Fluorescent Quantitative Detection System

Quant Gene 9600 Series

Instruction for Use

REF **FQD-96C**

IVD

Attention Users are recommended to read the contents of this manual thoroughly before operating the Bioer Fluorescent Quantitative Detection System.

To carefully observe all special Warnings and Cautions outlined in this manual.

This manual should be maintained properly in good condition for reference.

Thank you for your purchase of this product.
Before initial use of this instrument, please read this manual thoroughly ！

File No.: BYQ66190000000ESM

File Version: July 2021 Version 2.0

Important Notes

1 Practice

Note:	Very important information is contained within this manual and it should be carefully read before first use of the instrument. Failure to operate instrument according to the instruction could result in damage or abnormal functioning of the instrument.

Warning:	The warning message requires extremely careful operation of a certain step. If the instrument is not used in the manner prescribed by the manufacturer, the protection provided may be compromised.

2 **Safety**

During operation, maintenance and repair of this instrument, the following basic safety notes must be observed. In case of failure to follow these measures or the warnings or notes indicated herein, the basic protection provided by the instrument, its safety criteria of design and manufacture, and its predicted use range would be impaired.

Hangzhou Bioer Technology Co., Ltd. shall not be held responsible for any consequences resulting from the user's failure to observe the following requirements.

Note:	The instrument, complying with the Standard GB4793.1/IEC61010-1, is a general instrument of classI, the protection degree is IP20. It is intended for indoor use

Note:	The instrument complying with the Standard YY0648/IEC61010-2-101 is used for IVD Medical Equipment.

a) Instrument earth

In order to avoid an electric shock, the input power cable of the instrument must be properly earthed. This instrument uses a 10A 3-core earthed plug, which is provided with a third (earth) pin. It is for use with an earth type power socket and is a safety unit. If the plug cannot be inserted into the socket, the socket must be fixed by a qualified electrician, to maintain the safety function of the plug and the protection it provides.

b) Keeping apart from the live circuit

Operators are not allowed to disassemble instrument protection, replace components or make

internal adjustment without authorization. If necessary, it must be completed by certified professional maintenance personnel. It is forbidden to replace components when power supply is connected.

c) Use of power supply

Before connecting to the mains and switching the instrument on, make sure the voltage is consistent with the instruments requirements (220V~,50Hz). The rated load for the power socket must not be less than the instruments maximum load of 1000VA

d) Power wire

The instrument is supplied with a power cable which should be used at all times when operating the instrument. If the power cable is damaged it should be replaced with a new one of the same specification. When using this instrument, do not press anything on the power cord and do not put the power cord in the traffic area. If the power cord comes in contact with the hot surface, add protection to prevent the insulation from being damaged.

e) Insertion and withdrawal of power cable

At insertion and withdrawal of power cable, the back of the plug shall be firmly held with the hand. The plug must be completely and tightly inserted into the socket and must not be removed by pulling the cable.

f) Placement of instrument

This instrument should not be positioned in a place where it is difficult to cut off the power supply.

This instrument should be placed in a low relative humidity (RH) and low dust environment well away from any water (e.g. sinks and pipes). The room should be well ventilated, and free from corrosive gas, or interference from a strong magnetic field. The instrument should not be placed in a wet or dusty location, but should be positioned on a sturdy, level and secure table appropriate to its weight.

The openings on this instrument are for ventilation purposes and in order to avoid over-heating of the instrument they shall not be blocked or covered. When a single set or several sets of instruments are used, the space between its ventilation openings and the nearest object should not be less than 30cm. When multiple instruments are used at the same time, the distance between each instrument should not be less than 50cm.

Excessive environmental temperature would impair the test performance and could result in failure of the instrument. This instrument should not be used in locations subjected to direct sunlight or strong radiation or light source, as this could impair the fluorescence detection. The instrument should be kept away from hot gas, furnaces, stoves and all other sources of heat.

When switched off, the power should also be switched off. If the instrument is not going to be used for a long time, the power should be switched off, the power plug withdrawn and the instrument covered with soft cloth or plastic film to prevent dust or foreign bodies entering the machine.

g) Notes during operation

During test, cares shall be taken to prevent liquid from dropping onto the instrument. The castoff used in test, such as consumables, reagent, and so on, should be treated as require, and should not be thrown away or poured.

During test, if there are hazardous substances, user must be trained before using.

Hazardous substances, which have been used, should be coped with and saved according to defection for use.

User, who operates the instrument, must be trained and has relevant quantification

Caution: If any of the following should occur, you should immediately switch off the power supply, withdraw the power plug from the power socket, and contact the supplier to effect a repair: Repairs can only be carried out by suitably qualified engineers.

- Liquid gets inside the instrument.
- The instrument is rained upon or water is spilled over it.
- The instrument works abnormally, or generates an abnormal sound/s or generates a strange odour.
- The instrument is dropped or its casing is damaged.
- There is an obvious change in the function of the instrument.

Caution: When you deal with potential contagious matter such as body's tissue sample or reagent, which is likely to touch skin, protecting glove or other protecting measures are need to be used.

h) Re-transport

If the instrument needs to be transported again, the detection hole position and the instrument

should be thoroughly cleaned and sterilized with ultraviolet light before transportation.

i) Warning Sign

- Warning identification

DANGER!		Area with the mark pasted on the instrument shall avoid improper use and be careful of danger.
SCALDING!		Area with the mark pasted on the instrument causes high temperature and is scalding during use.
BIOHAZARD		Area with the mark pasted on the instrument will caused biohazard during use.
PROTECT CONDUCTOR TERMINAL		PROTECT CONDUCTOR TERMINAL is near to the area with the mark pasted on the instrument

- Warning mark

Warning! When "HOT SURFACE!" is pasted in the instrument, it means that the metal part (module) near this sign shall not be touched with any part of the body during the operation of the instrument or a period of time immediately after the operation of the program to avoid burns !

Warning! The operator may come into contact with or remain substances harmful to the organism or infectious substances during the use of the instrument. The operator should be aware of its hazards and strictly comply with the relevant provisions of the national PCR laboratory in accordance with the use environment of the instrument. Operators need to be trained and qualified.

j) Equipment Safety

The instrument was designed, produced and tested in accordance with EN 61010-1 (IEC 61010-1) "Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements". It has left the factory in a perfectly safe condition.

The instrument meets the requirements of the DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

k) Other symbols on the packaging

Date of manufacture		Indicates the date when the medical device was manufactured.
RoHS		Restriction on the use of certain hazardous materials(restriction of hazardous substances)
Consult instructions for use		Indicates the need for the user to consult the instructions for use.
Serial number		Indicates the manufacturer's derail number so that a specific medical device can be identified.
Catalogue number		Indicates the manufacturer's catalogue number so that the medical device can be identified.
In vitro diagnostic medical device		Indicates a medical device that is intended to be used as an *in vitro diagnostic medical device*.
CE mark		Indicates the medical device meets the CE related Directives.
Manufacturer		Indicates the medical device manufacturer.
Authorised representative in the European Community		Indicates the authorized representative in the European Community.
Up		Indicates that the correct position of the transport package is vertical upward.
Fragile		The transport packages contain fragile goods, so they should be handled with care.
Keep dry		The package should be rain-proof.
The limit of stacking layer		Maximum stacking layer of the same package is 2.
Temperature limit		Indicates that the temperature limit of transportation package should be - 20 ℃ to 55 ℃.

3 Maintenance of Instrument

If there is any stain on the surface of the instrument, it can be cleaned with soft cloth and cleaning paste. Heat conducting oil medium is not allowed in the module hole of this instrument.

The drawer should be closed in time after the normal storage and use of the instrument to prevent dust accumulation.

Warning! When cleaning the instrument, the power should be turned off.
The instrument surface should not be cleaned with corrosive cleaning agents.
The instrument module includes precise optics, dust, foreign matter and residue should be avoided.

4 Disposal

 Potentially infectious material and all parts that may come in contact with potentially infectious material must be disposed in accordance with the relevant legal provisions.

All parts which have been replaced must be disposed in accordance with the relevant legal provisions.

 Disposal of the instrument must be carried out in accordance with the relevant legal provisions.

Disposal of the packaging material must be carried out in accordance with the relevant legal provisions.

5 After-sales Services

The warranty content and scope are shown in the warranty sheet.

Note:

- After unpacking, immediately check the goods against the packing list. If any parts are damaged or missing, please contact the supplier immediately.
- After qualification of acceptance, complete the product acceptance sheet and send (or fax) the copied sheet to the supplier for filing and maintenance.
- Before first use of the product, the user shall complete the instrument registration form and send to Hangzhou Bioer Technology Co., Ltd. for product registration.
- After unpacking, the packing box and packing materials should all be kept in case it is required for transportation or service in the future.
- In the event that a repair is required, the instrument must be disinfected before being sent to the repair department.
- It is recommended that service personnel disinfect the instrument on receipt in the service department, before commencing any scheduled work.
- Hangzhou Bioer Technology Co., Ltd. shall bear no liability in the event of any damage to the instrument occurring during transportation to the service department due to improper packaging.

Contents

Chapter 1 General description

This chapter mainly describes the intended use, principle, characteristics, specifications, performance parameters and software functions of the instrument.

1. Intended use

The Fluorescent Quantitative Detection System is an automated instrument for quantitative analyses the related DNA/RNA in human sample using the polymerase chain reaction fluorescent quantitative detection. The instrument is for in vitro diagnostic only. Application areas include research into the human genome, forensics, cancer, tissue, population biology, paleontology, zoology and botany and in clinical diagnosis of virus, cancer and research.

The Fluorescent Quantitative Detection System is intended for use by professional user trained in molecular biological techniques and the operation of The Fluorescent Quantitative Detection System.

2. Principle

The Fluorescent Quantitative Detection System is based on the Polymerase chain reaction. Its principle is based on the use of DNA polymerase which is an in vitro replication of specific DNA sequences. This method can generate tens of billions of copies of a particular DNA fragment (the sequence of interest, DNA of interest, or target DNA) from a DNA extract (DNA template). We can therefore amplify nucleotide sequences from infinitesimal amounts of DNA extract. PCR is therefore a technique of purification or cloning.

The principle of the PCR is based on the temperature variations of heating and cooling-thermocycling reaction divided into three steps:

Denaturation： The dsDNA becomes single-stranded at a higher temperature during denaturation. Here hydrogen bonds between two DNA strands break.

Annealing： in The primer binds or anneals to its exact complementary sequence on a DNA during the annealing step. The primer provides a site for the initiation of synthesis.

Extension： Taq DNA polymerase uses the 3’ end of the primer and starts DNA synthesis by adding nucleotides to the growing DNA strand.

All three steps are repeated for 25 to 40 cycles and in each cycle the DNA becomes double.

The PCR machine is known as a thermocycler. This machine is simply a heating block (just like

our iron) which provides the constant temperature and even rapidly changes between two temperature states.

The machine has a lower block of metal having deep wells for putting PCR tubes. Also, the temperature of the inner environment is maintained by the heating block present on the upper side of the lead. Further, the machine contains the display, power on and off switch, and cooling assembly. The machine has the ability to heat and cool the PCR tube in a short period of time.

Real-time fluorescent quantitative PCR technology refers to the method of adding fluorescent groups to the PCR reaction system, using the accumulation of fluorescent signals to monitor the entire PCR process in real time, and finally quantitatively analyzing the unknown template through the standard curve.

3. Features

- New, user-friendly operation, operation interface, smooth operation
- Fluorescence real-time detection method is adopted to realize simultaneous amplification and detection in the same tube without post-processing
- Advanced thermoelectric refrigeration technology ensures super high speed heat cycle system heating, fast and stable refrigeration
- Multi-point temperature control ensures higher temperature uniformity of 96 sample wells
- 6 partition temperature control function
- Stable and accurate gradient functions of 1 ~ 36℃ ensure optimized PCR conditions
- the thermostatic function of SOAK allows the PCR reagent to be stored at low temperature
- Long life LED excitation light source requries no maintenance
- Advanced fiber conduction technology makes photoelectric detection system more sensitive and reliable
- Real-time dynamic monitoring of the whole process of PCR amplification was carried out Real-time dynamic monitoring of the whole process of PCR amplification was carried out
- Wide linear range, initial DNA copy Numbers up to 10 orders of magnitude do not require gradient dilution
- There is no need to turn on the PCR reaction tube, which can avoid product contamination during and after PCR and ensure the accuracy of the results
- Multi-color fluorescence detection in a single reaction obtains more information
- The application of thermal cover technology has realized the oil-free operation of PCR
- Chinese language interface, flexible program setting, comprehensive analysis and

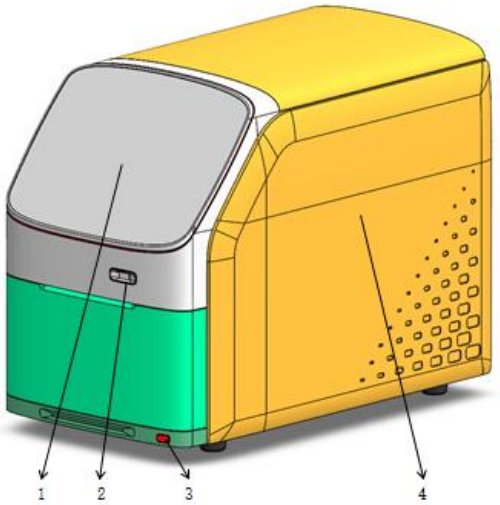
reporting functions, all parameters can be stored

- Multiple or single sample reports can be printed
- The automatic, accurate and timely service of remote network provides the most advanced technical support for the 96-well quantitative PCR analyzer

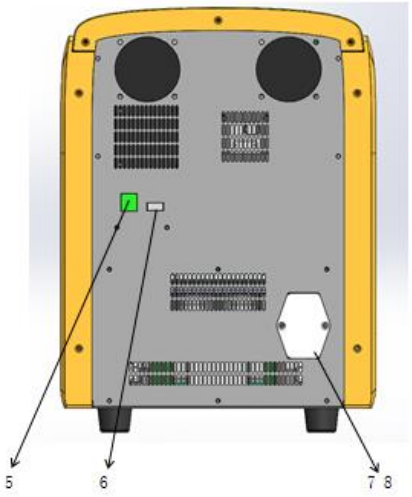
4. Product Structure and Composition

This product is mainly composed of control parts, thermal cover parts, thermal cycle parts, photoelectric parts, transmission parts, power parts and software (V1).

The external appearance of the Fluorescent Quantitative Detection System is described as below:



Front view



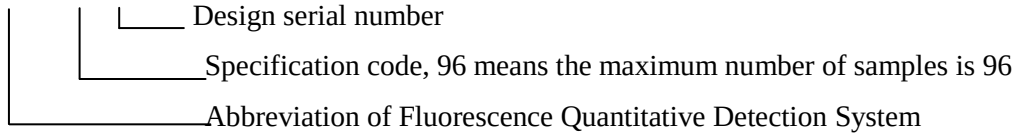
Back view

Indication of the items

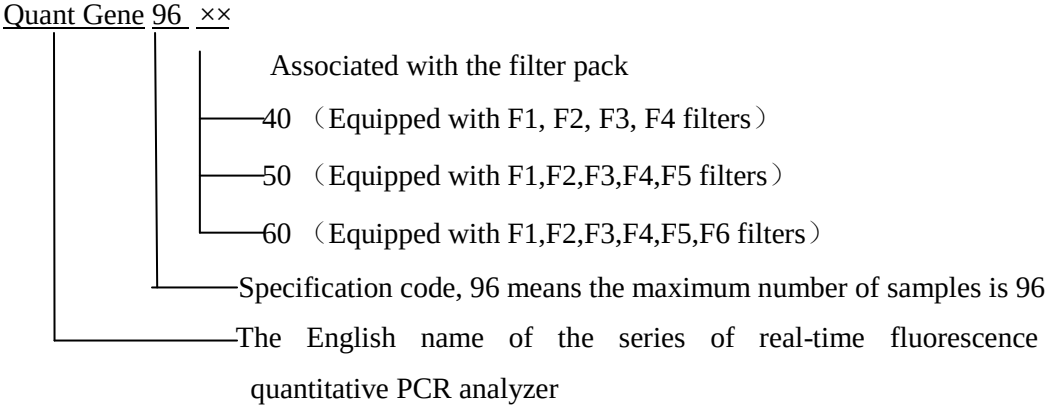
1. Display
2. USB interface
3. Start switch
4. Case body
5. Network interface
6. USB interface
7. Standard power outlet
8. Power switch

5. Specification and Model Description

Model: FQD – 96 C



Specification:



6. Performance Parameters

Model	**FQD-96C**					
Sample size	96×0.2ml（Suitable for single tube, 8 row tube and 96-well plate (no skirt board, half skirt board)）					
Detection channel	F1	F2	F3	F4	F5	F6
Applicable dye	FAM, SYBR Green I	VIC, HEX, TET, JOE,	ROX, TEXAS -RED	Cy5 Quasar - 670	Cy5.5 Quasar - 705	Optional
Module operating temperature range	4℃～99.9℃(Minimum setting scale:0.1℃)					
Average heating rate	When rising from 50℃ to 90℃, it should be no less than 3.5℃/s					
Average cooling rate	From 90℃ to 50℃, should not be less than 3.0℃/s					
Module temperature control accuracy	Should be no greater than 0.1 ℃					
Temperature uniformity	The temperature difference is within ±0.3℃					
Temperature control accuracy of hot cover	105℃±5℃					
Fluorescence intensity test repeatability	CV≤3％					
Mode of operation	Continuous operation					
Operating system	Windows XP/Windows Vista/Windows7/Windows8					

Input power	100-240V～ 50Hz 1000VA
Overall dimensions	490mm×290mm×391mm
Weight	28kg

7. Production Date and Service Life

Production date: see label for details.

Product life: 5 years

8. Function Overview of Supporting Software

a) Parameter setting function (including temperature, time, cycle number, rise and drop rate, detection channel selection);
b) Note function of text content;
c) Sample data recording function (sample number, sample name, sample data);
d) File operation display function (PCR thermal cycle data display, fluorescence detection data display, real-time display of various data during the operation of the instrument);
e) Test data analysis function (analysis function can be used alone without instrument connection);
f) Analysis results output function (one can output the analysis results to other types of files, such as :EXCEL, TXT files; be able to query and print the analysis results; one can change the print format and select the print item);
g) File storage function (setting data, running data, analysis results);
h) Fault protection and alarm function.

Caution:	The above software functions are for reference only, without prior notice to the change of software functions.

9. Product Software Version

Release version of this product software: V1

Chapter 2 Preparations

This chapter mainly introduces the use, transportation and storage conditions, structure composition, software installation/unloading, and preparation before starting up the Quant Gene 96xx series fluorescence quantitative PCR analyzer.

1. Transportation and Storage Conditions of the Instrument

Ambient temperature: -20℃～55℃

Relative humidity:≤80％

Atmospheric pressure:75kPa～106kPa.

2. Normal Working Condition

Ambient temperature:10℃～30℃

Relative humidity:≤70％

Atmospheric pressure:100-240V～ 50Hz 1000VA

Caution:	Before using the instrument, please confirm whether the Working Conditions meet the above requirements. Note that the power socket is a 3-hole socket with reliable grounding.

3. Preparation before the Instrument is Switched on

Power cord connection: the power cord attached to the instrument should be used. When connected, the instrument power switch should be in the closed state; After connecting, check whether the power cord and the instrument socket are too loose, if too loose, it should be replaced.

Caution:	The attached power cord is reliable, but may cause the connection to be too loose after several unplugging. In this case, the power cord should be replaced. The power cord should be replaced with the same specification.

4. Installation Procedure

4.1 Installation of the instrument

4.1.1 Scope of Delivery

Caution:	Fluorescent Quantitative Detection System is heavy (28kg), It needs two persons moved out from the case carefully!

The components listed in the below packing list will be delivery together with the instrument.

Packing List

No.	Title	Model and Specification	Unit	Amount	Remarks
1	Fluorescent Quantitative Detection System	FQD-96C	Set	1	The instrument
2	Power cable	250V 10A □	Piece	1	Accessory（optional）
3	Power cable	125V 12A □	Piece	1	Accessory（optional）
4	Fuse	250V 12A	Piece	2	Accessory
5	Wireless mouse and keyboard kit	Logitech MK270 Black	set	1	Accessory
6	USB flash disk (BIOER)	Quant Gene 9600	Piece	1	Accessory
7	Touch Screen Software User Manual	/	Copy	1	Following file
8	Instruction for use	/	Copy	1	Following file
9	Performance test table	/	Copy	1	Following file
10	Packing List	/	Copy	1	Following file
11	Precautions of Using QuantGene 9600	/	Copy	1	Following file
12	Pressure balance plate	/	Piece	1	Accessory
13	Finished network cable	/	Piece	1	Accessory
14	Silicone pad	/	Piece	1	Accessory

4.1.2 Transportation

Please observe the following Safety Notes when transporting and storage the Fluorescent Quantitative Detection System:

The Fluorescent Quantitative Detection System is supplied in an aluminium case. Visually inspect the box for damage before delivery.

- Ensure that transport and storage temperatures conform to the technical data.
- Always place the device on a stable surface.
- Check product information on the box.
- Visually inspect the box for loose or broken parts.

If the package had been damaged in transit, it is particularly important that you retain it for inspection by the carrier in case there has also been damaged to the instrument.

Neither the manufacturer nor its agents can be held responsible for any damage incurred intransit, but the manufacturer will make every effort to help obtain restitution from the carrier.

If any parts are damaged, contact Bioer or the distributer(s).

4.2 Unpacking Procedure

Please observe the following safety notes when unpacking, storing the Fluorescent Quantitative Detection System:

- The Fluorescent Quantitative Detection System is supplied in an aluminum case. Visually inspect the container for damage before opening.
- Move the packed instrument to its site of operation. Unpack Fluorescent Quantitative Detection System and accessories carefully with the arrows on the transport package pointing upwards. Remove the instrument from the package and place it on a level surface.
- Check if all system components are presents using the delivery note.
- Ensure that transport and storage temperatures conform to the technical data.
- Place the device on a stable work surface.
- Compare the serial number on the rear panel of the device with the serial number on the delivery note.
- Visually inspect the instrument for loose, bent or broken parts.
- Retain the packaging for use when storing for long periods or to return the device to the manufacturer.

Caution:	When unpacking, use Packing list described in Chapter 4.1.1 to ensure that all components are present.

4.3 Installation of Supporting Software

4.3.1 Selection of a Computer System

System environment

Operating system: Windows XP/Windows Vista/Windows7/Windows8

Operating environment: Net Framework 4.0

Other software: PDF reader

Minimum configuration:

Processor: Intel Core i3

Memory: 2GB

Hard disk:10GB

4.3.2 LineGene96xx Software Installation

Double click PcrServer installation file（PcrServerSetup.exe）▶ Display the installation interface (select the installation language) ▶ Set installation path ▶install

Double click LineGene96xx installation file（LineGene96xxDiagnosisSetup.exe）▶ Display the installation interface (select the installation language)▶ Set installation path ▶install

4.3.3 LineGene96xx Software Uninstall

Control panel ▶Add/remove programs▶ PcrServer ▶uninstall

Control panel ▶Add/remove programs▶LineGene96xx▶uninstall

Chapter 3 Start

1. Check before Starting

Before putting in the power plug and powering up the detection system, the following contents should be confirmed:

- Whether the power supply is consistent with the voltage required by the system;
- Make sure the power cord plug is correctly and reliably plugged into the power socket;
- Whether the surrounding working environment and equipment placement conditions meet the requirements.

2. Boot

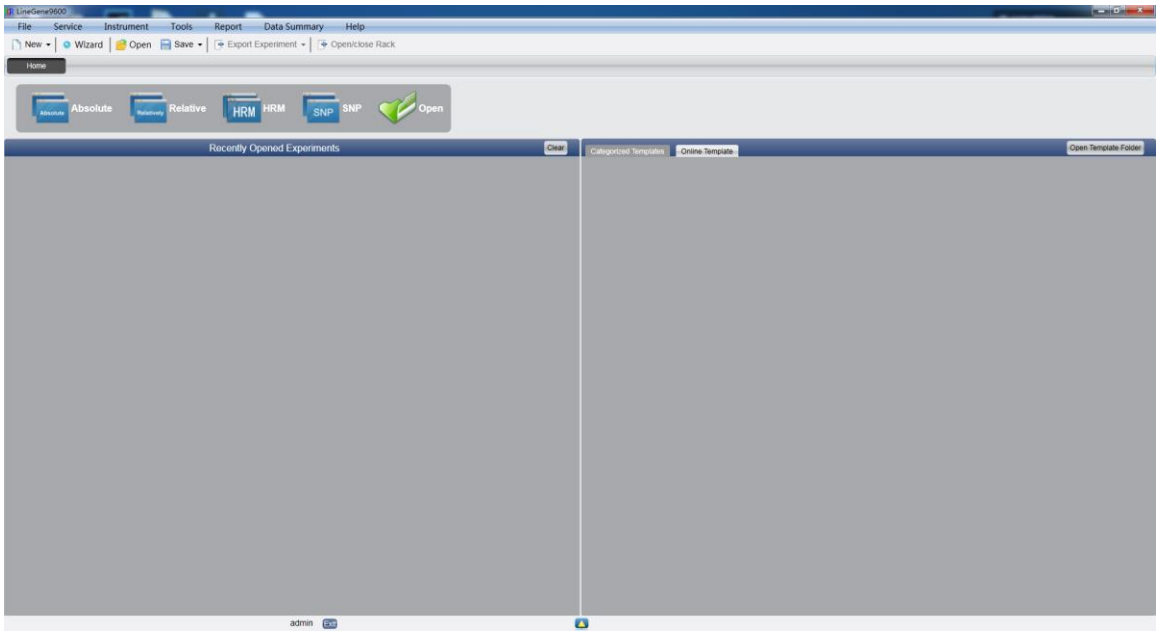
Step 1: turn on the power switch of the backboard of the instrument;

Step 2: after entering the operating system, start the Quant Gene 96xx series real-time fluorescence quantitative PCR analyzer.

To start the software, click "LineGene 96xx" on the start/program menu or double click on the shortcut icon on the desktop.

3. Software Startup Interface

Double click any software shortcut icon of the LineGene 9600 series real-time quantitative PCR analyzer on the desktop, the corresponding startup screen will appear.



The system window consists of the menu bar, the toolbar and the main page.

Chapter 4 Absolute Quantification

1. Design Experiment

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

This section describes how to design a new absolute quantification experiment and covers inspection item setting, sample information setting, reaction plate setting and programme setting.

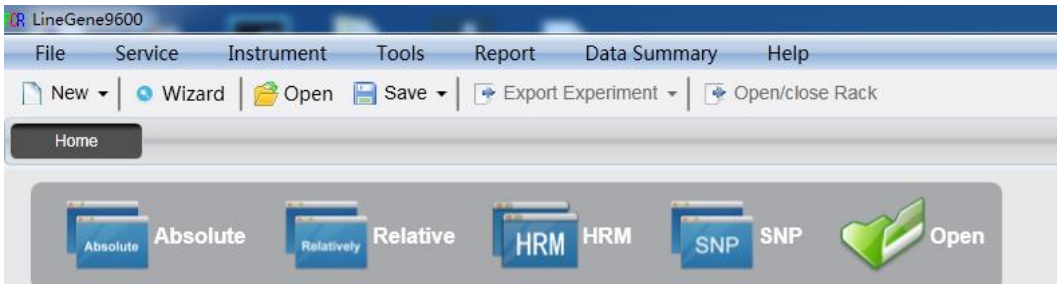
1.1 Create New Absolute Quantitative Experiment

1. Click build **Absolute** on the **Home** interface and this will open the absolute quantitative experiment window.

NOTE: The Absolute quantitative experiment can be also created by:

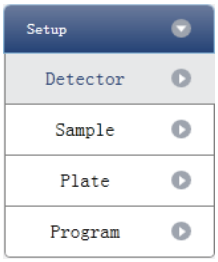
a. Clicking **File ► New ► Absolute** on the menu bar

b. Clicking **New ► Absolute** on the toolbar



1.2 Detector Setting

1. Click **Setup ► Detector**



2. Input experiment properties

Input the experiment name, user name and any comments in the experiment properties column.

3. Detector Setting

Set up the Detector, Assay, Dye and Colour.

If necessary, the user can also:

a. Add detector

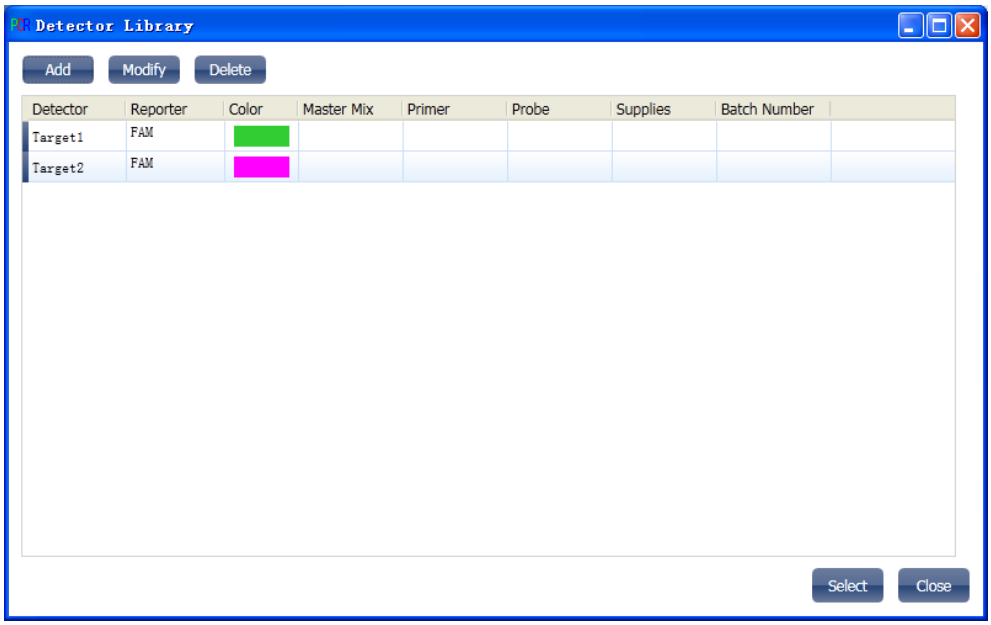
b. Add assay

c. Delete detector

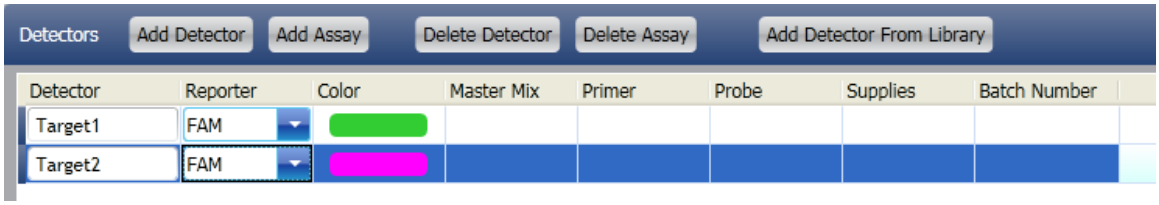
d. Delete assay

e. Add the detector in the Detector Library: click **Add Detector From Library ►** the **Detector Library** window will pop up ► select the Detector in the window to be added

The user can also conduct Add, Modify and Delete operations in the item library.



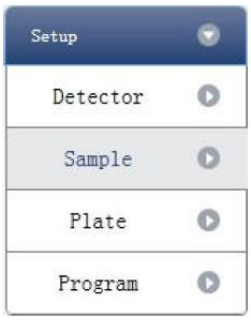
f. Set up the detector, set up the assay, set up the dye name and set up the colour



4. Set up reference dye

1.3 Sample Information Setting

1. Click **Setup ► Sample**



2. Add sample information

a. Itemized addition: input ID in **Sample ID ►** press **Enter ►** add information for one sample

b. Batch addition: click **Batch Add ►** the Batch Add window will pop up

3. Delete sample information

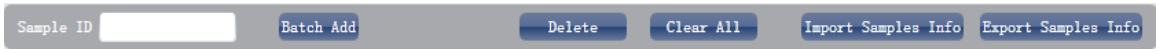
a. Itemized deletion: select one sample ► click **Delete ►** delete the selected sample information

b. Delete all: click **Clear All ►** deletes all sample information

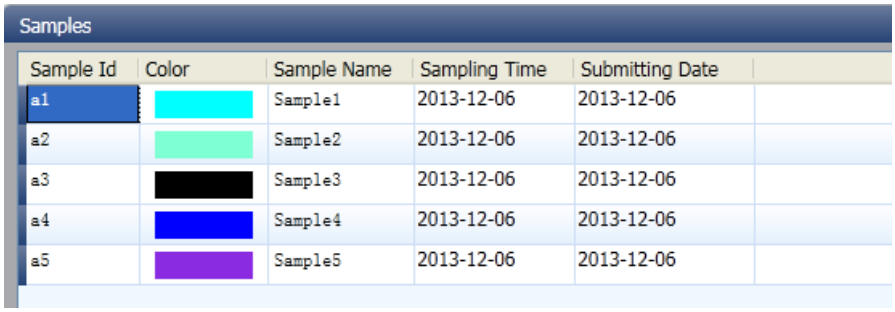
4. Import/Export sample information

a. Click **Import Sample Info ►** the File Import window will pop up ► import sample information file in CSV format

b. Click **Export Sample Info ►** the Save As window will pop up ► the sample information will be exported in CSV file format

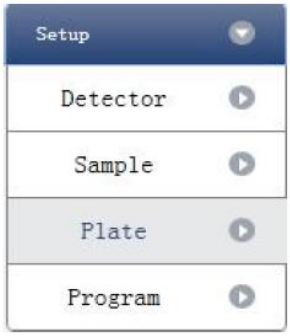


5. Set up sample information



1.4 Reaction Plate Setting

1. Click **Setup ► Plate**

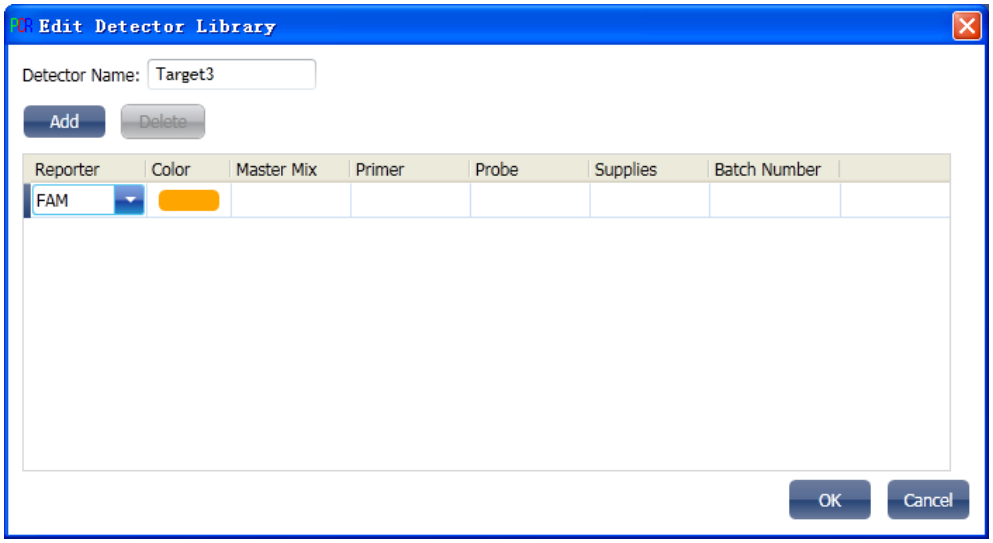


2. Set up the inspection criteria of the reaction plate

a. Select reaction plate well site: click Reaction Plate well Site

The user can also right click the reaction plate well site to Copy, Paste and Add New Detector.

Adding a new detector will open the **Edit Detector Library** window.



b. Select Assay item and modify the property, concentration and concentration unit.

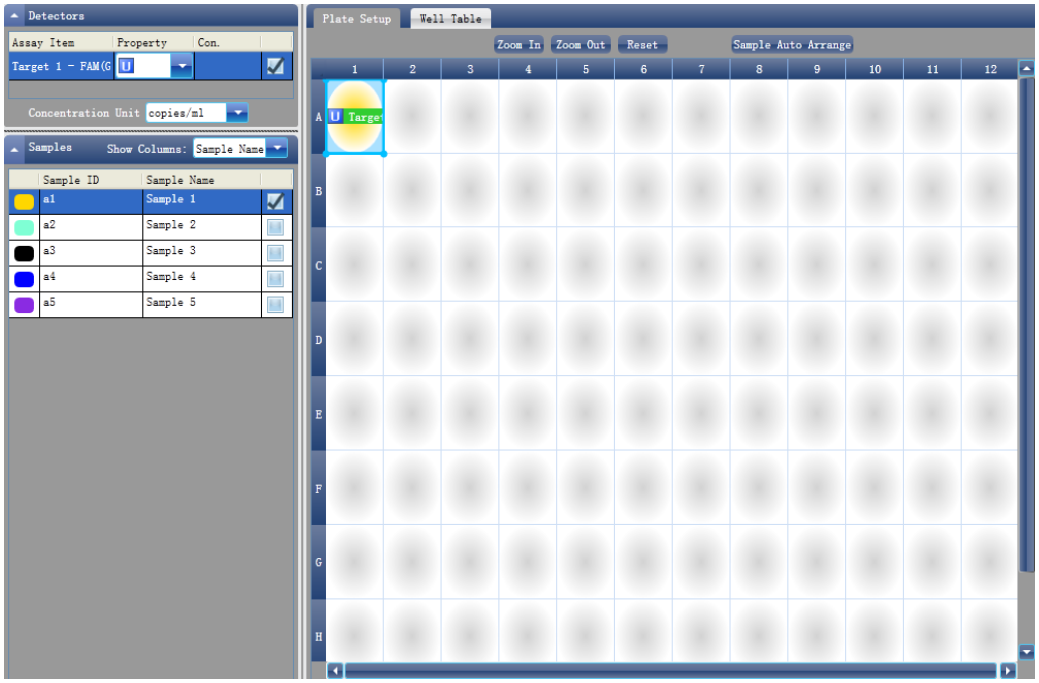
Property	Name	Concentration	Concentration unit
U	Unknown	NO	Copies/ml
S	Standard	YES	IU/ml
N	Negative	NO	Fg/ml
P	Positive	NO	Pg/ml

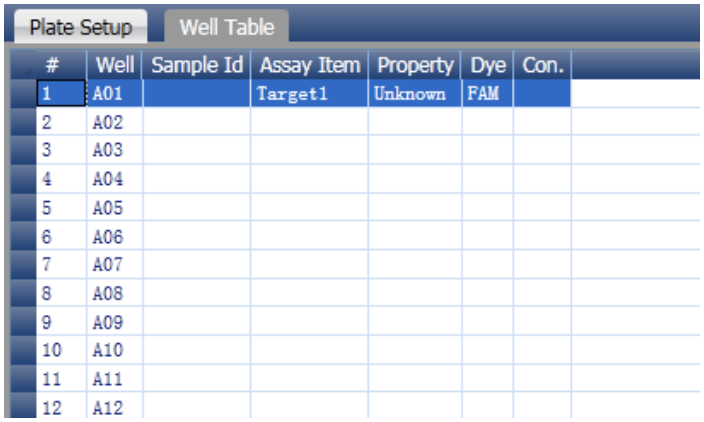
c. Select a sample and the list displayed will change

d. Zoom-In, Zoom-Out and reset the reaction plate.

e. Sample Auto Arrange

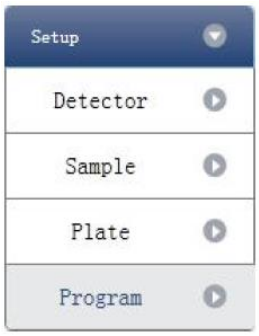
f. Check Well Table





1.5 Programme Setting

1. Click **Setup ► Programme**



2. Run Programme Setup

a. Create new stage: the user can create a new **Hold Stage**, **Cycling Stage** or **Melting Stage**

The user can also click **Add Stage** directly and the default will be creating a new **Cycling Stage**.

b. Create new step: the user can create a new step **Before** or **After** the currently selected step

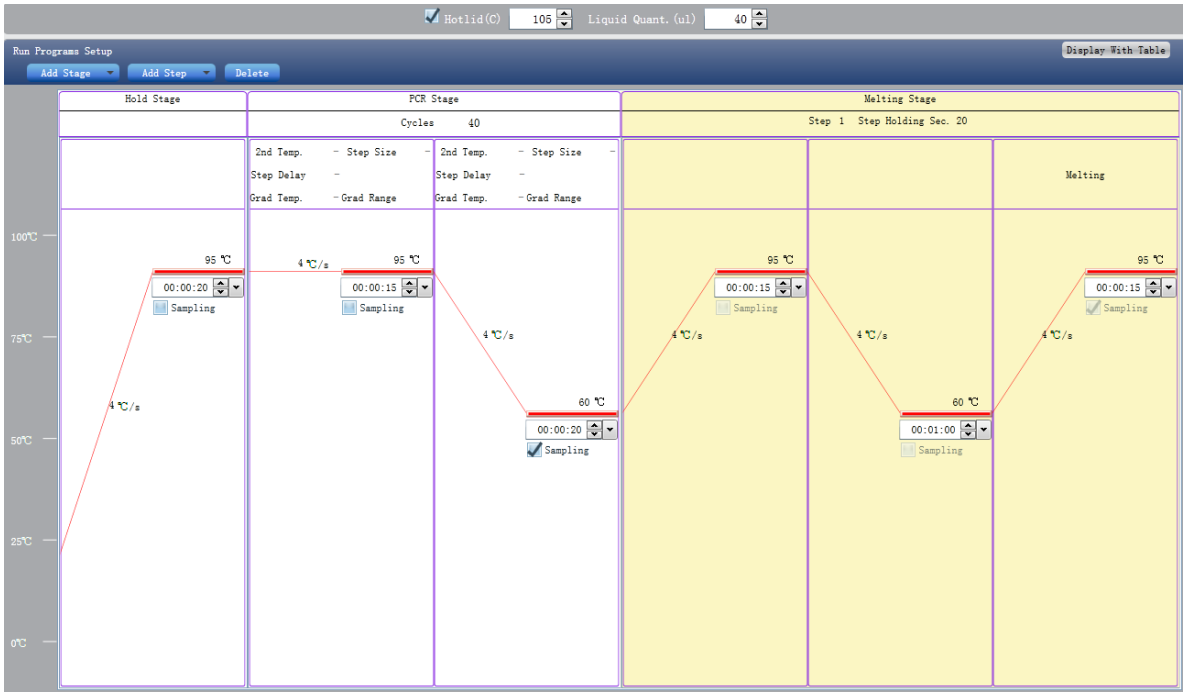
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

c. Delete: the user can delete the currently selected step or stage

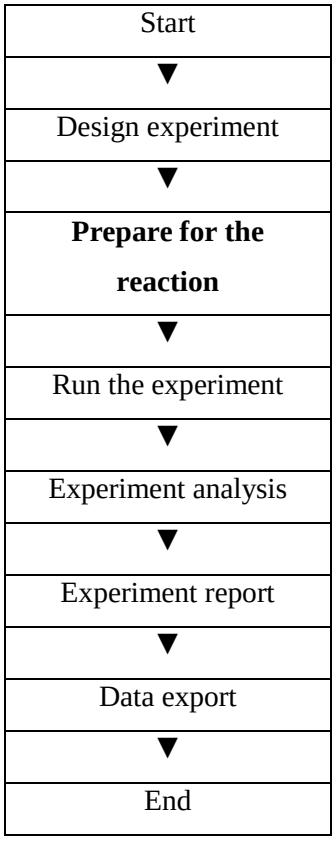
d. Display form: click **Display With Table ►** new window will pop up **►** the details of the current experiment will be displayed in a table.

e. Set up the experimental data of the hold stage, cycling stage and melting stage melting section

f. Set up the hot-lid temperature and liquid volume



2. Prepare for Reaction



The user should make full preparations prior to the experiment:

• Ensure appropriate materials are used.

• Ensure the arrangement of the PCR reaction plate is consistent with the setting layout of the reaction plate in Section 1.4.

3. Run the Experiment

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

This section describes how to run/operate the experiment after loading the reaction plate and includes how to operate the fluorescence curve, the temperature curve and programming

Caution: Before starting the machine, please confirm that you have completed the inspection before starting the machine, and carry out the correct operation according to the starting steps. Turn on the system, and the system is in running state.

3.1 Preparation for reagent sample

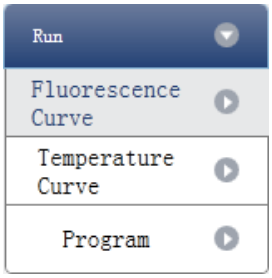
- Prepare reagent: Quant Gene 9600 series real-time fluorescence quantitative PCR analyzer adopts 0.2ml centrifuge tube to place reagent samples, and 10μl～50μl is recommended for the best reaction system for samples.
- The instrument allows the use of standard single tube, rack tube, skirt-free plate and other types of top optical transparent tube.
- Centrifugal operation: Before placing reactions into the instrument, it is recommended that a short centrifugal spin is used to ensure that the reagent is at the bottom of the reaction tube and the reagent/sample mix is free from bubbles.
- Placement of test tubes: if the number of samples is less than the number of holes in the module, try to distribute the sample tubes evenly in the holes of the module during the placement of test tubes, so as to ensure the smooth pressure of hot cover on the top of the tube during operation. Meanwhile, the load of the module is uniform, and the temperature change of each test tube is uniform.

Correct.
The sample is at the bottom of the PCR tube

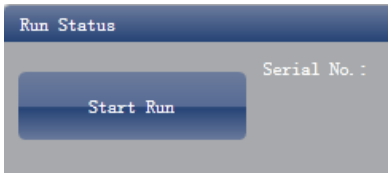
Incorrect
1. Requires a greater spin speed
2. Requires a longer spin time

3.2 Run Fluorescence Curve

1. Click **Run ► Fluorescence Curve**



2. Click **Start Run**



3. Operating confirmation

    a. Modify hot-lid temperature and liquid quantity (sample volume).

4. After it starts operating, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run

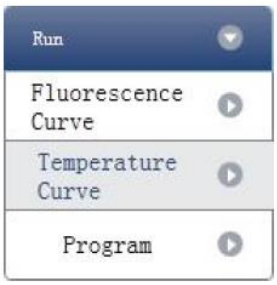
5. Plot display setting

    a. Assay item

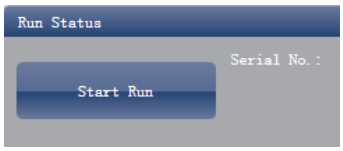
    b. Plot colour

3.3 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Start Run**



3. Operating confirmation

    a. Modify hot-lid temperature and liquid quantity (sample volume).

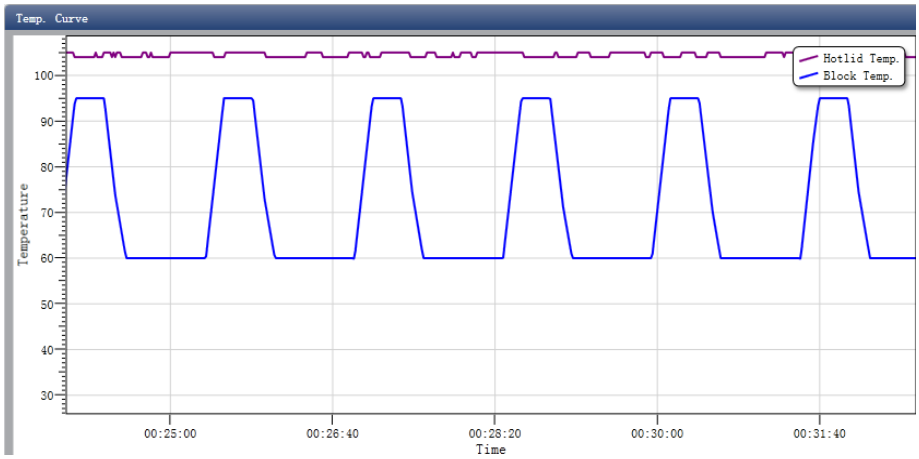
4. After it starts running, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run



3.4 Programme Setting

The user can only check the programme setting but cannot make modifications.

3.5 Prompts which may occur during running

- Hot-lid temperature sensor alarm prompt
- Sink temperature sensor alarm prompt
- Environmental temperature sensor alarm prompt
- Module temperature sensor alarm prompt
- Module sensor short-circuit or short-circuit alarm prompt

Caution: In case the temperature alarm displays during the running of a programme, the PCR detection system will terminate the current programme. The instrument should be switched off and then re-started.

4. Experiment Analysis

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

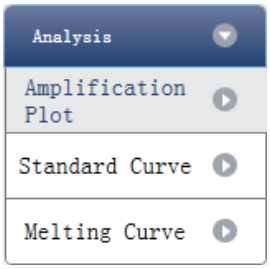
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

This section covers the analysis of amplification curves and standard curves, adjusting parameters for re-analysis and importing parameters.

4.1 Check Results

4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



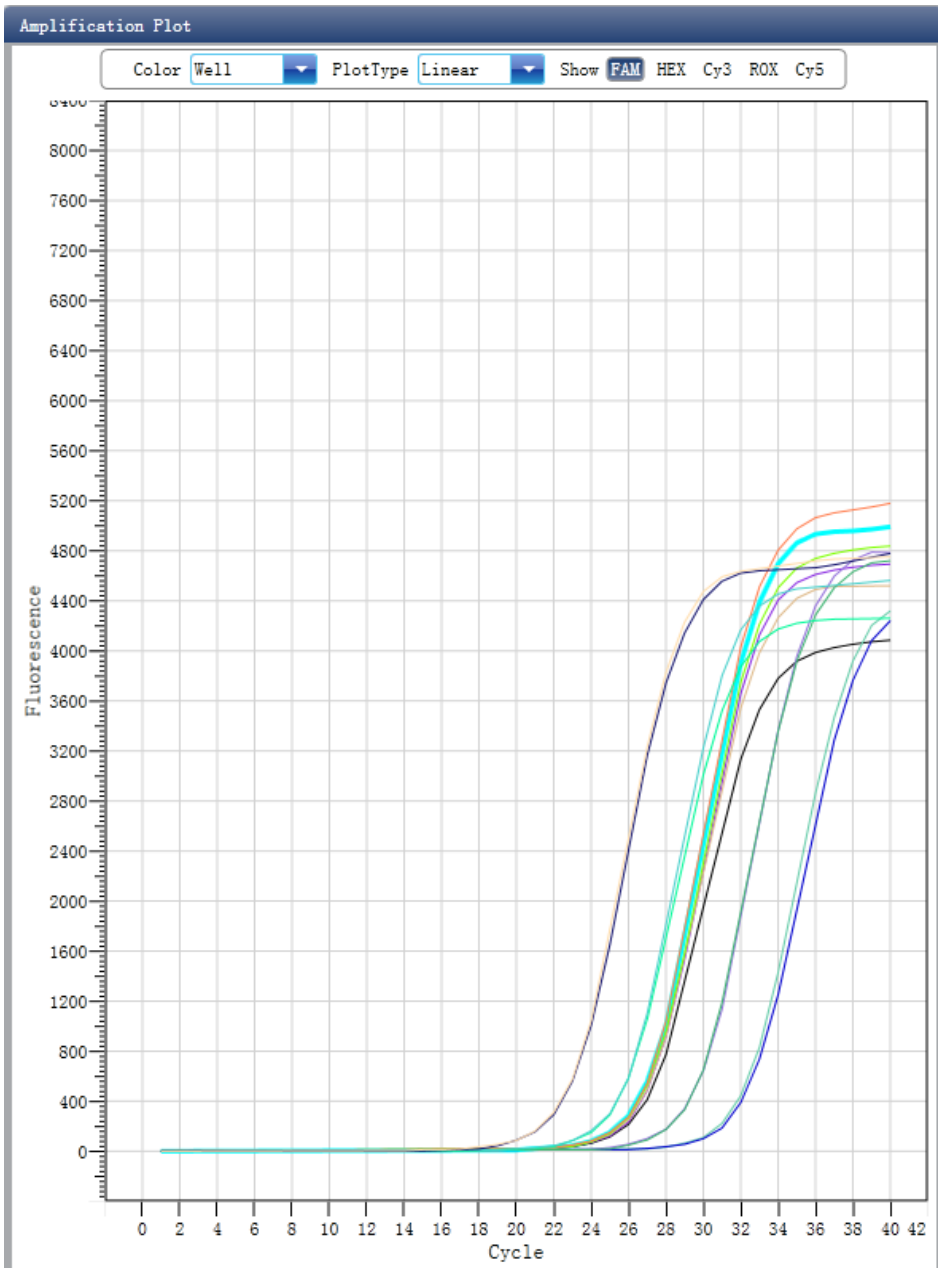
2. Check the amplification curve

a. Set up colour

b. Set up plot type

c. Set up show dye

When the background colour of a dye name is blue, it will be displayed; while white indicates it will not be displayed.



3. Check the reaction plate

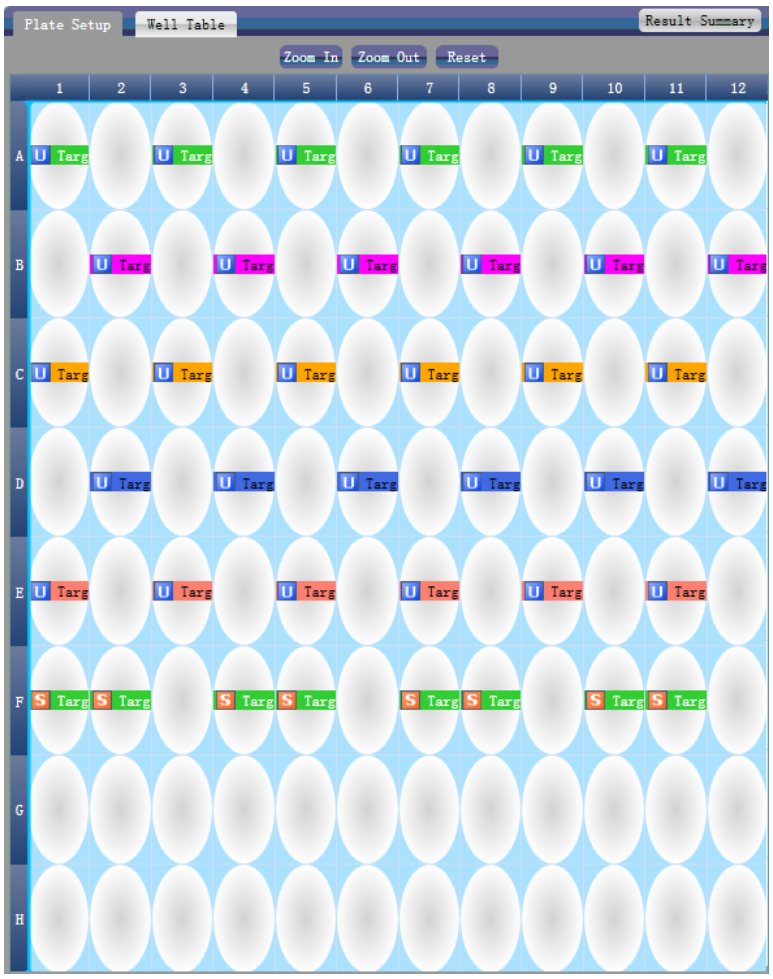
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

b. Zoom-In, Zoom-Out and reset the reaction plate

c. Check well table

d. Check results summary



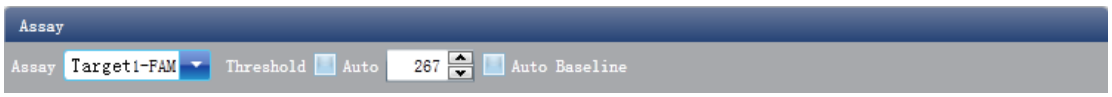
4. Set up assay

a. Set up assay

b. Set up threshold

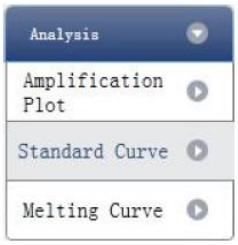
c. Set up automatic baseline

When the threshold value is not automatic, the user cannot set up the automatic baseline



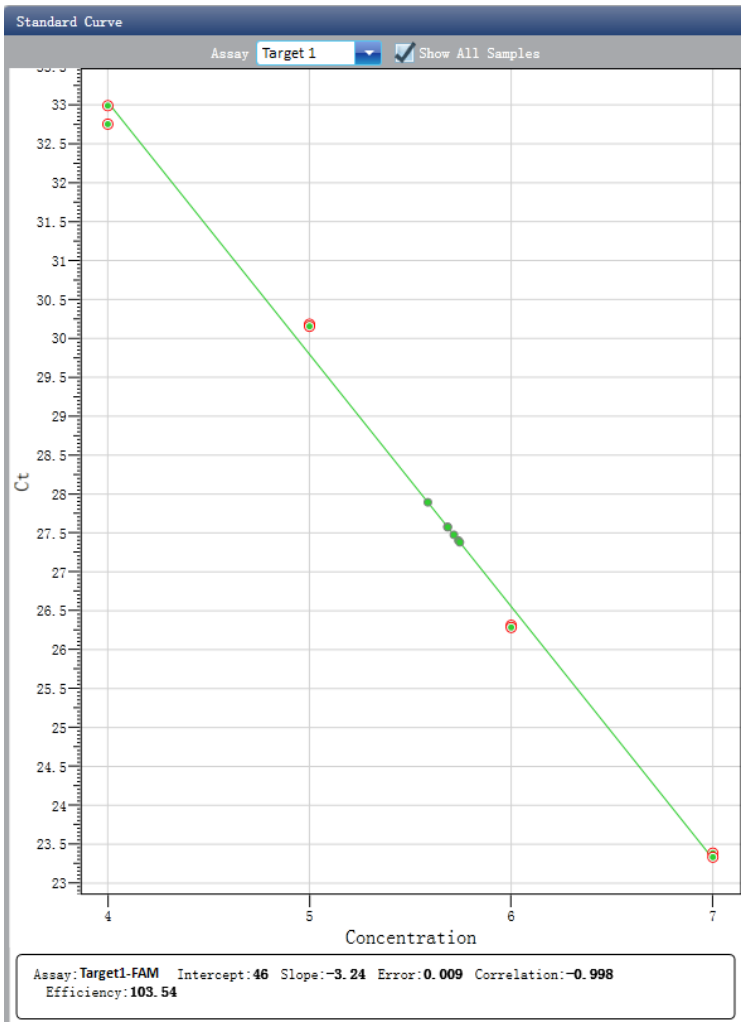
4.1.2 Check Standard Curve

1. Click **Analysis ►Standard Curve**



2. Check standard curve

a. Set up assay



3. Check the reaction plate

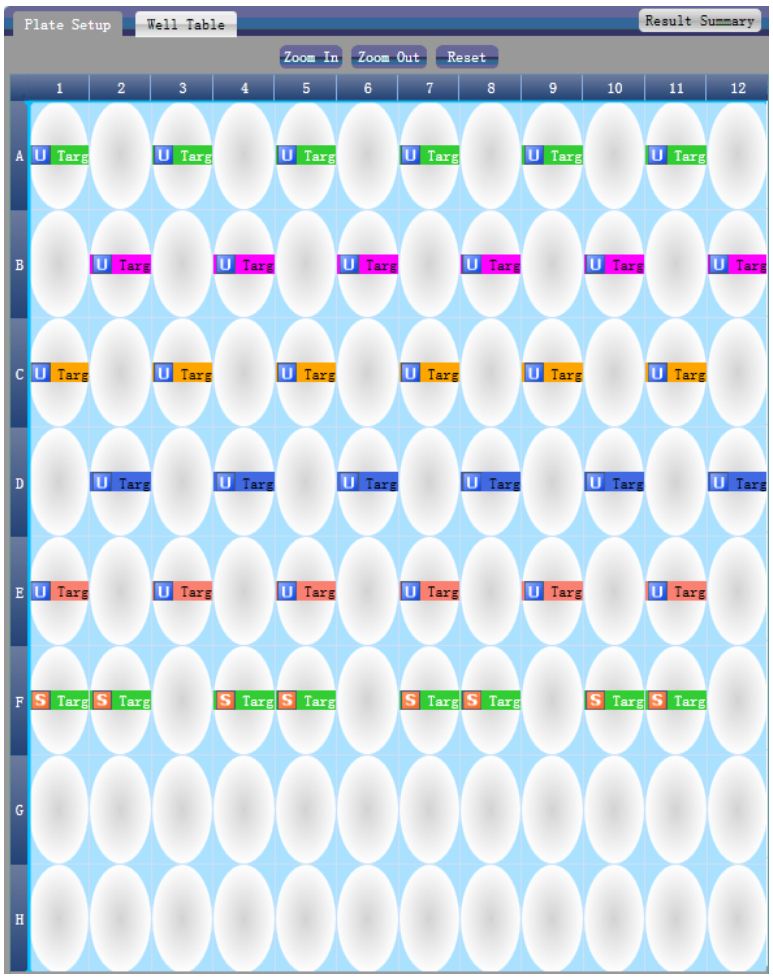
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

b. Zoom-In, Zoom-Out and reset the reaction plate

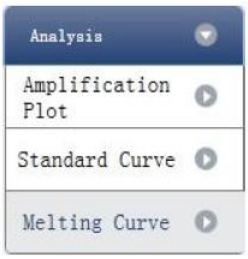
c. Check well table information

d. Check results summary



4.1.3 Check Melting Curve

1. Click **Analysis ► Melting Curve**

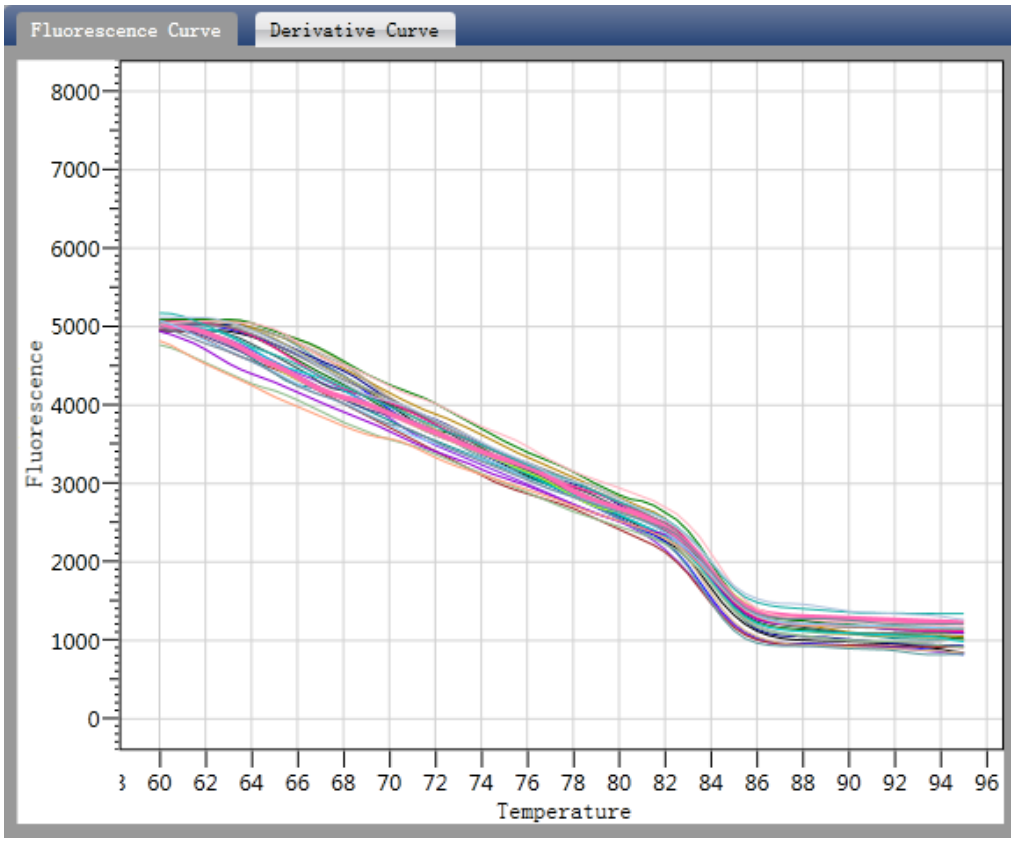


2. Check the melting curve

a. Check the fluorescence curve

b. Check the derivative curve

c. Set up colour



3. Check the reaction plate

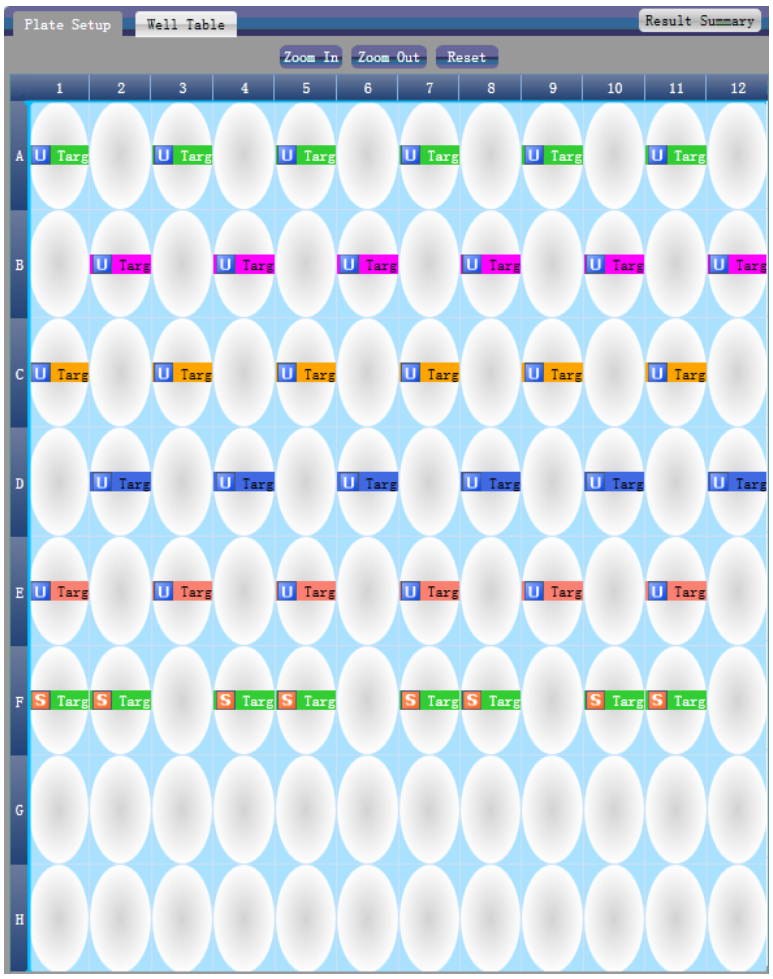
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

b. Zoom-In, Zoom-Out and reset the reaction plate

c. Check well table information

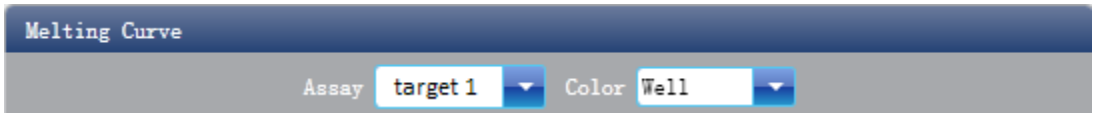
d. Check results summary



4. Set up assay

a. Set up assay

b. Set up colour



4.2 Adjusting Parameters and Re-analysis

1. Click **Analysis Settings** ► the Analysis Settings dialog box will pop up

    a. Adjust the start cycle and end cycle of the baseline

    b. Adjust Ct analysis algorithm

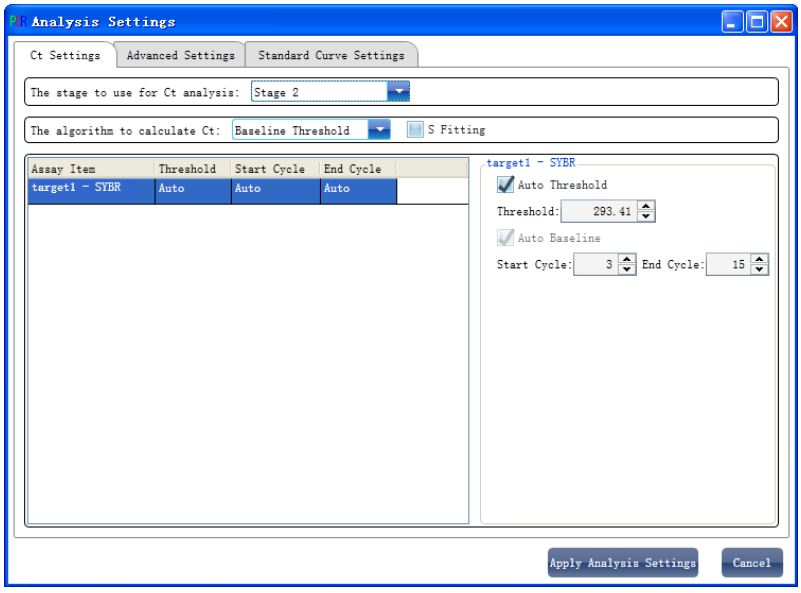
    c. Set up the use of S fitting

    d. Set up the stage to use for Ct analysis

    e. Set up the automatic threshold value

    f. Advanced setting

    g. Standard curve setting



5. Experiment Report

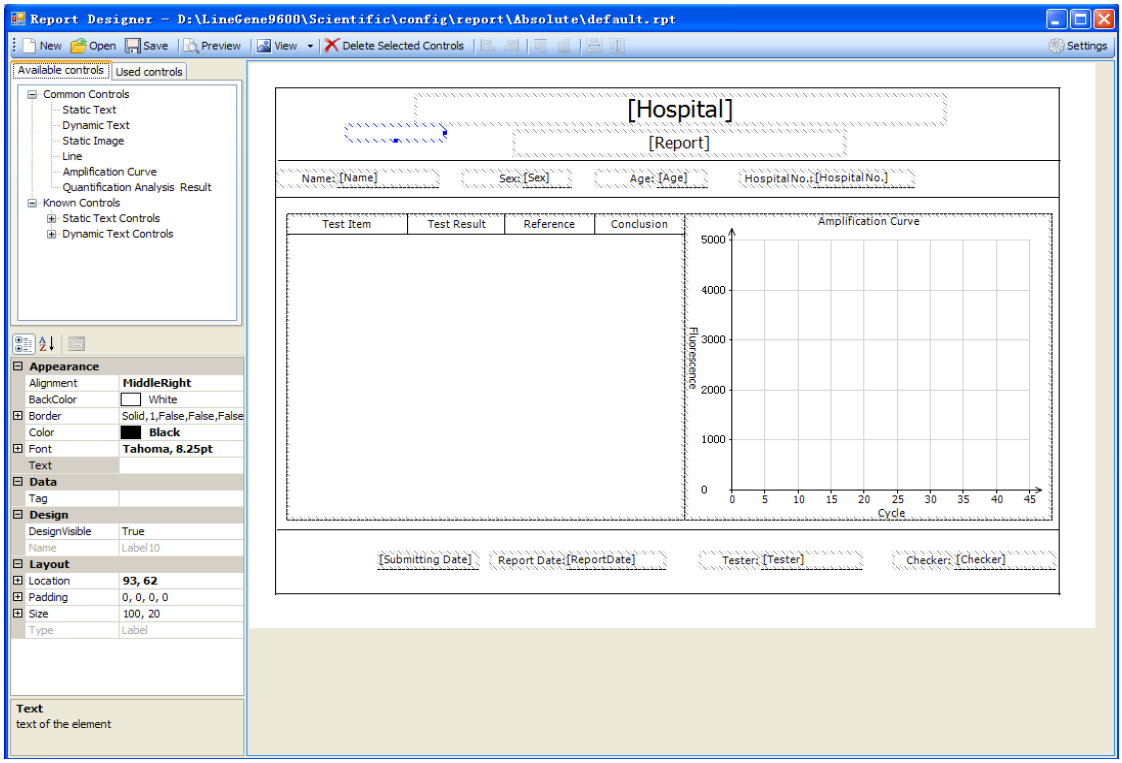
Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

This section describes how to print an experiment report and covers designing of a report template and print settings.

5.1 Designing a Report Template

1. Click **Report ► Report Template Editor ►** the Report Designer window will pop up

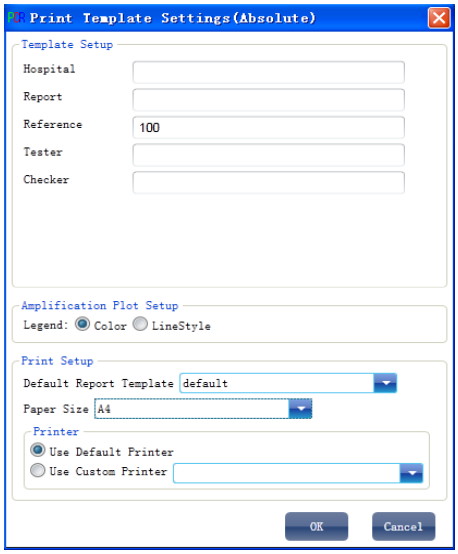
The report consists of controls and the user can add, modify and delete controls. Available controls include Static Text, Dynamic Text, Line, Static Image, Amplification curve and Quantification Analysis Results.



5.2 Print Setting

1. Click **Report ► Print Template Setting ►** the Print Template Setting window will open

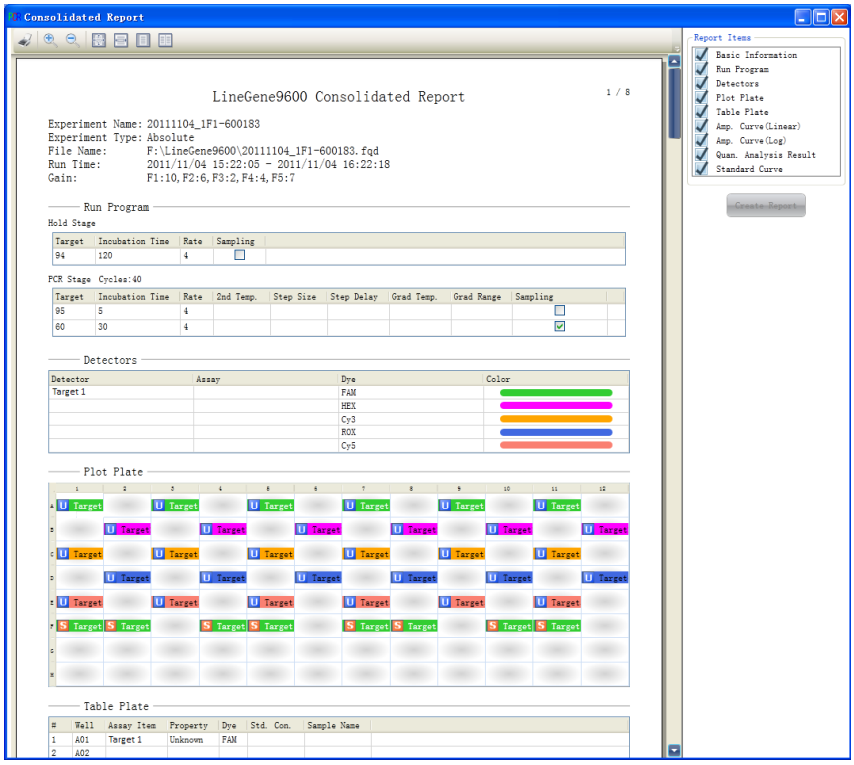
The user can set up the laboratory name, report name, reference value, tester, checker, amplification plot, default report template and paper size.



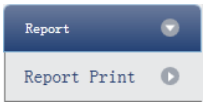
5.3 Comprehensive Report

1. Click **Report ► Consolidated Reports ►** the Consolidated Report window will pop up

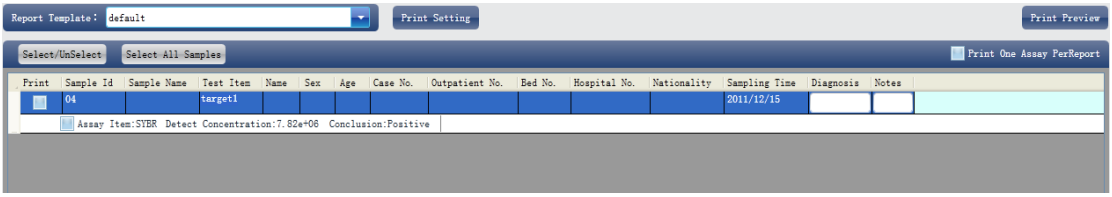
The Consolidated Report includes the basic information, sample information, amplification curve, standard curve, plate information, etc..



5.4 Report Printing



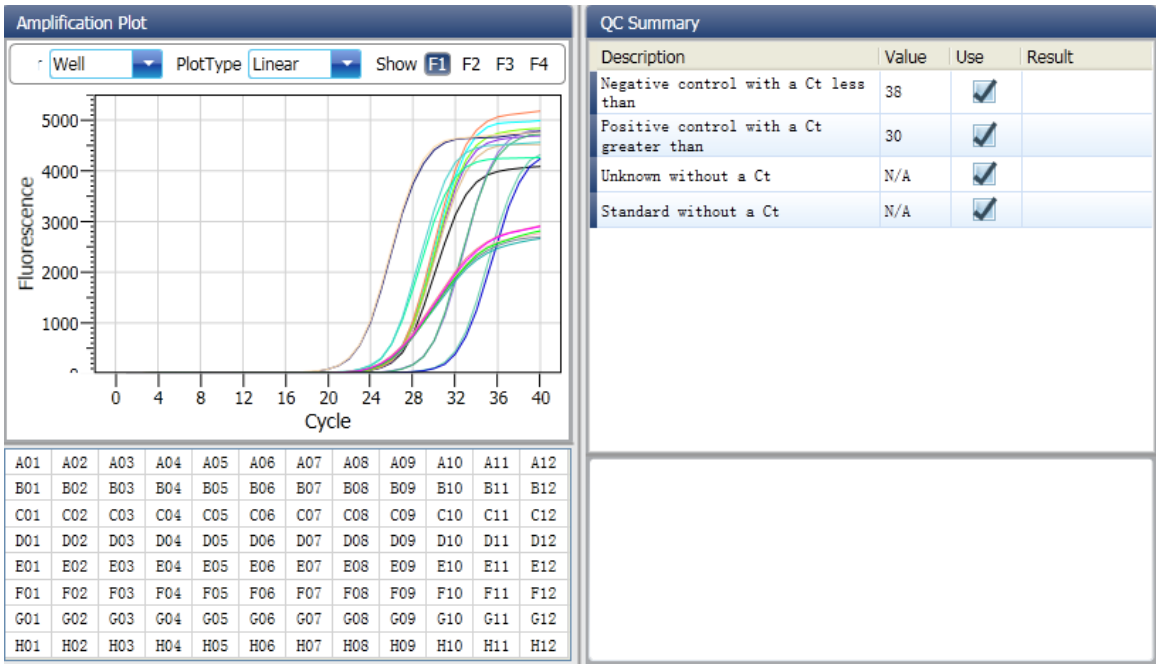
1. Click **Report ► Report Print**
2. Report print setting
    a. Set up report template
    b. Print setting (please refer to Section 5.2)
    c. Select items to print
    d. Print preview
    e. Print the report



5.5 QC Summary

1. Click **Report ► QC Summary**

2. Check the QC summary



6. Data Export

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

This section describes how to export data and covers exporting to a database, experiment filing and exporting the experiment data to EXCEL.

6.1 Export to Database

Click **Data Summary ► Export to Database ►** the Save File dialog box will pop up **►** save the exported database file

6.2 Experiment Filing

1. Click **Data Summary ► Archived Experiment Directory ►** the Experimental archive storage directory window will pop up **►** set up the storage path of file.

2. Experiment filing

Click **Data Summary ► Archived Experiment ►** export the filed experiment file

The suffix of the filed experiment file is .fqh

6.3 Export Experiment Data to EXCEL

Click **Data Summary►Export Experiment ► Export Experiment to Excle ►**the exported experiment data will generate EXCEL file

6.4 Export Experiment Data to TEXT

Click **Data Summary►Export Experiment ► Export Experiment to Text►** the exported experiment data will generate TEXT file

Chapter 5 Relative Quantitative

1. Design Experiment

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

This section describes how to design a relative quantitative experiment and covers creating new relative quantitative experiment, inspection item setting, sample information setting, reaction plate setting and programme setting.

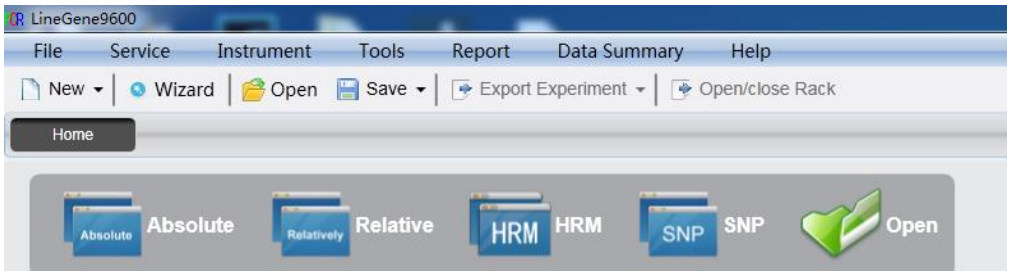
1.1 Create New Relative Quantitative Experiment

1. Click **Relative** on **Home** interface and create Relative Quantitative Experiment window.

Relative quantitative experiment can be also created by:

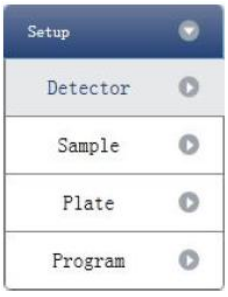
a. Clicking **New ► Relative** on the toolbar

b. Clicking **File ► New ► Relative** on the menu bar



1.2 Detector Setting

1. Click **Setup ► Detector**



2. Input Experiment Properties

Input the Experiment name, User name and Comment in the basic information column.

3. Inspection Item Setting

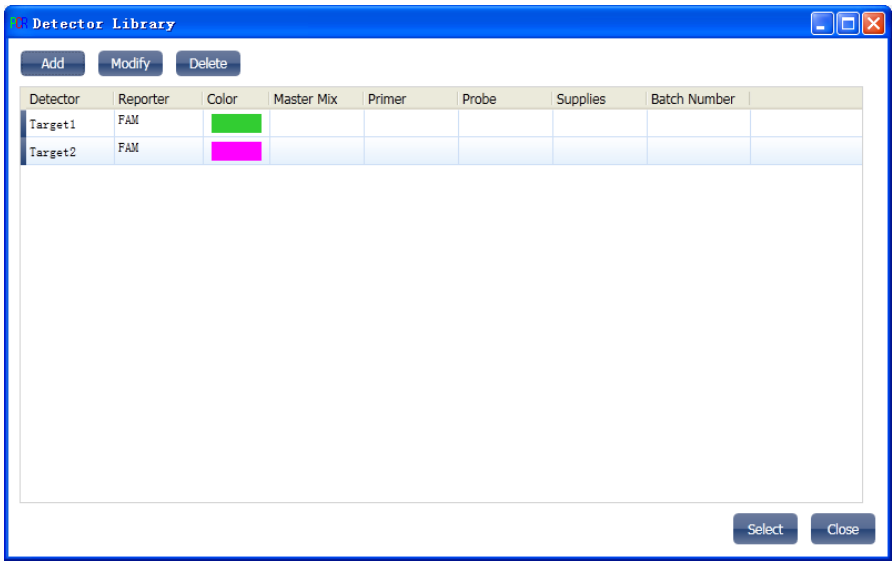
a. Set up the Detector, Assay, Dye and Colour.

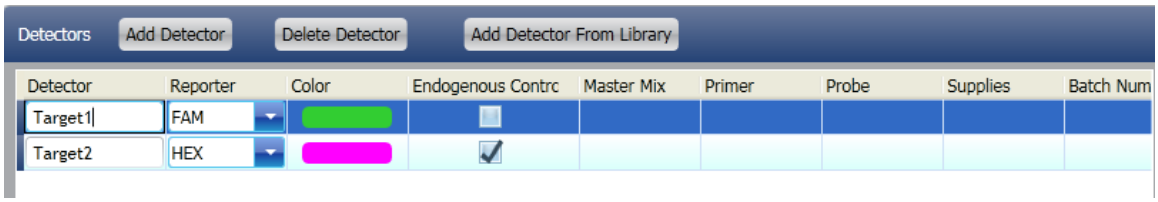
b. Add detector

c. Delete detector

d. Add detector from library

The user can also conduct Add, Modify and Delete operations in the item library.

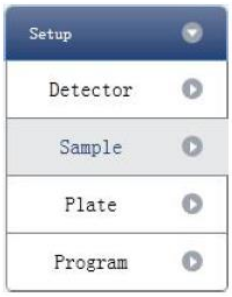




4. Set up reference dye

1.3 Sample Information Setting

1. Click **Setup ► Sample**



2. Add sample information

a. Itemized addition: input ID in **Sample ID** ► press **Enter** ► add information for one sample.

b. Batch addition: click **Batch Add** ►the Batch Add window will pop up

3. Delete sample information

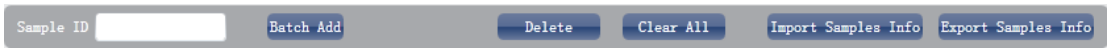
a. Itemized deletion: select one sample ► click **Delete** ► delete the selected sample information

b. Delete all: click **Clear All** ► delete all sample information

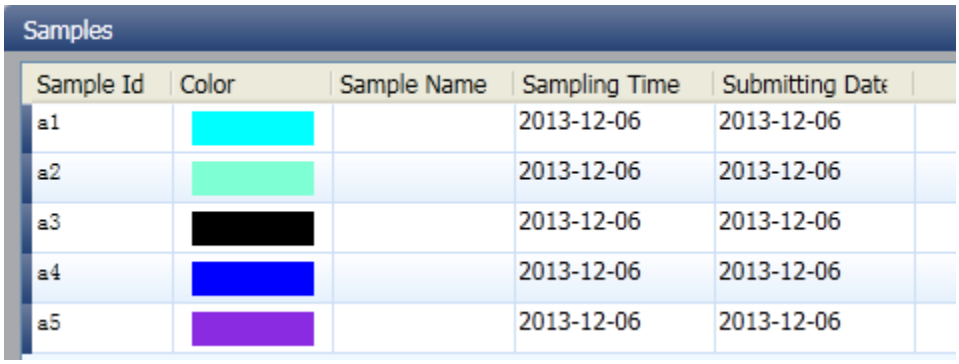
4. Import/Export sample information

a. Click **Import Sample Info** ► the File Import window will pop up ► import sample information file in CSV format

b. Click **Export Sample Info** ► the Save As window will pop up ► the sample information will be exported in CSV file format

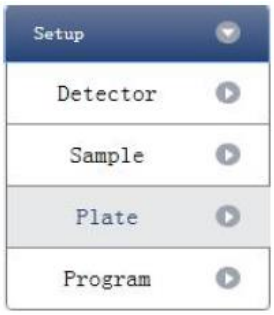


5. Set up sample information



1.4 Reaction Plate Setting

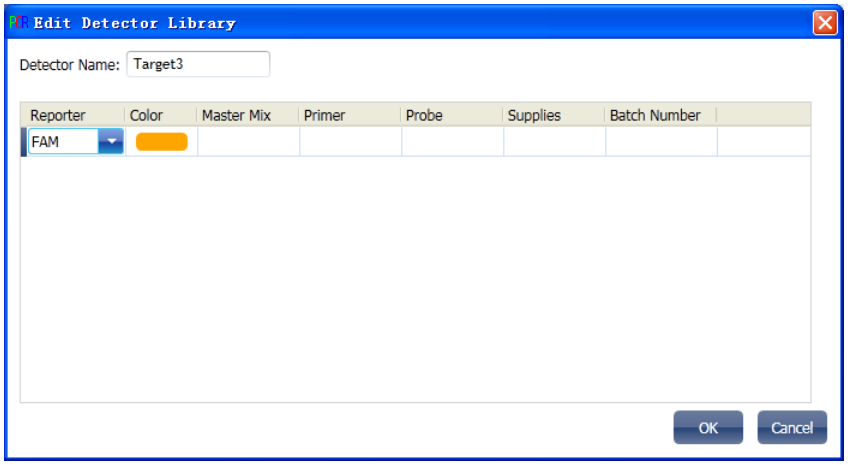
1. Click **Setup ► Plate**



2. Set up the inspection criteria of the reaction plate

a. Select reaction plate well site: click Reaction Plate well Site

The user can also right click the reaction plate well site to Copy, Paste and Add New Detector. Adding a new detector will open the **Edit Detector Library** window.



b. Select inspection item and modify the property, concentration and concentration unit.

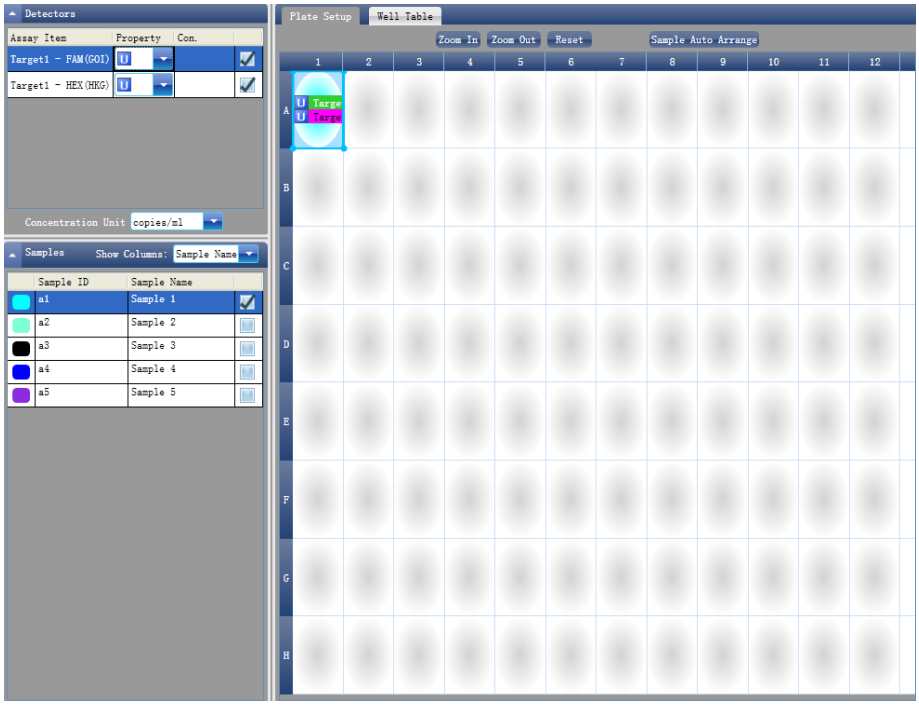
Property	Name	Concentration	Concentration unit
	Unknown	NO	Copies/ml IU/ml Fg/ml Pg/ml
	Standard	YES	
	Negative	NO	

c. Select a sample and the list displayed will change

d. Zoom-In, Zoom-Out and reset the reaction plate.

e. Sample Auto Arrange

f. Check Well Table



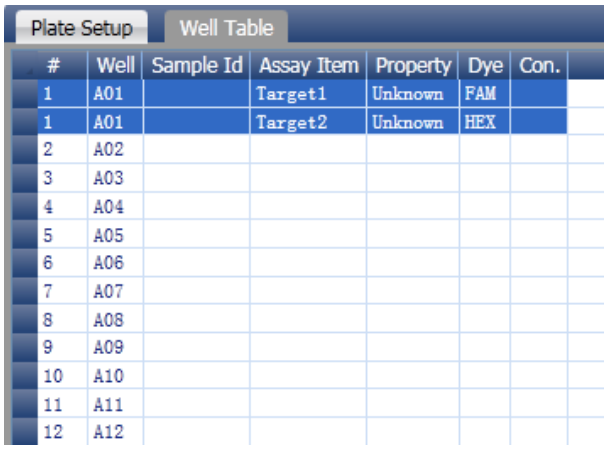
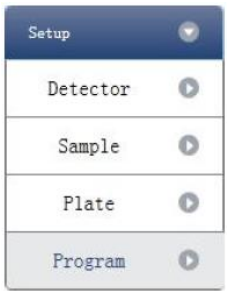


Plate Setup | Well Table

#	Well	Sample Id	Assay Item	Property	Dye	Con.
1	A01		Target1	Unknown	FAM	
1	A01		Target2	Unknown	HEX	
2	A02					
3	A03					
4	A04					
5	A05					
6	A06					
7	A07					
8	A08					
9	A09					
10	A10					
11	A11					
12	A12					

1.5 Programme Setting

1. Click **Setup ► Programme**



2. Run Programme Setup

a. Create new stage: the user can create a new **Hold Stage**, **Cycling Stage** or **Melting Stage**

The user can also click **Add Stage** directly and the default will be creating a new **Cycling Stage**.

b. Create new step: the user can create a new step **Before** or **After** the currently selected step

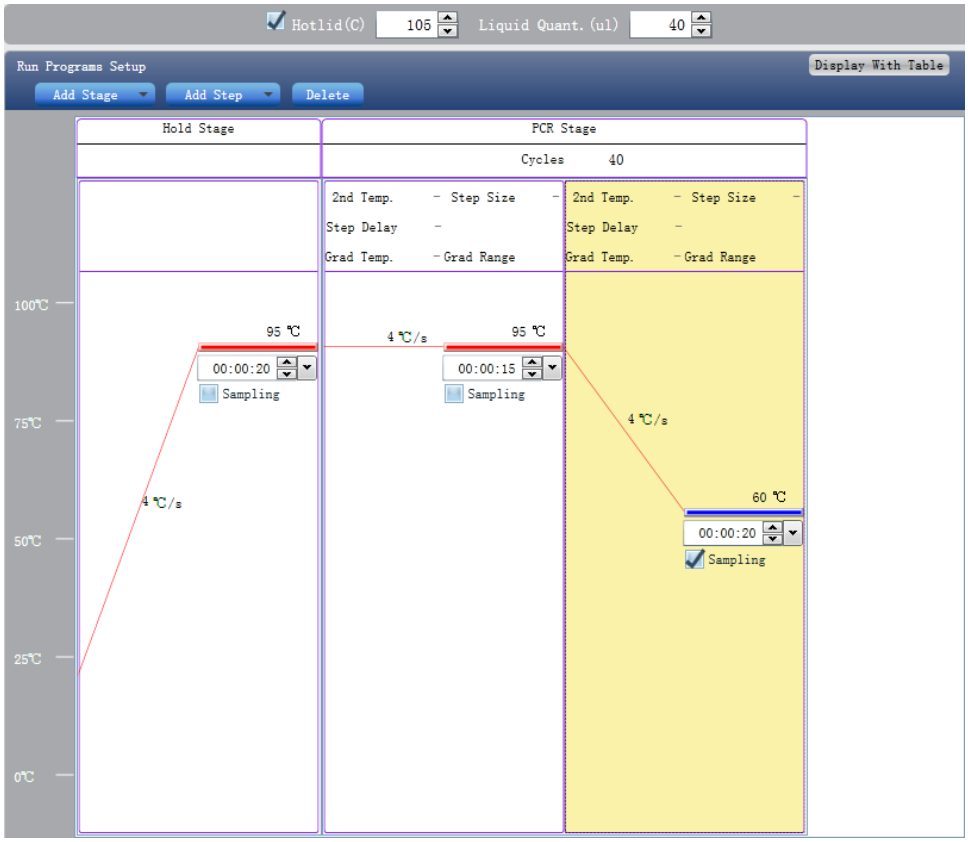
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

c. Delete: the user can delete the currently selected step or stage

d. Display form: click **Display With Table** ► new window will pop up ► the details of the current experiment will be displayed in a table.

e. Set up the experimental data of the hold stage, cycling stage and melting stage melting section

f. Set up the hot-lid temperature and liquid volume



2. Prepare for Reaction

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

The user should make full preparations prior to the experiment

• Ensure appropriate materials are used.

• Ensure the arrangement of the PCR reaction plate is consistent with the setting layout of the reaction plate in Section 1.4.

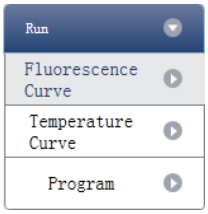
3. Run the Experiment

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

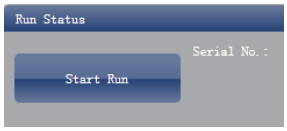
This section describes how to run/operate the experiment after loading the reaction plate and includes how to operate the fluorescence curve, the temperature curve and programming

3.1 Run Fluorescence Curve

1. Click **Run ► Fluorescence Curve**



2. Click **Start Run**



3. Operating confirmation

    a. Modify hot-lid temperature and liquid quantity (sample volume)

4. After it starts running, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run

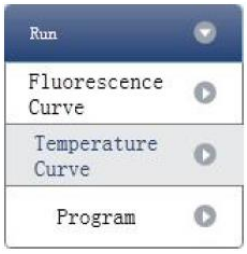
5. Plot display setting

a. Assay item

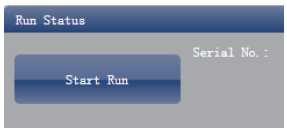
b. Plot colour

3.2 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Run ► Start**



3. Operating confirmation

a. Modify hot-lid temperature and liquid quantity (sample volume)

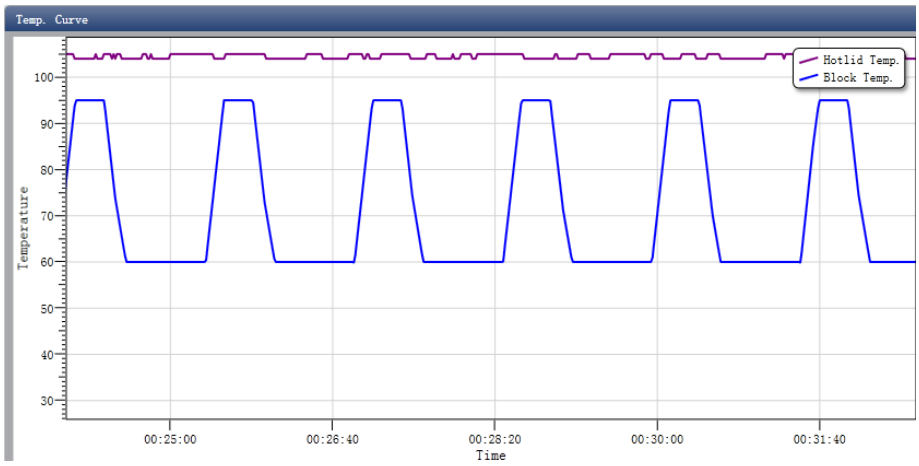
4. After it starts running, the user can:

a. Skip the current stage

b. Add a cycle

c. Delete a cycle

d. Stop run



3.3 Programme Setting

The user can only check the programme setting but cannot make modifications.

4. Experiment Analysis

Start
▼
Design experiment
▼
Prepare for the reaction
▼
Run the experiment
▼
Experiment analysis
▼
Experiment report
▼
Data export
▼
End

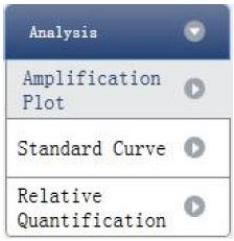
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

This section covers the analysis of amplification curves and standard curves, the analysis of relative quantification, adjusting parameters for re-analysis and importing parameters.

4.1 Check Results

4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



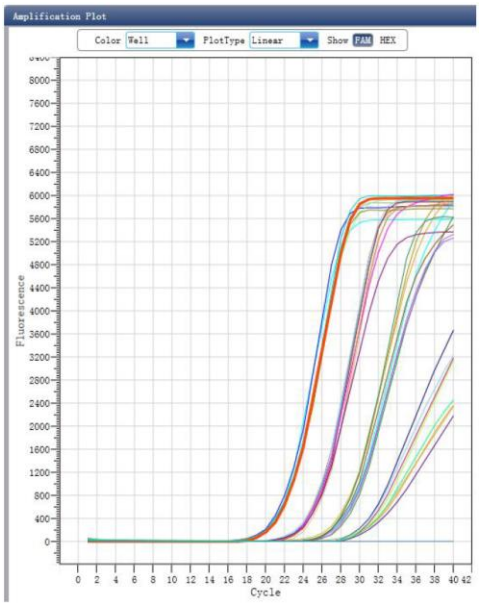
2. Check the amplification curve

a. Set up colour

b. Set up plot type

c. Set up show dye

When the background colour of a dye name is blue, it will be displayed; while white indicates it will not be displayed.



3. Check the reaction plate

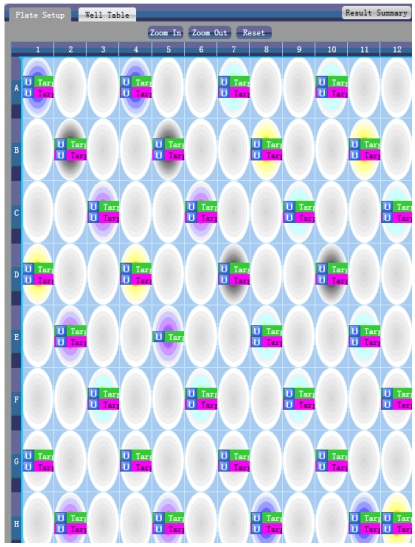
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

b. Zoom-In, Zoom-Out and reset the reaction plate

c. Check well table

d. Check results summary



4. Set up assay

a. Set up assay

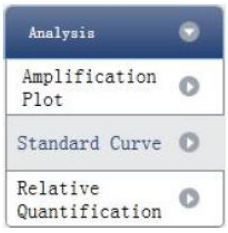
b. Set up threshold

c. Set up automatic baseline

When the threshold value is not automatic, the user cannot set up the automatic Baseline

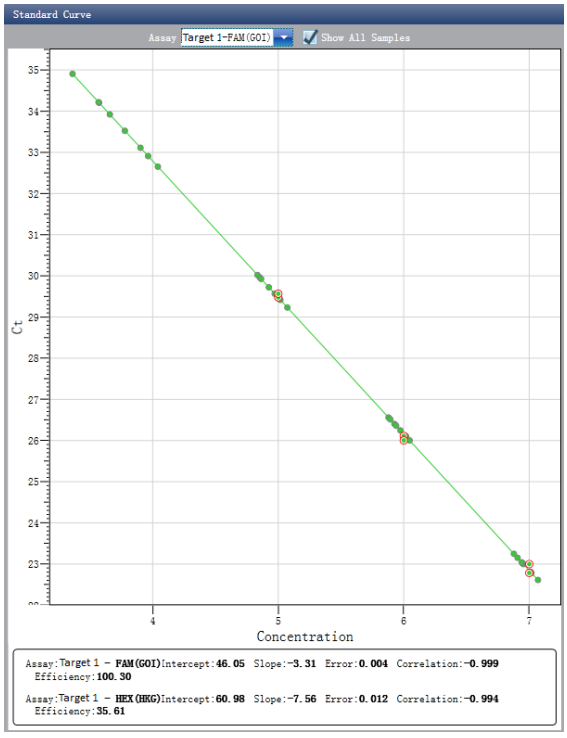
4.1.2 Check Standard Curve

1. Click **Analysis ► Standard Curve**



2. Check standard curve

a. Set up assay



3. Check the reaction plate

a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected