

REAL-TIME FLUORESCENCE QUANTITATIVE PCR SERIES



Suzhou Molarray Co., Ltd.
Profession, Innovation and People oriented



Global Headquarters

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Profession, Innovation and People oriented

Molarray

ABOUT US

Suzhou Molarray Co., Ltd. was established in 2010. As a hi-tech enterprise with molecular diagnosis technology, Molarray is located in the China-Singapore Suzhou Industrial Park (SIP).

Molarray has accumulated self-developed technologies in automatic control, image processing, optical detection, microscopy, liquid circuits, electronic application and software, and has more than 20 patents and 13 software copyrights.

Molarray independently developed the world's leading gene detection platform, automatic liquid extraction platform and automatic microbial detection platform. With these successful technology platforms, it formed the product portfolio of fluorescence quantitative PCR, Loop-mediated isothermal amplification PCR, portable fluorescence quantitative PCR, nucleic acid extraction and loading system, and nucleic acid rapid diagnosis system.

Adhering to the spirit of Profession, Innovation and People oriented, Molarray products serve the global market wholeheartedly.



Development

Qualification & Reputation

THE COMPANY ESTABLISHED

2010

In 2010, Molarray was established in SIP, with 3,000 square meters of production workshop.

R&D/MARKETING CENTER ESTABLISHED

2016

In 2016, the R&D center was established in Canada to realize the integration of research, production and sales.

2017

In 2017, Molarray obtained the manufacturing license for Class III medical devices.

2018

In 2018, MA-1620Q portable qPCR solved a multitude of detection problems during outbreaks of African swine fever.

RAPID DEVELOPMENT

2020

In 2020, Molarray made great contributions to the national epidemic prevention, donated hundreds of equipment, and received the commendation from the State Council.

IPO PREPARATION & EXECUTION

2021

In June 2021, Molarray completed the shareholding system transformation.

2022

Stay true to our original aspiration and forge ahead.



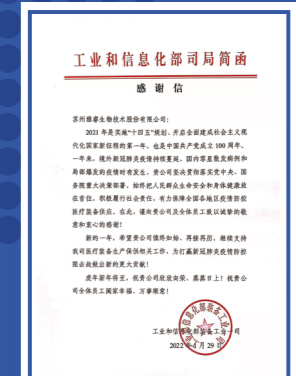
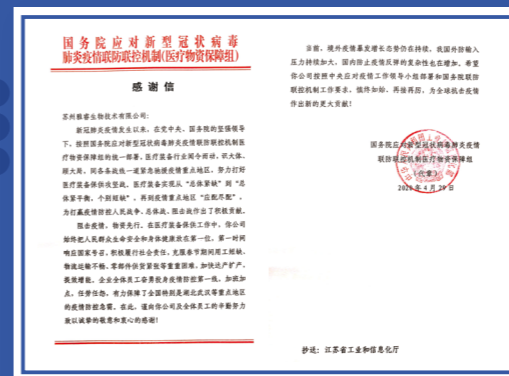
ISO 9001



ISO 13485



CE



Main Products



Technological Innovation

- 2000 >>> Precise and intelligent temp. control over six independent zones for PCR optimization
- 2000 >>> The optical fiber transmission of excitation and emission light, effectively solved the optical edge effect
- 2003 >>> 6 independent channels of fluorescence quantitative multiplex detection
- 2005 >>> The tech of infrared thermal synchronization temp. improved the ramp rate and temp. uniformity
- 2008 >>> Humanized integration of Windows workstation and system
- 2012 >>> Multiple detection of eight independent channels and enabled channels mismatch function
- 2015 >>> Thermal superconducting tech improved the ramp rate and temp. uniformity further

Application Field

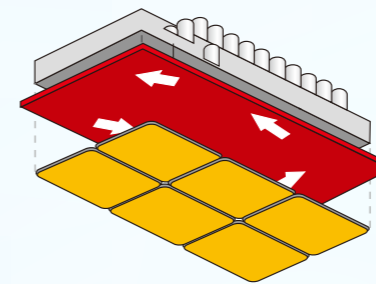
BASIC RESEARCH
 Research on molecular cloning, gene expression and genotyping in scientific research institutes and universities

MEDICAL DIAGNOSIS
 Pathogen detection, genetic screening, tumor diagnosis in medical institutions

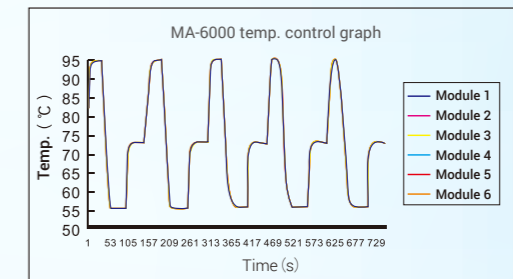
EPIDEMIC PREVENTION AND CONTROL
 Identification and monitoring of epidemics (avian influenza, SARS, dengue fever, etc.) by national systems such as CDC and Customs

TEMP. CONTROL INNOVATION

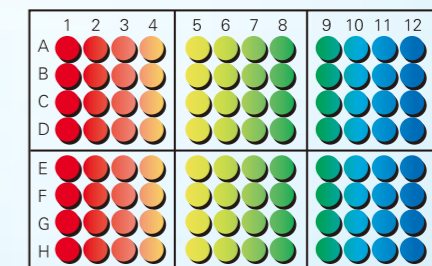
Based on six-zone independent temp. control, using the high efficiency of closed liquid conduction, combining with the auxiliary infrared heating adjusted by the environmental scanning monitoring and intelligent frequency conversion of voltage and current system, to ensure a fast ramp rate and effectively prevent temp. overshoot without the edge effect and evaporation, enable to achieve better temp. uniformity and reproducibility in amplification, while saving time and increasing efficiency.



■ Semiconductor Chilling Plate (Marlow)
 ● Temp. Sensor



6-zone temp. control repeatability graph



Different temp. distributions of plate

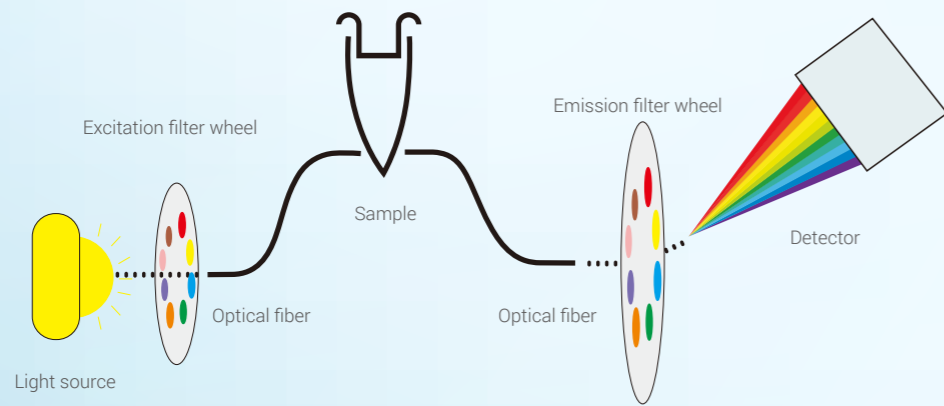
Molarray



Technological Innovation

OPTICAL DETECTION ADVANTAGES

Representing the world's leading optical transmission and collection technology, the optical fiber is used to transmit the excitation and emission light to each reaction well and cooled CCD without attenuation, while ensuring the consistency and authenticity of excitation and detection, improving the detection sensitivity to enable low-copy samples to be effectively detected. The added channel mismatch function extends the application field of qPCR to the protein level, and provides a new way for the construction of multiplex systems of diagnostic reagents.



| Channel | Excitation wavelength (nm) | Emission wavelength (nm) | Examples of fluorescent dyes |
|----------------|----------------------------|--------------------------|------------------------------|
| 1 Blue | 460~480 | 512~528 | FAM/SYBR Green I/EvaGreen... |
| 2 Green | 515~535 | 562~578 | VIC/JOE/HEX/TET... |
| 3 Yellow | 560~580 | 612~628 | ROX/Texas Red... |
| 4 Red | 610~630 | 662~678 | Cy5... |
| 5 Red | 660~680 | 702~718 | Cy5.5/Quasar705... |
| 6 Customizable | | | |

◆ Channel combination: 6-color excitation and emission filter can detect ≥ 21 different fluorescence spectra, ≥ 6 channels are completely open. Supporting the third-party reagent optimization and FRET application.

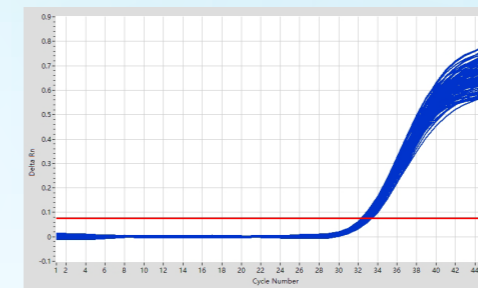
◆ Multi-channel static fluorescence function: Analysis of starting template and end product.

◆ Filters can be customized according to customer needs.

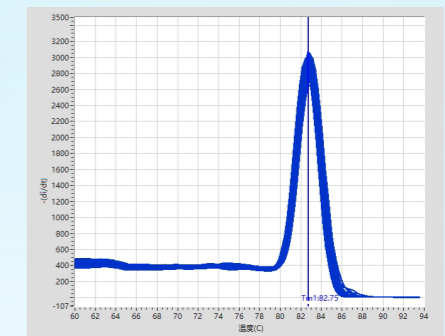
Technological Innovation

HUMANIZED SOFTWARE PLATFORM

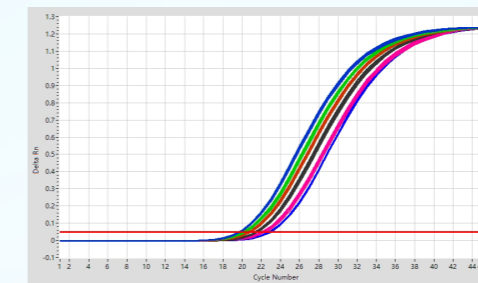
Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, quality control graphic analysis, fluorescence calibration, PCR amplification efficiency, etc.



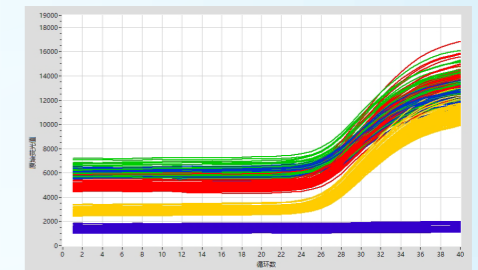
Weak positive repeatability validation



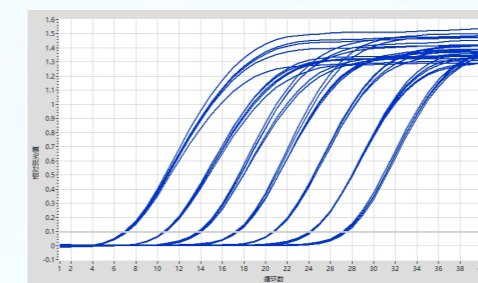
Melting curve validation



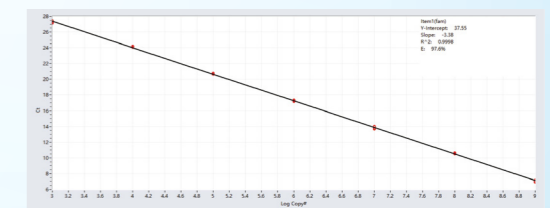
1.5 times effective distinction



Multi-channel experimental curves (FAM, VIC, ROX, Cy5)



10 to 10^{10} copies template validation



10 to 10^{10} gradient standard curve validation

◆ Chinese/English system, suitable for Win7, Win8, Win10, etc.

Main Products



Awarded As Excellent Medical Equipment



FEATURES

- 96*0.2ml, compatible with 8-tube strip and single tube
- 6-zone independent temp. control to set different reaction conditions
- 5-color fluorescence channels and support the custom 6th one
Thermal compensation tech without edge effects, gradient function in wide temp. range
- Maintenance-free long-life continuous-spectrum excitation light source
- Isometric optical fiber conduction tech in excitation and detection
- Simultaneous fast acquisition of 0.15s per color by cooled CCD
- High-resolution melting curve, 1.5 times high sensitivity distinction of relative quantitative
- Support multiple connections to one computer and LIMS/LIS system

MA-6000

SPECIFICATIONS

| Basic | Sample Capacity | 96x0.2ml | |
|--------------------------------|-----------------------------|--|---|
| | Applicable Consumables | 0.2ml single tube, 8x0.2ml tube strip, 96-well plate | |
| | PCR volume range | 10-120µL | |
| | Working Temperature | 15-30°C | |
| | Storage Temperature | -20-55°C | |
| | Ambient Relative Humidity | ≤85% | |
| | Dimensions and Weight | 600*390*320mm (W*D*H), 23kg | |
| | Power | 100-240V, 50Hz, 1500VA | |
| | Temp. Control System | Heating/cooling Method | Peltier, independent and intelligent temp. control over 6 zones |
| | | Temperature range | 4°C-100°C |
| Ramp Rate | | Heating: 3.5°C/S, Cooling: 3.5°C/S | |
| Temperature Accuracy | | ±0.1°C | |
| Temperature Uniformity | | ±0.2°C | |
| Temperature Control technology | | 6-zone independent temp. control combined with thermal compensation tech to reduce edge effect | |
| Gradient Temp. Function | | Yes | |
| Gradient Temp. Columns | | 12 | |
| Gradient Temp. Range | | 1°C-32°C | |
| Gradient Temp. Zones | | 6 | |
| Detection System | Excitation source | Halogen Tungsten Lamp | |
| | Detection Device | -20°C Cooled CCD | |
| | Light Propagation Medium | Dual-96 high temperature resistant optical fibers for Space | |
| | Detection channels | 5 (Enable to 6) | |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 620nm±10nm 5th Channel: 670nm±10nm 6th Channel: Customized | |
| | Detection range | 1st Channel: 512nm-528nm 2nd Channel: 562nm-578nm 3rd Channel: 612nm-628nm 4th Channel: 662nm-678nm 5th Channel: 702nm-718nm 6th Channel: Customizable | |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein;VIC/HEX/TET/Cy3/JOE/Alexa555; ROX/Cy3.5/Texas Red; Cy5/LC Red640; Cy5.5/LC Red705; Tamara | |
| | Detection Sensitivity | ≥1 copy | |
| | Confidence Coefficient | 99.90% | |
| | Sensitivity | Allowed 1.5-fold in single reaction | |
| Software | Software Language | Chinese/English | |
| | Control Method | USB connection to PC, multiple connections, support LIMS/LIS system | |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, key method genotyping (Taqman probe method), Tm value determination, quality control graphic analysis, PCR amplification efficiency, etc. | |
| | Output | EXCEL/WORD/PDF | |
| | Medical Device Registration | CFDA No. 20173401410 | |
| | Safety compliances | CE/ISO9001/ISO13485 | |

Main Products



FEATURES

- 96*0.2ml, compatible with 8-tube strip and single tube
- 6-zone independent temp. control to set different reaction conditions
- 5-color fluorescence channels and support the custom 6th one
- 7 inch high-definition capacitive touch screen, easy to operate
- Support multiple connections to one computer and LIMS/LIS system

MA-9600P

SPECIFICATIONS

| Basic | Sample Capacity | 96x0.2ml | |
|--------------------------------|---------------------------|--|---|
| | Applicable Consumables | 0.2ml single tube, 8x0.2ml tube strip, 96-well plate | |
| | PCR volume range | 15-120µL | |
| | Working Temperature | 15-30°C | |
| | Storage Temperature | -20-55°C | |
| | Ambient Relative Humidity | ≤85% | |
| | Dimensions and Weight | 540*351*310mm (W*D*H), 20kg | |
| | Power | 100-240V, 50-60Hz, 1500VA | |
| | Temp. Control System | Heating/cooling Method | Peltier, independent and intelligent temp. control over 6 zones |
| | | Temperature range | 4°C-100°C |
| Ramp Rate | | Heating: 4.2°C/S, Cooling: 4.2°C/S | |
| Temperature Accuracy | | ±0.1°C | |
| Temperature Uniformity | | ±0.2°C | |
| Temperature Control technology | | 6-zone independent temp. control combined with thermal compensation tech to reduce edge effect | |
| Gradient Temp. Function | | Yes | |
| Gradient Temp. Columns | | 12 | |
| Gradient Temp. Range | | 1°C-32°C | |
| Gradient Temp. Zones | | 6 | |
| Detection System | Excitation source | LED | |
| | Detection Device | PD | |
| | Light Propagation Medium | Dual-96 high temperature resistant optical fibers for Space | |
| | Detection channels | 5 (Expandable to 6) | |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 620nm±10nm 5th Channel: 670nm±10nm 6th Channel: Customized | |
| | Detection range | 1st Channel: 512nm-528nm 2nd Channel: 562nm-578nm 3rd Channel: 612nm-628nm 4th Channel: 662nm-678nm 5th Channel: 702nm-718nm 6th Channel: Customizable | |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE/Alexa555; ROX/Cy3.5/Texas Red; Cy5/LC Red640; Cy5.5/LC Red705; Tamara | |
| | Detection Sensitivity | ≥1 copy | |
| | Confidence Coefficient | 99.90% | |
| | Sensitivity | Allowed 1.5-fold in single reaction | |
| Software | Software Language | Chinese/English | |
| | Control Method | Touch screen operation, connect to PC for data analysis, multiple connections, support LIMS/LIS system | |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, key method genotyping (Taqman probe method), Tm value determination, quality control graphic analysis, PCR amplification efficiency, etc. | |
| | Output | EXCEL/WORD/PDF | |
| | Safety compliances | CE/ISO9001/ISO13485 | |

Main Products



FEATURES

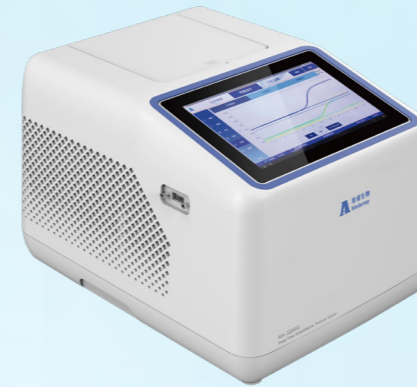
- 48*0.2ml, compatible with 8-tube strip and single tube
- Independent and intelligent temp. control over 4 zones
- 4-color fluorescence channels, applicable for most tests
- Support multiple connections to one computer and LIMS/LIS system
- Run experiments in 30s without preheating time

MA-688

SPECIFICATIONS

| | | |
|----------------------|--------------------------------|--|
| Basic | Sample Capacity | 48x0.2ml |
| | Applicable Consumables | 0.2ml single tube, 8x0.2ml tube strip |
| | PCR volume range | 15-120µL |
| | Working Temperature | 15-30°C |
| | Storage Temperature | -20-55°C |
| | Ambient Relative Humidity | ≤85% |
| | Dimensions and Weight | 466*310*273mm (W*D*H), 17.5kg |
| | Power | 220 V, 50 Hz, 865VA |
| Temp. Control System | Heating/cooling Method | Peltier, independent and intelligent temp. control over 4 zones |
| | Temperature range | 4°C-100°C |
| | Ramp Rate | Heating: 4°C/S, Cooling: 4°C/S |
| | Temperature Accuracy | ±0.1°C |
| | Temperature Uniformity | ±0.15°C |
| | Temperature Control technology | 4-zone independent temp. control combined with thermal compensation tech |
| | Gradient Temp. Function | Yes |
| | Gradient Temp. Columns | 8 |
| | Gradient Temp. Range | 1°C-32°C |
| | Gradient Temp. Zones | 4 |
| Detection System | Excitation source | LED |
| | Detection Device | PD |
| | Light Propagation Medium | Dual-48 high temperature resistant optical fibers for Space |
| | Detection channels | 4 |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 628nm±10nm |
| | Detection range | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm 3rd Channel: 628nm±10nm 4th Channel: 670nm±10nm |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE; ROX/Cy3.5/Texas Red; Cy5 etc |
| | Detection Sensitivity | ≥1 copy |
| | Confidence Coefficient | 99.90% |
| | Sensitivity | Allowed 1.5-fold in single reaction |
| | Sample Detection Repeatability | CV≤1% |
| | Linear Range | 1-10 ¹⁰ |
| Sample Linearity | ≥0.99 | |
| Software | Software Language | Chinese/English |
| | Control Method | Connect to PC for data analysis, USB, support LIMS/LIS system |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, key method genotyping (Tagman probe method), Tm value determination, quality control graphic analysis, PCR amplification efficiency, etc. |
| | Output | EXCEL/WORD/PDF |
| | Medical Device Registration | CFDA No. 20173401410 |
| Safety compliances | CE/ISO9001/ISO13485 | |

Main Products



FEATURES

- 32*0.2ml, compatible with 8-tube strip and single tube
- Independent and intelligent temp. control over 2 zones
- 4-color fluorescence channels, applicable for most tests
- 8 inch high-definition capacitive touch screen, easy to operate
- Support multiple connections to one computer and LIMS/LIS system

MA-3200Q

SPECIFICATIONS

| | | |
|----------------------|--------------------------------|---|
| Basic | Sample Capacity | 32x0.2ml |
| | Applicable Consumables | 0.2ml single tube, 8x0.2ml tube strip |
| | PCR volume range | 15-120µL |
| | Working Temperature | 15-30°C |
| | Storage Temperature | -20-55°C |
| | Ambient Relative Humidity | ≤85% |
| | Dimensions and Weight | 370*280*250mm (W*D*H), 9.7kg |
| | Power | 220 V, 50 Hz, 450VA |
| Temp. Control System | Heating/cooling Method | Peltier, independent and intelligent temp. control over 2 zones |
| | Temperature range | 4°C-100°C |
| | Ramp Rate | Heating: 5.2°C/S, Cooling: 5.2°C/S |
| | Temperature Accuracy | ±0.1°C |
| | Temperature Uniformity | ±0.2°C |
| Detection System | Excitation source | LED |
| | Detection Device | PD |
| | Light Propagation Medium | Optical fibers for Space |
| | Detection channels | 4 |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 628nm±10nm |
| | Detection range | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm 3rd Channel: 628nm±10nm 4th Channel: 670nm±10nm |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE; ROX/Cy3.5/Texas Red; Cy5 etc |
| | Detection Sensitivity | ≥1 copy |
| | Confidence Coefficient | 99.90% |
| | Sensitivity | Allowed 1.5-fold in single reaction |
| | Sample Detection Repeatability | CV≤1% |
| | Linear Range | 1-10 ¹⁰ |
| Sample Linearity | ≥0.99 | |
| Software | Software Language | Chinese/English |
| | Control Method | 8 inch touch screen operation and data analysis, multiple connections, support LIMS/LIS system |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, Tm value determination, quality control graphic analysis, PCR amplification efficiency, etc. |
| | Output | EXCEL/WORD/PDF |
| | Medical Device Registration | CFDA No. 20223220527 |
| Safety compliances | CE/ISO9001/ISO13485 | |

Main Products



FEATURES

- Small size and light weight for outdoor experiments
- 16*0.2ml, compatible with 8-tube strip and single tube
- 3-color fluorescence channels, applicable for various tests
- 7 inch high-definition capacitive touch screen, easy to operate
- Convenient and efficient multiple connections

MA-1600Q Series

SPECIFICATIONS

| | | | | |
|--------------------------------|---------------------------|---|--|---|
| Basic | Sample Capacity | 16x0.2ml | | |
| | Applicable Consumables | 0.2ml single tube, 8x0.2ml tube strip | | |
| | PCR volume range | 15-120µL | | |
| | Working Temperature | 4-35°C | | |
| | Storage Temperature | -20-55°C | | |
| | Ambient Relative Humidity | ≤85% | | |
| | Dimensions and Weight | 320*250*155mm (W*D*H), 4.5kg | | |
| Temp. Control System | Power | 220 V, 50 Hz, 180VA, optional external battery | | |
| | Heating/cooling Method | Peltier, intelligent temp. control | | |
| | Temperature range | 4°C-100°C | | |
| | Ramp Rate | Heating: 4°C/S, Cooling: 4°C/S | | |
| | Temperature Accuracy | ±0.1°C | | |
| Detection System | Excitation source | LED | | |
| | Detection Device | PD | | |
| | Light Propagation Medium | Optical fibers for Space | | |
| | Detection channels | 2 | 3 | 4 |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 628nm±10nm |
| | Detection range | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm 3rd Channel: 620nm±10nm | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm 3rd Channel: 628nm±10nm 4th Channel: 670nm±10nm |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE/Alexa555, etc. | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE/Alexa555; ROX/Cy3.5/Texas Red, etc. | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE/Alexa555; ROX/Cy3.5/Texas Red; Cy5/LC Red640, etc. |
| | Detection Sensitivity | ≥1 copy | | |
| | Confidence Coefficient | 99.90% | | |
| | Sensitivity | Allowed 1.5-fold in single reaction | | |
| Sample Detection Repeatability | CV≤1% | | | |
| Linear Range | 1-10 ¹⁰ | | | |
| Sample Linearity | ≥0.99 | | | |
| Software | Software Language | Chinese/English | | |
| | Control Method | 7 inch touch screen operation and data analysis | 7 inch touch screen operation and data analysis, multiple connections, support LIMS/LIS system | |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, automatic establishment of standard curve, absolute/relative quantification, multiple quantification, melting curve, gene mutation, Tm value determination, quality control graphic analysis, PCR amplification efficiency, etc. | | |
| | Output | EXCEL/WORD/PDF | | |
| Medical Device Registration | CFDA No.20203220944 | | | |
| Safety compliances | CE/ISO9001/ISO13485 | | | |

Main Products



FEATURES

- Handheld, small and light for outdoor experiments
- 3*0.2ml reaction module
- 4-color fluorescence channels, applicable for most tests
- Bluetooth tablet connection, easy to operate

P30

SPECIFICATIONS

| | | |
|--------------------------------|-------------------------------------|--|
| Basic | Sample Capacity | 3x0.2ml |
| | Applicable Consumables | 0.2ml single tube |
| | PCR volume range | 20-120µL |
| | Working Temperature | 15-35°C |
| | Storage Temperature | -20-55°C |
| | Ambient Relative Humidity | ≤85% |
| | Dimensions and Weight | 130*130*220mm (W*D*H), 2kg |
| Temp. Control System | Power | 100-240V, 50-60Hz, 180VA, optional external battery |
| | Heating/cooling Method | Peltier, independent and intelligent temp. control |
| | Temperature range | 4°C-100°C |
| | Ramp Rate | Heating: 7.5°C/S, Cooling: 7.5°C/S |
| | Temperature Accuracy | ±0.1°C |
| Detection System | Temperature Uniformity | ±0.2°C |
| | Excitation source | LED |
| | Detection Device | PD |
| | Light Propagation Medium | Optical fibers for Space |
| | Detection channels | 4 |
| | Excitation range | 1st Channel: 470nm±10nm 2nd Channel: 525nm±10nm 3rd Channel: 570nm±10nm 4th Channel: 628nm±10nm |
| | Detection range | 1st Channel: 520nm±10nm 2nd Channel: 570nm±10nm 3rd Channel: 628nm±10nm 4th Channel: 670nm±10nm |
| | Dye compatibility (name) | FAM/SYBR Green/Eva Green/LC Green/Fluorescein; VIC/HEX/TET/Cy3/JOE/Alexa555; ROX/Cy3.5/Texas Red; Cy5/LC Red640 etc. |
| | Detection Sensitivity | ≥1 copy |
| | Confidence Coefficient | 99.90% |
| Sensitivity | Allowed 1.5-fold in single reaction | |
| Sample Detection Repeatability | CV≤1% | |
| Linear Range | 1-10 ¹⁰ | |
| Sample Linearity | ≥0.99 | |
| Software | Software Language | Chinese/English |
| | Control Method | Bluetooth tablet connection, breakpoint signal acquisition |
| | Software Function | Real-time monitoring, automatic identification and calculation of positive and negative results, report export |
| | Output | EXCEL/WORD/PDF |
| Safety compliances | CE/ISO9001/ISO13485 | |