

## 3 Description of the Assay Principle

The  $\mu$ TASWako system employs Liquid-phase Binding Assay (LBA) as the assay principle, which does not use any solid-phase reaction but relies on liquid-phase binding reactions between receptor and its ligand or antibody and antigen.

The kit includes a target specific antibody or receptor conjugated with an anionic polymer such as DNA (Anionic Conjugate) and another affinity molecule conjugated with fluorescent dye (Fluorescent Conjugate) in electrophoresis buffer solution.

The assay is done in following five steps:

### Step 1:

A liquid-phase binding reaction step where the Anionic Conjugate is mixed with the Fluorescent Conjugate and target analyte to generate a ternary immunocomplex.

### Step 2:

An ITP stacking step where the ternary immunocomplex, having higher electrophoretic mobility due to the anionic polymer, migrates and stacked by isotachophoresis.

### Step 3:

A hand-off step where the ITP stacking step is switched to the zone electrophoresis step at the appropriate time by monitoring the change of the floating electrode voltage (Figure).

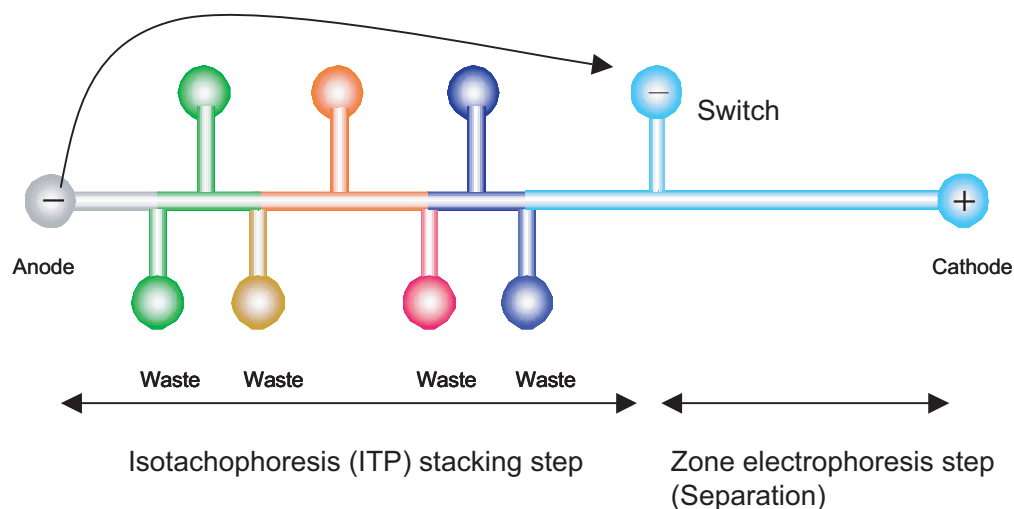


Fig. Switching from ITP stacking to zone electrophoresis

### Step 4:

A zone electrophoresis step where the immunocomplex is separated from contaminants. If lectin is added to the separation medium, lectin-affinity electrophoretic separation can be used to resolve glyco-isoforms of analytes.

### Step 5:

A detection step where the immunocomplex labeled with fluorescent dye is measured by Laser-Induced Fluorescence.

## Operation Flow

1. Delivery of the chip onto the chip transport stage

- The chip is transferred from the chip cassette.



2. Dispensing the reagents and sample to the chip wells

- The chip wells are filled with the assigned reagent, and sample is diluted in the dilution well.
- The 1st immunoreaction occurs between the target antigen and the Fluorescent Conjugate (Ag + Dye-Ab) in the dilution well.



3. Loading the reagents and sample into the chip channel

- The microchannel is filled with the reagent/sample, by using hydrodynamic flow generated by pressure difference.



4. Electrophoresis

- Isotachopheresis
- Zone electrophoresis
- Fluorescence detection

- The 2nd immunoreaction occurs while the Anionic Conjugate is electrophoresed through the Fluorescent Conjugate/Sample zone to generate the ternary immunocomplex (DNA-Ab + Ag + Dye-Ab).
- Zone electrophoresis separation occurs.
- Fluorescence detection of the immunocomplex occurs after separation.



5. Peak analysis and calculation

- Antigen concentration is calculated based on the peak area.

## 4 Operations

### 4.1 Startup Inspection

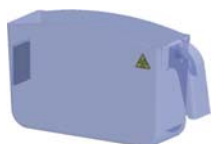
According to Section 4.1.1 (P4-2) and Section 4.1.2 (P4-4), perform the following startup inspection.

Check points before turning the Stand-by switch ON Refer to Sec. 4.1.1.

Clean chip disposal box.

Dispose of chips of the chip disposal box.

Refer to Sec. 4.1.1 (1).



Check recording paper.

Check that there are no red lines along the sides of the paper.

Refer to Sec. 4.1.1 (5).

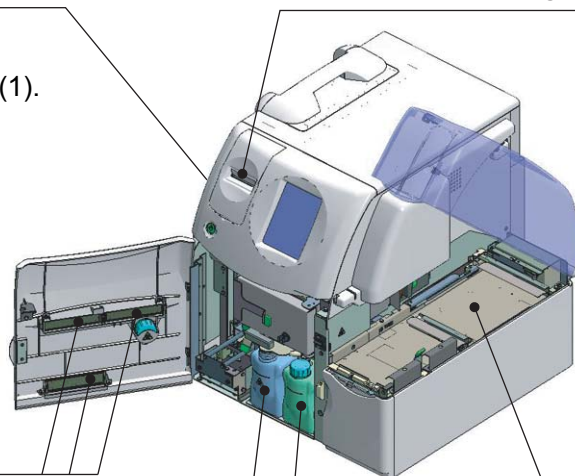
Check air filters.

Check that air filters are equipped and clean.

Refer to Sec. 4.1.1(3).

Check purified water and waste fluid.

Check the remaining amounts visually.  
Refer to Sec. 4.1.1 (4).



Sample racks and the sample rack station base

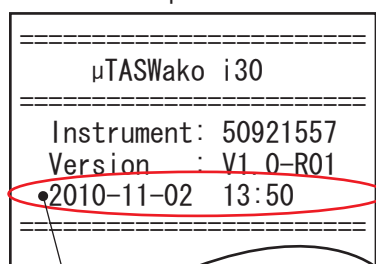
Take all sample racks out.  
Check that the sample rack station base is clean.

Refer to Sec. 4.1.1 (2).

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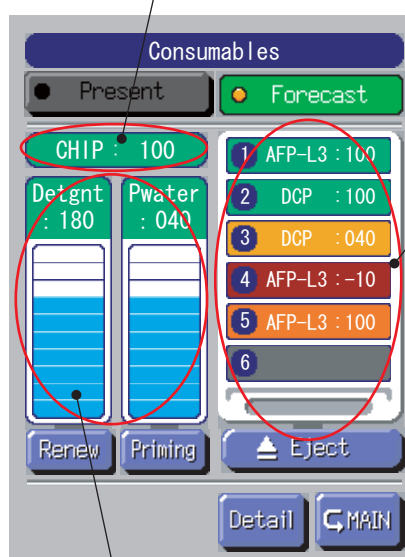
Check points after turning the Stand-by switch ON Refer to Sec. 4.1.2.

<Printout example>



Check date & time.

Check the printed date and time.



Check chips.

Check that chips are set to the analyzer and the remaining number is sufficient.

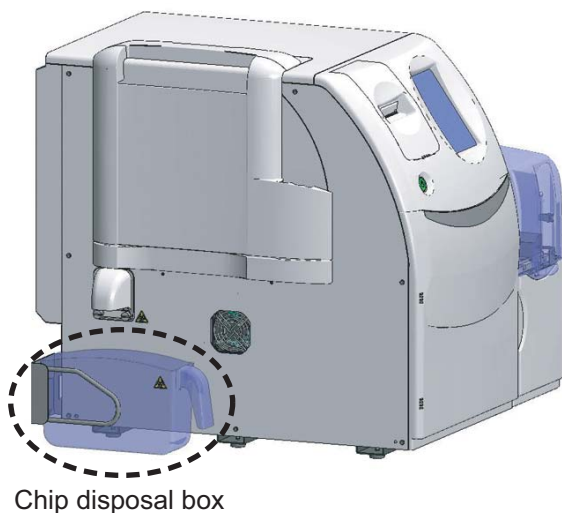
Check the reagents.

Check that the reagents necessary for tests are stored and their remaining amounts are sufficient.

Check purified water and detergent.

Check that the purified water and detergent are set and their remaining amounts are sufficient.

### 4.1.1 Preparation before Turning the Stand-by Switch On



- (1) Make sure that the chip disposal box is empty.

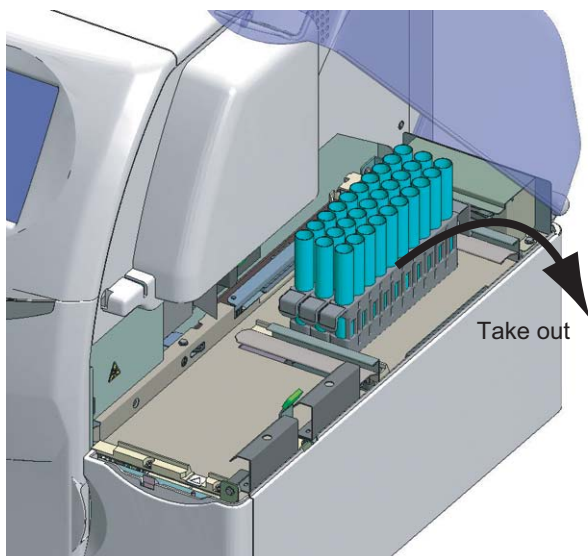
If the chip disposal box is full, dispose of chips, referring to Section 4.1.4 (P4-7).

## 4

### WARNING

Do not touch the used chips with bare hands. Otherwise, it may cause infection.

If any part of the body comes in contact with the contaminated chips, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

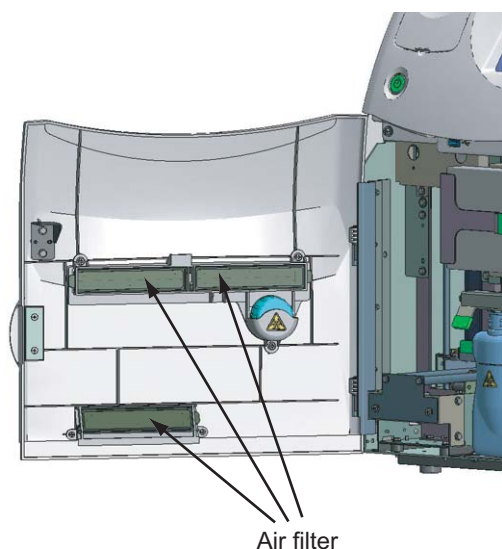


- (2) Open the rack cover and take the used sample racks out.  
Make sure that the sample rack station base is clean.

### CAUTION

If the sample rack station base is unclean, an error on the sample rack transfer may occur, which may cause interruption of operations.

If the base plate is unclean, clean it, referring to Section 5.5.2.4 (P5-22).



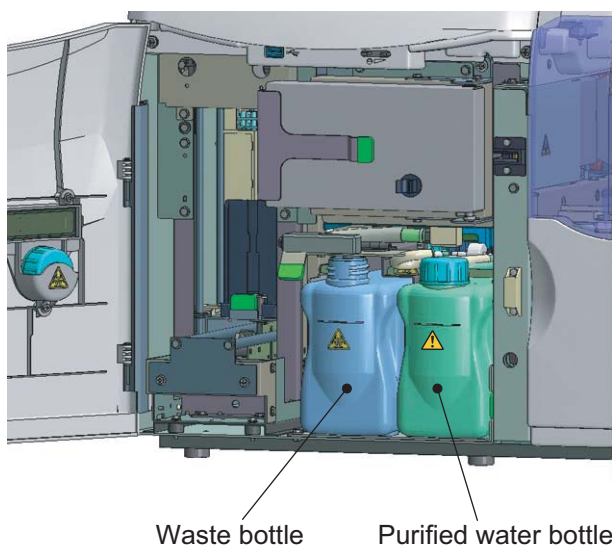
- (3) Open the front door and make sure that the air filters are equipped.

**! IMPORTANT**

If the air filters are not set in their pockets, adverse effects on test results may occur.

Make sure that the air filters are neither clogged with dust nor torn.

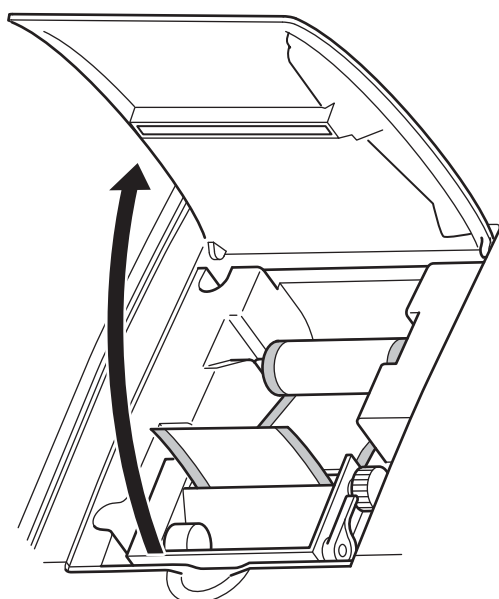
NOTE: Refer to Section 5.5.3.1 (P5-24) for the details of cleaning and replacement.



- (4) Check the remaining amounts of purified water and waste fluid.

If the purified water is insufficient or the waste fluid is full, supply the purified water and pour off the waste fluid, referring to Section 5.3.4 (P5-14).

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- (5) Check the remaining recording paper.

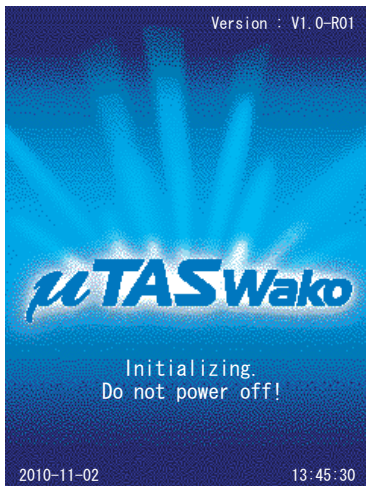
When red lines appear along the sides of the recording paper, replace the recording paper roll with a new one.

Refer to Section 5.5.4 (P5-25) for the details of replacing recording paper.

**! CAUTION**

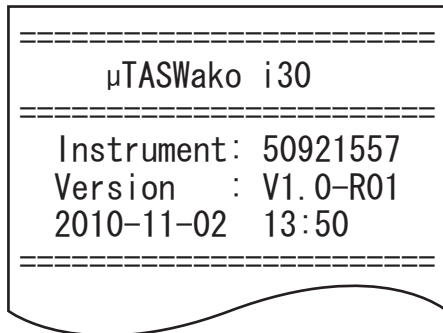
Do not touch the edge of the paper cutter with bare hands.

### 4.1.2 Turning the Stand-by Switch ON



- (1) Close the front door and the rack cover.
- (2) Press the Stand-by switch.
- (3) The startup message is displayed, and the analyzer starts the startup operation.

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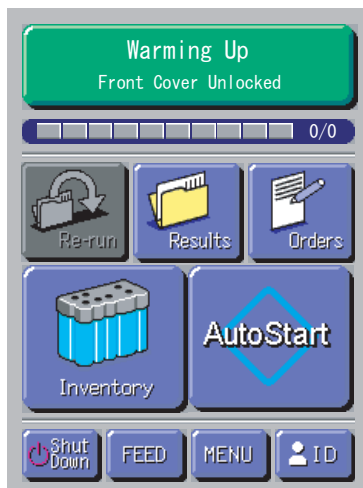


- (4) When the startup operation is completed, the analyzer information will be printed out.

Check the printed date and time.

NOTE: If the current date and time are not accurate, adjust them, referring to Section 7.3.4 (P7-11).

MAIN dialog



- (5) When the analyzer has started up properly, the MAIN dialog with the message, "Warming Up" will appear.

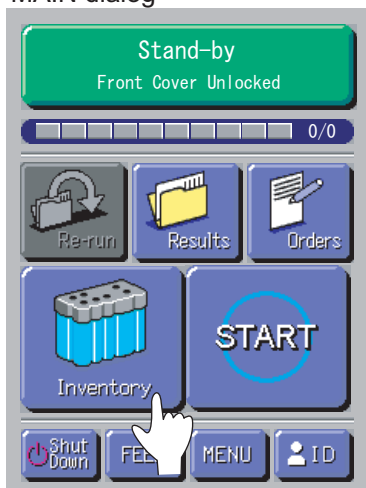
NOTE: If the [Operator ID Function] is active, refer to Section 4.1.3 (P4-6).

NOTE: When an error occurs during the startup, the analyzer displays the error. The keys related to operations are inactive. Refer to Section 6 for the details of the errors.

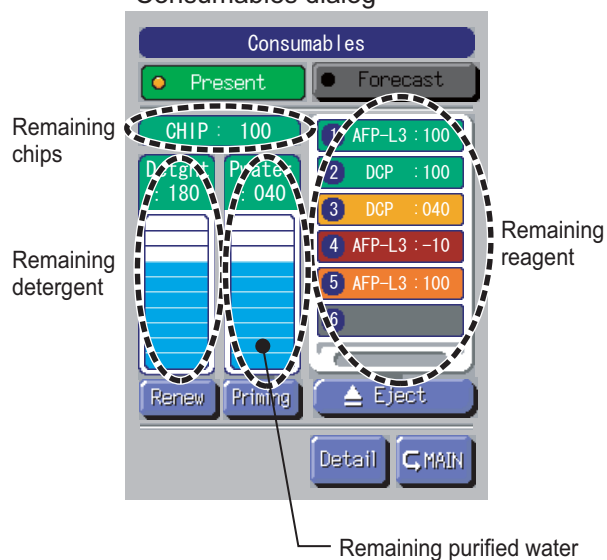
- (6) Check the remaining amounts of reagents, chips, detergent and purified water.

Select [Inventory] key on the MAIN dialog.

MAIN dialog



Consumables dialog



Check the remaining amounts of reagents, chips, detergent and purified water on the Consumables dialog.

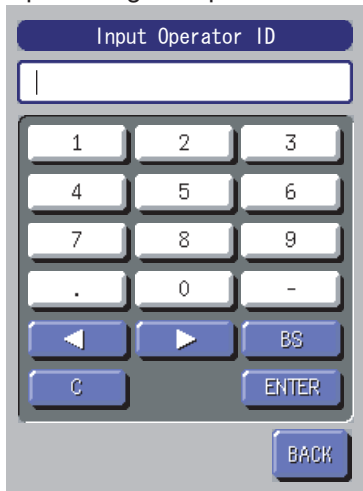
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If the reagents or consumables are insufficient, supply them, referring to Section 5.3 (P5-4).

### 4.1.3 When the [Operator ID Function] Is Active

NOTE: For the Operation ID setting, refer to Section 7.3.9 (P7-16).

Input dialog for Operator ID



After the startup, the input dialog for operator ID is displayed.

- (1) Input an operator ID using the numeric keyboard.

Input the registered 4-digit number as the operator ID of a general operator, and select the [ENTER] key.

NOTE: Only registered IDs are acceptable.

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MAIN dialog



- (2) The MAIN dialog is displayed.

NOTE: If the operator ID is not input, the operations cannot start.

NOTE: If the operator ID is not input, the analyzer will keep displaying the input dialog for operator ID even after the warming up is completed.



### 4.1.4 Turning off the Analyzer (Shut Down)

- (1) Select the [Shut Down] key on the operation menu.

NOTE: The [Shut Down] key is inactive during operation process.

Normally, select the [Execute] key.

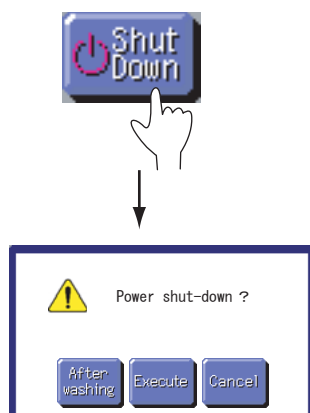
When selecting the [After washing] key, the analyzer will be automatically turned off after the shutdown procedures (the pipetting probe wash and electrode wash) are performed.

<Pop-up keys and actions>

Key name	Action
After washing	Shuts down the analyzer after shutdown procedures such as electrode wash. Analyzer uses 1 chip.
Execute	Shuts down without any other procedures.
Cancel	Cancels the shutdown.

NOTE: The Stand-by switch of the analyzer is used only for the startup. The switch cannot power the analyzer off.

Shut Down button



- (2) Empty the chip disposal box.

#### WARNING

Do not touch the used chips with bare hands. Otherwise, it may cause infection.

If any part of the body comes in contact with chips, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection.

Seek medical assistance if necessary.

#### WARNING

The used chips must be disposed of as infectious waste.

#### CAUTION

If the chip disposal box is full, the error on chip conveyor may occur, which may cause interruption of operations.

Remove the chip disposal box from the analyzer and dispose of the used chips.

#### WARNING

If the liquid from the used chips is spilled over accidentally, wipe the contaminated part thoroughly and then disinfect the part using ethanol for disinfection.

- (3) Open the rack cover and take operated sample racks out.

## 4 Operations

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(4) Process the waste fluid.



### WARNING

The waste fluid must be processed appropriately in compliance with any applicable regulations in your country such as laws for preventing water pollution and for sewerage system. Otherwise, it may cause deterioration of environment or result in breach of law.

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### WARNING

The waste fluid may contain infectious substances. Do not touch the fluid with bare hands and take appropriate measures (e.g., wearing gloves, lab coat, and safety goggles) for handling the fluid in the same way as patient specimens to prevent infection. If any part of the body comes in contact with waste fluid, immediately rinse the body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

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### WARNING

If the waste fluid is spilled over accidentally, take appropriate measures (e.g., wearing gloves, lab coat, and safety goggles) for preventing infection, and then, wipe off the fluid and disinfect the part using ethanol for disinfection.

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(5) Close the front door.

### 4.1.5 Check List for Daily Checks before Use

Daily Checks before Use (Before turning the Stand-by switch on)

No.	Item	Contents	Check
1	Cleaning the chip disposal box	Dispose of the chips of the chip disposal box.	
2	Taking sample racks out	Take all sample racks out.	
3	Checking recording paper	Check that there are no red lines along the sides of the paper.	
4	Checking air filters	Make sure that the air filters are equipped and no dirt is on the filters.	
5	Inspection on purified water and waste fluid	Check the remaining amounts visually with your eyes.	

Daily Checks before Use (After turning the Stand-by switch on)

No.	Item	Contents	Check
1	Checking date & time	Check the printed date and time.	
2	Checking chips on the Consumables dialog	Check that chips are set into the analyzer and the remaining number is sufficient.	
3	Checking reagents on the Consumables dialog	Check that the reagents necessary for tests are set into the analyzer and their remaining amounts are sufficient.	
4	Inspection on purified water and Detergent on the Consumables dialog	Check that the purified water and the detergent are set into the analyzer and their remaining amounts are sufficient.	

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### 4.1.6 Check List of Daily Checks after Use

Daily Checks after Use (After the analyzer is turned off by the [Shut down] key.)

No.	Item	Contents	Check
1	Cleaning chip disposal box	Dispose of the chips of the chip disposal box.	
2	Taking sample racks out	Take all sample racks out.	
3	Pouring off waste fluid	Pour off the waste fluid.	

## 4 Operations

### 4.1.7 Preparation of Sample Rack

This analyzer has 8 sample racks and a sheet of label (Rack barcode label) as its standard accessories.

According to the following chart, place a rack No. label onto each sample rack, and prepare 3 types of sample racks.

#### **IMPORTANT**

A wrong labeling on a sample rack may cause misidentification of samples. Be sure to place the labels correctly.

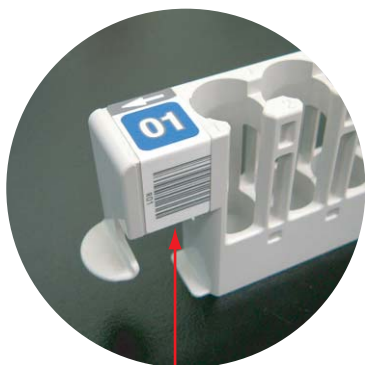
NOTE: The operator can determine the number of sample racks prepared for each type.

Sample rack type	Rack name	Number of racks (General)	Number of racks (Maximum)	Label's color
Standard rack	01-20	4	20	Blue
Rack for calibration and QC operation (QC rack)	Q1-Q3	2	3	Yellow
Rack for emergency samples (STAT rack)	E1-E5	2	5	Red

NOTE: The standard rack labels for "11 to 20" are not supplied as a standard accessory. Please contact your customer support to order.

## Placing Labels

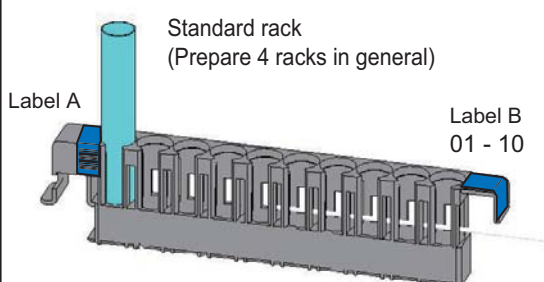
Label A



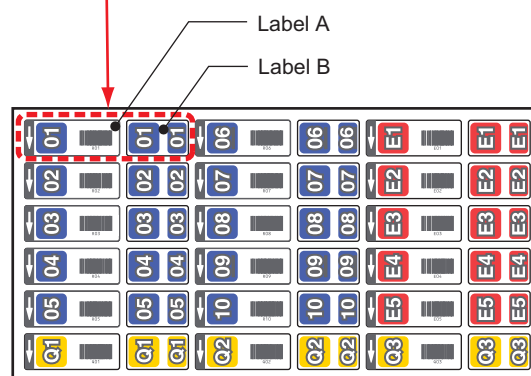
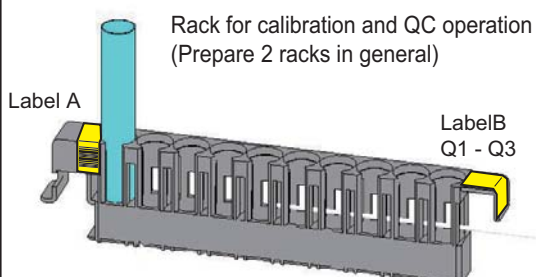
Label B



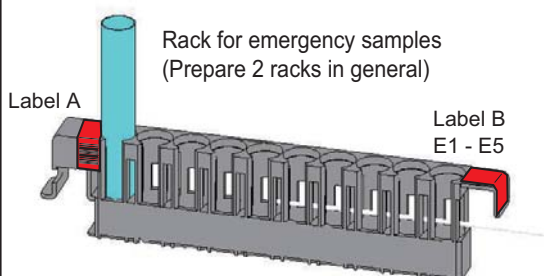
NOTE: Place a label within the specified area.



NOTE: Place a pair of label A and label B onto one sample rack.



Rack barcode label



After the labels are placed on the sample racks, set up the numbers of prepared sample racks according to Section 7.3.15 (P7-31).

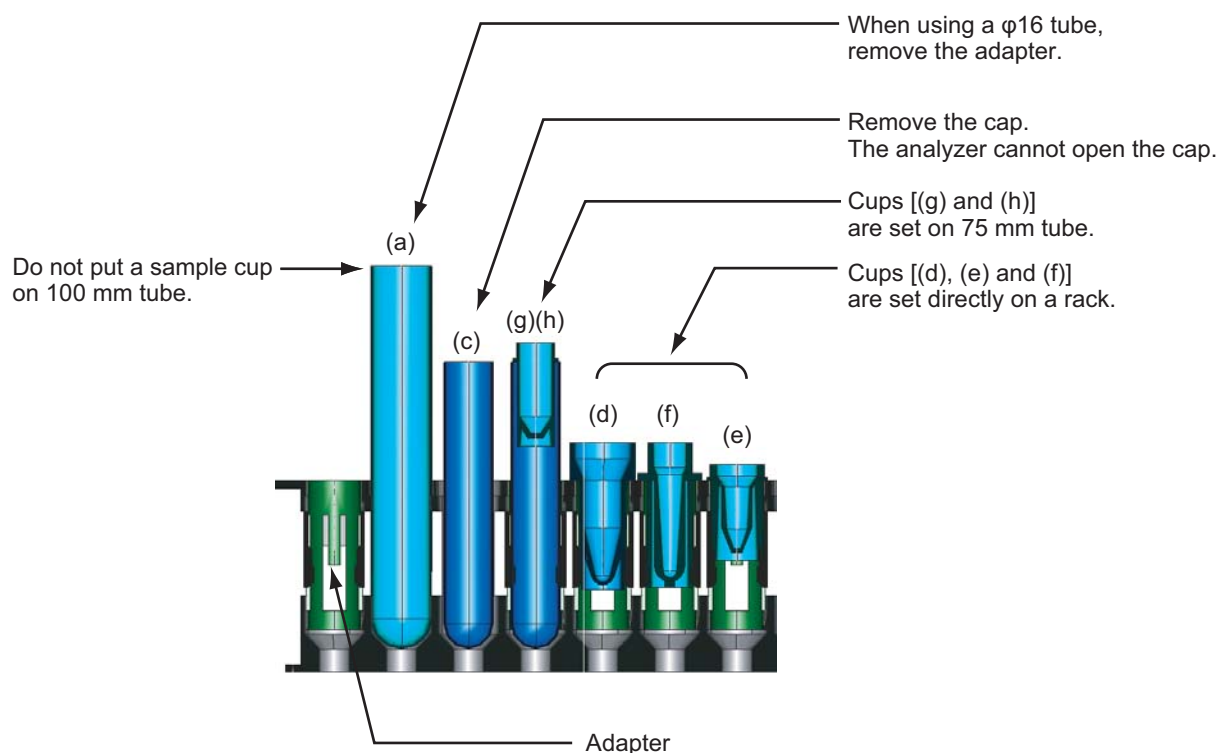
NOTE: Use an appropriate sample rack for each type of operation.

4.1.8 Blood Collection Tube for  $\mu$ TASWako i30

Usable test tubes and sample cups for  $\mu$ TASWako i30 are as follows.

Code	Names of Tubes	Adapter	Remarks
a	$\phi 16 \times 100$ mm blood collection tube	Not necessary	Remove the adapter of a sample rack. Do not put a sample cup on this 100 mm tube.
b	$\phi 13 \times 100$ mm blood collection tube	Necessary	Do not put a sample cup on this 100 mm tube.
c	$\phi 13 \times 75$ mm blood collection tube		
d	HITACHI Sample cup (43-000230)		Without removing the adapter, set the cup on the sample rack.
e	0.5 mL Cup (43-000005)		
f	HITACHI Micro cup (25-729102)		
g	TOSHIBA S Cup (12-006080)		Set on 75 mm tube.
h	Sample cup for LiBASys		Set on 75 mm tube.

NOTE: Remove the cap of tubes before loading. The analyzer cannot open the cap.

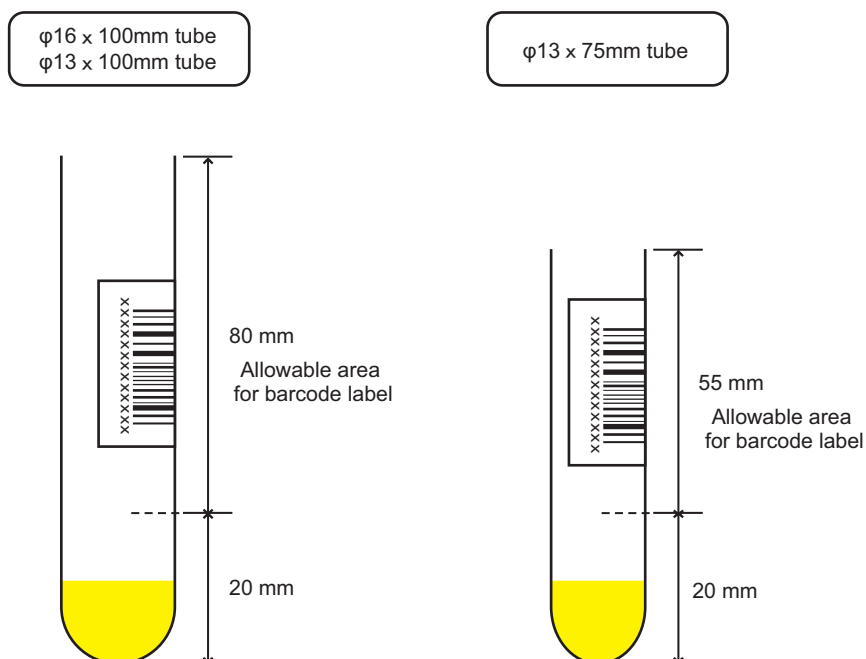


### 4.1.9 Placing Area for Barcode Label

A barcode label must be placed onto the specified area of the blood collection tube.

If it is placed onto wrong area, the barcode data cannot be read, and the tube cannot be operated.

If an error occurs in barcode reading, order the operation manually according to Section 4.5.1 (P4-42).



NOTE: Usable sample barcode is as below:

Barcode specification	UPC-A, UPC-E, EAN(JAN)-13, EAN(JAN)-8, ITF STF(5BER), NW-7, CODE39, CODE93, CODE128, EAN128
Digit number	Max. 13

NOTE: The smaller line of the barcode must be more than 0.19 mm.

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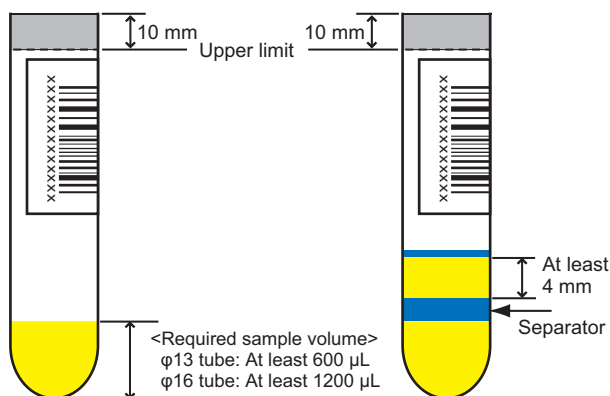
### 4.1.10 Amount of Sample

#### WARNING

When handling a sample, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. If any part of the body comes in contact with samples, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

#### IMPORTANT

Make sure that there are no bubbles and no foreign matter such as fibrin on the sample surface. The existence of those may interfere sample aspiration and may cause wrong test results. If you use immediate sample after drawing, make sure that the centrifuge separation is performed properly and the sample volume is sufficient.



The minimum amount for each tube is required as follows.

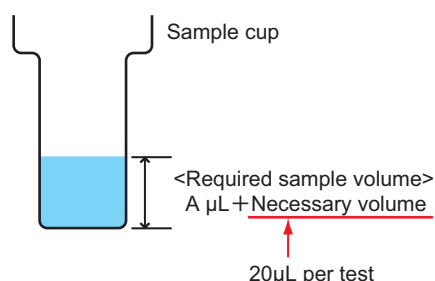
Tube size	Required volume
φ13 tube	At least 600 μL
φ16 tube	At least 1200 μL

If sample is less than the amount described above, the analyzer cannot aspirate it. Use a sample cup in this case.

When using a blood collection tube containing serum separator, the sample surface must be separated at least 4 mm from the separator.

For the amount in a sample cup, set “A” μL plus necessary amount for the operation (20μL / test).

The amount “A” for each cup is required as follows.



Name of Cup	A [μL]
HITACHI Sample cup (43-000230)	100
0.5 mL Cup (43-000005)	
HITACHI Micro cup (25-729102)	
TOSHIBA S Cup (12-006080)	75
Sample cup for LiBASys	



## 4.2 Calibration Operation

### WARNING

When handling calibrator, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. If any part of the body comes in contact with calibrator, immediately rinse the infected body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

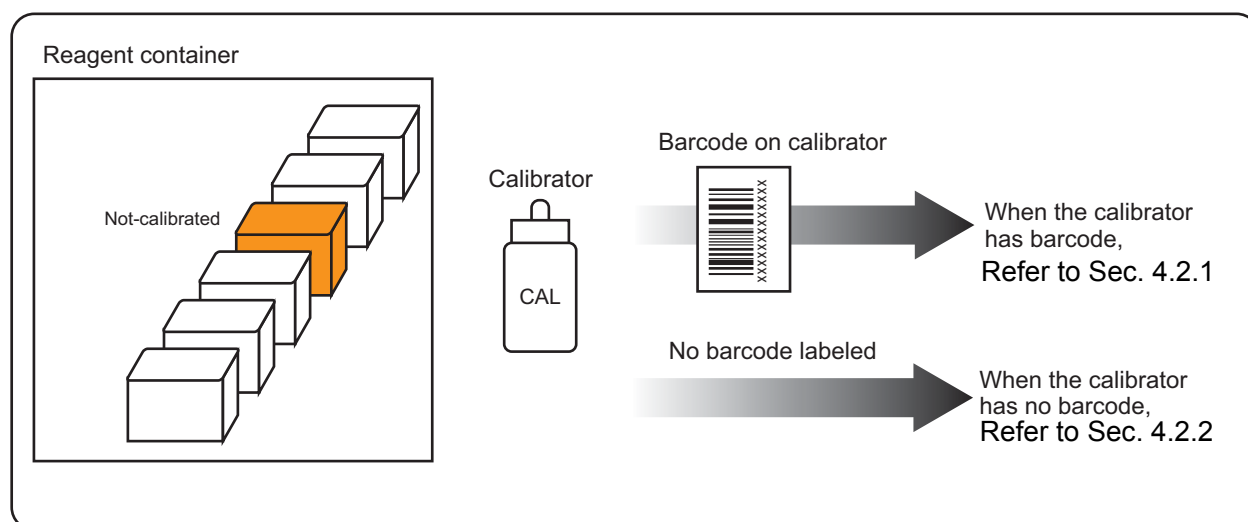
### IMPORTANT

If the date and time in the analyzer are not accurate, the analyzer may fail to determine the expiration dates of the reagents and the calibrators correctly. As a result, adverse effects on test results may occur.

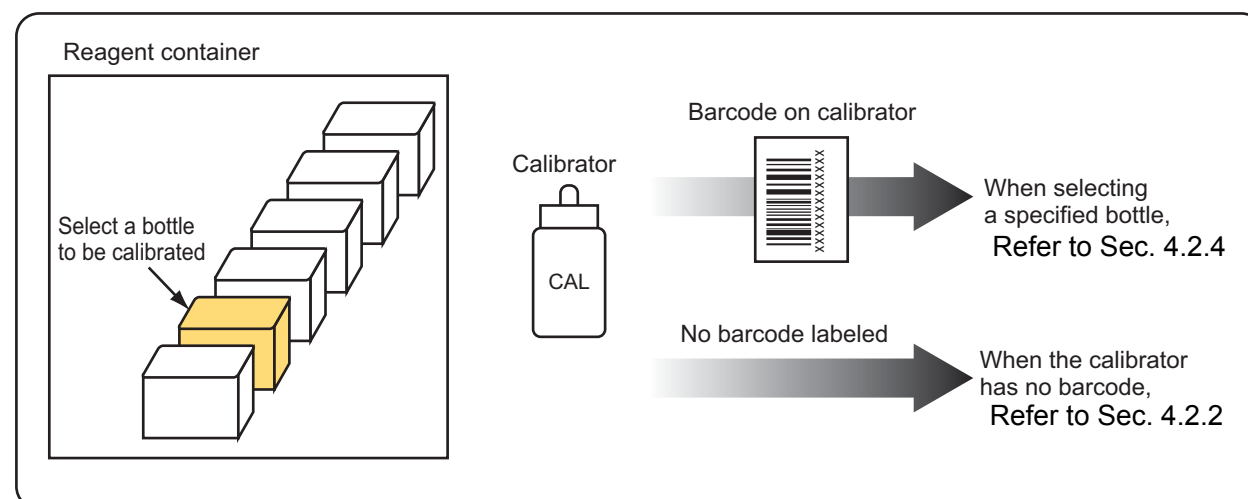
NOTE: Not-calibrated reagent bottles cannot be used for operation.

There are 2 methods of calibration operation.

- (a) To calibrate automatically for all not-calibrated reagent bottles in the reagent container:  
Set QC racks with calibrators into the analyzer, and start the calibration. The not-calibrated bottles in the reagent container will be calibrated automatically.



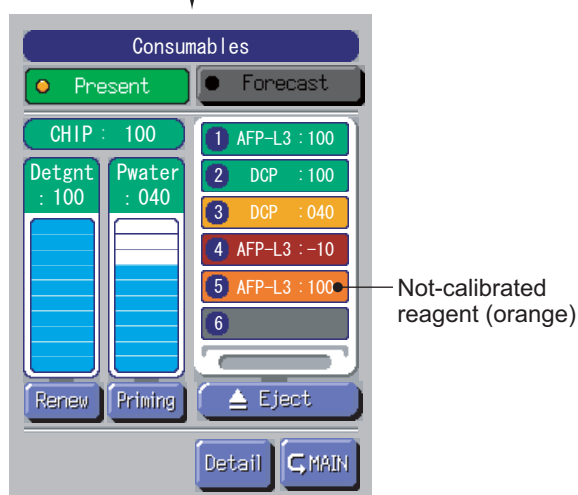
- (b) To calibrate by selecting a reagent bottle:  
Select a reagent bottle to be calibrated manually on the CAL/QC Order dialog, then set calibrators and perform the calibration.





- (1) When a new reagent is loaded into the analyzer, the message "Not Calibrated" is displayed.

- (2) How to find the not-calibrated reagents  
Select [Inventory] key to display the Consumables dialog. The not-calibrated bottle is indicated in orange as shown in the left figure.

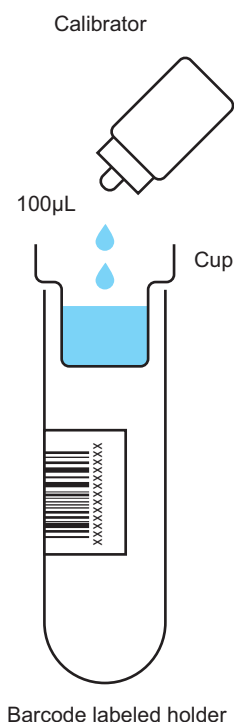


### Color indication for the remaining

The remaining is indicated by color as follows.

Green	Sufficient	} Operation is able to start
Yellow	Insufficient	
Red	Empty	
Orange	Not calibrated : After calibration completed, operation is able to start.	
Purple	The Exp. date is no longer valid: Operation cannot start.	
Gray	No reagent loaded or the reagent bottle has been used once by another analyzer.	

### 4.2.1 Calibration Operation Using Barcode Labeled Holder



#### (1) Prepare calibrators.

Put calibrator into a sample cup, and set the cup on the corresponding barcode labeled holder.

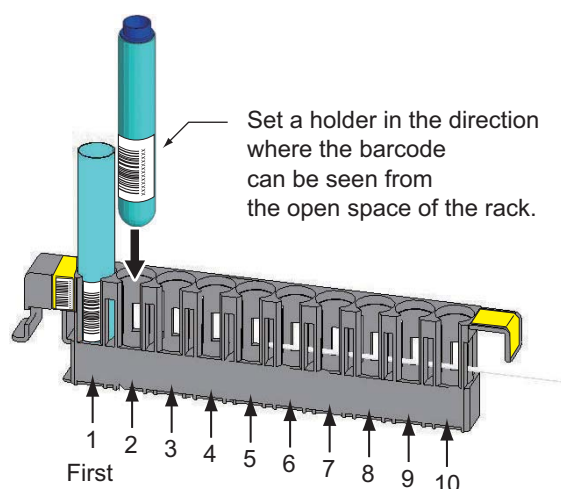
NOTE: For calibration, use either TOSHIBA S Cup or sample cup for LiBASys.

NOTE: Put 3 drops (approximately 100 µL) of calibrator into the cup.  
When calibrating for several reagent bottles, put 3 drops (approximately 100 µL) per bottle. (If 3 bottles, 9 drops are needed.)

#### **! IMPORTANT**

Ensure that calibrator in the sample cup has no bubbles.

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#### (2) Set barcode labeled holders into QC rack.

NOTE: The calibrators must be set in order from the first position of the rack.

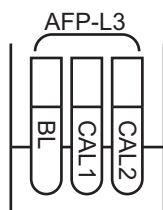
NOTE: The barcode on the holder must be seen from the open space of the rack.

## 4 Operations

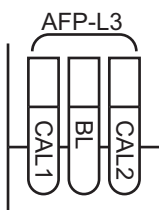
NOTE: To perform calibrations for several reagents, set the calibrators (2 or 3) for a same reagent into the consecutive rack positions.

Calibrators for a same reagent must be set in consecutive positions of the rack.

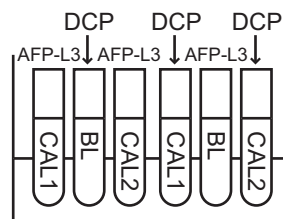
Example 1) **OK**



Example 2) **OK**



Example 3) **INCORRECT**



NOTE: In case that not-calibrated reagent bottles do not exist in the reagent container, the calibrations will not be performed even if calibrators are set into the analyzer.

### (3) Start the calibration operation.

Set the QC racks with calibrators into the analyzer according to Section 4.6 (P4-55).

Select the [START] key to start the calibration.



Calibration processing



This key turns to blue when the all calibrations are completed properly.

The message [Not Calibrated] in the status indicator key changes to [In Cal/QC (Needs xx min)].

NOTE: The remaining sample indicator will display only for the standard operation and not display for during QC operation.

NOTE: The emergency sample (STAT) cannot be operated during the calibration or QC operation.

The red [Inventory] key (means the existence of not-calibrated reagents in the reagent container) turns to blue after the calibrations for the reagents are completed properly.

NOTE: If the calibrations are not properly completed, the color of the [Inventory] key remains red.

(4) The calibration results will be printed out.

Printout example

Calibration			
2010-10-25		09:15	
DCP			
Lot. : AB0001 - 0001		← Reagent lot No. & Reagent serial No.	
CAL	Pos	Lot.	Exp.
BL	: Q1-01	0101	0910
CAL1	: Q1-02	0101	0910
CAL2	: Q1-03	0101	0910
← Calibrator position Lot No. Expiration			
Conc		Area	
[ng/mL]			
BL	= xxx. xxx	xxx. xxx	← Measured values
CAL1	= xxx. xxx	xxx. xxx	
CAL2	= xxx. xxx	xxx. xxx	
a= x. xxxx, b= xx. xxxx		← Calibration curve factor	
Calibration Accepted ← Result			
OP:0010			

A

B  
1 set

4

After the calibrations are completed properly, the calibration curve factors are printed out.

NOTE: If the calibration is failed, refer to Section 6.2 (P6-2).

When calibration is failed:

Calibration Failed	
--------------------	--

## 4 Operations

<Calibration curve description>

In case of AFP-L3:

Calibration curve for AFP-L1:  $Y \text{ (ng / mL)} = a \times X \text{ (Area)} + b$

Calibration curve for AFP-L3:  $N \text{ (ng / mL)} = d \times M \text{ (Area)} + e$

Inputs Area and Concentration of L1 for BL and CAL1 into X and Y respectively and calculates a, b from the simultaneous equation.

Inputs Area and Concentration of L3 for BL and CAL2 into M and N respectively and calculates d, e from the simultaneous equation.

As the concentration of BL is 0, the values of a, d can be obtained from the Concentration and the Area of L1 (CAL1) and L3 (CAL2).

When defining as follows:

CAL1: Concentration = Y1, Area = X1

CAL2: Concentration = Y2, Area = X2

$$Y1 = a \times X1$$

$$Y2 = d \times X2$$

Therefore,

$$a = Y1 / X1$$

$$d = Y2 / X2$$

Example)

CAL1: Concentration of L1 = 99 (ng / mL), Area = 320

CAL2: Concentration of L3 = 96 (ng / mL), Area = 310

In case of the above example,

$$a = 99 / 320 = 0.3094, b = 0$$

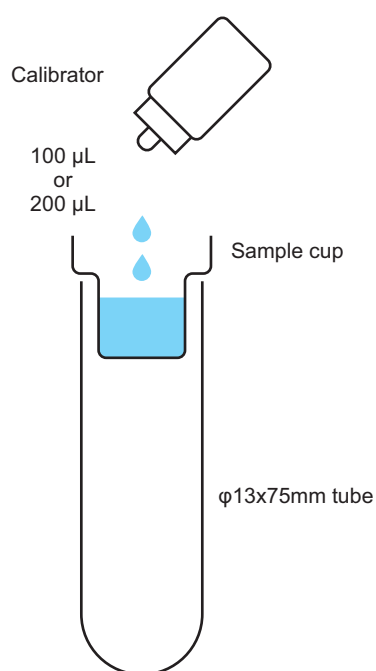
$$d = 96 / 310 = 0.3097, e = 0$$

When calibrating with n=2, input the average of Area into X and M to obtain a, d.

And, after obtaining the concentrations of L1 and L3, L3% can be calculated by the following formula:

$$L3\% = L3 / (L1 + L3)$$

### 4.2.2 Calibration Operation with No Barcode Labeled



In case of no barcode for the calibrator, perform the calibration according to the following procedure.

NOTE: Check the expiration dates of calibrators, as the analyzer does not check them.

#### (1) Prepare calibrators.

Set a sample cup with a calibrator on  $\phi 13 \times 75$  mm tube.

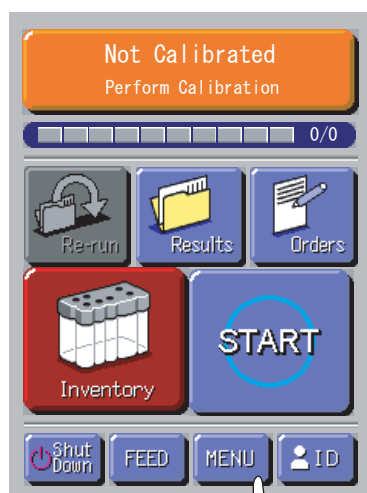
#### **! IMPORTANT**

Ensure that calibrator in the sample cup has no bubbles.

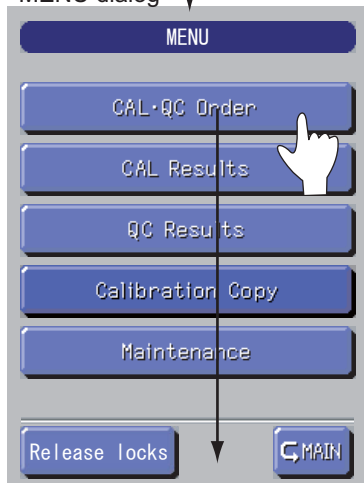
Prepare the required amount of calibrator for each sample cup by following the below.

Name of Cup	Amount of calibrator
HITACHI Sample cup	5 drops (approx. 200 $\mu$ L)
0.5mL Cup	
HITACHI Micro cup	
TOSHIBA S Cup	3 drops (approx. 100 $\mu$ L)
Sample cup for LiBASys	

4



MENU dialog



#### (2) Select the [MENU] key on the MAIN dialog.

#### (3) Select the [CAL · QC Order] key on the MENU dialog.

CAL/QC Order dialog

CAL/QC Order

Select one Reagent bottle.

<input type="checkbox"/>	AFP-L3 :100	Lot: 15345/2000 Exp. 2010-09-30
<input type="checkbox"/>	DCP :040	Lot: 14520/3000 Exp. 2010-10-20
<input type="checkbox"/>	AFP-L3 :000	Lot: 15345/2000 Exp. 2010-09-30
<input checked="" type="checkbox"/>	DCP :100	Lot: 14520/3000 Exp. 2010-10-20
<input type="checkbox"/>	AFP-L3 :100	Lot: 13214/2002 Exp. 2010-11-30
<input type="checkbox"/>	AFP-L3 :008	Lot: 13214/2002 Exp. 2010-11-30

BACK Manual Order ENTER

Rack key  
CAL/QC Manual Order dialog

Q1 BACK

01	AFP-L3:BL
02	AFP-L3:CAL1
03	AFP-L3:CAL2
04	
05	
06	
07	
08	
09	
10	

Information for selected reagent bottle

Rack : Q1 Pos : 04

DCP :100 Lot: 014520  
Exp. 2010-10-20

CAL QC

BL CAL1

A. Value DCP : 0

C BACK ENTER

A. Value

1 2 3  
4 5 6  
7 8 9  
. 0 -  
← → BS  
C ENTER

(4) On the CAL/QC Order dialog, select bottles necessary for calibration, and then select the [Manual Order] key.

(5) Select a QC rack for the calibrators using the Rack key.

(6) Select a position for the calibrator.

(7) Select the [CAL] tab.

(8) Select a calibrator to be set in the QC rack.

(9) Input the Assigned value for the calibrator.

For AFP-L3 test, input two Assigned values.

Rack : Q1 Pos : 01

AFP-L3 :100 Lot: 015345  
Exp. 2010-09-30

CAL QC

BL CAL1 CAL2

A. Value L1 : 0

A. Value L3 : 0

C BACK ENTER



CAL/QC Manual Order dialog (individual)

CAL/QC Manual Order dialog

CAL/QC Order dialog

MANU dialog

MAIN dialog

(10) Select the [ENTER] key to return to the CAL/QC Manual Order dialog.

NOTE: When operating several calibrators, repeat the procedures from (5) to (10).

NOTE: Refer to Section 7.3.7 (P7-14) for the Repeat number of calibration.

(11) Select the [BACK] key to return to the CAL/QC Order dialog.

NOTE: To calibrate another reagent bottle, select a desired reagent bottle and then select the [Manual Order] key.

(12) Return to the MENU dialog.

(13) Return to the MAIN dialog.

(14) Place the calibrators into the QC rack and load the rack into the analyzer.

Refer to Section 4.2.1 (P4-17) for how to load calibrators.

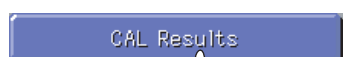
Set the rack into the analyzer according to Section 4.6 (P4-55).

(15) Start the calibration operation.

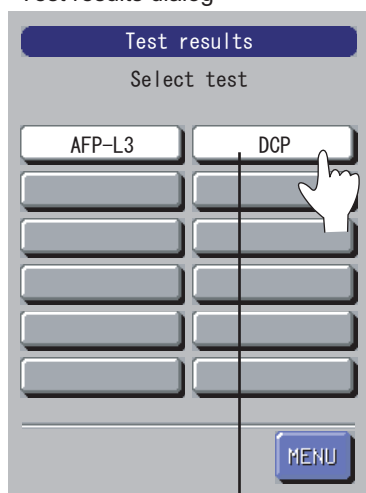
Select the [START] key.

NOTE: The standard operation can be performed continuously after the calibration.

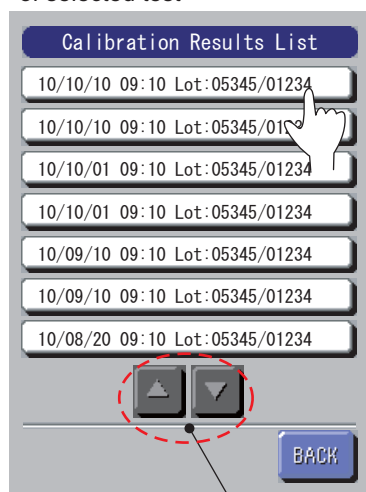
## 4.2.3 How to Check the Past Calibration Results



Test results dialog



Calibration Result List dialog of selected test



Scroll up and down to browse.

This function is used to display or print out past calibration results.

Select the [MENU] key on the MAIN dialog to display the MENU dialog.

- (1) Select the [CAL Results] key to display the Test results dialog.
- (2) Select a test name to check its calibration results.

NOTE: The tests are listed in order of test No.

NOTE: The test No. is a unique identification number for each test.

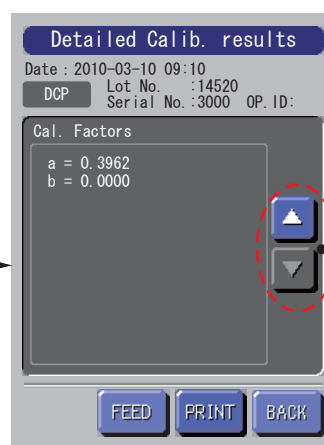
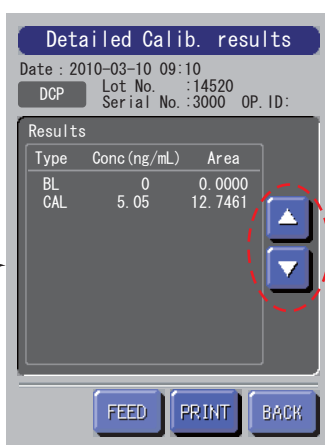
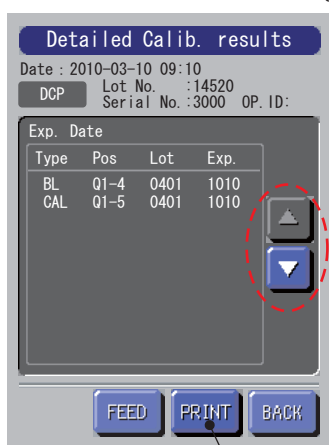
- (3) The calibration results of the selected test are displayed in order from the latest operation date.

Each calibration key displays the operation date, the lot No. and the serial No. of the reagent bottle.

- (4) Select a specific calibration key to display the result.

NOTE: The calibration results cannot be printed out during operation process.

Detailed Calib. results dialog



Scroll up/down

To print out the calibration result:

### 4.2.4 How to Calibrate by Selecting Reagent Bottle

To perform calibration for specified reagent bottles in the reagent container or to perform calibration for the already calibrated reagents (recalibration), perform the following procedure.



Select the [MENU] key on the MAIN dialog to display the MENU dialog.

Select the [CAL · QC Order] key on the MENU dialog.

(1) On the [CAL/QC Order] dialog, select reagent bottles to be calibrated.

(2) Select the [ENTER] key to return to the MENU dialog.

(3) Select the [MAIN] key to return to the MAIN dialog.

Place the barcode labeled calibrators into the QC rack and set the rack into the analyzer.

Refer to the following:

Setting on the rack: Section 4.2.1 (P4-17).

Setting into the analyzer: Section 4.6 (P4-55)

(4) Start the calibration operation.

Set the calibrators into the analyzer according to Section 4.6 (P4-55).

Select the [START] key.

**NOTE:** The standard operation can be performed continuously after the calibrations (or QC).

When the calibrator has no barcode labeled, refer to Section 4.2.2 (P4-21).

**NOTE:** When the recalibration is performed, the result of the recalibration will apply to the test results for the later operations.

### 4.2.5 Calibration Copy

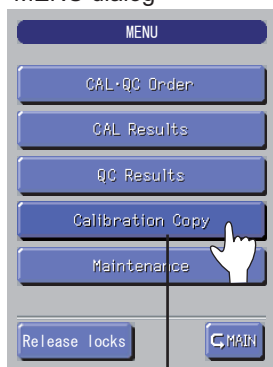
The calibration information can be copied to new (not-calibrated) reagent bottles on condition of the the following:

- (a) Same test name
- (b) Same lot No.
- (c) Not-calibrated

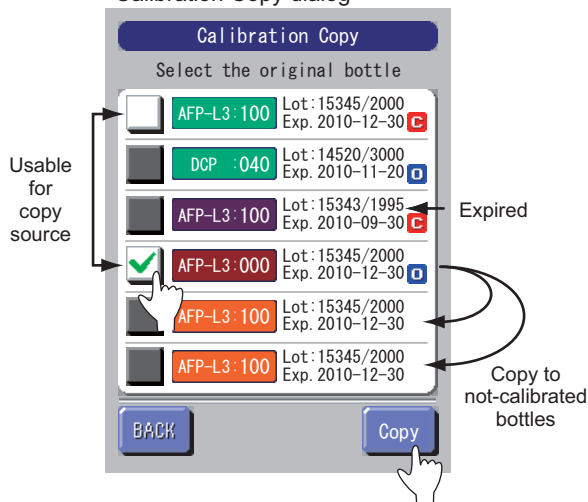
MAIN dialog



MENU dialog



Calibration Copy dialog



< Indication meanings >

- O Original calibration (copy source)
- C Copied calibration

(1) Select the [MENU] key on the MAIN dialog.

(2) Select the [Calibration Copy] key on the MENU dialog.

(3) The Calibration Copy dialog will be displayed.

(4) Select a copy source of reagent bottle.  
The calibration information of the selected reagent bottle will be copied to not-calibrated reagent bottles.

(5) Select the [Copy] key.  
The message "Copy to brand-new bottle?" will be displayed.  
Selecting [Yes] starts the copying.

NOTE: The reagent bottles for which the Calibration Copy is performed will have mark "C" (Copy mark). If recalibration is performed for the reagent bottle with "C", the mark turns to "O" (Original mark).

## 4.3 Quality Control Operation

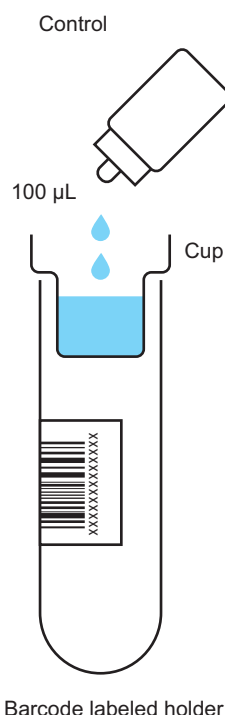
### ! IMPORTANT

To maintain the accuracy of your test results, the daily quality control is necessary.  
Perform quality control by running controls.  
When performing quality control, input control range, referring to Section 4.3.4 (P4-34).

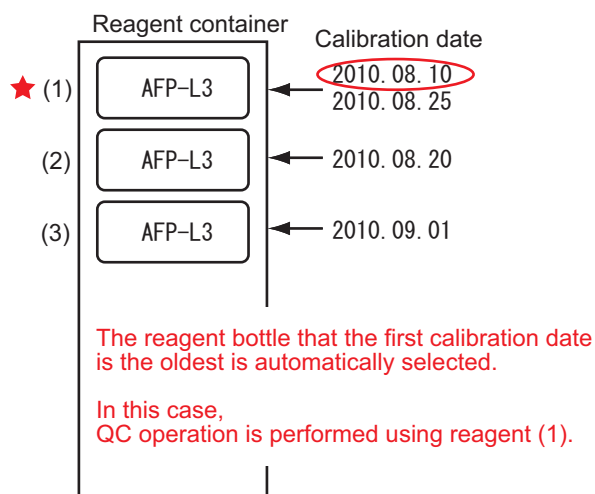
There are 2 methods of QC operation:

- QC operation performed automatically with barcode reading  
Refer to Section 4.3.1 (P4-27).
- QC operation performed by selecting reagent bottles from the menu  
Refer to Section 4.3.2 (P4-30).

### 4.3.1 QC Operation Performed Automatically with Barcode Reading



QC operation when same reagent bottles exist in the reagent container.



#### (1) Prepare control.

Put control into a sample cup, and set the cup on a barcode labeled holder.

NOTE: Put 3 drops of control (approximately 100 µL) into the cup.

NOTE: Controls for one test can be set up to a maximum of 3 levels.

NOTE: For QC operation, use either TOSHIBA S Cup or a sample cup for LiBASys.

### ! IMPORTANT

Ensure that control in the sample cup has no bubbles.

NOTE: If same reagent bottles are stored in the reagent container, the analyzer automatically selects the opened bottle with the oldest calibration date to perform QC operation.

If you want to calibrate by selecting another reagent bottle, refer to Section 4.3.2 (P4-30).

#### (2) Set the barcode holders with controls into the QC rack and then load the rack into the analyzer.

Refer to the following:

Setting on the rack: Section 4.2.1 (P4-17)

Setting into the analyzer: Section 4.6 (P4-55)

NOTE: In case that the reagent container has reagent bottles which have different calibration date, refer to Section 4.3.3 (P4-33).

### (3) Start QC operation.

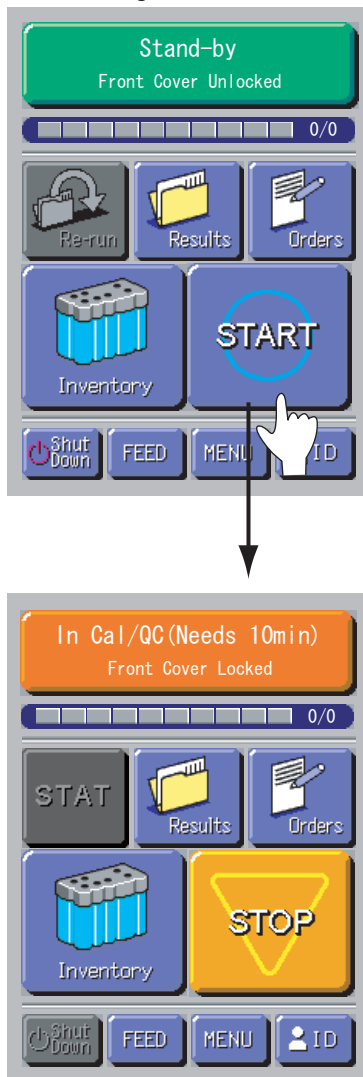
Select the [START] key to start the QC operation.

The status indicator dialog displays the message "In Cal/QC (Needs xx min)".

NOTE: The remaining sample indicator will display only for the standard operation and not display for during QC operation.

NOTE: The emergency sample (STAT) cannot be operated during calibration or QC operation.

MAIN dialog



## (4) The results will be printed out.

The SID of QC operation is numbered in order starting from "C0001".

NOTE: Even if errors occur in the results of QC operation, the standard operation, which has already been ordered, will be performed continuously.

## &lt;Reagent bottle change marker&gt;

When the reagent bottle to be used for the next has changed from the one used for the previous test, the bottle change marker (test name and the reagent serial No.) will be printed out.

NOTE: When the number of repeating operations is N=2 or N=3, the analyzer judges the QC operation results for each N1, N2 and N3 at first. Then, even if one of those is out of the acceptable range, the analyzer will indicate [Out of range] as the final decision.

When the communication address has been set up, the results of the QC operation will be sent to the address.

Printout example (N=2)

During QC operation,  
error will be printed out  
before the result.

Printout example (N=2)

During QC operation,  
error will be printed out  
before the result.

Reagent bottle change marker

Control

2010-10-25 09:15

AFP

Lot. : AB1000 - 0001

CTR1 Pos: Q1-01

Lot. : 0300 Exp. : 1011

SID : 20101025C0001

Assigned Value = xxx. x

CTR1 = xxxx. xxx ng/mL

CTR1 = xxxx. xxx ng/mL

Results --- OK

OP: 0010

Control

2010-10-25 09:15

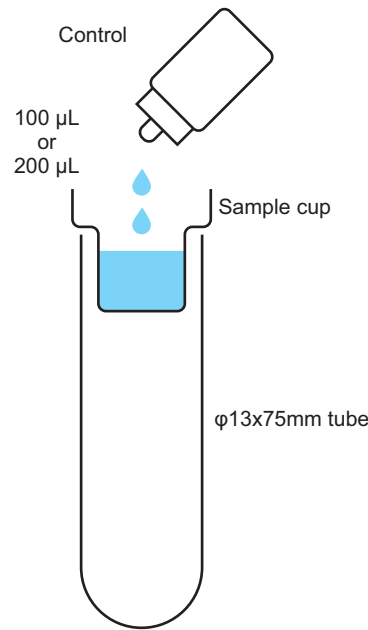
AFP-L3

Lot. : AB1000 - 0001

Printed separately  
for each control

4.3.2 QC Operation by Selecting Reagent Bottle

To perform QC operation for specified reagent bottles, or to perform QC operation for controls without barcode labels, perform the following procedure.



When the controls do not have barcodes, input the reagent information manually to order.

NOTE: Check the expiration dates of the controls, as the analyzer does not check the expiration dates.

(1) Prepare control.

Set a sample cup with control into a φ13 x 75 mm tube.

**! IMPORTANT**

Ensure that control in the sample cup has no bubbles.

Prepare the required amount of control for each sample cup by following the below.

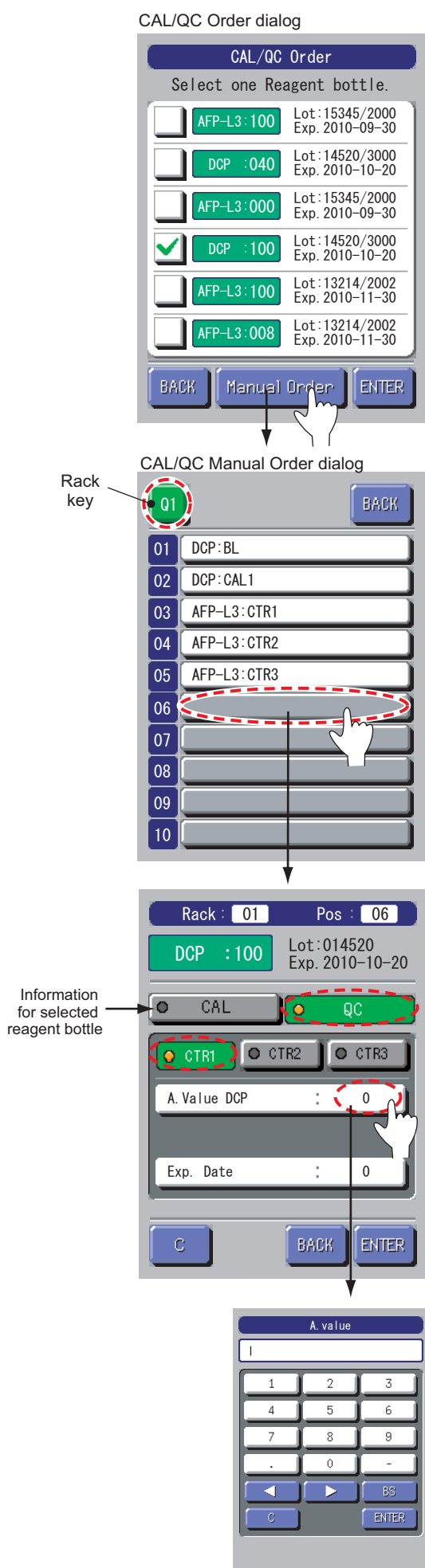
Name of Cup	Amount of control
HITACHI Sample cup	5 drops (approx. 200 μL)
0.5mL Cup	
HITACHI Micro cup	3 drops (approx. 100 μL)
TOSHIBA S Cup	
Sample cup for LiBASys	

(2) Select the [MENU] key on the MAIN dialog.

(3) Select the [CAL · QC Order] key on the MENU dialog.







(4) On the [CAL/QC Order] dialog, select a bottle necessary for QC operation, and select the [Manual Order] key.

(5) Using the Rack key, select a QC rack for setting controls.

(6) Select a position for setting the control.

(7) Select the [QC] tab.

(8) Select the solution to be set in the QC rack.

(9) Input the Assigned value.

CAL/QC Manual Order dialog (individual)

Rack : 01 Pos : 06

DCP : 100 Lot: 014520 Exp. 2010-10-20

☐ CAL ☒ QC

☒ CTR1 ☐ CTR2 ☐ CTR3

A. Value DCP : 0

Exp. Date : 0

CAL/QC Manual Order dialog

01 AFP: BL

02 AFP: CAL1

03 AFP: CTR1

04 AFP: CTR2

05 DCP: BL

06 DCP: CTR1

07

08

09

10

CAL/QC Order dialog

CAL/QC Order

Select one Reagent bottle.

<input type="checkbox"/>	AFP-L3: 100	Lot: 15345/2000	Exp. 2010-09-30
<input type="checkbox"/>	DCP: 040	Lot: 14520/3000	Exp. 2010-10-20
<input type="checkbox"/>	AFP-L3: 000	Lot: 15345/2000	Exp. 2010-09-30
<input checked="" type="checkbox"/>	DCP: 100	Lot: 14520/3000	Exp. 2010-10-20
<input type="checkbox"/>	AFP-L3: 100	Lot: 13214/2002	Exp. 2010-11-30
<input type="checkbox"/>	AFP-L3: 008	Lot: 13214/2002	Exp. 2010-11-30

MENU dialog

MENU

MAIN dialog

Stand-by

Front Cover Unlocked

0/0

For AFP-L3 test, input two Assigned values.

Rack : 01 Pos : 05

AFP-L3 : 100 Lot: 014520 Exp. 2010-10-20

☐ CAL ☒ QC

☒ CTR1 ☐ CTR2 ☐ CTR3

A. Value AFP : 0

A. Value L3 : 0

Exp. Date : 0

- (10) Press the [ENTER] key to return to the QC Manual Order dialog.

NOTE: When performing several QC operations, repeat the procedures from (5) to (10).

NOTE: Refer to Section 7.3.7 (P7-14) for the Repeat number of control operation.

- (11) Select the [BACK] key to return to the CAL/QC Order dialog.

NOTE: To operate another reagent bottle, select a desired reagent bottle and then select the [Manual Order] key.

- (12) Return to the MENU dialog.

- (13) Return to the MAIN dialog.

- (14) Place the controls into the QC rack and then load the rack into the analyzer.

Refer to the following:

Setting on the rack: Section 4.2.1 (P4-17)

Setting into the analyzer: Section 4.6 (P4-55)

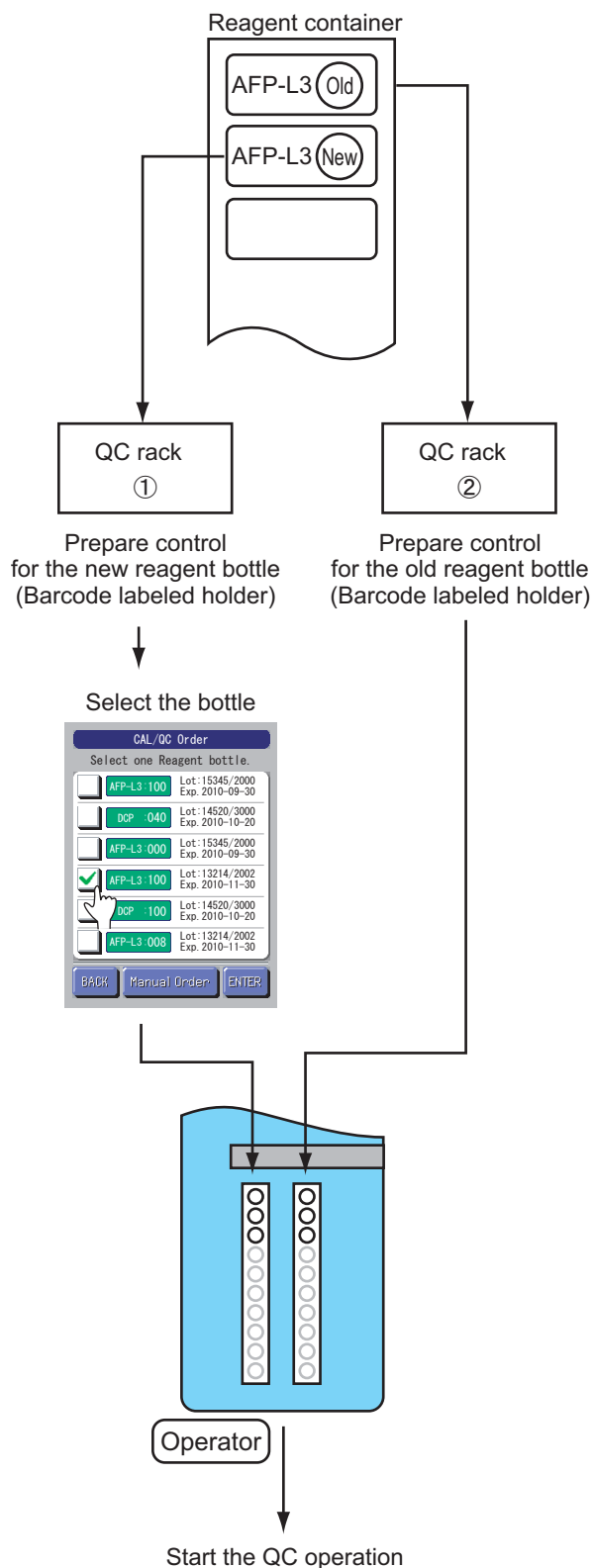
- (15) Start QC operation.

Select the [START] key to start the QC operation.

The standard operation can be performed continuously after the QC operation.

### 4.3.3 QC Operation for Old and New Reagent Bottles

In case that an old reagent bottle and a new bottle which have different calibration date exist in the reagent container and you want to perform QC operation using both bottles, perform the QC operation according to the following procedure.



(1) Prepare 2 QC racks.

The first QC rack is used for the new reagent bottle.

The second QC rack is used for the old reagent bottle.

(2) For the new reagent bottle, select the new bottle to perform QC operation.

Referring to Section 4.3.2 (P4-30), prepare control (with barcode labeled holder) on a QC rack (first) for the new reagent bottle and select the bottle on the CAL/QC Order dialog.

(3) For the old reagent bottle, perform auto QC operation using barcode reading.

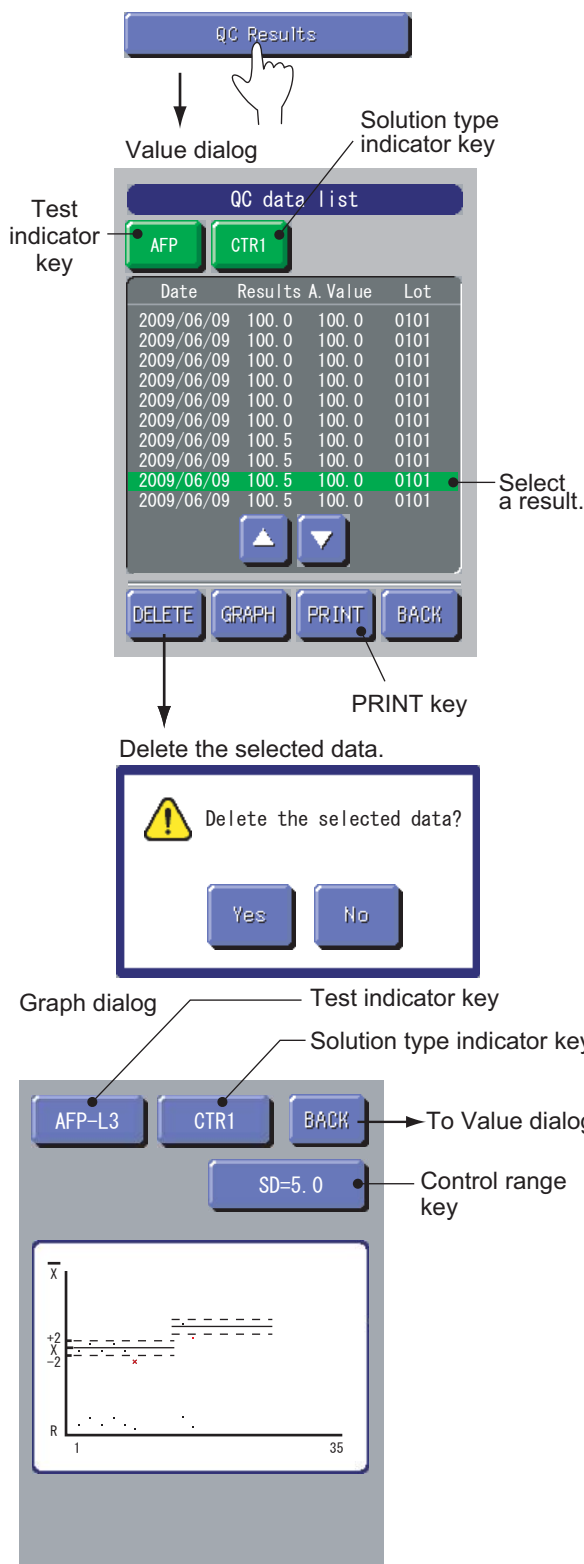
Referring to Section 4.3.1 (P4-27), prepare control (with barcode labeled holder) on another QC rack (second) for the old reagent bottle.

(4) Load the QC racks in the order (first and then second) and start the QC operation.

(5) The results will be printed out.

## 4.3.4 How to Browse Results of QC Operation (Quality Control Chart)

The analyzer can display the latest 35 data of QC results each for maximum of 12 test names.



(1) Select the [MENU] key on the MAIN dialog, and then select the [QC Results] key to display the Value dialog.

(2) Select the [Test indicator] key to select a test name to be displayed.

(3) Select the [Solution type indicator] key to select a control to be displayed.

NOTE: Use the scroll keys to browse all latest data of 35.

NOTE: The results of recalculation (see Section 4.11.4 (P4-70)) are not reflected in the display.

(4) When the [GRAPH] key is selected, the Graph dialog is displayed.

(5) When the [Control range] key is selected, the numeric keyboard is displayed for changing the control range.

When the [BACK] key is selected, the Value dialog is displayed.

<Graph description>

- The dashed line indicates 2SD.
- The solid line indicates the Assigned value.
- Average values are plotted.
- The red dot indicates that the results are out of the control range.
- When "N" is other than 1, the range (R) is also plotted.
- An abnormal data are plotted with "x".

(6) Following functions are also available.

- The QC results can be exported to a USB memory.  
=> Refer to Section 7.3.12 (P7-26) for details.
- The data can be sent to the host computer.  
=> Refer to Section 4.11.5 (P4-72) for details.

## 4.4 Standard Operation

### IMPORTANT

When handling samples, always follow biohazard procedures (e.g., wearing gloves, lab coat, and safety goggles), referring to the sample handling rules of your facility. If any part of the body comes in contact with samples, immediately rinse the contaminated body part thoroughly under running water and then disinfect the body part using ethanol for disinfection. Seek medical assistance if necessary.

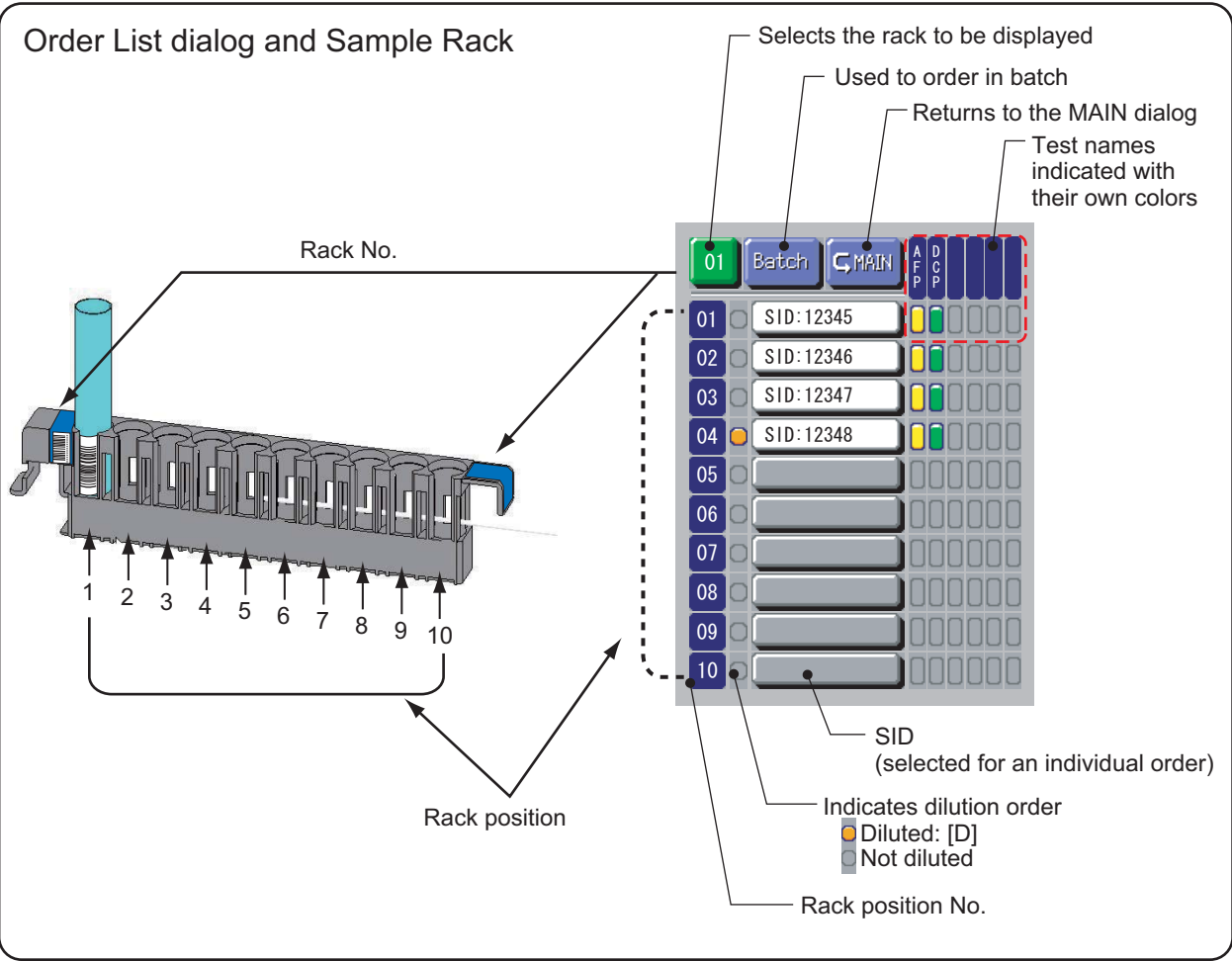
The following chart describes the methods of standard operation.

Operation methods	Descriptions	Reference
Manual order operation (Individual)	Orders tests for each sample manually.	Section 4.5.1 (P4-42)
Manual order operation (Batch)	Orders tests for several samples in batch. Editing the order is available.	Section 4.5.2 (P4-46)
Auto request operation (with barcode)  <Setup menu name> [Bidirectional + Individual]	In advance, the operator loads barcode labeled samples into the analyzer. Then, selecting the [START] key will automatically start the operations by receiving the test names and the other order information from the host computer. * The results will be automatically sent to the host computer.	Section 4.5.5 (P4-49)
Auto request operation (without barcode)  <Setup menu name> [Bidirectional + Individual]	In advance, the operator loads samples without barcode into the analyzer. Then, selecting the [START] key will automatically start the operations by receiving the test information from the host computer according to the rack No. and the rack position. * The results will be automatically sent to the host computer.	Section 4.5.5 (P4-49)
Worksheet request operation (with barcode)  <Setup menu name> [Bidirectional + Batch + Barcode]	The operator requests a worksheet for the host computer, and then loads the barcode labeled samples into the analyzer and then starts the operation. * The results will be automatically sent to the host computer.	Section 4.5.6 (P4-50)
Worksheet request operation (without barcode)  <Setup menu name> [Bidirectional + Batch - Barcode]	The operator requests a worksheet for the host computer. According to the worksheet's order, the operator sets the samples into the racks, and then starts the operations. * The results will be automatically sent to the host computer.	Section 4.5.7 (P4-52)

NOTE: The Manual order operation (Individual) and the Manual order operation (Batch) can be used in combination.

4.4.1 Order List Dialog and Sample Rack

The relation between the indications on the Order List dialog and the corresponding positions of the sample rack is as follows.



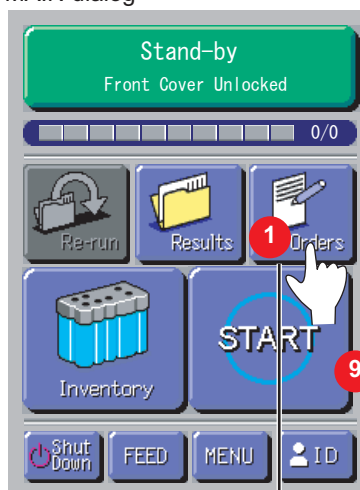
## 4.4.2 Manual Order Operation (Individual)

## Manual Order (Individual)

- ① Select the [Orders] key.
- ② ★ Select a rack No.
- ③ Select a rack position.
- ④ ★ Input SID.
- ⑤ ★ Input dilution factor.
- ⑥ ★ Input PID.
- ⑦ Select test names.
- ⑧ Select the [ENTER] key to accept the order.
- ⑨ Return to the MAIN dialog, set samples, and select the [START] key to start the operations.

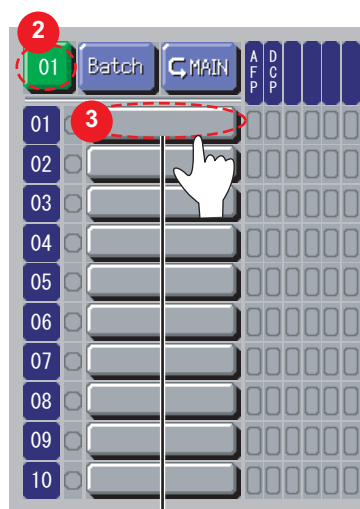
The process with the mark ★ can be skipped.

MAIN dialog

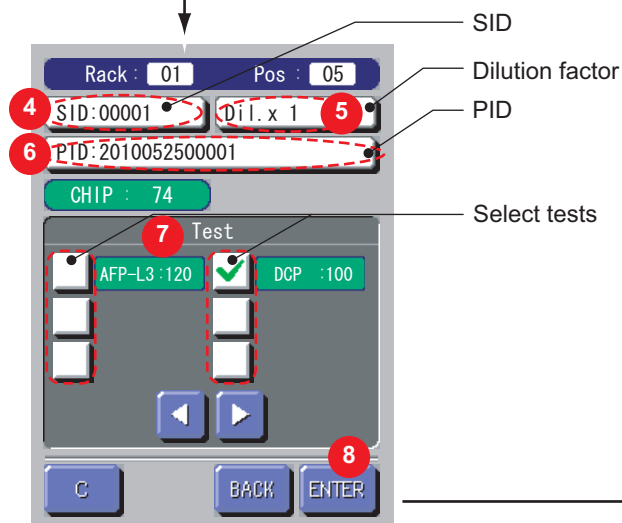


After setting samples, start operations.

Order List dialog



Manual Order (Individual) dialog



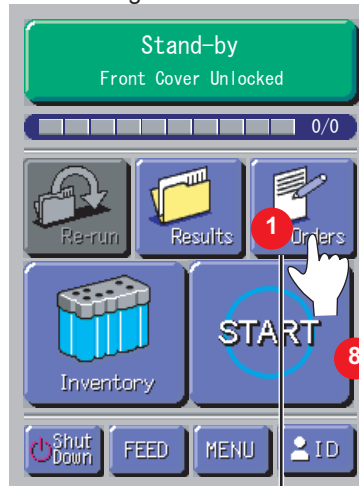
## 4.4.3 Manual Order Operation (Batch)

## Manual Order (Batch)

- ① Select the [Orders] key.
- ② ★ Select a rack No.
- ③ Select the [Batch] key.
- ④ ★ Input SID.
- ⑤ Input the number of samples for the batch order.
- ⑥ Select test names.
- ⑦ Select the [ENTER] key to accept the order.
- ⑧ Return to the MAIN dialog, set samples, and select the [START] key to start the operations.

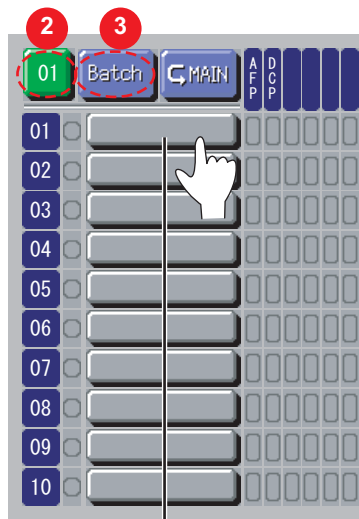
The process with the mark ★ can be skipped.

MAIN dialog

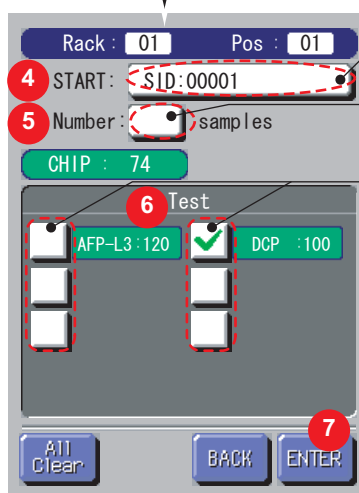


After setting samples, start operations.

Order List dialog



Manual Order (Batch) dialog



SID

Number of samples in batch

Select tests



#### 4.4.4 Auto Request Operation (with Barcode)

##### Auto Request (with Barcode)

- ① Set samples in the sample rack.
- ② Select the [START] key.

- 1 Set samples in the sample rack.

MAIN dialog



Start operations

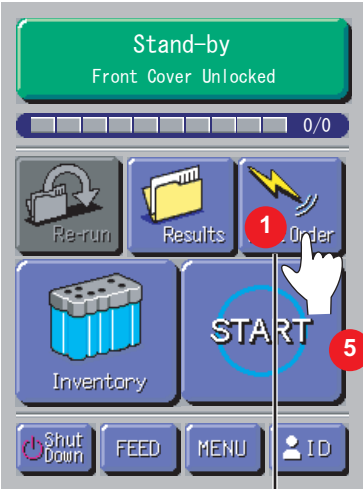
4.4.5 Worksheet Request Operation (with Barcode)

Worksheet Request (with Barcode)

- ①Select the [Host Order] key.
- ②★Input START SID.
- ③Select the [Auto Order] key.  
The worksheet is received from the host computer.
- ④Return to the MAIN dialog.
- ⑤After setting samples, select the [START] key to start the operations.

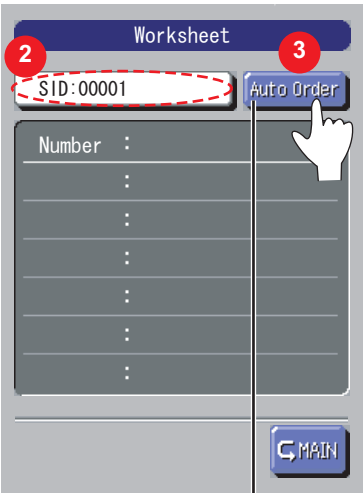
The process with the mark ★ can be skipped.

MAIN dialog

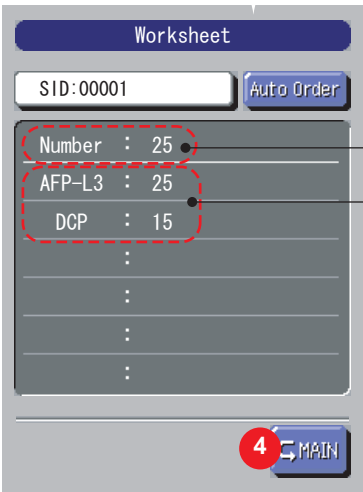


After setting samples, start operations.

Worksheet dialog



Worksheet dialog



Number of samples

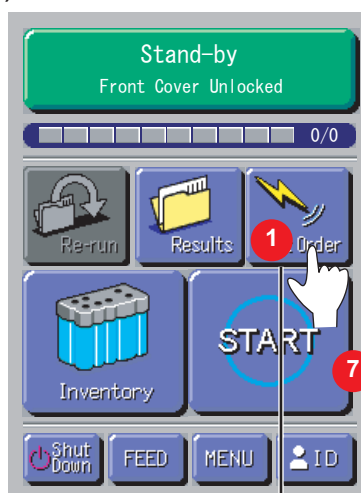
Number of tests

## 4.4.6 Worksheet Request Operation (without Barcode)

## Worksheet Request (without Barcode)

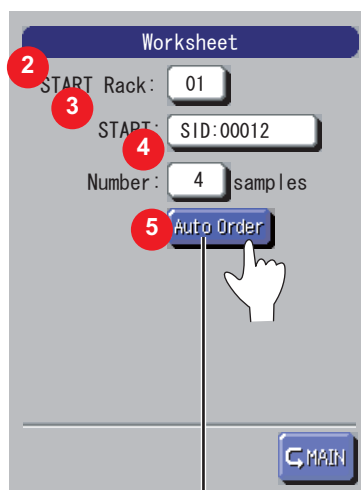
- MAIN dialog
- ① Press the [Host Order] key.
  - ② ★ Select the first sample rack.
  - ③ ★ Input START SID.
  - ④ Input the number of samples.
  - ⑤ Select the [Auto Order] key.
- When the worksheet is received from the host computer, the Order List dialog appears.
- ⑥ Set each sample into each rack position in the order corresponding to the Order List.
  - ⑦ Select the [START] key to start the operations.

The process with the mark ★ can be skipped.



After setting samples, start operations.

## Worksheet dialog



## Order List dialog

