QuantGene 9600

Fluorescent Quantitative Detection System

Instruction for Use

REF FQD-96C(EA4), FQD-96C(EA5), FQD-96C(EA6)

IVD

Hangzhou Bioer Technology Co., Ltd.

Attention Users are recommended to read the contents of this manual thoroughly before operating the Bioer QuantGene 9600 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: May. 2022 Version 2.2

Important Notes

01. 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.

02. 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 class I, 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

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 instrument's 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 always used 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 meets 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 has been used, should be coped with and saved according to direction 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 affect 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-transportation

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) 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 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

03. Instrument labels

A) 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.
PROTECTIVE EARTH		Protective earth is near to the place pasted this mark in 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 immediately after the operation of the program to avoid burns !

Warning!	The operator may meet 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.

B) 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 ℃.
Relative humidity limit		The relative humidity should be controlled below 93%.
USB port		The location of the mark in the instrument indicates that the interface is USB.
Network interface		The position of the mark in the instrument indicates that the interface is a network cable interface.

04. 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.

05. Disposal

 Potentially infectious material and all parts that may meet 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.

06. 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.
- If 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 uses, characteristics, specifications, performance parameters and software functions of QuantGene 9600 Fluorescent Quantitative Detection System.

1.1 Scope of Application

The product is based on the principle of fluorescence quantitative polymerase chain reaction (PCR) and is used together with the supporting detection reagent. It is used for quantitative detection of the analytes from human pathogens nucleic acid samples in the field of clinical labs and hospitals and so on.

1.2 Intended Use

The QuantGene 9600 Fluorescent Quantitative Detection System is an automated instrument used for quantitative detection of analytes in the related pathogen nucleic acids (DNA/RNA) from human samples using the polymerase chain reaction process. The samples can be nasopharyngeal and oropharyngeal samples, whole blood, blood plasma, blood serum, saliva samples and so on. The instrument is for in vitro diagnostic only.

The QuantGene 9600 Fluorescent Quantitative Detection System is intended for used in medical and biological laboratories by professional user trained in molecular biological techniques and the operation of QuantGene 9600 Fluorescent Quantitative Detection System.

1.3 Applied Reagents

The product is a standalone instrument and can be applied to various polymerase chain reaction (PCR) detection kits. Just like the Influenza A Virus / Influenza B Virus Nucleic Acid Detection Kit (Fluorescence RT-PCR) form Hangzhou Bioer Technology Co., Ltd.

1.4 Features

- New, user-friendly operation, operation interface, smooth operation

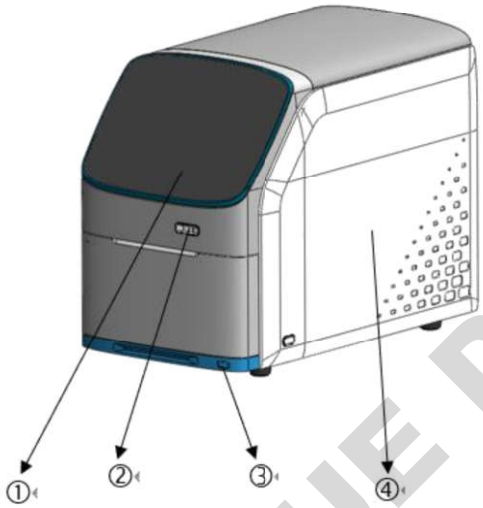
- Fluorescence real-time detection method is adopted to realize simultaneous amplification and detection in the same tube without post-processing
- Advanced thermoelectric refrigeration technology ensures super high speed heat cycle system heating, fast and stable refrigeration
- Multi-point temperature 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
- User friendly interface with flexible programme setting and analysis and reporting using the stored parameters.
- 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 QuantGene 9600 Fluorescent Quantitative Detection System.

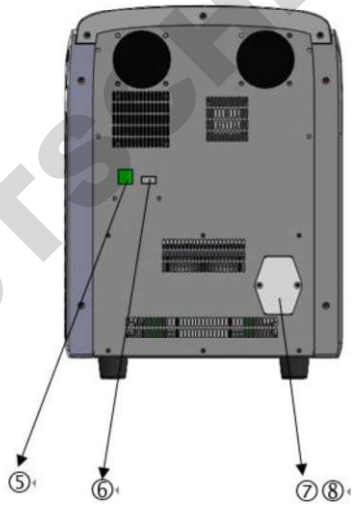
1.5 Product Structure and Composition

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 QuantGene 9600 Fluorescent Quantitative Detection System is described as below:



Front view



Back view

Indication of the items

①Display

②USB Interface

③Start Switch

④Case Body

⑤Network Interface

⑥USB Interface

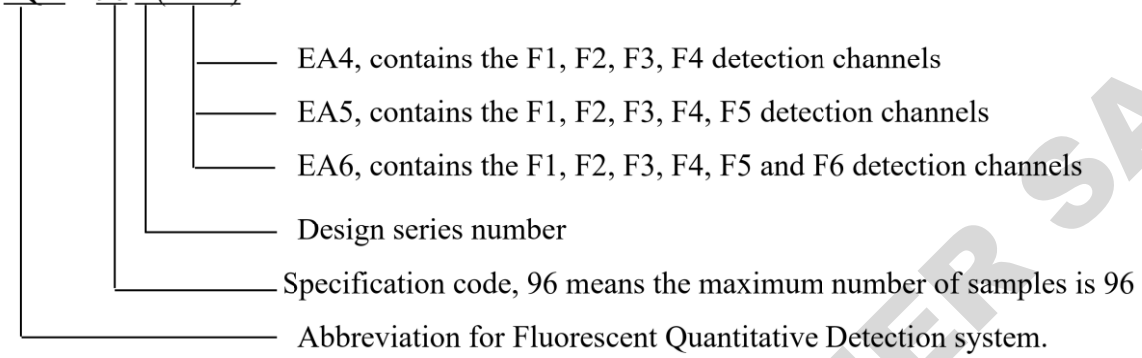
⑦Standard Power Outlet

⑧Power Switch

1.6 Specification and Model Description

Model:

FQD – 96 C(EAX)



1.7 Performance Parameters

Model	FQD-96C(EA4), FQD-96C(EA5), FQD-96C(EA6)					
Sample size	96×0.2ml（Suitable for Single Tube, PCR 8-Strip Tube and 48-well PCR Microplate）					
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	Cy3, Tamra
Module operating temp. 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 temp. control accuracy	Should be no greater than 0.1 ℃					
Temperature uniformity	The temperature difference is within ±0.3℃					
Temp. control accuracy of hot lid	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					

1.8 Production Date and Service Life

Production date: See label for details.

Product life: 5 years

1.9 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.

1.10 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 QuantGene 9600 Fluorescent Quantitative Detection System.

2.1 Transportation and Storage Conditions of the Instrument

Ambient temperature:－20℃～55℃

Relative humidity:≤80％

Atmospheric pressure:75kPa～106kPa.

2.2 Normal Working Condition

Ambient temperature:10℃～30℃

Relative humidity:≤70％

Power supply:100-240V～ 50/60Hz 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.

2.3 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.

2.4 Installation of Supporting Software

2.4.1 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

2.4.2 Gene-9660 Software Installation

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

Double click Gene-9660 installation file（Gene-9660DiagnosisSetup.exe）▶ Display the installation interface (select the installation language)▶ Set installation path ▶install

2.4.3 Gene-9660 Software Uninstall

Control panel ▶Add/remove programs▶ PcrServer ▶uninstall

Control panel ▶Add/remove programs▶Gene-9660▶uninstall

Chapter 3 Start

3.1 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.

3.2 Boot

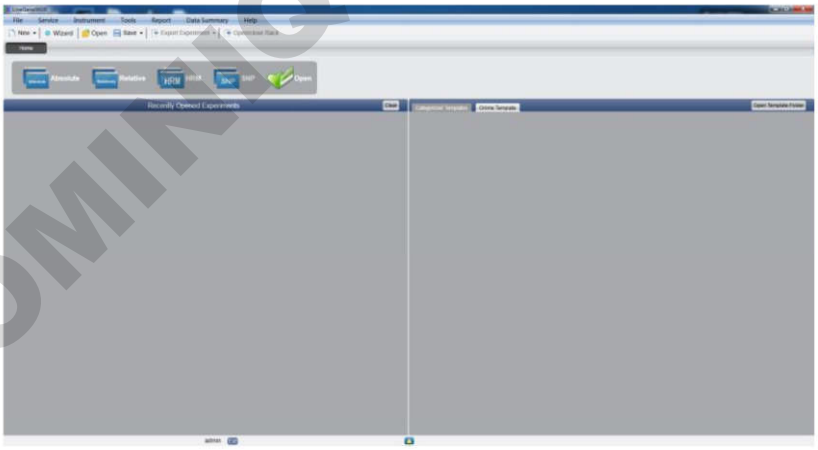
Step 1: turn on the power switch of the backboard of the instrument.

Step 2: after entering the operating system, start the QuantGene 9600 Fluorescent Quantitative Detection System.

To start the software, click "Gene-9660 Software" on the start/program menu or double click on the shortcut icon on the desktop.

3.3 Software Startup Interface

Double click any software shortcut icon of the QuantGene 9600 Fluorescent Quantitative Detection System 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

4.1. Design Experiment

Start
▼
Design experiment
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Prepare for the reaction
▼
Run the experiment
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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.

4.1.1 Create New Absolute Quantitative Experiment

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

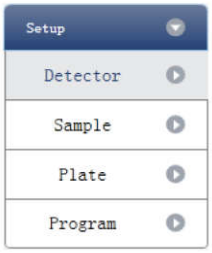
NOTE: The Absolute quantitative experiment can be also created by:

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

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

4.1.2 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

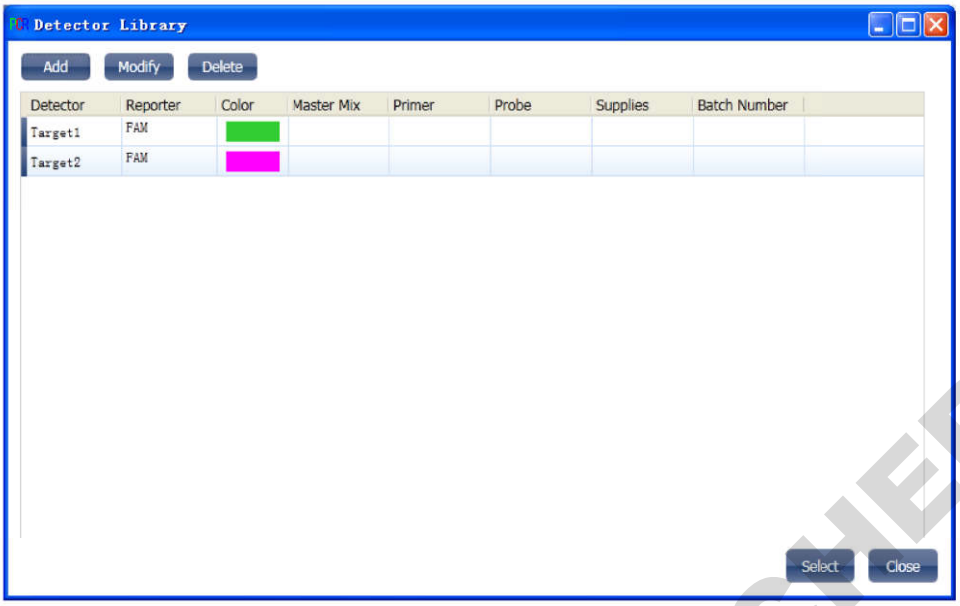
b. Add assay

c. Delete detector

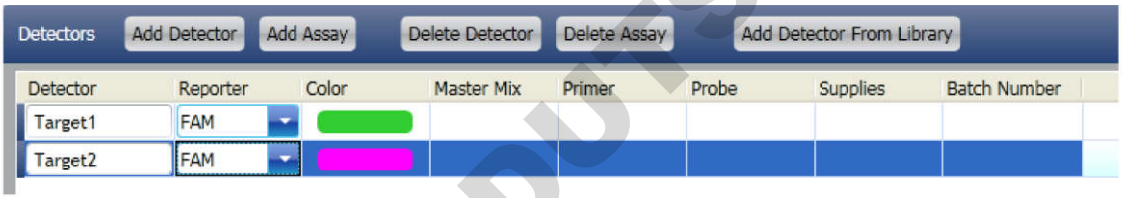
d. Delete assay

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.



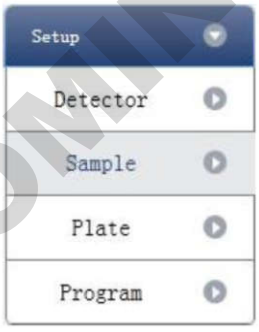
f. Set up the detector, set up the assay, set up the dye name and set up the colour



4. Set up reference dye

4.1.3 Sample Information Setting

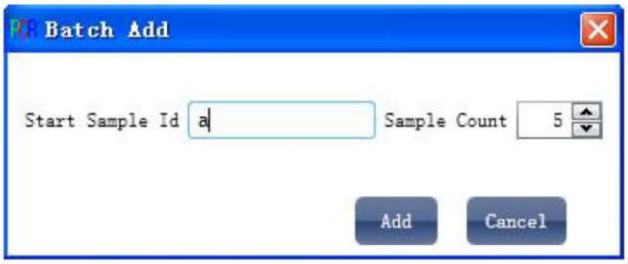
1. Click **Setup ► Sample**



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

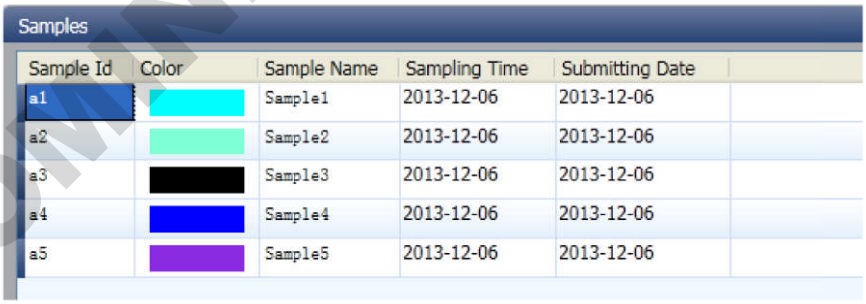
b. Delete all: click **Clear All** ► delete all sample information

4. Import/Export sample information

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

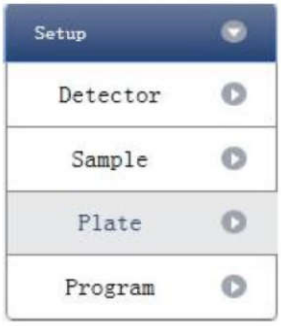
b. Click **Export Sample Info** ► the Save As window will pop up ► the sample information will be exported in CSV file format

5. Set up sample information



4.1.4 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.

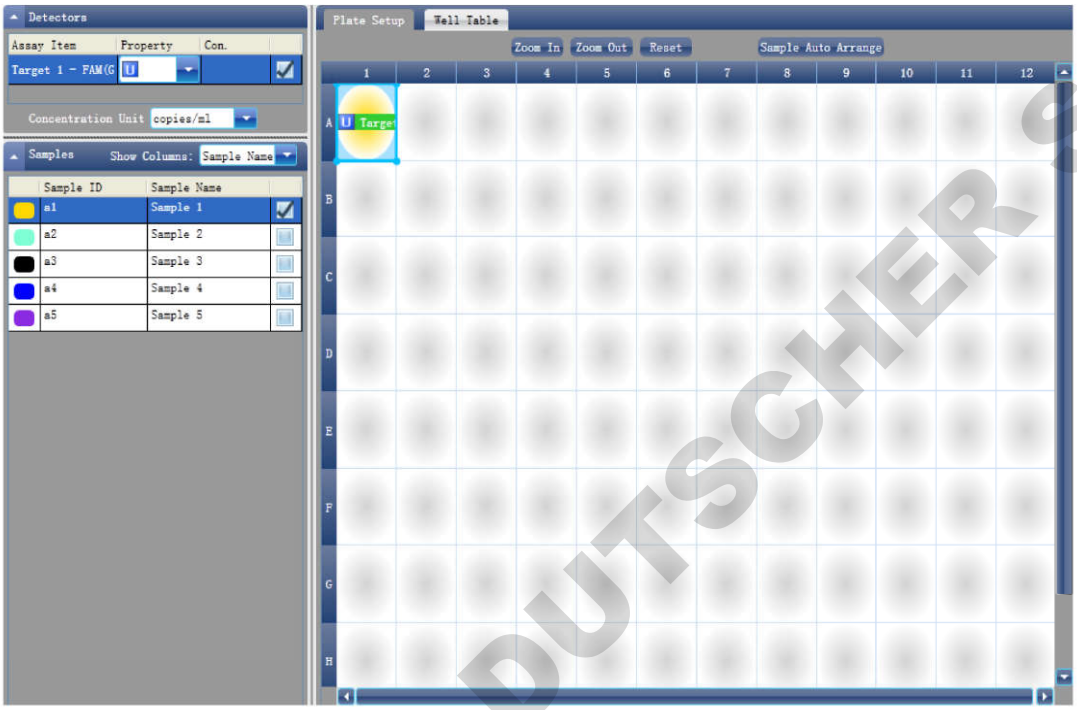
Property	Name	Concentration	Concentration unit
U	Unknown	NO	Copies/ml
S	Standard	YES	IU/ml
N	Negative	NO	Fg/ml
P	Positive	NO	Pg/ml

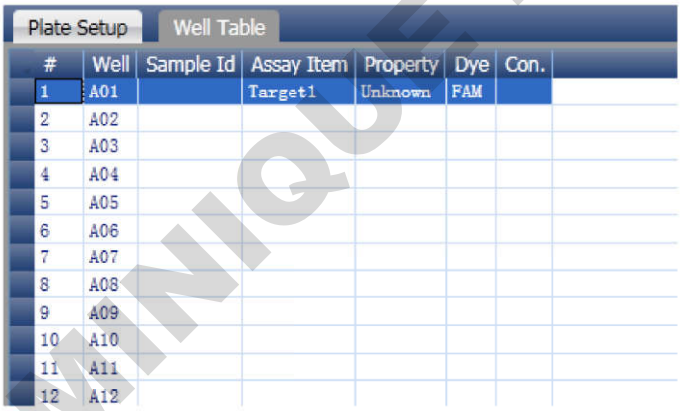
c. Select a sample and the list displayed will change

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

e. Sample Auto Arrange

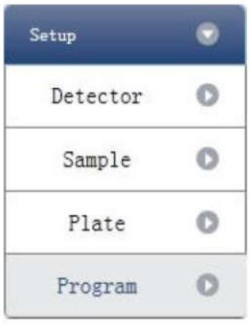
f. Check Well Table





4.1.5 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

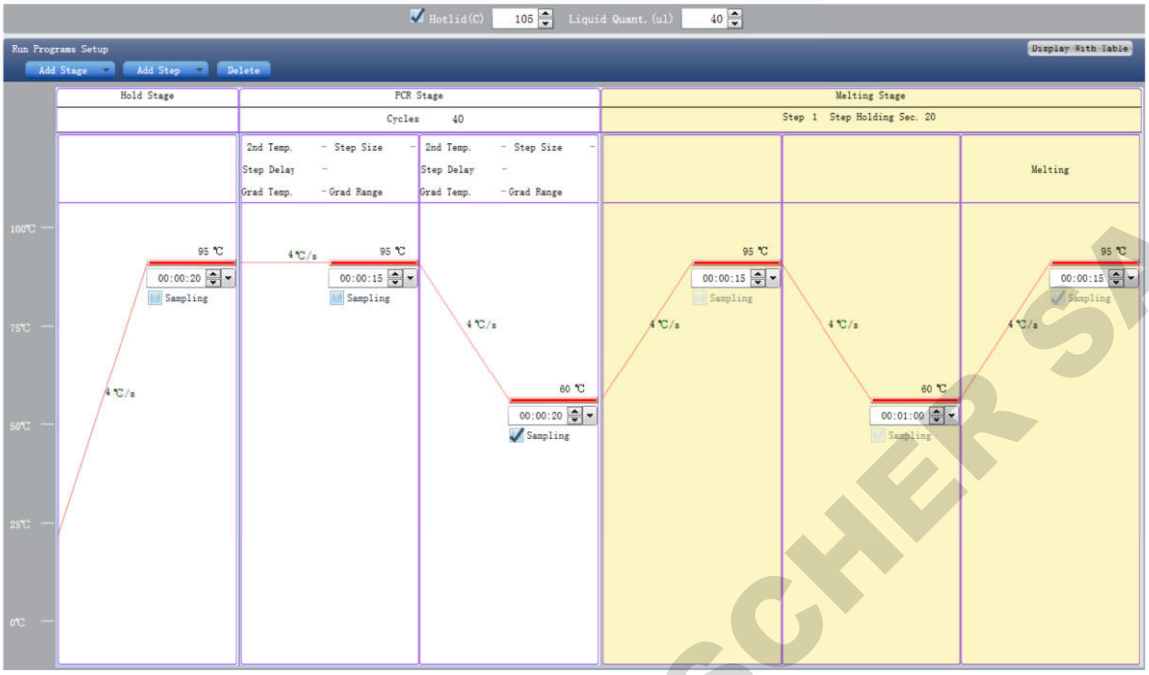
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

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

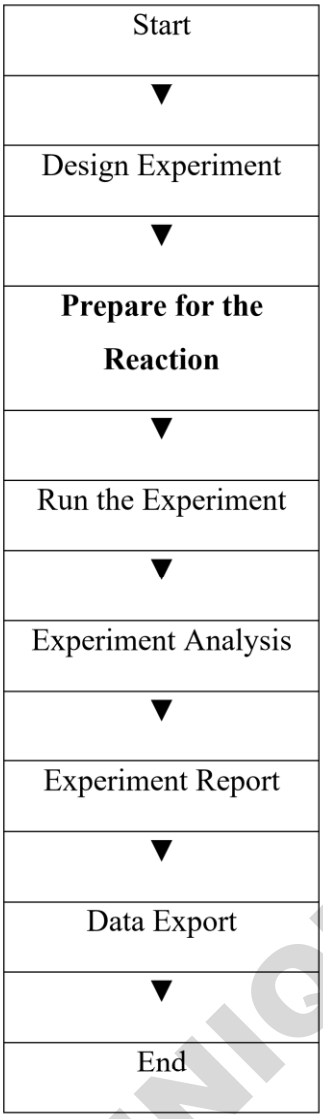
d. Display form: click **Display With Table ►** new window will pop up **►** the details of the current experiment will be displayed in a table.

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



4.2 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 4.1.4.

4.3 Run the Experiment

Start
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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.

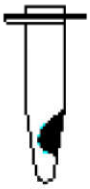
4.3.1 Preparation for reagent sample

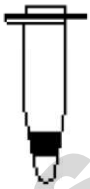
- Prepare reagent: QuantGene 9600 Fluorescent Quantitative Detection System adopts 0.2ml centrifuge tube to place reagent samples, and 10μl～50μl is recommended for the best reaction system for samples.
- The instrument allows the use of standard single tube, rack tube, skirt-free plate, and other types 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, 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.





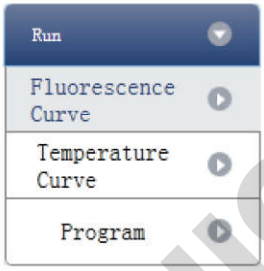
Incorrect

Requires a greater spin speed

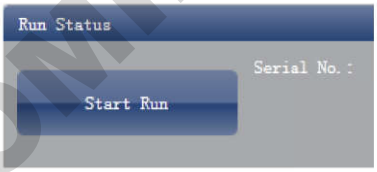
Requires a longer spin time

4.3.2 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

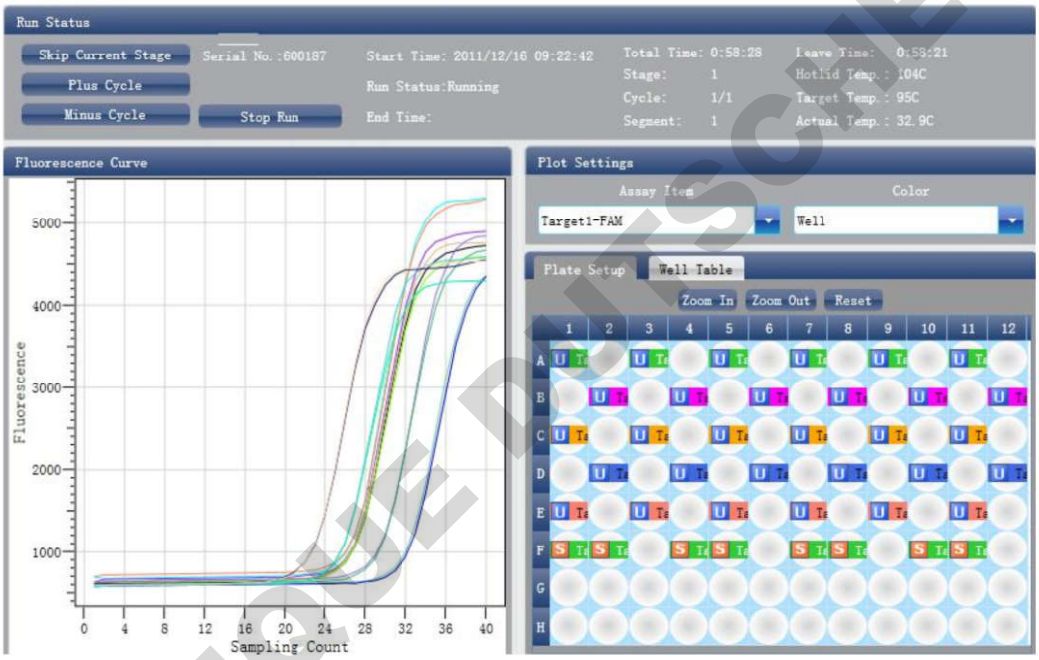
c. Delete a cycle

d. Stop run

5. Plot display setting

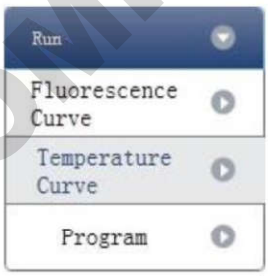
a. Assay item

b. Plot colour

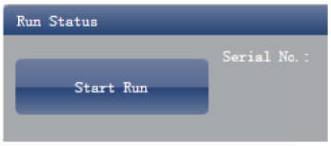


4.3.3 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Start Run**



3. Operating confirmation

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

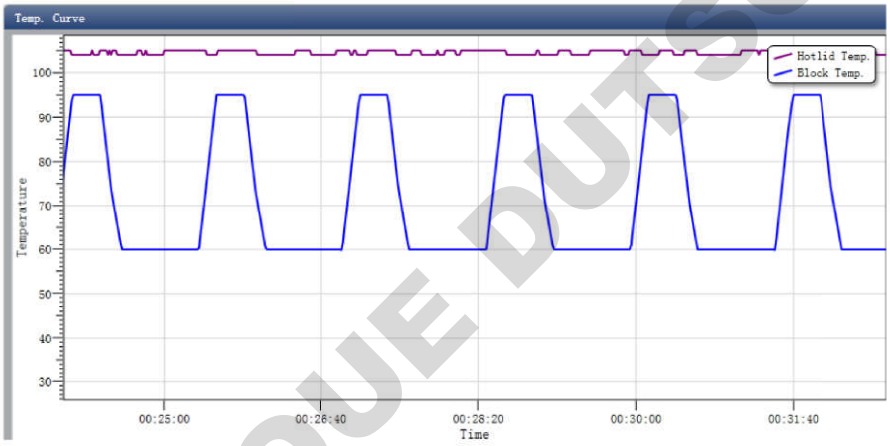
4. After it starts running, the user can:

a. Skip the current stage

b. Add a cycle

c. Delete a cycle

d. Stop run



4.3.4 Programme Setting

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

4.3.5 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.

4.4 Experiment Analysis

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

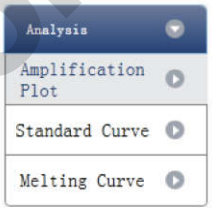
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

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

4.4.1 Check Results

4.4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



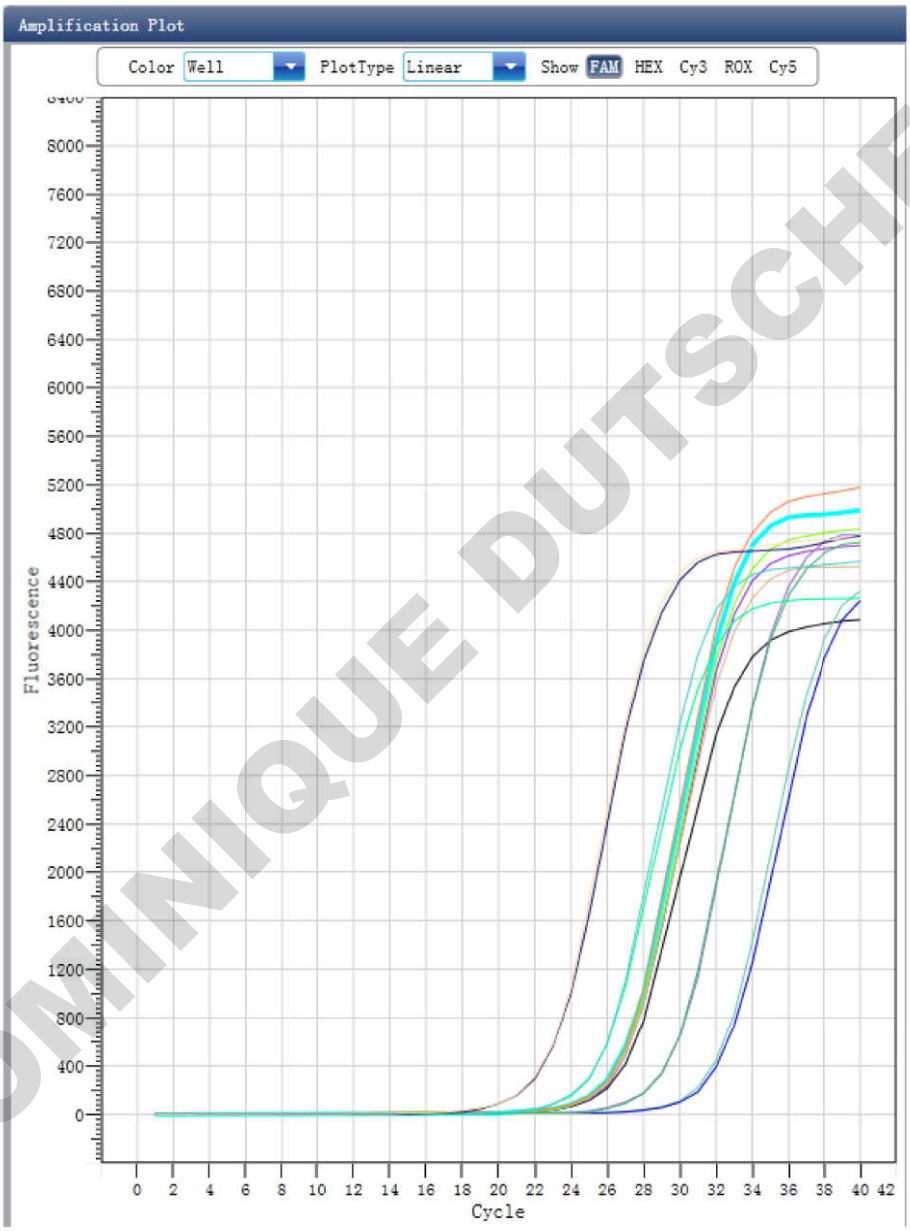
2. Check the amplification curve

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

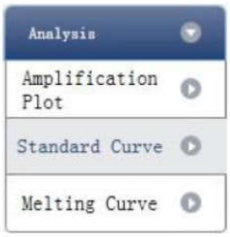
b. Set up threshold

c. Set up automatic baseline

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

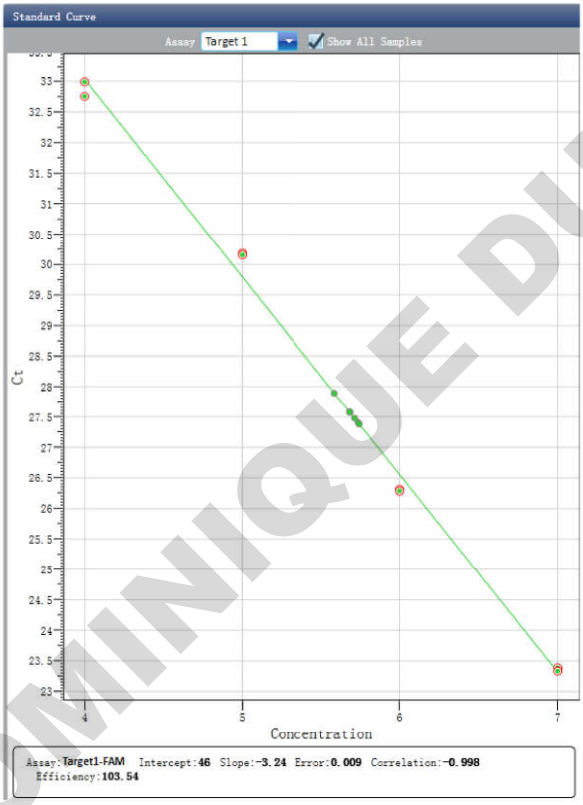
4.4.1.2 Check Standard Curve

1. Click **Analysis ►Standard Curve**



2. Check standard curve

a. Set up assay



3. Check the reaction plate

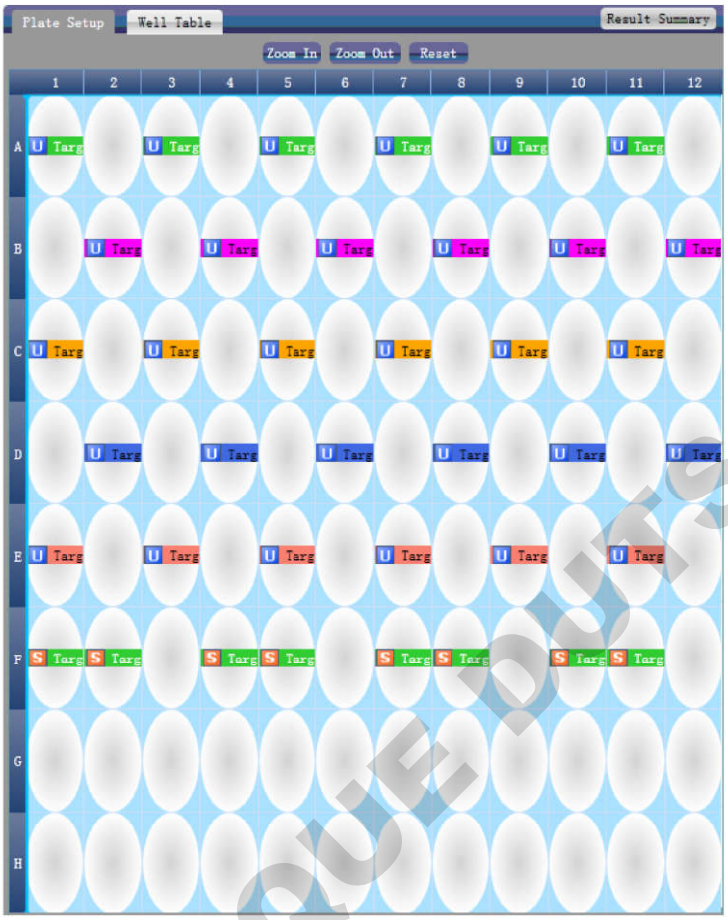
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

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

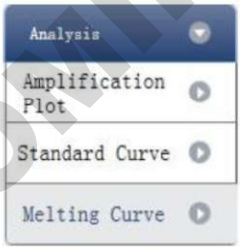
c. Check well table information

d. Check results summary



4.4.1.3 Check Melting Curve

1. Click **Analysis ► Melting Curve**

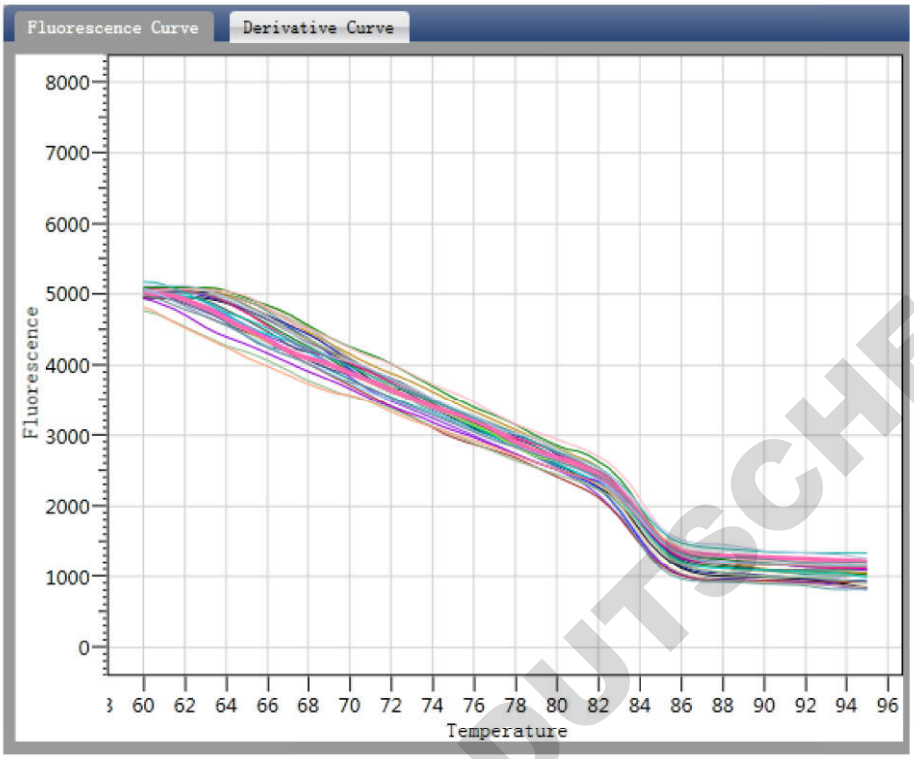


2. Check the melting curve

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

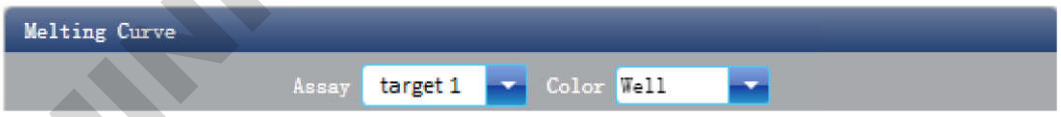
c. Check well table information

d. Check results summary

4. Set up assay

a. Set up assay

b. Set up colour



4.4.2 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

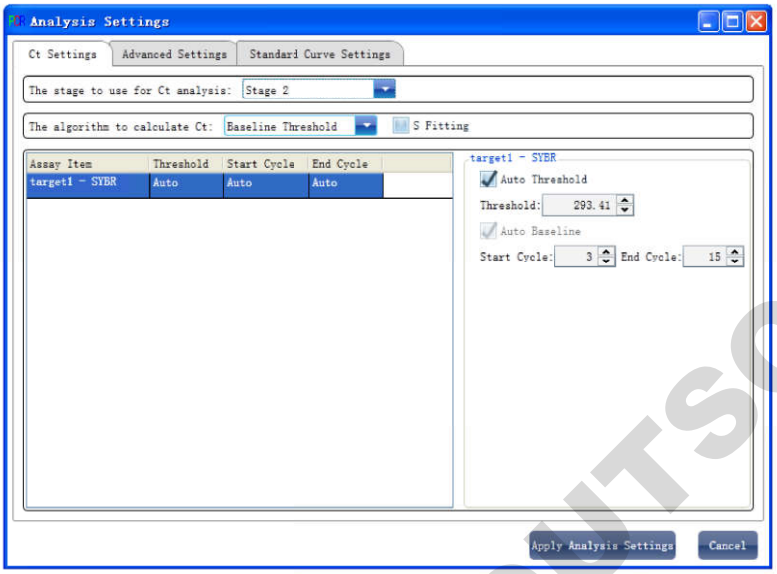
c. Set up the use of S fitting

d. Set up the stage to use for Ct analysis

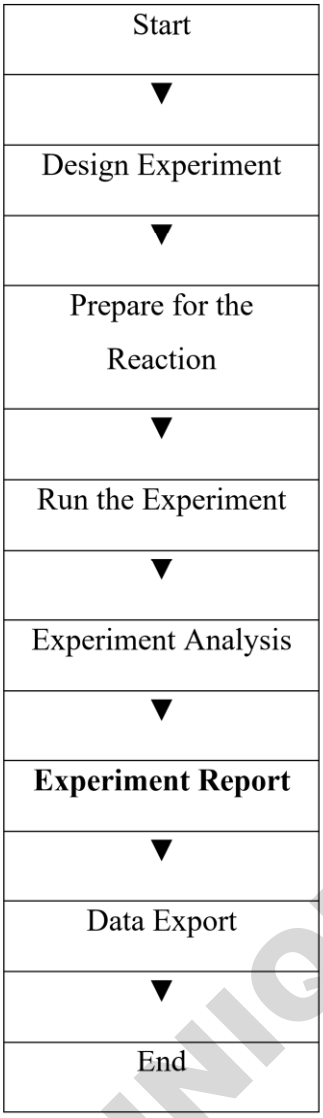
e. Set up the automatic threshold value

f. Advanced setting

g. Standard curve setting



4.5 Experiment Report

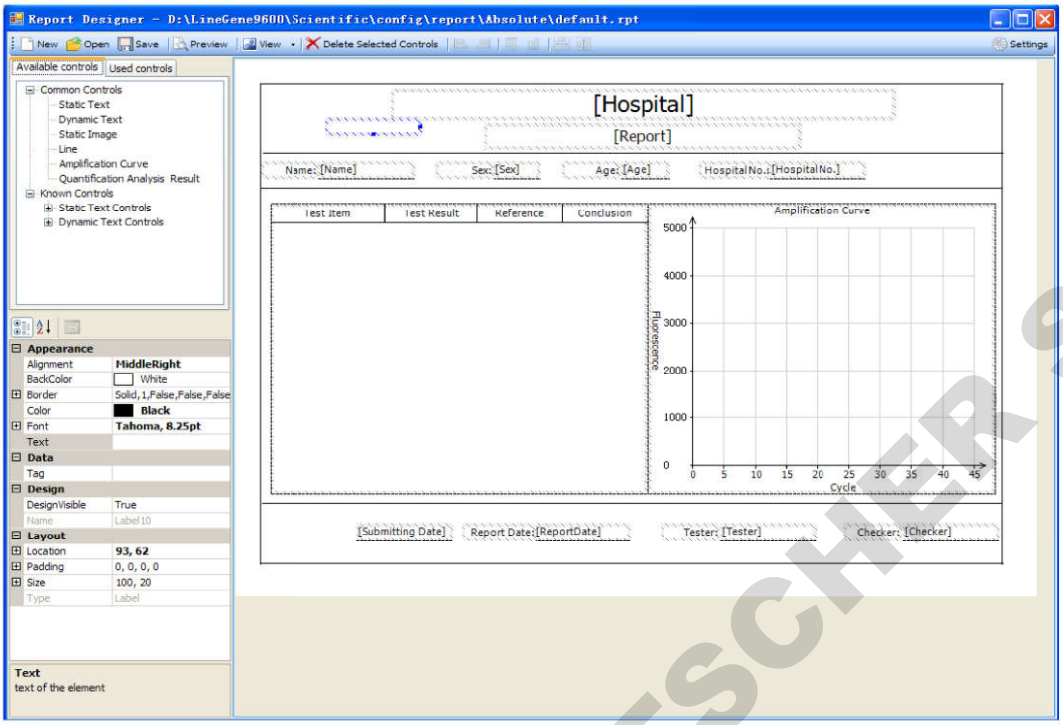


This section describes how to print an experiment report and covers designing of a report template and print settings.

4.5.1 Designing a Report Template

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

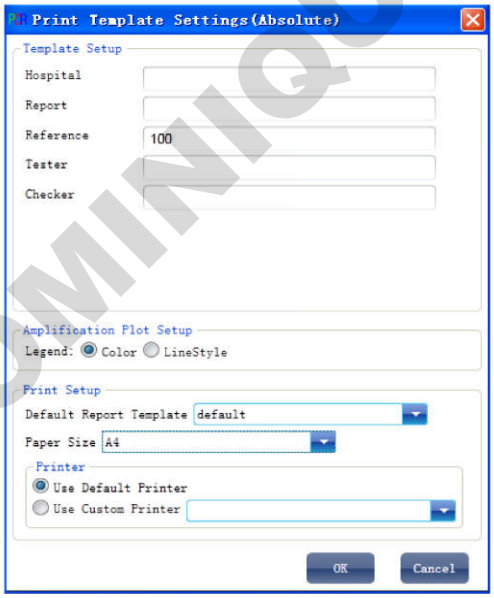
The report consists of controls and the user can add, modify, and delete controls. Available controls include Static Text, Dynamic Text, Line, Static Image, Amplification curve and Quantification Analysis Results.



4.5.2 Print Setting

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

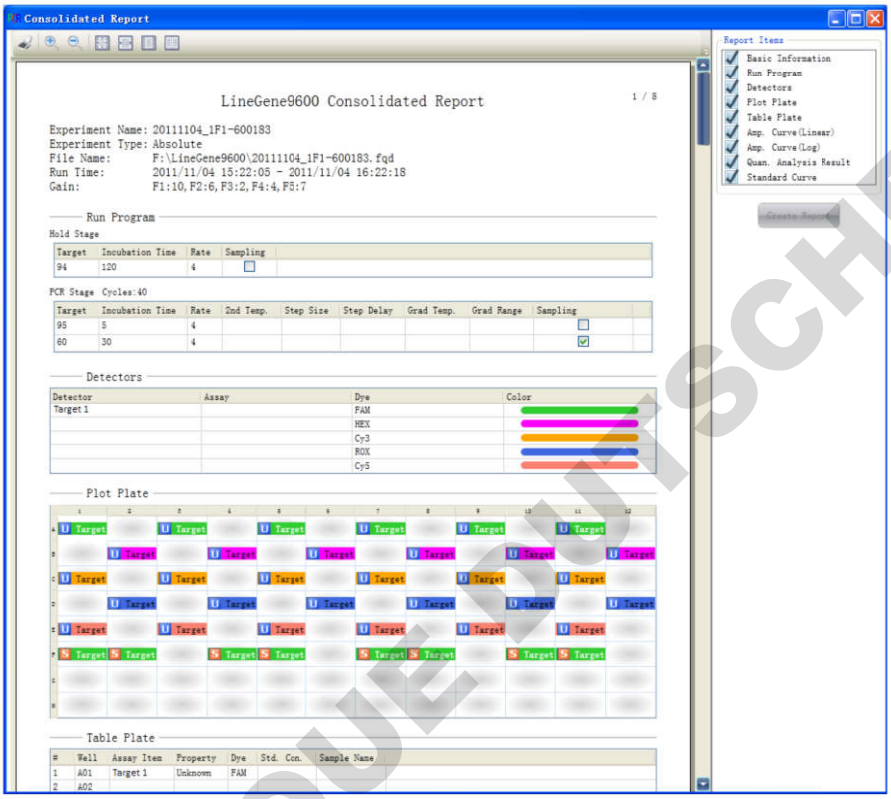
The user can set up the laboratory name, report name, reference value, tester, checker, amplification plot, default report template and paper size.



4.5.3 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..



4.5.4 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

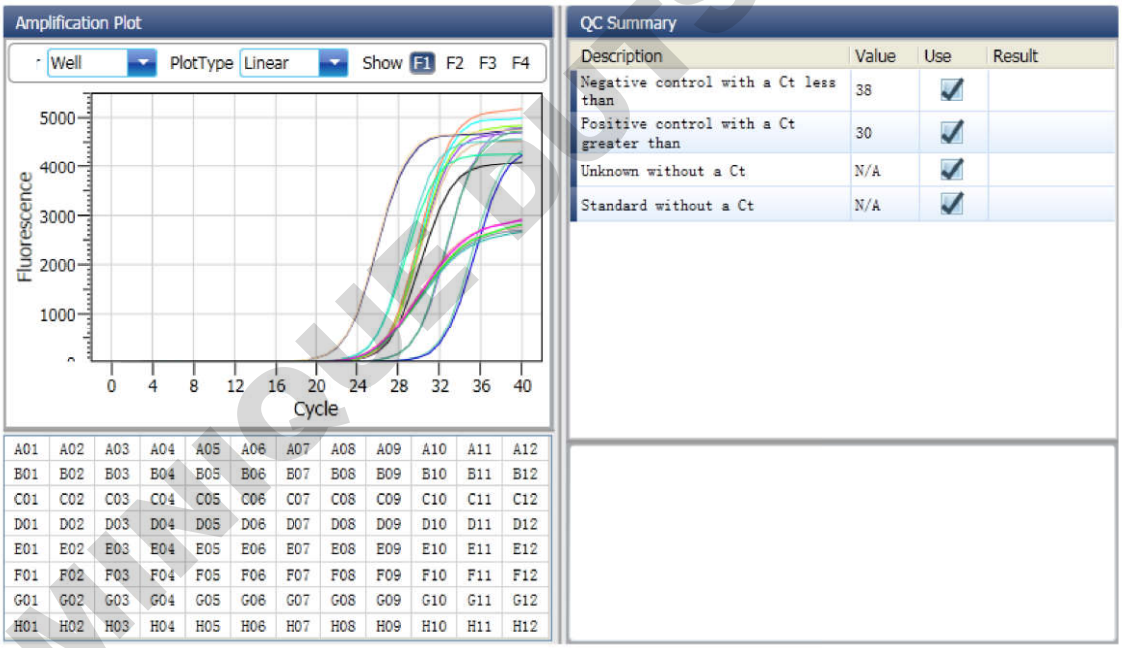
d. Print preview

e. Print the report

4.5.5 QC Summary

1. Click **Report ► QC Summary**

2. Check the QC summary



4.6 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.

4.6.1 Export to Database

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

4.6.2 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

4.6.3 Export Experiment Data to EXCEL

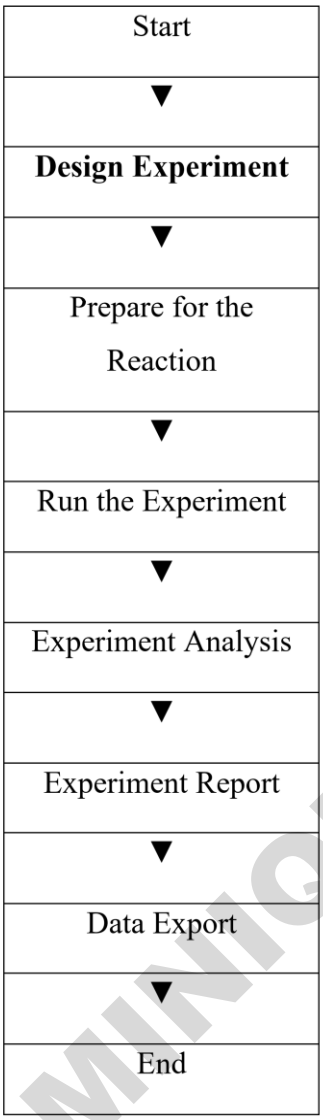
Click **Data Summary►Export Experiment ► Export Experiment to Excle ►**the exported experiment data will generate EXCEL file

4.6.4 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

5.1 Design Experiment



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.

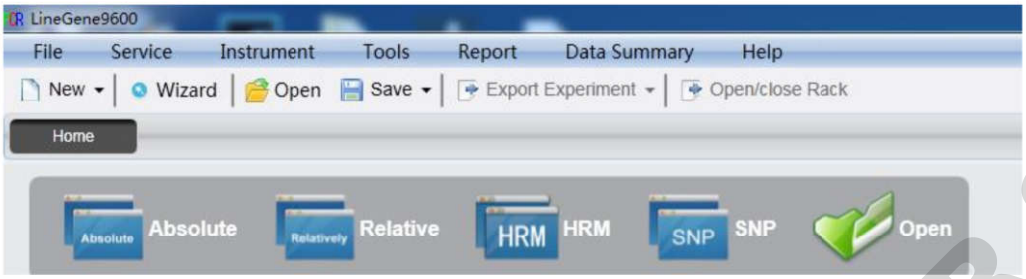
5.1.1 Create New Relative Quantitative Experiment

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

Relative quantitative experiment can be also created by:

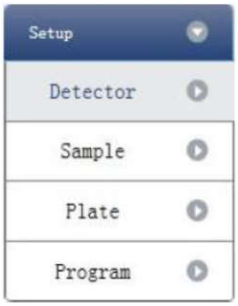
a. Clicking **New ► Relative** on the toolbar

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



5.1.2 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

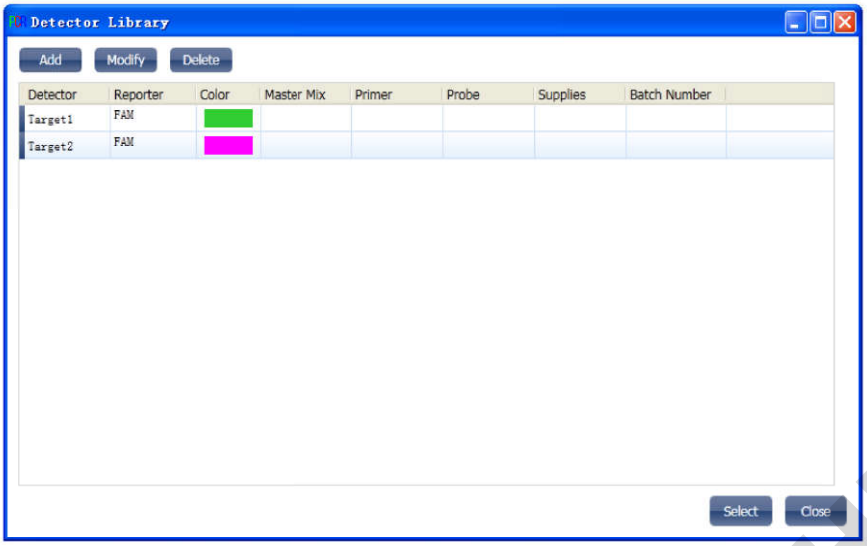
a. Set up the Detector, Assay, Dye and Colour.

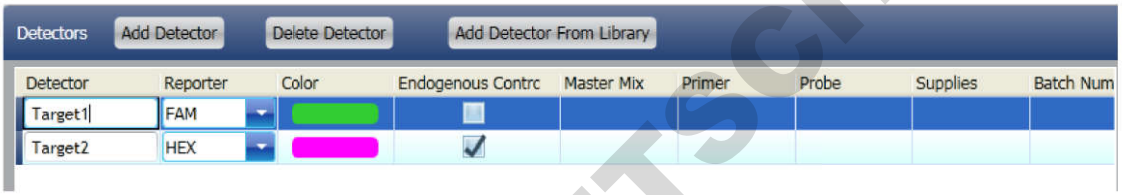
b. Add detector

c. Delete detector

d. Add detector from library

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

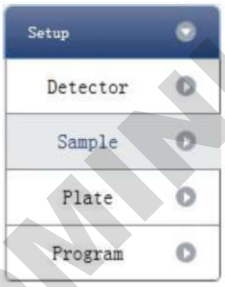




4. Set up reference dye

5.1.3 Sample Information Setting

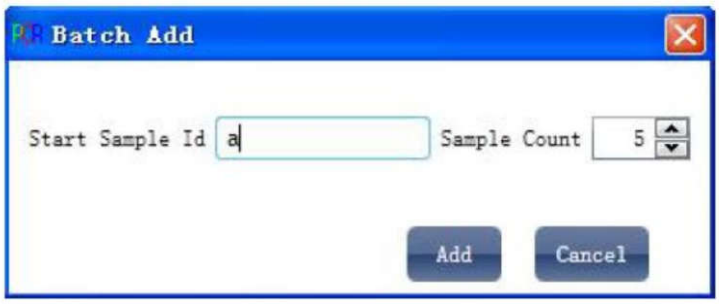
1. Click **Setup ► Sample**



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

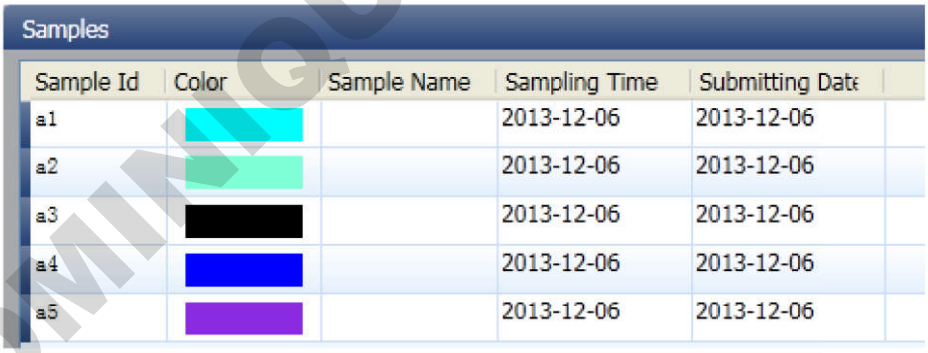
b. Delete all: click **Clear All** ► delete all sample information

4. Import/Export sample information

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

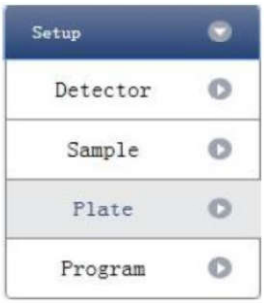
b. Click **Export Sample Info** ► the Save As window will pop up ► the sample information will be exported in CSV file format

5. Set up sample information



5.1.4 Reaction Plate Setting

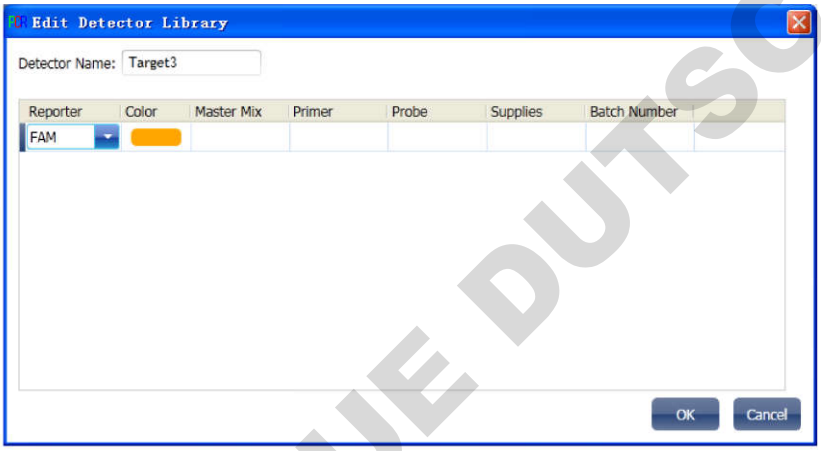
1. Click **Setup** ► **Plate**



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.

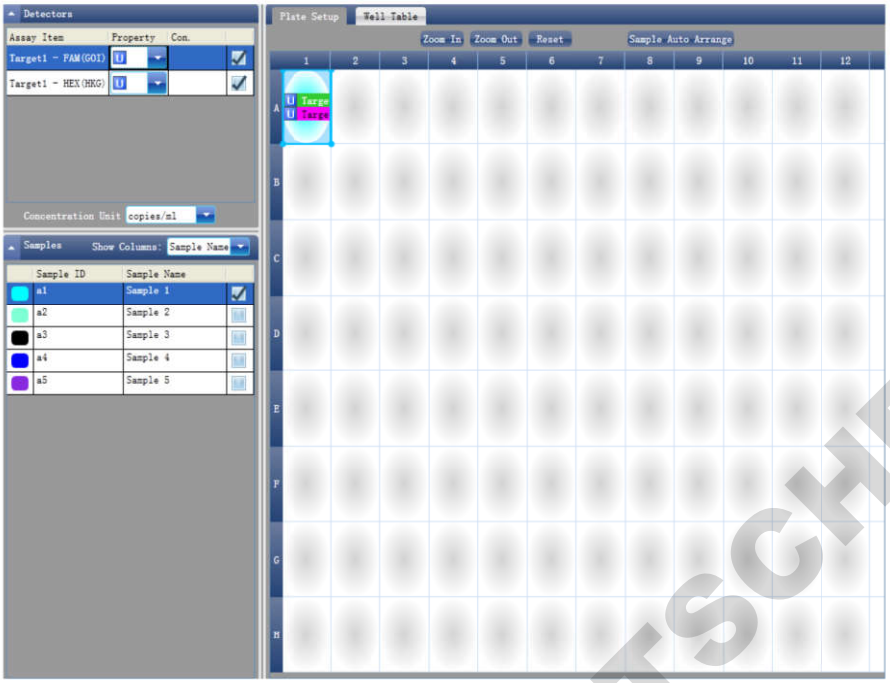
Property	Name	Concentration	Concentration unit
	Unknown	NO	Copies/ml IU/ml Fg/ml Pg/ml
	Standard	YES	
	Negative	NO	

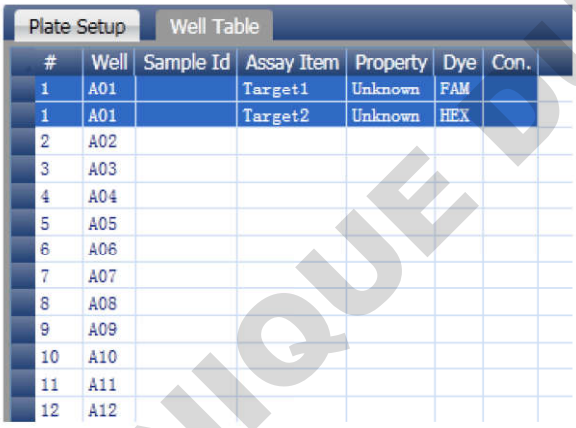
c. Select a sample and the list displayed will change

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

e. Sample Auto Arrange

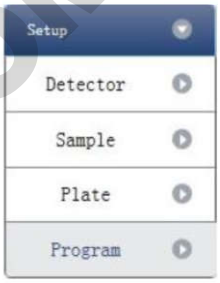
f. Check Well Table





5.1.5 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

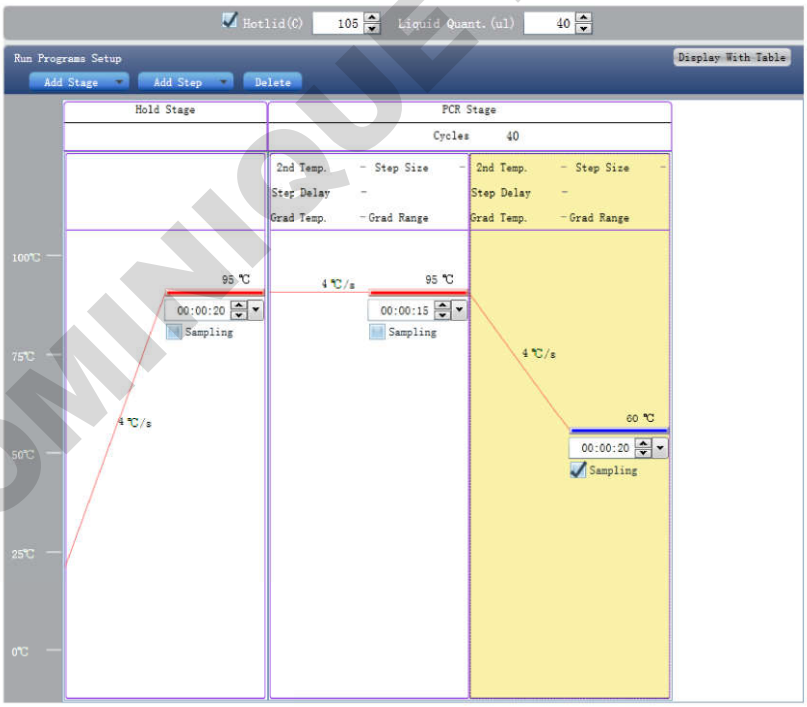
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

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



5.2 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 5 1.4.

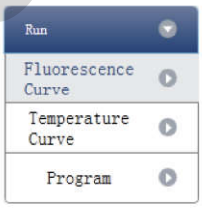
5.3 Run the Experiment

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

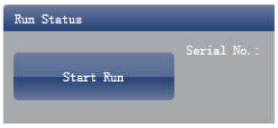
This section describes how to run/operate the experiment after loading the reaction plate and includes how to operate the fluorescence curve, the temperature curve and programming.

5.3.1 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

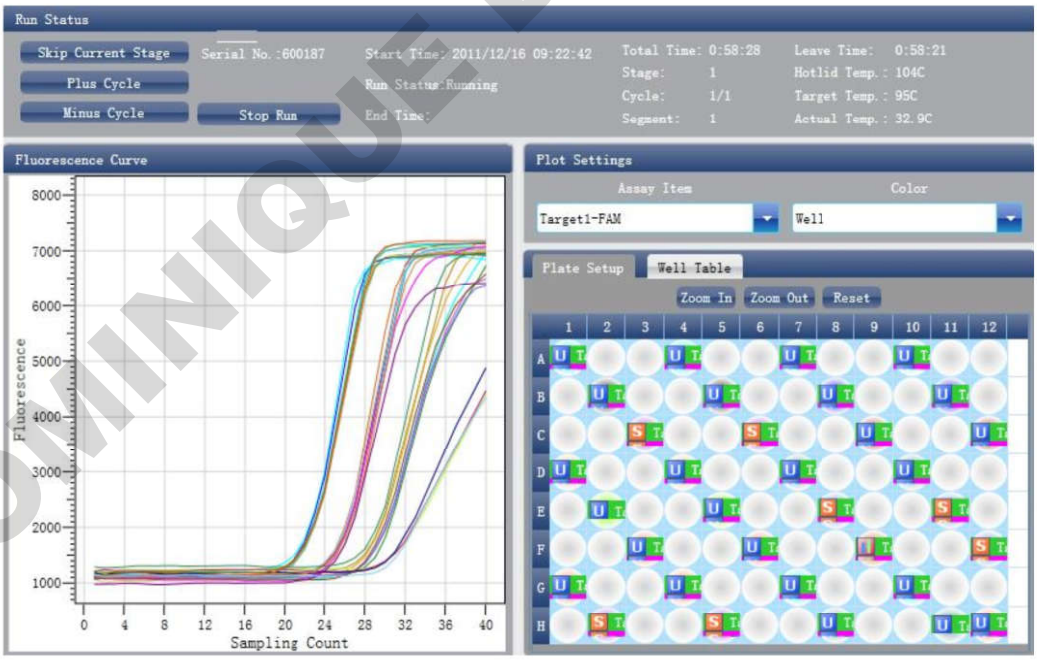
c. Delete a cycle

d. Stop run

5. Plot display setting

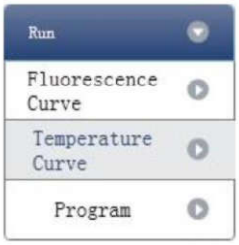
a. Assay item

b. Plot colour

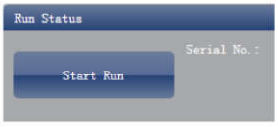


5.3.2 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Run ► Start**



3. Operating confirmation

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

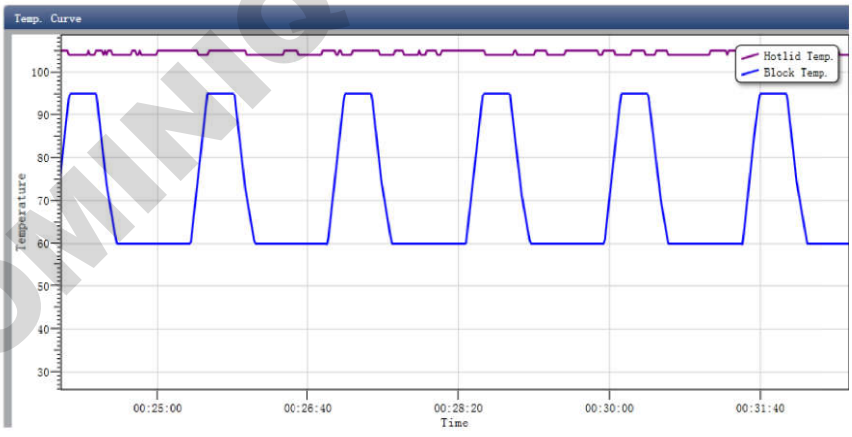
4. After it starts running, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run



5.3.3 Programme Setting

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

5.4 Experiment Analysis

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

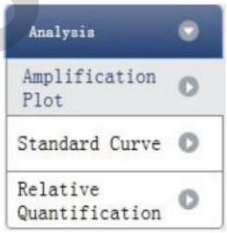
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

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

5.4.1 Check Results

5.4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



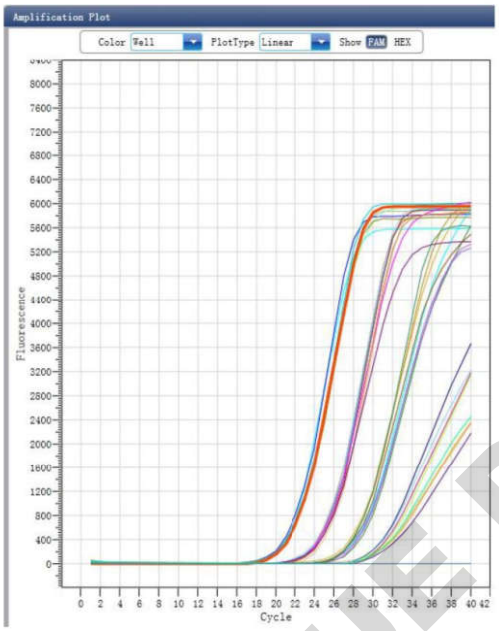
2. Check the amplification curve

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

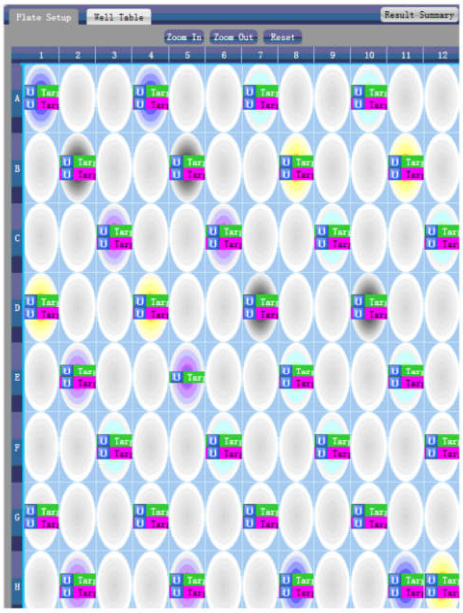
a. Select reaction plate well site and check corresponding well site curve

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

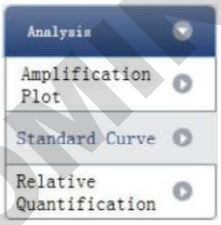
b. Set up threshold

c. Set up automatic baseline

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

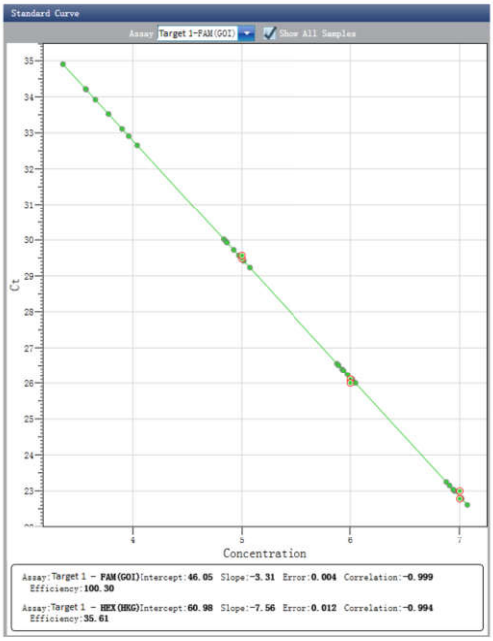
5.4.1.2 Check Standard Curve

1. Click **Analysis ► Standard Curve**



2. Check standard curve

a. Set up assay



3. Check the reaction plate

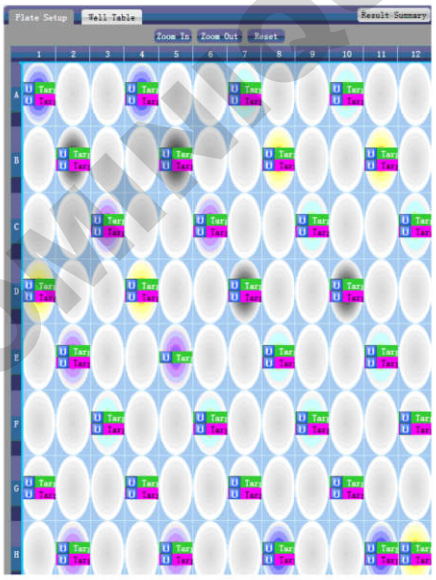
a. Select reaction plate well site and check corresponding well site curve

The default is all wells are selected

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

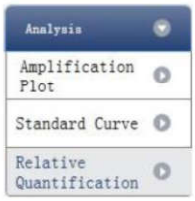
c. Check well table

d. Check results summary



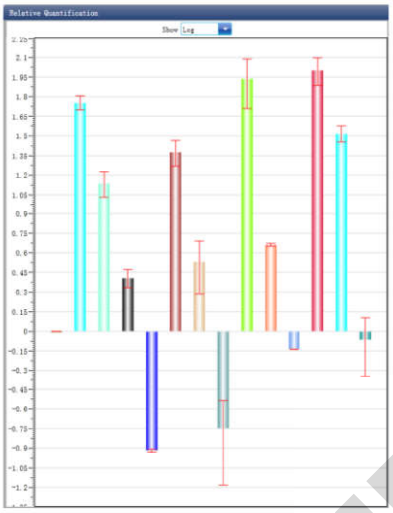
5.4.2 Check Relative Quantification

1. Click **Analysis ► Relative Quantification**



2. Check relative quantitative

a. Set up the show type



b. Check the analysis results

Result

Sample Id	Assay Item	Property	GOI Aver. Con.	GOI Con. SD	HKG Aver. Con.	HKG Con. SD	Max	Min	Aver.
	target1	Comparison	7.99e+03	0.00e+00	1.37e+04	0.00e+00	1	1	1
01	target1	Unknown	1.10e+07	1.05e+06	1.93e+05	1.48e+04	63.92	49.95	56.94
02	target1	Unknown	8.48e+05	1.31e+05	6.14e+04	9.61e+03	16.84	10.78	13.81
03	target1	Unknown	9.40e+04	1.40e+04	3.67e+04	2.06e+03	2.97	2.15	2.56
04	target1	Unknown	3.72e+03	2.66e+01	3.08e+04	8.82e+02	0.12	0.12	0.12
06	target1	Unknown	9.44e+05	1.43e+05	3.95e+04	6.33e+03	29.18	18.63	23.9
07	target1	Unknown	9.33e+04	3.53e+04	2.73e+04	5.86e+03	4.9	1.93	3.41
08	target1	Unknown	4.14e+03	2.62e+03	2.33e+04	8.42e+02	0.29	0.07	0.18
09	target1	Unknown	8.44e+06	5.34e+05	9.71e+04	3.93e+04	122.5	51.28	86.89
11	target1	Unknown	7.21e+04	1.20e+03	1.57e+04	2.97e+02	4.7	4.47	4.58
12	target1	Unknown	1.10e+04	0.00e+00	1.51e+04	0.00e+00	0.73	0.73	0.73
13	target1	Unknown	8.12e+06	8.33e+05	8.05e+04	1.74e+04	125.02	76.77	100.89
14	target1	Unknown	8.25e+05	6.25e+04	2.50e+04	2.87e+03	37.59	28.5	33.05
16	target1	Unknown	6.87e+03	3.28e+03	8.01e+03	4.28e+02	1.27	0.45	0.86

5.4.3 Adjust Parameter Reanalysis

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

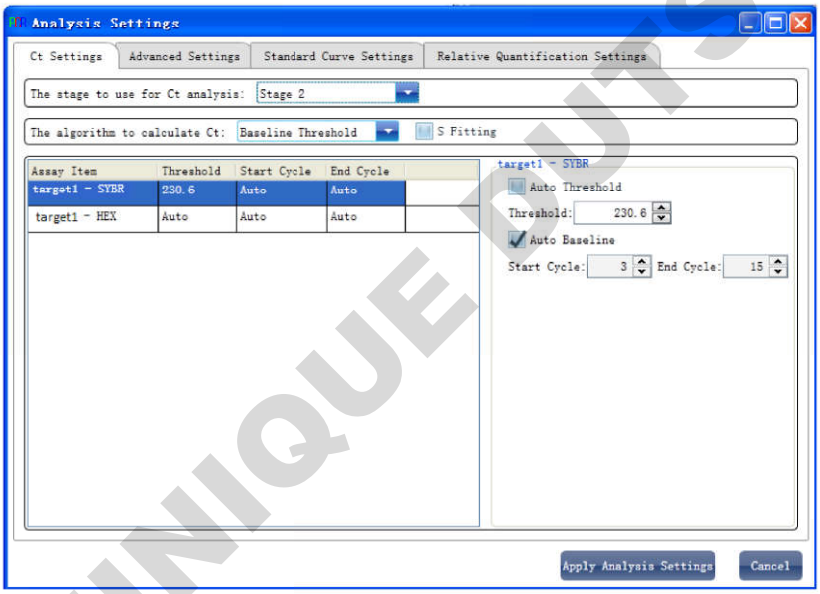
d. Set up the stage to use for Ct analysis

e. Set up the automatic threshold value

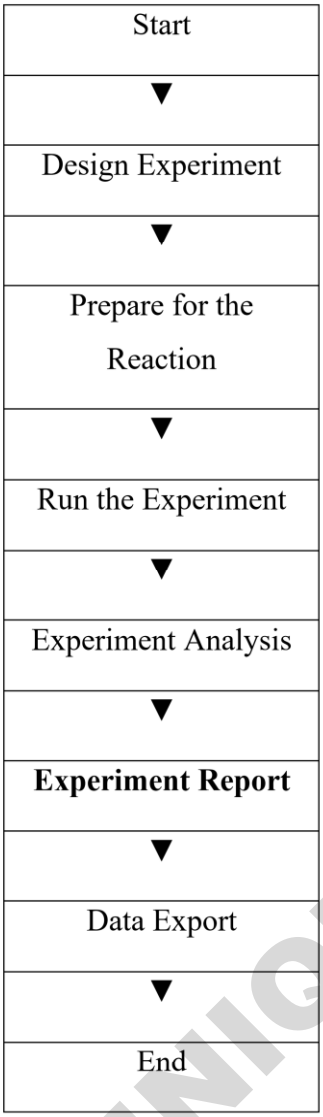
f. Advanced setting

g. Standard curve setting

h. Relative quantification setting



5.5 Experiment Report

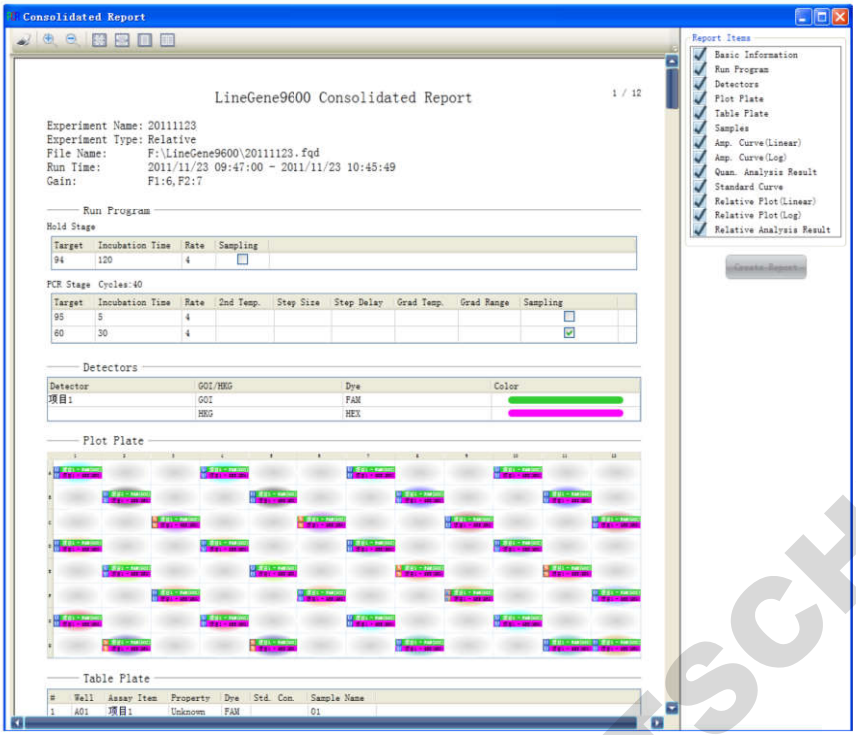


This section describes how to print an experiment report and covers designing of a report template and print settings.

5.5.1 Comprehensive Report

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

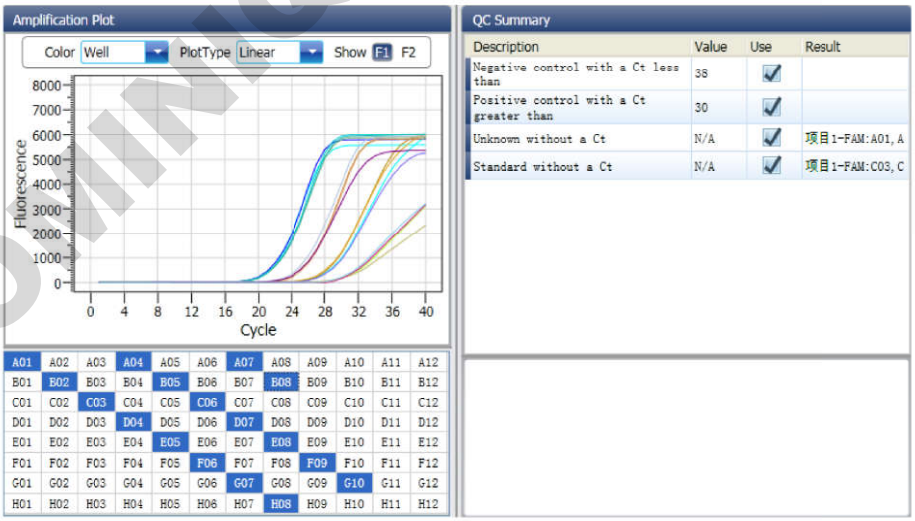
The Consolidated Report includes the basic information, sample information, amplification curve, standard curve, plate information, etc..



5.5.2 QC Summary

1. Click **Report ► QC Summary**

2. Check the QC summary



5.6 Data Export

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

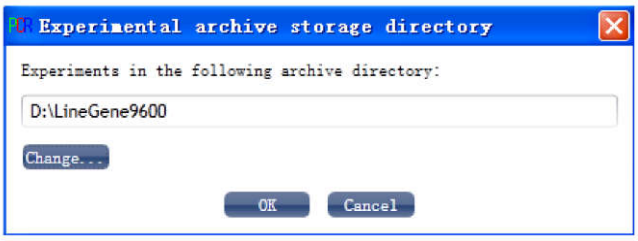
This section describes how to export data and covers exporting to a database, experiment filing and exporting the experiment data to EXCEL.

5.6.1 Export to Database

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

5.6.2 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

5.6.3 Export Experiment Data to EXCEL

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

5.6.4 Export Experiment Data to TEXT

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

Chapter 6 SNP

6.1 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 an SNP experiment and covers creating a new SNP experiment, inspection item setting, sample information setting, reaction plate setting and programme setting.

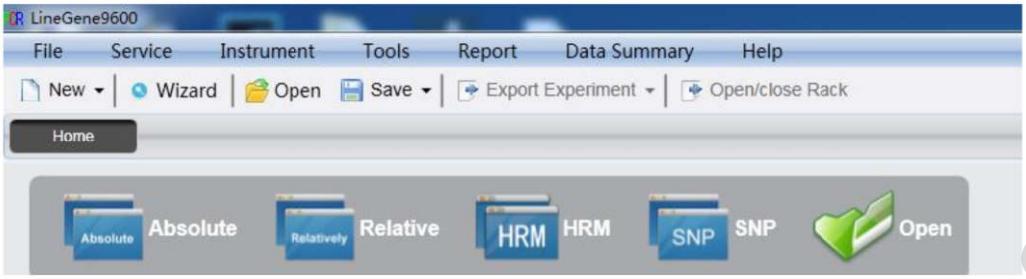
6.1.1 Create SNP Experiment

1. Click **SNP** on **Home** interface and create SNP Experiment window.

An SNP experiment can be also created by:

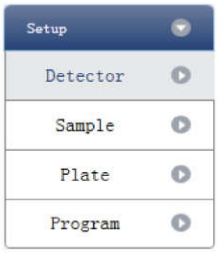
a. Clicking **New** ► **SNP** on the toolbar

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



6.1.2 Detector Setting

1. Click **Setup ► Detector**



2. Input basic information

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

3. Inspection Item Setting

Set up the Detector, Allele, Dye and Colour.

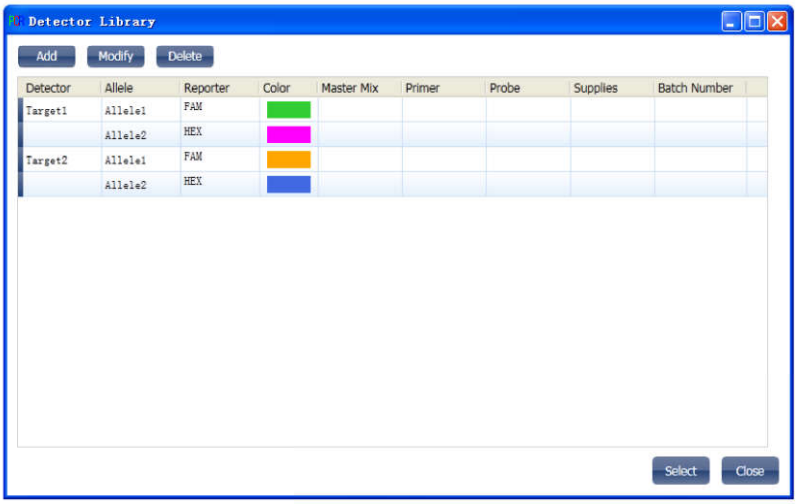
If necessary, the user can also:

a. Add Detector

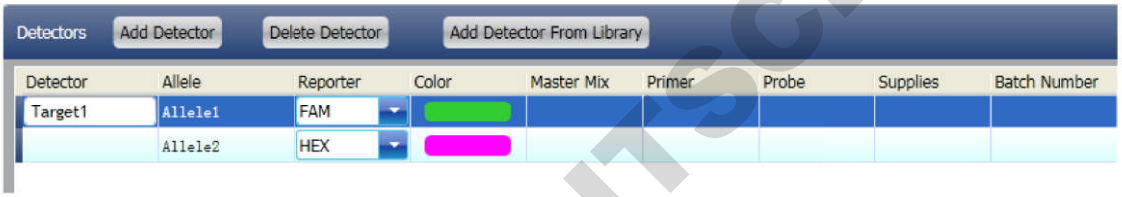
b. Delete Detector

c. Add the Detector in the Detector library: click **Add Detector From Library ►** the **Detector Library** window will pop up ► select the Detector on the window to be added

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



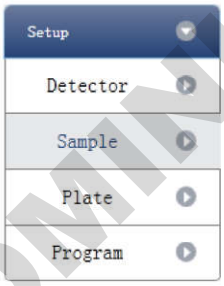
d. Set up the item name, set up the dye name and set up the colour



4. Set up reference dye

6.1.3 Sample Information Setting

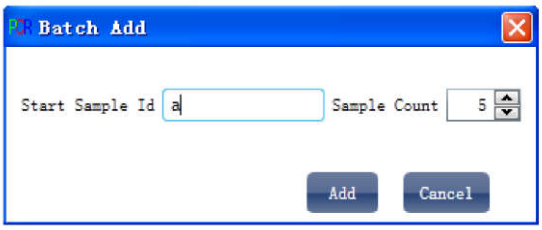
1. Click **Setup ► Sample**



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

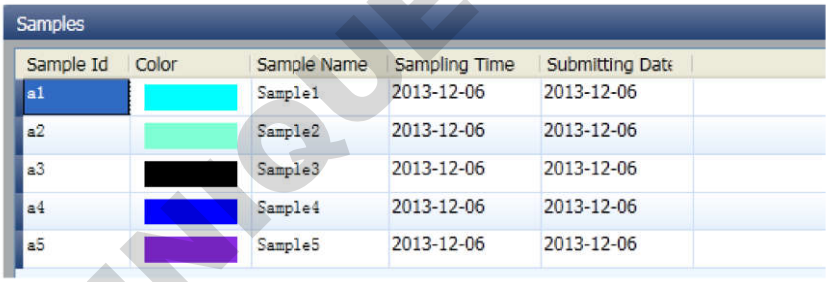
b. Delete all: click **Clear All** ► delete all sample information

4. Import/Export sample information

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

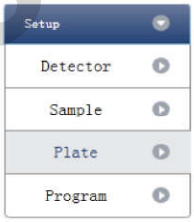
b. Click **Export Sample Info** ► the Save As window will pop up ► the sample information will be exported in CSV file format

5. Set up sample information



6.1.4 Reaction Plate Setting

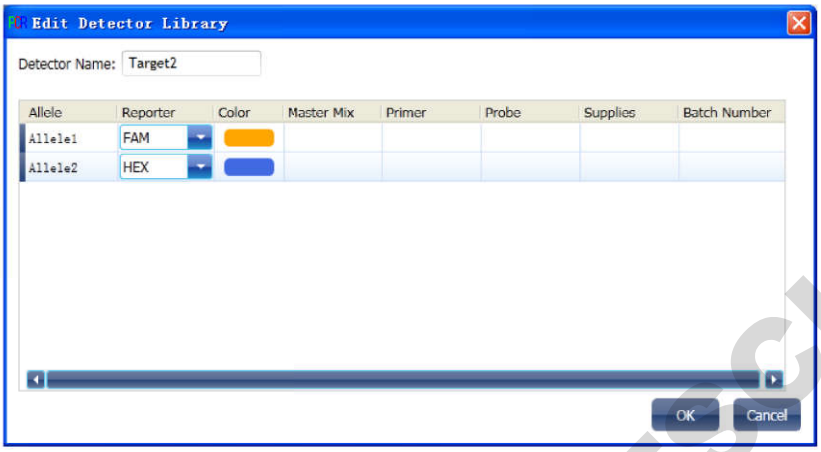
1. Click **Setup** ► **Plate**



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.

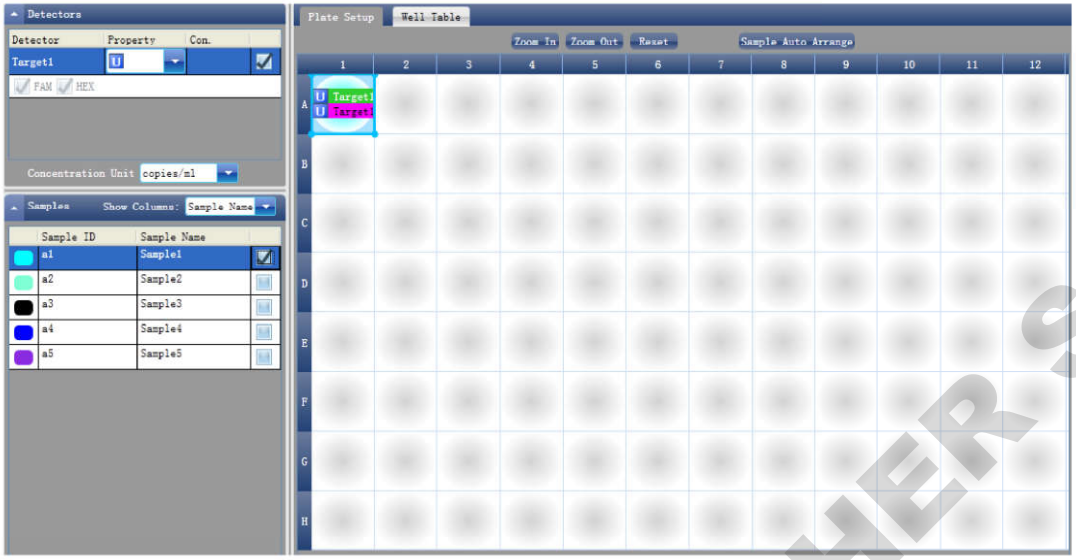
Property	Name	Concentration	Concentration unit
	Unknown	NO	Copies/ml IU/ml Fg/ml Pg/ml
	Negative	NO	
	Positive Allelic gene 1	NO	
	Positive Heterozygous	NO	
	Positive Allelic gene 2	NO	

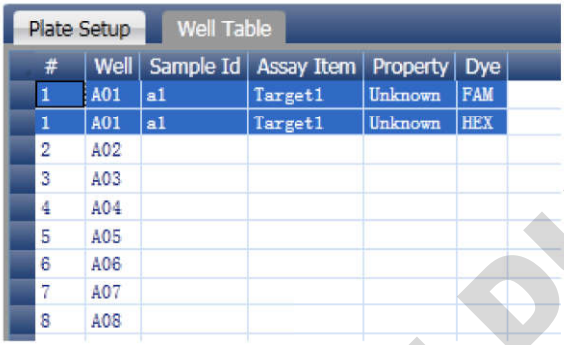
c. Select a sample and the list displayed will change

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

e. Sample Auto Arrange

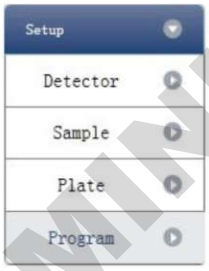
f. Check Well Table





6.1.5 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

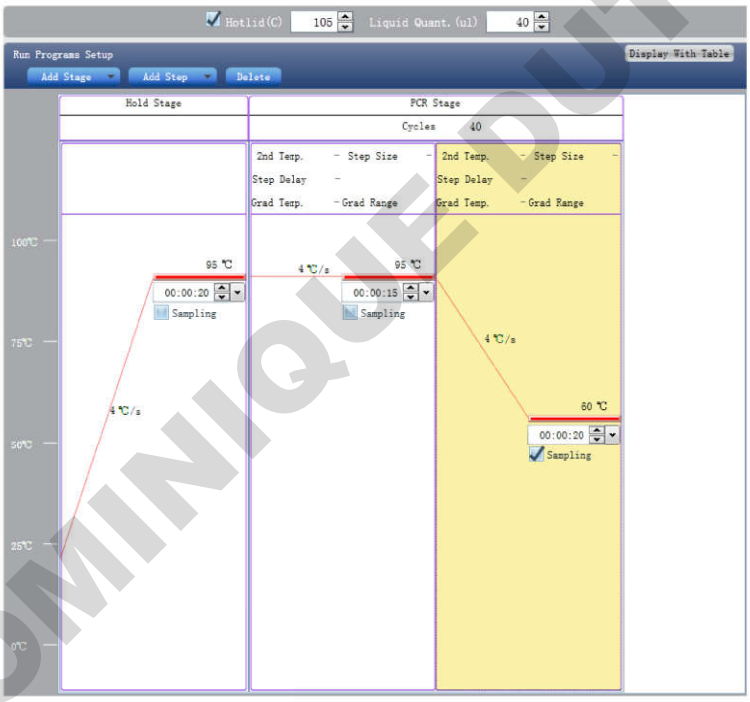
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

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

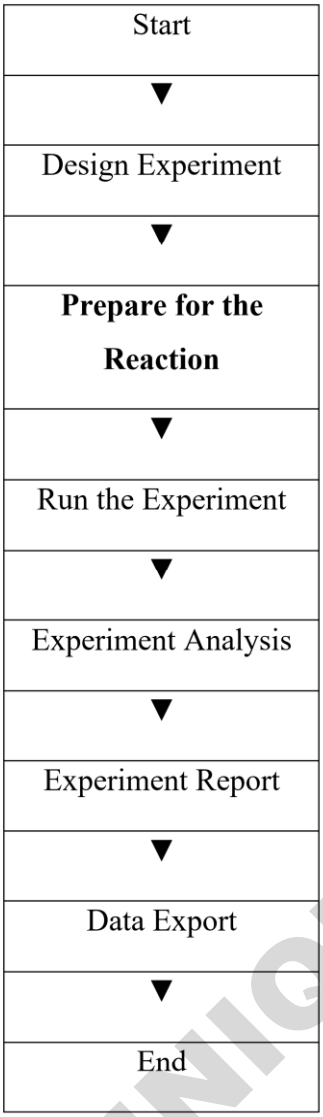
d. Display form: click **Display with Table** ► new window will pop up ► the details of the current experiment will be displayed in a table.

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



6.2 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 reaction plate in Section 6.1.4.

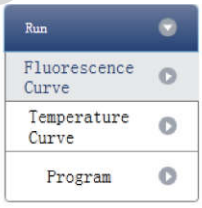
6.3 Run the Experiment

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

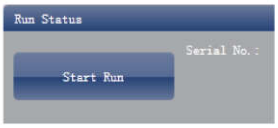
This section describes how to run/operate the experiment after loading the reaction plate and includes how to operate the fluorescence curve, the temperature curve and programming.

6.3.1. 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

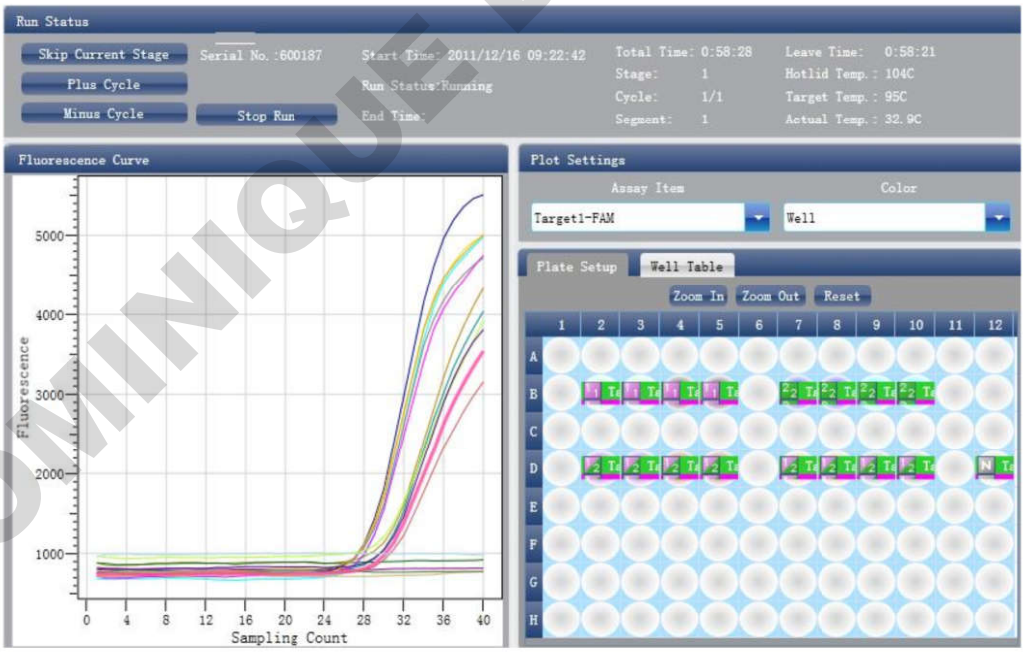
c. Delete a cycle

d. Stop run

5. Plot display setting

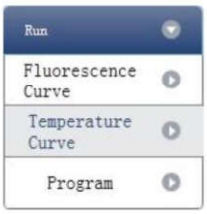
a. Assay item

b. Plot colour

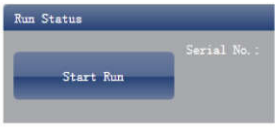


6.3.2 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Start Run**



3. Operating confirmation

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

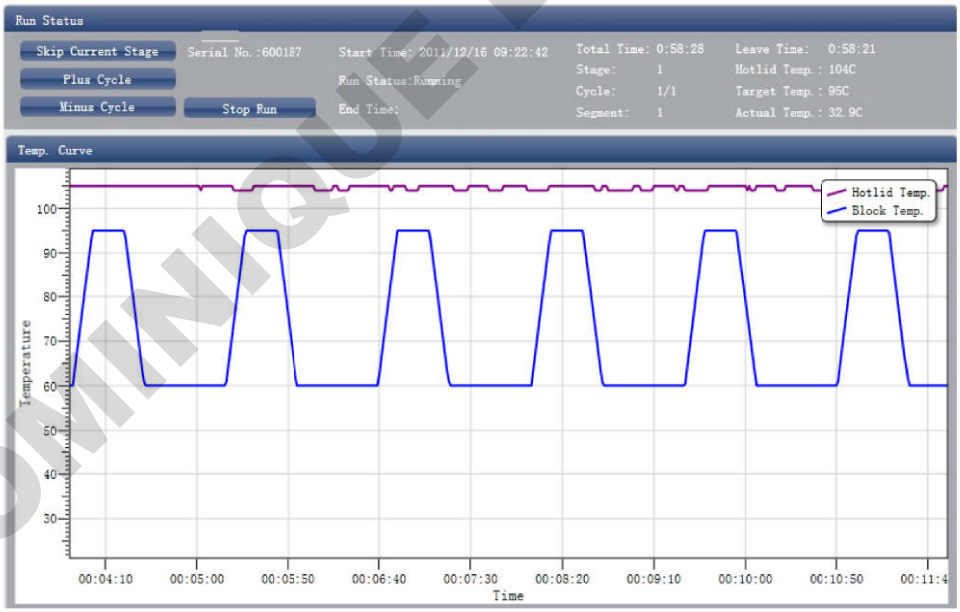
4. After it starts running, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run



6.3.3 Programme Setting

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

6.4 Experiment Analysis

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

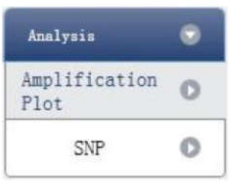
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

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

6.4.1 Check Results

6.4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



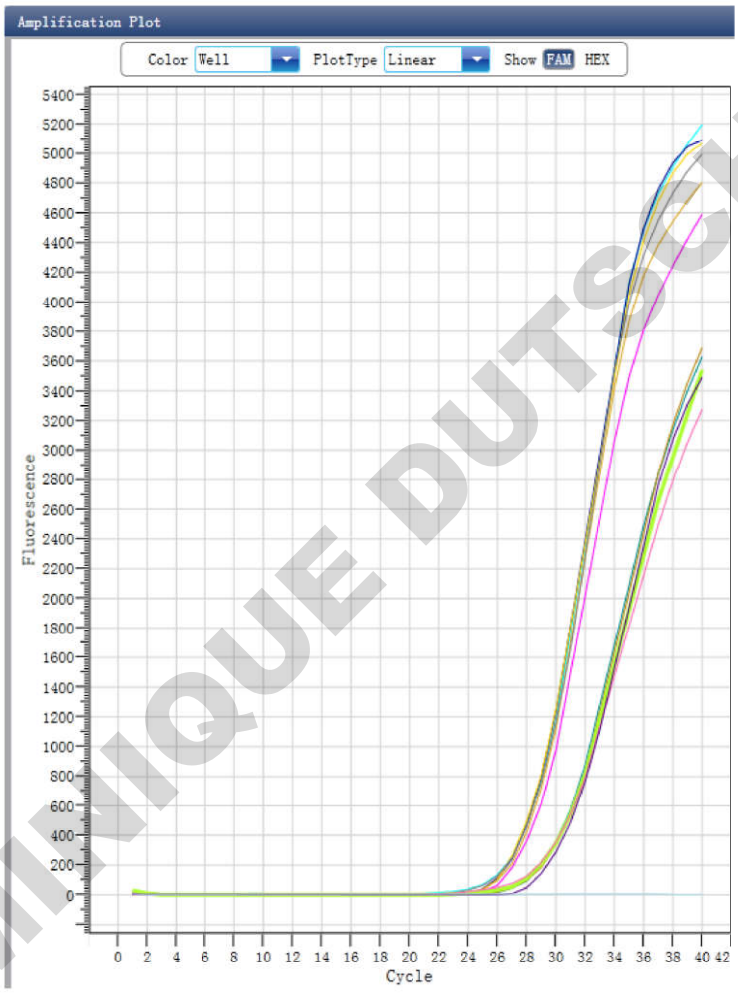
2. Check the amplification curve

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 inspection item

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

6.4.1.2 Check SNP

1. Click **Analysis ► SNP**

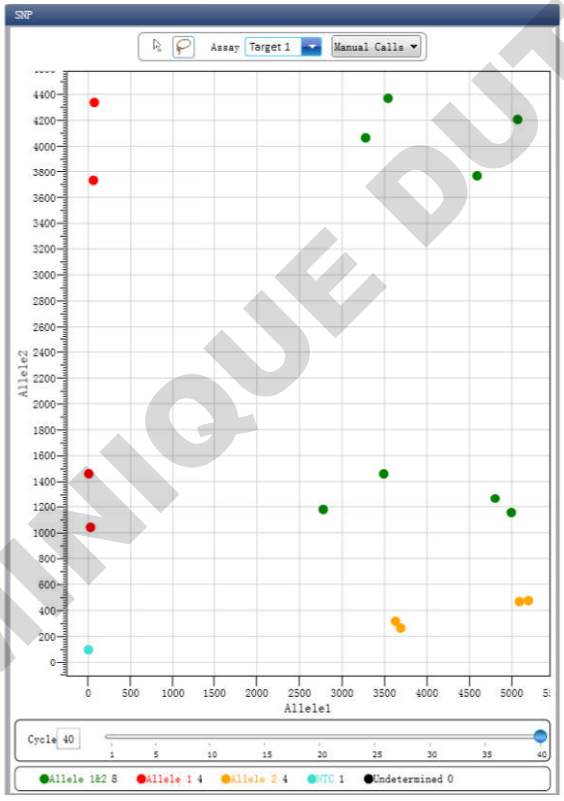
2. Check SNP

a. Select well site

The user can select well site by dragging a rectangle with the mouse around the wells of interest or select wells one by one.

b. Set up Assay

c. Set up manual calls



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

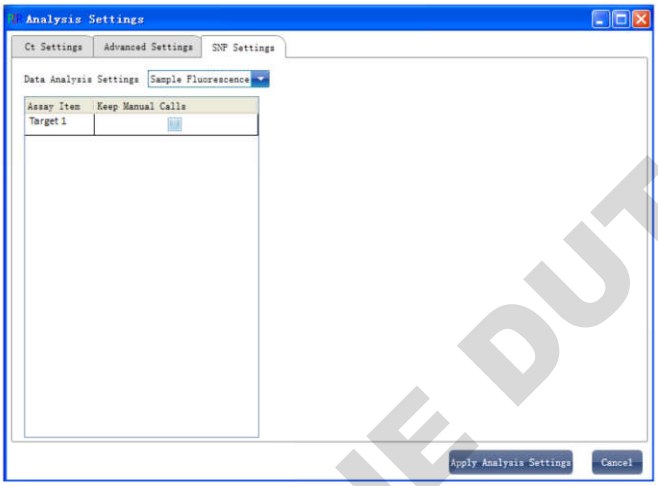
d. Check results summary

6.4.2 Adjust Parameter Re-analysis

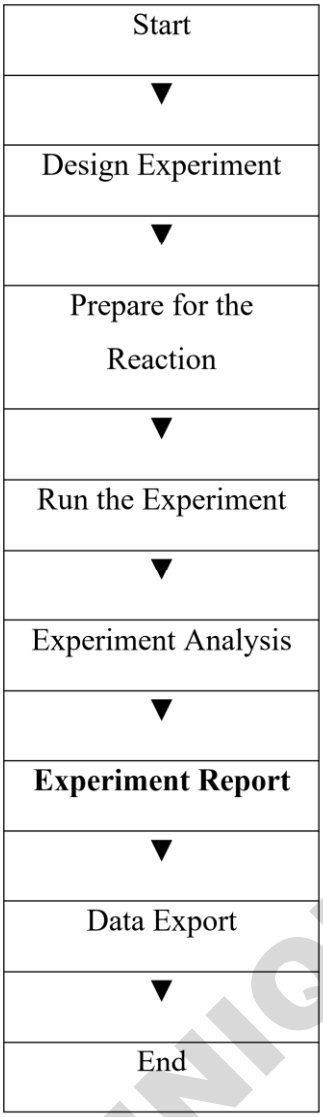
1. Click **Analysis Settings** ► the Analysis Settings dialog box will pop up

a. Adjust analysis data

b. Adjust whether the inspection item will retain manual recognition genotype



6.5 Experiment Report

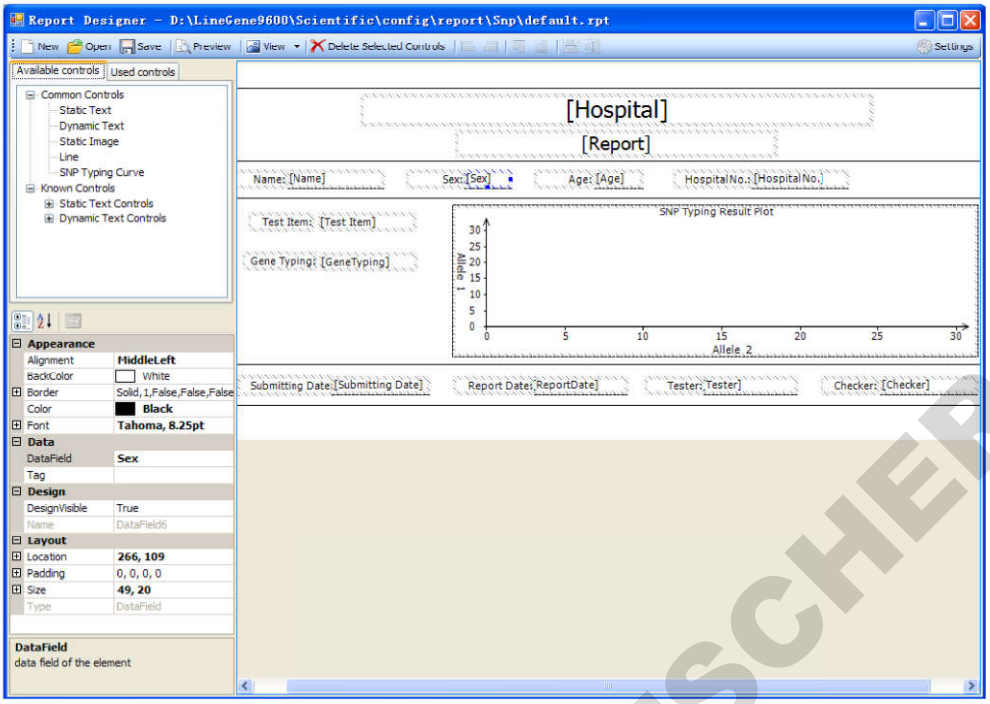


This section describes how to print an experiment report and covers designing of a report template and print setting.

6.5.1 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 and SNP Typing Curve.



6.5.2 Print Setting

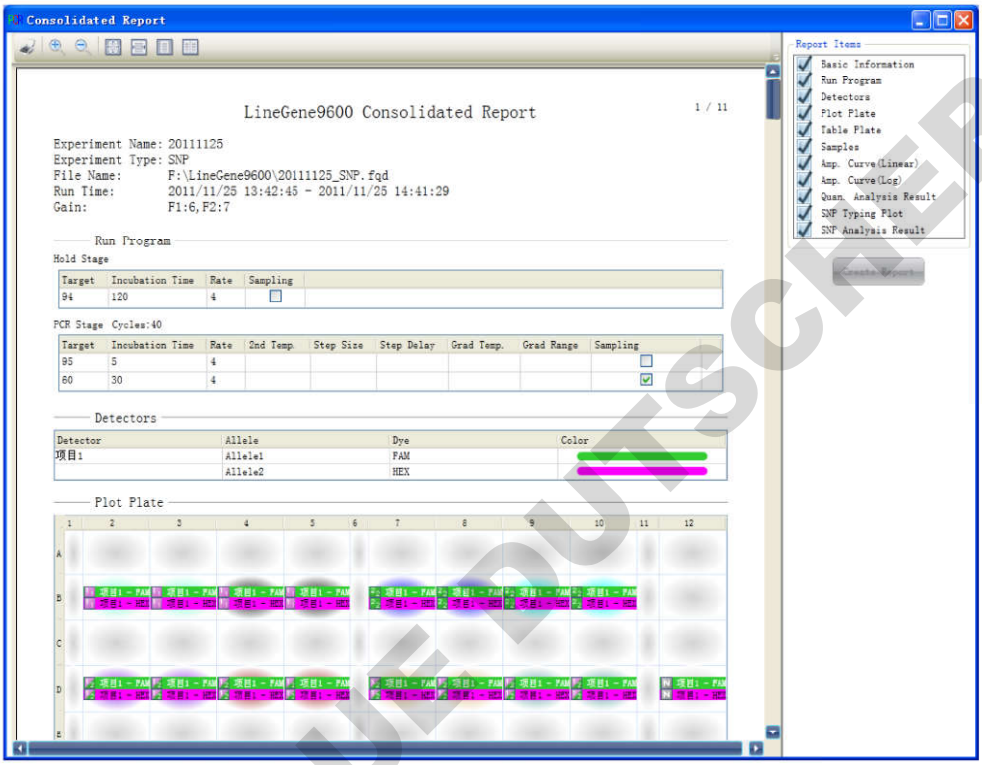
1. Click **Report ► Print Template Setting ►** the Print Template Setting window will pop up

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

6.5.3 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, SNP, plate information, etc..



6.5.4 Report Printing

1. Click **Report ► Report Print**

2. Report print setting

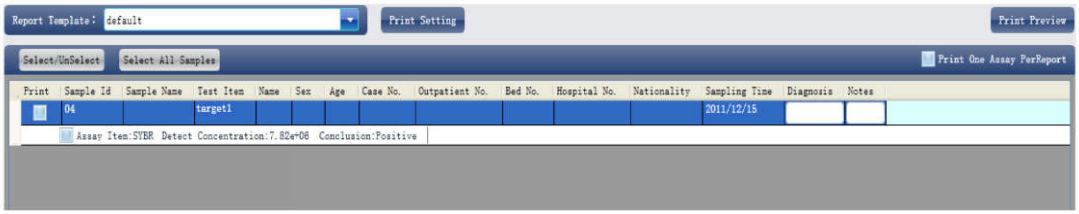
a. Set up report template

b. Print setting (please refer to Section 5.2)

c. Select print items

d. Print preview

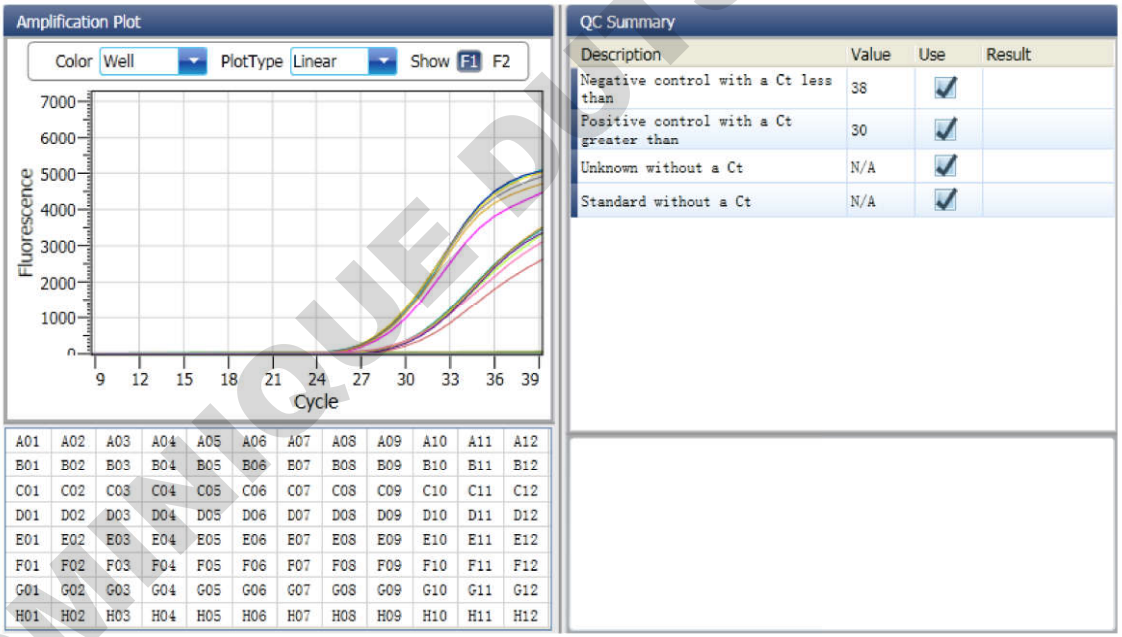
e. Print the report



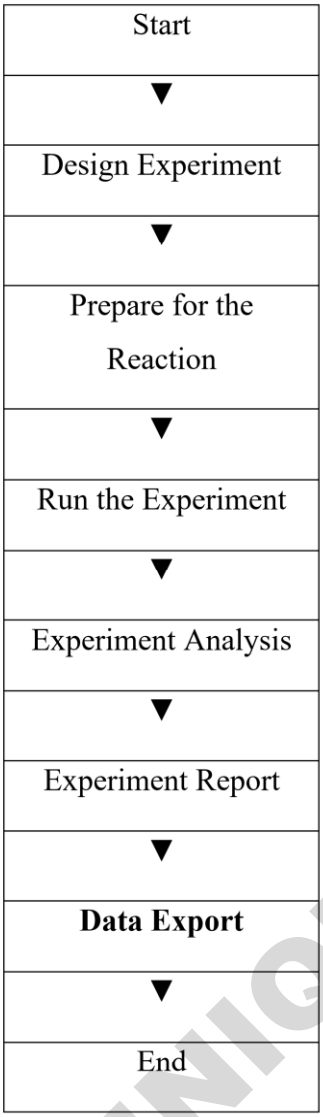
6.5.5 QC Summary

1. Click **Report ► QC Summary**

2. Check the QC summary



6.6 Data Export



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

6.6.1 Export to Database

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

6.6.2 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 filed experiment file is .fqh

6.6.3 Export Experiment Data to EXCEL

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

6.6.4 Export Experiment Data to TEXT

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

Chapter 7 High Resolution Melting

7.1 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 an SNP experiment and covers creating a new SNP experiment, inspection item setting, sample information setting, reaction plate setting and programme setting.

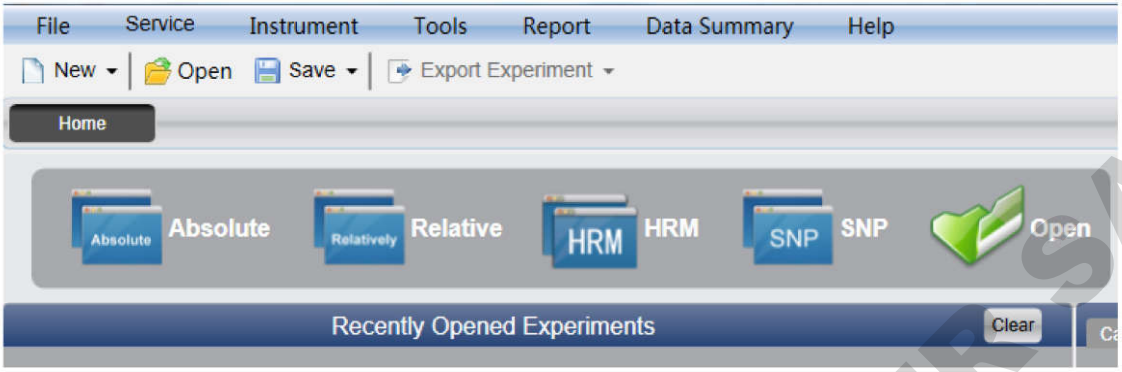
7.1.1 Create High Resolution Melting Experiment

1. Click **HRM** on **Home** interface and create SNP Experiment window.

An SNP experiment can be also created by:

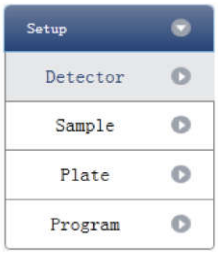
a. Clicking **New** ► **HRM** on the toolbar

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



7.1.2 Detector Setting

1. Click **Setup ► Detector**



2. Input basic information

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

3. Inspection Item Setting

Set up the Detector, Allele, Dye and Colour.

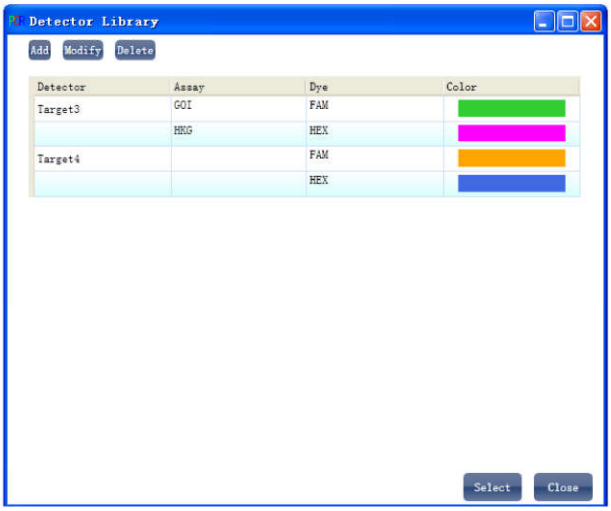
If necessary, the user can also:

a. Add Detector

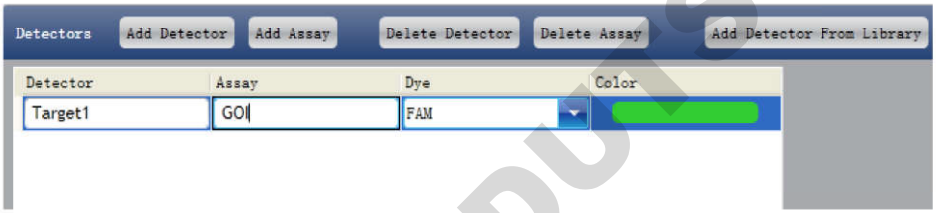
b. Delete Detector

c. Add the Detector in the Detector library: click **Add Detector From Library ►** the **Detector Library** window will pop up ► select the Detector on the window to be added

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



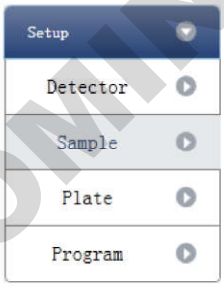
d. Set up the item name, set up the dye name and set up the colour



4. Set up reference dye

7.1.3 Sample Information Setting

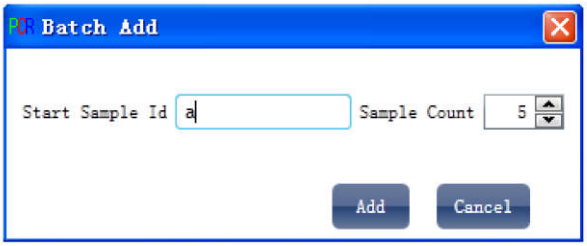
1. Click **Setup ► Sample**



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

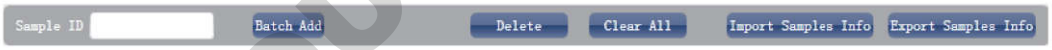
a. Itemized deletion: select one sample ► click **Delete** ► delete the selected sample information

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

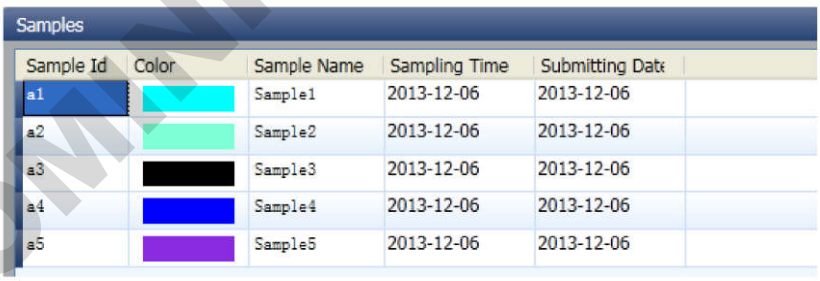
4. Import/Export sample information

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

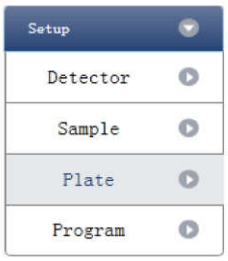


5. Set up sample information



7.1.4 Reaction Plate Setting

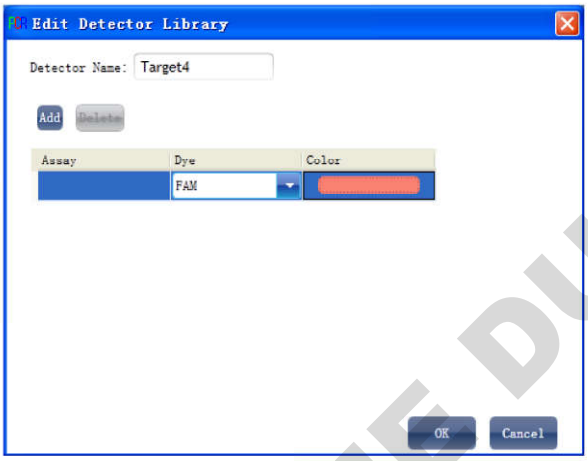
1. Click **Setup** ► **Plate**



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.

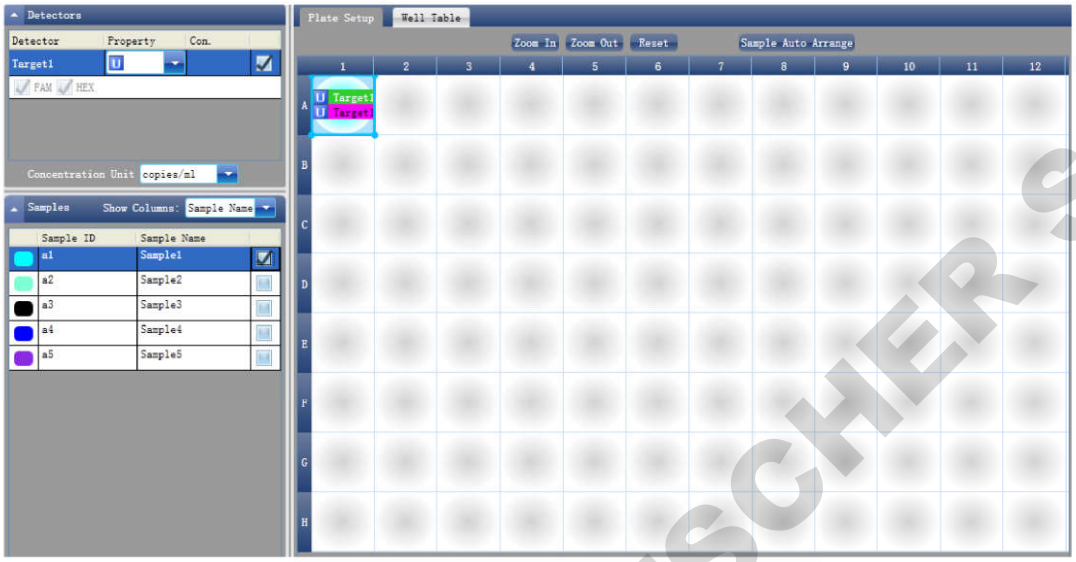
Property	Name	Concentration	Concentration unit
U	Unknown	NO	Copies/ml
S	Standard	YES	IU/ml
N	Negative	NO	Fg/ml
P	Positive	NO	Pg/ml

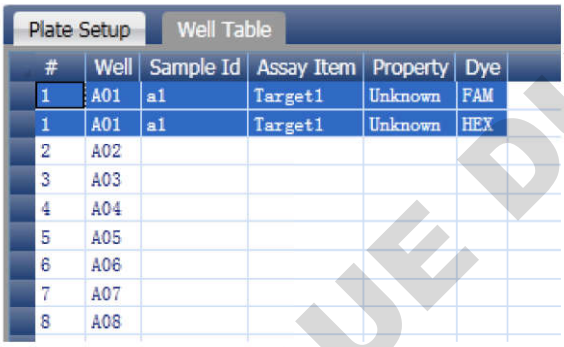
c. Select a sample and the list displayed will change

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

e. Sample Auto Arrange

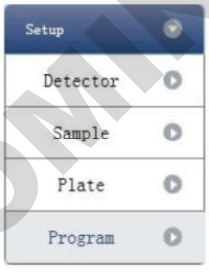
f. Check Well Table





7.1.5 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

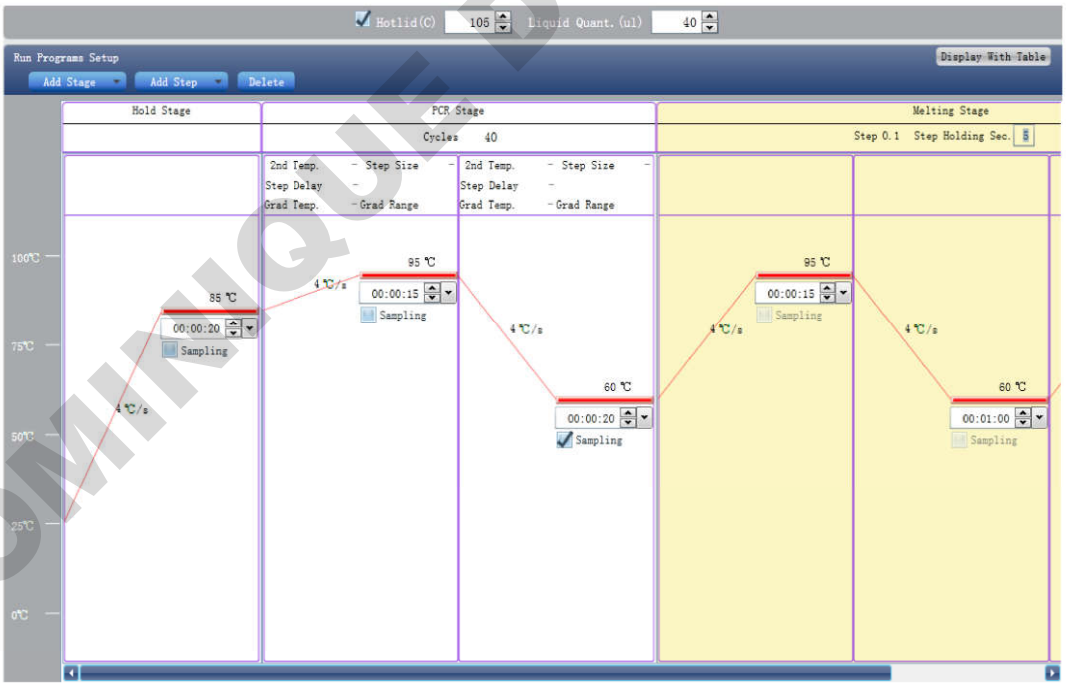
The user can also click **Add Step** and the default will be adding a new Step at the end of the currently selected stage or after the currently selected step.

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



7.2 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 reaction plate in Section 7.1.4.

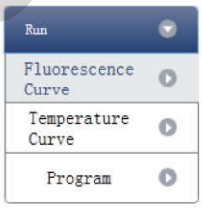
7.3 Run the Experiment

Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

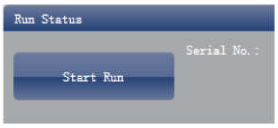
This section describes how to run/operate the experiment after loading the reaction plate and includes how to operate the fluorescence curve, the temperature curve and programming.

7.3.1 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

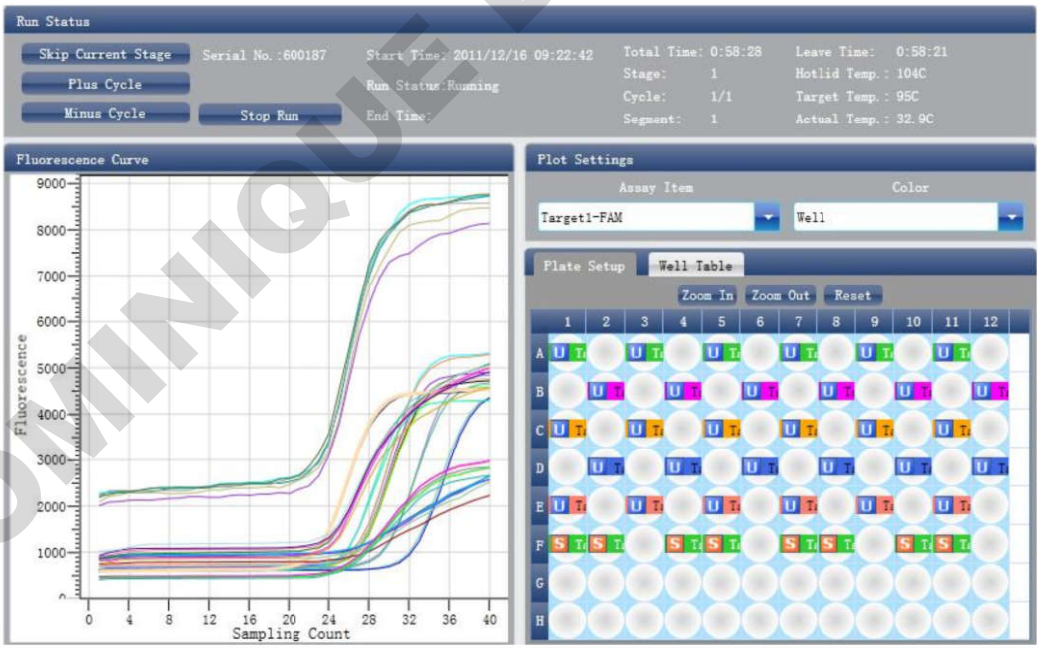
c. Delete a cycle

d. Stop run

5. Plot display setting

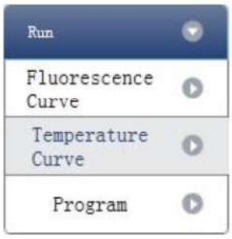
a. Assay item

b. Plot colour

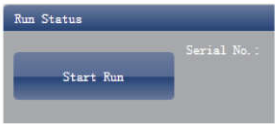


7.3.2 Run Temperature Curve

1. Click **Run ► Temperature Curve**



2. Click **Start Run**



3. Operating confirmation

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

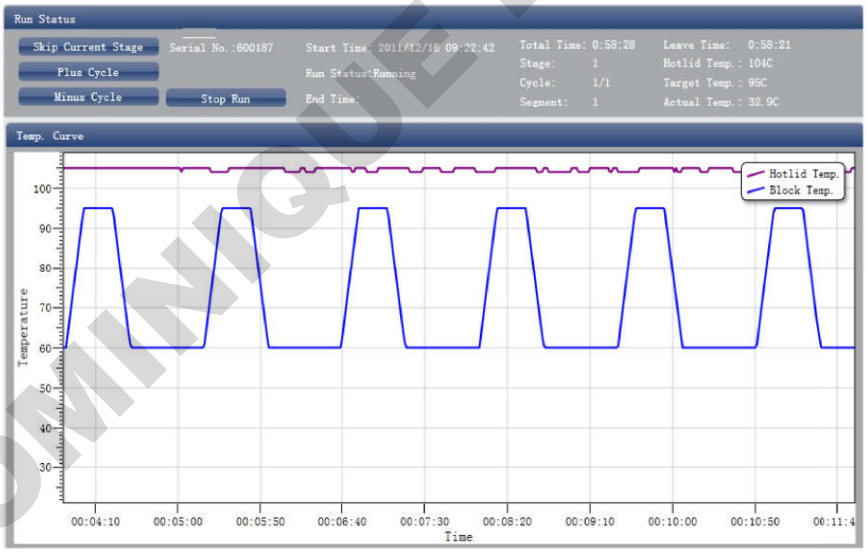
4. After it starts running, the user can:

    a. Skip the current stage

    b. Add a cycle

    c. Delete a cycle

    d. Stop run



7.3.3 Programme Setting

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

7.4 Experiment Analysis

Start

▼

Design Experiment

▼

Prepare for the Reaction

▼

Run the Experiment

▼

Experiment Analysis

▼

Experiment Report

▼

Data Export

▼

End

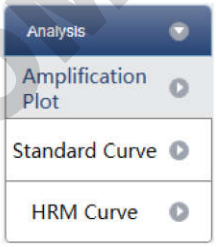
This section describes how to view the experiment analysis results after running an experiment and adjusting parameters for re-analysis.

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

7.4.1 Check Results

7.4.1.1 Check the Amplification Plot

1. Click **Analysis ► Amplification Plot**



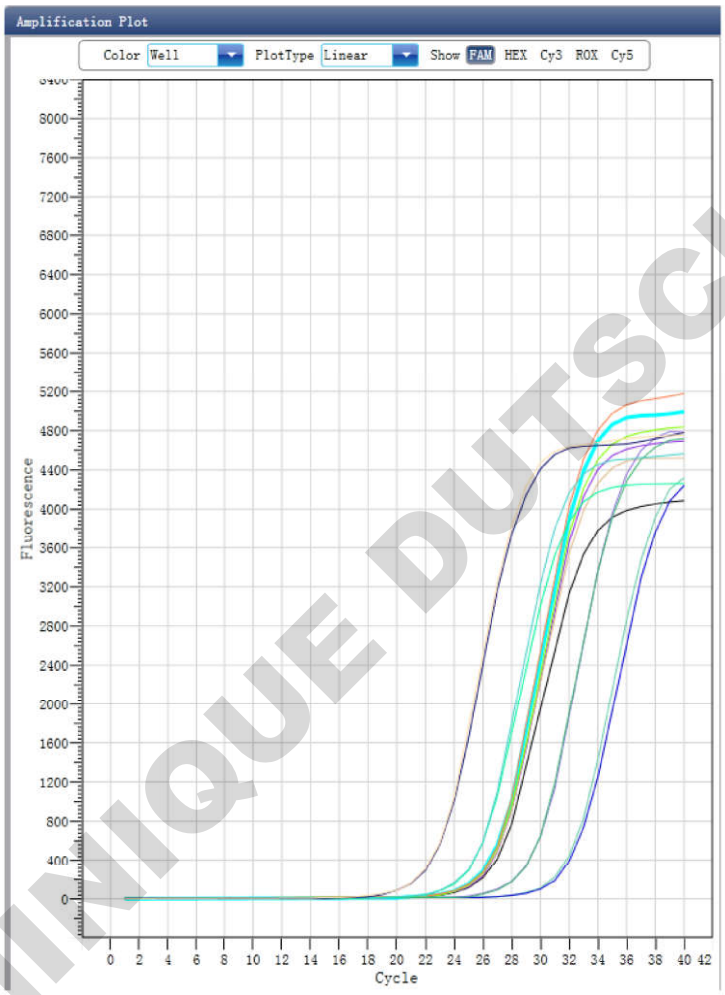
2. Check the amplification curve

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

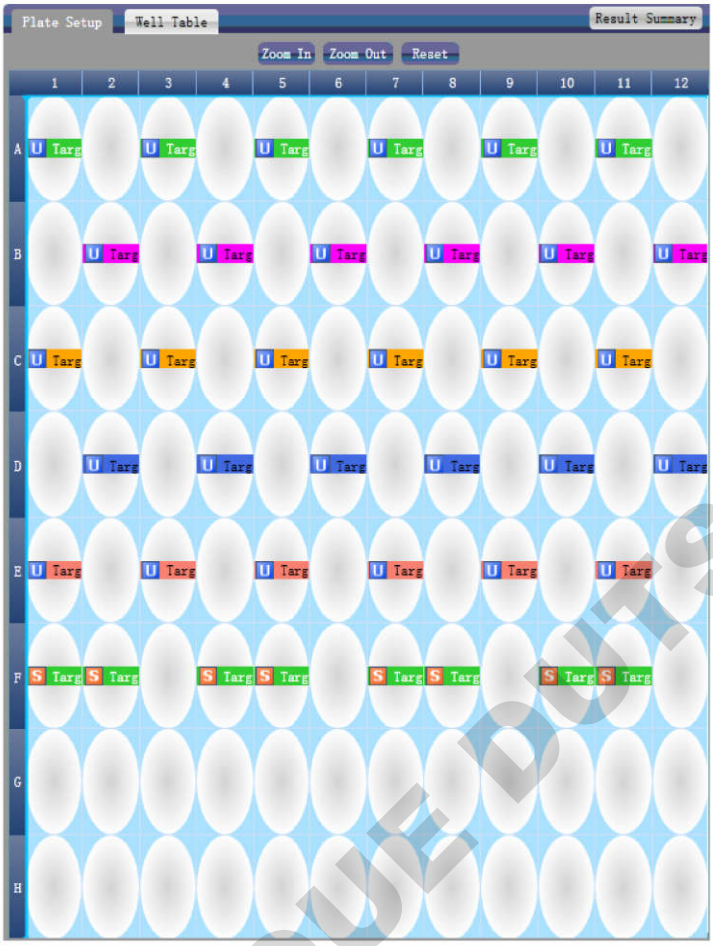
a. Select reaction plate well site and check corresponding well site curve

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 inspection item

a. Set up assay

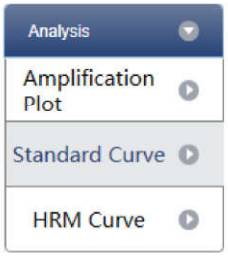
b. Set up threshold

c. Set up automatic baseline

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

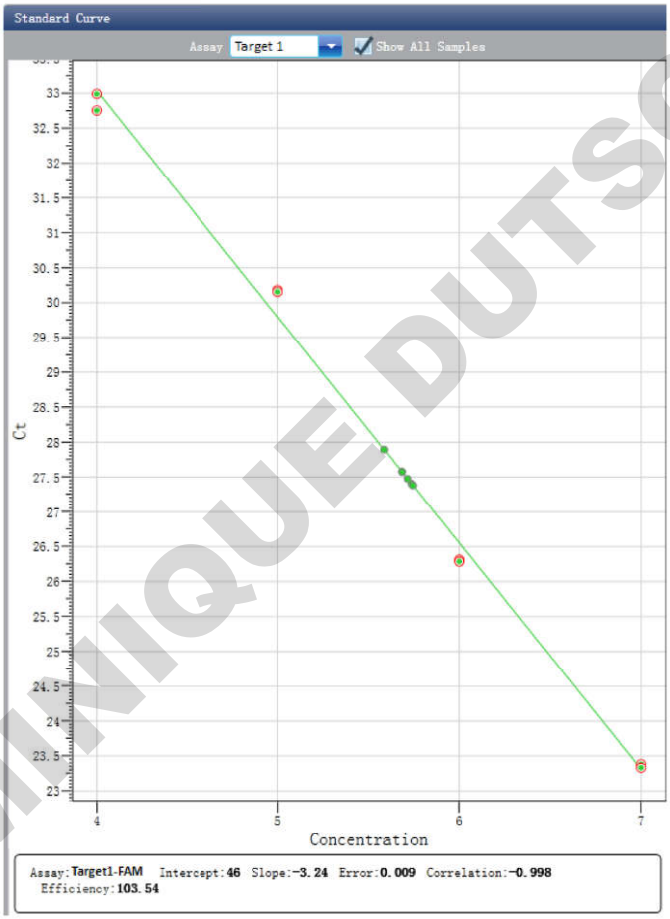
7.4.1.2 Check the Standard Curve

1. Click **Analysis ► Standard Curve**



2. Check the Standard Curve

a. Set up array



3. Check the reaction plate

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

The default is all wells are selected

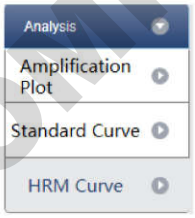
b. Zoom-In, Zoom-Out and reset the reaction plate

c. Check well table

d. Check results summary

7.4.1.3 Check HRM

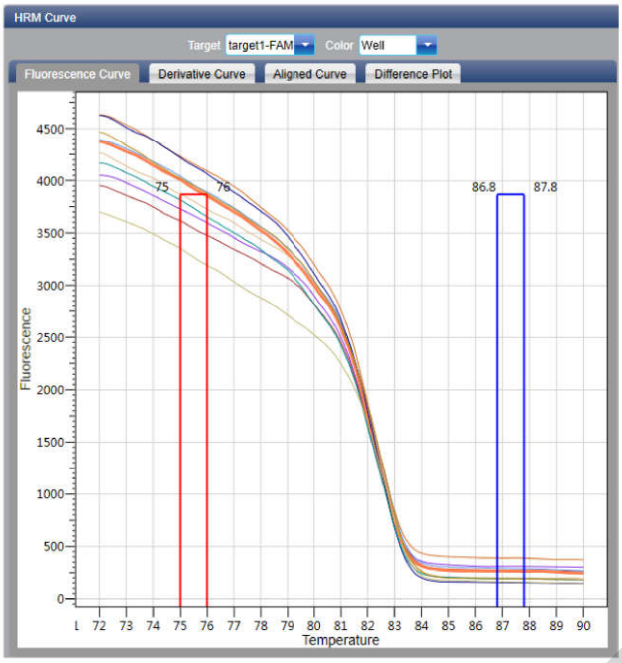
1. Click **Analysis ► HRM Curve**



2. Check the fluorescence curve

a. Set up target

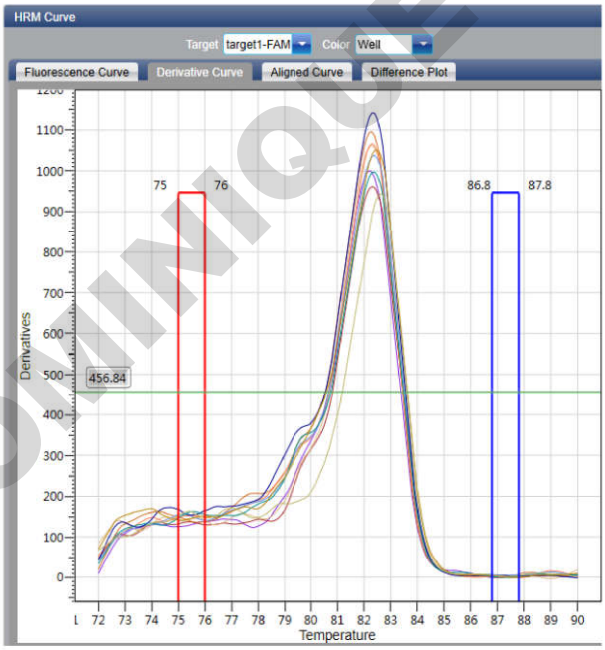
b. Set up color



3. Check the derivative curve

a. Set up target

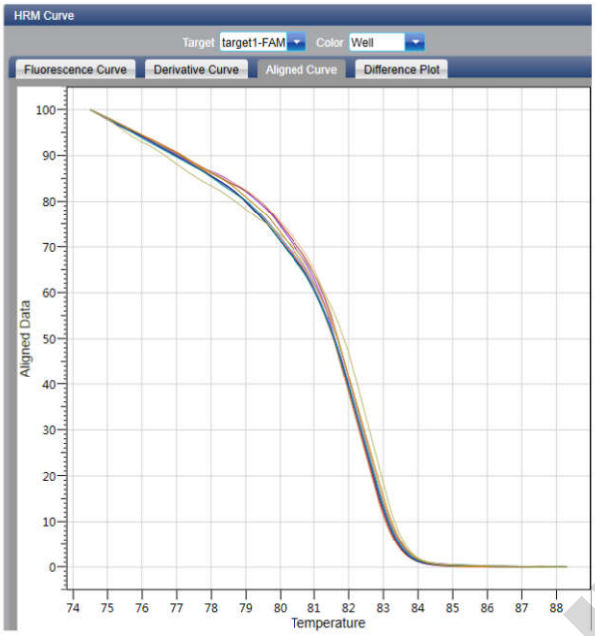
b. Set up color



4. Check the aligned curve

a. Set up target

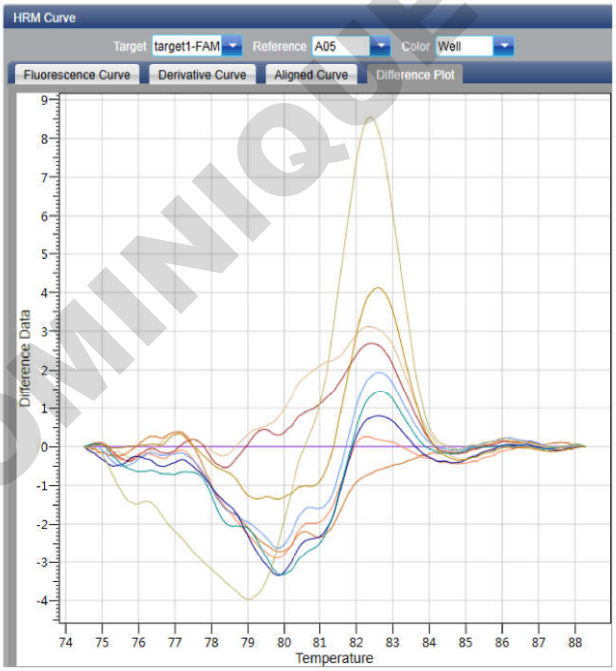
b. Set up color



5. Check the Different Pilot

a. Set up target

b. Set up color



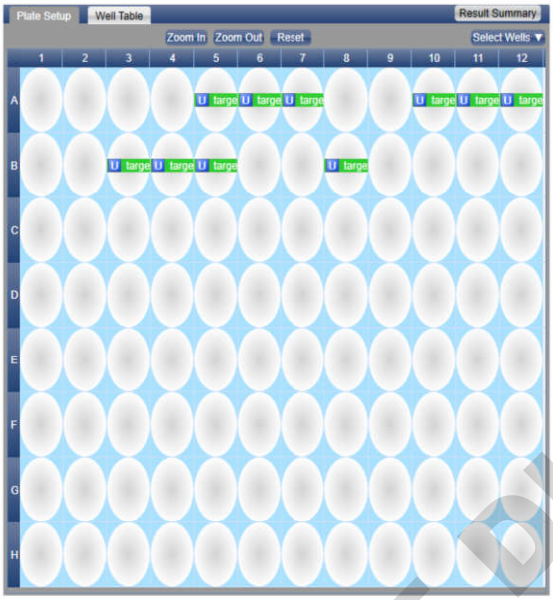
6. Check the reaction plate

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

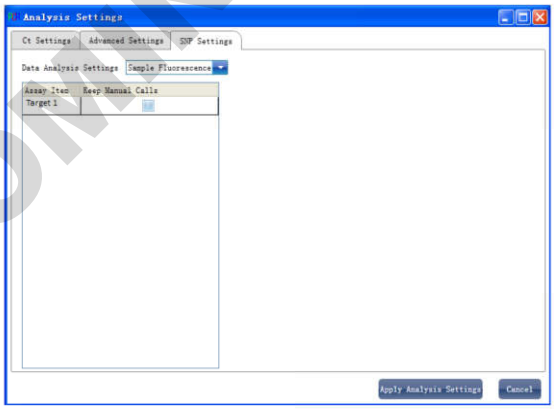


7.4.2 Adjust Parameter Re-analysis

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

a. Adjust analysis data

b. Adjust whether the inspection item will retain manual recognition genotype



7.5 Experiment Report

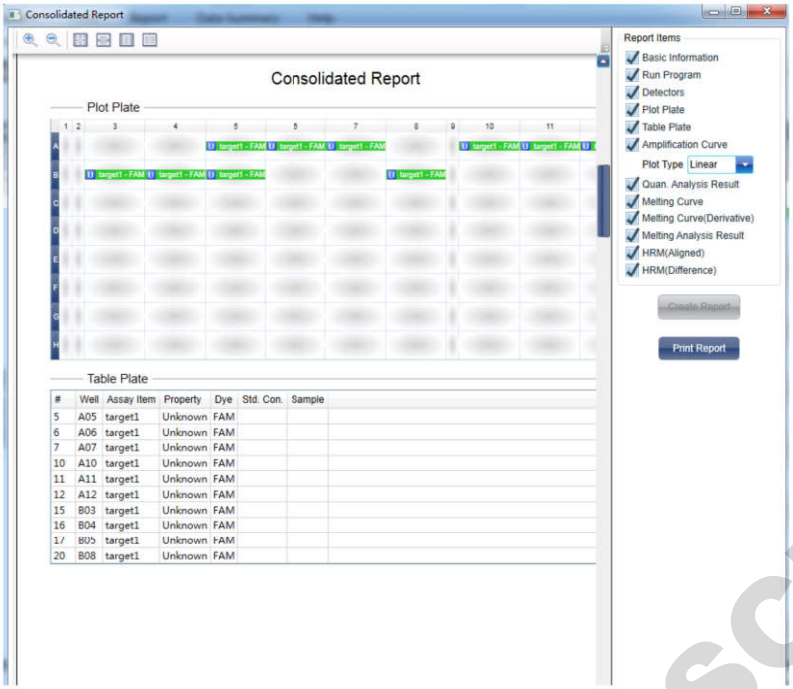
Start
▼
Design Experiment
▼
Prepare for the Reaction
▼
Run the Experiment
▼
Experiment Analysis
▼
Experiment Report
▼
Data Export
▼
End

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

7.5.1 Comprehensive Report

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

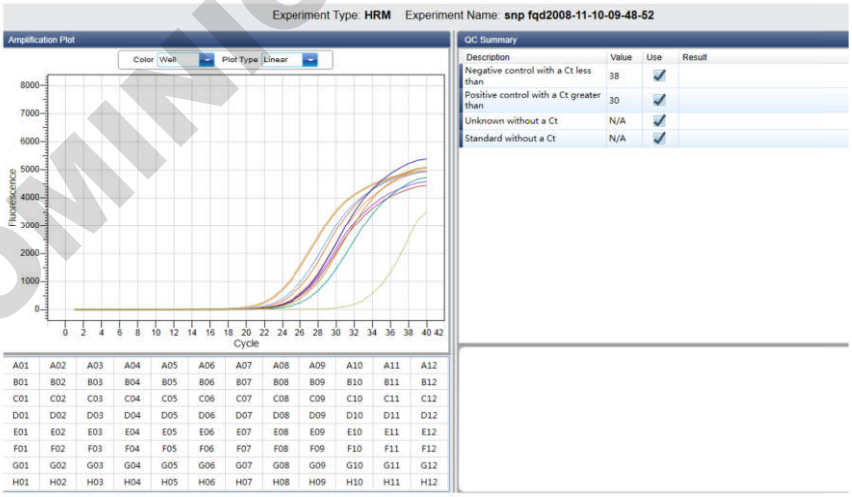
The Consolidated Report includes the basic information, sample information, amplification curve, HRM curve, plate information, etc..



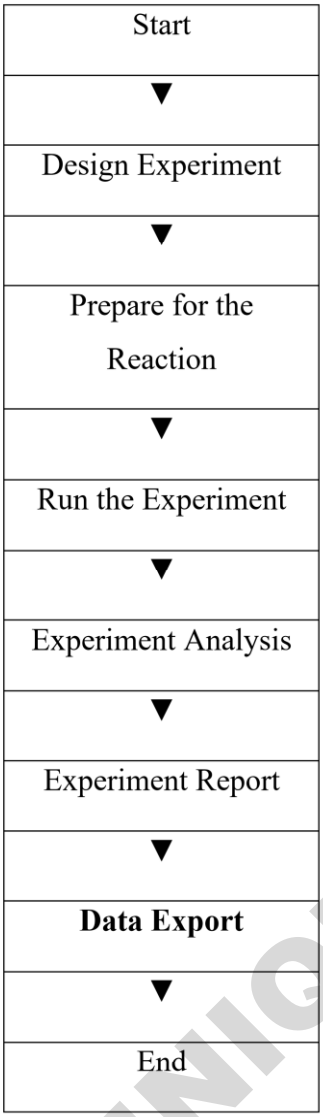
7.5.2 QC Summary

1. Click **Report ► QC Summary**

2. Check the QC summary



7.6 Data Export



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

7.6.1 Export to Database

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

7.6.2 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 filed experiment file is .fqh

7.6.3 Export Experiment Data to EXCEL

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

7.6.4 Export Experiment Data to TEXT

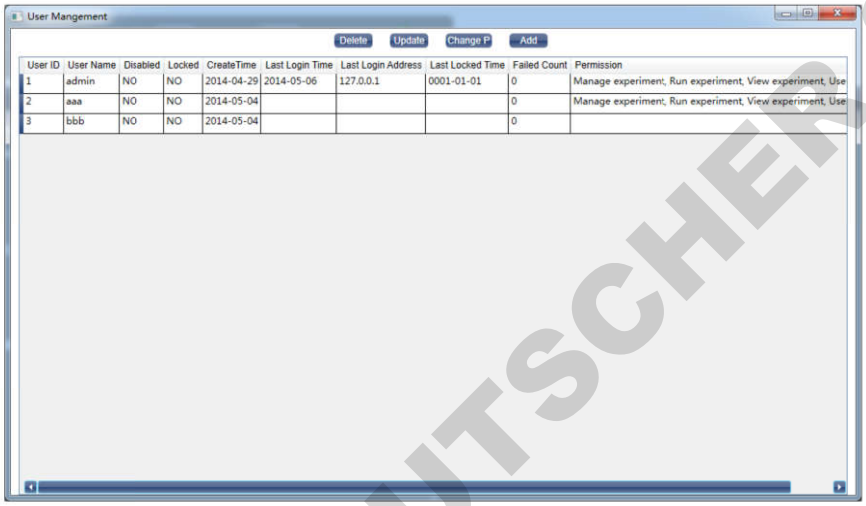
Click **Data Summary►Export Experiment ► Export Experiment to Text►** the exported experiment data will generate TEXT file.

Chapter 8 Service

8.1 User Management

User management is used to manage user information

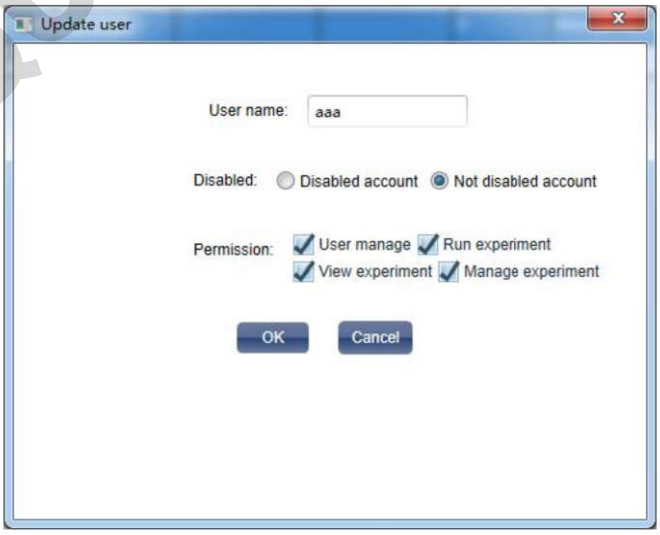
Click **Service▶User Management** on the menu bar



The user can:

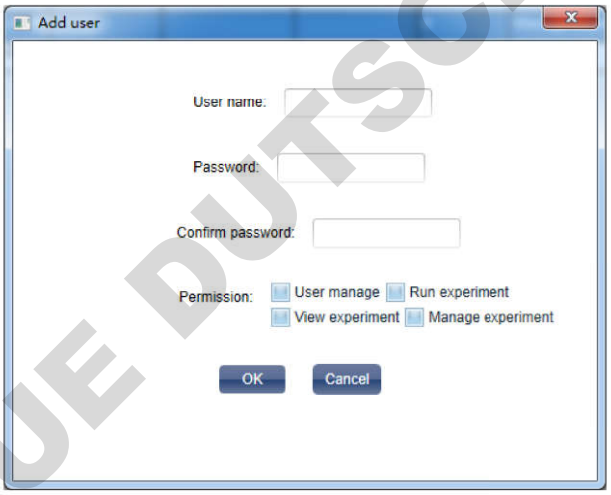
a. delete user

b. update user



c. change password

d. add user



8.2 Experiment Management

Experiment Management is used to manage experiment information and deleted experiment information.

8.2.1 Experiment Management

Click **Service►Experiment management► Experiment management** on the menu bar the user can：

a. clear query condition

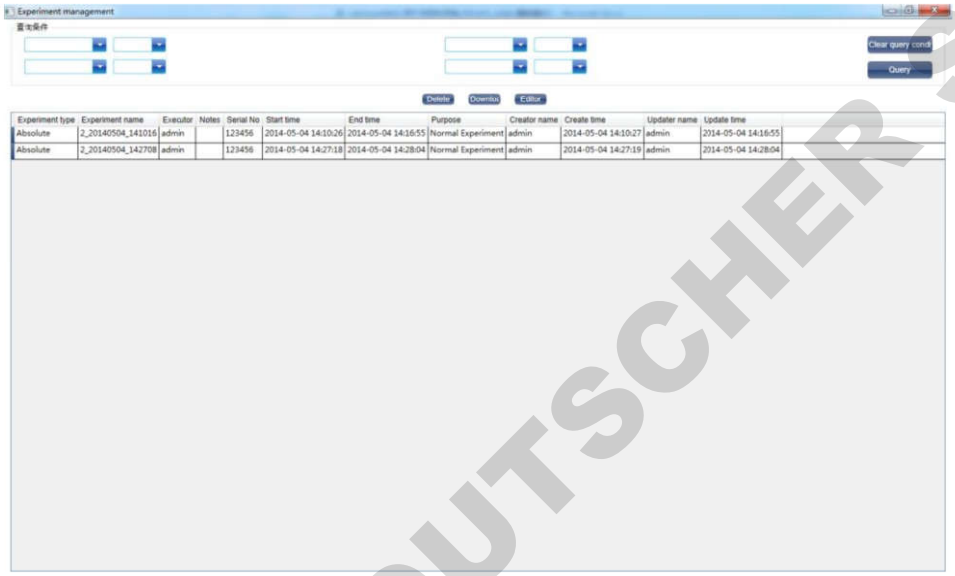
b. set query condition

c. query

d. delete experiment

e. download experiment

f. edit experiment



8.2.2 Deleted Experiment Management

Click **Service▶Experiment Management▶Deleted Experiment Management** on the menu bar

The user can：

a. clear query condition

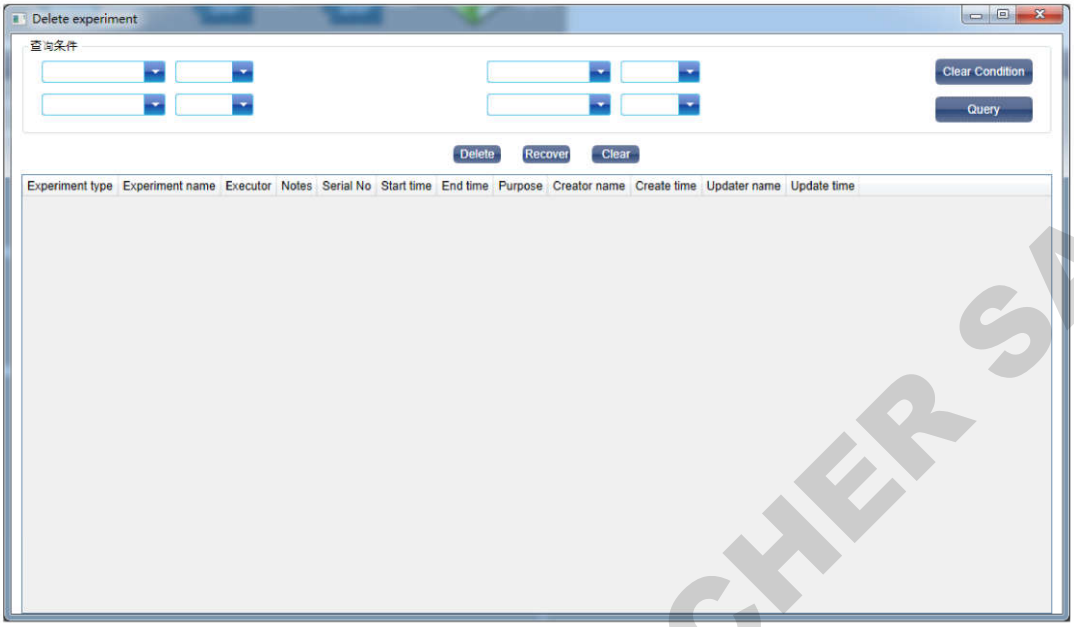
b. set query condition

c. query

d. delete experiment

e. recover experiment

f. clear experiment



8.3 Template Management

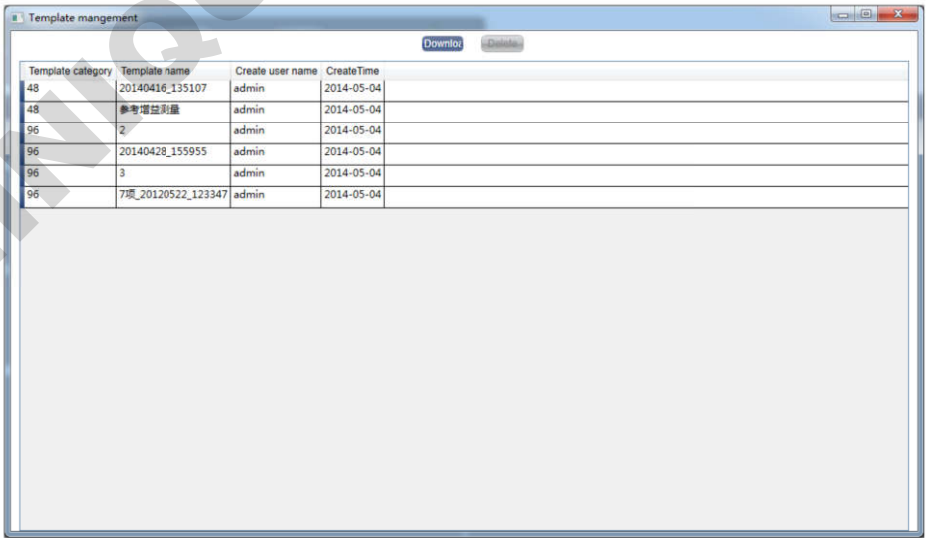
Template Management is used to manage template information。

Click **Service▶Template Management** on the menu bar

The user can：

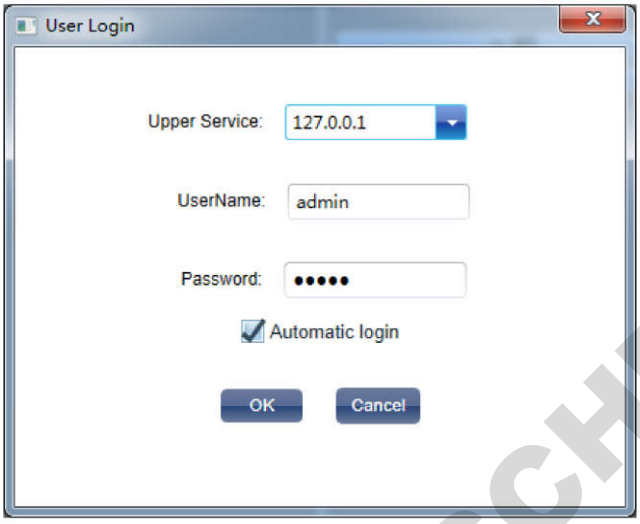
a. download template

b. delete template



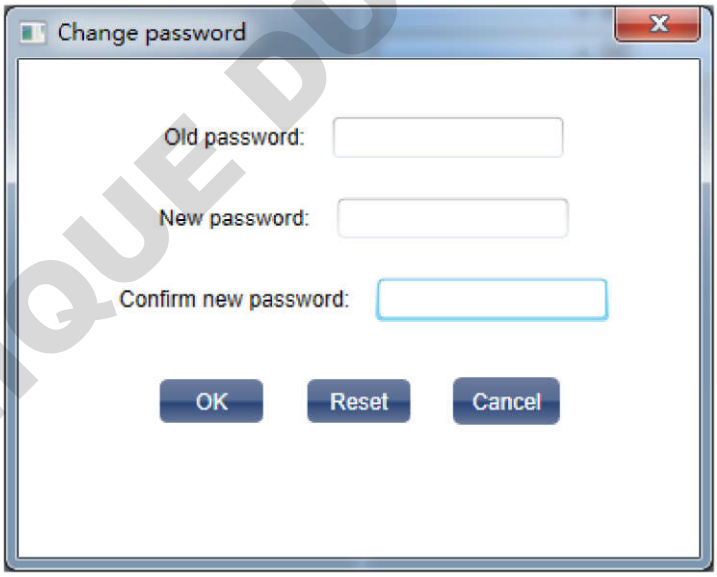
8.4 User Login

Click **Service▶User Login** on the menu bar



8.5 Change Password

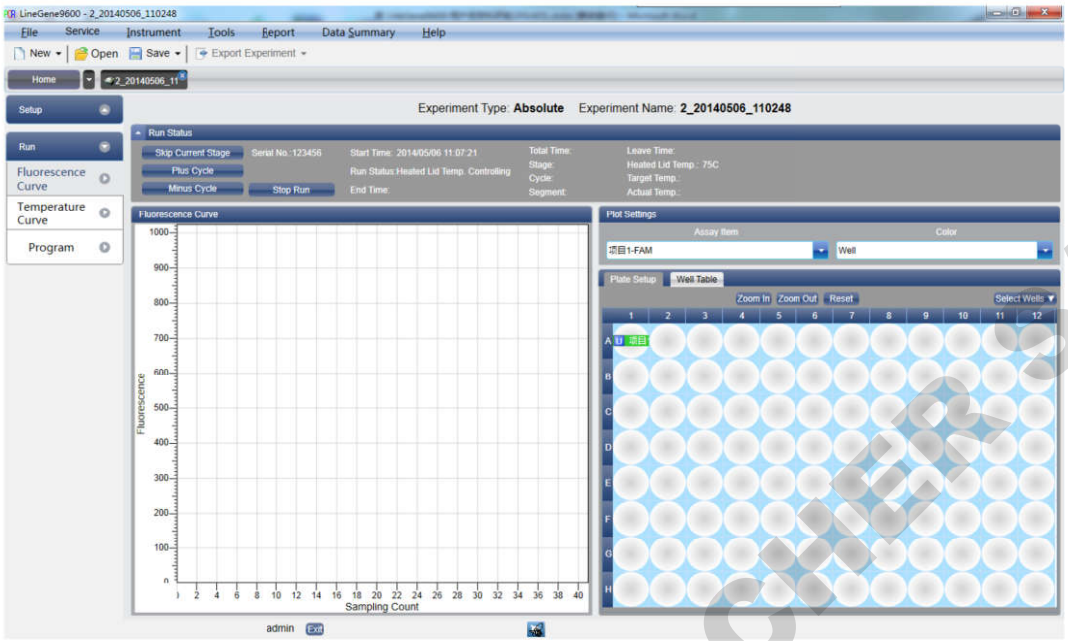
Click **Service▶Change Password** on the menu bar



8.6 See Running Experiment

See Running Experiment is used to see running experiment which is running on connected instrument。

Click **Service▶ See Running Experiment** on the menu bar



Chapter 9 Tool Usage

9.1 Gain Setting

Instrument is the automatic gain version, and there is no need to set the gain manually.

9.2 Block Scan Method

There is no need to set Block Scan Method

9.3 Detector Library

The **Detector Library** tool is used to set up the inspection libraries of absolute quantitative, relative quantitative and SNP analysis.

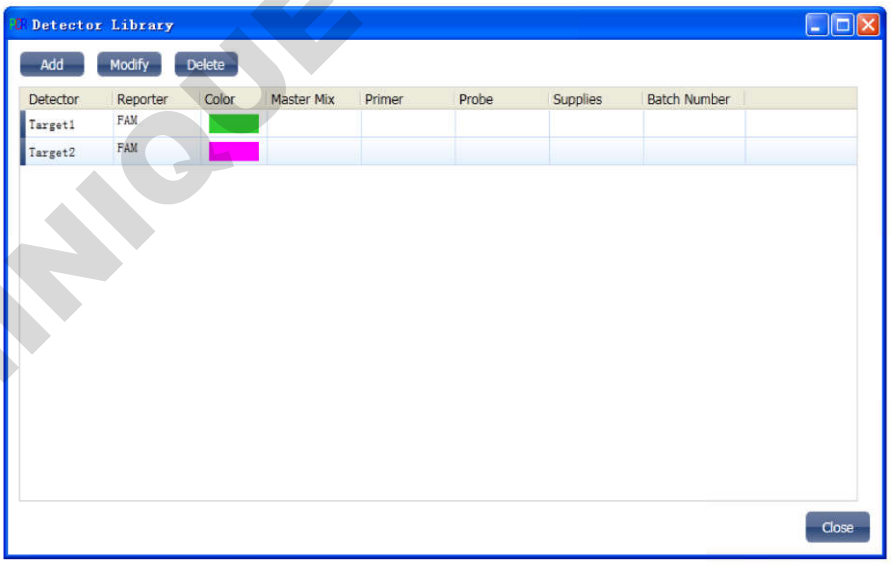
Click **Tools ► Detector Library ► (Absolute /Relative/SNP) ►** open the following window

The user can:

a. Add Detector

b. Modify Detector

c. Delete Detector



9.4 Customized Dyes

The **Customized Dyes** tool is used to set up existing dyes and newly added dyes.

Click **Tools ► Customize Dyes ►** open the following window

The user can:

a. Create dye

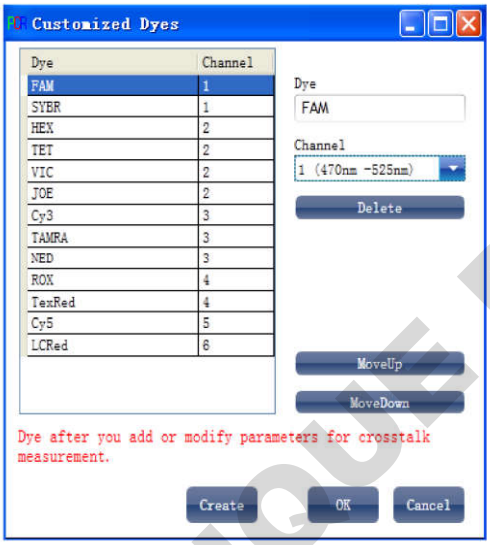
b. Modify dye name and channel

c. Delete dye

d. Move dye upward

e. Move dye downward

After adding new dyes or modifying dyes, the user should conduct crosstalk parameter measurements.



9.5 Customize Columns

Click **Tools ► Customize Columns ►** the following window will pop up

The user can:

a. Add columns

b. Delete columns

c. Modify column name

9.6 Column Selection

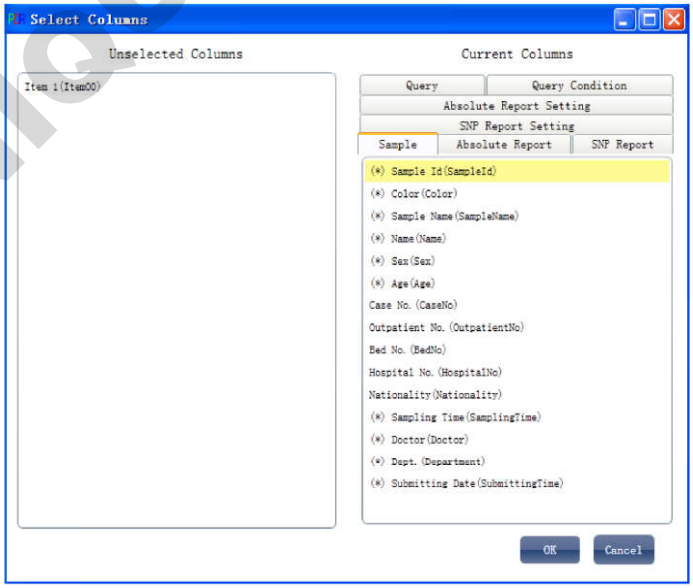
The **Select Columns** tool is used to add the new columns in above section into current existing columns or remove existing columns in current column.

Click **Tools ► Select Columns ►** the following window will pop up

1. Current existing column items include sample, report, report setting, query and query condition

2. Double click column can add or remove a column

3. Column with (*) indicates it cannot be removed



9.7 Sample Column Library

The **Sample Column Library** tool is used in the experiment design phase. The user can select the definition of contents in the drop-down box when setting up sample information.

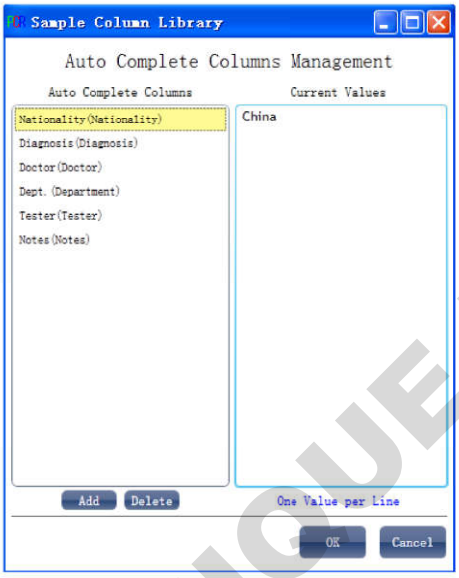
Click **Tools ► Sample Column Library ►** the following window will pop up

The user can:

a. Add columns

b. Delete columns

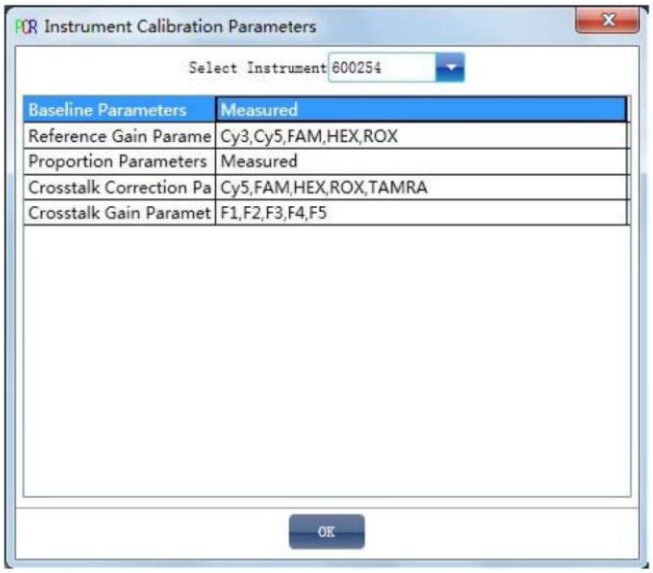
c. Edit the columns content



9.8 Instrument Calibration Parameters

The **Instrument Calibration Parameters** tool is used to calibrate the instrument parameters.

Click **Tools ► Instrument Calibration Parameters ►** the following window will pop up

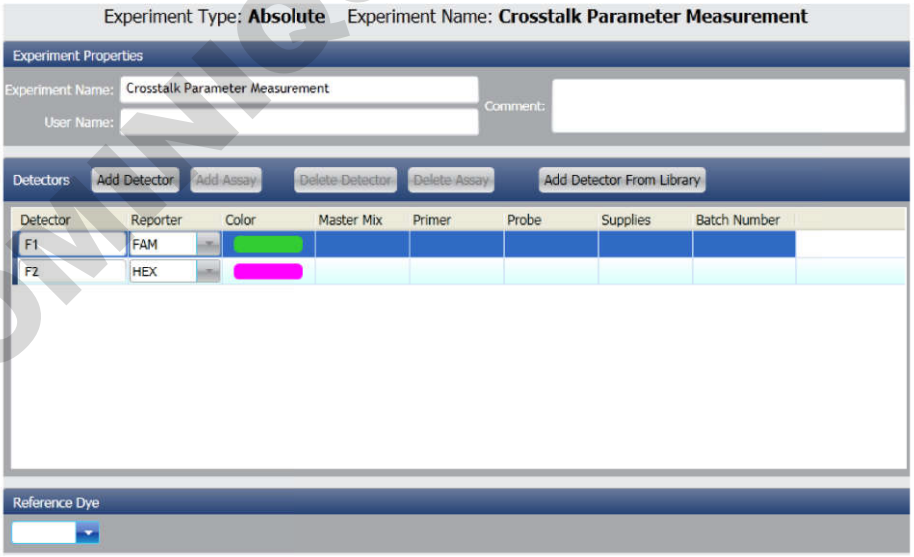


9.9 Measure Crosstalk Calibration Parameters

The **Measure Crosstalk Calibration Parameters** tool is used to measure crosstalk correction parameters.

Click **Tools ► Measure Crosstalk Calibration Parameters ►** the following window will pop up

The user can add and modify the channels to be tested and dyes according to his needs; upload corresponding reaction plates and operate the experiment. When the experiment is over, the system will automatically save the crosstalk correction parameters.

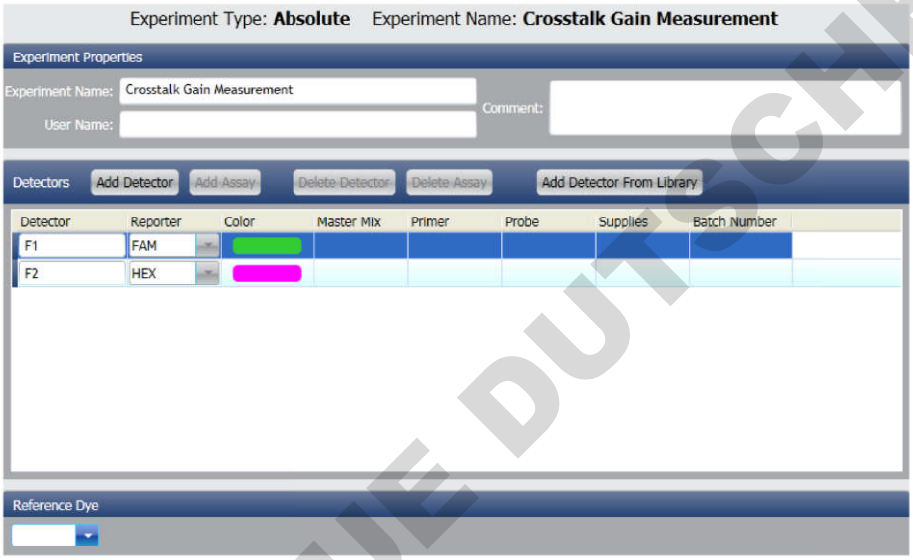


9.10 Crosstalk Gain Parameter Measurement

The **Crosstalk Gain Parameter Measurement** tool is used to measure crosstalk gain parameters.

Click **Tools ► Measure Crosstalk Gain Parameters ►** the following window will pop up.

The user can add and modify the channels to be tested and dyes according to his needs; upload corresponding reaction plates and operate the experiment. When the experiment is over, the system will automatically save the crosstalk gain parameters.



9.11 System Maintenance

The **System Maintenance tools** are used for system maintenance.

Click **Tools ► System Maintenance ►** the Password Input box will pop up ► input the correct Password ► conduct the following settings:

a. Y-axis commissioning

b. X-axis origin calibration

c. Machine serial number setting

d. Photomultiplier setting

e. Runtime zero clearing

f. Background measurement

g. Reference gain measurement

h. Fluorescence incremental calibration

i. Firmware Upgrades

Firmware Upgrade tools are used to upgrade the firmware.

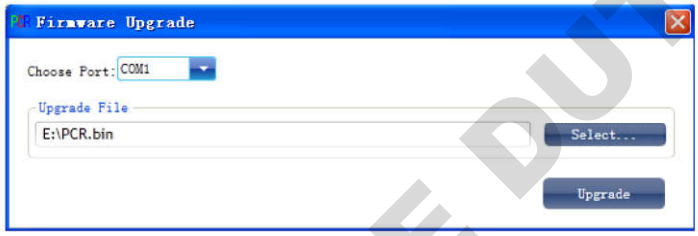
Click **Tools ► System Maintenance ►Firmware Upgrade ►** the following window will pop up.

The user can:

a. Select serial ports

b. Select the BIN file to be upgraded

c. Upgrade



9.12 Upgrade Experiment File Format

The Upgrade Experiment File Format tools are used to convert old files with the suffix of .fqj or .fqs into new files with the suffix of .fqd.

Click **Tools ► Upgrade Experiment File Format ►** the following window will pop up.

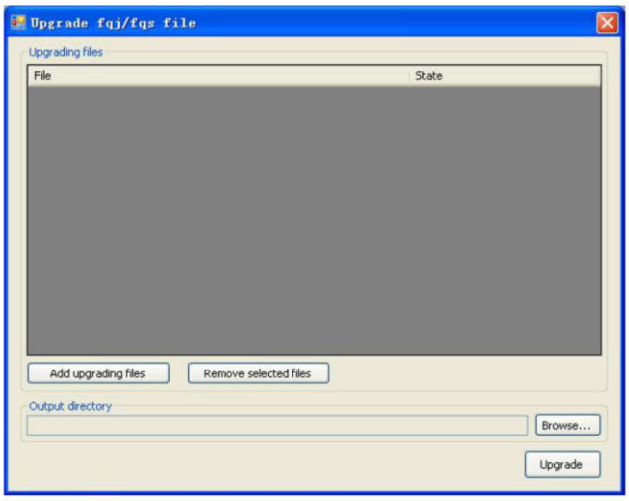
The user can:

a. Add files to be upgraded

b. Remove selected files

c. Select the output directory of new files

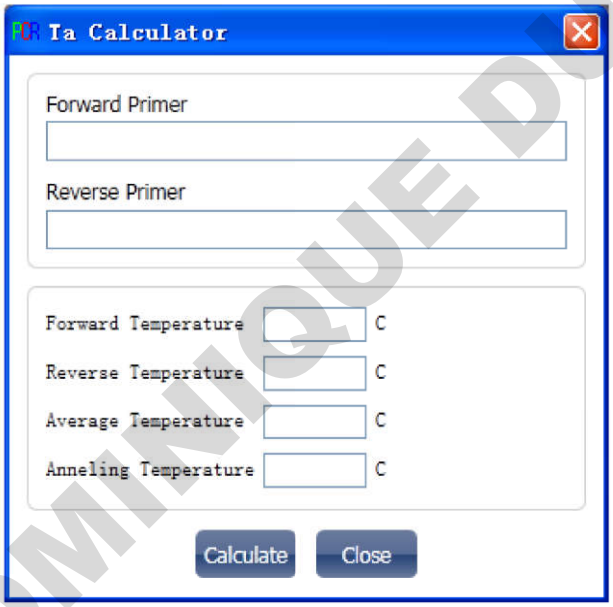
d. Upgrade



9.13 Ta Calculator

Click **Tools ► Ta Calculator ►** the following window will pop up.

Input Forward Primer and Reverse Primer,click Calculate to gain Forward Tempperature. Reverse Tempperature, Average Tempperature and Anneling Tempperature.



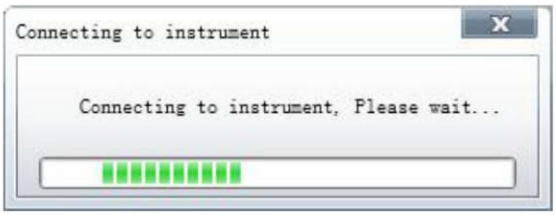
Chapter 10 Other Functions

10.1 Instrument Operation

The Instruments operations include **Connect** instrument, **Disconnect** instrument and **Instrument Information**.

10.1.1 Connect

Click **Instrument ► Connect ►** select port number or select automatic port matching.



When the instrument is connected, the icon on the status bar will be  ; if the instrument is disconnected, the icon on the status bar will be 

10.1.2 Disconnect

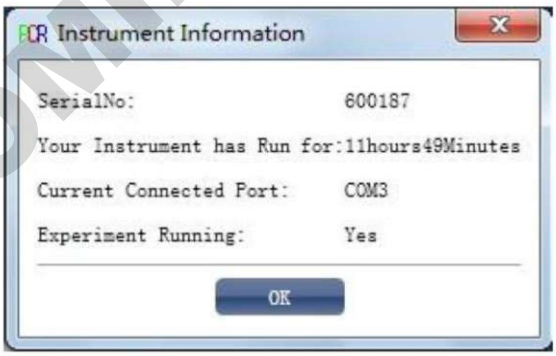
Click **Instrument ► Disconnect ►** disconnect currently connected instrument

10.1.3 Instrument Information

When the instrument is connected, the user can check the instrument information.

Click **Instrument ► Instrument Information ►** the following dialog box will pop up

Instrument information includes instrument serial number, runtime, currently connected ports, and whether an experiment is in operation.



10.2 Data Query

Data Query is used to query the data already exported to the database.

Click **Data Summary ► Data Query ►** the following window will pop up

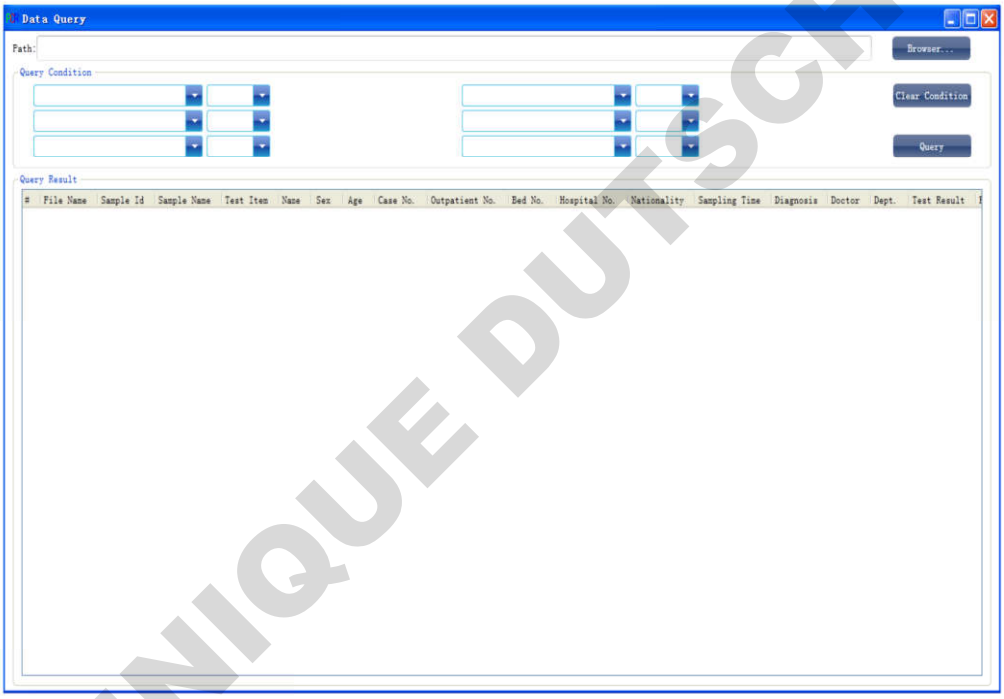
The user can:

a. Select database files

b. Set up query condition

c. Query

d. Clear all query conditions



10.3 System Help

Click **Help ► Help Topics**

Chapter 11 Maintenance

11.1 Regular cleaning

To ensure the normal operation and test use of the instrument, it is suggested to clean the instrument regularly.

- Surface cleaning: use a soft cloth to clean; If necessary, dip in alcohol, distilled water, or clean paste to clean.
- Cleaning of module hole: clean cotton swabs with dust-free and dip a small amount of 95% medical anhydrous ethanol or distilled water when necessary.

Warning!

1. When cleaning the instrument, the power must be cut off.

2. Corrosive cleaning agent is strictly prohibited on the surface of this instrument. If in doubt, please consult the manufacturer or its agent.

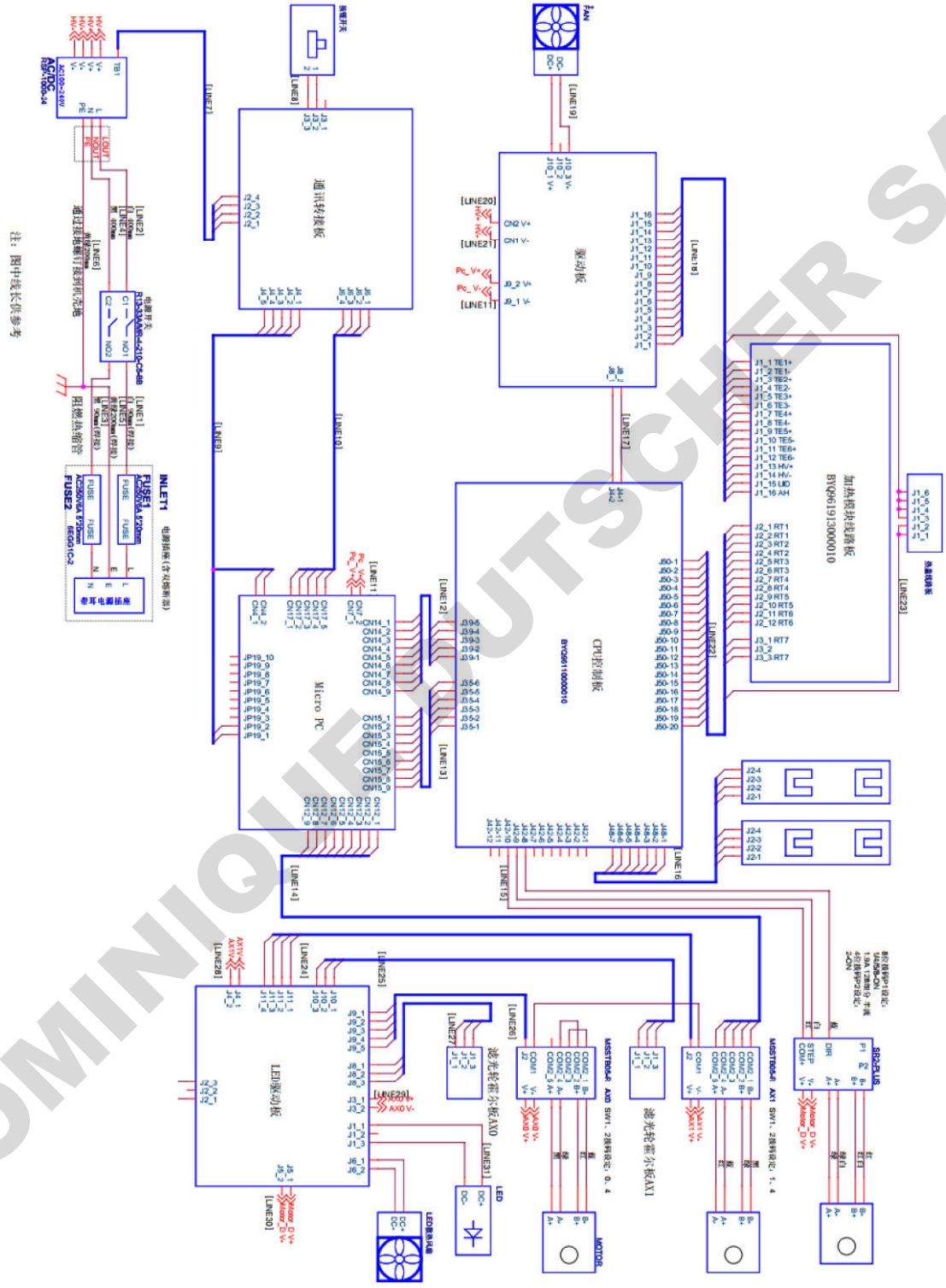
11.2 Analysis and Troubleshooting

S.N.	Fault Phenomenon	Cause Analysis	Way of Handling
1	The power switch behind the instrument has been set ON, but the instrument is not responsive	The RUN SWITCH in front of the instrument is not pressed.	Press RUN SWITCH.
2	System parameters menu shows that "password" needs to be entered.	The system parameters are used for internal calibration of the instrument manufacturer and need special password to enter.	Users do not need to use this feature. For calibration, please contact the manufacturer's service personnel.
3	The rising and cooling speed of module obviously slows down or the temperature control is inaccurate	The vent is blocked	Remove obstructions from vents
		Loose connection	Contact with the supplier or manufacturer
		Refrigeration piece is damaged	
		Fan is damaged or doesn't work	

		Temperature sensor is damaged	
4	The modules are neither heated nor cooled	Internal instrument fault	Contact with the supplier or manufacturer
		Refrigeration piece is damaged	
		Hot cover heating process	When the hot cover temperature of the instrument reaches the target value. The module temperature is automatically controlled at 30℃ when it stops running
5	Temperature or Fluorescence Curve Exception: straight line,	The Run Program was infected with a virus and the computer CPU was severely occupied.	After antivirus reinstall the application software.
6	The hot cover won't heat	Thermal fuse is damaged	Contact with the supplier or manufacturer
		Connector is loose	
		The heating element in the hot cover is damaged	
		Temperature sensor in hot cover is damaged	
7	The fluorescence value of each hole increased, or the background was very large without test tube	Contamination of test tube holes or hot covers. Baseline background parameters are misused.	depollution, each instrument should correspond to BaselineFile. After long-term use, the optical element is offset. Please contact the manufacturer to recalibrate the background.
8	Reagent evaporation	Tube quality problems, loose seal; Tube cover or film is not correct, not appropriate.	Select suitable consumables with better sealing performance
9	Signal crosstalk between channels	There is crosstalk between dye signals in different channels objectively.	It can be measured by "crosstalk coefficient measurement" function in the software, and the calibration parameters can be saved for correction.
10	Abnormal fluorescence detection values	External strong light irradiation	Turn off external light source
		Photovoltaic system is damaged	Contact with the supplier or manufacturer

Caution:	During the warranty period, users are forbidden to open the expansion instrument shell for self-inspection. If there is a fault in the above table that requires the instrument shell to be opened for inspection, timely contact with the supplier or manufacturer. Users are strictly forbidden to inspect or replace parts without permission. Only manufacturers or agencies can inspect or provide parts.

Appendix: Quant Gene 9600 series wiring



Hangzhou Bioer Technology Co., Ltd.

Hangzhou Bioer Technology Co., Ltd.

1192 BinAn Rd, Binjiang District, 310053 Hangzhou,

PEOPLE'S REPUBLIC OF CHINA

Website: www.bioer.com.cn

Tel: +86-571-85800535，87774558

Fax: +86-571-85800537，87774559

E-mail: oversea@bioer.com.cn

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany