

Operation Manual

Automated Nucleic Acid Isolation System
QuickGene-Auto240L



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.



■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.

Symbols

| Symbol | Explanation | Symbol | Explanation |
|--------|--|--------|--|
| | In vitro diagnostic medical device | | Consult instructions for use |
| | CE marking | | Temperature limitation |
| | Manufacturer information | | Humidity limitation |
| | European authorized representative | | Recyclable materials |
| | Caution! Consult accompanying documents | | Do not dispose of this product as unsorted municipal waste |

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 | | | Manufacturer |
|-----------------------------|---|--|------------------------|
| Whole Blood DNA Reagent Kit | QuickGene DNA whole blood kit L (DB-L) | | KURABO INDUSTRIES LTD. |
| Consumable Supply Kit | QuickGene-Auto240L Consumables Kit (QG-240L-CK) | | KURABO INDUSTRIES LTD. |

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 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.

Intended Use

The combination of QuickGene-Auto240L system and QuickGene DNA whole blood kit L (DB-L) kit is intended to isolate high-quality genomic DNA automatically from human whole blood sample. Generally, DNA isolated by the system is useful for PCR based analysis like HLA typing or karyotyping to know patients' genotype before transplantation, and for Next Generation Sequencing (NGS) for selection of the molecular-targeted agents. Such high-quality genomic DNA is also suitable for the long-term storage project like bio banking with less DNA degeneration/ degradation. DNA isolated from the system can't be used for diagnosis, prevention, or treatment of a disease purpose directly. The system and the kit are intended for use by professional users; adequately skilled in molecular biological techniques and trained to operate the system.

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.

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1 System Installation Procedures

The installation procedures for this system are explained below.

1

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 cause 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 shock may result from a damaged power cable.



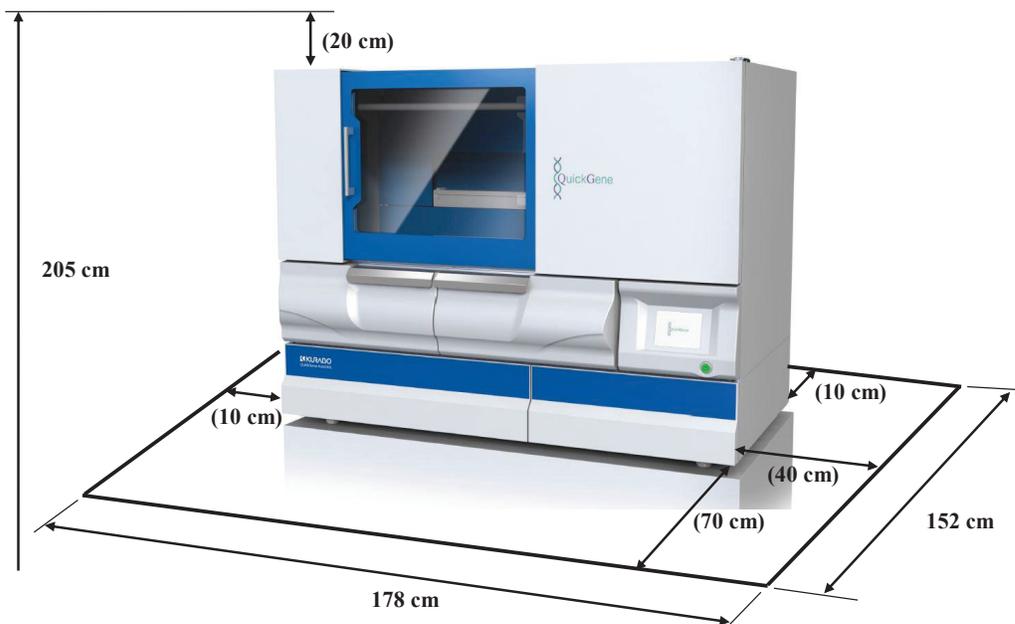
Caution:

- 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 \times Depth ≥ 152 cm \times Height ≥ 205 cm (when placed on an 80-cm high experiment table)



1 System Installation Procedures

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 $\geq 350\text{kg}$ 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 (°C) | In operation | 15-30 |
| | During standby | 15-30 |
| Humidity (%) | In operation | 30-80 |
| | During standby | 10-80 |
| Max. Wet-bulb Temp. (°C) | In operation | 29 (no condensation) |
| | During standby | 29 (no condensation) |
| Temperature Gradient (°C / 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

1.3 How to Remove the Interior Packing Material and Fixtures

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

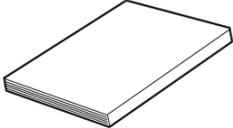
1

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.

1

| | | |
|---|---|---|
| <input type="checkbox"/> System Main Unit | <input type="checkbox"/> Operation Manual | |
|  |  | |
| <input type="checkbox"/> Power Cable | <input type="checkbox"/> Reagent Container Holder | <input type="checkbox"/> Sample Tip Holder |
|  |  |  |
| <input type="checkbox"/> Reagent Tip Holder | <input type="checkbox"/> Sample Holder ×3 | <input type="checkbox"/> Cartridge Holder ×3 |
|  |  |  |
| <input type="checkbox"/> Waste Tube Holder ×3 | <input type="checkbox"/> Collection Tube Holder ×3 | <input type="checkbox"/> Waste Container |
|  |  |  |
| <input type="checkbox"/> Wash Buffer Bottle | <input type="checkbox"/> Reagent Container S ×3 | <input type="checkbox"/> Reagent Container L ×4 |
|  |  |  |
| <input type="checkbox"/> UV Lamp | <div data-bbox="646 1627 743 1709" style="display: inline-block; vertical-align: middle;">  </div> <div data-bbox="743 1656 837 1686" style="display: inline-block; vertical-align: middle;"> <p>Caution:</p> </div> <hr style="border: 1px solid gray; margin: 10px 0;"/> <div data-bbox="711 1751 1360 1829" style="display: inline-block; text-align: center;"> <p>Note: Use power cables, holders, containers included in package</p> </div> <hr style="border: 1px solid gray; margin: 10px 0;"/> | |
|  | | |

1.5 Names of Parts

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

■ System Front View

1



■ System Side View

Right Side

Left Side

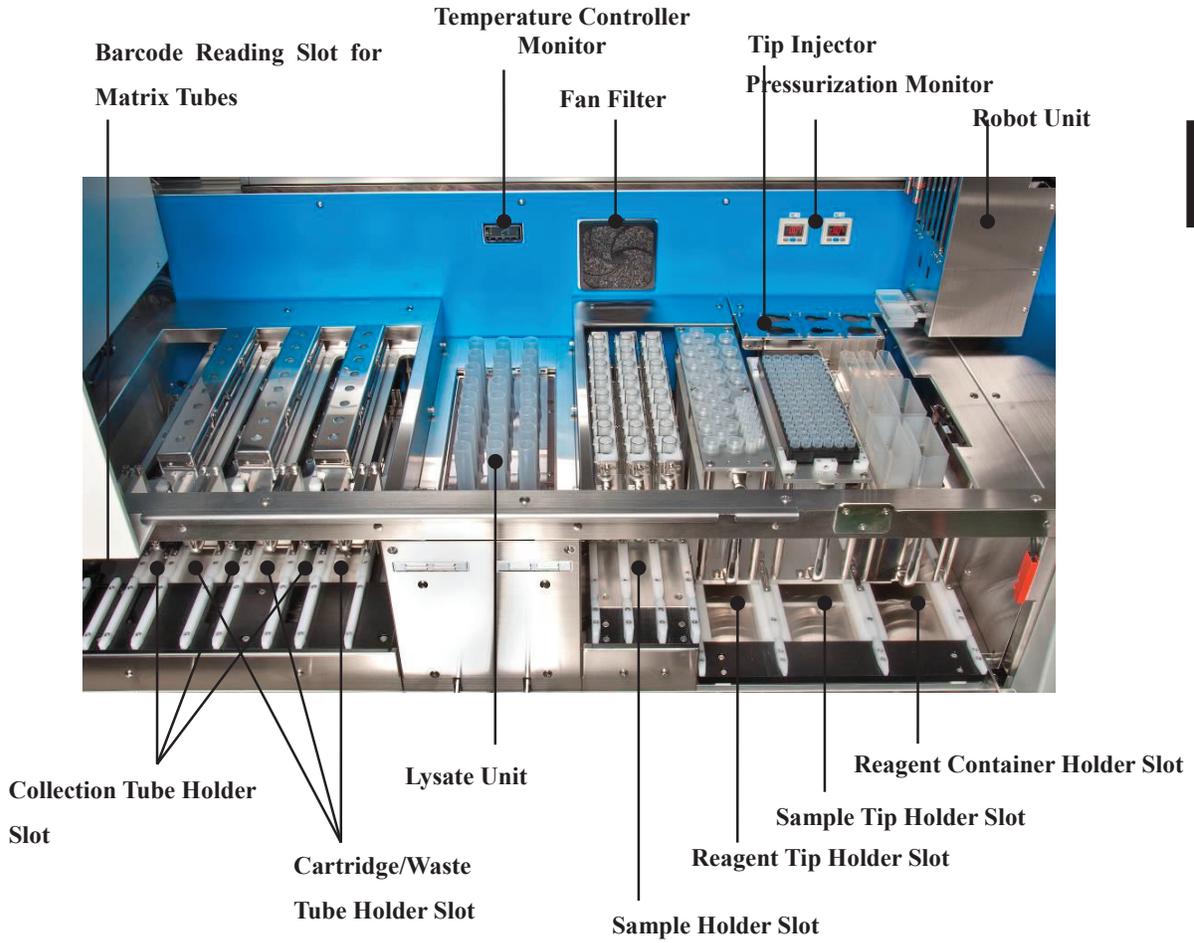


USB Port 2
USB Port 1
LAN Port
Serial Port (9 pin)

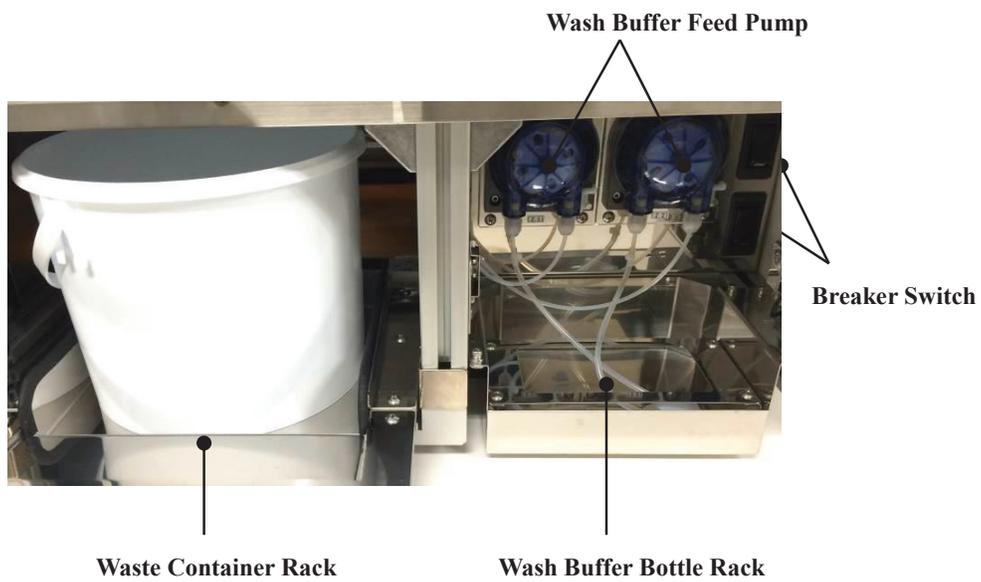


Inlet
Power Cable

■ 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

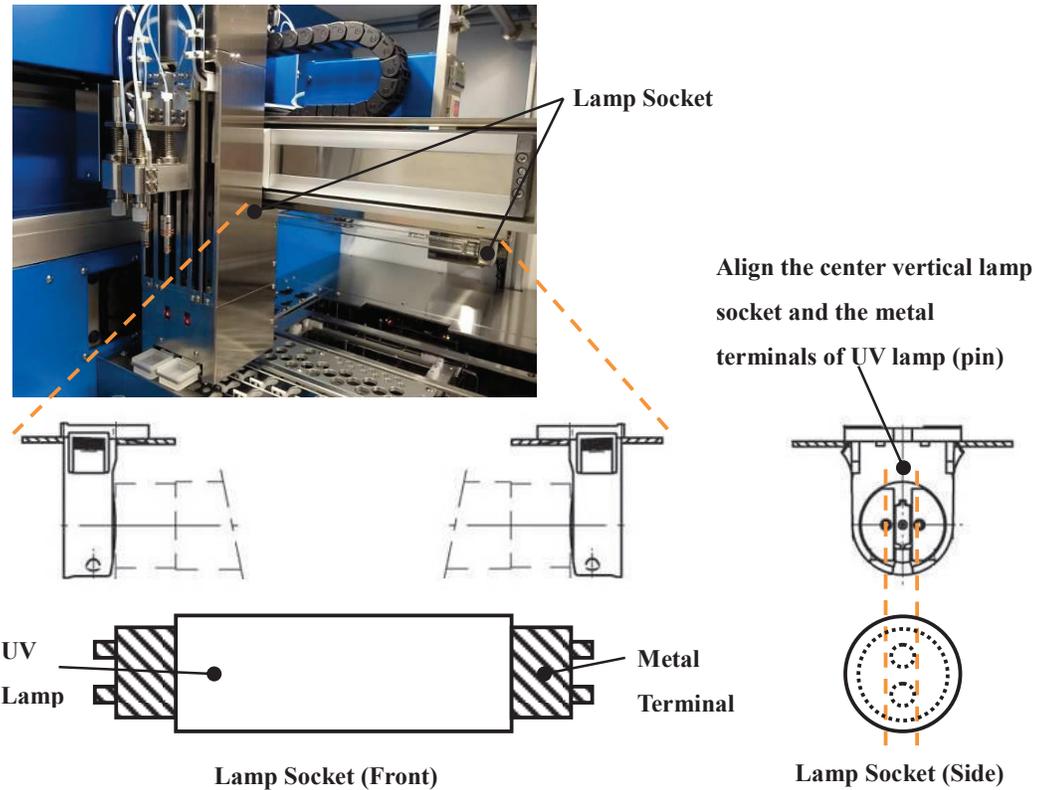
Syringe

1.6 Mounting of UV Lamp

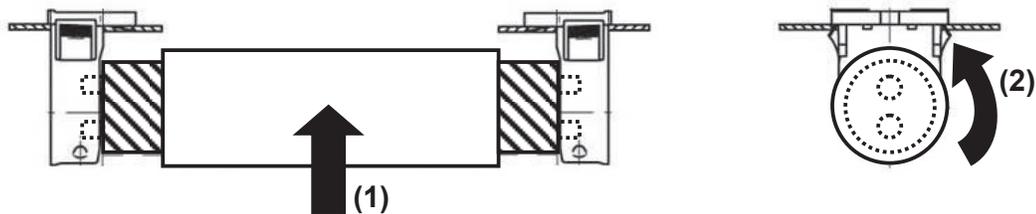
The mounting procedures for the UV lamp are explained below.

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

1.7 Checking the System Functions

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

1

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

2.1 Components Configuring the System

The major components of this system are shown:

■ View of the System



■ Work Area



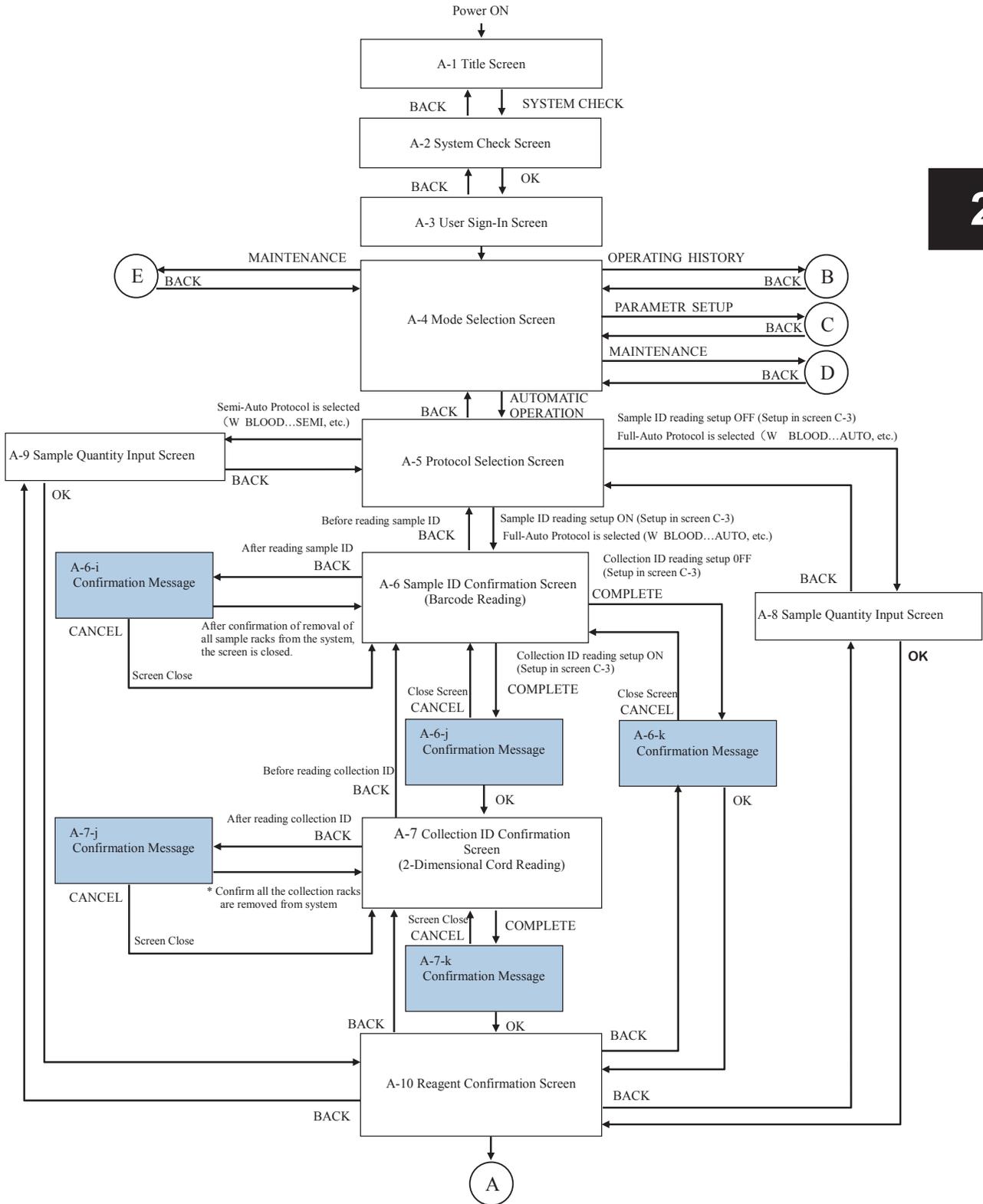
■ Inside Drawer



| 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. 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. |

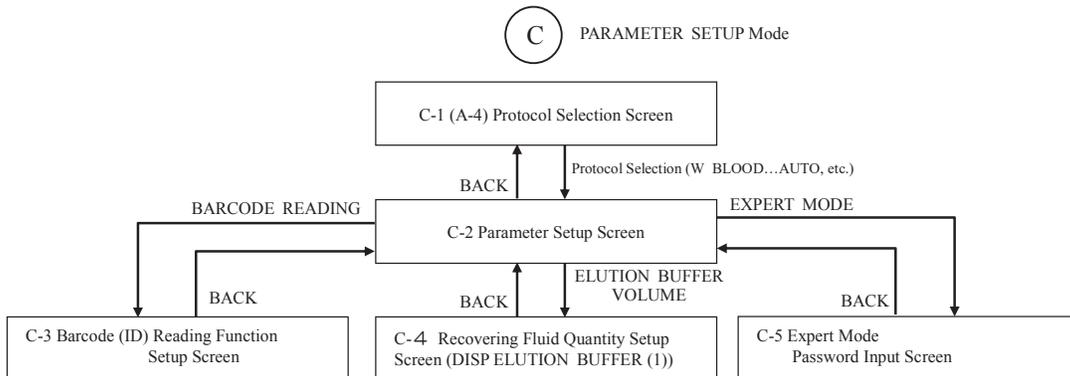
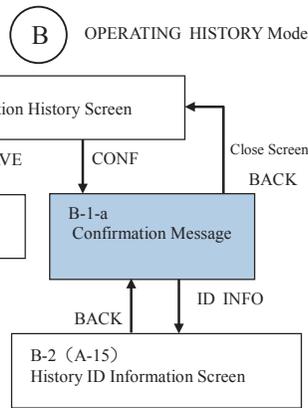
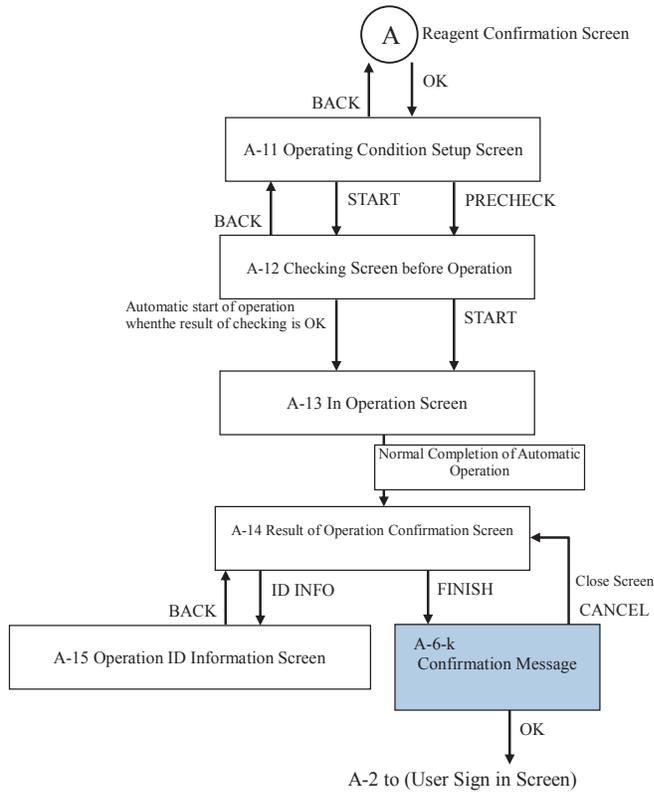
2.2 Basic Operations, Basic Functions

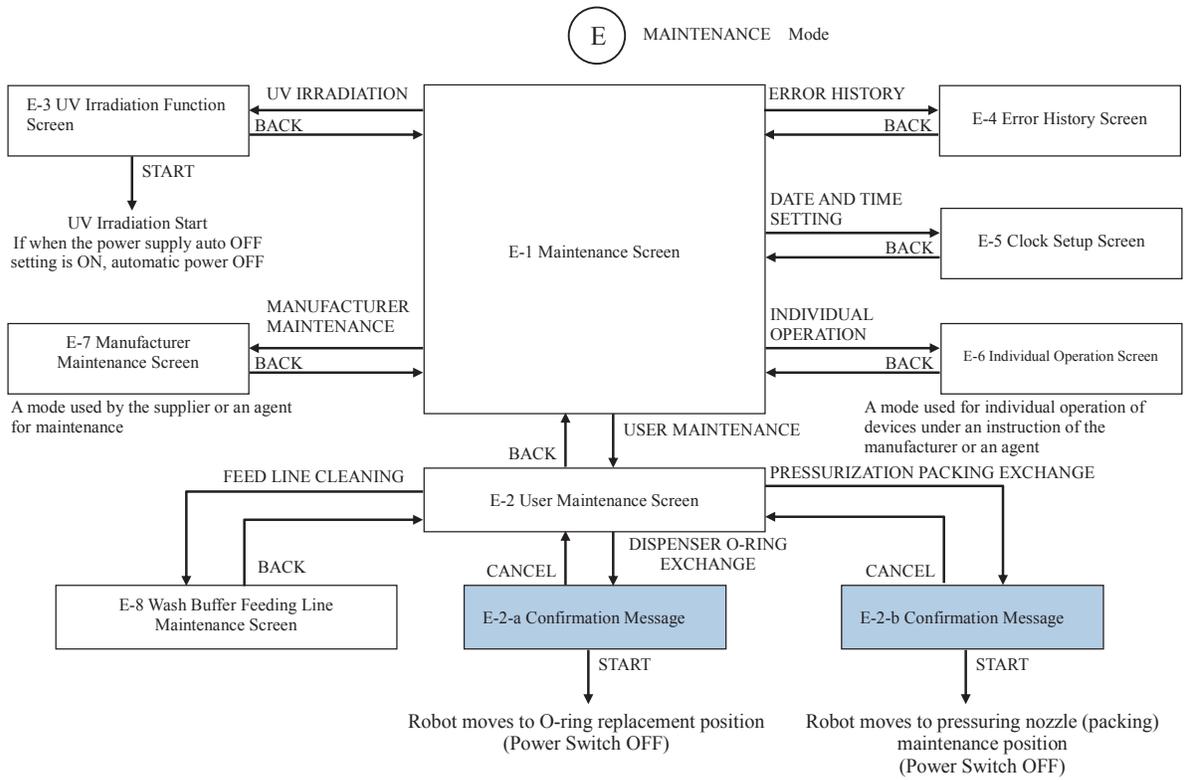
The system operation flow is as follows:



2

2





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

2

■ 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

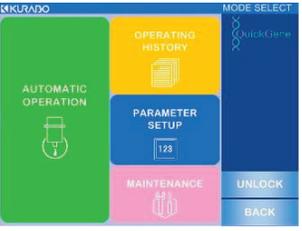
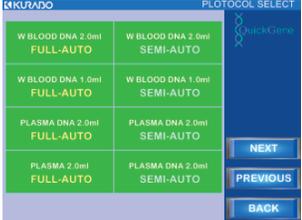
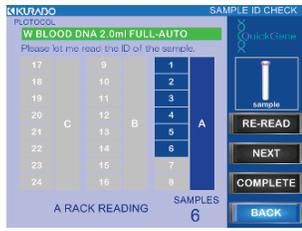
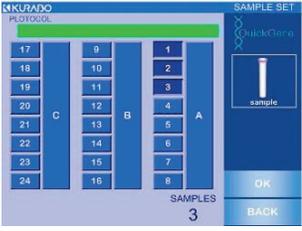
The displays on the operation panel while in normal operation are explained below.

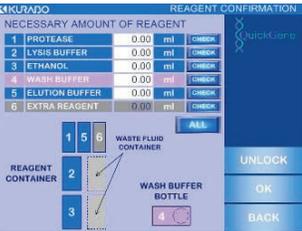
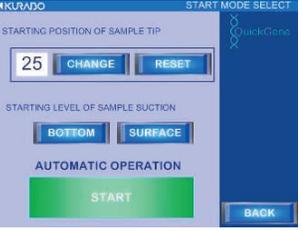
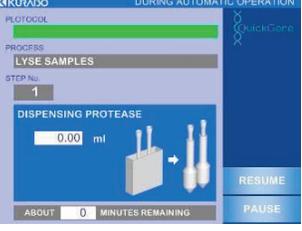
For the screens displayed in the case of an abnormality, refer to “8.2 Error Message”.

| No. | Screen | Description |
|-----|---|--|
| 1 |  | <ul style="list-style-type: none"> ■ Company Logo Screen Automatically moves to the Title Screen. |
| 2 |  | <ul style="list-style-type: none"> ■ Title Screen Displayed after system power ON. [SYSTEM CHECK] button is enabled while all system doors are locked. Press [SYSTEM CHECK] to move on to the system check screen, and the system check will start. |
| 3 |  | <ul style="list-style-type: none"> ■ System Check Screen Displayed for system checking. The item lamps indicate completion in green, incompleteness 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 |  | <ul style="list-style-type: none"> ■ User Sign-In Screen Displayed for user sign-in. 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 |  | <ul style="list-style-type: none"> ■ User ID Registration Screen Displayed for registration of User ID. 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 Basic Functions

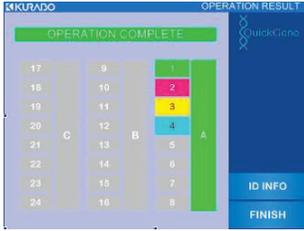
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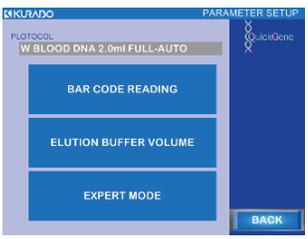
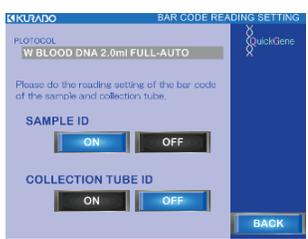
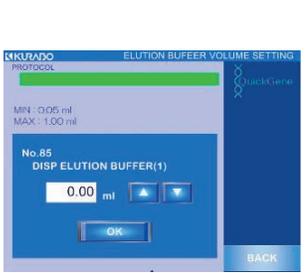
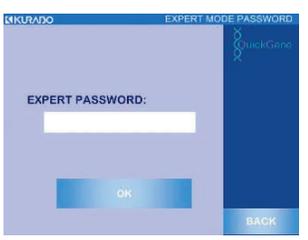
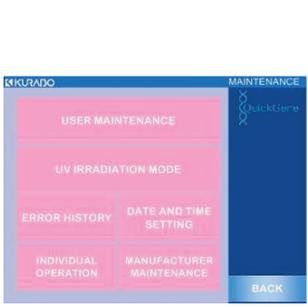
| No. | Screen | Description |
|-----|---|--|
| 6 |  | <p>■ User ID Delete Screen</p> <p>Displayed when deleting a User ID.</p> <p>Touch the white frame of [USER ID] and select a registered user ID. Then touch the white frame of [EXPERT PASSWORD] to display a ten-key entry pad, enter a password for an expert and press [ENT]. Finally, press [DELETE] to delete a User ID. Please contact our sales agent regarding the password for an expert.</p> |
| 7 |  | <p>■ Mode Select Screen</p> <p>Displayed when selecting various modes. Press a button to move on to one of the modes.</p> <ul style="list-style-type: none"> • [AUTOMATIC OPERATION]: The mode for isolating operation • [OPERATING HISTORY]: The mode for checking operating history, checking ID information and storing data • [PARAMETER SETUP]: The mode for confirmation and setup of operating conditions and parameters • [MAINTENANCE]: The mode for confirmation of functioning for maintenance and other setups. <p>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.</p> |
| 8 |  | <p>■ Protocol Select Screen</p> <p>Displayed when the isolating operation protocol is selected.</p> <p>[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.</p> |
| 9 |  | <p>■ Sample ID Check Screen</p> <p>Displayed when reading ID information and detecting number of samples while the sample ID barcode reading function is [ON].</p> <p>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.</p> |
| 10 |  | <p>■ Number of Samples Entry Screen</p> <p>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.</p> |

| No. | Screen | Description |
|-----|---|--|
| 11 |  | <p>■ Collection ID Check Screen</p> <p>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.</p> |
| 12 |  | <p>■ Reagent Confirmation Screen</p> <p>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.</p> |
| 13 |  | <p>■ Operating Condition Setup Screen</p> <p>Displayed for setting up operating conditions.</p> <p>[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.</p> <p>[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.</p> |
| 14 |  | <p>■ Pre-Operation Check Screen</p> <p>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.</p> |
| 15 |  | <p>■ In Operation Screen</p> <p>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.</p> |

2 Basic Functions

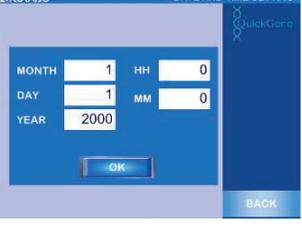
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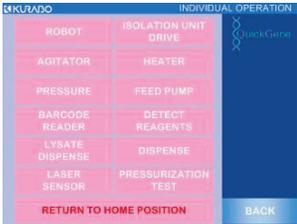
| No. | Screen | Description |
|-----|---|---|
| 16 |  | <p>■ Processing Result Confirmation Screen</p> <p>A screen displayed when the automatic operation is complete. The background color for sample number indicates the operation result: green for normal completion, red (NG1) for chip clogging at sample 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.</p> <p>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].</p> |
| 17 |  | <p>■ Operation ID Information Screen</p> <p>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.</p> |
| 18 |  | <p>■ Operating History Screen</p> <p>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.</p> |
| 19 |  | <p>■ History ID Information Screen</p> <p>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.</p> |
| 20 |  | <p>■ Operating History Save Screen</p> <p>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.</p> |

| No. | Screen | Description |
|-----|---|--|
| 21 |  | <p>■ Parameter Setup Screen</p> <p>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.</p> |
| 22 |  | <p>■ Barcode (ID) Reading Function Setting Screen</p> <p>A screen displayed when [BARCODE READING] is pressed in the parameter setup screen. Select [OK] for reading and [OFF] for not reading the Sample ID on the sample (blood collection tube) and the Collection ID on the collection tube.</p> |
| 23 |  | <p>■ Fluid Collection Volume Setting Screen</p> <p>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.</p> <p>[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].</p> <p>[Change the value using (Δ▽) buttons] One press of the [Δ] 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.</p> |
| 24 |  | <p>■ Expert Mode Password Entering Screen</p> <p>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.</p> |
| 25 |  | <p>■ Maintenance Screen</p> <p>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.</p> <ul style="list-style-type: none"> • [USER MAINTENANCE]: User maintenance screen • [UV IRRADIATION]: UV (ultraviolet light) irradiating function screen • [ERROR HISTORY]: Error history screen • [INDIVIDUAL OPERATION]: Individual operation screen (NB: used under instruction of the manufacturer or sales agent) • [DATE AND TIME SETTING]: Clock setting screen • [MANUFACTURER MAINTENANCE]: Manufacturer maintenance screen (NB: use by the user is prohibited) |

2 Basic Functions

2

| No. | Screen | Description |
|-----|---|--|
| 26 |  | <p>■ User Maintenance Screen</p> <p>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).</p> |
| 27 |  | <p>■ Wash Buffer Feeding Line Maintenance Screen</p> <p>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. [Directly enter a value using ten-key pad] Touch a white frame to display the ten-key, enter a value and press [ENT]. [Change the value using the (Δ▽) button] One press of the [Δ] 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.</p> |
| 28 |  | <p>■ UV (ultraviolet light) Irradiating Function Screen</p> <p>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.</p> |
| 29 |  | <p>■ Error History Screen</p> <p>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.</p> |
| 30 |  | <p>■ Clock Setup Screen</p> <p>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.</p> |

| No. | Screen | Description |
|-----|---|--|
| 31 |  | <p>■ Individual Operation Screen (NB: use under instruction of the manufacturer or sales agent)</p> <p>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.</p> <ul style="list-style-type: none"> • [ROBOT]: Motor individual operation screen • [ISOLATION UNIT DRIVE]: Isolation unit individual operation screen • [AGITATOR]: Agitator motor individual operation screen • [HEATER]: Heater individual operation screen • [PRESSURE]: Pressurizing unit individual operation screen • [FEED PUMP]: Fluid feeding pump individual operation screen • [BARCODE READER]: Barcode/2-dimensional code reader confirmation screen • [DETECT REAGENTS]: Fluid surface detection function confirmation screen • [LYSATE DISPENSE]: Lysate fluid transferring function confirmation screen • [DISPENSE]: Dispenser function confirmation screen • [LASER SENSOR]: Laser sensor function confirmation screen • [PRESSURIZATION TEST]: Pressurizing test function confirmation screen |
| 32 |  | <p>■ Ten-Key Input Pop-Up Screen</p> <p>Displayed when a value is to be entered in each screen</p> <ul style="list-style-type: none"> [0-9]: Enter values [.]: Enter decimal point [+/-]: Enter +/- sign [ENT]: Finalize the entered data (Finalization is not accepted if the entered number of characters is insufficient for ID, password, etc.) [BS]: Delete 1 entered digit [CL]: Delete all entered digits [ESC]: Return to previous screen from the ten-key input screen |
| 33 |  | <p>■ Keyboard Input Pop-Up Screen</p> <p>Displayed for entering characters in each screen</p> <ul style="list-style-type: none"> [0-9]: Enter the values [.]: Enter decimal point [A-Z]: Enter alphabetical characters [Symbol]: Enter a symbol [SPACE]: Enter a space [SHIFT]: Shift Key [ENTER]: Finalize the entered data (Finalization is not accepted if the entered number of characters is insufficient for ID, password, etc.) [BS]: Delete 1 entered digit [CL]: Delete all entered digits [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. |

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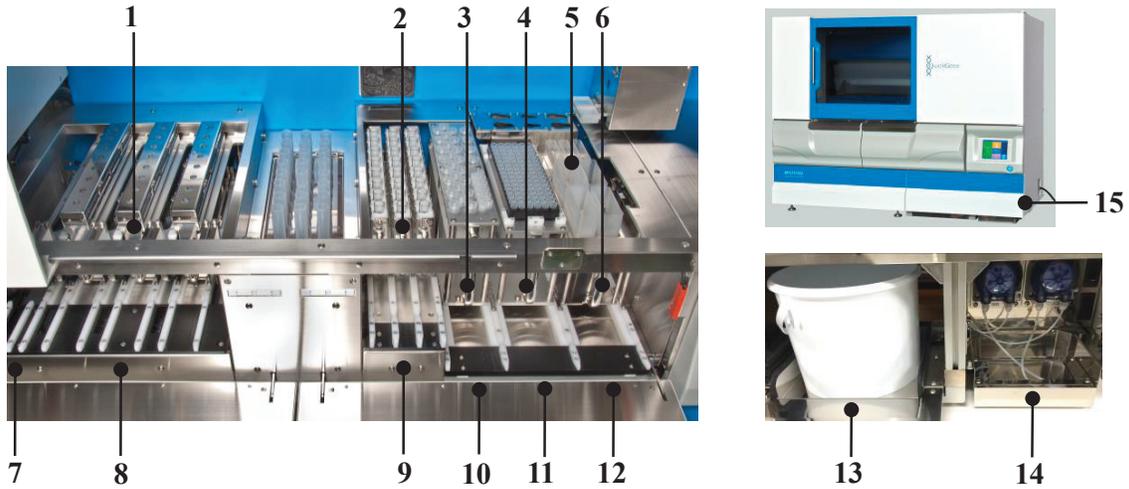
2.6 Basic Specifications

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: ϕ 13 x 100 mm 10 mL: ϕ 16 x 100 mm * ϕ 13 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 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 Humidity: 30%-80%RH (no condensation) |
| Altitude | ≤1600 m for use |

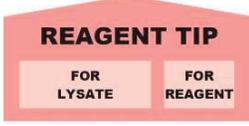
2.7 Product Labeling

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



2

| No. | Label | Description |
|-----|-------|---|
| 1 | | Labels indicating the collection tube holder The alphabetical characters A – C are the holder identifications. |
| | | Labels indicating the cartridge holder. The alphabetical characters A – C are the holder identifications. |
| | | Labels indicating the waste tube holder. The alphabetical characters A – C are the holder identifications. |
| 2 | | Labels indicating the sample holder. 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 |
|-----|---|---|
| 5 |  | Label indicating reagent container setting position No.6. |
| |  | 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. 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. The alphabetical characters A – C are the holder identifications. |
| |  | Label indicating slot for setting cartridge/waste tube holder. The alphabetical characters A – C are the holder identifications. |
| 9 |  | Label indicating slots for setting sample holder. The alphabetical characters A – C are the holder identifications. |
| 10 |  | Label indicating slot for setting reagent tip holder. “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. 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. The setting position is in a location pointed with an arrow. |
| 14 |  | Label indicating reagent container setting position No.4. |

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2 Basic Functions

| No. | Label | 内容 |
|-----|---|---|
| 15 |  <p>KURABO INDUSTRIES LTD. Advanced Technology Division, Bio-Medical Department 14-30, Shimokita-cho, Neyagawa City, Osaka, 572-0823, Japan</p> <p>Med Net GmbH Borkstrasse10, 48163Muenster, Germany</p> <hr/> <p>NAME: Automated Nucleic Acid Isolation System MODEL: QuickGene-Auto240L REF: 40321301003 INPUT: AC230V 3.0A 50-60Hz SN: _____</p> <p>CE IVD</p> | <p>Label indicating Model (Name Plate)</p> <p>Affixed on the bottom right side surface of this system (front side).</p> <p>“MODEL” indicates the model number of this system.</p> <p>“INPUT” indicates the input power voltage, current and frequency.</p> <p>“REF” indicates the serial number.</p> <p>CE and IVD symbol marks are clearly stated.</p> |

2

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: The parameter “W BLOOD DNA 2.0 mL FULL-AUTO” is input in protocols 1-4 as a default value. To change the parameters, a separate input of EXPERT PASSWORD is required. |

2

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.

3

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.

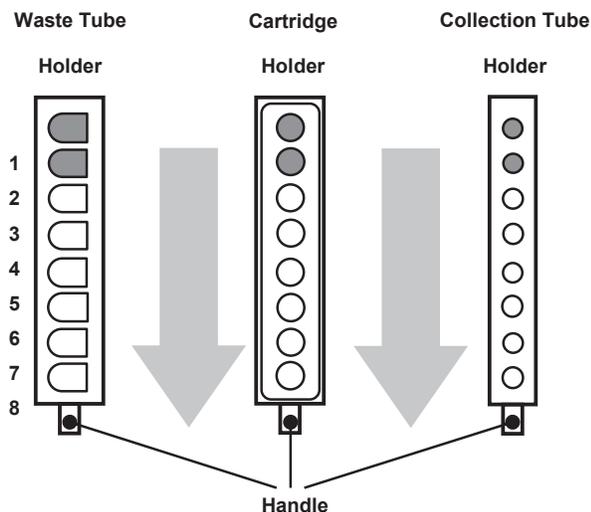
- Abide by the setting order for accessories and consumables and set correctly.
- Set the waste tubes, cartridges and collection tubes in correct position.

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.

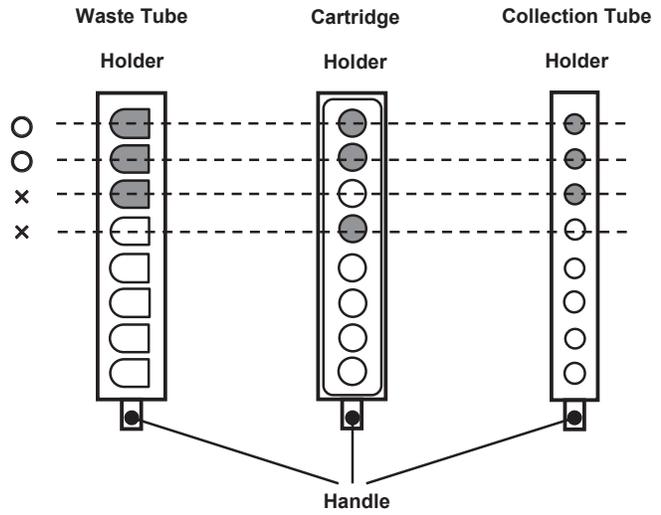
Waste tubes, cartridges and collection tubes should be set in order from opposite side of handle.



3

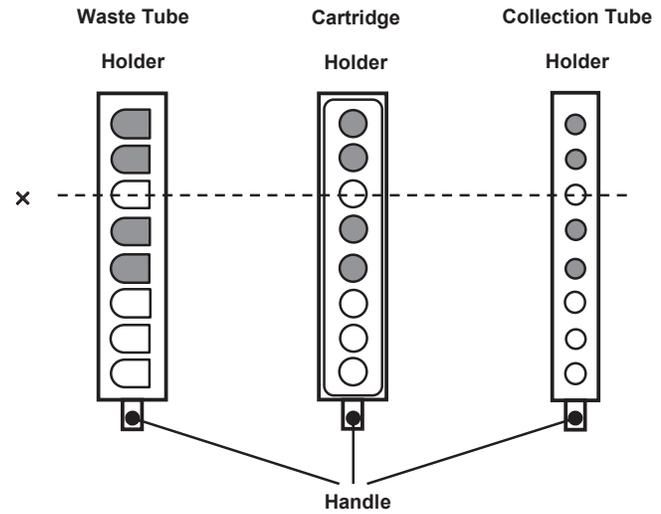
Rule 2.

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



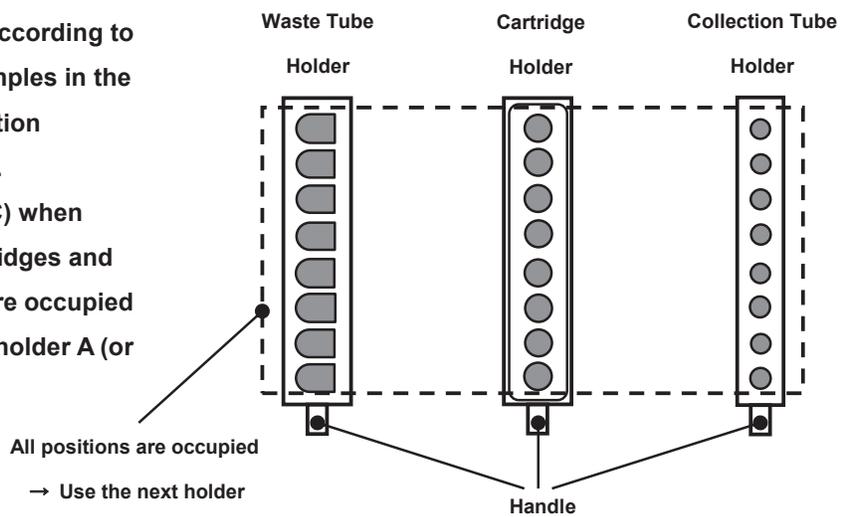
Rule 3.

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

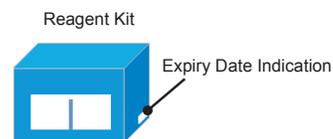
3.3 Preparation of Reagents

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.

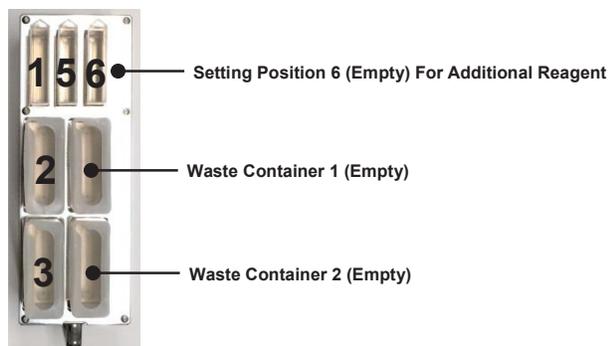
- (1) Refer to the table above and split the required quantity of reagent in a reagent container for QG-Auto240L.

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.



3

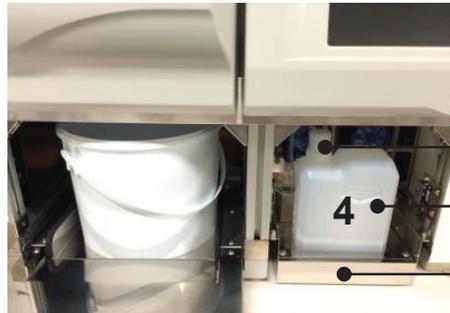
Note: Be sure to set a waste container in empty status.

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



Inlet Tube
Wash Buffer Bottle
Wash Buffer Bottle Rack

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.
-

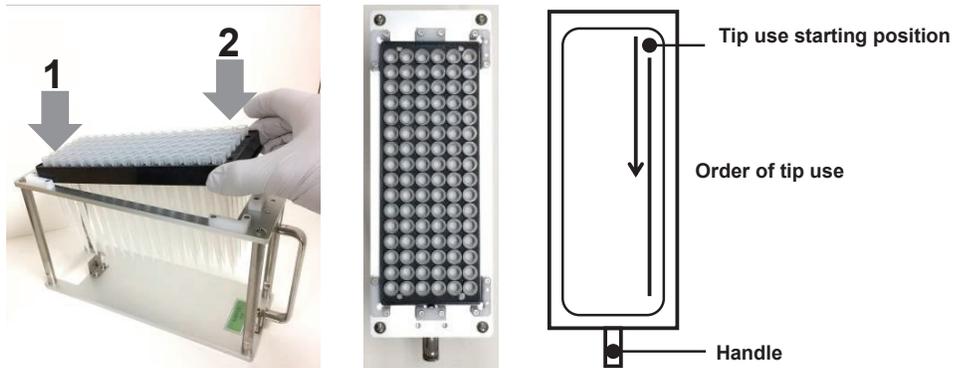
3.4 Preparation of Consumables and Accessories

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.



3

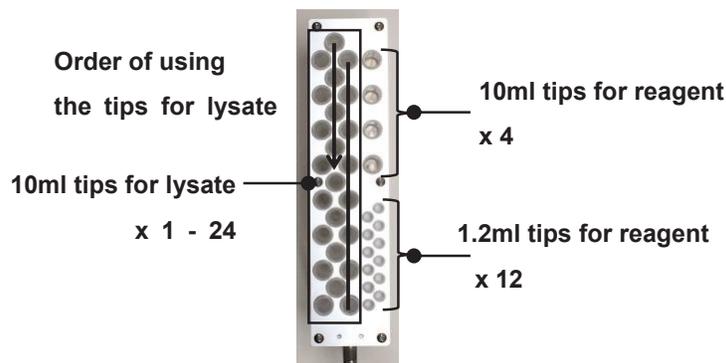
Note:

- 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

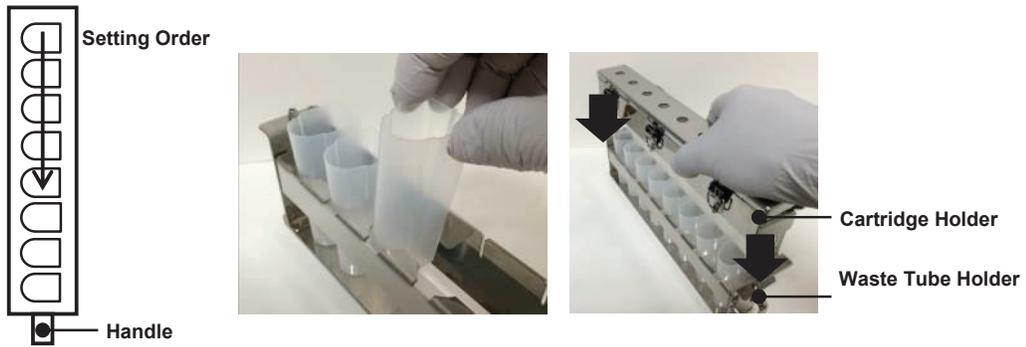


Note: Set all reagent tips (1.2ml tips x 12, 10ml tips x4) in the holder

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.



3

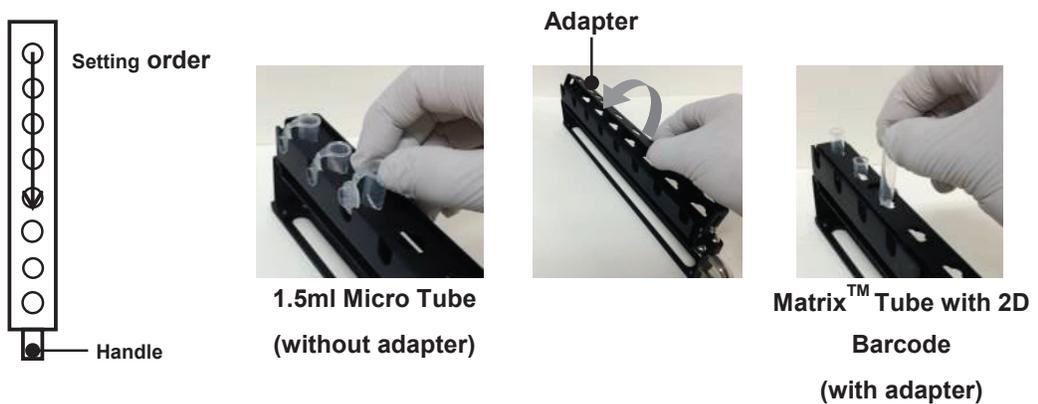
(4) Set the number of cartridges equal to the number of samples in the cartridge holder.

After setting, close the cover and lock the locks in 3 places.



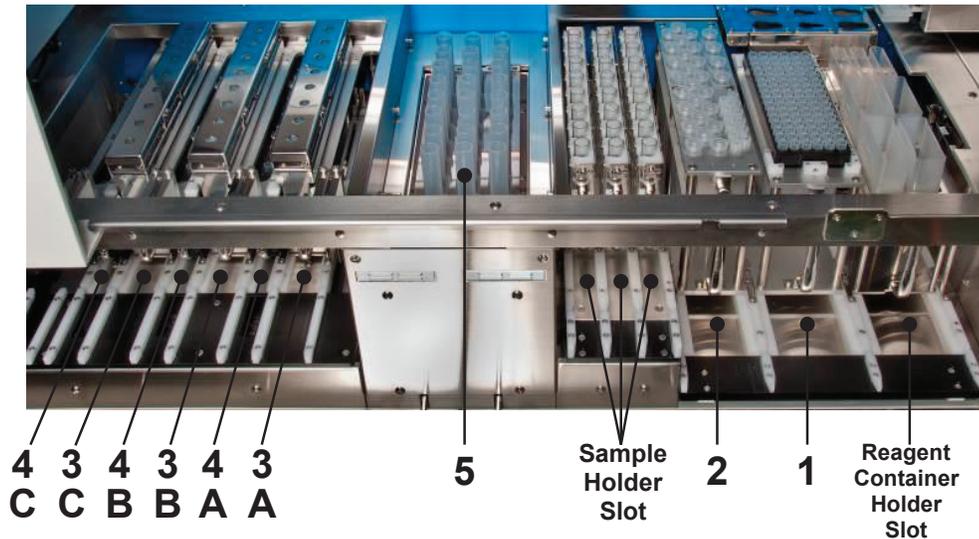
(5) Set the number of collection tubes equal to the number of samples in the collection tube holder.

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



3

| 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

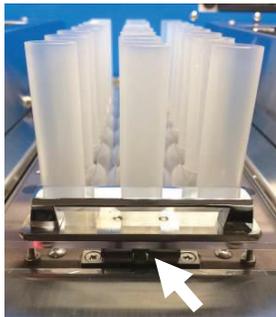
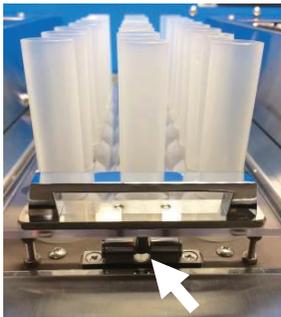
- (1) Open the sliding door of the system.
- (2) Open the agitator cover of the lysate unit.



- (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.

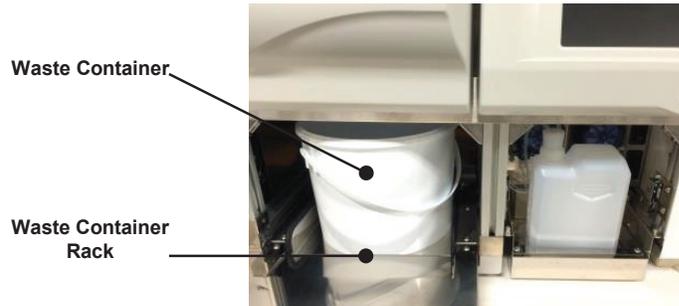


Note: Be sure to securely close and fix the agitator cover until a click is heard. If the fixing is insecure, an error will occur during the system check before operation.

- (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.

**X****O**

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

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.

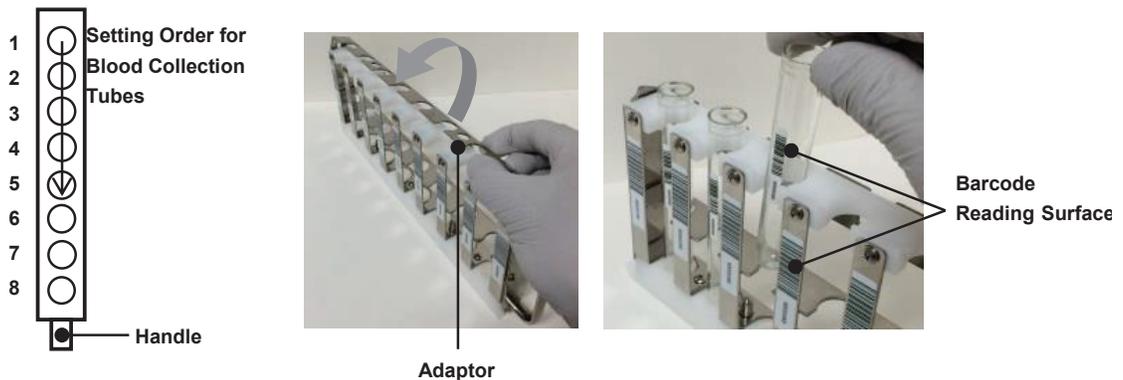
3

■ 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 adaptor 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".



3

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



3



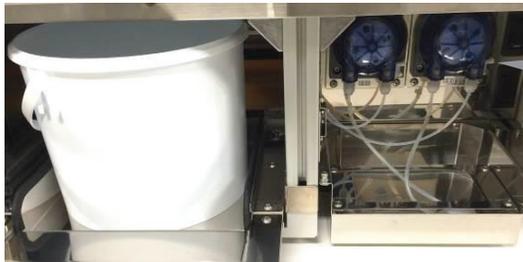
Warning:

- 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"



Breaker Switch

(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

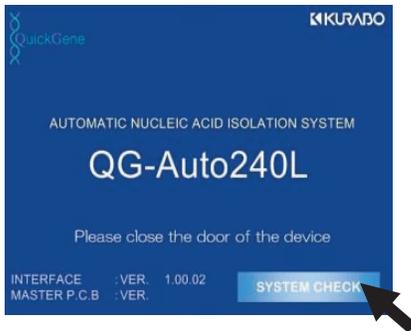


- (1) Confirm that the sliding doors, left/right flap doors and drawer are closed, and press the power switch.**

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

Wait until the title is displayed.

3



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

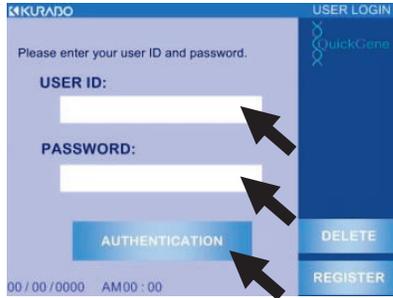
[SYSTEM CHECK] button will be enabled after the sliding doors and left/right flap doors are locked.



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

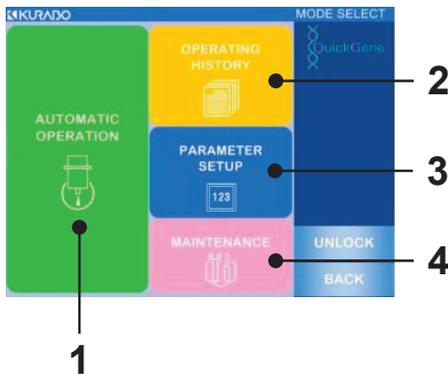
If an item with an indication of [NG] is found, press [NG], confirm the error message, and refer to "8.2 Error Messages" for solving a problem.

3 Operation Method - Full-Auto Protocol



- (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]

3

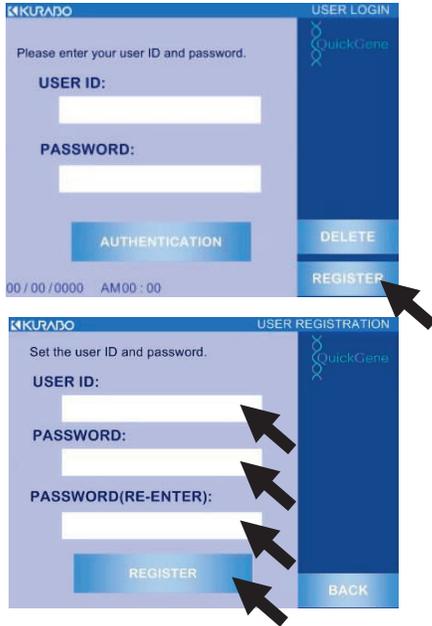


- (7) Each of the modes is executed from the mode select screen.
 1. AUTOMATED OPERATION / Automatic Isolating Operation Mode
Refer to "3.8 Isolating Operation".
 2. OPERATING HISTORY / Operation History Mode
Refer to "5 Operation History".
 3. PARAMETER SETUP / Parameter Setup Mode
Refer to "6 Parameter 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.

3

■ 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.

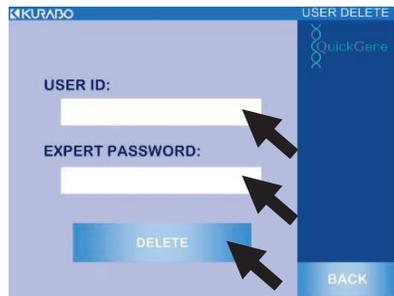
Select a User ID to delete.

- (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



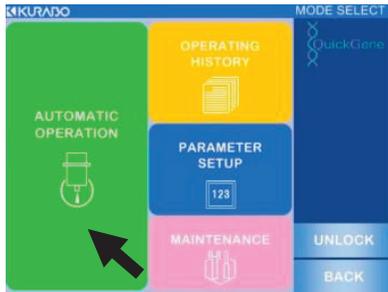
3.8 Isolating Operation

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



- (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

3



(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.



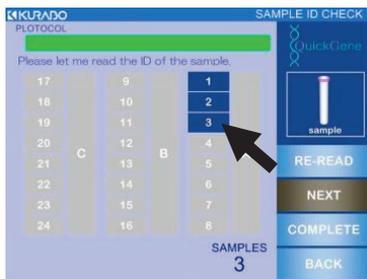
Barcode Reader (Inside of system)



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:

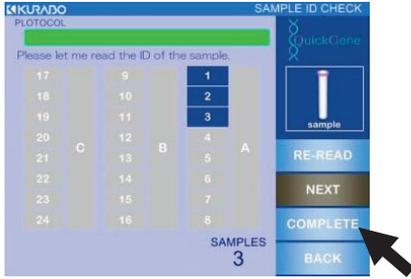
- When setting a holder in the slot, securely set until it contacts the stopper on the end.
- When several holders are used, pay attention to the holder identification symbols A-C for setting.



(A-1) The reading of complete samples will be displayed in reversed deep blue on the operation screen.

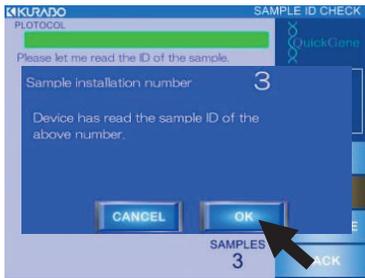
Check for the correctness of readout positional information and the position of the set sample.

(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.

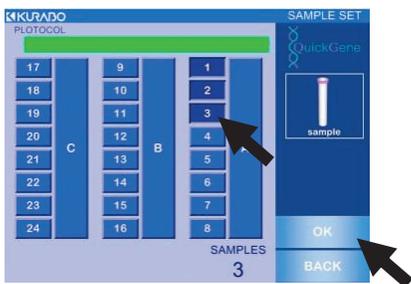
Premature removal will cause an error, the sample ID information will be deleted, and the system will go back to "<2> Enter Sample Information"

3

(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

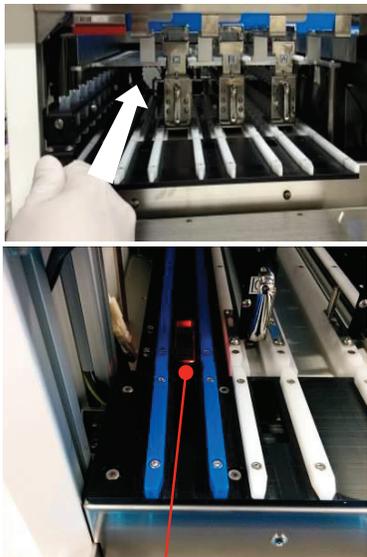
C. When the collection ID reading function is ON

3



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.

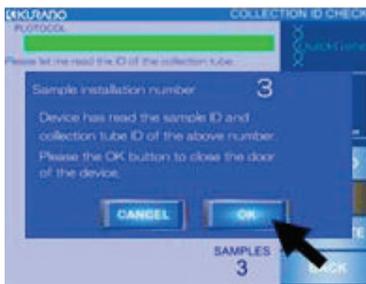
(C-2) If there are more holders to set, press [NEXT] and carry out (C-2), (C-3) for holders B, C.

(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”

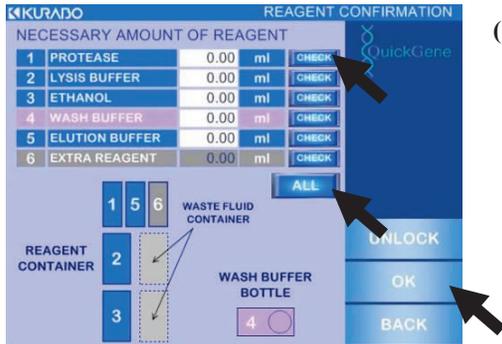
D. When the collection ID reading function is OFF

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”

3

<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.

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

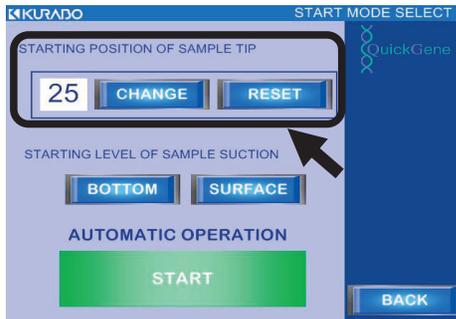
If [ALL] is pressed, all [CHECK] buttons are pressed at the same time.

- (2) Press [OK].

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

3

<5> Setting up Operating Conditions



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 |

(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.

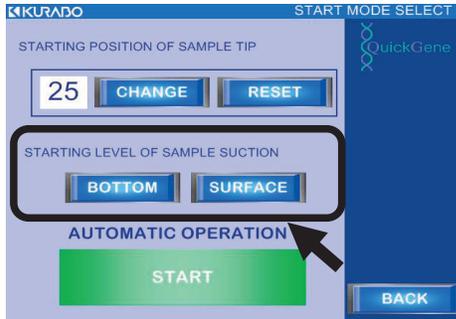
Refer to the figure on the left for the relation of set-up values and tip positions.

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

3

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.

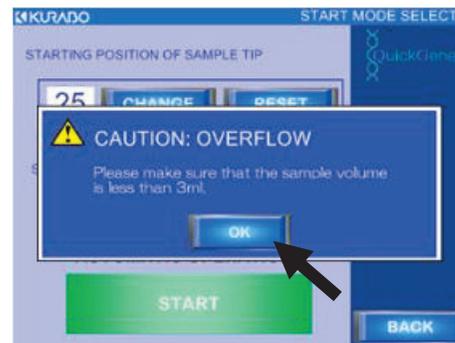
[BOTTOM]: Suction from a fixed position

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

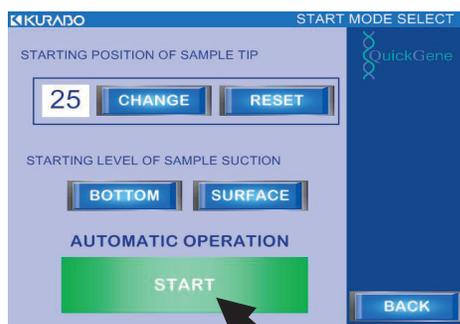
3

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 | |

3

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

3



(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.

3

(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.

3

- (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 | <p>Remove reagent containers from reagent container holder. Residual reagents in reagent containers should be stored in sealed container.</p> <p>Remove waste fluid container from reagent container holder and dispose of waste fluid collected in waste container.</p> <p>Refer to "7 Daily Inspection and Maintenance" and clean reagent containers and waste fluid containers.</p> | <p>Note:</p> <p>Residual reagent in reagent container should be consumed as soon as possible.</p> <p>Waste fluid should be disposed of in accordance with rules.</p> |
| 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. | <p>Biohazard:</p> <p>Remaining blood sample and blood collection tubes should be disposed of in accordance with customer's infectious waste treatment manuals.</p> |
| Lysate Tube | Dispose of lysate tubes | <p>Biohazard:</p> <p>Dispose of lysate tubes in accordance with customer's infectious waste treatment manuals.</p> |

3

| Holder/Wear Parts | Treatment | Remarks |
|-----------------------|---|---|
| Cartridge Holder | Open cover by releasing locks at 3 places on cartridge holder. Pull out and dispose of cartridges one by one. | Note: Remove cartridge in such a way that tip does not contact cartridge holder. 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: 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. When washing cleaning fluid bottle, refer to "7 Daily Inspections and Maintenance". | Note: When storing cleaning fluid bottles, securely close caps. |
| Waste Container | Dispose of waste in waste container. When cleaning waste container, refer to "7 Daily Inspections and Maintenance". | Biohazard: 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

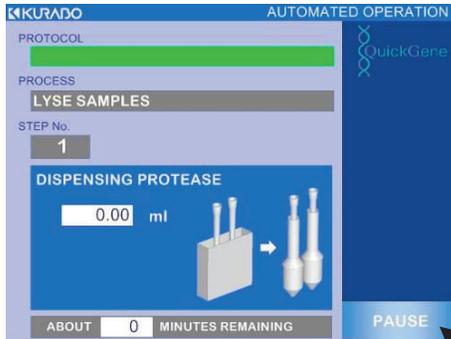
The isolating operation is now complete.

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

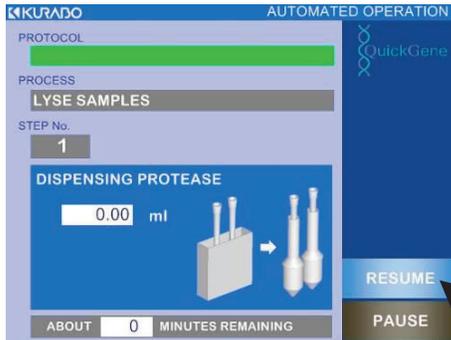
Important: If the system will not be used again for more than 1 week, refer to "7.2 When System Not in Use for More than One Week" and carry out maintenance.

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.
-

3

3

4 Operating Procedures (Semi-Automatic Protocol)

The isolation work using semi-auto protocol is explained as below.

Note: Reading/management functions for sample IDs and collection IDs are not available in Semi-Automatic Protocols.



Biohazard

Wear appropriate gloves, mask, and protective goggles for isolation work with risk of infection.



Caution

Furthermore, after conducting isolation work with risk of infection, wear proper gloves and mask when contacting the system because the system may be contaminated.

Do not put a tray, etc. with fluid in it on top or inside this system.

The fluid may be spilt and the operation panel or inside devices may fail.

Important: Wear proper gloves and mask for isolation work if appropriate. Be careful not to contaminate with sweat or sputum from preparation of sample until completion of isolation work.

4.1 For Isolating Operation

Abide by the following when conducting isolation work.

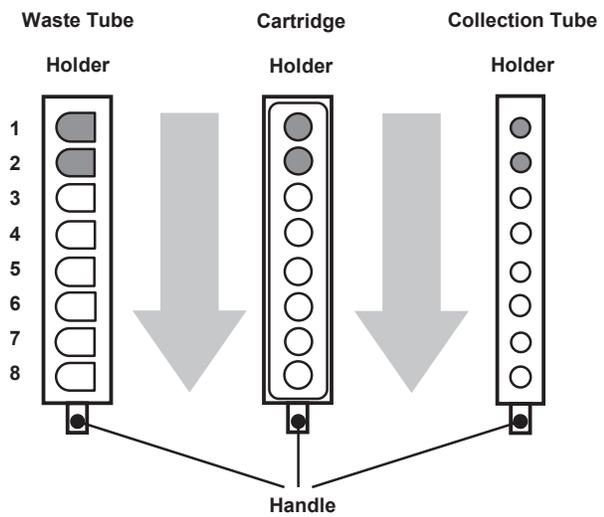
- Follow the setting order for accessories and consumables and set them correctly.
- Set the waste tubes, cartridges and collection tubes in correct positions.

Important: Erroneous setting of waste tubes, cartridges and collection tubes will cause spilling of reagents or dissolved samples, results will not be gained, and the sample will be wasted.

In addition, beware of the risk of contamination or system failure.

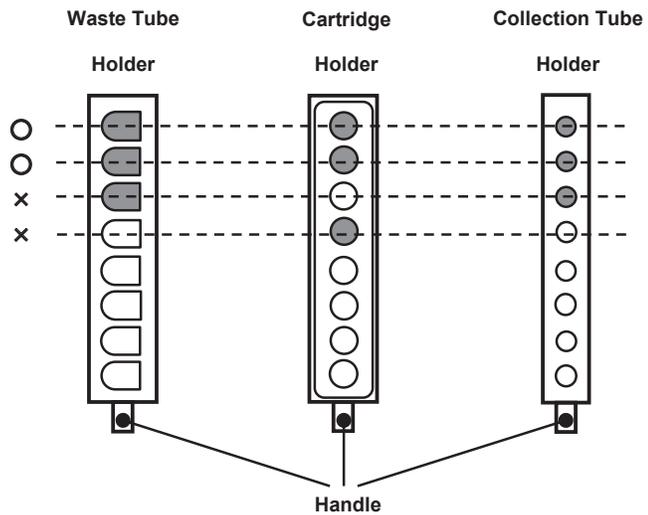
Rule 1

Waste tubes, cartridges and collection tubes be set in order from side handle.



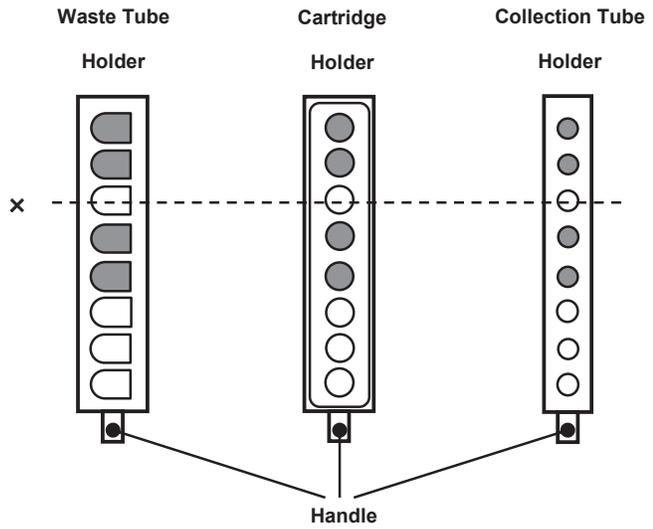
Rule 2

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



Rule 3

Setting be order without a vacancy



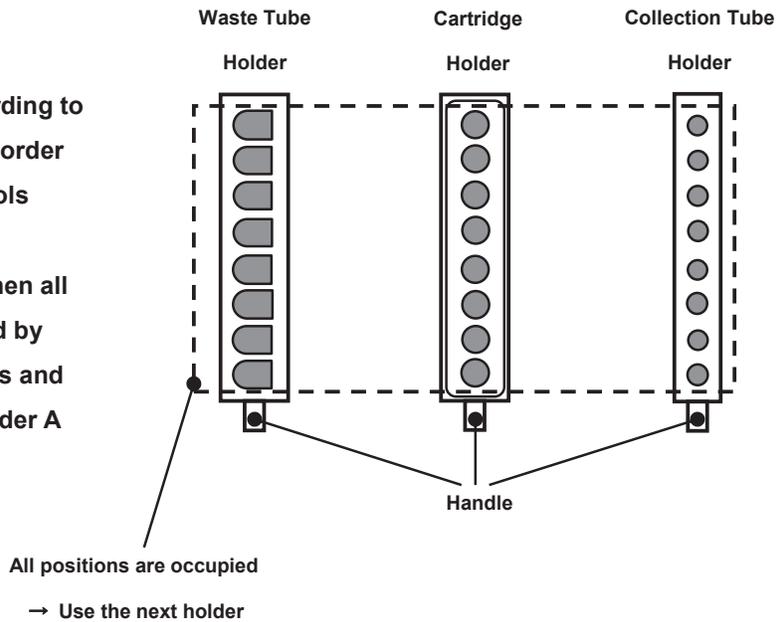
4

Rule 4

Use each holder according to number of samples in order of identification symbols

A → B → C.

Use holder B (or C) when all positions are occupied by waste tubes, cartridges and collection tubes in holder A (or A and B)



4.2 Confirmation of Articles to be Prepared

Confirmation of articles that should be prepared before conducting isolation work is explained below.

■ 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 should be prepared. NB: They are not included in the system package but must be prepared independently.

- ◆ **QuickGene DNA Whole Blood Kit L (DB-L) 48 Specimens/1 Kit**
 - Cartridge x48
 - Waste Tube x48
 - Reagents x 1 set
- ◆ **QuickGene-Auto240L Consumables Kit (QG-240L-CK) 48 Specimens/1 Kit**
 - Lysate Tube x48
 - 10-mL Tip x60
 - 1.2-mL Tip x96

- ◆ **1.5-mL Micro Tube or 1.4-mL Matrix™ Tube with 2D barcode**

(Used as collection container [collection tube] for DNA.)

NB: ID reading/management using barcodes is not available with semi-auto protocols.

- ◆ **Special Grade Ethanol (>99%)**
- ◆ **Nuclease-free Water (used for dissolution of pretreated enzyme (EDB) and for confirmation of system functioning)**
- ◆ **Protective Gloves**
- ◆ **Safety Goggles**

4.3 Preparation of Reagents

Explanation of reagent preparation before conducting isolation work.

■ 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)**

NB: Not used in this system with semi-auto protocol.

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 stability period for an enzyme, but avoid repetitive 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 on container and invert.

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

Insufficient dissolution may result in clogged cartridge or shortage of yield to the target.

◆ **Lysis Buffer (LDB)**

NB: Not used in this system with semi-auto protocol.

Mix well before use.

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

◆ **Wash Buffer (WDB)**

Delivered in concentrate form.

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

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

◆ **Elution Buffer (CDB)**

Used for elution of nucleic acid.

■ **Set Reagents in System**

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

◆ **Reagent Container and Required Reagent Quantity (for processing 2-mL sample)**

| Reagent | Reagent Container | Setting Position No. | Quantity of Use /1 sample | Other Required Quantity* | Required Quantity/1 Operation | | |
|-----------------------------|---------------------|----------------------|---------------------------|--------------------------|-------------------------------|------------|------------|
| | | | | | 8 Samples | 16 Samples | 24 Samples |
| 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 to fill the system fluid feeding line and the additional quantity for a stable fluid suction.

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

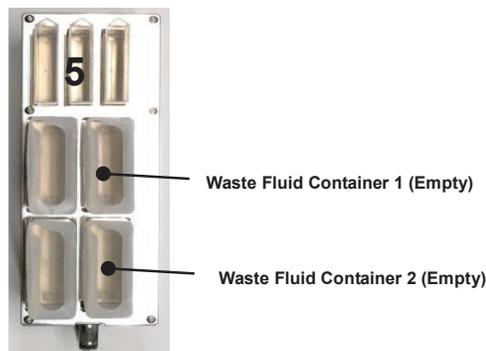
4

Note: After operation, the quantity of reagent included in the kit may fall short if residual reagent in the reagent container is discarded.

The residual reagent in the reagent container should be preserved in a sealed container and consumed as soon as possible.

- (2) Set 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 unused reagent containers and waste containers.

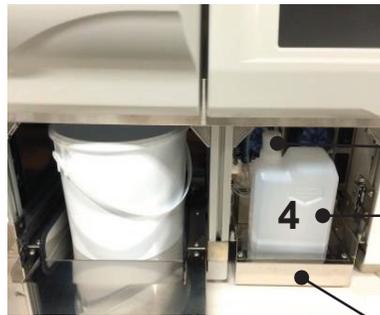


Note: Be sure to set waste container in empty status. Operation with residual waste fluid in waste fluid container may cause overflow of waste fluid. Dispose of fluid before setting container in holder.

(3) Set reagent container holder in reagent container holder slot of this system.



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



Inlet Tube
Wash Buffer Bottle
Wash Buffer Bottle Rack

4

Note: If setting is incomplete, the inability to absorb wash buffer may influence operation results.

Abide by the following and correctly set wash buffer bottle:

- Wash buffer bottle is set so that opening comes to left side of rack.
- Ends of 2 inlet tubes reach bottom of wash buffer bottle.
- Inlet tubes are not kinked midway.

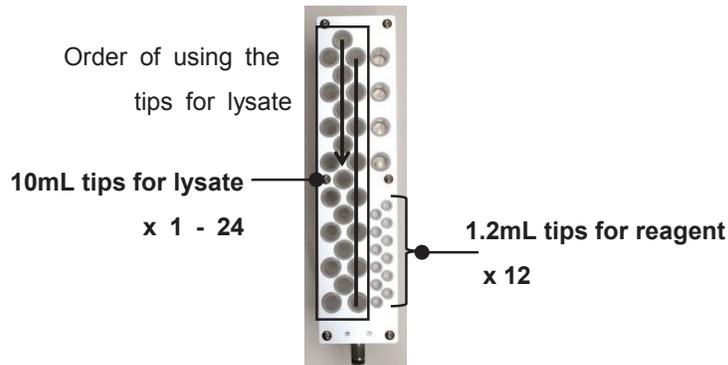
4.4 Preparation of Consumables and Accessories

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

■ Set consumables and accessories on each holder

(1) Set 1.2-mL tips and 10-mL tips in reagent tip holder.

Only the necessary quantity of 1.2-mL tips should be removed from the 1.2-mL tip rack and set in place.



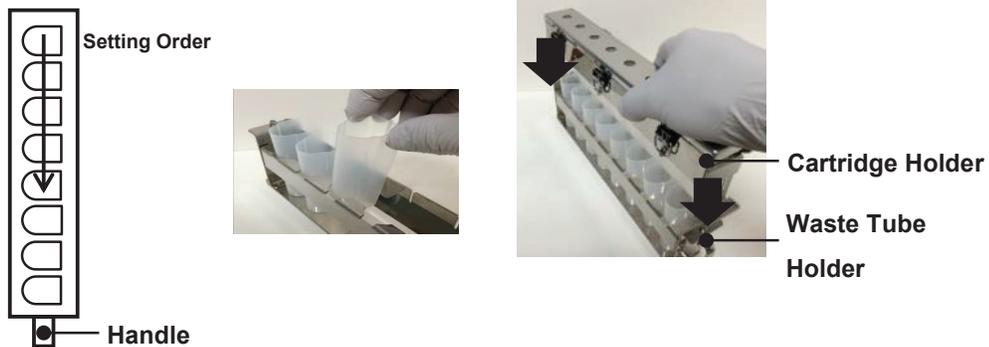
4

Note: Set all reagent tips (1.2-mL tip x 12) in the holder.

Set number of tips for lysate (10-mL x 1-24) equal or more to the number of samples.

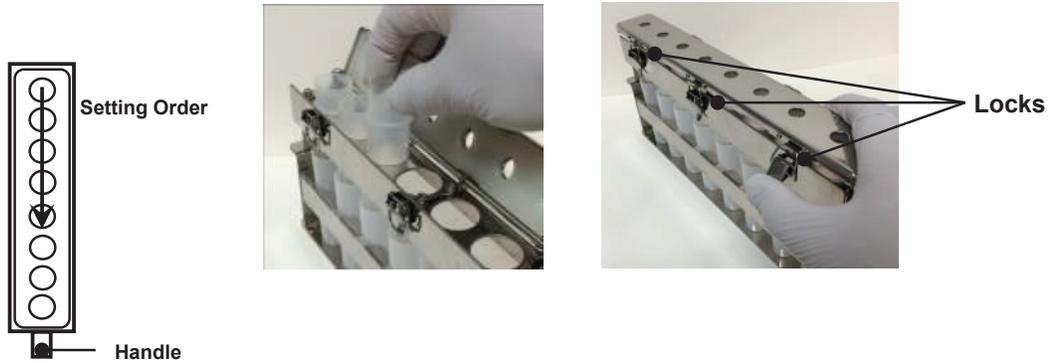
(2) Set number of waste tubes equal to number of samples in waste tube holder.

After setting, attach cartridge holder from above.



- (3) Set number of cartridges equal to number of samples in cartridge holder.

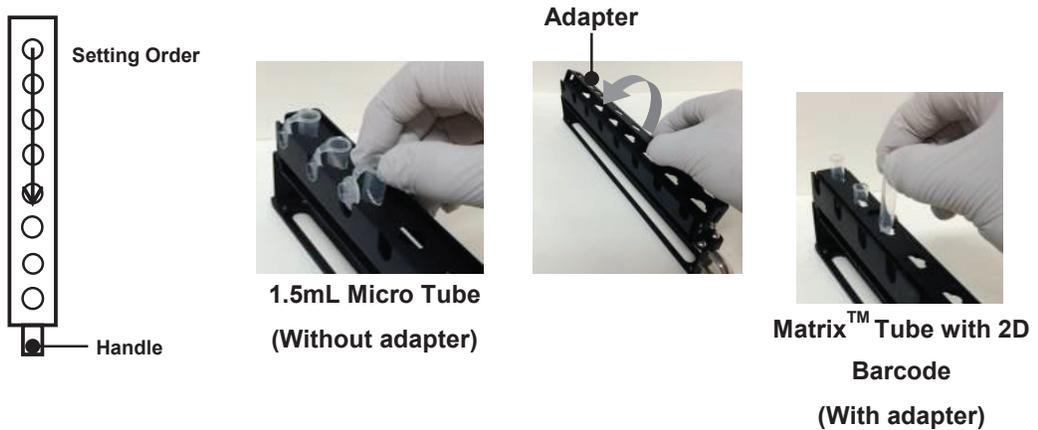
After setting, close cover and lock locks in 3 places.



- (4) Set number of collection tubes equal to number of samples in collection tube holder.

Use adapters according to type of collection tubes.

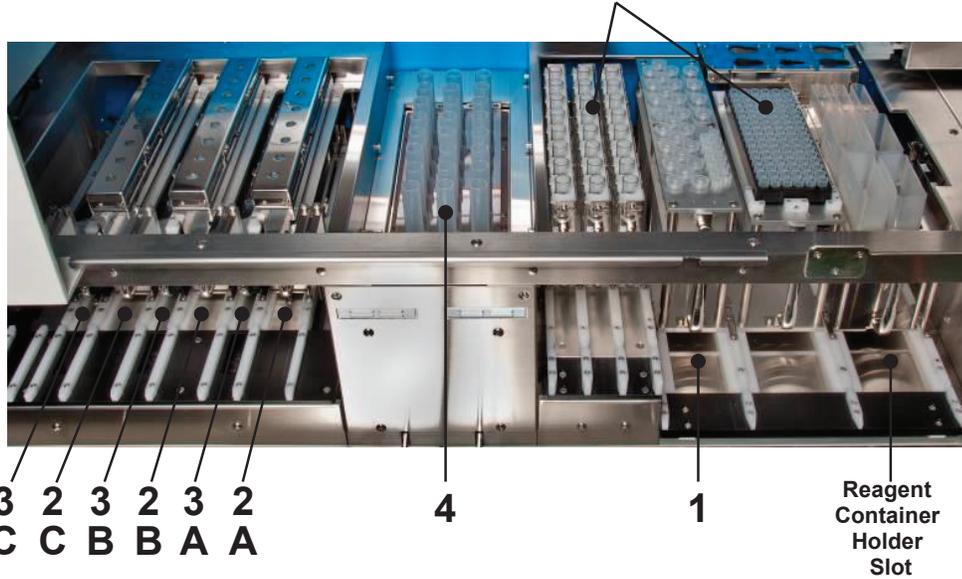
4



Note: When several holders are used, set collection tubes according to holder identification symbols A-C.

■ Set holders in system

*For a use with semi-auto protocol, it is not necessary to set the sample holders and sample tip holders.



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

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

(2) Set prepared holders in corresponding slot in reference to above chart.

Note:

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

(3) Close left/right flap doors.

4

■ Set lysate tubes in system

- (1) Open system sliding door.
- (2) Open agitator cover of lysate unit.



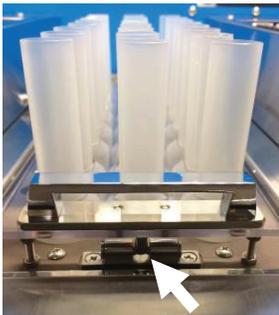
- (3) Set lysate tubes with lysate (pre-treatment fluid) in them.
Refer to “4.5 Preparation of Samples” for preparation of lysate.

4

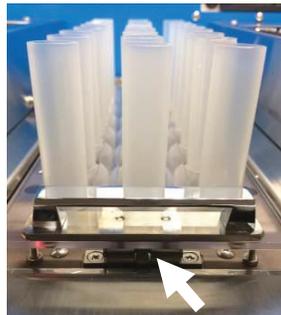
Note: After setting lysate tubes, promptly start system operation.



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



×



○

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

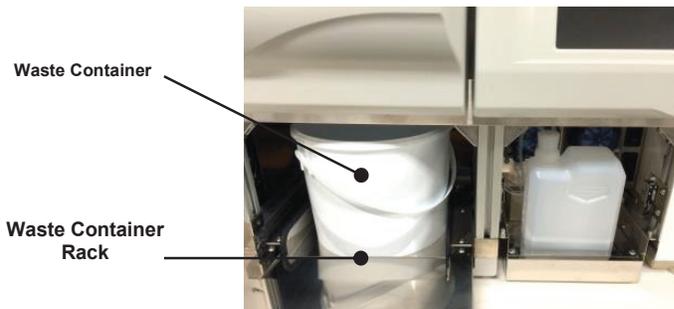
(5) Close sliding doors.

■ Set waste container in system.

(1) Open system drawer.

(2) Set waste container in waste container rack.

Securely set waste container to fit rack groove.



4



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○

Note: Be sure to correctly set empty waste container included in delivery. Use of container not included in delivery, use of unemptied container, or use with an erroneous setting may cause waste overflow.

(3) Close drawer.

4.5 Preparation of Samples

■ Preparation of sample

- Use full blood collected using EDTA-2NA, EDTA-2K, or heparin.
- Use full blood collected within 3 days as far as possible. Use of blood preserved for a long period or use of that on which freezing and thawing procedures have been repeated may cause cartridge clogging or decrease in yield.

■ Preparation of Lysate

- (1) Refer to handbook included in dedicated reagent kit (QuickGene DNA Whole Blood Kit L (DB-L)) and prepare lysate.
- (2) Move prepared lysate to lysate tube.

Note:

- If lysate is left as it is, a sufficient nucleic acid quality or yield may not be acquired. After completion of lysate preparation, promptly start system operation. If unavoidable, it may be left for up to 30 minutes without affecting yield.
 - When moving lysate, take care not to let lysate adhere to outside or opening of lysate tube. If lysate adheres to outside or opening of tube, wipe it off using soft paper, etc. containing 0.1% sodium hypochlorite solution or ethyl alcohol.
-

4.6 Isolating Operation

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

Refer to "3.6 Start-Up of System" and "3.7 Registration and Deletion of User IDs" for start-up of system, etc.

Refer to "4.3 Preparation of Reagents", "4.4 Preparation of Consumables/Accessories" and "4.5 Preparation of Samples" for necessary preparations for isolation operation.

<1> Start-Up of Automatic Isolation Operation and Selection of Protocol

4



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

(2) Press [AUTOMATED OPERATION].



(3) Press [OK] on displayed pop-up window.

(4) Check that waste container in system drawer is empty and execute.

(5) Press semi-automatic protocol button to operate.

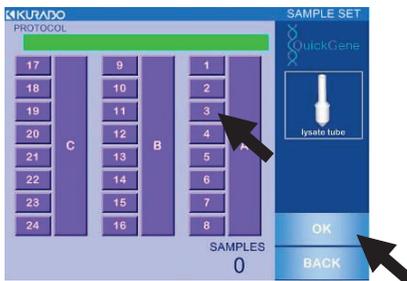
(Ex : W BLOOD DNA 2 mL SEMI-AUTO)

Refer to "2.8 Implemented Protocols" for explanations on protocols.

(6) Move to next section "<2> Enter Sample Information".

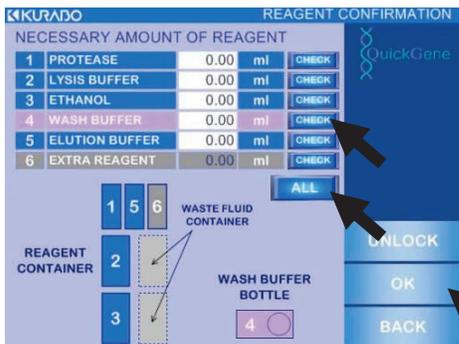
<2> Enter Sample Information

Note: Reading and management functions of sample IDs and collection IDs are not available in SEMI-AUTO protocols.



- (1) Press numeric button corresponding to number of set samples.
 - Pressed button will be indicated in reversed deep violet on operation screen.
 - Selection will be canceled if pressed button is pressed again.
 - Pressing A, B or C button will result in selection of all holders in each row.
- (2) Check that selected button coincides with set-up number of samples and press [OK].
- (3) Move to next section "<3> Confirmation of Reagent".

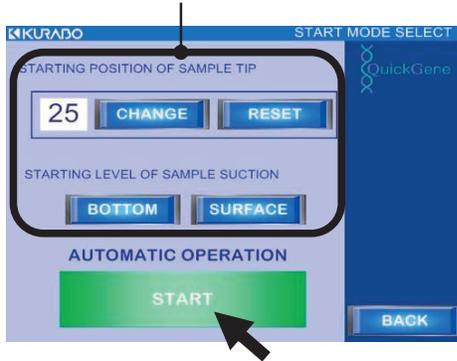
4

<3> Confirmation of Reagent

- (1) Refer to indicated information on screen regarding reagents used for automatic isolation operation, and confirm that required quantity is set in correct position.
- (2) Press [CHECK] for a confirmed reagent.
If [ALL] is pressed, the [CHECK] buttons for all reagents are pressed at one time.
- (3) Press [OK]
When all [CHECK] buttons are pressed, [OK] button will be enabled.

<4> Automatic Operation Start

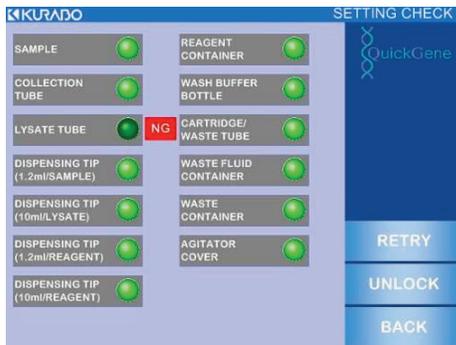
*Not available in Semi-Automatic protocol



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

After completing check of various parts using sensors, isolation operation starts. For those items determined as “NG”, refer to the below and solve the problems.

4

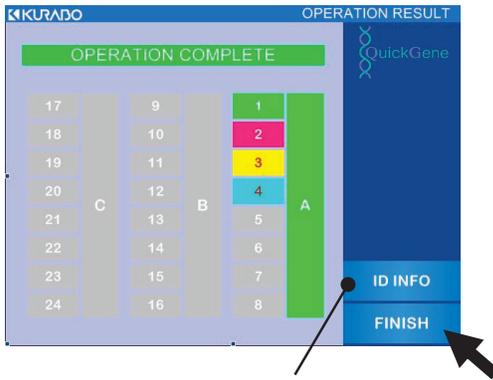


| Checking Items | Reference |
|--------------------------------|---|
| REAGENT CONTAINER | 4.3 Preparation of Reagents |
| WASH BUFFER BOTTLE | |
| WASTE FLUID CONTAINER | |
| COLLECTION TUBE | 4.4 Preparation of Consumables/ Accessories |
| LYSATE TUBE | |
| DISPENSING TIP (10ml/LYSATE) | |
| DISPENSING TIP (1.2ml/REAGENT) | |
| CARTRIDGE/WASTE TUBE | |
| WASTE CONTAINER | |
| AGITATOR COVER | |

Note:

- To suspend isolation operation during automatic system operation, refer to "3.9 Operation to Stop Automatic Operation".
- When isolation operation is suspended during automatic operation due to an error or trouble, refer to “8.1 Troubleshooting” or “8.2 Error Messages”.

<5> Ending the Operation / Confirmation of Operation Results



*Not used in Semi-Automatic Protocol

- (1) Operation ends when left screen is displayed.
Background color for sample number indicates operation results.

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

4

Note : Refer to “8.1 Troubleshooting” or “8.2 Error Messages” for an incomplete isolation.



- (2) Press [FINISH] on operation result screen.
- (3) Press [OK] on displayed pop-up window.
- (4) Press system power switch and turn power OFF.

<6> Collection of Isolation Samples

- (1) Confirm system power is OFF.

- (2) Open left flap door and remove collection tube holder.

Note: Isolation sample inside may spill if collection tube holder is tilted. Remove while holding onto collection tube holder handle with one hand and supporting bottom surface of holder with other hand.

- (3) Close collection tube cap and remove.

4

Note:

- Securely close cap.
 - Carefully conduct removal and management of collection tubes, paying attention to holder identification symbols A-C.
-

<7> Disposal of Consumables and Wastes

- (1) Confirm system power is OFF.
- (2) Open left/right flap doors and remove all holders and consumables.
- (3) Refer to table below and treat removed holders and consumables appropriately.

| Holder/Consumables | Treatment | Remarks |
|--------------------------|---|--|
| Reagent Container Holder | Remove reagent containers from reagent container holder. Residual reagents from reagent containers should be stored in sealed container. Remove waste fluid container from reagent container holder and dispose of waste fluid collected in waste container. Refer to "7 Daily Inspection and Maintenance" and clean reagent containers and waste fluid containers. | Note: Residual reagent from reagent container should be consumed as soon as possible. Waste fluid should be disposed of in accordance with rules and regulations. |
| Sample Tip Holder | Remaining tips should be stored in clean environment with no contamination. | |
| Lysate Tube | Dispose of lysate tubes | Biohazard: Treat lysate tubes in accordance with customer's infectious waste treatment manuals. |
| Cartridge Holder | Release locks at 3 places on cartridge holder and open cover. Pull out and dispose of cartridges singly. | Note: Remove cartridge so that tip does not contact cartridge holder. If cartridge tip contacts cartridge holder, refer to "7 Daily Inspection and Maintenance" and wash cartridge holder. |
| Waste Tube Holder | Remove waste tubes from waste tube holder and dispose of waste fluid and waste tubes. | Biohazard: Removed waste fluid and waste tubes should be treated in accordance with customer's infectious waste treatment manuals. |

| Holders/Consumables | Treatment | Remarks |
|---------------------|---|--|
| Wash Buffer Bottle | Reagents remaining in wash buffer bottle should be sealed as is and stored. When washing the wash buffer bottle, refer to "7 Daily Inspection and Maintenance". | Note: When storing the wash buffer bottles, securely close caps. |
| Waste Container | Dispose of wastes in waste container. When cleaning waste container, refer to "7 Daily Inspection and Maintenance". | Biohazard: Waste should be treated in accordance with customer's infectious waste treatment manuals. |

<8> Post-treatment of System

4

(1) Refer to "7. Daily Inspection and Maintenance" and carry out system maintenance as necessary.

(2) Close all system doors.

Isolation operation is now complete.

If operation is to be continued with semi-automatic protocol, start from "4.3 Preparation of Reagent".

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

5 Operation History

Confirmation and saving procedures for operation histories are explained below.

5.1 Checking Operation History

Procedures for confirmation of operation histories are explained below.



- (1) Turn ON system power (see "3.6 Start-Up of System") and move mode select screen.
- (2) Press [OPERATING HISTORY].
- (3) Operation histories are displayed.

| No. | DATE/TIME | USER ID | DETAILS |
|-----|----------------|------------|---------|
| 94 | 20150715/09:00 | ABCDEF1234 | VIEW |
| 95 | 20150715/11:00 | ABCDEF1234 | VIEW |
| 96 | 20150715/13:00 | ABCDEF1234 | VIEW |
| 97 | 20150716/09:00 | GHIJKL5678 | VIEW |
| 98 | 20150716/11:00 | GHIJKL5678 | VIEW |
| 99 | 20150717/09:00 | GHIJKL5678 | VIEW |
| 100 | 20150717/11:00 | GHIJKL5678 | VIEW |

1. **No.:** Operation Management Number
Numbers allocated to past 100 operation histories.
When number of records exceeds 100, they are automatically deleted, oldest record first.
2. **DATE/TIME:** Operation date and time
3. **USER ID:** User ID who performed the operation
4. **VIEW:** Move to detailed information
Press this to move to "5.2 Checking ID Information".
5. **NEXT:** Go to next item.
6. **PREVIOUS:** Return to previous item.
7. **DATA SAVE:** Move to data save mode.
Press this to move to "5.3 Storing the Operation History".
8. **BACK:** Return to mode select screen.

5.2 Checking ID Information

Procedures for checking ID information are explained below.



(1) Press [VIEW] of operation history to check ID information in "5.1 Checking Operation History".



(2) Press [ID INFO] in displayed pop-up window.

(3) ID information displayed.

1. **Sample No.**

Sample management number within operation.

2. **Operation Result**

Displays operation results.

OK: Normal Completion

NG1: Chip Clogging at Sample Suction

(Incomplete Isolation)

NG2: Pressure Leakage of Cartridge

(Incomplete Isolation)

NG3: Clogged Cartridge (Incomplete Isolation)

3. **Sample ID**

Barcode information on sample (blood collection tube) is displayed.

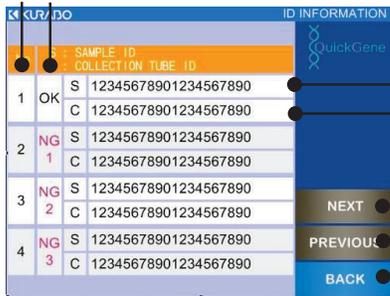
When sample ID reading function is "OFF", sample position information (Ex: A-1, A-2) is displayed in sample ID columns.

4. **Collection ID**

Barcode information on collection tube is displayed.

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

1 2



3
4
5
6
7

5

5. **NEXT:** Go to next item.
6. **PREVIOUS:** Return to previous item.
7. **BACK:** Return to operation history checking screen.

5.3 Storing Operation History

Procedures for saving operation histories are explained below.

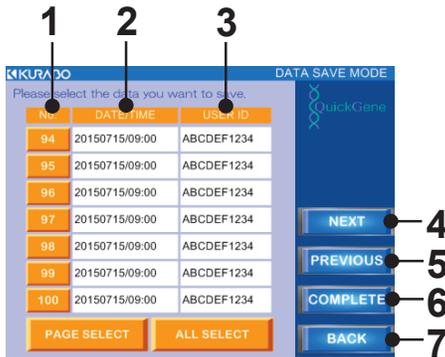


(1) Press [DATA SAVE] in "5.1 Checking Operation History".



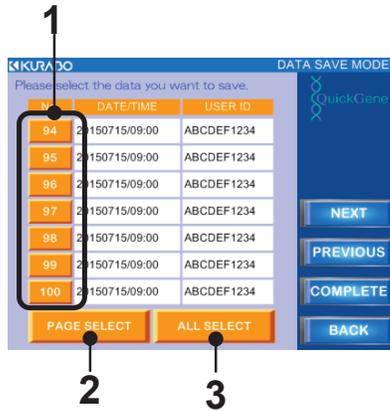
(2) Press [OK] in displayed pop-up window.

5



(3) Data saving screen is displayed.

1. **No: Operation Management Number**
Numbers allocated to past 100 operation histories.
2. **DATE/TIME: Operation date and time.**
3. **USER ID: User ID of current operator.**
4. **NEXT: Move to next item.**
5. **PREVIOUS: Return to previous item.**
6. **COMPLETE: Execution of data saving.**
Press after selecting operation history to save.
7. **BACK: Return to operation history checking screen.**



(4) Select management number of operating history to save using combination of buttons 1-3 below.

1. **No.: Operation management number selection button**

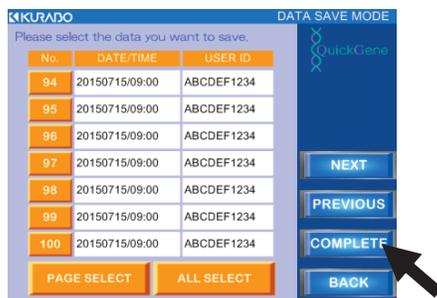
Press operation management number selection button to select operation histories singly.

2. **PAGE SELECT: Page select button**

Press page selection button to select displayed operation histories page by page.

3. **ALL SELECT: All select button**

Press all select button to select all operation histories up to past 100 items.



(5) Press [COMPLETE] after selecting operation histories to save.

5



(6) When pop-up window is displayed, insert USB memory stick in USB port on side surface of system. Then press [SAVE] in pop-up window.

(7) When saving is complete, remove USB memory stick from system.

6 Parameter Setup Procedures

The parameter setup procedures are explained below.

6.1 Parameters

"Parameters" refers to the parameters controlling nucleic acid isolation processes in the system; they are set up per isolation protocol.

Among the parameters, there are those for which a change by the user is permitted and those for which a change is permitted only by an administrator who possesses an EXPERT password (EXPERT mode).

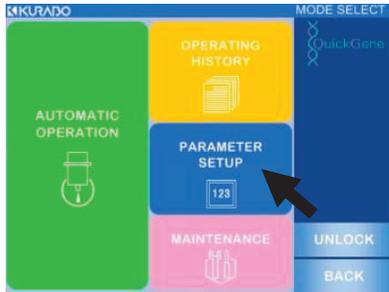
The items that can be changed by the user are explained below.

Important: Changes in EXPERT mode include critical items. Do not effect such a change on customer's own judgment.

6.2 Starting up the Parameter Setup Mode

A change of parameter setup value is made in the parameter setup mode.

The procedures for changing the parameter setup are explained below:



(1) Refer to "3.6 Start-up of System", turn system power ON, and move to mode selection screen.

(2) Press [PARAMETER SETUP].

(3) Press button for a protocol to change parameters.

(Ex: W BLOOD DNA 2-mL FULL-AUTO)

Refer to "2.8 Implemented Protocols" for explanations on the protocol.

(4) Parameter setup mode will start. Then select parameter items to change.

1. **BARCODE READING: Setup of barcode (ID) reading functions.**

Item to set up ON/OFF of barcode (ID) reading function.

Refer to "6.3 Setup of Barcode (ID) Reading Function".

2. **ELUTION BUFFER VOLUME: Setup of elution buffer volume.**

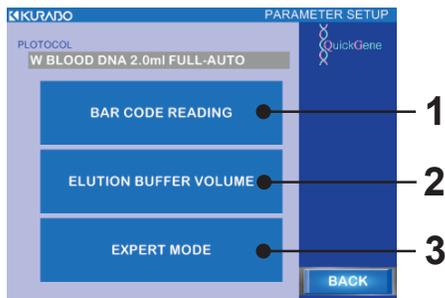
Item to set up injection volume of elution buffer.

Refer to "6.4 Setup of DNA Elution Buffer Volume".

3. **EXPERT MODE**

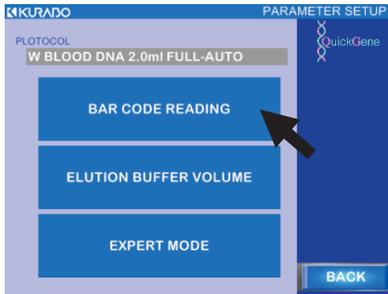
Item controlled by EXPERT password. Please contact our sales agent to start up EXPERT mode and change procedures.

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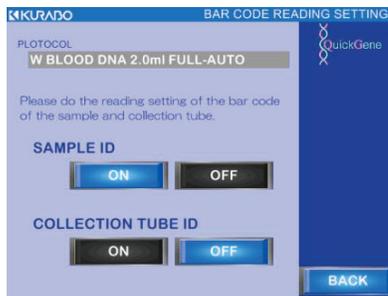


6.3 Setup of Barcode (ID) Reading Function

The setup procedures for the barcode (ID) reading functions are explained below:



- (1) Press [BARCODE READING] in parameter setup mode.



- (2) Regarding IDs given to samples (blood collection tubes) and IDs given to collection tubes, select [OK] for reading or [OFF] for not reading.

Note: ON/OFF of barcode (ID) reading functions are available in three combination patterns:

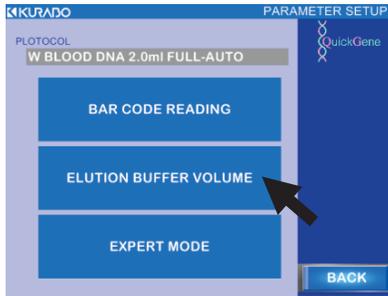
| Pattern | Sample ID | Collection ID |
|---------|-----------|---------------|
| 1 | ON | ON |
| 2 | ON | OFF |
| 3 | OFF | OFF |

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- (3) Press [BACK] to end setup of barcode (ID) reading functions.

6.4 Setup of DNA Elution Buffer Volume

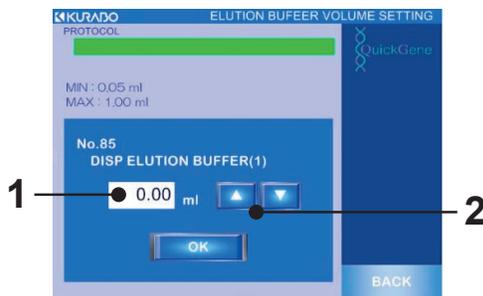
The procedures for setting up the DNA elution volume are explained as below:



- (1) Press [ELUTION BUFFER VOLUME] in parameter setup mode.

- (2) Enter injection quantity for collection fluid in accordance with one of the following two methods.

The setup range (MIN-MAX) is 0.05-1.00 mL, and the increment is 0.01 mL.



1. Directly enter value using ten-key entry pad screen. Touch white frame in which value is entered to display ten-key pad, enter a value within setup range, and press [ENT].

2. Change value using up/down (Δ / ∇) buttons. One press of [Δ] button will increase setup value by 0.01, and one press of [∇] will decrease setup value by 0.01.

6



- (3) After entering value, press [OK] to complete.

6.5 Parameters Setup/Changed with the EXPERT Mode

The parameters that can be changed with EXPERT mode are shown below.

EXPERT mode is accessed with EXPERT password.

Please contact our sales agent regarding start-up of EXPERT mode and procedures for parameter change.

(1) EXPERT Mode Parameters

| No. | Screen Display | Parameter Name | Unit |
|-----|---------------------|---|--------|
| 1 | DISP PROTEASE | Protease divided injection quantity | ml |
| 2 | LB SUCTIONING SP | Protease suction speed | mm/sec |
| 3 | LB DISCHARGING SP | Protease discharge speed | mm/sec |
| 4 | DISP SAMPLES | Sample divided injection quantity | ml |
| 5 | SAMP SUCTIONING SP | Sample absorption speed | mm/sec |
| 6 | SAMP DISCHARGING SP | Sample discharge speed | mm/sec |
| 7 | MIXING SPEED(1) | Primary mixing speed | * |
| 8 | MIXING TIME(1) | Primary mixing time | sec |
| 9 | MIXING SPEED(2) | Secondary mixing speed | * |
| 10 | MIXING TIME(2) | Secondary mixing time | sec |
| 11 | DISP LYSIS BUFFER | Lysis reagent divided injection quantity | ml |
| 12 | LB SUCTIONING SP | Lysis reagent suctioning speed | mm/sec |
| 13 | LB DISCHARGING SP | Lysis reagent discharging speed | mm/sec |
| 14 | MIXING SPEED(1) | Primary mixing speed | * |
| 15 | MIXING TIME(1) | Primary mixing time | sec |
| 16 | MIXING SPEED(2) | Secondary mixing speed | * |
| 17 | MIXING TIME(2) | Secondary mixing time | sec |
| 18 | INCUBATING TEMP | Incubating temperature | degC |
| 19 | INCUBATING TIME | Incubating time | sec |
| 20 | HEATER ON TIMING | Heat ON timing | sec |
| 21 | DISP ETHANOL | Ethanol divided injection quantity | ml |
| 22 | EN SUCTIONING SP | Ethanol suction speed | mm/sec |
| 23 | EN DISCHARGING SP | Ethanol discharging speed | mm/sec |
| 24 | MIXING SPEED(1) | Primary mixing speed | * |
| 25 | MIXING TIME(1) | Primary mixing time | sec |
| 26 | MIXING SPEED(2) | Secondary mixing speed | * |
| 27 | MIXING TIME(2) | Secondary mixing time | sec |
| 28 | TRANSFER LYSATE | Lysate transferring quantity | ml |
| 29 | LS SUCTIONING SP | Lysate suctioning speed | mm/sec |
| 30 | LS DISCHARGING SP | Lysate discharging speed | mm/sec |
| 31 | BIND SPEED | Binding process pressurizing speed | rpm |
| 32 | BIND PEEK | Binding process pressurizing peak pressure | Kpa |
| 33 | BIND UP TM | Binding process pressurizing time over | sec |
| 34 | BIND RETRY | Binding process pressurizing retry peak pressure | Kpa |
| 35 | BIND LOWER | Binding process depressurizing threshold | Kpa |
| 36 | BIND DOWN TM | Binding process depressurizing time over | sec |
| 37 | BIND R DOWN TM | Binding process depressurizing retry time over | sec |
| 38 | BIND FALL | Binding process depressurizing monitoring pressure(variation) | Kpa |
| 39 | WB DISPENSING SP | Washing reagent divided injection speed | rpm |
| 40 | DISP WASH BUFFER 1 | Washing reagent divided injection quantity | ml |

6 Parameter Setup Procedures

| No. | Screen Display | Parameter Name | Unit |
|-----|-----------------------|--|--------|
| 41 | WASH SPEED(1) | Washing process pressurizing speed (1st) | rpm |
| 42 | WASH PEEK(1) | Washing process peak pressure (1st) | Kpa |
| 43 | WASH UP TM(1) | Washing process pressurizing time over (1st) | sec |
| 44 | WASH RETRY(1) | Washing process pressurizing retry peak pressure (1st) | Kpa |
| 45 | WASH LOWER(1) | Washing process depressurizing threshold (1st) | Kpa |
| 46 | WASH DOWN TM(1) | Washing process depressurizing time over (1st) | sec |
| 47 | WASH R DOWN TM(1) | Washing process depressurizing retry time over (1st) | sec |
| 48 | WASH FALL(1) | Washing process depressurizing monitoring pressure (variation) (1st) | Kpa |
| 49 | DISP WASH BUFFER 2 | Washing reagent divided injection quantity | ml |
| 50 | WASH SPEED(2) | Washing process pressurizing speed (2nd) | rpm |
| 51 | WASH PEEK(2) | Washing process peak pressure (2nd) | Kpa |
| 52 | WASH UP TM(2) | Washing process pressurizing time over (2nd) | sec |
| 53 | WASH RETRY(2) | Washing process pressurizing retry peak pressure (2nd) | Kpa |
| 54 | WASH LOWER(2) | Washing process depressurizing threshold (2nd) | Kpa |
| 55 | WASH DOWN TM(2) | Washing process depressurizing time over (2nd) | sec |
| 56 | WASH R DOWN TM(2) | Washing process depressurizing retry time over (2nd) | sec |
| 57 | WASH FALL(2) | Washing process depressurizing monitoring pressure (variation) (2nd) | Kpa |
| 58 | DISP WASH BUFFER 3 | Washing reagent divided injection quantity | ml |
| 59 | WASH SPEED(3) | Washing process pressurizing speed (3rd) | rpm |
| 60 | WASH PEEK(3) | Washing process peak pressure (3rd) | Kpa |
| 61 | WASH UP TM(3) | Washing process pressurizing time over (3rd) | sec |
| 62 | WASH RETRY(3) | Washing process pressurizing retry peak pressure (3rd) | Kpa |
| 63 | WASH LOWER(3) | Washing process depressurizing threshold (3rd) | Kpa |
| 64 | WASH DOWN TM(3) | Washing process depressurizing time over (3rd) | sec |
| 65 | WASH R DOWN TM(3) | Washing process depressurizing retry time over (3rd) | sec |
| 66 | WASH FALL(3) | Washing process depressurizing monitoring pressure (variation) (3rd) | Kpa |
| 67 | DISP WASH BUFFER 4 | Washing reagent divided injection quantity | ml |
| 68 | WASH SPEED(4) | Washing process pressurizing speed (4th) | rpm |
| 69 | WASH PEEK(4) | Washing process peak pressure (4th) | Kpa |
| 70 | WASH UP TM(4) | Washing process pressurizing time over (4th) | sec |
| 71 | WASH RETRY(4) | Washing process pressurizing retry peak pressure (4th) | Kpa |
| 72 | WASH LOWER(4) | Washing process depressurizing threshold (4th) | Kpa |
| 73 | WASH DOWN TM(4) | Washing process depressurizing time over (4th) | sec |
| 74 | WASH R DOWN TM(4) | Washing process depressurizing retry time over (4th) | sec |
| 75 | WASH FALL(4) | Washing process depressurizing monitoring pressure (variation) (4th) | Kpa |
| 76 | DISP WASH BUFFER 5 | Washing reagent divided injection quantity | ml |
| 77 | WASH SPEED(5) | Washing process pressurizing speed (5th) | rpm |
| 78 | WASH PEEK(5) | Washing process peak pressure (5th) | Kpa |
| 79 | WASH UP TM(5) | Washing process pressurizing time over (5th) | sec |
| 80 | WASH RETRY(5) | Washing process pressurizing retry peak pressure (5th) | Kpa |
| 81 | WASH LOWER(5) | Washing process depressurizing threshold (5th) | Kpa |
| 82 | WASH DOWN TM(5) | Washing process depressurizing time over (5th) | sec |
| 83 | WASH R DOWN TM(5) | Washing process depressurizing retry time over (5th) | sec |
| 84 | WASH FALL(5) | Washing process depressurizing monitoring pressure (variation) (5th) | Kpa |
| 85 | DISP ELUTION BUFFER 1 | DNA elution reagent divided injection quantity | ml |
| 86 | EB SUCTIONING SP | DNA elution reagent suctioning speed | mm/sec |
| 87 | EB DISCHARGING SP | DNA elution reagent discharging speed | mm/sec |
| 88 | WAITING | Waiting | sec |
| 89 | ELUTION SPEED(1) | DNA eluting process pressurizing speed (1st) | rpm |

| No. | Screen Display | Parameter Name | Unit |
|-----|-----------------------|--|--------|
| 90 | ELUTION PEEK(1) | DNA eluting process peak pressure (1st) | Kpa |
| 91 | ELUTION UP TM(1) | DNA eluting process pressurizing time over (1st) | sec |
| 92 | ELUTION RETRY(1) | DNA eluting process pressurizing retry peak pressure (1st) | Kpa |
| 93 | ELUTION LOWER(1) | DNA eluting process depressurizing threshold (1st) | Kpa |
| 94 | ELUTION DOWN TM(1) | DNA eluting process depressurizing time over (1st) | sec |
| 95 | ELUTION R DOWN TM(1) | DNA eluting process depressurizing retry time over (1st) | sec |
| 96 | ELUTION FALL(1) | DNA eluting process depressurizing monitoring pressure (variation) (1st) | Kpa |
| 97 | DISP ELUTION BUFFER 2 | DNA eluted reagent divided injection quantity | ml |
| 98 | WAITING | Waiting | sec |
| 99 | ELUTION SPEED(2) | DNA eluting process pressurizing speed (2nd) | rpm |
| 100 | ELUTION PEEK(2) | DNA eluting process peak pressure (2nd) | Kpa |
| 101 | ELUTION UP TM(2) | DNA eluting process pressurizing time over (2nd) | sec |
| 102 | ELUTION RETRY(2) | DNA eluting process pressurizing retry peak pressure (2nd) | Kpa |
| 103 | ELUTION LOWER(2) | DNA eluting process depressurizing threshold (2nd) | Kpa |
| 104 | ELUTION DOWN TM(2) | DNA eluting process depressurizing time over (2nd) | sec |
| 105 | ELUTION R DOWN TM(2) | DNA eluting process depressurizing retry time over (2nd) | sec |
| 106 | ELUTION FALL(2) | DNA eluting process depressurizing monitoring pressure (variation) (2nd) | Kpa |
| 107 | DIS CARRIER RNA | Additional reagent divided injection quantity | ml |
| 108 | CR SUCTIONING SP | Additional reagent suctioning speed | mm/sec |
| 109 | CR DISCHARGING SP | Additional reagent discharging speed | mm/sec |
| 110 | MIXING SPEED(1) | Primary mixing speed | * |
| 111 | MIXING TIME(1) | Primary mixing time | sec |
| 112 | MIXING SPEED(2) | Secondary mixing speed | * |
| 113 | MIXING TIME(2) | Secondary mixing time | sec |
| 114 | DETECT PRES | Pressurizing threshold pressure | Kpa |
| 115 | DOWN PRES | Depressurizing threshold pressure during pressurizing | Kpa |

*Mixing speed setup/0: 1300rpm, 1: 1400rpm, 2: 1500rpm, 3: For origin return

(2) EXPERT Mode Parameter Setups

| No. | Screen Display | Protocol Name (Default values) | | | | | | | |
|-----|---------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|
| | | W BLOOD DNA 2.0ml FULL- AUTO | W BLOOD DNA 1.0ml FULL- AUTO | PLASMA DNA 2.0ml FULL- AUTO | PLASMA DNA 1.0ml FULL- AUTO | W BLOOD DNA 2.0ml SEMI- AUTO | W BLOOD DNA 1.0ml SEMI- AUTO | PLASMA DNA 2.0ml SEMI- AUTO | PLASMA DNA 1.0ml SEMI- AUTO |
| 1 | DISP PROTEASE | 0.30 | 0.15 | 0.30 | 0.15 | - | - | - | - |
| 2 | LB SUCTIONING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 3 | LB DISCHARGING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 4 | DISP SAMPLES | 2.00 | 1.00 | 2.00 | 1.00 | - | - | - | - |
| 5 | SAMP SUCTIONING SP | 5 | 5 | 5 | 5 | - | - | - | - |
| 6 | SAMP DISCHARGING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 7 | MIXING SPEED(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 8 | MIXING TIME(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 9 | MIXING SPEED(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 10 | MIXING TIME(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 11 | DISP LYSIS BUFFER | 2.50 | 1.25 | 2.50 | 1.25 | - | - | - | - |
| 12 | LB SUCTIONING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 13 | LB DISCHARGING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 14 | MIXING SPEED(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 15 | MIXING TIME(1) | 120 | 120 | 120 | 120 | - | - | - | - |
| 16 | MIXING SPEED(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 17 | MIXING TIME(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 18 | INCUBATING TEMP | 50 | 50 | 50 | 50 | - | - | - | - |
| 19 | INCUBATING TIME | 300 | 300 | 300 | 300 | - | - | - | - |
| 20 | HEATER ON TIMING | 0 | 0 | 0 | 0 | - | - | - | - |
| 21 | DISP ETHANOL | 2.50 | 1.25 | 2.50 | 1.25 | - | - | - | - |
| 22 | EN SUCTIONING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 23 | EN DISCHARGING SP | 10 | 10 | 10 | 10 | - | - | - | - |
| 24 | MIXING SPEED(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 25 | MIXING TIME(1) | 90 | 90 | 90 | 90 | - | - | - | - |
| 26 | MIXING SPEED(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 27 | MIXING TIME(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 28 | TRANSFER LYSATE | 7.30 | 3.65 | 7.30 | 3.65 | 7.30 | 3.65 | 7.30 | 3.65 |
| 29 | LS SUCTIONING SP | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| 30 | LS DISCHARGING SP | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| 31 | BIND SPEED | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 32 | BIND PEEK | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 33 | BIND UP TM | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 34 | BIND RETRY | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 35 | BIND LOWER | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 36 | BIND DOWN TM | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 37 | BIND R DOWN TM | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 38 | BIND FALL | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 39 | WB DISPENSING SP | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |
| 40 | DISP WASH BUFFER 1 | 7.50 | 7.50 | 7.50 | 7.50 | 7.50 | 7.50 | 7.50 | 7.50 |
| 41 | WASH SPEED(1) | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 42 | WASH PEEK(1) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 43 | WASH UP TM(1) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 44 | WASH RETRY(1) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 45 | WASH LOWER(1) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 46 | WASH DOWN TM(1) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 47 | WASH R DOWN TM(1) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 48 | WASH FALL(1) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |

| No. | Screen Display | Protocol Name (Default values) | | | | | | | |
|-----|-----------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|
| | | W BLOOD DNA 2.0ml FULL- AUTO | W BLOOD DNA 1.0ml FULL- AUTO | PLASMA DNA 2.0ml FULL- AUTO | PLASMA DNA 1.0ml FULL- AUTO | W BLOOD DNA 2.0ml SEMI- AUTO | W BLOOD DNA 1.0ml SEMI- AUTO | PLASMA DNA 2.0ml SEMI- AUTO | PLASMA DNA 1.0ml SEMI- AUTO |
| 49 | DISP WASH BUFFER 2 | 6.50 | 6.50 | 6.50 | 6.50 | 6.50 | 6.50 | 6.50 | 6.50 |
| 50 | WASH SPEED(2) | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 51 | WASH PEEK(2) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 52 | WASH UP TM(2) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 53 | WASH RETRY(2) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 54 | WASH LOWER(2) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 55 | WASH DOWN TM(2) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 56 | WASH R DOWN TM(2) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 57 | WASH FALL(2) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 58 | DISP WASH BUFFER 3 | 5.50 | 5.50 | 5.50 | 5.50 | 5.50 | 5.50 | 5.50 | 5.50 |
| 59 | WASH SPEED(3) | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 60 | WASH PEEK(3) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 61 | WASH UP TM(3) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 62 | WASH RETRY(3) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 63 | WASH LOWER(3) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 64 | WASH DOWN TM(3) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 65 | WASH R DOWN TM(3) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 66 | WASH FALL(3) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 67 | DISP WASH BUFFER 4 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 68 | WASH SPEED(4) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 69 | WASH PEEK(4) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 70 | WASH UP TM(4) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 71 | WASH RETRY(4) | 70 | 70 | 70 | 70 | 70 | 70 | 70 | 70 |
| 72 | WASH LOWER(4) | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 45 |
| 73 | WASH DOWN TM(4) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 74 | WASH R DOWN TM(4) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 75 | WASH FALL(4) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 76 | DISP WASH BUFFER 5 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 77 | WASH SPEED(5) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 78 | WASH PEEK(5) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 79 | WASH UP TM(5) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 80 | WASH RETRY(5) | 70 | 70 | 70 | 70 | 70 | 70 | 70 | 70 |
| 81 | WASH LOWER(5) | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 45 |
| 82 | WASH DOWN TM(5) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 83 | WASH R DOWN TM(5) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 84 | WASH FALL(5) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 85 | DISP ELUTION BUFFER 1 | 0.50 | 0.25 | 0.10 | 0.10 | 0.50 | 0.25 | 0.10 | 0.10 |
| 86 | EB SUCTIONING SP | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| 87 | EB DISCHARGING SP | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| 88 | WAITING | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 89 | ELUTION SPEED(1) | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 90 | ELUTION PEEK(1) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 91 | ELUTION UP TM(1) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 92 | ELUTION RETRY(1) | 120 | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| 93 | ELUTION LOWER(1) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 94 | ELUTION DOWN TM(1) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 95 | ELUTION R DOWN TM(1) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 96 | ELUTION FALL(1) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |

| No. | Screen Display | Protocol Name (Default values) | | | | | | | |
|-----|-----------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|
| | | W BLOOD DNA 2.0ml FULL- AUTO | W BLOOD DNA 1.0ml FULL- AUTO | PLASMA DNA 2.0ml FULL- AUTO | PLASMA DNA 1.0ml FULL- AUTO | W BLOOD DNA 2.0ml SEMI- AUTO | W BLOOD DNA 1.0ml SEMI- AUTO | PLASMA DNA 2.0ml SEMI- AUTO | PLASMA DNA 1.0ml SEMI- AUTO |
| 97 | DISP ELUTION BUFFER 2 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 98 | WAITING | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 99 | ELUTION SPEED(2) | 450 | 450 | 450 | 450 | 450 | 450 | 450 | 450 |
| 100 | ELUTION PEEK(2) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| 101 | ELUTION UP TM(2) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| 102 | ELUTION RETRY(2) | 70 | 70 | 70 | 70 | 70 | 70 | 70 | 70 |
| 103 | ELUTION LOWER(2) | 45 | 45 | 45 | 45 | 45 | 45 | 45 | 45 |
| 104 | ELUTION DOWN TM(2) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 105 | ELUTION R DOWN TM(2) | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| 106 | ELUTION FALL(2) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 107 | DIS CARRIER RNA | 0.00 | 0.00 | 0.00 | 0.00 | - | - | - | - |
| 108 | CR SUCTIONING SP | 1 | 1 | 1 | 1 | - | - | - | - |
| 109 | CR DISCHARGING SP | 1 | 1 | 1 | 1 | - | - | - | - |
| 110 | MIXING SPEED(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 111 | MIXING TIME(1) | 0 | 0 | 0 | 0 | - | - | - | - |
| 112 | MIXING SPEED(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 113 | MIXING TIME(2) | 0 | 0 | 0 | 0 | - | - | - | - |
| 114 | DETECT PRES | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| 115 | DOWN PRES | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |

7 Daily Inspections and Maintenance

The maintenance procedures for this system are explained below.



Biohazard When cleaning, wear proper gloves, mask and protective goggles.



Caution Carry out cleaning of system main unit and accessories at every operation.
Operation while contaminated will cause cross-contamination.



Warning Ethyl alcohol is an inflammable substance. Do not use in proximity of open flame.

7.1 What to Do before Using the System

Before using system, carry out the following:

- Check for any contamination of system and accessories. If contaminated, they must be cleaned.
- (→"7.3 Cleaning of System Main Unit and Accessories" and "7.6 UV (Ultraviolet Light) Irradiating Function")
- Check for any deterioration or damage of consumables. Replace if deteriorated or damaged.
- (→"7.4 Replacement of Consumables")
- Replenishment or replacement of reagents.
- Check for any residual used reagent in wash buffer feeding lines.
If any remains, discharge and clean inside of fluid feeding lines.
(→"7.5 Cleaning of Wash Buffer Feeding Line")

7.2 When System Not in Use for More Than One Week

If system use is not planned for more than one week after previous use, carry out the following:

- Check for contamination of system and its accessories. If contaminated, they must be cleaned.
(→"7.3 Cleaning of System Main Unit and Accessories", "7.6 UV (Ultraviolet Light) Irradiating Function")
- Check for any residual used waste or waste fluids. Dispose of if any remain.
- Clean wash buffer feeding lines.
(→"7.5 Cleaning of Wash Buffer Feeding Line")

7.3 Cleaning of System Main Unit and Accessories

Locations and procedures for cleaning system main unit and accessories are explained below:

| Parts Requiring Cleaning | Cleaning Procedures |
|----------------------------------|--|
| System Main Unit (Exterior) | Grit and dust should be wiped off using soft cloth, etc. Strong stains should be wiped off using soft paper, etc. containing 0.5% sodium hypochlorite solution or ethyl alcohol. Be sure to wipe off area where sodium hypochlorite solution was applied using soft paper, etc. containing nuclease-free water and dry. |
| System Main Unit (Interior) | |
| Pressurizing Nozzle (Packing) | Refer to "Cleaning of Pressurizing Nozzle (Packing)" explained later. Note: If strong stains or any abnormality such as blemishes, deformation or hardening are observed, replace parts. (→"7.4 Replacement of Consumables") |
| Reagent Container Holder | Wipe off using soft paper, etc. containing 0.5% sodium hypochlorite solution or ethyl alcohol. Be sure to wipe off area where sodium hypochlorite solution was applied using soft paper, etc. containing nuclease-free water and dry. |
| Sample Tip Holder | |
| Reagent Tip Holder | |
| Sample Holder | |
| Cartridge Holder | |
| Waste Tube Holder | |
| Collection Tube Holder | |
| Holder Packing | Refer to "Cleaning of Holder Packing" explained later regarding cleaning holder packing included in cartridge holder. Note: If strong stains or any abnormality such as blemishes, deformation or hardening are observed, replace parts. |
| Wash Buffer Bottle | Dispose of residual reagents and waste fluids in containers. |
| Reagent Container S | Rinse inside of containers using 0.5% sodium hypochlorite solution or ethyl alcohol as necessary. |
| Reagent Container L | |
| Waste Fluid Container | Wash inside containers using nuclease-free water and dry. |
| Waste Container | If contaminated, immerse in 0.5% sodium hypochlorite solution for 30 minutes. Then wash stain with water and dry. |
| Drip Tray | Refer to "Cleaning of Drip Tray" explained later. Note: If strong stains or any abnormality such as blemishes, deformation or hardening are observed, replace tray. |

■ Cleaning Pressurizing Nozzle (Packing)



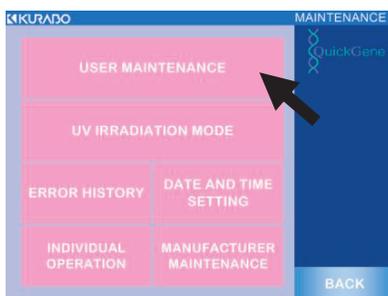
Pressurizing nozzle (packing) is mounted on robot unit.

Cleaning procedures for pressurizing nozzles (packing) are explained below.



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

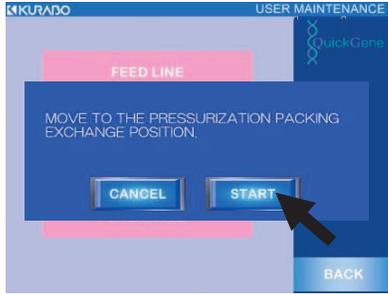
(2) Press [MAINTENANCE] and start maintenance mode.



(3) Press [USER MAINTENANCE].



(4) Press [PRESSURIZATION PACKING EXCHANGE].



- (5) Press [START] in displayed pop-up window.
Press [CANCEL] to close window.

- (6) Robot unit moves near opening of system sliding doors.
When motion is complete, a message will be displayed.

- (7) Press system power switch to turn OFF power.



- (8) Open sliding doors, refer to below and clean pressurizing nozzle (packing).

| Parts to Clean | Cleaning Procedures |
|-------------------------------|--|
| Pressurizing Nozzle (Packing) | Wipe off using soft paper, etc. containing 0.5% sodium hypochlorite solution or ethyl alcohol. Be sure to wipe off area where sodium hypochlorite solution was applied using soft paper, etc. containing nuclease-free water and dry. |

7

Note: Clean pressurizing packing for every operation. Operation while pressurizing packing is contaminated will cause cross-contamination. Furthermore, if strong stains or abnormality such as blemishes, deformation or hardening are present, normal isolation may not be possible due to insufficient pressurizing. Replace pressurizing packings as necessary. (→"7.4 Replacement of Consumables")

■ Cleaning Holder Packings

Cartridge Holder



Holder Packing



Holder packings are mounted inside cartridge holder cover.

Procedures for cleaning and replacement of holder packings are explained below.

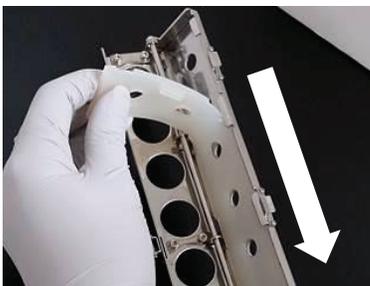
- (1) Open cover by releasing locks at 3 places on cartridge holder.

Projection



- (2) Pull on projection of holder packing and remove end from cartridge holder.

Note: When removing packing, work while supporting cartridge holder with one hand.



- (3) Switch grip to end of packing and completely remove holder packing.

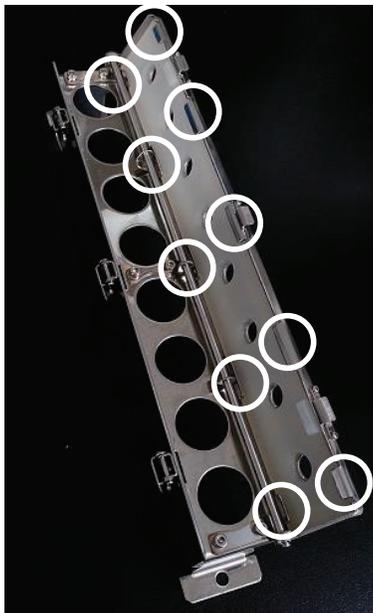


(4) Refer to below and clean holder packing.

| Parts to Clean | Cleaning Procedures |
|----------------|---|
| Holder Packing | <p>Wipe off using soft paper, etc. containing 0.5% sodium hypochlorite solution or ethyl alcohol.</p> <p>Be sure to wipe off area where sodium hypochlorite solution was applied using soft paper, etc. containing nuclease-free water and dry.</p> |

Note: Clean holder packing for every operation. Operation while holder packing is contaminated will cause cross-contamination. Furthermore, if holder packing stain is sticky or abnormalities such as blemishes, deformation or hardening are present, normal isolation may not be possible due to insufficient pressurizing. Replace holder packings as necessary.

Cartridge Holder Lugs (10 pcs)



(5) Fit cleaned or new holder packing onto cartridge holder



7

Note: If fitting of holder packing is omitted or incomplete, normal isolation operation may not be possible due to insufficient pressurizing. After fitting holder packing, be sure to confirm that packings are fit properly onto 10 cartridge holder hooks.

■ Cleaning Drip Tray



Drip trays are mounted on lower part of robot unit.

Procedures for cleaning and replacement of drip trays are explained below.

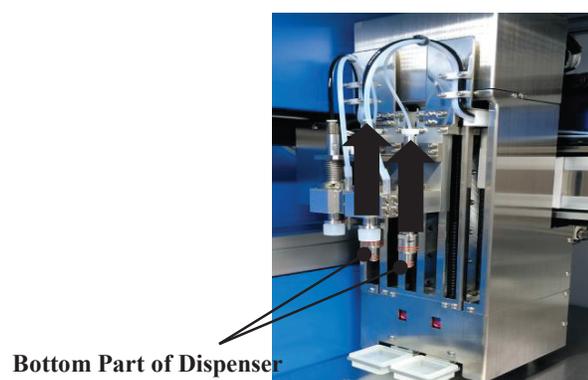
- (1) Refer to "Cleaning Pressurizing Nozzles (Packing)" explained above and move robot unit near opening of system sliding doors.
- (2) Press system power switch to turn OFF power.
- (3) Open sliding doors and remove drip trays from drip tray guide.

If drip trays are not pulled out (housed in the robot), slowly lift bottom part of dispenser and pull out the drip trays manually.



Drip Tray
Drip Tray Guide

Drip trays are housed in



Bottom Part of Dispenser



(4) Refer to below and clean drip trays.

| Parts to Clean | Cleaning Procedures |
|----------------|---|
| Drip Trays | Wipe off using soft paper, etc. containing 0.5% sodium hypochlorite solution or ethyl alcohol. If stain is sticky, immerse in 0.5% sodium hypochlorite solution for 30 minutes. Then wash stain area with water and dry. |

Note: Clean drip trays for every operation. Operation while drip trays are contaminated will cause cross contamination. Replace drip trays depending on condition such as irremovable stain.



(5) Mount cleaned or new drip trays on drip tray guide.

Drip Tray Flange

Drip Tray Guide Frame

Note: Securely mount drip tray so that flanges tightly contact drip guide frame. Omitted or incomplete fitting of drip tray will cause cross-contamination.

7



Tight Contact

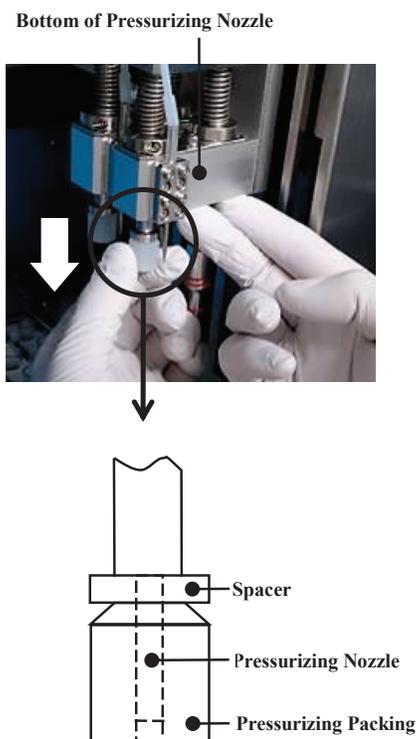
7.4 Replacement of Consumables

Procedures for replacement of consumables used for system are as follows.

■ Replacement of Pressurizing Packing

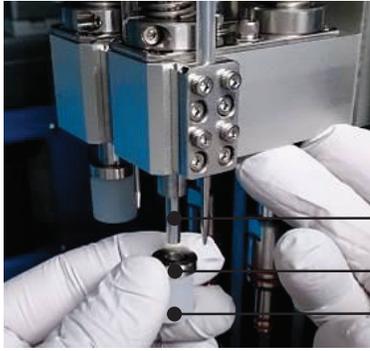
Procedures for replacement of pressurizing packings are explained below.

- (1) Refer to "Cleaning Pressurizing Nozzles (Packing)" in "7.3 Cleaning System Main Unit and Accessories" and move the robot unit near opening of system sliding doors.
- (2) Press system power switch to turn OFF power.
- (3) Hold pressurizing packing with fingers as shown in figure, and support bottom of pressurizing nozzle with other hand. Pull down and remove pressurizing packing from pressurizing nozzle.



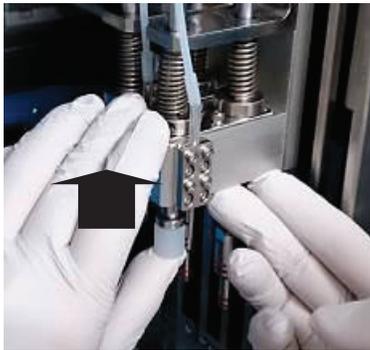
Note:

- When removing pressurizing packing, be sure to work while supporting bottom of pressurizing nozzle with one hand.
- Spacer set in upper part of pressurizing packing is removed when pressurizing packing is removed. Take care not to drop spacer during removal.



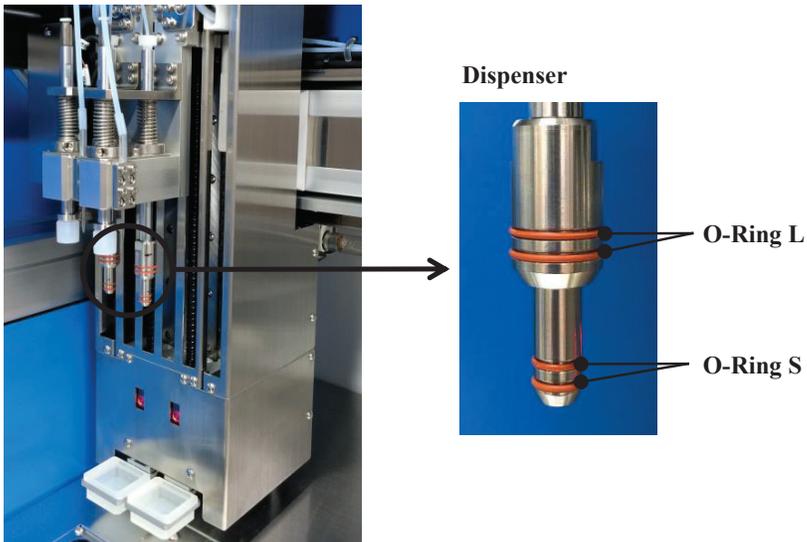
- (4) Securely insert upward and in order spacer and new pressurizing packing into pressurizing nozzle.

Pressurizing Nozzle
Spacer
Pressurizing Packing



Note: If spacer fitting is omitted or pressurizing packing fitting is incomplete, normal isolation operation may not be possible due to insufficient pressurizing. After fitting pressurizing packing, check secure mounting of pressurizing nozzle, spacer and pressurizing packing without a gap.

■ Replacement of Dispenser O-Ring



In this system, 2 large and 2 small O-rings (O-ring L: 2 pcs, O-ring S: 2 pcs) are set in each of the 2 dispensers.

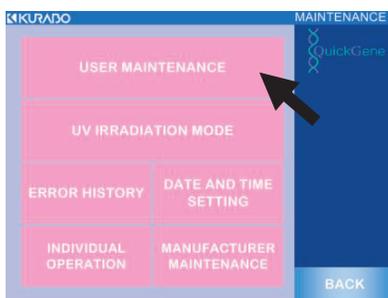
Procedures for replacing dispenser O-rings are explained below.

Note: If any abnormality such as blemishes, deformation or hardening are observed on the O-rings, normal isolation may not be possible due to defective divided injection of samples, reagents and lysates. Furthermore, it may cause cross-contamination. Replace dispenser O-rings as necessary. We also recommend that you change it every three months.

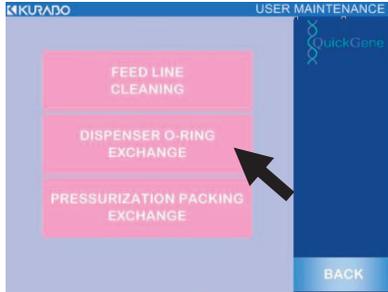


(1) Refer to "3.6 Start-Up of System", turn system power ON and move to mode select screen.

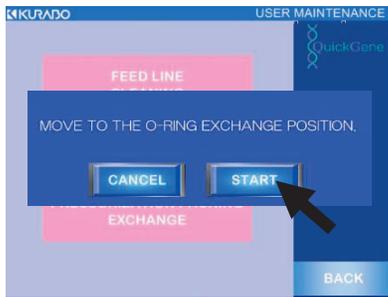
(2) Press [MAINTENANCE] to start maintenance mode.



(3) Press [USER MAINTENANCE].



- (4) Press [DISPENSER O-RING EXCHANGE].



- (5) Press [START] in displayed pop-up window.
Press [CANCEL] to close window.



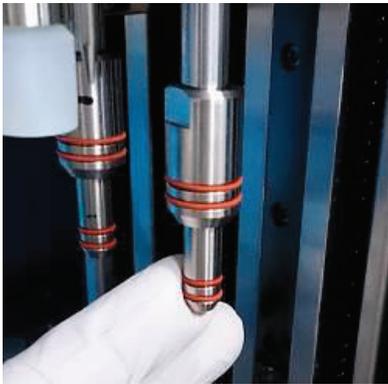
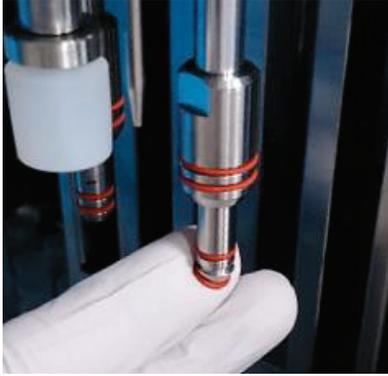
- (6) Robot unit will move near opening of system sliding doors.
When movement is complete, a message will be displayed.

- (7) Press system power switch to turn OFF power.



- (8) Open system sliding doors and remove O-rings using small slotted screwdriver, etc.

Note: When removing dispenser O-rings, take care not to damage dispenser.

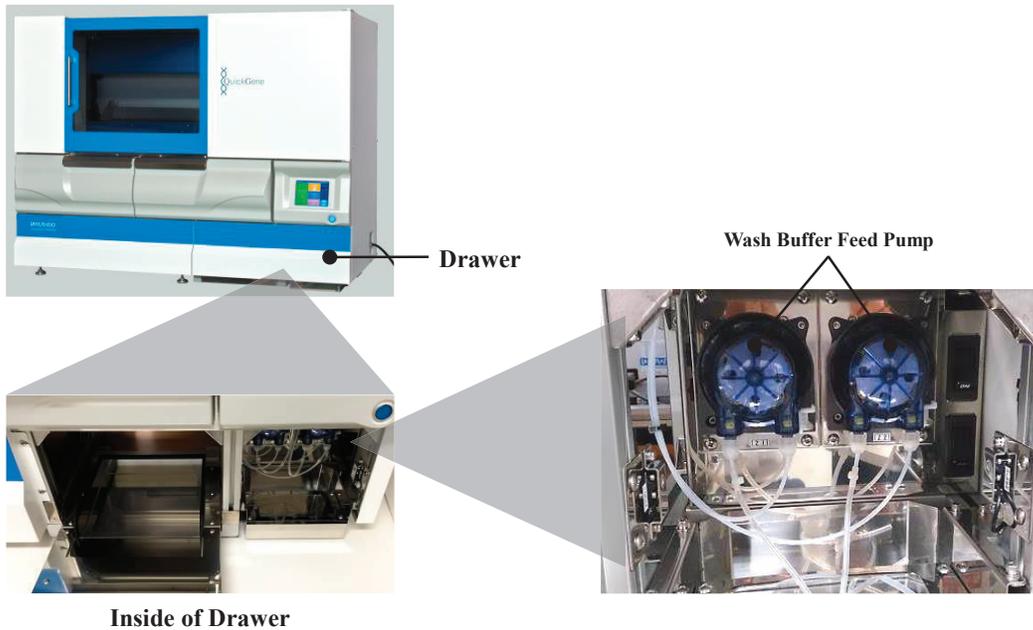


(9) Fit new O-ring onto groove on dispenser.

Note:

- When fitting O-ring onto dispenser, take care not to damage O-ring.
 - If O-ring fitting is omitted or incomplete, normal isolation may not be possible due to defective divided injection of samples, reagents and lysates. Furthermore, it may cause cross-contamination.
-

■ Replacement of Wash Buffer Pump Tubes



Two wash buffer feed pumps for wash buffer are installed in the system drawer, and one pump tube is used for each pump.

The procedures for replacement of wash buffer feed pump tubes are explained below.

Note: Deterioration of wash buffer pump tubes may influence nucleic acid isolation processes due to abnormal injection of wash buffer.

Replace wash buffer feed pump tubes every 6 months as a standard.

7

(1) Check that system power is OFF.



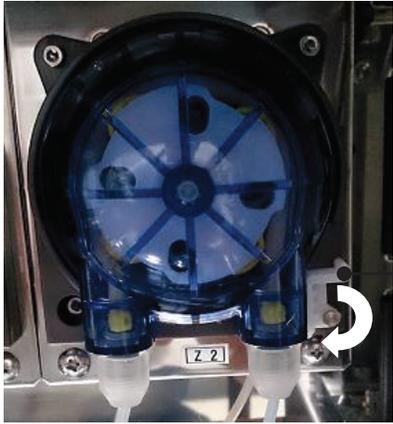
Waste Container

Wash Buffer Bottle

(2) Pull out drawer and take out waste container and wash buffer bottle.

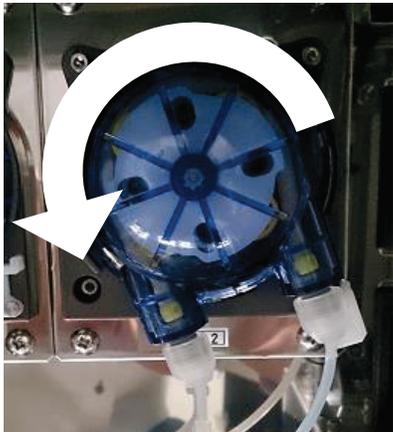
Wash buffer pump will appear behind wash buffer bottle.

Note: Store inlet tube tip inserted into wash buffer bottle in clean bag, etc.



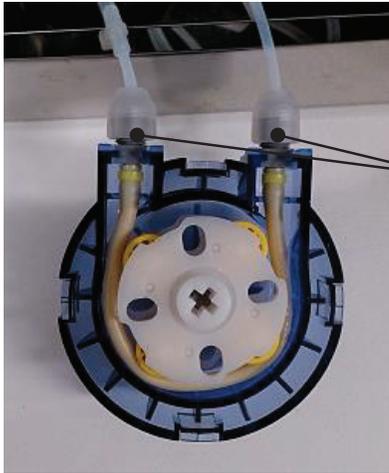
(3) Release wash buffer pump lock.

Lock



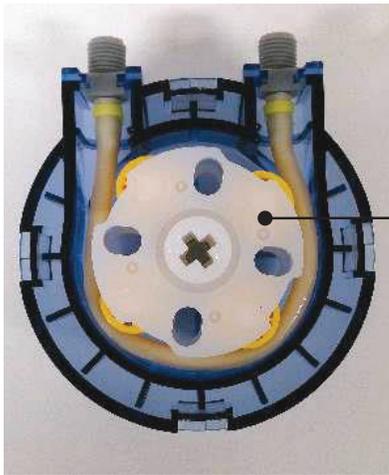
(4) Grasp plastic cover of wash buffer pump and turn counterclockwise (in direction of arrow) until it stops (approximately 20 degrees). Then pull and remove wash buffer pump toward you.

7



(5) Turn two connected tube joints in direction of arrows and remove.

Tube Joints

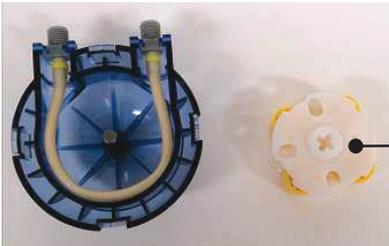


(6) Remove rotating component.

Rotating Component



7



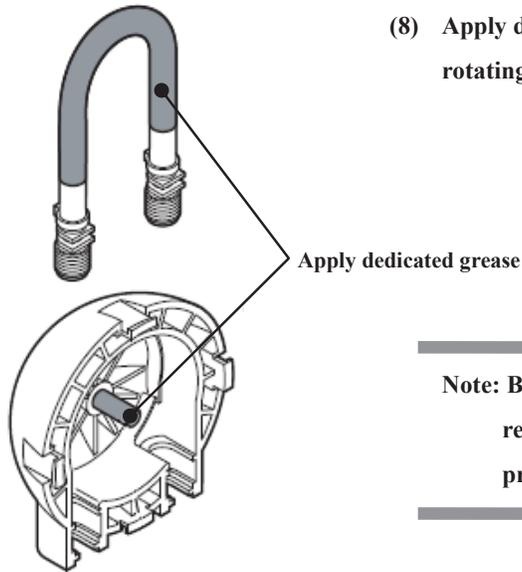
Rotating Component



(7) Remove wash buffer pump tube.

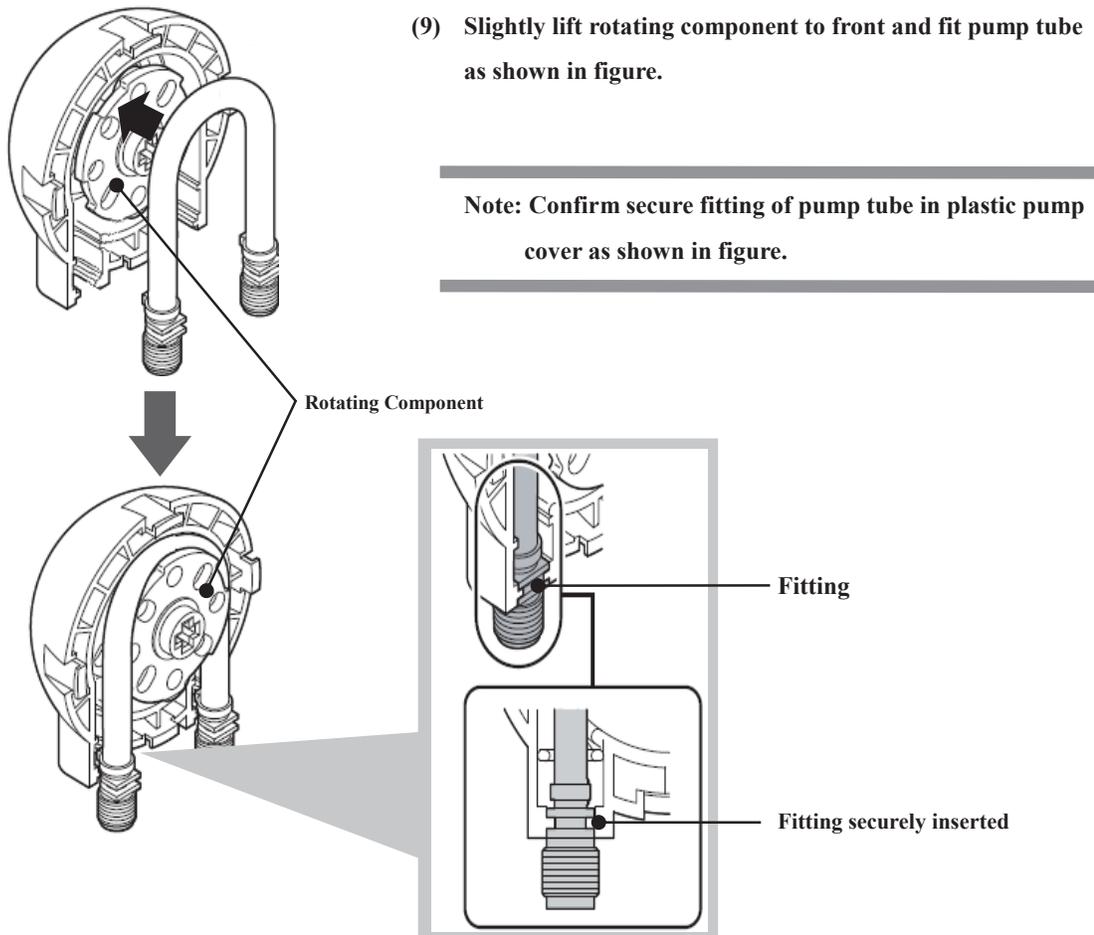
Wash Buffer Pump Tube

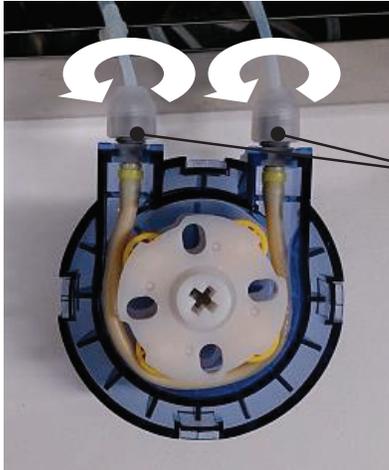
- (8) Apply dedicated grease to new wash buffer pump tube and rotating component shaft (gray areas in figure).



Note: Be sure to use only dedicated grease included with replacement parts. Use of other greases will cause problems such as degraded durability.

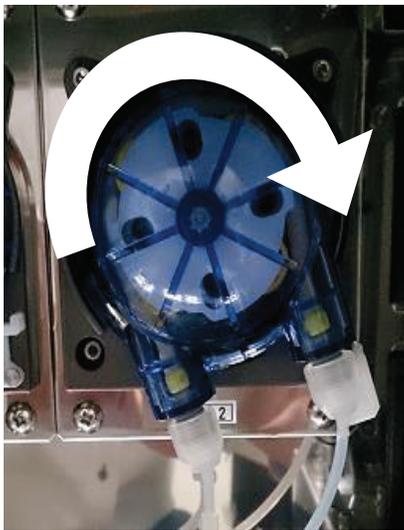
- (9) Slightly lift rotating component to front and fit pump tube as shown in figure.





(10) Set two tube joints while turning in direction of arrows in figure.

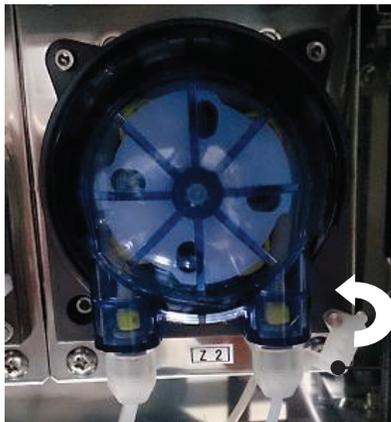
Tube Joints



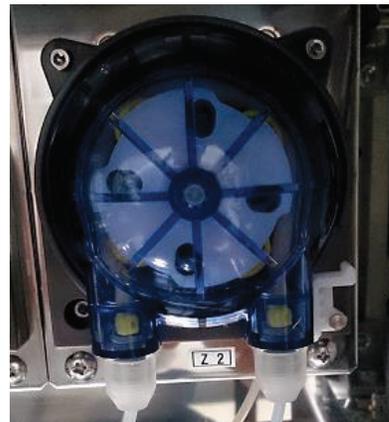
(11) Fit wash buffer pump in tilted position on fitting groove as shown in figure. Then turn wash buffer pump clockwise (in direction of arrow) until it stops (approximately 20 degrees).

(12) Lock wash buffer pump as shown in figure.

7



Lock



■ Replacement of Fan Filter

Fan (Filter)



A fan filter is used in fan installed in rear of system work area. A fan filter is used inside the fan. Procedures for fan filter replacement are explained below.

Note: Normal ventilation of inside of system may not be possible if fan filter deteriorates or becomes dirty.
Replace fan filter every year as a standard.

(1) Check that system power is OFF.

(2) Fully open system sliding doors.



Sliding Door

Note: Beware of any persons or other obstacles when fully opening sliding doors.

7



(3) Grasp side of fan cover and remove toward front.



Fan Cover



Fan Cover

Fan Filter

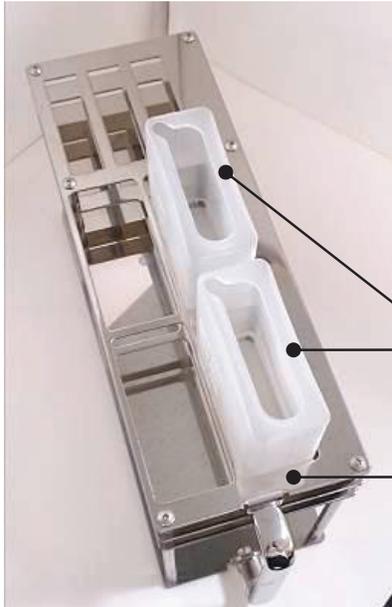
(4) Remove filter from fan cover.

(5) Set new filter following reverse order.

7

7.5 Cleaning of Wash Buffer Feeding Line

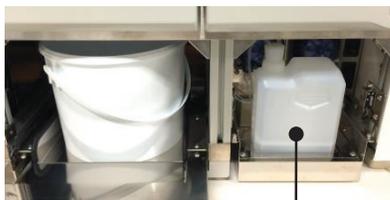
When power is turned OFF after completion of work, a small quantity of reagents remains in wash buffer feeding lines. If this system will not be reused for more than one week, any residual fluid may crystallize and clog nozzles or damage tube. Clean wash buffer feeding lines in accordance with the following procedures. This cleaning should always be conducted before using system after a long period of shutdown.



- (1) Set 2 waste fluid containers (reagent container L) in reagent container holder and set reagent container holder in system.

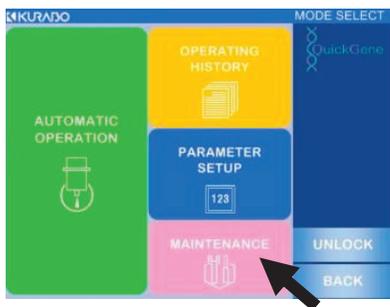
Note: Waste fluid container should be set in specified position as shown in figure.

-
- Waste Fluid Container (Reagent Container L)
- Reagent Container Holder

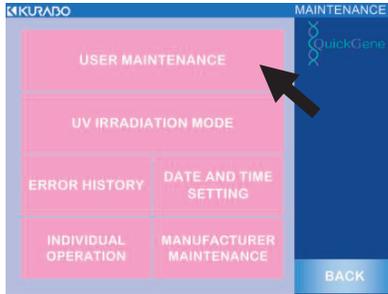


Wash Buffer Bottle

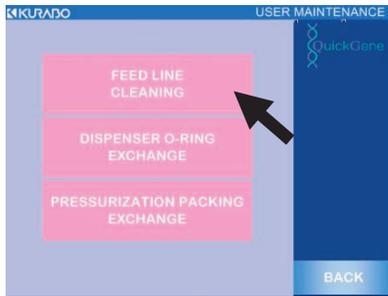
- (2) Supply nuclease-free water to wash buffer bottle and set wash buffer bottle in system. Close drawer after setting.



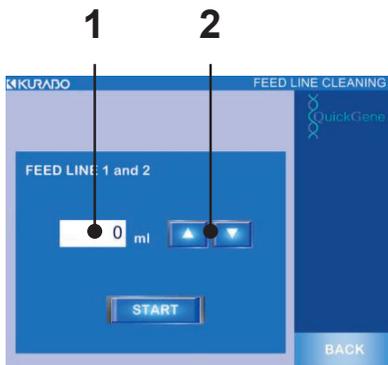
- (3) Refer to "3.6 Start-Up of System", turn system power ON and move to mode select screen.
- (4) Press [MAINTENANCE] to start maintenance mode.



(5) Press [USER MAINTENANCE].



(6) Press [FEED LINE CLEANING].



(7) Cleaning mode for feed line starts.

Enter fluid feeding quantity as "15 mL" with either of following procedures:

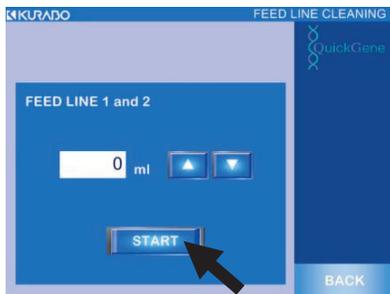
1. **Directly enter a value using ten-key entry pad.**

Touch white frame in which a value is entered to display ten-key pad, enter value for feeding fluid quantity, and press [ENT].

2. **Change value using up/down (Δ / ∇) buttons.**

One press of [Δ] button increases setup value by 1, and one press of [∇] decreases setup value by 1.

Note: Too great a fluid feeding quantity may cause fluid overflow from waste fluid container. Do not enter value exceeding 20 mL.



- (8) Enter value and press [START].

Wash buffer pump will operate and fluid in wash buffer bottle will be fed and discharged into waste fluid container.

Note: Too frequent fluid feeding may cause fluid overflow from waste fluid container. Dispose of waste fluid in waste fluid container as necessary to prevent overflow.

Inlet Tube



- (9) **Remove inlet tube of fluid feeding line from wash buffer bottle and press [START] while empty.**

Supply air to fluid feeding lines and discharge residual fluid from line.

- (10) Set inlet tube in container with ethyl alcohol and press [START].

Feed ethyl alcohol into fluid feeding lines.

- (11) **Remove inlet tube from container with ethyl alcohol, and press [START] while empty.**

Supply air to fluid feeding lines and discharge residual fluid from lines.

- (12) **Press [START] several times if necessary while empty.**

Supply air to fluid feeding lines and dry inside of lines with air flow.

- (13) **Turn system power OFF and dispose of waste fluid in waste fluid container.**

7.6 UV (Ultraviolet Light) Irradiating Function



UV Lamp

UV (ultraviolet light) lamp is included in system robot unit, and UV is irradiated in work area in UV irradiating mode. Procedures for using UV irradiation mode are explained below.

Cartridge Holder Sample Holder



Collection Tube Holder

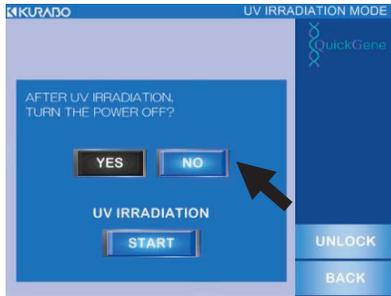
- (1) Remove sample holder, cartridge/waste tube holder and collection tube holder from system.

Note: To prevent sample damage, UV irradiation is not permitted while sample holder, cartridge/water tube holder and collection tube holders are set in system.

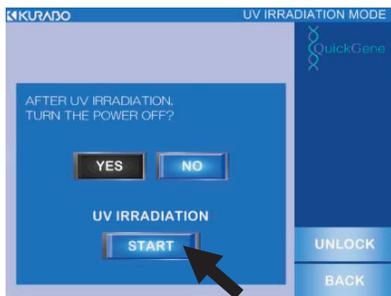
- (2) Refer to "3.6 Start-Up of System", turn system power ON, and move to mode select screen.
- (3) Press [MAINTENANCE] to start maintenance mode.
- (4) Press [UV IRRADIATION MODE].



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- (5) Setup screen for UV irradiation mode is displayed. Select [YES] to automatically turn OFF system power after UV irradiation or press [NO] to maintain system power.



- (6) Press [START] to start UV irradiation.

Important: Before starting UV irradiation, check that all system sliding doors, L/R flap doors and drawers are closed.

8 Before Concluding as a Failure

"Was the operation a failure?" Error messages displayed on the operation panel are explained below.

8.1 Troubleshooting

If sample isolation is unsuccessful, check setup values for parameters.

If the setup values for parameters are improper, sample isolation may fail due to excessive or insufficient buffer, abnormal pressurizing process, improper heating temperature or insufficient agitation of lysate solution. Parameters should be changed in accordance with instructions of manufacturer or its sales agent.

Refer to "6 Parameter Setup Procedures" regarding parameter setup.

If problem is still not resolved, contact our customer consultation desk.

If you feel that isolation was a failure, please check the following before contacting us.

| Phenomenon | Possible Cause | Countermeasure |
|--|--|--|
| Does not operate when power is turned ON | Is the power plug connected in an outlet? | Securely insert the power plug in an outlet |
| Breaker is shut off | Overcurrent or risk of electrical leakage due to system failure | Contact our customer consultation desk. |
| Abnormal noise from system | Possibility of system failure | Contact our customer consultation desk. |
| Strange smell from the system | | Promptly pull the power cable off from the outlet. Then contact our customer consultation desk. |
| Cartridge fluid is not correctly caught in collection tubes and waste tubes. | Are cartridges securely set in cartridge holder? | - Securely set cartridge in setting position of holder. - Set twaste tube to match setting position of cartridge. |
| | Are the snap locks (3 places) of the cartridge holder securely locked? | Securely lock the snap locks of the cartridge holder |
| Wash buffer does not exit nozzle. | Does wash buffer bottle contain buffer? | If wash buffer bottle is empty, supply buffer. |

8 Before Concluding as a Failure

| Phenomenon | Possible Cause | Countermeasure |
|---|---|---|
| Isolation work skipped steps / was interrupted midway. | Clogged with tips during sample (blood) suction. | Check for any solid substances that may cause clogging of tips in set sample. |
| | Pressure did not increase when cartridge was pressurized. | - Securely set cartridge in holder setting position. - Securely lock cartridge holder snap locks. |
| | The cartridge was clogged | Check for any solid substances that may cause clogging of cartridge in the set sample. Refer to the troubleshooting described in the handbook for the dedicated reagent kit. |
| The DNA yield is low. DNA is not acquired. | - | Refer to the troubleshooting described in the handbook for the dedicated reagent kit. |
| The sequential experiments such as PCR are not successful | - | Refer to the troubleshooting described in the handbook for the dedicated reagent kit. |
| Precipitate in reagent | - | Refer to troubleshooting described in handbook for dedicated reagent kit. |

8.2 Error Messages

When error message is displayed on operation panel, promptly take measure indicated in table below and contact our customer consultation desk as necessary.

Error messages displayed on operation panel are as follows:

◇System Check Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|---|--|--|
| 0003 | HEATER SINGULARITY | Abnormal heater operation found during system check | If similar error occurs in a retry of operation, contact our customer consultation desk. |
| 0005 | PRESSURE SINGULARITY/No.1 No.1 pressure head of can not be pressurized. Turn of the power of the device, please check the pressure packing. | Pressure leakage abnormality in pressurizing packing 1 during system check (Check Timeout) | Turn system power OFF and check or replace abnormal pressurizing packing. |
| 0006 | PRESSURE SINGULARITY/No.2 No.2 pressure head of can not be pressurized. Turn of the power of the device, please check the pressure packing. | Pressure leakage abnormality in pressurizing packing 2 during system check (Check Timeout) | |
| 0011 | OPEN AGITATION COVER | Lysate unit cover is open during system check | Press door lock release button to open flap doors; close and lock lysate unit cover. |
| 0012 | NO WASTE CONTAINER1 waste container1 has not been set. Press the BACK button to turn off the display, open the door by pressing the UNLOCK button, set the waste container1. | During system check, waste fluid container 1 or holder is not set in reagent container holder in system. | Press door lock release button to open flap doors and set waste fluid container corresponding to reagent container holder. Or securely set reagent container holder in system. |
| 0013 | NO WASTE CONTAINER2 waste container2 has not been set. Press the BACK button to turn off the display, open the door by pressing the UNLOCK button, set the waste container1. | During system check, waste fluid container 2 or holder is not set in reagent container holder set in system. | |

| Code No. | Message | Description | Countermeasure |
|----------|---|--|--|
| 0014 | NO WASTE TIP CONTAINER Waste tip container1 has not been set. Set the waste tip container. | During system check, waste container is not set in system. | Open drawer and set waste container in waste container rack. Press door lock release button after setting and open/close sliding doors or flap doors. (System check will re-start.) |

◇Sample ID/Collection ID Reading Related Errors

| Code No. | Message | Descriptions | Countermeasure |
|----------|---|---|---|
| 0020 | SAMPLE RACK WRONG The wrong sample rack was installed. Please install the correct sample rack. | Information other than specified holder is read during sample holder ID reading. (Ex: Information from holder B was read during reading of holder A) | Press [BACK] in pop-up display and re-read ID of specified holder. |
| 0021 | SAMPLE ID READ ERROR Samples of the following number has not been installed, or ID could not be read. <u>sampleNo.</u> Let again, read a sample of the ID. | Gap in read-out sample numbers when sample IDs read. (Ex: 1, 2, <u>3</u> , 5, 6...) | Press [BACK] in pop-up display and press [RE-READ] to re-read sample IDs. |
| 0022 | SAMPLE-RACK REMOVED Sample rack has been removed. All sample rack is removed from the device, please let me read again sample ID. | Sample holder (already read) set in system removed during sample ID reading. | Remove all sample holders from system and press [BACK] in pop-up display to re-read sample IDs. |
| 0030 | COLLECTION-RACK EXIST Has been installed collection tube rack A B C is already in the device. Please remove the collection tube rack A B C. | When collection IDs to be read, collection tube holders set before reading. | Remove all collection tube racks from system and re-read collection ID. |

| Code No. | Message | Description | Countermeasure |
|----------|---|--|--|
| 0031 | COLLECTION RACK WRONG The wrong collection rack was installed. Please install the correct collection rack. | When reading collection tube holder IDs, information other than specified holder is read. (Ex: When reading holder A, information for holder B was read.) | Press [BACK] in pop-up display and re-read ID of specified holder. |
| 0032 | COLLECTION ID READ ERROR Collection tubes of the following number has not been installed, or ID could not be read. <u>tubeNo.</u> Let again, read a collection tube of the ID. | When reading collection IDs, number of read out tubes and samples are different. (Ex: Samples 1, 2, 3, 4, 5, /Tubes 1, 2, 3, 5) | Press [BACK] in pop-up display and press [RE-READ] to re-read collection IDs. |
| 0033 | COLLECTION-RACK REMOVED Collection rack has been removed. All collection rack is removed from the device, please let me read again collection tube ID. | When reading collection IDs, collection tube holder (already read) in system was removed. | Remove all collection tube holders from system, press [BACK] in pop-up display, and re-read collection IDs. |
| 0040 | SAMPLE-RACK REMOVED Sample rack has been removed. All sample rack is removed from the device, please let me read again sample ID. | Sample ID reading setup is ON and sample holder removed from system after door locks are released via reagent quantity confirmation screen or work check screen. | Remove all sample holders from system, press [BACK] in pop-up display and return to protocol selection screen. |

| Code No. | Message | Description | Countermeasure |
|----------|--|--|--|
| 0041 | SAMPLE-RACK REMOVED Sample rack has been removed. All sample rack and collection rack is removed from the device, please let me, read again sample ID and collection tube ID. | Reading setups for sample IDs and collection IDs are ON and sample holder removed from system after releasing door lock via reagent quantity confirmation screen or work check screen. | Remove all sample holders and collection tube holders from system and press [BACK] in pop-up screen and return to protocol selection screen. |
| 0042 | COLLECTION-RACK REMOVED Collection rack has been removed. All collection rack is removed from the device, please let me read again collection tube ID. | Reading setups for sample IDs and collection IDs are ON and collection tube holder is removed from system after releasing door lock via reagent quantity confirmation screen or work check screen. | |

◇ Door Open Related Errors during Automatic Operation

| Code No. | Message | Description | Countermeasure |
|----------|---------------------|---|---|
| 0098 | AGITATOR COVER OPEN | Locking abnormality on lysate unit cover during system check, automatic operation or manual operation. (Cover opens due to loose locks.) | Turn system power OFF, open slide doors and check lysate unit cover. If cover lock is loose, securely lock and restart automatic operation. If error is unresolved, contact our customer consultation desk. |
| 0099 | FRONT DOOR OPEN | Locking abnormality on sliding doors or flap doors during system check, automatic operation or manual operation. (Door opens due to loose locks.) | Contact our customer consultation desk. |

◇USB/System Control Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|---|---|---|
| 0100 | USB NOT INSTALL USB flash drive is not installed. | USB flash drive (USB memory) is not inserted in USB port. | Insert USB flash drive (USB memory) in USB port and operate on touch panel. |
| 0101 | USB CAPACITY SHORTAGE USB flash drive of the capacity is not enough. | Free space in USB flash drive (USB memory) is insufficient when saving operation histories. | Check free space of USB flash drive (USB memory). |
| 0102 | FIRMWARE UPDATE ERROR | Firmware (control software) update abnormality | Contact our customer consultation desk. |
| 0103 | SD BACKUP ERROR | Data backup abnormality in SD card. | Contact our customer consultation desk. |
| 0104 | GET TIME ERROR | Communication abnormality when system main unit acquires time from touch panel. | Contact our customer consultation desk. |

◇Automatic Operation Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|-----------------------|--|---|
| 0110 | TIP EJECT ERROR | Abnormality in tip ejecting operation during automatic operation | If similar error repeats during retry of operation, contact our customer consultation desk. |
| 0111 | TIP SET ERROR | Abnormality in tip mounting operation during automatic operation. | |
| 0113 | LIQUID DETECT ERROR | Abnormality in fluid surface detection operation during automatic operation. | |
| 0114 | FILTER PRESS ERROR | Abnormality at start of cartridge pressurization operation during automatic operation. | |
| 0118 | SYRINGE SUCTION ERROR | Abnormality at start of syringe suction operation during automatic operation. | |

| Code No. | Message | Description | Countermeasure |
|----------|-------------|--|--|
| 0120 | TRAY REMOVE | Abnormality when sample holder, waste tube holder or collection tube holder removed or lysate tube unit cover lock released after releasing door locks during automatic operation in reagent quantity confirmation screen. | If holders are removed, restart operation from protocol selection screen. If error is found with lysate unit cover locks, check cover locking status. If error continues, contact our customer consultation desk. |

◇Heater/Fan Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|-------------------|---|---|
| 0150 | DIGITAL OUT ERROR | Abnormality when digital output control fails. | Contact our customer consultation desk. |
| 0151 | HEATER ALERT | Abnormality when temperature controller alert occurs during system check. | If similar error repeats during retry of operation, contact our customer consultation desk. |
| 0152 | FAN ALARM | Abnormality when exhaust fan alarm activates at time of system power ON. | |

◇UV Irradiation Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|-------------------------|---|--|
| 0201 | SAMPLE RACK A EXIST | Sample holder A is set in system when UV irradiated. | Press door lock release button, open flap doors, and remove relevant holder from system. |
| 0202 | SAMPLE RACK B EXIST | Sample holder B is set in system when UV irradiated. | |
| 0203 | SAMPLE RACK C EXIST | Sample holder C is set in system when UV irradiated. | |
| 0204 | FILTER RACK A EXIST | Cartridge holder A is set in system when UV irradiated. | |
| 0205 | FILTER RACK B EXIST | Cartridge holder B is set in system when UV irradiated. | |
| 0206 | FILTER RACK C EXIST | Cartridge holder C is set in system when UV irradiated. | |
| 0207 | WASTE RACK A EXIST | Waste tube holder A is set in system when UV irradiated. | |
| 0208 | COLLECTION RACK A EXIST | Collection tube holder A is set in system when UV irradiated. | |
| 0209 | WASTE RACK B EXIST | Waste tube holder B is set in system when UV irradiated. | |
| 0210 | COLLECTION RACK B EXIST | Collection tube holder B is set in system when UV irradiated. | |
| 0211 | WASTE RACK C EXIST | Waste tube holder C is set in system when UV irradiated. | Press door lock release button, open flap doors, and remove relevant holder from system. |
| 0212 | COLLECTION RACK C EXIST | Collection tube holder C is set in system when UV irradiated. | |

◇ Password Input Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|--|--|--|
| 0900 | PASSWORD INCORRECT Password for this user is incorrect. | Mismatch of user login and user delete passwords. | Re-enter password to check. If password is forgotten, contact our customer consultation desk. |
| 0901 | PASSWORD INCORRECT Password for the EXPERT MODE is incorrect. | Mismatch of expert mode password. | |
| 0902 | PASSWORD INCORRECT Password for the MANUFACTURER MODE is incorrect. | Mismatch of manufacturer maintenance mode password. | |
| 0950 | INPUT DATA ERROR The entered value is not accepted. | User registration ID/password is out of range of 5-10 digits. | Check that number of entered digits is in range of 5-10 digits. |
| 0951 | INPUT DATA ERROR The entered value is not accepted. | Mismatch of first-time and second-time user registration passwords. | Recheck entered password. |
| 0952 | INPUT DATA ERROR The entered value is not accepted. | ID entered for user registration is identical to previously registered ID. | Check registering user ID and re-try user registration. |
| 0953 | INPUT DATA ERROR The entered value is not accepted. | Number of registered users already at maximum 24 when user registration attempted. | Delete some registered users and re-try user registration. |

◇Origin Return Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|----------------|--|--|
| 9001 | M501 ORG ERROR | Abnormality of origin return on X axis of isolation unit | If similar error repeats with operation retry, contact our customer consultation desk. |
| 9002 | M502 ORG ERROR | Abnormality of origin return on Z axis of isolation unit | |
| 9003 | M601 ORG ERROR | Abnormality of origin return on X axis of robot unit | |
| 9004 | M602 ORG ERROR | Abnormality of origin return on Y axis of robot unit | |
| 9005 | M701 ORG ERROR | Abnormality of origin return on dispenser 1 (Z1) | |
| 9006 | M702 ORG ERROR | Abnormality of origin return on dispenser 2 (Z2) | |
| 9007 | M801 ORG ERROR | Abnormality of origin return on syringe 1 (Line Z1) | |
| 9008 | M802 ORG ERROR | Abnormality of origin return on syringe 2 (Line Z2) | |
| 9009 | M401 ORG ERROR | Abnormality of origin return on lysate unit agitator motor | |

◇Positioning Operation Related Errors

| Code No. | Message | Description | Countermeasure |
|----------|-------------------------|--|--|
| 9101 | M501 POSITIONING ERROR | Abnormality of positioning operation on X axis of isolation unit | If similar error repeats with operation retry, contact our customer consultation desk. |
| 9102 | M502 POSITIONING ERROR | Abnormality of positioning operation on Z axis of isolation unit | |
| 9103 | M601 POSITIONING ERROR | Abnormality of positioning operation on X axis of robot unit | |
| 9104 | M602 POSITIONING ERROR | Abnormality of positioning operation on Y axis of robot unit | |
| 9105 | M701 POSITIONING ERROR | Abnormality of positioning operation on dispenser 1 (Z1) | |
| 9106 | M702 POSITIONING ERROR | Abnormality of positioning operation on dispenser 2 (Z2) | |
| 9107 | M801 POSITIONING ERROR | Abnormality of positioning operation on syringe 1 (Line Z1) | |
| 9108 | M802 POSITIONING ERROR | Abnormality of positioning operation on syringe 2 (Line Z2) | |
| 9109 | M901 POSITIONING ERROR | Abnormality of operation on wash buffer pump 1 (Line Z1) | |
| 9110 | M902 POSITIONING ERROR | Abnormality of operation on wash buffer pump 2 (Line Z2). | |
| 9111 | M1001 POSITIONING ERROR | Abnormality of operation on pressurizing pump 1 (Line Z1). | |
| 9112 | M1002 POSITIONING ERROR | Abnormality of operation on pressurizing pump 2 (Line Z2) | |

| Code No. | Message | Description | Countermeasure |
|----------|------------------------|--|--|
| 9113 | M401 POSITIONING ERROR | Abnormality of operation on agitator motor for lysate unit | If similar error repeats with operation retry, contact our customer consultation desk. |

Appendix A

A.1 Options

The following options are provided:

Name : Holder Set

P/N :

Name : Reagent Container Holder

P/N : 40321300096

Name : Sample Tip Holder

P/N : 40321300097



Name : Reagent Tip Holder

P/N : 40321300098

Name : Sample Holder x3

P/N : 40321300088

Name : Cartridge Holder x3

P/N : 40321300090



Name : Waste Tube Holder x3

P/N : 40321300091

Name : Collection Tube Holder x3

P/N : 40321300089

Name : Waste Container

P/N : 40321301203



Name : Wash Buffer Bottle

P/N : 40321301204

Name : Reagent Container S x3

P/N : 40321301201

Name : Reagent Container L x4

P/N : 40321301202



A

A.2 Warranty

- Warranty period is one (1) year from delivery of system.
- Free repair warranty is applied when failure occurs during normal use (conditions of use in accordance with precautions in this manual, etc.) during warranty period.
- Repair fee will be charged for cases below even if warranty has not expired:
 - Improper use, damage caused by products other than those our company approves, or damage caused by other devices.
 - Failure or damage caused by transportation or rough handling.

A.3 After-Sales Service

- Before requesting repair, please refer to "8. Before Concluding a Failure" and check conditions of problem. If problem is not subsequently solved, please contact our system service personnel or sales agent.
- If failure occurs, please contact our system service personnel or sales agent.

A.4 Customer Consultation Desk

Kurabo Industries Ltd. Advanced Technology Division, Bio-Medical Department

Osaka 14-30 Shimokida-cho, Neyagawa, Osaka 572-0823

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Tokyo 103-0023

TEL. +81 3 3639 7077 FAX. +81 3 3639 6998

URL: <http://www.kurabo.co.jp/bio/>

A.5 Precautions for Transportation

When system is to be transported, please be sure to contact our system service personnel or sales agent.

A.6 Disposal



System disposal should be conducted in accordance with disposal procedures specified by law and local ordinance.

A

This system has a user authentication function, and OpenSSL is used as a cryptographic communication protocol.

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This product includes cryptographic software written by Eric Young (ey@cryptsoft.com). This product includes software written by Tim Hudson (tjh@cryptsoft.com).

Automated Nucleic Acid Isolation System QuickGene-Auto240L Operation Manual

Issuer: Kurabo Industries, Ltd.

**Advanced Technology Division, Bio-Medical Department
14-30, Shimokida-cho, Neyagawa City, Osaka, 572-0823, Japan**

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