# Galaxy Lite

## Automated Fully Enclosed qPCR Instrument

### Galaxy Lite User Manual



Igenesis

**IGENESIS(SHANGHAI)CO, LTD.**
Preparation Date: Novermber 6,2023
Version: A/3
Name of Manufacturer: Igenesis (Shanghai) Co., Ltd.
Manufacturer Address: Floor 3, Building 1, Lane 500, Furonghua Road,
Pudong New Area, Shanghai, P. R. China
Tel:021-38016598

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# Preface

## Description

Thank you for purchasing Galaxy Lite Automated Fully Enclosed qPCR Instrument (hereinafter referred to as "Galaxy Lite").

Please read this manual carefully before using the instrument so as to use the product properly. Please keep this manual with care after reading so that it can be consulted at any time when necessary.

**Product Name:** Automated Fully Enclosed qPCR Instrument

**Product Model:** Galaxy Lite

**Product Specifications:** Galaxy Lite has four models, including 1.0, 2.0, 3.0 and 4.0 which is classified by the configurations. Please see details in the following table:

| Specification | Configuration |
|---|---|
| 1.0 | 0ne Instrument |
| 2.0 | 2-cascade Instrument |
| 3.0 | 3-cascade Instrument |
| 4.0 | 4-cascade Instrument |

**Intended Use**: Galaxy Lite Automated Fully Enclosed qPCR Instrument can be used for real-time fluorescence PCR experiment and analysis. The instrument can be operated in a laboratory or in a stable environment and together with corresponding detection reagents. It can automatically complete the extraction and purification of nucleic acid, QPCR amplification and result analysis.

## The Relevant Labels of Galaxy Lite

| Symbol | Description |
|---|---|
|  | **Protective Grounding:**<br>Identifies the terminal connected to the outer protection conductor to prevent electric shock in case of failure. |
|  | **Alternating Current:**<br>Identify the terminals for AC power, indicating that the equipment is only suitable for AC power. |

| | |
|---|---|
|  | **Manufacturer** |
|  | **Date of Manufacture** |
|  | **Refer to instructions for use.** |
|  | **Serial Number** |
|  | **In Vitro Diagnostic Apparatus** |
|  | **Temperature Limit** |
|  | **Expiry Date** |
|  | **Fragile, handle with care:**<br>Indicates that the product or some of its components are fragile and reminds handling personnel to handle it with care. |
|  | **Avoid Rain:**<br>Indicates that the product is afraid of rain and should be kept dry. |
|  | **Upper:**<br>Indicates that this arrow is kept upward during transportation of this product. |
|  | **No Hand Hook:**<br>Indicates that hand hooks are not allowed when handling transport packages. |
|  | **No Stacking:**<br>Indicates that the package is only allowed to be stacked in a single layer. |
| **REF** | **Reference** |
| CE | The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC |

## Contact Information

Igenesis (Shanghai) Co., Ltd.

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## Intellectual property



## Statement

Igenesis owns the final right to interpret this user manual.

Only when all of the following requirements are met, Igenesis will take the responsibility upon safety, reliability and performance of the product:

- The product Installation, debugging, maintenance, repair and improvement shall be conducted by professionals from Igenesis.
- All spare parts and consumables for maintenance are original (factory-packed) Igenesis from or approved by Igenesis.

- The application environment of this product shall be in conformity with the requirements of this user manual.
- The operation of the instrument shall be carried out according to this user manual.
- **Instrument Service Life**: 8 years. The service life is confirmed by the aging test. Please use, clean and maintain the instrument according to the user manual.
- **Instrument Maintain Period**: Every 12 months. Please contact the after-sale service.
- **Instrument Calibration Period**: Every 12 months. Please contact the after-sale service or the qualified agency.

## Warranty and Maintenance

- The warranty period of the product is 15 months.
- The consumable mentioned in this user manual is the disposable consumable or vulnerable material that needs to be replaced after each use, and the consumables have no warranty.
- The warranty period starts from the "Delivery date".In order to safeguard your rights and interests, please fill in the warranty card correctly after the installation of the equipment, and give the second copy of the warranty card (retained by Igenesis) to the installation personnel or post it back to the user service department of Igenesis.
- Please note that the following conditions will not be covered by the warranty:
- The equipment serial number provided by the user is incorrect (Igenesis confirms whether the warranty is guaranteed by the equipment serial number.).
- Disassemble the instrument without the approval of Igenesis.

- During the warranty period, all products enjoys free after-sales service. However, please note that even if the products need to be repaired during the warranty period, Igenesis will implement the chargeable maintenance service due to the following reasons, and user needs to pay for the maintenance fee and accessories fee:
- The product is not operated according to the user manual.
- Artificial damage.
- Improper use
- User does not follow the user manual to operate the instrument.
- The grid voltage exceeds the specified range of the product.
- Unexpected natural disasters.

- Replace or use parts, accessories and consumables that are not approved by Igenesis, or repair them by personnel not authorized by Igenesis.
- Other faults not caused by the product itself.
- After the expiration of the warranty period, Igenesis can continue to provide chargeable maintenance service. If your party do not pay or delay to pay the chargeable maintenance service fee, Igenesis will suspend the service until you pay.

## After-sale Service

- **After-Sales Service**: Igenesis (Shanghai) Co., Ltd.
- **Manufacturer Address**: Floor 3, Building 1, Lane 500, Furonghua Road, Pudong New Area, Shanghai, P. R. China.
- **Email**: support@igenesisbio.com
- **Tel**: +86-21-38016598

# Contents

# 1 About User Manual

## 1.1 Overview

This section describes how to use the Galaxy Lite user manual which is attached with the instrument gives a detailed description of the use, function and operation of the Galaxy Lite instrument. Before using the instrument, please read this manual carefully and familiarize yourself with contents to ensure the correct use of the instrument the safety of the operator.

Please be sure to strictly follow the instructions in the manual. User could operate the instrument with protective gloves and facial mask after trained.

The illustrations provided in this manual are for example only and please do not use it for other purposes. The graphics, settings, or data in the illustration may not exactly match the actual display you see on the instrument.

## 1.2 Application Scope of Manual

This manual is suitable for professionals or trained doctors, nurses, experimenters, distributor, agent, after-sale personnel, etc. to read.

- Understand the performance and function of Galaxy Lite instrument.
- Set system parameters.
- Perform daily operation.
- Perform system maintenance and troubleshooting.

## 1.3 Guide of User Manual

This manual contains ten chapters. The operator can find the corresponding chapters according to the required information.

| Section | Reference |
|---|---|
| 1 About Manual | To know the manual |
| 2 System Overview | Intended use and composition of Galaxy Lite instrument |
| 3 Instrument Characteristics | The performance characteristics and parameter of |

| | |
|---|---|
| | Galaxy Lite |
| 4 Instrument Installation | The installation requirements and steps |
| 5 System Software Functions | The function of the software of galaxy lite instrument system |
| 6 Operating Introductions | The daily operation of Galaxy Lite instrument |
| 7 Calibration and Quality Control | The basic requirements of Galaxy Lite calibration |
| 8 Precautions | The operation precautions and limits of Galaxy Lite instrument |
| 9 Service and Maintenance | The maintenance methods of Galaxy Lite instrument |
| 10 Troubleshooting | The causes and solutions of Galaxy Lite instrument failure |

## 1.4 Security information

This instrument is an electromechanical instrument. If it is not used strictly in accordance with the use manual, it may bring potential hazards to the user, such as electric shock or hand pinching.

- In connection of the power cable, ensure that the power supply is turned off.
- It is forbidden to touch the power switch and power cable with wet hands.
- It is forbidden to unplug and plug the power cable when the instrument is not powered off.
- It is forbidden to clean the instrument while it is not powered off.
- Please turn off the power supply when the instrument is no longer in use.
- To avoid electric shock, the instrument must be grounded properly.
- Please operate the instrument in accordance with the safety instructions.
- It is forbidden to touch the heating module to avoid scalding while the instrument is operating or for a period of time after operation.
- User should keep patients' data complete and confidential in terms of physics, technology and administrative management.
- If users do not follow the given advice, it may cause system damage, data loss or structural failure.
- When user may touch any motion part labeled warning signs indicating that the operator is not allowed to

touch it without trained. Please strictly follow the warning sign. Please do not touch the iCassette Tray when Galaxy Lite instrument compartment door opens and closes, or there is a danger of hands pinching.

- Safety masks and protection gloves must be worn when handling toxic, corrosive or infectious substances following the relevant local safety regulations. If a spatter or leakage occurs accidentally, please immediately handle it to protect the laboratory personnel and instruments from contamination.
- Please follow the necessary procedures to clean and disinfect instrument before return it to factory service.

## 1.5 Label

The following signs will be shown in the user manual or instrument:

| Sign | Title | Description |
|---|---|---|
| O | Power off | Cut off instrument power supply. |
| \| | Power on | Provide power for instrument. |
|  | WARNING | If does not follow the warning, it may result in injury to the human body or damage to the instrument. This is the important information for a proper use of the instrument. |
|  | High Temperature | It indicates that a certain area of Galaxy Lite may produce high temperature. Remind users to carefully operate and caution against burns. |
|  | Biohazard | Be cautious in contact with potential infectious and hazardous substances. |
|  | Warning Hands Pinching | It indicates that a certain moving part of Galaxy Lite may cause hands pinching. |
|   | In Vitro Diagnostic | It indicates that Galaxy Lite is an In Vitro Diagnostic (IVD) device. |

Please refer to the following labels position on Galaxy Lite.


Figure 1-1 Label Position

① **Warning:** User shall not open instrument shell or replace other components. Any damage to instrument will not covered under the warranty.

② **Warning Hands Pinching:** It is forbidden to touch the heating module to avoid scalding while the instrument is operating and a period of time after operation.

③ **Biohazard:** Safety masks and gloves must be worn to handle toxic, corrosive or infectious substances; if a spatter or leakage occurs accidentally, appropriate disinfectant should be used immediately to prevent contamination for laboratory personnel and instruments.

④ **High Temperature**: Do not touch this area to avoid burn.

# 2 System Overview

## 2.1 Instrument Overview

The Automated Fully Enclosed qPCR Instrument is an automatic fluorescence PCR analysis and detection system with precision temperature control, stable optics system, easy operation, excellent software, etc. The instrument is capable of performing nucleic acid extraction, real-time fluorescence analysis, whole procedure detection. It aims to provide a flexible, safe, quick and contamination-free automated solution for nucleic acid detection in vitro diagnostic.

## 2.2 Basic Principle

Galaxy Lite Instrument could conduct nucleic acid extraction, purification, amplification and analysis based on real-time polymerase chain reaction (PCR).

Put the reagent kit that loads sample and pre-loaded reagent into the iCassette Tray of the instrument. The heating module heats up the lysis area in reagent box to release the nucleic acid from sample to solution. After magnetic beads adsorption, the extracting solution will be pushed in a physical way to wash area to wash the impurities on magnetic beads. Then, the extracting solution will be pushed in a physical way to elution area to realize nucleic acid extraction and purification by adsorbing the magnetic beads to reagent box via magnetic device. The extracted and purified nucleic acid solution is pushed to PCR area in a physical way and the instrument starts to control the temperature in PCR amplification area and, simultaneously, reads fluorescence signal. Finally, the software could analyze the read fluorescence signal to generate amplification curves, Ct value, etc. automatically.

## 2.3 Application Scope

Based on real-time PCR principle and combined with detection reagent, Galaxy Lite is, clinically, intended to extract, purify and quantitatively detect the target nucleic acid (DNA/RNA) from human being samples, such as oropharynx swab, nasopharyngeal swab, genital tract swab, sputum, feces, cervical exfoliated cell. The item of pathogen is one of them.

## 2.4 Structure and Components

Galaxy Lite mainly consists of extraction module that is composed of mechanical motion unit, temperature

control unit and magnetic unit and PCR module that is composed of optics, temperature control unit, electric system and relative software functions and system software (Version: V1). The instrument structure is as shown in figure 2-1(The pad in following figure is only an example.).

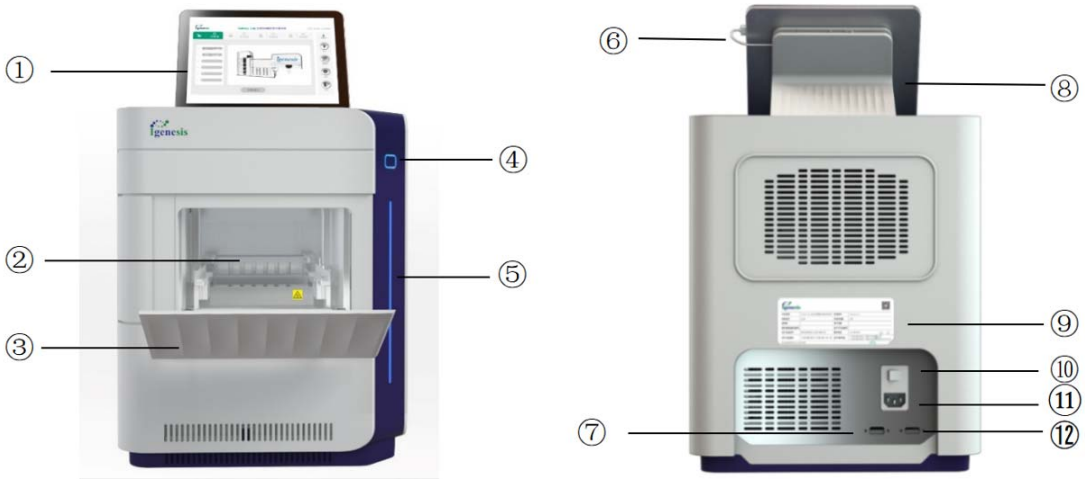



Figure 2-1 Galaxy Lite structure

| | | | |
|---|---|---|---|
| 1. External Device | 2. iCassette Tray Holder | 3. Compartment Door | 4. Switch |
| 5. Power Indicator | 6. USB Type-C Port | 7. IN | 8. Pad Holder |
| 9. Nameplate | 10. Power Switch | 11. Power Input | 12. OUT |

1. **External Device**: The external device is a computer which is connected to instrument from USB port to control the instrument and collect the data. The computer configuration can be selected by user him or herself.
2. **iCassette Tray Holder**: This is used for placing the iCassette Tray.
3. **Compartment Door**: It can be opened and closed by software and shall be opened when load or unload iCassette Tray while shall be closed when the instrument is running.
4. **Switch**: The switch is located in instrument face. After plugging the power cord and turning on power switch, please press the instrument switch over 1 second and the instrument will be started with the power indicator is blue. While, press the instrument switch over 5 seconds when the instrument is on to shut down the instrument. The power indicator will be off.
5. **Power Indicator**: It indicates the status of the instrument. The indicator is off when the instrument is shutdown while it is blue when the instrument is on. The monitoring procedure is blue breathing light. The error is periodically flickering.
6. **USB Type-C Port**: It is used for connecting computer via USB cable to realize data communication.

7. **IN**: This is a dedicated port where shall use the matched cable from Igenesis to connect 4 instruments maximally and simultaneously.
8. **Pad Holder**: It is used to place pad.
9. **Nameplate**: It displays the instrument model, SN, etc.
10. **Power Switch**: It is the instrument AC power switch.
11. **Power Input**: This is the AC power supply input port.
12. **OUT**: This is a dedicated port where shall use the matched cable from Igenesis to connect 4 instruments maximally and simultaneously.

## 2.5 Accessories

**iCassette Tray**: It is used for loading reagent kit.

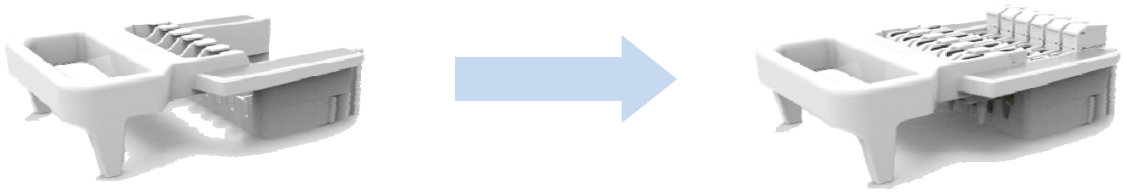


Figure 2-2 iCassette Tray

**Reagent Kit**: It is a disposal detection consumable and is charged. Please contact the after-sale service or agent to purchase the reagent kit.

**Biohazard**: Please keep the reagent kit properly. The improperly preservation may cause regent invalidity. Please do not disassemble the reagent kit and handle it with care according to the local regulation and lows.

**Communication Cable**: It is recommended to use the communication cable by Igenesis.

**Power Cord**: Please use the power cord provided by Igenesis.

## 2.6 Running Environment

Galaxy Lite's running environment:

- Hardware: 32-bite MCU Microprocessor;
- Network: Without connection;

Pad or PC running environment:

- CPU: 2GHz or higher;
- Memory: 2GB or higher;
- Hard Drive: 2GB or higher:
- Software Configuration: Window 10, 64-bite;
- Network: The pad or PC connected to instrument could access to wired (with internet port RJ-45, bandwidth 10M or higher) or wireless (Wi-Fi IEEE 802.11, bandwidth 10M or higher) LIS network.

# 3 Instrument Characteristics

## 3.1 Overview

This section introduce the Galaxy Lite instrument characteristics and key parameters.

## 3.2 General Specifications

- **Instrument Specification:**

  Dimension: 480mm(L) × 330mm (W) × 400mm (H);

  Weight: 35kg;

- **Application Environment:**

  Temperature: 15°C-35°C;

  Relative Humidity: 20%-85%RH;

- **USB Port:**

  There is a USB port in instrument functioned to connect to a computer.

## 3.3 Throughput

The instrument owns 6 throughputs which can be expanded to 24 maximally via 4 instruments cascade.

## 3.4 Fluorescence Channel

The instrument possesses 7 channels and dyes like FAM, HEX, TAMRA, ROX/TEXAS RED, CY5, CY5.5, AMCA is available. Please see details in the following table.

| Channel No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Excitation Filter | 460nm | 525nm | 543nm | 571nm | 624nm | 675nm | 350nm |
| Emission Filter | 525nm | 564nm | 584nm | 624nm | 675nm | 710nm | 460nm |
| Suitable Dyes | FAM | HEX | TAMRA | ROX/ TEXAS RED | CY5 | CY5.5 | AMCA |
| Light Source | white LED | | | | | | UV LED |

## 3.5 PCR Temperature Parameters

- **PCR Temperature Range:**

  5℃～99℃

- **Temperature Control Precision:**

  0.5℃

- **Temperature Uniformity:**

  ≤1℃

- **Max. Heating Rate:**

  ≥4.2℃/s

- **Max. Cooling Rate:**

  ≥3.5℃/s

# 4 Instrument Installation

## 4.1 Overview

This section describes the installation process and precautions of Galaxy Lite.

In order to ensure the proper operation of the instrument after installation, the installation and initial settings at delivery of Galaxy Lite needs to be performed by authorized personnel of Igenesis.

**Warning**: Installation by personnel unauthorized from Igenesis may cause damage to the instrument so do not install Galaxy Lite instrument without the presence of Igenesis authorized personnel.

## 4.2 Installation Requirements

The operator must ensure that the following requirements of space, power supply and environment are met before installation.

### 4.2.1 Space Requirements

- The instrument installation must meet the following requirements:
- The space between instrument left and right sides and the wall should be greater than or equal to 28cm.
- The space between the instrument back and the wall should be greater than or equal to 10cm.
- The Galaxy Lite instrument shall be placed on a stable and horizontal platform with a bearing capacity ≥50 kg.
- The instrument shall not be placed in the strong electromagnetic disturbance environment.
- The instrument shall not be placed in the air outlet.
- The instrument shall not be exposed to a direct sunlight.
- The platform length shall be greater than or equal to 210cm.
- Please do not place the device in a position where it is difficult to disconnect the device.

### 4.2.2 Electrical Requirements

- Power Voltage: 100-240VAC；
- Overvoltage category:II；
- Power Frequency： 50/60Hz;
- Input power：≥350VA for a single instrument run.
- The power shall be grounded properly.
- The instrument shall not use the same power supply with the high-power and electromagnetic disturbance devices.
- Please evaluate the electromagnetic environment before using the instrument.
- Please take protection measures if use the instrument home because it may generate radio interference.

**Warning**: In order to prevent electric shock, the Galaxy Lite instrument must be connected to a three-pin grounded socket conforming to safety standards. The power cable should be three-core and matched with the instrument.

### 4.2.3 Electromagnetic Compatibility

The emission and disturbance immunity of Galaxy Lite instrument is in conformity with IEC 61326-2-6.

- The instrument shall be used in lab or the area where the electromagnetic environment is in control. Please do not use the instrument besides the strong radiation source (e.g. unshielded RF) because it may disturb instrument running.
- Please evaluate the electromagnetic environment before using the instrument.
- The instrument is designed and tested according to Class A equipment in CISPR 11 IDT. The instrument may cause radio interference at home environment and the protective measures are required.
- The manufacturer is responsible for providing electromagnetic compatibility information of instruments to users.
- The user is responsible for ensuring the electromagnetic compatibility environment of the instrument so that the instrument can run normally.

### 4.2.4 Environmental Requirements

The environment where the instrument runs shall meet the following requirements:

- Operating temperature: 15～35℃;
- Relative Humidity: 20%～85%;
- Atmosphere Pressure：85.0kPa～106.0kPa;
- The environment should be dust-free and well ventilated for indoor use.
- The environment should not be disturbed by the strong electromagnetic.
- User shall ensure that the environment is in conformity with the electromagnetic compatibility requirements.
- Please do not place anything save the holder and pad.
- Pollution degree of the intended environment:Level 2.

**Warning**: User shall ensure that the instrument is operated in the required environment so as to make sure the instrument runs in a good condition.

### 4.2.5 Fuse Requirements

The fuse used in instrument is T10AL 250VAC 5*20mm.

**Warning**: Please replace the fuse with an equal one, or it may damage the instrument.

**Warning**: Please unplug the instrument before replacing the fuse to avoid electric shock.

### 4.2.6 Computer Requirements

The computer matched to the instrument shall meet the following requirements

- Dominant Frequency: 2GHz or higher;
- Memory: 2GB or higher;
- Hard Drive: 2GB or higher;
- Operation System: Windows 10 64-bite;

- Software Installed: Microsoft.Net Framework 4.5;
- Computer system time is right.
- Please exit the computer dormancy mode while the instrument is running.
- Please keep the display on while the instrument is running.
- Please set screen protection for the computer so as to the data cannot be viewed by the unauthorized person.
- Please install the professional antivirus software, data security defense software and network security protection software and regularly upgrade them.
- Please do not connect the computer to the network at risk.
- Please close the account, communication port, shared file, service, etc. Of the non-medical use.
- Within the instrument life cycle, user could contact Igenesis after-sale for any cyber security problems. If necessary, Igenesis could send the technical staff for a site service.

**Warning**: It is strongly recommended that user should install the professional antivirus software, data security defense software and network security protection software to avoid the experiment data is acquired in an illegal way.

## 4.3 Installation Process

### 4.3.1 Instrument Placement

After the arrival of the instrument, please carefully check whether the package of the instrument has physical damage. If there is any damage, please immediately inform the after-sales service or local agent of Igenesis.

After confirming that there is no external damage, open, carry, and place the instrument by following the below requirements:

- During carrying the instrument, please protect it from impact and collision.
- During carrying the instrument, please keep it upright.
- Before taking out the instrument, please keep the package stable and upright.
- Open the package and take out the instrument with care.
- Place the instrument on the lab platform according to “4.2 Installation Requirements”
- If needs to move the instrument after placed, please move it slowly with care.
- Keep the package well in order to need it again when carries the instrument.

### 4.3.2 Unpacking Steps

Please check out the packing list as blew.

| No. | Name | Quantity |
|---|---|---|
| 1 | Automated Fully Enclosed qPCR Instrument | 1 |
| 2 | Galaxy Lite User Manual | 1 |
| 3 | Quick Guide | 1 |
| 4 | Warranty Card | 1 |
| 5 | Certificate of Quality | 1 |
| 6 | Power Cable | 1 |
| 7 | iCassette Tray | 1 |
| 8 | Pad Holder | 1 |
| 9 | PCR Tube Installation Tool | 2 |
| 10 | System Software（USB Flash Drive） | 1 |
| 11 | Communication Cable | 1 |
| 12 | Magnetic Connector | 1 |
| 13 | DB9 Communication Accessories | 2 |
| 14 | DB9 Communication Cable | 1 |
| **If there is any shortage or damage, please contact the after-sale service.** | | |

### 4.3.3 Instrument Installation

The instrument shall be installed as the following steps.

- Please place the instrument according to “4.3.1 Instrument Placement”;
- Please make sure that the power grid where the instrument connects is 100-240VAC and the socket is a one-phase three-pin.
- If only install one instrument, the power of the grid shall be greater than one equal to the single instrument’s. Please refer the instrument power to “4.2.2 Electric Requirement”.

- If install more than one instruments, the power of the grid shall be greater than one equal to the total power of instrument's.
- Please close the AC power switch, insert the power cable in the package into the jack and than plug the instrument.
- Please make sure the IN and OUT port is properly connected.
- Connect the communication cable to USB Type-C port in instrument and connect the other side to the computer's USB-A port (Please ensure the port is well functioned.).

### 4.3.4 System Software Installation

Please follow steps below to install the system software.

- Take out the USB flash drive and insert it into the computer.
- Find the "Ecantools" driver software installation package, double-click "Ecantools-Setup.exe" and follow the installation prompts to install it. Igenesis will provide all services of the third-party ready-made software within Galaxy Lite system life cycle.
- Copy "**Galaxy Lite controller software" file** to the PC,send the "**Galaxy Lite.exe"** to the desktop shortcut**,** and double-click the "Galaxy Lite controller" icon to open the software. At this time, the software installation is completed.
- The system software upgrade is conducted by Igenesis staff or the personnel authorized by Igenesis.

### 4.3.5 Instrument Startup and Test

Please start and test the instrument after instrument and system software installation.

- Press the "Switch" key of the Galaxy Lite instrument. When the "Switch" is on, the instrument is turned on.
- Press the "Switch" key for 1 second to turn on the instrument.
- Double-click "Galaxy Lite" on desktop to enter software interface.
- Please use Admin account (Username: Admin, password: 123456) to log in the software for the first login.
- After login, the instrument will automatically perform self-inspection.
- During and after self-inspection, if there is no abnormity, the user can use it normally. If there is abnormity, please contact the after-sale service.

### 4.3.6 Instrument Shutdown

Please shut down the instrument by following the below steps.

- Log out the system software.
- Press instrument switch more than 5 seconds to shut it down.
- Please unplug the instrument if it is not used for a long time.

### 4.3.7 Instrument Cascade

It is available that 4 Galaxy Lite instruments can be connected each other maximally. 4 instruments could run simultaneously. Please follow the steps below to complete instrument cascade.

- Please pace the instruments to be cascaded on the lab platform form left to right according to the single instrument placement requirements.
- Connect each instrument's power cord to power grid according to the single instrument power cord connection requirements.
- Connect the first instrument to the computer with communication cable.
- Take off the first instrument's rear OUT connector and connect one end of cascade cable to the OUT port while the other end is connected to the second instrument's IN port so connect the rest of the instruments in same way.
- Please keep the IN and OUT connectors with care because they will be reused when run the instrument singly or transport it.
- Open and log in the system software, click "Setting"--> "Device Cascades" function key and the system software will prompt "Whether to initialize cascade?".
- Please ensure that all instruments are turned off and click "Yes". The system software displays device cascade prompt window and user could follow the software prompts to operate.
- After the instruments are connected, the connection status on interface will be changed from "Uninstall" to "Available".
- If user needs to change the instrument position or instrument, the instrument cascade shall be re-connected according to the above first 8 steps.

# 4.4 Storage and Transportation

## 4.4.1 Storage

If the instrument is unpacked, please store it as the following requirements.

- Ambient Temperature: - 20℃-50℃.
- Relative Humidity: 20%-85%, non-condensing.
- The instrument shall not be stored in the environment with corrosive gas.
- The instrument shall not be exposed to the sunlight.

If have any questions, please contact the after-sales service personnel.

## 4.4.2 Transportation

The product should be transported according to the following requirements

- Please close compartment door.
- Please take off the instrument power cord and communication cable.
- Please disinfect the instrument.
- Please pack the instrument the original package.
- Please keep the instrument package stable with materials against the package two sides so as to avoid the package impact and collision.
- The transport temperature and humidity requirements are same to storage's.
- The transport temperature atmosphere pressure：85.0kPa～106.0kPa.

If have any questions, please contact the after-sales service personnel.

# 5 System Software Functions

## 5.1 Overview

This section systematically introduces the functions of system software so that user could operate instrument properly.

## 5.2 Login Interface

After double-click “Galaxy Lite.exe”, the login interface is shown in figure 5-1.


Figure 5-1 Login Interface

**Warning**: Please enter the right user ID and password.

## 5.3 Initial Interface

After entering user ID and password and logging in the system software, the initial interface is as shown in figure 5-2.

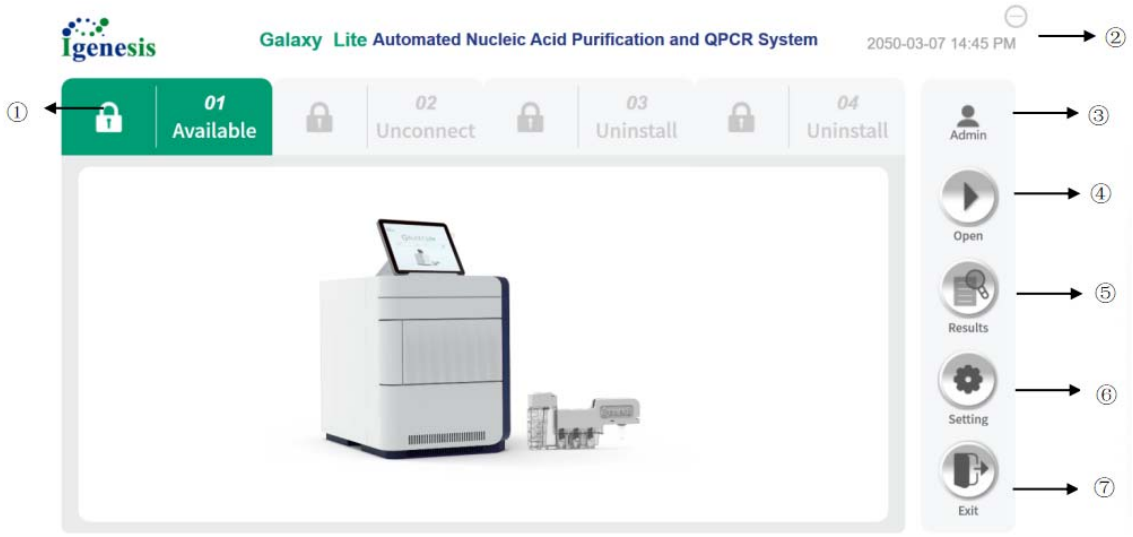
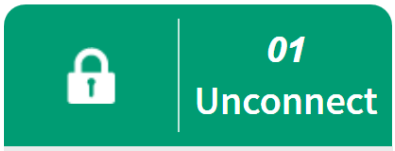



Figure 5-2 Initial Interface

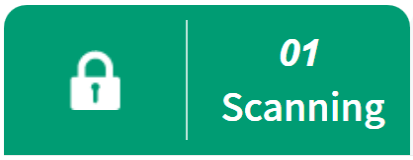
① **Instrument Connection Status**: If the instrument is installed and connected to the computer properly, it is unlocking status and figure 01-04 is the cascade instrument No.

The description of the keys in the interface.

| Key | Description |
|---|---|
|  | Uninstall means the instrument is uninstalled or cascaded improperly. |
|  | Available means the instrument is installed properly and connected to system software. |
|  | Unconnect means the instrument is disconnected. |


Initializing means the instrument is connected properly and the motor is moving to the zero position.


Checking means the instrument is initialized and starts to self-checking.




Scanning means the instrument is performing scanning before running the program.

② **System Time**: It is the system time displayed in computer in real time.

③ **User Icon**: It is the username that logs in currently.

④ **Open/Close**: Open or close the compartment door.

⑤ **Results**: User could click this key to view the history results of the current user.

⑥ **Setting**: To check the instrument ‘s information, program management, etc.

⑦ **Exit**: User could exit and close the software by clicking this key.

## 5.4 Menu and Function

### 5.4.1 Open/Close

If the compartment door is closed, click Open to open the compartment door while if is open, click Close to close the compartment door.

### 5.4.2 Results

After clicking Results, it enters the results checking interface, as shown in figure 5-3.

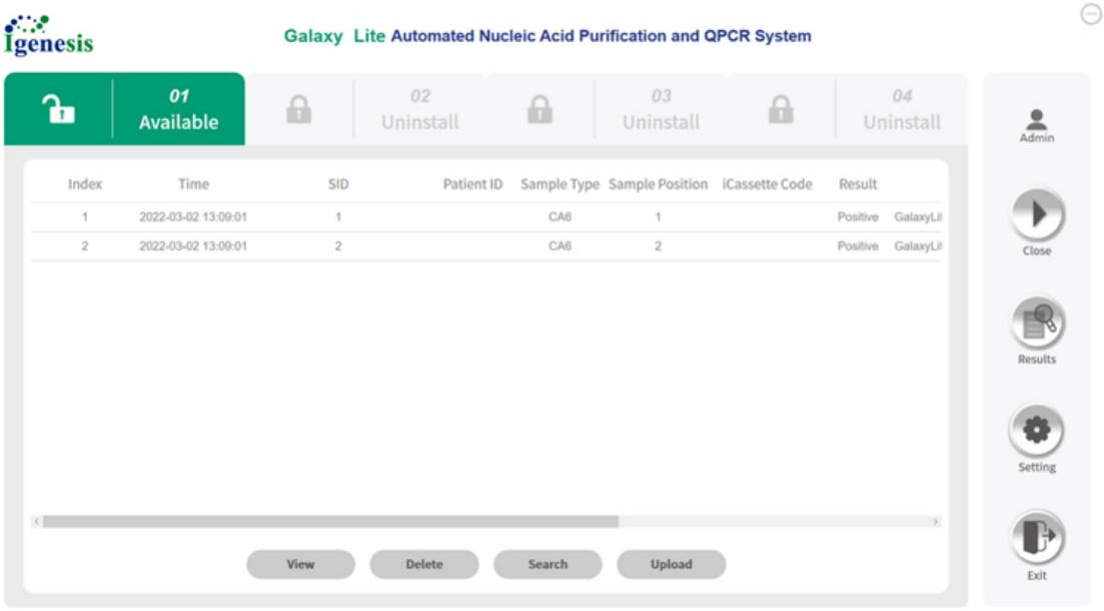



Figure 5-3 Results Interface

- The results interface consists of index, time, SID, patient ID, sample type, sample position, program, user, instrument, etc.
- Four function keys are at the bottom of this interface, including **View**, **Delete**, **Search** and **Upload**.
- The data information excludes the user's real information which is only the character code.
- Click the result to select it while clicks it again to cancel the selection. Maximally, 6 results can be selected.
- After selecting the result, the 4 function keys at the bottom can be used, or the system software will prompt "Please select the sample first."
- Click **Search** and there pops up a window where user could filter the experiment results by selecting SID, program, device, user, start date and end date.

### 5.4.2.1 Result View

User could select one or more than one result records and click View, the result view interface is as shown in figure 5-4.

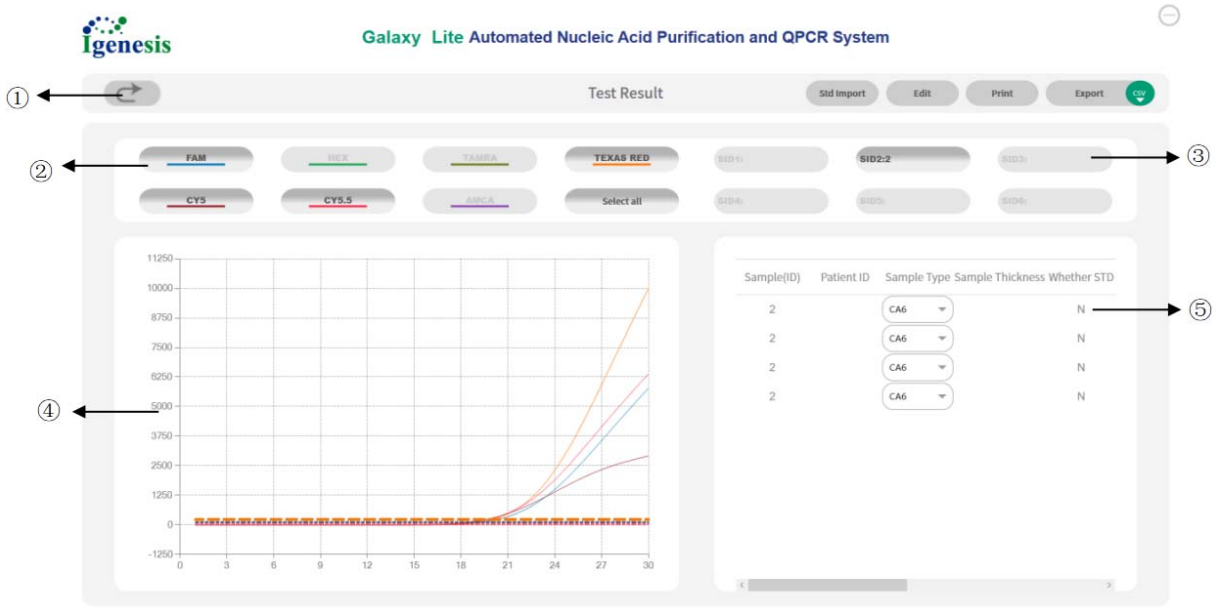



Figure 5-4 Result View Interface

① Back：Click this key to return to last step.

② Fluorescence Channel: Click to select the channel and click again to cancel the selection. The selected fluorescence will be displayed in the result curve.

③ Select Sample: Click to select the channel and click again to cancel the selection. The sample result table will display the selected sample's name, fluorescence channel, threshold value, Ct value.

④ Result Curve: It is the result curve of the current selected sample and fluorescence.

⑤ Sample Table: It is the result table of the current selected sample and fluorescence.

#### 5.4.2.2 Export Result

User could select one or more than one result records and click View, then click Export, the result export interface is as shown in figure 5-5. User could define a file name and the save as type could be CSV and TXT. Here only exports the current selected result record.

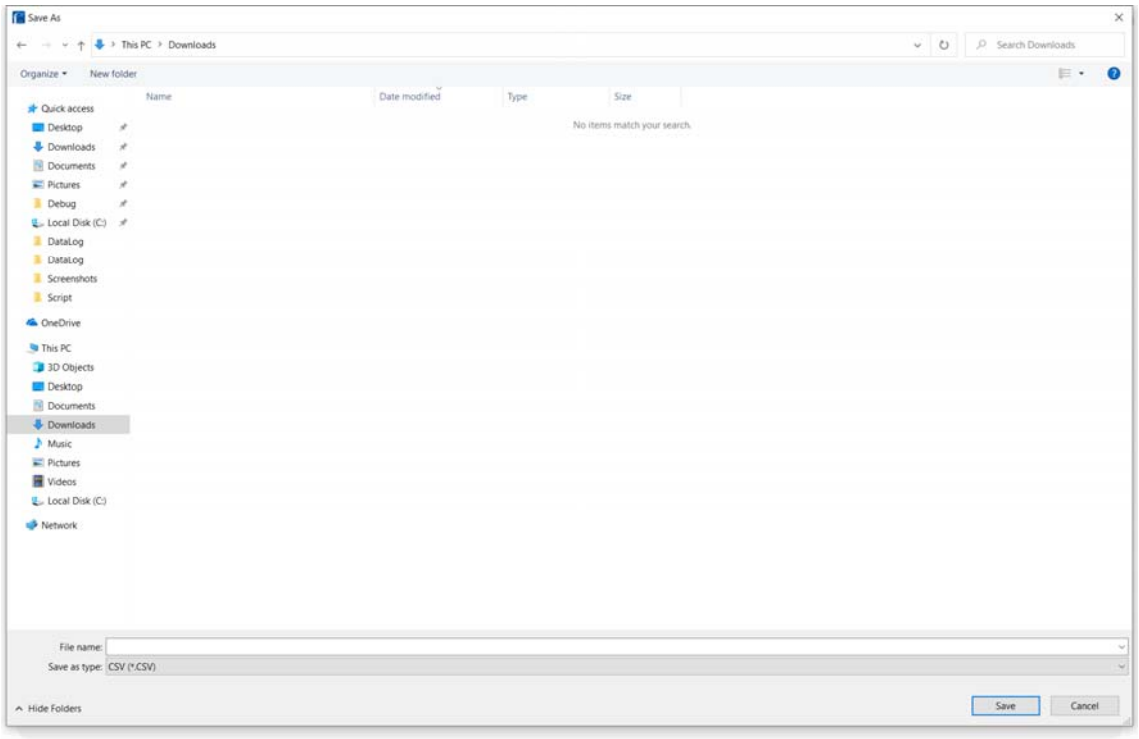



Figure 5-5 Export Result

#### 5.4.2.3 Result Deletion

User could select one or more than one result records and click Delete. The pop-up window will prompt “Are you sure to delete the result record?”. Click “Yes” to delete it while “No” to keep it. If the result record once deleted, it will never be recovered.

Warning: Please double check the result record to be deleted because it cannot be recovered. Igenesis recommends that user should backup the experiment data.

#### 5.4.2.4 Result Search

Click **Search** to filter and check the experiment result, as shown in figure 5-6.

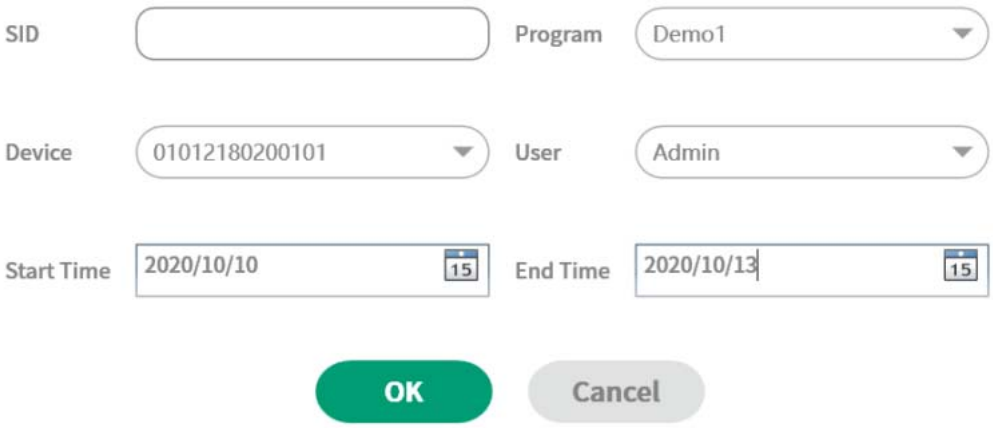



Figure 5-6 Result Search

### 5.4.3 Setting

The setting interface is composed of **System Information, Language Setting, User Management, Modify Password, Program Management, PCR Program Setting, LIS Setting, Device Cascades, Sample Type and System Log,** as shown in figure 5-7.

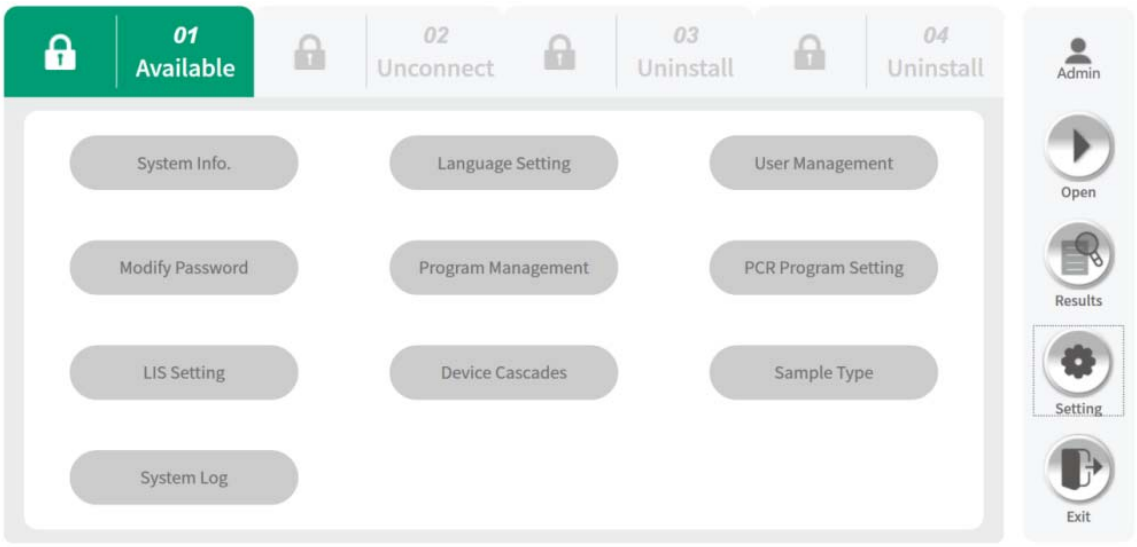



Figure 5-7 Setting Interface

#### 5.4.3.1 System Information

The system information displays the instrument SN that belongs to the connected instrument and the current software version. The unconnected instrument SN is empty.

#### 5.4.3.2 Language Setting

User could set system language as Chinese and English, as shown in figure 5-8.


Figure 5-8 Language Setting

#### 5.4.3.3 User Management

User is classified as common user, admin and factory user. The illegal user cannot log in the system software to operate the instrument. The user management interface is as shown in figure 5-9.

All three users could perform open/close compartment door and exit function. Besides that, they own the following different accesses.

- **Common User**: The common user could view his or her own account results. The function of system information, language setting, modify password and LIS setting of setting interface can also be conducted by common user.
- **Admin**: Besides the above common user's accesses, admin also enjoys the function of program management, user management, PCR program setting, device cascades, LIS setting and sample type.
- **Factory User**: The factory user could view his or her own account results. The function of system information, program management, user management, language setting, PCR program setting, device cascades, LIS setting and sample type.

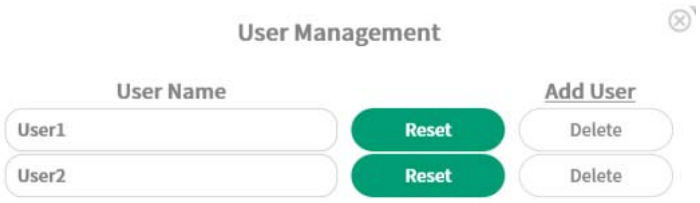



Figure 5-9 User Management

- **User Name**: The admin or factory user could view the users in the user list.
- **Reset**: Click reset after selecting a user and there pops up a window where prompts whether to reset the user. Click "Yes" to reset the password as 123456 while click "No" to cancel the reset operation, as shown in figure 5-10.

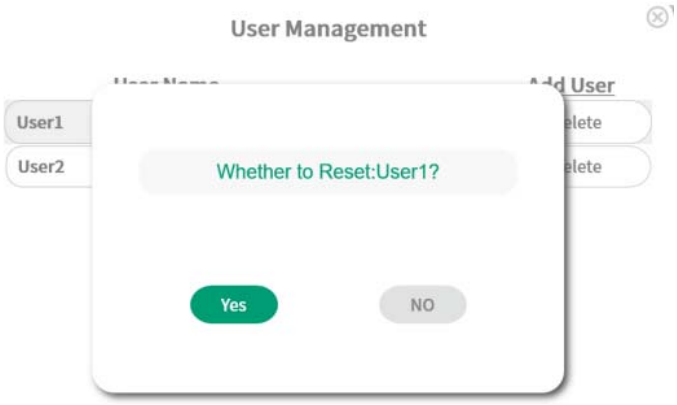



Figure 5-10 Reset User

- **Delete**: User could click delete key to delete the selected user in the list, as shown in figure 5-11.

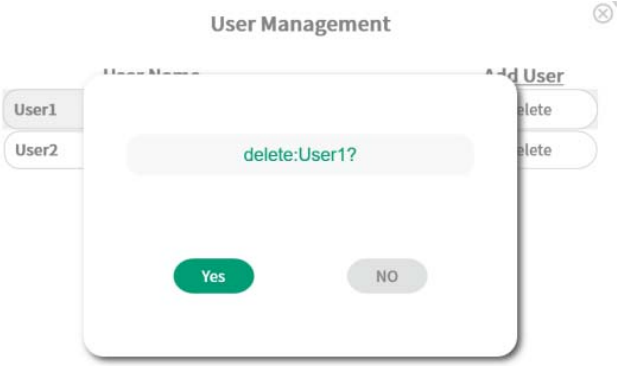



Figure 5-11 Delete User

- **Add User**: This function key is for adding a user, as shown in figure 5-12.

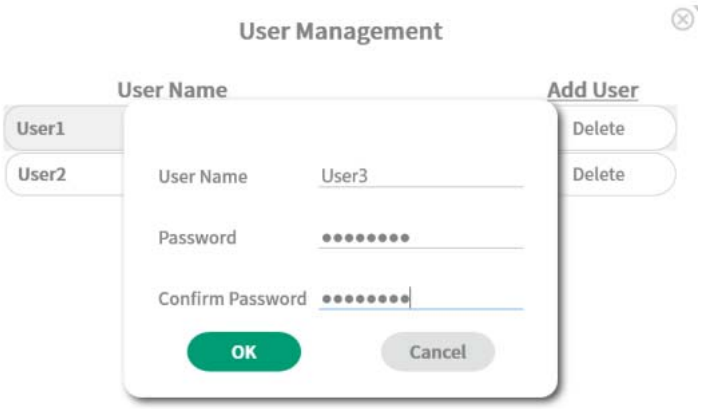



Figure 5-12 Add User

The new user name should be different with the existing user names and the character length should be less than or equal to 15. The new password characters shall be 6-20 with figure, letter and symbol allowed.

**Warning**: The factory user could reset the admin account password but cannot delete admin while the admin could only to reset and delete the common user account.

#### 5.4.3.4 Modify Password

The current user's password can be modified here, as shown in figure 5-13.

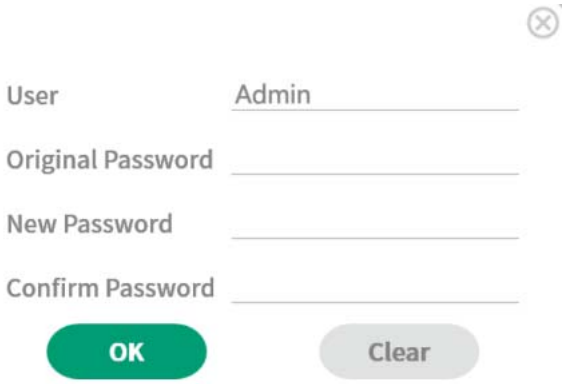



Figure 5-13 Modify Password

- **User**: It displays the currently logging in user by default.
- **Original Password**: Enter the original password correctly.
- **New Password**: Enter a new password whose format shall be same to the password in user management interface.
- **Confirm Password**: Enter the new password again.

- **Ok**: Click ok to complete password modification. If the original password is incorrect or the passwords confirmed are inconsistent, there pops up a window with “Clear” function that could clear the inputs.

#### 5.4.3.5 Program Management

User could manage the detection program in program management interface, as shown in figure 5-14.

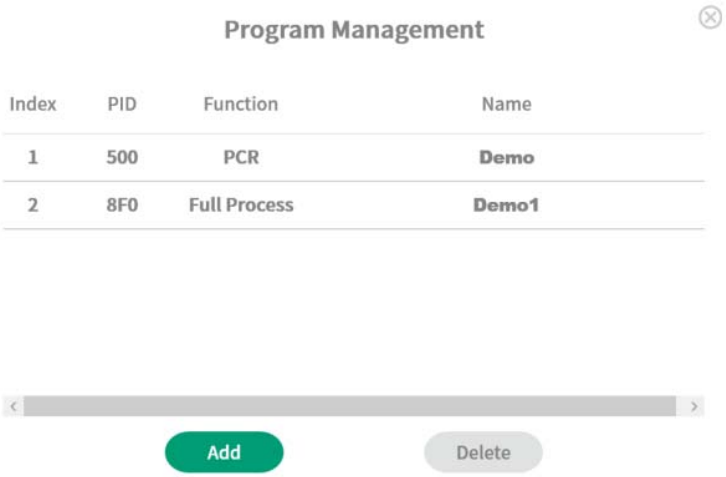



Figure 5-14 Program Management

- **Index**: The detection No. Of the existing software.
- **PID**: It is the code marking the detection program.
- **Function**: It is the function marking the detection program, including extraction, PCR and whole process.
- **Name**: It is the name of detection program.
- **Add**: It displays the folder path after clicking this key, select the file suffixed with .sf and click “Open” to add a program.
- **Delete**: It is to delete the selected program in the list.

#### 5.4.3.6 PCR Program Setting

User could modify the existed or new PCR program in the corresponding interface, as shown in figure 5-15.

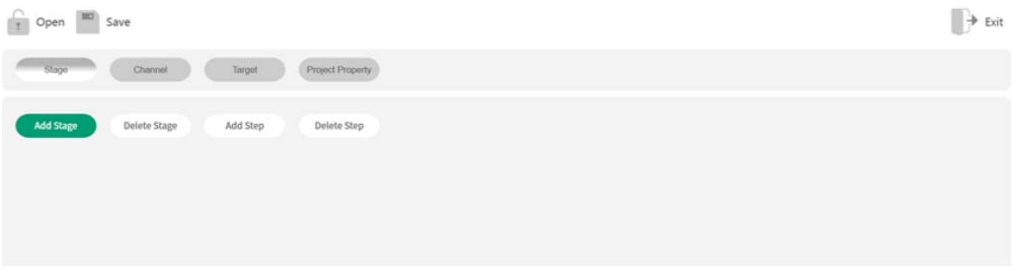



Figure 5-15 PCR Program Setting

- **Open**: This key to to open the PCR program in the folder of Script.
- **Save**: This key is to save the opened or added PCR program.
- **Add Stage**: This is to add PCR program.
- **Delete Stage**: This key is to delete PCR program.
- **Add Step**: This is to add PCR program steps.
- **Delete Step**: This is to delete PCR program steps.
- **Channel**: This key is to check the selected fluorescence channel.
- **Project Property**: This key is to add reagent type and detection type.
- **Exit**: This key is to return to software home page.

#### 5.4.3.7 Device Cascade

Maximally, 4 instrument can be cascaded via one computer. Please refer to Section “4.3.7 Instrument Cascade”.

#### 5.4.3.8 LIS Setting

User could select the needed data, select the file format CSV and TXT, configure the data path, check “Auto-export” and click “Save”. Make sure to export the experiment data to LIS.

#### 5.4.3.9 Sample Type

User could enter the new sample information like oropharyngeal swab and click “Add”. The new sample type is added and saved in “Original Type” and user could select sample type in “Sample Details”.

#### 5.4.3.10 System Log

User could view the operation records, including login, logout, initialization, stop, exit, program name run, reagent kit QR code and experiment completion.

### 5.4.4 Running

#### 5.4.4.1 Sample Information Entry

User could enter the sample information like sample barcode, as shown in figure 5-16.

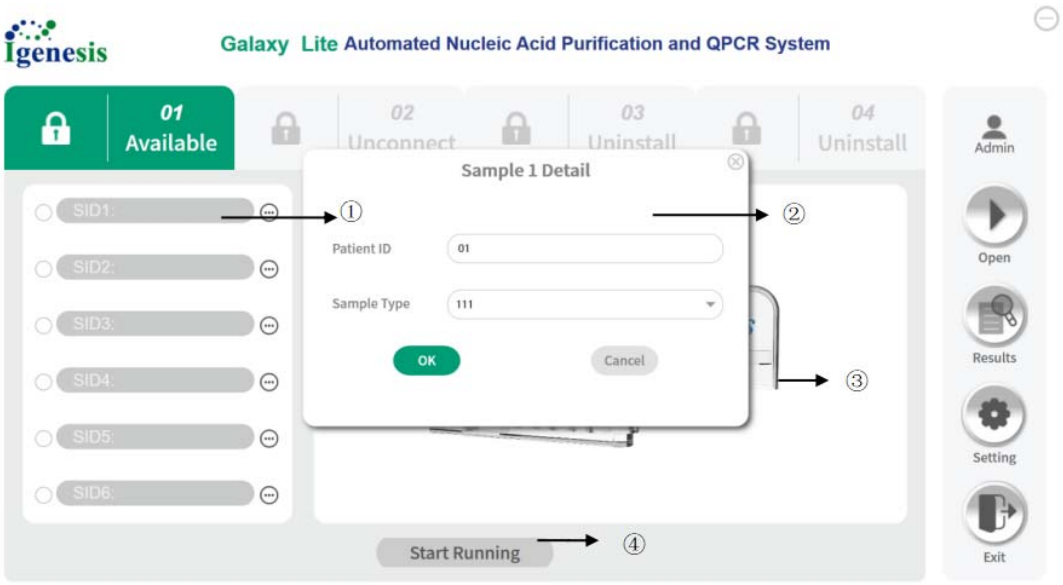



Figure 5-16 Sample Information Entry

- **SID**: User could enter the sample ID here which shall be corresponded to the reagent position in reagent kit.
- **Sample Detail**: User could enter patient ID and sample type here.
- **Start Running**: User could click this key to start running the experiment program.

#### 5.4.4.2 Run Experiment Program

Please select a program to be run after loading the tray with reagent kit inside and run the program. The experiment program running window is as shown in figure 5-17.

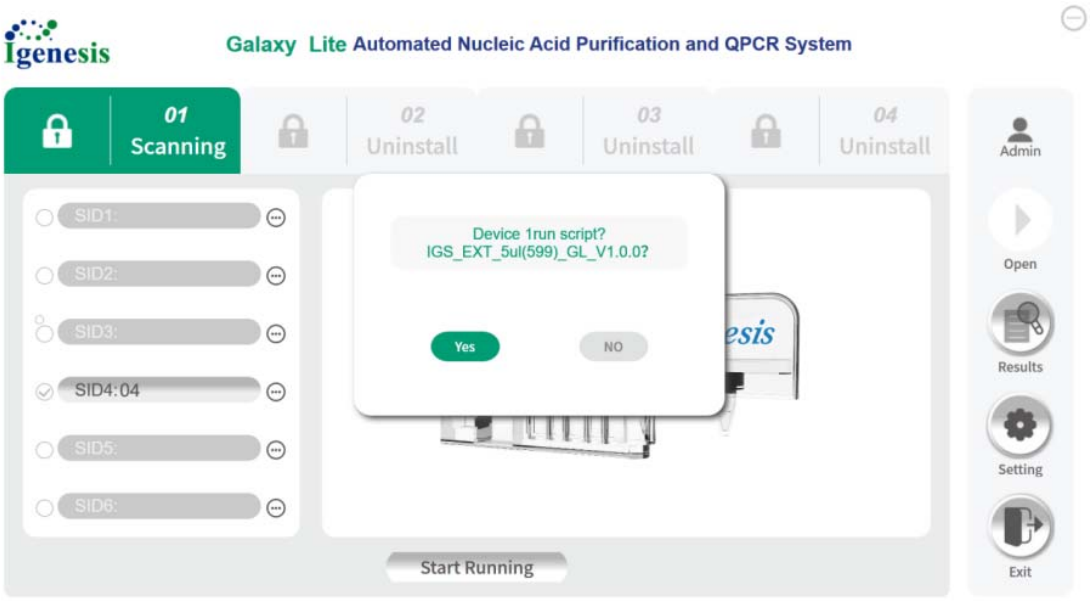



Figure 5-17 Experiment Program Running

- **Start Running**: After the instrument completing automatic scanning, the interface pops up a window about whether to run XXXX ( The real program name refers to the running program's.) that is the name the program.
- Click "Yes" to conduct automatic whole process experiment.
- Click "No" to cancel the operation.

#### 5.4.4.3 Experiment Monitoring

Please refer to the below figure about running process, as shown in figure 5-18.

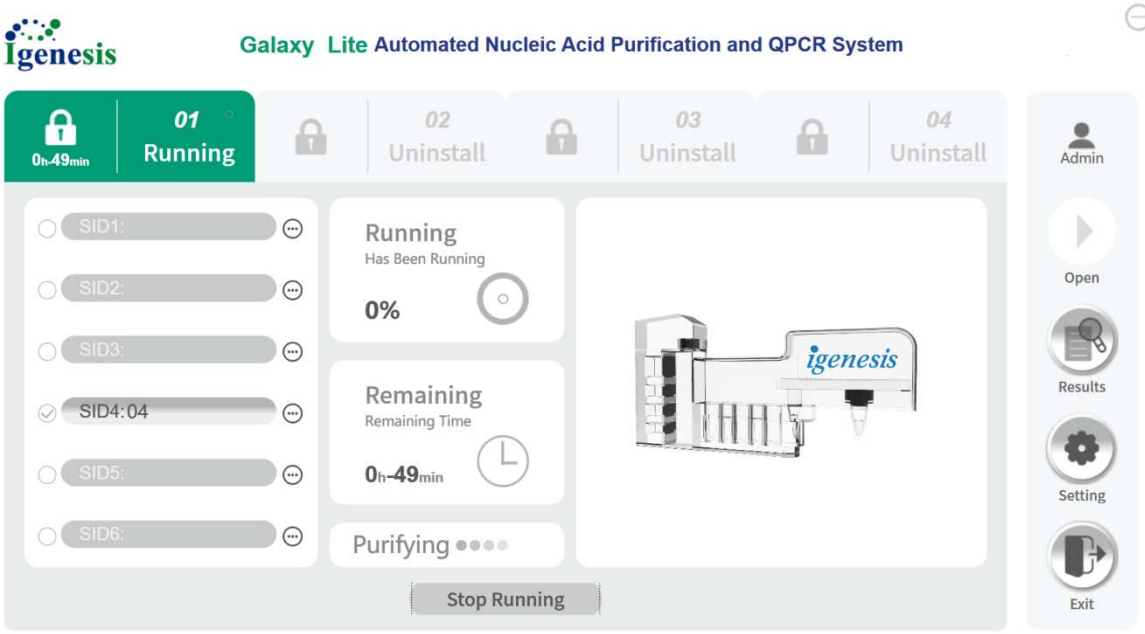



Figure 5-18 Experiment Monitoring

The experiment monitoring interface displays the experiment progress, remaining time, etc. after experiment program started.

#### 5.4.4.4 Experiment Result View

Please refer to the experiment result to figure 5-19.

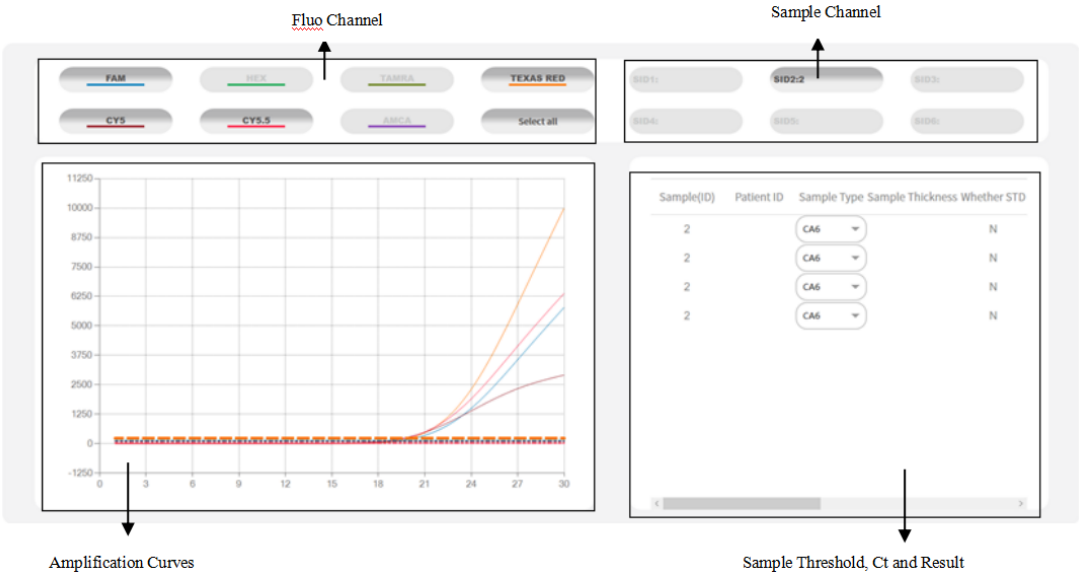



Figure 5-19 Experiment Result Viewing

- **Fluorescence Channel:** All fluorescence channels of the currently selected sample are Fam, Hex, Tamra, Rox/Texas Red, Cy5, Cy5.5 and Amca, and users can freely choose to view the amplification results of any

fluorescence channel.

- **Sample:** Six sample positions can be placed by Galaxy Lite instrument.
- **Amplification Curve:** The amplification curve in the figure is the amplification curve of the corresponding fluorescence channel of the selected sample.
- **Threshold:** Fluorescence threshold is a fluorescence intensity standard set during the exponential growth period of fluorescence amplification curve. Double-click on the fluorescence threshold to be set to change the fluorescence threshold.
- **Ct:** Ct value, the number of amplification cycles when the amplification product reaches the threshold during PCR amplification.
- **Increment**: The fluorescence signal value after PCR amplification.
- **Result**: Negative and positive.

### 5.4.5 Software Logout

Please refer to the below figure about software logout, as shown in figure 5-20.

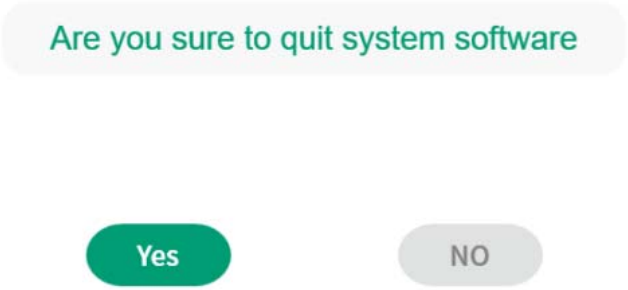



Figure 5-20 Software Logout Window

User could check the operation logs under the catalog DataLog folder where records the key operation information.

# 6 Operating Introductions

## 6.1 Overview

This section describes how to use the Automated Fully Enclosed qPCR Instrument for in vitro diagnosis (IVD) detection and manage the result data.

## 6.2 Section Guide

| Steps | Procedure | Section |
|---|---|---|
| 1 | Software Login | Section 6.3 |
| 2 | Instrument Self-inspection | Section 6.4 |
| 3 | Load reagent to iCassette Tray | Section 6.5 |
| 4 | Load iCassette Tray to compartment | Section 6.6 |
| 5 | Sample Information Entry | Section 6.7 |
| 6 | Run Program | Section 6.8 |
| 7 | Process Monitoring | Section 6.9 |
| 8 | iCassette Tray out of compartment | Section 6.10 |
| 9 | Result View | Section 6.11 |

## 6.3 Software Login

Please log in the software according to the following steps.

- Please connect instrument with the computer with the USB cable.
- Plug the instrument and turn on the power switch at back of the instrument.
- Press the instrument switch for 1 second to turn on the instrument.
- Open Galaxy Lite system software.
- Log in the software with correct user name and password, after that,
- The initial interface is displayed.

## 6.4 Instrument Self-inspection

Please conduct the self-inspection according to the following steps.

- Please initialize each mechanical module to zero position.
- Please perform the automatic self-inspection for each function component.

**Warning**: During the self-check process, the sample compartment door will automatically open and then close. This process is a normal self-check process. Please do not touch the iCassette Tray with your hand or pull it out forcibly. Or hands may be pinched, resulting in your disability or damage to the instrument.

**Warning**: During the self-check, make sure that the iCassette Tray is not placed in the instrument.

## 6.5 Load Reagent kit to iCassette Tray

Please load the reagent kit to iCassette Tray according to the following steps.

- Please take out the reagent kit that is stored in the proper ambient.
- Insert the reagent kit into iCassette Tray from the bottom and confirm that it is loaded in tray tightly.

## 6.6 Load iCassette Tray to Compartment

Please load the iCassette Tray to compartment according to the following steps.

- Please click “Open” in initial interface to open the compartment door.
- Load the iCassette Tray in to the iCassette Tray Holder.
- Push the iCassette Tray into the iCassette Tray Holder along the slot till to then end.
- Click “Close” in initial interface to close the compartment door.

Warning: Please make sure that the iCassette Tray is loaded into the iCassette Tray Holder totally to avoid any errors during compartment in or running.

## 6.7 Sample Information Entry

Please load the iCassette Tray to compartment according to the following steps.

- The order of the reagent kit from left to right is 1 to 6.
- Click SID input box and input the sample ID information which is self-defined or same to the QR code information of reagent kit.
- Click PID input box and input general sample information which could be self-defined by user.

> **Warning**: The detection channel where loads reagent kit corresponding to the SID and PID shall enter the relative information, or the later program cannot be run.

## 6.8 Run Program

Please run the program according to the following steps.

- Click "Start running" button and the system will pop up a window to prompt "Whether to start.", as shown in figure 6-1.
- Then, Galaxy Lite instrument will automatically scan the QR code above each reagent kit and prompt user to select a program.
- After clicking and confirming the program. It start running.
- Click stop to stop the current program.


Figure 6-1 Program Run Confirmation

### 6.8.1 Automatic Whole Process

If the user needs to implement the whole process of automation, after scanning, the window will prompt that "Device 1 run script? XXXX?". XXXX stands for the program name, as shown in figure 6-2 (The sample drawing is only an example while the specific program name refers to the actual running program.). Click "Yes" to start the whole process of automation and "No" to stop the operation.

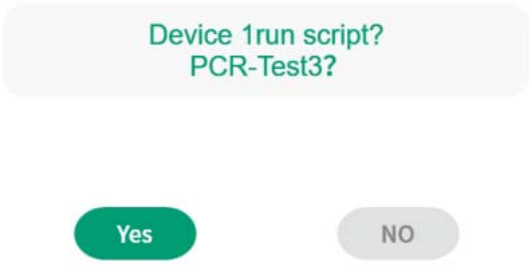



Figure 6-2 Automatic Whole Process Confirmation

### 6.8.2 Nucleic Acid Extraction Function

If the user needs to perform nucleic acid extraction, after scanning, the pop-up window will remind the user to select "Purify" and "PCR" function.

The user clicks the " Purify" button to start the nucleic acid extraction process and "Cancel" to stop the operation.

If the user is only need to purify, the required nucleic acid can be obtained by simply decapping the PCR tube after the nucleic acid extraction operation.


Figure 6-3 "Purify" And "PCR" Function

### 6.8.3 PCR Function

Before the Galaxy Lite instrument starts to run the PCR process, the user needs to edit and save the PCR program according to the experimental requirements. Please see Section "5.4.3.6 PCR program setting" for PCR programming.

The user prepares the PCR reagent kit and PCR kit tube, replaces the empty PCR tube in the PCR reagent kit with PCR kit tube, and ensure the PCR kit tube is tightened to the qPCR consumable rack. Then load qPCR consumables into the cassette tray.

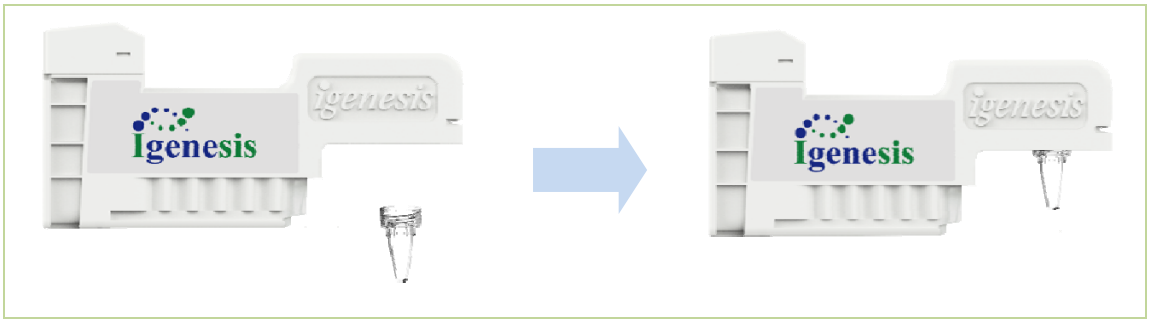



Figure 6-4 Load PCR Tube

If the user needs to run the PCR process, after scanning, the pop-up window will remind the user to select "Purify" and "PCR", as shown in figure 6-3. The user clicks the "PCR" button and select the PCR program to be executed, as shown in figure 6-5, and then click "OK" to start the specified PCR process while click "Cancel" to stop the operation.

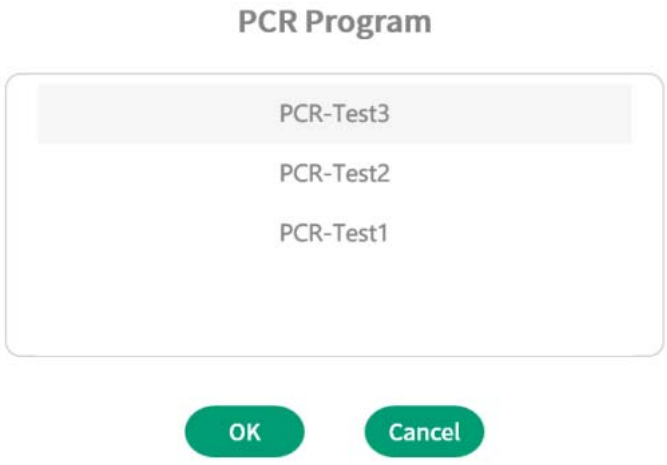



Figure 6-5 PCR Program Window

After nucleic acid extraction completed and obtaining nucleic acid, user can adjust the amount of nucleic acid and add PCR reagent according to the PCR reaction demand. Then execute the steps from Section 6.5 to Section 6.8. After the automatic code scanning is successful, user can select the "PCR" button, and then select the PCR program to be executed PCR process to complete PCR operation.

### 6.8.4 Application of Third-party PCR Reagent

If the user needs to implement the automatic whole process when using the third-party PCR reagent, please manually decap the PCR tube of Galaxy TPT cassette, fill the PCR tube with PCR reagent, and then cap the PCR tube filled with reagent onto the cassette. Then load the Galaxy TPT cassette into the iCassette Tray, and then execute the steps from Section 6.5 to Section 6.8. After the automatic code scanning is successful, the page will pop up and prompt "Device 1run script XXX?", XXX represents the name of the script. Click "Yes" to start the whole process of automation and click "No" to stop the operation.

## 6.9 Process Monitoring

User can monitor the detection process in the current operation interface, as shown in figure 6-6.

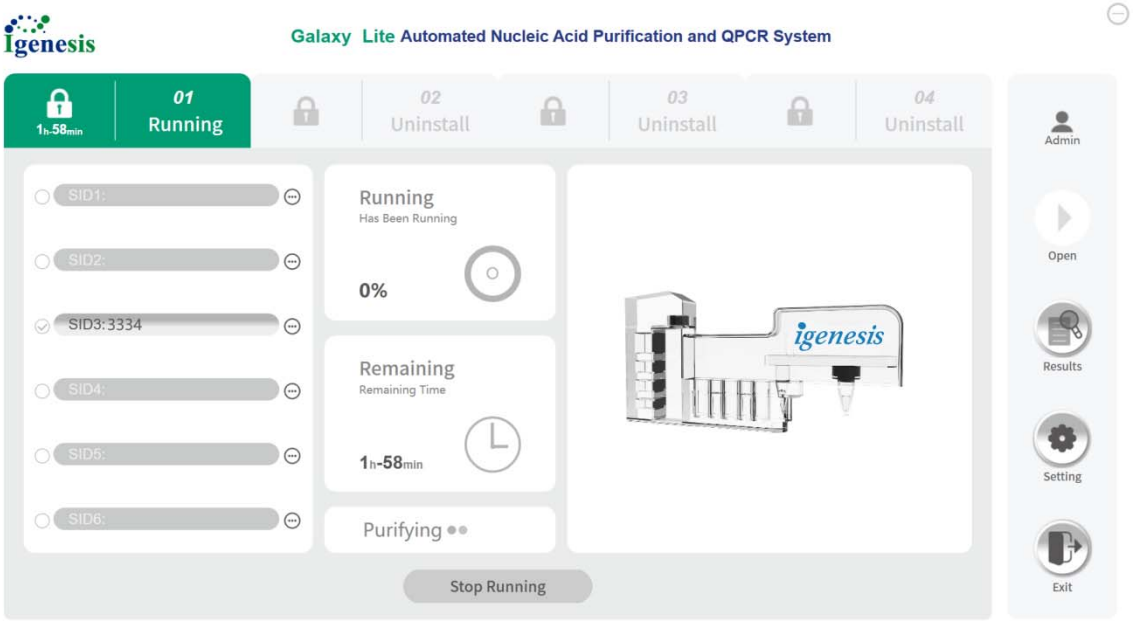



Figure 6-6 Program Monitoring Interface

- **Running**: It displays the the program progress.
- **Remaining Time**: This is the time remaining of the program.
- **Process**: The current running process category;

When the instrument is running automatically, the processing progress will be displayed, and the user can reasonably arrange the time according to the progress display.

## 6.10 iCassette Tray out of Compartment

When the program is completed, there pops up a window about iCassette Tray out of the compartment, as shown in figure 6-7.

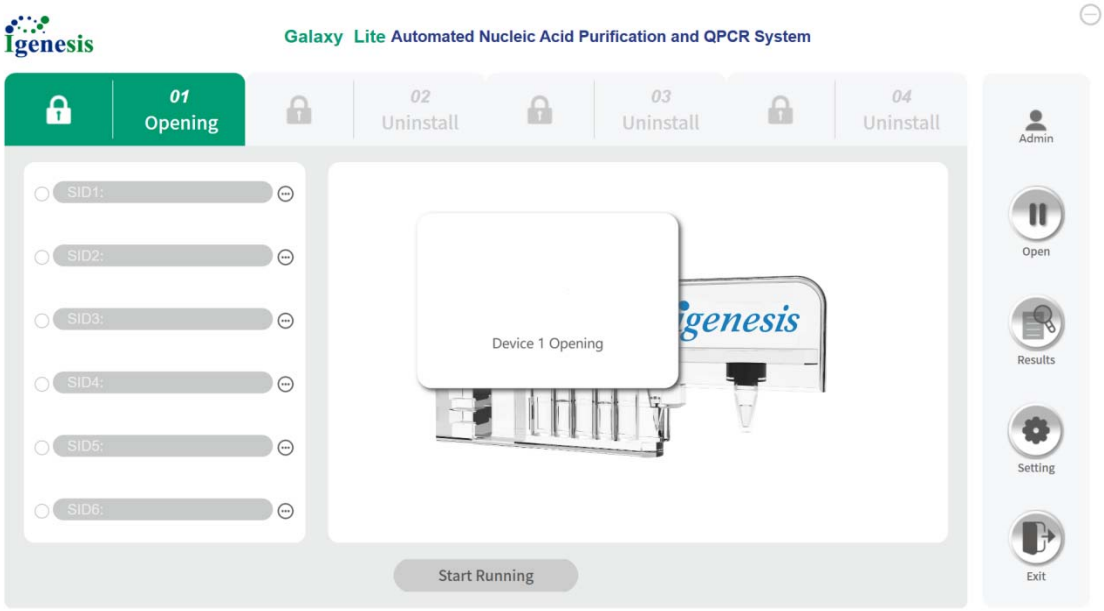



Figure 6-7 iCassette Tray out of Compartment

The instrument will conduct the compartment-out automatically after the program is completed. User could take out the iCassette Tray from the iCassette Tray Holder, check the reagent kit appearance and then take out the reagent kit from iCassette Tray.

## 6.11 Result View

Please check out the following result combined with Section 5.4.4.4, as shown in figure 6-8.

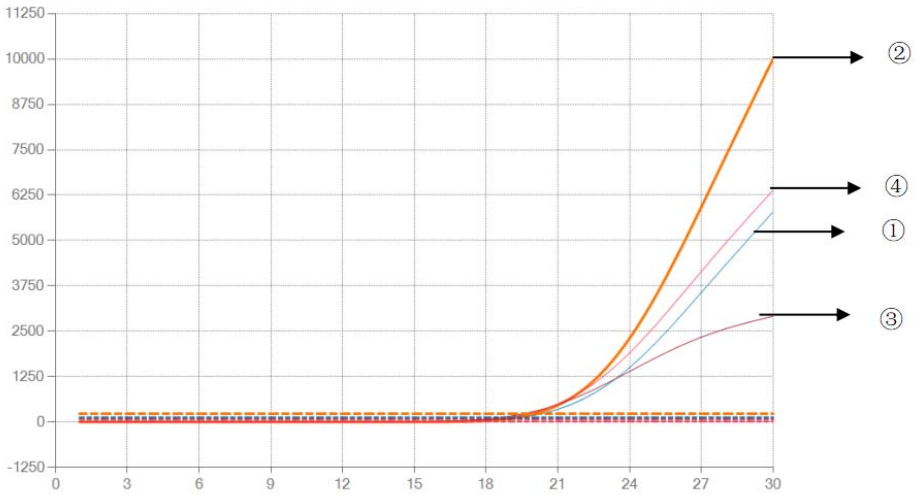



Figure 6-8 Result View

① **FAM**: Amplification curve of FAM channel;

② **TEXAS RED**: Amplification curve of TEXAS RED channel;

③ **CY5**: Amplification curve of CY5 channel;

④ **CY5.5**: Amplification curve of CY5.5 channel.

# 7 Calibration and Quality Control

## 7.1 Overview

This section describes the calibration procedure for the Galaxy Lite instrument.

## 7.2 Calibration

The user does not need to calibrate the Galaxy Lite instrument. Igenesis has performed all necessary calibrations before the user receives the Galaxy Lite instrument. If user needs to arrange calibration, please contact the after-sale service.

## 7.3 Internal Quality Control

The accuracy of the test results can be ensured only when the instrument performs the test accurately. The Galaxy Lite instrument automatically controls the quality of each sample. In each test, the system will use one or more of the following measures for control:

- **Sample Processing Control**: Make sure the samples are processed correctly. The quality control material is included in the reagent kit, processed with the sample and detected by PCR.
- **PCR Detection control**: The instrument could verify the performance of PCR reagents and prevent false negative results. The internal standard is to evaluate whether there are possible inhibitors in the samples to be tested during PCR test. The internal standard should be positive in negative samples.
- **Probe Test**: the Galaxy Lite instrument adds the probe test function that is able to verify the labeled probe in the first stage during PCR detection. If the probe passes the inspection, it means that the probe inspection results meet the requirements.

## 7.4 External Quality Control

External quality control can be controlled according to the relevant reference standards or certification issued by local or national organizations to ensure the accuracy of instrument detection results.

# 8 Precautions

## 8.1 Overview

In this section introduces the instrument operation precautions.

### 8.2 Safety Precautions

Igenesis strongly recommends user to take the following precautions:

- Please take care with the detection result and data in the instrument.
- User shall protect patients' personal privacy and take measures from physical, technical and administrative aspects to ensure the integrity, confidentiality, authenticity and reliability of patients' personal health data, such as network and system access control, user identity authentication, installing anti-virus software, etc. in order to meet the relevant standards of network security.
- In particular, the system administrator should be configured for all system users, and the system administrator has the highest authority. Besides, the users shall not access to each other's data.
- Consult your system administrator if it is necessary so as to ensure that all applicable regulations are followed internally.

## 8.3 Application Environment Requirements

Before installing the Galaxy Lite instrument, please make sure your laboratory meets the space and environmental requirements specified in Section "4.2 Installation Requirement".

## 8.4 Instrument and Software

Please follow the tips below. When the test is in progress:

- Please do not move the instrument.
- Please do not run other software in the computer.
- Please do not change the date and time of the computer.
- Please do not set the computer as auto-shutdown or dormancy mode.

## 8.5 Detection

For each detection, please be sure to follow the requirements of the user manual of the instrument.

## 8.6 Reagent Kit

In order to protect against the hazards from cross-contamination, please do not reuse the reagent kit.

**Warning**: Please dispose the elution after each experiment in light of the laws, regulations and lab rules to protect the lab from contamination.

**Warning**: The used reagent kit shall be disposed as medical waste and do not dispose it into the public trash site.

## 8.7 iCassette Tray

If damage or abrasion occurs on the iCassette Tray, please immediately contact Igenesis after-sale service or the agent. It is recommended to replace the iCassette Tray every two years or each 4000-time test run.

# 9 Service and Maintenance

## 9.1 Overview

This section introduces how to maintain the Galaxy Lite instrument.

## 9.2 Maintenance Task

Although the system itself has the function of preventing cross-contamination and ensuring accurate results, as a preventive measure, user should regularly check and clean the instrument. The table below lists the basic maintenance tasks user can perform.

| Task | Section |
|---|---|
| Instrument Disinfection | Section 9.3 |
| Instrument Cleaning | Section 9.4 |
| iCassette Tray Holder Cleaning | Section 9.5 |
| iCassette Tray Cleaning | Section 9.6 |
| Others | Section 9.7 |

## 9.3 Instrument Disinfection

In order to prevent bio-hazards, user should disinfect instrument surface regularly.

**Warning**: Please turn off and unplug the instrument before disinfecting the instrument.

**Warning**: Galaxy Lite instrument must be disinfected before cleaning.

**Warning**: If the hazardous substance leaks to instrument surface or interior, please disinfect in a proper way.

**Warning:** Please do not use the detergent or disinfectant that may be reacted with the instrument materials.

**Warning:** If user is not sure about the compatibility of the detergent or disinfectant to the instrument materials, please contact the after-sale service.

**Warning**: If hazardous substances leak to the surface of the iCassette Tray of the Galaxy Lite instrument or enter the interior of the instrument, the following disinfection methods should be adopted.

- When the Galaxy Lite instrument is powered on and idle, click on "Open/Close " on the system interface.
- The “compartment door” is opened, load the iCassette Tray (No reagent loaded) to the tray holder with 1/3 part inside, as shown in figure 9-1.
- In this case, the Galaxy Lite instrument should be shut down and unplugged.
- Turn on the UV disinfection lamp or UV disinfector to irradiate the Galaxy Lite instrument compartment door, the iCassette Tray Holder and iCassette Tray area.
- After the UV irradiation lasts for 30 minutes, the disinfection of the Galaxy Lite instrument is finished and turn off the UV disinfection lamp.

Figure 9-1 UV Disinfection

## 9.4 Instrument Cleaning

It is recommended that you clean the surface of the instrument once a month or more frequently if necessary. To do this, you need the following materials:

- 75% ethanol;
- Lint free cloth;
- Disposable gloves;

Please make sure you wear disposable gloves during cleaning, which can protect you from direct contact with bio-hazards.

Please clean the surface of the instrument as follows:

**a.** When you use or spray cleaning solution on the instrument, please keep cleaning solution away from the AC power module.

**b.** Wipe the surface of the instrument thoroughly with a lint free cloth and wait for 10 minutes;

**c.** Use the lint free cloth wet by 75% ethanol to wipe the surface of the instrument again.

**d.** Discarded lint free rags should be disposed according to standard laboratory procedures.

## 9.5 iCassette Tray Holder Cleaning

It is recommended that you clean the iCassette Tray and iCassette Tray Holder once a month or more frequently if necessary. To do this, you need the following materials:

- 75% ethanol;
- Lint free cloth;
- Disposable gloves;

Please clean the iCassette Tray holder as follows:

**a.** Please wipe the iCassette Tray holder thoroughly with lint free cloth after opening the compartment door and turning off the instrument.

**b.** Wipe the iCassette Tray holder thoroughly with lint free cloth wet by 75% ethanol.

**c.** Turn on the instrument and close the compartment door.

**d.** Discarded lint free rags should be disposed according to standard laboratory procedures.

**Warning**: If hazardous substances leak to the surface of the iCassette Tray of the Galaxy Lite instrument or enter the interior of the instrument, the following disinfection methods should be adopted.

## 9.6 iCassette Tray Cleaning

It is recommended that you clean the iCassette Tray often. To do this, you need the following materials:

- 75% ethanol;
- Lint free cloth;
- Disposable gloves;

Please clean the iCassette Tray as follows:

**a.** Please wipe the iCassette Tray thoroughly with lint free cloth wet by 75% ethanol.

**b.** After 5 minutes, please repeat Step a.

**c.** Discarded lint free rags should be disposed according to standard laboratory procedures.

## 9.7 Other Maintenance

If the fuse is broken during instrument running, please replace the fuse according to the Section “4.2.5 Fuse Requirement”. In order to ensure the instrument power and the fuse in a good performance, please replace the fuse as follows:

**a.** Please take out the fuse tube with the proper tool in the power switch area at back of the instrument, as shown in figure 9-2.


Figure 9-2 Take Fuse Box

**Warning**: Please switch off and unplug the instrument before replacing the fuse.

**b.** Please take off the original fuse and replace it with a new one, as shown in figure 9-3.

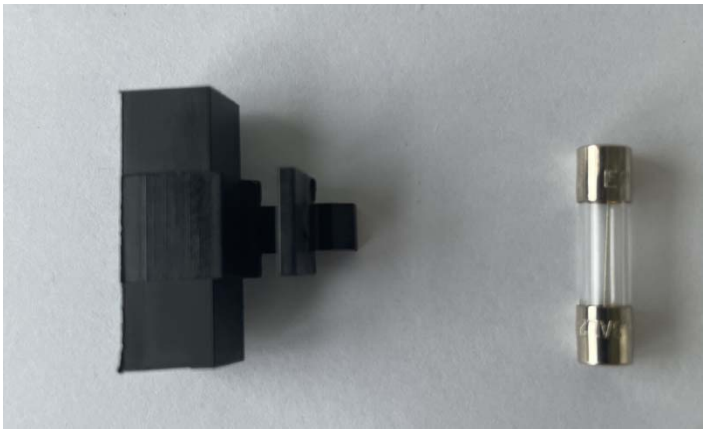


Figure 9-3 Take Fuse Tube

**c.** Please load the fuse box with the new fuse tube inside to the slot, as shown in figure 9-4.


Figure 9-4 Take Fuse Tube

Within the instrument validity, Igenesis could provide the chargeable service to keep the instrument in a good condition. If the instrument runs out of the validity, Please do not dispose the instrument in a random way and shall contact Igenesis to get a better way to dispose it.

# 10 Troubleshooting

## 10.1 Overview

This section will provide the tips how to solve the problems or error messages that may occur on the instrument.

## 10.2 Fault Table

This table shows the possible problems that may occur on the instrument.

| Fault | Reason | Solutions |
|---|---|---|
| The system cannot be started. | 1. The instrument is not connected to a power socket.<br>2. The instrument AC power switch is not on.<br>3. The fuse is broken.<br>4. The instrument power in the front is not pressed properly.<br>5. The instrument still cannot be started after trying the above 4 steps. | 1. Plug the instrument to the socket.<br>2. Turn of the power switch at back of the instrument.<br>3. Check and replace the fuse.<br>4. Press the instrument switch 1 second till the indicator light is on.<br>5. Please contact the after-sale service.. |
| System software cannot be opened. | 1. The computer cannot run the unauthorized program.<br>2. The computer does not install Microsoft.Net Framework 4.5 or higher version.<br>3. The software still cannot be opened after trying the above 2 steps. | 1. Please contact the computer admin.<br>2. Please contact the admin to install the correct Microsoft.Net Framework or higher version.<br>3. Please contact the after-sale service. |
| User name or password is not correct. | Enter a wrong user name or password. | Please contact the admin for the right user name and password. |

| | | |
|---|---|---|
| Device x is not connected. | 1. The communication cable is not connected to the computer.<br>2. Software EcanTools is not installed on the computer properly. | 1. Please check the communication cable is connected to the computer properly and whether the USB port is normal.<br>2. Please install EcanTools according to Section “4.3.4 Software Installation”. |
| Errors occur when self-inspection. | 1. iCassette Tray in the instrument when self-inspection.<br>2. The hardware error is reported by mistake or the hardware is damaged. | 1. Please do not put the iCassette Tray in the instrument when the experiment is not run.<br>2. Please unplug the instrument and log in the system software again. If the problem is not solved, please contact the after-sale service. |
| When entering the compartment, the iCassette Tray is jammed or bumped. | 1. The iCassette Tray or the reagent kit on the iCassette Tray is not loaded properly.<br>2. The reagent kit is not loaded in position. | 1. Reload the iCassette Tray or reload the reagent kit on the iCassette Tray properly.<br>2. Reload the reagent kit. |
| The PID entered is not matched with the reagent kit loaded. | 1. The PID information is not entered in the corresponding channel where loads reagent kit.<br>2. The QR code on reagent kit is unclear so it is not identified. | 1. The PID information shall be entered in the corresponding channel where loads reagent kit.<br>2. Please ensure the QR code intact. |
| It prompts user to enter SID information. | The SID information is not entered in the corresponding channel where loads reagent kit | The SID information shall be entered in the corresponding channel where loads reagent kit. |
| The motor does not arrive in the sensor position. | 1. Motor or sensor errors.<br>2. The mechanical part interferes. | Please contact the after-sale service if the problem is not solved after reboot. |
| Motor errors | 1. The sensor errors.<br>2. The mechanical part interferes. | Please contact the after-sale service if the problem is not solved after reboot. |
| The heating tip errors | 1. Errors reported by mistake.<br>2. The heating module is damaged. | Please contact the after-sale service if the problem is not solved after reboot. |
| The reagent kit cannot scanned. | 1. The reagent is not loaded into the icassette Tray.<br>2. The reagent kit QR code is lost or unclear. | 1. Please load the reagent kit into the icassette Tray.<br>2. Change a new reagent kit or contact after-sale service. |

| | | |
|---|---|---|
| The reagent kit type is inconsistent. | The reagent kit of the inconsistent PID kind code is loaded into the iCassette Tray. | Please load reagent kit whose PID kind code is consistent. |
| There is no matched program. | The PID kind code of the reagent kit used cannot be identified. | Please contact the after-sale service to handle it. |
| The reagent is non-effective. | 1. The reagent kit is invalid.<br>2. The time of the computer is wrong. | 1. Please use the valid reagent.<br>2. Please ensure the computer system time is right. If the problem is not solved, please contact the after-sale service. |