KURABO

# Operation Manual

## Automated Nucleic Acid Isolation System

# QuickGene-Auto240L


CE

Ver. 1.0.1

# Introduction

Thank you very much for purchasing our Automated Nucleic Acid Isolation System QuickGene-Auto240L (hereafter referred to as "this system"). This document contains important information about correct and safe use of the functions of this system. Before using, **be sure to read this document**. For quick reference, please keep this document within easy reach of this system.

## Application of Infectious Waste Rules

If a potentially infectious sample is to be disposed of after use, it should be treated with incineration, melting, sterilization, disinfection, etc. in accordance with the rules at your facility (institute) or relevant laws because it is classified as infectious industrial waste.
If disposal is outsourced, use a licensed contractor as a waste disposer of industrial waste subject to special control together with a manifest of industrial waste subject to special control.


Biohazard Symbol

## ■Disclaimer

- **The contents of this document are subject to change without prior notification.**
- **Our company shall not be liable for:**
  - **Any violation of patent right of a third party or other rights through use of data described in document.**
  - **Any failure or damage caused by installation, relocation, remodeling, maintenance or repair carried out by any party other than our company or other than a contractor designated by our company**
  - **Any failure or damage of our product caused by a product delivered by other than our**
  - **Any failure or damage caused by remodeling, maintenance, repair, etc. using any parts other than genuine parts designated by our company**
  - **Any failure or damage resulting from non-compliance with precautions and operation procedures described in this document**
  - **Any failure or damage due to deviation in surrounding conditions from the conditions of use of this system, such as power source or installation environment**
  - **Any failure or damage caused by fire or natural disasters such as earthquake, flood, lightning, etc.**
- **Unauthorized reproduction in whole or in part of the contents of this document is prohibited.**

# How to Read This Document

## Warning Labels

The precautions required for the safe use of this system are described in this document.

Be sure to read the precautions and thoroughly understand the contents before using this system.

SAFETY SYMBOLS:

**"Warning" indicates the risk of death or serious injury if not avoided.**

**Warning: "Warning" indicates a risk of death or serious injury.**

**Biohazard: "Biohazard" indicates a risk of infection.**

**Caution: "Caution" indicates a risk of lighter or moderate injury, or property damage.**

**Important: "Important" indicates critical or prohibited actions.**

**Note: "Note" indicates precautions, instructions to abide by, supplemental explanations, etc.**

# Precautions for Use

For safe use of this system, please abide by the safety descriptions below.

## Symbol

Please check all contents carrying this symbol.

## System

**Warning:**

- **If the following are not abided by, fire or electric shock may result.**
  - **Use the power cable supplied with this system.**
  - **Connect to a power outlet with a grounding terminal.**
  - **Do not handle the power plug with wet hands.**
  - **Do not use with a voltage other than the indicated voltage, and avoid branch connections or extension cords.**
  - **Do not use with a damaged power plug or loose outlet.**
  - **With a dry cloth, wipe off any dust completely from the power plug electrode and the outlet.**
  - **Do not pull on the power cable, but be sure to grip the power plug to remove from the outlet.**
  - **Remove the power plug from the outlet for safety during maintenance work.**
  - **Do not touch the power plug when thunder is heard or lightning is seen.**
  - **When a breaker is shut off, leakage is possible. Do not disassemble this system.**
- **Do not spill liquid on this system. Do not place a container of liquid on this system. It may failure, fire or electric shock.**
- **If heat, smoke or a strange odor is generated by the system, remove the power plug from the outlet.**

**Caution:**

- **Any remodeling of this system without authorization by our company is prohibited. Fire or electric shock may result.**
- **Do not place any object on this system. Do not drop any object onto or cause shock to the system. A system failure or malfunction may occur.**
- **Do not ride above this system. Falling and injury may occur.**
- **If any liquid, etc. adheres to this system, promptly wipe it off with soft paper, etc. System damage may result.**
- **The sliding doors, flap doors and drawers are not fixed halfway. Releasing halfway or leaving them open will cause injury or system failure.**
- **In this system, the noise peak during operation is more than 63dB(A) and less than 70dB(A).**
- **Wear protective gloves when replacing consumables.**
- **If ethyl alcohol is spilled, promptly remove power plug from outlet.**
- **Repair of this system must be conducted by a contractor designated by our company.**
- **Use genuine parts designated by our company.**
- **The repair of this system shall be conducted by a contractor designated by our company.**
- **Use reagents and consumables included in our genuine parts and reagent kits.**

## Overvoltage Categories

**Warning:**

**This system is an overvoltage category II device.**

**Be sure to use the power cable delivered with the system.**

**NB: Overvoltage category II indicates a device that consumes energy supplied from stable wiring (a permanent outlet, etc.)**

## QuickGene-Auto240L Kit

(Hereafter, the QuickGene-Auto240L Kit is referred to as a "dedicated kit" in this document.)

**Caution:**

- **Refer to the procedures for use of the dedicated kit in the handbook attached to the kit.**
- **Handle the reagents in the kit in accordance with the safety precautions for handling and use.**
- **Use in a laboratory or work space suitable for isolation work.**

| QuickGene-Auto240L Kit List | |
|---|---|
| **Whole Blood DNA Reagent Kit** | **QuickGene DNA whole blood kit L (DB-L)** |
| **Consumable Supply Kit** | **QuickGene-Auto240L Consumables Kit (QG-240L-CK)** |

**NB:** These products are not included in this system package. Please purchase separately.

## Reagents Used for Other than Dedicated Kits

**Caution:**

- **For reagents used for other than a dedicated kit, the work should be carried out in accordance with the safety precautions for handling and use of each reagent.**
- **Use in a laboratory or work space suitable for isolation work. Some reagents must be prepared in a draft chamber.**

## Cleaning Agents for Cleaning or Washing

**Caution:**

- **Work with agents for cleaning or washing the main unit and its accessories should be conducted in accordance with the safety precautions for handling and use of each cleaning agent.**

**Biohazard:**

- **Ethyl alcohol is an inflammable substance. Do not use in the proximity of open fire.**
- **Wear proper gloves, mask and protective goggles for cleaning work.**

## Samples

**Biohazard:** **Use proper gloves, mask and protective goggles for handling samples with a risk of infection.**

# Laser Standards

**The laser sensor used in this system for detecting the workpiece/consumables is classified as "Class 1" according to standard IEC60825-1 in accordance with stipulation in FDA Laser Notice No. 50.**

**The barcode reader (light source component) for reading the barcode on blood sample collection tubes is classified as “Exempt Group” in accordance with standard IEC62471.**

**The 2-dimensional barcode reader (target pointer component for reading position adjustment) for reading the code on collection tubes is classified as "Class 1" in standard IEC60825-1 in accordance with stipulation in FDA Laser Notice No. 50.**

**NB: The 2-dimensional barcode reader is an optional component for this system. It is implemented only when included as an option.**

**Warning:** **Do not attempt to peer into the system and directly view the barcode reader or 2-dimensional code reader red light source during the sample ID reading operation. Direct viewing at length may cause eye disorders.**

**Warning:** **Operation with a procedure other than indicated in the operation manual may lead to exposure to dangerous laser irradiation.**

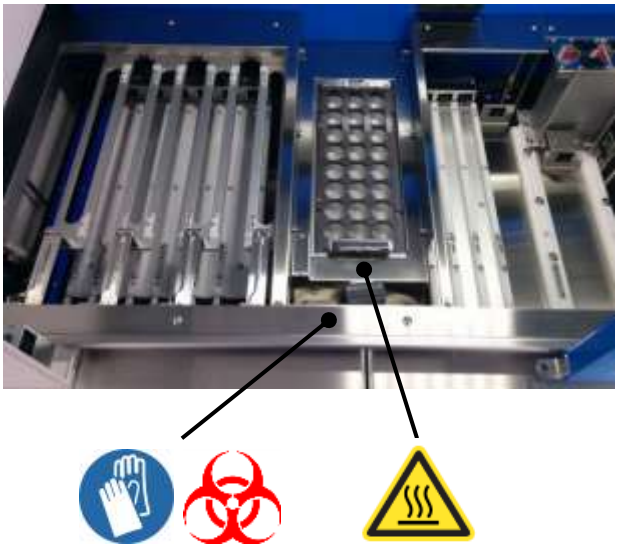
| Laser Device Specification | | |
|---|---|---|
| **Specification/Name** | **Laser Sensor (for detection of workpiece/consumables)** | **2-Dimensional Code Reader (for reading collection tube information)** |
| **Wavelength (nm)** | **655** | **660** |
| **Output (mW)** | **0.39** | **0.06** |
| **Coverage Angle (°)** | **X direction: 0.20<br>Y direction: 0.53** | **-** |
| **Laser Class** | **CLASS 1 Laser Product (IEC60825-1：2007 FDA (CDRH) Part 1040.10)** | **CLASS 1 Laser Product (IEC60825-1：2007 FDA (CDRH) Part 1040.10)** |

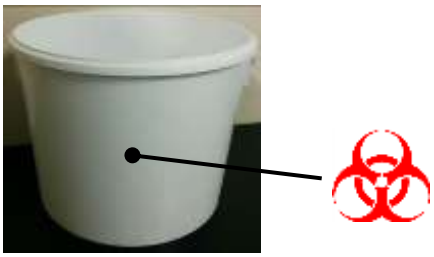
# Ultraviolet Light (UV) Irradiating Function

**Warning:** **Operation of the UV irradiating function of this system will cause a small quantity of ultraviolet leakage from the sliding door window, fan area, joints with exteriors, etc. Exposure to ultraviolet light may cause damage such as eye or skin irritation. Avoid exposure of skin or eyes to ultraviolet light.**

# Warning Labels

Warning, caution, instruction and obligation labels are affixed to this system.








**: Wear protective equipment**

**This system may become contaminated with infectious substances, etc. When inserting your hands into the system, be sure to wear protective gloves.**

**: Biohazard Risk Label**

**This label indicates a biohazard risk.**

**Warning: Hot Surface**

**Risk of burns: do not touch immediately after operation.**

**Warning: Laser Light**

**Direct viewing of the laser light source may cause eye damage. Do not directly view the laser light at length.**


**Warning: UV**

**Do not work for a long time in the proximity during UV irradiation. Risk of damage to eyes and skin.**


**Caution: Damage**

**Do not apply force to the flap door by leaning or sitting on it or by placing any objects on it. Doing so may cause damage or injury.**

# Restrictions on Use

This section indicates the restrictions on use of QuickGene-Auto240L and QuickGene Consumables.

- **No liability is assumed for the results regardless of the purpose of use.**
- **Validation of performance on samples shall be based on the judgment and responsibility of the user.**

When using this system, please thoroughly read this document and abide by the safety rules of your facility.

# Contents

# INDEX

# 1 System Installation Procedures

The installation procedures for this system are explained below.



## 1.1 Conditions for Installation, Operating Environment

The conditions for system installation and the operating environment are explained here.

### ■ Conditions for Installation

**Warning**

- **Do not install this system where water may be poured or spilt, which may failure, fire or electric shock.**
- **Be sure to remove the power plug from the outlet whenever this system is moved. Watch your step carefully while operating. Injury, fire or electric may result from a damaged power cable.**

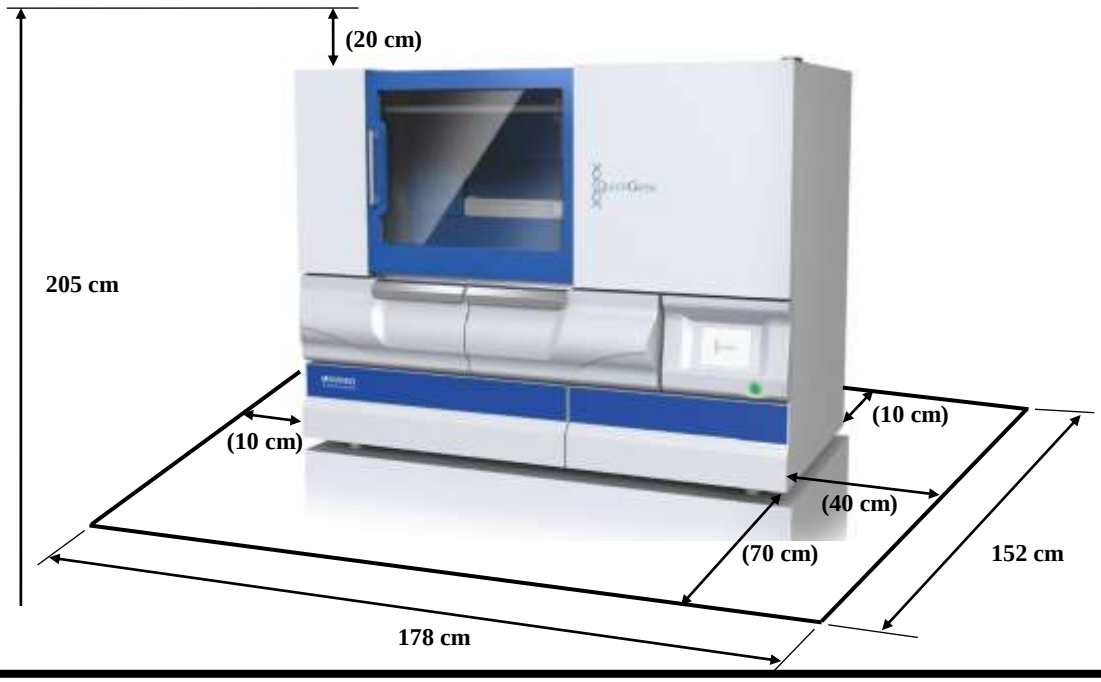
**Caution:**

- **Do not install this system in a location with intense vibration or at an unstable incline. This may cause injury or failure.**
- **Do not install this system in a location exposed to direct sunlight or in the proximity of a heating or cooling appliance. This may cause a shortened lifetime or failure.**

Please install this system in an indoor location as shown below for normal, safe use.

- **A location with the following secure space for installation.**

**Required footprint: Width ≧178 cm × Depth ≧152 cm × Height ≧205 cm (when placed on an 80-cm high experiment table)**



**A location with a secure power source (This system is an overvoltage category II device. Be sure to use the included power cable.)**

- **Operating temperature 15°C-30°C, room humidity 30%-80% (no condensation)**
- **A stable horizontal location with load-bearing capacity of ≧350kg and minimal vibration.**
- **A location not exposed to direct sunlight or strong light (Use a curtain, blind, etc. for obstructing light as necessary.)**
- **A location with good ventilation and minimal dust**
- **A location with no abrupt variation in temperature (Swift heating of a very cold room or moving this system from a lower temperature to a warm place, etc. will generate water droplets in the system (condensation), and the isolation result will be adversely influenced.)**
- **A location where temperature and humidity within the specified ranges can be maintained (Water faucets, boilers, coolers, heaters, etc. should not be in proximity.)**
- **A location where strong magnetism (motors, transformers, televisions, speakers, magnets, etc.) is not in proximity (Approaching a magnetic source will cause malfunction.)**

## ■ Operating Environment

| Item | | Specification |
|---|---|---|
| Temperature (ºC) | In operation | 15-30 |
| | During standby | 15-30 |
| Humidity (%) | In operation | 30-80 |
| | During standby | 10-80 |
| Max. Wet-bulb Temp. (ºC) | In operation | 29 (no condensation) |
| | During standby | 29 (no condensation) |
| Temperature Gradient (ºC / Hr) | | ≦12 (no condensation) |
| Humidity Gradient (% / day) | | ≦30 (no condensation) |
| Altitude (m) | | Use at ≦1600 |

## 1.2 How to Open the Package

Refer to the separately attached "**QuickGene-Auto240L unpacking instruction**"

## 1.3 How to Remove the Interior Packing Material and Fixtures

Refer to the separately attached "**QuickGene-Auto240L Fixture Removing Procedures**".

# 1.4 Checking of Packed Contents

Please check that the accessories, operation manual and warranty certificate for the system main unit are included in the box.

If any item is missing, please contact our customer consultation desk.



□ **System Main Unit**

□ **Operation Manual**

□ **Power Cable**

□ **Reagent Container Holder**

□ **Sample Tip Holder**

□ **Reagent Tip Holder**

□ **Sample Holder ×3**

□ **Cartridge Holder ×3**

□ **Waste Tube Holder ×3**

□ **Collection Tube Holder ×3**

□ **Waste Container**

□ **Wash Buffer Bottle**

□ **Reagent Container S ×3**

□ **Reagent Container L ×4**

□ **UV Lamp**

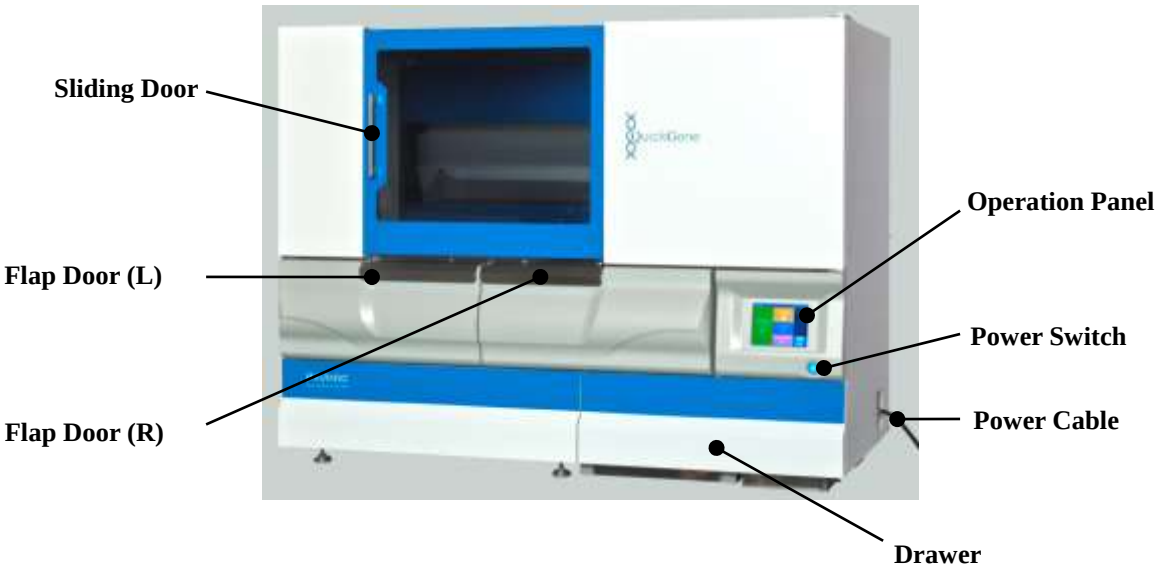
**Caution:**

**Note: Use power cables, holders, containers included in package**

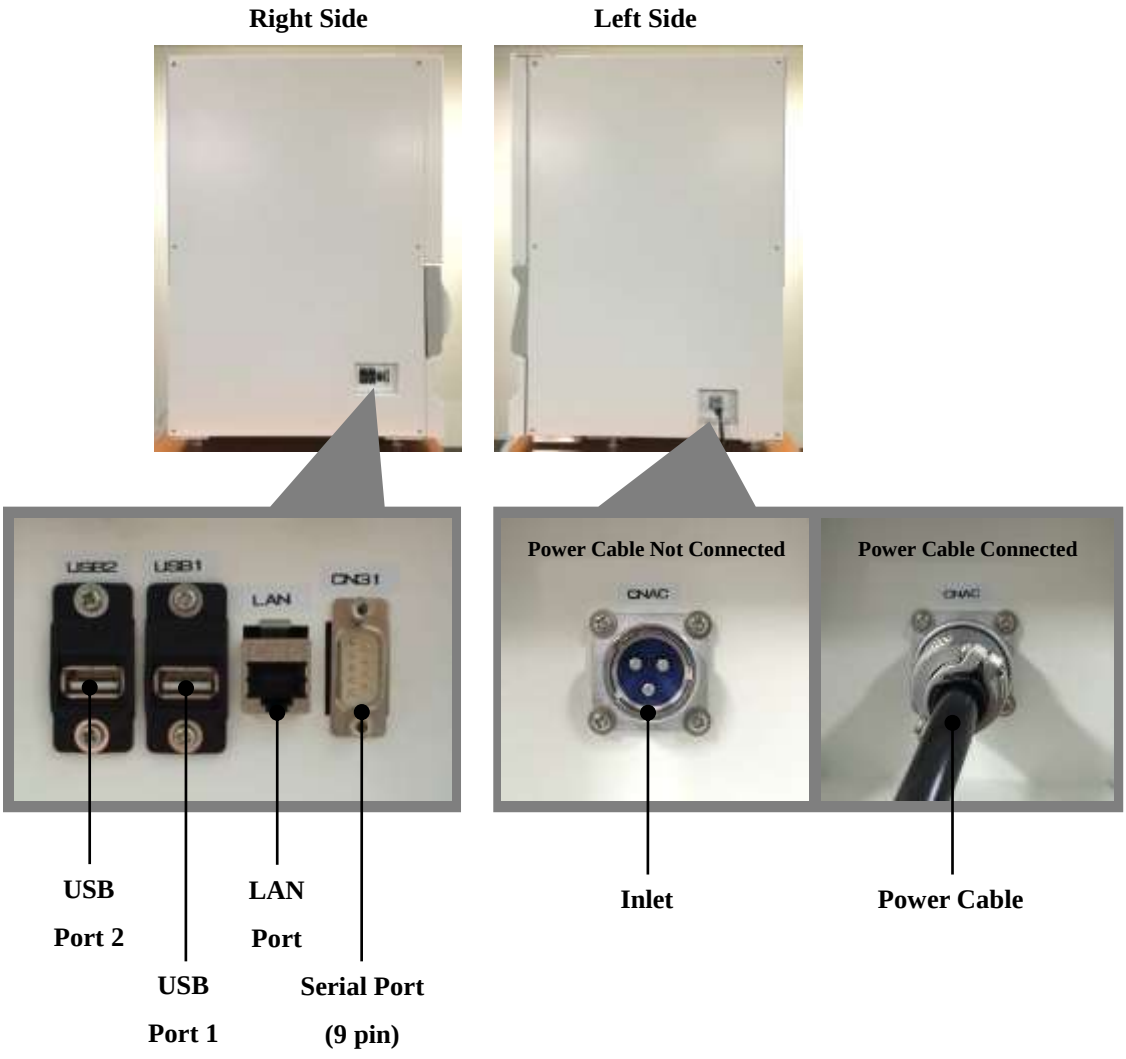
# 1.5 Names of Parts

The names of system parts and their functions are explained below.

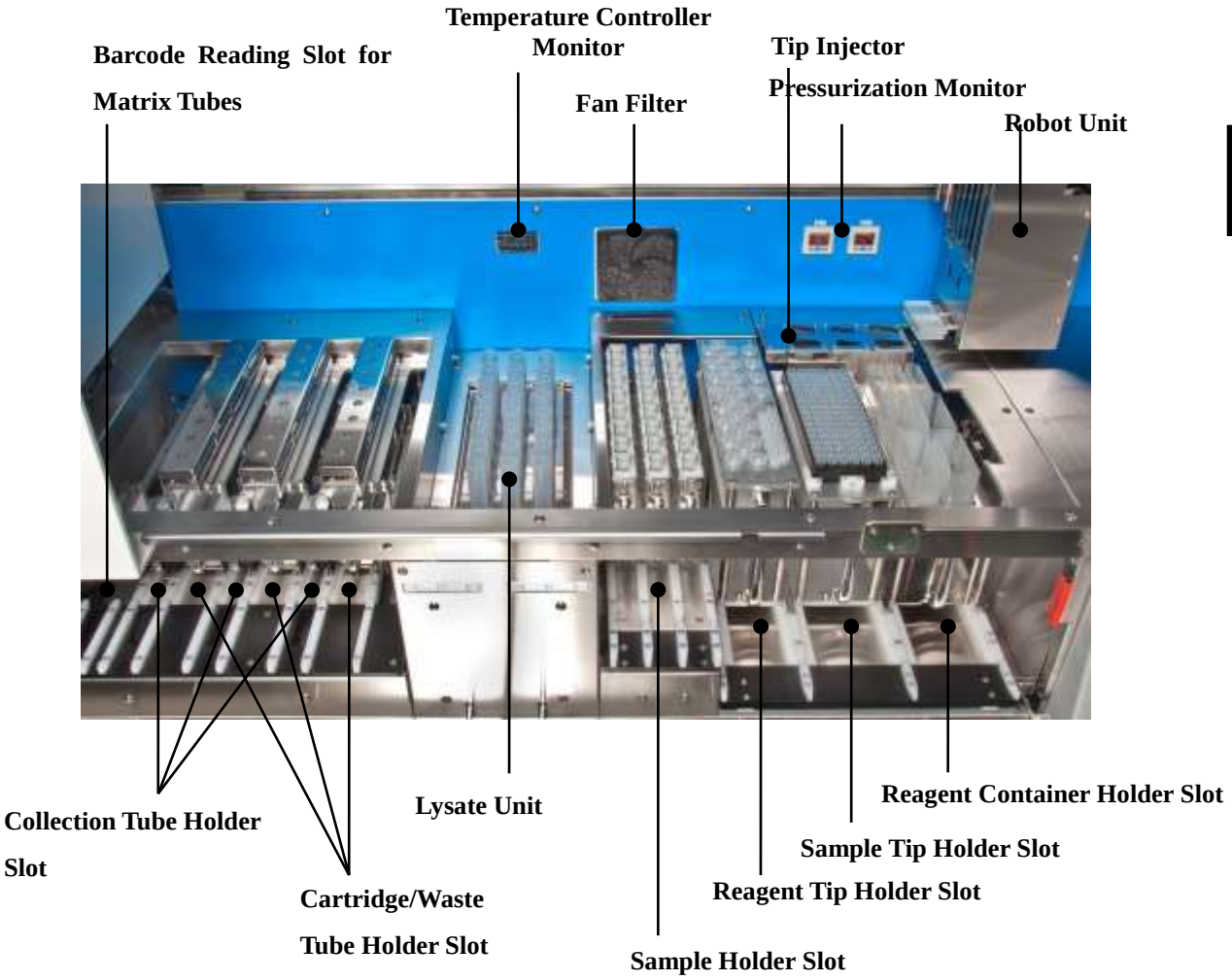
## ■ System Front View



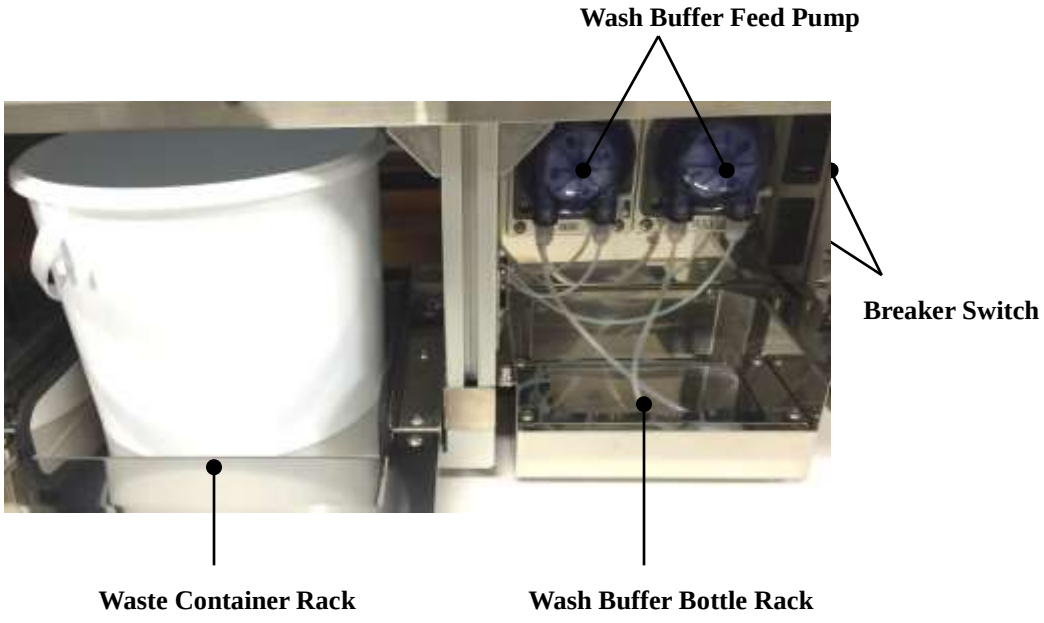

## ■ System Side View



## ■ Work Area



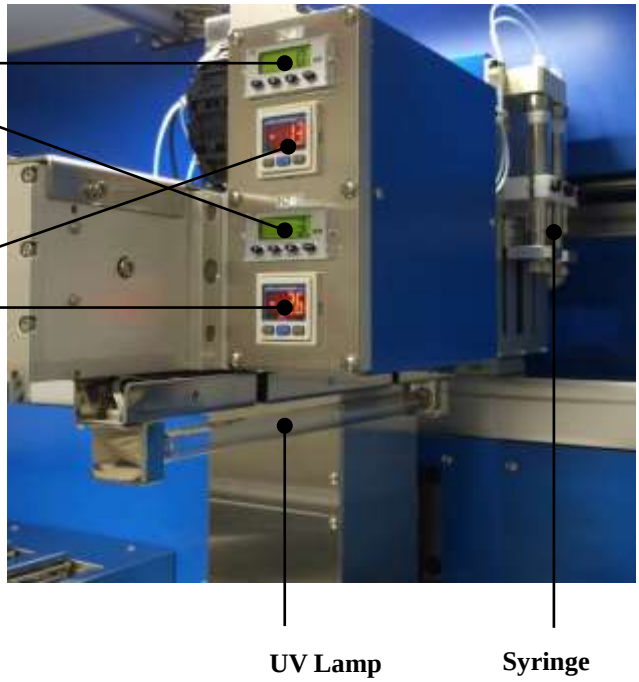

## ■ Inside Drawer



1

## ■ Robot Unit


Laser Sensor (Rear)
[For detection of
Work/Consumables]
Wash Buffer Nozzle
Pressurizing Nozzle/
Pressurizing Packing
Dispenser
Drip Tray


Level Detection
Monitor Panel
Tip Pressure
Monitor Panel
UV Lamp
Syringe

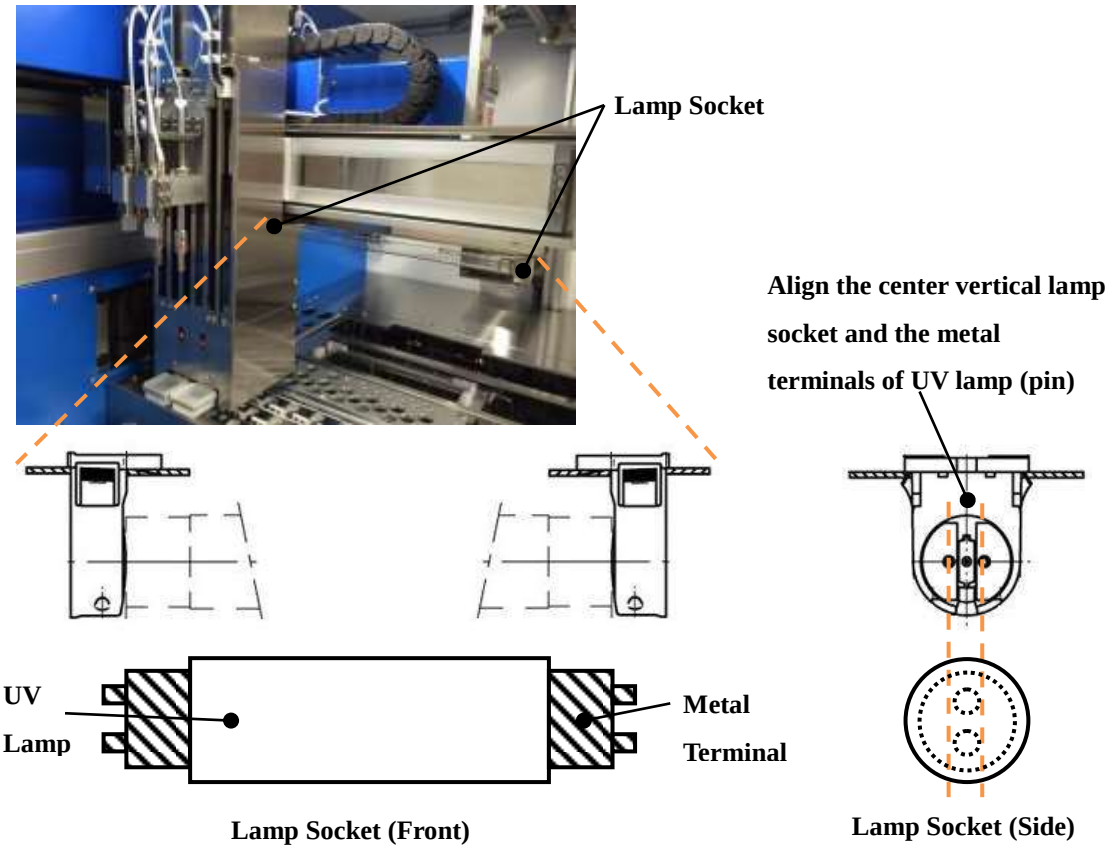
# 1.6 Mounting of UV Lamp

The mounting procedures for the UV lamp are explained below.

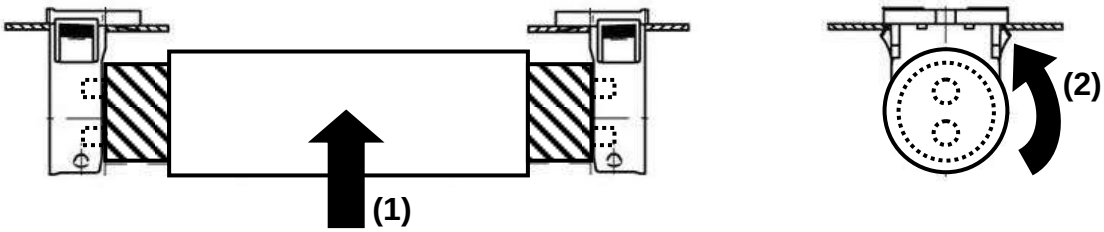
Mount the UV lamp (1 pc) included in the package onto the lamp socket in the system.



**■Align the UV lamp metal terminals and the lamp socket inserting position.**




**■Insert the UV lamp and mount on the lamp socket**




(1) Insert the UV lamp along the vertical groove of the lamp socket (to the end).

(2) Turn the UV lamp 90° to mount on the lamp socket. (Turn until a clicking sound is heard.)

**NB: To remove the UV lamp, follow the reverse order of above.**

## 1.7 Checking the System Functions

The checking procedures for the functioning of this system are explained below.



A functioning check should be conducted after opening the system package, removing the interior packing materials and fixtures, and checking the contents of the package.
The functioning check should be conducted using nuclease-free water in place of the reagent (sold separately) and the dedicated kit sample, using the same procedure as for a normal isolating operation.
Refer to "3. How to Operate" for separating operation.

## 1.8 Precautions for Storage

The precautions for storing this system are as follows:

- **Do not store this system while connected to the power source.**
- **Do not store in an unstable location.**
- **Store after disposal of used consumables and reagents.**
- **Strong stains inside and outside the system should be cleaned before storage. ***
- **Clean the fluid feeding line with wash buffer before storage.***
- **If the system will be stored for a lengthy period, place an appropriate cover over it for protection from dust and staining.**

*** Refer to "7 Daily Inspections and Maintenance"**

# 2 Basic Functions

The QuickGene-Auto240L is a system that can isolate high-purity and high-yield DNA in a short time. All of the processes from the primary tube (from 2 mL of whole blood) to the collection of DNA are automatically processed within the system. The DNA is isolated in the collection tube on the dedicated holder set.

The basic functions of this system are explained as follows:



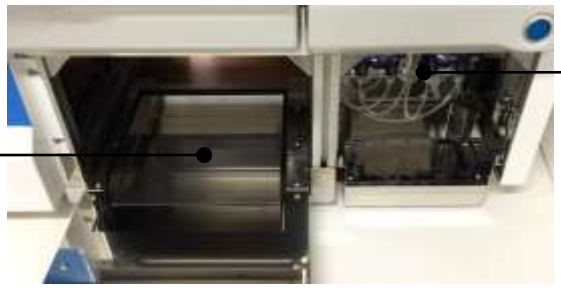
## 2.1 Components Configuring the System

The major components of this system are shown:

### ■ View of the System


### ■Work Area

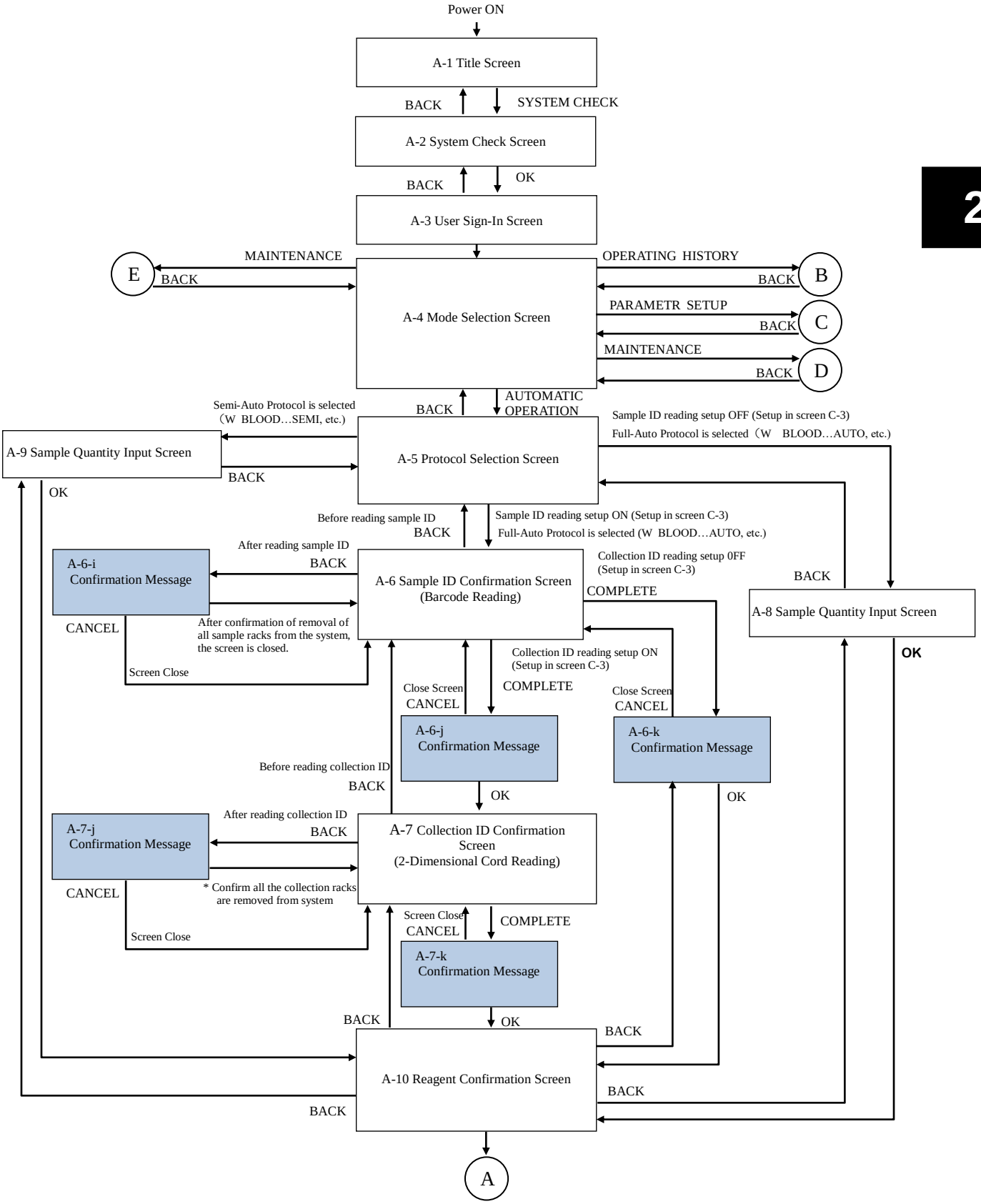

### ■Inside Drawer



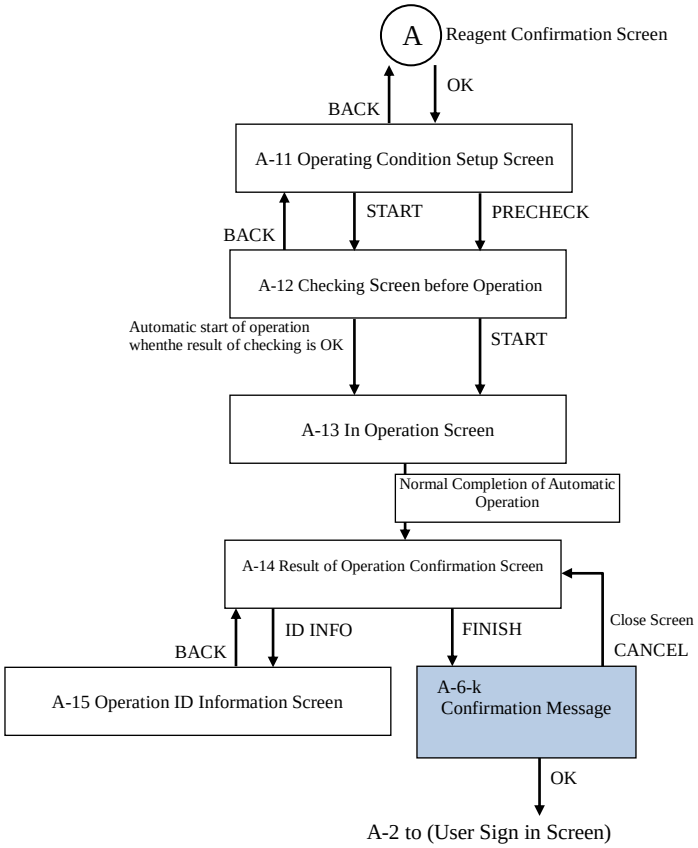
| No. | Component | Functions |
|---|---|---|
| 1 | Entry Zone | Open the sliding door and set the sample processing container (lysate tube). Fully open for daily inspection, care and maintenance. |
| 2 | Holder Slot Zone | The holders are set in the system through this opening. |
| 3 | Operation Zone | Isolating operation, checking operation histories, barcode information management, parameter changes, UV irradiation, etc. are conducted via a touch panel. |
| 4 | Power Switch | Turns ON/OFF power. Power ON is indicated with LED light ON and power OFF with LED light OFF. |
| 5 | Isolation Unit | Consists of cartridge holder, waste tube holder and collection tube holder. Processes the adsorption of nucleic acid on the membrane, washing and elution. |
| 6 | Lysate Unit | The agitation unit and heater are activated, the sample and reagent are mixed in the set lysate tube, and the preparation of lysate is processed. On the upper surface of the unit an openable agitator cover is attached to prevent the lysate tube from ejecting. |
| 7 | Robot Unit | The activated dispenser, pressurizing nozzles and wash buffer nozzles feed the fluid, pressurize the cartridge, and add the wash buffer.<br>Work progress detection with the laser sensor and ultraviolet light irradiation using the UV lamp are conducted within the operable range in the work area. |
| 8 | Tip Ejector | The mounted tip on the dispenser is inserted or ejected. |
| 9 | Sample Setting Zone | The sample holders are set. |
| 10 | Consumables Setting Zone | Reagent container holders, sample tip holders and reagent tip holders are set. |
| 11 | Tip Disposal Zone | The tips consumed by the isolating operation are collected in a waste container set in the disposal zone by the tip ejector. |
| 12 | Fluid Feeding Zone | The wash buffer used for isolation is fed from the feeder zone to the wash buffer nozzle of the robot unit in accordance with the isolation program. |

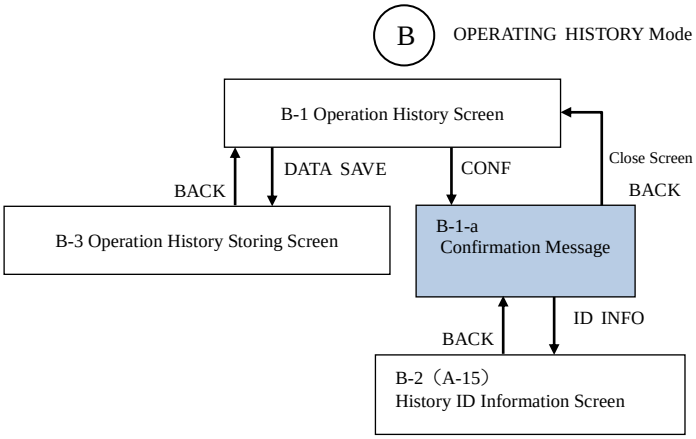
# 2.2 Basic Operations, Basic Functions

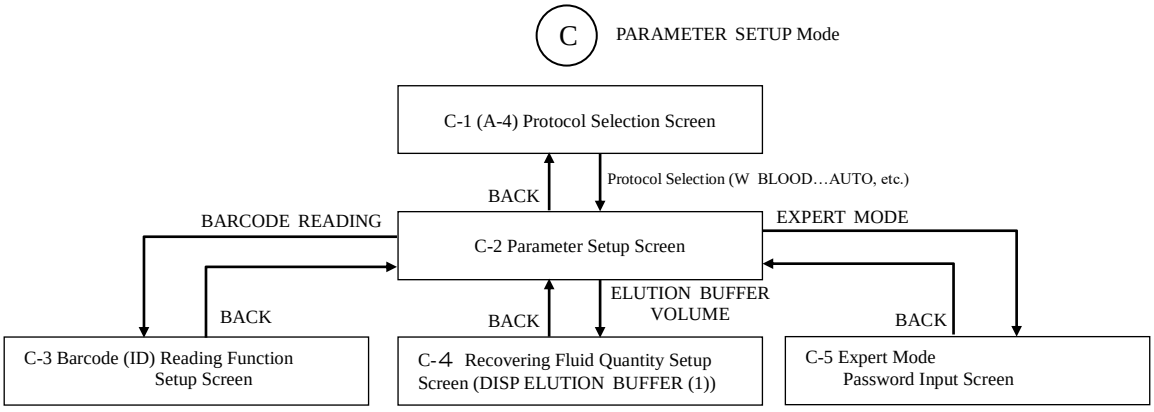
The system operation flow is as follows:

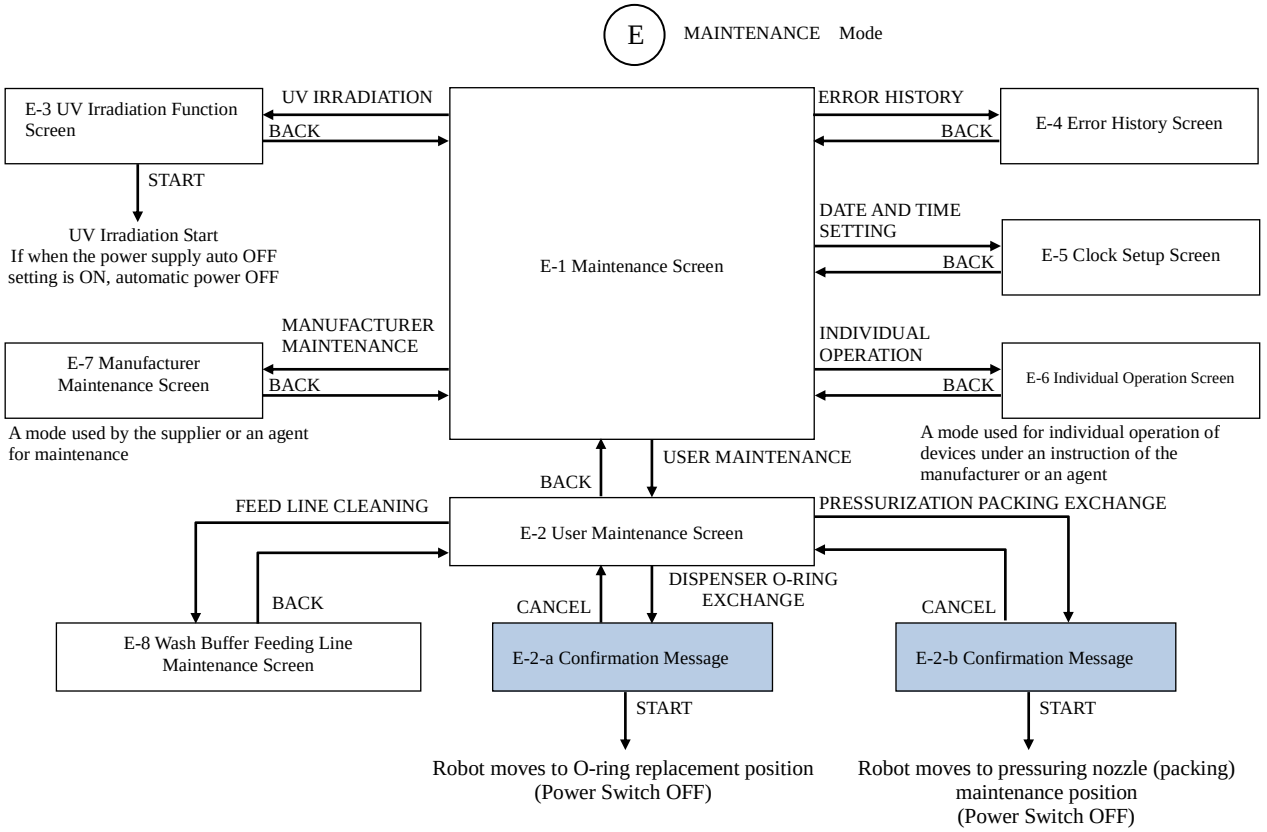


2


A
Reagent Confirmation Screen
OK
BACK
A-11 Operating Condition Setup Screen
START
PRECHECK
BACK
A-12 Checking Screen before Operation
Automatic start of operation whenthe result of checking is OK
START
A-13 In Operation Screen
Normal Completion of Automatic Operation
A-14 Result of Operation Confirmation Screen
Close Screen
CANCEL
ID INFO
FINISH
BACK
A-15 Operation ID Information Screen
A-6-k
Confirmation Message
OK
A-2 to (User Sign in Screen)


B
OPERATING HISTORY Mode
B-1 Operation History Screen
Close Screen
DATA SAVE
CONF
BACK
BACK
B-3 Operation History Storing Screen
B-1-a
Confirmation Message
ID INFO
BACK
B-2（A-15）
History ID Information Screen


C
PARAMETER SETUP Mode
C-1 (A-4) Protocol Selection Screen
Protocol Selection (W BLOOD…AUTO, etc.)
BACK
BARCODE READING
EXPERT MODE
C-2 Parameter Setup Screen
ELUTION BUFFER VOLUME
BACK
BACK
BACK
C-3 Barcode (ID) Reading Function Setup Screen
C-4 Recovering Fluid Quantity Setup Screen (DISP ELUTION BUFFER (1))
C-5 Expert Mode Password Input Screen


E
MAINTENANCE Mode
E-3 UV Irradiation Function Screen
UV IRRADIATION
BACK
START
UV Irradiation Start
If when the power supply auto OFF setting is ON, automatic power OFF
E-1 Maintenance Screen
ERROR HISTORY
BACK
E-4 Error History Screen
DATE AND TIME SETTING
BACK
E-5 Clock Setup Screen
MANUFACTURER MAINTENANCE
E-7 Manufacturer Maintenance Screen
BACK
A mode used by the supplier or an agent for maintenance
INDIVIDUAL OPERATION
BACK
E-6 Individual Operation Screen
A mode used for individual operation of devices under an instruction of the manufacturer or an agent
BACK
USER MAINTENANCE
FEED LINE CLEANING
E-2 User Maintenance Screen
PRESSURIZATION PACKING EXCHANGE
BACK
E-8 Wash Buffer Feeding Line Maintenance Screen
CANCEL
DISPENSER O-RING EXCHANGE
E-2-a Confirmation Message
START
Robot moves to O-ring replacement position (Power Switch OFF)
CANCEL
E-2-b Confirmation Message
START
Robot moves to pressuring nozzle (packing) maintenance position (Power Switch OFF)

# 2.3 Safety Mechanisms

The safety mechanisms of this system are explained below.

This system is equipped with the following safety mechanisms.

- Sliding door, flap door
- Earth leakage breaker
- Agitation cover
- Operation panel, buzzer



## ■ Sliding Door, Flap Door

After power activation, the sliding doors and flap doors are locked. Temporary unlocking or door opening/closing is possible after power activation via panel operation, but panel operation is restricted while in unlocked status.

The opening and closing of doors are monitored with a sensor, and operations such as the isolation process are prohibited while a door is open.

## ■ Earth Leakage Breaker

When an overcurrent occurs due to earth leakage or system malfunction, the earth leakage breaker will shut off power.

The breaker condition can be checked on the breaker switch by opening the drawer of the system.

“ON” is seen while the breaker switch is in normal status, and “OFF” is seen when the circuit is shut off.

If the earth leakage breaker is shut off, please contact our customer consultation desk.

## ■ Agitator Cover

The system lysate unit is equipped with an open/close type cover to prevent the ejection of the lysate tube during automatic operation.

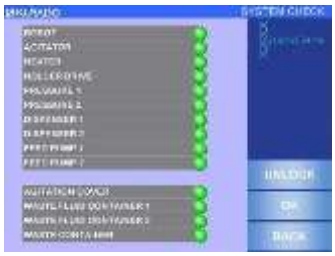
## ■ Operation Panel, Alarm

The system operating condition is indicated using the operation panel and the alarm.

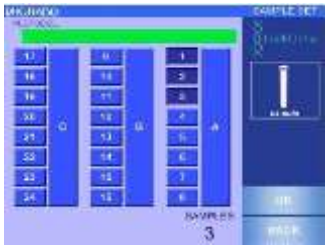
# 2.4 Operation Panel Displaying Contents

The displays on the operation panel while in normal operation are explained below.

For the screens displayed in the case of an abnormality, refer to “8.2 Error Message”.

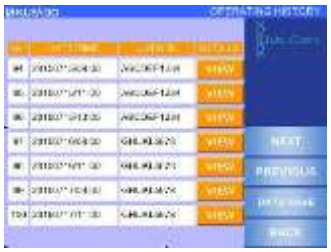
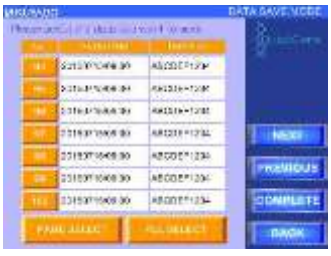
| No. | Screen | Description |
|---|---|---|
| 1 |  | ■ Company Logo Screen<br>Automatically moves to the Title Screen. |
| 2 |  | ■ Title Screen<br>Displayed after system power ON.<br>[SYSTEM CHECK] button is enabled while all system doors are locked.<br>Press [SYSTEM CHECK] to move on to the system check screen, and the system check will start. |
| 3 |  | ■ System Check Screen<br>Displayed for system checking.<br>The item lamps indicate completion in green, incompletion in gray and checking failed in flashing red accompanied by the display of [NG]. If the checking fails, press [UNLOCK] to cancel the door lock and fix the problem. After that the door will lock when the door is closed, and the system check will automatically restart. The [OK] button will be enabled when the checking of all items is complete, and the display will move to the user sign-in screen by pressing [OK]. |
| 4 |  | ■ User Sign-In Screen<br>Displayed for user sign-in.<br>Touch the white frame of [USER ID] and select a registered User ID. Then touch the white frame of [USER PASSWORD] to display a ten-key entry pad, enter a password that is set up per user ID, and press [ENT]. Press [SIGN IN] to move on to the mode selection screen after matching the ID and password. If the ID and password do not match, a warning message is displayed. For registration of a User ID, move on to the User ID registration screen by pressing [REGISTER]. To delete a User ID, move to the User ID deletion screen by pressing [DELETE]. |
| 5 |  | ■ User ID Registration Screen<br>Displayed for registration of User ID.<br>Touch the white frame of [USER ID] to display the alphabetical keys, enter an arbitrary alphanumeric string within 5-10 digits, and press [ENT]. Then touch the white frame of [PASSWORD] to display an alphabet keypad enter an arbitrary number of 5-10 digits and press [ENT]. Similarly, re-enter an identical number with [PASSWORD] in the [PASSWORD (RE-ENTER)] frame as well and press [ENT]. Finally, press [REGISTER] to register the User ID. If the passwords in the 2 places do not match, the User ID will not be registered. |

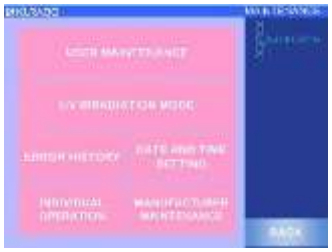
2

| No. | Screen | Description |
|---|---|---|
| 6 |  | ■ User ID Delete Screen<br>Displayed when deleting a User ID.<br>Touch the white frame of [USER ID] and select a registered user ID. Then touch the white frame of [EXPERT PASSWORD] to display a ten-key entry pad, enter a password for an expert and press [ENT]. Finally, press [DELETE] to delete a User ID. Please contact our sales agent regarding the password for an expert. |
| 7 |  | ■ Mode Select Screen<br>Displayed when selecting various modes. Press a button to move on to one of the modes.<br>・[AUTOMATIC OPERATION]： The mode for isolating operation<br>・[OPERATING HISTORY]: The mode for checking operating history, checking ID information and storing data<br>・[PARAMETER SETUP]: The mode for confirmation and setup of operating conditions and parameters<br>・[MAINTENANCE]: The mode for confirmation of functioning for maintenance and other setups.<br>All the door locks will be canceled by pressing [UNLOCK]. While the door lock is canceled, parts of functions are restricted. The doors are locked again when the door is closed. |
| 8 |  | ■ Protocol Select Screen<br>Displayed when the isolating operation protocol is selected.<br>[FULL-AUTO] is a protocol for automatic operation from the blood collection tube, [SEMI-AUTO] is a protocol for starting from the status of lysate preparation complete and [CUSTOM] is a spare protocol that allows the change of setups. Press [NEXT] to move on to the next item, and [PREVIOUS] to return to a previous item. |
| 9 |  | ■ Sample ID Check Screen<br>Displayed when reading ID information and detecting number of samples while the sample ID barcode reading function is [ON].<br>ID information is read out from the barcode on the side surface of the blood collection tube when setting a sample holder. The sample position will turn blue when the reading is successful. If there is no gap in the order of detected samples, the [COMPLETE] button will be enabled. The [NEXT] button will be enabled when all 8 samples in a holder are read, and the next holder will be rendered acceptable for setting by pressing [NEXT]. Press [COMPLETE] to move on to the next screen after confirmation of the number of samples. |
| 10 |  | ■ Number of Samples Entry Screen<br>Displayed for entering the number of samples while the sample ID barcode reading function is [OFF]. The color of a button will be reversed and the sample number can be selected by pressing one of the sample numbers (1–24) or the buttons (A, B and C) for sample holder names. Numbers smaller than the pressed one will be automatically selected. By pressing a button with reverse color again, selection of the relevant sample will be canceled. Press [OK] to move on to the next screen. |

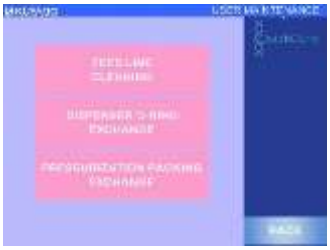
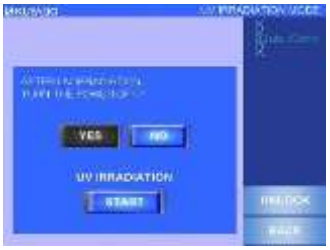
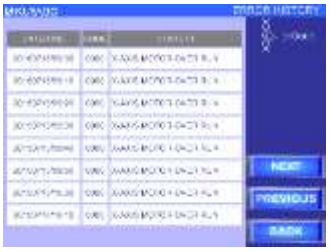
| No. | Screen | Description |
|---|---|---|
| 11 |  | ■ Collection ID Check Screen<br>Displayed for reading ID information and detecting the number of samples while the collection ID barcode reading function is [ON]. When a collection tube holder is inserted in a barcode reading slot, the ID information is read out from the barcode on the bottom surface of the collection tube. The sample position turns green when the reading is successful. If the detected positions match the sample positions, the [COMPLETE] button will be enabled. When all 8 samples are read, the [NEXT] button will be enabled and by pressing it the next holder will be readied for reading. Press [COMPLETE] to confirm the number of samples and move on to the next screen. |
| 12 |  | ■ Reagent Confirmation Screen<br>The required reagent quantity and the position numbers for setting will be displayed according to the selected protocol and the number of samples. Press [CHECK] for each reagent or [ALL] as a confirmation procedure for setting the required reagent quantity to a correct position. If the reagent quantity is insufficient or the setting position is incorrect, press [UNLOCK], open the doors and correct the problem. After that, the doors are locked again when the door is closed, and screen operation will be enabled. The [OK] button will be enabled by pressing all [CHECK] buttons on the set reagent positions or pressing [ALL]. Press [OK] to move on to the next screen. |
| 13 |  | ■ Operating Condition Setup Screen<br>Displayed for setting up operating conditions.<br>[Setup of Starting Position of Sample Tip] Press [RESET] to start from the default position and set the value to "1". To start from another position, press [CHANGE] to display a ten-key entry pad, enter an arbitrary value and press [ENT] to set.<br>[Selection of Starting Level of Sample Suction] Select [BOTTOM] for suction from the bottom level of the blood collection tube. If [SURFACE] is selected, the sample is drawn from the fluid surface using the fluid surface detecting function. When [BOTTOM] mode is selected, an overflow warning window will pop up. Press [START] to start checking before operation. |
| 14 |  | ■ Pre-Operation Check Screen<br>A screen displayed when the various portions are to be checked using the sensors after pressing [START]. The green lamp will light if no problem is detected after checking various portions. If a problem is found, "NG" will be displayed at the right side of the relevant item. If at least one "NG" is detected, the operation will be suspended on this screen and the [RETRY] and [UNLOCK] buttons will be enabled. Press [UNLOCK], open the doors, and then close the doors after solving the problem of any “NG” item and press [RETRY]. When checking all items is complete, the operation will automatically move on to the isolation process. |
| 15 |  | ■ In Operation Screen<br>A screen displayed while in automatic operation of isolation process. [PROTOCOL NAME], [PROCESS IN PROGRESS], [PROCESS STEP No.], [OPERATION DETAILS] and [REMAINING TIME (REF)] are displayed at the top of the screen. Normally [PAUSE] is displayed at the bottom right of the screen, and the isolation process will be suspended after a currently operating action ends. The [RESUME] button will be enabled when the operation is suspended. Press [RESUME] to resume automatic operation. |

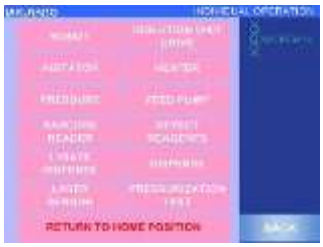
2

| No. | Screen | Description |
|---|---|---|
| 16 |  | ■ Processing Result Confirmation Screen<br>A screen displayed when the automatic operation is complete. The background color for sample number indicates the operation result: green for normal completion, red (NG1) for chip clogging at sample suction, yellow (NG2) for pressure leakage of cartridge, blue (NG3) for clogged cartridge. NG 1 to 3 become improper isolation. In addition, gray for unset samples.<br>Press [ID INFO] to move on to the operation ID information screen (only when the sample ID reading function is ON). After completion of ID confirmation, press [FINISH]. |
| 17 |  | ■ Operation ID Information Screen<br>A screen for confirmation of sample ID information for which an isolating operation has been conducted. The "Sample No.", "Isolation Result", "Sample ID information (S)" and "Collection ID Information (C)" are displayed at the left side of the screen. Press [NEXT] to move on to the next item; press [PREVIOUS] to return to the previous item. Press [BACK] to go back to the operation result confirmation screen. |
| 18 |  | ■ Operating History Screen<br>A screen for confirmation of operation history, displayed after pressing the [OPERATING HISTORY] button in the mode select screen. "Operation Management No." (numbers allocated to the past 100 operating records), "Operation Date and Time", "User ID of operator" and "Display of Details (VIEW)" buttons are displayed at the left side of the screen. Press [VIEW] to move on to the history ID information screen. Press [NEXT] to move on to the next item, press [PREVIOUS] to go back to the previous item. Press [DATA SAVE] to move on to the operating history save screen. Press [BACK] for returning to the mode select screen. |
| 19 |  | ■ History ID Information Screen<br>A screen for confirmation of ID information is displayed after pressing [VIEW] on the operating history screen. "Sample No.", "Isolation Result", "Sample ID Information (S)" and "Collection ID information (C)" are displayed at the left side of screen. Press [NEXT] to move on to the next item, and press [PREVIOUS] to go back to the previous item. Press [BACK] to return to the operating history screen. |
| 20 |  | ■ Operating History Save Screen<br>A screen for saving operating history data is displayed after pressing [DATA SAVE] on the operating history screen. "Operation Management No." (numbers allocated to the past 100 operating records), "Operation Date and Time" and "User ID of Operator" are displayed at the left side of the screen. Select the management number of an operating history to be saved using the combination of operation management number [No.] button, page selection [PAGE SELECT] button and select all [ALL SELECT] button. Press [NEXT] to move on to the next item; press [PREVIOUS] to go back to the previous item. Press [COMPLETE] while selecting data to save, and then the data can be saved in an external memory after a confirmation message. Press [BACK] to return to the operating history screen. |

| No. | Screen | Description |
|---|---|---|
| 21 |  | ■ Parameter Setup Screen<br>A screen for confirmation and change of parameters for each protocol implemented in the system. Displayed after pressing [PARAMETER SETUP] in the mode select screen and selecting a protocol in the protocol select screen. The "Selected Protocols" are displayed on the screen, and "Barcode (ID) Reading Function Setup", "Collecting Fluid Quantity Setup" and a button for moving to "EXPERT Mode" are displayed. |
| 22 |  | ■ Barcode (ID) Reading Function Setting Screen<br>A screen displayed when [BARCODE READING] is pressed in the parameter setup screen. Select [ON] for reading and [OFF] for not reading the Sample ID on the sample (blood collection tube) and the Collection ID on the collection tube. |
| 23 |  | ■ Fluid Collection Volume Setting Screen<br>A screen displayed when [ELUTION BUFFER VOLUME] button is pressed on the parameter setting screen. The quantity for injection of collection fluid is entered with either of 2 methods below. The range for setting up (MIN–MAX) is 0.05–1.00 mL with an increment of 0.01 mL.<br>[Directly enter a value using a ten-key entry pad] Touch a white frame to display a ten-key pad, enter a value within an available range for setup, and press [ENT].<br>[Change the value using (△▽) buttons] One press of the [△] button will increase the setup by 0.01, and one press of the [▽] button will decrease the setup by 0.01. After setting a value, press [OK] to complete the setup. |
| 24 |  | ■ Expert Mode Password Entering Screen<br>A screen displayed when [EXPERT MODE] button is pressed in the parameter setup screen. Touch the white frame of [EXPERT PASSWORD] to display a ten-key pad, enter a password for an expert, and press [ENT]. After entering the password and pressing [OK], the system will crosscheck the password and move on to the EXPERT mode. Contact our sales agent regarding the password for an expert. |
| 25 |  | ■ Maintenance Screen<br>A screen for management of system maintenance. Displayed when [MAINTENANCE] is pressed on the mode select screen. Press one of the buttons to move on to each screen.<br>・[USER MAINTENANCE]: User maintenance screen<br>・[UV IRRADIATION]: UV (ultraviolet light) irradiating function screen<br>・[ERROR HISTORY]: Error history screen<br>・[INDIVIDUAL OPERATION]: Individual operation screen (NB: used under instruction of the manufacturer or sales agent)<br>・[DATE AND TIME SETTING]: Clock setting screen<br>・[MANUFACTURER MAINTENANCE]: Manufacturer maintenance screen (NB: use by the user is prohibited) |

2

| No. | Screen | Description |
|---|---|---|
| 26 |  | ■ User Maintenance Screen<br>A screen for management of issues regarding user maintenance. Displayed when [USER MAINTENANCE] is pressed in the maintenance screen. Press [FEED LINE CLEANING] to move on to the maintenance screen for cleaning the wash buffer feeding line. If [DISPENSER O-RING EXCHANGE] is pressed, a message appears and the robot will move to the maintenance position for dispenser O-ring. If [PRESSURIZATION PACKING EXCHANGE] is pressed, a message appears and the robot moves to the maintenance position for the pressurizing nozzle (packing). |
| 27 |  | ■ Wash Buffer Feeding Line Maintenance Screen<br>A screen displayed when [FEED LINE CLEANING] is pressed in the user maintenance screen. Enter the injection quantity for collection fluid using either of the following 2 methods.<br>[Directly enter a value using ten-key pad] Touch a white frame to display the ten-key, enter a value and press [ENT].<br>[Change the value using the (△▽) button] One press of the [△] button will increase the setup by 1, and one press of the [▽] button will decrease the setup by 1. After setting a value, press [START] to start the wash pump, feed the wash buffer into the wash buffer bottle, and discharge into the waste container. |
| 28 |  | ■UV (ultraviolet light) Irradiating Function Screen<br>A screen displayed when [UV IRRADIATION] is pressed in the maintenance screen. If the system power is to be automatically turned off after UV irradiation, select [YES]; select [NO] for not turning off the system power. Press [START] to start irradiating UV. |
| 29 |  | ■ Error History Screen<br>A screen to confirm error history, displayed after [ERROR HISTORY] on the Maintenance Screen is pressed. "Error Occurrence Date and Time", "Error Code" and "Error Descriptions" are displayed at the left side of the screen. Press [NEXT] to move on to the next item; press [PREVIOUS] to go back to the previous item. Press [BACK] to return to the maintenance screen. |
| 30 |  | ■ Clock Setup Screen<br>A screen to set up the system clock. Displayed when [DATE AND TIME SETTING] is pressed on the maintenance screen. Touch the white frame for each "MONTH", "DAY", "YEAR", "HH" (hour) and "MM" (minute) to display a ten-key pad, enter a value, and press [ENT]. Finally, press [OK] to set up the clock. |

| No. | Screen | Description |
|---|---|---|
| 31 |  | ■ Individual Operation Screen (NB: use under instruction of the manufacturer or sales agent)<br>A screen for individual operation of functions for various parts of the system. Displayed when [INDIVIDUAL OPERATION] is pressed on the Maintenance Screen. If [RETURN TO HOME POSITION] is pressed, the robot will return to the default position. Press one of the following buttons to move on to each of the screens.<br>・[ROBOT]: Motor individual operation screen<br>・[ISOLATION UNIT DRIVE]: Isolation unit individual operation screen<br>・[AGITATOR]: Agitator motor individual operation screen<br>・[HEATER]: Heater individual operation screen<br>・[PRESSURE]: Pressurizing unit individual operation screen<br>・[FEED PUMP]: Fluid feeding pump individual operation screen<br>・[BARCODE READER]: Barcode/2-dimensional code reader confirmation screen<br>・[DETECT REAGENTS]: Fluid surface detection function confirmation screen<br>・[LYSATE DISPENSE]: Lysate fluid transferring function confirmation screen<br>・[DISPENSE]: Dispenser function confirmation screen<br>・[LASER SENSOR]: Laser sensor function confirmation screen<br>・[PRESSURIZATION TEST]: Pressurizing test function confirmation screen |
| 32 |  | ■ Ten-Key Input Pop-Up Screen<br>Displayed when a value is to be entered in each screen<br>[0-9]: Enter values<br>[・]: Enter decimal point<br>[+/-]: Enter +/- sign<br>[ENT]: Finalize the entered data (Finalization is not accepted if the entered number of characters is insufficient for ID, password, etc.)<br>[BS]: Delete 1 entered digit<br>[CL]: Delete all entered digits<br>[ESC]: Return to previous screen from the ten-key input screen |
| 33 |  | ■ Keyboard Input Pop-Up Screen<br>Displayed for entering characters in each screen<br>[0-9]: Enter the values<br>[・]: Enter decimal point<br>[A-Z]: Enter alphabetical characters<br>[Symbol]: Enter a symbol<br>[SPACE]: Enter a space<br>[SHIFT]: Shift Key<br>[ENTER]: Finalize the entered data (Finalization is not accepted if the entered number of characters is insufficient for ID, password, etc.)<br>[BS]: Delete 1 entered digit<br>[CL]: Delete all entered digits<br>[ESC]: Return to previous screen from the ten-key input screen |

# 2.5 Barcode Scanning Function

The barcode scanning function implemented in this system is explained below.

Refer to “3. How to Operate” regarding the selection of barcode scanning mode and the barcode reading flow during operation.

## ■ Types and functions of barcode readers

| Barcode Reader Type | Implementation in System | Readable ID | Functions |
|---|---|---|---|
| **Barcode Reader for Blood Collection Tube** | **Standard** | **Sample ID** | **Reads out the sample ID from the 1-dimensional barcode on the side surface of a sample tube such as a blood collection tube. The ID information readout is checked against the location information (A-1, A-2…) for the collection tube.** |
| **Barcode Reader for Matrix Tube** | **Option** | **Collection ID** | **Reads out the collection ID from the 2-dimensional code on the bottom surface of a collection tube such as a matrix tube with 2-dimensional code. The ID information readout is checked against the sample ID.** |

## 2.6 Basic Specifications

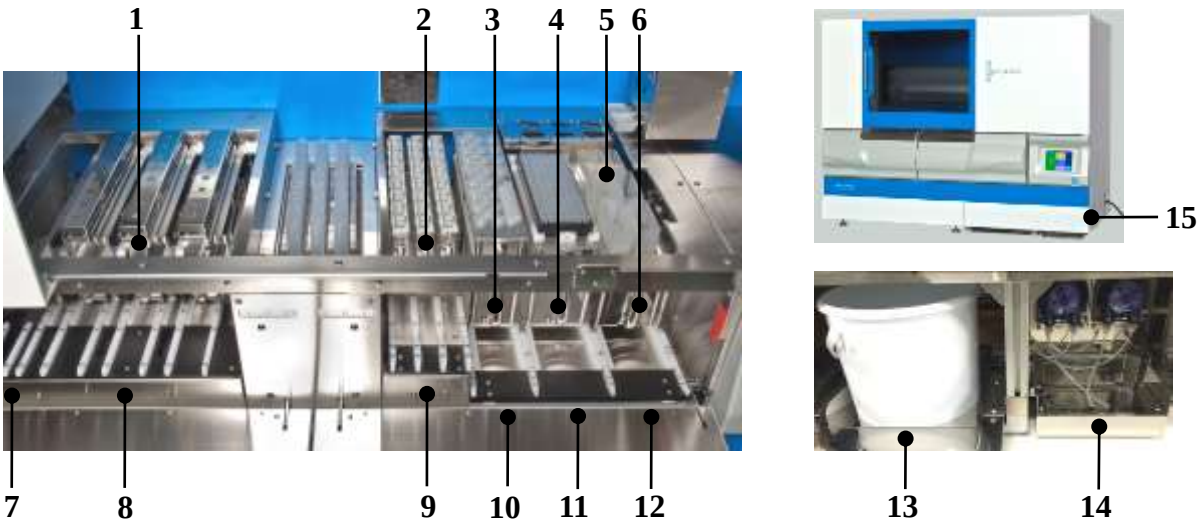
The basic specifications of this system are as shown below:

| Item | Specification |
|---|---|
| **Product Name** | **Automated Nucleic Acid Isolation System** |
| **Model** | **QuickGene-Auto240L** |
| **Max. Set Number for Blood Collection Tubes** | **24** |
| **Size of Blood Collection Tube** | **6 mL: φ13 x 100 mm**<br>**10 mL: φ16 x 100 mm *φ13 x 75 mm (option)** |
| **Outline Dimensions** | **1280 mm (W) × 720 mm (D) × 990 mm (H)** |
| **Mass** | **Approx. 300 kg (System main unit only)** |
| **Operation Panel** | **LC Touch Panel** |
| **Rated Input Voltage/Current** | **100 VAC/8.6 A, 110 VAC/8.3 A, 120 VAC/8.0 A**<br>**220 VAC/4.0 A, 230 VAC/3.6 A, 240 VAC/3.6 A** |
| **Voltage Fluctuation** | **±10%** |
| **Phase** | **Single Phase** |
| **Frequency** | **50-60 Hz** |
| **Environment for Use** | **Indoor Use** |
| **Overvoltage Category** | **Transient overvoltage category II** |
| **Applied Rated Contamination** | **Pollution Degree 2** |
| **IP Classification** | **IPX0** |
| **Temp. /Humid. Range for Use** | **Temperature: 15°C-30°C**<br>**Humidity: 30%-80%RH (no condensation)** |
| **Altitude** | **≦1600 m for use** |

2

## 2.7 Product Labeling

The product labels affixed to this system are as shown below:




| No. | Label | Description |
|---|---|---|
| 1 |   | Labels indicating the collection tube holder<br>The alphabetical characters A – C are the holder identifications. |
| |   | Labels indicating the cartridge holder.<br>The alphabetical characters A – C are the holder identifications. |
| |   | Labels indicating the waste tube holder.<br>The alphabetical characters A – C are the holder identifications. |
| 2 |   | Labels indicating the sample holder.<br>The alphabetical characters A – C are the holder identifications. |
| 3 |   | Label indicating the reagent tip holder. |
| 4 |   | Label indicating the sample tip holder. |
| 5 |   | Label indicating reagent container setting position No.1. |
| |   | Label indicating reagent container setting position No.2. |
| |   | Label indicating reagent container setting position No.3. |
| |   | Label indicating reagent container setting position No.5. |

| No. | Label | Description |
|---|---|---|
| |  | Label indicating reagent container setting position No.6. |
| 5 |  | Label indicating waste fluid container position No.1. |
| |  | Label indicating waste fluid container position No.2. |
| 6 |  | Label indicating reagent container holder. |
| 7 |  | Label indicating collection ID reading slot.<br>When reading a 2-dimensional barcode on a matrix tube, insert a collection tube holder in a slot indicated by this label and read the barcode. |
| 8 |  | Label indicating slot for setting collection tube holder.<br>The alphabetical characters A – C are the holder identifications. |
| |  | Label indicating slot for setting cartridge/waste tube holder.<br>The alphabetical characters A – C are the holder identifications. |
| 9 |  | Label indicating slots for setting sample holder.<br>The alphabetical characters A – C are the holder identifications. |
| 10 |  | Label indicating slot for setting reagent tip holder.<br>"FOR LYSATE" and "FOR REAGENT" indicate the purpose for a tip to be set in a holder. |
| 11 |  | Label indicating slot for setting sample tip holder. |
| 12 |  | Label indicating slot for setting reagent container holder.<br>The numbers 1-6 indicate the setting positions for reagent containers in the holder, and "WASTE" indicates the setting position for the waste fluid container. |
| 13 |  | Label indicating setting position for waste container.<br>The setting position is in a location pointed with an arrow. |
| 14 |  | Label indicating reagent container setting position No.4. |

| No. | Label | 内容 |
|---|---|---|
| 15 |  | Label indicating Model (Name Plate)<br>Affixed on the bottom right side surface of this system (front side).<br>“MODEL” indicates the model number of this system.<br>“INPUT” indicates the input power voltage, current and frequency.<br>“S/N” indicates the serial number.<br>CE symbol marks are clearly stated. |

## 2.8 Implemented Protocols

The protocols implemented in this system are listed below:

NB: Some of the protocols may not be displayed depending on the specifications of the delivered system.

| Protocol Name | Automatic Process | Relevant Sample | Final Product | Remarks |
|---|---|---|---|---|
| W BLOOD DNA 2.0 mL FULL-AUTO | Full-Auto | Whole Blood 2 mL | DNA | Change of parameters other than nucleic acid solution fluid quantity and barcode reading setups is not permitted. |
| W BLOOD DNA 1.0 mL FULL-AUTO | Full-Auto | Whole Blood 1 mL | DNA | |
| PLASMA DNA 2.0 mL FULL-AUTO | Full-Auto | Plasma 2 mL | DNA | |
| PLASMA DNA 1.0 mL FULL-AUTO | Full-Auto | Plasma 1 mL | DNA | |
| W BLOOD DNA 2.0 mL SEMI-AUTO | Semi-Auto | Whole Blood 2 mL | DNA | |
| W BLOOD DNA 1.0 mL SEMI-AUTO | Semi-Auto | Whole Blood 1 mL | DNA | |
| PLASMA DNA 2.0 mL SEMI-AUTO | Semi-Auto | Plasma 2 mL | DNA | |
| PLASMA DNA 1.0 mL SEMI-AUTO | Semi-Auto | Plasma 1 mL | DNA | |
| CUSTOM 1-4 | (Full-Auto) | (Whole Blood 2 mL) | (DNA) | Change of parameters is permitted:<br>The parameter “W BLOOD DNA 2.0 mL FULL-AUTO” is input in protocols 1-4 as a default value.<br>To change the parameters, a separate input of EXPERT PASSWORD is required. |

2

# 3 How to Operate (Full -Automatic Protocol)

The procedures for power ON and the isolating operation with full auto protocol are explained below.

**Biohazard:** **Wear appropriate gloves, mask, and protective goggles for isolation work with risk of infection.**
**Furthermore, after once conducting isolation work with risk of infection, wear proper gloves and mask if contacting the system because the system may be contaminated.**

**Caution:** **Do not put a tray, etc. with fluid in it on top of or inside the system. The fluid may be spilt and the operation panel or inside devices may fail.**



**Important: Wear proper gloves and mask for isolation work according to the work contents. Take care not to cause contamination with sweat or sputum from preparation of sample until completion of isolation work.**

## 3.1 For Isolating Operation

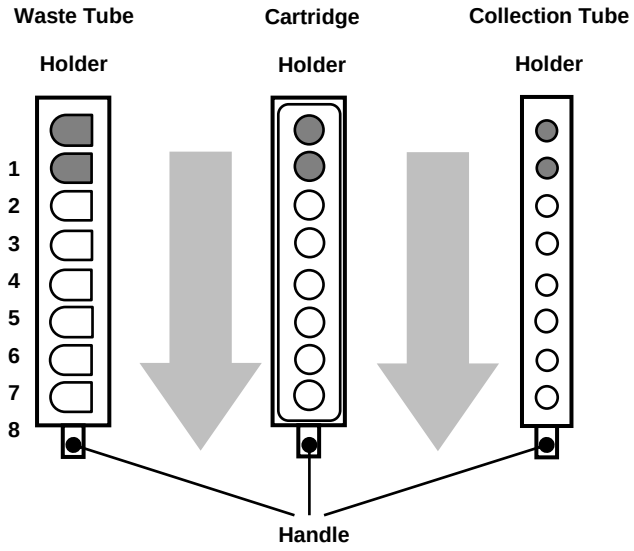
Abide by the following when conducting an isolating operation.

- **Abide by the setting order for accessories and consumables and set correctly.**
- **Set the waste tubes, cartridges and collection tubes in correct position.**

**Important: Erroneous setting of waste tubes, cartridges or collection tubes will cause spilt reagents or dissolved samples, results will not be gained, and the sample will be wasted.**
**In addition, pay attention to the risk of causing contamination or system failure.**

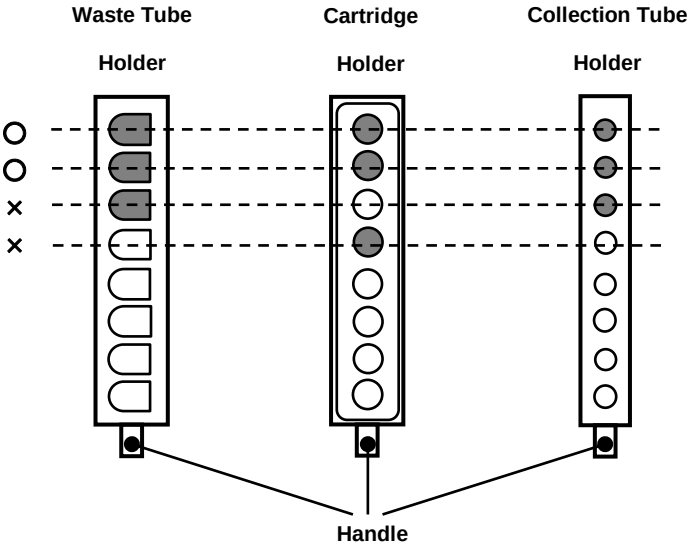
**Rule 1.**

**Waste tubes, cartridges and collection tubes should be set in order from opposite side of handle.**



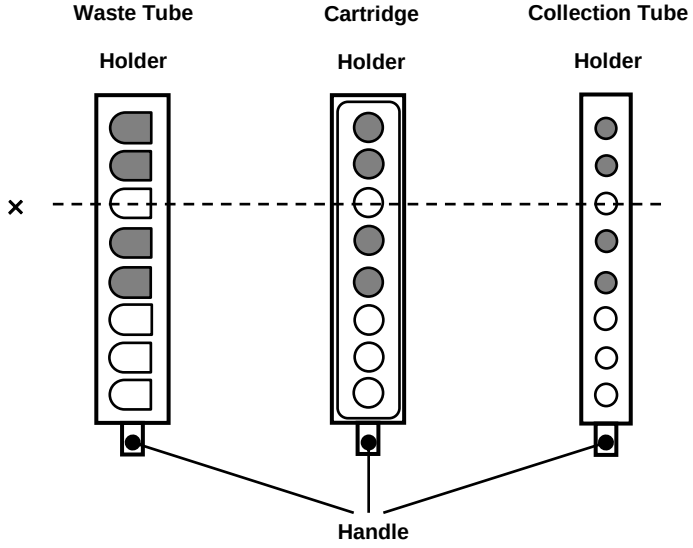
**Rule 2.**

**The 3 components, waste tube, cartridge and collection tube should be set in parallel positions avoiding dislocation**



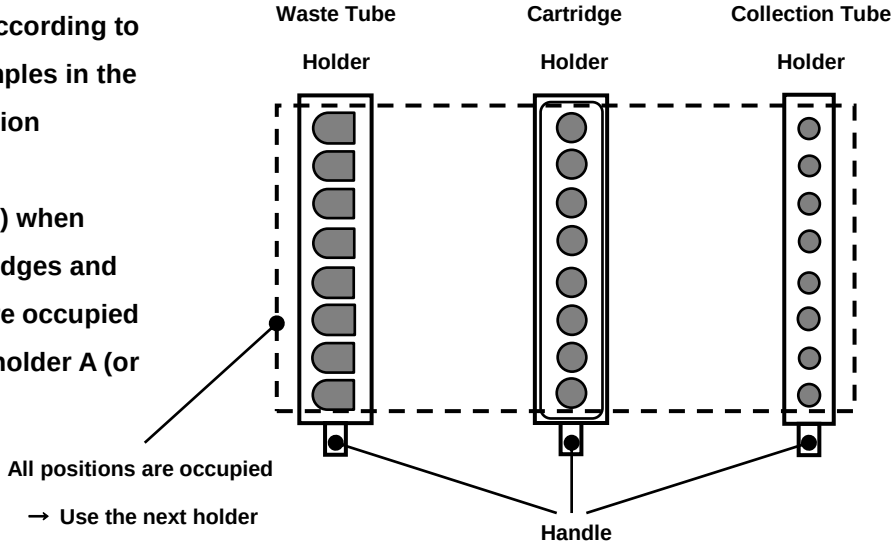

**Rule 3.**

**The setting be without a vacancy and in order.**




**Rule 4.**

**Use each holder according to the number of samples in the order of identification symbols A→B→C.**
**Use holder B (or C) when waste tubes, cartridges and collection tubes are occupied in all positions in holder A (or**



# 3.2 Confirmation of Articles to be Prepared

Explanation regarding confirmation of prepared articles before conducting isolation work.

## ■QuickGene-Auto240L Main Unit and Accessories

Refer to "1.4 Checking of Packed Contents" and confirm that all are included.

## ■Other articles to prepare

The following articles shall be prepared. NB: They are not included in the package of this system but must be separately prepared.

- **QuickGene DNA Whole Blood kit L (DB-L) for 48 Specimens/1 Kit**
  - **Cartridge x 48**
  - **Waste Tube x 48**
  - **Reagents x 1 set**
- **QuickGene-Auto240L Consumables Kit (QG-240L-CK) for 48 Specimens/1 Kit**
  - **Lysate Tube x 48**
  - **10-mL Tip x 60**
  - **1.2-mL Tip x 96**
- **1.5-mL Micro Tube, or 1.4-mL Matrix™ Tube with 2D barcode**
  **[Used as collection container (collection tube) for DNA]**
- **Special Grade Ethanol (>99%)**
- **Nuclease-free Water (Used for dissolution of pretreated enzyme (EDB) and for confirmation of system functioning)**
- **Protective Gloves**
- **Safety Goggles**

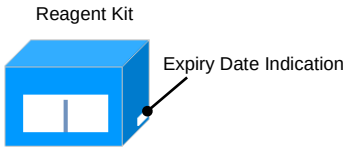
# 3.3 Preparation of Reagents

Explanation of reagent preparation before conducting isolating work

**Note:** **Use reagents within their expiration dates.**

If an expired reagent is used, the expected yield and purity may not be attained.

The expiry date is indicated on the outer box of the reagent kit.




## ■ Preparation of Reagents

Prepare the reagents included in the package of QuickGene DNA Whole blood kit L (DB-L: selling separately) in the following manner.

◆ **Protease (EDB)**

Add 3.3 mL of nuclease-free water in a bottle containing freeze-dried product and dissolve completely.

It is recommended to preserve the dissolved pretreated enzyme (EDB) in a refrigerator (4°C), which will provide stability for 2 months. Preservation at -20°C will prolong the stable period for an enzyme, but avoid repetition of thawing and freezing.

**Note:** **Use the pretreated enzyme (EDB) after completely dissolving in accordance with the following procedures:**

Add 3.3 mL of nuclease-free water, set a lid, and invert.

Leave for more than 30 minutes while occasionally agitating, and confirm the complete dissolution of powder before use.

Insufficient dissolution may result in shortage of targeted yield or clogged cartridge.

◆ **Lysis Buffer (LDB)**

Mix well before use.

If undissolved solid is observed, dissolve at 37°C.

◆ **Wash Buffer (WDB)**

Delivered in condensed form.

Add 160 mL of special grade ethanol in the bottle before use and mix well.

After mixing with ethanol, close the bottle lid and preserve at room temperature.

◆ **Elution Buffer (CDB)**

Used for elution of nucleic acid

## ■ Set the Reagents in the System

Set the reagents prepared in the previous section in the system as below:

◆ **Reagent Container and Required Reagent Quantity (for 2 mL of sample to treat)**

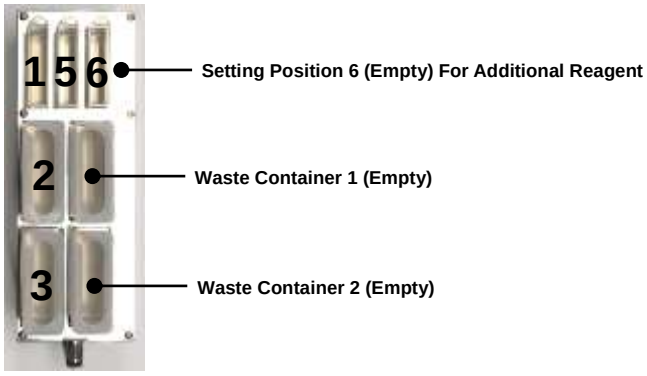
| Reagent | Reagent Container | Setting Position No. | Quantity of Use /1 sample | Other Required Quantity* | Required Quantity/1 Operation | | |
|---|---|---|---|---|---|---|---|
| | | | | | 8 Samples | 16 Samples | 24 Samples |
| EDB | Reagent Container S | 1 | 0.3 ml | 1 ml | 3.4 ml | 5.8 ml | 8.2 ml |
| LDB | Reagent Container L | 2 | 2.5 ml | 10 ml | 30 ml | 50 ml | 70 ml |
| Special Grade Ethanol (>99%) | Reagent Container L | 3 | 2.5 ml | 10 ml | 30 ml | 50 ml | 70 ml |
| WDB (mixed with ethanol) | Wash Buffer Bottle | 4 | 19.5 ml | 50 ml | 206 ml | 362 ml | 518 ml |
| CDB | Reagent Container S | 5 | 0.5 ml | 1 ml | 5 ml | 9 ml | 13 ml |

*The "Other Required Quantity" includes the quantity for filling the fluid feeding line in the system and the additional quantity for stable suction of fluid.

**(1) Refer to the table above and split the required quantity of reagent in a reagent container for QG-Auto240L.**

**Note: After operation, the quantity of reagent included in the kit may fall short if the residual reagent in the reagent container is disposed of.**
**The residual reagent in the reagent container should be preserved in a sealed container and consumed as soon as possible.**

**(2) Set the reagent containers S and L with reagent in them in the reagent container holder according to the setting position numbers.**
**Set an empty container at the setting position numbers for reagent containers not to be used and waste containers.**

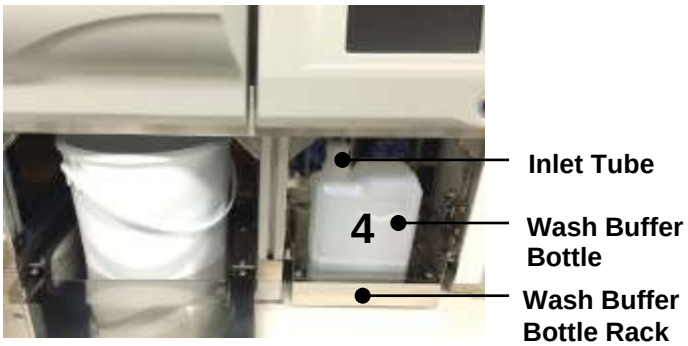


**Note:** **Be sure to set a waste container in empty status.**

**Operation with residual waste fluid in the waste fluid container may cause an overflow of waste fluid. Dispose of the fluid before setting a container in the holder.**

**(3) Set a reagent container holder in a reagent container holder slot.**

**(4) Set awash buffer bottle in the wash buffer bottle rack in the drawer (at setting position No.4).**




**Note:** **If the setting is not complete, the inability to absorb wash buffer may influence the operation result. Abide by the following and set a wash buffer bottle correctly:**

- **The wash buffer bottle is set in such a way that the opening comes to the left side of the rack.**
- **The ends of 2 inlet tubes must reach the bottom of the wash buffer bottle.**
- **The inlet tubes should not be kinked midway.**

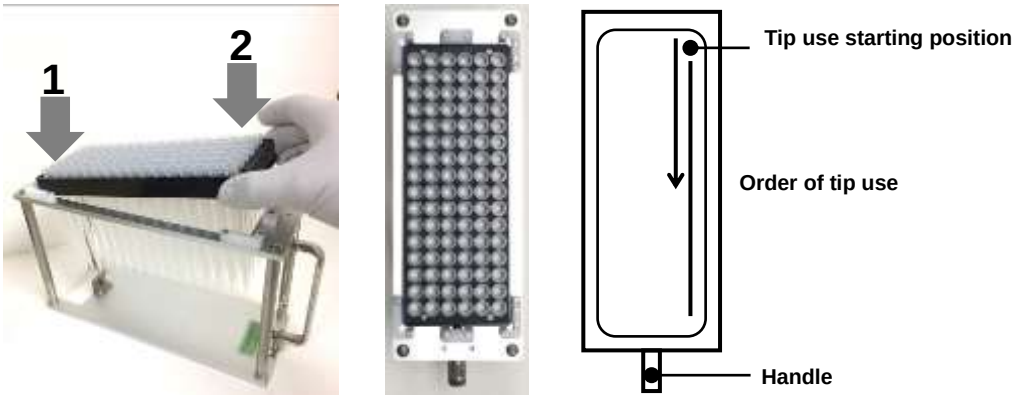
# 3.4 Preparation of Consumables and Accessories

Explanation regarding the preparation of consumables and accessories before isolation work.

## ■ Set the consumables and accessories on each holder

**(1) Set a 1.2-mL tip rack (containing 96 pcs) in the sample tip holder.**

First insert the groove on the short side of the tip rack into the opposite side of the holder handle, and then insert in the handle side.



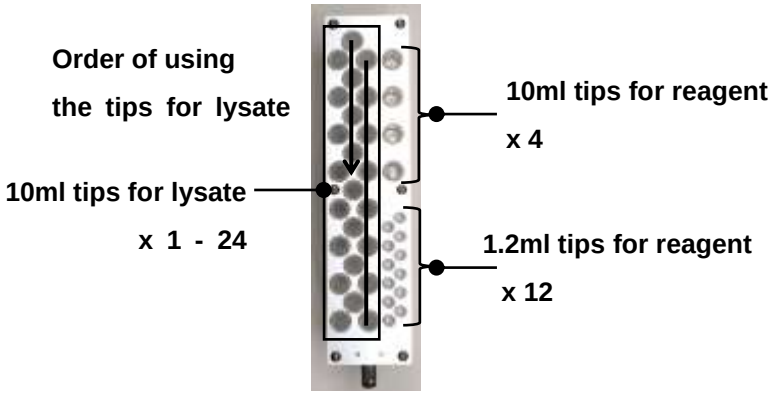

**Note:**

- **Confirm the secure setting of tip rack with the holder without an uplift.**
- **Confirm that equal to or more 1.2-mL tips than the samples are set from the starting position.**

  The tip use starting position can be changed in accordance with "3.8 Isolating Operation"

**(2) Set 1.2ml tips and 10ml tips in a reagent tip holder.**

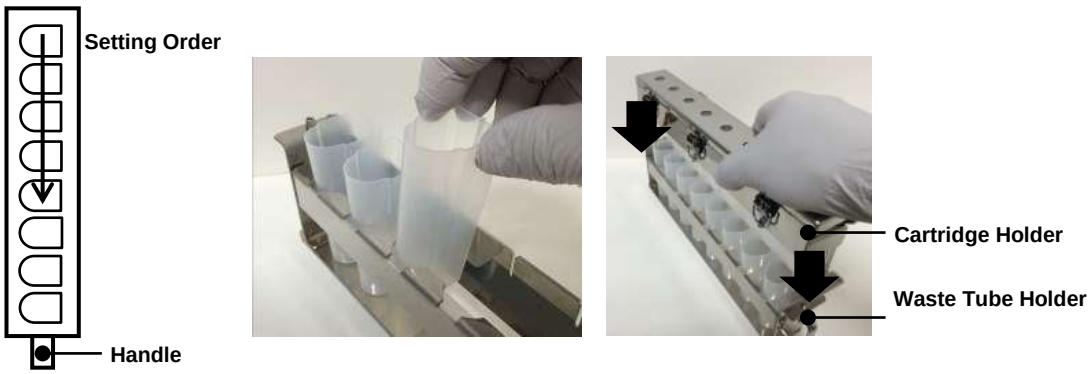
Remove and set the required number of 1.2ml tips from the 1.2ml tip rack




**Note: Set all reagent tips (1.2ml tips x 12, 10ml tips x4) in the holder**

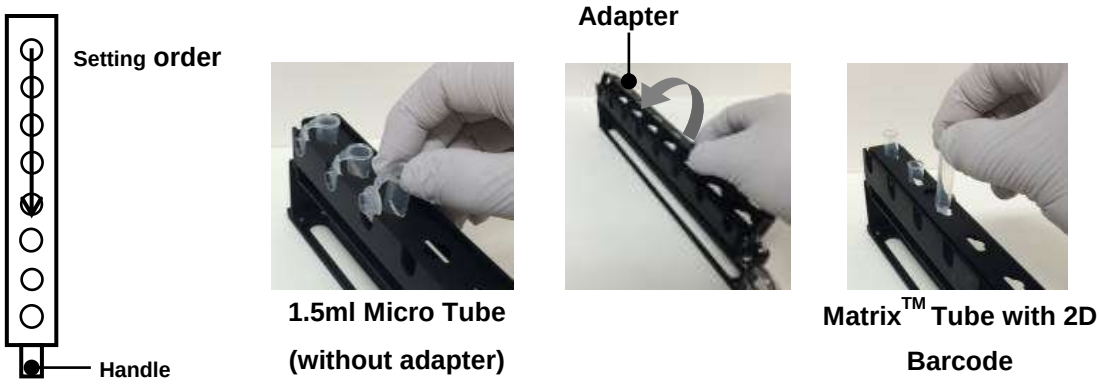
**Set the number of tips for lysate (10ml x 1 – 24) equal or more to the number of samples**

**(3) Set the number of waster tubes equal to the number of samples in the waste tube holder. After setting, attach the cartridge holder from the top.**



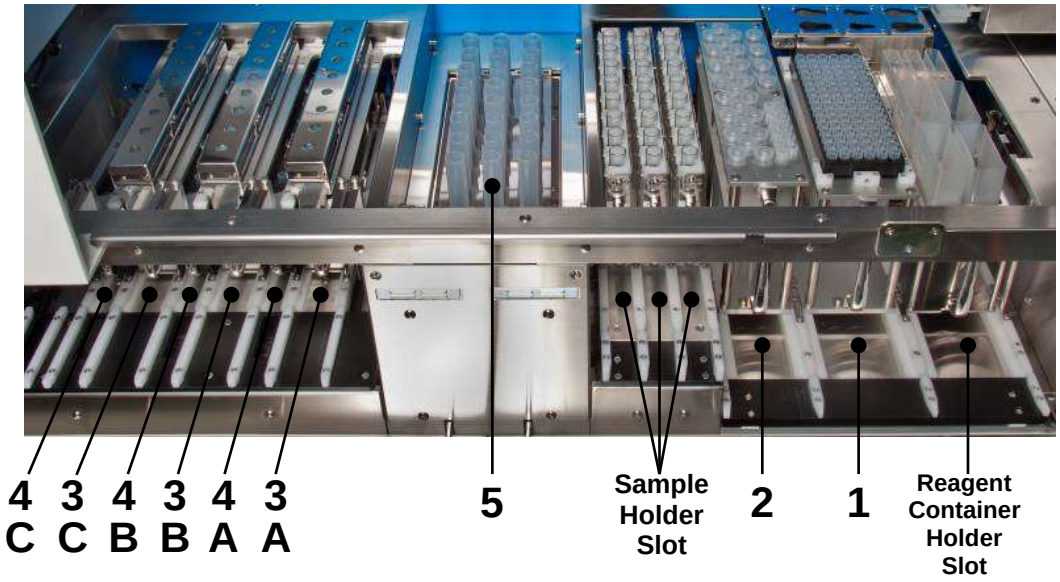

**(4) Set the number of cartridges equal to the number of samples in the cartridge holder. After setting, close the cover and lock the locks in 3 places.**


**(5) Set the number of collection tubes equal to the number of samples in the collection tube holder.**
Use the adapters according to the type of collection tubes.




**Note: When several holders are used, set the collection tubes while paying attention to the holder identification symbols A-C.**

## ■ Set the holders in the system




| Holder Name | Slot No. |
|---|---|
| Sample Tip Holder | 1 |
| Reagent Tip Holder | 2 |
| Cartridge/Waste Tube Holder | 3A - C |
| Collection Tube Holder | 4A - C |
| Lysate Tube | 5 |

**(1) Open the flap doors in the left/right side of the system**

**(2) Set the prepared holders in the corresponding slot with reference to the above chart.**
**To use the collection tube ID reading function, the collection tube holder should not be set in this step, but instead set in accordance with the instructions of the operation panel in "3.8 Isolating Operation"**

**Note:**

- **The holder should be securely set in the slot until it contacts the stopper on the end.**
- **Set a holder in the correct slot according to the manual and the identification label. If a holder is forcibly set in a wrong slot, the holder or system may be damaged.**

**(3) Close the left/right flap doors.**

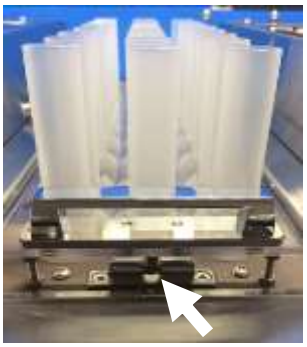
## ■ Set the lysate tubes in the system

**(1) Open the sliding door of the system.**

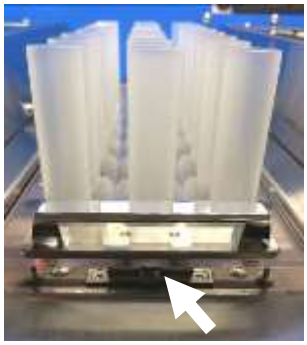
**(2) Open the agitator cover of the lysate unit.**

**(3) Set the number of lysate tubes equal to the number of samples.**

**(4) After setting the lysate tubes, close the agitator cover until a click is heard.**



×



○

**Note: Be sure to securely close and fix the agitator cover until a click is heard. If the fixing is insecure, an error will occur during the system check before operation.**

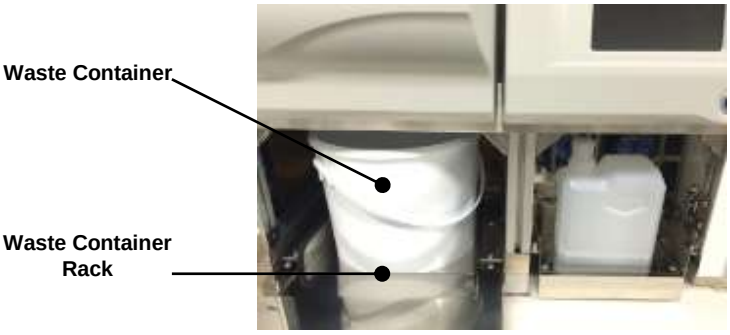
**(5) Close the sliding doors**

## ■ Set a waste container in the system

**(1) Open the drawer of the system**

**(2) Set a waste container in the waste container rack**

Securely set the waste container to fit the rack groove.




× ○

**Note: Be sure to correctly set an empty waste container included in the delivery. The use of container not included in the delivery, use of un-emptied container or use with an erroneous setting may cause waste overflow.**

**(3) Close the drawer**

# 3.5 Preparation of Samples

## ■ Prepare a sample

- Use full blood collected using EDTA-2NA, EDTA-2K or heparin.
- Use full blood collected within 3 days as far as possible. The use of blood preserved for a long period or subjected to repeated freezing and thawing procedures may result in a decrease in yield or clogging of the cartridge.
- If full blood is left untreated, the hematocyte layer will be isolated and may pose a problem in system operation or isolation results. Gently mix by inverting before use and start system operation as soon as possible.



## ■ Set the samples in the sample holder

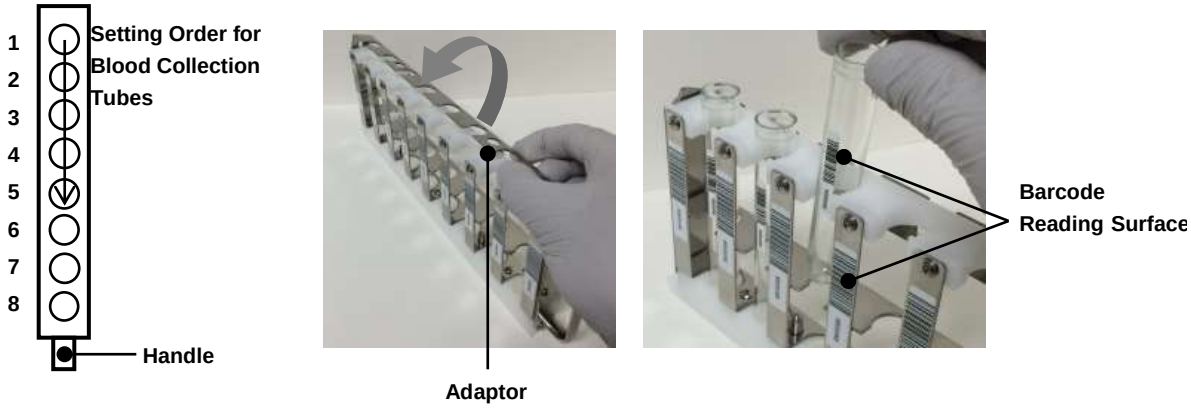
**(1) Gently mix contents of the blood collection tube (sample) by inverting.**

**(2) Remove the lids of blood collection tubes.**

**(3) Set the blood collection tubes on the sample holder.**

Use an adapter according to the type and size of the blood collection tube.

To use the sample (blood collection tube) ID reading function, set the barcode on the blood collection tube to the direction and position of the barcode on the sample holder.

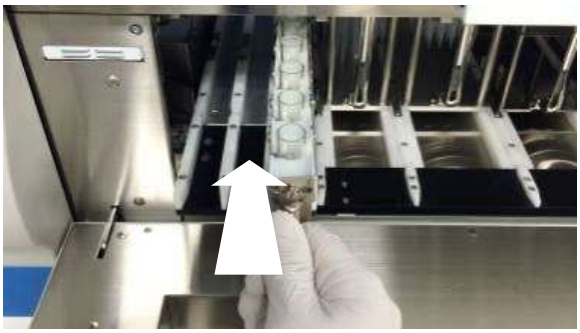



**Note: When several holders are used, set the blood collection tubes while paying attention to the holder identification symbols A – C.**

**(4) Set the sample holders in which blood collection tubes are set in the sample holder slots.**

**After setting, start system operation within 10 minutes to avoid isolation of blood.**

To use the sample ID reading function, the sample holder should not be set in this step, but instead set in accordance with the instructions of the operation panel in "3.8 Isolating Operation ".





**Note:**

- **The holder should be securely set in the slot until it contacts the stopper on the end of the system.**
- **Set a holder in the correct slot according to the manual and the identification label. If a holder is forcibly set in a wrong slot, the holder or system may be damaged.**

# 3.6 Start-up of System

The start-up of this system is explained below.

## ■ How to Turn ON Power

**(1) Confirm that the power cable is connected.**

Confirm that the power cable is connected to the system and the outlet.


Connection of Main Unit Side

Connection of Outlet Side

**Warning:**

- **Connect to a power outlet with a grounding terminal.**
- **Do not disassemble this system. This may cause electric shock.**

**(2) Confirm that the switches for 2 breakers are ON**

Check whether the breaker is shut off. “ON” at the breaker switch is seen while in normal status, and “OFF” at the breaker switch is seen when the circuit is shut off.

When the breaker is shut off, refer to "8.1 Troubleshooting"


**(3) Confirm that the sliding doors, left/right flap doors and drawer are closed.**

The power can be turned ON with doors open, but power will not be supplied to the driving system and the system check will not be conducted.

**(4) Press the Power Switch**

When the power is turned ON, the power switch LED will be lit and the LC panel will be started up. After start-up, the screen will automatically move to the title screen.

## ■ How to turn OFF power

**(1) Press the power switch**

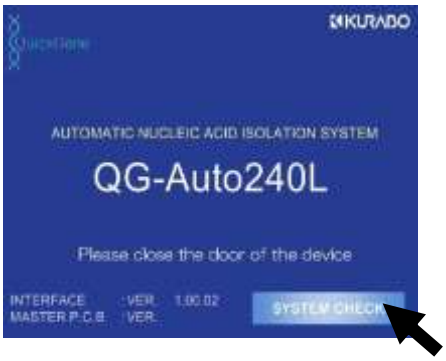
When the power is turned OFF, the power switch LED will go off and the LC panel will be terminated.

## ■ How to move on to the mode select screen

**(1) Confirm that the sliding doors, left/right flap doors and drawer are closed, and press the power switch.**

Refer to the previous section "How to turn ON power".

Wait until the title is displayed.




**(2) Press [SYSTEM CHECK] on the title screen and start the system check.**

[SYSTEM CHECK] button will be enabled after the sliding doors and left/right flap doors are locked.


(3) **Press [OK] when the system check for all the items is complete and move on to the user sign on screen.**

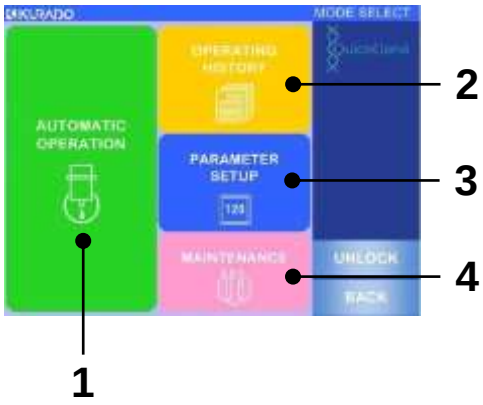
If an item with an indication of [NG] is found, press [NG], confirm the error message, and refer to "8.2 Error Messages" for solving a problem.


(4) **Touch the white frame of [USER ID] and select a registered user ID.** Refer to "3.7 Registration/Deletion of User IDs" for registration/deletion of a user ID.

**(5) Touch the white frame of [USER PASSWORD] to display a ten-key entry pad, enter a password which is set up per user ID, and press [ENT].**

**(6) Press [SIGN IN]**






**(7) Each of the modes is executed from the mode select screen.**

1. AUTOMATED OPERATION / Automatic Isolating Operation Mode
   Refer to "3.8 Isolating Operation".

2. OPERATING HISTORY / Operation History Mode
   Refer to "5 Operation History".

3. PARAMETER SETUP / Parameter Setup Mode
   Refer to "6 Parameter Set-up Procedures".

4. MAINTENANCE / Maintenance Mode
   Refer to "7 Daily Inspection and Maintenance".

# 3.7 Registration and Deletion of User IDs

The procedures for registration and deletion of user IDs are explained below.

## ■ How to register a User ID


**(1) Press [REGISTER] on the user sign-on screen.**

Refer to the previous section "How to move on to the mode select screen" for how to move on to the user sign-on screen.

**(2) Touch the white frame of [USER ID] to display an alphabetical keyboard, enter an arbitrary 5-10 digit alphanumeric string, and press [ENT].**

Set up an alphanumeric string displayed as a user ID.

(3) **Touch the white frame of [PASSWORD] to display an alphabet keypad, enter a 5-10 digit number, and press [ENT]**

Set up a password for the user ID.

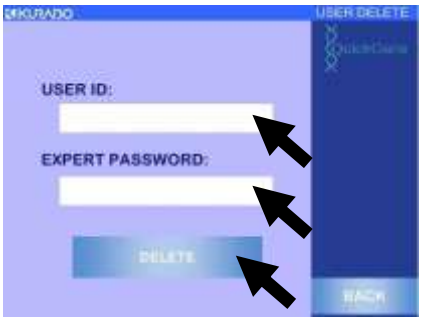
**(4) Re-enter an identical number with [PASSWORD] in the [PASSWORD (RE-ENTER)] frame and press [ENT].**

**(5) Press [REGISTER] and register the User ID.**

## ■ How to delete User IDs


**(1) Press [DELETE] in the user sign on the screen.**

Refer to the previous section "How to move on to the mode select screen" for how to move on to the user sign-on screen.




**(2) Touch the white frame of [USER ID] and select a registered User ID.**

Select a User ID to delete.

**(3) Touch the white frame of [EXPERT PASSWORD] to display a ten-key pad, enter a password for an expert, and press [ENT].**

Contact our sales agent regarding the password for an expert.

**(4) Press [DELETE] to delete the User ID**

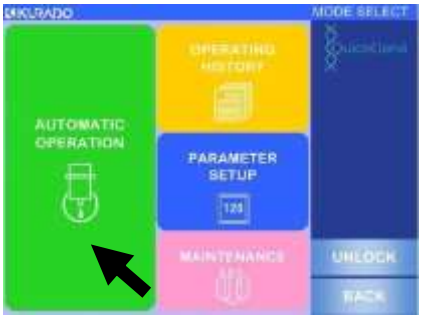
# 3.8 Isolating Operation

Operations before starting the isolation and operation after completion are explained below.

Refer to "3.3 Preparation of Reagents", "3.4 Preparation of Consumables and Accessories", and "3.5 Preparation of Samples" for necessary preparations for isolating operation.

## <1> Start-Up of Automatic Isolating Operation Mode / Selection of Protocol

(1) Refer to "**3.6** Start-Up of System", turn ON system power, and move on to the mode select screen.




**(2)** Press **[AUTOMATED OPERATION]**


**(3)** Press **[OK]** in the displayed pop-up window.
Check that the waste container in the system drawer is empty and execute the automated operation mode.

(4) Press the full automatic protocol button to operate.
**(Ex：W BLOOD DNA 2 mL FULL-AUTO)**
Refer to "2.8 Implemented Protocols" for explanation on protocols.

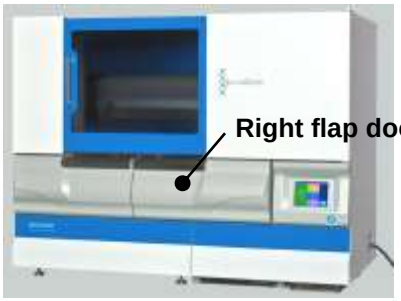
**(5)** Move on to the next section "**<2>** Enter Sample Information".

## <2> Enter Sample Information

**Sample ID Read Function ON** to A-1

**Sample ID Read Function OFF** to B-1

### A. When Sample ID reading function is ON




**(A-1)** When the door lock is released, open the right flap door.

**(A-2)** **Insert sample holder A in slot A slowly over approx. 8 seconds. The ID is read.** Securely set until it contacts the stopper on the end.

Barcode Reader (Inside of system)

**Warning** **Do not peer into the system during sample ID reading and view the red LED light source for the barcode reader. Direct viewing at length may cause eye disorders.**

**Note:**

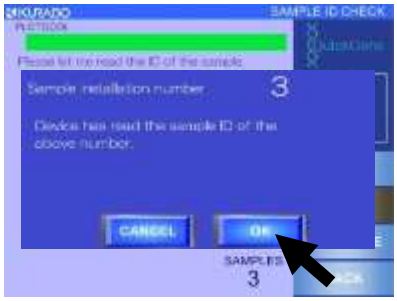
- When setting a holder in the slot, securely set until it contacts the stopper on the end**.**
- When several holders are used, pay attention to the holder identification symbols A-C for setting.


**(A-1)** **The reading of complete samples will be displayed in reversed deep blue on the operation screen.**
**Check for the correctness of readout positional information and the position of the set sample.**

**(A-4)** If there are more holders to set, press **[NEXT]** and carry out **(A-2), (A-3)** for holders **B, C.**


**(A-5)** After confirming the reading of all sample ID information, press [**COMPLETE**].

**(A-6)** The number of samples whose **IDs** are read out will be displayed in a pop-up window. If it is correct, close all doors and press **[OK]**.

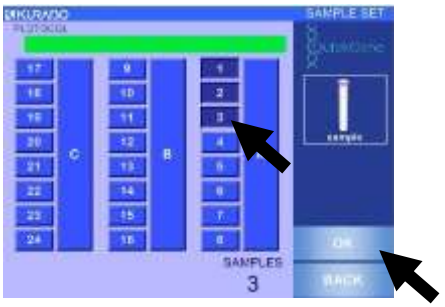



**Note:** Do not take out the sample holder until the automatic operation is complete after this operation.
**Premature removal will cause an error, the sample ID information will be deleted, and the system will go back to "<2> Enter Sample Information"**

**(A-7)** Go to the next section "<3> Enter Collection Information "

## B. When Sample ID Reading Function is OFF

**Note: When the sample ID reading function is OFF, refer to "3.5 Preparation of Samples" and set the sample holders before turning the system power ON.**




**(B-1) Press the numeric button corresponding to the number of set samples.**

- The pressed buttons will be indicated in reversed deep blue on the operation screen.
- The selection will be canceled if the pressed button is pressed again.
- Pressing A, B or C button will enable selection of all for each holder row.

**(B-2) Check that the selected button coincides with the number of set samples and press [OK].**

**(B-3) Move on to the next section "<3> Enter Collection Information"**

## <3> Enter Collection Information

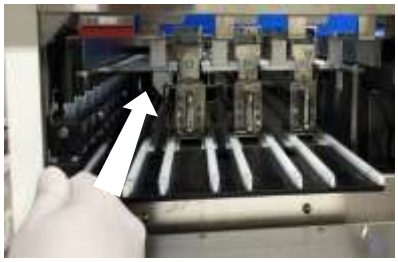
**Collection ID Read Function ON** to C-1

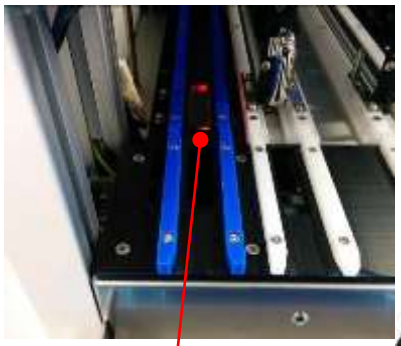
**Collection ID Read Function OFF** to D-1

### C. When the collection ID reading function is ON

Left flap door

**(C-1) Open the left flap door**





2D Barcode Reader

**(C-2) Insert the collection tube holder A in the collection ID reading slot slowly over approx. 8 seconds. The ID is read.**

- Securely set until it contacts the stopper on the end.
- Position of the collection tubes completed with reading will be displayed in reversed green on the operation screen.
- When the position of the read-out collection tube and the previously entered sample setting position.

**Warning**

The laser light source categorized Class 1 is used for the 2D code reader. Do not peer into the system while reading the collection ID and directly view the red light source. Direct viewing at length may cause eye disorders.

**Note: If a pop-up window is not displayed, check the set position of collection tubes and execute the reading again.**

**(C-1) Set collection tube holder A in collection tube holder slot A.**

- Securely set the collection tube holder until it contacts the stopper on the end.
- The pop-up window will disappear when the collection tube holder is set in a correct slot.

**(C-2) If there are more holders to set, press [NEXT] and carry out (C-2), (C-3) for holders B, C.**


**(C-3) Confirm that all the holders are set in each slot and press [COMPLETE].**

When the positions of all the collection tubes and samples (blood collection tubes) coincide, the [COMPLETE] button will be enabled.

**(C-6) The number of samples whose IDs are read out will be indicated in the pop-up window. If they are correct, close all the doors and press [OK].**

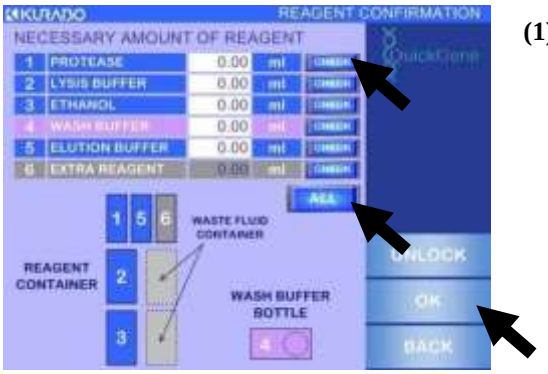

**(C-7) Go to the next section "<4> Confirmation of Reagent"**

## D. When the collection ID reading function is OFF

**Note: When the collection ID reading function is OFF, refer to "3.4 Consumables and Accessories" and set the collection tube holders before turning system power ON.**

**(D-1) Go to the next section "<4> Confirmation of Reagent"**

## <4> Confirmation of Reagent




**(1) Refer to the indicated information on the screen regarding the reagents to be used for the automatic isolating operation and confirm that the required quantity is set in the correct position.**

3

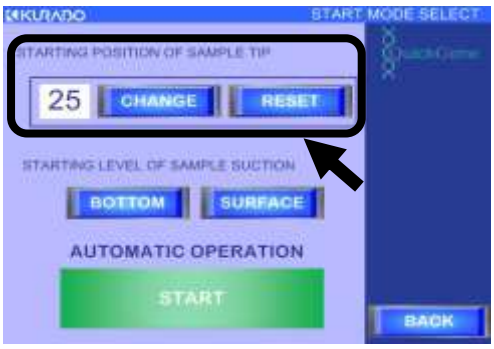
**(1) Press [CHECK] for a confirmed reagent.**

**If [ALL] is pressed, all [CHECK] buttons are pressed at the same time.**

**(2) Press [OK].**

When all [CHECK] buttons are pressed, the [OK] button will be enabled.

## <5> Setting up Operating Conditions




**(1) Setup of sample tip use starting position.**

Press [**RESET]** to start from the default position, and then set the value to "1". To start from another position, press **[CHANGE]** to display a ten-key pad, enter a chosen value and press **[ENT]** to set up.

Refer to the figure on the left for the relation of set-up values and tip positions.

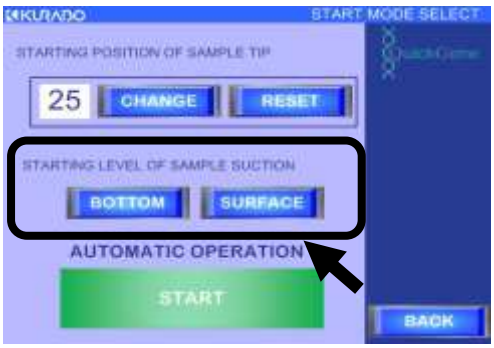
The number of used sample tips is recorded based on the operation history; the use starting position will be automatically set up accordingly.

**Relation of Setup Values and Tip Positions**

| | | | | | |
|---|---|---|---|---|---|
| 81 | 65 | 49 | 33 | 17 | 1 |
| 82 | 66 | 50 | 34 | 18 | 2 |
| 83 | 67 | 51 | 35 | 19 | 3 |
| 84 | 68 | 52 | 36 | 20 | 4 |
| 85 | 69 | 53 | 37 | 21 | 5 |
| 86 | 70 | 54 | 38 | 22 | 6 |
| 87 | 71 | 55 | 39 | 23 | 7 |
| 88 | 72 | 56 | 40 | 24 | 8 |
| 89 | 73 | 57 | 41 | 25 | 9 |
| 90 | 74 | 58 | 42 | 26 | 10 |
| 91 | 75 | 59 | 43 | 27 | 11 |
| 92 | 76 | 60 | 44 | 28 | 12 |
| 93 | 77 | 61 | 45 | 29 | 13 |
| 94 | 78 | 62 | 46 | 30 | 14 |
| 95 | 79 | 63 | 47 | 31 | 15 |
| 96 | 80 | 64 | 48 | 32 | 16 |

**Note:**

- **Confirm whether the number of 1.2-mL tips is equal to or more than the number of samples and set from the use starting position.**
- **If the sum of setup value and the number of samples automatically operated exceeds 96, reset the value of use starting position.**




**(2) Select the sample suction starting position.**

**Select [BOTTOM] for sample suction from the bottom of the blood collection tube; select [SURFACE] for suction from the fluid surface.**

[BOTTOM]: Suction from a fixed position

[SURFACE]: Suction from fluid surface by detecting the surface using the differential pressure type fluid surface detecting function

3

Note: When [BOTTOM] mode is selected, a pop-up window to warn of overflow will appear. After confirming that the sample quantity in the blood collection tube is not more than 3 mL, press [OK] and return to the setup screen.

If the set sample quantity is more than 3 mL, press [BACK] to go back to the mode select screen, press [UNLOCK] to release the door locks, and then take out the sample holder from the system and adjust the sample quantity.

## <6> Automatic Operation Start



**(1) Press [START] to start the automatic operation.**

After completing the check of various parts using the sensors, the isolating operation starts. For those items determined "NG", refer to the table below and solve the problem.

| Checking Items | Reference |
|---|---|
| SAMPLE | 3.5 Preparation of Samples |
| REAGENT CONTAINER | 3.3 Preparation of Reagents |
| WASH BUFFER BOTTLE | |
| WASTE FLUID CONTAINER | |
| COLLECTION TUBE | 3.4 Preparation of Consumables/ Accessories |
| LYSATE TUBE | |
| DISPENSING TIP (1.2ml/SAMPLE) | |
| DISPENSING TIP (10ml/LYSATE) | |
| DISPENSING TIP (1.2ml/REAGENT) | |
| DISPENSING TIP (10ml/REAGENT) | |
| CARTRIDGE/WASTE TUBE | |
| WASTE CONTAINER | |
| AGITATOR COVER | |

**Note: When the isolating operation is suspended due to an error or trouble during automatic operation, refer to "8.1 Troubleshooting" or "8.2 Error Messages"**

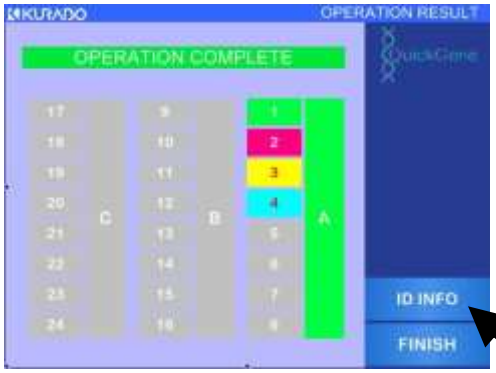
## <7> Confirmation of Operation End/Operation Results


**(1) The operation ends when the left screen is displayed.**

The background color for the sample number indicates the operation result.

| Color | Operation Result |
|---|---|
| Green | Normal End |
| Red (NG1) | Chip Clogging at Sample Suction (Incomplete Isolation) |
| Yellow (NG2) | Pressure Leakage of Cartridge (Incomplete Isolation) |
| Blue (NG3) | Clogged Cartridge (Incomplete Isolation) |
| Gray | No Sample |

**Note : Refer to "8.1 Troubleshooting" or "8.2 Error Messages" for incomplete isolation.**

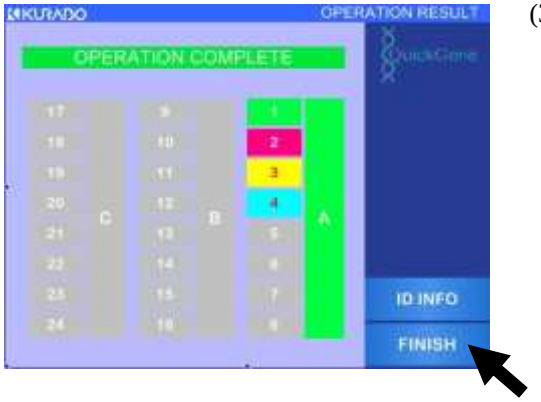



**(2) The sample ID and collection ID information will be displayed by pressing [ID INFO]. After confirmation of ID information, press [BACK] and return to the operation result screen.**

The [ID INFO] button will be enabled only when the ID reading function is [ON].

When the collection ID reading function is [OFF], the sample position information (Ex: A-1, A-2) is displayed in the collection ID columns.

The ID information will be confirmed and saved later. Refer to "5 Operation History" for the procedures.




(3) **Press [FINISH] on the operation result screen.**


**(4) Press [OK] in the displayed pop-up window.**

**(5) Press the system power switch and turn the power OFF.**

## <8> Collection of Isolation Samples

**(1) Confirm the power OFF of system**

**Open the left flap door and remove the collection tube holder.**

**Note: The isolation sample may be spilt if the collection tube holder is tilted. Take out while holding the handle of the collection tube holder with one hand and supporting the bottom surface of the holder with the other hand.**



**(2) Close the collection tube cap (if a cap is used) and remove the tube**

**Note:**

- **Securely close the cap.**
- **If the collection ID reading function is "OFF", carefully conduct the removal and management of collection tubes paying attention to the holder identification symbols A-C.**

## <9> Disposal of Consumables and Wastes

**(1) Confirm system power OFF.**

**(2) Open the left/right flap doors and take out all holders and consumables.**

**(3) Refer to the table below and treat the various removed holders and consumables.**

| Holder/Wear Parts | Treatment | Remarks |
|---|---|---|
| Reagent Container Holder | Remove reagent containers from reagent container holder. Residual reagents in reagent containers should be stored in sealed container.<br>Remove waste fluid container from reagent container holder and dispose of waste fluid collected in waste container.<br>Refer to "7 Daily Inspection and Maintenance" and clean reagent containers and waste fluid containers. | Note:<br>Residual reagent in reagent container should be consumed as soon as possible.<br>Waste fluid should be disposed of in accordance with rules. |
| Sample Tip Holder | Remaining tips should be stored in clean environment with no contamination. | |
| Reagent Tip Holder | Remaining tips should be stored in clean environment with no contamination. | |
| Sample Holder | Remove blood collection tube from sample holder and dispose of remaining blood sample and blood collection tubes. | Biohazard:<br>Remaining blood sample and blood collection tubes should be disposed of in accordance with customer's infectious waste treatment manuals. |
| Lysate Tube | Dispose of lysate tubes | Biohazard:<br>Dispose of lysate tubes in accordance with customer's infectious waste treatment manuals. |

| Holder/Wear Parts | Treatment | Remarks |
|---|---|---|
| Cartridge Holder | Open cover by releasing locks at 3 places on cartridge holder.<br>Pull out and dispose of cartridges one by one. | Note:<br>Remove cartridge in such a way that tip does not contact cartridge holder.<br>If cartridge tip contacts cartridge holder, refer to "7 Daily Inspections and Maintenance" and wash and dispose of cartridge holder. |
| Waste Tube Holder | Remove waste tubes from waste tube holder and dispose of waste fluid and waste tubes. | Biohazard:<br>Removed waste fluid and waste tubes should be disposed of in accordance with customer's infectious waste treatment manuals. |
| Cleaning Fluid Bottle | Reagents remaining in cleaning fluid bottle should be sealed as is and stored.<br>When washing cleaning fluid bottle, refer to "7 Daily Inspections and Maintenance". | Note:<br>When storing cleaning fluid bottles, securely close caps. |
| Waste Container | Dispose of waste in waste container.<br>When cleaning waste container, refer to "7 Daily Inspections and Maintenance". | Biohazard:<br>Waste should be processed in accordance with customer's infectious waste treatment manuals. |



## <10> Post Treatment of System

Refer to "7. Daily Inspections and Maintenance" and carry out system maintenance as necessary.

**(1) Close all system doors**

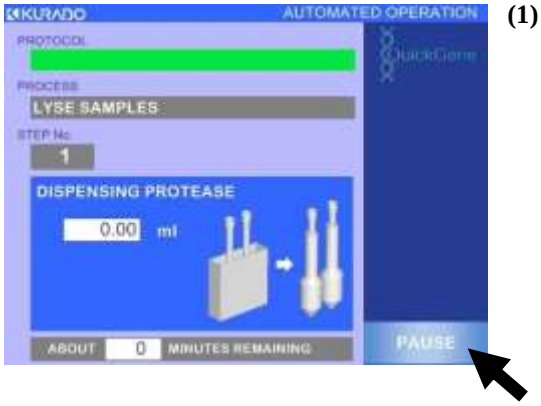
The isolating operation is now complete.

If the operation is to be continued with a full-automatic protocol, start from "3.3 Preparation of Reagent".

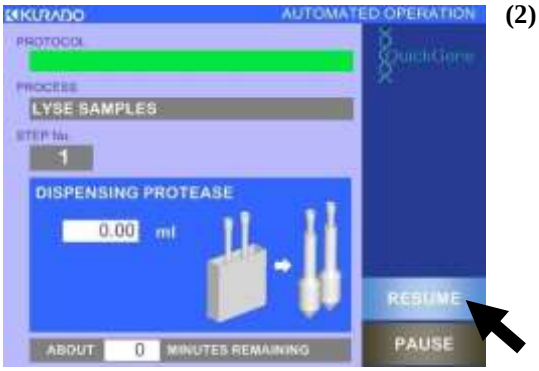
**Important: If the system will not be used again for more than 1 week, refer to "7.2 When System Not in Use for More than One Week" and carry out maintenance.**

# 3.9 Operation to Stop Automatic Operation

To stop isolating operation during automatic operation of the system, follow the procedures below:




**(1) Press [PAUSE] at the lower right of the operation screen.**




**(2) Visually confirm the complete stop of system motion.**

Continue the following operations as necessary:

- Press [RESUME] to resume automatic operation.
- Press the system power switch to shut the system power OFF.

**Important:**

- **The system will complete active movements before stopping when [PAUSE] is pressed. Confirm a complete stop and then start the next operation.**
- **Once power is shut down, no resumption of the stopped movement is possible.**
- **Even if operation is resumed after stoppage, a sufficient quality/yield of nucleic acid may not be achievable if the stoppage was repeated or lengthy in duration.**