text
- Valid Homozygous Interpretation text
- Inconclusive Interpretation text

Similar logic is applied when validating Positive and Negative controls. For full details please contact your Elitech Customer Services representative.

6.7.3.8 Model 12 - Two tubes, multiple targets, Ct and Tm with interpreted results, IC

This model is used for multiplex assays with two tubes (e.g. PCR Mix 1 and PCR Mix 2) with one or more targets (different genes) with one or more types (type A with Tm interval A, type B with Tm interval B), where the Ct and/or Tm of different types (none, one or more Tm) is used to interpret results.

Model 12 requires Internal Control.

A single multiplexed control set is expected to be used to monitor each different target in a multiplexed assay.

Model 12 can discriminate up to a maximum of two different target melting temperature windows per wavelength (=target).

Model 12 shall always be constrained to run one or more targets in two tracks, each with its own dedicated dye. The IC is needed.

When Model 12 is selected, the software shall check that the Assay Programmer has configured the following products:

- Two PCR Mixes
- One Internal Control
- One Positive Control Set
- One Negative Control Set

6.7.3.9 Model 13 - Qualitative Results with Target identification using melting curve

This model is used with a qualitative assay with one or more targets where Melting Temperature (Tm) limits can be used.

The IC is common for all targets.

Model 13 can discriminate up to a maximum of three different pathogen melting temperature windows per channel.

Multiple pathogens can have the same dye and they are discriminated by Tm analysis in Sample and in the Controls.

When Model 13 is selected, the software shall check that the Assay Programmer has configured the following products:

- One PCR Mix
- One Internal Control
- Zero Calibrators
- One to five PCR Only Positive Control Set
  OR
  One to five Extract+PCR Positive Control Set
- One PCR Only Negative Control Set
  OR
  One Extract + PCR Negative Control Set

6.7.3.10 Model 14 - Quantitative with Ct Limits and Quantity Limits for Positive Controls

This model is used with simple quantitative assay with one or more targets where both C_T and quantity limits are used.

The IC is common for all targets.

Model 14 shall support a single target (SWV1.1)

When Model 14 is selected, the software shall check that the Assay Programmer has configured the following products:

- One PCR Mix
- Zero or One Internal Control
- One to six Calibrators (up to one per target) (only one for SWV1.1)
- One to six Positive Control Sets (up to one per target) (only one for SWV1.1)
- One Negative Control Set (shared across all targets)

6.7.4 Add Model

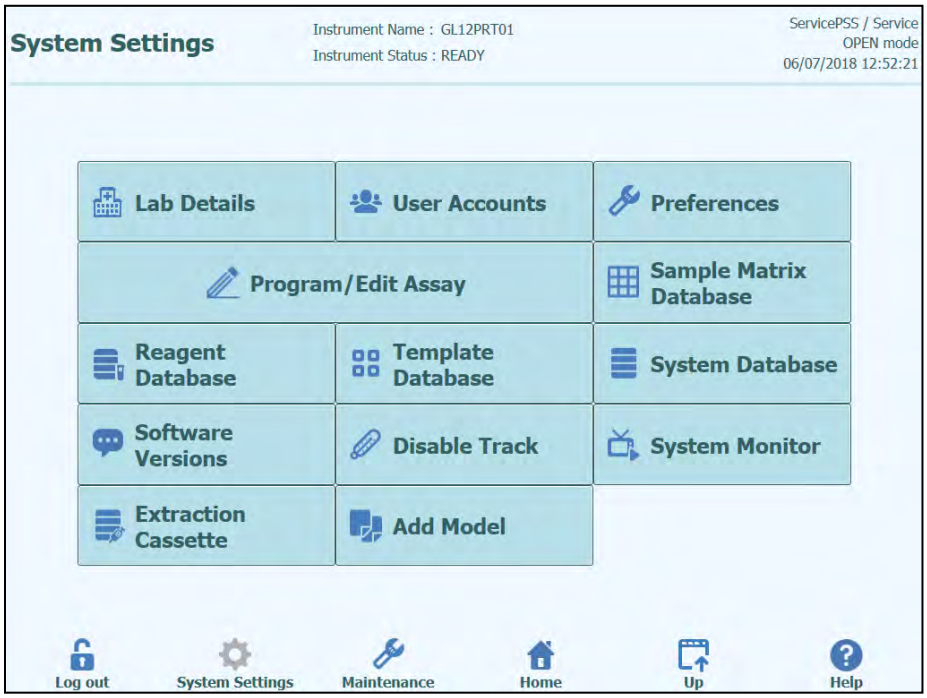


Figure 6-28: Add Model Tab

The function “Add Model” allows loading in the software new interpretation models without change software version.

New interpretation models can be generated exclusively by ELITechGroup S.p.A.

6.7.5 Edit Assay: Assay Products Tab

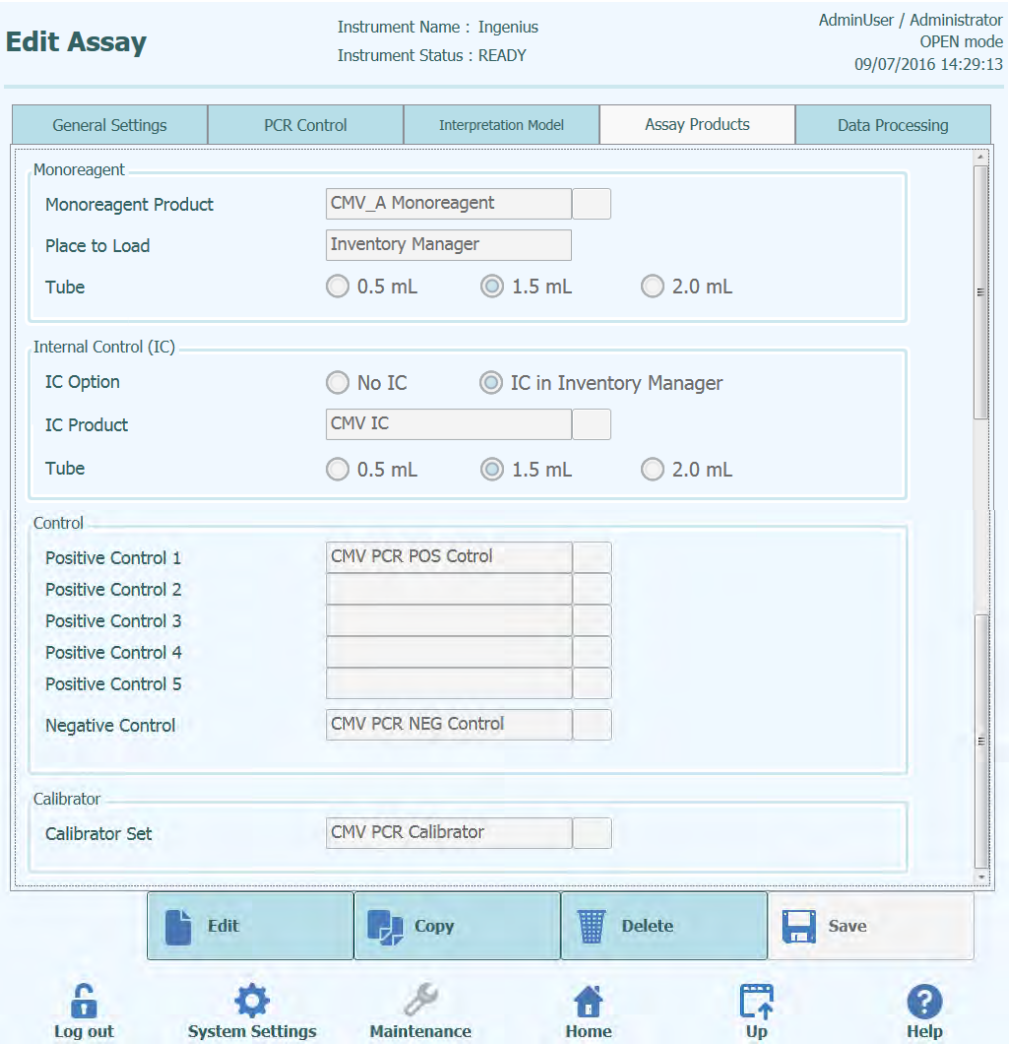


Figure 6-29: Edit Assay Assay Products Tab

- Monoreagent
  This specifies the Monoreagent that is used by this Assay. You can choose from the list of Monoreagents that are stored in the reagent database (see section 6.9). The current release of the ELITe InGenius software only supports placing of Monoreagents in the Inventory Manager area. Specify also the size of Monoreagent tube that will be used.

- IC
  This specifies the Internal Control that is used by this Assay. You can choose from the list of Internal Controls that are stored in the reagent database (see section 6.9). The current release of the ELITe InGenius software only supports placing of Internal Controls in the Inventory Manager area. Specify also the size of Internal Control tube that will be used.

- Control
  Specifies the control sets used to monitor the process quality for the Assay. Provision is made to specify up to five positive controls (for multiplexed assays), which is dependent on the number of targets specified in Interpretation Model tab. A negative control set should also be specified here. Control sets are read from the Control manager database (see section 5.3)

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

Assay. Since this version of the ELITe InGenius software only supports a single target, only a single calibration entry is available. Calibration sets are read from the Calibration manager database (see section 5.3)

6.7.6 Edit Assay: Data Processing Tab

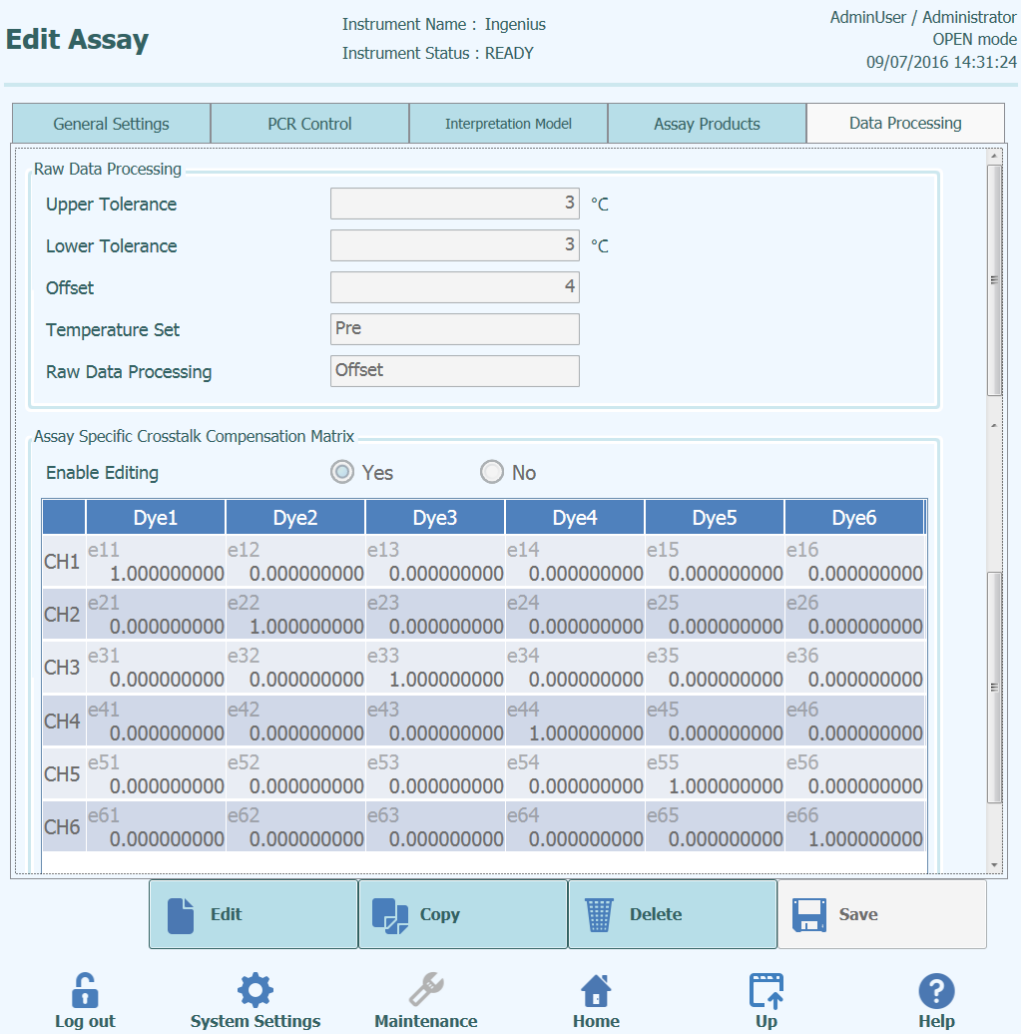


Figure 6-30: Edit Assay Data Processing Tab

The settings in this tab are used to fine tune processing of raw fluorescence data from the instrument. Further details about these settings can be obtained by contacting your Elitech Product Support representative.

6.8 Sample Matrix Database

The Sample Matrix Database is a database of the details for the Sample Matrices that may be used by the Assays on the ELITe InGenius system.

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

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

Sample Matrix settings can be loaded onto the system using either

- USB Flash Drive
- On-screen Keyboard entry

A number of common Sample Matrices used by ELITech assays are already registered in the Sample Matrix database.

To add a new Sample Matrix using the on-screen keyboard;

1. click on the “Add New” button
2. fill out the Name and Extraction Efficiency in the boxes on the right hand side of the screen
3. Press SAVE

It is only possible to delete the settings for a Sample Matrix when no Assay Program is setup to use that Sample Matrix. A warning will be given by the software if you try to delete a Sample Matrix that is still in use by the system.

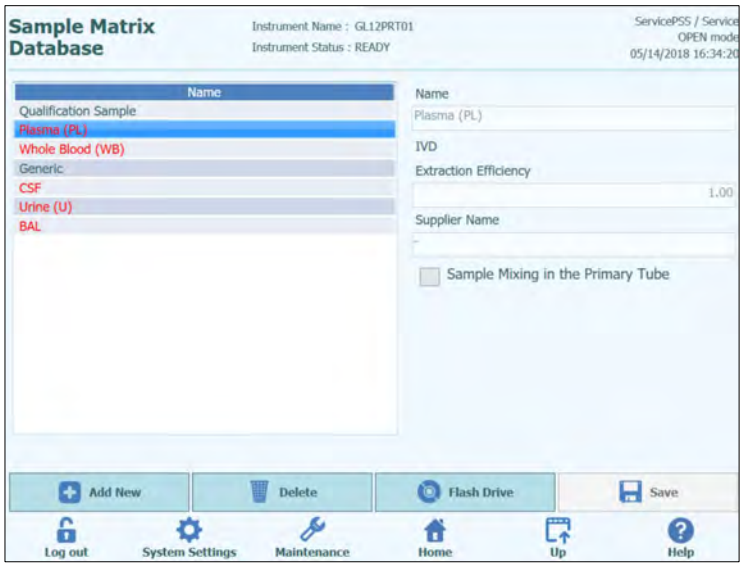


Figure 6-31: Sample Matrix Database screen

6.9 Reagent Database

The Reagent Database is a database of the details for PCR mono-mixes and Internal Controls that may be used by the Assays 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 pressing the “Reagent Database” button in the System Settings screen.

Reagent settings can be loaded onto the system using

- USB Flash Drive

A number of common ELITech reagents are already registered in the Reagent database. Please contact ELITech for the Barcodes or Settings files for any additional reagents you wish to use.

It is only possible to delete the settings for a Reagent when no Assay Program is setup to use that Reagent. A warning will be given by the software if you try to delete a Reagent that is still in use by the system.

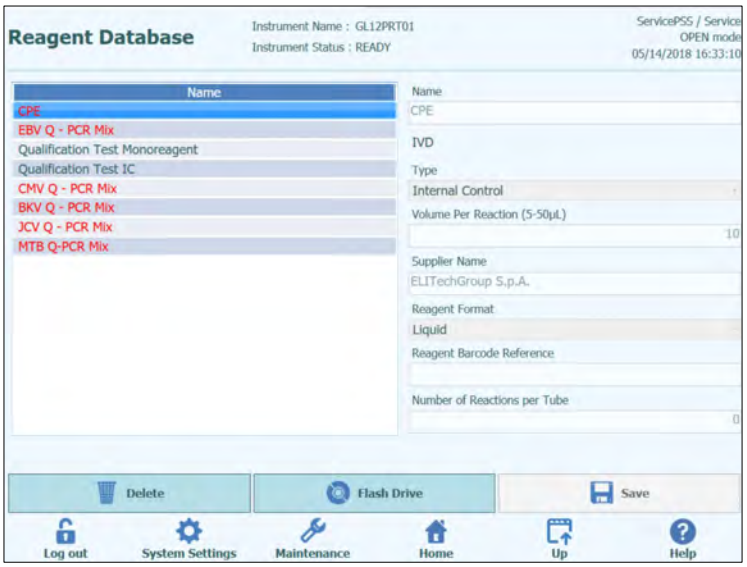


Figure 6-32: Reagent Database screen

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.

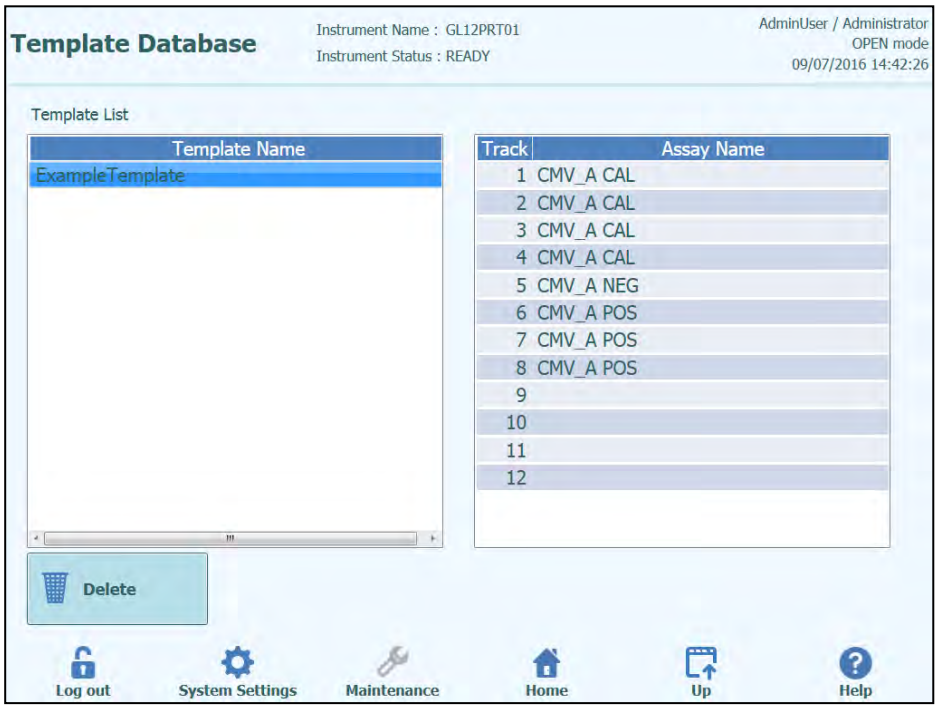


Figure 6-33: Templates Database screen.

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.

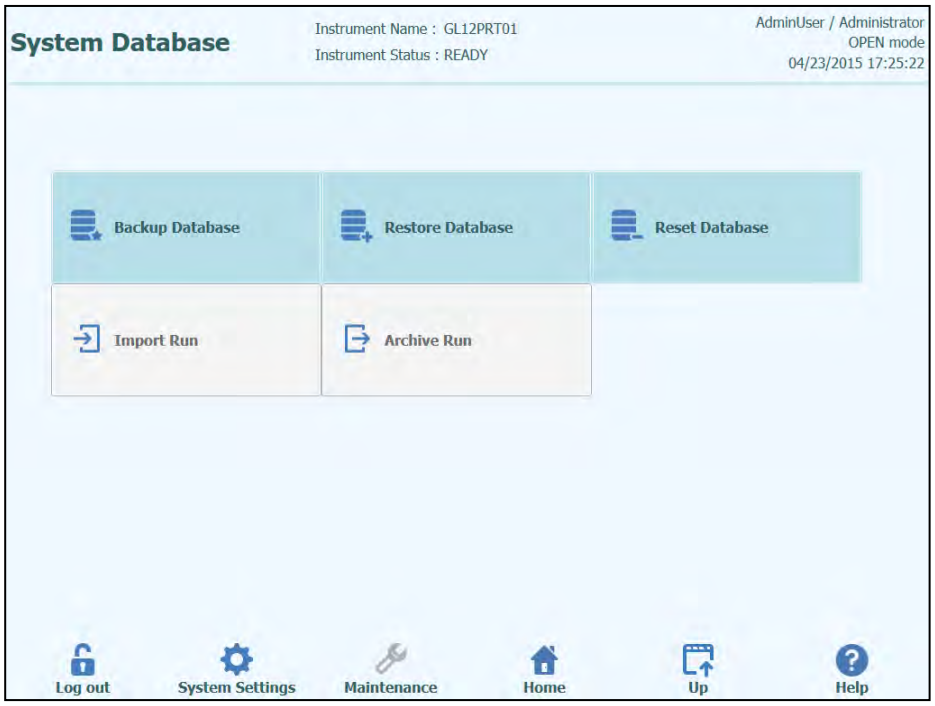


Figure 6-34: System Database Screen.

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.

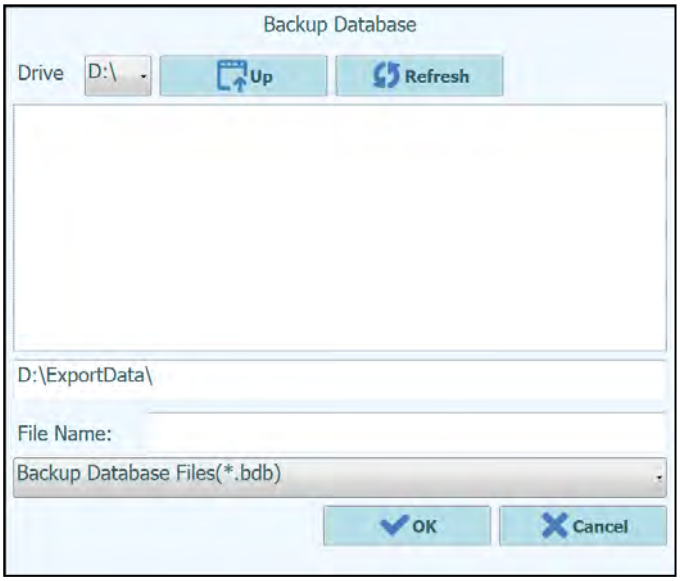


Figure 6-35: Backup Database Destination Selection

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.

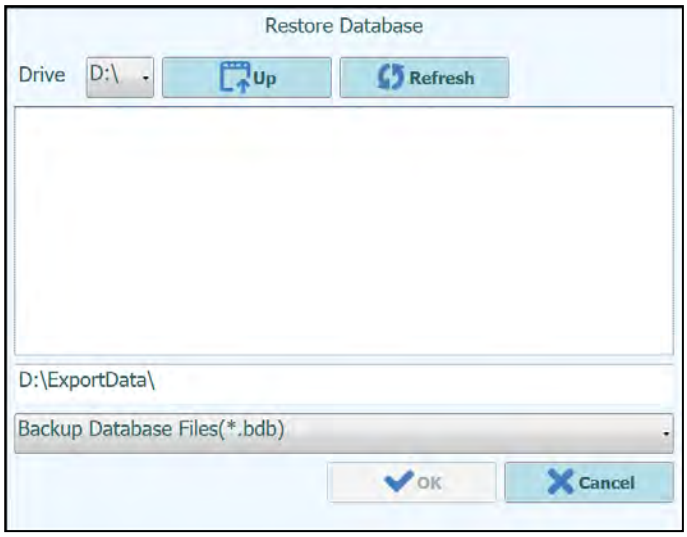


Figure 6-36: Restore Database Source Selection

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.

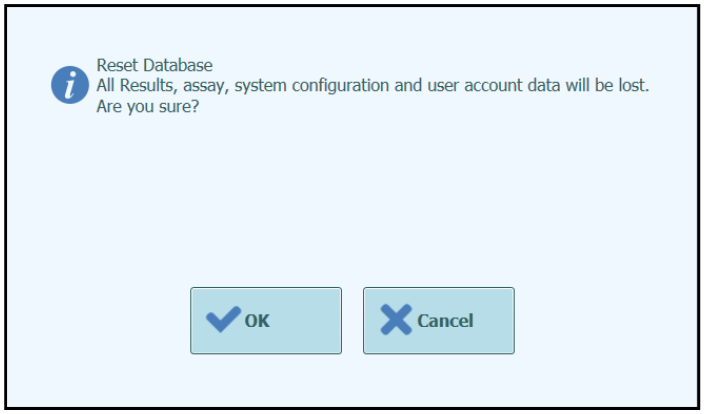


Figure 6-37: Reset Database Confirmation

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 6-38: 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

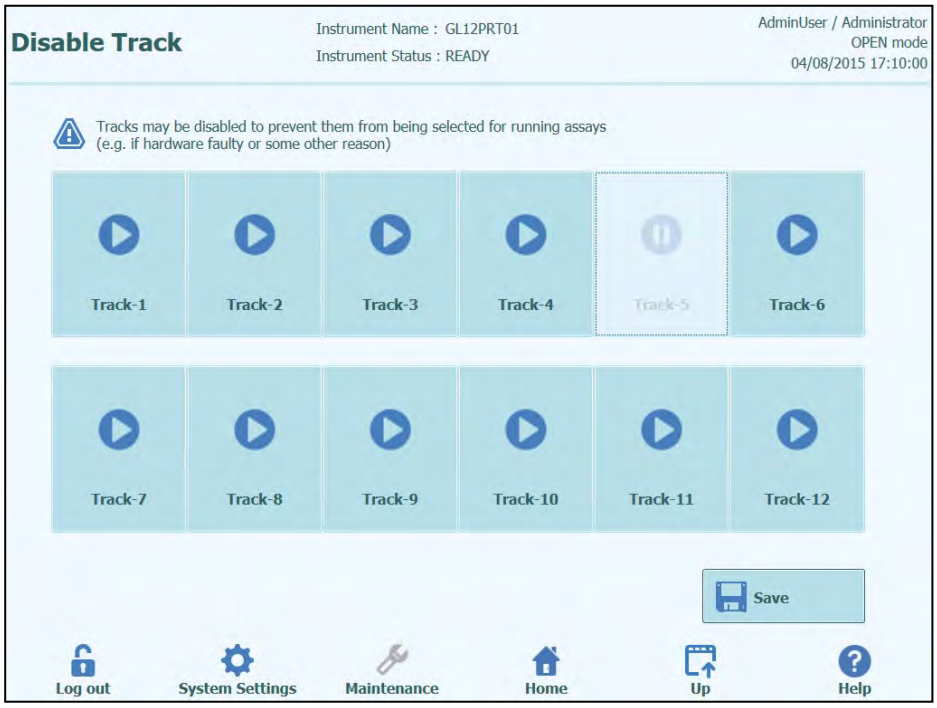


Figure 6-39: Disable Track screen

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.

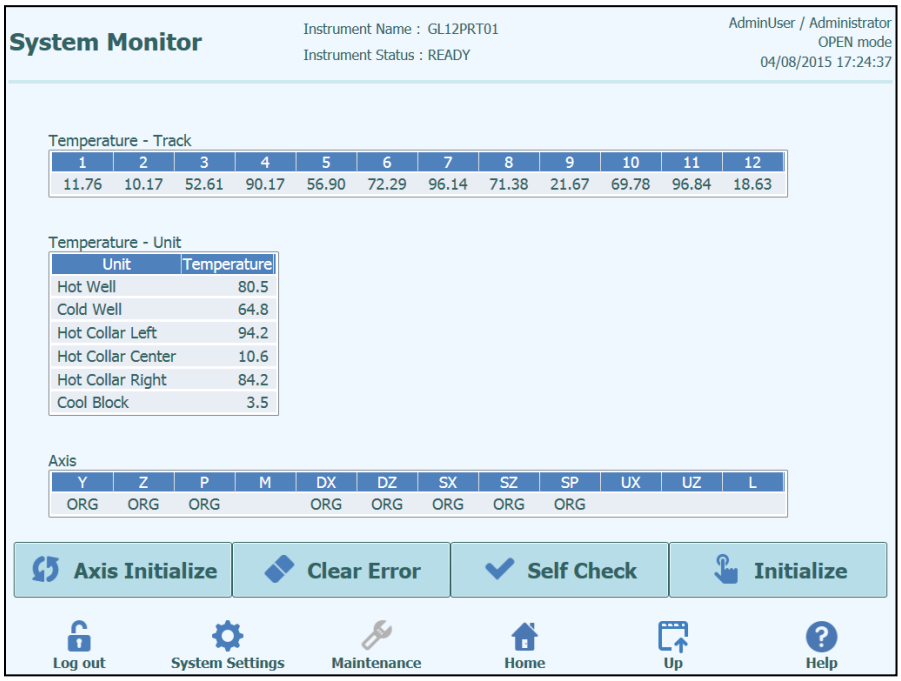


Figure 6-40: System Monitor screen

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 during the extraction and PCR Setup sessions will be traced in the report files. The error codes (ID) useful for traceability and technical service.

Barcode Reading Error

When an Error occurred during the Barcode Reading process, an executed RUN is aborted and moved to the Barcode Read Error screen.

Error causes and coping processes are described in this paragraph.

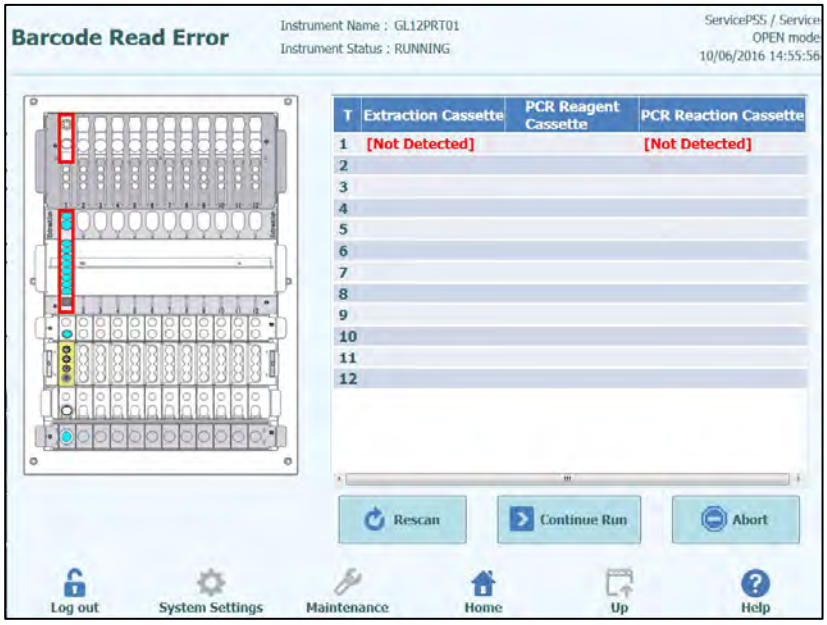


Figure 7-1: Preferences display

ID Error of PCR or Extraction Cassette

This error occurred when PCR Cassette ID of Assay information, which registered in the Program Assay, is mismatch with a read ID by inner barcode reading. In this case, an Error is solved by setting an intended cassette in accordance with the Assay information on a stage.

(Procedure of Retry the Barcode Reading process)

An instrument unlocks the door automatically.

The user opens the front door.

Remove the cassette which is highlighted on the screen.

Set the registered cassette that has been registered on Program Assay screen for a PCR cassette, or on Extraction Registration screen for an Extraction cassette.

Close the front door.

Press “Retry” button.

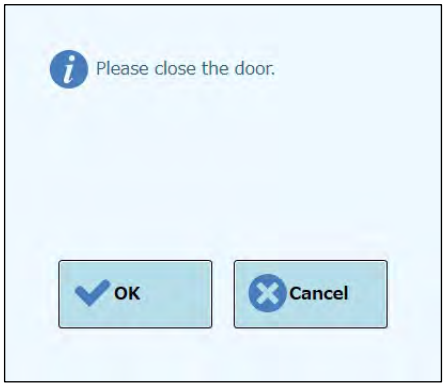


Figure 7-2: Popup message about to confirm that the front door is closed

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

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

Detecting a Used Cassette

When a cassette that used previous RUN is used for a relevant RUN, this function makes a barcode scan as an error. If the same RUN information, that assigned as sequential number in a barcode information, detected from previous 10 RUN, this error occurs.

(Procedure of Retry in case of a used cassette is detected)

Retry the same procedure as previous section.

	Used Cassette need to be discarded on a designated area.

	Gloves need to be worn while operation.

8 Maintenance

8.1 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.

8.2 Periodic maintenance by user

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.

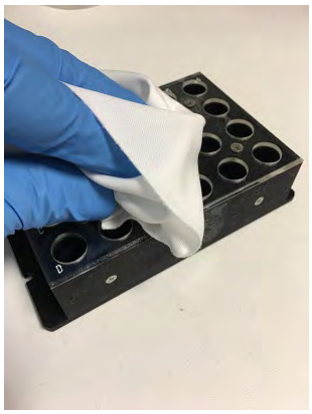
- **Clock Block**

As this unit is temperature controlled, condensation may form on the surface of the Cool 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.

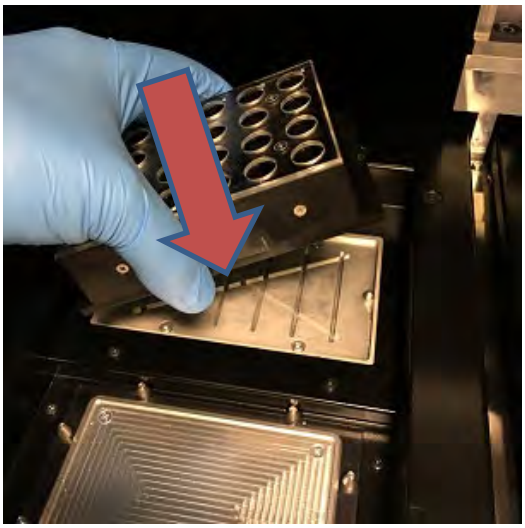
Proceed by:

1) Extracting the Cool Block (EXT).

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



3) After cleaning and drying the Cool Block (EXT) and the worksurface reinstate the Cool 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.

9 Remote 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.

9.1 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.

9.2 Using the ELITech Remote Access feature

In order to use the remote access software, the User should follow the follow steps

1) Connect one end of a network cable to the LAN port on the instrument and the other end to a properly configured network port, identified by the customer's facility networking group.
2) If not already done, exit the ELITe InGenius software to the Windows Desktop.
3) Insert a flash drive containing a software for remote access and control (ex. VNC, TeamViewer etc.).
4) connect a USB keyboard with the windows key press the Windows key (see picture below) to bring up the start menu and press the „Computer“ entry and then choose your flash drive.
5) Install the chosen software with the dedicated procedure.
6) From a separate computer that has a registered copy of the same software, ensure that the remote connection is functional.

10 Technical Specification

10.1 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)

10.2 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.

10.2.1 Transport and storage environment conditions

Storage temperature shall be within +5 to +40°C.

Storage humidity shall be within 20 to 80 RH%.

Transport temperature shall be within -25 to +60°C.

Transport humidity shall be within 20 to 80 RH%.

10.3 Noise levels

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

10.4 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

10.5 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)

10.6 Pipetting performance

Pipetting range:

Single-nozzle pipettor: 5 - 300 µL

12-nozzle pipettor: 10 - 1000 µL

10.6.1 Single-nozzle Pipettor unit

Volume	Accuracy	Precision (%CV)
5 to <10 µL	±10%	5.0%
10 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

10.6.2 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%

10.7 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 extraction/sonication 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)

10.8 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

10.9 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)

10.10 PCR 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)

10.11 Optics 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

10.12 Cool block (Inventory Manager) specifications

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

10.13 Operating system

Windows Embedded 10, 64 Bit.

10.14 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

10.15 Barcodes compatibility

A broad range of barcode ise 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 .

10.16 Calorific value and power consumption

Calorific value: 3,384 kJ/h

Power consumption: 940 W

Stand-by power: 300 W

10.17 Battery information

Number of Li-ion battery : 1

Manufacturer: FDK

Model: CR2032 coin type

Voltage: 3V

Capacity: 240 mAh

Watt-hour raiting: 0,72 Wh

Weight: 3g