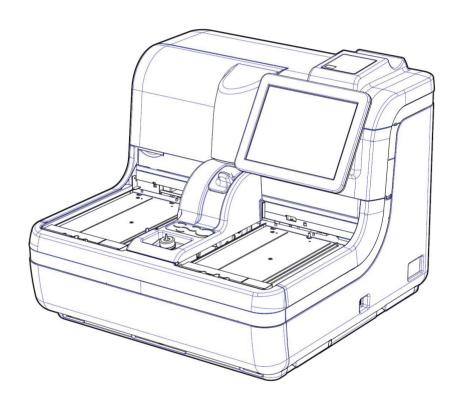Original instructions

OC-SENSOR
PLEDIA
Operation Manual
REF MV5 H00

Be sure to read "Safety Precautions" before use.
Safely use this product after reading this Operation Manual carefully.
Store this Operation Manual in a safe place so that it can be referred to when necessary.

◆Manufacturer: EIKEN CHEMICAL CO., LTD.
4-19-9, TAITO, TAITO-KU, TOKYO   110-8408, JAPAN

◆Authorized Representative: Advena Ltd.
Tower Business Centre, 2nd Flr., Tower Street,
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CE

Important

- Copyright for this Operation Manual belongs to Eiken Chemical Co., Ltd. and Hitachi, Ltd. Use, reprinting, duplication, and modification of its contents in part or in whole without permission is strictly prohibited.

- The content in this Operation Manual and system specifications may be changed without notice in order to make improvements.

- We are not responsible for any damages or the like if the system is not used in accordance with this Operation Manual.

- In vitro Diagnostic Medical Device Regulation (EU)2017/746

- EN 61010-1 : Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements.
- IEC 61010-2-101 : Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
- EN 61326-1 : Electrical equipment for measurement, control, and laboratory use. EMC requirements. General requirements.
- EN 61326-2-6 : Electrical equipment for measurement, control, and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment.

Introduction

Prior to reading this Operation Manual

OC-SENSOR PLEDIA is a fully automated fecal occult blood analyzer—that is, it is a movable and discrete clinical chemistry automatic analysis system (below, "system").
The system and its Operation Manual is meant for doctors, clinical laboratory technicians, and those who have received specialized education or training in test procedures that use diagnosis systems outside the body.
Read this Operation Manual carefully prior to use, in order to use the system properly.
Note that using the system in a manner not described in this Operation Manual or in conditions outside the system specifications could negatively impact the system's safety and performance.
Be sure to use the system according to the instructions in this Operation Manual.

Operation Manual organization

This Operation Manual consists of the following chapters:

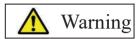|		
Introduction	:	Describes the organization and notation of this Operation Manual, as well as "Safety Precautions" when using the system.
Chapter 1　Overview	:	Gives an overview of the system, including measurement principles, analysis flow, as well as the names and functions of each part.
Chapter 2　Operation (Basic)	:	Gives an overview of initial settings prior to use, and describes basic operation of the system, such as daily operation.
Chapter 3　Operation (Applied)	:	Describes applied operation of the system, such as searching measured data, recalculation, output, and deletion of test data, as well as quality control.
Chapter 4　Support Functions	:	Describes support functions run prior to analysis, such as priming and cell blanking.
Chapter 5　Maintenance	:	Describes inspection and maintenance methods users should follow in order to safely use the system, maintain performance, and discover malfunctions and the like as early as possible.
Chapter 6　Settings	:	Describes details on initial settings for operating the system.
Chapter 7　Help	:	Describes analysis flow, as well as inspection and maintenance methods after use.
Chapter 8　Error Handling	:	Describes how to read the error screen.
Chapter 9 Operator/Latex Management Function (Option)	:	Describes how to Login/Logout, and managing Latex/QC Lots
Appendix	:	Describes data processing, analysis operations, printing examples, and errors.
Index/Glossary		
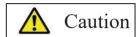
Operation Manual notation

This Operation Manual describes matters that must be followed in order to safely use the system, prevent danger to the user and others, and prevent damage to property.

■ "Warnings," "Cautions," and "Requests"

⚠ **Warning** — Indicates a possibility that improper use of the system will cause death or severe personal injury to the user.

⚠ **Caution** — Indicates a possibility that improper use of the system will cause personal injury to the user or damage to property.

⚠ **Request** — Indicates something the user should do to prevent damage or degradation to the product and to use the system efficiently.

Severe injuries: Injuries that result in permanent damage or which require long-term hospitalization or outpatient treatment. Examples include loss of eyesight, injury, burns, electric shock, fractures, poisoning, and infection.

Personal injuries: Injuries that do not require long-term hospitalization or outpatient treatment.

■ Symbols

Caution symbols: Indicate that users should use caution.

Attention   Biohazard   Electrical shock   Pinching hazard

Prohibition symbols: Indicate prohibited actions.

Prohibited   Disassembly prohibited

Instructional symbol: Indicates instructions users must follow.

Required

■ Other notations

Explanatory note : Describes related supplementary notes.

{   }: Indicates something that can be operated, such as a tab or a button on the screen.

[   ]: Indicates the name of a screen, or settings that require selection or input.

☞: Indicates reference locations.

Safety Precautions

Be sure to read this section before using the system.

Installation precautions

Power supplies and cords

⚠ Warning	
🚫 Prohibited	· Do not connect the power cord to an extension cord or an adaptor plug. · Do not insert or remove the power plug with wet hands. · Do not damage or alter the power cord. · Do not apply excessive force to the power cord. · Do not fasten the power cord using metal fixtures or the like. · Do not use power cords other than that provided. Failure to observe this precaution may lead to electric shock or fire.

⚠ Warning	
❗ Required	· Make sure that the system is grounded. Failure to observe this precaution may lead to electric shock.
❗ Required	· Connect to the appropriate power supply. Power supply voltage : ~100-240 V Frequency : 50/60 Hz Power consumption : 500 VA Socket : The power plug uses a protective earth terminal. Use a fixed power socket (electrical outlet for medical use) that is correctly grounded. Failure to observe this precaution may lead to electric shock or fire.

Installation conditions

⚠ Caution

❗ **Required**	· Use indoors. · Avoid exposure to water. · Avoid harmful effects that can result from barometric pressure, atmospheric temperature, humidity, poor ventilation, sunlight, dust, saline matter, or air including sulfur. · Install in a location that is flat and free of vibration or impact. · Install in a chemical storage area or in a location free from gas emission.

⚠ Caution

❗ **Required**	· Do not move the system. This system should only be installed or moved by a maintenance person who has been certified by Eiken Chemical. · Use a platform that can support the weight of the system. Make sure that the platform is stable. If the system falls, it could cause unexpected injury. · Install the system in a location with plenty of space, so as to not hinder operation or maintenance. (Refer to the following diagram.)
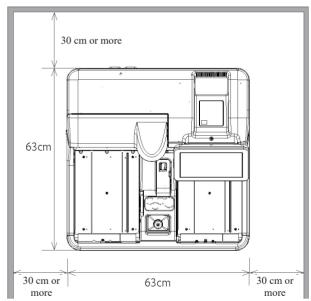
30 cm or more

63cm

30 cm or more   63cm   30 cm or more

· Size(cm) and weight (kg) of system

Width 63 x Length 63 x Height 56   Weight : approx. 60

· Do not place the system near the exhaust ports of heating and cooling equipment.

Doing so could result in incorrect analytical results.

Environmental conditions

⚠ Caution	
! Required	· Adhere to the following environmental conditions:

Usage conditions	Temperature: 15°C to 30°C Humidity: 20% to 80% (no condensation) Height of 2,000 m or less* Pollution degree 2* Overvoltage category II*
Storage conditions	Temperature: 0°C to 55°C Humidity: 20% to 90% (no condensation)
Transport conditions	Temperature: -20°C to 60°C Humidity: No more than 95% when the temperature is 25°C to 55°C (no condensation)

Explanatory note : * Standardized conditions are based on EN61010-1:2010 "Safety requirements for electrical equipment for measurement, control, and laboratory use–Part 1: General requirements."

EMC (Electromagnetic Compatibility)

⚠ Caution	
! Required	· This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. · This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interface, correct operation may be restored by increasing the distance between the equipment and the source of the interface. · The electromagnetic environment must be evaluated before operating the device. · Do not use this device in proximity to sources if strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

Security

⚠ Caution

! Required

Observe the following to prevent leakage or falsification of data.

・ To avoid unauthorized access, restrict the operation of the system to authorized personnel only.

・ Make sure that only verified computers are connected to the system network.

・ Conduct cybersecurity assessments regularly to ensure an appropriate level of data security.

・ Do not use personally identifiable information for sample IDs and patient IDs. Instead, use anonymized IDs for management.

・ For network security, address the security of IT infrastructure in your facility to ensure that IT security is not compromised by malicious software or hacker attacks.

   - Protect all devices and services used in your facility from malicious software and unauthorized access.

   - Connect the system only to the internal network of your facility that is not connected to the external network.

・ Regularly protect your data by strong it on external media. There is a possibility of data corruption due to cyber attacks, disasters, etc.

・ Please review your users and passwords regularly.

・ Check the USB flash drive in advance for viruses and make sure that no viruses have been detected.

Failure to observe this precaution may lead to infection by computer viruses.
Failure to observe this precaution may lead to leakage or falsification of information.

Usage precautions

Work and operation precautions

⚠ Warning	
Biohazard	・ Wear protective equipment when handling samples. ・ Wash your hands well after using the system. 　 Failure to observe this precaution may lead to infection from samples.
Biohazard	・ Dispose of drainage after using the system. ・ Make sure that drainage does not leak into the area surrounding the device when detaching the drain tank hose. ・ Make sure the drain tank is empty prior to using the system. 　 Failure to observe this precaution may lead to infection from samples.
Biohazard	・Be careful not to let the sample container fall over when attaching / detaching the sample rack or tray. 　 Failure to observe this precaution may lead to infection/contamination from samples. 　 Failure to observe this precaution may lead to loss samples.
Biohazard	・ Be careful of sample splattering when removing the sampling bottle from the rack. 　 Failure to observe this precaution may lead to infection from samples.
Disassembly prohibited **Electrical shock**	・ Do not disassemble the system. ・ Do not remove any of the system's exterior parts. 　 Failure to observe this precaution may lead to electric shock.
Prohibited	・ Do not spill any samples or reagents inside the system. 　 Failure to observe this precaution may lead to electric shock.
Prohibited	・ Do not mix the washing solution with acid washing solution. 　 Failure to observe this precaution may damage the operator's health.

⚠ Caution	
Pinching hazard	・ Do not open the cover of the analysis chamber during operation. ・ Keep out of the operational range of the system during operation. 　 Failure to observe this precaution may lead to injury or damage.

⚠ Caution
Required ・Do not move the rack while it is conveying. If the rack is accidentally moved, remeasure (retest) all samples in the rack. If the rack is misaligned, it could result in incorrect measurements.

⚠ Caution
Required • Connect each tank (purified water, wash solution, and drainage) correctly with each hose. • Monitor the quality control function and positive rate change periodically. Failure to observe this precaution may lead to a false diagnosis.

⚠ Caution
Required • Be careful of static electricity when operating the reaction processing section, such as when replacing cells Electronic components may be damaged by static electricity. For example, you can discharge static electricity by touching a grounded metal part around the device.

⚠ Caution
Required • Use only recommended external media (such as USB memory). Contact us for details on recommended products. • Manage external media appropriately. Check for viruses periodically. Failure to observe this precaution may lead to infection by a computer virus.

⚠ Caution
Required • Use only reagents that have not expired. Failure to observe this precaution may lead to a false diagnosis.

⚠ Caution
Required • If the reagent compartment or buffer compartment becomes abnormally hot, dispose of the reagent or buffer that was set. Failure to observe this precaution may lead to a false diagnosis.

⚠ Caution
Required • Do not turn off the primary power switch until the system shut downs completely. The hard disk(SSD) inside the system could be damaged and data could be lost.

Maintenance and inspections

⚠ Warning

Biohazard
· Wear protective equipment when maintaining and inspecting the system.

· The tip of the nozzle is sharp. Use caution when handling it.

· The tip of the puncture needle is sharp. Use caution when handling it.

Failure to observe this precaution may lead to infection from samples.

⚠ Request

· Inspect the system before starting operations each time.
- Check that there is no water leakage.
- No devices other than the designated ones should be connected.
- The environmental conditions are satisfied.
· Be sure to maintain and inspect the system daily, and keep it clean.

⚠ Request

· If the system has not been used for some time, check that the system is operating properly prior to use.

⚠ Request

· If system failure is suspected, do not touch the system, and do not attach a failure notice or other notification. Immediately contact the manufacturer or a legal representative.

Disposing of drainage and waste

⚠ Warning

Biohazard
· Dispose of drainage and waste (reagent containers, reaction containers, sampling bottles, and sample cups) appropriately in accordance with facility safety management procedures and the instructions of the person in charge of infectious medical waste management.
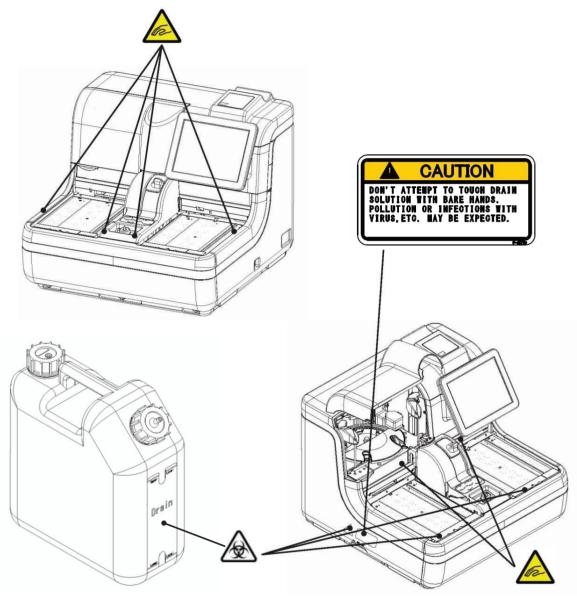
(Some examples of infectious medical waste include reagent containers, reaction containers, sampling bottles, and sample cups.)

· Refer to the usage instructions attached to the reagent for information on how to dispose of reagent containers and drainage.

· Contact your dealer for information on disposing of the system.

· Wear protective equipment during disposal.

Failure to observe this precaution may lead to environmental contamination.

Caution labels and where they are affixed
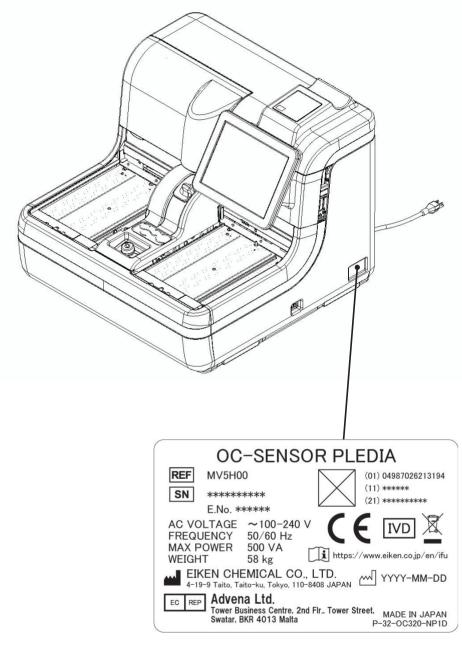
The following caution labels are affixed to the system.
Understand where the caution labels are and what they mean before using the system.

CAUTION

DON'T ATTEMPT TO TOUCH DRAIN
SOLUTION WITH BARE HANDS.
POLLUTION OR INFECTIONS WITH
VIRUS, ETC. MAY BE EXPECTED.

Tank (for drain)

Caution Label	Meaning
	Keep out of operational range during system operation. Failure to observe this precaution may lead to injury.
	Do not handle drainage with bare hands. Failure to observe this precaution may lead to infection or contamination.

Identification plate and where affixed

OC-SENSOR PLEDIA

REF	MV5H00		(01) 04987026213194
SN	**********		(11) ******
	E.No. ******		(21) **********

AC VOLTAGE ～100–240 V
FREQUENCY 50/60 Hz
MAX POWER 500 VA
WEIGHT 58 kg

CE   IVD

https://www.eiken.co.jp/en/ifu

EIKEN CHEMICAL CO., LTD.
4-19-9 Taito, Taito-ku, Tokyo, 110-8408 JAPAN   YYYY-MM-DD

EC REP **Advena Ltd.**
Tower Business Centre, 2nd Flr., Tower Street,
Swatar, BKR 4013 Malta   MADE IN JAPAN
P-32-OC320-NP1D

A two-dimensional code (GS1-DataMatrix) is printed in the "⊠" area.

Table of Contents

Chapter 2   Operation (Basic)

Chapter 3   Operation (Applied)

Chapter 5   Maintenance

Chapter 6   Settings

Chapter 7   Help

Chapter 8   Error Handling

Chapter 9 Operator/Latex Management Function（Option）

Appendix

1   Calculation Processing

2   Test Operations

6 Save to External Media

7 Management USB Stick Setting

Index/Glossary

Chapter 1   Overview

OC-SENSOR
PLEDIA

Chapter 1　Overview

This section gives a general outline of the system and describes the configuration of OC-SENSOR PLEDIA, a fully automated fecal occult blood analyzer (movable and discrete clinical chemistry automatic analysis system).

1.1　OC-SENSOR PLEDIA Features

- OC-SENSOR PLEDIA (below, "system") is equipped with functions required for immunoanalytical equipment, such as automatic sample dilution, a wide range of measurements, carryover countermeasures, and prozone checking.
- The system is always in standby. Reagents and buffers are managed by the thermal insulation system allowing for 24-hour sample measurement.

1.2　Use

The system determines the quantity of hemoglobin etc. in feces by detecting changes in transmitted light caused by latex agglutination reactions.

1.3　Measurement Principles

Latex turbidimetry

An antigen-antibody reaction is a specific reaction that occurs between an antigenic determinant and the active group of an antibody. The amount of bonding depends on the concentrations of the antigen and antibody.

A latex agglutination reaction is the clumping of antigen- or antibody-sensitized polystyrene latex particles caused by an antigen-antibody reaction. A light beam is passed through the reaction liquid to measure changes in the intensity of the transmitted light beam. This method is called "latex turbidimetry." This system makes use of this "latex turbidimetry."

1.4 System Configuration

Check the configuration prior to using the system.

Name		Model	Number	Remark
Body	Fully automated fecal occult blood analyzer (movable and discrete clinical chemistry automatic analysis system) OC-SENSOR PLEDIA	OC-320	1	
Accessories	(1) Software package			
	・ Software program		1	Preinstalled in hard disk(SSD)
	(2) Racks			
	・ Sample racks	OC-RK-41A	2 boxes	10 units/box
	・ STD/QC racks	OC-RK-42A	1	2 units/box
	・ Retest rack	OC-RK-33C	1	1 unit/box
	・ Dilute test rack	OC-RK-34C	1	1 unit/box
	(3) Tanks/bottles			
	・ Tank (for purified water)	NBU-4033-W1	1	10 L tank w/ zero-level sensor
	・ Tank (for wash solution)	NBU-4033-W2	1	5 L tank w/ zero-level sensor
	・ Tank (for drain)	NBU-4033-W3	1	10 L tank w/ maximum-level sensor
	・ Tank (for wash solution preparation)	NBU-4033-W4	1	5 L tank
	・ Auxiliary tank	5BL	1	5 L tank
	・ Empty bottle (for buffer)	PB-11	1	
	・ Beaker	PP200ML	1	
	・ Tank nozzles		2	Attached to tank (for wash solution preparation) and auxiliary tank
	(4) Others			
	・ End ring	OC-RING-2	1	
	・ Cap spacer		1	For 10 L tank
	・ Cap spacer		1	For 5 L tank
	・ Cap spacer		1	For buffer bottle
	・ Sample cups	DSP-SC-20B	1 bag	Consumable supplies
	・ Power cable	CP-114 or K-CP-700	1	
	・ Barcode labels for rack		3 sheets	"001-010," "011-020," "091-099"
	・ Measurement cells	LX-CELL-1B5	1 box	Consumable supplies
	・ Thermal roll paper	P-58-40	1 roll	Consumable supplies
Papers	・ Operation Manual	NN1-1384	1	
	・ Tank label		1	Affixed to tank
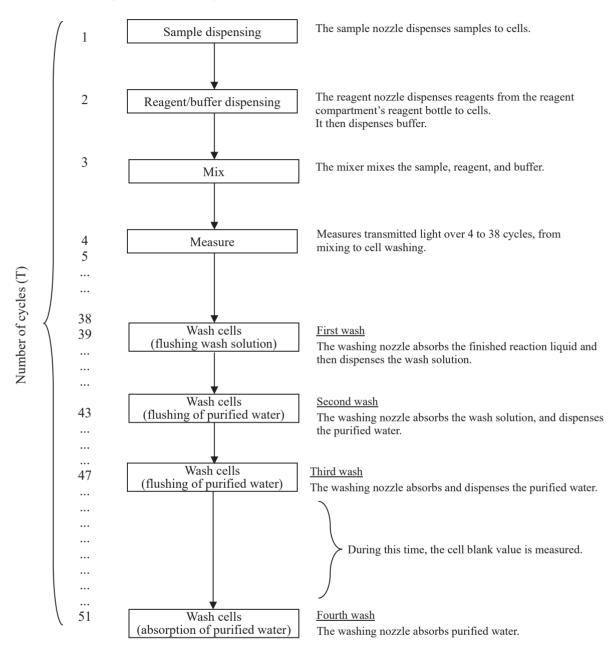
■   Options

Name	Model	Number	Remark
Rack trays	OC-TR-20	1	2/box
Two-dimension code reader	OC-320-OP1	1	1/Box
Temperature change driver board	OCP-NBP-4033-502DU	1	1/Box (Buffer Temperature control system 25°C-30°C)

1.5   Analysis Flow

The analysis flow for this system is as follows:

Number of cycles (T)	Flow step	Description
1	Sample dispensing	The sample nozzle dispenses samples to cells.
2	Reagent/buffer dispensing	The reagent nozzle dispenses reagents from the reagent compartment's reagent bottle to cells. It then dispenses buffer.
3	Mix	The mixer mixes the sample, reagent, and buffer.
4 5 38	Measure	Measures transmitted light over 4 to 38 cycles, from mixing to cell washing.
39	Wash cells (flushing wash solution)	**First wash** The washing nozzle absorbs the finished reaction liquid and then dispenses the wash solution.
43	Wash cells (flushing of purified water)	**Second wash** The washing nozzle absorbs the wash solution, and dispenses the purified water.
47	Wash cells (flushing of purified water)	**Third wash** The washing nozzle absorbs and dispenses the purified water.
51	Wash cells (absorption of purified water)	**Fourth wash** The washing nozzle absorbs purified water.

During this time, the cell blank value is measured.

(Explanatory note) : 11.3 seconds are required for a single cycle.

1.6　System Specifications

■　Basic specifications

Name	Specification
Measurement Principles	Latex turbidimetry
Method	Discrete method, random access method
Test mode	1-Step rate
Samples	Feces
Processing capacity	320 tests/hour (including 1 measurement using sample cup)
Measurement method	1-day, 2-day, or 3-day
Sample setting	200 samples: 20 special 10-sample racks
Sample container	S sampling bottle (Eiken Chemical special bottle) Sample cup (DSP-SC-20B)
Calibration curve generation	Automatic generation of calibration curves
Stat sample setting	Up to 10 samples
Dilute test	15- or 250-times dilution
Measurement cells	Semi-disposable, 11-cell plastic holder (up to five loadable), automatic washing with wash solution and purified water
Sample dispensing	Non-disposable sampling (with a nozzle washing function)
Sample dispensing range	0 μL, 5-80 μL (1 μL unit)
Reagent dispensing	Non-disposable reagent sampling (with a nozzle washing function)
Reagent dispensing range	Latex reagent: 0 μL, 5-300 μL (1 μL unit) Buffer: 0 μL, 5-350 μL (1 μL unit)
Mix	Mixer (with washing function)
Barcode reading	Rack barcodes, sample barcodes, reagent barcodes
Prozone check	PRC method, RBC method
Check reagent blank	Detection using A1 value check
Temperature control system	Latex reagent　　(24-hour control)　25°C-30°C heat block method
	Buffer　　　　　(24-hour control)　35°C-41°C heat block method　*25-30°C (The upper limit is room temperature) when using option (OCP-NBP-4033-502DU)
	Reaction table　　　　　　　　　40±0.5°C air bath method
Light source	LED (Wavelength: 660 nm)
Detector	Photo diode
Operation control/data processing	Multi-CPU system on internal LAN
External online	RS-232C, Ethernet

Name	Specification
Sample dispensing accuracy	20 μL ±2 μL, C.V. 1.0% or less
Reagent dispensing accuracy	20 μL ±2 μL, C.V. 1.0% or less
Buffer dispensing accuracy	300 μL ±10 μL, C.V. 1.0% or less
Security	Whitelist
Input method	Color LCD screen (10.5-inch), touch panel, barcode reader
Output method	Thermal printer (thermal paper width: 58 mm) Internal hard disk(SSD) External media over USB connection
Dimensions	Approx. 630 mm × approx. 630 mm × approx. 560 mm (W × D × H)
Weight	Approx. 58 kg
Power	~100-240 V ±10% 50/60 Hz 500 VA or less
Sound level	65 dBA or less

Explanatory note : The acceptable range of dimensions is within ±5%; The acceptable range of weight is within ±10%.

■   Sample barcode specifications

Type	No. of Digits	Check Digit	Remark
NW-7	5-17 digits (including start/stop character)	Modulus 10/3 weight Modulus 16 Modulus 11 Modulus 10/2 weight 7 check DR Weighing modulus 11 Loons	
ITF	6-15 digits	Modulus 10/3 weight	
IND 2 of 5	6-15 digits	None	
COOP 2 of 5	6-15 digits	None	
CODE39	5-15 digits (including start/stop character)	Modulus 43	
JAN	5-15 digits	Modulus 10/3 weight	
CODE128	5-15 digits	None	

■   Usable life

5 years (self-certified [based on manufacturer data]) from start of use (installation)

* Assuming periodic inspection/maintenance, part replacement, and repairs/overhaul

(when required after inspection) are conducting as described in this Operation Manual.

1.7 Reagents Used by System

Refer to the reagent's attached document for reagents used with this system.
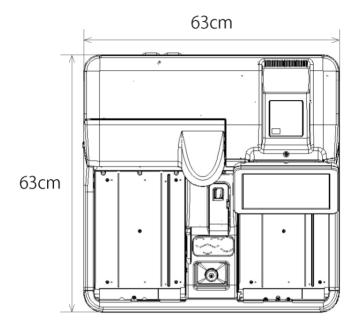
■ Reagents for hemoglobin measurement

Product Name	Product Code	Package
OC-SENSOR DIANA Latex Reagent	V-PZ01	15 mL x 5
OC-SENSOR DIANA Buffer	V-PZ03	500 mL x 1
OC-Calibrator 2 kit	V-PH52	3 mL x 1
OC-Control LV1	V-PH53	5 mL x 2
OC-Control LV2	V-PH54	5 mL x 2
OC-Control LV3	V-PH59	5 mL x 2
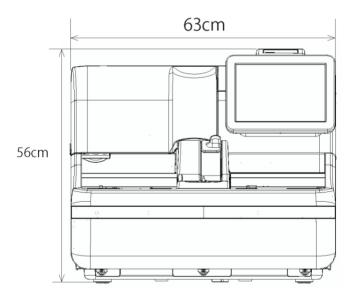
■ Common

Product Name	Product Code	Package
OC-SENSOR Sample Diluent	V-PH19	45 mL x 3

1.8 System Dimensions
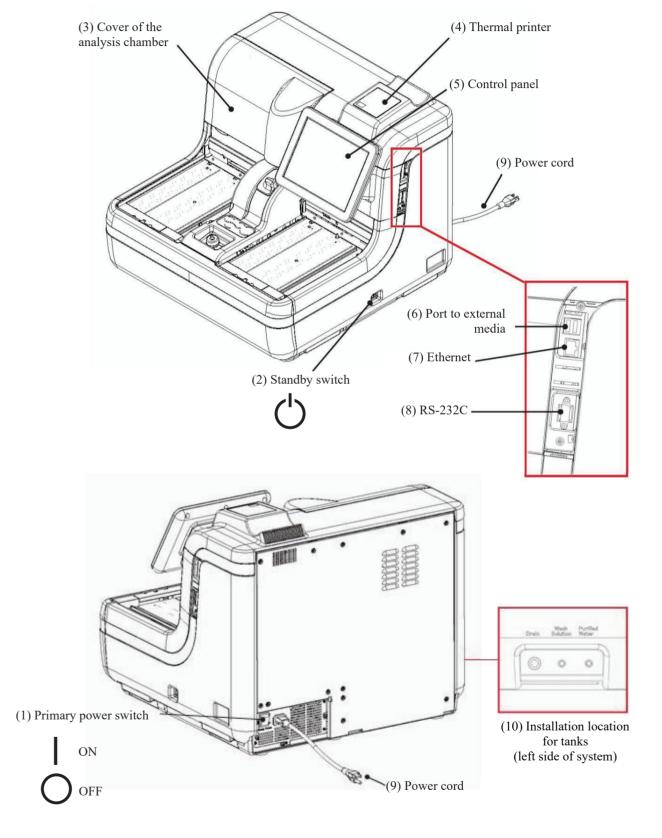
Top view

Front view
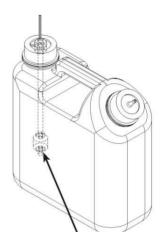
1.9 Names and Functions of Parts

1.9.1 Exterior parts

(3) Cover of the analysis chamber

(4) Thermal printer

(5) Control panel

(9) Power cord

(6) Port to external media

(7) Ethernet

(8) RS-232C

(2) Standby switch

(1) Primary power switch

ON

OFF

(9) Power cord

(10) Installation location for tanks (left side of system)

(11) Wash solution tank

(12) Purified water tank

(13) Drain tank

Zero-level sensor
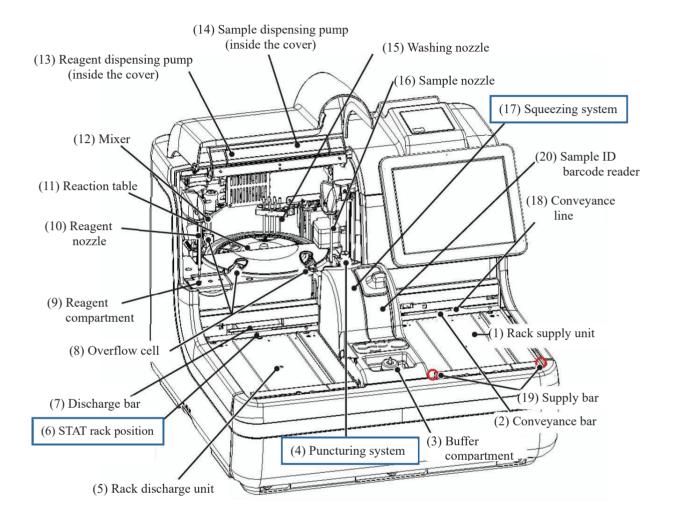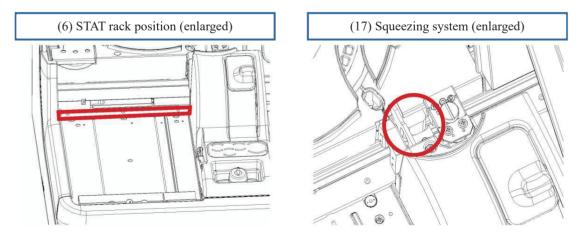
Zero-level sensor

Maximum-level sensor
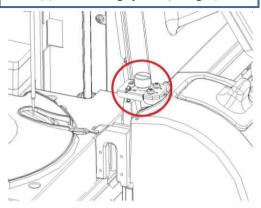
Name	Function
(1) Primary power switch	If the primary power switch is turned on, the system controls the temperature of the reagent compartment and buffer compartment. The primary power switch should normally be left on.
(2) Standby switch	If the standby switch is turned on, the system starts and controls the temperature of the reaction table.
(3) Cover of the analysis chamber	Safety feature to prevent accidents during system operation.
(4) Thermal printer	Prints setup conditions, measurement results, error messages, or other data. ☞Page 382 "Handling the Printer"
(5) Control panel	Shows operation screens and analytical results. The screen can be touched directly to operate.
(6) Port to external media	Allows connection to external media for storage of measured data.
(7) Ethernet	Connects to the host computer.
(8) RS-232C	Connects to the host computer.
(9) Power cord	The power cord for this system.
(10) Installation location for tanks	Connects piping and wiring to the tanks (for wash solution, purified water, and drainage).
(11) Wash solution tank (Wash Solution)	Filled with wash solution.
(12) Purified water tank (Purified Water)	Filled with purified water.
(13) Drain tank (Drain)	Stores liquid disposed by washing the sample nozzle, reagent nozzle, mixer, and cells.

1.9.2   Internal parts

(14) Sample dispensing pump
(inside the cover)

(15) Washing nozzle

(13) Reagent dispensing pump
(inside the cover)

(16) Sample nozzle

(17) Squeezing system

(12) Mixer

(20) Sample ID
barcode reader

(11) Reaction table

(18) Conveyance
line

(10) Reagent
nozzle

(9) Reagent
compartment

(1) Rack supply unit

(8) Overflow cell

(7) Discharge bar

(19) Supply bar

(6) STAT rack position

(2) Conveyance bar

(3) Buffer
compartment

(4) Puncturing system

(5) Rack discharge unit

| (6) STAT rack position (enlarged) | (17) Squeezing system (enlarged) |

(4)   Puncturing system (enlarged)

Name	Function
(1) Rack supply unit	Location where racks are placed. Up to 20 racks can be placed.
(2) Conveyance bar	Conveys a rack along the conveyance line.
(3) Buffer compartment	Location for setting the special 500 mL bottle for buffer. Constantly maintained at 35°C-41°C.
(4) Puncturing system	Punctures the double-layered aluminum seal attached to sampling bottles.
(5) Rack discharge unit	Location where racks are discharged from.
(6) STAT rack position	Location where rack is placed for cut-in analysis.
(7) Discharge bar	Feeds a rack to the rack discharge unit at the end of analysis.
(8) Overflow cell (OF)	<u>For sample nozzles</u> Washes the inner and outer wall of sample nozzles using purified water and wash solution. Drainage is sent to the drain tank. <u>For reagent nozzles</u> Washes the inner and outer wall of reagent nozzles using purified water. Drainage is sent to the drain tank. <u>For mixer</u> Washes mixer blades using purified water and wash solution. Drainage is sent to the drain tank.
(9) Reagent compartment	Location to set hemoglobin reagents. Simultaneous installation is not possible. Constantly maintained at 25°C-30°C.
(10) Reagent nozzle	Dispenses reagents.
(11) Reaction table	Performs antigen-antibody reaction and photometry.
(12) Mixer	Mixes samples and reagents.
(13) Reagent dispensing pump	Absorbs and flushes reagents and buffers.
(14) Sample dispensing pump	Absorbs and flushes samples.
(15) Washing nozzle	Washes measurement cells.
(16) Sample nozzle	Dispenses samples. Also creates calibrator dilution series and dilutes during dilute tests.
(17) Squeezing system	Raises the sample's level of liquid in the sampling bottle.
(18) Conveyance line	Conveys racks from the rack supply unit to the rack discharge unit.
(19) Supply bar	Feeds racks placed in the rack supply unit to the conveyance line.
(20) Sample ID barcode reader	Reads barcodes on reagent bottles and racks.

1.9.3   Accessories/other

(1) Buffer bottle

(2) Reagent bottle

(3) Sample rack (light blue)

(4) Retest rack (green)

(5) Dilute test rack (orange)

(6) STD/QC rack (blue)

(7) Tray (optional)

Tray lever

Pull forward to release the
lock on the set racks.

Name	Function
(1) Buffer bottle	Holds the buffer.
(2) Reagent bottle	Holds the latex reagent.
(3) Sample racks	Holds sampling bottles and sample cups.
(4) Retest rack	
(5) Dilute test rack	
(6) STD/QC racks	
(7) Tray (optional)	Used to place each rack.

MEMO

Chapter 2   Operation (Basic)

OC-SENSOR
PLEDIA

Chapter 2   Operation (Basic)

2.1   Basic Screen Operation

This section describes functions that can be run from the [MENU] screen, as well as buttons displayed on the screen and their basic operation.

2.1.1   [MENU] screen and functions

When the system is started, the [MENU] screen is displayed.

The following functions (from **a** - **h**) can be run from the [MENU] screen.
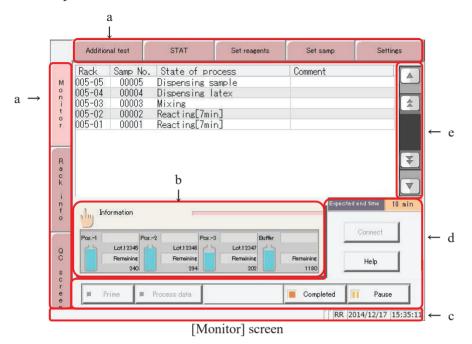
[MENU] screen

a	Test	Sets conditions for running tests (such as Test mode, Latex/CC settings, Set reagents, and Test setting).
b	Set latex	Set latex after reading the latex barcode. Touching the {Close} button completes reagent setting.
c	Prep functions	Display the [Prep functions] screen. Initialize, Prime, Cell blank, and Wash can be run from "Prep functions."
d	Data processing	Run "Process data" or "Process QC." A password must be entered to open the "Select measured data" screen (if a password is set).
e	Help	Display the [Help] screen. Used to confirm how to operate the system.
f	Settings	Perform "System settings" and "Protocol settings" for the system.
g	Maintenance	Confirm parts to check and exchange, or perform maintenance.
h	Close	Shut off the system. Running "Close mode" or "Long suspense" will automatically turn the standby switch off.

2.1.2   Screen composition and button operation

This section describes the {Buttons} and {tabs} displayed on the screen, and how to input settings.

■   Screen composition

[Monitor] screen

a	Tabs	Buttons to select functions in the same hierarchical directory at the top of the screen. They are located on the top and left side of the screen.
b	{Information} button	Touching the button displays the [Information] screen. ☞ Page 24 "2.1.3 [Monitor] screen and functions"
c	Status bar	Displays messages and the date.
d	Buttons	Buttons for running processes. Buttons are displayed according to the screen. ({Start/Cancel}, {Register/Cancel},{abort}, etc.) ☞ Page 20 "■ □ {Start/Cancel} button and {Register/Cancel} button"
e	Next page button	Switches the page up and down on the screen.
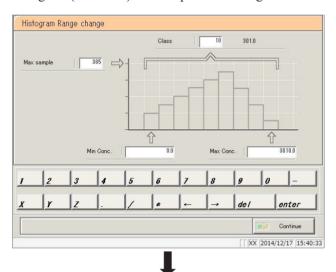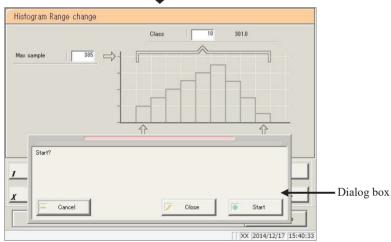
■ {Start/Cancel} button and {Register/Cancel} button

There is a {Start/Cancel} button on the processing screen, and a {Register/Cancel} button on the setting screen. The description will now continue with the [Histogram Range change] and [Latex/CC settings] screens as examples.

[Histogram Range change] screen

Touching the {Continue} button opens the dialog box.

Dialog box

{Start}: Start processing (in this case, change the histogram range).

{Close}: Cancel processing and return to the previous screen (in this case, the [Histogram] screen).

{Cancel}: The dialog box closes.
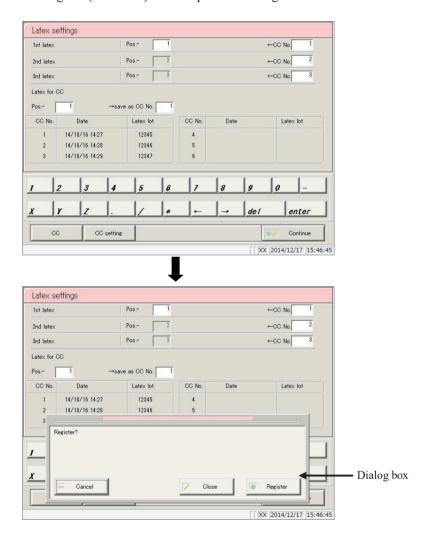
| Explanatory note | : The {Del} button appears on screens such as Process data and Process QC. Touching the {Del} button deletes the data in memory, but does not delete data from the hard disk(SSD). To update data, touch the {Register} button. |

[Latex settings] screen

Touching the {Continue} button opens the dialog box.

{Register}: Register settings (in this case, register Latex settings).

{Close}: Cancel setting registration and return to the previous screen (in this case, the [Test] screen).

{Cancel}: The dialog box closes.
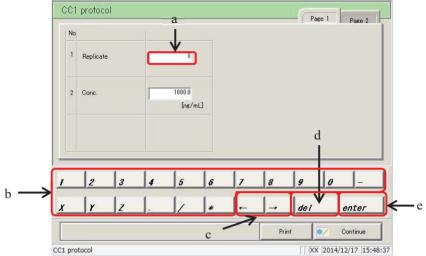
■   Setting input

This section describes how to input, insert, and delete numerical values.
([MENU] - [Settings] - [Protocol settings] - [CC1 protocol])

[CC No. 1 protocol] screen

Numerical input

① Touch the input field (a).
② Touch the numeric keypad (b) and input the numerical value.
③ Touch {enter} (e) (confirm the numerical value).

Single character insertion

① Touch the input field (a).
② Move the cursor to the left of the character to insert using the {←} and {→} buttons (c).

Single character deletion

① Touch the input field (a).
② Move the cursor to the left of the character to delete using the {←} and {→} buttons (c).
③ Touch the {del} key (d).

[Explanatory note] : Explanatory note: Item settings can be skipped by inputting an asterisk (*).
"*" cannot be input for some settings. See the message displayed in the status bar at the bottom of the screen to confirm what can be input.
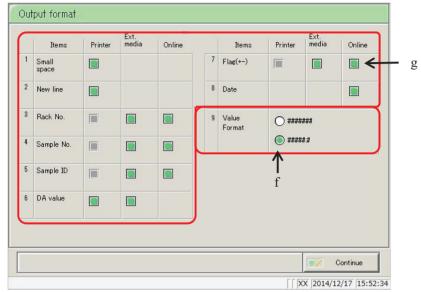
[Explanatory note] : Input using the keypad is the same as input using the numeric keypad. (right page)
Touch the {A/a} button to switch between uppercase and lowercase letters; touch the {Sign} button to input symbols.
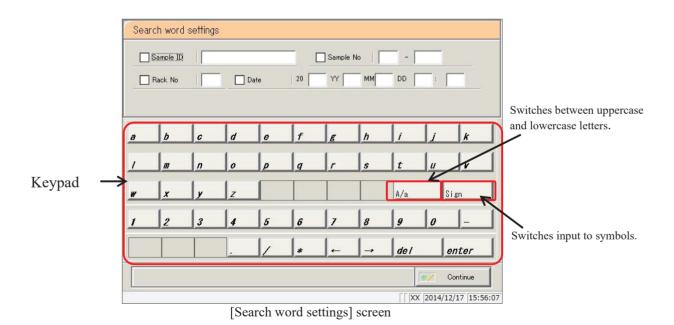
■ Radio buttons and check buttons

Radio buttons and check buttons are for selecting one or several items when configuring conditions.

[Output format] screen
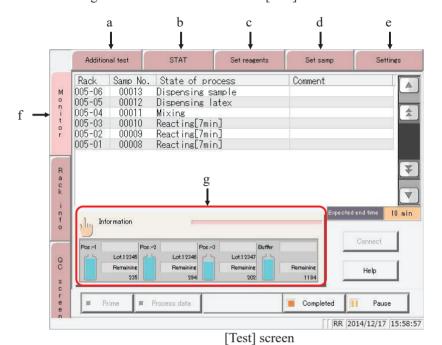
f	Radio buttons	●	Allow selection of a single item.
g	Check buttons	▣	Allow selection of several items.

[Search word settings] screen

2.1.3 [Monitor] screen and functions
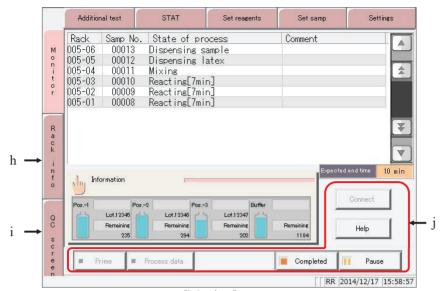
Touching the {Start} button on the [Test] screen starts the self check function.
After the self check is complete, the [Test] screen is displayed.
The following functions can be run from the [Test] screen.

[Test] screen

a	Additional test	Test conditions such as "Test mode" and "Latex/CC settings" can be changed while testing.
		☞Page 73 "2.4.13 Additional tests (changing test conditions while testing)"
b	STAT	Cut-in analysis for test racks and STD/QC racks can be run during testing.
		☞Page 78 "2.4.14 Cut-in analysis"
c	Set reagents	Reagents 1 through 3 and the buffer can be set to the system during testing.
		☞Page 42 "2.4.6 Setting buffer" ☞Page 50 "2.4.9 Setting reagents (Pos.-2/Pos.-3)"
d	Set samp	Racks can placed on the rack supply unit during testing.
		☞Page 52 "2.4.10 Placing samples"
e	Settings	Open the "System settings" screen. The system settings and protocol settings can be confirmed.
		☞Page 266"Chapter 6 Settings"

f	Monitor	
	Rack	The rack number and position in the rack of the sample (stat samples, STD samples, and QC samples) being tested is displayed.
	Samp No.	The number of the sample (stat samples, STD samples, and QC samples) being tested is displayed.
		Symbols shown after the sample number have the following meanings: A: Retest A*: 15-times dilution retest A**: 250-times dilution retest
	State of process	The current state of processing is displayed. The following is displayed: Dispensing sample Dispensing latex Mixing Reacting [# min] The time until analytical results are output is shown in the brackets ([ ]). Data (when the measurement has completed normally) Err* (when the measurement has not completed normally) (Explanatory note) : *Main errors No Tube, Puncture Err, Sample Short, L. Dispense Err, S. Dispense Err, No Cal. Curve, Mixing error, Latex Blank Err, B/C Duplication, B/C Read NG B/C Read NG are displayed in the comment field.
	Comment	The sample ID that was read is displayed. "Barcode read err" is displayed if the sample barcode could not be read.
	Expected end time (min)	Display the expected time that washing will complete for all reaction cells and the system will stop. (Explanatory note) : This time will not change while sample dispensing continues.
g	{Information}	Touching the {Information} button opens the [Information] screen and displays Latex information, Test condition, and Latex settings information. Touching the {Close} button returns to the [Monitor] screen. ☞Page 68 "■ Viewing information"

[Monitor] screen

h	Rack info	The [Rack info] screen is displayed. The condition of the rack in the rack discharge unit can be confirmed here. ☞Page 234 "3.9 Rack Information"
i	QC screen	Opens the [QC lot select] screen, and displays the QC lot list. Switch the tab to display the inter-day/intra-day data and $\overline{X}$-R control diagram. ☞Page 210 "3.8 Quality Control"
j	Buttons	
	{Connect}	If an abnormality communicating with an outside computer is detected and the communication is disconnected, the {Connect} button is displayed. Resume communication using the following method. ① Resolve the communication error. ② Touch the {Connect} button. 　　* Communication resumes and remaining data is output. ⎡Explanatory note⎤ : If you stop the testing with the {Close} button, communication finishes even if there is data that has not been output. In this case, specify the range of measured data on the [Test data] screen and then output it.
	{Help}	The [Help] screen opens. ☞Page 318 "Chapter 7 Help"
	{Completed}	Finish testing.
	{Pause}	Pause testing.
	{Prime}	Functions when testing of the sample placed on the rack supply unit is finished, and the system is waiting. Prime purified water and wash solution.
	{Process data}	Functions when testing of the sample placed on the rack supply unit is finished, and the system is waiting. Output measured data to a printer, external media, or online.

2.2 Starting the System

When the system is started, the [MENU] screen is displayed. Operation once the system starts varies according to how the system was shut down. There are three patterns:

- Shut down normally (with all settings configured to "NO")

- "Exchange buffer and wash solution to purified water" set to "YES" in Close mode, or Long close mode selected

- "Cell blank settings" or "Test" checked under "Settings of auto start up" in Close mode

---

2.2.1 Shut down normally (with all settings configured to "NO")

1 Check that the primary power switch is on.

If the system is not on, turn the switch on.

[Startup] screen

2 Turn the standby switch on.

* The startup screen is displayed.

[MENU] screen

* The [MENU] screen is displayed.

<div style="border:1px solid">

2.2.2 "Exchange buffer and wash solution to purified water" set to "YES" in Close mode, or Long suspense mode selected
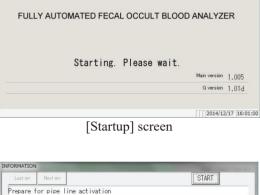
</div>

1 Check that the primary power switch is on.

If the system is not on, turn the switch on.

[Startup] screen

2 Turn the standby switch on.

* The startup screen is displayed.

3 Set the buffer bottle and wash solution tank according to the operation guide.

① Remove the bottle filled with purified water and the wash solution.

② Set a buffer bottle filled with buffer.

③ Fill the wash solution tank with wash solution.

④ Touch the {Start} button.

* Pipe line activation begins.

⚠ Caution	
⚠ Pinching hazard	· Do not open the cover of the analysis chamber during operation. · Keep out of the operational range of the system during operation. Failure to observe this precaution may lead to injury or damage.

4   Activate prime
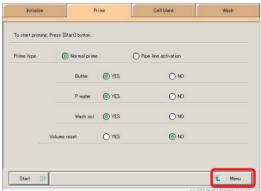
  * When pipe line activation is complete the dialog box closes.
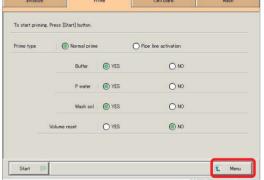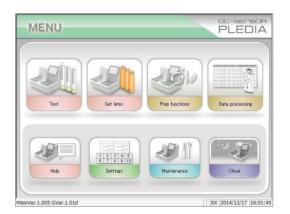
{Pause}:   Processing pauses.
{Start}:   Resume processing.
            If the Pause button is touched, it will change to the Start button.
{Abort}:   Abort processing.

5   Touch the {MENU} button.

  * The system returns to the [MENU] screen.
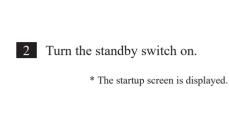
2.2.3　"Cell blank" checked under "Settings of auto start up" in Close mode
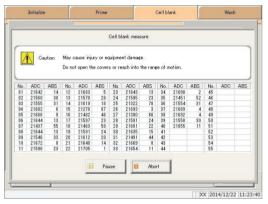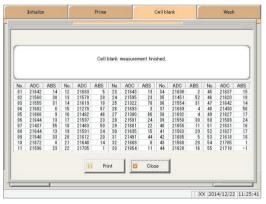
1 Check that the primary power switch is on.
If the system is not on, turn the switch on.

2 Turn the standby switch on.

　　　　* The startup screen is displayed.
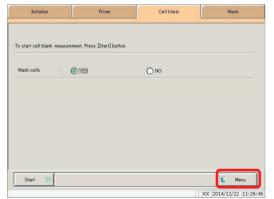
3 Cell blank measurement is run.

When cell blank measurement is complete, touch the {Close} button.
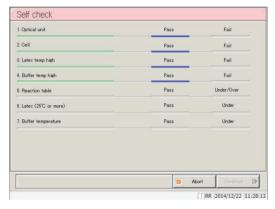
4 Touch the {MENU} button.

2.2.4 "Test" checked under "Settings of auto start up" in Close mode

1 Turn the standby switch on.

* The startup screen is displayed.

2 Self check begins.

3 The [Monitor] screen opens and testing begins.

2.3 Initial Settings
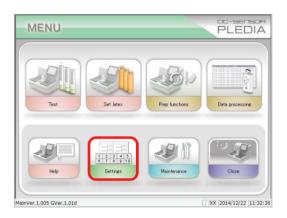
Initial settings must be configured to use the system for the first time.
Initial settings are broadly classified into two categories: "system settings" and "protocol settings."
Touching the {Settings} button on the [MENU] screen displays a screen from which settings can be selected for both.
This section will give an overview of system settings and protocol settings.
See page 266 "Chapter 6 Settings" for details on operation.
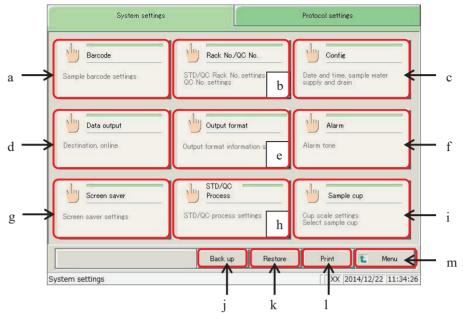
2.3.1 System settings

1 Touch the {Settings} button.

2 Touch the {Button} for the item to configure.

> * The settings screen for each is displayed. (See the following page.)
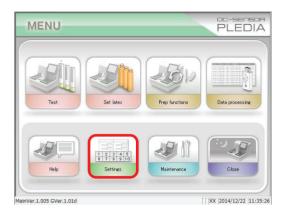
[System settings] screen

a	Barcode	Set conditions for reading sample barcodes.
b	Rack No./QC No.	Register STD/QC racks, retest racks, and dilute test racks. Configure the QC sequence number.
c	Config	Configure the date. Register a password for data processing Select the supply method for purified water and the drainage method for drainage. Select automatic rack supply. Set the automatic logout time when using the operator/latex management function.
d	Data Output	Select the output destination for the data. Select the format of data output to a printer, external media, or online. Configure settings for online communication control. Configure test items.
e	Output format	Select the output format. Select items for output to a printer, external media, or online.
f	Alarm	Configure the type of alarm and how long it sounds.
g	Screen saver	Configure the screen saver activated on the [MENU] screen.
h	STD/QC Process	Configure conditions for checking measured data for STD samples/QC samples.
i	Sample cup	Register the shape of the sample cup.
j	Back up	Save system setting/protocol setting information to external media.
k	Restore	Read system setting and protocol setting information saved to external media, and restore it to the system.
l	Print	Print system setting information.
m	Menu	The system returns to the [MENU] screen.

2.3.2   Protocol settings
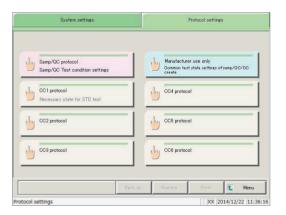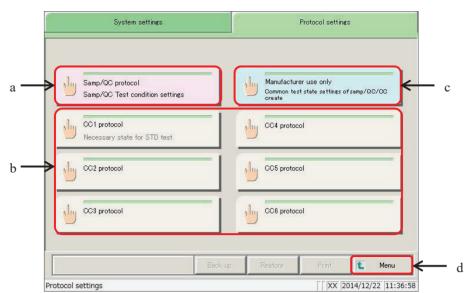
1 Touch the {Settings} button.

2 Touch the {Protocol settings} tab.

3 Touch the {Button} for the item to configure.

* The settings screen for each is displayed. (See the following page.)

Protocol settings screen
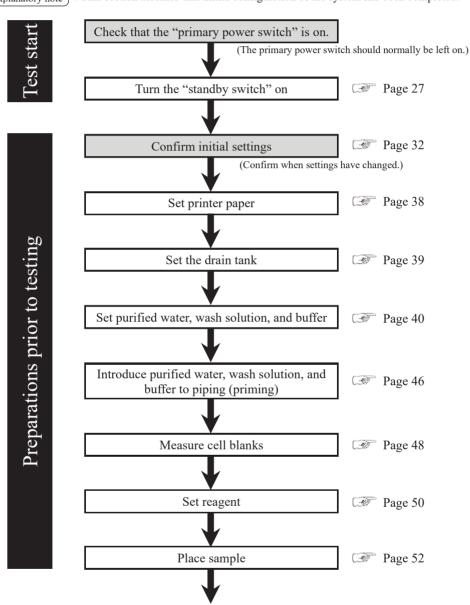
a	Samp/QC protocol	Set test conditions when measuring samples and QC samples.
b	CC1 to CC6 protocol	Allows for registration of calibration curves for protocols No. 1 through No. 6.
c	Manufacturer use only	Configure common conditions required for measuring samples, stat samples, QC samples, and STD samples (for maintenance people only).
d	Menu (Close)	The system returns to the [MENU] screen. (The {Close} button is displayed during testing. The system returns to the [Monitor] screen.)

2.4   Daily Operation

This section describes daily operation processes and procedures.
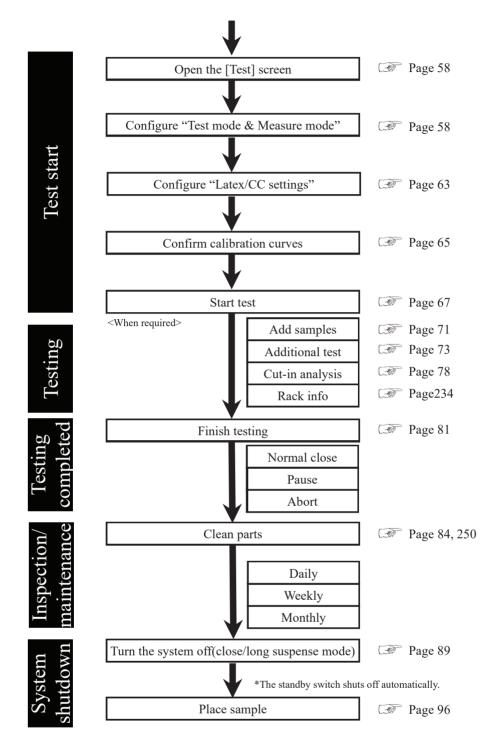
2.4.1   Daily operation flow

Explanatory note : This section assumes that initial configuration of the system has been completed.

Test start

Check that the "primary power switch" is on.
(The primary power switch should normally be left on.)

↓

Turn the "standby switch" on   ☞ Page 27

↓

Preparations prior to testing

Confirm initial settings   ☞ Page 32
(Confirm when settings have changed.)

↓

Set printer paper   ☞ Page 38

↓

Set the drain tank   ☞ Page 39

↓

Set purified water, wash solution, and buffer   ☞ Page 40

↓

Introduce purified water, wash solution, and buffer to piping (priming)   ☞ Page 46

↓

Measure cell blanks   ☞ Page 48

↓

Set reagent   ☞ Page 50

↓

Place sample   ☞ Page 52

↓

To next page

Explanatory note : If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be automatically run when the system starts.

Test start	Open the [Test] screen	☞ Page 58
	Configure "Test mode & Measure mode"	☞ Page 58
	Configure "Latex/CC settings"	☞ Page 63
	Confirm calibration curves	☞ Page 65
	Start test	☞ Page 67

<When required>

Add samples	☞ Page 71
Additional test	☞ Page 73
Cut-in analysis	☞ Page 78
Rack info	☞ Page234

Testing

Finish testing	☞ Page 81

Testing completed

Normal close
Pause
Abort

Clean parts	☞ Page 84, 250

Inspection/ maintenance

Daily
Weekly
Monthly

Turn the system off(close/long suspense mode)	☞ Page 89

*The standby switch shuts off automatically.

Place sample	☞ Page 96

System shutdown

2.4.2 Setting printer paper

This section describes printer paper setting.
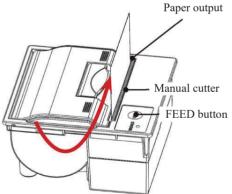
Paper cover

Paper cover open lever

LED lamp   FEED button   Manual cutter

> ⚠ **Caution**
>
> ❗ Required
>
> · Be careful of the blade of the manual
>   Failure to observe this precaution may lead to injury.

Paper cover

① Raise the paper cover open lever and open the cover.

② Set the paper as shown in the diagram to the left. (If this is set with the opposite facing, the system will be unable to print.)
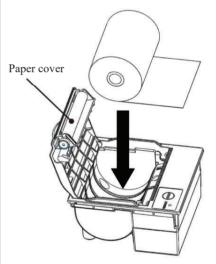

Paper output

Manual cutter

FEED button

③ Set the paper so that its edge sticks out of the paper output.

④ Press both edges of the paper cover to close it. Confirm that the paper cover is locked.

⑤ Touch the FEED button.

⑥ Cut the paper using the manual cutter.

Preparations prior to testing

2.4.3   Check the drain tank (connected to system by maintenance person)

Confirm that the maximum level sensor and hose attached to the drain tank are connected to the system.

⚠ Warning	
![Biohazard] **Biohazard**	· Wear protective equipment when handling the drain tank. Failure to observe this precaution may lead to contamination.
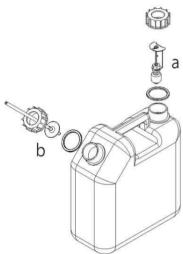
⚠ Caution	
! **Required**	· Empty the drain tank prior to using the system. If the system detects that the drain tank is full, dispensing will stop. · Install the waste liquid tank below the equipment. If the waste tank is above the equipment, it may not be able to drain properly.
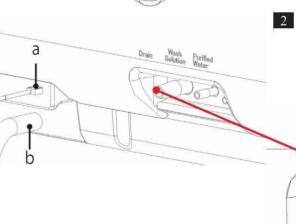
1   Attach a maximum-level sensor (a) and hose (b) to each drain tank port (two).

2   Confirm that the maximum-level sensor (a) and hose (b) are connected to "Drain" at the "installation location for tanks" on the left side of the system.

<div style="border:1px solid black">

2.4.4   Setting purified water

</div>

Add purified water to the purified water tank.
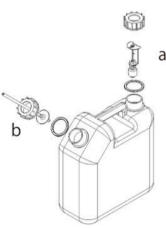
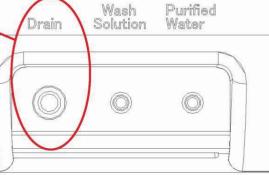| ⚠ Request |
|---|
| ・ After setting the purified water tank (including adding purified water), be sure to prime it. |
| ・ Be sure to use the included purified water tank. |

Explanatory note : Purified water tank dpe size: 10 L tank

1 Add purified water to the purified water tank.

2 Attach a zero-level sensor (a) and hose (b) to each purified water tank port (two).

3 Confirm that the zero-level sensor (a) and hose (b) are connected to "Purified Water" at the "installation location for tanks" on the left side of the system.
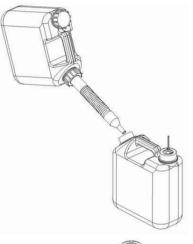
2.4.5   Setting wash solution
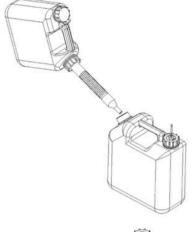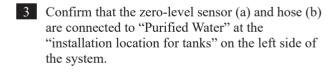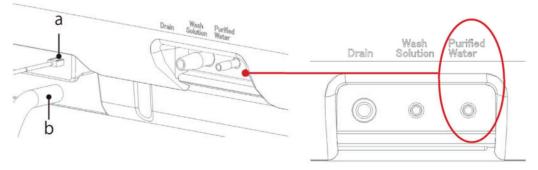
Fill the wash solution tank with 3% distilled wash solution.
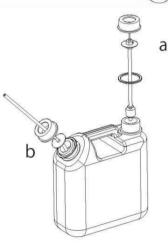
> ⚠ **Request**
>
> ・ After setting the wash solution tank (including adding wash solution), be sure to prime it.
>
> ・ Make sure there is enough wash solution prior to using the system.
>
> ・ Be sure to use the included wash solution tank.
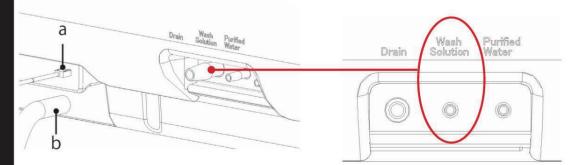
1 Dilute the wash solution 3%.

  ① Fill the tank (for wash solution preparation) with 150 mL of washing solution (undiluted).
  ② Add purified water to the tank in ① so that it contains 5 L of total liquid.

2 Fill the wash solution tank with the 3% wash solutions.

3 Attach a zero-level sensor (a) and hose (b) to each wash solution tank port (two).

4 Confirm that the zero-level sensor (a) and hose (b) are connected to "Wash Solution" at the "installation location for tanks" on the left side of the system.

[Explanatory note] : Wash solutions not indicated with "(undiluted)" refer to 3% wash solutions.

2.4.6   Setting buffer

Set the buffer bottle to the "buffer compartment."

⚠ **Request**
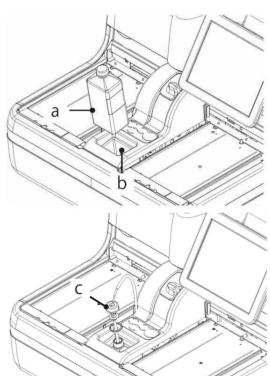
       · After setting the buffer bottle (including adding purified water), be sure to prime it.
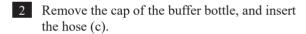
Explanatory note : After touching the {Reset} button on the [Set reagents] screen, priming automatically begins once the buffer bottle has been set.
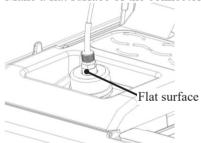
Explanatory note : If the buffer is reset, the number of remaining tests stored by the system will be deleted, and a new number of remaining tests will be stored (that is, the number of remaining tests will be overwritten).
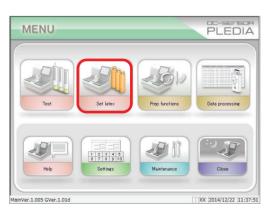
1 Set the buffer bottle (a) to the buffer compartment (b).

2 Remove the cap of the buffer bottle, and insert the hose (c).
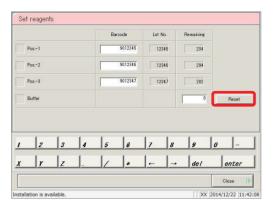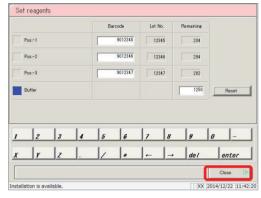
Make a flat surface of the connector to the front.

Flat surface

3 Touch the {Set latex} button on the [MENU] screen.

4 Touch the {Reset} button.

 * The buffer is reset, and the number of remaining tests is displayed.

 Explanatory note : Touch the "Remaining tests" field for the buffer and use the numeric keypad to modify the value.

5 Touch the {Close} button.

 * Pipe line activation begins.

 * The system returns to the [MENU] screen.

Explanatory note : If the remaining volume in [Information] - [Buffer bottle] is 50 mL or less, the number of remaining tests will be "0," and the user will be asked to change the buffer bottle via alarm and message.

Preparations prior to testing

2.4.7 Priming (normal prime, pipe line activation)

There are two kinds of priming. "Normal prime" removes air bubbles in the piping, while "pipe line activation" introduces buffer to the piping.

⚠ Caution
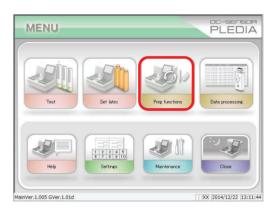
	・ Do not open the cover of the analysis chamber or reach into the range of motion during operation.
Pinching hazard	Failure to observe this precaution may lead to injury or damage.
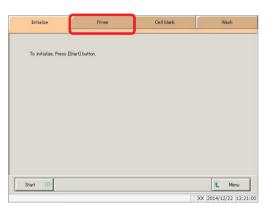
■ Normal priming

Used to remove air bubbles in the piping.

"Normal prime" is also used when the system has been left off for some time.

1 Touch the {Prep functions} button.

2 Touch the {Prime} tab.

3 Select normal priming.

① Check Normal prime.
② Select items to prime.
○ YES: Prime.
○ NO: Do not prime.
Select whether or not to reset the buffer volume ([YES] or [NO]).
③ Touch the {Start} button.

* Normal priming begins.

4 Priming

* When priming is complete, the dialog box closes.

{Pause}: Processing pauses.
{Start}: Resume processing.
If the {Pause} button is touched, it will change to the {Start} button.
{Abort}: Abort processing.
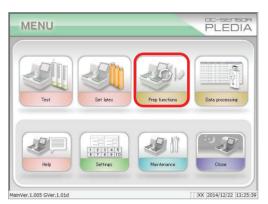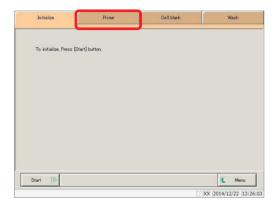
Explanatory note : If the cover of the analysis chamber is opened during normal priming, "Cover open" is displayed at the bottom right of the screen.

Preparations prior to testing

■ Pipe line activation
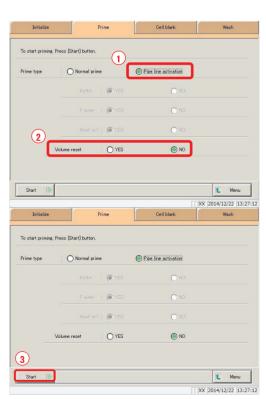
Used to introduce buffer into the piping.

1 Touch the {Prep functions} button.

2 Touch the {Prime} tab.

3 Select pipe line activation.

① Check "Pipe line activation."
② Select "Volume reset."
③ Touch the {Start} button.

* Pipe line activation begins.

<div style="writing-mode: vertical">Preparations prior to testing</div>

4   Activate prime

* When priming is complete, the dialog closes.

{Pause}:   Processing pauses.

{Start}:   Resume processing.
If the {Pause} button is touched, it will change to
the {Start} button.

{Abort}:   Abort processing.

Explanatory note : If the cover of the analysis chamber is opened during pipe line activation, "Cover open" is
displayed at the bottom right of the screen.

Preparations prior to testing

Preparations prior to testing

2.4.8   Measure cell blanks

Run cell blanking to wash cells and evaluate them on a pass/fail basis.

If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be automatically run when the system starts.

| ⚠ Caution |
| --- |
| ⚠ Pinching hazard | · Do not open the cover of the analysis chamber or reach into the range of motion during operation.

Failure to observe this precaution may lead to injury or damage. |
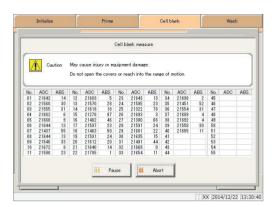
1 Touch the {Prep functions} button.
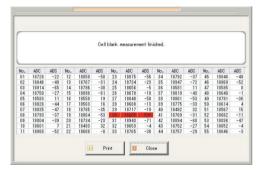
2 Touch the {Cell blank} tab.

3 Select measurement cell washing.

① Check "YES."

② Touch the {Start} button.

* Cell blank measurement begins.
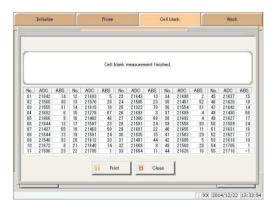
4   Cell blank measure

* When measurement is complete, the {Abort} button will change to {Close}.

Explanatory note   : Cells that cannot be used are displayed in red.

Explanatory note   : When 10 or more cells can no longer be used "There are more than 10 unclean measurement cells. [COMMENT_RANGE]Please exchange cells."[/COMMENT_RANGE VALUE::This could reduce processing performance. Replace the measurement cells

☞ Page 258 "5.1.9 Replacing measurement cells (when cell blank value is abnormal)"

5   Touch the {Print} button to print the measurement results.

* The results of the measured cells are printed.

Touch the {Close} button.

* The system returns to the [Cell blank] screen.

{Pause}:   Processing pauses.

{Start}:   Resume processing.
If the {Pause} button is touched, it will change to the {Start} button.

{Print}:   Print the measurement results.

{Close}:   Displayed when processing completes.
The system returns to the measurement cell washing selection screen.

{Abort}:   Abort processing.

{MENU}:   The system returns to the [MENU] screen.

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Preparations prior to testing

2.4.9 Setting reagents (Pos.-1/Pos.-2/Pos.-3)

After reading the reagent barcodes for Pos.-1, Pos.-2, and Pos.-3, set the reagent bottle to the reagent compartment. The positioning of the reagent bottles is Pos.-1, Pos.-2, and Pos.-3 in order, from the left of the reagent compartment.

There are two ways to enter barcodes: "input using barcode reader" and "keypad input."

⚠ Request

Reagent barcode information

・ Barcodes on reagent bottle labels are of the CODE 39 type, consisting mainly of eight characters (excluding the initial and terminal characters).

・ When entering barcodes, follow the format below.

<u>AACMXXXD (barcode)</u>

AA: Item code, two digits (numeric, 0 to 99; 90: feces Hb)

C: Last digit of the year (numeric, 0 to 9)

M: Month (alphanumeric, 1 to 9, or X, Y, or Z)

XXX: Serial number for the year (numeric, 0 to 999)
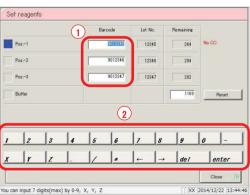
D: Check digit (alphanumeric)

Explanatory note : Reagents can be set from the [Test] screen or the [Monitor] screen.

1 Touch the {Set latex} button.

2 Enter the reagent barcode.

<Keypad input>

① Touch the barcode field for the appropriate reagent.

＊ The check box turns blue.

② Use the numeric keypad to enter the seven digits of the eight-digit barcode affixed to the reagent bottle, excluding the last digit (check digit).

Explanatory note : If there is no calibration curve in the reagent lot, the "No CC" message is displayed. Create a calibration curve.

⚠	Caution	
❗ Required	・	After setting the reagent bottle, close the lid of the reagent compartment. If the cover is left open, the reagent nozzle could make contact with the cover.
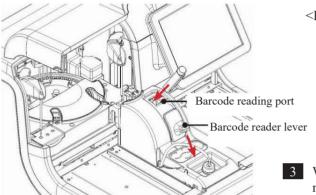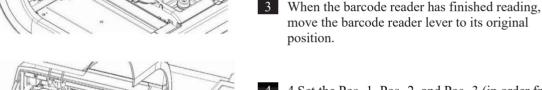
⚠	Request
	・ Close the lid of the reagent bottle when reading the reagent barcode. Failure to observe this precaution could result in the reagent being spilled.
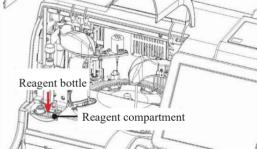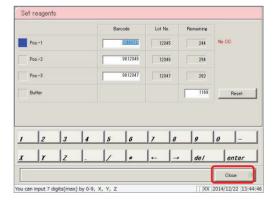
Preparations prior to testing

<Barcode reader input>

① Touch the barcode field for the appropriate reagent.

　　* The check box turns blue.

② Lower the barcode reader lever.

③ Place the reagent bottle into the barcode reading port with the barcode surface facing to the front.

　　* The seven-digit barcode (excluding the check digit) is displayed.

Barcode reading port

Barcode reader lever

3 When the barcode reader has finished reading, move the barcode reader lever to its original position.

Reagent bottle

Reagent compartment

4 4 Set the Pos.-1, Pos.-2, and Pos.-3 (in order from left to right) bottles to the reagent compartment.

① Open the lid of the reagent compartment.

② Remove the cap of the reagent bottle.

③ Insert the reagent bottles into the reagent insertion port, with the barcode surface facing to the front.

④ After setting all reagents, close the lid of the reagent compartment.

5 Touch the {Reset} button to reset the number of remaining tests for buffer.

Touch the {Set complete} button.

　　* When the reagent bottle has been set, confirm the volume of the reagent bottle with the reagent nozzle.

　　* The system returns to the [MENU] screen.

{Set complete}:　Finish setting reagent.

{Reset}:　Update the buffer information. Pipe line activation automatically begins when the reagent is set.

Explanatory note : If the number of remaining tests is "0" on the [Information] reagent bottle display, the user will be asked to change the reagent bottle via alarm and message.

2.4.10   Installing samples

Place the rack to which samples have been set in the rack supply unit. If you are using a tray (optional), place the tray to which the sample rack has been set in the rack supply unit.

1   Set the sample (sampling bottle) to the rack.

[Explanatory note] : Use a measurement mode and rack that suit the sample to be measured.

- · When measuring a sample, specify the test mode and use a "sample rack."
- · When remeasuring a sample, specify the remeasure/retest mode and use a "sample rack."
- · When retesting a sample, use a "retest rack" (there is no need to specify a mode).
  ☞ Page 52 "Setting samples using measurement method (1 day/2 day/3 day)"
- · When measuring an STD or QC sample, use an "STD/QC rack."
  (There is no need to specify the mode.)
  ☞ Page 55 "Setting STD/QC samples"
- · When running a dilute test on a sample, use a "dilute test rack" (there is no need to specify a mode).
  ☞ Page 54 "Setting samples when running a dilute test"

[Explanatory note] : Install a sampling bottle vertically.
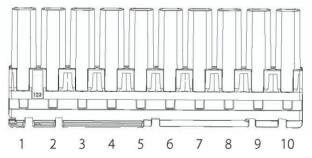
- · When the installation of a sampling bottle at an angle, there is a possibility that the puncture is not performed normally.

Setting samples using measurement method (1 day/2 day/3 day)

Sample arrangement on racks varies according to the measurement method (1 day/2 day/3 day). Samples are arranged on the rack as follows.

☞ Page 58 "Setting test modes, measurement methods, and measurement modes"

\<1 day\>

Sampling bottles can also be installed alone
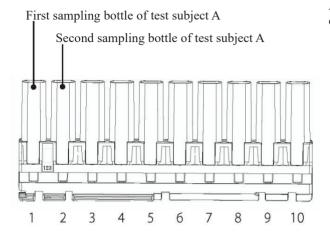
Sampling bottles for up to ten people can be set to a single rack.

1   2   3   4   5   6   7   8   9   10

[Explanatory note] : Set the sampling bottle to the rack, so that the barcode is facing to the front.

[Explanatory note] : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

\<2 day\>

First sampling bottle of test subject A

Second sampling bottle of test subject A
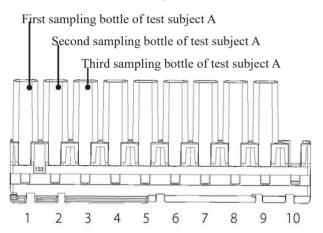
Arrange two sampling bottles (two day's worth) for a single person.

Sampling bottles for up to five people can be set to a single rack.

1 2 3 4 5 6 7 8 9 10

\<3 day\>

First sampling bottle of test subject A

Second sampling bottle of test subject A

Third sampling bottle of test subject A

Arrange three sampling bottles (three day's worth) for a single person.

Sampling bottles for up to three people can be set to a single rack.

1 2 3 4 5 6 7 8 9 10

Preparations prior to testing

Explanatory note : For 3 day measurement, a container is not tested even if the sample is set to rack position number 10 (right edge).

Explanatory note : Set the sample to the rack, so that the barcode is facing to the front.

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Explanatory note : For 2 day/3 day, if the samples are not gathered for the number of days, leave a space with no samples (do not set the samples all together).

Setting samples when running a dilute test

⚠ Request
・ Confirm that there are no bubbles mixed in when filling the sample cups with retest diluent and samples. ・ When measuring at 15-times dilution, set an empty sample cup only at the "× 15" position. ・ When measuring at both 15-times dilution and 250-times dilution, or when measuring at 250-times dilution, set empty sample cups at the "× 15" and "× 250" positions. Do not set sampling bottles at rack positions No. 3, 4, 6, 7, 9, and 10. In this case, it is necessary to set the manufacturer setting [× 15 simultaneous test] to "YES."

Explanatory note : When running a dilute test, use the "dilute test rack."
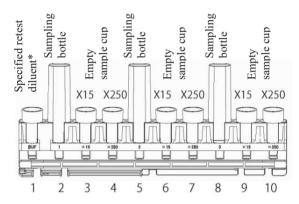
Explanatory note : Customers cannot modify manufacturer settings.

Explanatory note : Set containers filled with diluted sample at rack positions No. 2, 5, and 8.
  Either sampling bottles or sample cups may be used.
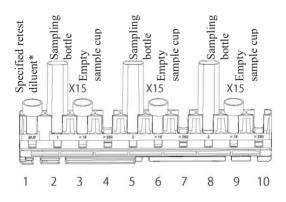
<Measuring at both 15-times dilution and 250-times dilution, or at 250-times dilution>

* Approximately 2 mL of retest diluent is required.

<Measuring at 15-times dilution>

* Approximately 2 mL of retest diluent is required.

Explanatory note : Set the sample to the rack, so that the barcode is facing to the front.

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Setting STD/QC samples

⚠ Request
・ Confirm that there are no bubbles mixed in when filling the sample cups with calibrator, calibrator buffer, and QC samples. ・ When measuring only QC samples, set them to rack holes No. 9 and No. 10.
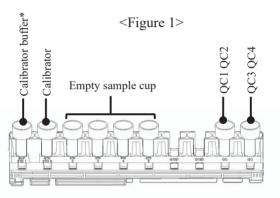
Explanatory note : When measuring STD samples and QC samples, use the "STD/QC rack."
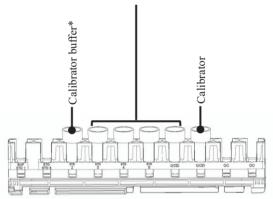
Explanatory note : QC samples can be ID-managed by erection of containers with QCID (bar code for QC) attached to positions No. 7 and No. 8 in the rack.

<Figure 1>

<Figure2> (when a dilution series has been created)

Sample cups for which a dilution series has been created
(In order of concentration weakness, from left to right.)

* Approximately 2 mL of calibrator buffer is required.

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Explanatory note : It is possible to set only STD samples or only QC samples to the rack.

Calibration curve creation method (if a dilution series has not been created)

(1) Set calibrator, calibrator buffer, and empty sample cups to the STD/QC rack according to the tests to run.

☞ Page 55 "Setting STD/QC samples" (Figures 1)

(2) Enter the concentration listed in the INSTRUCTIONS FOR USE for the calibrator into "Conc." in [Protocol settings] - [CC No. # protocol settings].

☞ Page 314 "6.2.2 CC No. 1 to CC No. 6 protocol settings"

(3) Place the STD/QC rack in the rack supply unit.

(4) Touch the {Start} button on the [Test] screen.

* Start testing.

* When placing a QC sample, measure along with the QC sample.

* A calibration curve is created.

(5) Confirm that the calibration curve has been properly created.

(6) Touch the {Register} or {Cancel} button.

Calibration curve creation method (if a dilution series has been created)

(1) Set the calibrator to rack position No. 8.

(2) Set the sample cups in order of concentration weakness in rack positions No. 4 through No. 7.

(3) Set the calibrator buffer to rack position No. 3.

☞ Page 55 "Setting STD/QC samples" (Figure 2)

Explanatory note : Do not set sample cups to rack positions No. 1 and No. 2.

(4) Place the STD/QC rack in the rack supply unit.

(5) Touch the {Start} button on the [Test] screen.

* Start testing.

* When placing QC samples in rack positions No. 9 and No. 10, measure along with the QC samples.

* A calibration curve is created without creating a dilution series.

(6) Confirm that the calibration curve has been properly created.

(7) Touch the {Register} or {Cancel} button.

Placing a rack as is in the supply unit (standard specification)
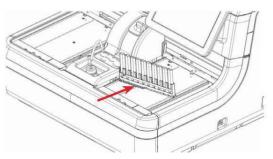
2 Placing racks in the system

⚠ Caution
! **Required** · Set racks to the system with the rack barcode facing to the front. If the barcode is facing the system, a barcode read error could occur.

Set the rack to the rack supply unit with rack position No. 1 on the left side.

Set it so that the metal claws fit into the depressions on the lower left of the rack.

Placing a rack in the rack supply unit using a tray (optional)

2'-1　Setting the rack to a tray
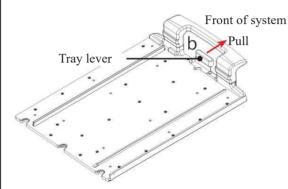
⚠ Caution
❗ Required	・ Set racks to the tray with the rack barcode facing to the front. If the barcode is facing the system, a barcode read error could occur.
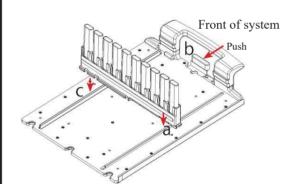
Front of system

Tray lever

b

Pull

1 Pull the tray lever (b) to the front.
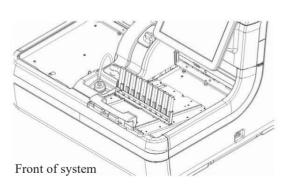
* The guide lock releases.

Front of system

b

Push

c

a

2 Set the rack to the tray.

① Insert the groove on the left edge of the rack into the guide (a).

② Align the groove on the right edge of the rack with the guide (c).

③ Push the tray lever (b) and lock it.

2'-2　Placing the tray in the rack supply unit
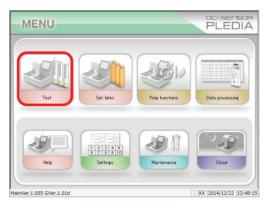
Place the tray from the front of the rack supply unit.

Front of system

Test start
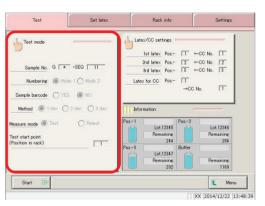
2.4.11 Starting tests

Open the [Test] screen, and configure the test conditions displayed on the screen after selecting the {Test} tab. Test conditions are broadly categorized into "Test mode" and "Latex/CC settings." Touching the {Start} button starts testing after the self check is run.
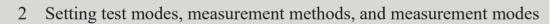
1 Opening the [Test] screen

1 Touch the {Test} button.

2 Touch the {Test mode} button.

2 Setting test modes, measurement methods, and measurement modes
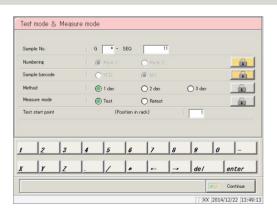
1 Configure items (see the following page).
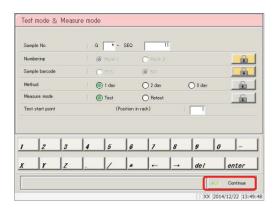
Item	Range/Selection	Details

Sample No.
G □ - SEQ □□
 	
Group No. (G)
Sequence No. (SEQ)
 	
(Maintained in memory until the system power is turned off.)
	*, 1-9
	1 - 99999
		Configure the number of the head sample.
		    A sample number consists of a group number (G) and a sequence number (SEQ).
		    Enter "*" to skip configuring a group number.

Numbering
 	
(Maintained in memory even if the system power is turned off.)
	YES:
	
	NO:
		If there is a rack position in which a sample has not been set, configure how to allocate sequence numbers.
		
		    Allocate sequence numbers only to set samples.
		
		Even if there are empty positions, a "No tube" error will not occur.
		
		    Allocate sequence numbers even to positions in which samples are not set.
		
		A "No tube" error will occur if there are any empty positions.

Explanatory note : Configuring group numbers allows for the positive rate change to be calculated per group.

Explanatory note : Serial numbers starting from the configured sequence number will be allocated to samples.

Test start

Test start

Explanatory note : Sequence numbers are managed for each measure mode (test mode, remeasure/retest mode, dilute test).

Item	Range/Selection	Details
Sample barcode (Configuration maintained in memory even if the system power is turned off.)	 YES: NO:	Configure whether or not to use sample barcodes. - Settings are also applied to [Settings] - [System settings] - [Samp barcode settings]. Use sample barcodes. Do not use sample barcodes.
Measurement method (Configuration maintained in memory even if the system power is turned off.)	 1 day: 2 day: 3 day:	Select the measurement method. Measure using 1 day method. Measure using 2 day method. Measure using 3 day method.
Measure mode (Configuration maintained in memory until the system power is turned off.)	 Test: Retest:	Select the measurement mode. · Measured data when remeasuring a sample in remeasure/retest mode is applied to the positive rate. · Measured data when using a retest rack or dilute test rack is not applied to the positive rate. Select when first making a measurement. Select when remeasuring or retesting a sample.
Test/remeasure test start position (position in rack) (Not applied when starting new test.)	1 - 10	Configure the head rack test start position. · Sequence numbers are allocated from the test start position configured here. · This setting does not apply to retest or dilute test racks.

2 Touch the {Continue} button.

3 Touch the {Register} button.

* The settings were registered.

3 Configuring [Latex/CC settings]

Explanatory note : Touch the {MENU} button to return to the [MENU] screen after registration.

Test start
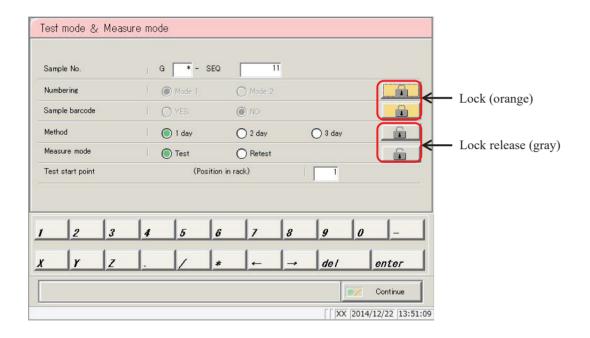
■ How to use the [padlock] (padlock) button to avoid operation errors

There is a button that looks like a padlock on the right side of the [Test mode & Measure mode] screen.
Touching this button locks the applicable settings so that they cannot be operated.
Touching the button once more releases the lock and allows operation again.
When locked it is orange; when unlocked it is gray.

Test start
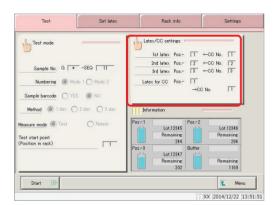
3   Configuring [Latex/CC settings]

Touching the {Test} button on the [MENU] screen opens the [Test] screen.
This section will explain operation from the [Test] screen.
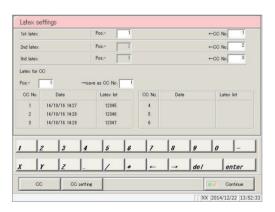
⚠ **Request**

- Check that the lot number of the reagent to use is the same as that of the reagent for the calibration curve (CC No.).
- If a calibration curve has not been prepared, do so prior to starting the test.

     If testing is started with mismatched reagent lots, a "No CC" error message will be displayed.

Test start

1   Touch the {Latex/CC settings} button.

2   Configure the reagent and calibration curve.

(See the following page.)

Explanatory note : [Latex/CC settings] can also be configured during testing on the [Additional test] screen.
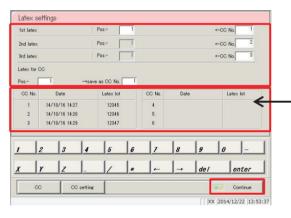
Explanatory note : Touch the {CC setting} button to open the [Protocol settings] screen. CC No. # protocol setting can be performed here. ☞ Page 314 "6.2.2 CC No. 1 to CC No. 6 protocol settings"

Explanatory note : Touch the {CC} button to open the [Check CC] screen.
The measurement date and time, reagent lot information, and graph can be checked for each calibration curve.
☞ Page 65 "■ Calibration curve confirmation"

Test start

Item	Range/Selection	Details
Reagents used by system Pos.- ☐ ← CC No. ☐	1-3 1-6	Configure the number of the reagent bottle to use. Configure the calibration curve number to use when measuring the sample.
2nd latex Pos.-2 ←CC No. ☐	1-6	Configure the calibration curve number to use when measuring the sample. ┌ Explanatory note ┐ ： The 2nd latex is the reagent that was not set as the 1st latex.
3rd latex Pos.-3 ← CC No. ☐	1-6	It is automatically configured when the 1st latex is set.
Latex for CC Pos.- ☐ → Save as CC No. ☐	1-3 1-6	Configure the number of the reagent bottle to use. Enter Save as CC No. for the reagent and calibration curve used when drawing the calibration curve.
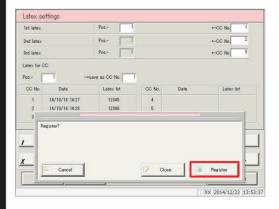
A list showing "Date" and "Latex lot" for the registered CC number is displayed. If no calibration curve is registered, nothing is displayed.

3   Touch the {Continue} button.

CC No.	Date	Latex lot
1	14/10/16 14:27	12345
2	14/10/16 14:28	12346
3	14/10/16 14:29	12347

CC No.	Date	Latex lot
4		
5		
6		

4   Touch the {Register} button.

* The settings were registered.
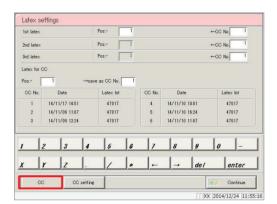
→ Page 67
   4 Starting tests
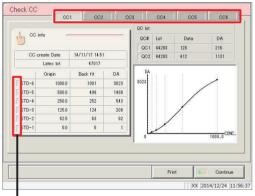
■ Calibration curve confirmation

Touch the {CC} button on the [Latex/CC settings] screen to display calibration curve information (such as date and time, and reagent lot) and the calibration curve graph.
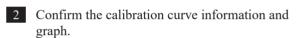
Use the tabs on the top of the screen to switch between calibration curves CC No. 1 through CC No. 6.

Test start

1 Touch the {CC} button.

2 Confirm the calibration curve information and graph.

Touch the {CC#} tab, and switch the calibration curve information.

To edit or remeasure the calibration curve,
☞ page 66 "■ Edit and recalculate calibration curves"
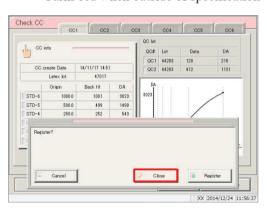
Turns red when outside of specification

3 Touch the {Continue} button.

4 Touch the {Close} button.

* The system returns to the [Latex/CC settings] screen. (Pressing the {Continue} - {Close} buttons on the [Latex/CC settings] screen in order returns to the [Test] screen.)
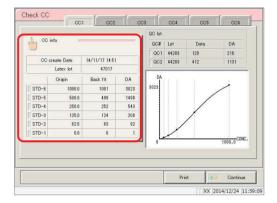
Explanatory note : The origin and DA values can be changed from the [Edit and Recal CC] screen.

☞ Page 66 "■ Edit and recalculate calibration curves"
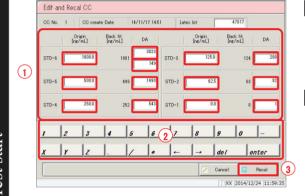
Explanatory note : If STD sample measurement results fall outside standards, the box to the left of STD-# will turn red.

☞ Page 298 "6.1.10 STD/QC analysis process settings"

Test start

■ Edit and recalculate calibration curves

Touch the {CC info} button on the [Check CC] screen to open the [Edit and Recal CC] screen. Origins and DA values are edited using the keypad, and calibration curves can be recalculated.

1 Touch the {CC info} button.

2 Edit the origin or DA value.

① Touch the "Origin" or "DA value" field to edit.

② Input the value.

3 Touch the {Recal} button ③.

* The results of recalculating the calibration curve and QC are displayed on the [Check CC] screen.
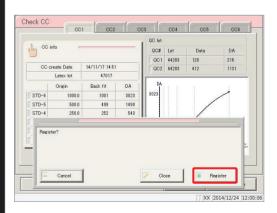
Explanatory note : The DA values of STD-1 through STD-5 are all input using DA1.
The upper DA value for STD-6 is input using DA1, while the lower value input using DA2.

Explanatory note : DA-2 of STD-6 is used for the PRC check.

☞ Page 352 "Appendix: 1.5 Prozone Check"

4 Touch the {Continue} button.
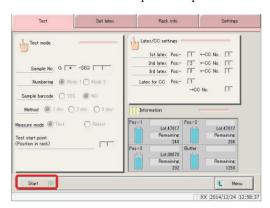
5 Touch the {Register} button.

* The result of recalculating the calibration curve and QC were registered.

* The system returns to the [Latex/CC settings] screen. (Pressing the {Continue} - {Register} buttons on the [Latex/CC settings] screen in order returns to the [Test] screen.)
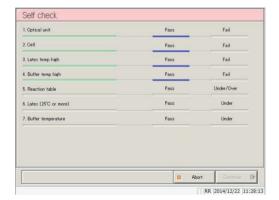
4 Starting tests

This section will explain the procedure from the [Test] screen.
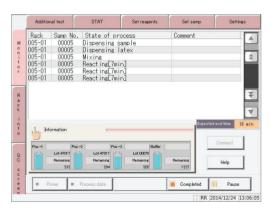
1 Touch the {Start} button.

* Self check begins.

2 Confirm the following diagnostic results

1. Optical unit (Detector)
2. Cell
3. Latex temp high (Reagent abnormal temperature)
4. Buffer temp high (Buffer abnormal temperature)
5. Reaction table (Reaction table abnormal temperature)
6. Latex (25°C or higher)
7. Buffer temperature

If self check results in "Fail",

☞ page 70 "■ Self check failed"

3 Begin testing (sample dispensing automatically starts once priming and cell blank measurement preparation is complete prior to the test starting).

* The cell blank value is calculated.

| Explanatory note | : If a calibration curve has not been created, "There is no calibration curve for~. Measure STD." is displayed.

{Cancel}: Cancel testing.

{Continue}: Continue testing without a calibration curve. Or, begin measuring the calibration curve.
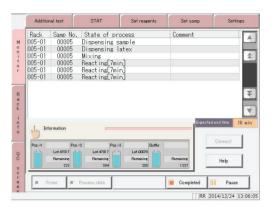
| Explanatory note | : If pipe line activation is aborted during operation using {Abort}, pipe line activation is performed when testing begins.

Test start

■ Viewing information

There is an {Information} button on the [Monitor] screen. The lot number, remaining tests for the reagent, and the remaining tests for the buffer are displayed in the button.

The images of the reagent bottle and buffer bottle show how much reagent is left in the bottles.
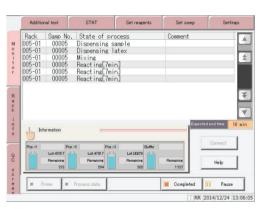
Light blue: 11% or more

Yellow: 10% or less

Red: 5% or less

Reagent Lot No.: Reagent lot number (five digits)
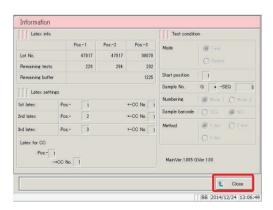
Remaining tests: Displays how many tests (approximate) can be processed based on the amount of reagent and buffer in the bottles.

1 Touch the {Information} button.

2 Confirm the information.

Touching the {Close} button returns to the [Monitor] screen.

Testing
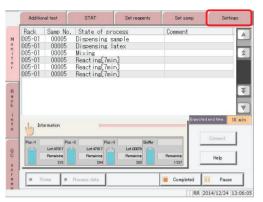
■ Confirming settings on the {Settings} tab.

Touch the {Settings} tab when the [Monitor] screen or [Additional test] screen is displayed to confirm system settings and protocol settings.

Switching to the settings screen from the [Additional test] screen allows for the modification of "cut-off value," "QC LOT," and "Max/min QC control value" settings.

Switching to the settings screen from the [Monitor] screen allows for checking settings only.

1 Touch the {Settings} button.
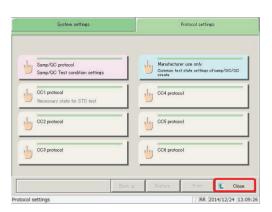
2 Touch the button of the setting to confirm.

* The setting screen is displayed.

To confirm protocol settings, touch the {Protocol settings} tab to switch to the appropriate screen.

3 Touch the button of the protocol setting to confirm.

* The protocol settings screen is displayed.

Testing

Testing

4 Touch the {Close} button.

* The system returns to the [Monitor] screen.

■ Self check failed

The method for handling a "Fail" result varies according to the diagnostic item.
Refer to the following chart.

Diagnostic Item	Handling Method
Optical unit	(1) Touch the {Abort} button. → The previous and current values are shown, and "Register the current detector maximum output value?" is displayed. (2) Touch the {Register} button. (The current value is registered)
Cell	Touch the {Abort} button. Set the cell.
Latex temp high	An error in the reagent compartment was detected when the standby switch was turned on. Touch the {Abort} button. Contact the "Customer Support Technical Center." Dispose of the reagent.
Buffer temp high	An error in the reagent compartment was detected when the standby switch was turned on. Touch the {Abort} button. Contact the "Customer Support Technical Center." Dispose of the buffer.
Reaction table	Wait until the system reaches the set temperature. When the system has reached the set temperature, the diagnostic result changes to "OK" and operation continues.
Latex (25°C or more)	
Buffer temperature	The {Continue} button can also be pressed to start testing without waiting until the temperature is reached.

Explanatory note : "Under/Over" is displayed if the self check shows that the reaction table temperature has not reached the set temperature; "Under" is displayed if the reagent or buffer has not reached the set temperature.
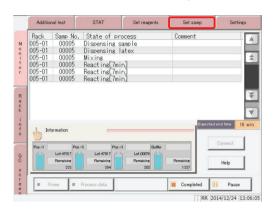
2.4.12   Adding samples (continue testing)
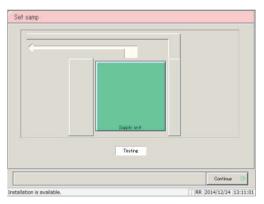
This section describes the procedure for adding samples to the rack supply unit during testing.
Auto supply of the rack begins once the rack or tray is placed in the rack supply unit.
(If [Config] - [Rack auto start] is set to "YES" ☞ page 276 "6.1.4 Config")

Explanatory note : When the last rack in the supply unit (tray) is sent to the conveyance line, the supply bar automatically moves to the front.

1 If [Rack auto start] is set to "NO", or if using a tray (optional), touch the {Set samp} tab.

* The supply bar of the supply unit moves to the front.
* If there is one rack on the tray, the supply bar moves to the front after the rack is supplied.

2 Place the rack in the supply unit.

Trays (optional) can also be individually placed in racks.

⚠ Request

· When placing a tray in the supply unit, hold it by hand so that the head rack does not jump to the conveyance line or fall.

⚠ Caution	
🚫 Prohibited	· Do not forcibly change the tray while the supply bar has not returned to the front. Failure to observe this precaution may damage the supply bar.
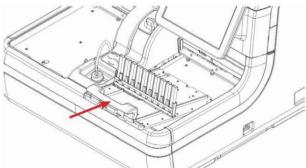
⚠ Request	
❗ Required	· When setting racks to trays, face the rack barcode to the front. Failure to observe this precaution could cause a barcode reading error.
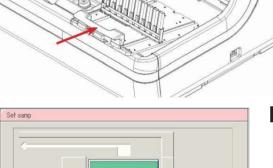
[Explanatory note] : Trays cannot be placed in the supply unit while the supply bar has not returned to the front.
In this case, place racks individually in the supply unit tray.
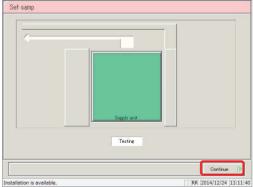
<Placing racks at the tray level>
(1) Remove the empty tray.
(2) Place the tray to which the rack has been set in the supply unit.
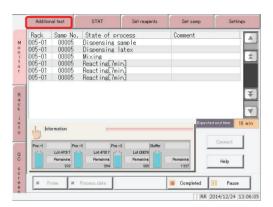
3 Touch the {Continue} button.

* The system returns to the [Monitor] screen.
* Rack supply begins.

Testing

NN1-1384 Rev.0
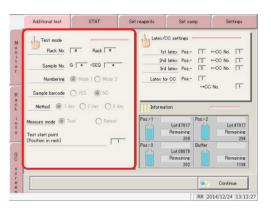
2.4.13 Additional tests (changing test conditions while testing)

Perform an "additional test" when changing test conditions and testing a sample, during testing.

During additional testing, configure the "Rack No." and "Rack" to start testing with the modified conditions.

When testing of the number of specified racks is finished, the system returns the test conditions to their previous values. However, the sample number does not revert.

1 Select the {Additional test} tab.

2 Touch the {Test mode} button.

3 Change the test conditions.

(See the chart on the following page.)

Explanatory note : When the last rack in the rack supply unit (tray) is sent to the conveyance line, the supply bar automatically moves to the front.

Testing
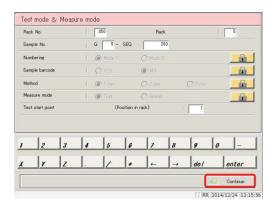
Item	Range/Selection	Details
Rack No. ☐	*(default) 1-99	Configure the [Rack No.] to start testing with the modified conditions. If the value is not changed from "*", an error will occur when the {Continue} button is touched.
Rack ☐	*(default) 1-99	Configure the [Rack] to test with the modified conditions. If "*" is input, all racks from the configured rack number will be tested with the modified conditions.

Sample No.
G ☐ - SEQ ☐
		Configure the number of the head sample.
		    A sample number consists of a group number (G) and a sequence number (SEQ).
		    Enter "*" to skip configuring a group number.

Group No. (G) Sequence No. (SEQ)	*, 1-9 1 - 99999	If "*" is input for the sequence number, sequence numbers will be assigned in sequence from the previous sample number.
Numbering		If there is a position in which a sample has not been set, configure how to allocate sequence numbers.
	YES:	Allocate sequence numbers only to set samples. Even if there are empty positions, a "No tube" error will not occur.

Continued on next page

┌─────────────────┐
│ Explanatory note │ : Sequence numbers are allocated in serial order for each measure mode (test mode,
└─────────────────┘   remeasure/retest mode, dilute test).

Testing

Item	Range/Selection	Details
Numbering	NO:	Allocate sequence numbers even to positions in which samples are not set. A "No tube" error will occur if there are any empty positions.
Sample barcode		Configure whether or not to use sample barcodes. ・ Settings are also applied to [Settings] - [System settings] - [Samp barcode settings].
	YES:	Use sample barcodes.
	NO:	Do not use sample barcodes.
Measurement method		Select the measurement method. (If S-Hb is selected, [Method] cannot be configured.)
	1 day:	Measure using 1 day method.
	2 day:	Measure using 2 day method.
	3 day:	Measure using 3 day method.
Measure mode		Select the measurement mode. ・ Measured data when remeasuring a sample in remeasure/retest mode is applied to the positive rate. ・ Measured data when using a retest rack or dilute test rack is not applied to the positive rate.
	Test:	Select when first making a measurement.
	Retest:	Select when remeasuring a sample.
Test/remeasure test start position (position in rack)	1-10	Configure the head rack dispensing start position. ・ This setting does not apply to retest or dilute test racks. ・ Sequence numbers are allocated from the test start position.

Testing

4 Touch the {Continue} button.

5 Touch the {Register} button.
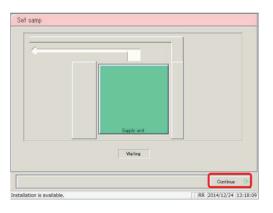
{Register}: Register configured settings.

{Close}: Cancel test mode and measure mode selection, and return to the [Additional test] screen.

{Cancel}: The dialog box closes.
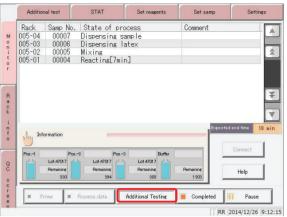
6 Touch the {Continue} button.

* The system returns to the [Monitor] screen.
* Rack supply begins.

Explanatory note : When an additional test has been received, "Additional Testing" is displayed on the [Monitor] screen.

Explanatory note : When the number of racks has been configured and the applicable rack is supplied, the "Additional Twating" message changes to "Running additional test."
Once testing is complete for all configured racks, the "Running additional test" message disappears.

Explanatory note : If the number of racks has not been configured ("*" input), the "Running additional test" message is not displayed.
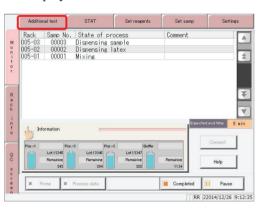
Explanatory note : Additional tests cannot be made while the "Additional Testing" or "Running additional test" messages are displayed.
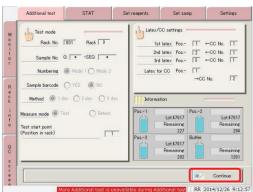
■ Canceling additional tests

Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.

1 Select the {Additional test} tab.

2 Cancel the additional test.
① Touch the {Continue} button.
  * The dialog box is displayed.
② Touch the {Cancel} button.
  * The additional test is canceled.

2.4.14 Cut-in analysis

Cut-in analysis for sample racks and STD/QC racks can be run during testing. (Cut-in analysis)

The measurement mode and method for cut-in analysis are "Test mode" and "1 day," respectively.

Cut-in analysis cannot be performed on retest racks and dilute test racks.

⚠ Request	
❗ Required	· Wait for the "Please wait, a rack is still being tested" message to disappear, then place the rack at the STAT rack position. If a rack is left on the conveyance line, the system will misidentify it and testing cannot begin.
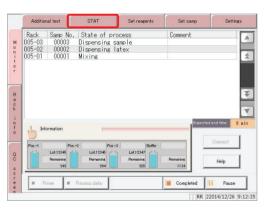
⚠ Request	
🚫 Prohibited	· Do not stop cut-in analysis when measuring an STD sample. The data being measured will be deleted.

Explanatory note : If a retest rack or dilute test rack is cut-in during cut-in analysis, the system will display "Rack barcode Unavailable" and the rack will be discharged to the STAT rack position.
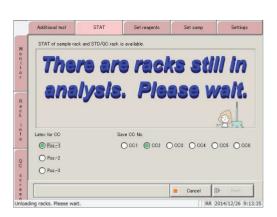
1 Select the {STAT} tab.

    * Rack supply stops.
    * The conveyance line rack is discharged.
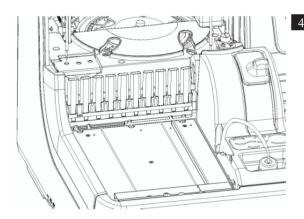
2 Wait until the "There are racks still in analysis. Please wait." message disappears.
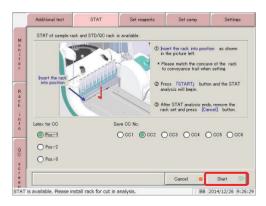
3 To cut-in an STD/QC rack, configure Latex for CC and registration destination CC number.
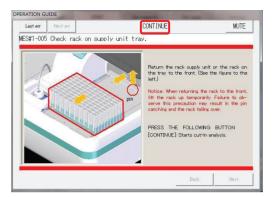
Item	Range/Selection	Details
Latex for CC	Pos.-1 Pos.-2 Pos.-3	Select the reagent to use.
Save CC No.	CC 1-CC 6	Configure the registration destination CC number of the created calibration curve.

4 Latch the "STAT rack position" conveyance bar into the groove in the middle of the rack, and place the rack.

5 Touch the {Start} button.

　　　* The rack is conveyed to the right.

Testing

6   Check the rack supply unit and the rack on the tray.

<Cut-in STD/QC rack>
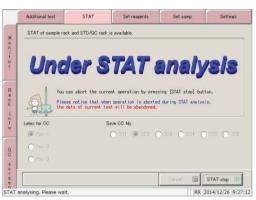
① Return the rack supply unit or the rack on the tray to the front. (See the figure to the left.)

Explanatory note : When returning the rack to the front, lift the rack up temporarily. Failure to observe this precaution may result in the pin catching and the rack falling over.

② Touch the {Continue} button.

<Cut-in sample rack>

Touch the {Continue} button.

7   Begin testing the STAT rack.

{STAT stop}: Stop cut-in analysis.
The STAT rack is discharged to the STAT rack position.
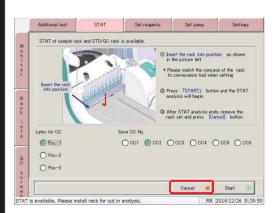
Explanatory note : Follow operations **4** and **5** to run cut-in analysis again on a rack for which cut-in analysis was stopped.

Explanatory note : When cut-in analysis is stopped during calibration curve creation, the current measurement data is lost.

8   Finish cut-in analysis.

* Racks for which testing has completed are discharged to the STAT rack position.

① Remove the STAT rack.

② Touch the {Cancel} button.

* Normal testing resumes.

2.4.15   Completing testing (normal close)

To complete testing, touch the {Completed} button on the [Monitor] screen, and select {Normal close}. When testing is complete for all samples on the reaction table, the system returns to the [MENU] screen.

To pause or abort testing, see the sections explaining each operation.

To "pause" testing, see page 82 "■ Pausing testing."
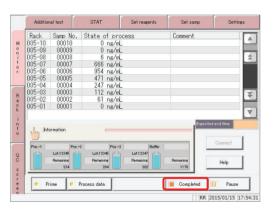
To "abort" testing, see page 83 "■ Aborting testing."
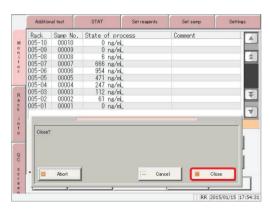
1 Touch the {CLOSE} button.

To continue testing, place the sample rack in the rack supply unit.
☞ Page 71 "2.4.12 Adding samples (continue testing)"

2 Touch the {Completed} button.

3 Touch the {Close} button.

* The system returns to the [MENU] screen.
* The results of the measured samples are printed.
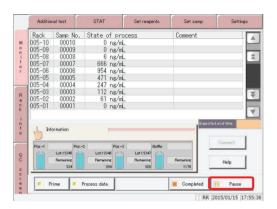
{Close}:   Finish testing.
{Cancel}:   The dialog box closes.
{Abort}:   Finish testing during processing.

Testing completed
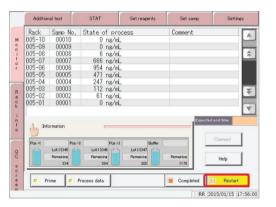
■ Pausing testing

Touching the {Pause} button on the [Monitor] screen pauses sample dispensing. (Reagent dispensing, mixing, detection, and washing operations are not stopped.)

Testing completed
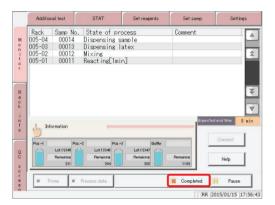
1 Touch the {Pause} button.

* The {Pause} button changes to the {Restart} button.
* Sample dispensing pauses.
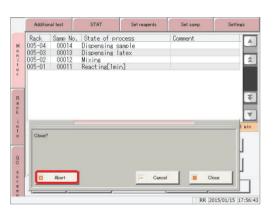
2 Touch the {Restart} button.

* Operation is resumed.

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■ **Aborting testing**

Touching the {Abort} button on the [Monitor] screen stops all operations and returns to the [MENU] screen.

1 Touch the {Completed} button.

2 Touch the {Abort} button.

 * The system returns to the [MENU] screen.
 * The result of the sample being measured is discarded.

{Close}: Finish testing.

{Cancel}: The dialog box closes.

{Abort}: Finish testing during processing.

Testing completed

2.5　Inspection/Maintenance after Use

Run daily inspection and maintenance before turning the system off.
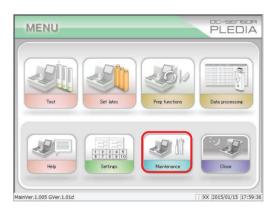
Touch the {Maintenance} button from the [MENU] screen to open the [Maintenance] screen.

"Inspection/maintenance" items are displayed on the screen. Follow the instructions on screen to clean each part periodically.
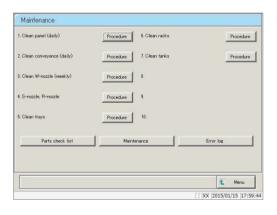
The "Parts check list" and "Error list" can also be displayed from the [Maintenance] screen.

Check these as needed.

2.5.1　Cleaning parts

1 Touch the {Maintenance} button.

2 Clean each part.

The parts to clean are as follows.

1. Clean panel (daily) : Clean touch panel
2. Clean conveyance (daily)
    : Clean conveyance line
3. Clean W-nozzle (weekly)
    : Clean washing nozzle
4. S-nozzle, R-nozzle (weekly)
    : Clean sample & reagent nozzles
5. Clean trays (weekly)
6. Clean racks (weekly)
7. Clean tanks (monthly)

Explanatory note : If there are parts for which the exchange period has been exceeded, "Some parts should be exchanged. Please check list of parts to check and exchange." is displayed.

Inspection/maintenance

3 To view procedures touch the {Procedure} button. Cleaning procedures are displayed.

4 When cleaning is complete, touch the {Close} button.

{Parts check list}:	Display a list of parts that need to be inspected or exchanged.	

☞ Page 86 "2.5.2 Opening the parts check list"

{Error log}: The error log is displayed. Up to 1000 error log entries can be viewed.
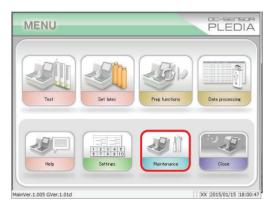
☞ Page 88 "2.5.3 Opening the error log"

[MENU]: Return to the [MENU] screen.
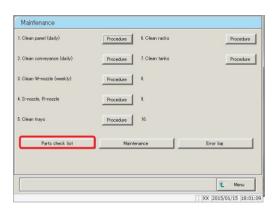
{Maintenance}: Adjust the system and check operation. (This is for maintenance people.)

Inspection/maintenance

```
┌─────────────────────────────────────────────────────────────────┐
│   2.5.2     Opening the parts check list                          │
└─────────────────────────────────────────────────────────────────┘
```
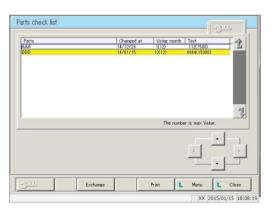
The [Parts check list] screen displays parts, when they were last changed, the number of months they were used (maximum months used), and how many times they have been used (maximum times used).

1 Touch the {Maintenance} button.

2 Touch the {Parts check list} button.
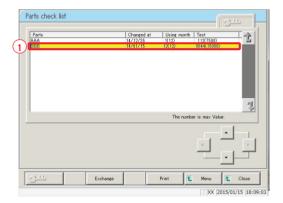
3 Check whether there are any parts that need to be exchanged.
Displayed content is shown in the chart on the following page.

If there are parts that have exceeded the maximum values for number of months used and number of times used, the background of the part turns yellow.

No.	Item	Details	Remark
(1)	Parts	Name of the part to exchange	Up to 15 (full-width alphanumeric characters) or 7 (full-width characters) digits can be displayed.
(2)	Changed at	Date the part was exchanged (YY/MM/DD)	
(3)	The number of months used	The number of months used since last exchange	
	( )	Maximum months used	
(4)	Test	The number of times used since last exchange	
	( )	Maximum times used	

4   Exchange the part.

① Select the part to exchange (in yellow).

② Exchange the part.
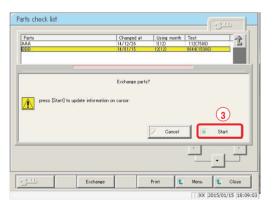
③ Touch the {Exchange} button.

　* A confirmation dialog box asking "Exchange parts?" is displayed.

{Exchange}: Touch after the part has been exchanged.

{Print}: Print the parts check list.

{MENU}: Return to the [MENU] screen.

{Close}: Return to the [Maintenance] screen.

④ Touch the {Start} button.

　* "Changed at" is updated to the current day.
　* "Using month" and "Test" are reset to "0."
　* The dialog box closes.

{Start}: Part exchange information is updated.

{Cancel}: The dialog box closes.
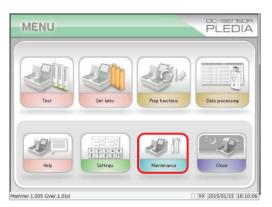
Explanatory note : Part can be exchanged even if a part that is not yellow is selected.

Inspection/maintenance

<div style="border: 1px solid;">
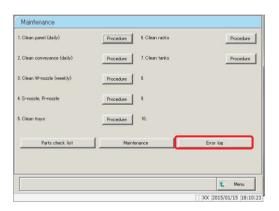
2.5.3　Opening the error log

</div>

The [Error log] screen displays the date the error occurred, the error code, and the name of the error (details).
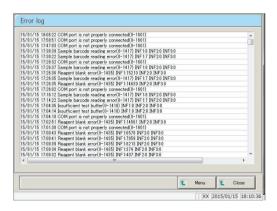
Up to 20 errors can be displayed on a single screen, and up to 1,000 errors can be displayed on a single list. If there are 21 or more errors, use the scroll bar to scroll the list.

1　Touch the {Maintenance} button.

2　Touch the {Error log} button.

3　Confirm the error details.

{MENU}： Return to the [MENU] screen.
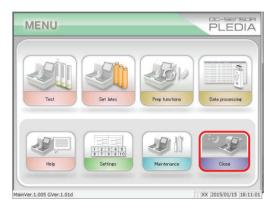
{Close}： Return to the [Maintenance] screen.

2.6   System shutdown (Close mode/Long suspense mode)
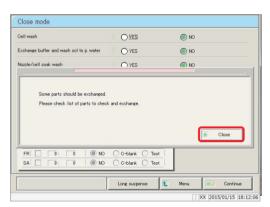
There are two methods to shut the system down: "Close mode" and "Long suspense."

Select "Close mode" to shut the system down normally. Select "Long suspense" when the system will not be used for a long time. Both modes will automatically turn the standby switch off. (The primary power switch is not turned off.)

2.6.1   Close mode

1 Touch the {Close} button.

2 If there are parts for which the exchange period has been exceeded, "Some parts should be exchanged. Please check list of parts to check and exchange." is displayed.
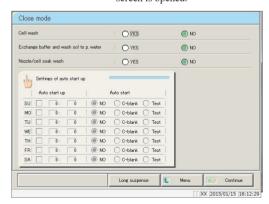
Touch the {Close} button and then the {MENU} button in order to return to the [MENU] screen.

☞ Page 86 "2.5.2 Opening the parts check list"

{Long suspense}: Transition to the [Long suspense] screen.

Explanatory note : It is also possible to close without exchanging parts. To do so, touch the {Close mode} button, then select the process to run when complete. However, the same message will be displayed the next time the [Close mode] screen is opened.
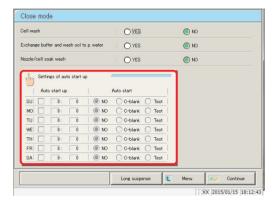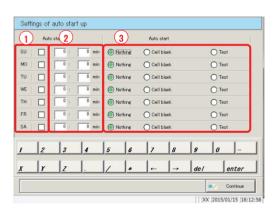
3 If there are no parts for which the exchange period has been exceeded, select the process to run when complete.
(See the chart on the following page.)

System shutdown

Item	Range/Selection	Details
Cell wash	YES: NO:	Wash measurement cells when complete. Do not wash measurement cells when complete.
Exchange buffer and wash sol to p. water	YES: NO:	Exchange with purified water. Do not exchange with purified water.
Nozzle/cell soak wash	YES: NO:	Run soaking preservation. Do not run soaking preservation.

4 Touch the {Settings of auto start up} button.

5 Configure the day of the week and time to automatically start the system next (see the following chart).

① Check the day of the week.

② Input the time.
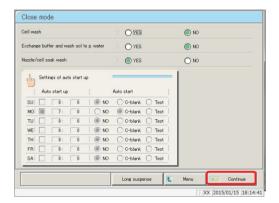
Configure the operation to run automatically after start up, for each day of the week (see the following chart).

③ Check either "Nothing," "Cell blank," or "Test."
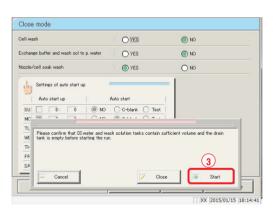
6 Register configured settings.

① Touch the {Continue} button.
  * The dialog box opens.

② Touch the {Register} button.

System shutdown

Item	Range/Selection	Details
None	● Check: ○ Do not check:	Display the [MENU] screen after starting. Run the selected operation after starting.
Cell blank	● Check: ○ Do not check:	Run [Prep functions] - [Cell blank] after starting, then display the results. Do not run cell blank measurement after starting.
Test	● Check: ○ Do not check:	Automatically start testing after starting. If a rack is not placed in the rack supply unit, the system operates for a short while, then enters standby mode. Testing does not start automatically after starting.

7   Touch the {Continue} button.

8   Run close mode.

    ①   Confirm that the "purified water tank" and "wash solution tank" are not empty.

    ②   Confirm that the "drain tank" is not full.

    ③   Touch the {Start} button.

{Start}:   Run close mode.

{Close}:   Cancel close mode and return to the [MENU] screen.
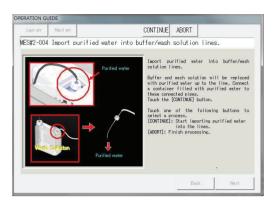
{Cancel}:   The dialog box closes.

9   Start washing cells (when "Cell wash" is set to "YES").

System shutdown

10 Exchange buffer and wash solution in the piping with purified water (when "Exchange buffer and wash solution to purified water" is set to "YES").

① Remove the piping connected to the buffer bottle.

② Connect a container filled with purified water to the piping in ①.

③ Remove the piping connected to the wash solution tank.

④ Connect a container filled with purified water to the piping in ③.

⑤ Touch the {Continue} button.

⚠ Request

・ If buffer and wash solution have been exchanged with purified water, be sure to run pipe line activation the next time the system is started.

---

11 Soak wash the nozzle and cell (when "Nozzle/cell soak wash" is set to "YES").

* The standby switch shuts off.
* Settings made in close mode are saved.

12 The system turns off.
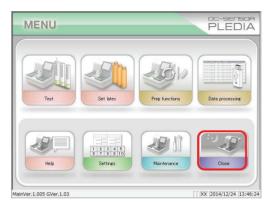
Explanatory note : If power is forced off when the system is processing in close mode, the process is disabled even if "Cell blank" and "Test" are set to run (● check) in the automatic start settings.

System shutdown
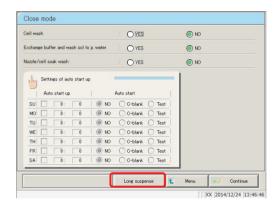
MEMO
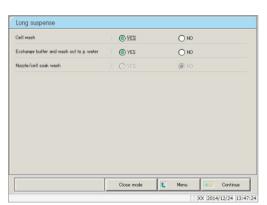
2.6.2 Long suspense

1 Touch the {Close} button.
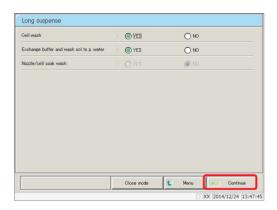
2 Touch the {Long suspense} button.
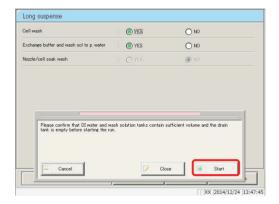
3 Select the process to run when complete. (See the chart below)

{Close mode}: The [Close mode] screen is displayed.

Item	Range/Selection	Details
Cell wash	YES: NO:	Wash cells when complete. Do not wash cells when complete.
Exchange buffer and wash sol to p. water	YES: NO:	Exchange with purified water. Do not exchange with purified water.
Nozzle/cell soak wash	YES: NO:	Cannot be selected.

System shutdown

4 Touch the {Continue} button.

5 Run close mode.
- ① Confirm that the "purified water tank" and "wash solution tank" are not empty.
- ② Confirm that the "drain tank" is not full.
- ③ Touch the {Start} button.

{Start}: Run close mode.

{Close}: Cancel close mode and return to the [MENU] screen.
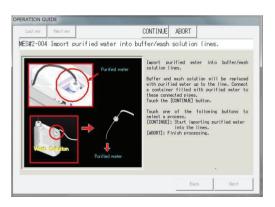
{Cancel}: The dialog box closes.

6 Begin washing the cell.

(When "Cell wash" is set to YES.)

→ to **8**

7 Exchange buffer and wash solution in the piping with purified water (when "Exchange buffer and wash solution to purified water" is set to "YES").
- ① Remove the piping connected to the buffer bottle.
- ② Connect a container filled with purified water to the piping in ①.
- ③ Remove the piping connected to the wash solution tank.
- ④ Connect a container filled with purified water to the piping in ③.
- ⑤ Touch the {Continue} button.

Explanatory note : If buffer and wash solution have been exchanged with purified water, be sure to run pipe line activation the next time the system is started.

System shutdown

Remove the purified water/wash solution/buffer piping.

2.7   Drain Tank Processing

Remove the maximum-level sensor and hose attached to the drain tank, then dispose of the drainage in the tank.

Run through the procedure listed on page 39 "2.4.3 Setting the drain tank" in reverse to remove the maximum-level sensor and hose.

⚠ Warning	
Biohazard	· Wear protective equipment when handling the drain tank. Failure to observe this precaution may lead to contamination.

System shutdown

Chapter 3   Operation (Applied)

OC-SENSOR
PLEDIA

Chapter 3   Operation (Applied)

3.1   Measured Data Processing
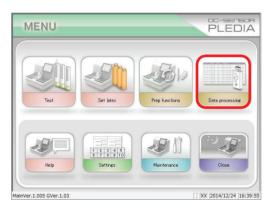
Select the measured data from the [Process data] screen, and then edit, delete, change the positive rate, or display the histogram.

> Explanatory note : ・Measured data is saved for each item.
>
> ・ Up to 100,000 sample and STAT sample tests can be saved to the hard disk(SSD). Once 100,000 tests have been reached the system will begin overwriting the oldest data.
>
> ・ Up to 5,000 QC sample tests can be saved to the hard disk(SSD). Once 5,000 tests have been reached the system will begin overwriting the oldest data.
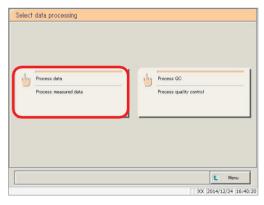
3.1.1   Opening the [Process data] screen

Open the [Process data] screen by touching the {Data processing} - {Process data} buttons on the [MENU] screen, or by touching the {Process data} button on the [Monitor] screen. A password will need to be entered if one was set in the environment settings.

1   <Opening from the menu screen>

① Touch the {Data processing} button.
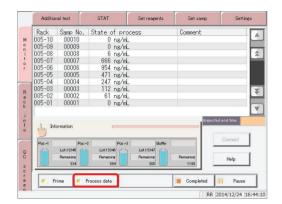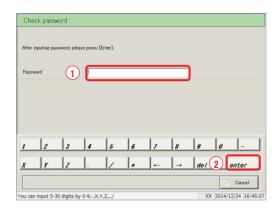
② Touch the {Process data} button.

<Opening from the monitor screen>

Touch the {Process data} button.
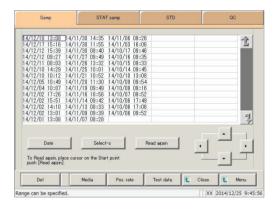
2 Enter a password (displayed when a password was registered in [System settings] -[Config]).

① Enter a password.

② Touch the {enter} key.

3 The [Process data] screen was displayed.

* The {Samp} tab is selected.
* The measurement date and time list is displayed.

Explanatory note : The measurement date and time is the time the system started up.
If there is no data to process, the time is not displayed.
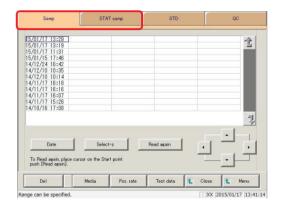
3.1.2   Displaying the [Test data] screen

Select measured data by switching between the {Samp}, {STAT samp},{STD}, and {QC} tabs on the [Process data] screen. Press the {Test data} button after selecting measured data and specifying a measurement date to display the specified data (the [Test data] screen varies according to whether the {Samp} or {STAT samp} tabs were selected, or the {QC} tab was selected).

[Explanatory note] : The displayed date and time is the date and time the standby switch was turned on. (That is, the system startup time.) Data measured until the standby switch is turned off is saved to the hard disk(SSD) as data from that day.

[Explanatory note] : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

■1   Touch the tab of the measured data to display.

{Samp} tab
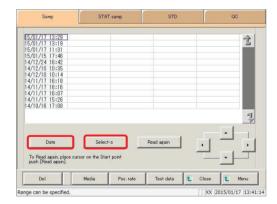
{STAT samp} tab

{STD} tab

☞   Page 182 "3.7.2 Displaying the [Replicate (STD)] screen"

{QC} tab

☞   Page 186 "3.7.4 Displaying the [Replicate (QC)] screen"

■2   Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞   Page 104 "3.1.3 Specifying measured data by measurement date" ■2

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞   Page 106 "3.1.4 Specifying measured data by range" ■2
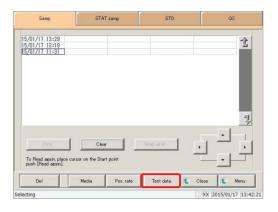
[Explanatory note] : If {Date} or {Select-s} are not used, all displayed measured data (a max of 5,000 samples of data) will be processed.

3 Touch the {Test data} button.
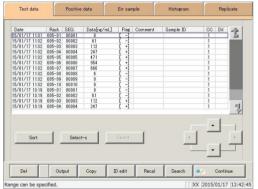
{Close}:   Return to the [Data process selection] screen.
          Or, return to the [Monitor] screen.
          (If {Test data} button on [Monitor] screen as touched.)
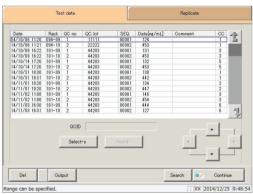
{MENU}:   Return to the [MENU] screen.

4 The measured data was displayed.

{Samp} or {STAT samp} tabs were selected

(Explanatory note) : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is
                       displayed in blue text.

{QC} tab was selected

Content displayed on [Test data] screen (Samp/STAT samp)

Display	Details		Remark
Date	Date and time sample was measured		
RACK	Rack No. - Position number in rack		
SEQ.	Group No. - Sequence No.		
Data [ng/mL]	Measurement results (concentration value)		
Flag	-, +, 1 +, 2 +, 3 +		
Comment	Error information (excluding reading errors)		
	UR	: Under range	Blank output for measured data and judgment result
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode information on sampling bottles		
CC	Calibration curve used to calculate measured data (CC No.)		
Dil	Dilution information		
	Space	: No dilution (test mode, remeasure mode)	
	A	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Content displayed on [Test data] screen (QC)

Display	Details		Remark
Date	Date and time QC sample was measured		
RACK	Rack No. - Position number in rack		The rack position number of QC samples is 9 or 10.
QC No.	QC No.1 - 4		
QC LOT	QC lot (five digits)		
SEQ.	QC sequence number		
Data [ng/mL]	Measurement results (concentration value)		
Comment	Error information (excluding reading errors)		
	UR	: Under range	
	OR	: Over range	
	PRC	: Prozone	
CC	Calibration curve used to calculate measured data (CC number)		
QC ID	QC ID of QC sample at cursor position		

3.1.3 Specifying measured data by measurement date
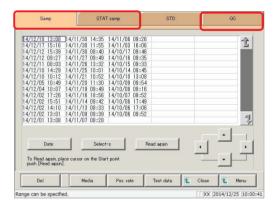
Specify the measurement date of the measured data to display from the [Process data] screen.

(Explanatory note) : When entering the measurement date, if part of the year, month, or day is omitted, the system will begin a search from the latest measurement date to find the measured data with the latest date that matches the entered conditions.

☞ **3** on the following page (example)
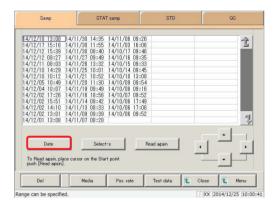
(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

(Explanatory note) : A measurement date is not specified for STD measured data.

1 Touch the tab of the measured data to display.
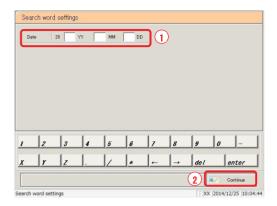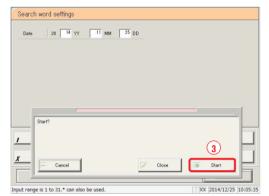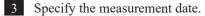
{Samp} tab
{STAT samp} tab
{QC} tab

2 Touch the {Date} button.

3 Specify the measurement date.

① Touch the input field and enter the year, month, and day.

If part of the year, month, or day is omitted, the system will begin a search from the latest measurement date to find the data with the latest date that matches the entered conditions.

(Example) If October 5 is entered and the year is omitted, the search will display only data for the current year.

For example, if the current year is 2013:

2013/10/05 10:10 (displayed)
2013/10/05 10:15 (displayed)
2013/10/05 10:20 (displayed)
2012/10/05 14:25 (not displayed)

·
·
·

2012/10/05 14:30 (not displayed)
2012/10/05 14:35 (not displayed)

② Touch the {Continue} button.
③ Touch the {Start} button.
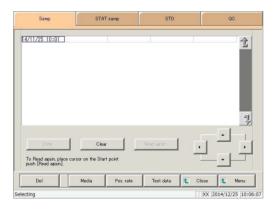
{Start}: Search for data using the specified measurement date.

{Close}: Cancel measurement date specification, and return to the [Data process selection] screen.

{Cancel}: The dialog box closes.

4 The data for the specified measurement date is displayed.

Explanatory note: To specify a new measurement date, touch the {Clear} button.

All measured data is displayed, and the system returns to the state it was in before the range was specified.

3.1.4   Specifying measured data by range

Specify the measured data to display using a measurement date and time range (start point/end point).

Specify the range by touching the measurement date and time on the [Process data] screen, or by using the cursor buttons.

Specify the start point and touch the {Select-s} button to confirm the measured data at the start point.

Then, specify the end point and touch the {Select} button to confirm the measured data at the end point.
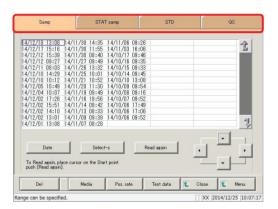
After confirming the start and end points, the measured data between the start and end points is specified as the range.

(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the
                          [Process data] screen.

(Explanatory note) : If a range is not specified, all data (up to 5,000 samples' worth) displayed on screen will be
                          processed.

1   Touch the tab of the measured data to display.

{Samp} tab
{STAT samp} tab
{STD} tab
{QC} tab
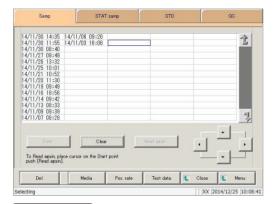
2   Specify the measurement date and time at the start point.

① Touch the date and time that will be the start point.

② Touch the {Select-s} button.

    * The measurement date and time at the start point was confirmed. (The text turns blue)
    * When the start point is confirmed, the {Select-s} button changes to the {Select} button.

(Explanatory note) : The date and time of the start and end points can also be specified using the cursor buttons.

3   Specify the measurement date and time at the end point.

①   Touch the measurement date and time that will be the end point.

②   Touch the {Select} button.

* The measurement date at the end point is confirmed.

* When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Clear}:   Clear the range specification.

4   The measured data for the specified range is displayed.
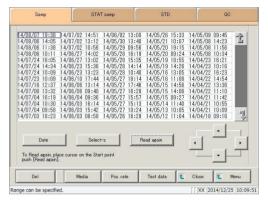
Explanatory note : · If the dates and times specified for the start and end points are the same, the system will handle it as though only a single sample of measured data was specified.

· To specify a new range, touch the {Clear} button. All measured data is displayed, and the system returns to the state it was in before the range was specified.

<div style="border:1px solid">

3.1.5 Reading "measured data" not in the list (reading again)

</div>
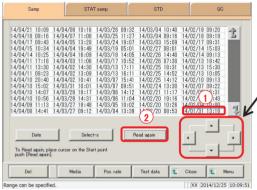
Up to 5,000 samples' worth of measured data can be displayed in the list and edited. (Up to 100,000 samples' worth of measured data can be saved to each test item.) Data must be read in order to edit measured data not displayed in the list. Specify the date and time that will be the start point from the list, select whether to display data before or after that point, then read the data to edit.

[Explanatory note] : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1 Touch the tab of the measured data to read.

{Samp} tab
{STAT samp} tab
{STD}
{QC}

2 Specify the start point and read the measured data.

① Touch the measurement date and time that will be the start point.

(The cursor buttons at the bottom right of the screen can also be used to select this.)

② Touch the {Read again} button.

③ Select the reading method. (See the chart below.)

④ Touch the {Start} button.

* Begin reading measured data.

{Cancel}: Close the dialog box.

{Close}: Return to the [Data process selection] screen.
Or, return to the [Monitor] screen.
(When the {Test data} button has been touched on the monitor screen.)

{MENU}: Return to the [MENU] screen.

Selection	Details
● Get data before the date on the cursor.	Read data from before the date and time at the cursor position. (This does not include the date and time at the cursor position.)
● Get new data after the date on the cursor.	Read data from after the date and time at the cursor position. (This does not include the date and time at the cursor position.)

3.1.6 Reading "measured data" from external media (switching external media)

Read measured data saved to external media and display it on the screen.
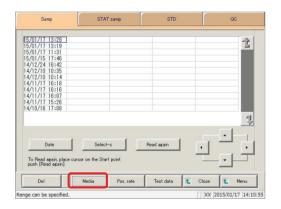
This function is not available for STD and QC sample measured data.

Explanatory note : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1 Touch the tab of the measured data to read.
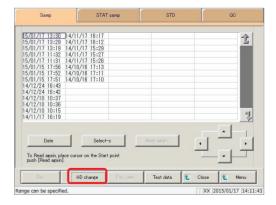
{Samp} tab

{STAT samp} tab

2 Touch the {Media} button.

* Read the data from the hard disk(SSD).

* Measured data (up to 5,000 samples' worth) saved to the external media is displayed.

* Data is displayed in order of date, with data having the latest measurement date and time displayed first.
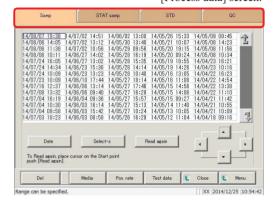
3 Touch the {HD change} or {SSD change} button.

3.1.7   Sorting measured data

Sort the measured data by measurement date and time or group, and narrow down measured data to process.
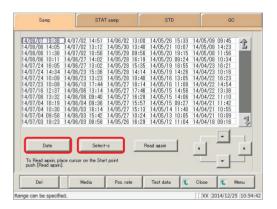
When sorting by measurement date and time, measured data is displayed in ascending order by "date."

When sorting by group, measured data is displayed in ascending order by "sample number group."

⬚ Explanatory note ⬚ : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1 Touch the tab of the measured data to display.

{Samp} tab
{STAT samp} tab
{STD}
{QC}

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time"   **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range"   **2**
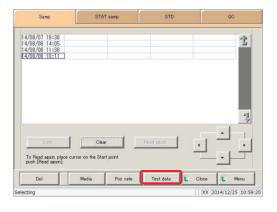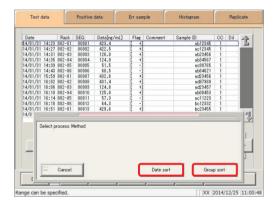
3 Touch the {Test data} button.

4 Touch the {Sort} button.

5 Touch the {Date sort} button or the {Group sort} button.
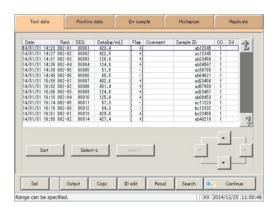
              * The sorted measured data is displayed.

{Date sort}:   Sort measured data in ascending order by measurement date and time.

{Group Sort}:   Sort measured data in ascending order by sample number group.

{Cancel}:   Cancel sorting measured data.

6 Specify a range to further narrow down the measured data being displayed.

The procedure is the same as in the [Process data] screen.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

3.1.8   Searching for measured data
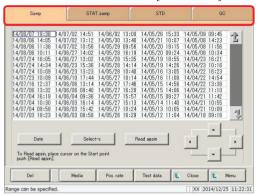
Search measured data based on sample ID, sample number, rack number, and measurement date and time.

> ⎡Explanatory note⎤ : Measured data cannot be searched for using the rack position number.
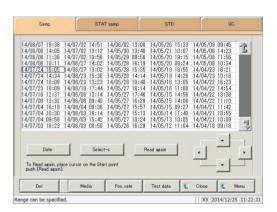
> ⎡Explanatory note⎤ : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.
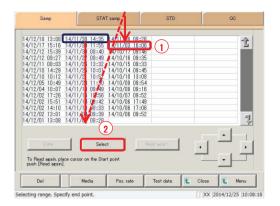
1   Touch the tab of the measured data to display.

{Samp} tab

{STAT samp} tab

{STD}

{QC}

2   Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞   Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞   Page 106 "3.1.4 Specifying measured data by range" **2**

3   Touch the {Test data} button.
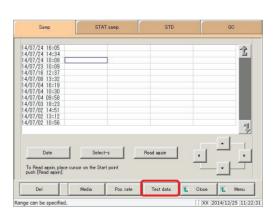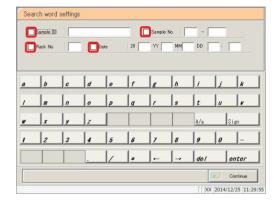
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4   Search for target samples.

① Touch the target tab.

② Touch the {Search} button.
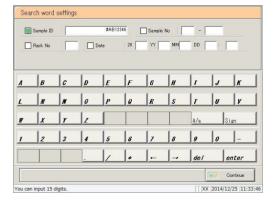
5   Select the type of keyword to search.

☐ Sample ID

☐ Sample No.

☐ Rack No.

☐ Date

6   Enter a keyword.

① Touch the "input field" next to the name of the keyword.

② Enter a keyword using the keypad.

③ Touch the {enter} key.
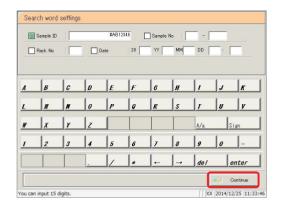
Explanatory note : The {A/a} and {Sign} buttons are available when the cursor is in the input field.

Explanatory note : Entry of the group number and measurement date and time can be omitted. However, if a measurement date and time box is checked, it is necessary to input at least one of the following: year, month, date, hour, and minute.

{A/a}:   Switch input between uppercase and lowercase.
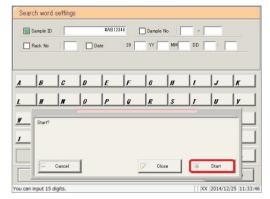
{Sign}:   Allows for input of symbols.
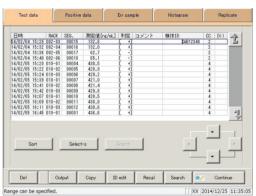
7 Touch the {Continue} button.

8 Touch the {Start} button.

    * Start searching.

9 Search results are displayed.

{Search}: Allows search to continue.

——————— MEMO ———————

3.1.9   Recalculating measured data

Recalculate measured data using modified cut-off values, as well as factors A and B.

[Explanatory note] : The values used for judging measured data for which a range has been specified are shown in Cut off 1, Cut off 2, and Cut off 3.
If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1, Cut off 2, and Cut off 3.

[Explanatory note] : If the factor value differs according to the measured data, factor A and factor B are displayed as 1.00 and 0.00, respectively.

[Explanatory note] : Values configured in the [Recalculation condition settings] screen are not applied to protocol settings. Recalculation is a form of calculation for the purpose of correction using values configured in condition settings. It is not fitting calculation to a calibration curve

---

1 Touch the tab of the measured data to recalculate.

{Samp} tab

{STAT samp} tab

---

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

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3 Touch the {Test data} button.

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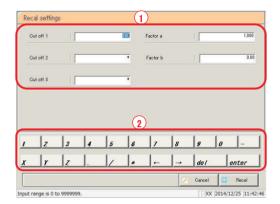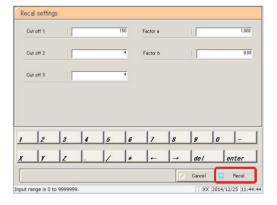
4 Touch the {Recal} button.
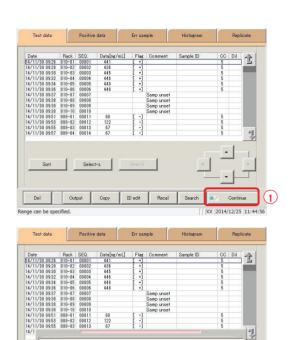
5 Configure the recalculation conditions.

① Touch the "input field" next to the setting.
- Cut off 1
- Cut off 2
- Cut off 3
- FACTOR A
- FACTOR B

② Enter numbers using the numeric keypad.

Setting	Input Range
Cut off 1	0-9,999,999
Cut off 2	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
FACTOR A	0.001-99,999.999
FACTOR B	-999.99-999.99

6 Touch the {Recal} button.

{Cancel}: Cancel recalculation and return to the [Test data] screen

7 The recalculated measured data was displayed.

To update the recalculated data:
① Touch the {Continue} button.
② Touch the {Register} button in the dialog box.

Recalculation results when the Samp/QC protocol settings have changed

⚠ Request
! Required	· When changing the Samp/QC protocol settings and recalculating, touch the {Memory} button on the [Check CC] screen first, and then recalculate. ☞ Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)"

· If the maximum measurement value [ng/mL] is set to "*" and recalculation is run, data that resulted in OR will have a result other than OR.

· If the maximum measurement value [ng/mL] is configured and recalculated so that the result will be OR, the result will be OR.

· If the minimum measurement value [ng/mL] is configured and recalculated so that the dilute recalculation data will not result in UR, data that resulted in UR will have a result other than UR.

· If the minimum measurement value [ng/mL] is configured and recalculated so that the dilute recalculation data will result in UR, the result will be UR.

3.1.10   Outputting measured data
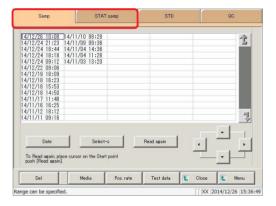
Specified measured data is output to the selected output destination.

・   Printing measured data

・   Saving measured data to external media

・   Outputting measured data to a host computer online
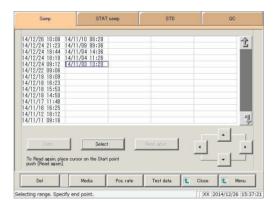
> [Explanatory note] : When there is both 15-times dilution and 250-times dilution measured data, the final results
> are judged.
> If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured
> data for either was deleted by the operator, the final results are not judged.

1   Touch the tab of the measured data to output (print).

{Samp} tab

{STAT samp} tab
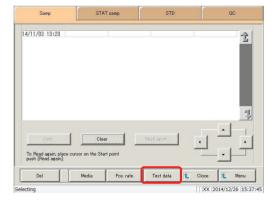
2   Specify the measured data by date and time or range.

\<Specifying by measurement date and time\>

Touch the {Date} button, and specify the measurement date.

☞   Page 104 "3.1.3 Specifying measured data by measurement date and time"   **2**

\<Specifying by range\>

Touch the {Select-s} button, and specify the measurement date range.

☞   Page 106 "3.1.4 Specifying measured data by range"   **2**
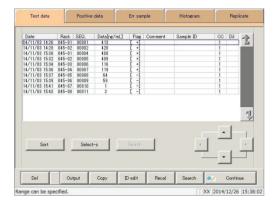
3   Touch the {Test data} button.

⚠ **Request**
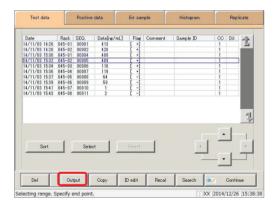
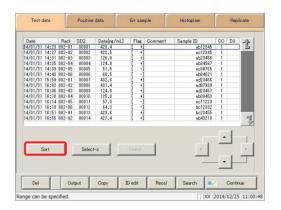|	
![Required icon] **Required**	・ If the external media runs out of space during output, exchange it with a new device and touch the {Retry} button.

---
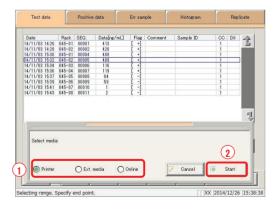
4 Specify the output range.

The procedure is the same as in the [Measured data selection] screen.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

---

5 Touch the {Output} button.

---
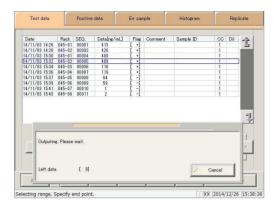
6 Output the measured data.

① Select the output destination.

○ Printer

○ External media

○ Online

② Touch the {Start} button.

{Cancel}: The dialog box closes.

Explanatory note : If an error has occurred in communicating the measurement results, "Online" cannot be selected in the [Output destination selection] dialog box.

3.1 Measured Data Processing

* The following information is output to the selected output destination.
* When output is complete the [Outputting] dialog closes.

MEMO
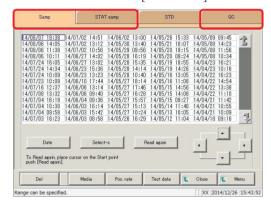
3.1.11 Deleting measured data

Delete measured data for the specified measurement date and time.

If a range is not specified, all displayed data (up to 5,000 samples' worth) will be deleted.

Explanatory note : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1 Touch the tab of the measured data to display.

{Samp} tab
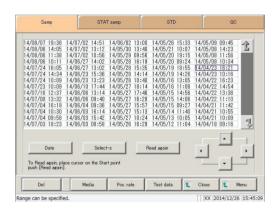
{STAT samp} tab
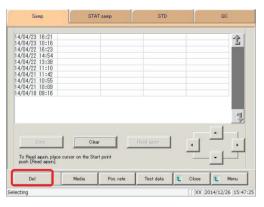
{QC} tab

Explanatory note : STD measured data cannot be deleted.

2 Specify the data to delete using a measurement date and time range (start point/end point).
(It is not necessary to specify the range when deleting all data.)

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

3 Touch the {Del} button.

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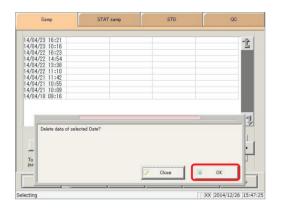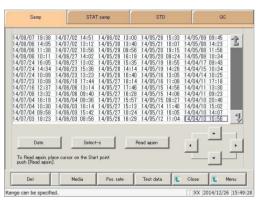
⚠ Request	
🚫 Required	· When deleting measured data, be sure to confirm the specified range. All measured data (up to 5,000 samples' worth) displayed on the screen will be deleted.

4 Confirm the specified date and time, and touch the {OK} button.

{Cancel}: The dialog box closes.
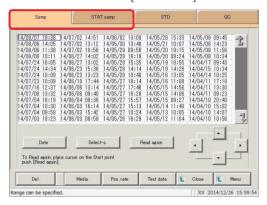
5 Measured data for the specified date and time was deleted.

3.1.12   Copying measured data

Copy specified measured data to other measured data.

Copied information includes sample IDs, measured data, judgment results, and comments.

 Explanatory note : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the
[Process data] screen.

1   Touch the tab of the measured data to display.

{Samp} tab
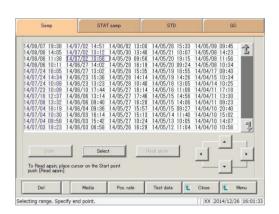
{STAT samp} tab

{QC} tab

2   Specify the measured data by date and time or range.

<Specifying by measurement date and time>

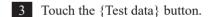Touch the {Date} button, and specify the measurement date.

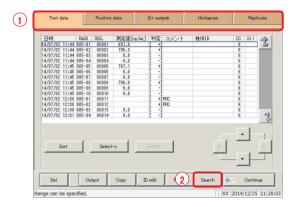☞   Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞   Page 106 "3.1.4 Specifying measured data by range" **2**
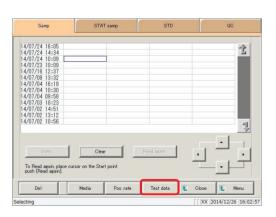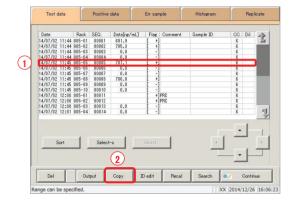
3   Touch the {Test data} button.
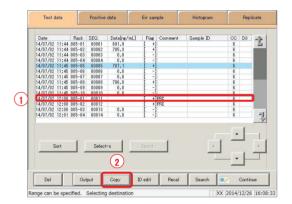
Explanatory note : When copying measured data to other data, individual data obtained through replicate testing will not be copied.
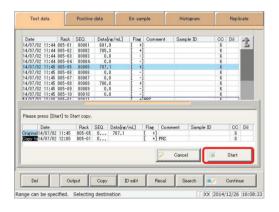
4 Specify the measured data to copy.

① Touch the measured data to copy (the cursor buttons on the bottom right of the screen can also be used).

② Touch the {Copy} button.

5 Specify the measured data to copy to.

① Touch the measured data to copy to (the cursor buttons on the bottom right of the screen can also be used).

② Touch the {Copy} button.

6 Touch the {Start} button.

* Copying is performed.

{Cancel}:   Cancel copying, and return to the [Test data] screen.

3.2 Editing Sample IDs
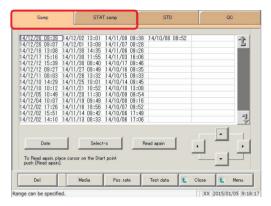
Edit sample IDs for data selected on the [Test data] screen.

Explanatory note : If [Duplicated check] is set to "YES" in [Samp barcode settings] on the [System settings] ・ [Samp barcode settings] screen, a duplication check is run for sample IDs.
However, a duplication check is not run when editing sample IDs for "retest data" or "dilute test data."

1 Touch the tab of the measured data to display.
{Samp} tab
{STAT samp} tab

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>
Touch the {Date} button, and specify the measurement date.
☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>
Touch the {Select-s} button, and specify the measurement date range.
☞ Page 106 "3.1.4 Specifying measured data by range" **2**
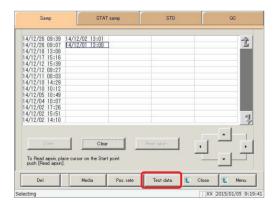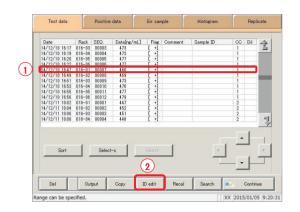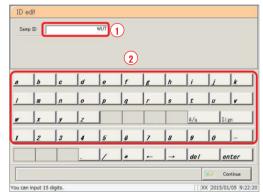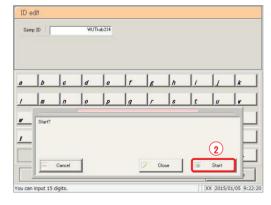
3 Touch the {Test data} button.

4 Select the sample ID.

① Touch the sample ID to edit (sample IDs can also be selected by using the {Cursor} buttons to move the cursor).

② Touch the {ID edit} button.

5 Input the sample ID.

① Touch the "input field" of the sample ID.

② Enter the sample ID using the keypad.

{A/a}: Switch input between uppercase and lowercase.

{Sign}: Allows for input of symbols.

6 Update the sample ID.

① Touch the {Continue} button.

② Touch the {OK} button in the dialog box.

      * The edited sample ID is stored.

{Cancel}: Cancel editing the sample ID, and return to the [Test data] screen.

{Cancel}: The dialog box closes.

3.3   List of Positive Samples

Display the samples that were measured in test mode or remeasure mode and received "positive judgment" in a list.

Positive samples displayed in the list can be sorted, searched, recalculated, output, cut-off back calculated, and deleted.

Explanatory note : · Error samples do not have judgment results, and thus are not displayed on the list.

· OR, RBC, and PRC samples are positive samples.

· Samples that were measured in test mode or remeasure mode are displayed on the list.

3.3.1   Displaying the positive sample list

Two display modes are available for the positive sample list: sample mode and testee mode. The positive rate is shown in either mode. Calculation is performed as follows.

Sample mode: Positive rate (%) = Number of positive samples ÷ Number of all samples × 100
("Number of all samples" is the number of samples within the range specified on the [Test data] screen.)

Testee Mode: Positive rate (%) = Number of positive testees ÷ Number of all testees × 100
("Number of all testees" is the number of testees within the range specified on the [Test data] screen.)
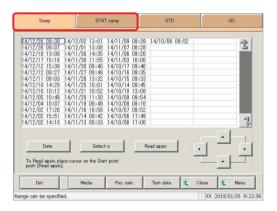
Explanatory note : · Only positive measured data is displayed in sample mode.

· For testee mode, if even a single sample is positive in the 2 day or 3 day measured data, all measured data for that patient is displayed.
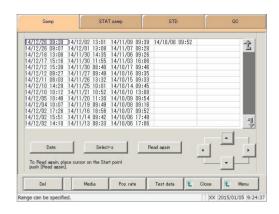
· For testee mode, positive samples are displayed reversed.

Explanatory note : All data will be displayed if no range is specified.

1   Touch the tab of the measured data to display.

{Samp} tab

{STAT samp} tab

2 Specify the measured data by date and time or range.
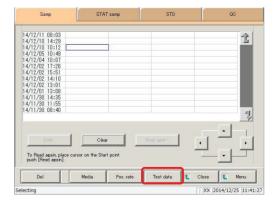
  <Specifying by measurement date and time>

    Touch the {Date} button, and specify the measurement date.

    ☞ Page 104 "3.1.3 Specifying measured data by measurement date" **2**
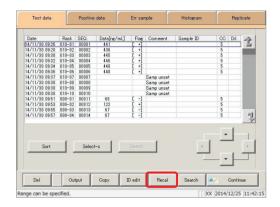
  <Specifying by range>

    Touch the {Select-s} button, and specify the measurement date range.

    ☞ Page 106 "3.1.4 Specifying measured data by range" **2**


3 Touch the {Test data} button.

4 Specify the measured data by range of measurement date and time.

① Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can also be used to select this).

② Touch the {Select-s} button.

  * The text in the row of the specified date and time turns blue. (Start point)

  * The {Select-s} button changes to the {Select} button.

③ Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can also be used to select this).

④ Touch the {Select} button.

  * The text in the row of the specified range turns blue. (End point)

{Sort}: Sort the displayed measured data.

{Select-s}: Confirm start point data for the specified range.

{Select}: Confirm end point data for the specified range.
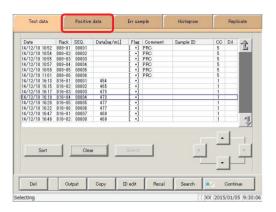
{Clear}: Clear the specified range.

☞ Page 110 "3.1.7 Sorting measured data" **4**
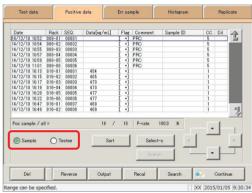
3.3 List of Positive Samples

5 Touch the {Positive data} tab.

* The specified list of positive samples is displayed.

6 Positive samples are displayed by sample or by testee.

\<When selecting sample mode\>

Touch the {Sample} button.

\<When selecting testee mode\>

Touch the {Testee} button.

When the positive sample has been updated through recalculation, deletion, etc.:

① Touch the {Continue} button.

② Touch the {Register} button in the dialog box.

* Updated positive sample data is registered.

{Del}: Delete specified positive sample data.

☞ Page 148 "3.3.8 Deleting positive sample data"

{Reverse}: Calculate the cut-off value using the input positive rate.

☞ Page 142 "3.3.6 Calculating cut-off values from positive rates"

{Output}: Output specified positive sample data.

☞ Page 146 "3.3.7 Outputting positive sample data"

{Recal}: Recalculate measured data using modified cut-off values, as well as factors A and B.

☞ Page 140 "3.3.5 Recalculating positive sample data"

{Search}: Search positive samples based on sample ID, sample number, rack number, and measurement date and time.

☞ Page 138 "3.3.4 Searching positive sample data"

Content displayed on the [Positive data] screen

Display	Details		Remark
Date	Date and time sample was measured		
RACK	Rack No. - Position number in rack		
SEQ.	Group No. - Sequence No.		
Data [ng/mL]	Measurement results (concentration value)		
Flag	-. +, 1 +, 2 +, 3 +		
Comment	Error information (excluding reading errors)		
	UR	: Under range	Blank output for measured data and judgment result
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode information on sampling bottles		
CC	Calibration curve used to calculate measured data (CC No.)		
Dil	Dilution information		
	Space	: No dilution (test mode, remeasure mode)	
	A	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

(Explanatory note) : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.

3.3.2   Sorting positive sample data

Positive samples specified on the [Test data] screen can be sorted by measurement date and time, and by group. When sorting by measurement date and time, positive samples are displayed in ascending order by "date."

When sorting by group, positive samples are displayed in ascending order by "sample number group."
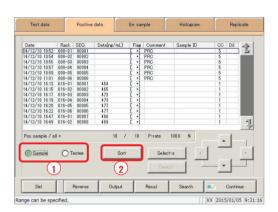
This section describes the procedure from the [Positive data] screen.
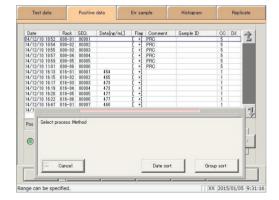
Explanatory note : If a range is not specified, all positive samples displayed on the [Positive data] screen will be sorted.

Explanatory note : The range of positive samples can also be specified using the {Select-s} button on the [Positive data] screen.
The method is the same as on page 136 "3.3.3 Specifying positive sample data by range."

1 Select the display mode for positive samples to sort (by sample/testee).

① Touch the {Sample} or {Testee} buttons.

② Touch the {Sort} button.

2 Touch the {Date sort} button or the {Group sort} button.

※ The sorted measured data is displayed.

{Date sort}: Sort measured data in ascending order by measurement date and time.

{Group Sort}: Sort measured data in ascending order by sample number group.
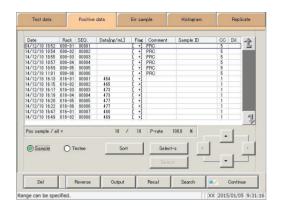
{Cancel}: Cancel sorting.
The dialog box closes.
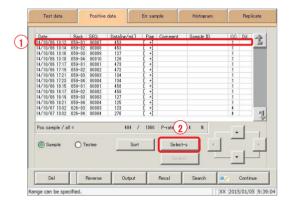
3 Positive sample data was sorted.

3.3.3 Specifying positive sample data by range
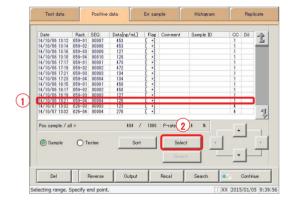
Touch the measurement date and time on the [Positive data] screen or operate the cursor buttons to specify positive sample data by range of measurement date and time (start point/end point).
Specify the date and time at the start point and touch the {Select-s} button to confirm the positive sample data at the start point. Next, specify the date and time at the end point and touch the {Select} button to confirm the positive sample data at the end point. After the start and end points are confirmed, the positive sample data between the start and end points is specified.

This section describes the procedure from the [Positive data] screen.

☞

1 Specify the measured data at the start point.

① Touch the date and time that will be the start point.

② Touch the {Select-s} button.

    * The measured data at the start point was confirmed.
    * When the start point is confirmed, the {Select-s} button changes to the {Select} button.

2 Specify the measured data at the end point.

① Touch the date and time that will be the end point.

② Touch the {Select} button.

    * The measured data at the end point was confirmed.
    * When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}: Confirm the measured data at the start point.
{Select}: Confirm the measured data at the end point.
{Clear}: Clear the specified range.

Explanatory note : If the measured data specified for the start and end points is the same, the system will handle it as though only a single sample of measured data was specified.

Explanatory note : To specify a new range of measured data, touch the {Clear} button. All measured data is displayed, and the system returns to the state it was in before the range was specified.

3 Positive sample data was specified.

* The specified measured data is displayed.

Explanatory note : The display mode for positive samples can be switched with the {Sample} or {Testee} buttons.

3.3.4   Searching positive sample data

Search positive samples based on sample ID, sample number, rack number, and measurement date and time.

This section describes the procedure from the [Positive data] screen.

☞ Page 130 "3.3.1 Displaying the positive sample list"   1   through   5
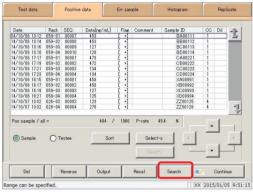
| Explanatory note | : If a range is not specified, all positive samples displayed on the [Positive data] screen will be searched. Measured data cannot be searched for using the rack position number. |

| Explanatory note | : The range of positive sample data can also be specified using the {Select-s} button on the [Positive data] screen. The method is the same as on page 136 "3.3.3 Specifying positive sample data by range." |

| Explanatory note | : Sort positive sample data using the {Sort} button on the [Positive data] screen. The method is the same as on page 134 "3.3.2 Sorting positive sample data." |
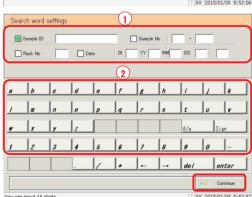
1   Touch the {Search} button.

2   Select the type of keyword to search.

☐   Sample ID

☐   Sample No.

☐   Rack No.

☐   Date

3   Enter a keyword.

①   Touch the "input field" next to the name of the keyword.

②   Enter a keyword using the keypad.

③   Touch the {enter} key.

{A/a}:   Switch input between uppercase and lowercase.

{Sign}:   Allows for input of symbols.

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Explanatory note : Entry of the group number and measurement date and time can be omitted. However, if a measurement date and time box is checked, it is necessary to input at least one of the following: year, month, date, hour, and minute.

Explanatory note : The {A/a} and {Sign} buttons are available when the cursor is in the input field.

4   Touch the {Continue} button.

5   Touch the {Start} button.

* Searching begins.

{Cancel}: Cancel searching, and return to the [Positive data] screen.
{Cancel}: The dialog box closes.

6   Search results were displayed.

Explanatory note : The display mode for positive samples can be switched with the {Sample} or {Testee} buttons.

Explanatory note : The search range is the range specified on the [Test data] screen.

3.3.5 Recalculating positive sample data

Recalculate measured data using modified cut-off values, as well as factors A and B.

This section describes the procedure from the [Positive data] screen.

☞ Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

| Explanatory note | : ・ The values used for judging measured data for which a range has been specified are shown in Cut off 1, Cut off 2, and Cut off 3.

　　・ If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1, Cut off 2, and Cut off 3.

　　・ If the factor value differs according to the measured data, factor A and factor B are displayed as 1.00 and 0.00, respectively.

| Explanatory note | : Values configured in the [Recalculation condition settings] screen are not applied to protocol settings.
Recalculation is a form of calculation for the purpose of correction using values configured in condition settings. It is not fitting calculation to a calibration curve
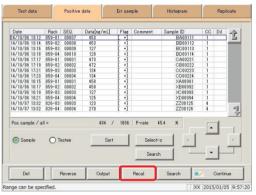
| Explanatory note | : Recalculation applies not only to data displayed on the [Positive data] screen, but to all data specified on the [Test data] screen.
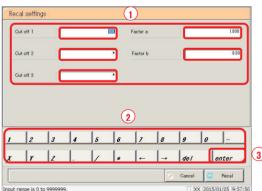
| Explanatory note | : The range of positive samples can also be specified using the {Select-s} button on the [Positive data] screen.
The method is the same as on page 136 "3.3.3 Specifying positive sample data by range."
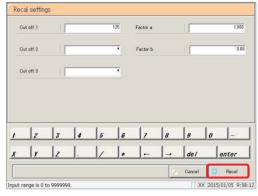
1 Touch the {Recal} button.
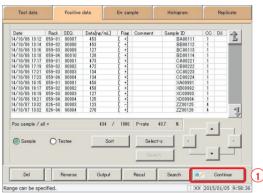
2 Configure the recalculation conditions.
① Touch the "input field" next to the setting.
② Enter numbers using the numeric keypad.
③ Touch the {enter} key.
　　・ Cut off 1
　　・ Cut off 2
　　・ Cut off 3
　　・ FACTOR A
　　・ FACTOR B

Setting	Input Range
Cut off 1	0 - 9,999,999
Cut off 2	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
FACTOR A	0.001 - 99,999.999
FACTOR B	-999.99 - 999.99

3 Touch the {Recal} button.

{Cancel}: Cancel recalculation, and return to the [Positive data] screen.

4 The recalculated positive sample data was displayed.

To update the recalculated data:
① Touch the {Continue} button.
② Touch the {Register} button in the dialog box.

Explanatory note : The display mode for positive samples can be switched with the {Sample} or {Testee} buttons.

⚠ Request	
ⓘ Required	· When changing the Samp/QC protocol settings and recalculating, touch the {Memory} button on the [Check CC] screen first, and then recalculate. ☞ Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)"

3.3.6 Calculating cut-off values from positive rates

The cut-off value is back calculated using the measured data of the displayed positive sample and the input positive rate. Cut-off values are calculated differently in sample mode and testee mode.
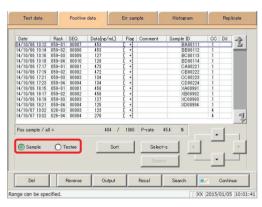
☞ Page 145 "■ Calculation methods for cut-off values according to display mode"

This section describes the procedure from the [Positive data] screen.

☞ Page 130 "3.3.1 Displaying the positive sample list" **1** through **5**
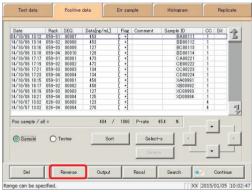
Explanatory note : ・ If no range is specified, cut-off values are calculated with "all measured data" and with "input positive rate."

・ The range of positive samples is specified using the {Select-s} button on the [Positive data] screen.

☞ Page 136 "3.3.3 Specifying positive sample data by range"
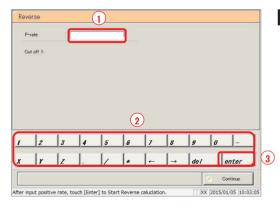
1 Select the display mode for positive samples (by sample/testee).

Touch the {Sample} or {Testee} buttons.
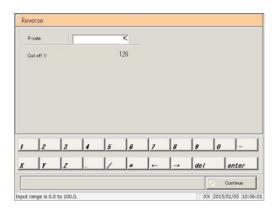
2 Touch the {Reverse} button.
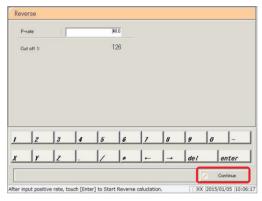
3 Enter the positive rate.

① Touch the input field for the positive rate.

② Enter the positive rate using the numeric keypad.

Input range: 0.0 to 100.0

③ Touch the {enter} key.

* Calculate the cut-off value.

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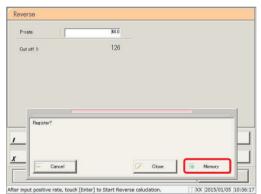
4 The calculated cut-off value is displayed in the Cut off 1 field.

> Cut-off value range: 0 to 9,999,999

5 Touch the {Continue} button.

6 Touch the {Memory} button.
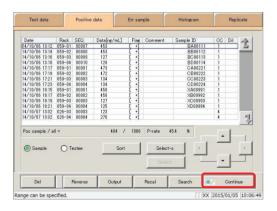
> * Applied to Cut off 1 on the [Recal settings] screen.

{Memory}: Save calculation results to memory.

{Close}: Cancel calculation, and return to the [Process data] screen.
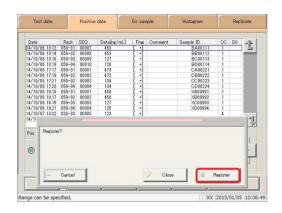
{Cancel}: The dialog box closes.

7 Touch {Continue}.

8   Touch {Register}.

{Register}:   Register the cut-off value.

{Close}:   Cancel registration, and return to the [Reverse] screen.

{Cancel}:   The dialog box closes.

Explanatory note   : Pressing the {Continue} button will apply the calculated cut-off value to cut-off value 1 on the [Recal settings] screen. ☞ Page 140 "3.3.5 Recalculating positive samples"

When changes have been applied to cut-off value 1 on the [Recal settings] screen, cut-off values 2 and 3 change to "*." Use cut-off values 1, 2, and 3 to calculate when recalculating.

Explanatory note   : If the measured data for the Nth positive sample is PRC or OR, the cut-off value is not calculated.

■   Calculation methods for cut-off values according to display mode

Two display modes are available: sample mode and testee mode.

Cut-off value calculation for each mode is as follows.

> Sample mode: N = Input positive rate ÷ Number of all samples × 100 (fractional portions rounded down to nearest integer)
> (N = the number of samples that should be positive)

Explanatory note :

1. Decimal points are rounded down for the number of samples.

2. For cut-off values, the measured data of the Nth sample becomes an integer shown when less than the number. (Integer between 0 and 9,999,999)

   Example 1: Nth sample measured data: 100.1 → 100.

   Example 2: Nth sample measured data: 100 → 99.

3. When N = 0 in the examples in 2 above, the cut-off value is an integer that exceeds the first measured data.

   Example: First sample measured data: 100.1 → 101.

4. When there are multiple measured data identical to the Nth sample, they may not follow the specifications listed in 2 and 3 above.

   Example: There are 29 samples with measured data of 200 and 71 samples with measured data of 100, for a total of 100 samples. Calculating the cut-off value at a positive rate of 30% results in a cut-off value of 99.
   However, if recalculated with a cut-off value of 99, the positive rate will be 100%.

> Testee mode: N = Positive rate ÷ Number of all testees × 100
> (N = number of testees that should be positive)

Explanatory note : 1. Decimal points are rounded down for the number of testees.

2. For cut-off values, the measured data of the Nth testee becomes an integer shown when less than the number (an integer between 0 and 9,999,999).

   Example 1: Nth testee measured data: 100.1 → 100.

   Example 2: Nth testee measured data: 100 → 99.

3.3.7   Outputting positive sample data

Output positive sample data specified on the "list of positive samples" to the selected output destination.

- ・ Printing positive sample data
- ・ Saving positive sample data to external media
- ・ Outputting positive sample data to a host computer online

This section describes the procedure from the [Positive data] screen.

☞ Page 130 "3.3.1 Displaying the positive sample list" 　**1**　 through 　**5**
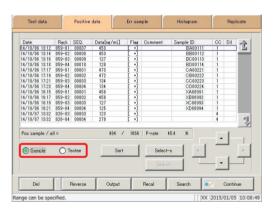
Explanatory note : If an error has occurred in communicating the measurement results, "Online" cannot be selected in the [Output destination selection] dialog box.

Explanatory note : When there is both 15-times dilution and 250-times dilution measured data, a qualitative assessment is performed.
If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured data for either was deleted by the operator, a qualitative assessment is not performed.
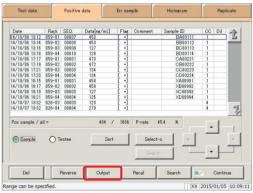
Explanatory note : When outputting time code course data, set "Time course to Ext. media" to YES in [Settings] - [System settings] - [Output settings].
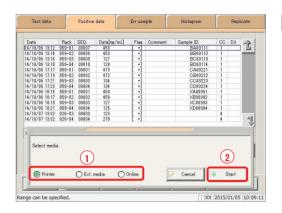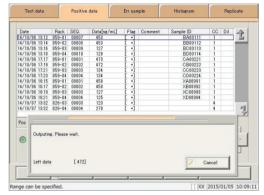
1 Select the display mode for positive samples (by sample/testee).

Touch the {Sample} or {Testee} buttons.

2 Touch the {Output} button.

3 Output the positive sample data.

① Select the output destination.

- ○ Printer
- ○ Ext. media (External media)
- ○ Online

② Touch the {Start} button.

* Specified positive sample data is output to the selected output destination.
* When output has completed, the system returns to the [Positive data] screen.

{Cancel}:   Cancel output, and return to the [Positive data] screen.

Explanatory note : When "Ext. media" has been selected for the output destination and no external media is connected, "Not connected with external media." is displayed. Connect the external media and touch the {Retry} button.

Explanatory note : If the external media runs out of space during output, "There is not enough space on the external media. Replace it with new media." is displayed. Replace with new media and touch the {Retry} button. Resume data output.
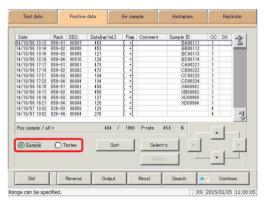
3.3.8 Deleting positive sample data

Delete positive sample data for the selected measurement date and time.
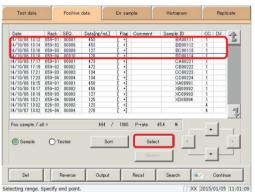
This section describes the procedure from the [Positive data] screen.

☞ Page 130 "3.3.1 Displaying the positive sample list" **1** through **5**

1 Select the display mode for positive samples (by sample/testee).

Touch the {Sample} or {Testee} buttons.
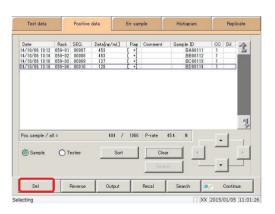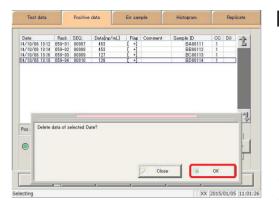
2 Specify the measurement date and time range (start point/end point) of the data to delete.

(It is not necessary to specify the range when deleting all data.)

☞ Page 136 "3.3.3 Specifying positive sample data by range" **2**

⌐ Explanatory note ⌐ : If a range is not specified, all positive samples displayed on the [Positive data] screen will be deleted.

3 Touch the {Del} button.

4 Confirm the specified date and time, and touch the {OK} button.
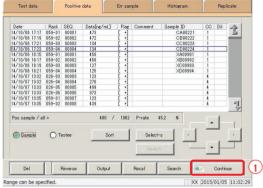
{OK}:   Delete data for the specified date and time.
{Close}:   The dialog box closes.
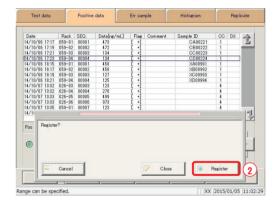
5 Positive sample data for the specified date and time was deleted.

To update positive sample data:
① Touch the {Continue} button.
② Touch the {Register} button in the dialog box.
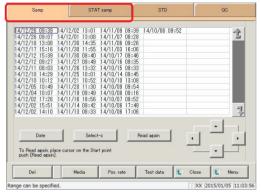
3.4 List of Error Samples

Display a list of error samples.
Error samples displayed in the list can be sorted, searched, output, and deleted.
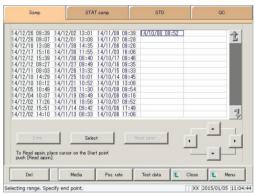
3.4.1 Displaying the list of error samples
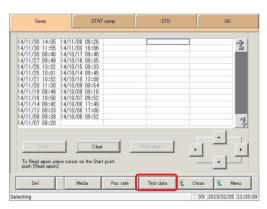
1 Touch the tab of the measured data to display.

{Samp} tab
{STAT samp} tab
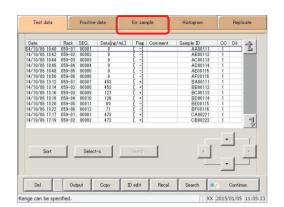
2 Specify the measurement date and time.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2** Specify the range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

3 Touch the {Test data} button.

4 Touch the {Err sample} button.

* The list of error samples is displayed.

Content displayed on the [Err sample] screen

Display	Details		Remark
Date	Date and time sample was measured		
RACK	Rack No. - Position number in rack		
SEQ.	Group No. - Sequence No.		
Data [ng/mL]	Measurement results		
Flag	-, +, 1 +, 2 +, 3 +		
Comment	Error information (excluding reading errors)		
	UR	: Under range	Blank output for measured data and judgment result
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode information on sampling bottles		
CC	Calibration curve used to calculate measured data (CC No.)		
Dil	Dilution information		
	Space	: No dilution (test mode, remeasure mode)	
	A	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Explanatory note : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.

3.4.2 Sorting error sample data

Error samples specified from measured data can be sorted by measurement date and time, and by group.
When sorting by measurement date and time, error samples are displayed in ascending order by "date."
When sorting by group, error samples are displayed in ascending order by "sample number group."
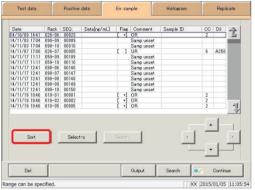
This section describes the procedure from the [Err sample] screen.
☞ Page 150 "3.4.1 Displaying the list of error samples" **1** through **4**

Explanatory note : If a range is not specified, all error samples displayed on the [Err sample] screen will be sorted.

Explanatory note : The range of error samples can also be specified using the {Select-s} button on the [Err sample] screen.
The method is the same as on page 154 "3.4.3 Specifying error sample data by range."

1 Touch the {Sort} button.
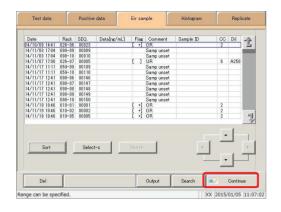
2 Touch the {Date sort} button or the {Group sort} button.

* Sorted results are displayed.

{Date sort}: Sort measured data in ascending order by measurement date and time.

{Group Sort}: Sort measured data in ascending order by sample number group.

{Cancel}: The dialog box closes.

3   Register the sorted results.

①   Touch the {Continue} button.

②   Touch the {Register} button.

> * Sorted results were registered.
> * The system returns to the [Process data] screen.

{Register}:   * Sorted data is registered.

{Close}:   Cancel registration, and return to the [Process data] screen.

{Cancel}:   The dialog box closes.

3.4.3 Specifying error sample data by range
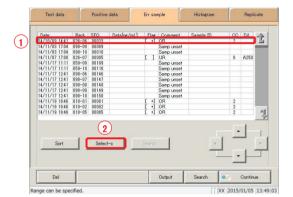
Touch the measurement date and time on the [Err sample] screen or operate the cursor buttons to specify positive sample data by range of measurement date and time (start point/end point).
Specify the start point and touch the {Select-s} button to confirm the error sample data at the start point.
Specify the end point and touch the {Select} button to confirm the error sample data at the end point.
After the start and end points are confirmed, the error sample data between the start and end points is specified.
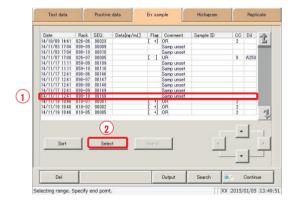
This section describes the procedure from the [Err sample] screen.

☞ Page 150 "3.4.1 Displaying the list of error samples" **1** through **5**

1 Specify the underlined error sample data at the start point.

① Touch the date and time that will be the start point.

② Touch the {Select-s} button.

* The data at the start point was confirmed.
(The text in the row of the specified date and time turns blue.)
* When the start point is confirmed, the {Select-s} button changes to the {Select} button.

2 Specify the underlined error sample data at the end point.

(1) Touch the data row that will be the end point.

(The text in the row of the specified range turns blue.)

(2) Touch the {Select} button.

* The data for the specified range is displayed.
* When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}: Confirm start point data for the specified range.
{Select}: Confirm end point data for the specified range.
{Clear}: Clear the specified range.
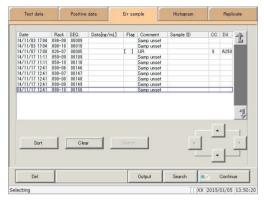
| Explanatory note | : If the data specified for the start and end points is the same, the system will handle it as though only a single sample of data was specified. |

| Explanatory note | : To specify a new range of data, touch the {Clear} button. All data is displayed, and the system returns to the state it was in before the range was specified. |
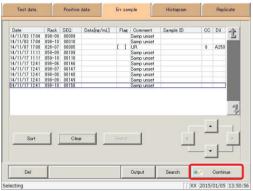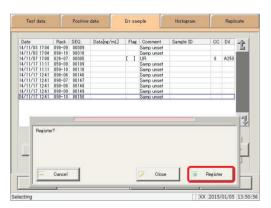
3 Error sample data was specified.

To clear the specified range, touch the {Clear} button.

4 Register the error sample data.

① Touch the {Continue} button.

② Touch the {Register} button.

* Specified data was registered.

{Register}: Specified data is registered.

{Close}: Cancel registration, and return to the [Process data] screen.

{Cancel}: The dialog box closes. Touch the {Clear} button to specify a new range.

3.4.4   Searching error sample data

Search error samples based on sample ID, sample number, rack number, and measurement date and time.

This section describes the procedure from when the [Err sample] screen is displayed.

☞ Page 150 "3.4.1 Displaying the list of error samples" 　1　 through 　5

[Explanatory note] : If a range is not specified, all error samples displayed on the [Err sample] screen will be searched.

[Explanatory note] : Measured data cannot be searched for using the rack position number.
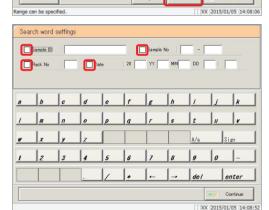
[Explanatory note] : The range of error sample data can also be specified using the {Select-s} button on the [Err sample] screen.
The method is the same as on page 154 "3.4.3 Specifying error sample data by range."
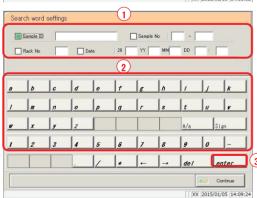
[Explanatory note] : Sort error sample data using the {Sort} button on the [Err sample] screen.
The method is the same as on page 152 "3.4.2 Sorting error sample data."

1 Touch the {Search} button.

2 Select the type of keyword to search.

☐　Sample ID

☐　Sample No.

☐　Rack No.

☐　Date

3 Enter a keyword.

①　Touch the "input field" next to the name of the keyword.

②　Enter a keyword using the keypad.

③　Touch the {enter} key.

{A/a}:　　Switch input between uppercase and lowercase.
{Sign}:　　Allows for input of symbols.

> **Explanatory note** : Entry of the group number and measurement date and time can be omitted. However, if a measurement date and time box is checked, it is necessary to input at least one of the following: year, month, date, hour, and minute.
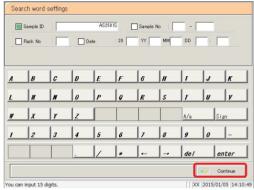
> **Explanatory note** : The measured data specified on the [Test data] screen will be searched.
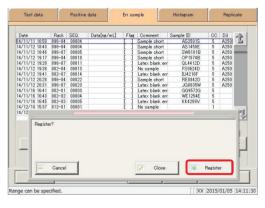
> **Explanatory note** : The {A/a} and {Sign} buttons are available when the cursor is in the input field.

4 Touch the {Continue} button.

5 Touch the {Start} button.

* Searching begins.
* Search results are displayed.

6 Register the search results.

① Touch the {Continue} button.
② Touch the {Register} button in the dialog box.

{Register}: Search data is registered.

{Close}: Cancel registration, and return to the [Process data] screen.

{Cancel}: The dialog box closes.

3.4.5   Outputting error sample data

Output error sample data specified on the "list of error samples" to the selected output destination.

- Printing error sample data
- Saving error sample data to external media
- Outputting error sample data to a host computer online

This section describes the procedure from when the [Err sample] screen is displayed.

☞ Page 150 "3.4.1 Displaying the list of error samples" **1** through **5**
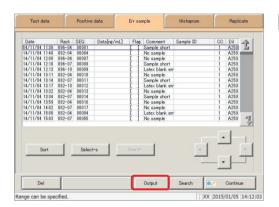
Explanatory note : If an error has occurred in communicating the measurement results, "Online" cannot be selected in the [Output destination selection] dialog.

Explanatory note : When there is both 15-times dilution and 250-times dilution measured data, a qualitative assessment is performed.
If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured data for either was deleted by the operator, a qualitative assessment is not performed.

1 Touch the {Output} button.

2 Output the error sample data.
   ① Select the output destination.
      ○ Printer
      ○ Ext. media (External media)
      ○ Online
   ② Touch the {Start} button.

{Start}: Data is output.
{Cancel}: The dialog box closes.

Error sample data is output to the selected output destination.
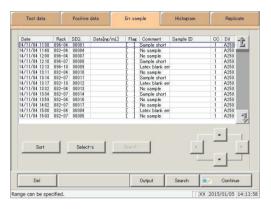
3.4.6 Deleting error sample data

Delete error sample data for the specified measurement date and time.
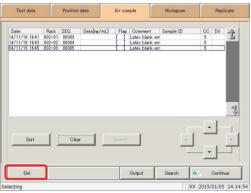
This section describes the procedure from the [Err sample] screen.

☞ Page 150 "3.4.1 Displaying the list of error samples" **1** through **5**
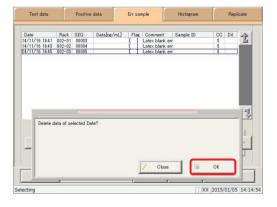
1 Specify the data to delete using a measurement date and time range (start point/end point). (It is not necessary to specify the range when deleting all data displayed on the screen.)

☞ Page 154 "3.4.3 Specifying error sample data by range" **2**

2 Touch the {Del} button.
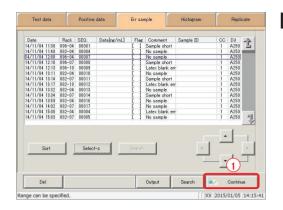
3 Confirm the specified date and time, and touch the {OK} button.

{OK}: Data for the specified date and time is deleted.

{Close}: The dialog box closes.

(Explanatory note) : If a range is not specified, all samples displayed on the [Err sample] screen will be deleted.

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4 The error sample data for the specified date and time was deleted.

To update error sample data:

① Touch the {Continue} button.

② Touch the {Register} button in the dialog box.
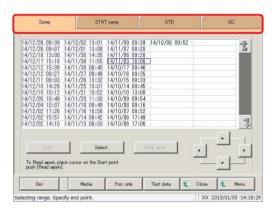
3.5 Histogram

Display a histogram for the specified measured data.

Histograms can be output to the selected output destination and their ranges can be changed.

3.5.1 Displaying histograms
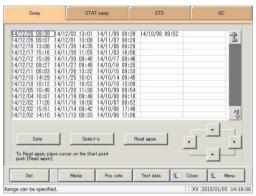
Display a histogram for the specified measured data.

1 Touch the tab of the measured data to display.

{Samp} tab

{STAT samp} tab

{STD}

{QC}

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

Explanatory note : Measured data calculated in the test or remeasure modes will be displayed on the histogram.
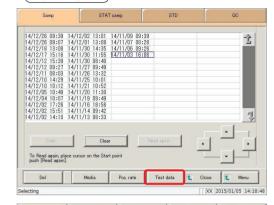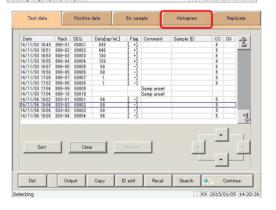
Explanatory note : A histogram for all data will be displayed if no range is specified.

3 Touch the {Test data} button.

4 Specify the measured data by range of measurement date and time.

① Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can be used to select this).

② Touch the {Select-s} button.

* The text in the row of the specified date and time turns blue (start point).

* The {Select-s} button changes to the {Select} button.

③ Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can be used to select this).

④ Touch the {Select} button.

* The text in the row of the specified range turns blue (end point).

{Select-s}:   Confirm start point data for the specified range.

{Select}:   Confirm end point data for the specified range.

{Clear}:   Clear the specified range.

5 Touch the {Histogram} tab.

3.5 Histogram

6 The histogram was displayed.

{Close}:　　Return to the [Test data] screen.

Explanatory note ： The "▼" symbol displayed on the histogram can be moved with the cursor buttons. The cursor's numeric information is displayed in ★.
The meaning of the display is as shown in a, b, and c below.

#.# -	#.#	# sample	a	: Measured data minimum
↑	↑	↑	b	: Measured data maximum
a	b	c	c	: Number of samples within the range between the measured data maximum and minimum

———   MEMO   ———

3.5.2   Changing the histogram range
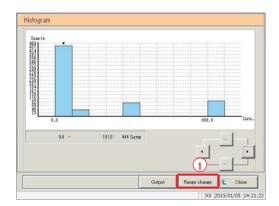
Input "Max sample," "Min Conc.," "Max Conc.," or "Class" to modify the histogram range.

This section describes the procedure from the [Histogram] screen.
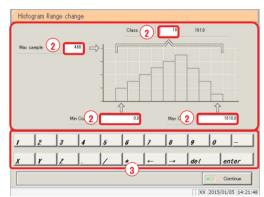
☞ Page 162 "3.5.1 Displaying histograms" `1` through `5`

[Explanatory note] : Measured data calculated in the test or remeasure modes will be displayed on the histogram.

[Explanatory note] : All data will be subject to range modification if no range is specified.
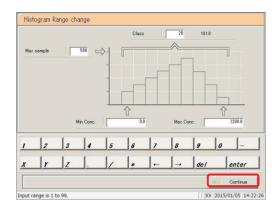
`1` Modify the range.
   ①   Touch the {Range change} button.
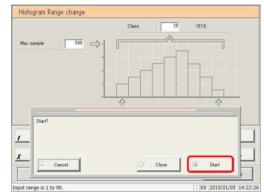
②   Touch the input field for the condition to change.
   ·   Max sample
   ·   Min Conc.
   ·   Max Conc.
   ·   Class
③   Modify the setting with the numeric keypad.

Setting	Input Range
Max sample	0 - 9,999
Min Conc.	0 - 999,999,999.9
Max Conc.	0 - 999,999,999.9
Class	1 - 99

[Explanatory note] : "Class" is the number of segments the histogram is divided into

2 Touch the {Continue} button.

3 Touch the {Start} button.

* The histogram is displayed again.
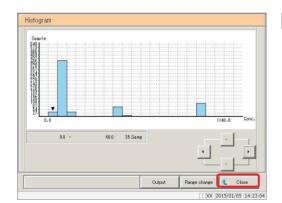
{Start}:	Modify the range.
{Close}:	Cancel range modification, and return to the [Histogram] screen.
{Cancel}:	The dialog box closes.

Explanatory note : Range modification is not saved to the hard disk(SSD).

4 Touch the {Close} button.

* The system returns to the [Test data] screen.
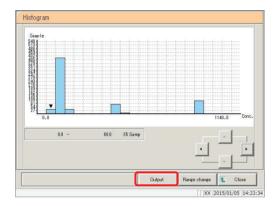
3.5.3   Outputting histograms

Output histograms (data) to external media or a printer.

・ Printing histograms
・ Saving histograms to external media

This section describes the procedure from the [Histogram] screen.

1 Touch the {Output} button.

2 Output the measured data.
① Select the output destination.
○ Printer
○ Ext. media (External media)
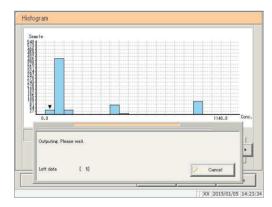
② Touch the {Start} button.

* The histogram is output.
* When output has completed, the system returns to the [Histogram] screen.

{Start}:   The histogram is output.
{Cancel}:   The dialog box closes.

—————— MEMO ——————

3.6 Positive Rate Change

Display the positive rate change of measured data.
Modify maximum/minimum positive rates, or output positive rate changes to external media or a printer.
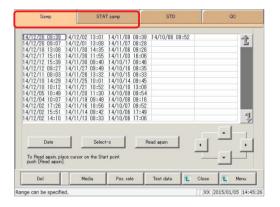
> Explanatory note : The system can store up to ten years of positive rate changes. A single year's worth of data can be displayed at once.

3.6.1 Displaying positive rate changes

Two display modes are available: sample mode and testee mode.

☞ Page 130 "3.3.1 Displaying the positive sample list"

> Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."

1 Touch the tab of the measured data to display.

{Samp} tab
{STAT samp} tab

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**
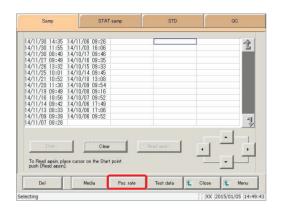
3 Touch the {Pos. rate} button.

Explanatory note : Selecting "Testee" displays the values for the number of positive testees/number of all testees.

4 The positive rate change graph was displayed.

{Output}: Output positive rate changes to the selected location.

{Range change}: Change the maximum/minimum positive rates.

[MENU]: Return to the [MENU] screen.

{Close}: Return to the [Process data] screen.
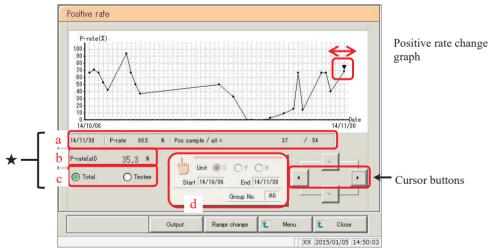
Explanatory note : The "▼" symbol displayed on the positive rate change graph can be moved with the cursor buttons.

The cursor's numeric information is displayed in ★ (a through d). (Refer to the following diagram.)

Explanatory note : The cursor's numeric information is managed in units of measurement date. If the date is changed during testing, the data that was output after the date changed is managed separately from the data from the previous date.

Positive rate change graph

Cursor buttons

a: Measurement dates, positive rates, numbers of positive samples, and all samples (sample mode)
Measurement dates, positive rates, number of positive testees, number of all testees (testee mode)

b: Positive rates for all samples (positive rates for all data displayed)

c: Button to switch between sample mode and testee mode

d: Calculation condition settings for {Date settings} button positive rates

☞ Page 184 "3.6.2 Configuring calculation conditions for positive rates"
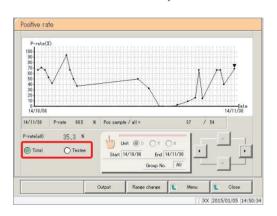
3.6.2   Configuring calculation conditions for positive rates

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Configure the measurement start date, measurement close date, and positive rate calculation unit (day, week, month), then calculate the positive rate. Positive rate changes can also be displayed by group number of the sample number (if "All" is selected for group selection, positive rate changes are displayed for all data).

This section describes the procedure from the [Positive rate change] screen.

☞ Page 170 "3.6.1 Displaying positive rate changes"
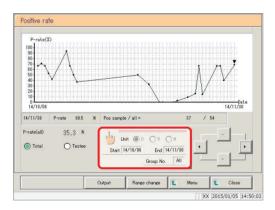
Explanatory note : The range from the start date until the close date may be a maximum of one year long. Touch the input field to enter a date.
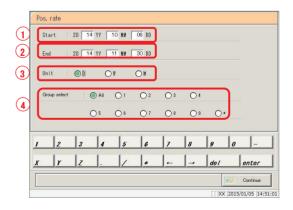
1   Select the display mode for positive samples (by sample/testee).
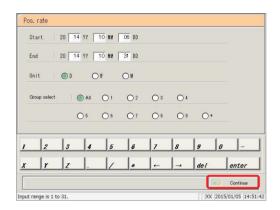
Touch the {Sample} or {Testee} buttons.

2   Touch the {Date settings} button.

3   Configure the calculation conditions.

① Enter a start date (year/month/day).

② Enter a close date (year/month/day).

③ Select a calculation unit (day/week/month).

④ To display by group number, select a number ("*" displays the positive rate changes for samples for which a group has not been specified).

4 Touch the {Continue} button.

5 Touch the {Register} button.

* The positive rates are calculated.
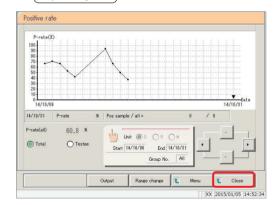
{Start}: Calculate positive rates.

{Close}: Cancel calculation, and return to the [Positive rate change] screen.

{Cancel}: The dialog box closes.

Explanatory note : For "Week," seven consecutive days' worth of positive rates will be calculated.

6 Touch the {Close} button.

* The system returns to the [Process data] screen.

[MENU]: Return to the [MENU] screen.

<Month calculation example>

Start date is December 29, 2012, close date is February 15, 2013

→ Calculate "December positive rate" using data measured from December 29 until December 31, 2012

→ Calculate "January positive rate" using data measured in January 2013

→ Calculate "February positive rate" using data measured from February 1 until February 15, 2013
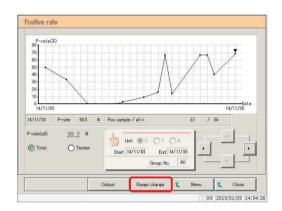
3.6.3 Changing the range of positive rate change

Enter the "Max Value" and "Min Value," then change the range of positive rate change.
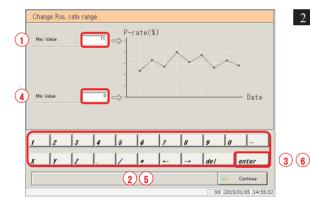
This section describes the procedure from the [Positive rate change] screen.

☞ Page 170 "3.6.1 Displaying positive rate changes"
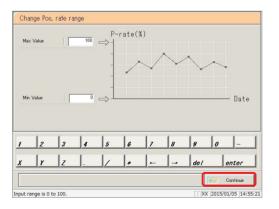
Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."
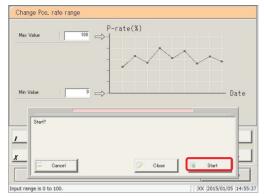
1 Touch the {Range change} button.

2 Change the positive rate.
① Touch the [Max Value] field.
② Enter numbers using the numeric keypad.
③ Touch the {enter} key.
④ Touch the [Min Value] field.
⑤ Enter numbers using the numeric keypad.
⑥ Touch the {enter} key.

3 Touch the {Continue} button.
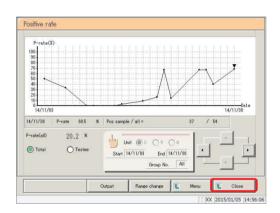
4 Touch the {Start} button.

　　　* The positive rate change is displayed again.

{Start}:　　Calculate positive rates.

{Close}:　　Cancel calculation, and return to the [Positive rate change] screen.

{Cancel}:　　The dialog box closes.

5 Touch the {Close} button.

　　　* The system returns to the [Measured data select] screen.

3.6.4 Outputting positive rate changes
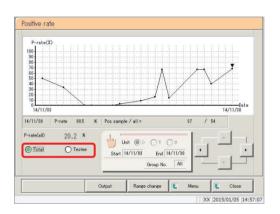
Output positive rate changes to external media or a printer.

- Printing positive rate changes
- Saving positive rate changes to external media

This section describes the procedure from the [Positive rate change] screen.

☞ Page 170 "3.6.1 Displaying positive rate changes"

Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."
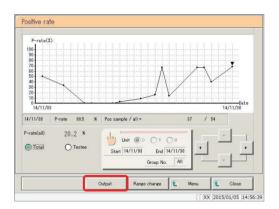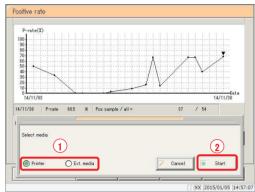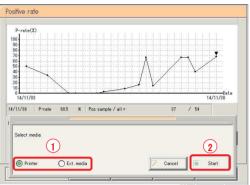
1 Select the display mode for positive samples (by Total/Testee).

Touch the {Total} or {Testee} buttons.

2 Touch the {Output} button.

3 Output positive rate changes.

① Select the output destination.

    ○ Printer

    ○ Ext. media (External media)

② Touch the {Start} button.

         * Positive rate changes are output.

         * When output has completed, the system
           returns to the [Positive rate change] screen.

{Start}:   Output positive rate changes.

{Cancel}:   The dialog box closes.
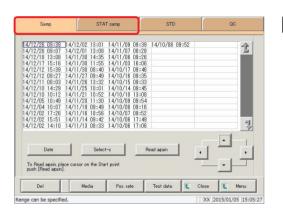
3.7 Replicate

Display the replicate data of the measured data specified on the [Test data] screen.
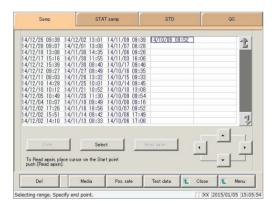
3.7.1 Displaying the replicate list (samples/STAT samples)

Display the replicate data for samples and STAT samples.

(Explanatory note) : All data will be displayed if no range is specified.

1 Touch the tab of the measured data to display.

{Samp} tab

{STAT samp} tab

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**

3   Touch the {Test data} button.

4   Specify the measured data by range of measurement date and time.

① Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can also be used to select this).

② Touch the {Select-s} button.

   * The text in the row of the specified date and time turns blue (start point).
   * The {Select-s} button changes to the {Select} button.

③ Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can also be used to select this).

④ Touch the {Select} button.

   * The text in the row of the specified range turns blue (end point).

{Select-s}:   Confirm start point data for the specified range.

{Select}:   Confirm end point data for the specified range.

{Clear}:   Clear the specified range.

5   Touch the {Replicate} tab.

   * The replicate list is displayed.

6   The replicate list (samples/STAT samples) was displayed.

{CC}:   Edit and recalculate the calibration curve of the specified replicate data.

☞ Page 197 "3.7.9 Editing/recalculating calibration curves"

{Time course}: Display time course data.

☞ Page 204 "3.7.12 Displaying/printing time courses (samples/STAT samples)"

{Recal}:   Recalculate replicate data using modified cut-off values, as well as factors A and B.

☞ Page 194 "3.7.8 Recalculating replicate data"

{Search}:   Search samples based on sample ID, sample number, rack number, and measurement date and time.

☞ Page 192 "3.7.7 Searching replicate data"

Content displayed on the [Replicate] screen
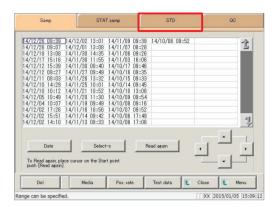
Display	Details		Remark
Date	Date and time sample was measured		
RACK	Rack No. - Position number in rack		
SEQ.	Group No. - Sequence No.		
Data [ng/mL]	Measurement results (concentration value)		
Flag	-, +, 1 +, 2 +, 3 +		
Comment	Error information (excluding reading errors)		
	UR	: Under range	Blank output for measured data and judgment result (displayed during dilute test)
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode information on sampling bottles		
CC	Calibration curve used to calculate measured data (CC No.)		
Dil	Dilution information		
	Space	: No dilution (test mode, remeasure mode)	
	A	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Explanatory note : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.
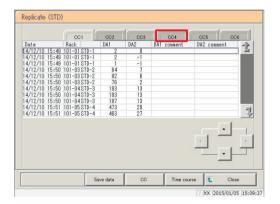
3.7.2 Displaying the [Replicate (STD)] screen
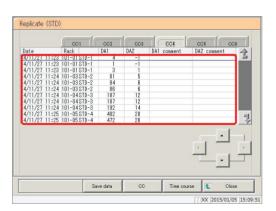
Display STD replicate data.

1 Touch the {STD} tab.

2 Touch the {CC#} tab.

3 Data for each selected calibration curve (CC#) was displayed.

Content displayed on the [Replicate (STD)] screen

Display	Details	Remark
Date	Date and time STD was measured	
RACK	Rack No. - Position number in rack	
DA1	Amount of change for ABS (A#) A3-A1	☞ Page 350 "Appendix: 1.3 DA value calculation"
DA2	Amount of change for ABS (A#) A2-A1	
DA1 comment	Comment for DA1	
DA2 comment	Comment for DA2	

{Save data}:   Save replicate data to external media.

        ☞ Page 184 "3.7.3 Saving replicate data (STD) to external media"

{CC}:   Edit and recalculate the calibration curve of the specified replicate data.

        ☞ Page 197 "3.7.9 Editing/recalculating calibration curves"

{Time course}:   Display the [Time course data] screen.
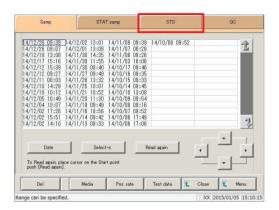
        ☞ Page 205 "3.7.13 Displaying/printing time courses (STD)"

        ☞ Page 208 "3.7.15 Changing the range of the time course (STD)"
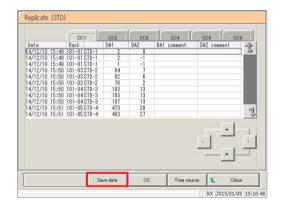
3.7.3 Saving replicate data (STD) to external media

Open the [Replicate (STD)] screen, then save the replicate data displayed on the screen to external media.

1 Touch the {STD} tab.

2 Touch the {Save data} button.

* STD replicate data is saved to external media.

(Explanatory note) : If no external media is connected, "Not connected with external media." is displayed.
Connect the external media and touch the {Retry} button.

MEMO

<div style="border: 1px solid black; padding: 10px;">
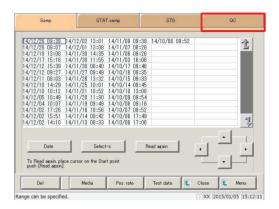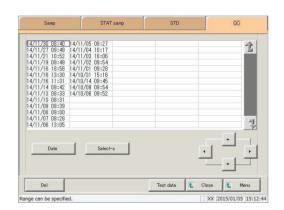
3.7.4 Displaying the [Replicate (QC)] screen

</div>

Display QC replicate data.

Explanatory note : All data will be displayed on the screen if no range is specified.

1 Touch the {QC} tab.

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

☞ Page 104 "3.1.3 Specifying measured data by measurement date and time" **2**

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

☞ Page 106 "3.1.4 Specifying measured data by range" **2**
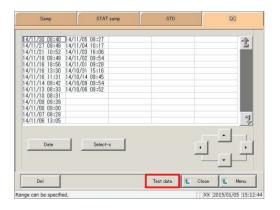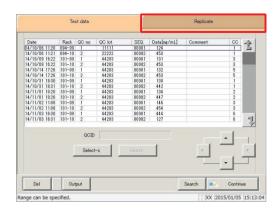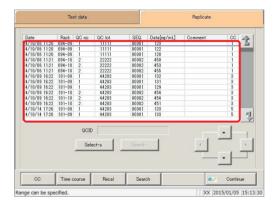
3 Touch the {Test data} button.

4   Touch the {Replicate} tab.

5   The [Replicate (QC)] screen was displayed.

   * Test items and QC IDs are displayed.

Content displayed on the [Replicate (QC)] screen

Display	Details	Remark
Date	Date and time STD was measured	
RACK	Rack No. - Position number in rack	
QC No.	QC sample number	
QC LOT	QC sample lot number	
Seq.	QC sample sequential number	
Data [ng/mL]	QC sample measured data	
Comment	QC IDs and barcode reading errors	
CC	Calibration curve numbers (numbers 1 through 6)	

{CC}:   Edit and recalculate the calibration curve of the specified replicate data.

               ☞ Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT
                  samples)"

{Time course}: Display time course data.

               ☞ Page 204 "3.7.12 Displaying/printing time courses (samples/STAT
                  samples)"

{Recal}:   Recalculate replicate data using modified cut-off values, as well as factors A and B.

               ☞ Page 194 "3.7.8 Recalculating replicate data"

{Search}:   Search samples based on sample ID, sample number, rack number, and measurement
                date and time.

               ☞ Page 192 "3.7.7 Searching replicate data"

3.7.5 Sorting replicate data (samples/STAT samples)

Sort sample and STAT sample replicate data by measurement date and time or by group, and narrow down measured data to process.

When sorting by measurement date and time, replicate data is displayed in ascending order by "date."

When sorting by group, replicate data is displayed in ascending order by "sample number group."
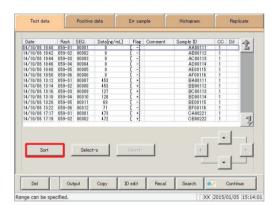
This section describes the procedure from the [Replicate] screen.

☞ Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" **1** through **5**
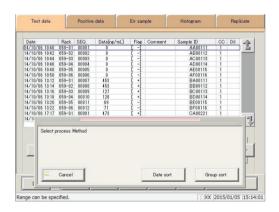
(Explanatory note) : If a range is not specified, all samples displayed on the [Replicate] screen will be sorted.

(Explanatory note) : The range of samples can also be specified using the {Select-s} button on the [Replicate] screen. The method is the same as on page 190 "3.7.6 Specifying replicate data by range."

1 Touch the {Sort} button.

2 Touch the {Date sort} button or the {Group sort} button.
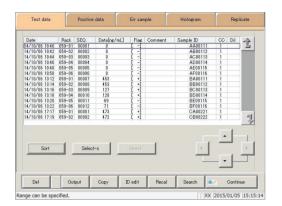
{Date sort}:	Sort measured data in ascending order by measurement date and time.
{Group Sort}:	Sort measured data in ascending order by sample number group.
{Cancel}:	The dialog box closes.
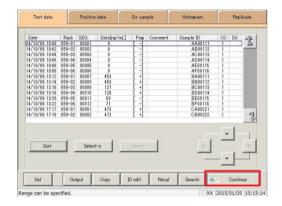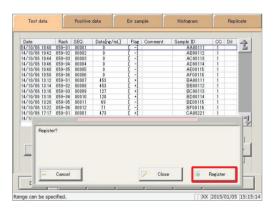
3 Replicate data was sorted.

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}: Register sorted replicate data.

{Close}: Cancel sorting, and return to the [Measured data select] screen.

{Cancel}: The dialog box closes.
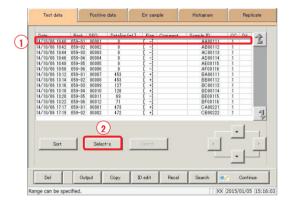
3.7.6 Specifying replicate data by range

Touch the measurement date and time on the [Replicate] screen or operate the cursor buttons to specify replicate data by range of measurement date and time (start and end points).
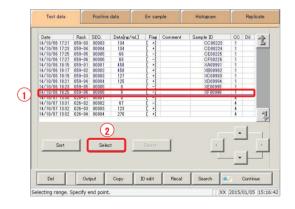
Specify the start point and touch the {Select-s} button to confirm the replicate data at the start point.

Specify the end point and touch the {Select} button to confirm the replicate data at the end point.

After the start and end points are confirmed, the replicate data between the start and end points is specified.

This section describes the procedure from the [Replicate] screen.

☞ Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" **1** through **5**

1 Specify <u>replicate data</u> at the start point.

① Touch the date and time that will be the start point.

② Touch the {Select-s} button.

* Data at the start point is confirmed (the text in the row of the specified date and time turns blue).

* When the start point is confirmed, the {Select-s} button changes to the {Select} button.

2 Specify <u>replicate data</u> at the end point.

① Touch the date and time that will be the end point.

* The text in the row of the specified range turns blue.

② Touch the {Select} button.

* The data for the specified range is displayed.

* When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}: Confirm start point data for the specified range.

{Select}: Confirm end point data for the specified range.

{Clear}: Clear the specified range.
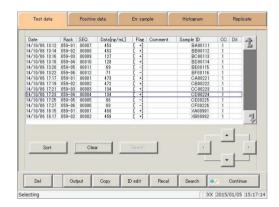
Explanatory note : If the replicate data selected for the start and end points is the same, the system will handle it as though only a single sample of replicate data was specified.

Explanatory note : To specify a new range of replicate data, touch the {Clear} button.

All replicate data is displayed, and the system returns to the state it was in before the range was specified.

3 Replicate data was specified.

* The specified replicate data is displayed.

3.7.7 Searching replicate data

Search replicate data based on sample ID, sample number, rack number, and measurement date and time.

This section describes the procedure from the [Replicate] screen.

☞ Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" **1** through **5**

Explanatory note : If a range is not specified, all error samples will be searched.
Replicate data cannot be searched for using the rack position number.
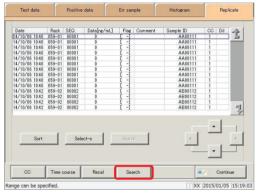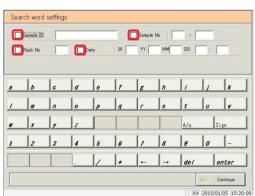
Explanatory note : The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.
The method is the same as on page 190 "3.7.6 Specifying replicate data by range."

Explanatory note : The replicate data can also be sorted using the {Sort} button on the [Replicate] screen.
The method is the same as on page 188 "3.7.5 Sorting replicate data (samples/STAT samples)."
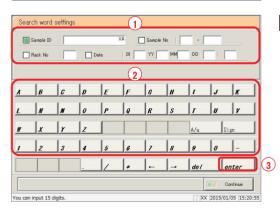
1 Touch the {Search} button.

2 Select the type of keyword to search.

☐ Sample ID

☐ Sample No.

☐ Rack No.

☐ Date

3 Enter a keyword.

① Touch the "input field" next to the name of the keyword.

② Enter a keyword using the keypad.

③ Touch the {enter} key.

{A/a}: Switch input between uppercase and lowercase.
{Sign}: Allows for input of symbols.

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Explanatory note : Entry of the group number and measurement date and time can be omitted. However, if a
measurement date and time box is checked, it is necessary to input at least one of the following: year,
month, date, hour, and minute.

Explanatory note : The search range is the range specified on the [Test data] screen.

Explanatory note : The {A/a} and {Sign} buttons are
available when the cursor is in the input
field.

4 Touch the {Continue} button.

5 Touch the {Start} button.

* Searching begins.

* Search results are displayed.

6 Register the search results.

① Touch the {Continue} button.

② Touch the {Register} button in the dialog box.

3.7.8 Recalculating replicate data

Recalculate replicate data using modified cut-off values, as well as factors A and B.

Edited calibration curves can also be used for recalculation.

This section describes the procedure from the [Replicate] screen.

☞ Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 5

Explanatory note : ・The values used for judging replicates for which a range has been specified are shown in Cut off 1, Cut off 2, and Cut off 3.

・If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1, Cut off 2, and Cut off 3.

Explanatory note : If the factor value differs according to the replicate data, factor A and factor B are displayed as 1.00 and 0.00, respectively.

Explanatory note : Values configured in the [Recalculation condition settings] screen are not applied to protocol settings.

Explanatory note : If the {Memory} button on the [Check CC] screen is touched before touching the {Recal} button, recalculation will be performed using the calibration curve in memory.

Example 1:

{Recal} run on CC1 and CC2 after saving with {Memory}

→ Data that references CC1 and CC2 is fit to the calibration curve in memory, then recalculation is performed.

→ Data that does not reference CC1 and CC2 is not fit to the calibration curve, then corrective calculation (factor A/factor B/dilution ratio calculation) is performed.

Example 2:

{Recal} run after saving CC2 to CC1 with {Memory}

→ Data that references CC1 is fit to the calibration curve in memory, then recalculation is performed.

→ Data that does not reference CC1 is not fit to the calibration curve in memory, then corrective calibration (factor A/factor B/dilution ratio calculation) is performed.

Example 3:

{Recal} is run without saving using {Memory} on the [Check CC] screen

→ Cut-off, factor A, and factor B recalculation is performed, then calibration curve fitting calculation is not performed.

Explanatory note : Recalculation results are applied to measured data, positive sample data, error sample data, and histograms.
After registering recalculation results, they are also applied to values on the [Positive change] screen.
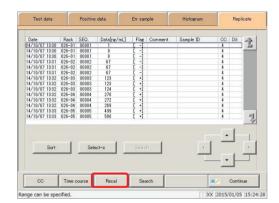
Explanatory note : If a range is not specified, all replicate data displayed on the [Replicate] screen will be recalculated.

Explanatory note : The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.
The method is the same as on page 190 "3.7.6 Specifying replicate data by range."
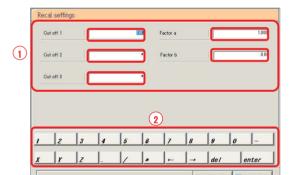
1 Touch the {Recal} button.

Explanatory note : If recalculating using an edited calibration curve, first save the edited calibration curve to memory prior to recalculation.
☞ Page 190 "3.7.9 Editing/recalculating calibration curves" **7** through **8**
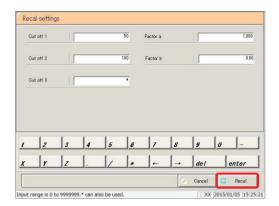
2 Configure the recalculation conditions.
① Touch the "input field" next to the setting.
② Enter numbers using the numeric keypad.
   ・ Cut off 1
   ・ Cut off 2
   ・ Cut off 3
   ・ Factor A
   ・ Factor B

{Cancel}: Cancel recalculation, and return to the [Replicate] screen.

Setting	Input Range
Cut off 1	0 - 9,999,999
Cut off 2	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
Factor A	0.001 - 99,999.999
Factor B	-999.99 - 999.99
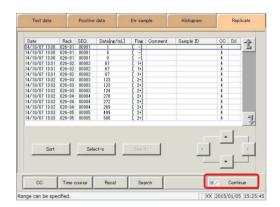
3.7 Replicate
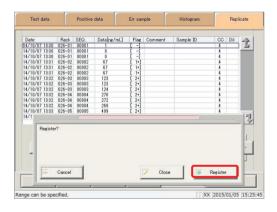
3 Touch the {Recal} button.

    * Recalculation performed with the conditions that were input.

Explanatory note : If the calibration curve was not saved to memory (if the {Memory} button was not touched), recalculation is performed with cut-off, factor A, and factor B, then calibration curve fitting calculation is not performed.

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}: Register the recalculation results.

{Close}: Cancel registration, and return to the [Replicate] screen.

{Cancel}: The dialog box closes.

3.7.9   Editing/recalculating calibration curves (samples/STAT samples)

Edit the origin and DA values of the calibration curve, then recalculate or save the recalculated calibration curve to memory.

Calibration curves displayed on the screen can also be (memory) saved to other calibration curves (CC numbers), and calibration curve fitting calculation can be redone.

This section describes the procedure from the [Replicate] screen.

Explanatory note : The following DA values can be input through calibration curve editing.

STD-1 through STD-5: DA1

STD-6: DA1, DA2
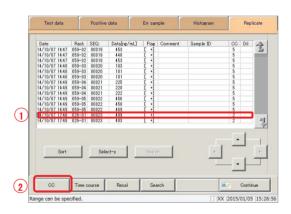
Explanatory note : DA-2 of STD-6 is used for the PRC check.

Explanatory note : If a range is not specified, all replicate data displayed on the [Replicate] screen will be recalculated.

Explanatory note : The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.
The method is the same as on page 190 "3.7.6 Specifying replicate data by range."
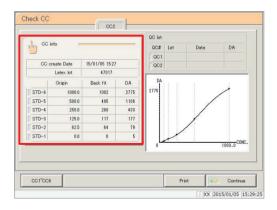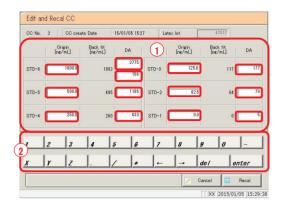
1 Display the calibration curve.

① Touch the row of the applicable data.

② Touch the {CC} button.

* The calibration curve of the specified replicate data is displayed.

2 Touch the {CC info} button.
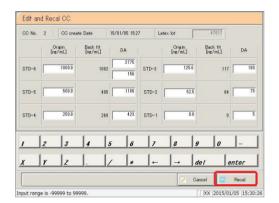
3.7 Replicate
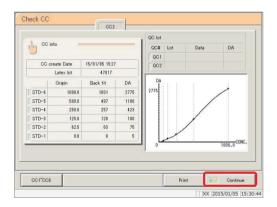
3 Edit the data.

① Touch the input field for the item to edit.

② Enter a value.

Explanatory note : The following items can be input
through calibration curve editing.
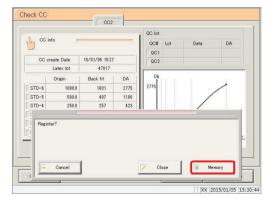
STD-1 - STD-5 : DA1

STD-6 : DA1, DA2

4 Touch the {Recal} button.

* The result of recalculating the calibration
curve and QC is displayed.

5 Touch the {Continue} button.
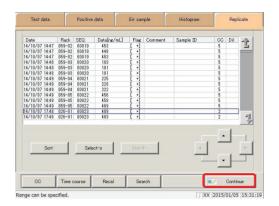
6 Touch the {Memory} button.

* The calibration curve data is saved to memory
(it is not registered to the system).

{Memory}: Save calibration curve data to memory.
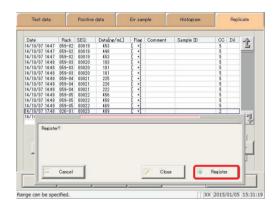
{Close}: Cancel saving to memory, and return to the
[Replicate] screen.

{Cancel}: The dialog box closes.

7 Touch the {Continue} button.

8 Touch the {Register} button.

{Register}:   Register the recalculation results.
{Close}:   Cancel registration, and return to the [Replicate] screen.
{Cancel}:   The dialog box closes.
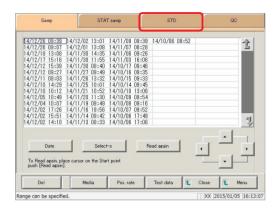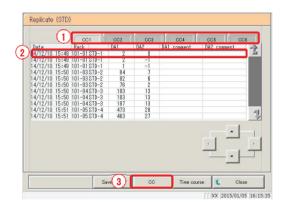
3.7.10   Editing/recalculating calibration curves (STD)
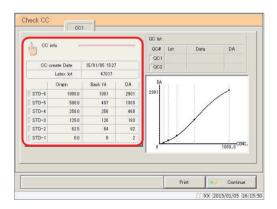
Edit the origin and DA values of the calibration curve, then recalculate or save the recalculated calibration curve to the hard disk(SSD).
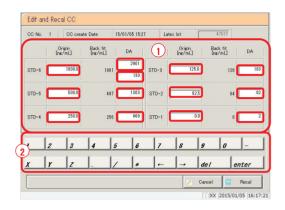
1   Touch the {STD} tab.

2   Select the calibration curve.

①   Touch the {CC#} tab.

②   Select the measurement date and time.

③   Touch the {CC} button.

* The calibration curve is displayed.
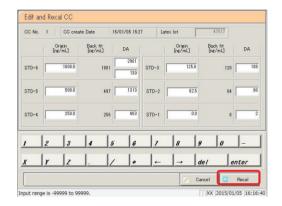
3   Touch the {CC info} button.
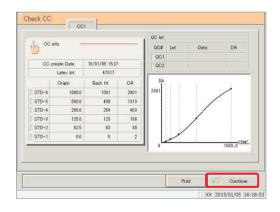
4 Edit the calibration curve.

① Touch the input field for the item to edit.

② Enter a value.
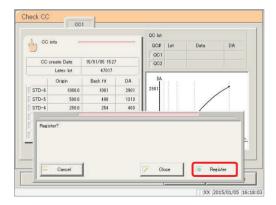
Explanatory note : The following items can be input
through calibration curve editing.
STD-1 - STD-5 : DA1
STD-6 : DA1, DA2

5 Touch the {Recal} button.

* The result of recalculating the calibration
curve is displayed.

6 Touch the {Continue} button.

7 Touch the {Register} button.

* The calibration curve was registered.

{Register}: Register the calibration curve data.
{Close}: Cancel registration, and return to the [Replicate (STD)] screen.
{Cancel}: The dialog box closes.
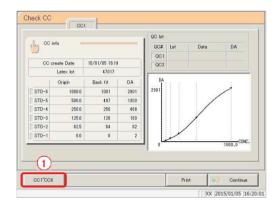
> ## 3.7.11   Reading/registering calibration curves (samples/STAT samples)

Read calibration curves and display them on the screen, or register displayed calibration curves to other calibration curves (calibration curves are registered to the hard disk(SSD)).

This section describes the procedure from the [Check CC] screen.
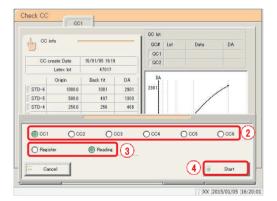
☞ Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)" **1**

1 Read the calibration curve.

(Calibration curve CC1 is displayed.)

①   Touch the {CC1} ~ {CC6} buttons.

②   Select the calibration curve (CC2 through CC3).

③   Check "Reading."

④   Touch the {Start} button.

* The calibration curve is read.

{Cancel}:   The dialog box closes.
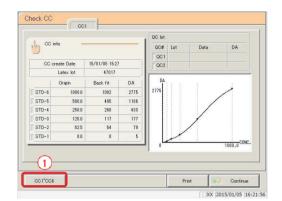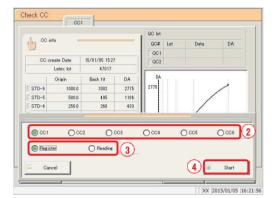
(Explanatory note) : "Reading" causes the specified calibration curve to be read and displayed on the screen.

(Explanatory note) : If the reagent lot of the displayed calibration curve differs from that of the calibration curve selected for reading, the calibration curve is not read.
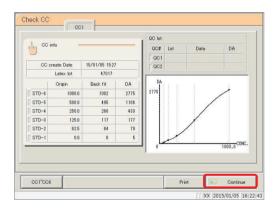
2 Register the calibration curve shown on the screen.

① Touch the {CC1} ~ {CC6} buttons.
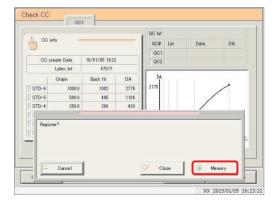
② Select the calibration curve of the registration destination.

③ Check "Register."

④ Touch the {Start} button.

＊ The calibration curve is registered to the hard disk(SSD).

{Cancel}: The dialog box closes.

3 Touch the {Continue} button.

{Print}: Print the calibration curve.

4 Touch the {Memory} button.

＊ The system returns to the [Replicate] screen.

{Memory}: Save the calibration curve to memory.

{Close}: Cancel saving to memory, and return to the [Replicate] screen.

{Cancel}: The dialog box closes.
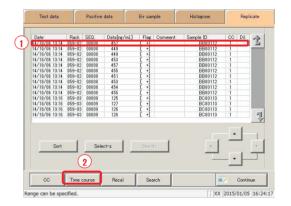
3.7.12   Displaying/printing time courses (samples/STAT samples)

Display the time course of the replicate data (samples/STAT samples).
The time course (graph), number of cycles (cycles), and absorbance (ABS) are displayed on the screen.
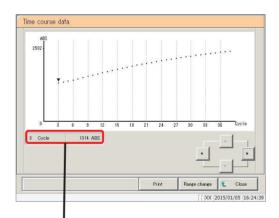
This section describes the procedure from the [Replicate] screen.

☞ Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)"   **1**   through   **3**

1   Display the time course.

   ①   Touch the date and time field.

        * The specified data is enclosed in a blue box.

   ②   Touch the {Time course} button.

        * The time course of the specified data is displayed.

2   The time course was displayed.

Touch the {Print} button to print the time course.

{Print}:	Print the time course.
{Range change}:	Change the range of the time course.
{Close}:	Return to the [Replicate] screen.

Explanatory note : The "▼" symbol displayed on the screen can be moved with the cursor buttons.
The cursor's numeric information is displayed in ⬚.
The meaning of the display is shown below.

#Cycle   #ABS
  ↑   ↑
  a   b

a   : Number of cycles

b   : Absorbance (measured data - cell-blank value)

3.7.13 Displaying/printing time courses (STD)

Display the time course of the replicate data.

The time course (graph), number of cycles (cycles), and absorbance (ABS) are displayed on the screen.

This section describes the procedure from the [Replicate (STD)] screen.
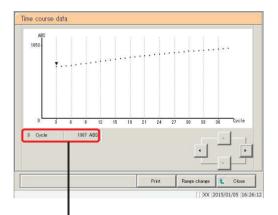
☞ Page 182 "3.7.2 Displaying the [Replicate (STD)] screen"

1 Touch the {Time course} button.

    * The time course of the specified data is displayed.

2 The time course was displayed.

    Touch the {Print} button to print the time course.

{Print}:	Print the time course.
{Range change}:	Change the range of the time course.
{Close}:	Return to the [Replicate] screen.

Explanatory note : The "▼" symbol displayed on the screen can be moved with the cursor buttons.
The cursor's numeric information is displayed in ⬚.
The meaning of the display is shown below.

#Cycle #ABS
  ↑   ↑
  a   b

a : Number of cycles
b : Absorbance (measured data - cell-blank value)
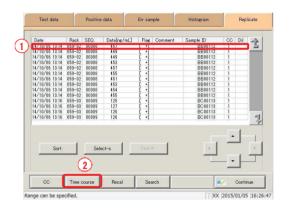
3.7.14   Changing the range of the time course (samples/STAT samples)

Enter the "Max Value" and "Min Value" and change the range on the [Time course data Range change] screen.

This section describes the procedure from the [Replicate] screen.
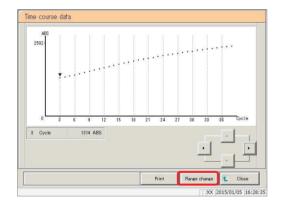
☞   Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)"   **1**
    through   **3**

Explanatory note   : Time course data for which the range has been changed is not saved to the hard disk(SSD).

1   Display the time course.

①   Touch the date and time field.
    * The specified data is enclosed in a blue box.

②   Touch the {Time course} button.
    * The time course of the specified data is displayed.
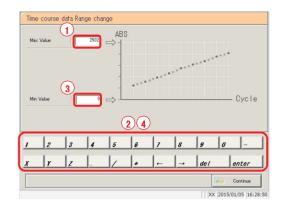
2   Touch the {Range change} button.

{Print}:   Print the time course.
{Range change}:   Change the range of the time course.
{Close}:   Return to the [Replicate] screen.
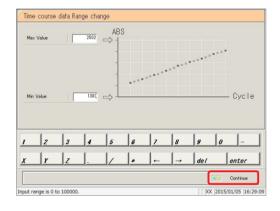
3 Enter the absorbance.

(input range: 0 to 10,000)

① Touch the [Max Value] input field.

② Enter numbers using the numeric keypad.

③ Touch the [Min Value] input field.

④ Enter numbers using the numeric keypad.

4 Touch the {Continue} button.
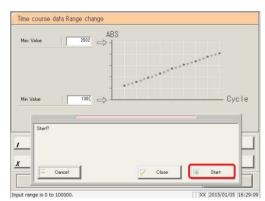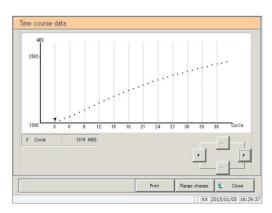
5 Touch the {Start} button.

　　　　* The range is modified.

{Cancel}: The dialog box closes.

{Start}: Modify the range.

{Cancel}: Cancel range modification, and return to the [Time course data] screen.

6 The time course with modified range was displayed.

{Print}: Print the time course.
To cancel printing, touch the {Cancel} button during printing.

{Close}: Return to the [Replicate] screen.
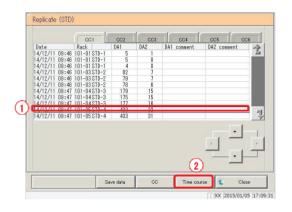
3.7.15   Changing the range of the time course (STD)

Enter the "Max Value" and "Min Value" and change the range on the [Time course data Range change] screen.

This section describes the procedure from the [Replicate (STD)] screen.
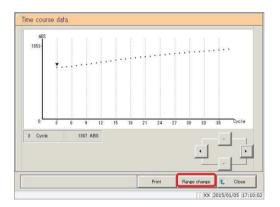
☞   Page 182 "3.7.2 Displaying the [Replicate (STD)] screen"

Explanatory note : Time course data for which the range has been changed is not saved to the hard disk(SSD).

1   Display the time course.

①   Touch the date and time field.

* The specified data is enclosed in a blue box.

②   Touch the {Time course} button.

* The time course of the specified data is displayed.
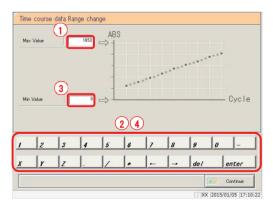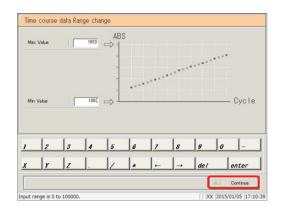
2   Touch the {Range change} button.

3   Enter the absorbance.
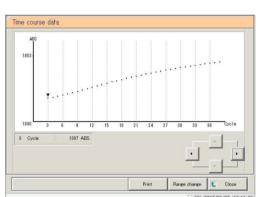
(input range: 0 to 10,000)

①   Touch the [Max Value] input field.

②   Enter numbers using the numeric keypad.

③   Touch the [Min Value] input field.

④   Enter numbers using the numeric keypad.

4   Touch the {Continue} button.

5   Touch the {Start} button.

{Start}:   Modify the range.

{Close}:   Cancel range modification, and return to the
                [Time course data] screen.

{Cancel}:   The dialog box closes.

6   The time course with modified range was
        displayed.

{Print}:   Print the time course.
                To cancel printing, touch the {Cancel} button
                during printing.

{Close}:   Return to the [Replicate (STD)] screen.

3.8　Quality Control

The QC lot list, inter/intra-day data, and $\overline{X}$-R control graph are displayed in quality control.
Quality control also allows for editing inter/intra-day data, and changing the range of the X-R control graph.
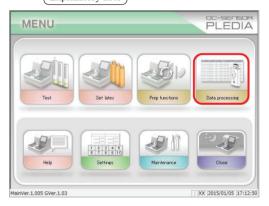
3.8.1　Displaying the QC lot list ([QC lot select] screen)

Touch the {Data processing} - {Process QC} buttons from the [MENU] screen, or touch the {Quality control} tab on the [Monitor] screen to display the QC lot list ([QC lot select] screen).
(Test items must be selected and the {Start} button must be operated.)
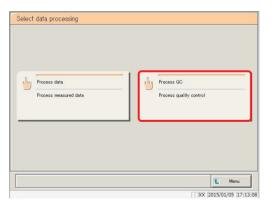
In addition to the {QC lot select} tab, this screen also has {Intra-day/Inter-day} and {$\overline{X}$-R control graph} tabs.

☞　Page 212 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"
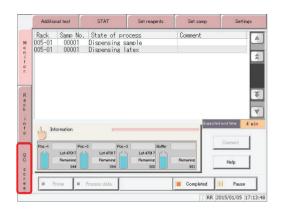
Explanatory note ： If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.

1　<Opening from the menu screen>

①　Touch the {Data processing} button.

②　Touch the {Process QC} button.

<Opening from the monitor screen>

Touch the {QC screen} tab.
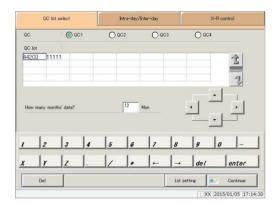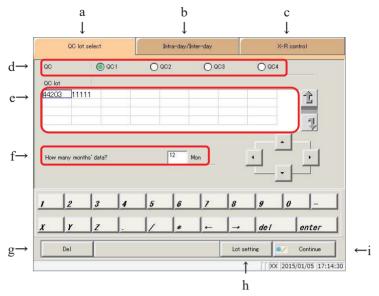
2 The [QC lot select] screen opened.

·   {QC lot select} tab

·   {Intra-day/Inter-day} tab

·   {X-R control graph} tab

* The recently used QC lots are displayed in order.

(Displayed from left to right, up to down.)

a   b   c

[Screen]: QC lot select screen

a	QC lot select	The "QC lot list" saved to QC1 through QC4 is displayed.
b	Intra-day/Inter-day	Intra-day and inter-day data for the specified QC# and QC lots are displayed.
c	$\overline{X}$-R control graph	Displays $\overline{X}$-R control graphs of intra-day/inter-day data.
d	QC	Select the QC# of the QC lot to display.
e	QC lot	The QC lot of the selected QC# is displayed. Select the QC lot to use.
f	☐ Mon	Specify the QC lot to use by in month units. Enter the number of months for data processing.
g	Del	Delete the selected QC lot.
h	Lot setting	The [STD/QC process settings] screen is displayed. ☞ Page 298 "6.1.10 STD/QC analysis process settings"
i	Continue	Register the modified data.

MEMO
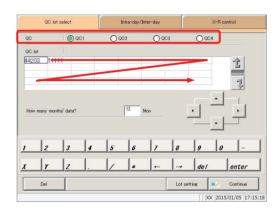
3.8.2   Selecting QC lots

Open the [QC lot select] screen to display the QC lot list. The QC number and QC lot selected from this list will be processed on the {Intra-day/Inter-day} and {$\overline{X}$-R control graph} tabs.

☞   Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"

☞   Page 228 "3.8.9 Displaying the $\overline{X}$-R control graph"
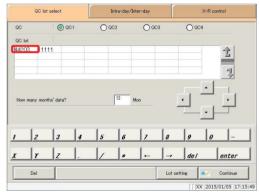
This section describes the procedure from the [QC lot select] screen.

☞   Page 210 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"
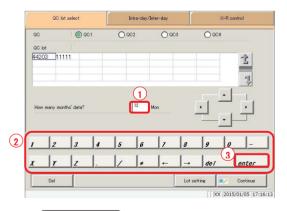
1   Touch the QC number. (QC1 to QC4)

* Recently used QC lots are displayed in order on the list.

(Displayed from left to right, up to down.)

2   Touch the QC lot (can also be selected using the cursor keys).

3   Enter the amount of data to process in months. (See the [Explanatory note] for an example.)

① Touch the input field.

② Enter numbers using the numeric keypad.

③ Touch the {enter} key button.

[Explanatory note] : The QC lot list shows data from the month of the latest data to the specified number of months back (from 1 to 36 months, entered in single month units).

Example 1: "1 mon" entered with June 15 as current date: June 1 to June 15
Example 2: "3 mon" entered with June 15 as current date: April 1 to June 15

3.8.3   Deleting QC lots

Delete QC number-QC lot selected in "3.8.2 Selecting QC lots."
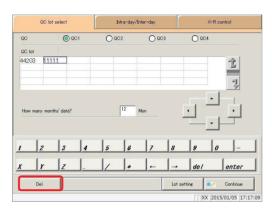
After selecting the QC lot to delete, touch the {Continue} button, then touch the {OK} button in the dialog box.

Data for which QC number-QC lot has been deleted is updated in the hard disk(SSD).
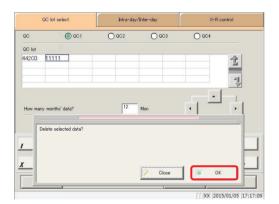
* If the {OK} button is not touched, the updated data is only in memory, and is not updated in the hard disk(SSD).

This section will explain from the point where the procedure in "3.8.2 Selecting QC lots"   **2**   has been completed.

☞ Page 214 "3.8.2 Selecting QC lots"
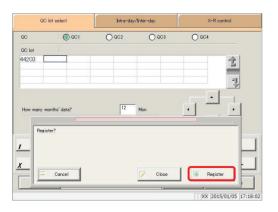
1   Touch the {Del} button.

2   Touch the {OK} button.

* Data in memory was updated.

{Cancel}:   Cancel deletion of QC lot.

3   Save updated data.

① Touch the {Continue} button.

② Touch the {Register} button.

* The updated data was saved to the hard disk(SSD).

{Close}:   Return to the [Data process selection] screen.

{Cancel}:   The dialog box closes.
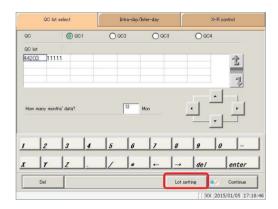
3.8.4　Changing STD/QC measurement process settings from the [QC lot select] screen

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Pressing the {Lot setting} button on the [QC lot select] screen opens the [STD/QC process settings] screen. From here settings can be changed.
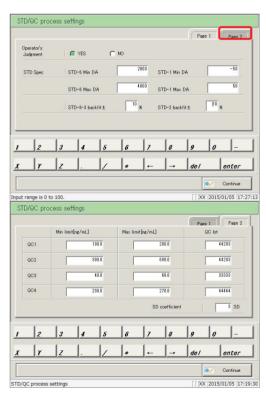
This is the same screen that opens when the {STD/QC process settings} button is touched on the [MENU] - [Settings] - [System settings] screen. However, settings cannot be modified during testing.

This section describes the procedure from the [QC lot select] screen.

☞　Page 210 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"

1　Touch the {Lot setting} button.

2　Change the data.

　　Touch the {Page 2} tab.

Explanatory note ： For details on settings, see page 298 "6.1.10 STD/QC analysis process settings."

MEMO
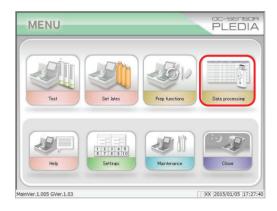
3.8.5   Opening the [Intra-day/Inter-day] screen

Touching the {Intra-day/Inter-day} tab on the [QC lot select] screen opens the {Intra-day/Inter-day} screen. The inter/intra-day data of the QC number-QC lot specified on the [QC lot select] screen is displayed.

> Explanatory note   : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1   <Opening from the menu screen>

① Touch the {Data processing} button.

② Touch the {Process QC} button.

<Opening from the monitor screen>

Touch the {QC screen} tab.

2   The [QC lot select] screen opened.

* The recently used QC lots are displayed in order.

(Displayed from left to right, up to down.)

3   Select the QC and QC lot.

☞   Page 214 "3.8.2 Selecting QC lots"
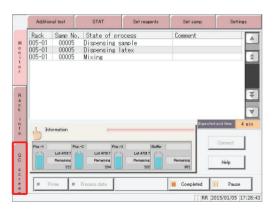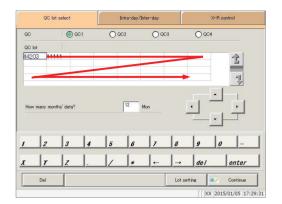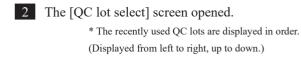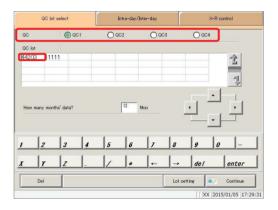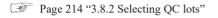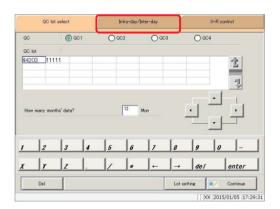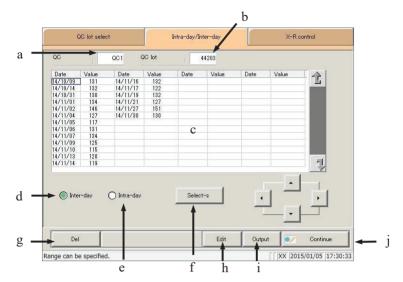
4   Touch the {Intra-day/Inter-day} tab.

* The [Intra-day/Inter-day] screen is displayed.

(See the following page.)

[Screen]: Intra-day/inter-day data

a	QC	The QC (QC1 to QC4) that was specified on the [QC lot select] screen is displayed.
b	QC lot	The QC lot specified on the [QC lot select] screen is displayed.
c	Quality control data (The measurement date and mean value.)	Inter-day data selected The measurement date and mean value of the specified QC/QC lot is displayed. Intra-day data selected The measurement time and mean value of the specified QC/QC lot is displayed.
d	Inter-day	Display the inter-day data (measurement date/mean value).
e	Intra-day	Display the intra-day data (measurement date and time/mean value).
f	{Select-s}	Specify the range of inter-day or intra-day data. The range of data can also be specified using the cursor buttons.
g	{Del}	Delete the specified inter-day or intra-day data.
h	{Edit}	Edit inter-day or intra-day data.
i	{Output}	Output inter-day or intra-day data (printer, external media).
j	{Continue}	Register edited inter-day or intra-day data to the hard disk(SSD). The data [Registration confirmation] screen is displayed; touch the {Register} button.

MEMO

3.8.6   Editing (recalculating) inter/intra-day data

Touching the {Intra-day/Inter-day} tab on the [QC lot select] screen opens the {Intra-day/Inter-day} screen. The inter-day or intra-day data of the specified QC number-QC lot is displayed.
Select a radio button to switch between inter-day and intra-day data.

> Inter-day: Edit each item of intra-day data.
> Intra-day: Edit each item of replicate data.

This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

* This assumes that the QC lot has already been selected on the [QC lot select] screen.
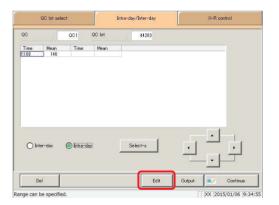
Explanatory note : If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.

Explanatory note : Up to ten measurements may be made per day for a single QC lot and QC number. Results of the 11th or later measurement for the day will not be stored.
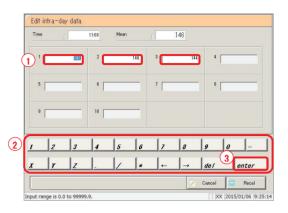
1 Select the data to edit.

○   Inter-day
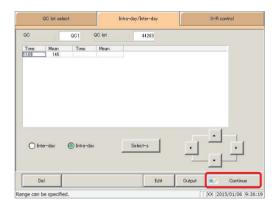
○   Intra-day
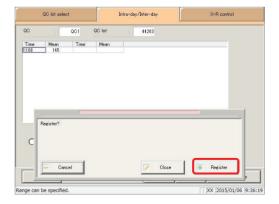
2 Touch the {Edit} button.

3 Edit inter-day data (or intra-day data).

① Touch the input field for the data.

② Enter numbers using the numeric keypad.

③ Touch the {enter} key button.

4 Touch the {Recal} button.

{Cancel}: Cancel editing inter-day or intra-day data. The system returns to the [Intra-day/Inter-day] screen.

5 Touch the {Continue} button.

   * The new mean value is displayed.

6 Touch the {Register} button.

   * Recalculated results were registered.

{Close}: Return to the [Data process selection] screen.

{Cancel}: The dialog box closes.

3.8.7 Deleting inter/intra-day data
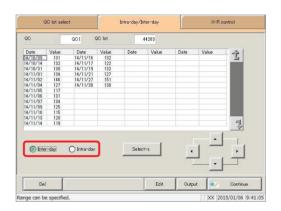
Specify a range of data on the [Intra-day/Inter-day] screen, then delete inter-day or intra-day data. When deleted, specified data will no longer appear on the screen. However, data is not updated until the {Register} button is touched (hard disk(SSD) data is not updated).

This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

* This assumes that the QC lot has already been selected on the [QC lot select] screen.
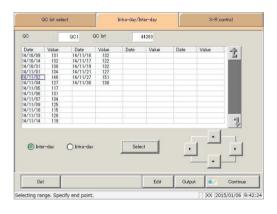
☞ Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"
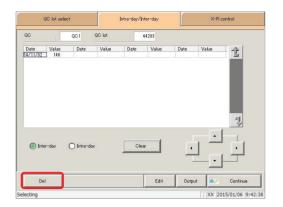
Explanatory note : If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.

1 Select the data to edit.

○ Inter-day

○ Intra-day

2 Specify the range of data to delete.

* Only the selected data is displayed.

☞ Page 226 "3.8.8 Specifying inter/intra-day data by range"

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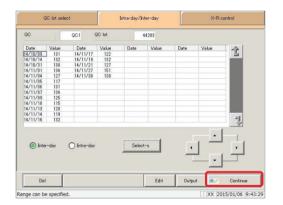
3 Touch the {Del} button.

4 Touch the {OK} button.
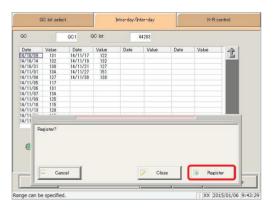
      * Data in memory is updated.
      * Data specified on the screen is deleted.

{Cancel}:   Cancel the deletion of inter/intra-day data.

5 Touch the {Continue} button.

6 Touch the {Register} button.

{Close}:   Return to the [Data process selection] screen.
{Cancel}:   The dialog box closes.

3.8.8   Specifying inter/intra-day data by range
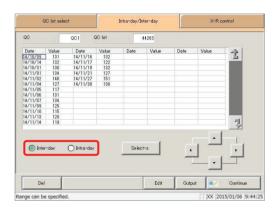
Specify the data using a measurement date and time range on the [Intra-day/Inter-day] screen (start point/end point).

Use this to delete inter/intra-day data in bulk, or when displaying the $\overline{X}$-R control graph.
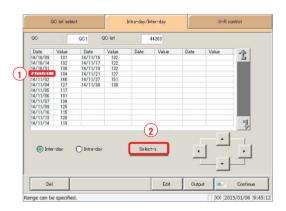
This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

> * This assumes that the QC lot has already been selected on the [QC lot select] screen.
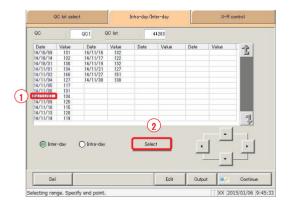
☞   Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"

1   Select the data to specify.

- ○   Inter-day
- ○   Intra-day

2   Specify the measurement date at the start point.

① Touch the measurement date that will be the start point.

② Touch the {Select-s} button.

> * The data at the start point was confirmed.
> * When the start point is confirmed, the {Select-s} button changes to the {Select} button.

3   Specify the measurement date at the end point.

① Touch the measurement date that will be the end point.

② Touch the {Select} button.

> * The data at the end point was confirmed.
> * When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}:   Confirm start point data for the specified range.

{Select}:   Confirm end point data for the specified range.

{Clear}:   Cancel the range specification.

Explanatory note : If the data selected for the start and end points is the same, the system will handle it as though only a single sample of data was specified.

Explanatory note : To specify a new range of data, touch the {Clear} button. All data is displayed, and the system returns to the state it was in before the range was specified.

Explanatory note : If the [X-R control graph] screen is opened without opening the [Intra-day/Inter-day] screen from the [QC lot select] screen first, all data will be specified.
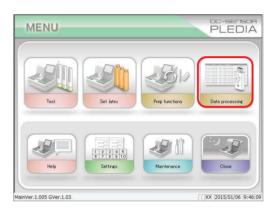
3.8.9 Displaying the X̄-R control graph

Displays X̄-R control graphs of intra-day/inter-day data.
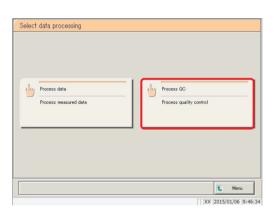
If inter-day data is selected on the [QC lot select] screen, the X̄-R control graph for inter-day data is displayed.

If intra-day data is selected on the [QC lot select] screen, the X̄-R control graph for intra-day data is displayed.
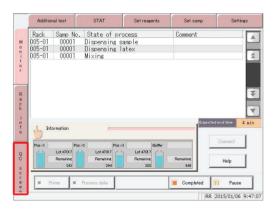
> [Explanatory note] : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1 <Opening from the menu screen>

① Touch the {Data processing} button.

② Touch the {Process QC} button.

<Opening from the monitor screen>

Touch the {QC screen} tab.

2 The [QC lot select] screen opened.

  * The recently used QC lots are displayed in order.
   (Displayed from left to right, up to down.)

3 Select the QC and QC lot.

  ☞ Page 214 "3.8.2 Selecting QC lots"

4 Touch the {Intra-day/Inter-day} tab.
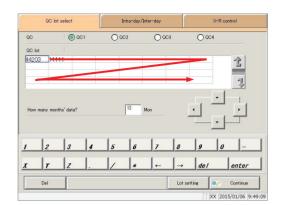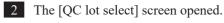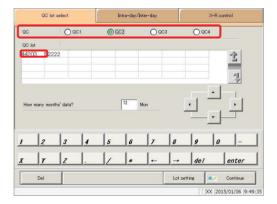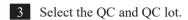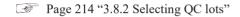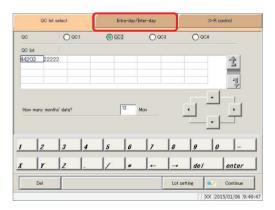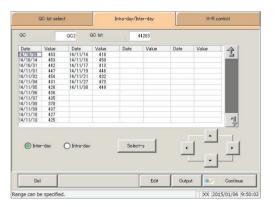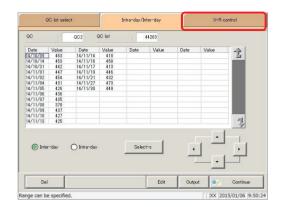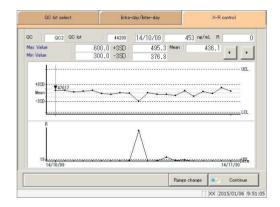
5 Select the data to display an $\overline{\text{X}}$-R control graph for.

  ☞ Page 226 "3.8.8 Specifying inter/intra-day data by range"
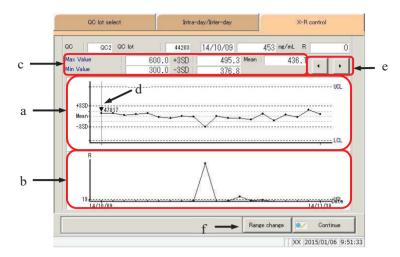
6   S Touch the {$\bar{\text{X}}$-R control graph} tab.

7   The $\bar{\text{X}}$-R control graph was displayed.

Explanatory note : An R graph's maximum control limit value is calculated based on the total measurement
determined across multiple repeated measurements. If the number of repeated measurements
varies, it is calculated based on the total measurement of the smallest number of measurements.

[Screen]: $\overline{\text{X}}$-R control graph
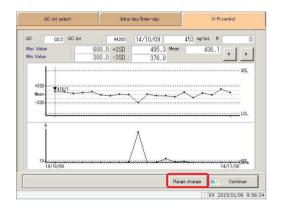
a	X graph (upper graph)	·	Data is displayed for the measurement date and measurement time.
		·	The overall mean and ±#SD are displayed.
		·	The maximum control limit value (UCL) and minimum control limit value (LCL) set on the [System settings] - [STD/QC process settings] screen are displayed in blue.
		·	Data that meets the criteria of <u>less than LCL value + 1</u> or <u>not less than ULC value + 1</u> is plotted in red.
b	R graph (lower graph)	·	A <u>range of data</u> is displayed for the measurement date and measurement time.
		·	The R upper limit value is displayed.
c	Max limit	·	The maximum control limit value (UCL) set on the [System settings] - [STD/QC process settings] screen is displayed.
	Min limit	·	The minimum control limit value (LCL) set on the [System settings] - [STD/QC process settings] screen is displayed.
	+ #SD	·	Calculated + # SD value
		·	The standard deviation coefficient (# = 1 to 9) set on the [System settings] - [STD/QC process settings] screen is displayed.
	- #SD	·	Calculated - # SD value
		·	The standard deviation coefficient (# = 1 to 9) set on the [System settings] - [STD/QC process settings] screen is displayed.
	Mean	·	Calculated mean value
d	▼ (in graph)	·	Shows that a calibration curve that was used has changed.
		·	The reagent lot is displayed next to the ▼ symbol.
e	{◄}, {►}	·	Move the cursor (vertical line) displayed in the graph.
f	{Range change}	·	Change the range (maximum concentration, minimum concentration, R maximum) of the $\overline{\text{X}}$-R control graph.

3.8.10 Changing the range of the $\overline{X}$-R control graph
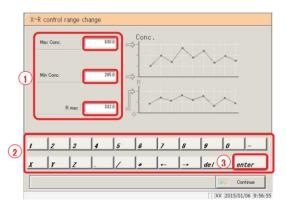
Change the range of the $\overline{X}$-R control graph.

This section will begin explaining from the [$\overline{X}$-R control graph] screen.
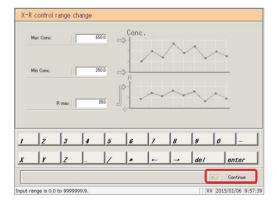
☞   Page 228 "3.8.9 Displaying the $\overline{X}$-R control graph"
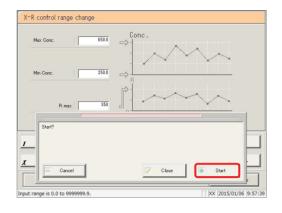
1   Touch the {Range change} button.
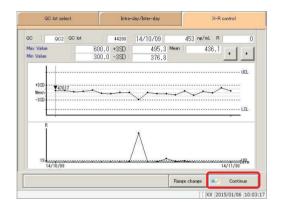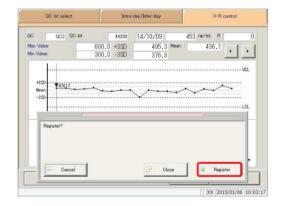
2   Modify the range.

①   Touch the input field for the setting.

②   Enter numbers using the numeric keypad.

・   Max Conc.

・   Min Conc.

・   R max

③   Touch the {enter} key.

3   Touch the {Continue} button.

4 Touch the {Start} button.

  * The $\overline{X}$-R control graph with modified range is displayed.

{Close}: Cancel range modification, and return to the [$\overline{X}$-R control graph] screen.

{Cancel}: The dialog box closes.

5 Touch the {Continue} button.

6 Touch the {Register} button.

  * The $\overline{X}$-R control graph is registered.

  * The system returns to the [Data process selection] screen.

{Close}: Cancel $\overline{X}$-R control graph registration, and return to the [Data process selection] screen.

{Cancel}: The dialog box closes.

3.9 Rack info

Touch the {Rack info} button on the [Test] screen or [Monitor] screen to confirm rack information, change trays, and more.

<Available functions on the rack information screen>
- Analytical information about the rack on the rack discharge unit
- Type of measured rack (STD/QC rack, retest rack, dilute test rack, sample rack)
- Rack position number
- Sample status display (error, OR/PRC, positive, normal, unfinished, unset)
- Rack information printing
- Tray (optional) replacement
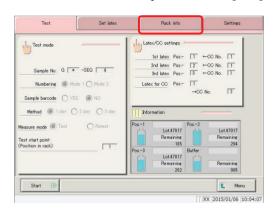
> (Explanatory note) : Rack information for up to 500 racks can be stored after the system is started (up to 25 racks can be displayed). This rack information is deleted if the power is turned off (rack information remains if power is lost due to a power outage or the like).

3.9.1 Displaying the [Rack info] screen
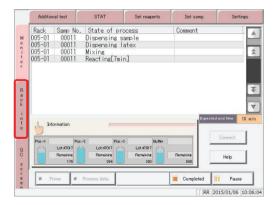
Touch the {Rack info} tab and display rack information.

This section will explain from the [Test] screen and [Monitor] screen.
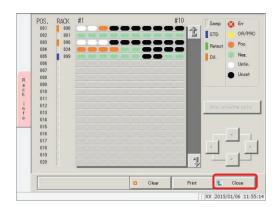
1 <From the [Test] screen>

Touch the {Rack info} tab.
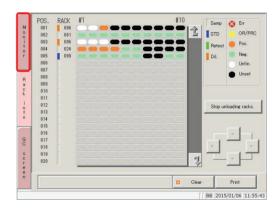
<From the [Monitor] screen>

Touch the {Rack info} tab.
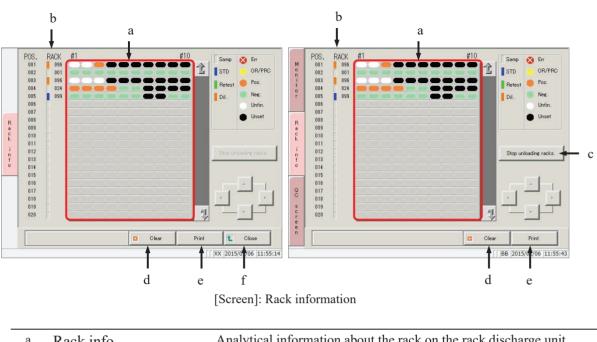
2 The [Rack info] screen was displayed.

   * Information about the rack that was last
     discharged is displayed at the top of the screen.

Explanatory note : Touch the {Close} button to return to the [Test] screen.

Explanatory note : Touch the {Monitor} tab to return to the [Monitor] screen.

3.9 Rack info

[Screen]: Rack information

a	Rack info		Analytical information about the rack on the rack discharge unit
	White × in a red background		Error (including sample barcode reading errors and order errors)
	Yellow		OR/PRC
	Yellowish orange		Positive sample
	Light green		Normal sample
	White		Unfinished
	Black		Unset
b	RACK No.		Rack number and measurement rack (displayed to left of rack number)
	Gray		Sample rack (normal)
	Blue		STD/QC rack
	Green		Retest rack
	Orange		Dilute test rack
c	{Stop unloading racks.} Or, {Restart unloading racks.}		Change the tray. <Procedure> (1) Touch the {Stop unloading racks.} button. When touched it changes to {Restart unloading racks.}. (2) Remove the rack discharge unit tray. (3) Place an empty tray in the rack discharge unit. (4) Touch the {Restart unloading racks.} button.
d	{Clear}		Delete rack information. <Procedure> (1) Touch the {Clear} button. (2) Touch the {OK} button in the confirmation dialog box. (Touching the {Cancel} button cancels rack information deletion.)
e	{Print}		Print rack information.
f	{Close}		Return to the [Test] screen.

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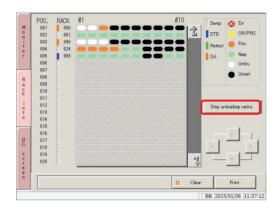
Explanatory note : If "Numbering" is set to "NO" in [Test] - [Request test/select operation], Unset (white) is displayed as an error (× in red).

3.9.2 Replacing trays (optional)
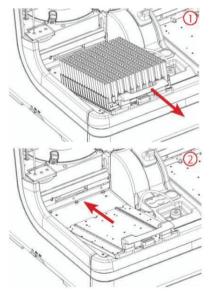
When a tested rack has been discharged to the rack discharge unit, replace it with an empty tray and clear the "rack information."

This section will begin explaining from the [Rack info] screen.
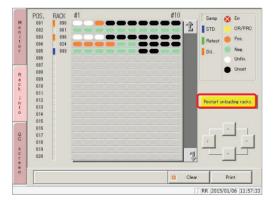
☞ Page 234 "3.9.1 Displaying the [Rack info] screen"

1 Touch the {Stop unloading racks.} button.

2 Exchange the rack.

① Remove the tray from the rack discharge unit.

② Place an empty tray.

3 Touch the {Restart unloading racks.} button.

3.10　Measuring Using Sample Cups

The following settings must be changed when measuring samples using sample cups.

⚠ Caution
① Required　・ When using sample cups, make sure to set them in the correct order. Failure to observe this precaution may lead to jumbled samples.

■　Modification of rack number settings

Cups will stick out of a normal sample rack, so a wide rack (STD rack or dilute test rack) must be used.

Some rack number settings will need to be changed on the [Rack/QC sequence No. settings] screen to use STD racks or dilute test racks.

☞ Page 272 "6.1.3 Rack/QC sequence number settings"

■　Modification of sample barcode settings

Sample barcode labels cannot be affixed to sample cups.

Set "Sample barcode" to "NO" on [Samp barcode settings] - [Common].

☞ Page 266 "6.1.1 Sample barcode settings (common)"

MEMO

Chapter 4　Support Functions

OC-SENSOR
PLEDIA

Chapter 4　Support Functions

4.1　Initialization

Initialize (move to standby position) each system component. The following components are initialized:

・ Sample nozzle	・ Reagent nozzle	・ Cell washing nozzle
・ Mixer	・ Reaction table	
・ Puncturing system	・ Squeezing system	
・ Supply bar	・ Conveyance bar	・ Discharge bar

Touch the {Prep functions} button on the [Menu] screen to display the [Initialize] screen.
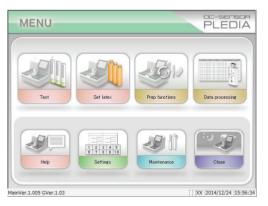
⚠ Caution	
![Pinching hazard] Pinching hazard	・ Do not open the cover of the analysis chamber or reach into the range of motion during operation.
	Failure to observe this precaution may lead to injury or could damage the system.
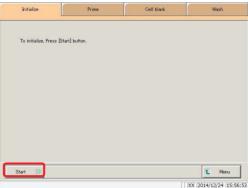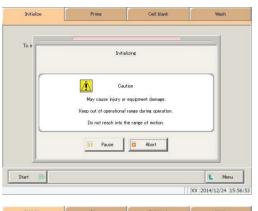
1 Touch the {Prep functions} button.

2 Touch the {Start} button.
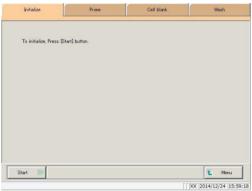
[MENU]:　　Return to the [MENU] screen.

3   Initialization was run.

{Pause}:   Pause initialization.
{Start}:   Resume initialization.
{Abort}:   Cancel initialization.

4   Initialization completed.

4.2   Priming

There are two kinds of priming. "Normal prime" removes air bubbles in the piping, while "pipe line activation" introduces buffer, wash solution, and purified water into piping.

Normal prime: Used to remove air bubbles in the piping.
                           Also used when the system has been left unused for a while.

Pipe line activation: Used to introduce buffer, wash solution, and purified water into piping.

☞ Page 44 "2.4.7 Priming (normal prime/pipe line activation)"

4.3   Cell Blanking

Run cell blanking to wash cells and evaluate them on a pass/fail basis.

If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be automatically run when the system starts.

☞ Page 48 "2.4.8 Measuring cell blanks"

☞ Page 89 "2.6.1 Close mode"

4.4 Washing

Touch the {Wash} tab on the [MENU]-[Prep functions] screen to display the [Wash] screen.
Select the wash part and preservation processing (soaking preservation), then touch the {Start}
button. Washing of each part begins.

⚠ Caution	
⚠ Pinching hazard	· Do not open the cover of the analysis chamber or reach into the range of motion during operation. Failure to observe this precaution may lead to injury or could damage the system.
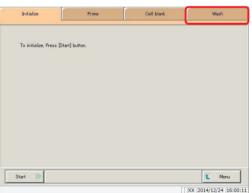
⚠ Request	
	· Run preservation processing (soaking preservation) in close mode. Soaking preservation can also be run from support functions, but is normally run from close mode.

☞ Page 89 "2.6.1 Close mode"
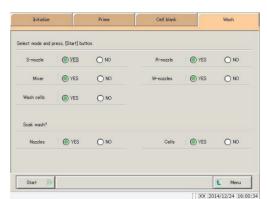
1 Touch the {Prep functions} button.
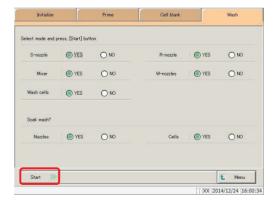
2 Touch the {Wash} tab.

3 Select whether or not to wash each part ("YES" or "NO").

Wash Part	Range/Selection	Details
● Washing		
S-nozzle (Sample nozzle)	YES: NO:	Wash sample nozzle. Do not wash sample nozzle.
R-nozzle (Reagent nozzle)	YES: NO:	Wash reagent nozzle. Do not wash reagent nozzle.
Mixer	YES: NO:	Wash mixer. Do not wash mixer.
W-nozzles (Cell washing nozzle)	YES: NO:	Wash cell washing nozzle. Do not wash cell washing nozzle.
Wash cells	YES: NO:	Washes measurement cells. Do not wash measurement cells.
● Preservation processing		
Nozzles	YES: NO:	Run soaking preservation for nozzles and mixer. Do not run soaking preservation for nozzles and mixer.
Cells	YES: NO:	Run soaking preservation for measurement cells. Do not run soaking preservation for measurement cells.

4 Touch the {Start} button.

[MENU]:   Return to the [MENU] screen.
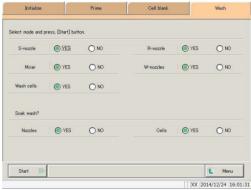
Explanatory note : Soaking preservation of measurement cells is a process where residual liquid in cells is absorbed using the washing nozzle, then the cell is filled with purified water using the sample nozzle.

5   Washing was run.

{Pause}:   Pause washing.
{Start}:   Resume washing.
{Abort}:   Cancel washing.

6   Washing completed.

Chapter 5　Maintenance

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5.1　Inspection/maintenance

The [Maintenance] screen displays inspection and maintenance items to run at each frequency (daily, weekly, monthly).
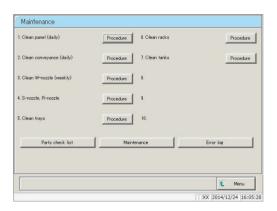
Touch the {Procedure} button to reference inspection and maintenance procedures.

5.1.1　Opening the [Maintenance] screen

Touch the {Maintenance} button on the [MENU] screen to open the [Maintenance] screen.

1 Touch the {Maintenance} button.
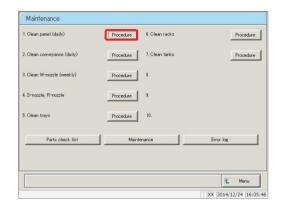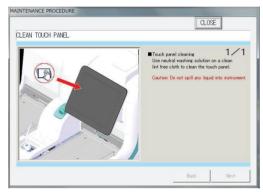
2 The [Maintenance] screen opens.

5.1.2   Clean touch panel (daily)

Touch the {Procedure} button to the right of [1. Clean panel (daily)] on the [Maintenance] screen to display the cleaning procedure.
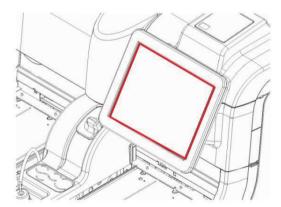
■ Procedure

Use "LCD panel cleaner" to wipe the touch panel clean.
If "LCD panel cleaner" is not available, use a cloth that has been soaked in mild detergent to wipe the panel clean.
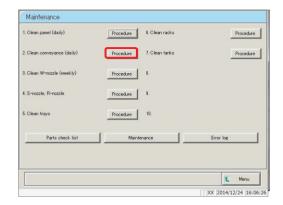
⚠ Caution: Wring the cloth out thoroughly.

{Close}:   Return to the [Maintenance] screen.
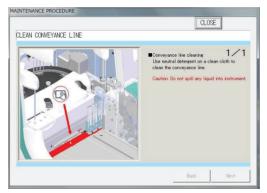
5.1.3   Clean conveyance line (daily)
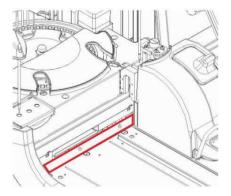
Touch the {Procedure} button to the right of [2. Clean conveyance (daily)] on the [Maintenance] screen to display the cleaning procedure.

■ Procedure

① Soak a soft cloth in mild detergent.
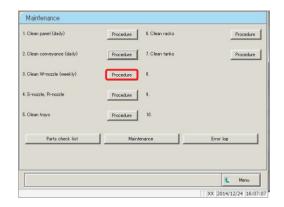
② Use the cloth from ① to wipe the conveyance line clean (the area enclosed in the red box in the diagram to the left).

⚠ Caution: Wring the cloth out thoroughly.
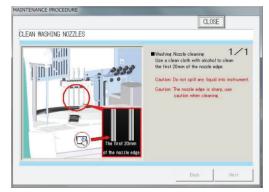
{Close}:   Return to the [Maintenance] screen.

5.1.4   Clean washing nozzle (weekly)

Touch the {Procedure} button to the right of [3. Clean W-nozzle (weekly)] on the [Maintenance] screen to display the cleaning procedure.

■ Procedure

① Soak a soft cloth in ethanol.

② Use the cloth from ① to wipe the area around 20 mm from the tip of the washing nozzle clean.

⚠ Caution: Wring the cloth out thoroughly.
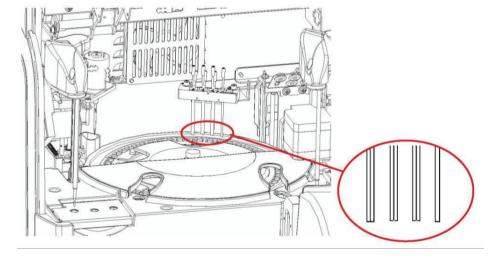
⚠ Caution: Be especially careful when handling the washing nozzle.
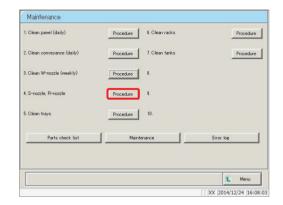
> The tip of the nozzle is sharp and could cause injury.

{Close}:   Return to the [Maintenance] screen.
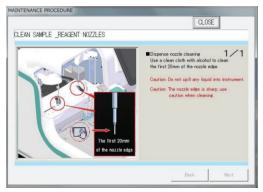
5.1.5 Clean sample & reagent nozzles (weekly)

Touch the {Procedure} button to the right of [4. S-nozzle, R-nozzles] on the [Maintenance] screen to display the cleaning procedure.

■ Procedure

① Soak a soft cloth in ethanol.

② Use the cloth from ① to wipe the area around 20 mm from the tip of the sample nozzle and reagent nozzle clean.

⚠ Caution: Wring the cloth out thoroughly.
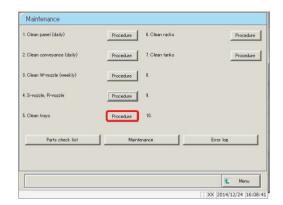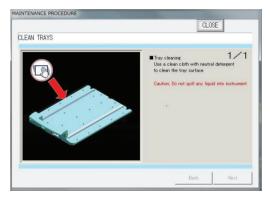
⚠ Caution: Be especially careful when handling the sample nozzle and reagent nozzle.

The tip of the nozzle is sharp and could cause injury.

{Close}: Return to the [Maintenance] screen.

Sample nozzle

Reagent nozzle

20mm

5.1.6   Clean tray (weekly)
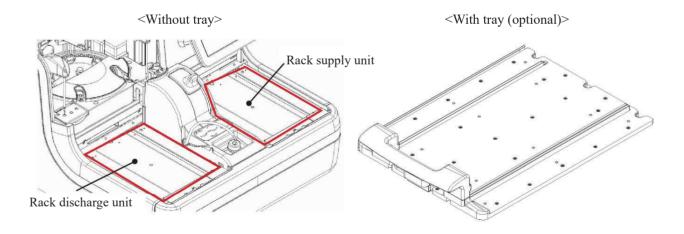
Touch the {Procedure} button to the right of [5. Clean trays] on the [Maintenance] screen to display the cleaning procedure.

■ Procedure

① Soak a soft cloth in mild detergent.
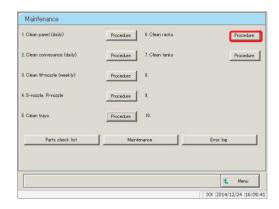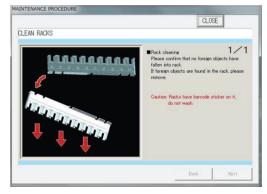
② Use the cloth from ① to wipe the rack supply/discharge unit and tray surface clean.

⚠ Caution: Wring the cloth out thoroughly.

<Without tray>   <With tray (optional)>

Rack supply unit

Rack discharge unit

5.1.7   Clean racks (weekly)

Touch the {Procedure} button to the right of [6. Clean racks] on the [Maintenance] screen to display the cleaning procedure.
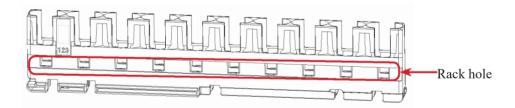
■ Procedure
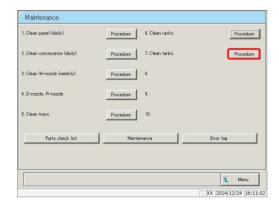
① Check that there are no foreign objects in the rack holes.

② If there are any foreign objects, remove them (for example, by turning the rack over and shaking it).

⚠ Caution: Do not wash the rack.

> Doing so could cause the barcode affixed to the rack to peel off.

Rack hole

5.1.8   Clean tank (monthly)

Touch the {Procedure} button to the right of [7. Clean tanks] on the [Maintenance] screen to display the cleaning procedure. Clean the tank once per month.

■ Procedure

<Normal cleaning>

After thoroughly cleaning the tank with tap water, rinse it lightly with distilled water.

<If tank is extremely dirty>

① Clean the tank thoroughly with tap water.

② Fill the tank with tap water and LX wash solution. Tap water: 2 L, LX wash solution: 20 mL

③ Close the tank lid tightly and shake the tank (if very dirty, set it aside for around one hour).

④ Rinse the tank thoroughly with tap water, so that no wash solution remains.

⑤ Rinse the tank lightly with distilled water.

5.1.9   Replacing measurement cells (when cell blank value is abnormal)

When 10 or more measurement cells can no longer be used during cell blank measurement, "There are more than 10 unclean measurement cells. This could reduce processing performance. Replace the measurement cells" is displayed. Follow the procedure below to replace the measurement cells.
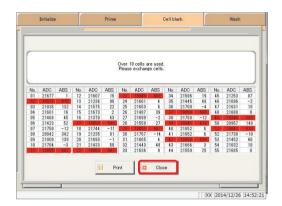
⚠ Caution
Finger pinching hazard	· Turn the system power off when replacing measurement cells. Failure to observe this precaution may lead to injury.
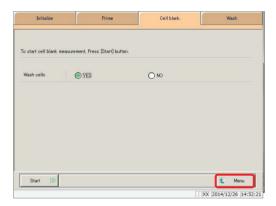
1 Measurement cells that cannot be used are shown in red.
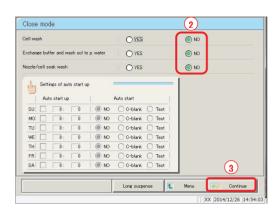
Touch the {Close} button.
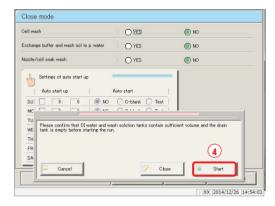
2 Touch the {MENU} button.
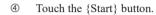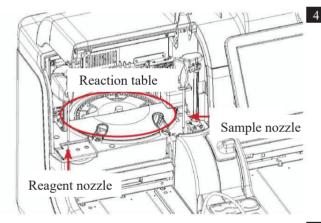
3 Shut off the system.
①   Touch the {Close} button.
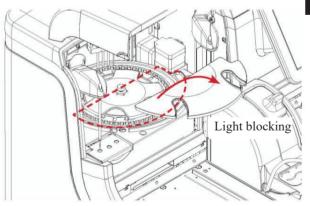
②   Select "NO" for "Cell wash," "Exchange buffer and wash sol to p. water" and "Nozzle/cell soak wash."

③   Touch the {Continue} button.

④   Touch the {Start} button.
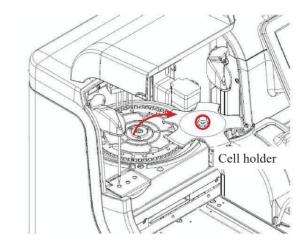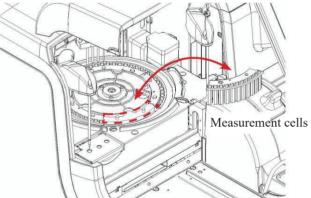
4   If the sample nozzle and reagent nozzle are on the reaction table, move them by hand so as to not hinder work.

Reaction table

Sample nozzle

Reagent nozzle
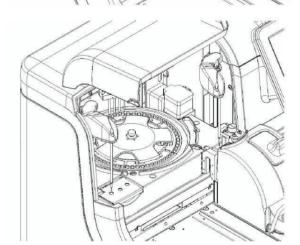
5   Remove the light blocking cover.

Light blocking

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Cell holder

6 Remove the cell holder.

①   Loosen the screw.

②   Remove the cell holder.

Measurement cells

7 Replace the measurement cells.

①   Remove the dirty measurement cells.

②   Set the new measurement cells.

     * Replace all five.

8 Install the cell holder and light blocking cover in order to their original locations.

Follow the removal procedure in reverse to install the parts.

⚠ Caution	
![Required] **Required**	・ When setting measurement cells, make sure they are fully attached. Failure to observe this precaution may impact measurement results.
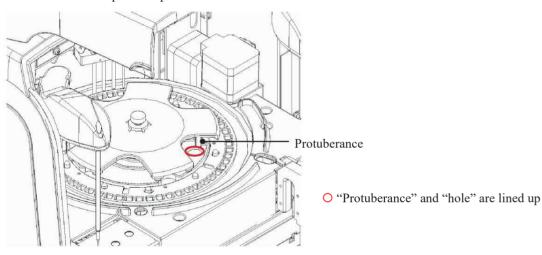
⚠ Caution	
![Required] **Required**	・ When setting the cell holder, install so that the cover is pinched by the reaction table fixing screw. If the fixing screw is covered by the cover the system will be unable to measure properly.
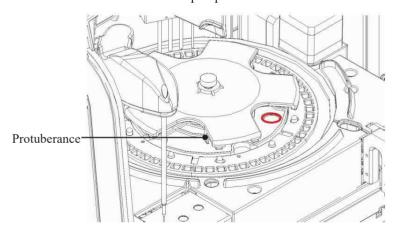
<Example: acceptable installation>

Protuberance

○ "Protuberance" and "hole" are lined up

<Example: poor installation>

Protuberance
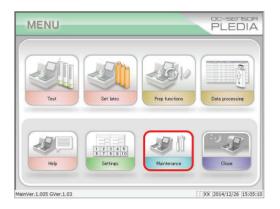
× "Protuberance" and "hole" are not lined up

5.2　List of Parts to Check and Exchange
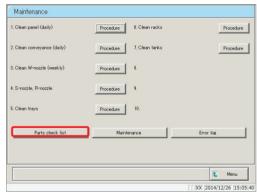
The [Parts check list] screen displays registered parts, when they were last changed, the number of months they were used, and how many times they have been used.

5.2.1　Opening the [Parts check list] screen
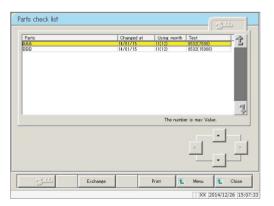
Touch {Parts check list} on the [Maintenance] screen to open the [Parts check list] screen. The line for parts that need to be changed (that have exceeded the set number of usage months or number of uses) are displayed in yellow.

1 Touch the {Maintenance} button.

2 Touch the {Parts check list} button.
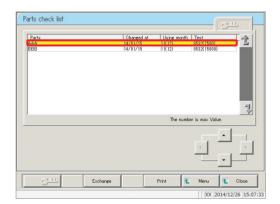
3 The [Parts check list] screen was displayed.

Explanatory note ： The rows of parts that need to be changed turn yellow.
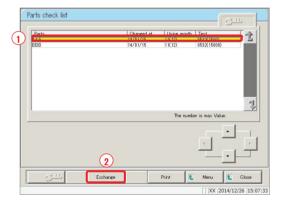
5.2.2 Changing parts

Change parts that need to be replaced.
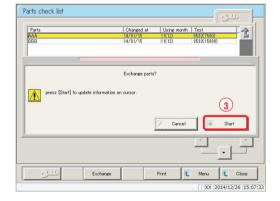
This section describes the procedure from the [Parts check list] screen.

1 Change parts displayed in yellow.

2 Reset the months used and number of uses counters to replace parts.

① Touch the row of the part that was changed.

② Touch the {Exchange} button.

③ Touch the {Start} button.

  * The months used and number of uses are reset to "0."

  * The dialog box closes.

{Cancel}: Cancel resetting the months used and number of uses counters.

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Chapter 6　Settings

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Chapter 6   Settings

6.1   System settings

In order to use the system for the first time, the system settings must be configured. Once set, settings will not need to be touched during everyday analysis unless changes are made.
See page 32 "2.3.1 System settings" for an overview of "system settings" items.
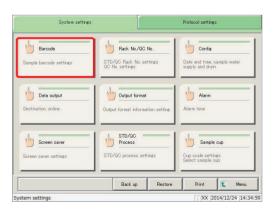
6.1.1   Sample barcode settings (common)

Set common setting items for reading sample barcodes.
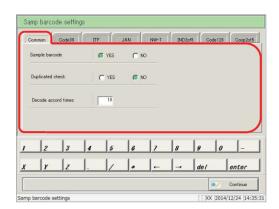
1   Touch the {Settings} button.

> (Explanatory note)   : The [System settings] screen can also be displayed by touching the {Settings} button on the [Test]
> screen.

2   Touch the {Barcode} button.

3 Configure the settings in the {Common} tab.

Setting	Choice/Setting	Details
Sample barcode	YES: NO:	Barcodes are affixed to samples. Barcodes are not affixed to samples.
Duplicated check	YES: NO:	From when the system starts up to when the power is turned off: Check whether a sample with the same barcode has already been read. Do not check whether a sample with the same barcode has already been read. However, even if this is set to "YES" duplicated check is not performed when the measure mode is "retest" or "dilute test."
Decode accord times	Numerical input	The recommended value is around ten times.
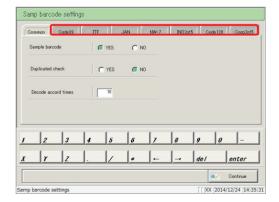
Explanatory note : Decode accord times

When reading a sample barcode, the sample ID barcode reader scans the barcode a maximum of 500 times. The number of times the barcode was read correctly is called the number of decode times.
"Decode accord times" is the number of times a barcode must be read for the system to determine that the barcode has been read correctly.
Increasing the number of decode accord times can prevent misreading barcodes, but increases the frequency of "barcode reading errors."

4 Configure detailed settings for each barcode type.

6.1.2   Sample barcode settings (detailed settings by barcode type)

In addition to common settings, [Samp barcode settings] includes settings for each type of barcode.
Usable barcodes include CODE39, ITF, JAN, NW-7, IND2of5m CODE128, and COOP2of5.
Barcodes are selected by switching the {Barcode names } tab.

This section will begins explaining from the {Samp barcode settings} screen.

☞ Page 266 "6.1.1 Sample barcode settings (common)"
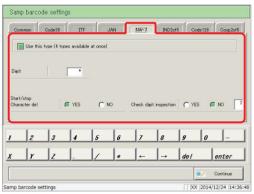
1 Touch the tab of the type of barcode to configure.

Example:
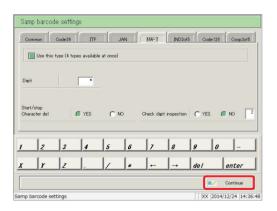
Touch the {NW-7} tab.

(This explanation assumes that NW-7 has been selected.)
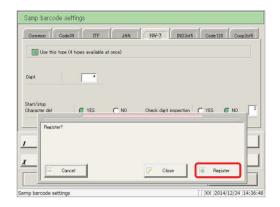
2 Configure each item.

(See Charts 6.1.1 through 6.1.4.)

⟨ Explanatory note ⟩: The check digit calculation method cannot be changed for Code39, JAN, or ITF barcodes.

3 Touch the {Continue} button.

4   Touch the {Register} button.

{Register}   : Register configured settings.

{Close}   : Cancel registration of sample barcode settings, and return to the [System settings] screen.

{Cancel}   : The dialog box closes.

6.1 System settings

> (Explanatory note) : If "YES" is selected for "Check digit inspection," the system will perform a check digit inspection using the last character of the barcode (the digit before the start/stop character) as the check digit.

Chart 6.1.1　Samp barcode settings

Setting	Choice/Setting	Details
■ Use this type (4 types available at once)		Check the barcode to use. Up to four types of barcodes can be selected at the same time.
Digit Sample □ digits		Configure the number of digits for sample barcodes. Enter "*" to skip checking the barcode digit. (Used when sample barcodes have multiple digits.) The input range varies according to whether "Start/stop character delete" is set to "YES" or "NO." For details, see Chart 6.1.2.
Start/stop Character del	YES: NO:	Set whether or not to delete the start/stop character. (Available when NW-7 is selected.) Delete start/stop character. Do not delete start/stop character.
Check digit inspection	YES: NO:	Decide whether or not to perform check digit inspection. Perform check digit inspection. Do not perform check digit inspection.
Check digit calculation method	See Chart 6.1.3	Configure the check digit calculation method.

> (Explanatory note) : See Chart 6.1.3 for information on input numbers and calculation methods for check digits.

Chart 6.1.2　Barcode digit input range

Barcode Type	Start/Stop Character Delete	Input Range	
		Upper Limit	Lower Limit
NW-7	YES	17	5
NW-7(2)	None	15	
ITF			
IND2of5	Disabled	15	6
COOP2of5			
CODE39			
JAN	Disabled	15	5
CODE128			

Chart 6.1.3   Input No. and Calculation method

Input No.	Calculation Method
1	Modulus 10/3 weight
2	Modulus 16
3	Modulus 11
4	Modulus 10/2 weight
5	Modulus 10/3 weight
6	7 check DR
7	Weighing modulus
8	Loons

Chart 6.1.4   Barcode Type and Calculation Method
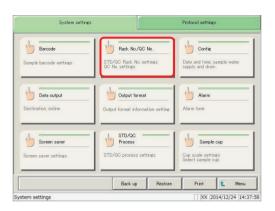
Barcode Type	Calculation Method
CODE39	Modulus 43 (fixed)
JAN	Modulus 10/3 weight (fixed)
ITF	Modulus 10/3 weight (fixed)
NW-7	Modulus 10/3 weight
	Modulus 16
	Modulus 11
	Modulus 10/2 weight
	7 check DR
	Weighing modulus
	Loons
IND2of5	No check digit
CODE128	No check digit
COOP2of5	No check digit

6.1.3 Rack No./QC No.
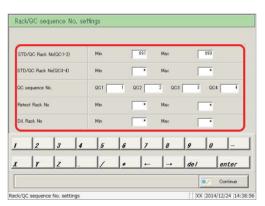
Configure the STD/QC rack number, retest rack number, dilute test rack number, and QC sequence number. The system identifies the type of rack from the rack number. During testing, racks with numbers other than STD/QC rack numbers, retest rack numbers, dilute test rack numbers configured here are treated as "sample racks."

This section describes the procedure from the [System settings] screen.
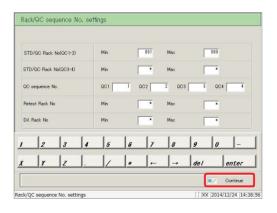
☞ Page 266 "6.1.1 Sample barcode settings (common)"
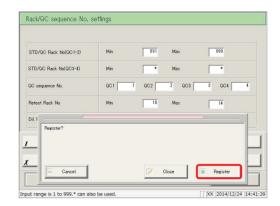
1 Touch the {Rack No./QC No.} button.

2 Configure each item.

(See page 274.)

3 Touch the {Continue} button.

* A dialog box appears to confirm changes/registration

4 Confirm the changes and touch the {Register} button.

{Register}: Register configured settings.

{Close}: Cancel rack/QC sequence number configuration, and return to the [System settings] screen.

{Cancel}: The dialog box closes.

Explanatory note : If no changes were made, the range for each test item/rack number is not displayed.

Explanatory note : If there are duplicate rack numbers, the values of the duplicate locations will be red.

Explanatory note : If the maximum and minimum rack number values are reversed, the values will be red.

Explanatory note : If only one value of the rack number range setting is "*" that location will be red (if the value input changes after entering "*").

Chart 6.1.5   Rack/QC Sequence Settings

Setting	Choice/ Setting	Details
STD/QC Rack No. (QC1・QC2) Min: Max:	1 - 999	Configure a range of STD/QC rack numbers (QC1/QC2). Enter "*" to disable range specification. <u>Example 1: If entering rack number 094,</u> enter 94. <u>Example 2: If registering only one rack:</u> Enter the same rack number for the minimum and maximum (maximum = minimum).
STD/QC Rack No. (QC3・QC4) Min: Max:	1 - 999	Configure a range of STD/QC rack numbers (QC3/QC4). Enter "*" to disable range specification.
QC sequence No. QC1: QC2: QC3: QC4:	1 - 99999	Configure the QC sequence number. Enter "*" to disable range specification. There are two ways to set QC sequence numbers. (1) Allocate numbers individually to each QC sequence number (2) Set QC1 as the initial value, and assign numbers in sequence for QC2 though QC4 from QC1 For (2), if a value in entered for QC1 and "*" is set for other QC values, sequence numbers will be allocated in sequence from QC1 for QC2 on. (Explanatory note) : If set by serial number, values are retained in the system until its power is turned off.
Retest Rack No Min: Max:	1 - 999	Configure a range of retest rack numbers. Enter "*" to disable range specification.
Dil. Rack No Min: Max:	1 - 999	Configure a range of dilute test rack numbers. Enter "*" to disable range specification.

(Explanatory note) : Enter "*" to disable rack number configuration.
    If "*" is entered for either the minimum or maximum, the other value (maximum or minimum) is automatically set as "*," and rack number configuration is disabled.

(Explanatory note) : STD/QC rack numbers (QC1/QC2) and STD/QC rack numbers (QC3/QC4) cannot both be disabled.

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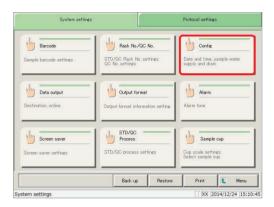
6.1.4 Environment settings

The following settings are configured in the environment settings.
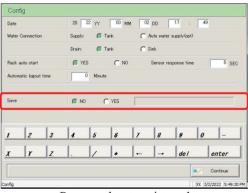
- ・ Date and time settings
- ・ Water supply and water drainage methods
- ・ Automatic rack supply (sample setting wait time)
- ・ Automatic logout
- ・ Password registration

This section describes the procedure from the [System settings] screen.
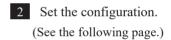
☞ Page 266 "6.1.1 Sample barcode settings (common)"

1 Touch the {Config} button.
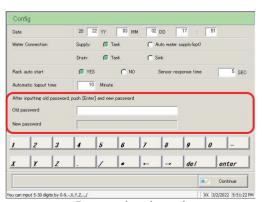
Password not registered

2 Set the configuration.
(See the following page.)

| Explanatory note | : The screen varies based on whether a password is registered or not.
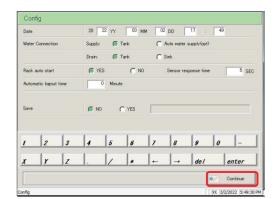
Password registered

Setting	Choice/Setting	Details
Date 20YY, MM, DD, HH, MM	YY: 0 to 99, MM: 1 to 12, DD: 1 to 31, HH: 1 to 24, MM: 0 to 59	Configure the year, month, day, and time.
Water connection Supply: Drain:	 Tank Auto water supply(opt) Tank Sink	Select the water supply/drainage methods. Supply water from tank. Automatically supply water (optional). Drain water to tank. Drain water using drain hose.
Rack auto start YES: NO:		Select automatic rack supply. Supply rack automatically. Do not supply rack automatically.
Sensor response time (SEC)	0 to 60	When "Rack auto start" is set to "YES," configure the time from when the rack is placed in the supply unit, to when all racks are completely placed (sensor response time). Rack supply will begin once the sensor response time has elapsed.
Automatic logout time (Minute)	0 to 99	When the Operator mode is set, if the automatic logout time passes while the [MENU] screen is still displayed after logging in, automatic logout occurs. The automatic logout function is disabled setting 0 minutes. ☞ Page 329 "Chapter 9 Operator/Latex Management Function (Option)"
Save YES: NO: Password:	 5 to 30 characters (0 to 9, -, X, Y, Z, ., /)	Select whether to register a password or not for data processing. Register a password. Do not register a password. Enter a password.
Old password New password	5 to 30 characters (0 to 9, -, X, Y, Z, ., /)	(When a password has been set) Change the password.

(Explanatory note) : To use no password, do not input a password, then touch the {Continue} button to complete
        registration.

6.1 System settings

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}: Register configured settings.

{Close}: Cancel environment configuration and return to the [System settings] screen.

{Cancel}: The dialog box closes.

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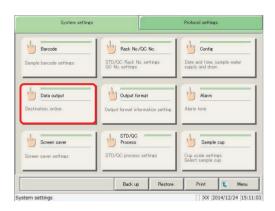
6.1.5 Data output settings - [Destination]

The following settings are configured in "Destination."
- Measured data printer output (print)
- Measured data external media output
- Time course external media output
- Measured data online output
- STAT online output
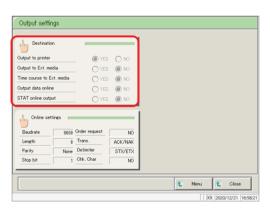
This section describes the procedure from the [System settings] screen.

☞ Page 266 "6.1.1 Sample barcode settings (common)"
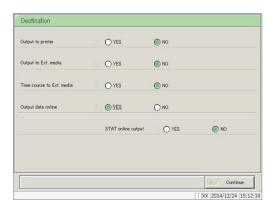
1 Touch the {Data output} button.
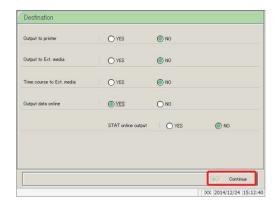
2 Touch the {Destination} button.
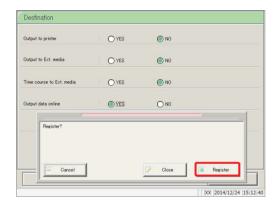
3 Select the output destination for the data (see the following page).

Setting	Choice/Setting	Details
Output to printer		Select whether to print measured data or not.
	YES	Print measured data in real time during testing. If you would like to "Print Saving mode" in which only the "STD/ QC" measurement result and the error is printed, please contact us.
	NO	Do not print measured data.
Output to Ext. media		Select whether to automatically send measured data to external media when testing is complete.
	YES	Output to external media.
	NO	Do not output to external media.
Time course to Ext. media		Select whether to output time course to external media or not.
	YES	Output to external media.
	NO	Do not output to external media.
Output data online		Select whether to output measured data online or not. Detailed online output settings are made on the [Online settings] screen.
	YES	Output online.
	NO	Do not output online.
STAT online output		Select whether to output sample data measured during cut-in analysis online or not. Online output of measured data is available if set to "YES."
	YES	Output cut-in analysis measured data online.
	NO	Do not output cut-in analysis measured data online.

(Explanatory note) : If all [Destination] settings are set to "NO," nothing will be output to external media.

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}: Register configured settings.

{Close}: Cancel data output selection, and return to the [Data output destination settings] screen.

{Cancel}: The dialog box closes.

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6.1.6   Data output settings - [Online settings]

Configure the following conditions to control online communication.

- ・ Communication mode
- ・ Baud rate
- ・ Data length
- ・ Parity
- ・ Stop bit
- ・ Transmission procedure
- ・ Delimiter
- ・ Check character
- ・ Separator
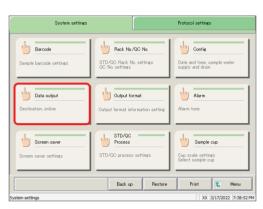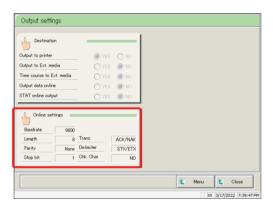
For details, see "OC-PLEDIA Computer Interface Specifications."

This section describes the procedure from the [System settings] screen.

☞ Page 266 "6.1.1 Sample barcode settings (common)"
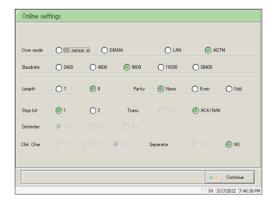
1 Touch the {Data output} button.

2 Touch the {Online settings} button.
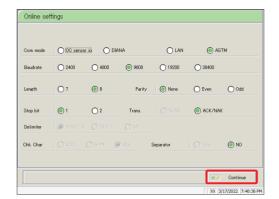
3 Select online communication conditions (see the following page).

Setting	Choice/Setting	Details
Com mode		Select the communication mode.
	OC sensor io	OC sensor io compatibility mode.
	OC sensor DIANA	OC sensor DIANA compatibility mode.
	LAN	LAN communication mode.
	ASTM	ASTM communication mode.
Baud rate		Select the communication speed.
	2400	2400 baud rate
	4800	4800 baud rate
	9600	9600 baud rate
	19200	19200 baud rate
	38400	38400 baud rate
Length		Select the data length.
	7(bit)	
	8(bit)	Select when sending two-byte characters.
Parity		Select parity checking.
	None	Do not check parity.
	Even	Run even number parity checking.
	Odd	Run odd number parity checking.
Stop bit		Select the stop bit.
	1	One bit.
	2	Two bits.
Trans.		Select the transmission control procedure.
	NONE	Do not use a transmission control procedure. (No
	ACK/NAK	procedure)
		Use ACK/NAK method.
Delimiter		Select the delimiter
	STX/ETX	
	CR/LF	
	CF	
Chk. char		Select the error detection method.
	BCC	
	SUM	
	None	Do not use check character.
Separator		Select whether or not to insert a separator comma (,) in between data items.
	YES	Separate using a comma.
	NO	Do not separate.
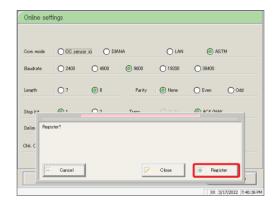
Explanatory note : Delimiter, check character, and separator are all set to "NO" for LAN communication.

Explanatory note : The delimiter is set to "STX/ETX" for ASTM communication. This cannot be controlled on the screen.

Explanatory note : The check character for ASTM communication is "SUM1, SUM2." This cannot be controlled on the screen.

6.1　System settings

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}:　Register configured settings.

{Close}:　　 Cancel online configuration, and return to the [Output settings] screen.

{Cancel}:　　The dialog box closes.

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6.1.7   Output format

Configure the output formats for data (such as rack, sample number, and sample ID), for each output destination (printer, external media, online).
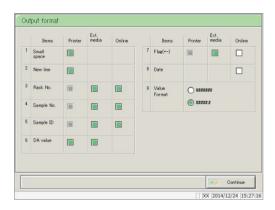
Rack, sample number, and sample ID settings cannot be changed for printer output.

This section describes the procedure from the [System settings] screen.
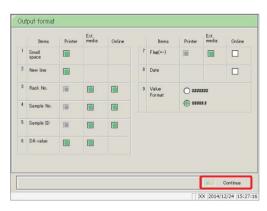
☞ Page 266 "6.1.1 Sample barcode settings (common)"
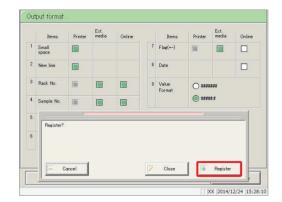
1 Touch the {Output format} button.

2 Select the output item (see the following page).

3 Touch the {Continue} button.

4 Touch the {Register} button.

{Register}:   Register configured settings.

{Close}:   Cancel output format configuration, and return to the [System settings] screen.

{Cancel}:   The dialog box closes.

Explanatory note : Checked items will be output.

Output Items	Details
1. Small space (narrow) Printer	Line spacing when printing to a printer is narrowed.
2. New line Printer	A new line is inserted in the following locations when printing to a printer. ・ Between measured data ・ Between items when multiple items were tested (This applies to printing during real time printing and measured data processing.)
3. Rack No. External media Online	The rack number and rack position number are output. The rack number and rack position number are output.
4. Sample No. External media Online	Output the sample number. Output the sample number.
5. Sample ID External media Online	Output the sample ID. Output the sample ID.
6. DA value Printer External media	Print the DA value to a printer. Output the DA value.
7. Flag(+-) External media Online	Output the judgment results. Output the judgment results.
8. Date Online	Output the measurement date and time.
9. Value format ####### #####.#	Select the output format of measured data. Output as an integer. Output up to the first decimal place (all measured data is rounded up).

Explanatory note :All information applies when outputting to a hard disk(SSD), regardless of the output format settings.

Explanatory note : If ASTM communication is set as the communication mode on the [Online settings] screen, only the [Value format] setting is applied. Other settings are ignored.

6.1.8　Alarm

Configure the time and pattern for alarms to sound when testing is completed, the system is waiting for a new rack to be placed, when there is an operation error, or other situations.
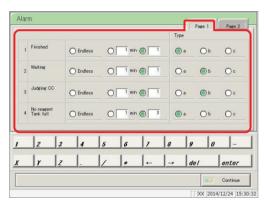
The [Alarm] screen is composed of two pages. Switch pages by touching the {Page 1} and {Page 2} tabs.

This section describes the procedure from the [System settings] screen.
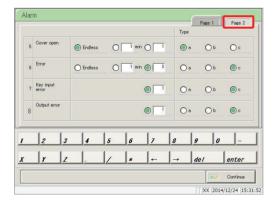
☞ Page 266 "6.1.1 Sample barcode settings (common)"
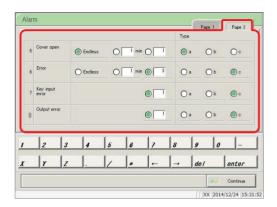
1 Touch the {Alarm} button.

2 Configure the alarm time and pattern.

1　Finished

2　Waiting

3　Judging CC

4　No reagent/Tank full

(See page 294.)
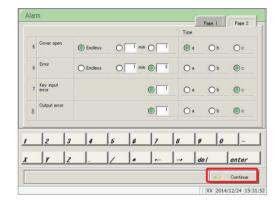
3 Touch the {Page 2} tab.

4   Configure the alarm time and pattern.

    5   Cover open

    6   Error

    7   Key input error

    8   Output error

       (See page 295.)

5   Touch the {Continue} button.

6   Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel alarm configuration and return to the [System settings] screen.
{Cancel}:	The dialog box closes.

{Page 1} tab

Output Items	Details
1. Finished	Sounds when testing of the sample placed in the rack supply unit is finished, and the system is waiting.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Type c	Alarm sounds with type c.
2. Waiting	Sounds to notify the user when the rack supply is fed from the rack supply unit.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Type c	Alarm sounds with type c.
3. Judging CC	Sounds when the system is waiting for the operator's determination following calibration curve judgment.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Type c	Alarm sounds with type c.
4. No reagent Tank full	Sounds when the system detects insufficient reagent, buffer, wash solution, or purified water, or when the drain tank is full.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Type c	Alarm sounds with type c.

{Page 2} tab
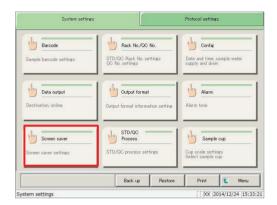
Output Items		Details
5. Cover open		Sounds when the protective cover is opened during operation.
	Endless	Continues to sound until the error is cleared.
	min	Configure the time (minutes) for the alarm to sound. (1 to 99)
	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of times
	Type a	Alarm sounds with type a.
	Type b	Alarm sounds with type b.
	Type c	Alarm sounds with type c.
6. Error		Sounds when an operational error has occurred.
	Endless	Continues to sound until the error is cleared.
	min	Configure the time (minutes) for the alarm to sound. (1 to 99)
	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of times
	Type a	Alarm sounds with type a.
	Type b	Alarm sounds with type b.
	Type c	Alarm sounds with type c.
7. Key input error		Sounds when an incorrect entry is made using the keypad.
	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of times
	Type a	Alarm sounds with type a.
	Type b	Alarm sounds with type b.
	Type c	Alarm sounds with type c.
8. Output error		Sounds when there is an error with the output destination when outputting to a printer or online.
	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of times
	Type a	Alarm sounds with type a.
	Type b	Alarm sounds with type b.
	Type c	Alarm sounds with type c.

```
┌─────────────────────────────────────────────────────────────────────┐
│                                                                       │
│    6.1.9      Screen saver                                            │
│                                                                       │
└─────────────────────────────────────────────────────────────────────┘
```
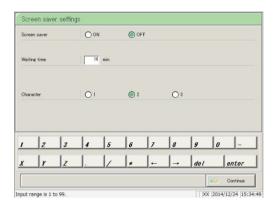
The screen saver starts up when there is no keypad activity on the [MENU] screen.

The time required until the screen saver starts is configured in the screen saver settings

This section describes the procedure from the [System settings] screen.
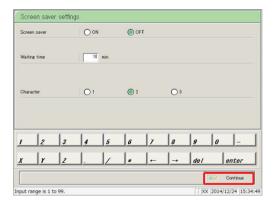
　　　　　Page 266 "6.1.1 Sample barcode settings (common)"
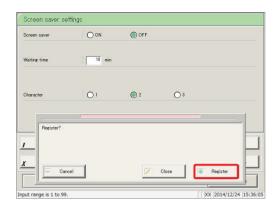
1　Touch the {Screen saver} button.

2　Configure settings for the screen saver (see the following page).

3　Touch the {Continue} button.

4 Touch the {Register} button.

{Register}: Register configured settings.
{Close}: Cancel screen saver configuration and return to the [System settings] screen.
{Cancel}: The dialog box closes.

Setting	Choice/Setting	Details
Screen saver		Select whether or not to start the screen saver when the configured wait time has elapsed.
	ON	Starts.
	OFF	Does not start.
Waiting time	1 to 99 minutes	Input the waiting time.
Character		Select the character.
	Character 1	Character 1 starts.
	Character 2	Character 2 starts.
	Character 3	Character 3 starts.

6.1.10　STD/QC analysis process settings

Configure the conditions for checking measured data for STD/QC samples.

The [STD/QC process settings] screen is composed of two pages.

STD specifications are set in {Page 1}, while limit values for each QC# are set in {Page 2}.
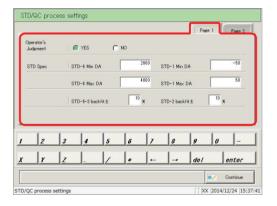
Touch the tabs to switch pages.

This section describes the procedure from the [System settings] screen.
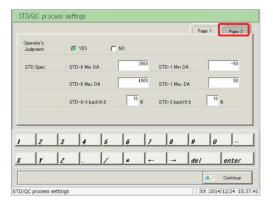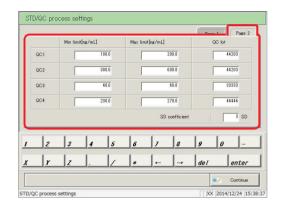
1　Touch the {STD/QC Process} button.
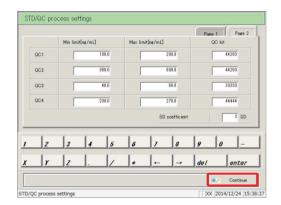
2　Configure STD specifications (see page 300).
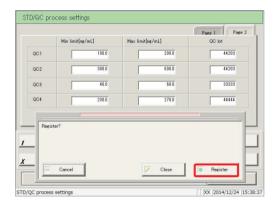
3　Touch the {Page 2} tab.

4 Configure QC control limit values (page 301).

5 Touch the {Continue} button.

6 Touch the {Register} button.

{Register}: Register configured settings.

{Close}: Cancel [STD/QC process] and return to the [System settings] screen.

{Cancel}: The dialog box closes.

{Page 1} tab

Setting	Choice/Setting	Details
Operator judgment		Select whether or not the operator makes a judgment following STD/QC measurement.
	YES	Operator makes a judgment. The system will wait for the operator's judgment following STD/QC measurement, so it will enter standby.
	NO	Operator does not make judgment. If the measured data is normal, measurement continues. If there is an error, the system enters standby and waits for the operator's judgment.
STD Spec		Configure specifications for each STD point. The system will determine STD pass/fail using the configured specifications.
STD-6 Min DA	-9999 - 99999	Check using DA1 value.
STD-6 Max DA	-9999 - 99999	Configure so that minimum < maximum.
STD-6 to 3 back fit ±(%)	0 - 100	Check using the deviation from origin.
STD-1 Min DA	-9999 - 99999	Check using DA1 value.
STD-1 Max DA	-9999 - 99999	Configure so that minimum < maximum.
STD-2 DA back fit ±(%)	0 - 100	Check using the deviation from origin.

(Explanatory note) :When measuring a QC sample only, the system will not wait for operator judgment even if the measured data is outside the limit value. Processing continues.

(Explanatory note) :See page 343 "Appendix: 1.1 STD/QC Sample Measured Data Check" for information on how to check STD/QC measured data.

{Page 2} tab

Setting	Choice/Setting	Details
QC1 to QC4 Min limit [ng/mL] Max limit [ng/mL]	0.0 - 9999999.9	Configure the maximum/minimum control limit values for QC1 through 4. QC pass/fail is determined using the maximum/minimum values set for each QC#. Configure so that minimum < maximum.
QC LOT	A string of characters composed from 0 through 9, X, Y, and Z. (Up to five half-width characters.)	
SD coefficient ☐ SD	1-9	The standard deviation coefficient can be set from 1 to 9 SD (initial setting is 3 SD). The standard deviation coefficient is used when calculating the $\overline{\text{X}}$-R control graph on Process QC.

6.1.11　Sample cup

Configure the shape of the sample cup. Two types of containers can be registered: {Cup 1} and {Cup 2}.
Touch the appropriate tab to switch between containers 1 and 2.

Explanatory note : Only one type of container can be used during testing. Two types of containers cannot be used at the same time.

This section describes the procedure from the [System settings] screen.

☞　Page 266 "6.1.1 Sample barcode settings (common)"

⚠ Caution	
![Required] Required	・ Confirm the correct size of the sample cup. If an incorrect size is configured, the nozzle may be inserted into the liquid too deeply when absorbing the sample, or it may absorb air, leading to incorrect analysis.
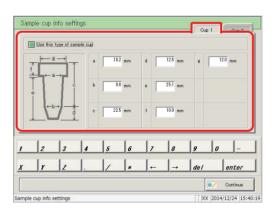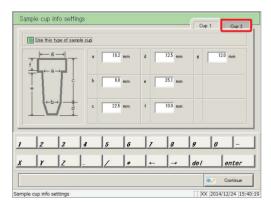
1 Touch the {Sample cup} button.
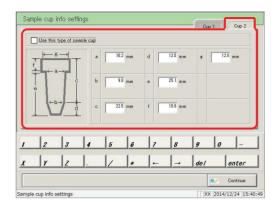
2 Configure the information for sample cup {Cup 1} (see page 304).
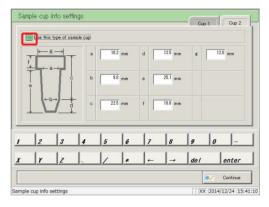
3 Touch the {Cup 2} tab, and switch to the settings screen.
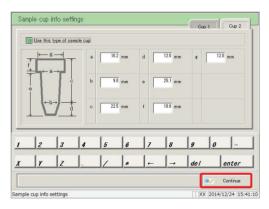
4 Configure the information for sample cup {Cup 2} (see page 304).
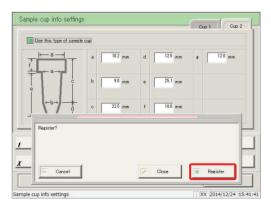
5 Check "Use this type of sample cup."

To select container 1, touch the {Cup 1} tab, and switch to the settings screen.

6 Touch the {Continue} button.

7 Touch the {Register} button.

{Register}: Register configured settings.
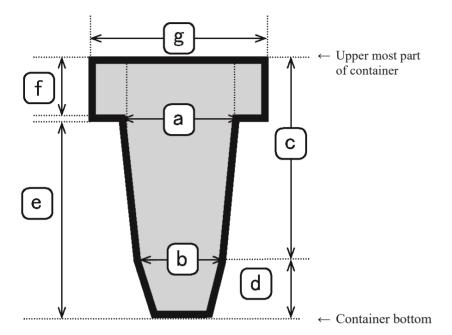
{Close}: Cancel [Sample cup info settings] and return to the [System settings] screen.

{Cancel}: The dialog box closes.

{Cup 1}/{Cup 2} tabs
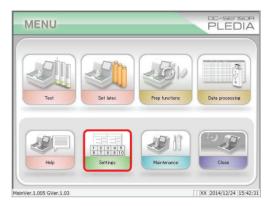
Setting	Setting Range	Details
a		Inside diameter of straight part
b	8.0 - 12.7 (mm)	Inside diameter of tapered part
c		Length of straight part
d		Length of tapered part
e	0.0 - 29.0 (mm)	Length from container bottom to top face of rack
f	0.0 - 10.0 (mm)	Length of straight part at the uppermost part of the container
g	8.0 - 22.0 (mm)	Inside diameter of straight part at the uppermost part of the container
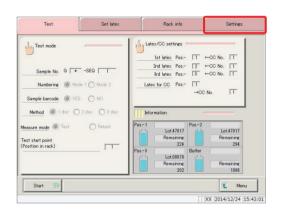
6.1.12   Printing information on system settings

Print information registered to system settings.

1 Touch the {Settings} button.

(Explanatory note) : The [System settings] screen can also be displayed by touching the {Settings} button on the [Test] screen.
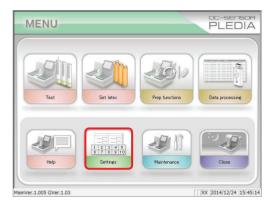
2 Touch the {Print} button.

* All setting information registered to [System settings] will be printed.

6.1.13 Backing up information on system settings/protocol settings
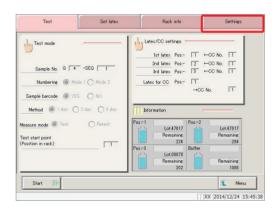
---

Back up information on system settings and protocol settings.
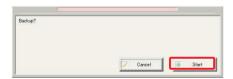
1 Touch the {Settings} button.

Explanatory note : The [System settings] screen can also be displayed by touching the {Settings} button on the [Test] screen.
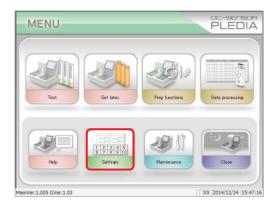
2 Touch the {Back up} button.

* Information on [System settings] and [Protocol settings] will be backed up to the external media.

{Cancel}: Cancel the backup.
{Start}: Start the backup.
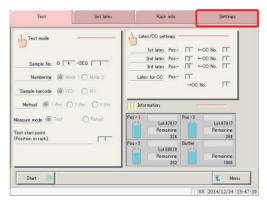
6.1.14   Restoring information on system settings/protocol settings

Read information on system settings and protocol settings from external media, and restore to the system.

1 Touch the {Settings} button.

Explanatory note : The [System settings] screen can also be displayed by touching the {Settings} button on the [Test] screen.

2 Touch the {Restore} button.

* The settings in [System settings] and [Protocol settings] will be restored from the external media to the system.

{Cancel}:   Cancel restore.
{Start}:   Start restore.

6.2　Protocol settings

Protocol settings are largely split into three condition settings.
- ・　Conditions when measuring samples and QC samples (sample/QC protocol settings)
- ・　Calibration curve settings used by protocols (CC No. 1 to CC No. 6 protocol settings)
- ・　Common conditions when measuring samples, STD samples, and QC samples (manufacturer settings)
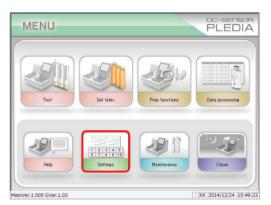
Protocol settings will not need to be touched during everyday analysis flow unless changes are made.
Manufacturer settings are configured at the factory and cannot be changed by the user.

6.2.1　Samp/QC protocol settings

Configure conditions when measuring samples (including STAT samples) and QC samples.
The setting screen is composed of two pages. Pages can be switched using the tabs.
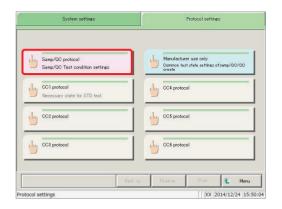
1　Touch the {Settings} button.
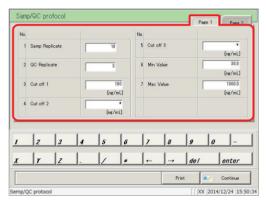
Explanatory note ： The [System settings] screen can also be displayed by touching the {Settings} button on the [Test] screen.
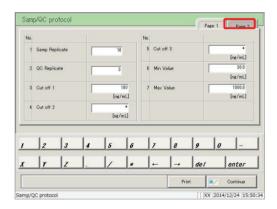
2　Touch the {Protocol settings} tab.
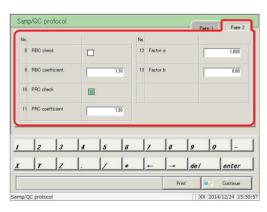
3 Touch the {Samp/QC protocol} button.

4 Configure items (see page 311).
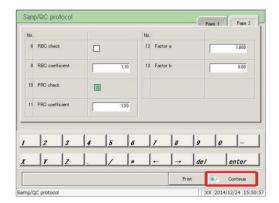
5 Touch the {Page 2} tab.
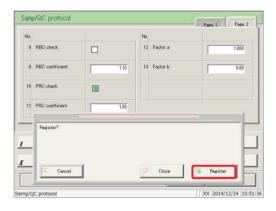
6 Configure items (see page 312).

{Print}: Print [Sample/QC protocol] settings.

7   Touch the {Continue} button.

8   Touch the {Register} button.

{Register}:   Register configured settings.

{Close}:   Cancel [Sample/QC protocol] settings, and return to the [Protocol settings] screen.

{Cancel}:   The dialog box closes.

{Page 1} tab

	Setting	Settings	Details		
1	Sample Replicate	1 to 10 times	Configure the number of times to measure samples.		
2	QC Replicate	1 to 10 times	Configure the number of times to measure QC samples.		
3	Cut off 1		Configure the judgment criteria for Cut off 1.		
		0- 9999999 (integer)		1+	Measured data is "above Cut off 1 value" or "Cut off 2 or lower"
				-	Measured data is "setting value or lower"
4	Cut off 2		Configure the judgment criteria for Cut off 2.		
		*, 0-9999999 (integer)		2+	Measured data is "above setting value," "larger than Cut off 1," or "Cut off 3 or less" If set to "*," Cut off 2 judgment will not be performed. Cut off 1 < Cut off 2
5	Cut off 3		Configure the judgment criteria for Cut off 3.		
		*, 0 - 999999 (integer)		3+	Measured data is "above setting value" If set to "*," Cut off 3 judgment will not be performed. Cut off 2 < Cut off 3
6	Min Value	0.0 - 9999999.9		UR	Displayed when measured data is "Min Value" or lower during dilute testing.
7	Max Value	0.0 - 9999999.9		OR	Displayed when measured data is larger than "Max Value."

{Page 2} tab

	Setting	Settings	Details
8	RBC check		Set whether or not to run RBC checking. Check to have it run. ☞ Page 352 "■ RBC method"
9	RBC coefficient	1.0 - 2.0	Samples with an absorbance larger than the absorbance × "RBC coefficient" of STD-6 at the RBC detection point are determined to be prozone samples. ☞ Page 352 "■ RBC method"
10	PRC check		Set whether or not to run PRC checking. Check to have it run. ☞ Page 353 "■ PRC method"
11	PRC coefficient	0.01-2.00	Samples with a DA2 value larger than the DA2 value × "PRC coefficient" of STD-6 at the second detection point (T2) are determined to be prozone samples. ☞ Page 353 "■ PRC method"
12	Factor A	0.001 - 9999.999	Measured data = A × concentration value + B
13	Factor B	-999.999- 999.999	

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6.2.2   CC No. 1 to CC No. 6 protocol settings

Configure conditions required for measurement of STD samples.

Up to six calibration curves can be registered (CC numbers 1 through 6).
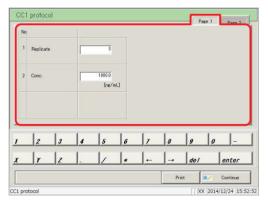
The setting screen is composed of two pages. Pages can be switched using the tabs.

This section describes the procedure from the [Protocol settings] screen.
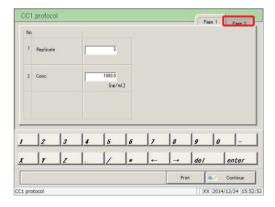
☞ Page 306 "6.2.1 Sample/QC protocol settings"

1 Touch the {CC No. # protocol settings} button (# is the protocol number).
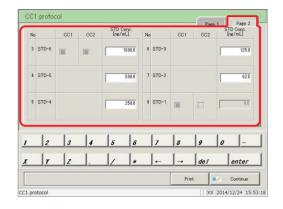
2   Configure items (see page 316).
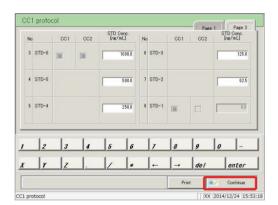
3   Touch the {Page 2} tab.
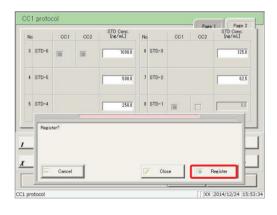
{Print}:   Print [CC No. # protocol] settings.

4 Configure items (see page 316).

{Print}: Print registered [CC No. # protocol] settings.

5 Touch the {Continue} button.

6 Touch the {Register} button.

{Register}: Register configured settings.

{Close}: Cancel [CC No. # protocol] settings, and return to the [Protocol settings] screen.

{Cancel}: The dialog box closes.

{Page 1} tab

	Setting	Settings	Details
1	Replicate	1 to 10 times	Configure the number of times to measure STD samples.
2	Conc.	0- 99999.9	Configure the concentration listed in the INSTRUCTIONS FOR USE for calibrator. Configuring the calibrator concentration will automatically calculate and configure the STD concentration for STD-1 through 6 on the second page.

{Page 2} tab

	Setting	Settings	Details
3	STD-6	0.1 - 9999999.9	Configure the STD concentration of STD-6.
4	STD-5	0.1 - 9999999.9	Configure the STD concentration of STD-5.
5	STD-4	0.1 - 9999999.9	Configure the STD concentration of STD-4.
6	STD-3	0.1 - 9999999.9	Configure the STD concentration of STD-3.
7	STD-2	0.1 - 9999999.9	Configure the STD concentration of STD-2.

Explanatory note :STD-2 through STD-6 are automatically configured when "calibrator concentration" on the first page is set.
Settings for STD-2 through STD-6 can be changed using the keypad.

Chapter 7   Help

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Chapter 7　Help

The [Help] screen is used to confirm the analysis flow, input methods on settings screens, and how to operate the system including sample placement.

Touch the {Help} button on the [MENU] screen or the {Help} button on the [Monitor] screen to open the [Help] screen table of contents. Then, select the button of the item to check.

7.1　Opening the [Help] Screen from the [MENU] Screen

1 Touch the {Help} button.

2 Touch the button of the item to check.

1. Test flow
2. How to input
3. Setting reagents
   Purified water, Wash sol.
   Buffer, Latex
4. Set samples
5. Test
   Change test mode
   Change measure mode
   Change Latex settings
   Create CC
6. Dispose

Example: Touch the {5. Test} button.

3   The page (1/#) is displayed at the top right of the screen.

Use the {Next} and {Back} buttons to check content.

{Next}:   Display the next page.

{Back}:   Display the previous page.

{CLOSE}:   Return to the [HELP] screen.

1 Touch the {Help} button.

2 Touch the button of the item to check.

1. Test flow
2. How to input
3. Setting reagents
    Purified water, Wash sol.
    Buffer, Latex
4. Set samples
5. Test
    Change test mode
    Change measure mode
    Change Latex settings
    Create CC
6. Dispose

Example: Touch the {5. Test} button.

3 The page (1/#) is displayed at the top right of the screen.

Use the {Next} and {Back} buttons to check content.

{Next}:   Display the next page.
{Back}:   Display the previous page.
{CLOSE}:   Return to the [Help] screen.

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Chapter 8   Error Handling

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Chapter 8   Error Handling

In the event of an error, the [Error] screen is displayed. If several errors have occurred, the following page is displayed. Touch {Next err}to display errors.

8.1   How to Read [Error] Screens

[Error] screen

a	Error status	Displays the error number and name.
b	Error location	Displays the location of the error using a graphic.
c	Error cause and cancellation method	Displays the cause of the error and how to clear it.
d	Page buttons	Switch pages when the handling method for a single error spans multiple pages.
	{Back}	Display the previous page.
	{Next}	Display the next page.
e	Error cancellation buttons	Buttons to recover from errors.
f	Error switching buttons	Switch the error display when multiple errors have occurred.
	{Last err}	Display the previous error.
	{Next}	Display the next error.

8.2 Error Cancellation Buttons

Buttons for clearing errors are displayed at the top of the [Error] screen.

The following are operations after a cancellation button has been touched:

Button Name	Function
{RETRY}	Retry processing on the sample for which an error had occurred.
{PASS}	Cancel processing for the sample that is being tested, and process the next sample.
{ABORT}	Terminate processing. If selected during testing, terminates processing for the sample being tested.
{CONTINUE}	Restart the operation of the working part that was halted due to error detection
{CLOSE}	Close the screen
{MUTE}	Mute the alarm.

Explanatory note : The cancellation buttons that are displayed depend on what error has occurred.
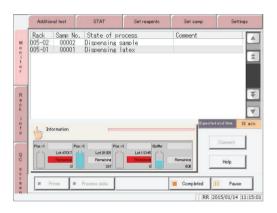
8.3   Clearing Errors

Clear errors using the following procedure:

1 Confirm the error.

① Confirm the error and its location.

② Select the cancellation button from the error cancellation methods and touch it.

☞ Page 323 "8.2 Error Cancellation Buttons"
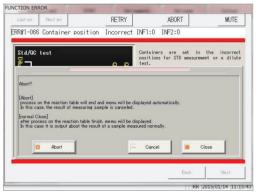
2 For all cancellation buttons other than the {ABORT} button, the error is cleared and operation continues.

2   (continued)

<If the {ABORT} button was selected>

① Touch the {ABORT} button.

② Touch the {Abort} button.

* Reaction table processing is aborted, and the system returns to the [MENU] screen.
The result of the sample being measured is canceled.

{Cancel}: Abort is canceled and the system returns to the [Error] screen.

{Close}: Reaction table processing is terminated and the system returns to the [MENU] screen.

Explanatory note : If an error occurs in the following situations, the process is aborted without the Abort confirmation dialog box being displayed even if the {ABORT} button is touched.

- Errors occurring during maintenance or support functions (errors outside of testing)
- Errors occurring on the reaction table (errors that cannot be normally closed)

MEMO

Chapter 9 Operator/Latex Management Function （Option）
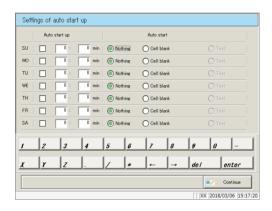
Chapter 9   Operator/Latex Management Function （Option）

This function is used to manage the operators that are using the system and expiration dates for latex being used with the system, in conformance with ISO15189 「Medical laboratories — Requirements for quality and competence.」

In order to use this function, operator information (ID information) must be registered and lot numbers must be entered when setting latex.

Explanatory note ： 「Analysis」 cannot be set in [Auto Startup/Auto Start Settings] for the completion mode when using the operator/latex management function.
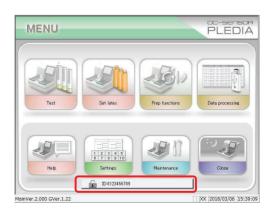
9.1   LOGIN・LOGOUT

You must login to use all functions on the [MENU] screen. Enter the ID information on the [LOGIN] screen to login. The ID of the user who is logged in is shown on the [MENU] screen.
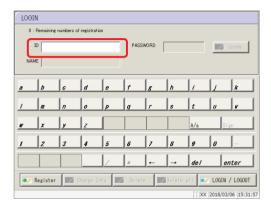
After logging in, if there is no operation on the [MENU] screen for a certain period of time, you will be automatically logged out.

☞ Page 276 "6.1.4 Environment settings"
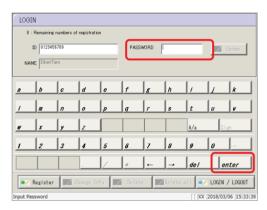
9.1.1   LOGIN
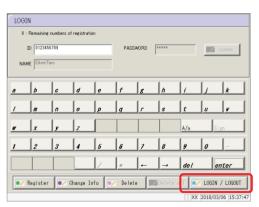
Start the system and run either introduction priming or cell blank measurement to open the [LOGIN] screen.
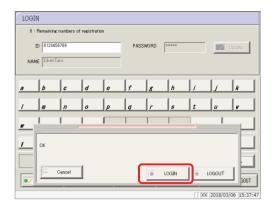
1 Enter the ID and then touch[enter].Confirm the name of the operator that is displayed.

2 Enter the PASSWORD and then touch [enter].

3 Touch [LOGIN/LOGOUT].
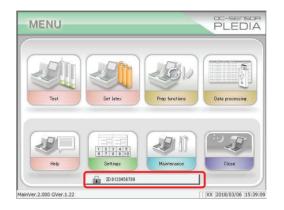
4 A confirmation message {OK} is displayed.
Touch [LOGIN].

5 The [MENU] screen is displayed, with the ID of the logged in user shown next to the [key]icon on the bottom of the screen.

Explanatory note : Touching 【enter】 without entering ID information will display that [MENU] screen without logging in.

9.1.2 LOGOUT
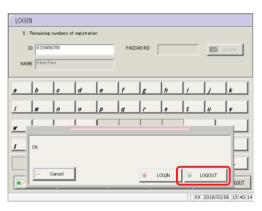
1 Touch the[key] icon (the ID of the logged in user is shown next to it) at the bottom of the [MENU] screen.

2 Touch [LOGIN/LOGOUT].

3 Touch [LOGIN].

4 The system returns to the [MENU] screen, and the ID display area switches to a message {Please login.}. You are now logged out.
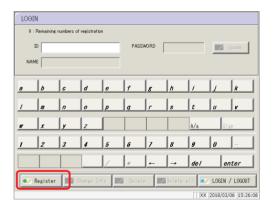
9.2 Registering, Modifying, and Deleting Operators (ID Information)

Up to 11 operators (including one administrator) can be registered. The remaining numbers of registration are shown on the top-left of the [LOGIN] screen. The first ID that is registered (the ID registered when the remaining numbers of registration are 11) will be the administrator.
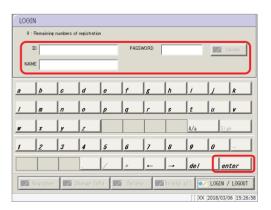
9.2.1 Registering ID Information

This method is used to register new ID information.
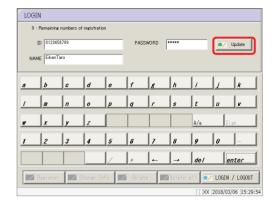
1 Open the [LOGIN] screen.If another operator is logged in, touch the [Key] icon on the [MENU] screen to logout. Once you return to the [MENU] screen, touch the [Key] icon again.

2 Touch [Register].Confirm the name of the operator that is displayed.
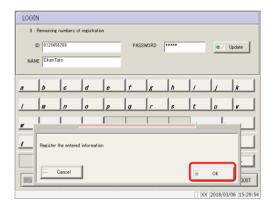
3 Enter the password and then touch [enter].

4 Touch [Update].A confirmation message
{ Register the entered information.} is displayed.

Explanatory note ：If you touch [enter] without entering the ID information, the "One or more required fields are empty" message is displayed.
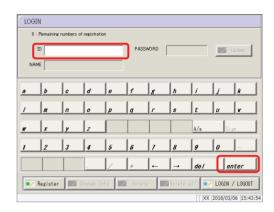
5 Touch [Update]

ID information registration is complete.
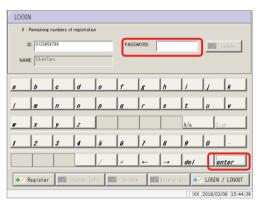
ID information will not be registered if you touch [Cancel].

9.2.2　Change ID
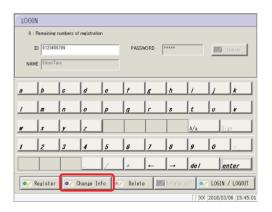
This method is used to change ID information that has already been registered.

1 Enter the ID and then touch [enter]. Confirm the name of the operator that is displayed.

2 Enter the PASSWORD and then touch [enter].
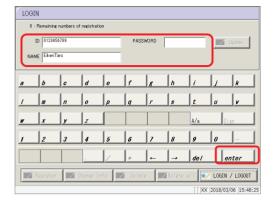
3 Touch [Change Info].The PASSWORD field is cleared.
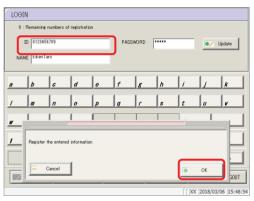
Explanatory note ： Entering an ID and password that have already been registered will activate the 【Change Info】 button.

4 Enter the new ID information and then touch [enter].

5 Touch [Update].

6 A confirmation message { Register the entered information?} is displayed.

ID information registration is complete.

ID information will not be registered if you touch [Cancel].

7 The ID information is updated with the new information.

9.2.3　Deleting ID Information
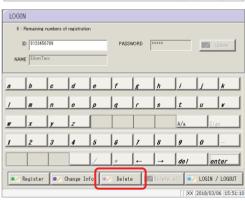
ID information for individual operators can be deleted by the administrator or the individual operator. The administrator can also delete all ID information that has been registered.

1　Enter the ID and then touch　[enter]. Confirm the name of the operator that is displayed.

2　Enter the PASSWORD and then touch　[enter].
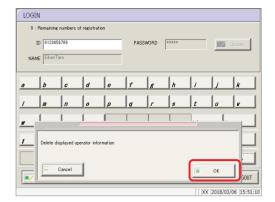
3　Touch [Delete].

A "Delete displayed operator information" confirmation message appears.
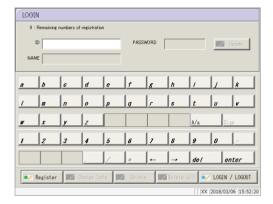
If you are an administrator,
a "Delete all information except administrator in the registration list" confirmation message is displayed.

4 A confirmation message { Delete the operator information in the registration list which displayed.} is displayed.

Touch [OK].

5 The system returns to the [LOGIN] screen.

To delete ID information for all operators, the administrator must touch [Delete all] during Step.

9.3 Managing Latex/QC Lots

When a lot number is entered when setting latex, the expiration date is calculated from the lot number information.
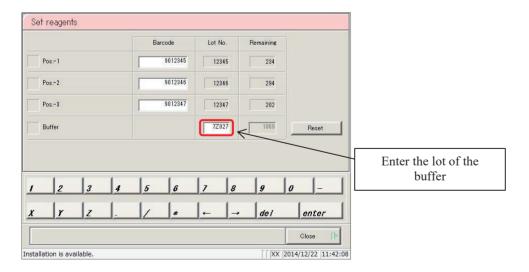
When sample or QC measurement is performed, the lot number and expiration date are recorded in the analysis results.

Explanatory note : Analysis can be performed even if the latex is past its expiration date, so always check the expiration date.

Lot management information	Details
Operator ID	The ID of the operator that is logged in.
Latex lot (*1)	The lot of the latex that was used.
Latex expiration date(*1)	The expiration date of the latex, calculated from the lot number entered when setting latex.
Buffer lot(*1) (*2)	The lot of the buffer that was used.
Buffer expiration date(*1)	The expiration date of the buffer, calculated from the lot number entered when setting buffer.
QC lot(*1)	The lot of the QC that was used.
QCexpiration date(*1)	The expiration date of the QC, calculated from the lot number entered when setting QC.

*1 If the dispensing operation is not performed, "" is output for the lot and expiration date.
*2 Enter the lot of the buffer on the　reagent set screen.

Enter the lot of the buffer

Appendix

1   Calculation Processing

The following calculations are processed during testing:

1.1   STD/QC Sample Measured Data Check

1.2   Calibration curve calculation

1.3   DA value calculation

1.4   Measured Data (Concentration) Calculation and Qualitative Assessment

1.5   Prozone check

1.6   Reagent Blank Check (A1 Check)

1.7   Calculate Cell Blank

1.1　STD/QC Sample Measured Data Check

Check whether the measurement results for STD or QC samples are correct.

1.　STD sample measured data check

(1)　Check that the calibration curve is rising from bottom left to top right from the magnitudes of the DA1 values at each point.

(2)　Check whether the magnitudes of DA1 values at adjoining points are not the same. If they are the same, the result is judged as "abnormal."

(3)　Check the deviation (%) between the origin and back fit.

The specifications for each STD are as follows:

- ・ STD-1　"Abnormal" if outside DA upper/lower range

- ・ STD-2

    │　　"Abnormal" if deviation is not within ±10% of the origin

- ・ STD-5

- ・ STD-6　"Abnormal" if outside DA upper/lower range

2.　QC sample measured data check

Check based on the control limit values set in the [STD/QC process settings] screen.

The result is judged as "abnormal" in the following cases:

- ・ The minimum control limit value is less than 1

- ・ The maximum control limit value is +1 or more

1.2   Calibration curve calculation

There are two curve types: Aloka curve, linear and cubic curve.

■   Aloka curve

Fits an Aloka curve to plotted DA1 value to obtain a calibration curve.

Aloka curves are composed of a linear fit portion and a cubic fit portion.

- ·   Linear fit → between STD-1 and STD-2 (Figure 1-a)
- ·   Cubic fit → between STD-2 and STD-6 (Figure 1-b)
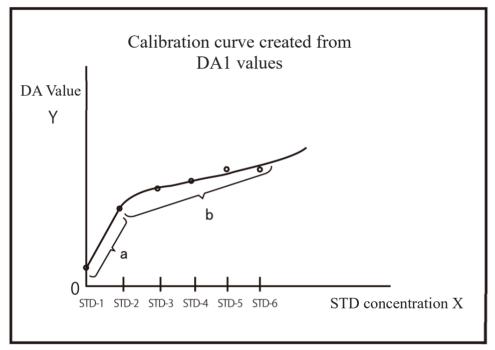
Figure 1

STD concentration (X):	Converted logarithmically, and a cubic-polynomial fitting is performed.
	$X = \log_{10} (\text{STD concentration})$
DA value (Y):	R converted logarithmically, and a cubic-polynomial fitting is performed.
	$Y = \log_e \{R \div (1–R)\}$
R:	Converted value for Aloka curve
	$R = (\text{DA value - NSB}) \div (\text{B0 - NSB})$
	$\text{NSB} = \text{Cmin} – \text{KL} (\text{Cmax} – \text{Cmin})$
	$\text{B0} = \text{Cmax} + \text{KH} (\text{Cmax} – \text{Cmin})$
	$\text{KL} = 0.2, \text{KH} = 0.2$
Cmax:	DA value maximum
Cmin:	DA value minimum

<Zero concentration point measured>

A linear line is fitted to the DA values of STD-1 and STD-2.
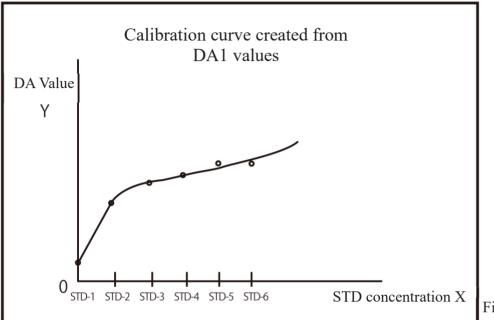
Figure 2

DA values used by calibration curve

Replicate n ≥ 3: The mean DA value excluding the maximum and minimum values
Replicate n < 3: The mean DA value

<DA value at zero concentration point larger than DA value at STD-2 concentration point>

Regression analysis is not performed between STD-1 and STD-2.

With this kind of calibration curve, measured data cannot be calculated from a DA value lower than the DA value of STD-2.
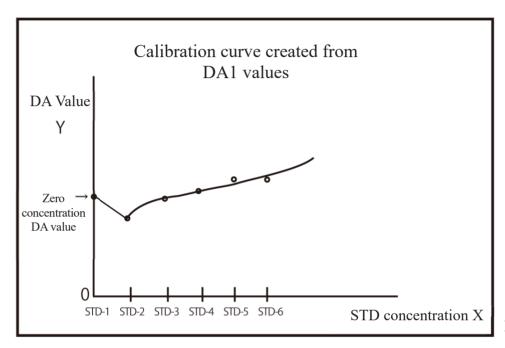
Figure 3

Explanatory note : In cubic regression calculation, calculation is performed with X and Y reversed.

(X: DA value, Y: concentration value)

In Aloka curve calculation, X and Y are not reversed.
DA value normalization is not performed

(normalized DA value = DA value ÷ DA value of maximum concentration point).

Incalculable range of measured data

The range outside maximum DA value, minimum DA value, and B0 cannot be calculated.

The range outside the maximum and minimum concentration values also cannot be calculated (the shaded regions in Figure 5).

Figure 4
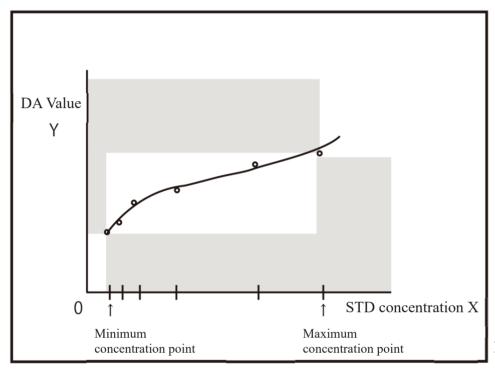
■   Linear and cubic curves

A linear line and cubic line are fitted to the DA1 values.

- ・   Linear fit → between STD-1 and STD-2 (Figure 1-a)
- ・   Cubic fit → between STD-2 and STD-6 (Figure 1-b)

The DA value of the linear STD-2 point is calculated using Newton's method from the cubic line.

349

<DA value at zero concentration point larger than DA value at STD-2 point>

☞   Page 346 "■ Aloka curve <DA value at zero concentration point larger than DA value at STD-2 concentration point>

1.3   DA value calculation

DA values are final measurement results. Measured data (concentration value: X) is calculated from DA values and calibration curves. When a reagent is dispensed to a cell that has dispensed a sample, latex agglutination proceeds and absorbance (ABS) changes.

The time course shows changes in absorbance.

The time course is monitored once a sample is dispensed into a cell (see Figure 5).
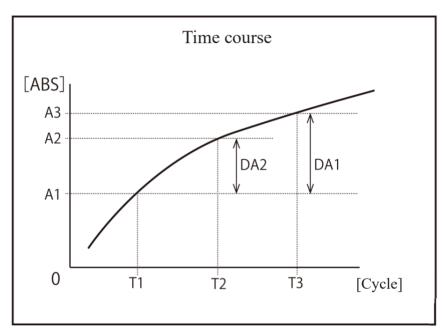
Figure 5

T1: 1st detection point	A1: T1 absorbance
T2: 2nd detection point	A2: T2 absorbance
T3: 3rd detection point	A3: T3 absorbance

A1, A2 and A3 are the mean values of absorbance of two consecutive cycles.

Example: T1 = 6, T2 = 8, T3 = 33 [Cycle]

A1 = (Absorbance of the 6th cycle + absorbance of the 5th cycle) ÷ 2

A2 = (Absorbance of the 8th cycle + absorbance of the 7th cycle) ÷ 2

A3 = (Absorbance of the 33rd cycle + absorbance of the 32nd cycle) ÷ 2
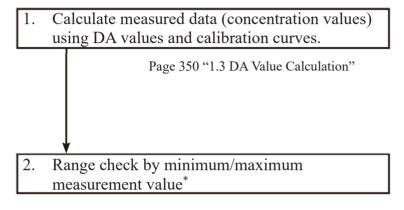
DA values are the amount of change for A1, A2, and A3.

DA1: A3 - A1

DA2: A2 - A1

1.4   Measured Data (Concentration) Calculation and Qualitative Assessment

Measured data (concentration values) is calculated from DA values and the calibration curve, normalized measured data and cut-off values are compared, and a qualitative assessment is performed.

```
┌─────────────────────────────────────────────────┐
│ 1.  Calculate measured data (concentration values) │
│     using DA values and calibration curves.        │
└─────────────────────────────────────────────────┘
```

Page 350 "1.3 DA Value Calculation"

```
┌─────────────────────────────────────────────────┐
│ 2.  Range check by minimum/maximum                │
│     measurement value*                             │
└─────────────────────────────────────────────────┘
```

OR: Displayed when measured data has exceeded maximum measurement value.

Concentration value: Displayed when measured data is at or below maximum measurement value.

UR: Displayed when measured data is lower than minimum measurement value during a dilute test.

Page 308 "6.2.1 Sample/QC protocol settings"

* Measured data is the value prior to correction (such as correction by factor A/B or by applying a dilution ratio).

1.5   Prozone check

Prozone checking is conducted using two methods: RBC method and PRC method.

RBC method: Compare the absorbance of the RBC points in STD-6 (maximum concentration point) and the sample.

PRC method: Compare the DA2 values in STD-6 (maximum concentration point) and the sample.

■   RBC method

Compare the RBC point sample absorbance (a) and STD-6 absorbance (b), if the following relationship is formed, designate the sample as "prozone samples."

$$(b) \times \text{RBC method coefficient} < (a)$$
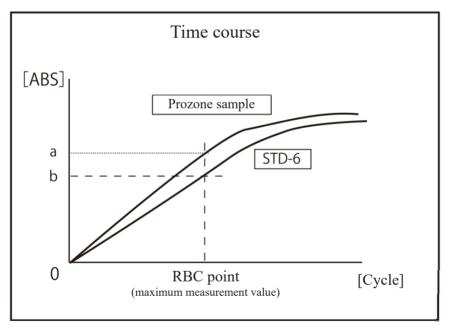
Figure 6

Explanatory note : The RBC method coefficient is set in "9RBC method coefficient" on {Page 2} of the [Protocol settings] · [Samp/QC protocol] screen.

Explanatory note : The sample absorbance (a) and STD-6 absorbance (b) are the mean values of each RBC point and its previous point.

   Example: When the RBC point is 5, (a) and (b) are each the value of (5th cycle absorbance + 4th cycle absorbance) ÷ 2.

■ PRC method

Compare the DA2 values of the sample and STD-6, forming the following relationship. Standing samples are designated as "prozone samples."

$$\text{DA2}_{\text{STD-6}} \times \text{PRC method coefficient} < \text{DA2}_{\text{sample}}$$

Time course

[ABS]

Prozone sample

STD-6

DA2 sample

$\text{DA2}_{\text{STD-6}}$

0   T1   T2   [Cycle]
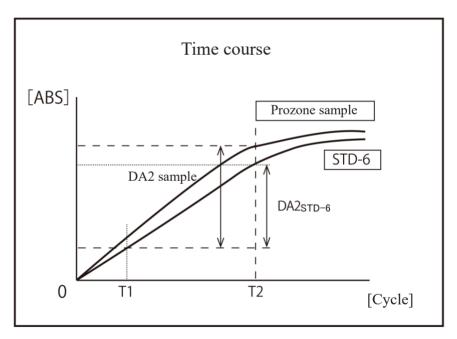
Figure 7

$\text{DA2}_{\text{sample}}$: DA2 value of prozone sample

$\text{DA2}_{\text{STD-6}}$: DA2 value of STD-6

1.6   Reagent Blank Check (A1 Check)

Checks whether or not a reagent was dispensed normally using the absorbance of the T1 cycle.
ADC values of the T1 cycle and the T1-1 cycle are averaged to obtain absorbance, which is compared with the maximum and minimum values of the A1 check.

If either of the following conditions is met, an error message appears displaying "Latex blank error."

Mean absorbance < A1 check minimum value

or

Mean absorbance > A1 check maximum value

Explanatory note : Absorbance = $\log_{10}$ (reference value ÷ ADC value) × 10,000 – cell-blank value

Explanatory note : The A1 check maximum and minimum values are set by the manufacturer.
They cannot be modified by the customer.

1.7   Calculate Cell Blank

Perform detection for each cycle for each of the 55 cells after the start analysis.

・ For the 55th cell, the ADC mean value is calculated using ADC values measured during the period of time between dispensing of purified water with the 3rd nozzle and absorbing of purified water with the 4th nozzle (four cycles), and this ADC mean value is used as the reference value.

$$\text{Reference value} = (\text{ADC mean value})$$
$$= \text{Four-cycle Accumulation of ADC values}$$
$$\div 4 \text{ (Cycles)}$$

・ For each of the 1st to 54th cells, calculate the mean value of ADC values in the same way as with the 55th cell, and calculate a cell-blank value according to the following equation.

$$\text{Cell-blank value} = \text{Log}_{10} (\text{Reference value} \div \text{ADC average})$$
$$\times 10{,}000$$

2　Test Operations
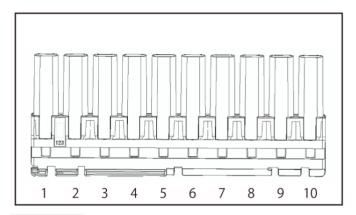
This section describes test operations according to the rack or measure mode being used.

2.1　Operation when first measuring a sample using a "sample rack" (first test)

2.2　Operation when retesting a sample using a "retest rack" (retest)

2.3　Operation when remeasuring a sample using a "sample rack" (remeasure)

2.4　Operation when diluting a sample again and measuring it using a "dilute test rack" (dilute test)

2.5　Operation when measuring STD/QC samples

2.6　Operation when performing cut-in analysis

2.1　Operation when first measuring a sample using a "sample rack" (first test)

This section describes the "first test" operation.
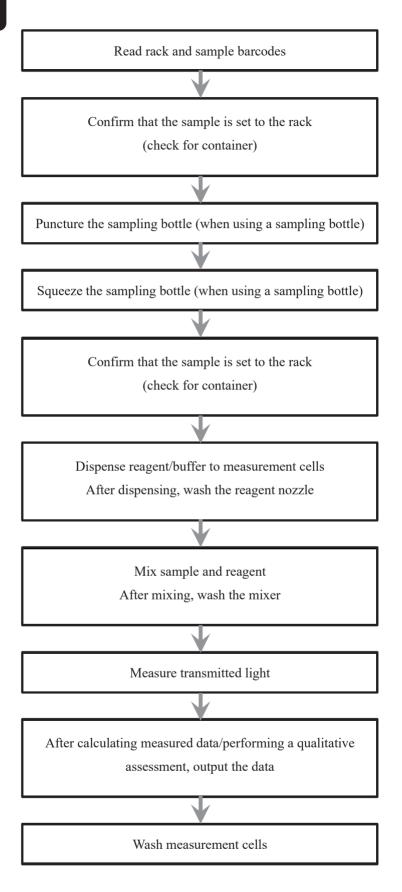
The sample is set as in the following figure.

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Explanatory note : If the accessory end ring is attached to a rack, racks from the one with the ring will not be analyzed.

First test

```
Read rack and sample barcodes
```
↓
```
Confirm that the sample is set to the rack
(check for container)
```
↓
```
Puncture the sampling bottle (when using a sampling bottle)
```
↓
```
Squeeze the sampling bottle (when using a sampling bottle)
```
↓
```
Confirm that the sample is set to the rack
(check for container)
```
↓
```
Dispense reagent/buffer to measurement cells
After dispensing, wash the reagent nozzle
```
↓
```
Mix sample and reagent
After mixing, wash the mixer
```
↓
```
Measure transmitted light
```
↓
```
After calculating measured data/performing a qualitative
assessment, output the data
```
↓
```
Wash measurement cells
```

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2.2   Operation when retesting a sample using a "retest rack" (retest)

This section describes the "retest" operation.

Analyzed samples will be reanalyzed, so do not puncture the sampling bottle.

Otherwise, the procedure is the same as that for "first test."

Retest

```
┌─────────────────────────────────────────────┐
│         Read rack and sample barcodes        │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│      Confirm that the sample is set to the   │
│                   rack                        │
│             (check for container)             │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│  Squeeze the sampling bottle (when using a   │
│              sampling bottle)                 │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│  Absorb the sample and dispense to           │
│              measurement cells                │
│   After dispensing, wash the sample nozzle   │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│  Dispense reagent/buffer to measurement      │
│                   cells                       │
│   After dispensing, wash the reagent nozzle  │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│           Mix sample and reagent             │
│         After mixing, wash the mixer         │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│          Measure transmitted light           │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│ After calculating measured data/performing a │
│  qualitative assessment, output the data     │
└─────────────────────────────────────────────┘
                      ↓
┌─────────────────────────────────────────────┐
│          Wash measurement cells              │
└─────────────────────────────────────────────┘
```

Explanatory note : Retest results have no impact on the positive rate.

"Duplicated sample barcode checking" is not performed during retests.

2.3   Operation when remeasuring a sample using a "sample rack" (remeasure)

This section describes the "remeasure" operation.

Measured samples will be remeasured, so do not puncture the sampling bottle.

Otherwise, the procedure is the same as that for "first test."

Remeasure

Read rack and sample barcodes

↓

Confirm that the sample is set to the rack
(check for container)

↓

Squeeze the sampling bottle (when using a sampling bottle)

↓

Dispense the sample to measurement cells
After dispensing, wash the sample nozzle

↓

Dispense reagent/buffer to measurement cells
After dispensing, wash the reagent nozzle

↓

Mix sample and reagent
After mixing, wash the mixer

↓

Measure transmitted light

↓

After calculating measured data/performing a qualitative
assessment, output the data

↓

Wash measurement cells

2.4 Operation when measuring a sample again it using a "dilute test rack" (dilute remeasure)

This section describes the "dilute test" operation.

Analyzed samples will be reanalyzed, so do not puncture the sampling bottle.

If the dilute test rack is used, automatic dilution will be performed. There are two dilution operations: 15-times dilution and 250-times dilution. The system determines which to use based on the arrangement of sample cups in the rack.

> ⚠ Request
>
> ・ Use the dilute test rack when remeasuring a sample that had a dilute test performed on it. Do not use the retest rack.
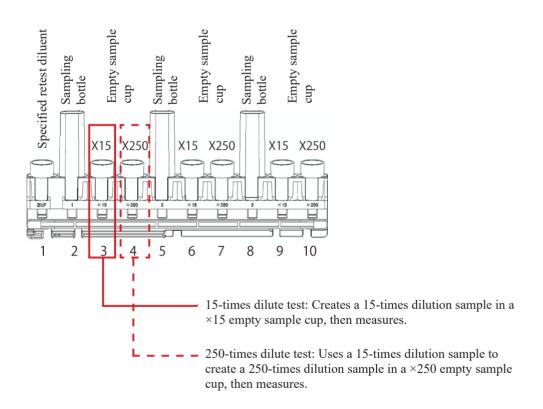
Explanatory note : See page 272 "6.1.3 Rack/QC sequence number settings" for information on how to set the retest rack or dilute test rack numbers.

Explanatory note : There are two dilution operations: 15-times dilution and 250-times dilution. The system determines which to use based on the containers arranged on the rack.

15-times dilute test: Creates a 15-times dilution sample in a ×15 empty sample cup, then measures.

250-times dilute test: Uses a 15-times dilution sample to create a 250-times dilution sample in a ×250 empty sample cup, then measures.
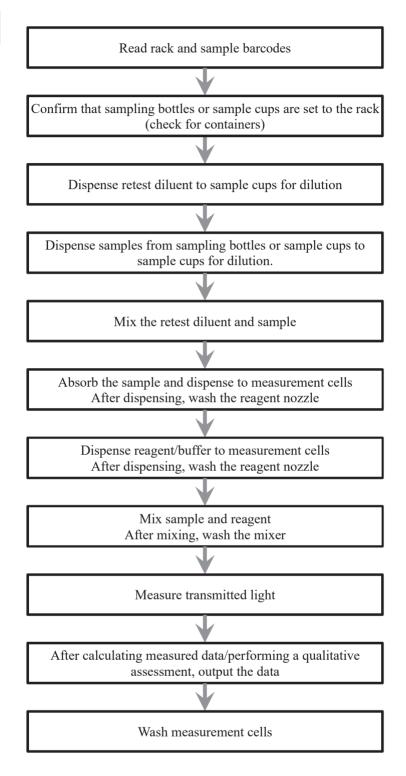
Explanatory note : ×15 simultaneous analysis involves creating 15-times dilution and 250-times dilution samples, and then measuring them (same as with 250-times dilute test).

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Dilute test

```
┌─────────────────────────────────────────────────────┐
│            Read rack and sample barcodes              │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│ Confirm that sampling bottles or sample cups are set  │
│           to the rack (check for containers)          │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│       Dispense retest diluent to sample cups for      │
│                        dilution                       │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│  Dispense samples from sampling bottles or sample     │
│          cups to sample cups for dilution.            │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│            Mix the retest diluent and sample          │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│   Absorb the sample and dispense to measurement cells │
│        After dispensing, wash the reagent nozzle      │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│   Dispense reagent/buffer to measurement cells        │
│        After dispensing, wash the reagent nozzle      │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│              Mix sample and reagent                   │
│            After mixing, wash the mixer               │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│              Measure transmitted light                │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│  After calculating measured data/performing a         │
│       qualitative assessment, output the data         │
└─────────────────────────────────────────────────────┘
                          ↓
┌─────────────────────────────────────────────────────┐
│              Wash measurement cells                   │
└─────────────────────────────────────────────────────┘
```

(Explanatory note) : "Duplicated sample barcode check" is not performed during dilute tests.
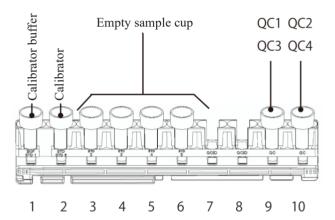
2.5   Operation when measuring STD/QC samples

This section describes the operation when measuring STD/QC samples.
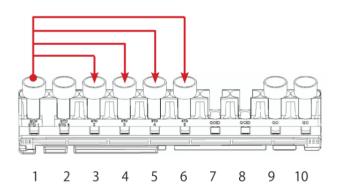
When STD/QC racks are placed in the rack supply unit, a calibration curve is created and the samples set to the rack are measured.

Calibration curves are created using "Latex/CC settings" specified on the [Test] screen. Created calibration curves are registered to "Registration CC No." on the [Test] screen.
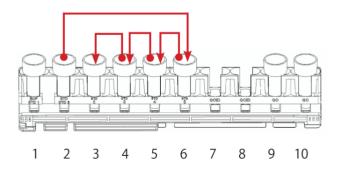
☞ Page 63 "Configuring [Latex/CC settings]"
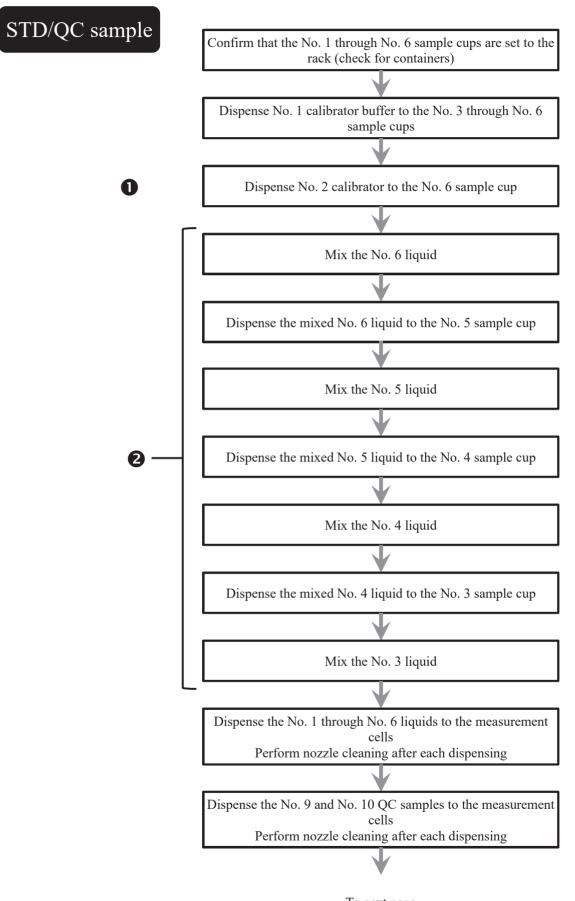
Set the sample cups to the STD/QC rack as shown in the diagram to the left.

1 Dispense No. 1 calibrator buffer to the sample cups in rack position numbers 3 through 6.
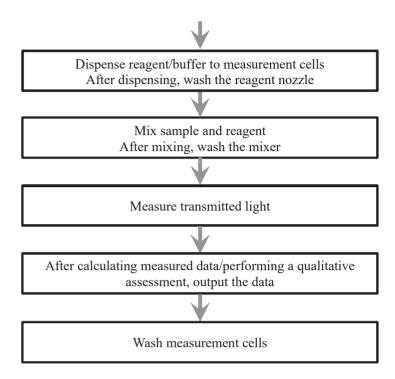
2 Create dilution series

STD/QC sample

Confirm that the No. 1 through No. 6 sample cups are set to the rack (check for containers)

↓

Dispense No. 1 calibrator buffer to the No. 3 through No. 6 sample cups

↓

❶

Dispense No. 2 calibrator to the No. 6 sample cup

↓

❷

Mix the No. 6 liquid

↓

Dispense the mixed No. 6 liquid to the No. 5 sample cup

↓

Mix the No. 5 liquid

↓

Dispense the mixed No. 5 liquid to the No. 4 sample cup

↓

Mix the No. 4 liquid

↓

Dispense the mixed No. 4 liquid to the No. 3 sample cup

↓

Mix the No. 3 liquid

↓

Dispense the No. 1 through No. 6 liquids to the measurement cells
Perform nozzle cleaning after each dispensing

↓

Dispense the No. 9 and No. 10 QC samples to the measurement cells
Perform nozzle cleaning after each dispensing

↓

To next page

From previous page

```
┌──────────────────────────────────────────────────────┐
│   Dispense reagent/buffer to measurement cells         │
│   After dispensing, wash the reagent nozzle            │
└──────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────┐
│   Mix sample and reagent                               │
│   After mixing, wash the mixer                         │
└──────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────┐
│   Measure transmitted light                            │
└──────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────┐
│   After calculating measured data/performing a         │
│   qualitative assessment, output the data              │
└──────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────┐
│   Wash measurement cells                               │
└──────────────────────────────────────────────────────┘
```

MEMO

MEMO

MEMO

2.6   Operation when performing cut-in analysis

This section describes the "cut-in analysis" operation.
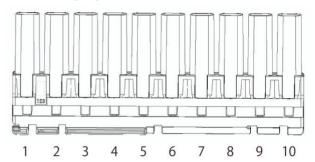
Cut-in analysis uses sample racks and STD/QC racks.

Retest racks and dilute test racks can not be used.
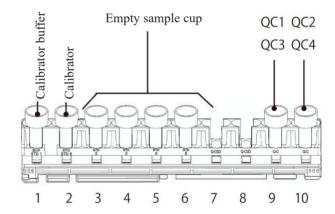
Set samples to sample racks and STD/QC racks as follows:

Sampling bottles can also be installed alone

Sample racks

1   2   3   4   5   6   7   8   9   10

STD/QC racks

Calibrator buffer

Calibrator

Empty sample cup

QC1 QC2
QC3 QC4

1   2   3   4   5   6   7   8   9   10

Cut-in analysis

```
┌─────────────────────────────────────────────────────────────┐
│        Begin testing from the cut-in installation position   │
└─────────────────────────────────────────────────────────────┘
                              │
┌─────────────────────────────────────────────────────────────┐
│                Read rack and sample barcodes                 │
└─────────────────────────────────────────────────────────────┘
```

<For STD/QC racks>   <For sample racks>

Confirm the position and quantity of sample cups set to the rack	Confirm that the containers are set
Create the dilution series	Puncture the sampling bottles
	Squeeze the sampling bottles
Dispense the dilution series sample/QC sample to the measurement cells	Dispense the sample to measurement cells

```
┌─────────────────────────────────────────────────────────────┐
│                   Wash the sample nozzle                     │
└─────────────────────────────────────────────────────────────┘
                              │
┌─────────────────────────────────────────────────────────────┐
│         Dispense reagent/buffer to measurement cells         │
│                  Wash the reagent nozzle                     │
└─────────────────────────────────────────────────────────────┘
                              │
```

To next page

From previous page

```
┌─────────────────────────────────────────────────┐
│          Mix liquid in measurement cells          │
│             Wash the mixer nozzle                 │
└─────────────────────────────────────────────────┘

┌─────────────────────────────────────────────────┐
│            Measure transmitted light              │
└─────────────────────────────────────────────────┘

┌─────────────────────────────────────────────────┐
│  After calculating sample measured data/performing a qualitative assessment,  │
│                   output the data                 │
└─────────────────────────────────────────────────┘

┌─────────────────────────────────────────────────┐
│             Wash measurement cells                │
└─────────────────────────────────────────────────┘
```

MEMO

3   Printing examples

This section describes various printing examples.

3.1   Negative sample printing

3.2   Final result printing when using a dilute test rack or when analyzing 15-times dilution simultaneously

3.3   1 day, 2 day, 3 day printing

3.4   Printing when measuring STD/QC samples

3.5   Error message printing

```
*******************************
 POWER ON          15/01/14 11:42
*******************************


*******************************
 START             15/01/15 17:51
*******************************
 CC No. 1          15/01/12 14:27
*******************************




005-01    1-00001          AB00123xx
 +   183              *  124.2ng/mL

005-02    1-00002          NO Tube


005-03    1-00003  L. Dispense Err


*******************************
*******************************
 END               15/01/15 17:56
*******************************
```

Time and data of system power on

Test start data and Time

Calibration curve number and measurement date and time

Rack No.-
Rack position No.

Qualitative assessment result

DA

Sample No.
Group No.-Sequence No.

Test complete date

Sample ID

DATA

Message indicating

Error message (Reagent dispensing error)
☞ Page 381
"3.5 Error message printing"

OR,UR,PRC is printed in * area.

3.1   Positive sample printing

<When replicate number = 1>

"Sample information" and <u>positive</u> "analytical results" are printed in bold.

```
005-02   1-00002           AB12345
   -         60          61 ng/mL

005-03   1-00003           CD23456
   +        120         112 ng/mL
```
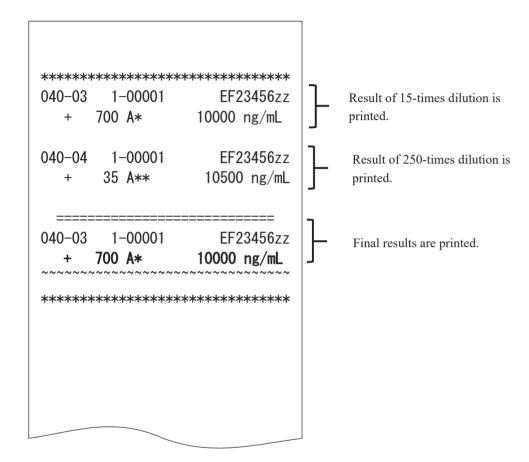
<When replicate number > 1 and mean value is a positive sample>

The mean value row only is printed in bold.

(Example : replicate = 2)

```
005-02    1-00002            AB12345
   -          95           95 ng/mL
   +         110          110 ng/mL
--------------------------------
   +                      103 ng/mL
```

3.2   Final result printing when using a dilute test rack or when analyzing 15-times dilution simultaneously

\<When replicate number = 1\>

```
*******************************
040-03   1-00001        EF23456zz
    +   700 A*        10000 ng/mL


040-04   1-00001        EF23456zz
    +    35 A**        10500 ng/mL


   ===========================
040-03   1-00001        EF23456zz
    +   700 A*        10000 ng/mL
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
*******************************
```

Result of 15-times dilution is printed.

Result of 250-times dilution is printed.

Final results are printed.

<When replicate number > 1>

```
********************************
040-03   1-00001        EF23456zz
   +    700 A*         10000 ng/mL
   +    700 A*         10000 ng/mL
─────────────────────────────────
   +    700 A*         10000 ng/mL
        0.00               0.0


040-04   1-00001        EF23456zz
   +     35 A**        10500 ng/mL
   +     35 A**        10500 ng/mL
─────────────────────────────────
   +     35 A**        10500 ng/mL
        0.00               0.0


==================================
040-03   1-00001        EF23456zz
   +    700 A*         10000 ng/mL
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~


********************************
```

Result of 15-times dilution is printed.

Result of 250-times dilution is printed.

Final results are printed.

3.3   1 day, 2 day, 3 day printing

1-day
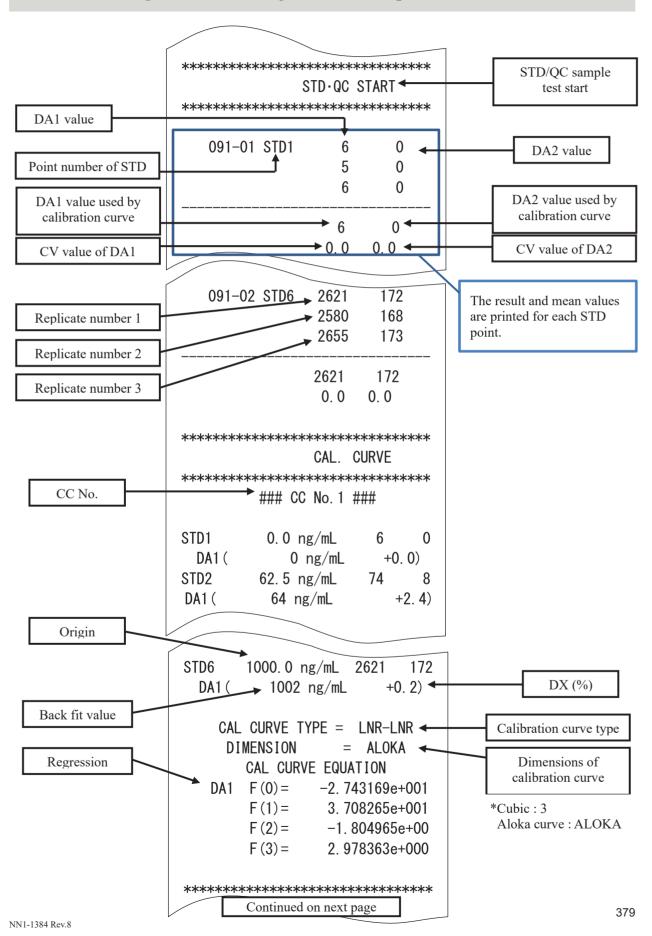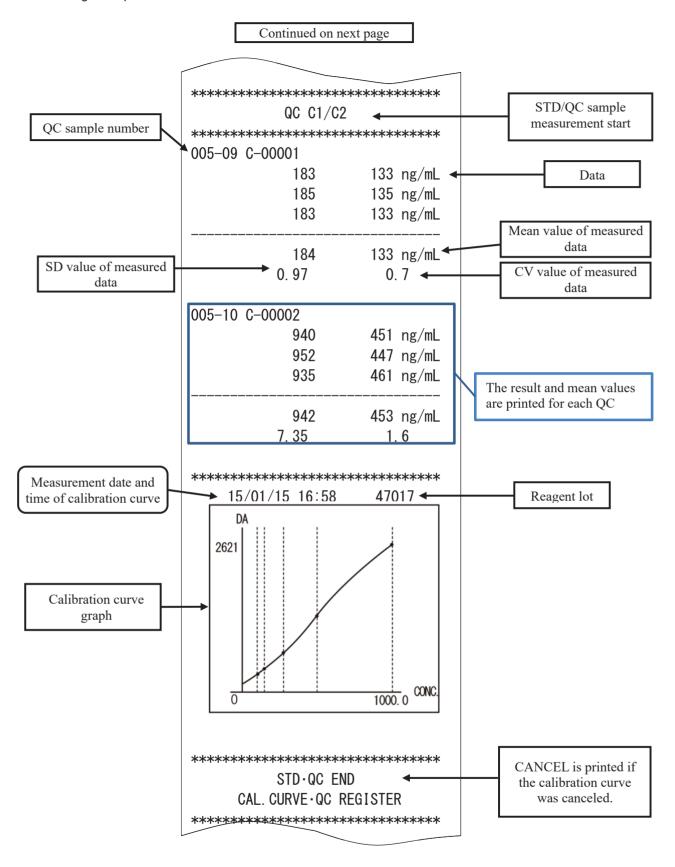
```
005-01    1-00001        AB00123xx
  +    183              124. 2ng/mL

005-02    1-00002        BC11234zz
  -      5                0. 0ng/mL
```

Sample number 1

Sample number 2

2-day

```
006-01    1-00001/1       CD99346dd
  +    295              200. 0ng/mL

006-02    1-00001/2       CE45813rr
  +    310              210. 0ng/mL

006-03    1-00002/1       ES74125dd
  -      4                0. 0ng/mL

006-04    1-00002/2       ET68542rr
  -     25               17. 0ng/mL
```

Sample number 1

First day sample

Second day sample

Sample number 2

First day sample

Second day sample

3-day

```
007-01    1-00001/1       GH78314dd
  +    295              200. 0ng/mL

007-02    1-00001/2       GI95155rr
  +    310              210. 0ng/mL

007-03    1-00001/3       GJ94357ss
  -      4                0. 0ng/mL

006-04    1-00002/1       GH68542dd
  -     25               17. 0ng/mL

006-05    1-00002/2       GI77445rr
  +    183              124. 2ng/mL

006-05    1-00002/3       GJ68585ss
  -     81               55. 0ng/mL
```

Sample number 1

First day sample

Second day sample

Third day sample

Sample number 2

First day sample

Second day sample

Third day sample

3.4   Printing when measuring STD/QC samples

DA1 value

Point number of STD

DA1 value used by calibration curve

CV value of DA1

STD/QC sample test start

DA2 value

DA2 value used by calibration curve

CV value of DA2

The result and mean values are printed for each STD point.

Replicate number 1

Replicate number 2

Replicate number 3

CC No.

Origin

Back fit value

Regression

DX (%)

Calibration curve type

Dimensions of calibration curve

*Cubic : 3
 Aloka curve : ALOKA

```
********************************
           STD·QC START
********************************

 091-01 STD1        6        0
                    5        0
                    6        0
 _____
                    6        0
                   0.0      0.0


 091-02 STD6    2621      172
                2580      168
                2655      173
 _____
                2621      172
                 0.0      0.0


 ********************************
           CAL.  CURVE
 ********************************
        ### CC No.1 ###

 STD1        0.0 ng/mL       6       0
    DA1(        0 ng/mL        +0.0)
 STD2       62.5 ng/mL      74       8
    DA1(       64 ng/mL        +2.4)


 STD6     1000.0 ng/mL    2621     172
    DA1(     1002 ng/mL        +0.2)

     CAL CURVE TYPE =   LNR-LNR
       DIMENSION    =   ALOKA
        CAL CURVE EQUATION
   DA1  F(0)=      -2.743169e+001
        F(1)=       3.708265e+001
        F(2)=      -1.804965e+00
        F(3)=       2.978363e+000


 ********************************
```

Continued on next page

Continued on next page

```
********************************
           QC  C1/C2
********************************
005-09 C-00001
               183      133 ng/mL
               185      135 ng/mL
               183      133 ng/mL
         ----------------------------
               184      133 ng/mL
         0.97             0.7
```

QC sample number

STD/QC sample measurement start

Data

Mean value of measured data

SD value of measured data

CV value of measured data

```
005-10 C-00002
               940      451 ng/mL
               952      447 ng/mL
               935      461 ng/mL
         ----------------------------
               942      453 ng/mL
         7.35             1.6
```

The result and mean values are printed for each QC

```
********************************
  15/01/15  16:58        47017
```

Measurement date and time of calibration curve

Reagent lot

```
DA

2621

                              CONC.
  0                   1000.0
```

Calibration curve graph

```
********************************
        STD·QC  END
   CAL.CURVE·QC REGISTER
********************************
```

CANCEL is printed if the calibration curve was canceled.

3.5   Error message printing

The meanings of error messages are shown in the chart below.

```
*******************************
 POWER ON          15/01/14 11:42
*******************************


*******************************
 START             15/01/15 17:51
*******************************
 CC No. 1          15/01/12 14:27
*******************************
005-01    1-00001          AB00123xx
  +   183              *  124.2ng/mL


005-02    1-00002          NO Tube



005-03    1-00003  L. Dispense Err




*******************************
```

Error message
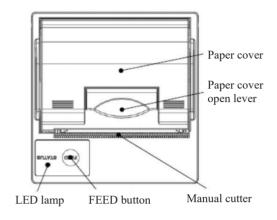
Error Message Text	Meaning
Sample Short	Sample insufficient
No Latex	No reagent
Latex Short	Reagent insufficient
Mixing Error	Mixing error
Latex Blank Error	Reagent blank error
No Cal. Curve	No calibration curve
Cal.Curve1 Error	STD error (DA1)
Cal.Curve2 Error	STD error (DA2)
S. Dispense Err	Sample dispensing error
L. Dispense Err	Reagent dispensing error
Puncture Error	Puncture error
None Result	No final results
Order Error	Order error
No Tube	Sample not placed
B/C Duplication	Double barcode
B/C Read NG	Barcode reading error
No Order	No Order
Printer Offline	Printer connection error and re-connection

Explanatory note : There are cases where before and after the printing of the "Printer Offline" is overlapping.

---

4   Handling the Printer

This section describes printer paper setting and LED lamp displays.
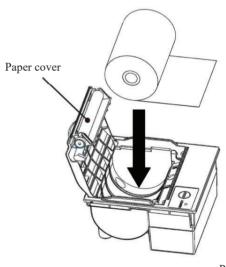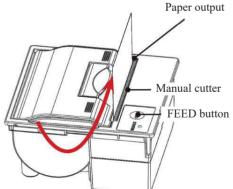
Paper cover

Paper cover open lever

LED lamp   FEED button   Manual cutter

⚠ Caution

① **·** Be careful of the blade of the manual
   Failure to observe this precaution may
   lead to injury.
   Required

4.1   Setting printer paper

Paper cover

①   Raise the paper cover open lever and open the cover.

②   Set the paper as shown in the diagram to the left. (If this is set with the opposite facing, the system will be unable to print.)

Paper output

③   Set the paper so that its edge sticks out of the paper output.

Manual cutter

FEED button

④   Press both edges of the paper cover to close it. Confirm that the paper cover is locked.

⑤   Touch the FEED button.

⑥   Cut the paper using the manual cutter.

4.2   LED lamp display

If the LED lamp is lit or blinking, there is a printer error.

\<Normal status\>

LED lamp	Printer Status
Lit green	Waiting to print
Blinking green	Initializing

\<When an auto carriage return error has occurred\>

LED lamp	Printer Status
Blinking red	Abnormal temperature (when it has been detected that the temperature is around 70°C or higher)
Lit red	Out of paper

\<When a carriage return error has occurred \>

LED lamp	Printer Status
Blinking red, green	Voltage upper limit error (when it has been detected that the voltage is around 9.2 V or higher)
Blinking red, green	Voltage lower limit error (when it has been detected that the voltage is around 4.0 V or lower)

5   Error List

This section describes error messages that are displayed on the screen, as well as error messages printed to a printer.

5.1   ERR# 0-1001 - 0-2005 (Main)

Error No. ERR#0-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1001	G communication error	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN]: Turn off the system power. [CLOSE]: CLOSE ERROR DISPLAY
	G Communication error	
1003	Unexpected command received	(Not displayed on screen) Operation will continue automatically.
	Unexpected command received	
1005	No reply from GLIFE command	(Not displayed on screen) Touch the [SHUT DOWN] button to turn off the system power. Finish the sample process currently being tested.
	No Reply from GLIFE Command	
1006	No reply from G command	(Not displayed on screen) Touch the [SHUT DOWN] button to turn off the system power. Finish the sample process currently being tested.
	No Reply from G Command	
1007	Abort failed	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN]: Turn off the system power. [CLOSE]: CLOSE ERROR DISPLAY
	Abort failed	

ERR# 0-1100 -

Error No. ERR#0-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1101	Online ACK timeout error	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online ACK timeout	
1102	Online NAK count error	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online NAK count	
1103	Online data reception error	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online data reception error	
1111	Online connection error	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online connection error	
1112	Online transmission error [Reception failed]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online transmission error [Reception failed]	

Error No. ERR#0-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
1113	Online transmission error [Faulty data received]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online transmission error [Faulty data received]	
1114	Online transmission error [Timeout error]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.
	Online transmission error [Timeout error]	
ERR# 0-1400 -		
1404	Detector error	(Not displayed on screen) Touch the [ABORT] button to display the detector maximum output registration screen. Select either [REGISTER] or [CANCEL], and restart the system. Finish the sample process currently being tested.
	Detector error	
1409	Insufficient test reagents	Reagent low volume. Analysis stopped. Reagents need to be set on the reagent setting screen, so press the [CLOSE] button to clear the warning message. Caution: Do not restart analysis until you have set the reagents and cleared the low reagent condition. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.
	Insufficient test reagents	
1410	Insufficient test buffer	Buffer low volume. Analysis stopped. Buffer needs to be set on the reagent setting screen, so press the [CLOSE] button to clear the warning message. Caution: Do not restart analysis until you have set the buffer and cleared the low buffer condition. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.
	Insufficient test buffer	
1412	No buffer left	(Not displayed on screen) (1) Open the [Set reagents] screen. (2) Add buffer. (3) (If you will update buffer information and run normal priming once reagents have been set). Touch the [RESET] button. (4) Touch the [Set complete] button.
	No buffer left	
1415	Reference cell acquisition failed	Reference data Value of cell blank measurement is out of Standard. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish cell blank measurement without updating the reference value. [COERCE]: Update the reference value and continue cell blank measurement.
	Reference cell acquisition failed	
1416	Double sample barcode	(Not displayed on screen) A sample barcode is duplicated. This sample will not be tested. Operation will continue automatically.
	Double sample barcode	

Error No. ERR#0-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
1417	Sample barcode reading error	(Not displayed on screen) A sample barcode couldn't be read. This sample will be tested. Operation will continue automatically.
	Sample barcode reading error	
1418	Sample barcode digit error	(Not displayed on screen) In sample barcode reading, a sample with a number of barcode digits exceeding the limit was found. This sample will be tested. Operation will continue automatically.
	Sample barcode digit error	
1419	Reagent barcode reading error	(Not displayed on screen) A reagent barcode couldn't be read. Try reading again. Operation will continue automatically.
	Reagent barcode reading error	
1420	Reagent barcode check digit error	(Not displayed on screen) An error is detected in a reagent barcode check digit inspection. Try reading again. Operation will continue automatically.
	Reagent barcode check digit error	
1423	Insufficient purified water Warning	Insufficient purified water Warning: Due to insufficient purified water in the tank (for purified water), sample dispensing is halted. During operation of the system, you cannot exchange tanks or add purified water. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.
	Insufficient purified water	
1424	Insufficient wash solution Warning	Due to insufficient wash solution in the tank (for wash solution), sample dispensing is halted. During operation of the system, you cannot exchange tanks or add the wash solution. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.
	Insufficient wash solution	
1425	Drain tank full Warning	Due to the drain tank being full, sample dispensing is halted. During operation of the system, you cannot exchange tanks. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.
	Drain tank full	

Error No. ERR#0-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1430	Cell check error	(Not displayed on screen) No cell has been set. Touch the [Abort] button and set the cells.
	Cell check error	
1431	All cell blank error	(Not displayed on screen) Cell blank status is abnormal for all cells. Touch the [Abort] button and change the cells.
	All cell blank error	
1435	Reagent blank error	(Not displayed on screen) Latex blank is abnormal. Operation will continue automatically.
	Reagent blank error	
1436	Cell Blank Error	(Not displayed on screen) Cell blank status is abnormal. Operation will continue automatically. To replace the cells, touch the [Abort] button.
	Cell Blank Error	
1437	Transportation Result Data Error	(Not displayed on screen) An error is detected in a reagent barcode check digit inspection. Try reading again. Operation will continue automatically.
	Transportation Result Data Error	
1438	Container check results error	(Not displayed on screen) SAMPLE CHECK FAIL This sample will not be tested. Operation will continue automatically.
	Container check results error	
1439	Maximum number of samples reached Warning	Rack loading stopped due to reaching maximum number of sample analysis after a system start up. Close error display. If testing, close the instrument under main analysis screen of [Completed]. After system restart, new analysis can be started. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY
	Maximum number of samples reached	
1440	Program error	Close error display. Close the instrument under main analysis screen of [Completed] <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY
	Program Error	

Error No. ERR#0-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
ERR# 0-1500 -		
1501	Startup failed	(Not displayed on screen) Unable to start system. Touch the [SHUT DOWN] button to turn off the system power.
	Startup failed	
1502	Analysis end processing failed	(Not displayed on screen) Unable to complete testing. Touch the [SHUT DOWN] button to turn off the system power.
	Analysis end processing failed	
1503	Program end processing failed	(Not displayed on screen) Unable to shut system down. Touch the [SHUT DOWN] button to turn off the system power.
	Program end processing failed	
1504	A required file cannot be found.	FILE MISSING INF1: Missing file No. 1 = Config.ini 2 = Support.ini <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN] Shut down the system.
	No file	
1505	func.ini is abnormal or cannot be found.	(Not displayed on screen) A file cannot be found. Touch the [SHUT DOWN] button to turn off the system power.
	func.ini is abnormal or cannot be found.	
1506	kinou.dat is abnormal or cannot be found.	(Not displayed on screen) A file cannot be found. Touch the [SHUT DOWN] button to turn off the system power.
	Kinou.dat Abnormal	
1509	Necessary common memory cannot be found.	(Not displayed on screen) Memory cannot be found. Touch the [SHUT DOWN] button to turn off the system power.
	No common memory	

Error No. ERR#0-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1511	Common memory initialization failed	PROGRAM ERROR (MEMORY) due to file setting failure INF1: Common memory No. 1-46 No. 01: Sample barcode (SysTBcr.txt) No. 02: Rack information (SysRack.txt) No. 03: Environment setting (SysEnv.txt) No. 04: Data output (SysDtOut.txt) No. 05: Output format (SysForm.txt) No. 06: RS232C setting (SysRS.txt) No. 07: Analysis method (SysSoku.txt) No. 08: Alarm setting (SysAlm.txt) No. 09: Screensaver (SysScrn.txt) No. 10: STD・QC run (SysStdQc.txt) No. 11: Sample cup (SysTube.txt) No. 12: Order・Test (SysOdrAna.txt) No. 13: SAMP・QC protocol (PrtSmpQc.txt) No. 14: CC1-CC6 protocol (PrtCC.txt) No. 15: Common protocol 1 (PrtCom1.txt) No. 16: Common protocol 2 (PrtCom2.txt) No. 17: Analysis (AnaInf.dat) No. 18: Test mode (SokuMode.dat) No. 19: Reagent・CC (SiyakuCC.dat) No. 20: Remaining volume (SiyakuZan.dat) \<ERROR CANCELLATION\> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN] Shut down the system.<hr>PROGRAM ERROR (MEMORY) due to file setting failure INF1: MEMORY No.1〜46 No.21:Buffer volume (KBufZan.dat) No.22:Shift register (-------------) No.23:Supply unit (KUnitInf.dat) No.24:Unload unit (HUnitInf.dat) No.25:Rack・Sample (RackInf.dat) No.26:Analysis data (AnaRslt.dat) No.27:STD result data (StdRslt.dat) No.28: cell blank analysis (CellBlnk.dat) No.29:Temperature information (-------------) No.30:Protocol DWLD (-------------) No.31:System status (-------------) No.32:Error information (-------------) No.33:Subsystem (-------------) No.34:Additional analysis (-------------) No.35:Test result (-------------) No.36:STD・QC result (-------------) No.37:Instrument informat (-------------) No.38:CC Information (-------------) No.39:Printer (-------------) No.40:Spare parts (U_Parts.dat) \<ERROR CANCELLATION\> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR 【 SHUTDOWN 】:Shut down the system.<hr>PROGRAM ERROR (MEMORY) due to file setting failure INF1: MEMORY No.1〜46 No.41:spare parts (S_Parts.dat) No.42:Additional analysis recovery (-------------) No.43:Reagnets・CC W (-------------) No.44:Auto Start (AutoStart.txt) No.45:CC1-CC6 Protocol (PrtCC_1.txt) No.46:CC1-CC6 Protocol (PrtCC_2.txt) \<ERROR CANCELLATION\> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR 【 SHUTDOWN 】:Shut down the system.

Error No. ERR#0-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
ERR# 0-1600 -		
1601	COM port is not properly connected	PRINT ERROR COM PORT CONNECTION FAIL CHECK CONNECTION <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY
	COM port error	
ERR# 0-2000 -		
2001	Waiting	The analysis is completed. (You can continue testing)
	(Message not printed)	
2002	Supply unit Exchange trays	The supply unit tray can be exchanged.
	(Message not printed)	

2003	Prepare for pipe line activation.	Prepare for pipe line activation.
		<Buffer bottle>
		  Exchange the purified water with buffer.
		<Tank (for wash solution)>
		  Exchange the purified water with wash solution.
		After exchanging, touch the [START] button.
		  Touch one of the following buttons to select a process.
		  [START]: Start pipe line activation.

	(Message not printed)	
2004	Shutdown error Warning	The system was shut down abnormally last time. The hard disk(SSD) may be damaged. If there is something wrong with the hard disk(SSD) after system startup, please contact our company. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Start up the system.
	Shutdown error Warning	
2005	Hard disk damaged Warning or SSD damaged Warning	A check found that the hard disk(SSD) is damaged. * Self-restoration was performed; however, the disk cannot be fully restored. Replace the hard disk(SSD).
	Hard disk damaged Warning or SSD damaged Warning	

5.2 ERR# 1-000 - 1-200(SS1)

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
000	Unknown error Unknown error	A fault occurred in communication within the system. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
001	Sample nozzle Jam (liquid level detection) SAMP Jam (LSU)	The sample nozzle jammed during detection of the liquid level of a sample. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish analysis.
004	Sample nozzle Jam (liquid level detection) SAMP Jam (LSU)	The sample nozzle jammed during detection of the liquid level of a sample. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of the same sample again. [ABORT]: Finish processing.
005	Sample nozzle Jam (STD) SAMP Jam (STD)	The sample nozzle jammed during detection of the liquid level of a sample. Creation of a dilution series failed <ERROR CANCELLATION> Check for sufficient storage of buffer and standard and place new sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
007	Sample nozzle Jam	The sample nozzle jammed during sample absorption. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish analysis.
	SAMP Jam (SSIP)	
008	Sample nozzle Jam	The sample nozzle jammed during sample absorption. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing.
	SAMP Jam (SSIP)	
010	Sample nozzle Jam (Dispensing to cells)	The sample nozzle jammed when it was dispensing to a cell. The nozzle may be in improper alignment with the reaction table. <ERROR CANCELLATION> If misalignment of the reaction table is the cause of the jamming of the nozzle, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip dispensing of the sample. [ABORT]: Finish analysis. If analysis is underway, it will also terminate.
	SAMP Jam (Cell)	
011	Sample nozzle Jam (STD)	The sample nozzle jammed while dispensing a sample to a sample cup in the creation of an STD dilution series. Unable to run dilution series. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Discharge the rack in process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	SAMP Jam (STD)	

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
012	Sample nozzle Jam (OF) / SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <ERROR CANCELLATION> If the sample nozzle is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Wash the nozzle and start normal operations. [ABORT]: Finish analysis.
013	Sample nozzle Jam (OF) / SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <ERROR CANCELLATION> If the sample nozzle is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish analysis.
014	Sample nozzle Jam (OF) / SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.
015	Sample nozzle Jam (dilute test) / SAMP Jam (DIL)	In the creation of a dilution series for a dilution test, the sample nozzle jammed while dispensing to a sample cup on the rack. The nozzle or rack may be misaligned. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
016	No sample / No sample	(Not displayed on screen) No sample was detected. Operation will continue automatically.
017	No sample (STAT STD) / No sample (INT STD)	No sample was detected. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
018	Sample dispensing error / Sample dispensing error	No sample was detected Operation will continue automatically.

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
019	Sample nozzle Liquid level error	(Not displayed on screen) Detected liquid level is abnormal. Operation will continue automatically.
	SAMP Liquid level error	
020	Sample nozzle　Liquid level error (STAT STD)	Detected liquid level is abnormal. The metallic portion at the tip of the sample nozzle may be conducting electrically through the remaining drops. <ERROR CANCELLATION> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack.
	SAMP Liquid level error (INT STD)	[ABORT]: Finish processing. If analysis is underway, it will also terminate.
021	Sample nozzle Absorption error	(Not displayed on screen) Absorption by the sample nozzle was not performed normally. Operation will continue automatically.
	SAMP Absorption error	
022	Insufficient sample	(Not displayed on screen) Sample amount is insufficient. Operation will continue automatically.
	Insufficient sample	
023	Insufficient sample (STAT STD)	Sample amount is insufficient. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Insufficient sample (INT STD)	
024	Absorption error by sample nozzle (STAT STD)	Absorption by the sample nozzle was not performed normally. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack.
	SAMP Absorption error (INT STD)	[ABORT]: Finish processing. If analysis is underway, it will also terminate.
032	Detection error　Purified water level in OF	No purified water was detected in OF on the sample nozzle side. Purified water may have not been supplied due to a reason such as broken piping. <ERROR CANCELLATION> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart purified water supply.
	Purified water　Pump trouble (OF)	[ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
033	Detection error Purified water level in OF	No purified water was detected in OF on the sample nozzle side. Purified water may have not been supplied due to a reason such as broken piping. <ERROR CANCELLATION> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of purified water again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Purified water Pump trouble (OF)	
034	Detection error Wash solution level in OF	No wash solution was detected in OF on the sample nozzle side. The wash solution may have not been supplied due to pipe breakage or other reason. <ERROR CANCELLATION> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart supply of the wash solution and clean the nozzle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Wash solution Pump trouble (OF)	
035	Detection error Wash solution level in OF	No wash solution was detected in OF on the sample nozzle side. The wash solution may have not been supplied due to pipe breakage or other reason. <ERROR CANCELLATION> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of wash solution again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Wash solution Pump trouble (OF)	
040	Rack on conveyance line	A rack is placed on the conveyance line. <ERROR CANCELLATION> Perform another attempt after manually removing the rack from the conveyance line. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks on the conveyance line again. [ABORT]: Finish processing.
	Rack online	
042	Supply unit 1 No tray	The tray is flowing over the supply unit, or no tray is in place. <ERROR CANCELLATION> Place trays on the supply unit. Ensure that the trays are placed directly on the unit. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Supply unit 1 No tray	

Error No. ERR#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
043	Supply unit 1 Rack supply error	A rack was not supplied normally from the supply unit to the conveyance line. <ERROR CANCELLATION> Arrange the racks on the tray in an orderly manner. Correctly place racks if they are not perpendicular. Remove any obstacles. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart rack supply. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Supply unit 1 Rack supply error	
044	Supply unit 1 Supply bar return error	The supply bar of the supply unit was not returned to the front normally. <ERROR CANCELLATION> Remove any obstacles. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Retry returning the supply bar to the front. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Supply unit 1 Return error	
045	Discharge unit 1 No tray	The tray is flowing over the discharge unit, or no tray is in place. <ERROR CANCELLATION> Place trays on the discharge unit. Ensure that the trays are placed directly on the unit. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Discharge unit 1 No tray	
046	Discharge unit 1 Abnormal discharge	A rack could not be discharged to the discharge unit. <ERROR CANCELLATION> Remove the rack on the discharge tray, make sure the discharge tray is fixed properly. and execute "RETRY". Execute "ABORT" where rack is unable to discharge for Rack would not be at discharge position due to Rack Transfer is not working properly. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt discharge again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Discharge unit 1 Abnormal discharge	
047	Discharge unit 1 Rack full	Rack discharge is halted because the discharge unit is full. <ERROR CANCELLATION> Close the error message. Exchange trays using the rack information screen. After exchanging, touching the button to complete the exchange will discharge the rack on the conveyance line to the discharge unit. Touch the following button. [CLOSE]: Close the alarm message.
	Discharge unit 1 Rack full	

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
048	Conveyance bar in system Working error Conveyance bar　Error	The conveyance bar in the system did not work correctly. A fault may have occurred in the conveyance bar component. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt to move the conveyance bar again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
050	Puncturing component Working error Puncturing　Error	The puncturing component did not work correctly. A fault occurred in the puncturing component. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt puncturing again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
052	Puncturing component　Jam Puncturing Jam	The puncturing component jammed. The component may be caught on a sampling bottle. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt puncturing again. [Pass]: Skip processing of sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
053	Barcode Reader Error Barcode Reader Error	There is a hardware-related error with the barcode reader. Unable to read barcode. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
054	Squeezing Error Squeezing　Error	The squeezing component did not work correctly. <ERROR CANCELLATION> Remove any obstacles. If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Retry squeezing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
055	Squeezing Error Squeezing Error	The squeezing component did not work correctly. The status of the squeezing component is unknown, so the rack cannot be conveyed. <ERROR CANCELLATION> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
059	Purified water/buffer tank Sensor error Purified water/buffer Sensor error	The sensor of the buffer tank did not switch to OFF. Possible causes are as follows: - Malfunctioning of sensor - Sample nozzle clogging - Malfunctioning of syringe pump or electromagnetic valve - Dirty buffer tank <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
060	Purified water/buffer tank Insufficient purified water Purified water Insufficient (buffer)	Purified water is not stored in the purified water/buffer tank (that is, not the purified water tank) in the system. Purified water may have not been supplied due to a reason such as broken piping. <ERROR CANCELLATION> Continue processing after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Pump purified water and restart sampling. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
061	Purified water/buffer tank Insufficient purified water Purified water Insufficient (buffer)	Purified water is not stored in the purified water/buffer tank (that is, not the purified water tank) in the system. Purified water may have not been supplied due to a reason such as broken piping. <ERROR CANCELLATION> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Pump purified water again. [ABORT]: Finish processing.

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
065	Discharge unit 1　Rack conveyance error Discharge 1　Discharge error	Rack discharge was not completed correctly. Because dispensed samples on the discharge line may become jumbled, a retest is recommended in this case. <ERROR CANCELLATION> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
066	Container position　Incorrect Container position　Incorrect	Containers are set in the incorrect positions for STD measurement or a dilute test. <ERROR CANCELLATION> Place containers in the rack correctly. Return the rack to the STAT rack position. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check whether the containers are set correctly. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
067	No buffer No buf.	No buffer remains in the rack for STD measurement or a dilute test. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. [RETRY]: Restart STD measurement or dilute test. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
068	Insufficient buffer Insufficient buf.	The buffer at the top position of a rack is insufficient for STD measurement or a dilute test. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. Touch one of the following buttons to cancel the error. [RETRY]: Restart STD measurement or dilute test. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
095	Rack barcode Reading error Rack barcode Reading error	A rack barcode could not be read. <ERROR CANCELLATION> Check the following. - Is a barcode labeled on the rack? - Is the orientation of the rack correct? - Is the barcode reader lever not tilted forward? If the same error occurs after another attempt, exchange the rack with a new one or the label with a new one before another attempt. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Reread the label. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
096	Rack conveyance error Supply 1 Rack conveyance error	The supplied rack was not conveyed normally. The conveyance bar in the system may be detached. <ERROR CANCELLATION> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
098	Rack barcode Unavailable Rack barcode Unavailable	The retest and dilution test racks are unavailable in a cut-in analysis. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Reread the label. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

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100	Discharge unit 1 Rack full Discharge unit 1 Rack full	Rack discharge is halted because the discharge unit is full. <ERROR CANCELLATION> Perform another attempt after exchanging trays. There is no need to use the rack info. screen to exchange trays. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Discharge the rack. [ABORT]: Finish processing.

Error No. ERR#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
103	No buffer	(Not displayed on screen) Buffer was used up during a dilute test. Operation will continue automatically.
	No buf.	
104	Insufficient buffer	(Not displayed on screen) The volume of buffer became insufficient during a dilute test. Operation will continue automatically.
	Insufficient buf.	
105	STAT Rack Detected	A rack was detected at the STAT Rack position. <ERROR CANCELLATION> Perform another attempt after manually removing the rack from the STAT rack position. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Recheck for a rack at the STAT Rack position. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Stat Rack Detected	
110	Sample nozzle Jam (STD)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing.
	SAMP Jam (STD)	

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
112	Sample nozzle　Liquid level error (STD)	Detected liquid level is abnormal. The metallic portion at the tip of the sample nozzle may be conducting electrically through the remaining drops. <ERROR CANCELLATION> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. Check for sufficient storage of buffer and standard and place new sample cups in the rack before a retry.
	SAMP Liquid level error (STD)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
113	No sample (STD)	No sample was detected. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack.
	No sample (STD)	[ABORT]: Finish processing.
114	Insufficient sample (STD)	Sample amount is insufficient. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack.
	Insufficient sample (STD)	[ABORT]: Finish processing.
115	Sample nozzle Jam (STD)	In the creation of an STD dilution series, the sample nozzle jammed during absorption from a sample cup on a rack. Creation of a dilution series failed <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack.
	SAMP Jam (STD)	[ABORT]: Finish processing.
116	Sample nozzle　Absorption error (STD)	Absorption by the sample nozzle was not performed normally. <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	SAMP　Absorption error (STD)	

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
119	Rack conveyance bar origin error Rack Bar ORC error	Unable to detect the origin of the conveyance line rack conveyance bar. Because dispensed samples on the discharge line may become jumbled, a retest is recommended in this case. <ERROR CANCELLATION> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
120	Sample nozzle Jam (STAT STD) SAMP Jam (INT STD)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
123	Sample nozzle Jam (STAT STD) SAMP Jam (INT STD)	The sample nozzle jammed during detection of the liquid level of a sample. Creation of a dilution series failed <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
124	Sample nozzle Jam (STAT STD) SAMP Jam (INT STD)	The sample nozzle jammed while dispensing a sample to a sample cup in the creation of an STD dilution series. Creation of a dilution series failed <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
125	No buffer (STAT STD) No buf. (INT STD)	No buffer remains in the top position of a rack for STD measurement or a dilute test. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
126	Insufficient buffer (STAT STD) Insufficient buf. (INT STD)	The volume of buffer at the top position of a rack is insufficient for STD measurement or a dilute test. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
127	Sample nozzle Jam (STAT STD)	In the creation of an STD dilution series, the sample nozzle jammed during absorption from a sample cup on a rack. Creation of a dilution series failed <ERROR CANCELLATION> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	SAMP Jam (INT STD)	
128	Sample nozzle Liquid level error	Liquid level was detected as abnormal. Operation will continue automatically.
	SAMP Liquid level error	
129	Sample nozzle Liquid level error (STAT STD)	Liquid level was detected as abnormal. <ERROR CANCELLATION> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	SAMP Liquid level error (INT STD)	
130	Sample nozzle Liquid level error (STD)	Liquid level was detected as abnormal. <ERROR CANCELLATION> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing.
	SAMP Liquid level error (STD)	
135	Barcode reading Timeout	No reply was received from the barcode reader. Check system status, which is output to INF1, INF2, and INF3. Please let our company know of this status. In the event of this error, you need to turn off the system. When the Menu screen appears after aborting, turn off the system in Close mode. Then turn on the system. If analysis is being performed, abort processing when the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Barcode reading Timeout	

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
140	Sample nozzle　Z-axis origin error SAMPZ ORG error	The Z-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after a pass, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
141	Sample nozzle　Z-axis origin error SAMPZ ORG error	The Z-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
142	Sample nozzle　Z-axis origin error (STD) SAMPZ ORG error (STD)	The Z-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the Z-axis origin again, and finish rack processing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
143	Sample nozzle　Z-axis origin error (STAT STD) SAMPZ ORG error (INT STD)	The Z-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the Z-axis origin again, and finish rack processing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
144	Rack conveyance bar origin error Rack Bar ORG error	Unable to detect the origin of the conveyance line rack conveyance bar. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Re-initialize and check the origin. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
145	Supply unit 1 origin error Supply unit 1 ORG error	Original position sensor and limit sensor of supply unit1 are on at same time. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check sensors again, and supply or discharge rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
146	Sample nozzle Theta-axis origin error SAMPT ORG error	The theta-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Theta-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
147	Sample nozzle P-axis origin error SAMPP ORG error	The P-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect P-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
148	Sample nozzle Jamming sensor error SAMP Jamming Sensor error	Jamming sensor of sample nozzle is on. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis original position again, and check jamming sensor. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
149	Sample nozzle P-axis origin error SAMPP ORG error	The P-axis origin of the sample nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SKIP]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
150	No STAT Rack	No STAT Rack is detected. Set the rack. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Recheck for a rack at the STAT rack position. [RETURN]: Return to the STAT screen.

Error No. ERR#1-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
180	Sample nozzle Jam SAMP　Jam	The sample nozzle jammed. The nozzle may be misaligned. <ERROR CANCELLATION> If misalignment of the rack is not the cause of the jamming of the sample nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.
181	Rack on conveyance line (RSTART) Rack on conveyance line (RSTART)	A rack is left on the conveyance line, due to a power failure. <ERROR CANCELLATION> Manually remove as many racks on the line as possible. Manually remove the rack left at the front of supply unit 1 after touching [START]. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [START]: Discharge the rack at the front of supply unit 1 to the position for placement of the STAT rack. [PASS]: Leave the racks on the conveyance line.
188	Residue in cell (soaking) Residue in cell (soaking)	A residual liquid was detected in a cell during cell soaking. The absorption by the washing nozzle may have not been completed normally. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Absorb residues in the cell again. [ABORT]: Finish processing.
189	Sample nozzle Liquid level error SAMP　Liquid level error (soaking)	The liquid level was detected as abnormal during cell soaking. The system may be conducting electrically through liquid droplets on the tip of the sample nozzle. <ERROR CANCELLATION> Use cloth, such as gauze, to remove liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of the same sample again. [ABORT]: Finish processing.
190	Sample nozzle　Jam (Cell soaking) SAMP　Jam (Soaking)	The sample nozzle jammed in a cell during cell soaking. The sample nozzle may be misaligned. <ERROR CANCELLATION> If the sample nozzle is in improper alignment with the reaction table, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.

Error No. ERR#1-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
195	There is no dispensing liquid (dispensing accuracy)	(Not displayed on screen) There is no sample in the container in the first hole of the rack in a dispensing accuracy check for samples. Touch the [Abort] button and finish processing.
	No liquid (dispensing check)	
200	Illegal receiving command	(Not displayed on screen) A fault occurred in communication within the system. Operation will continue automatically.
	ILLEGAL COMMAND	
202	No rack was found when the rack supply operation was started.	No rack was found when rack supply was started. Rack auto start is halted. If the same error occurs even after repositioning, the auto start sensor may be malfunctioning.
	(Message not printed)	

5.3   MES# 1-001 - 1-007(SS1)

Error No. MES#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
001	Set racks	(Not displayed on screen) There are no remaining racks to process. To continue processing, position racks in the supply unit and touch [CONTINUE]. Touch one of the following buttons to select a process. [CONTINUE]: Process the newly set rack continuously. [ABORT]: Finish processing.
	(Message not printed)	
002	Detect liquid level	(Not displayed on screen) Processing is halted at the step of liquid level detection. Check whether the liquid level is detected correctly. Touch one of the following buttons to select a process. [CONTINUE]: Detect the liquid level for the next hole. [RETRY]: Detect the liquid level at the first hole again. [ABORT]: Finish processing.
	(Message not printed)	
003	Check puncturing component (rack conveyance)	(Not displayed on screen) The puncturing component is brought to a halt. Check whether the alignment (X, Y, and Z) of the puncturing needle with the container is correct. Touch one of the following buttons to select a process. [CONTINUE]: Continue the process. [ABORT]: Finish processing.
	(Message not printed)	
004	Check squeezing component (rack conveyance)	(Not displayed on screen) The squeezing component is halted at the container-squeezing step. Check whether the squeezing component squeezes containers correctly. Touch one of the following buttons to select a process. [CONTINUE]: Continue the process. [ABORT]: Finish processing.
	(Message not printed)	
005	Check rack on supply unit tray.	Return the rack supply unit or the rack on the tray to the front. (See the figure to the left.) Notice : When returning the rack to the front, lift the rack up temporarily. Failure to observe this precaution may result in the pin catching and the rack falling over. PRESS THE FOLLOWING BUTTON [CONTINUE]: Starts cut-in analysis.
	(Message not printed)	

Error No. MES#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
006	Check that there is no liquid leaking from the nozzle tip.	The setting time has passed. Check that there is no liquid dripping from the nozzle tip. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Finish the leak check.
	(Message not printed)	
007	The rack supply operation will start	(Not displayed on screen) The rack will be supplied.
	(Message not printed)	

5.4   ERR# 2-001 - 2-200(SS2)

Error No. ERR#2-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
000	Unknown error Unknown error	(Not displayed on screen) A fault occurred in communication within the system. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
081	Reagent nozzle Jam (reagent bottle) Reagent Jam (bottle)	The reagent nozzle jammed during detection of the liquid level of a reagent. The reagent nozzle may be in improper alignment with the reagent bottle mouth. <ERROR CANCELLATION> Check for orientation of inserted reagent bottles. If the reagent nozzle tip does not cover the reagent bottle mouth, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Resume reagent dispensing in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
082	Reagent nozzle Jam (reagent absorption) Reagent Jam (REAG SIP)	(Not displayed on screen) The reagent nozzle jammed during absorption of a reagent. Operation will continue automatically.
084	Reagent nozzle Jam (dispensing to cell) Reagent Jam (REAG DISP)	The reagent nozzle jammed when it was dispensing to a cell. <ERROR CANCELLATION> If the reaction table is in improper alignment with the reagent nozzle, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Resume reagent dispensing in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
085	Reagent nozzle Jam (OF) Reagent Jam (OF)	The reagent nozzle jammed in the OF position. The reagent nozzle may be misaligned. <ERROR CANCELLATION> If the reaction table is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Wash the nozzle. [ABORT]: Finish analysis.
086	No reagent No reagent	(Not displayed on screen) No reagent is left. Operation will continue automatically.
088	Reagent nozzle Abnormal liquid level detected Reagent Incorrect level (REAG)	(Not displayed on screen) Detected liquid level is abnormal. Operation will continue automatically.

Error No. ERR#2-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
091	Reagent nozzle　Jam (reagent bottle)	The reagent nozzle jammed during detection of the liquid level of a reagent. The reagent nozzle may be in improper alignment with the reagent bottle mouth. <ERROR CANCELLATION> Check for orientation of inserted reagent bottles. If the reagent nozzle tip does not cover the reagent bottle mouth, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.
	Reagent Jam (bottle)	
093	Reagent nozzle　Jam (OF)	The reagent nozzle jammed in the OF position. The reagent nozzle may be misaligned. <ERROR CANCELLATION> If the reaction table is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.
	Reagent Jam (OF)	
095	Mixer　Operation error	The mixer did not work normally. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start the mixer again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer　Operation error	
096	Mixer　Operation error	The mixer did not work normally. <ERROR CANCELLATION> Abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer　Operation error	
097	Mixer　Jam	The mixer jammed. <ERROR CANCELLATION> If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the mixer in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer　Jam	
099	Mixer　Jam	The mixer jammed. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start the mixer again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer　Jam	

Error No. ERR#2-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
ERR# 2-101 - 200		
101	Cell washing component Operation error	The cell washing component did not work normally. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start the cell washing component again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Cell washing Operation error	
103	Cell washing component Absorption error	The cell washing component detected liquid leakage during cell washing. The contents of a cell could not be absorbed due to a problem such as breakage or clogging of the piping to the drain tank. <ERROR CANCELLATION> Check for pipe breakage to the drain tank, and continue processing. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also
	Cell washing Absorption error	terminate.
104	Cell washing component Liquid spill	The cell washing component detected a liquid leakage. The contents of a cell may have spilled over or splashed during cell washing. <ERROR CANCELLATION> If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also
	Cell washing Liquid spill	terminate.
105	Cell washing component Jam	The cell washing component jammed. <ERROR CANCELLATION> The washing nozzle may be in improper alignment with a cell. If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also
	Cell washing Jam	terminate.
106	Cell washing component Absorption error	The cell washing component detected liquid leakage during cell washing. The contents of a cell could not be absorbed due to a problem such as breakage or clogging of the piping to the drain tank. <ERROR CANCELLATION> Check for pipe breakage to the drain tank, and perform another attempt. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start absorbing the contents of the cell.
	Cell washing Absorption error	[ABORT]: Finish processing.

Error No. ERR#2-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
107	Cell washing component Jam Cell washing Jam	The cell washing component jammed. The washing nozzle may be in improper alignment with a cell. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move down the cell washing component again. [ABORT]: Finish processing.
108	Cell washing component Liquid spill Cell washing Liquid spill	The cell washing component detected a liquid leakage. The contents of a cell may have spilled over or splashed during cell washing. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check liquid spill sensor again. [ABORT]: Finish processing.
110	Insufficient purified water Insufficient purified water	The volume of purified water in the corresponding storage tank is insufficient. <ERROR CANCELLATION> Continue processing after adding purified water. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
111	Insufficient wash solution Insufficient wash solution	The volume of wash solution in the corresponding storage tank is insufficient. <ERROR CANCELLATION> Perform another attempt after adding wash solution. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
112	Drain tank Full Drain tank full	The drain tank is full. <ERROR CANCELLATION> Discard the contents of the tank. Continue processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No. ERR#2-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
114	Reagent dispensing instruction error	Unable to continue operation due to a program problem. <ERROR CANCELLATION> Abort and check the settings. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Reagent dispensing instruction error	
130	Detection Error (retry)	(Not displayed on screen) An error occurred in detection, so another attempt was made automatically. Operation will continue automatically.
	Detection Error (retry)	
131	Detection Error	(Not displayed on screen) An error occurred in detection. Another attempt was made automatically, again resulting in abnormal results. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Perform detection again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Detection Error	
132	Reagent nozzle Liquid level detection error	Liquid level was detected as abnormal. Continue processing automatically.
	Reagent Liquid level error (REAG)	
133	Timeout	The process timed out. Continue processing automatically.
	Timeout	
134	Timeout	The process timed out. Check system status, which is output to INF1, INF2, and INF3. Please let our company know of this status. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt the timed-out process again. [ABORT]: Finish processing. The menu screen will appear during system startup. If analysis is underway, it will also terminate.
	Timeout	
135	Mixer Rotation error	Unable to mix as the mixer rotation component is malfunctioning. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer error	
136	Mixer Rotation error	Unable to mix as the mixer rotation component is malfunctioning. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Mixer error	
140	Reagent nozzle Z-axis origin error	A reagent nozzle Z-axis origin error was detected. <ERROR CANCELLATION> Is the reagent compartment cover open? If the cover is open, close it. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing.
	Reagent Z ORG error	

Error No. ERR#2-	On-screen Message (Upper) Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
141	Reagent nozzle Z-axis origin error	A reagent nozzle Z-axis origin error was detected. <ERROR CANCELLATION> Is the reagent compartment cover open? If the cover is open, close it. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis origin again. [ABORT]: Finish processing.
	Reagent Z ORG error	
142	Reagent nozzle Theta-axis origin error	Reagent nozzle Theta-axis original position detection error. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Theta-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Reagent T ORG error	
143	Reagent nozzle P-axis origin error	The P-axis origin of the reagent nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect P-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Reagent P ORG error	
144	Reagent nozzle Jamming Sensor error	Jamming sensor of reagent nozzle is on. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis original position again, and check jamming sensor. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Reagent Jamming Sensor error	
147	Reagent nozzle P-axis origin error	The P-axis origin of the reagent nozzle was detected abnormal. <ERROR CANCELLATION> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
	Reagent P ORG error	
150	Liquid leak check	The time designated for checking leaks has passed. Check for leaks on the nozzle tip. Press the button below to complete the check after nozzle washing. [CONTINUE]: Resume the operation.
	Liquid leak check	

Error No. ERR#2-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
151	OF purified water supply error	The reagent nozzle was dropped at the OF position, but the system was unable to check the purified water. Check the OF position purified water supply component. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Resume purified water supply. [ABORT]: Finish processing.
	OF purified water supply error	
152	OF purified water supply error	The reagent nozzle was dropped at the OF position, but the system was unable to check the purified water. Check the OF position purified water supply component. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Resume purified water supply. [ABORT]: Finish processing.
	OF purified water supply error	
192	Reagent nozzle Jam	The reagent nozzle jammed. <ERROR CANCELLATION> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.
	Reagent Jam (maintenance)	
193	No reagent	(Not displayed on screen) No reagent was remaining in a dispensing accuracy check for reagents. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing.
	No reagent (dispensing test)	
200	Illegal receiving command	(Not displayed on screen) A fault occurred in communication within the system. Continue processing automatically.
	ILLEGALCOMMAND	

5.5   MES# 2-001 - 2-007(SS2)

Error No. MES#2-	On-screen Message (Upper) / Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
001	Check dispensing volume	(Not displayed on screen) Check the dispensing volume for cell washing. The line in the central area of the cell indicates the proper liquid level. To continue processing, return the cell to the reaction table, and touch [CONTINUE]. Touch one of the following buttons to select a process. [CONTINUE]: Check the dispensing volume of the next nozzle. [ABORT]: Finish processing.
	(Message not printed)	
002	Position sample cup	(Not displayed on screen) Position a sample cup in the 2nd reagent position. Position a sample cup and continue processing. Touch one of the following buttons to select a process. [CONTINUE]: Dispense latex or buffer into the newly positioned sample cup. [ABORT]: Finish processing.
	(Message not printed)	
003	Check liquid level detection position	(Not displayed on screen) Processing is halted at the step of liquid level detection. Check whether the liquid level is detected correctly. Touch one of the following buttons to select a process. [CONTINUE]: Put the nozzle back to the OF position. [RETRY]: Move the nozzle up and detect liquid level again. [ABORT]: Finish processing.
	(Message not printed)	
004	Import purified water into buffer/wash solution lines.	Import purified water into buffer/wash solution lines. Buffer and wash solution will be replaced with purified water up to the line. Connect a container filled with purified water to these connected pipes. Touch the [CONTINUE] button. Touch one of the following buttons to select a process. [CONTINUE]: Start importing purified water into the lines. [ABORT]: Finish processing.
	(Message not printed)	
005	Drain water from the system	(Not displayed on screen) Drain water from the system. Remove the pipes from the purified water tank, wash solution tank, and buffer bottles. Touch one of the following buttons to select a process. [CONTINUE]: Start draining off water. [ABORT]: Finish processing.
	(Message not printed)	
006	Check absorption performance	(Not displayed on screen) Check absorption performance. Position a bottle containing a reagent, such as tap water, in the first reagent position, and continue processing. Touch one of the following buttons to select a process. [CONTINUE]: Start liquid level detection. [ABORT]: Finish processing.
	(Message not printed)	

Error No. MES#2-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
	Printed Message (Lower)	
007	Dispensed volume # [μL] # times	(Not displayed on screen) "Dead volume" is defined as the difference between the volume of a liquid placed in the reagent bottle (before measurement of dead volume) and the total dispensed volume. Touch the following button to finish processing.
	Dispensed volume: # Times: #	[ABORT]: Finish processing.

6   Save to External Media

Saves the following data to external media: sample measured data information, sample replicate information, QC measured data information, QC replicate information, STD measured data information, STD replicate information, time course data information, histogram information, and positive rate change information.

Output data are variable-length data.

6.1   Sample Measured Data Information

Saves measured data information on samples and stat samples

[File name: ocsamp.csv]

No.	Item	Reference (△: Blank [20H])	Output
1	Data type	Measured data: 'N△' Stat data: 'S△' Retest (including dilution test) data: 'A△' When data is edited, △ becomes E. (Example) Measured data is edited :'NE'	-
2	Date of analysis	Date of analysis e.g.) Sep. 23, 2016 → 2016/09/23	-
3	Time of analysis	Time of analysis (24-hour indication) e.g.) 2:5 pm → 14:05	-
4	Rack No.	Barcode information on racks	Do
5	Position in rack	Position in rack: 1–10	Do
6	Sample ID	Barcode information on sampling bottles (*2)	Do
7	Sample group No.	Group number of a sample: 0–9（Stat samples:△） (If "*" is set to this number, "0" is given.)	Do

8	Sample sequence no.	Serial number of measurement: 1–99999
		 • Number ranges are predetermined.
		   Samples: 1–99999
		   Stat samples: 1–99999
			Do

9	Measurement method counter	Classification of measurement method by day: 1–3 (Number of samples for each subject) (Dilute remeasure: '△')	-
10	Number of replicates	Number of replicates for a replicate test: 1–10	-
11	DA value	Values at 1st to 3rd detection points. See Appendix 1.3 "Calculate DA Value."	Do
12	Measured data	Calculated data: Up to 7 digits in the integer part and 1 digit in the decimal part. (*1) (the number of digits in the decimal part can be changed from "Output Format Settings.")	-
13	Flag (+, -)	Qualitative Flag (+, -) of measured data by the cut-off values: (*1) △-, △+, 1+, 2+ and 3+	Do
14	SD values	SD values of measured data (statistic)	-
15	CV values	CV values of measured data (statistic)	-
16	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
17	Final results	"*" is recorded as final results of 15- or 250-times dilution tests. (*1)	-

No.	Item	Reference (△: Blank [20H])	Output
18	Test item code	Test item code It does not output at the time of order error. For the CSV format is displayed as ",,".	Do (*3)
19	Test item name	Test item name It does not output at the time of order error. For the CSV format is displayed as ",,".	Do (*3)
20	Unit	Unit of test item	Do (*3)
21	Cut off 1	Value of cut off 1	Do (*3)
22	Cut off 2	Value of cut off 2 (Undefined is "*".)	
23	Cut off 3	Value of cut off 3 (Undefined is "*".)	
24	Operator ID	ID of the operator that LOGIN	Do (*3)
25	Latex lot	Lot of using Latex	Do (*3)(*4)
26	Latex expiration date	The expiration date of the Latex	
27	Buffer lot	Lot of using Buffer	
28	Buffer expiration date	The expiration date of the Buffer	

> **Explanatory note**
> - **The name of an item is given in the header of a file, and is followed by data.**
> - **Items are divided by commas (,).**
> - **Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."**
> - **Zero suppression is performed on items other than the date and time of analysis.**
> - **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**

(*1) **"*" is not recorded if final results of 15- or 250-times dilution tests consist of UR data, OR data, PRC data, or data-free errors.**
In these cases, spacing is provided to fields of measured data and to Flag (+, -) of 15- or 250-times dilution tests.

(*2) **When Two-dimensional code is used (optional), sample ID is output up to 50 digits.**

(*3) **Contact us for changing No.18-No.28.**

(*4) If dispense operation cannot be performed, " " is displayed for the lot and expiration date.

■ **Example of Sample Measured Data Information Output**

Data type, Date of analysis, Time of analysis, Rack number, Rack position, Sample ID, Sample group number, Sample sequence number, Measurement method counter, Number of replicates, DA Value, Measured data, Flag (+, -), SD value, CV value, Error code, Final result, Test item code, Test item name, Unit, Cut off 1 , Cut off 2, and Cut off 3,Operator ID, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : Only 15 times dilution measurement result（F-Hb）
A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,1058,3+,0,0,,,90,F-Hb,ng/mL,100,200,300

Example2 : Only 250 times dilution measurement result（F-Hb）
A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,17633,3+,0,0,,,90,F-Hb,ng/mL,100,200,300

Example3 : The final result is 250 times with 15 times and 250 times dilution measurement（F-Hb）
(15 times dilution result)
A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,4523,,,,,,,,05,90,F-Hb,ng/mL,100,200,300
(250 times dilution result)
A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,17633,3+,0,0,,*,90,F-Hb,ng/mL,100,200,300

Example4 : When operator / reagent management function is enabled（F-Hb）
N,2018/02/24,14:02,5,1,123456789012345,0,1,1,10,272,148,+,3.3,2.2,,,90,F-Hb,ng/mL,100,*,*,eiken,7Z027,2018/12/31,7Y019,2018/11/30

6.2   Sample Replicate Information

Saves information on each replicate of samples or stat samples

[File name: ocrsamp.csv]

No.	Item	Remark	Output
1	Data type	See Appendix 6.1, "Sample Measured Data Information."	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
4	Relative cell No.	Cell No..: 1–55	
5	Rack No.	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
7	Sample ID	See Appendix 6.1, "Sample Measured Data Information." (*1)	Do
8	Sample group No.	See Appendix 6.1, "Sample Measured Data Information."	Do
9	Sample sequence No.	See Appendix 6.1, "Sample Measured Data Information."	Do
10	CC No.	CC No. for sample measurement: 1–6	-
11	Replicate counter	Replicate No. for a replicate test: 1–10	-
12	A1 value	See Appendix 1.3, " Calculate DA Value."	-
13	A2 value	See Appendix 1.3, " Calculate DA Value."	-
14	A3 value	See Appendix 1.3, " Calculate DA Value."	-
15	DA1 value	See Appendix 1.3, " Calculate DA Value."	Do
16	DA2 value	See Appendix 1.3, " Calculate DA Value." The value is output even if no measured data are obtained.	Do
17	Measured data	See Appendix 6.1, "Sample Measured Data Information."	-
18	Flag (+, -)	See Appendix 6.1, "Sample Measured Data Information."	Do
19	Error code	See "List of Error Codes for Output to External Media."	-
20	Final result	See Appendix 6.1, "Sample Measured Data Information."	-
21	Test item code	Test item code	Do(*2)
22	Test item name	Test item name	Do(*2)
23	Unit	Unit of test item	Do(*2)
24	Cut off 1	Value of cut off 1	Do(*2)
25	Cut off 2	Value of cut off 2 (Undefined is "*".)	
26	Cut off 3	Value of cut off 3 (Undefined is "*".)	
27	Operator ID	ID of the operator that LOGIN	Do(*2)
28	Latex lot	Lot of using Latex	Do(*2)
29	Latex expiration date	The expiration date of the Latex	(*3)
30	Buffer lot	Lot of using Buffer	
31	Buffer expiration date	The expiration date of the Buffer	

Explanatory note

- **The name of an item is given in the header of a file, and is followed by data.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."**
- **Zero suppression is performed on items other than the date and time of analysis.**
- **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**
- **"SAMPLE UNSET" is not output as an item of Sample Replicate Information.**
- **Sample Replicate information is not output in case of "No order" or "Order error".**

(*1)   When Two-dimensional code is used (optional), sample ID is output up to 50 digits.

(*2)   Contact us for changing No.21-No.31.

(*3)   If dispense operation cannot be performed, " " is displayed for the lot and expiration date.

■ **Example of Sample Replicate Information Output**

Data type, Date of analysis, Time of analysis, Relative cell number, Rack number, Rack position, Sample ID, Sample group number, Sample sequence number, CC number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Measured data, Flag (+, -), Error code, Final result, Test item code, Test item name, Unit, Cut off 1, Cut off 2, and Cut off 3,Operator ID, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : cut-off of 1 only (F-Hb)
N ,2016/07/18,11:39,1,032,1,123456789012345,0,1,5,1,1353,1369,1569,216,16,147.0,+,,,90,F-Hb,ng/mL,100,
,
N ,2016/07/18,14:39,2,032,1,123456789012345,0,1,5,2,1354,1369,1572,218,15,148.0,+,,,90,F-Hb,ng/mL,100,
,

Example2 : cut-off 1, 2, 3 (F-Hb)
N ,2016/07/18,11:40,3,032,2,33333,0,2,5,1,1392,1448,2490,1098,56,452.0,3+,,,90,F-Hb,ng/mL,100,200,300
N ,2016/07/18,14:40,4,032,2,33333,0,2,5,2,1384,1439,2447,1063,55,443.0,3+,,,90,F-Hb,ng/mL,100,200,300

Example3: When the operator/reagent control function is activated (F-Hb)
N,2018/2/24,14:02,1,5,1,123456789012345,0,1,1,1,1409,1430,1692,283,21,152,+,,,90,F-Hb,ng/mL,100,*,*,ei
ken,7Z027,2018/12/31,7Y019,2018/11/30
N,2018/2/24,14:02,2,5,1,123456789012345,0,1,1,2,1389,1408,1657,268,19,146,+,,,90,F-Hb,ng/mL,100,*,*,ei
ken,7Z027,2018/12/31,7Y019,2018/11/30
N,2018/2/24,14:02,3,5,1,123456789012345,0,1,1,3,1389,1411,1669,280,22,151,+,,,90,F-Hb,ng/mL,100,*,*,ei
ken,7Z027,2018/12/31,7Y019,2018/11/30

6.3   QC Measured Data Information

Saves QC measured data

[File name: ocqc.csv]

No.	Item	Remark	Output
1	Data type	QC Data: 'Cx' x: QC no. of 1–4.	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
4	Rack no.	See Appendix 6.1, "Sample Measured Data Information."	Do
5	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Sample sequence no.	See Appendix 6.1, "Sample Measured Data Information."	Do
7	QC lot	QC lot number	-
8	Number of replicates	See Appendix 6.1, "Sample Measured Data Information."	-
9	DA value	See Appendix 6.1, "Sample Measured Data Information."	Do
10	Measured data	See Appendix 6.1, "Sample Measured Data Information."	-
11	Flag (+, -)	Not output.	-
12	SD value	See Appendix 6.1, "Sample Measured Data Information."	-
13	Error code	See "List of Error Codes for Output to External Media."	-
14	Test item code	Test item code	Do(*2)
15	Test item name	Test item name	Do(*2)
16	QC ID	ID of QC (*1)	Do(*2)
17	Unit	Unit of test item	Do(*2)
18	Operator ID	See Appendix 6.1, "Sample Measured Data Information."	Do(*2)
19	QC expiration date		Do(*2)
20	Latex lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2)
21	Latex expiration date	See Appendix 6.1, "Sample Measured Data Information."	(*3)
22	Buffer lot	See Appendix 6.1, "Sample Measured Data Information."	
23	Buffer expiration date	See Appendix 6.1, "Sample Measured Data Information."	

Explanatory note

- **The name of an item is given in the header of a file, and is followed by data.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."**
- **Z Zero suppression is performed on items other than the date and time of analysis.**
- **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**

(*1)   **When Two-dimensional code is used (optional), sample ID is output up to 50 digits.**

(*2)   **Contact us for changing No.14-No.23**

(*3)   **If dispense operation cannot be performed, " " is displayed for the lot and expiration date.**

■ **Example of QC Measured Data Information Output**
   Data type, Date of analysis, Time of analysis, Rack number, Rack position, Sample sequence number, QC lot, Number of replicates, DA value, Measured data, Flag (+, -), SD value, Error code, Test item code, Test item name, QC ID, and Unit, Operator ID,QC expiration date, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

   Example1 : Normal (F-Hb)
   C1,2016/04/23,16:02,099,9,1,14102,3,222,150.7,,2.5,,90,F-Hb, 12345678901234,ng/mL

   Example2 : When the operator/reagent control function is activated (F-Hb)
   C1,2018/02/24,13:16,098,9,1,7Z007,3,271.148,,2.5,,90,F-Hb,, ng/mL,eiken,2018/12/31,7Y019,2018/11/30

6.4   QC Replicate Information

Saves information on each QC replicate

[File name: ocrqc.csv]

No.	Item	Remark	Output
1	Data type	See Appendix 6.3, "QC Measured Data Information"	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
4	Relative cell no.	See Appendix 6.2, "Sample Replicate Information"	-
5	Rack no.	See Appendix 6.1, "Sample Measured Data Information"	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information"	Do
7	Sample sequence no.	See Appendix 6.1, "Sample Measured Data Information"	Do
8	QC lot	See Appendix 6.3, "QC Measured Data Information"	-
9	CC no.	See Appendix 6.2, "Sample Replicate Information"	-
10	Replicate counter	See Appendix 6.2, "Sample Replicate Information"	-
11	A1 value	See Appendix 1.3, " Calculate DA Value."	-
12	A2 value	See Appendix 1.3, " Calculate DA Value."	-
13	A3 value	See Appendix 1.3, " Calculate DA Value."	-
14	DA1 value	See Appendix 1.3, " Calculate DA Value."	Do
15	DA2 value	See Appendix 1.3, " Calculate DA Value."	Do
16	Measured data	See Appendix 6.1, "Sample Measured Data Information"	-
17	Flag (+, -)	Not output.	-
18	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
19	Test item code	Test item code	Do(*2)
20	Test item name	Test item name	Do(*2)
21	QC ID	ID of QC (*1)	Do(*2)
22	Unit	Unit of test item	Do(*2)
23	Operator ID	See Appendix 6.1, "Sample Measured Data Information."	Do(*2)
24	QC expiration date		Do(*2)
25	Latex lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
26	Latex expiration date	See Appendix 6.1, "Sample Measured Data Information."	
27	Buffer lot	See Appendix 6.1, "Sample Measured Data Information."	
28	Buffer expiration date	See Appendix 6.1, "Sample Measured Data Information."	

Explanatory note

- **The name of an item is given in the header of a file, and is followed by data.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."**
- **Zero suppression is performed on items other than the date and time of analysis.**
- **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**

(*1)   **When Two-dimensional code is used (optional), sample ID is output up to 50 digits**

(*2)   **Contact us for changing No.19-No.28**

(*3)   **If dispense operation cannot be performed, " " is displayed for the lot and expiration date.**

■ **Example of QC Replicate Information Output**

Data type, Date of analysis, Time of analysis, Relative cell number, Rack number, Rack position, Sample sequence number, QC lot, CC number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Measured data, Flag (+, -), Error code, Test item code, Test item name, QC ID, and Unit, Operator ID, QC expiration date, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : Normal (F-Hb)
C1,2016/04/23,16:02,13,099,9,1,14102,1,1,1353,1370,1573,220,17,149.0,,,90,F-Hb,123456789012345,ng/mL
C1,2016/04/23,16:02,14,099,9,1,14102,1,2,1364,1380,1592,228,16,154.0,,,90,F-Hb,123456789012345,ng/mL
C1,2016/04/23,16:02,15,099,9,1,14102,1,3,1352,1367,1572,220,15,149.0,,,90,F-Hb,123456789012345,ng/mL

Example2 : When the operator/reagent control function is activated (F-Hb)
C1,2018/02/24,13:16,28,098,9,1,7Z007,1,1,1395,1416,1670,275,21,149.0,,,90,F-Hb,,ng/mL,eiken,2018/12/31,7Z 027,2018/12/31,7Y019,2018/11/30
C1,2018/02/24,13:16,29,098,9,1,7Z007,1,2,1393,1412,1668,275,19,149.0,,,90,F-Hb,,ng/mL,eiken,2018/12/31,7Z 027,2018/12/31,7Y019,2018/11/30
C1,2018/02/24,13:16,30,098,9,1,7Z007,1,3,1384,1403,1648,264,19,145.0,,,90,F-Hb,,ng/mL,eiken,2018/12/31,7Z 027,2018/12/31,7Y019,2018/11/30

6.5 Standard Measured Data Information

Saves STD measured data information

[File name: ocstd.csv]

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
3	Latex lot	Latex lot No. (consisting of five alphanumeric characters)	-
4	Rack No.	See Appendix 6.1, "Sample Measured Data Information"	Do
5	Rack position	See Appendix 6.1, "Sample Measured Data Information"	Do
6	STD point No.	Detection point No. (STD1–STD6): 1–6	-
7	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
8	DA2 value	See Appendix 1.3, "Calculate DA Value."	Do
9	DA1 back fit	Concentration estimated by fitting DA1 to a calibration curve	-
10	DA1CV value	CV value of DA1 (statistic)	-
11	DA2CV value	CV value of DA2 (statistic)	-
12	DA1SD value	SD value of DA1 (statistic)	-
13	DA2SD value	SD value of DA2 (statistic)	-
14	Origin	STD concentration of CC protocol	-
15	Number of replicates	Number of replicates for a replicate test: 1–10	-
16	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
17	Test item code	Test item code	-
18	Test item name	Test item name	-

Explanatory note

- **The name of an item is given in the header of a file, and is followed by data.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."**
- **Zero suppression is performed on items other than the date and time of analysis.**
- **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**

■ **Example of STD Measured Data Information Output**

Date of analysis, Time of analysis, Latex lot, Rack number, Rack position, STD point number, DA1 value, DA2 value DA1 back fit, DA1CV value, DA2CV value, DA1SD value, DA2SD value, Origin, Number of replicates, Error code, Test item code, and Test item name

2016/08/07,14:34,11111,098,1,1,6,1,0.0,0.0,0.0,0.0,0.0,0.0,3,,90,F-Hb
2016/08/07,14:34,11111,098,3,2,83,7,64.0,0.0,0.0,0.0,0.0,0.0,62.5,3,,90,F-Hb
2016/08/07,14:35,11111,098,4,3,191,15,120.0,0.0,0.0,0.0,0.0,0.0,125.0,3,,90,F-Hb
2016/08/07,14:36,11111,098,5,4,461,28,257.0,0.0,0.0,0.0,0.0,0.0,250.0,3,,90,F-Hb
2016/08/07,14:36,11111,098,6,5,1233,63,496.0,0.0,0.0,0.0,0.0,0.0,500.0,3,,90,F-Hb
2016/08/07,14:37,11111,098,2,6,2738,144,1001.0,0.0,0.0,0.0,0.0,0.0,1000.0,3,,90,F-Hb

6.6   Standard Replicate Information

Saves information on each STD replicate

[File name: ocrstd.csv]

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Latex lot	Latex lot No. (consisting of five alphanumeric characters)	-
4	Relative cell no.	See Appendix 6.2, "Sample Replicate Information."	-
5	Rack no.	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
7	STD point no.	See Appendix 6.5, "STD Measured Data Information."	-
8	Replicate counter	See Appendix 6.2, "Sample Replicate Information."	-
9	A1 value	See Appendix 1.3, "Calculate DA Value."	-
10	A2 value	See Appendix 1.3, "Calculate DA Value."	-
11	A3 value	See Appendix 1.3, "Calculate DA Value."	-
12	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
13	DA2 value	See Appendix 1.3, "Calculate DA Value."	Do
14	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
15	Test item code	Test item code	-
16	Test item name	Test item name	-

Explanatory note

- **The name of an item is given in the header of a file, and is followed by data.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."**
- **Zero suppression is performed on items other than the date and time of analysis.**
- **If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."**

■ **Example of STD Replicate Information Output**
Date of analysis, Time of analysis, Latex lot, Relative cell number, Rack number, Rack position, STD point number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Error code, Test item code, and Test item name

2016/08/07,14:34,11111,10,098,1,1,1,1345,1346,1351,6,1,,90,F-Hb
2016/08/07,14:34,11111,11,098,1,1,2,1321,1321,1327,6,0,,90,F-Hb
2016/08/07,14:34,11111,12,098,3,2,1,1330,1340,1417,87,10,,90,F-Hb
2016/08/07,14:34,11111,13,098,3,2,2,1336,1342,1419,83,6,,90,F-Hb
2016/08/07,14:34,11111,14,098,4,3,1,1347,1360,1533,186,13,,90,F-Hb
2016/08/07,14:35,11111,15,098,4,3,2,1344,1359,1535,191,15,,90,F-Hb
2016/08/07,14:35,11111,16,098,5,4,1,1372,1400,1848,476,28,,90,F-Hb
2016/08/07,14:35,11111,17,098,5,4,2,1360,1388,1821,461,28,,90,F-Hb
2016/08/07,14:35,11111,18,098,6,5,1,1397,1461,2677,1280,64,,90,F-Hb
2016/08/07,14:35,11111,19,098,6,5,2,1398,1461,2631,1233,63,,90,F-Hb
2016/08/07,14:36,11111,20,098,2,6,1,1480,1626,4218,2738,146,,90,F-Hb
2016/08/07,14:36,11111,21,098,2,6,2,1470,1611,4147,2677,141,,90,F-Hb

6.7   Time Course Data Information

Saves time course data information

[File name: tcourse.csv]

No.	Item	Remark	Output
1	Cell information 1	Time course information on relative cell 1	-
	.	.	.
	.	.	.
	.	.	.
n	Cell information n	Time course information on relative cell n	-

Cell information #

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Relative cell no.	See Appendix 6.2, "Sample Replicate Information."	-
4	Reference value	See Appendix 1.7, "Calculate Cell Blank."	-
5	Cell-blank value	See Appendix 1.7, "Calculate Cell Blank."	-
6	ABS value of cycle 1	See Appendix 1.3, "Calculate DA Value."	-
7	ABS value of cycle 2	See Appendix 1.3, "Calculate DA Value."	-
	.	.	.
	.	.	.
	.	.	.
60	ABS value of cycle 55	See Appendix 1.3, "Calculate DA Value."	-
61	Test item code	Test item code	-
62	Test item name	Test item name	-

Explanatory note

- **There is no header for the file, and only data are shown.**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows a comma that follows reference value and cell information. The file ends with "EOF."**
- **Zero suppression is performed on items other than the date and time of analysis.**

■ **Example of Time Course Data Information Output**

2016/07/23,16:51,1,14127,14,176,1393,1350,1341,1343,1347,1351,1356,1361,1367,1374,1380,1385,1391,1398,1404,1410,1417,1424,1430,1436,1441,1448,1453,1459,1463,1471,1476,1480,1482,1490,1494,1496,1499,1507,1513,1512,1517,0,0,0,0,0,0,0,12,0,0,-1,0,154,156,159,162,163,90,F-Hb
2016/07/23,16:51,2,14127,0,184,1375,1320,1314,1315,1316,1318,1319,1320,1322,1324,1325,1325,1327,1328,1328,1328,1329,1331,1331,1331,1330,1331,1332,1331,1331,1332,1333,1333,1332,1335,1335,1331,1330,1332,1333,1335,1334,0,0,0,0,0,0,0,13,16,0,0,0,2,162,167,170,173,175,90,F-Hb

6.8   Histogram Information

Saves histogram information

[File name: ochstgrm.txt]

No.	Item	Remark	Output
1	Title 1	"Histogram"	-
2	Title 2	"Date range"	-
3	Period of time	First date of calculation data	-
4	Period of time	Final date of calculation data	-
5	Title 3	"Test item name"	-
6	Test item code	Test item code	-
7	Test item name.	Test item name	
8	Title 4	"Measurement range", "Number of samples"	
9	Measurement range	Minimum and maximum limits of each class: Minimum limit - Maximum limit	
10	Number of samples	Number of samples in a class	
11	Title 5	"Total number of samples"	
12	Total number of samples	Total number of samples	

Explanatory note

- **As shown in the example below, a file begins with "HISTOGRAM."**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows the title, date range, number of samples, and total number of samples. A file ends with "EOF."**

■ **Example of Histogram Information Output**
HISTOGRAM
Date range, 2016/10/22,2016/10/23
Measurement range, Number of samples
Test item name,90,F-Hb
0.0-26.0,25
26.0-52.0,5
52.0-78.0,12
78.0-104.0,2
104.0-130.0,0
130.0-156.0,1
156.0-182.0,2
182.0-208.0,1
208.0-234.0,0
234.0-260.0,1
Total number of samples, 49

6.9   Positive Rate Change Information

Saves positive rate change information

Positive rate change according to testee   [File name: socprmps#.txt]

No.	Item	Remark	Output
1	Title 1	"POSITIVE RATE CHANGE ACCORDING TO TESTEE"	-
2	Title 2	"Date"	-
3	Date	The first date of a week or month in calculation of positive rates by week or month	-
4	Title 3	"Test item name"	-
5	Test item code	Test item code	-
6	Test item name.	Test item name	-
7	Title 4	"Positive rate (%)"	-
8	Positive rate (%)	Rate of testees with positive rates to the total testees (Positive testees ÷ Total testees × 100)	-

Explanatory note
- **"#" for a file name depends on the file type.**
  t: Positive rate change for all samples
  0–9: Positive rate change for the group indicated by the number (0: Group not specified)
- **As shown in the example below, a file begins with "POSITIVE RATE CHANGE ACCORDING TO TESTEE."**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows the title, date, positive rate change. A file ends with "EOF."**

■ **Example of Positive Rate Change According to Testee Output**
POSITIVE RATE CHANGE ACCORDING TO TESTEE
Date, 2016/10/22,2016/10/23
Test item name,90,F-Hb
Positive rate (%), 66.7,46.9

Positive rate change according to sample   [File name: socprmsa#.txt]

No.	Item	Remark	Output
1	Title 1	"POSITIVE RATE CHANGE ACCORDING TO SAMPLE"	-
2	Title 2	"Date"	-
3	Date	The first date of a week or month in calculation of positive rates by week or month	-
4	Title 3	"Test item name"	-
5	Test item code	Test item code	-
6	Test item name.	Test item name	-
7	Title 4	"Positive rate (%)"	-
8	Positive rate (%)	Rate of samples with positive rates to the total samples (Positive samples ÷ Total samples × 100)	-

Explanatory note
- **"#" for a file name depends on the file type.**
  t: Positive rate change for all samples
  0–9: Positive rate change of the group indicated by the number (0: Group not specified)
- **As shown in the example below, a file begins with "POSITIVE RATE ACCORDING TO SAMPLE."**
- **Items are divided by commas (,).**
- **Delimiter CR/LF follows the title, date, positive rate change. A file ends with "EOF."**

■ **Example of Positive Rate Change According to Sample Output**
POSITIVE RATE CHANGE ACCORDING TO SAMPLE
Date, 2016/10/22,2016/10/23
Test item name,90,F-Hb
Positive rate (%), 66.7,46.9

6.10 List of Error Codes for output to external Media

Error information is subject to change or addition without notice.

Code	Error	Measured data	Remark
10	BARCODE READING ERROR	Yes	
20	DOUBLE BARCODE ERROR (Check within a day)	-	Does not appear if "NO" is selected for "DUPLICATED SAMPLE BARCODE CHECK".
01	INSUFFICIENT SAMPLE/NO SAMPLE	-	Dispensing is not performed.
02	NO LATEX	-	
03	RBC (PROZONE)	Yes	
04	PRC (PROZONE)	*	
05	OR (OVER RANGE)	*	
06	UR (UNDER RANGE)	-	
07	SAMPLE DISPENSING ERROR (such as jamming in the sample nozzle)	-	Dispensing is not performed. Also appears in the case of a puncturing error.
08	LATEX DISPENSING ERROR (such as jamming in the reagent nozzle)	-	Dispensing is not performed.
09	Mixer error (such as jamming in the mixer)	-	It does not mixing.
0A	LATEX BLANK ERROR (A1 CHECK)	-	Abnormal latex blank
0B	NO CC	-	Includes mismatching of CC lot.
0C	UNSET		It is received an instruction from the host system without an order.
30	Combined error of Errors 10 and 01		Order request communication did not complete successfully. An order different from the requested sample ID and item code was returned.
90	UNSET	-	Doesn't appear if MODE 1 is selected for NUMBERING MODE.
11	Combined error of Errors 10 and 01	-	
12	Combined error of Errors 10 and 02	-	
13	Combined error of Errors 10 and 03	Yes	
14	Combined error of Errors 10 and 04	*	
15	Combined error of Errors 10 and 05	*	
16	Combined error of Errors 10 and 06	-	
17	Combined error of Errors 10 and 07	-	
18	Combined error of Errors 10 and 08	-	
19	Combined error of Errors 10 and 09	-	
1A	Combined error of Errors 10 and 0A	-	
1B	Combined error of Errors 10 and 0B	-	

* "11" to "1B" errors are combinations of two errors. No other combinations than those stated above are produced under present circumstances.

* "NO LATEX" error appears when the remaining volume of the first latex bottle is found to be 0 μL before reagent is dispensed. Normally, latex is supplied from the second latex bottle before the contents of the first latex bottle become empty (0 μL). Moreover, analysis will be stopped before the contents of the second latex bottle become empty (0 μL). The NO LATEX error will not normally appear.

*   Measured data and Flag (+, -) will be output in the case of an error in which "Yes" appears in the corresponding "Measured Data" box in the list described above.
Blanks (20H) are output as the Measured data and Flag (+, -) fields in the case of an error in which "-" appears in the corresponding "Measured Data" box in the list described above.
Blanks as measured data and Flag (+, -) will be output in the case of an error in which "*" appears in the corresponding "Measured Data" box in the list described above.

*   NUMBERING MODE
In the "Mode 1" setting containers are detected and sample numbers are assigned only to container-mounted positions.
In the "Mode 2" setting sample numbers are assigned to all positions, including blank positions (container-free positions). Error code "90" is output for blank positions.

*   If an end ring is positioned in a rack when Mode 2 is selected, no information is output from the ring's position through the last position of the rack.
If no end ring is positioned in Mode 2, error code "90" is output on all blank positions.

■ Final results of 15- or 250-times dilution tests and error codes

15-times \ 250-times	Normal (*1)	Normal (*2)	UR	OR	RBC	PRC	Error of no measured data
Normal	Final result: 15 times Measured data: Gained Error code: None	Final result: Undefined Measured data: Space Error code: 0A	Final result: 15 times Measured data: Gained Error code: None	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)
UR	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: UR	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)
OR	Final result: 250 times Measured data: Gained Error code: None	Final result: 250 times Measured data: Gained Error code: None	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)
RBC	Final result: 250 times Measured data: Gained Error code: None	Final result: 250 times Measured data: Gained Error code: None	Final result: Undefined Measured data: Space Error code: 0A	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data Diana : 250-times dilution data io: 250-times dilution data Error code: RBC	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: PRC	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)
PRC	Final result: 250 times Measured data: Gained Error code: None	Final result: 250 times Measured data: Gained Error code: None	Final result: Undefined Measured data: Space Error code: UR	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: PRC	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: PRC	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)
Error of no measured data	Final result: Undefined Measured data: Space Error code : Error code in 15-times analysis (*3)	Final result: Undefined Measured data: Space Error code : Error code in 15-times analysis (*3)	Final result: Undefined Measured data: Space Error code: UR	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: OR	Final result: Undefined Measured data Diana : 250-times dilution data io: 250-times dilution data Error code: RBC	Final result: Undefined Measured data Diana: Space (with Negative result) io: 9999 Fixed Error code: PRC	Final result: Undefined Measured data: Space Error code : Error code in 250-times analysis (*3)

(*1) DA1 value in 15-times dilution $\geq$ DA1 value in 250-times dilution
(*2) DA1 value in 15-times dilution $<$ DA1 value in 250-times dilution
(*3) Error status
    If an error occurs in a 250-times dilution test, the error of a final result indicates an error status in a 250-times dilution test.
    If no error occurs in a 250-times dilution test, the error of a final result indicates an error status in a 15-times dilution test.
(*4) This varies depending on the communication mode setting.
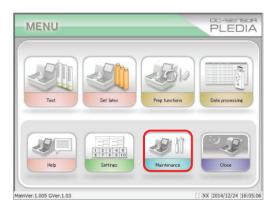
MEMO

7   Management USB Stick Setting

When saving measurement data or other data to a USB stick, the USB stick needs to be set as a management USB stick first.

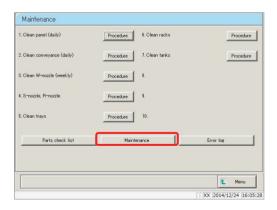This section describes the procedure to set a USB stick as a management USB stick.

Explanatory note : If you are using the operator and reagent management function, you need to log in with the administrator ID in order to set up management USB stick.

☞ Page 330 "Chapter 9   Operator/Latex Management Function (Option)"

7.1   How to Set a Management USB Stick
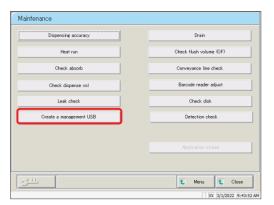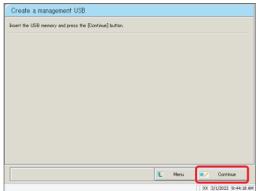
1   Touch {Maintenance} on the [MENU] screen.

* [Maintenance] screen opens.

2   Touch {Maintenance} button.
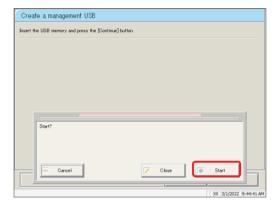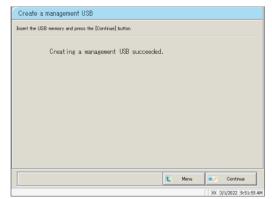
3 Touch {Create a management USB} button.

  *[Create a management USB] screen opens.

4 Insert the USB stick.

5 Touch {Continue}.

6 Touch {Start}.

{Cancel}: Closes the dialog box.
{Close}: Aborts setting and returns to [Maintenance] screen.
{Start}: Set the inserted USB stick as a management USB stick.

7 The inserted USB stick has been successfully set as a management USB stick.

8 Remove the USB stick from the system.

Index/Glossary

Index

Glossary

A

Absorbance
> A1, A2, A3
> Logarithm of ratio of strength of incident light striking sample (Io) and strength of transmitted light (I) (i.e. Io/I)

B

Back fit value
> The value obtained by fitting absorbance to a calibration curve

D

DA
> Absorbance difference. Calculated as the amount of change in absorbance.
>
> For example, DA1 = A3 − A1 [ABS]
> DA2=A2−A1[ABS]

DIL(Dil)
> Retest diluent

Data
> The concentration value of hemoglobin or transferrin.
> Calculates measured data (concentration values) using DA values and calibration curves.

Dilution test mode
> Tests the sample once again after the sample is diluted (15 or 250 times).
> However, it is not punctured.

J

Jamming
> An error where something is touching the sample nozzle or mixer.

P

PRC method

Method that compares the DA2 values of STD-6 (the highest concentration of an STD sample series) and a patient sample

Prozone

Phenomenon where there are excessive antibodies or antigens, and observable reactions in a mixture of specific antigens and antibodies no longer occur.
This is seen in high value samples. Samples where the amount of change decreases in the late stage of a reaction are referred to as prozone samples.

Q

QC (sample)

Control sample Also referred to as reference material or reference sample

QC value check

Check based on the control limit values set in the [STD/QC measurement process settings] screen.
Specification: The minimum control limit value is less than 1: abnormal
The maximum control limit value is +1 or greater: abnormal

R

RBC method

Method that compares the absorbance at the RBC point (in the initial stage of a reaction) of the highest concentration of an STD sample series (STD-6) and a patient sample

Remeasure mode

Measures the sample again. One measure mode
Remeasured samples are handled in the same manner as first test samples.

Retest mode

Retests sample depending on test results. However, it is not punctured. One measure mode

S

STD (sample)

The calibrator sample. Also referred to as standard material or standard sample.

T

Test mode

Measures a sample for the first time. One measure mode.

Time course

Results (graph) of measuring/recording changes in absorbance as time passes

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