PATHFAST COMPACT IMMUNO-ANALYZER

Operator's Manual

PHC Corporation

PATHFAST

Issue Date: 01/05/2024
Revision: ver.1

The PATHFAST system is for *In Vitro* Diagnostic Use.

The information in this manual was correct at the time of printing.
However, PHC Corporation continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures.

Ⅰ. Table of Contents

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II. Revision History

II – 1. Table of Revision History

This operator's manual is published by PHC Corporation.
If you have any questions on the contents in this manual, please contact with your sales representatives or customer support center in your area.
This manual is the latest revision and all the information contained is correct at the time of its printing. Please note that this manual may be revised because of continuous improvement of instrument and/or upgrade of software.

The following table shows the history of revisions made to this operator's manual.

Date Revised	Reason of Revision	Software Version	Manual Version
01/Nov/2005	1st Revision	2.0.0	2.00E
01/Nov/2007	Conformity to a new Software Version	2.0.4	2.10E
01/Apr/2009	Conformity to a new Software Version	2.0.6	2.20E
01/Apr/2012	Conformity to a new Software Version	3.0.0	3.00E
01/Apr/2014	Conformity to change of company name Conformity to a new Software Version	3.0.4	3.10E
01/Mar/2016	Conformity to a new Software Version	4.0.2	4.00E
25/Nov/2016	Application of optimized expression	4.0.2	4.10E
14/May/2019	Conformity to a new Software Version	4.0.8	4.20E
20/May/2019	Conformity to a new Software Version	4.0.9	4.30E
01/Dec/2020	Conformity to Change of European Authorized Representative (EC-rep)	4.0.9	4.40E

01/Mar/2022	1st Revision to conform REGULATION (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)	4.1.1	4.50EN
01/Oct/2022	Updated due to relocation of head office Minor corrections throughout	4.1.1	4.60EN
01/May/2024	Update due to company name and address change	4.1.1	4.70EN

Ⅲ. Records of User Trainings

Please put records of User Trainings you gave to your users in your laboratory.

Date	Time	Trainees	Contents, Items trained	Trainer

Ⅳ. Records of Maintenance

Please make records of maintenance performed on PATHFAST instrument.

Date	Time	Kinds	Contents, Items	Done By
Ex) 01/06/2022	Ex) 17:30	Ex) Daily maintenance	Ex) 1. Cleaning : Outside, Reagent Cartridge Rack, Stage, Waste Tip Box, Piercing Nozzles, Used ethanol 70%. 2. Executing Selfcheck	Ex)

1 About This Manual

1.1 Purpose of This Manual

This Operators Manual contains the information necessary to operate PATHFAST safely, properly and efficiently. It is important that you read this manual before attempting to operate the PATHFAST Chemi-Luminescence Enzyme Immuno-Assay (CLEIA) instrument.

The information in this manual is written assuming that the PATHFAST functions of "Access Level" and "QC Lockout" are activated. Differences from non-activated settings are provided when necessary. Please refer to Section **1.2 User ID and Access Level** and Section **1.3 About QC Lockout function** for detailed information.

1.2 User ID and Access Level

Because PATHFAST operators may have different technical responsibilities and/or expertise levels, each user can be assigned an "Access Level".
The assigned "Access Level" determines which functions of PATHFAST will be available to that user.

To activate this feature, the PATHFAST administrator must create an ID and Password, and assign an "Access" level for each user.

User ID :	May be up to 20 characters in length. All characters displayed on the full keyboard are valid.
Password :	Must be 4 to 8 characters in length. All characters displayed on the full keyboard are valid.
Access Level :	Must be a numeric value 1 through 4. Sets the user's "Access Level".

Table 1-1 "Access Level" and Accessible Functions
(QC Lockout function : activated)

× : Allowed – : Not Allowed

Menu	Screen Display	Functions	Access Level			
			1	2	3	4
ASSAY	SAMPLE	Assay patient samples	×	×	×	×
	QC	Assay QC samples	–	×	×	×
	CAL/QC	Assay calibrators & QC	–	–	×	×
	MC ENTRY	Register master calibration curve data	–	–	×	×
CHECK	RESULT CHECK	View patient result	×	×	×	×
	QC CHECK	View QC data	–	×	×	×
	CAL CHECK	View CAL data	×	×	×	×
	Hct% CORRECTION	Recalculation by Hct%	×	×	×	×
	TEMP CHECK	View heater temperatures	×	×	×	×
SETUP	USER REGISTRATION	Add, edit or delete users	–	–	–	×
	INSTRUMENT SETTINGS	Set or edit Config, locale/date, language	–	–	–	×
	ASSAY SETTINGS	Edit reference ranges, Hct% default value, CAL replicates or CAL/QC alert	–	–	–	×
	QC LOCKOUT	Set QC lockout on/off and set control ranges	–	–	–	×
	LIS SETTINGS	Set conditions for communicating with external computer	–	–	–	×
ADMIN	SHUT DOWN	Shut instrument power off	×	×	×	×
	USER SWITCH	Change current user	×	×	×	×
	SYSTEM	Display logs,	×	×	×	×
		Selfcheck	–	–	–	×
	FILE UTILITY	Update software	–	–	–	×
	MAINTENANCE	For authorized service personnel only	–	–	–	–

Note:

- Only authorized service personnel can access "MAINTENANCE".
- Accessibility function can be set to ON or OFF as described in Section **10.2.1 ACCESS MANAGEMENT**.

- The screen display and accessible functions when QC Lockout is ON are as follows:

Access Level (QC Lockout – ON)		
1	2	3 and above
SAMPLE	SAMPLE	SAMPLE
~~QC~~	QC	QC
~~CAL/QC~~	~~CAL/QC~~	CAL/QC
~~MC ENTRY~~	~~MC ENTRY~~	MC ENTRY

- The screen display and accessible functions when QC Lockout is OFF are as follows:

Access Level(QC Lockout – OFF)		
1	2	3 and above
SAMPLE	SAMPLE	SAMPLE
~~QC/SAMPLE~~	QC/SAMPLE	QC/SAMPLE
~~CAL/QC/SAMPLE~~	~~CAL/QC/SAMPLE~~	CAL/QC/SAMPLE
~~MC ENTRY~~	~~MC ENTRY~~	MC ENTRY

The primary difference between QC lockout ON and OFF is whether patient samples are assayed in same batch run with QC or CAL. Slant bars indicate functions not allowed for that access level. On the screen those function buttons not allowed are displayed in pale gray.

1.3 About QC Lockout Function

QC samples must be run periodically for quality control. The QC Lockout function monitors the system and prevents the operator from running patient samples,

- If QC samples for the reagent lot used have not been assayed within the specified period of time.
- or if QC sample data are not within the predefined control ranges.

If either of these conditions exists and you attempt to run patient samples, PATHFAST reports an error condition by showing the message "No valid QC available" and the run will be stopped. In order to assay patient samples, you are required to run the QC assay or CAL/QC assay if needed.

The QC Lockout function can be activated or deactivated through "SETUP/QC LOCKOUT" operation. Refer to Section **10.5 QC LOCKOUT** for details.

1.4 About the symbols on the product labels

PHC Corporation uses the following symbols and signs in addition to those listed in the EN ISO 15223-1:2021 (Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements)

This symbol means "Device for near patient testing".
(Symbols for self-testing and near-patient testing under the IVD Regulation 2017/746/EU. MedTech Europe. Dec. 13, 2018)

This "crossed-out wheeled bin" symbol indicates separate collection for all batteries, accumulators and battery packs.
(DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC)

STORAGE	: Storage Condition
TRANSPORT	: Transport Condition
INSTRUMENT	: Instrument
ACCESSORIES	: Accessories
Power Source	: Power Source
Fuse	: Fuse

2 About PATHFAST™

This chapter includes the PATHFAST™ Analyzer's intended use, performance characteristics and instrument specifications.

2.1 Intended Use

PATHFAST™ is an in vitro diagnostic medical device designed for use in near patient testing (NPT). PATHFAST is a small, easy-to-use, multi-analyte instrument that provides in vitro quantitative determinations using whole blood, plasma, serum, or other body fluids determined by the protocol of the test being run. PATHFAST is used by laboratory technician, nurse or physician, in hospital including emergency room, doctor's office and clinical laboratory.

Reagents used with PATHFAST have been developed and manufactured in specially prepared cartridges by PHC Corporation. The principle of measurement employed for the reagent system is CLEIA (Chemi-Luminescence Enzyme Immuno-Assay).

Note: Each PATHFAST reagent has its intended purpose. For more information, please refer to the Instruction For Use of each PATHFAST reagent.

The PATHFAST instrument utilizes Magtration® technology for Bound/Free (B/F) separation in several reaction steps.

Note: Magtration® is trade mark of Precision System Science Co., Ltd., which performs B/F separation in pipette tips using magnetic particles.

2.2 Characteristics

1. Compact — Space-saving design.
2. Full-automation — Fully automated processing of pipetting samples, reaction with reagents and detection.
3. Samples — Whole blood, plasma, serum, or other body fluids
4. Multi-item Processing
   Up to six different samples or up to six different items in a batch can be assayed.
5. Short Assay Time — Less than 17 minutes (depends on reagent protocol)
6. Easy to Use — Specially prepared prepackaged reagents and disposables make easy to run assay operation.
   No water, wash solution or waste bottles are needed.
   PATHFAST is a near patient testing (NPT) device.
7. High Sensitivity/Accuracy/Reproducibility
   Small amount of materials can be detected by using photon counting method with high accuracy and good reproducibility.
8. Minimum Cross Contamination
   Possibility of cross contamination among samples is minimized because of mono-test type reagents and disposables.
9. Bar-code Control — Assay items, factory-set calibration data and reagent expiration date are given by reagent barcode. Sample ID and User IDs are also available through Handheld Barcode Reader.
10. Sample Recognition Sensor
    Whole blood can be automatically differentiated from serum or plasma by the sample recognition sensor.

2.3 Specifications

Product Name	**PATHFAST™**
Class of device	Class-A, near patient testing (NPT) device
Instrument Type	Bench-top
Throughput	Samples : Maximum 6 samples/batch Process Time : Less than 17 minutes*/6 samples * Depends on protocol of each assay item, refer to package inserts.
Type of Samples	Whole blood, plasma, serum, or other body fluids
Temperature Control	Heat Block L : 37.5℃ Heat Block T : 35℃
Handling Volume	20～700ul
Dispensing Accuracy	50ul--------- CV less than or equal to 2% *Note : with distilled water, RT 20 – 25 °C.*
Wavelength	300～650nm (PMT Sensitivity Peak : 450±50nm)
Data Storage	Patient Data : 1000 QC Data : 1800 CAL Data : 300 *Note : Oldest data is lost when data overflows.*
Power Requirement	100 - 240 VAC, 50/60 Hz
Power Consumption	360 VA
Protection against electrical shock : class 1, type B	
Size	W343x D569 x H475 mm
Weight	About 28kg

2.4 Marks of Conformity

PATHFAST has the compatibility with the following standards. PATHFAST has been manufactured and checked in accordance with relevant safety standards prior to being shipped from the factory. The instrument has been approved for use by recognized institutions. This is confirmed by the test and conformity symbols.
You can check them on the label attached on the instrument.

Standards applied:

- EN ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices
- EN ISO 18113-1: 2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirements
- EN ISO 18113-3: 2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 3: In vitro diagnostic instruments for professional use
- EN ISO 15223-1: 2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- EN 13612: 2002+AC:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 61010-2-101: 2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-2-6: 2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- EN 62304:2006+A1:2015 Medical device software — Software life-cycle processes
- EN 62366-1: 2015 +AC:2016 Medical devices — Application of usability engineering to medical devices
- EN IEC 63000:2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- UL 61010-1 (3rd Edition)

Acronym	Test Symbol	Test Information
CE		According to REGULATION (EU) 2017/746
UL		According to test standards of UL (Underwriters Laboratory)
EAC		Eurasian Conformity (Евразийское соответствие)

3 Safety Instructions for Installation and Operation of PATHFAST

For safe and effective operation of PATHFAST, please become familiar with these safety instructions.

If your PATHFAST Analyzer is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

3.1 Installation

Unpacking and installation of your PATHFAST Analyzer will be arranged by your PATHFAST Representative. The following environmental conditions should be considered when selecting a placement location.

3.1.1 Power Supply

PATHFAST requires AC100 ～ 240V+/-10% 50/60Hz, 360VA. Be sure the instrument is correctly earthed. Use the power cable in the PATHFAST accessories box and insert its plug in an earthed socket. Avoid sharing a power source with other instruments and/or devices.

3.1.2 Environmental Conditions

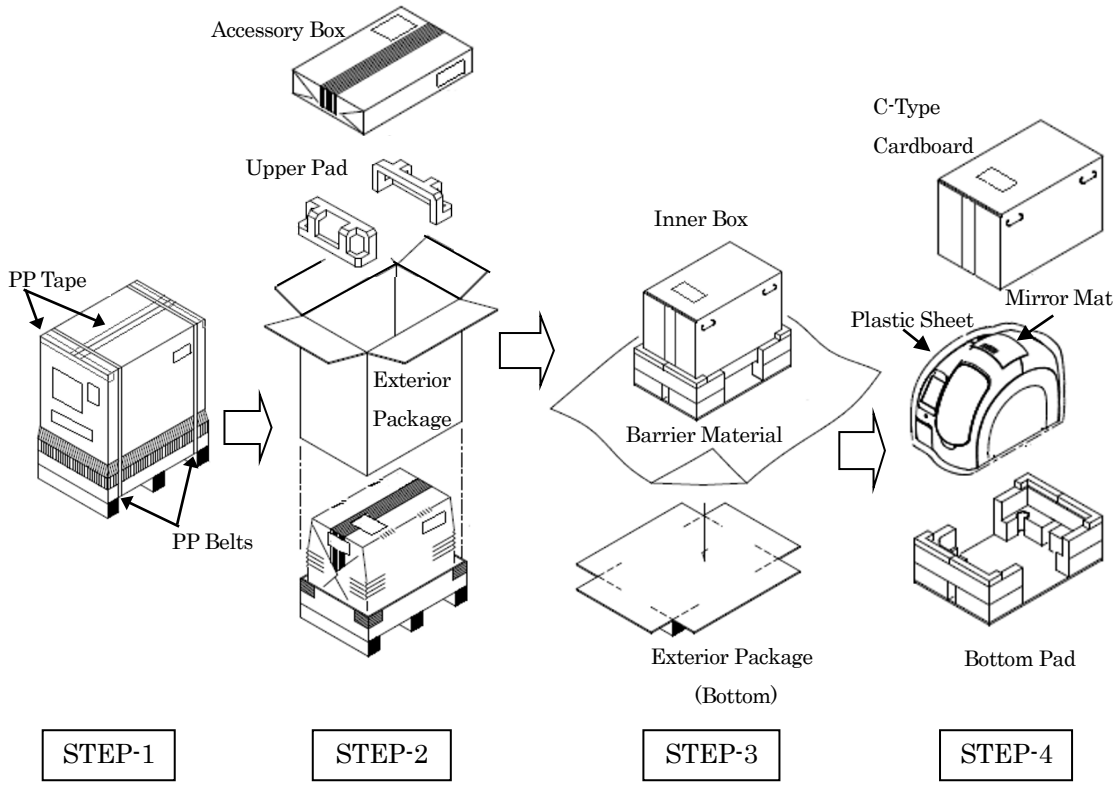
- PATHFAST is equipped with temperature controlling units for assay processing. Keep the environmental temperature and humidity within the following ranges.
  Temperature : 15 - 30°C
  Humidity : 20 - 80 % (relative, non-condensing)
- To avoid damage to the filter cover, place the instrument on a flat, level, and vibration-free surface.
- Place PATHFAST on a counter top or cart with enough capacity (more than 30 kg) to support the instrument and other equipment/disposables used for assays.
- Keep a clearance around a power inlet connector to pull out it immediately in an emergency situation.
- Keep a minimum 15 cm clearance around the device left-side and keep 10 cm clearance around rear- and right-sides.
- Avoid placing PATHFAST near instruments with large power consumption, or close to possible sources of AC voltage changes and/or electro-magnetic wave emission.
- Avoid placing PATHFAST where it will be exposed to direct sunlight or airflow from air-conditioners or other instruments.
- Do not obstruct the air intake at the bottom of the instrument. Keep area clear of papers or other objects that may interfere with airflow.
- Do not obstruct the exhaust openings on the rear top of the instrument. Also be careful not to drop anything through these openings.

- PATHFAST should only be used indoors (pollution degree is 2).
- PATHFAST can be used in altitudes up to 3000 m.
- Overvoltage category is II.
- Transient overvoltage 2500V

3.1.3 Storage and Transport Conditions

Storage Condition	:	Temperature	= +5～+40℃
		Humidity	= 20～80%RH
Transport Condition	:	Temperature	= -20～+70℃
		Humidity	= 20～80%RH

3.1.4 Unpacking Procedure



Step-1 Remove PP Belts and cut PP tape fixing top of Exterior Package to open Top Lid.
Step-2 Remove Accessory Box and Upper Pad to remove Exterior Package.
Step-3 Cut PP Tape at the bottom of Exterior Package and expand four bottom corners to remove Barrier Material covering Instrument Box.
Step-4 Remove C-Type Cardboard to take out the Instrument packaged. Then remove Plastic Sheet and Mirror Mat covering the instrument.

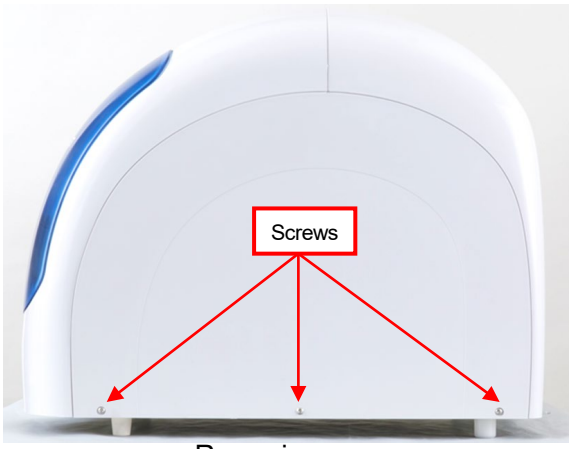
3.1.5 Procedure to Remove transport fixtures (Y-Axis, PMT-Axis)

NOTE: Keep all the fixtures for future use.

a) Removing Cover

Remove three screws fixing the cover on the right side of instrument, using hex wrench (2.5mm).

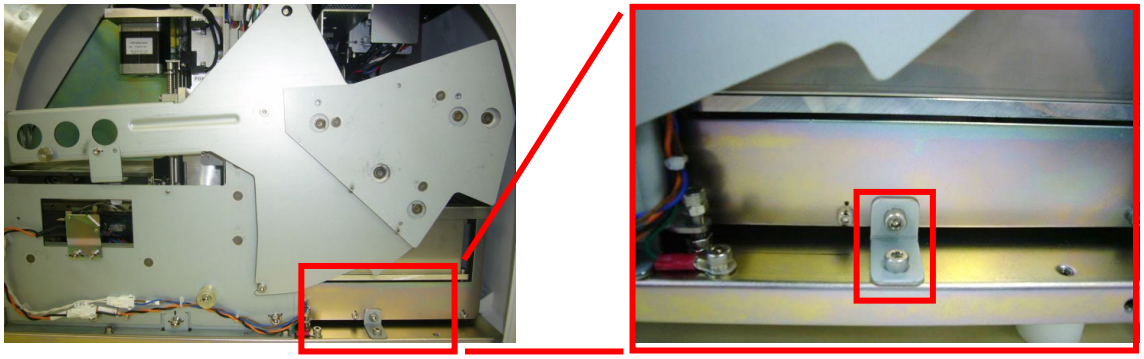
Because the cover drops when all screws are taken off, holding the cover by hand is necessary.



Removing cover

b) Y-Axis Fixture

Remove two fixing screws for Y-Axis Fixture using hex wrench (3mm).

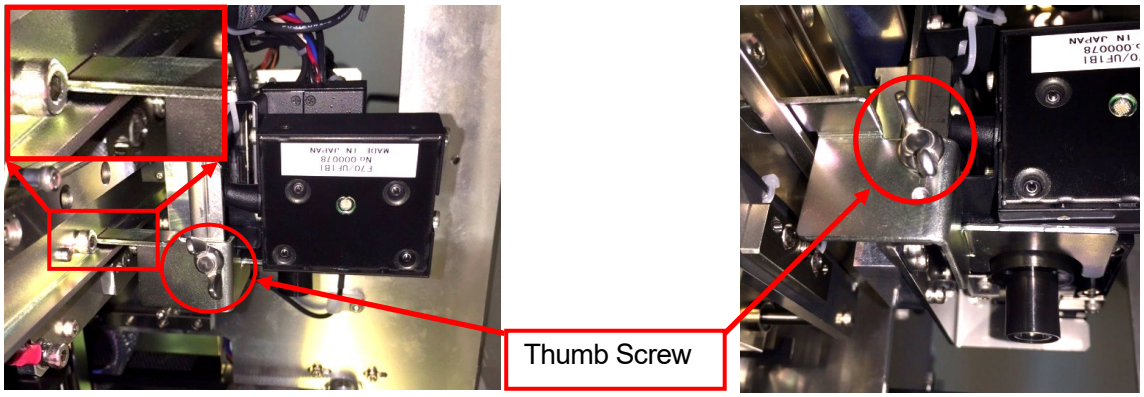


Fixing Screws for Y-Axis Fixture

Y-Axis Fixture

c) PMT-Axis Fixture

Remove the thumb screw which fixes the PMT-Axis Fixture securing PMT unit.
No tool is needed.



PMT-Axis Fixture PMT-Axis Fixture (bottom view)

PMT-Axis Fixture

d) Putting Cover

Put the side cover back on in reverse procedure.

e) The Log-In password for the first Log-In

At the first Log-In, select "Administrator" as the [USER] on the [LOG IN] screen and enter "4649" for the [PASSWORD].
And select [OK] to go to [ASSAY/HOME] screen.

NOTE: Do not disclose the password for [Administrator] to the others.

For further operation, refer to the appropriate chapters of this Manual.

3.2 Specimen Handling

Specimens should be handled as if infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories** and in CLSI Document M29-T. **Wash hands thoroughly afterwards.

* *Biosafety in Microbiological and Biomedical Laboratories. 1993*. Richmond, J.Y. and Mckinney, R.W. (eds.). HHS Publication Number (CDC) 93-8395.

** Clinical Laboratory Standards Institute. Protection of Laboratory workers from infectious disease transmitted by blood, body fluids, and tissue. Tentative Guideline M29-T, Villanova, PA : CLSI, 1989.

3.3 Caution Labels

Caution labels, based on international standards, are attached to the PATHFAST Instrument in areas where particular care is required during operation and maintenance.

Caution Label	Example of caution indicated
 High Temperature	Heat Blocks becomes hot. To prevent burns do not touch this area.
 Bio-Hazard	Samples assayed by PATHFAST, including whole blood, plasma, and serum, along with Quality Control materials and reagents should be treated as potentially infectious materials. Use the appropriate protective equipment during operation and maintenance of the instrument. Follow all regional guidelines and universal precautions for blood borne pathogens.
 Laceration	Piercers with extremely sharp edges that are used to make holes in the aluminum seal of the reagent cartridges are located inside. To prevent injury, extra care should be taken when setting reagent cartridge racks or cleaning piercers.

3.4 Safety Instructions

Please read this section carefully to understand any possible dangers associated with the symbols.

Symbol	Meaning
⚠ Danger	Not following directions can result in serious injury or even death. High urgency.
⚠ Warning	Not following directions can result in serious injury or even death. Low urgency.
⚠ Caution	Not following directions can result in being wounded or other physical damages.

* 1 : "serious injury" means becoming blind, hurt, burned (high or low temperature), electric shock, fracture or addiction for which the operator experiences an aftereffect that requires a long period of hospitalization.
* 2 : "wounded" means those injuries which do not require a long hospital stay.
* 3 : "physical damage" means abnormal effects to the results or extended damages to the neighboring equipments or devices.

[Cautions - related to PATHFAST]

⚠ **Danger** Electric shock is possible when touching the internal electrical components. Do not perform any operation or maintenance work other than described in this manual.

⚠ **Danger** Do not reconstruct or make modifications to the instrument. Do not use parts or disposables other than those designated. Also, never operate PATHFAST with the safety lock released.

⚠ **Danger** In an emergency, turn the instrument power off immediately and remove the power cable from the wall outlet. Contact your PATHFAST representative.

⚠ **Warning** PATHFAST complies with Class A EMC regulations, however, we cannot completely block the influence of strong external strong electro-magnetic radiation. Do not allow devices such as portable phones, transceivers, etc. close to PATHFAST.

⚠ **Caution** When any serious incident occurred in relation to the product, report to the manufacturer and the competent authority in which the user and / or the patient is located.

⚠ **Caution** Only operate PATHFAST after having been trained by a PATHFAST representative.

⚠ **Caution** Shut the instrument power off while not in use.

⚠ **Caution** If you have a problem, refer to Chapter **14 Troubleshooting** and take counter measures as needed. If the problem persists, contact your PATHFAST representative.

⚠ **Caution** If you want to move PATHFAST to a different location, first contact your PATHFAST representatives for assistance. Because of its weight and shape, at least two people are recommended for moving the instrument.

⚠ **Caution** Perform the periodic maintenance described in this manual appropriate to your user "Accessibility Level". Higher level maintenance will be done by an authorized PATHFAST representative.

⚠ **Caution** Follow the operating procedures described in this operator's manual when operating PATHFAST.

⚠ **Caution** Instrument operation may differ by assay items. Refer to each test's package insert for assay specific operations.

⚠ **Caution** Perform Quality Control using QC samples recommended by PHC Corporation.

⚠ **Caution** Do not attempt to upgrade the software, other than by following the designated procedure or as instructed by your PATHFAST representatives. Inappropriate operation may cause data loss and you may not be able to continue instrument operation.

⚠ **Caution** Do not insert anything other than genuine Handheld Barcode Reader of PATHFAST and USB memory stick for upgrade into the USB port of PATHFAST.

⚠ **Caution** The front cover is locked during assay operation and during system initialization. Do not try to open the cover by force.

⚠ **Caution** Do not push multiple buttons on the LCD display at the same time or press one button continuously. These actions can cause the system to malfunction.

⚠ **Caution** PATHFAST is equipped with one Ethernet port on the exterior, but this port is for factory use only and is closed with a cover at the time of shipment. Never remove this cover to access the port.

[Cautions - Related to Reagents]

⚠ **Warning** Use only reagents and disposables designated by PHC Corporation.

⚠ **Caution** Strictly follow the instructions for usage, storage, handling, etc. described in package inserts.

⚠ **Caution** Do not use expired reagent cartridges.

⚠ **Caution** Do not use used reagent cartridges and tips.

⚠ **Caution** Be aware of samples with substances which give non specific reactions or disruptive reactions.

⚠ **Caution** Diagnosis of disease based on the test result should be made by the physician from a comprehensive standpoint, considering other test results and the clinical condition of the patient.

⚠ **Caution** Store reagent kits, cartridge tray and reagent cartridges in upright position.

⚠ **Caution** When handling the reagent cartridge, do not touch the aluminum seal and detection well. Hold it by the cartridge edge.

⚠ **Caution** Introducing saliva into the detection well by blowing into the well may cause an erroneous result.

⚠ **Caution** Using reagent cartridges dropped on the floor may cause erroneous result.

⚠ **Caution** Before testing, remove any bubbles in the wells of the reagent cartridge or liquid on the aluminum seal inside, by softly tapping the cartridge on a flat surface.

⚠ **Caution** Samples with high turbidity, including high lipid concentrations, may be erroneously recognized as whole blood samples by the Sample Recognition Sensor. The results may be corrected by adjusting hematocrit values.

⚠ **Caution** Samples where blood cells or other physical materials are immixed when dispensing samples into sample wells, might be erroneously recognized as whole blood samples by the Sample Recognition Sensor. The results may be corrected by adjusting hematocrit values.

[Other Cautions]

⚠ **Warning** Samples assayed with PATHFAST are potentially infectious. Use personal protective equipment (gloves, glasses, lab-coat and lab-cap), when operating or maintaining the instrument.
If sample should get on your skin, wash the affected area and disinfect as necessary. Consult with your supervisor according to your laboratory's standard operation procedure.

⚠ **Warning** Follow regional safety instructions and related regulations when discarding waste materials.

⚠ **Warning** Contact your PATHFAST representative when discarding PATHFAST, because PATHFAST has a lithium battery inside.

⚠ **Warning** Used reagent cartridges, used PATHFAST tips, and the waste tip box should be considered as potentially infectious and handled accordingly.

⚠ **Caution** PATHFAST is a clinical analyzer of whole blood, plasma, or serum. Do not use the instrument for other purpose.

⚠ **Caution** Avoid injury by carefully inserting reagent cartridges in the rack.

⚠ **Caution** Be careful not to get hurt by paper cutter when replacing printer paper.

⚠ **Caution** Refer to package insert or MSDS (Material Safety Data Sheet) in technical documents for care instructions of chemical materials contained in disposables and reagents.

⚠ **Caution** Ethanol used for cleaning the PATHFAST system is flammable and needs to be handled carefully.

3.5 Exemption Clause

It is very important to follow the precaution instructions mentioned in the previous paragraphs when operating or maintaining PATHFAST. Even when precaution instructions are followed, the possibility of non-avoidable accidents still exists as explained below. PHC Corporation is not responsible for the loss or damage as explained in the following cases.

- Damages to the instrument or to users due to accidents beyond control such as earthquake or fire.
- Damages to the instrument or to users, or wrong results due to intentional, faulty or wrong operations made by the user.
- Ancillary damages derived from usage or non-usage of the instrument, such as lost of business income, abort of clinical examination, influence to the patients, etc.
- Damages derived from not following safety and precaution instructions explained in the operator's manual.
- Damages derived from malfunctions due to combination with external computers/devices and software in which PHC Corporation is not involved.
- Damages derived from repair or modification made by people who are not authorized by PHC Corporation.

4 Details of PATHFAST

PATHFAST is a fully-automated clinical analyzer using whole blood, plasma, serum, or other body fluids as samples.
In this chapter we discuss the principle of measurement, instrument configurations, accessories and disposables needed, and reagents used with PATHFAST.

4.1 Principle of the Procedure

The principle of measurement employed with PATHFAST is CLEIA (Chemi-Luminescence Enzyme Immunoassay) .
Reagents needed for each test are contained in the wells of a specially designed 15-well cartridge and sealed with aluminum foil.

The following explains the principle of measurement using cTnI (cardiac muscle troponin I) as an example.

[Reagent Configuration]

- Magnetic Latex Reagent
- Labeled Antibody Reagent (ALP labeled antibody solution)
- Wash Reagents (Washing solution for B/F separation)
- Luminescent Substrate

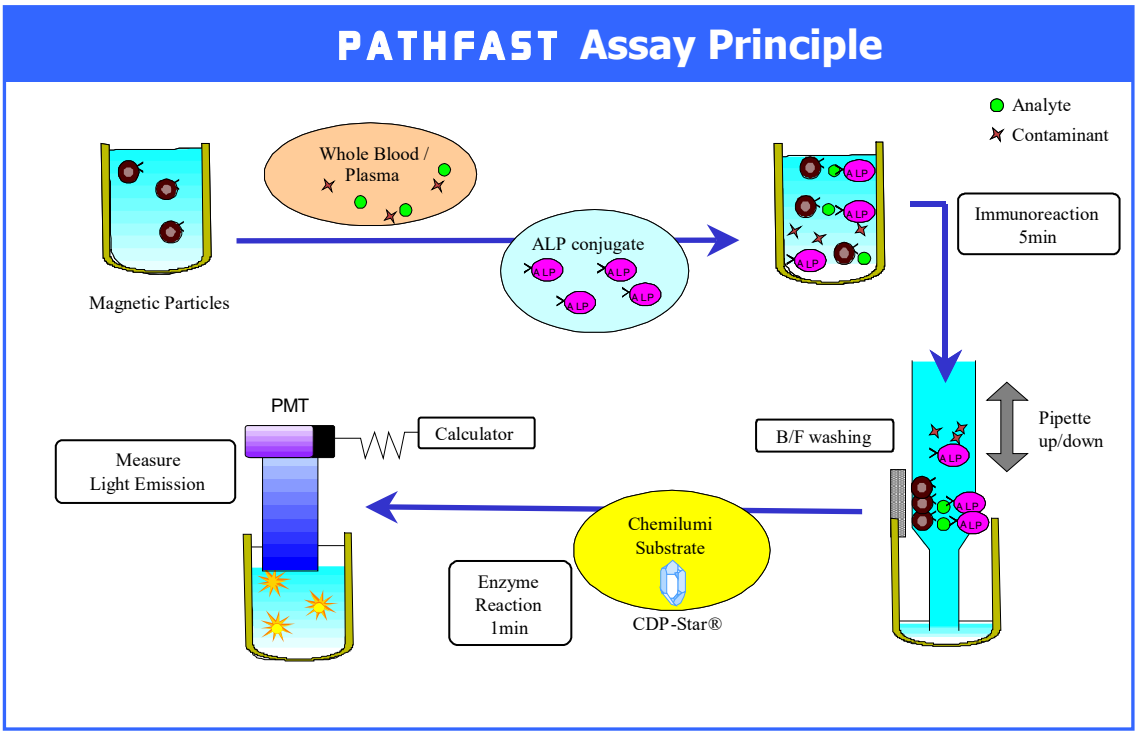
[Process of Assay]

1. Samples (whole blood or plasma) are mixed with magnetic latex reagent and ALP labeled antibody solution, and are incubated for five minutes.
   In this step, the following sandwich compounds are formed.
   Solid phase antibody - target material - ALP labeled antibody

2. B/F separation using Magtration® technology is performed to remove excessive reagents or residual materials in step 1 above.

3. Added luminescent substrate (CDP-Star) is catalyzed by ALP, resulting emission of light. The emitted photons are counted by PMT (Photo-Multiplier Tube) in PATHFAST detection system.

4. The chemiluminescent count obtained by PMT is applied to the standard curve calibrated and stored in PATHFAST to calculate the concentration of target material.



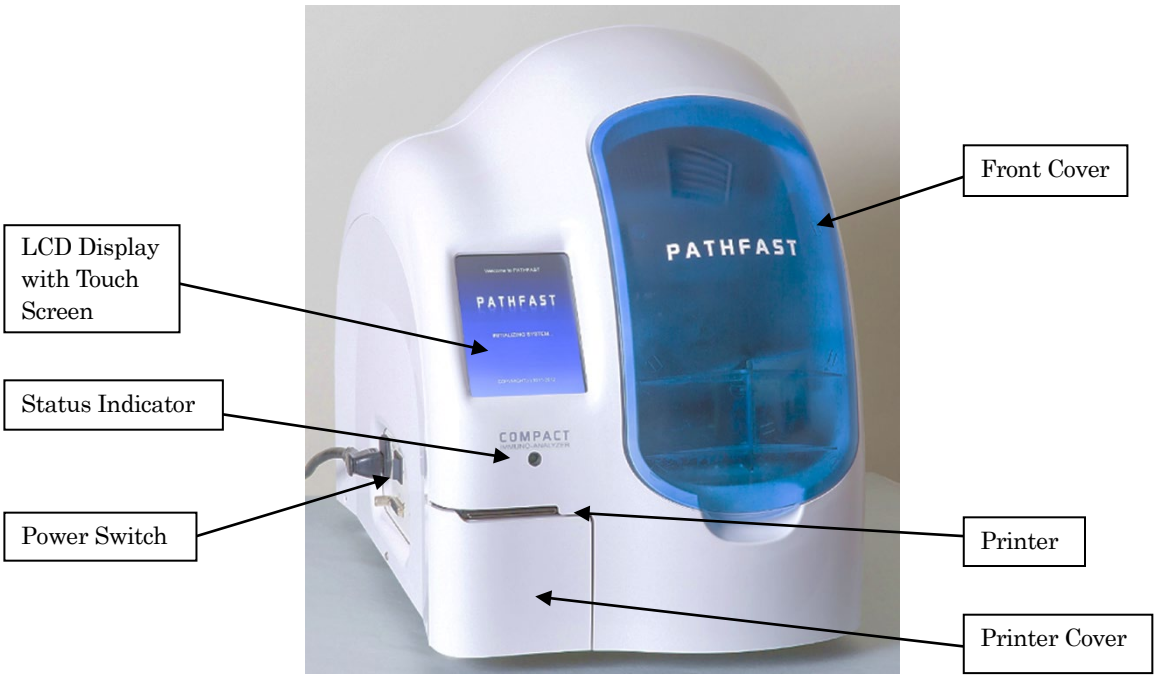
PATHFAST performs the assay process, which is stored as "assay protocol", and automatically prints the result on the built-in printer.

4.2 Components of PATHFAST

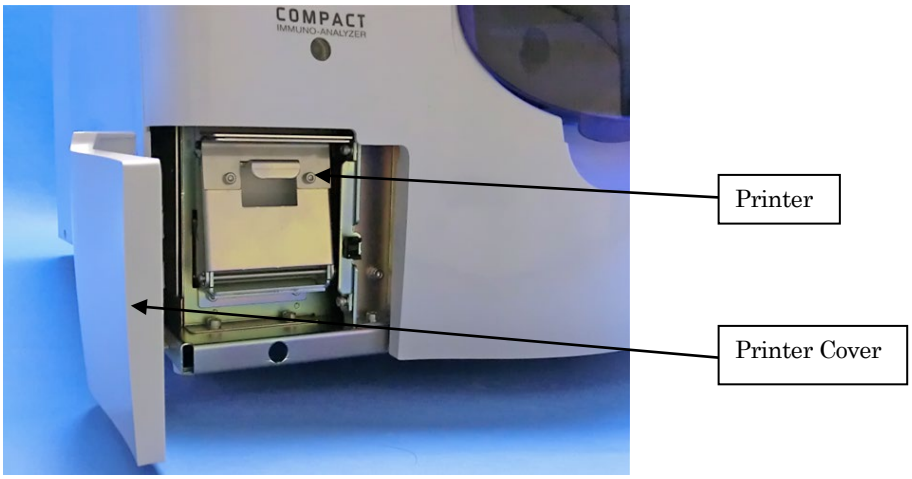
This section describes the components of PATHFAST and their functions.

4.2.1 Instrument Front View

Most of the components needed to operate PATHFAST are located on the front of instrument. The names and functions are described below.



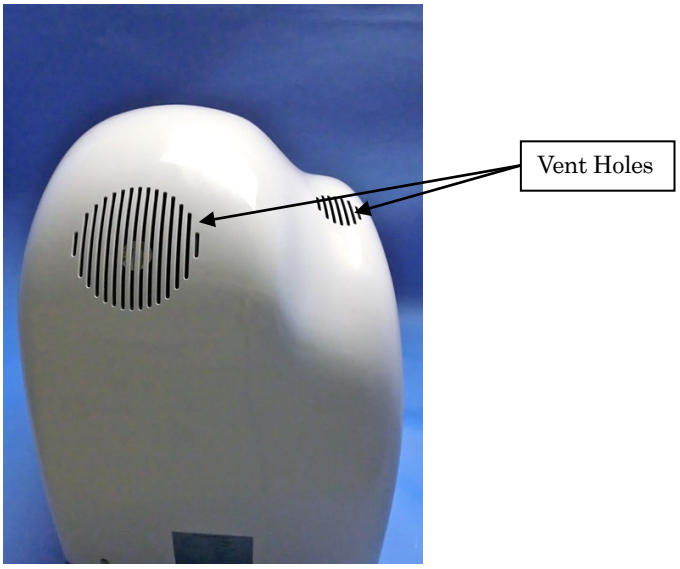
Status Indicator
-------- Lit green during normal operation.
LCD Display with Touch Screen
-------- Displays various status information and accepts operator input for instrument operation.
Power Switch ----- Main power switch for the instrument.
Front Cover ------- Slides upward to open. Open it to set reagent cartridge rack, samples and other disposables for assay or cleaning and maintenance.
Printer --------- Prints out measured results and other information.
Printer Cover ----- Open this cover to replace printer paper.



View : printer cover opened

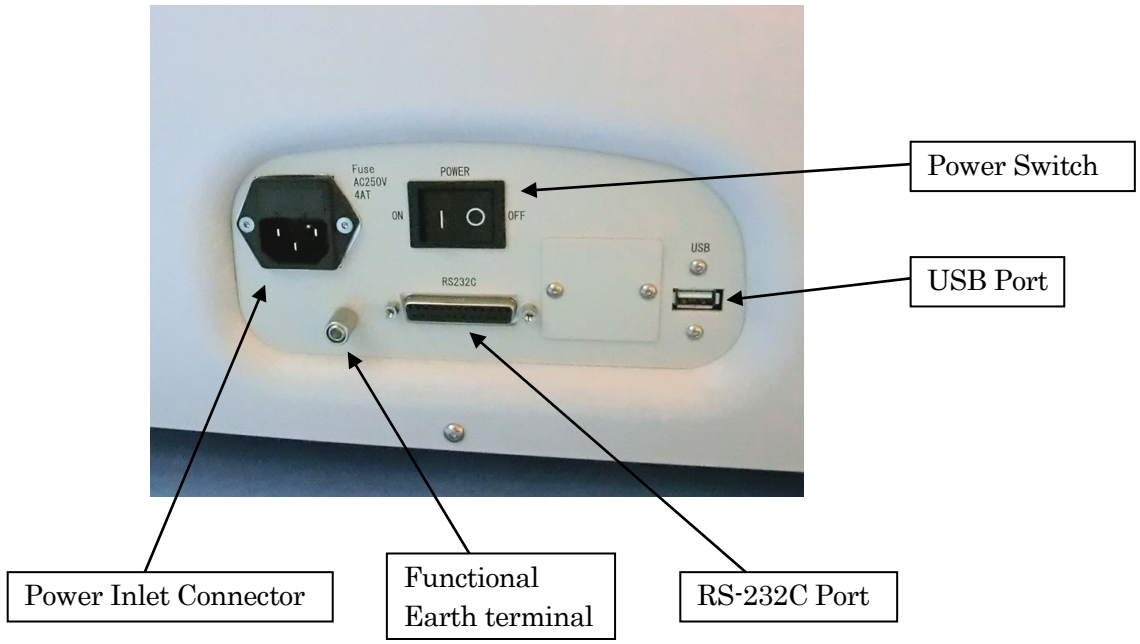
4.2.2 Instrument Rear View

Two vent holes are located on the rear of the instrument for air exhaust to control the temperature of the heat blocks. Keep a minimum 10 cm clearance around these vents.



Vent Holes ------- Holes for ventilating inside air for temperature control.

4.2.3 Instrument Left-side View



RS-232C Port ----- Serial port for communicating with external computers.

USB Port ------- USB port for connecting Handheld Barcode Reader or stick memory for upgrade.

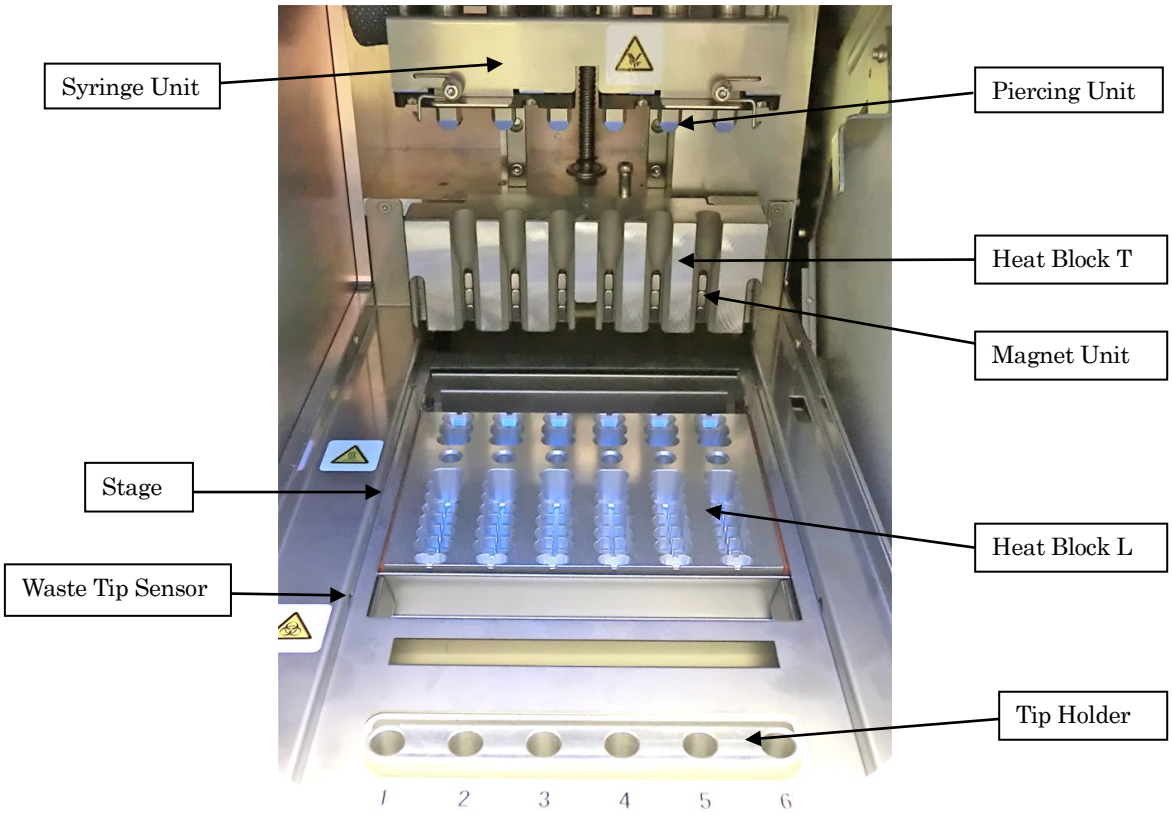
Power Inlet Connector
------- Connecter for Power Supply Cable.

Functional Earth Terminal
------- Use the earth terminal as needed in each country.

4.2.4 Interior of Instrument

By opening the front cover of PATHFAST, internal components of the instrument can be viewed. Here the internal components are explained with their functions.

[Interior view without disposables and reagent cartridge rack]



Syringe Unit ---------- A set of six syringes to aspirate and dispense samples and/or reagents. PATHFAST tips are attached on to the nozzles.

Stage ---------- Holds reagent cartridge rack, disposable tips and waste tip box and moves back and forth to process assay protocols.

Waste Tip Sensor -------- Checks if the waste tip box is set and if there are used tips in the waste tip box.

Heat Block T ---------- Heats liquid in the disposable tips during the reaction to keep the temperature of the mixture at 35°C.

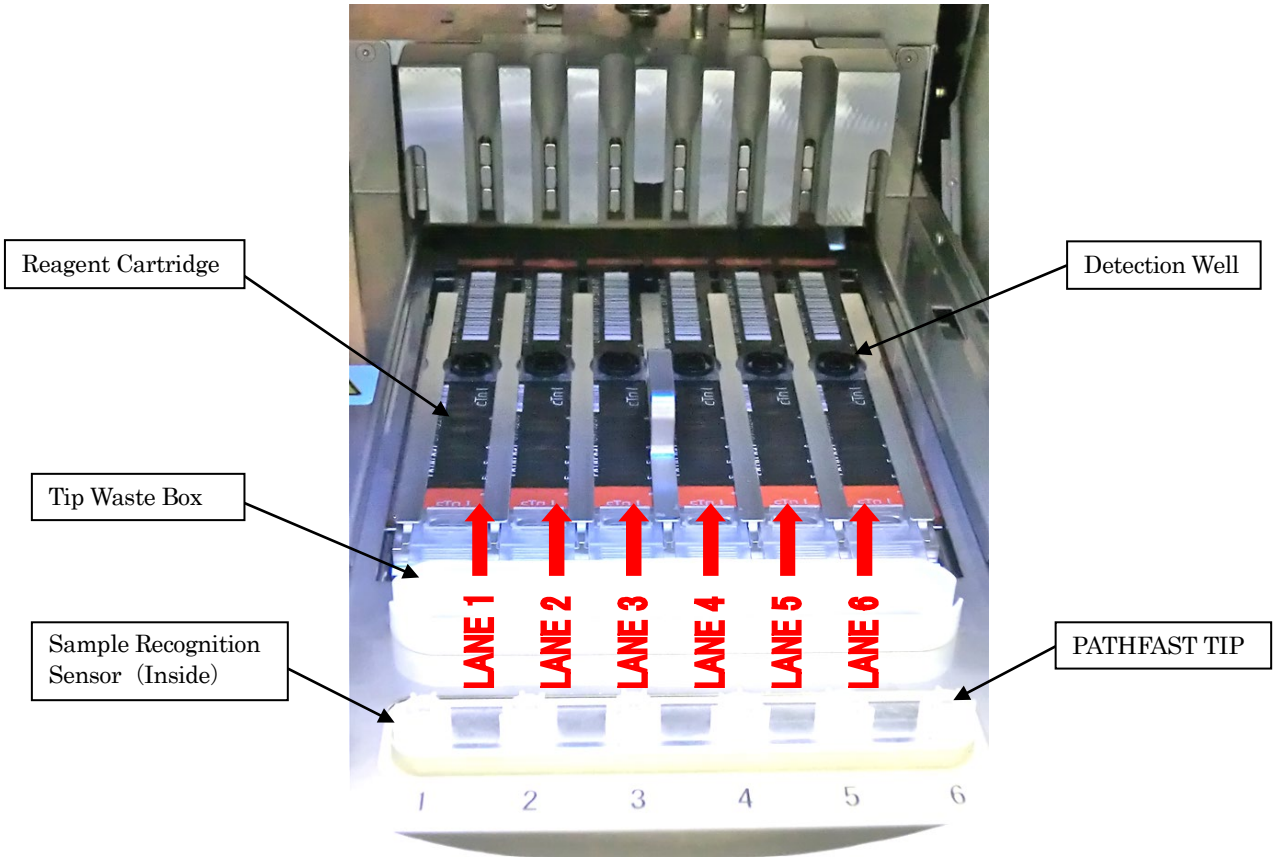
Piercing Unit ---------- Pierces the aluminum seals on the reagent cartridges allowing the disposable tips to extract reagent.

Magnet Unit ---------- Holds magnetic latex particles on inside walls of tips to perform B/F separation using Magtration® technology.

Heat Block L ---------- Keeps the temperature of the reagents in the reagent cartridge wells closer to sample wells at 37°C.

Tip Holder ---------- Holds new, unused disposable tips.

[Interior view with disposables and reagent cartridge rack]



Reagent Cartridge ---------- A specially designed plastic cartridge with 15 wells. Assay specific reagents are pre-dispensed into specified wells and sealed with aluminum foil. Barcoded reagent information is printed on the aluminum seal.

Detection Well ---------- Chemiluminescent light is detected in this well during the last step of the assay.

PATHFAST TIP ---------- Used for aspirating and dispensing samples or reagents, and also for B/F separation using Magtration® technology.

Tip Waste Box ---------- Replaceable plastic box holds used PATHFAST tips to be discarded.

Sample Recognition Sensor --- Detects light transmitted through the disposable tips when samples are aspirated to judge if the sample is whole blood or not. PATHFAST automatically corrects the measured results in accordance with Hct%.

4.3 Accessories

PATHFAST accessories are listed below.

Table 4 – 1 Accessories

Description	Qty Provided	Remarks
Power Cable, for 100-120VAC	1	
Power Cable, for 220-240VAC	1	
Fuse, 4A, 250V SLO-BLO type	1	Spare for replacement
Stylus Pen	1	
Reagent Cartridge Rack	1	
Handheld Barcode Reader	1	

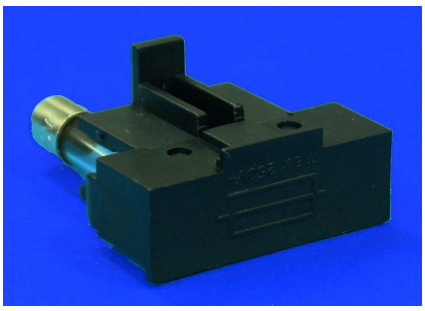
Note: One fuse is already set into the instrument before shipment.

1) Power Cable, for 100-120VAC

2) Power Cable, for 220-240VAC

■ Power cable used for 220 - 240 VAC regions.
Use the power cable in the accessories box.
Do not use another power cable.

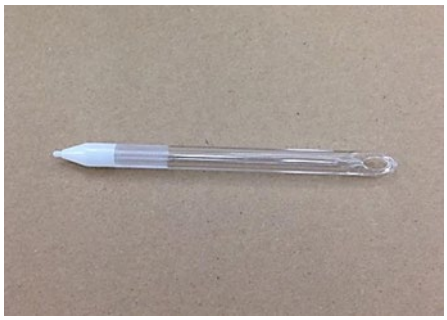
3) Fuse



Set in fuse holder

4) Stylus Pen

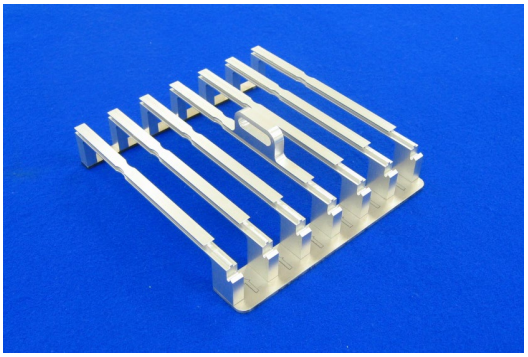
The Stylus Pen is used to input operating commands and/or various information to PATHFAST through the touch panel of the LCD display.

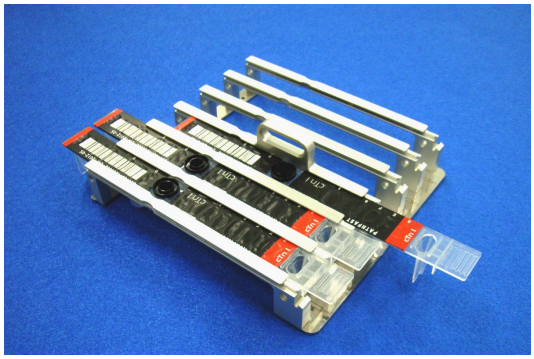


5) Reagent Cartridge Rack

Reagent Cartridge Rack is shown in the left side picture below. It has six slits in which reagent cartridges are inserted. After reagent cartridges are inserted into the rack as shown in the right picture below, the Reagent Cartridge Rack is set in the PATHFAST.

One Reagent Cartridge Rack is shipped with the PATHFAST. The rack is made of aluminum alloy and stainless steel and it can be autoclaved.





6) Handheld Barcode Reader

The Handheld Barcode Reader is used to:

Capture barcode data from the MC Entry Card.

Capture barcoded sample IDs or User IDs.

Use the Handheld Barcode Reader in the accessories box.
Do not use another Handheld Barcode Reader.
Connect or disconnect the Handheld Barcode Reader while the instrument power is off. USB port to connect Handheld Barcode Reader is located on the left-side of the instrument.

Type of readable barcodes are preset for the following standards:

- CODE39
- ITF
- CODABAR (NW7)
- CODE128

4.4 Disposables

The following disposables are needed for running assays with PATHFAST.

Table 4 -2 Disposables

Product Code	Product Name	Qty Provided	Qty per Package
300936	PATHFAST TIP	-	42 x 5 / box
300950	PATHFAST WASTE BOX	1	10 / box
300943	PATHFAST ROLL PAPER	1	10 / box

1) PATHFAST TIP (Disposable Tip)

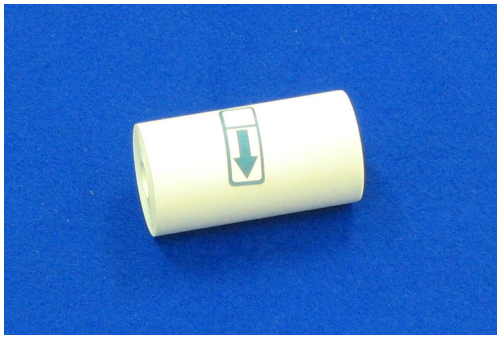
The PATHFAST TIP is a specially designed disposable tip and is used for aspirating/dispensing, or B/F separation by holding magnetic particles on its inside wall with the Magnet Unit. A small white filter is set in the tip to prevent liquid carry over.

2) PATHFAST WASTE BOX

PATHFAST WASTE BOX (tip waste box) is a container to hold used PATHFAST tips that are automatically discarded at the end of each assay run. After completion of an assay run, the tip waste box can be taken out to discard the used tips. This plastic tip waste box is semi disposable and should be replaced every 20 runs or once a week.

3) PATHFAST ROLL PAPER

PATHFAST ROLL PAPER is thermal paper used by the built-in printer.



4.5 Reagent Kit and Related Components

Reagents used for the PATHFAST are supplied as kits. In the kit, Reagent Cartridges, Calibrators with its dissolving solutions, an MC ENTRY CARD and the package insert are included.

Note : Kit configuration may vary by assay.

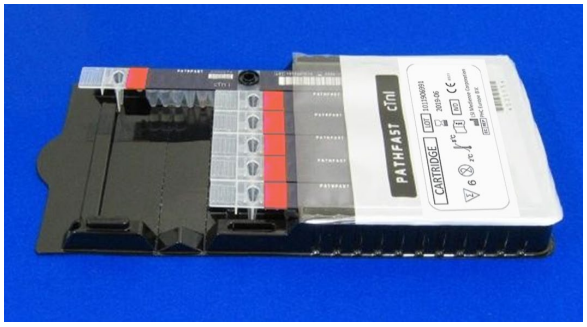
1) Reagent Cartridges

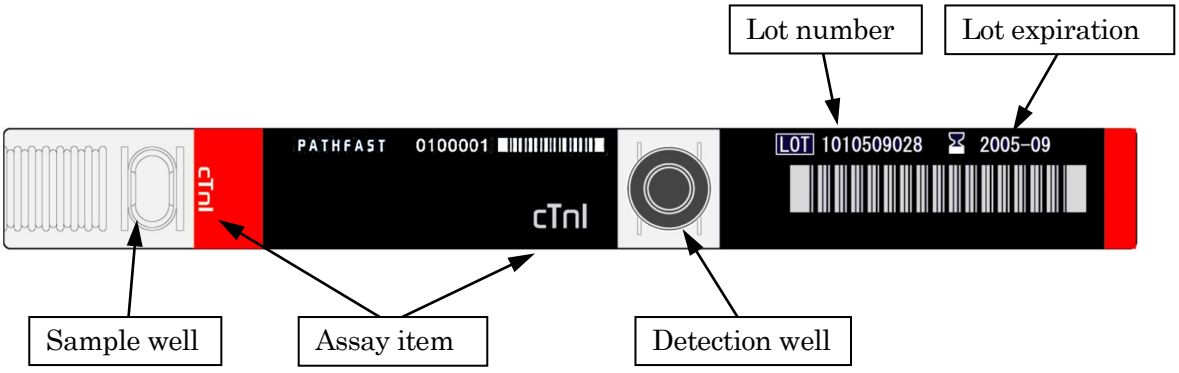
The Reagent Cartridge (shown below) is packed in a set of six cartridges per box. The surface of the Reagent Cartridge is sealed by aluminum foil with the barcode printed on each cartridge. The barcode contains the assay item, lot number, expiration date, and other identifying information.

Each cartridge should be handled/touched at the end of the strip.

Cartridges should be kept in the upright position.

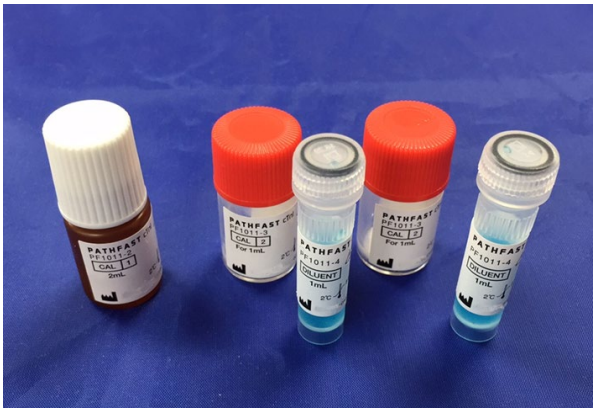
Check the assay item, lot number and expiration date of each cartridge prior to use.





2) Calibrator and Dissolving Solution

If the calibrator is freeze-dried, dissolve it with the included Calibrator Diluent. Refer to the package insert for complete details.

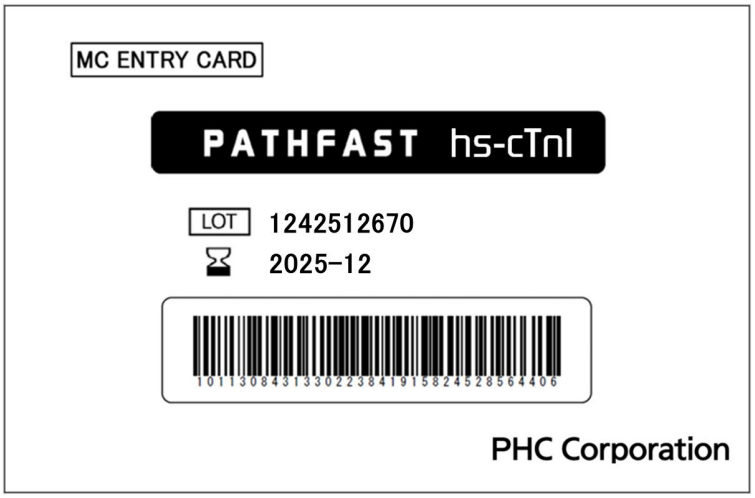


Calibrators (1), (2) and Calibrator Diluent

3) MC ENTRY CARD

The MC ENTRY CARD is supplied with each reagent kit.

This Card is needed the first time you run an assay or run an assay with a different lot of reagent. Capture barcode data from the MC ENTRY CARD, using the Handheld Barcode Reader. Refer to Chapter **8 CAL Assay** for details of this operation.

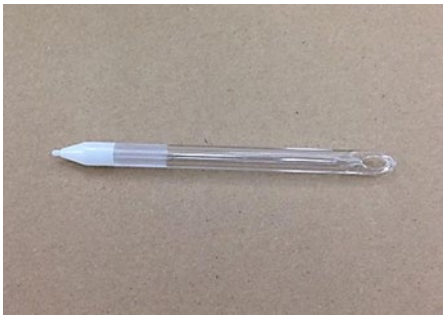


5 Preparation for Assay and Basic Operation

This chapter describes the preparation procedure for running assays on the PATHFAST. Procedures for running assays of patient samples, QC samples or calibrators are described in separate chapters.

5.1 Introduction

PATHFAST is operated through an LCD touch panel display using the Stylus Pen supplied. In this manual, the expression of "select --- button" means "touch the button on the screen with the Stylus Pen". Selected buttons are displayed in reverse.



[Stylus Pen]

5.2 Notation for Describing Operation

In this paragraph, notation used for describing the functions of buttons or the operation of the instrument is explained.

1. Selection Buttons
   Selection buttons on the screen are expressed by button names in boxes.
   Ex) ASSAY
2. Information Displayed
   Information displayed on the screen is enclosed by double quotation marks.
   Ex) "Operating Instruction"
3. Names of Display Area

Title Area

Title of the screen (name of the screen) currently selected is shown in this area.

Message Area

In this area, operating instruction or caution messages are displayed.

Subtitle Area

In this area, the subtitle of the selected screen or selectable buttons from the screen are shown.

Display Area

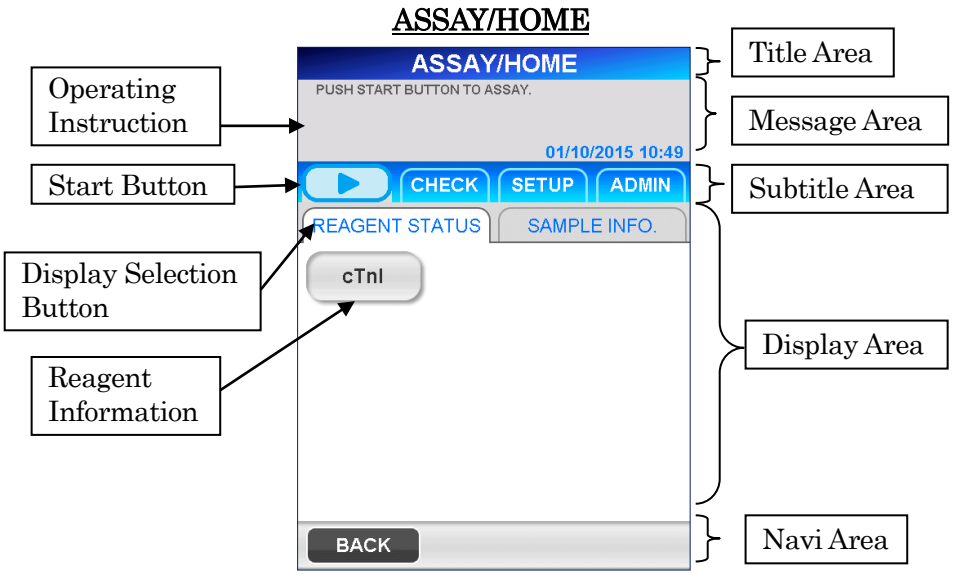
In this area, various information for the specific screen is shown. The messages shown vary by screens.

Navi Area

In this area, buttons for selection, confirmation, cancellation or transferring to other screens are shown.

4. Example of screen description

The following is an example of describing the screen.



In the Message Area, operating instructions or caution messages are displayed to advise the operator of the action to be taken.

Display Selection Buttons

REAGENT STATUS — Lists the currently registered assays by assay item buttons.

SAMPLE INFO. — Display sample information in each lane.

START BUTTON (▶) Starts assay operation.

5.3 Before Supplying Power

Before supplying power to PATHFAST make sure that:

- The power cable is connected to an appropriate wall outlet.
- No obstacles, such as packing materials or used disposables, are inside the instrument.
- No interfering materials, such as material blocking the air outlet on the back or anything that would interfere with the open/close operation of the Front Cover, are around PATHFAST when operating the instrument.

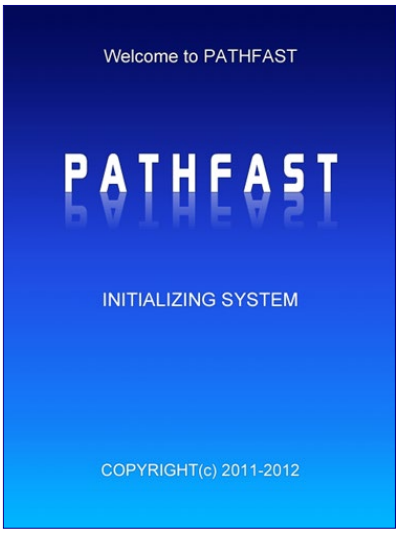
5.4 Power On and System Start-Up

1. Close Front Cover.

2. Turn the Power Switch to the on position. After the power is supplied, the following screens are displayed.

3. Start-up: The following [START-UP 1] screen is displayed while the operating system is initializing.

START-UP 1



4. Initialization: The PATHFAST software is then loaded and various mechanical checks are made. During initialization the [START-UP 2] screen is displayed and shows the process status by a progress bar.

START-UP 2

The system initialization process checks the following:

Check Items

- PMT power supply, ON/OFF
- Front Cover sensor/Front Cover Lock sensor
- Homing of Syringe Unit (Z-Axis)
- Homing of PMT Unit (PZ-Axis & PX-Axis)
- Homing of Magnet Unit (M-Axis)
- Homing of Stage Unit (Y-Axis)
- Homing of Plunger Unit (P-Axis)
  (Include tip release action to Waste Tip Box)
- Homing of PMT Iris Shutter
- Printer paper

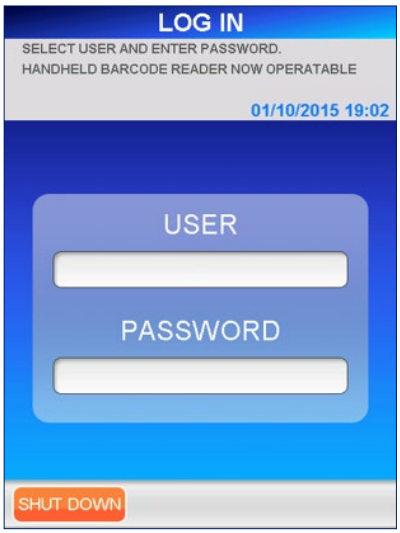
If any abnormality is found in the check process, the corresponding error message is shown on the screen. Operate the system as indicated or consult Chapter **14 Troubleshooting** for details on Error Messages.

5.5 Log-In

If the accessibility function is set to OFF, the [ASSAY/HOME] screen will appear and the following [LOG-IN] screen will not be displayed.

Input User ID and Password in [LOG-IN] screen.

LOG-IN



1. Select a User ID from the list shown by selecting display box.
   - ■ The Handheld Barcode Reader can be used to input a barcoded User ID.

2. In the password input screen, use the Full Keyboard to input the password. All characters displayed on the screen are allowed for password including upper/lower case characters and space. Select OK to go to the [ASSAY/HOME] screen.

   - ■ User ID and password are assigned to each operator by the PATHFAST administrator. Refer to section **1.2 User ID and Access Level** for details. Do not disclose User ID and password to the others.
   - ■ For security, the password is displayed by asterisks.

After log-in, PATHFAST checks the expiration status for calibration and QC and will warn the user with pop-up message if there are any pending expirations. Expiration status will be displayed on the [ASSAY/HOME] screen.

5.6 ASSAY/HOME

The [ASSAY/HOME] screen is the default screen for assay runs, data reviews, recalculations, environmental settings, etc.

- ■ 20 minutes warm-up time is needed before running assays.
  Message of "WARMING UP…" is displayed along with the time left the in message area.

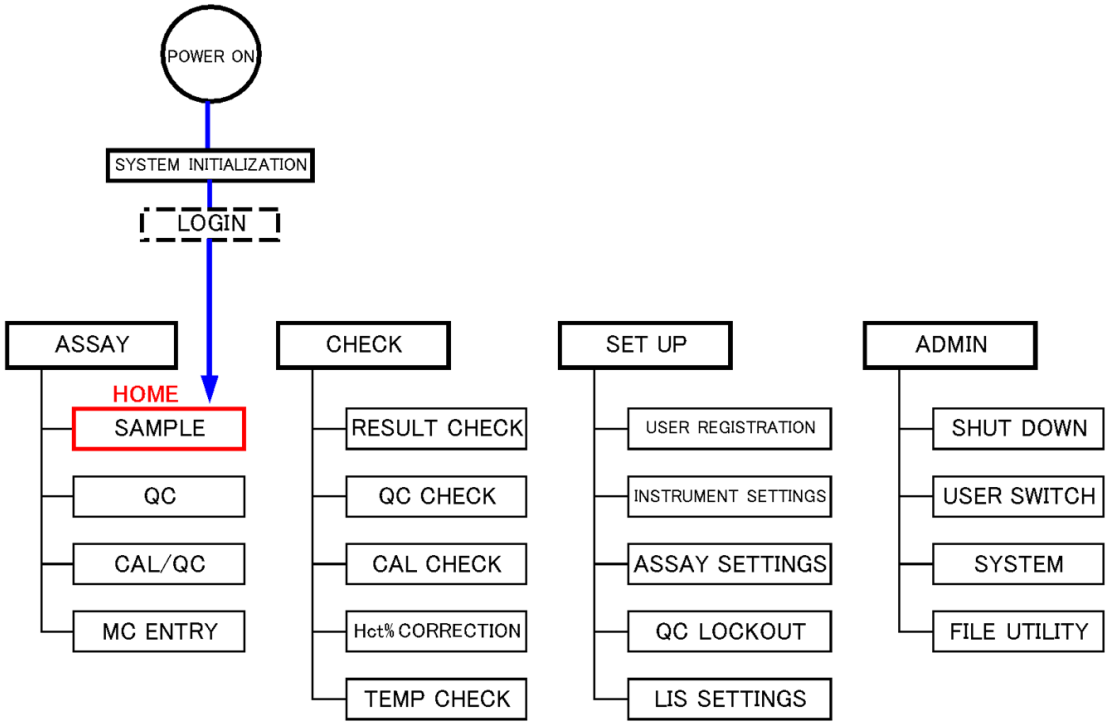
When warm-up is finished, "PUSH START BUTTON TO ASSAY…" is shown in message area.
Other messages such as expiration status for reagent, calibration or QC are also displayed if there are any.

■ Refer to Chapters 6, 7 and 8 or 9 for the operation of sample assay, QC assay or calibration assay.

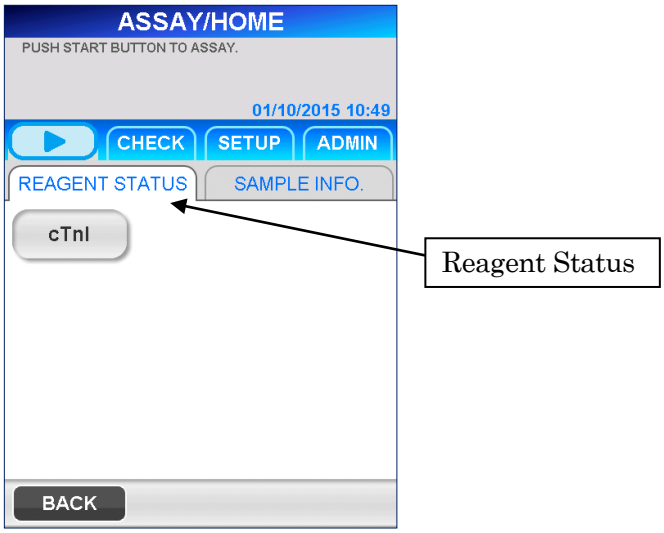
The [ASSAY/HOME] screen is identical with the screen shown by selecting SAMPLE in the [ASSAY] screen. Having SAMPLE as the "HOME" screen makes it easy to prepare for the run without instrument operation.

To show the [ASSAY/HOME] screen, select SAMPLE on the [ASSAY] screen or select HOME in the navi area.

Assay can be started by selecting  shown on the left of the Subtitle Area.



ASSAY/HOME


ASSAY/HOME
PUSH START BUTTON TO ASSAY.
01/10/2015 10:49
CHECK
SETUP
ADMIN
REAGENT STATUS
SAMPLE INFO.
cTnI
BACK
Reagent Status

On the screen shown above, the item names of registered assays are shown by buttons. The buttons are displayed differently depending on whether or not calibration and QC are within expiration dates, as follows.

Gray ---------- Assay run available. Calibration and QC are in the effective period.

Yellow (Blinking) ---------- Assay run available. Calibration and/or QC are in the alert period for expiration.

Pink ---------- Assay run not available. Calibration and/or QC are expired.

Hidden ------- Assay run not available. The assay has never been calibrated or the reagent lots are all expired.

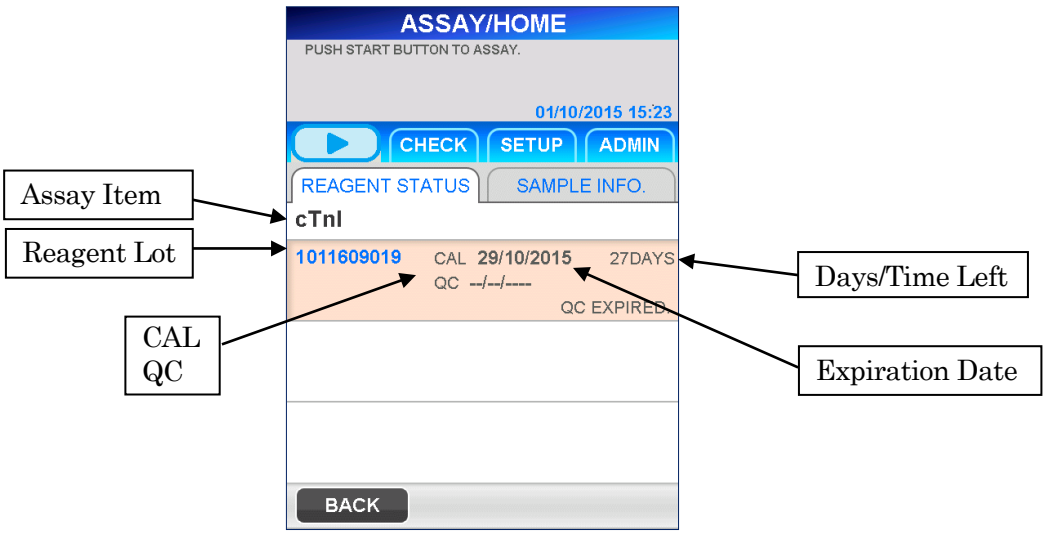
- The display status of the assay item button is based on the status of latest lot calibrated (except hidden ones.)
- The expiration date of calibration is automatically set when calibration run is performed. The expiration date of QC can be defined by the user for each assay item. Refer to the procedure described in **5.8 Setting QC Lock Out** section.

<Reagent Information>

Selecting the assay item in [ASSAY/HOME] screen shows the detailed reagent information as follows.

On this screen you can see the expiration dates and the time remaining before the calibration and QC expire.

CAL/QC STATUS



Note: Exp. Date of QC is not shown when QC Lockout is OFF.

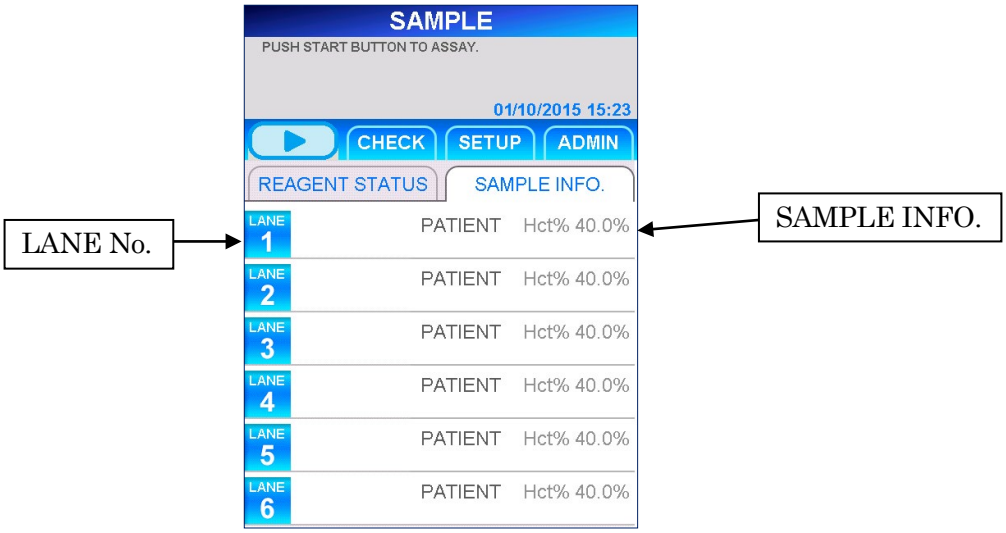
- Three reagent lots with longer expiration periods of calibration are shown at maximum.
- For same lot of reagent, the latest information of calibration and QC are displayed.
- Information for expired reagent lot is not displayed.
- The reagent lot expiration or the calibration expiration, whichever comes first, is indicated on the display.

Note: Check CAL/QC status in [CAL/QC STATUS] screen before running samples.

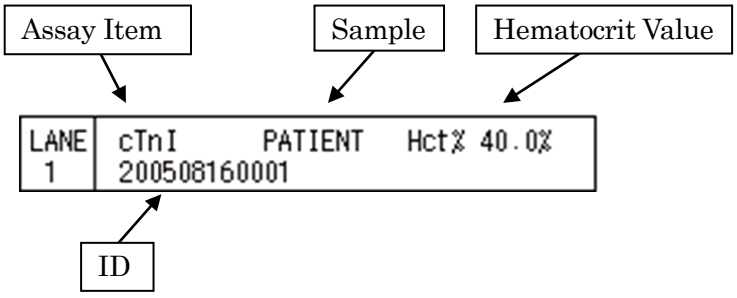
<Sample Information>

Selecting SAMPLE INFO. shows the [SAMPLE INFORMATION] screen.
You can edit or confirm information for each sample to be assayed.

SAMPLE INFORMATION

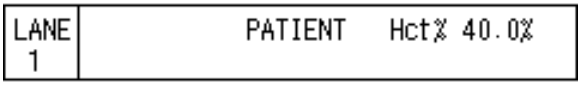


The following information is shown for each lane of [SAMPLE INFORMATION] screen.



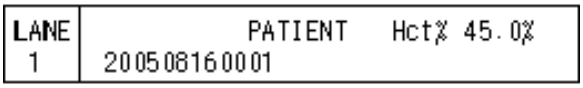
Information shown for each lane includes those edited by the user and those collected by the instrument after the assay run has started.

○ Initially displayed



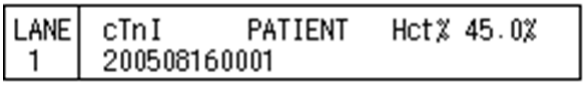
○ Edited information

1) ID
2) Hct%

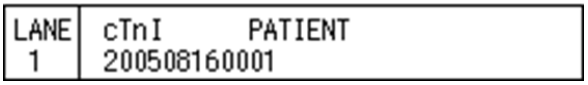


○ Collected information by instrument

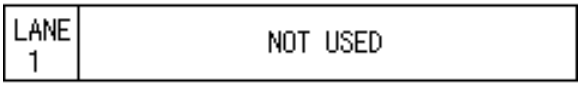
・Whole Blood



・Others



・Not used

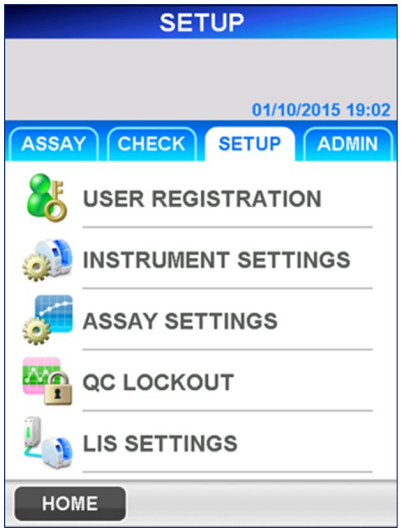


5.7 User ID and Accessibility

In this paragraph, the procedure for registering user and access level is described. The factory setting for Accessibility is ON.

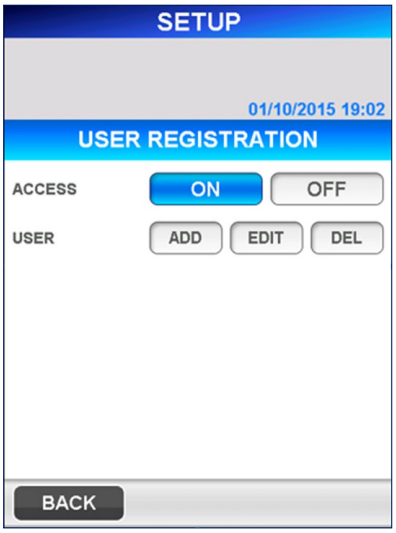
1. When selecting [SETUP] on those screens where you see selection buttons, the following screen is displayed.

SETUP



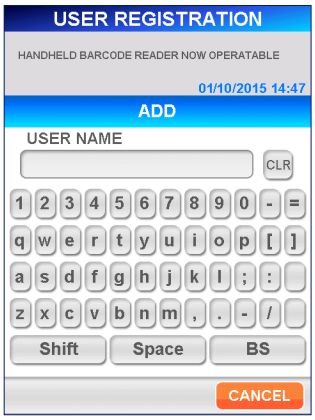
2. Select [USER REGISTRATION] to show the next screen.

USER REGISTRATION

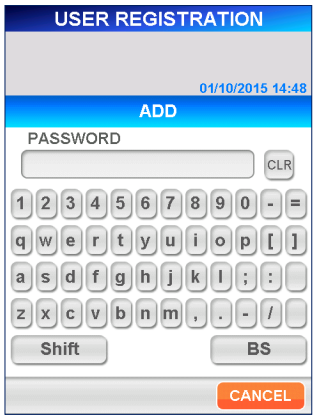


3. Select ADD to register a new user. A full keyboard is displayed to input User ID and password.

USER ID



PASSWORD



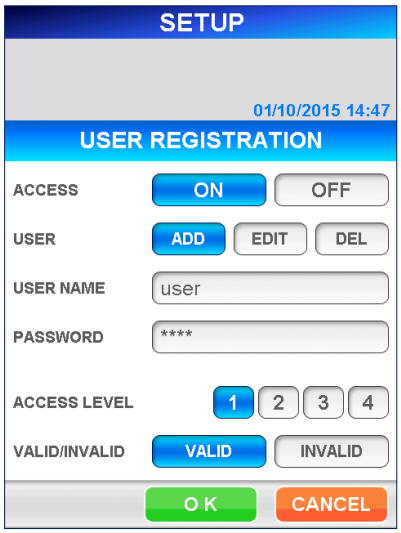
[Full Keyboard]

- Auxiliary Keys

  Shift : Toggle switch for upper/lower case characters
  CLR : All clear
  BS : Back space, clears one character
  Space: Set blank

4. Select OK after inputting the User ID and password to go to the screen to set the access level for the user. Select the appropriate access level number.
   - Refer to **1.2 User ID and Access Level** for details of functions allowed for each level.

ACCESS LEVEL SETTING



5. Select OK to get back to [USER REGISTRATION] screen.

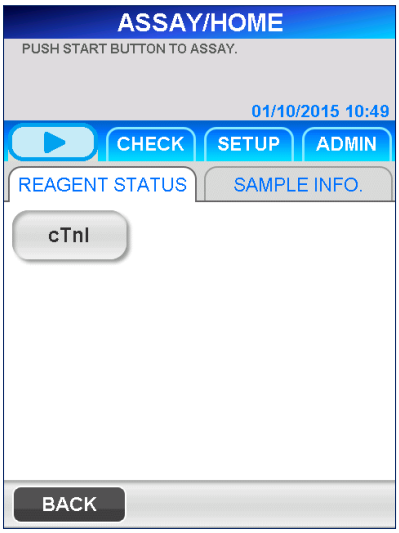
6. Although you can still register the user after selecting **INVALID** (displayed in reverse highlighting) for [VALID/INVALID], the user list shown on the [LOGIN] screen will not display the user ID for this user.

5.8 Setting QC Lock Out

Procedure for setting QC Lock Out function:
In the [QC LOCKOUT] screens, there is no item name at the time of shipment. At the factory settings, you cannot set/change the settings for [QC LOCKOUT]. Only names of items that have been read from [MC ENTRY CARD] on the [MC ENTRY] screen are listed.

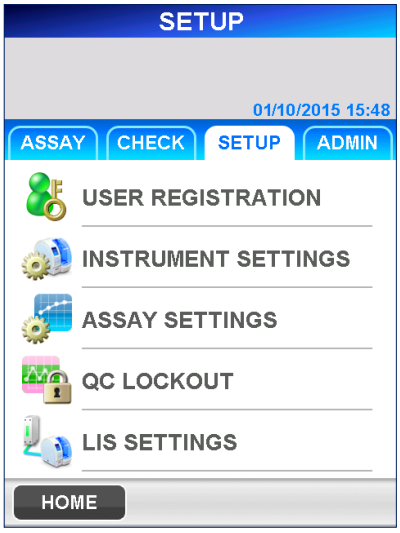
1. Select SETUP from any screen where you see selection buttons, such as ASSAY, CHECK, SETUP and ADMIN in the subtitle area.

SAMPLE/HOME



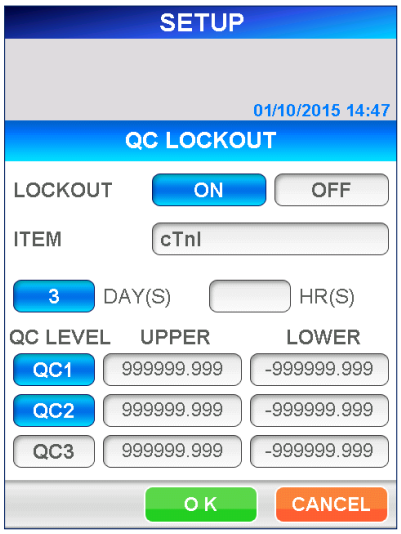
2. Select QC LOCKOUT on the following [SETUP] screen.

SETUP



3. The following [QC LOCKOUT] screen is displayed.

QC LOCKOUT



QC Lockout conditions:

LOCKOUT

Select [ON] to activate the QC lockout function or [OFF] to deactivate. When selected, the button is displayed in reverse.

ITEM

Select the assay item to set the lower/upper control limits for each QC.

DAY(s)/HR(s)

The effective period for QC data is set by days or hours. When selected, the button is displayed in reverse.

- **Range DAY(s) : 1 – 999 days(999 means "not activated")**
  HR(s) : 1 – 30 hours

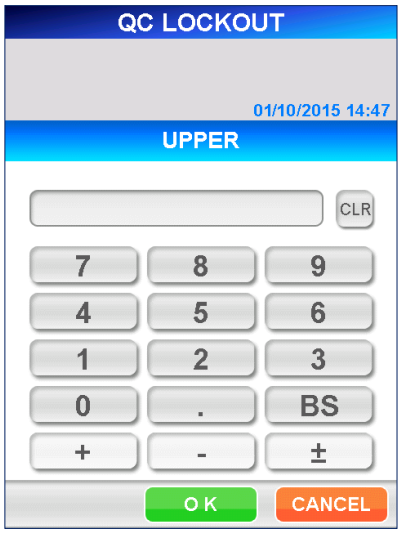
Note: Days and hours are not allowed to be set simultaneously.
The number displayed in reverse is effective.

QC LEVEL

Select QCs to be checked against the function.

Upper Limit/Lower Limit

Select each box to display the numeric keypad and input limit value.



[Numeric Keypad]

● Range : -999999.999 – 999999.999

Note: Make sure the Upper is equal or larger than the lower value.
These values are used for controlling the graph scale of QC Chart.

4. Select OK to store the input data and go back to [SETUP] screen.

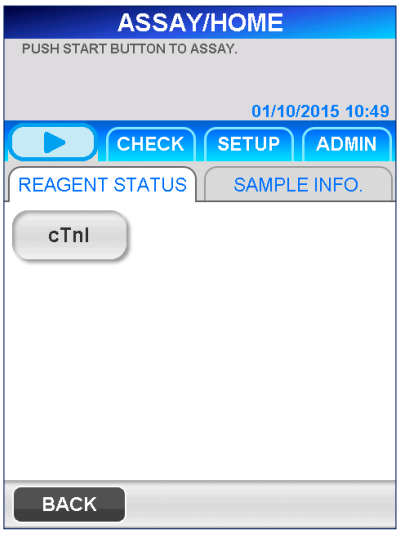
5.9 Shut Down Procedure

Strictly follow this procedure when you want to shut the power off.

> *Caution : Shutting the power off without following this procedure can result in loss of data and/or instrument malfunctions.*

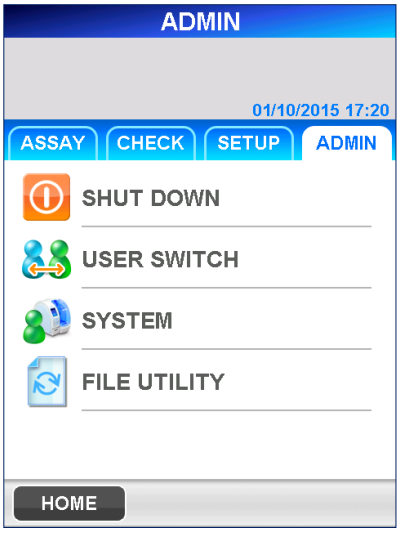
1. Select [ADMIN] on those screens where you see selection buttons, such as [ASSAY], [CHECK], [SETUP] and [ADMIN] in sub-title area.

SAMPLE/HOME



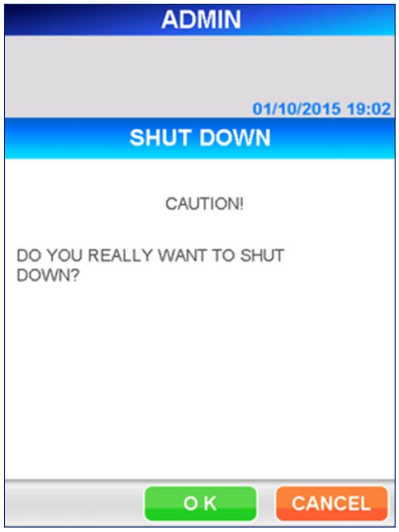
2. Then select [SHUT DOWN] from the [ADMIN] screen and follow the messages displayed on the screen.

ADMIN



3. The following message is displayed to confirm the shut down operation.

SHUT DOWN 1

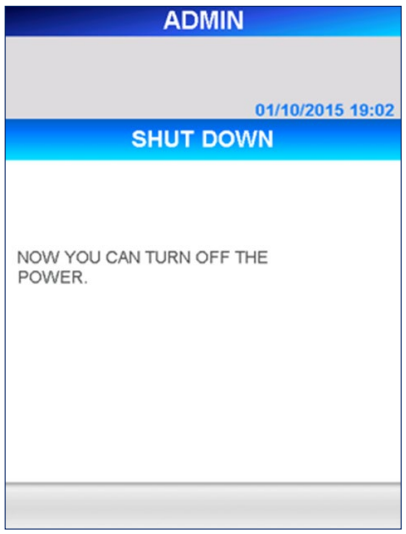


4. Select [OK] to shut the instrument power down.
   - ■ If you want to continue instrument operation, select [CANCEL] to go back to [ADMIN] screen.

5. Wait until "NOW YOU CAN TURN OFF THE POWER" is shown on the screen before turning the power switch off.

⚠ **Do not turn the device power off before "NOW YOU CAN TURN OFF THE POWER." is displayed.**

SHUT DOWN 2



6 Patient Sample Assay (Access Level: 1 and Above)

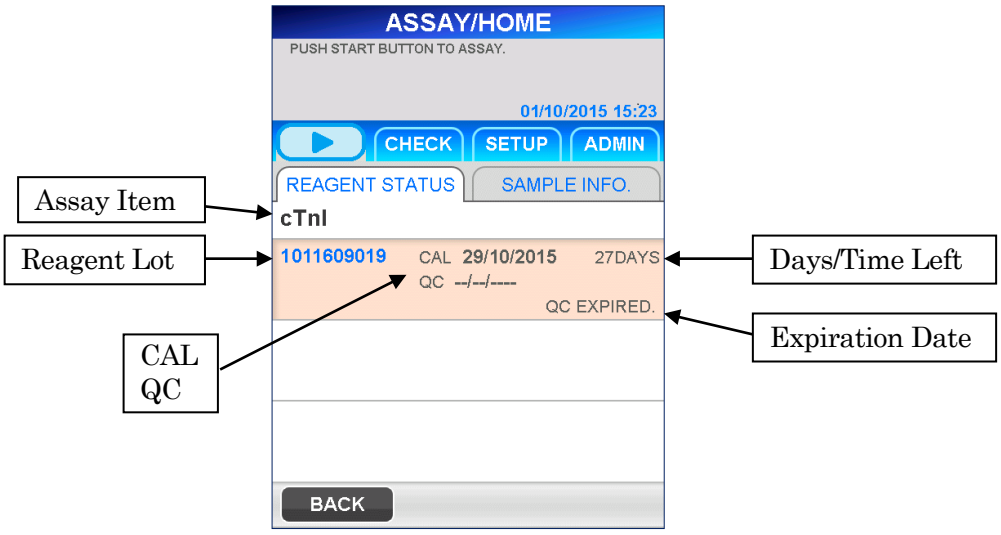
This chapter provides the procedure for running assays on patient samples.

6.1 Checking validity of calibration and QC

1. This section details how to check the assay name, lot number, and expiration date of the reagent cartridges to be used. The reagent cartridge lot number and expiration date can be found on the reagent cartridge, cartridge tray or MC ENTRY CARD. PATHFAST will not run an assay with expired reagent cartridges.

2. Check if the calibration and QC data are valid on the [CAL/QC STATUS] screen by selecting the assay name on the [ASSAY/HOME] screen.
   - ■ When QC Lockout is OFF, checking for QC is not required

CAL/QC STATUS



Note: Exp. Date of QC is not shown when QC Lockout is OFF.

Checking Validity of CAL & QC:

1 . Assay item and the lot are registered.
2 . CAL date is shown and not expired
3 . QC date is shown and not expired.

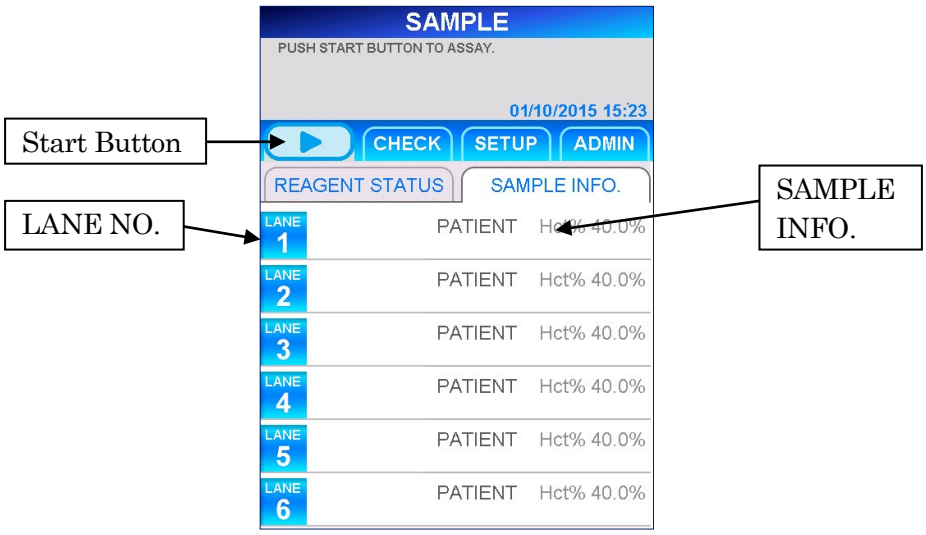
- ■ When QC Lockout is OFF, QC date is not shown.

6.2 Editing Sample Information

Follow the procedure below to input sample information.

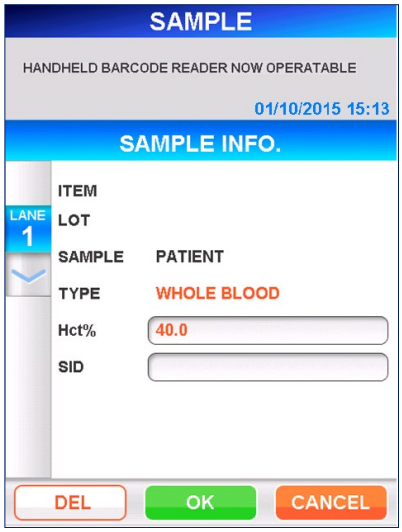
1. Select SAMPLE INFO. on the [ASSAY/HOME] screen to get to the following screen.

SAMPLE INFORMATION 1



2. Select LANE NO. to input sample information on the lane. The following [EDIT INFORMATION] screen is then displayed.

EDIT INFORMATION



Note: The assay item and lot are read by PATHFAST and displayed after the assay run is started.

3. The editable sample information is hematocrit value (Hct%) and Sample ID. Selecting the display box will popup the keyboard for input.

Hct%

Input the individual hematocrit value of the analyzed whole blood sample

to correct the assay result obtained. If no value is entered, the default value is used for the correction.

- **Range : 0.000 – 60.0 (default value is 40.0)**

The value is hidden when the sample is recognized as non whole blood by the Sample Recognition Sensor.

SID

Input SID of the sample

- **Length : 1 – 20 characters from Full Keyboard.**

Read sample barcode using the handheld barcode reader or input manually through the full keyboard.

[Reading by Handheld Barcode Reader]

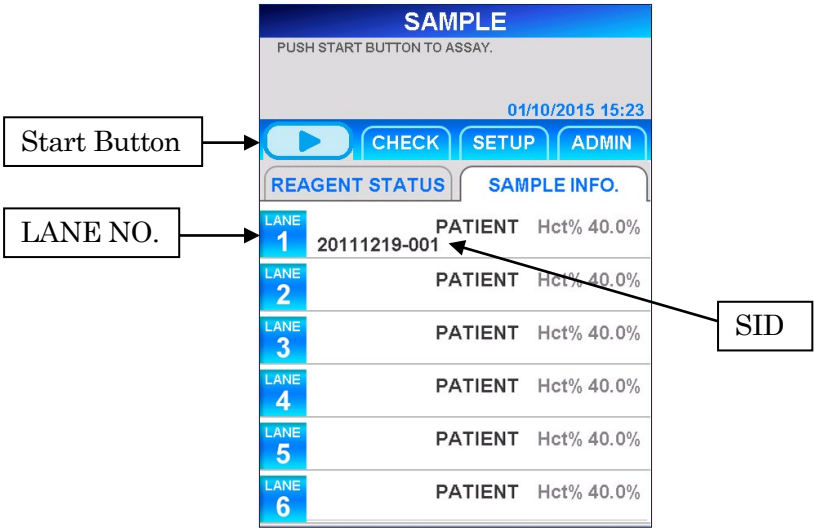
[Full Keyboard]

4. Once Hct% and/or the SID is entered, select OK to store the data and go back to the [SAMPLE INFORMATION] screen.

5. Repeat steps 2 to 4 for the other samples.

6. When all sample information has been entered, check the displayed information on the [SAMPLE INFORMATION 2] screen for correctness.

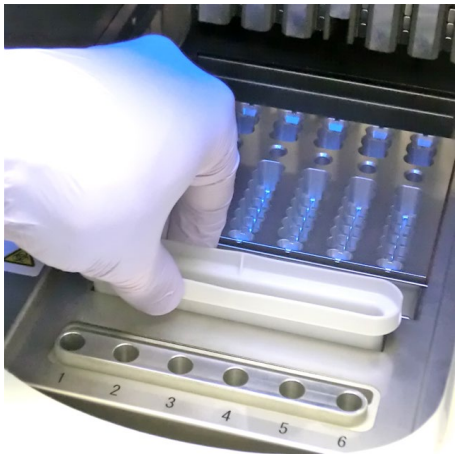
SAMPLE INFORMATION 2



6.3 Preparation of Instrument and Samples

6.3.1 Setting Tip Waste Box (PATHFAST WASTE BOX)

Before preparing samples and reagent, check if there are any used tips left in the tip waste box.
If necessary, remove the box and discard the used tips. Reset the waste box.
Note: Replace the tip waste box every 20 batch runs or weekly.



[Setting Tip Waste Box]

6.3.2 Sample preparation

Sample types (whole blood, plasma, or serum), anti-coagulants, and sample volume are assay dependent. Refer to the package insert of the appropriate reagent for details.
Follow the universal precaution instructions when collecting and handling samples.

6.3.3 Preparing Reagent Cartridges and Setting to PATHFAST

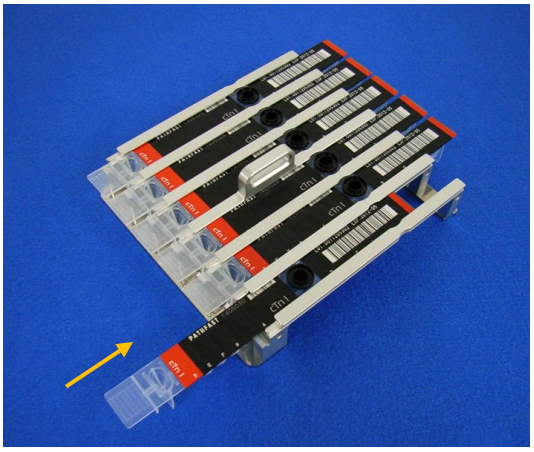
In preparing reagent cartridges for assay runs, follow the precaution instructions below.

- Wear appropriate personal protective equipment to prevent exposure from reagents or sample.
- Run assays soon after taking the reagent cartridges from refrigerator. Do not leave reagent cartridges unrefrigerated for extended period of time.
- Follow the precaution instructions described in the applicable package inserts.

1. Take reagent cartridges out of the refrigerator. Insert reagent cartridges needed in the slots of reagent cartridge rack and push them firmly into place.

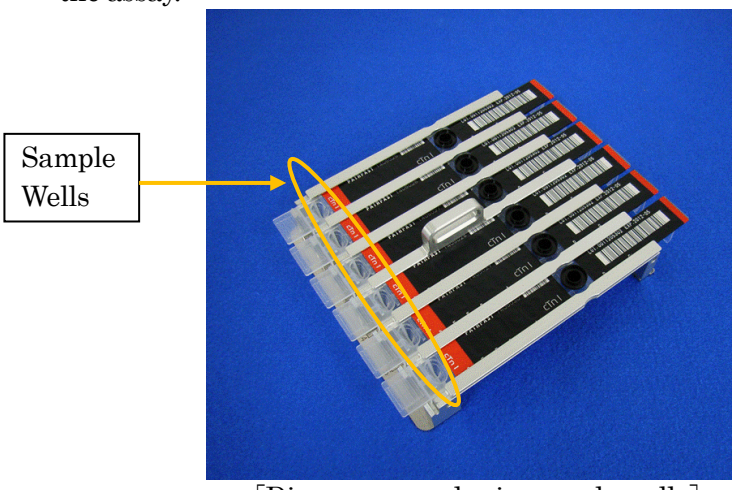
The following precautions should be taken for this procedure. Failure to comply may cause erroneous results.

- When handling the reagent cartridge, hold it by the edge. Avoid touching the aluminum seal and detection well.
- Be careful not to introduce saliva into the detection well by blowing into the well.
- Do not use reagent cartridges that have been dropped on the floor.
- Before testing, remove any bubbles in wells of reagent cartridge or liquid on the aluminum seal inside by softly tapping the cartridge on a flat surface.



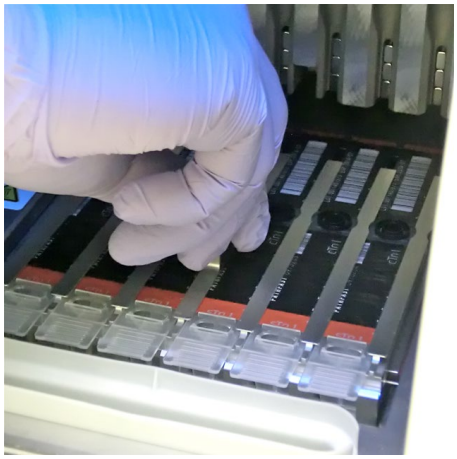
[Inserting Reagent Cartridge in Reagent Cartridge Rack]

2. Dispense sample into the sample well of reagent cartridge, filling to the line inside the well using pipette or dropper. Remove any bubbles before running the assay.



[Dispense samples in sample wells]

3. Open the front cover of the instrument and set the reagent cartridge rack properly into place.



[Set Reagent Cartridge Rack]

6.3.4 Setting Disposable Tips (PATHFAST TIP)

Use the designated disposable tips with PATHFAST.

[PATHFAST TIP]

1. Remove new tips from the tip box and set them into the tip holder holes of PATHFAST for the lanes in which reagent cartridges are set. Be careful that the tip ends are not dirty or damaged.

[Setting PATHFAST TIPs]

2. When finished setting disposable tips on tip holder, close the front cover completely.

[Close Front Cover]

6.4 Starting Assay Run and Assay Completion

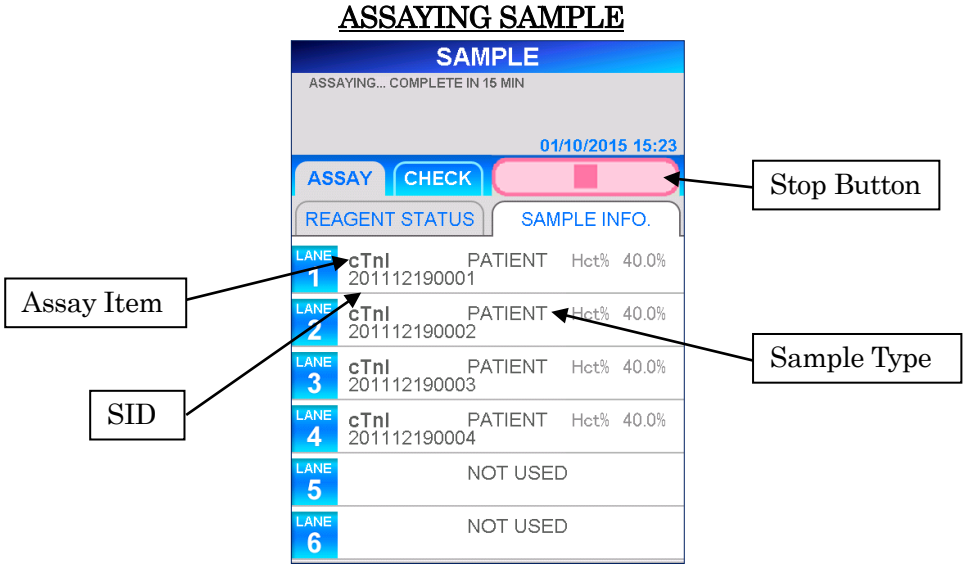
6.4.1 Starting Assay Run

1. Push the "  " button in the Subtitle Area of the screen to begin the assay run.

> *Note:*
> - *Start the assay run promptly when assay preparation is completed.*
> - *Precipitation of blood cells in a whole blood sample or sample evaporation may affect the result obtained.*

Before starting the actual assay, PATHFAST performs several checks.
An error message will be displayed if any abnormal condition is found.
Stay near the instrument so that, if necessary, you may take the appropriate actions according to the message displayed. Refer to Chapter **14 Troubleshooting** for further information on error messages.

2. The following screen is shown during assay operation.



- After the assay is started, PATHFAST checks reagent cartridges, assay item and type of sample (whole blood or other) for each lane in order to display the information on the screen above. If the sample is not recognized as whole blood, Hct% is not shown for that sample.
- Push "  " button in the Subtitle area of the screen to stop the assay continuing. A confirmation message will be displayed.

3. Sample information can be edited after you start an assay run.
Select LANE NO. on the [SAMPLE INFORMATION] screen and follow steps 2 to 6 of Section **6.2 Editing Sample Information**.

Note: Be sure to finish editing sample information before the assay run completes. If you keep the [EDIT INFORMATION] screen displayed, the measured results are not printed. The instrument gives you a message asking if you want to continue editing information or not. Follow the instructions displayed.

6.4.2 Result Output

When the assay run is completed, the measured results are printed on the built-in printer and the [ASSAY/HOME] screen is displayed.

Note: If the instrument is set to send the results to an external computer (LIS), the results are sent to the external computer before printing.

The following is a sample print out.

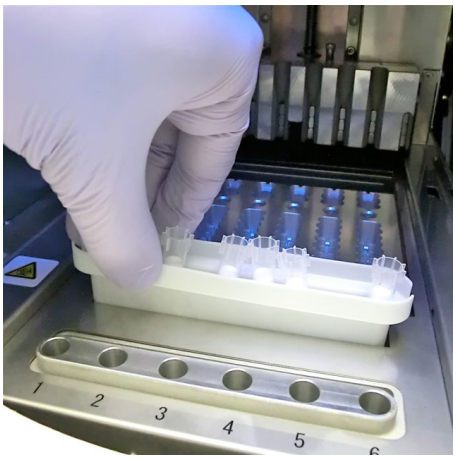
Printed Data	Description

DATE:10/01/2022 15:40	←Time Assay Started
SAMPLE ID:202201100001	←ID of Sample
LANE: 1	←LANE No.
cTnI	←Assay Item,
0.123 ng/mL	←Result with Unit
REMARK:DF	←Remarks Separated by comma
TYPE: WB (40.0 %)	←Whole Blood, Hct% Value
SAMPLE: PATIENT	←Sample (Patient)
INSTRUMENT SERIAL: 1511D2600	←Instrument Serial Number
PROGRAM VERSION: 4.1.1	←Program Version
OPERATOR ID: USER1	←User ID
REAGENT LOT: 1012210243	←Reagent Lot No.
CALIBRATED ON: 04/01/2022	←Date of Calibration

6.4.3 Discarding Used Reagent Cartridges and Tips

1. Discarding used tips:
   Remove the tip waste box from the instrument and discard the used tips following regional guideline for handling.

   After discarding tips return the tip waste box back to its position.
   Note: Replace the tip waste box every 20 batch runs or weekly.



[Tip Waste Box]

2. Discarding used reagent cartridges:
   Take the reagent cartridge rack out of the instrument and remove the used cartridges. Be careful not to drop or splash liquid from the cartridges. Refer to regional guidelines when discarding the reagent cartridges.

7 QC Assay (Access Level: 2 and Above)

In this chapter the procedure for QC (Quality Control) Assay is described.

7.1 Introduction

Prepare to run assays following instructions outlined in Chapter **5 Preparation for Assay and Basic Operation**, then perform QC following the procedure described below.

Note: While running QC, you cannot receive order information from an external computer.

7.2 Purpose of QC Assay

A QC assay is performed to check the validated calibration curves and store data from QC samples for quality control. A QC assay is indispensable for ensuring validity of sample results.

7.3 Overview of QC Assay

A QC (Quality Control) sample is a sample specially prepared for the purpose of quality control. Ask your PATHFAST representative for recommended quality control material.

1) Number of levels of QC

We recommend testing a minimum of 2 levels.

2) When to assay QC

1. When the QC designated period has expired (if QC Lockout function is set to ON).
2. After a calibration assay is performed.
3. At a frequency defined by the user.
4. When erroneous sample results are suspected.
5. After maintenance is done for optical/dispensing systems.
6. When needed for quality control.

3) Effective period of QC data

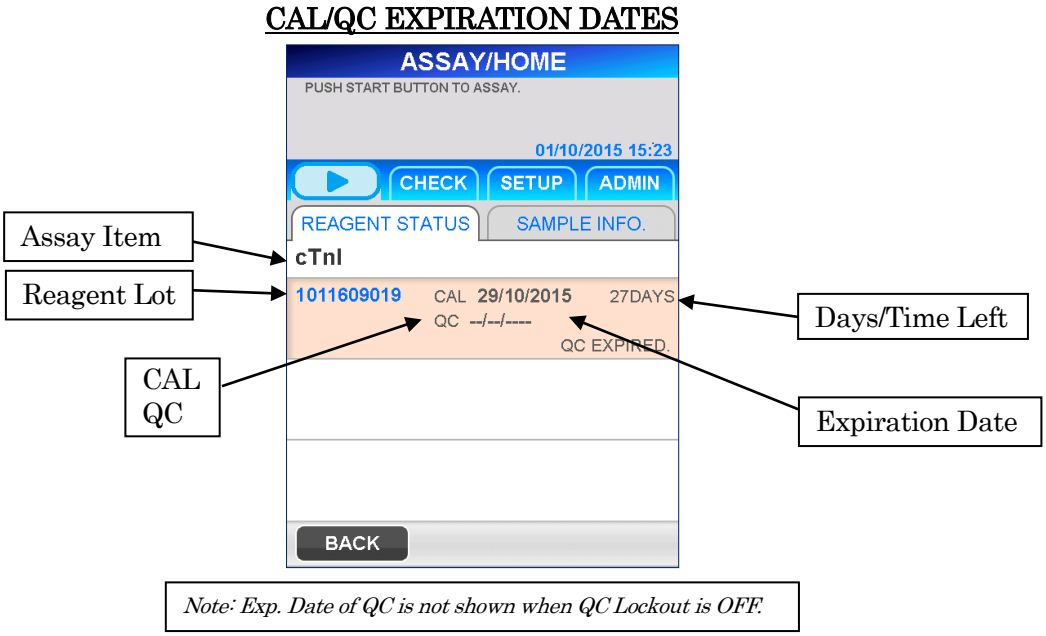
Define the effective period of QC data for your laboratory. The QC lockout function is useful for checking if the period is expired or not. Refer to **1.3 About QC Lockout Function** for details.

7.4 Preparing for QC Assay

7.4.1 Checking Validity of Calibration

1. Check the assay name, lot number and expiration date of the reagent cartridges to be used. The lot number can be found on the reagent cartridge, cartridge tray or MC entry card. Expired reagents can not be used for an assay run.

2. Check if the calibration data for the reagent cartridges is valid for running QC assay on the [CAL/QC EXPIRATION DATES] screen, by selecting the assay item on the [ASSAY/HOME] screen.



Note: Exp. Date of QC is not shown when QC Lockout is OFF.

＜Checking Validity of CAL & QC＞

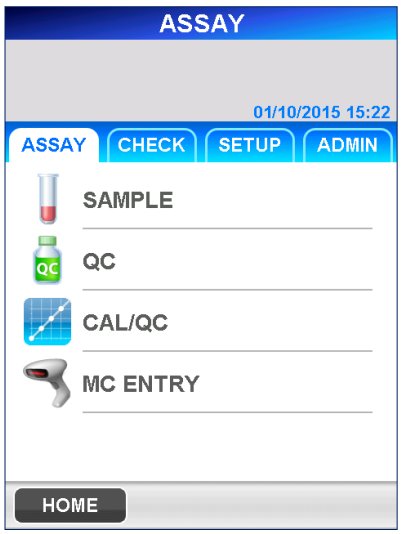
1 . Assay item and the lot are registered.
2 . CAL date is shown and not expired

■ When QC Lockout is OFF, QC date is not shown.

7.4.2 Editing QC Information

1. Select [BACK] on the [ASSAY/HOME] screen or the [ASSAY] button in the sub-title area to get the following [ASSAY] screen.

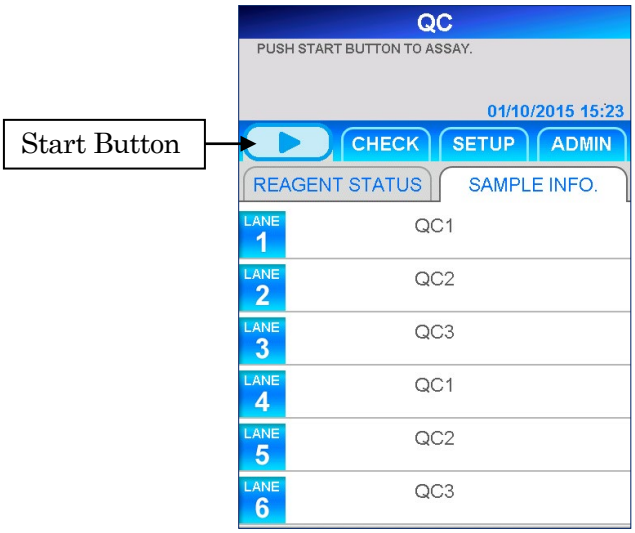
ASSAY



Note: When QC Lockout function is deactivated, the buttons above are changed as follows:
[QC] => [QC/SAMPLE] , [CAL/QC] => [CAL/QC/SAMPLE]

2. Select [QC] on the [ASSAY] screen to navigate to the following screen.

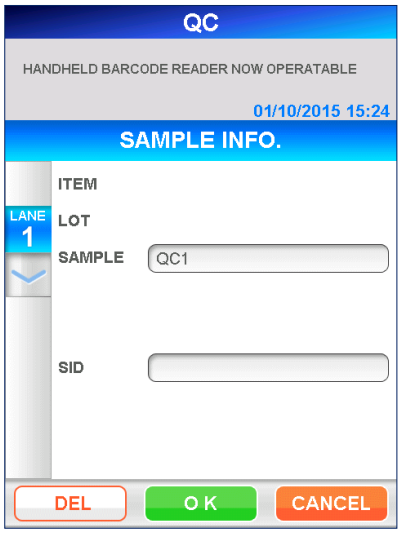
QC INFORMATION



Note: When QC Lockout function is deactivated, title is shown as " QC/SAMPLE *".*

3. On the [QC INFORMATION] screen, positions for each QC sample are pre-defined as shown above. Edit the information for each lane, as needed. To edit, select the lane number to go to the following screen.

EDIT QC INFORMATION



SAMPLE

Select the sample in the list shown by selecting the box .
Select one from QC1, QC2, QC3.

- When QC lockout function is deactivated, PATIENT sample is also allowed.

SID

Input SID of QC sample or patient sample.

- **Length : 1 – 20 characters**

Read the sample barcode using the handheld barcode reader or input manually through the displayed keyboard.

[Reading by Handheld Barcode Reader]

[Full Keyboard]

4. When finished editing, select OK on [EDIT QC INFORMATION] screen to go back to [QC INFORMATION] screen.

5. Repeat steps 3 and 4 for other lanes as needed.

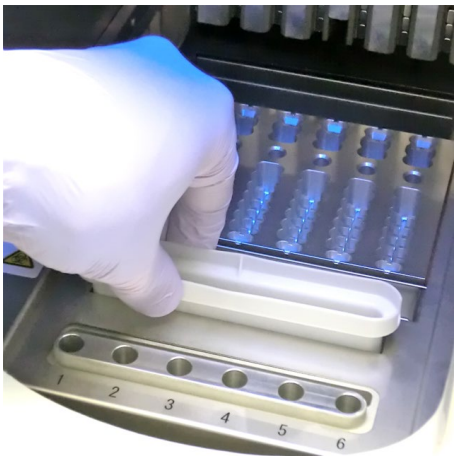
6. Re-check all the information edited in the [QC INFORMATION] screen.

7.5 Preparation of Instrument and QC Samples

7.5.1 Setting Tip Waste Box (PATHFAST WASTE BOX)

Before preparing samples and reagent, check if there are any used tips left in the tip waste box. If necessary, remove the box and discard the used tips. Reset the waste box.

Note: Replace the tip waste box every 20 batch runs or weekly.



[Setting Tip Waste Box]

7.5.2 Preparing QC Samples

Follow the common precaution instructions for handling QC samples.

7.5.3 Preparing Reagent Cartridges and Setting to PATHFAST

In preparing reagent cartridges for assay runs, follow the precaution instructions below:

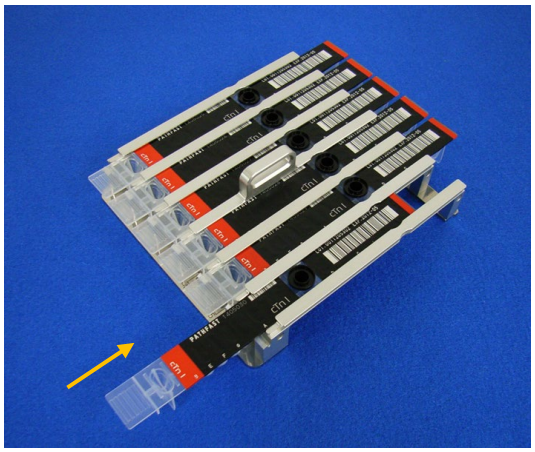
- Wear appropriate personal protective equipment to prevent exposure from reagents or sample.
- Run assays soon after taking the reagent cartridges from refrigerator. Do not leave reagent cartridges unrefrigerated for extended period of time.
- Follow the precaution instructions described in the applicable package inserts.

1. Take reagent cartridges out of the refrigerator. Insert reagent cartridges needed in the slots of reagent cartridge rack and push them firmly into place.

The following precautions should be taken to avoid erroneous results:

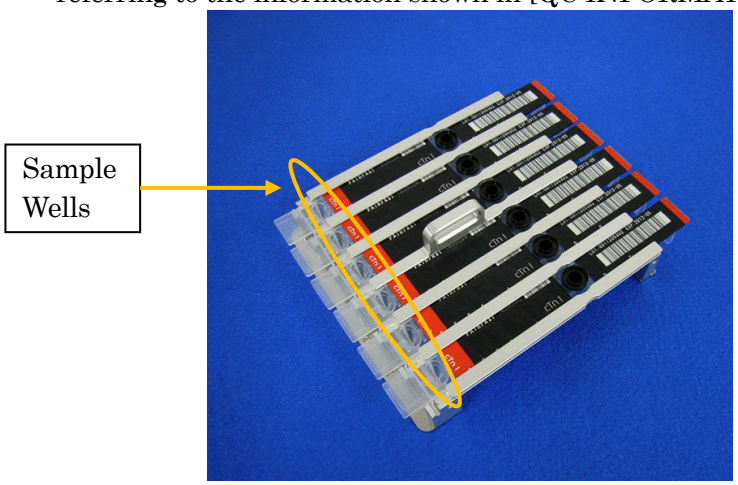
- When handling the reagent cartridge, hold it by the edge and avoid touching the aluminum seal and detection well.
- Be careful not to introduce saliva into the detection well by blowing into the well.
- Do not use reagent cartridges that have been dropped on the floor.

- Before testing, remove any bubbles in the wells of reagent cartridge or liquid on the aluminum seal inside, by softly tapping the cartridge on a flat surface.



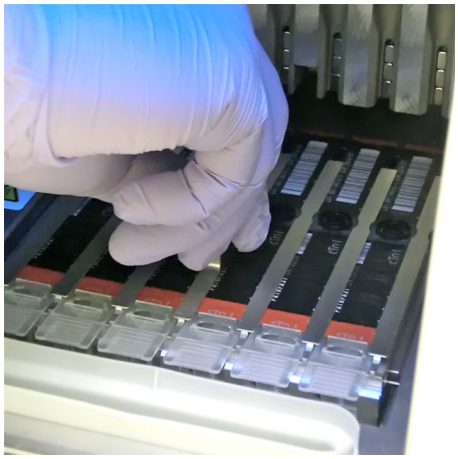
[Inserting Reagent Cartridge in Reagent Cartridge Rack]

2. Dispense QC sample into the sample well of reagent cartridge up to the line inside the well using pipette or dropper. Remove any bubbles before running the assay. Also take care that the correct QC material is put in each well, referring to the information shown in [QC INFORMATION] screen.



[Dispense QC samples in Sample Wells]

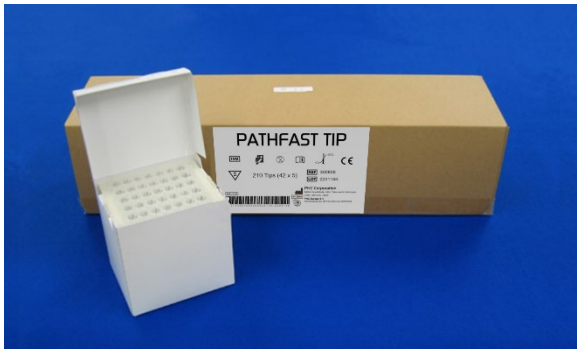
3. Open the front cover of the instrument and set the reagent cartridge rack properly into place.



[Set Reagent Cartridge Rack]

7.5.4 Setting Disposable Tips (PATHFAST TIP)

Use the designated disposable tips with PATHFAST.



[PATHFAST TIP]

1. Remove new tips from the tip box and set them into the tip holder holes for lanes in which reagent cartridges are set. Be careful that the tip ends are not dirty or damaged.

[Setting PATHFAST TIPs]

2. When finished inserting the tips in the holder, close the front cover completely.

[Close Front Cover]

7.6 Starting QC Assay Run and Assay Completion

7.6.1 Starting QC Assay Run

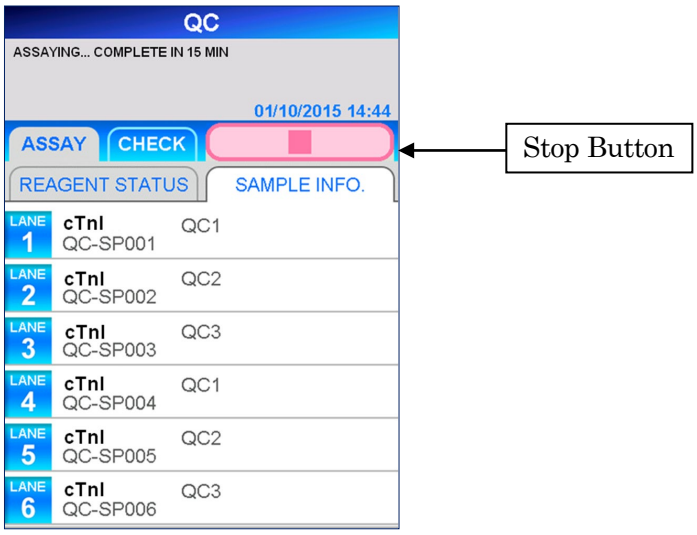
1. Push "  " button in the Subtitle Area of the screen to begin the assay run.

> *Note:*
> - *Start the assay run promptly when assay preparation is completed.*
> - *Precipitation of blood cells in a whole blood sample or sample evaporation may affect the result obtained.*

Before starting the actual assay, PATHFAST completes various checks. An error message will be displayed if any abnormal condition is found. Stay near the instrument so that, if necessary, you may take the appropriate actions according to the message displayed. Refer to Chapter **14 Troubleshooting** for further information on error messages.

2. The following screen is shown during assay operation.

ASSAYING QC SAMPLE



Note: When QC Lockout function is deactivated, title is shown as QC/SAMPLE.

■ When canceling QC assay after it has started, select the "  " button in the Subtitle area of the screen. A confirmation message is displayed.

3. Sample information can be edited after you started an assay run. Select LANE NO. on the [QC INFORMATION] screen and follow steps 2 to 4 of Section **7.4.2 Editing QC Information**.

> *Note: Finish editing QC information before the assay run completes. If you keep the [EDIT QC INFORMATION] screen open, the measured results are not printed. The instrument gives you a message asking if you want to continue editing information or not. Follow the instruction displayed.*

7.6.2 QC Result Output

When the assay run is completed, the measured results are printed on the built-in printer, and the [QC INFORMATION] screen is displayed.

The following is sample print out for duplicate assay of QC1 for cTnI.

Printed Data	Description

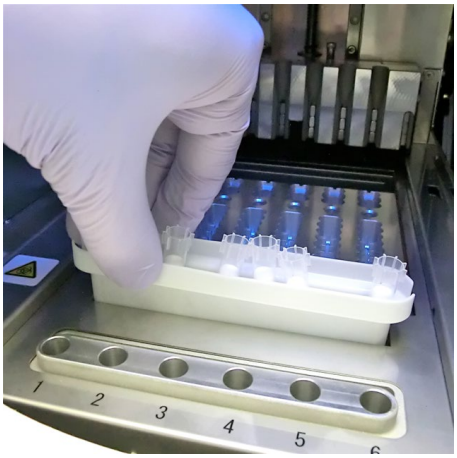
DATE:10/01/2022 15:40	←Time Assay Started
SAMPLE ID:	←ID of Sample
LANE: 1	←Lane No.
cTnI	←Assay Item
0.132 ng/mL	←Result with Unit
REMARK:	←Remarks Separated by comma
SAMPLE: QC1	←Sample (QC1)
INSTRUMENT SERIAL: 1511D2600	←Instrument Serial Number
PROGRAM VERSION: 4.1.1	←Program Version
OPERATOR ID: USER1	←User ID
REAGENT LOT: 1012210243	←Reagent Lot No.
CALIBRATED ON: :04/01/2022	←Date of Calibration

DATE: :10/01/20122 15:40	
SAMPLE ID:	
LANE: 2	
cTnI	
0.138 ng/mL	
REMARK:	
SAMPLE: QC1	
INSTRUMENT SERIAL: 1511D2600	
PROGRAM VERSION: 4.1.1	
OPERATOR ID: USER1	
REAGENT LOT: 1012210243	
CALIBRATED ON: 04/01/2022	

----------	Statistics for duplicate assay of QC1.
DATE: 10/01/2022 15:40	
INSTRUMENT SERIAL: 1511D2600	
OPERATOR ID: USER1	
REAGENT LOT: 1012210243	←Reagent Lot Number
cTnI	←Assay Item
QC1	←Sample (QC1)
UPPER: 0.138 ng/mL	←Upper Limit of Control
LOWER: 0.132 ng/mL	←Lower Limit of Control
N = 2	←Replicates
MEAN = 0.135 ng/mL	←Average
SD = 0.004	←Standard Deviation
CV = 3.14 %	←Coefficient of Variation

7.6.3 Discarding Used Reagent Cartridges and Tips

1. Discarding used tips:
   Remove the tip waste box from the instrument and discard the used tips.
   Follow regional guidelines for handling when discarding used tips.
   After discarding tips return the tip waste box back to its position.
   Note: Replace the tip waste box every 20 batch runs or weekly.



[Tip Waste Box]

2. Discarding used reagent cartridges:
   Take the reagent cartridge rack out of the instrument and remove the used cartridges. Be careful not to drop or splash liquid from the cartridges. Refer to the regional guidelines when discarding reagent cartridges.

8 CAL Assay (Access Level: 3 and Above)

The procedure for the calibration assay is described in this chapter.

8.1 Introduction

After preparing to run an assay, referring to Chapter **5 Preparation for Assay and Basic Operation**, perform a calibration assay following the procedure described below.

8.2 Purpose of Calibration

To ensure reliable results, calibration assays are performed to validate the calibration curve prior to assaying patient samples. Perform this calibration procedure with each new lot of reagents or when calibration is expired. The effective period of calibration is pre-defined for each assay item.
Assaying patient samples or QC is not allowed if the calibration has expired, however, they may be run with calibrators in the same batch.

8.3 Overview of Calibration

1) Calibrators (CAL)
   Use the recommended calibrator (normally packed with the reagent kit).
   Freeze-dried calibrators must be reconstituted with a dilution buffer (provided with calibrator where necessary) prior to use.
2) Levels of CAL
   Levels of calibrators may differ by reagent. Refer to the package insert of the applicable reagent kit for details.
3) Replication of CAL
   Run calibrators in duplicate (n=2). (n=3 is also available).
4) When to calibrate
   1. Introducing new assay item
   2. Reagent lot is changed
   3. Calibration is expired.
      If you do not run calibration assays in the above cases, the sample or QC assay run is stopped and an error message appears after the run is started.
   4. QC result(s) is out of the control range.
   5. Using newly purchased reagents though the lot numbers are same.
   6. After maintaining optical/dispenser system.
      In these three cases above (from 4 to 6) sample or QC assay run is not stopped if you do not perform calibration assay, but we recommend calibration assay to verify the reliability of the assay results.
5) Effective period of calibration

The effective period of calibration may differ from item to item. Refer to the applicable reagent kit package inserts for details.

6) Number of effective calibrations:

Three lots of effective calibrations per assay can be stored.

7) Please note:

1. Calibration assay shall be performed for one assay item of one lot of reagent in a batch.
2. Run calibration assay with replication of 2 or 3. Set the calibrators as indicated on the screen. Positions where calibration material is set is predefined.
3. Input barcode information from the MC ENTRY CARD included with the reagent kit when running a new assay item or new lot of reagent. Follow the procedure described in **8.8 MC ENTRY**.

8) Validity check of calibration

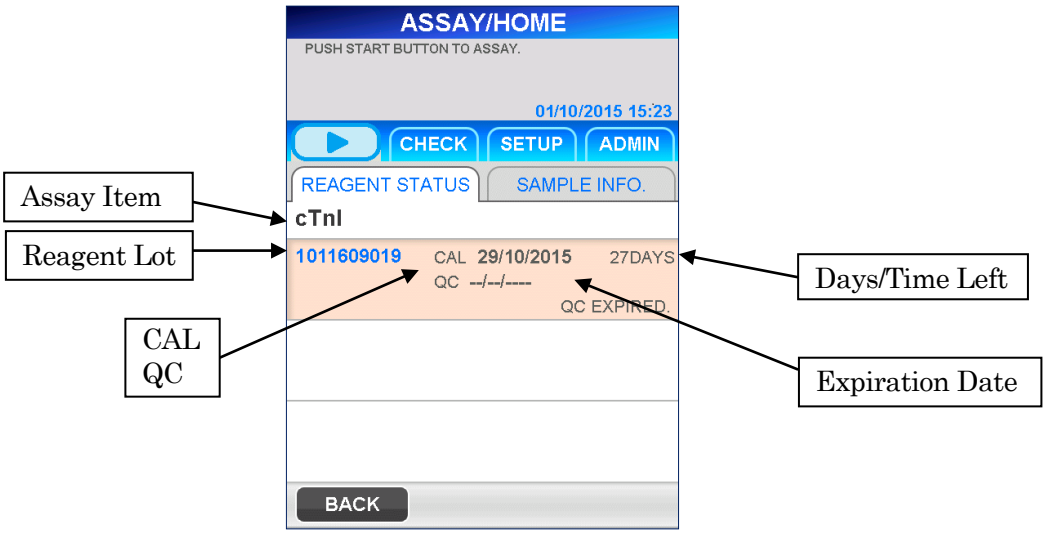
Validity of the calibration is confirmed by within-range QC assay results. Refer to Section **1.3 About QC Lockout Function** for details about the QC Lockout Function, and Chapter **7 QC Assay** for the QC assay procedure.

8.4 Checking Calibration Status

Verify that the master calibration (MC) data for the reagent being used is registered in PATHFAST prior to running a calibration assay.

1. Select the assay name to be checked on the [ASSAY/HOME] screen to show the following [CAL/QC STATUS] screen.

CAL/QC STATUS

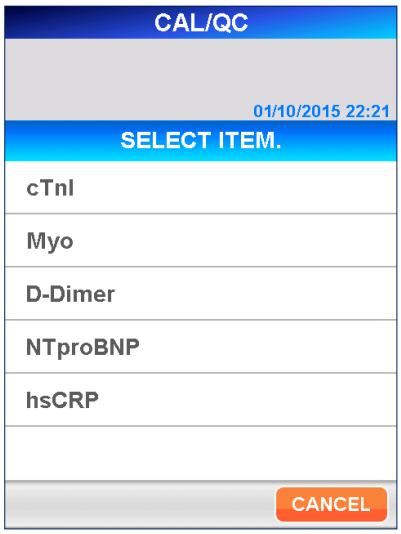


2. Check if the master calibration (MC) data is registered in PATHFAST, by checking if the lot number is shown on the [CAL/QC STATUS] screen.
   If the lot number is not shown, you will need to register the master calibration (MC) data prior to running the calibration assay. Refer to **8.8 MC ENTRY** for the detailed procedure.

8.5 Preparing Reagent Cartridges and Setting onto PATHFAST

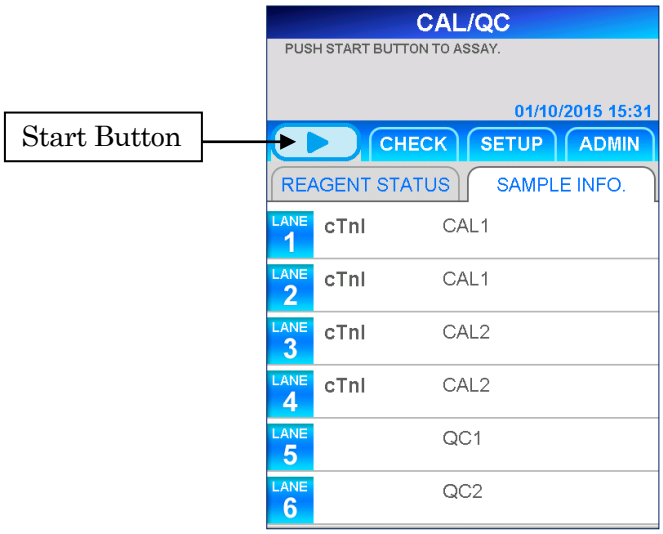
1. Select CAL/QC on the [ASSAY] screen to go to the following screen. Select the assay item to be calibrated from the list shown. Then select OK to go to the next screen.
2. In the [CAL ITEM SELECTION] screens, there is no item name at the time of shipment. Only names of items that have been read from [MC ENTRY CARD] on the [MC ENTRY] screen are listed.

CAL ITEM SELECTION



3. After selecting the assay item to be calibrated, the [CAL/QC INFORMATION] screen is displayed.

CAL/QC INFORMATION



■ The information shown in each lane varies depending on the predefined conditions of QC Lockout and replication of calibrators. Refer to the table below.

Positions to set samples depending on QC Lockout/CAL Levels/ CAL Replicates

	CAL/QC ASSAY (QC Lockout ON)				CAL/QC/SAMPLE ASSAY (QC Lockout OFF)			
CAL Levels	1	1	2	2	1	1	2	2
CAL Replicates	2	3	2	3	2	3	2	3
LANE1	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1
LANE2	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1	CAL1
LANE3	QC1	CAL1	CAL2	CAL1	QC1	CAL1	CAL2	CAL1
LANE4	QC2	QC1	CAL2	CAL2	QC2	QC1	CAL2	CAL2
LANE5	QC3	QC2	QC1	CAL2	QC3	QC2	QC1	CAL2
LANE6	QC1	QC3	QC2	CAL2	PATIENT	QC3	QC2	CAL2
Options	QC1,2,3	QC1,2,3	QC1,2,3	None	PATIENT	PATIENT	PATIENT	None

: Reserved by the software. Not allowed to edit. Be sure to set the designated samples for those lanes.

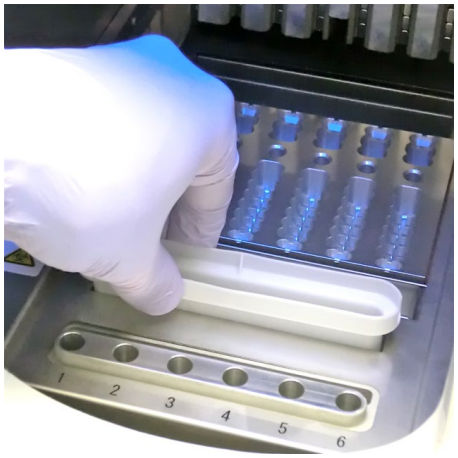
: Not reserved, allowed to edit.

8.6 Preparation of Instrument and Calibrators

8.6.1 Setting Tip Waste Box (PATHFAST WASTE BOX)

Before preparing samples and reagent, check if there are any used tips left in the tip waste box. If necessary, remove the box and discard the used tips. Reset the waste box.

Note: Replace the tip waste box every 20 batch runs or weekly.



[Setting Tip Waste Box]

8.6.2 Preparing Calibrators

Calibrators (CAL) are supplied with reagent kit.
Refer to the reagent kit package inserts for details on handling calibrators.

8.6.3 Preparing Reagent Cartridges and Setting to PATHFAST

In preparing reagent cartridges for assay runs, follow the precaution instructions below.

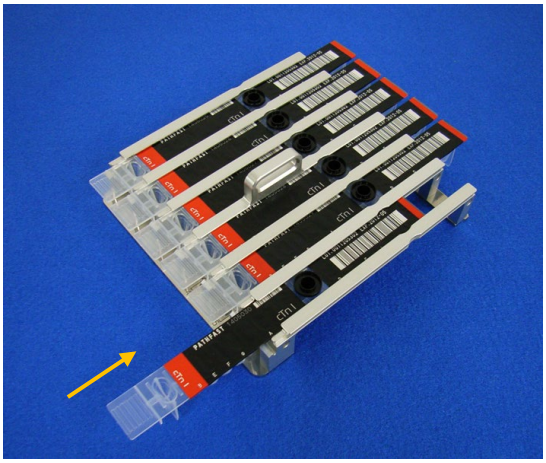
- Wear appropriate personal protective equipment to prevent exposure from reagents or sample.
- Run assays soon after taking the reagent cartridges from refrigerator. Do not leave reagent cartridges unrefrigerated for extended period of time.
- Follow the precaution instructions described in the applicable package insert.

1. Take reagent cartridges out of the refrigerator. Insert reagent cartridges needed in the slots of the reagent cartridge rack and push them firmly into place.

The following precautions should be taken to avoid erroneous results.

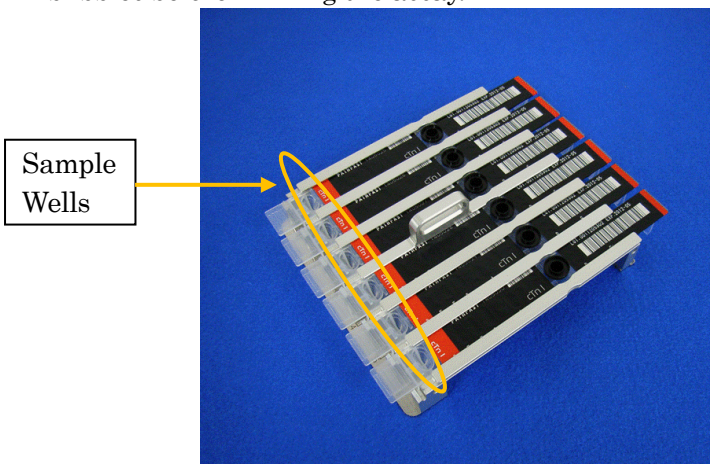
- When handling reagent cartridge, hold it by the cartridge edge. Avoid touching the aluminum seal and detection well.
- Be careful not to introduce saliva into the detection well by blowing into the well.
- Do not use reagent cartridges that have been dropped on the floor.
- Before testing, remove any bubbles in the wells of reagent cartridge or liquid on the aluminum seal inside, by softly tapping the cartridge on a flat surface.

2. On the [CAL/QC INFORMATION] screen with CAL replicate of 2, lanes 5 and 6 are assigned for QC samples. Refer to the information displayed on the screen to determine into which lanes to dispense samples.



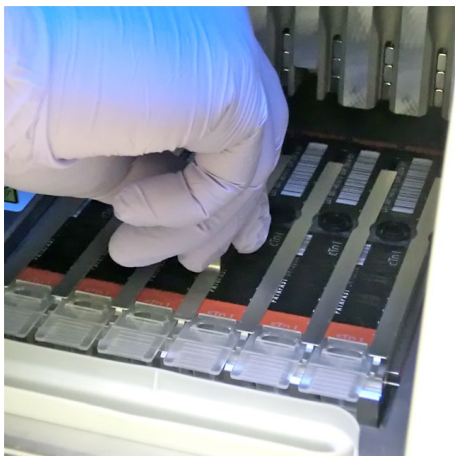
[Inserting Reagent Cartridge in Reagent Cartridge Rack]

3. Dispense calibrators and QC samples into the sample well of the reagent cartridge up to the line inside the well using a pipette or dropper. Remove any bubbles before running the assay.



[Dispense calibrators and QC samples in Sample Wells]

4. Open the front cover of the instrument and set the reagent cartridge rack properly into place.



[Set Reagent Cartridge Rack]

8.6.4 Setting Disposable Tips (PATHFAST TIP)

Use the designated disposable tips with PATHFAST.

[PATHFAST TIP]

1. Remove new disposable tips from the tip box and set them into the tip holder holes of PATHFAST for lanes in which reagent cartridges are set. Be careful that the tip ends are not dirty or damaged.

[Setting PATHFAST TIPs]

2. When finished setting disposable tips in the tip holder, close the front cover completely.

[Close Front Cover]

8.7 Starting CAL/QC Assay Run and Assay Completion

8.7.1 Starting CAL/QC Assay

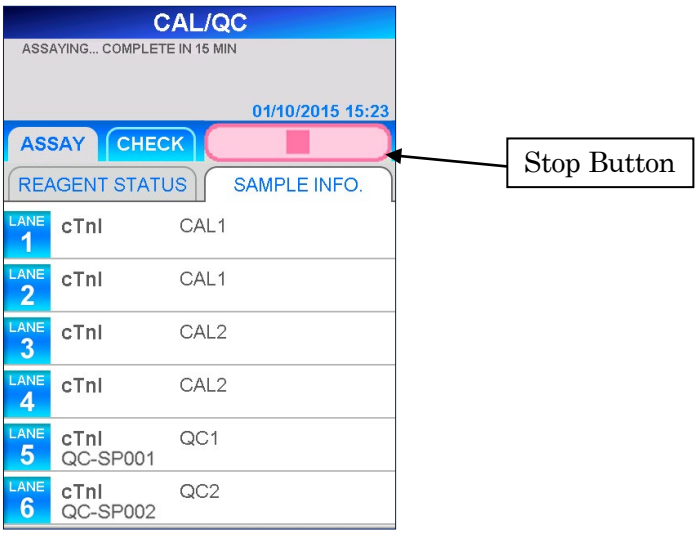
1. Push "  " button in the Subtitle Area of the screen to begin the assay run.

> *Note:*
> - *Start the assay run promptly when assay preparation is completed.*
> - *Precipitation of blood cells in a whole blood sample or sample evaporation may affect the result obtained.*

Before starting the actual assay, PATHFAST completes various checks. An error message will be displayed if any abnormal condition is found. Stay near the instrument so that, if necessary, you may take the appropriate actions according to the message displayed. Refer to Chapter **14 Troubleshooting** for further information on error messages.

2. The following screen is shown during assay operation.

ASSAYING CAL/QC



■ When canceling the QC assay after it has started, select the "  " button in the Subtitle area of the screen. A confirmation message is displayed.

3. When the calibration assay is completed, the calibration data is printed on the built-in printer and the [ASSAY/HOME] screen is displayed. If the calibration fails, the status is displayed on the screen and also printed.

CALIBRATION FAILED

Refer to Chapter **14 Troubleshooting** for action to be taken.

8.7.2 CAL Result Output

When the assay run is completed, the measured results are printed on the built-in printer and the [ASSAY/HOME] screen is displayed.

Note: No calibration data is sent to an external computer even though the instrument is set to send the results.

The following is sample print out for a calibration assay. Refer to **7 QC Assay** for sample print out of QC samples in the same batch.

Note: Calibrators are assayed in duplicate.

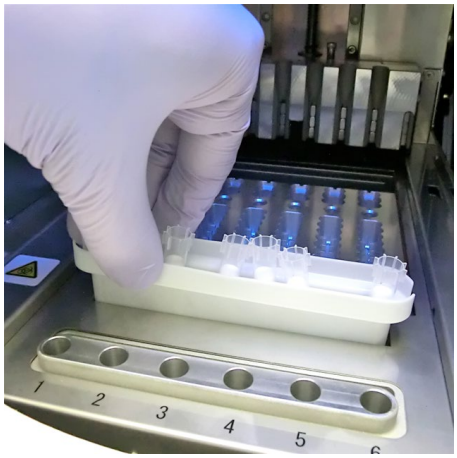
Printed Data	Description

DATE:04/01/2022 14:55	←Time Assay Started
INSTRUMENT SERIAL: 1511D2600	←Instrument Serial Number
PROGRAM VERSION: 4.1.1	←Program Version
OPERATOR ID:USER1	←User ID
cTnI	←Assay Item
REAGENT LOT 1012210243	←Reagent Lot No
CALIBRATION PASSED	←Calibration Status
CAL F: a(1.22) b(15.9)	←CAL Factor a & b
ERROR CODE:	←Error Codes Separated by comma
TYPE: COUNT :REMARK	
CAL1: 319:	←Count of CAL1
CAL1: 223:	←Count of second CAL1
CAL2: 2246851:	←Count of CAL2
CAL2: 2251386:	←Count of second CAL2

DATE: 04/01/2022 14:55	QC Sample
SAMPLE ID:	
LANE: 5	
cTnI	
0.132 ng/mL	
REMARK:	
SAMPLE: QC1	

8.7.3 Discarding Used Reagent Cartridges and Tips

1. Discarding used tips:
   Remove the tip waste box from the instrument and discard the used tips.
   Follow regional guidelines for handling when discarding used tips.
   After discarding tips return the tip waste box back to its position.
   Note: Replace the tip waste box every 20 batch runs or weekly.



[Tip Waste Box]

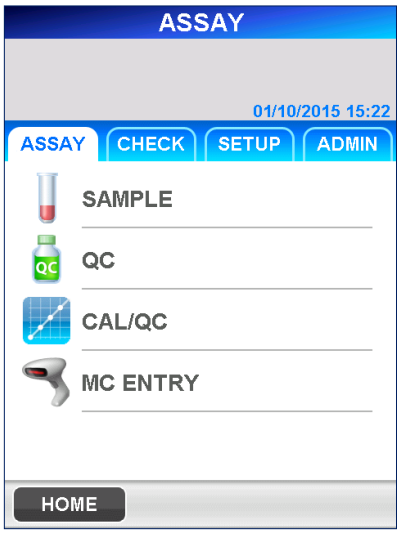
2. Discarding used reagent cartridges:
   Take the reagent cartridge rack out of the instrument and remove the used cartridges. Be careful not to drop or splash liquid from the cartridges. Refer to the regional guidelines when discarding the reagent cartridges.

8.8 MC ENTRY

When you introduce a new assay or use a new lot of a currently used assay, the master calibration (MC) data of the reagent must be registered in the instrument. Follow the procedure described below.

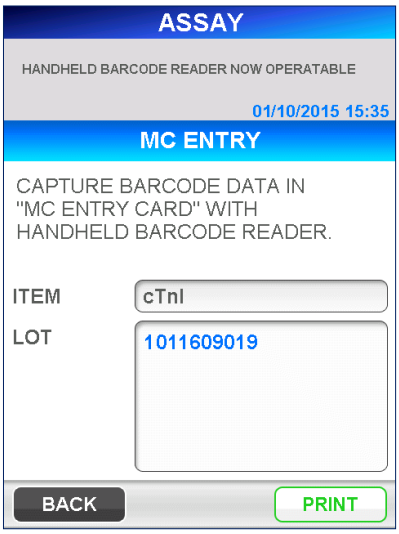
1. Select [ASSAY] on those screens where you see selection buttons, such as [ASSAY], [CHECK], [SETUP] and [ADMIN] in sub-title area.

ASSAY



2. Select [MC ENTRY] to show the following [MC ENTRY] screen.

MC ENTRY



■ To check that the lot's master calibration data has already been registered, select an item from the list shown by selecting display box.

■ To print the list of registered items, select PRINT.

Note) Names of registered items and availability depend on a region.

Printed Data	Description
DATE: 04/01/2022 16:40	←Time to print
INSTRUMENT SERIAL: 1511D2600	←Instrument Serial Number
OPERATOR ID: USER1	←User ID
PROGRAM VERSION: 4. 1. 1	←Program version
Registered item	
1 cTnI 003101	List of Item number, Item name, and Parameter number
2 Myo 911262	
3 CK-MB 911262	
4	
5 D-Dimer 911262	
6 NTproBNP 911262	
7 hsCRP 911263	
8	
9 HCG 805212	
10 cTnI-II 109203	
11 Myo-II 911262	
12 CK-MB-II 911262	
13 HCG preg 003311	
14 LH 003311	
15 FSH 003311	
16 PRL 003311	
17 E2 003101	
18 PROG 912221	
19 TES 103291	
20 P-SEP 011221	
21	
22 PCT 902211	
23 TB LAM 011302	
24 hs-cTnI 709261	

3. Using the hand held barcode reader, scan the barcode on the MC ENTRY CARD packaged in the reagent kit to store the master calibration data in PATHFAST.
   When scanning, hold the barcode reader 10 to 15 cm away from the barcode.

[Read the MC ENTRY CARD]

4. When MC ENTRY CARD is read by the barcode reader, PATHFAST stores the data in its memory, and shows the message of "CAPTURED." along with the assay name, lot number and expiration date.
   - If the information has been previously registered, the message of "MC DATA ALREADY EXIST." along with the assay item, lot number and expiration date will be shown.

5. Select OK to go back to the [ASSAY] screen.

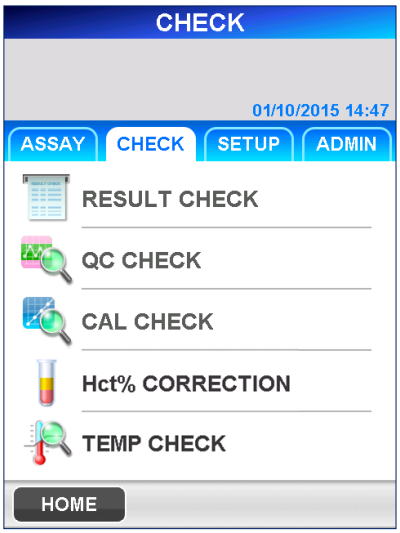
9 CHECK (Access Level: 1 and Above)

In this chapter, we describe the procedures to review or reprint results for patients, QC or calibration assays.

9.1 Introduction

From the home page select CHECK in subtitle area to go to the following [CHECK] screen.

CHECK



From the [CHECK] screen, the following operations are available by selecting each sub-menu in the above screen.

RESULT CHECK
- Review and reprint the sample or QC data.

QC CHECK
- Review and reprint QC data, display and print QC graph.

CAL CHECK
- Review and reprint calibration data.

Hct% CORRECTION
- Recalculate and reprint data by changing Hct% value.

TEMP CHECK
- Display temperature of each heater block.

9.2 RESULT CHECK

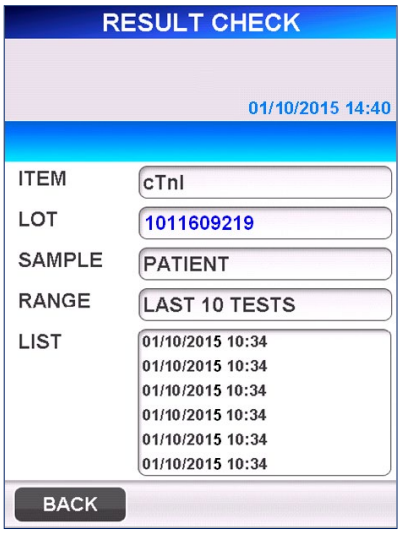
In this menu you can review or print stored patient or QC data.

1. By selecting [RESULT CHECK] , you are prompted to select items in the following order to define search criteria.
   (1) Assay Item
   (2) Reagent Lot
   (3) Sort of Sample
   (4) Searching Range

   - "LAST BATCH" is selectable in the assay item selection screen. Selection of "LAST BATCH" shows the list of data from the latest batch run.

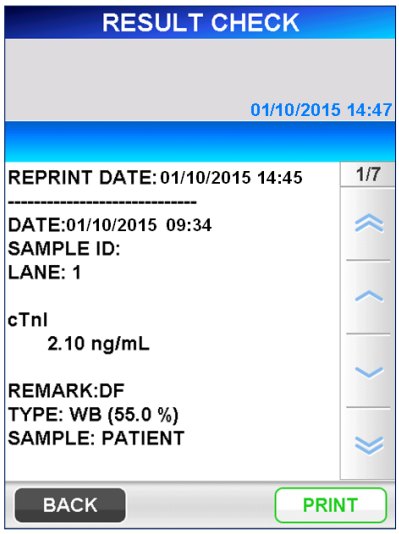
2. After selecting your search criteria, select [OK] to search data and to display a list of the data which will include the date and time assayed.

RESULT CHECK/LIST



3. Select the sample to be displayed and then select DATA to show the individual data on the screen in printout format.
   - ■ You may select up to 30 samples to review.

RESULT CHECK/DATA



4. Select PRINT on the [RESULT CHECK/DATA] screen to print the data for all selected items.
   When the instrument is set to communicate with host computer, a TRANSMIT button is also displayed. Selecting this button sends the data selected to the host computer.

5. To change the search criteria, select the display box on the [RESULT CHECK/LIST] screen to show the corresponding list. Select a new condition and select OK to search data.

9.3 QC CHECK

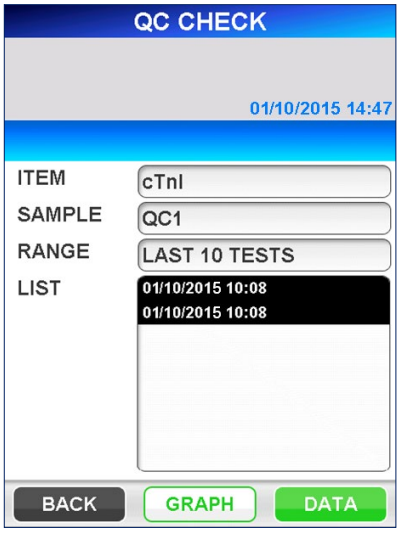
From this menu you can review the QC data stored and also print the data on the printer. Also you can choose to see the QC data as a graph.

1. By selecting [QC CHECK] , you are requested to select the items in the following order to define search criteria.
   (1) Assay Item
   (2) Sort of Sample
   (3) Searching Range

   ■ "LAST QC BATCH" is selectable on the assay item selection screen. Selection of "LAST QC BATCH" shows the list of data from the latest QC batch run.

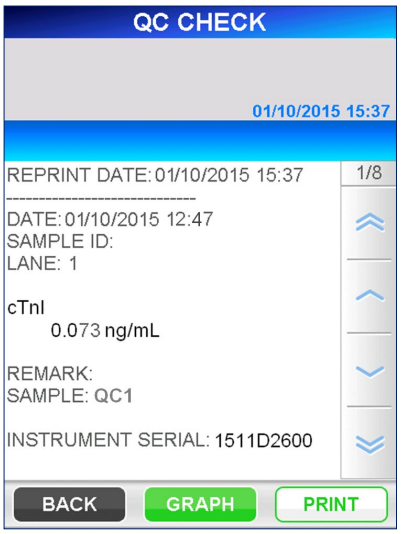
2. After selecting all of the items listed above, select [OK] to search the data and view the list of data along with the date and time assayed.
   ■ In the list , all the QC data found is shown in reverse highlight.

QC CHECK/LIST



3. In the navi area, DATA and GRAPH buttons are shown.
   Select DATA to show the individual data on the screen in printout format.

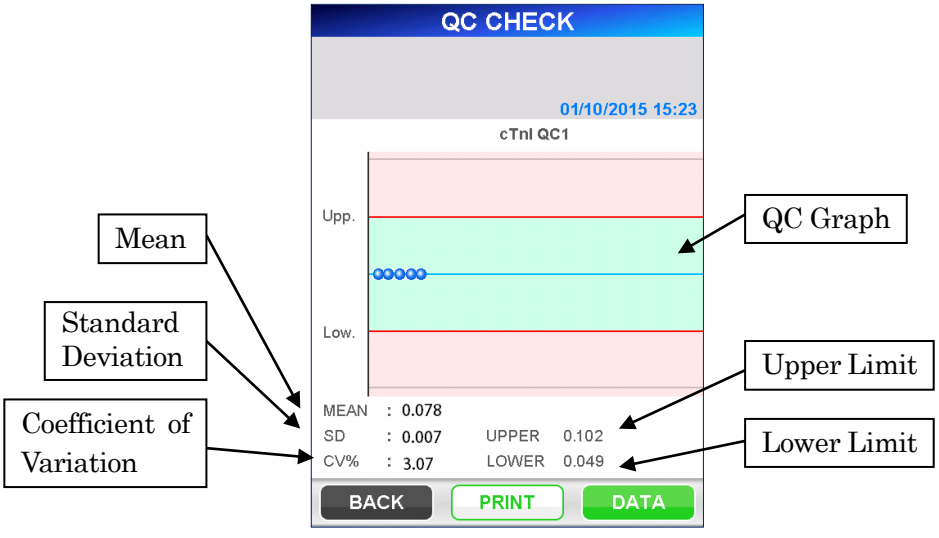
QC CHECK/DATA



4. Select PRINT on the [QC CHECK/DATA] screen to print the data for all selected items.

5. Select GRAPH to show the QC data plotted in a graph as follows.

QC CHECK/GRAPH



- The Upper/Lower limits defined in [SETUP]/[QC LOCKOUT] are used in the graph.
- Data searched are plotted starting with the oldest one on the left up to 30 in the graph.

6. Select PRINT on the [QC CHECK/ GRAPH] screen to print a copy of the screen.

7. To change the search criteria, select the display box on the [QC CHECK/ LIST] screen to show the dropdown list. Select a new condition and select OK to search the data.

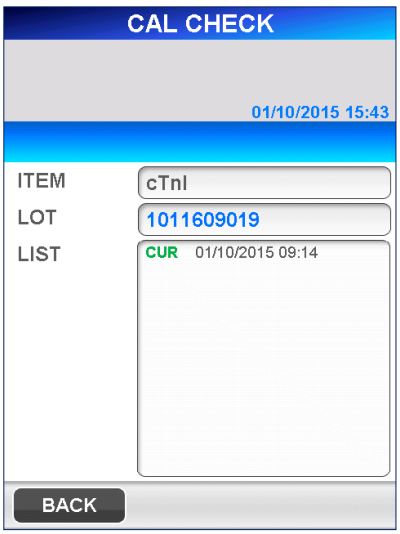
9.4 CAL CHECK

From this menu you can review stored calibration data and reprint the data on the printer.

1. By selecting CAL CHECK, you are requested to select items in the following order to define search conditions.
   (1) Assay Item
   (2) Reagent Lot

2. After selecting all the items listed above, select OK to search data and to show the list of data along with the date and time assayed.

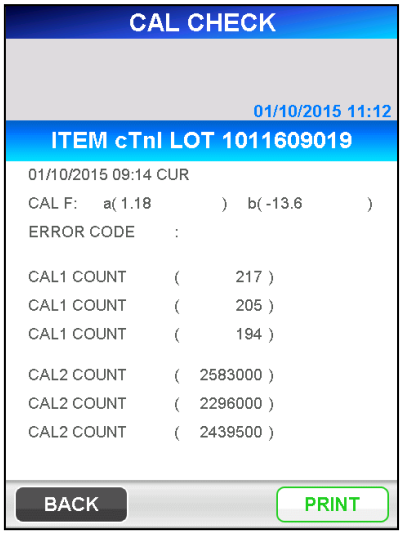
CAL CHECK/LIST



- Calibration data is searched for three lots of each reagent and up to ten calibrations per reagent lot.
- Data with "CUR" on the left means the currently effective calibration data. Data with "ERR" on the left indicates that calibration run had failed.

3. After choosing the calibration data, select DATA to show the calibration data as follows.

CAL CHECK/DATA



4. On the [CAL CHECK/DATA] screen, the following items are shown.

CAL F: a, b

Coefficients to correct the calibration curve against the master calibration curve for the reagent lot.

ERROR CODE

Shows the error code character(s) for the failed calibration, up to five errors separated by comma.

CAL1 COUNT

Measured counts for calibrator 1 is shown for each replicate.

CAL2 COUNT

Measured counts for calibrator 2 is shown for each replicate.

Remark

Up to 5 remarks for detected errors for each calibrator are shown next to the count, separated by a comma.

Note: No error codes or remarks are shown when the calibration was successful.

5. Select PRINT on the [CAL CHECK/DATA] screen to print a copy of the screen.

6. To change the search criteria, select the display box on the [CAL CHECK/LIST] screen to show the dropdown selection list. Select a new condition and select OK to search the data.

9.5 Hct% CORRECTION

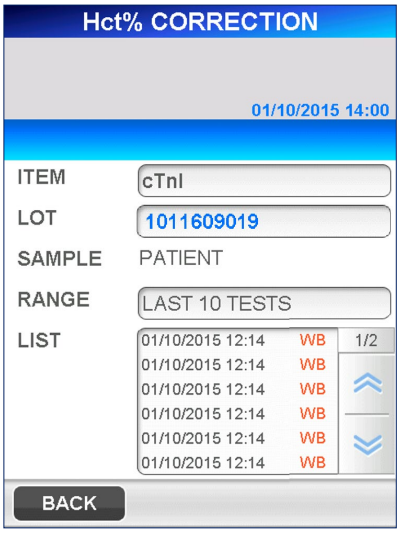
From this menu you can recalculate sample data stored for the new Hct% and print this data on the printer.

1. Selecting [Hct% CORRECTION] , you are requested to select items in the following order to define search criteria.
   (1) Assay Item
   (2) Reagent Lot
   (3) Searching Range

   ■ "LAST BATCH" is selectable on the assay item selection screen. Selection of "LAST BATCH" shows the list of data from the latest batch run.

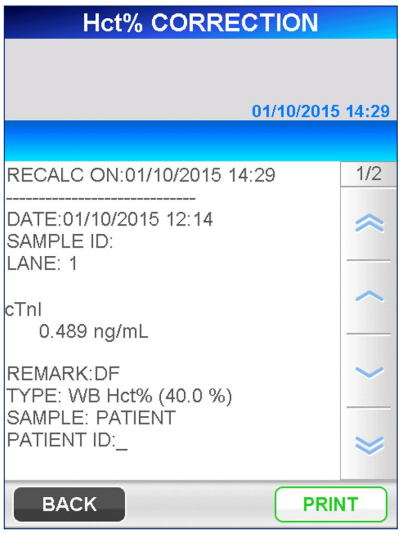
2. After selecting all the items listed above, select [OK] to search the data and to show the list of data with the date and time assayed.
   ■ "WB" on the right of the data indicates a whole blood sample.

Hct% CORRECTION/LIST



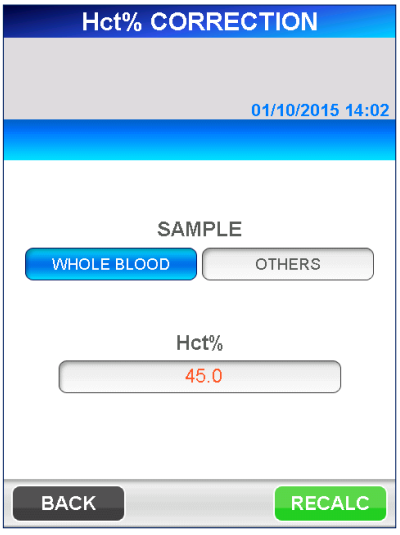
3. After choosing the sample, select NEXT shown in navi area to show the detailed data in printout format.
   ■ Only one data is selectable at one time.

Hct% CORRECTION/DATA



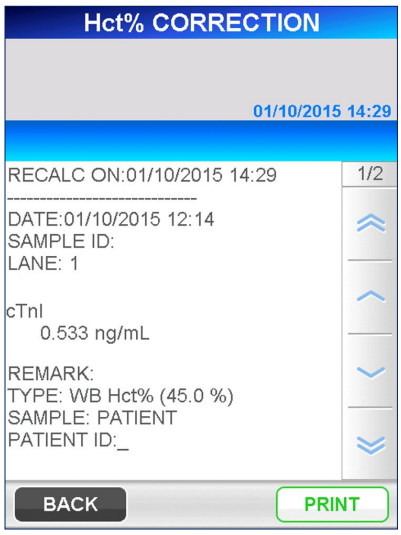
4. Select NEXT to show the following screen. The items shown on the screen differ depending on the sample selected, whole blood or other. To change the sort order, select the button to be displayed in reverse. Hct% is displayed for a whole blood sample or if you select the button. Input the new Hct% value through the numeric keypad displayed by selecting the box.
   ● **Range : 0.000 – 60.0 (Initial value: 40.0)**

Hct% CORRECTION/Hct%



5. After inputting the new Hct% value, select RECALC to show the recalculated sample data using new Hct% value.

Hct% CORRECTION/RECAL



6. Select PRINT on the [Hct% CORRECTION/RECAL] screen to output the recalculated data to the printer.
When the instrument is set to communicate with a host computer, the TRANSMIT button is also displayed. Selecting this button sends the data selected to the host computer.

- The date of recalculation is added next to the line of date assayed.
- For the data transmitted to the host computer, a remark of recalculation is also added.

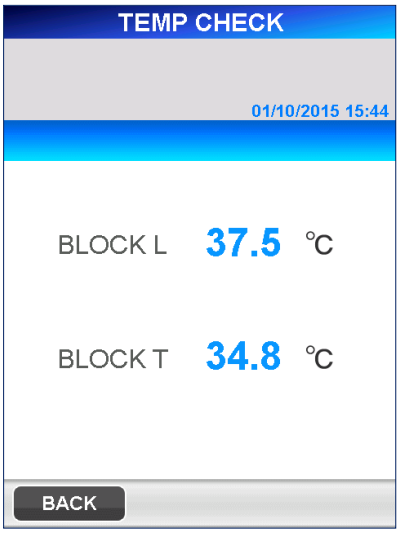
7. Select BACK to get back to [Hct% CORRECTION/ LIST] screen.
To change the search conditions, select the display box on the [Hct% CORRECTION/LIST] screen to show the dropdown selection list. Select a new condition and select OK to search data.

9.6 TEMP CHECK

From this menu, you can check the temperature of each heater block.

1. Select TEMP CHECK on the [CHECK] screen to show the following screen.

TEMP CHECK



2. The current temperature of each heater block is displayed.
   - ■ The current temperature is refreshed every one second.

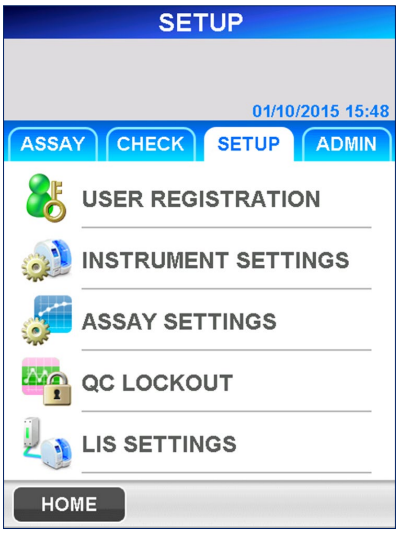
10 SETUP (Access Level: 4)

This chapter describes setting/editing procedure for PATHFAST parameters.

10.1 Introduction

Setup operations are started by selecting SETUP in the sub-title area. The following [SETUP] screen is displayed.

SETUP



From the [SETUP] screen, you can set or edit the following items.

USER REGISTRATION
- ADD/EDIT/DELETE
- ACCESS MANAGEMENT

INSTRUMENT SETTINGS
- CONFIG
- REGION/DATE
- LANGUAGE

ASSAY SETTINGS
- REFERENCE INTERVAL
- CAL REPLICATE
- CAL/QC ALERT
- Hct% DEFAULT
- C-FACTOR

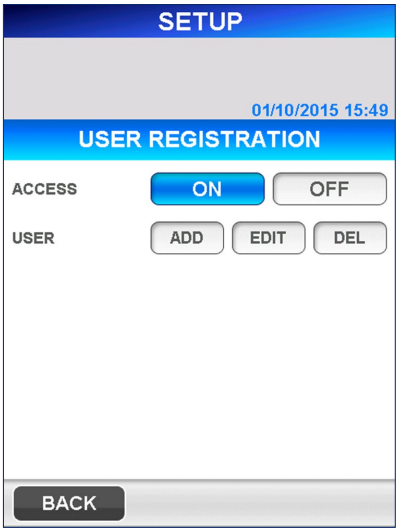
QC LOCKOUT
- ON/OFF and UPPER/LOWER Limits of QC

LIS SETTINGS
- Communication with External PC: ON/OFF
- Communication Parameters for RS232C port

10.2 USER REGISTRATION

Selecting [USER REGISTRATION] on the [SETUP] screen, displays the following screen that provides access management and the add/edit/delete operation for users.

USER REGISTRATION

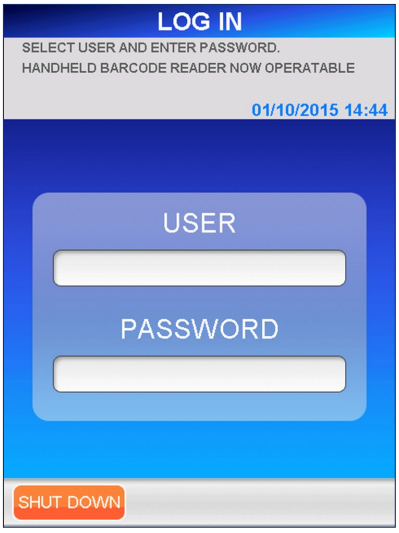


10.2.1 ACCESS MANAGEMENT

This allows you to activate (ON) or deactivate (OFF) the access management function, which is assigned by the PATHFAST Administrator. Access levels are used to limit and control the functions used by each user.
To activate or deactivate access management, select ACCESS [ON] or [OFF]. When access management is activated, the [LOGIN] screen is displayed in the following cases.

- Start up of PATHFAST
- The predetermined period of inactivity has elapsed.(Timeout period is definable in SETUP)

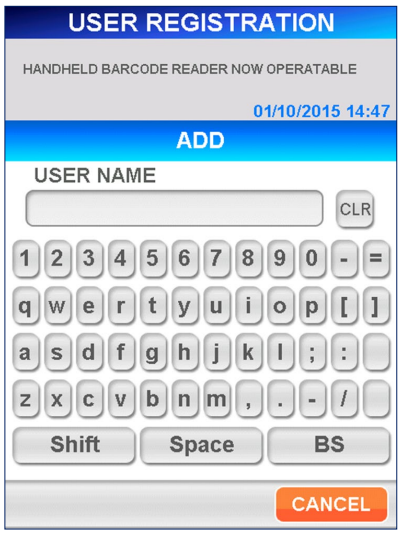
LOG IN


LOG IN
SELECT USER AND ENTER PASSWORD.
HANDHELD BARCODE READER NOW OPERATABLE
01/10/2015 14:44
USER
PASSWORD
SHUT DOWN

10.2.2 ADD

Here you can add a new user.

1. Select ADD on the [USER REGISTRATION] screen. The following screen is displayed requesting input of a new user ID.



[Full Keyboard]

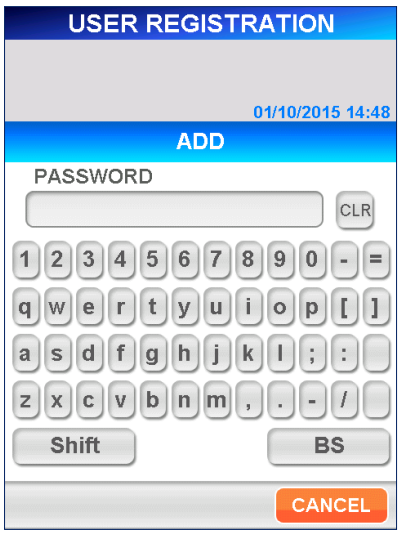
- Auxiliary Keys
  - Shift : Toggle switch for upper/lower case characters
  - CLR : All clear
  - BS : Back space, clear one character
  - Space : Set blank

2. Input user ID through the displayed Full Keyboard.
   - **Valid Characters : All characters displayed on the keyboard**
   - **Range : 1 through 20 characters**

   ■ The handheld barcode reader can be used to scan in a barcoded user ID.

3. Select OK . The following screen is displayed to input a password for the added user.

PASSWORD

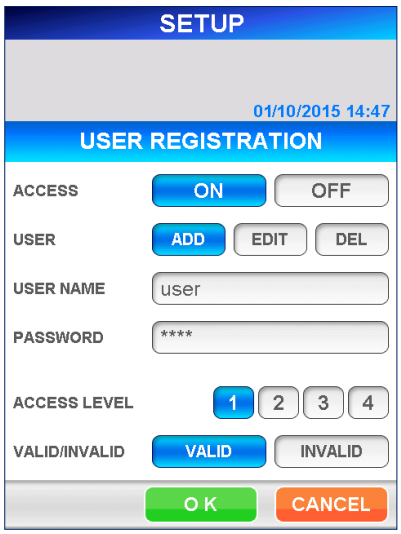


[Full Keyboard]

4. Input a password using 4 to 8 characters. For security, the characters input are displayed by asterisks (*).
   - **Valid Characters : All characters displayed on the keyboard**
   - **Length : 4 through 8 characters**
   - **Passwords are case sensitive**

5. Select OK . The following screen is shown to set the access level of the new user.

ACCESS MANAGEMENT



6. Select a number to indicate access level.
   - ■ Refer to **1.2 User ID and Access Level** to check the functions allowed for each access level.

7. Select [OK] to go back to the [USER REGISTRATION] screen.
   Selecting [CANCEL], to go back to the [USER REGISTRATION] screen without storing input data.

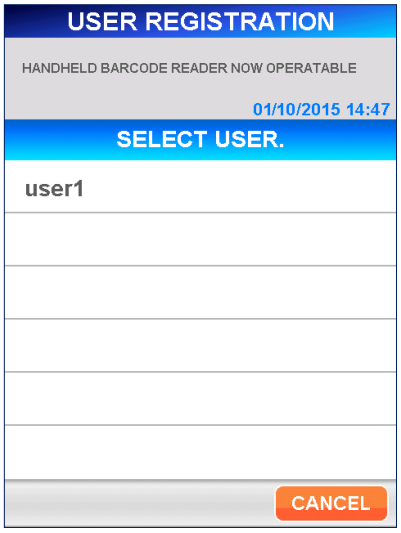
8. Although you can still register the user after selecting [INVALID] (displayed in reverse highlighting) for [VALID/INVALID], the user list shown on the [LOGIN] screen will not display the user ID for this user.

10.2.3 EDIT

From the [EDIT] screen, you can change passwords, access levels and [VALID/INVALID] for registered users. You can also reactivate users that have been deactivated after entering incorrect passwords in excess of PASSWORD RETRY LIMIT.

1. Select [EDIT] on the [USER REGISTRATION] screen. The following [USER LIST] screen is displayed to select a user to edit. Select a user from the list. The list on [USER LIST] displays all users including invalid users.

USER LIST

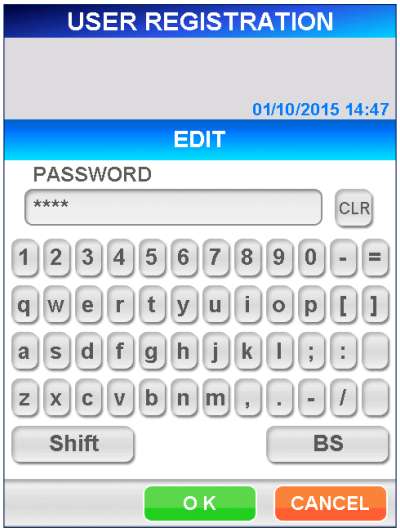


Note: The following users are not allowed to edit.

- System
- Administrator

2. Select [OK]. The following screen is displayed requesting input of the user's password. To edit, you need to change the password of the user that you are editing.

PASSWORD EDIT



[Full Keyboard]

Note: User ID can not be changed.

3. When changing the password, select CLR to delete the current password and input a new password (4 to 8 characters from the Keyboard). Input characters are displayed by asterisks (*).

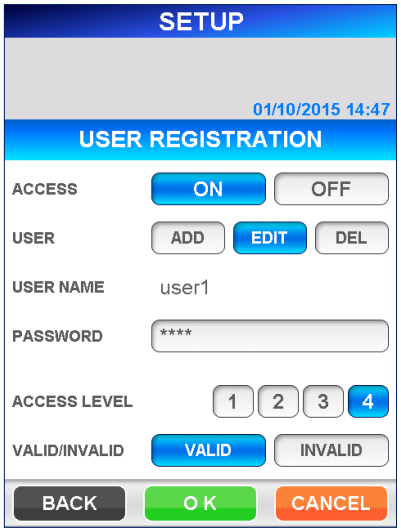
- **Valid Characters : All characters displayed on the keyboard**
- **Length : 4 through 8 characters**
- **Passwords are case sensitive**

To reactivate a user that has been deactivated, select VALID in the [ACCESS MANAGEMENT] screen (Display [VALID] in reverse highlighting).

4. Select OK . The following screen is shown to set the access level for the user. Select a number (1 through 4).

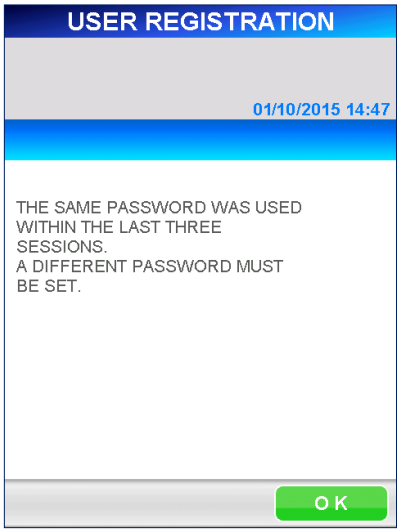
■ Refer to **1.2 User ID and Access Level** to check the functions allowed for each access level.

ACCESS MANAGEMENT



5. After entry, select OK to save changes and go back to the [SETUP/USER REGISTRATION] screen. If you have not changed the password or if the new password has been used as password for the last 3 passwords, changes will not be saved, and the screen will show a warning message. Select OK to return to the [SETUP/ACCESS MANAGEMENT] screen and reenter a new password.

PERVIOUSLY USED PASSWORD WARNING



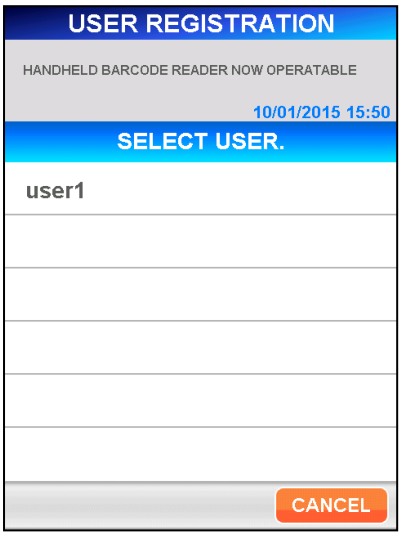
6. Although you can still register the user after selecting INVALID (displayed in reverse highlighting) for [VALID/INVALID], the user list shown on the [LOGIN] screen will not display the user ID for this user.

10.2.4 DEL

Here you can delete a registered user.

1. Select [DEL] on the [USER REGISTRATION] screen. The following [USER LIST] screen is displayed. Select the user to be deleted.

USER LIST



2. Select [OK]. A confirmation message for the delete user is displayed. Select [OK] to delete the user.

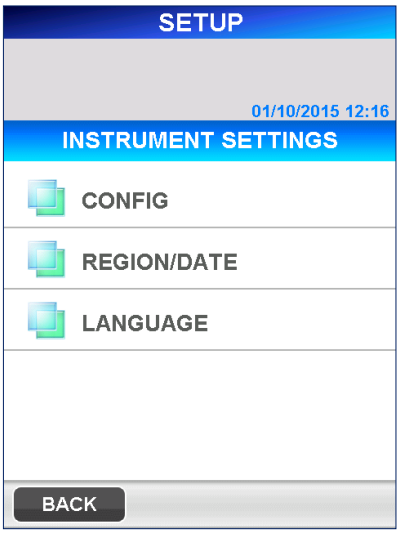
Note: You can not delete the following users.

- System
- Administrator
- The currently logged-in user

10.3 INSTRUMENT SETTINGS

Selecting INSTRUMENT SETTINGS on the [SETUP] screen displays the following where you can set the instrument configuration, region/date, and language.

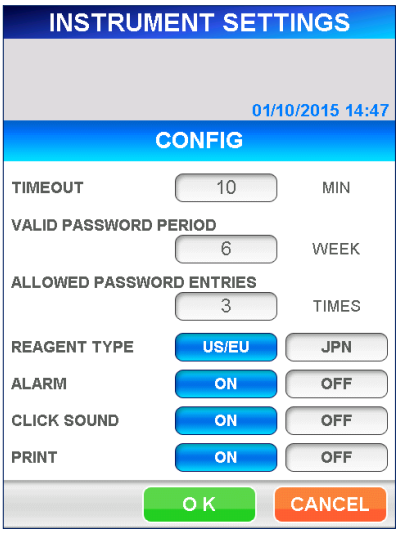
INSTRUMENT SETTINGS



10.3.1 CONFIG

1. Select CONFIG on the [INSTRUMENT SETTINGS] screen. The following [CONFIG] screen is displayed.

CONFIG



TIMEOUT

When "TIMEOUT" is set, the instrument shows the [LOG IN] screen automatically after the designated period of time has elapsed without any instrument operation. (This feature requires that Access Management be set to ON.)

Selecting the input box, the numeric keypad is displayed to input a

timeout period. Input the number of minutes and select [OK] to store.

- **Range : 0 to 999 minutes**

Note: When selecting "0", the timeout function is deactivated.

VALID PASSWORD PERIOD

After setting VALID PASSWORD PERIOD, if a password is not changed during the period set for VALID PASSWORD PERIOD, the password and user associated with this password will be deactivated. (Effective only if the access management is ACCESS/ON.)

Select the VALID PASSWORD PERIOD field and enter a value in the range below using the numeric keypad.

- **Range: 0 to 48 weeks**

Note: When setting to "0" week, VALID PASSWORD PERIOD is deactivated.

ALLOWED PASSWORD ENTRIES

After setting ALLOWED PASSWORD ENTRIES, if incorrect passwords are entered for a user for the number of times set in ALLOWED PASSWORD ENTRIES, the user will be deactivated. (Effective only if the access management is ACCESS/ON)

Select the VALID PASSWORD ENTRY field and enter a value in the range below using the numeric keypad.

- **Range: 0 to 10 times**

Note: When setting to "0" time, VALID PASSWORD ENTRY is deactivated.

- The deactivated users will not be displayed on the user list on the [LOGIN] screen.
- To reactivate the deactivated users, please follow the instructions described in "**10.2.3 EDIT**".

REAGENT TYPE

Reagent types are different for US/EU and Japan.

Select [US/EU] for outside Japan.

Note: If the reagent type is incorrectly set, the assay run cannot be performed.

CLICK SOUND/ALARM

You can select when the "CLICK SOUND" or "ALARM" sounds should beep by selecting [ON] or [OFF] for each.

PRINT

Select [ON] or [OFF] to print results upon completion of the run.

Note: Even though you select [OFF], PATHFAST will still print warning messages, or data when the "PRINT" button is selected.

2. Select [OK] to store the settings and go back to the [INSTRUMENT SETTINGS] screen.

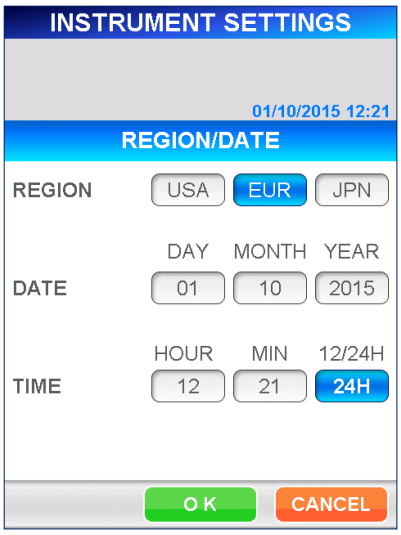
10.3.2 REGION/DATE

From this menu, select the region where PATHFAST is operated and set the system date and time.

> *Caution : PATHFAST in USA must be operated in the condition that* USA *is selected by the REGION setting.*

1. Select REGION/DATE on the [INSTRUMENT SETTINGS] screen. The following [REGION/DATE] screen is displayed.

REGION/DATE



REGION

Select the region where PATHFAST is operated. According to the selection, the display order of the year, month and date is changed as follows.

(Year : Y, Month : M, Day : D)

USA : MM/DD/YYYY

EUR : DD/MM/YYYY

JPN : YYYY/MM/DD

DATE

Edit the system date. Input date through numeric keypad by selecting each display box.

TIME

Edit the system time. Input time through the numeric keypad by selecting each display box. The 12/24H box toggles between the 12 and 24 hour systems. Selecting the box changes the time display system. When the 12 hour system is selected the AM/PM button is displayed.

2. Select OK , when finished setting the needed parameters.

10.3.3 LANGUAGE

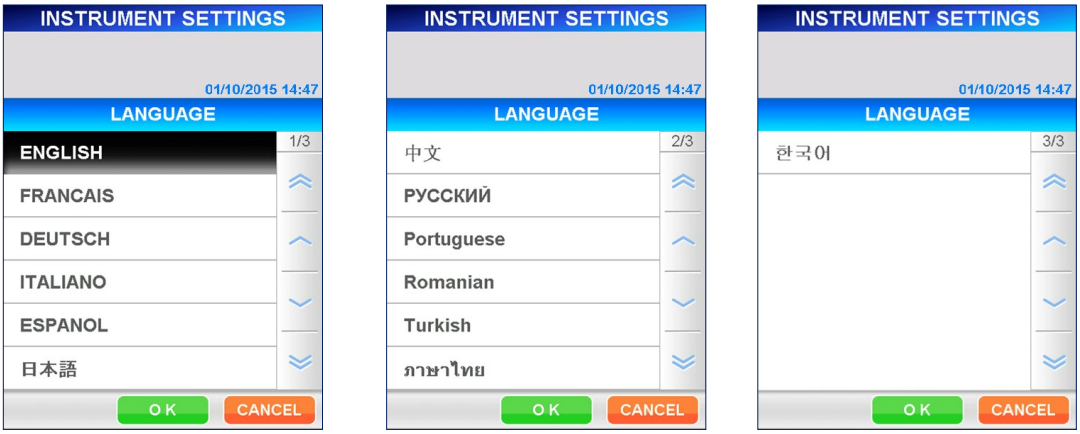
Select the language that will be used on the operating screen.

Note: Only English is used on the built-in-printer even if the other language is selected.

Caution : Make sure you select a language you understand.

1. Select LANGUAGE on the [INSTRUMENT SETTINGS] screen. The following [LANGUAGE] screen is displayed.

LANGUAGE

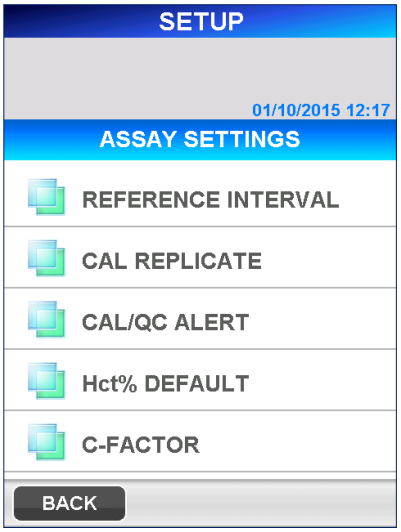


2. Select a language, (the selected language will be displayed in reverse highlighting). Select OK .

10.4 ASSAY SETTINGS

Select ASSAY SETTINGS on the [SETUP] screen. The following screen is displayed to allow you to set reference values for each assay item, number of replicates of calibrators, time for Cal/QC expiration alert.

ASSAY SETTINGS



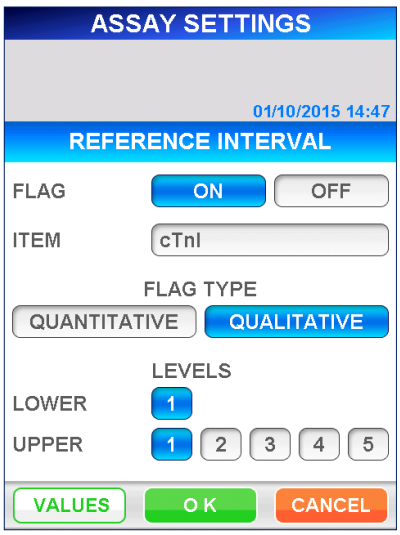
10.4.1 REFERENCE INTERVAL

You can flag assay items when the measured sample results do not fall within set reference ranges. To flag an assay result, you must set the values and the flag type for each assay.

In the [REFERENCE INTERVAL] screens, there is no item name at the time of shipment.
At the factory settings, you cannot set/change the settings for [REFERENCE INTERVAL].
Only names of items that have been read from [MC ENTRY CARD] on the [MC ENTRY] screen are listed.

1. Select REFERENCE INTERVAL on the [ASSAY SETTINGS] screen. The following [REFERENCE INTERVAL] screen is displayed.

REFERENCE INTERVAL



FLAG

Select [ON] or [OFF] .

ITEM

To set reference values, select the assay item from the list of registered assays shown by selecting the input box.

FLAG TYPE

Select [QUANTITATIVE] or [QUALITATIVE] .

LEVELS

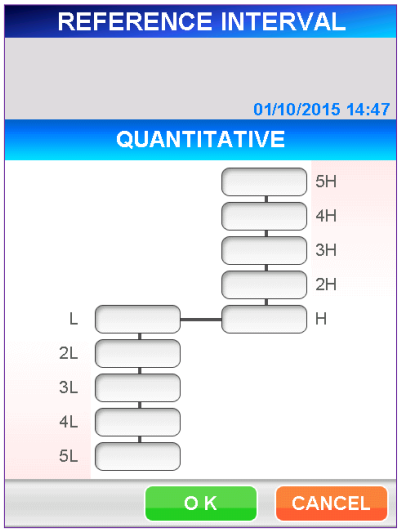
Select the numbers for levels of lower value and upper value of the reference range. Numbers are displayed in reverse when selected.

■ The number of the level for values lower than the reference range for a qualitative assay is fixed to "1".

2. Selecting [VALUES] gives you the input screen of reference values depending on the number of levels selected.

(A) For "QUANTITATIVE" results up to 5 levels are allowed for both upper and lower values.

QUANTITATIVE REF. VALUE



Select each box to input a value on the numeric keypad.

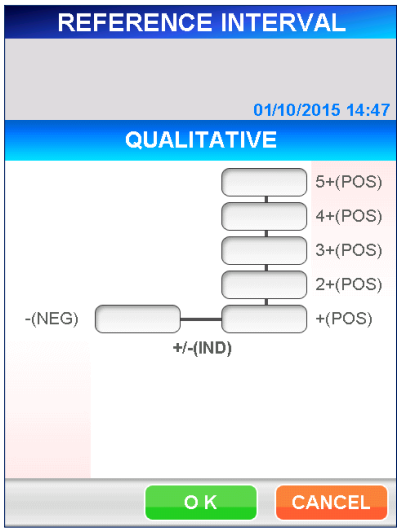
- **Range : 0.000 – 999999.999**

Note: Be sure the order of numeric values shall be as follows.

5L<4L<3L<2L<L<H<2H<3H<4H<5H

(B) For "QUALITATIVE" results, up to 5 upper levels may be set.

QUALITATIVE REF. VALUE



Select each box to input a value on the numeric keypad.

- **Range : 0.000 – 999999.999**

Note: Be sure the order of numeric values shall be as follows.

- (NEG)=< +/ - (IND)=< +(POS)<2+<3+<4+<5+

■ For qualitative assays you can set an indeterminate range by setting different values for "- (NEG)" and "+ (POS)" and setting a flag of "+/- (IND)".
If you use the same value for both, no indeterminate range exists.

3. Select [OK] to go back to the [REFERENCE INTERVAL] screen.

4. Select [OK] to store the settings and go back to the [ASSAY SETTINGS] screen.

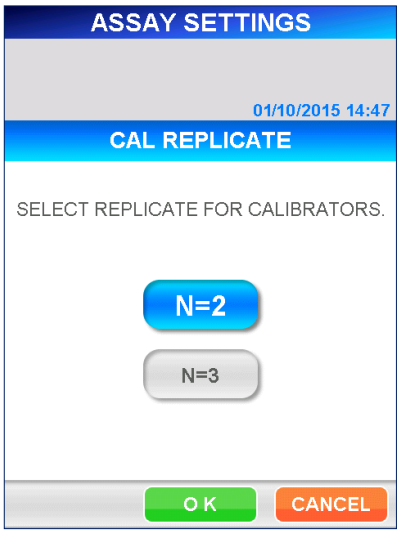
5. Repeat steps 1 through 4 for other assay items as needed.

10.4.2 CAL REPLICATE

From the [CAL REPLICATE] screen you can set the default number of replications of calibrators used during a CAL assay.
When running a calibration assay, the following procedure defines the lanes where calibrators are to be set.

1. Select [CAL REPLICATE] on the [ASSAY SETTINGS] screen. The following [CAL REPLICATE] screen is displayed.

CAL REPLICATE



2. Select [N=2] or [N=3] .

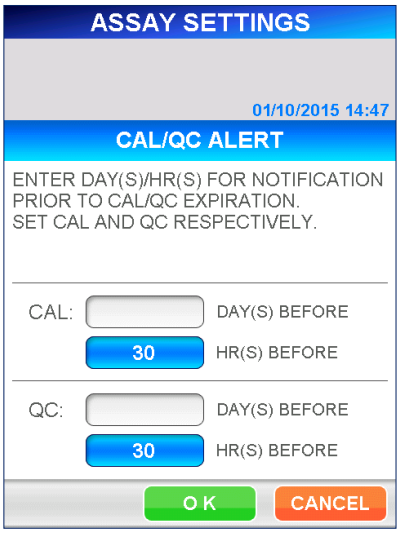
3. Select [OK] to store the change and go back to the [ASSAY SETTINGS] screen.

10.4.3 CAL/QC ALERT

From the [CAL/QC ALERT] screen you can set the time to inform the user of pending CAL or QC expiration. When the latest calibration or QC measurement date falls within this time frame, a warning message or alert is shown during system startup and on the [REAGENT STATUS] screen.

1. Select CAL/QC ALERT on the [ASSAY SETTINGS] screen. The following [CAL/QC ALERT] screen is displayed.

CAL/QC ALERT



2. Input the number of days or hours through the numeric keypad shown by selecting the display box of DAY(S) or HR(S). Set either by days or hours. When selected, the box is displayed in reverse with the number set and the other box is blanked.
   Set the time for CAL and QC separately.
   - **Range can be 0 – 999 DAYS**
     or 0 – 30 HOURS

   Note: Days and hours can not be set simultaneously.
   The number displayed in reverse is effective.

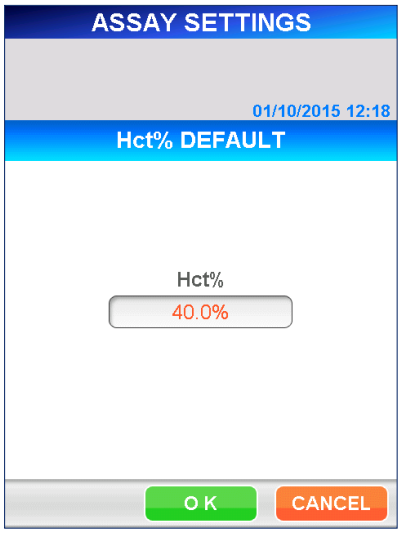
3. Select OK to store the setting and go back to the [ASSAY SETTINGS] screen.

10.4.4 Hct% DEFAULT

Set the default value of Hct% used for the hematocrit correction calculation for a whole blood sample result when the actual hematocrit value for the patient is not available.

1. Select Hct% DEFAULT on the [ASSAY SETTINGS] screen. The following [Hct% DEFAULT] screen is displayed.

Hct% DEFAULT



2. Input the new default value through the numeric keypad by selecting the display box.
   - **Range : 0.000 – 60.0 (initial setting : 40.0)**

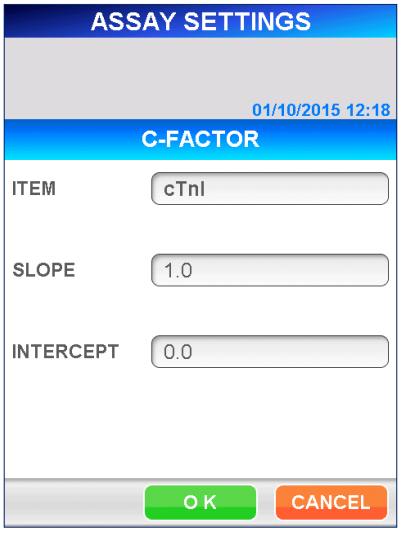
3. Select OK to store the new value and go back to the [ASSAY SETTINGS] screen.

10.4.5 C-FACTOR

Set a C-FACTOR when you want to correct the measured value based on the correlation factors with another assay method.
In the [C-FACTOR] screens, there is no item name at the time of shipment.
At the factory settings, you cannot set/change the settings for [C-FACTOR].
Only names of items that have been read from [MC ENTRY CARD] on the [MC ENTRY] screen are listed.

1. Select C- FACTOR on the [ASSAY SETTINGS] screen. The following [C-FACTOR] screen is displayed.

C- FACTOR



2. Select an assay item to set the C-Factor from the list shown by selecting display box.

The correction factors of SLOPE(a) and INTERCEPT(b) are defined by the following equation.

$$Y = aX + b$$

Where Y : Corrected value
X : Measure value by PATHFAST
a : Slope of regression
b : Y-Intercept of regression

SLOPE

Input a value through the numeric keypad by selecting the display box.

- **Range : -999999999 – 999999999**

INTERCEPT

Input a value through the numeric keypad by selecting the display box.

- **Range :-999999999 – 999999999**

3. Select OK to store the new value and go back to the [ASSAY SETTINGS] screen.

10.5 QC LOCKOUT

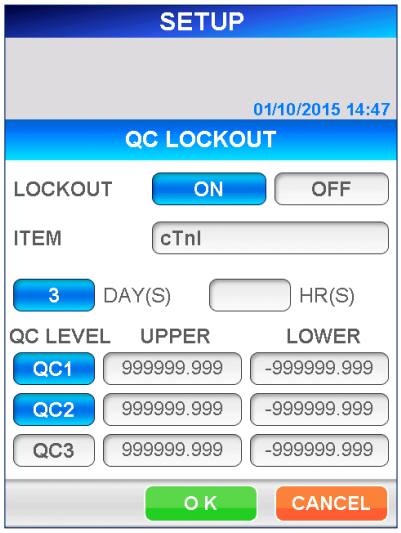
From this menu you can activate/deactivate the QC Lockout function and set the control ranges of each QC level.

- Details of QC Lockout function are described in Section **1.3 About QC Lockout Function** of Chapter **1 About This Manual**.

In the [QC LOCKOUT] screens, there is no item name at the time of shipment. At the factory settings, you cannot set/change the settings for [QC LOCKOUT]. Only names of items that have been read from [MC ENTRY CARD] on the [MC ENTRY] screen are listed.

1. Select QC LOCKOUT on the [SETUP] screen. The following [QC LOCKOUT] is displayed.

QC LOCKOUT



QC LOCKOUT conditions:

LOCKOUT

Select ON to activate the QC Lockout function or OFF to deactivate the function. The selected button is displayed in reverse. The input boxes of DAY(S) and HR(S) appear when ON is selected.

ITEM

Select the assay item from the list shown by selecting the box.

DAY(S)/HR(S)

When the QC Lockout function is activated you can set the effective periods for QC by days or hours.

- **Range :** DAY(S) : 1 – 999
  HR(S) : 1 – 30

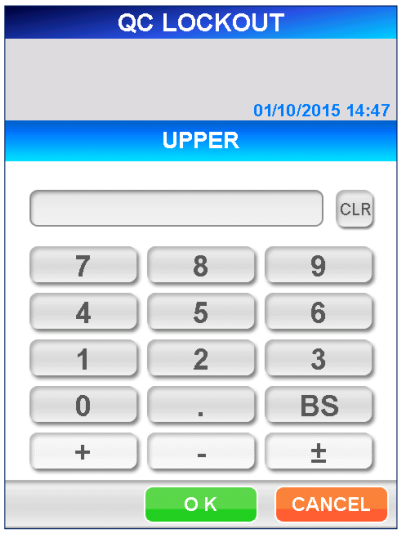
Note: You can not set both days and hours.
The effective number is displayed in reverse.

QC LEVEL

Select QC levels to be checked against the effective period. The selected button is displayed in reverse.

UPPER / LOWER

Set upper or lower values of the control range for each QC. Input the value through the numeric keypad shown by selecting the display box.



[Numeric keypad]

● Range : -999999.999 – 999999.999

Note: Make sure the upper value is equal to or larger than the lower value. These values control the graph scale of the QC Chart.

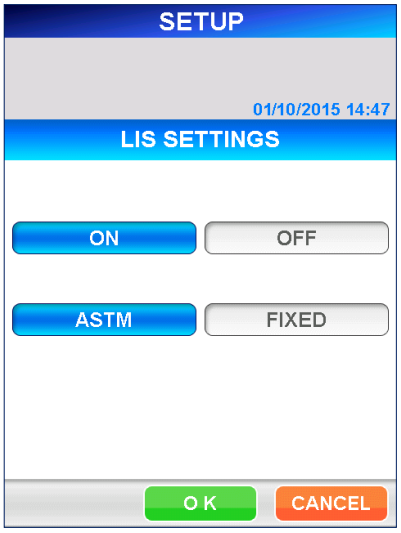
2. Select OK to store the data and go back to the [SETUP] screen.

10.6 LIS SETTINGS

From this menu, select whether or not you want to communicate with the host computer. Activate this function to set communication parameters.

1. Select [LIS SETTINGS] on the [SETUP] screen. The following [LIS SETTINGS] screen is displayed.

LIS SETTINGS



2. Select [ON] to activate the host communication function or [OFF] to deactivate the function. The selected button is displayed in reverse highlighting.

3. When [ON] is selected, [ASTM] and [FIXED] buttons are displayed. Depending on the mode of communication with host computer you require, select [ASTM] or [FIXED] .

ASTM

This mode is for host communication based on ASTM interface specifications. With this mode, PATHFAST initiates a query message to the host computer using Sample ID as a key. The assay results are automatically sent to the host computer when the assay run is completed.

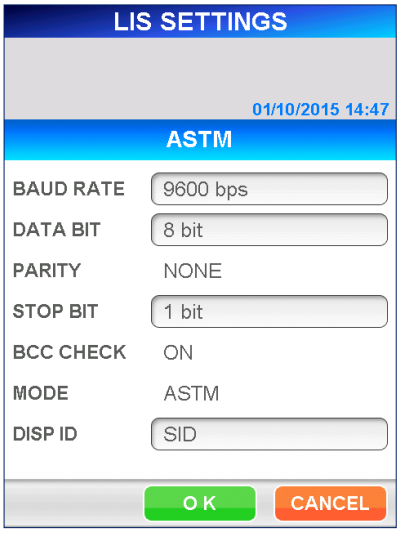
FIXED

In this mode PATHFAST outputs the assay results automatically to the host computer upon completion of assay run, however does not receive orders from the host computer.

4. Depending on which communication mode is selected the following screens are shown. For both screens, the default settings are shown below in bold letters. Select each parameter from the list by selecting display box.

[ASTM]

ASTM

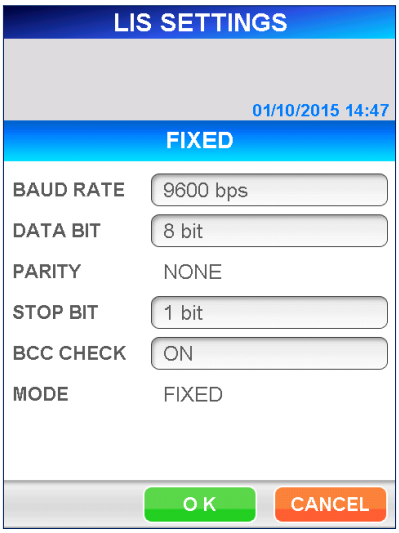


BAUD RATE : 4800, **9600,** 19200 bps
DATA BIT : 7, **8** bits
PARITY : DATA BIT=7: EVEN, ODD
DATA BIT=8: **NONE**
STOP BIT : **1,** 2 bit(s)
BCC CHECK : **ON** (fixed)
MODE : **ASTM** (Fixed)
DISP ID : **SID,** PID, PATIENT NAME

■ Defines item to be displayed in SID area in [SAMPLE INFO] screen.

[FIXED]

FIXED



BAUD RATE :	4800, **9600,** 19200 bps
DATA BIT :	7, **8** bits
PARITY :	DATA BIT=7: EVEN, ODD
	DATA BIT=8: **NONE**
STOP BIT :	**1,** 2 bit(s)
BCC CHECK :	**ON,** OFF
MODE :	**FIXED**(Fixed)

5. Select [OK] to store the data and to go back to the [SETUP] screen.

6. To make the new settings effective, reboot PATHFAST.
   Select [SHUT DOWN] from the [ADMIN] screen and follow the displayed messages.

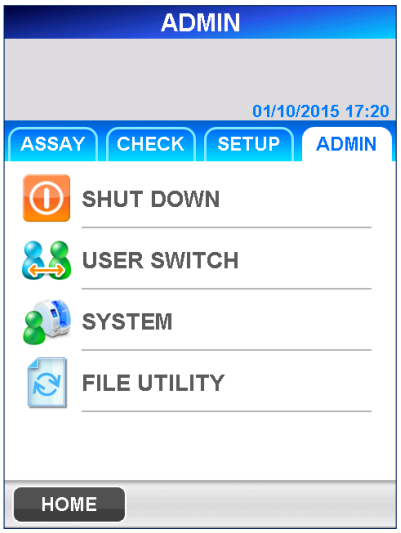
11 ADMIN (Access Level:1 and Above)

This chapter describes the procedures for instrument shut down, switching users, software version upgrade and checking instrument information.

11.1 Introduction

Admin operations are started by selecting ADMIN in sub-title area. The following [ADMIN] screen is displayed.

ADMIN



From the [ADMIN] screen, the following operations or review of information stored in the instrument are available.

SHUT DOWN
- Shut the instrument power off.

USER SWITCH
- Switch from the current user to another.

SYSTEM
- View user log.
- View system log.
- Instrument information.
- Selfcheck (Access Level: 4)

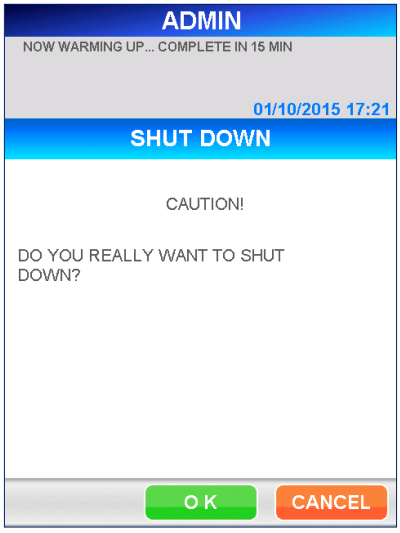
FILE UTILITY **(Access Level: 4)**
- Software version upgrade.
- Add new assay parameters

11.2 SHUT DOWN

Select [SHUT DOWN] to shut the instrument power off.

1. Select [SHUT DOWN] from the [ADMIN] screen. A message to confirm the shut down operation will appear as follows.

SHUT DOWN 1

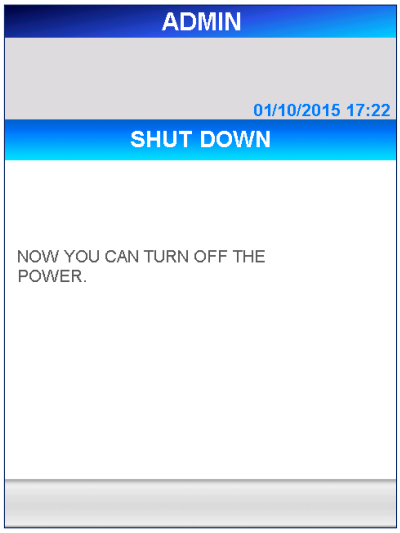


2. Select [OK] to shut the power off.
   - ■ If you want to cancel the shut down operation, select [CANCEL] to go back to the [ADMIN] screen.

3. When the message of "NOW YOU CAN TURN OFF THE POWER" is shown, you can safely move the Main Power Switch to the off position.

⚠ **Do not turn the instrument power off before "NOW YOU CAN TURN OFF THE POWER." is displayed.**

SHUT DOWN-2

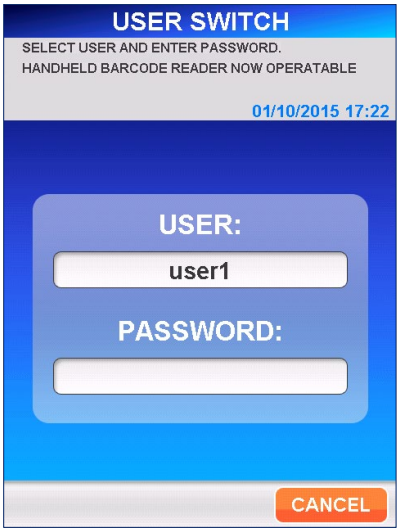


11.3 USER SWITCH

Select [USER SWITCH] when you want to change the user operating the instrument. The active user's ID is printed on the assay result print out.

1. Select [USER SWITCH] on the [ADMIN] screen. The following [USER SWITCH] screen is displayed.

USER SWITCH



2. Select the new user from the list shown by selecting the display box.
   - The handheld barcode reader can be used to scan a barcoded User ID.

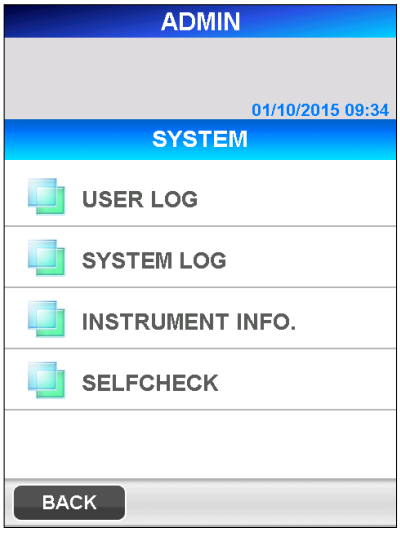
3. Select [OK] to show the Full Keyboard to input the user's password. Input the password and select [OK] to go back to the [ASSAY/HOME] screen.

11.4 SYSTEM

From this menu you can check the instrument logs.

Select SYSTEM on the [ADMIN] screen. The following [SYSTEM] screen is displayed. You can select USER LOG, SYSTEM LOG, INSTRUMENT INFO. or SELFCHECK.

LOG SELECTION

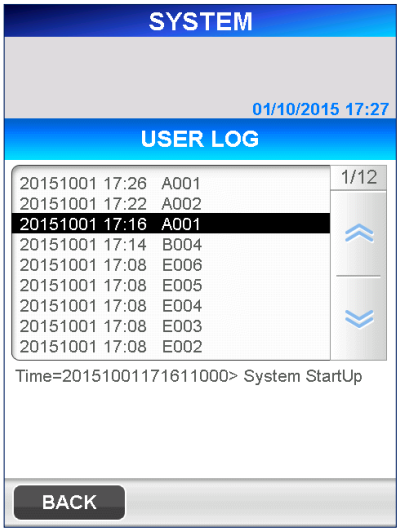


11.4.1 USER LOG

The User Log stores information such as boot up / shut down time, assay start/complete time and time of changes made to settings.

1. Select USER LOG on the [SYSTEM] screen. The following [USER LOG] screen is displayed.

USER LOG

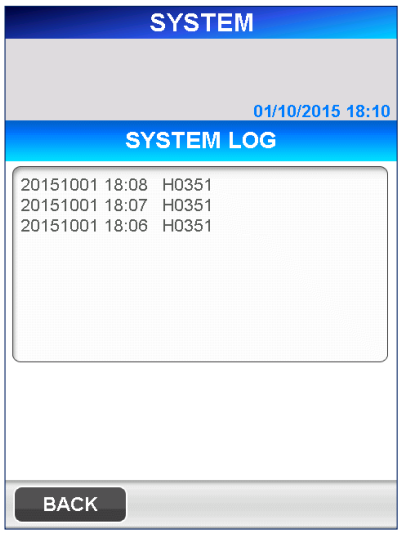


11.4.2 SYSTEM LOG

The System Log stores errors observed during operation.

1. Select SYSTEM LOG on the [SYSTEM] screen. The following [SYSTEM LOG] screen is displayed.

SYSTEM LOG



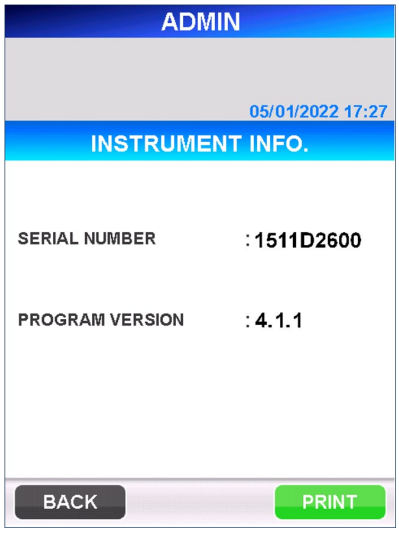
You may need to check and report the contents of this screen when troubleshooting or talking to your service specialist.

11.4.3 INSTRUMENT INFO.

The instrument serial number (S/N) and the program version number is shown on the [INSTRUMENT INFO.] screen.

1. Select INSTRUMENT INFO. on the [SYSTEM] screen. The following [INSTRUMENT INFO.] screen is displayed.

INSTRUMENT INFO.

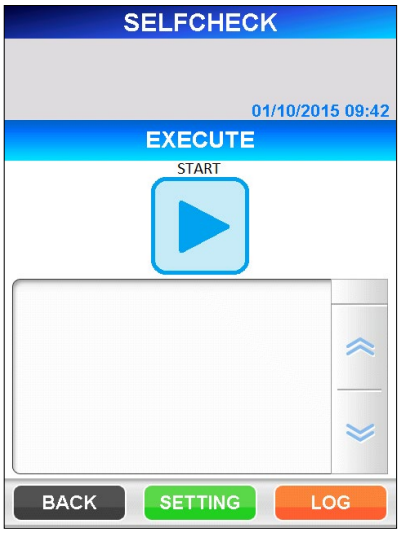


11.4.4 SELFCHECK (Access Level: 4)

"SELFCHECK" allows you to execute and set parameters using the selfcheck function. Selfcheck process is also executable manually.

1. Select SELFCHECK on the [SYSTEM] screen. The following [EXECUTE] screen is displayed.

EXECUTE

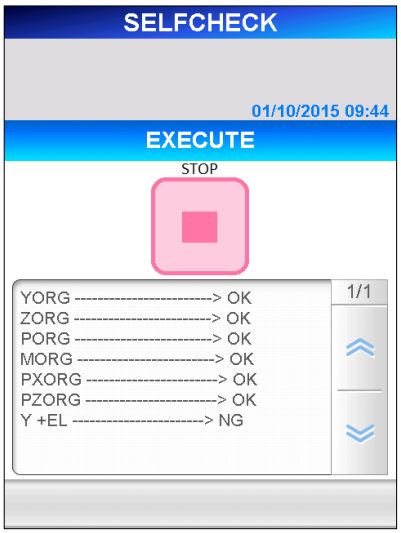


Before executing selfcheck, check if there are any used tips left in the tip waste box and any tips in the tip holder holes of PATHFAST and close the front cover completely. Also, set up the printer paper roll in the printer.

Select "  " button to initiate the selfcheck process.

Select "  " to cancel selfcheck process execution on the screen shown below.

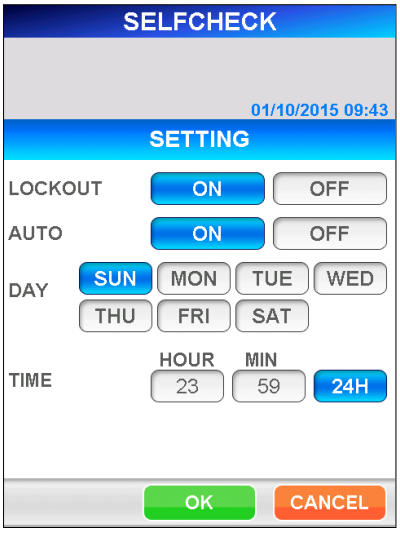
CANCELLATION OF SELFCHECK



The results shall be displayed on the screen as a log report along with printout date on the printer. For each check item "OK" or "NG" is displayed to show on which item a problem has been found. In cases where "NG" is shown, please contact our representatives.

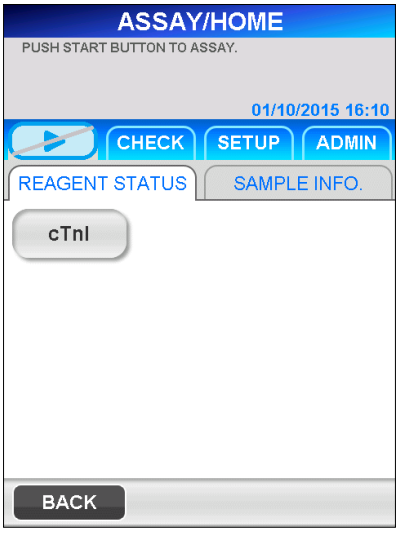
2. Select the SETTING button on the [EXECUTE] screen. The following [SETTING] screen is displayed.

SETTING



[ON] or [OFF] is selectable for [LOCKOUT] function (default setting : OFF). When [LOCKOUT] is set to [ON] and any problem is found once the selfcheck has been completed, the start button with a line through it is displayed and no assay shall be allowed thereafter (Lockout mode). In this case, initiate selfcheck again.

ASSAY/HOME (Lockout)

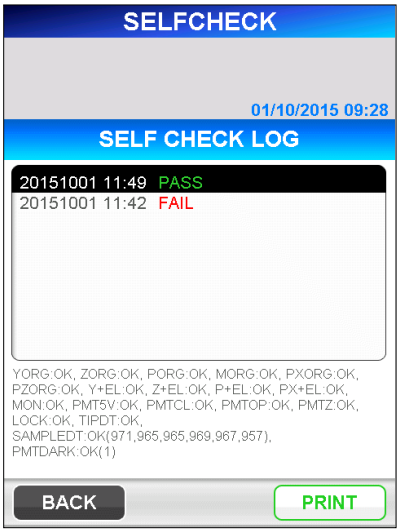


Also [ON] or [OFF] is selectable for the [AUTO] function (default setting : OFF). When [AUTO] is set to [ON], the selfcheck process shall be executed automatically at preset intervals. Intervals can be set by day of the week and time. Multiple days of the week are selectable.

Be aware that the automatic selfcheck shall be not executed in certain conditions. Conditions when automatic selfcheck is not executed are during warm up, login, during host communication, error indication etc.
When automatic selfcheck did not execute and [LOCKOUT] is set to [ON], the start button with a line through it is displayed and no assay shall be allowed thereafter (Lockout mode). In this case, execute selfcheck again.
Also, we recommend that the automatic selfcheck is set at times with less frequency with PATHFAST.

3. Select the LOG button on the [EXECUTE] screen. The following [LOG CHECK] screen is displayed

SELF CHECK LOG



In the screen above, results of selfchecks performed in the past can be reviewed and printed. By selecting an item on the screen, detailed information of the selected log is displayed in the lower part of the screen.

11.5 FILE UTILITY (Access Level: 4)

11.5.1 FILE UTILITY

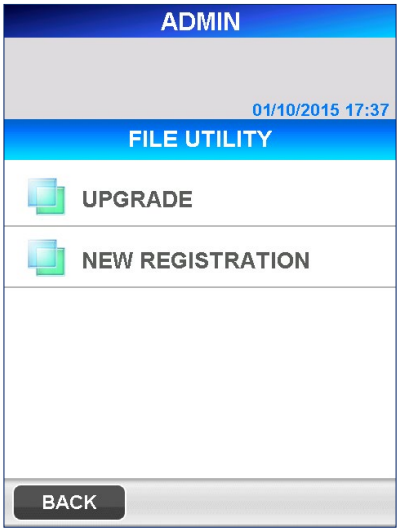
The [FILE UTILITY] is the function used for upgrading PATHFAST software.
This upgrade may be needed in the following cases.

- Program upgrade for problem solving or addition of functions
- Addition of new assay items

Note) Upgrade of PATHFAST software and the procedure of it will be informed by your PATHFAST representative, when prepared.

1. Select FILE UTILITY on the [ADMIN] screen. The following [FILE UTILITY] screen is displayed

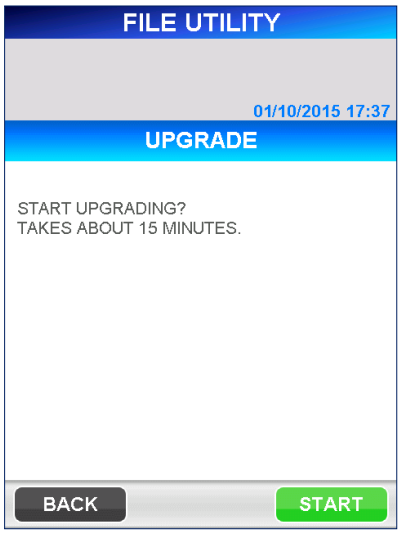
FILE UTILITY



2. Select UPGRADE to show the following [UPGRADE] screen. To start software upgrade, select the START button in navi area.

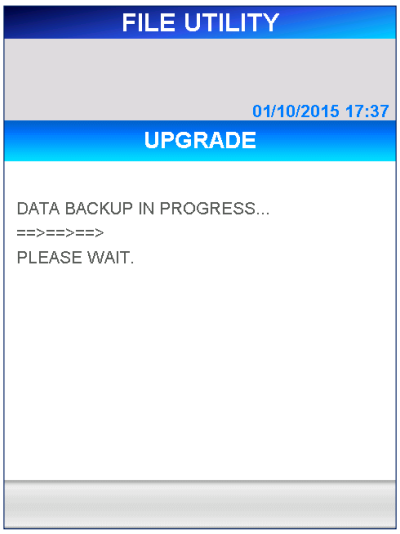
Note: Data backup cannot be cancelled until it is completed.

UPGRADE 1

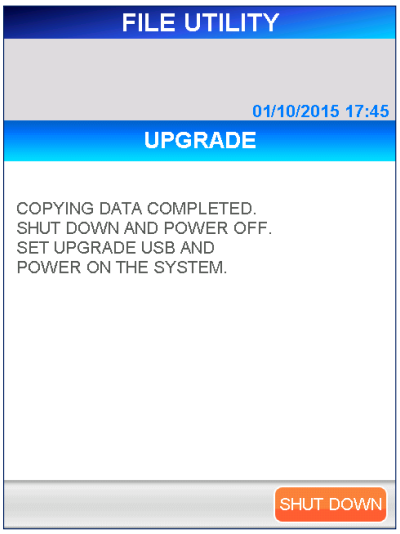


3. The following messages are displayed on the screen during data back up and on completion of data back up.

UPGRADE 2



UPGRADE 3

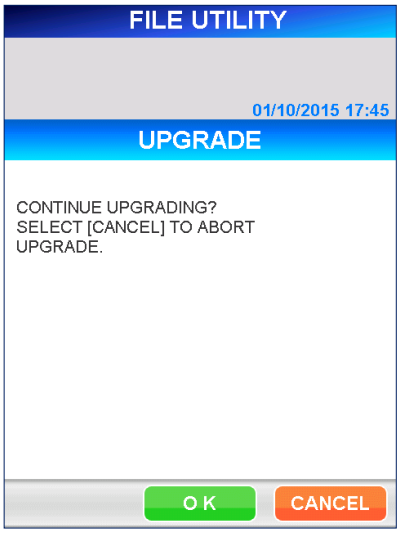


When the above message is shown on the screen, shut the power down. Refer to the procedure described in Section **11.2 SHUT DOWN** in this Chapter.

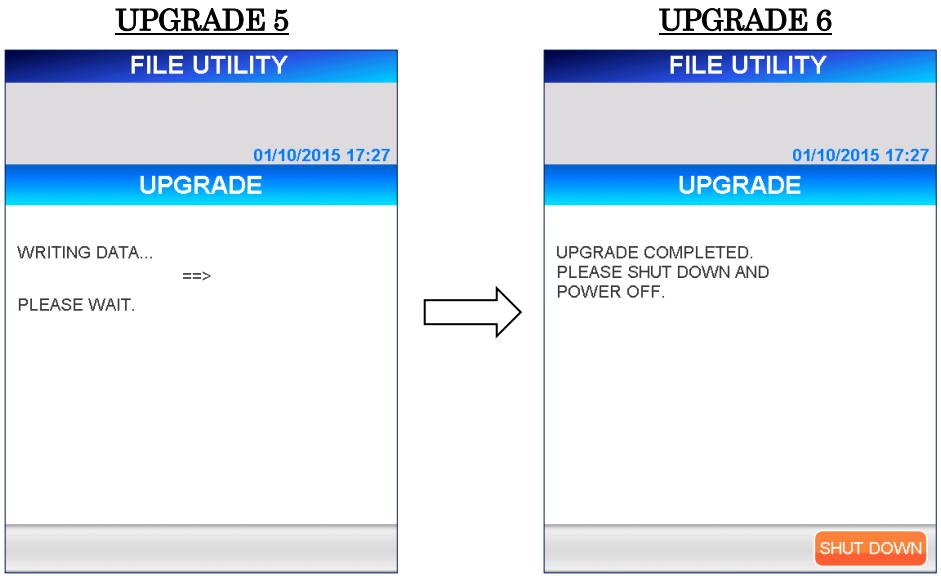
4. While the instrument power is off, disconnect Handheld Barcode Reader from the instrument and insert the USB memory stick provided.

5. Turn the instrument power on.
The following message will appear on the display asking if you want to continue the software upgrade operation. Select OK to continue.

UPGRADE 4



6. After selecting [OK], the following screens are shown.



7. After completion of shut down procedure, remove the USB memory stick and connect Handheld Barcode Reader and turn the instrument power on. Confirm the software version is upgraded by selecting the [ADMIN], [SYSTEM] and [INSTRUMENT INFO.] buttons consecutively.

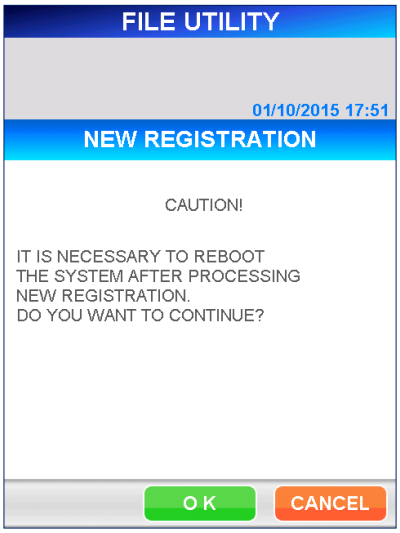
11.5.2 NEW REGISTRATION

From the [NEW REGISTRATION] screen, you can add assay parameters for new assay reagent items without upgrading the system program.
To perform this task, you will need "ITEM PARAMETER DATA SHEET" and the handheld barcode reader.

If a new assay reagent item is released, we will provide you with "ITEM PARAMETER DATA SHEET"

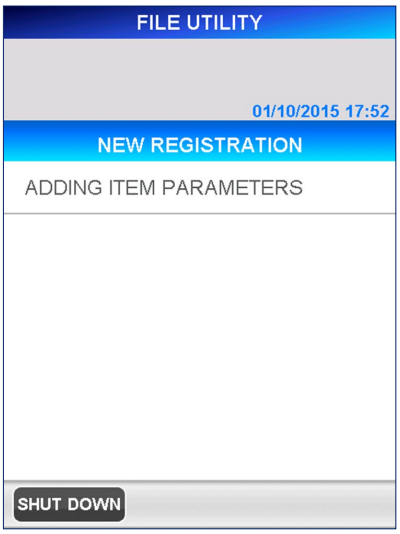
1. Selecting NEW REGISTRATION on the [FILE UTILITY] screen will display the following caution message.

NEW REGISTRATION 1

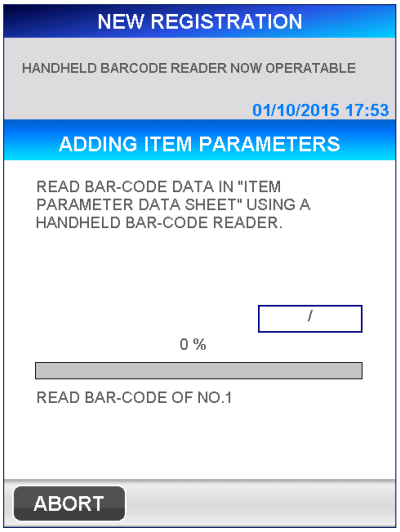


2. Select [OK] and select [ADDING ITEM PARAMETERS] from the [NEW REGISTRATION] screen to show the [ADDING ITEM PARAMETERS] screen.

NEW REGISTRATION 2

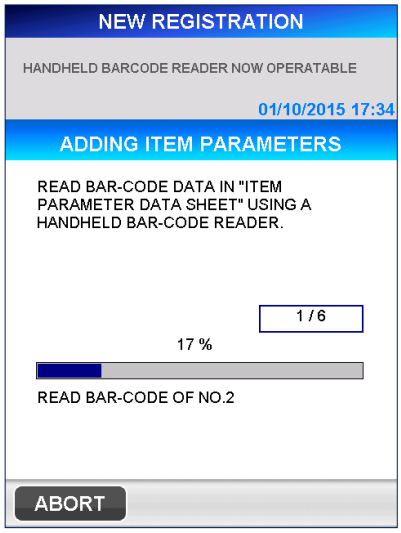


ADDING ITEM PARAMETERS 1



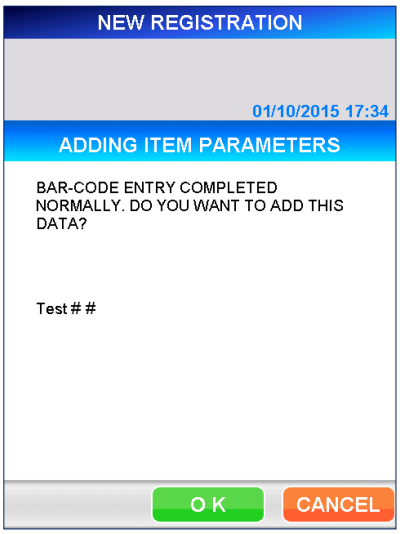
3. Follow the instructions on the screen to read the barcode information from "ITEM PARAMETER DATA SHEET" using a handheld barcode reader.

ADDING ITEM PARAMETERS 2



4. After completion of reading the barcode information, the confirmation screen to add the item parameter will be displayed. Select [OK] to finish reading.

ADDING ITEM PARAMETERS 3



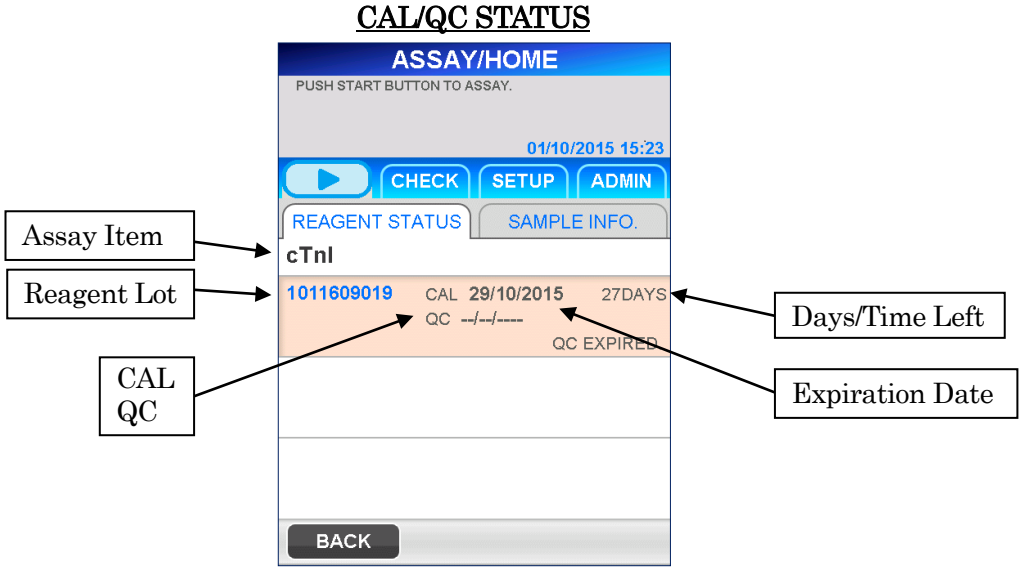
5. This will take you to the [ADDING ITEM PARAMETERS] screen. If you have added all items, select [SHUT DOWN] to reboot PATHFAST.

12 Sample Assay By Host Query (Access Level: 1 and Above)

This chapter provides the procedure for assaying patient samples by receiving orders from a host computer through a query operation using SID (Sample ID) as the indexing key. Please refer to Chapter **5 Preparation for Assay and Basic Operation** for information about preparation for starting the assay operation.

12.1 Checking Effectiveness of CAL and QC

1. Check if calibration data and QC are valid for all assay items registered in [CAL/QC STATUS] screen. Select an assay item on the [ASSAY/HOME] screen. (This step is not required for QC, when the QC Lockout function is deactivated.)



> *Note: For those assay items without valid calibration or QC data an error message is shown after the assay run has started. To continue the assay run, delete the order for that lane. Before running an assay of the patient sample, perform a CAL and/or QC assay run. Before receiving orders from the host computer, we recommend that you check the effectiveness of calibration and QC for all registered assay items.*

12.2 Getting Sample Information

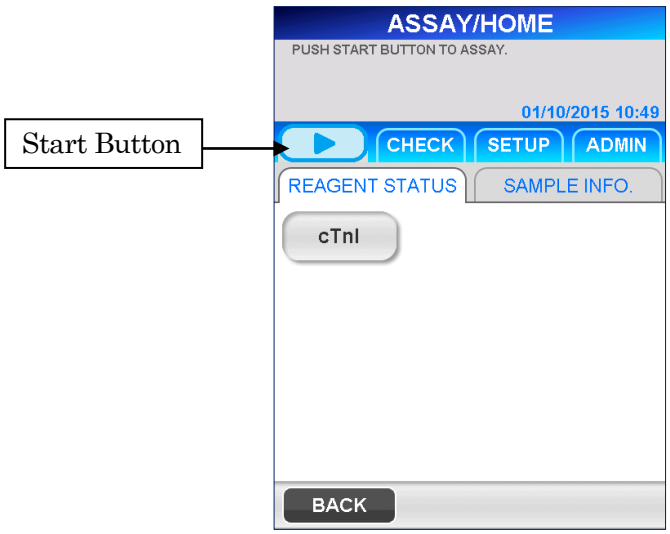
Get sample information by querying the host computer using the sample ID (SID) as the key. The procedure below describes how to get orders and other information for patient samples.

PATHFAST can receive the following sample information.

- Patient ID
- Patient Name
- Birth Date (Not displayed on PATHFAST screen)
- Gender (Not displayed on PATHFAST screen)
- Assay Item Numbers (Displayed as assay item on PATHFAST screen)

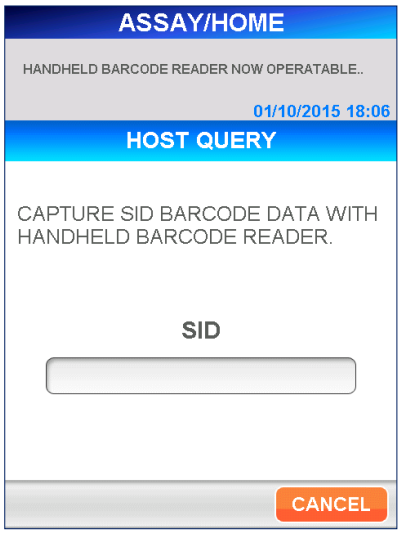
1. The QUERY button is shown in the navi area on the right of the [ASSAY/HOME] screen.
   - ■ This button only appears when the ASTM mode of communication with host computer is selected.

ASSAY/HOME



2. Select QUERY shows the following [QUERY1] screen.

QUERY1



3. Read the barcode of the sample to capture the sample ID.

[Reading by Handheld Barcode Reader]

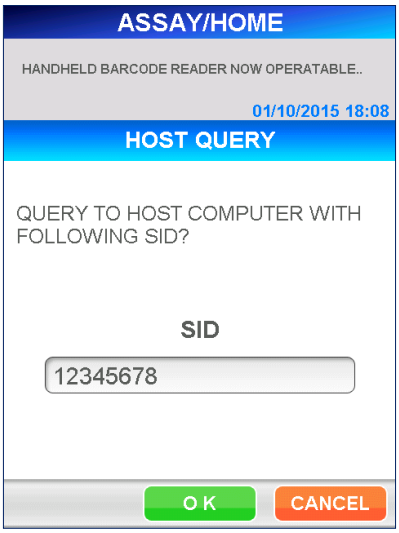
4. When the reader can not read the barcode or when you want to input the SID manually, select the display box for SID to show the Full Keyboard.

[Full Keyboard]

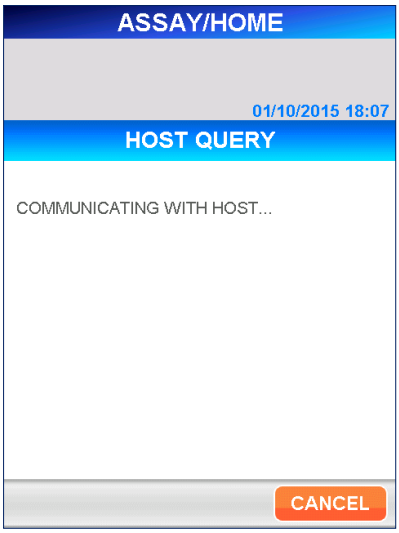
- **Length 1 – 20 characters from full keyboard, all letters are usable including space.**

5. Select OK in the keyboard screen to show the following confirmation message.

QUERY2

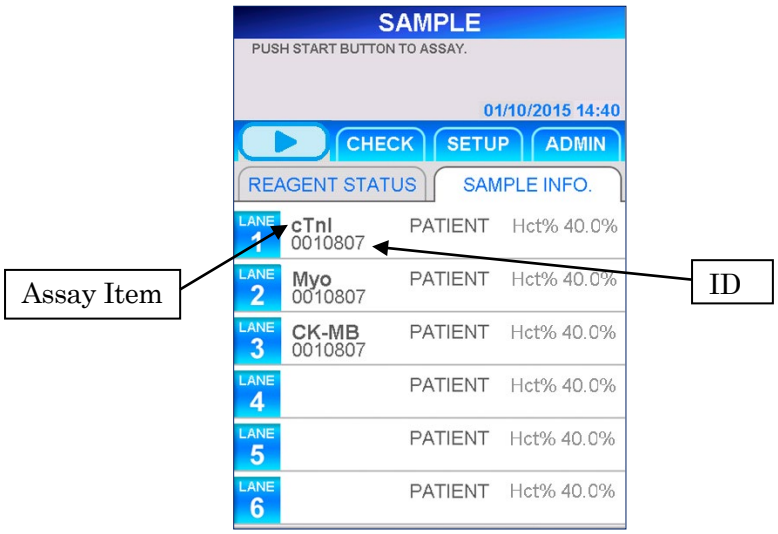


QUERY3



6. When sample information from the host computer is received, the following screen is automatically shown. On the [SAMPLE INFORMATION 1] screen, assay items and SIDs or predefined information of the patient are allocated to each available lane in the order received.

SAMPLE INFORMATION 1

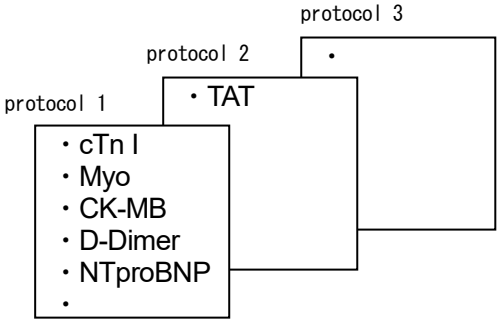


Caution : When orders are received from a host computer, each assay item is assigned to a lane as shown in the above screen. The reagent cartridges and patient samples must be set to correspond to the designated lane.

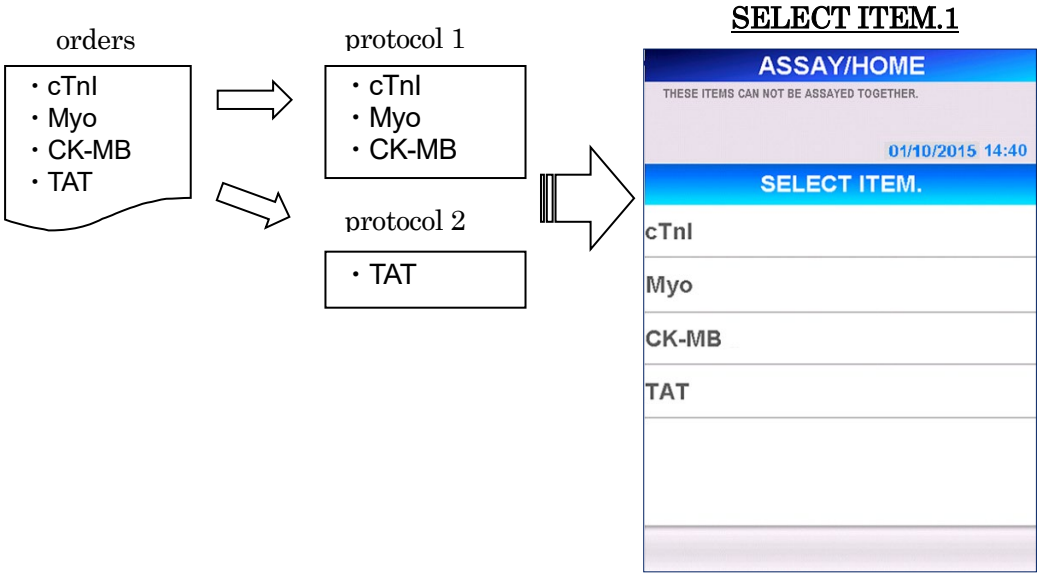
■ On the above screen you can designate which information is displayed for ID Refer to Section **10.6 LIS SETTINGS** in Chapter **10 SETUP** for details.

- SID (Sample ID)
- PID (Patient ID)
- Patient Name

7. Orders contain a combination of assay items that cannot be performed simultaneously. With PATHFAST, reagents must be used in accordance with the protocol set for each reagent. Assays using a same protocol can be performed simultaneously. However, if assays have to be performed using different protocols, these assays must be performed separately.

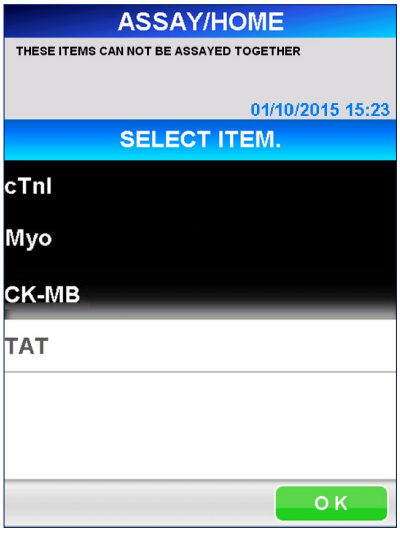


8. If orders received from the host computer contain a combination of assays that cannot be performed simultaneously, PATHFAST will group the assay items by protocol and display the assay groups.

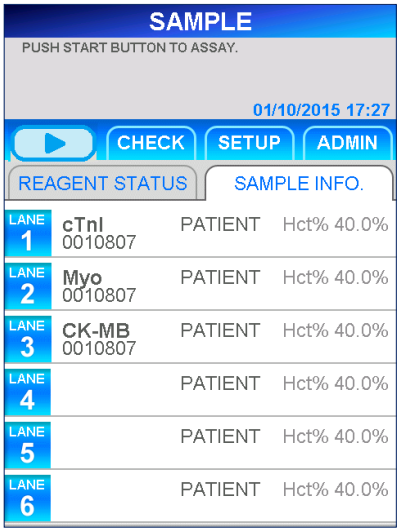


9. If you select a group to be assayed first and select OK , PATHFAST will display a message notifying that the assays are reserved on the [SAMPLE INFORMATION 2] screen.

SELECT ITEM.2

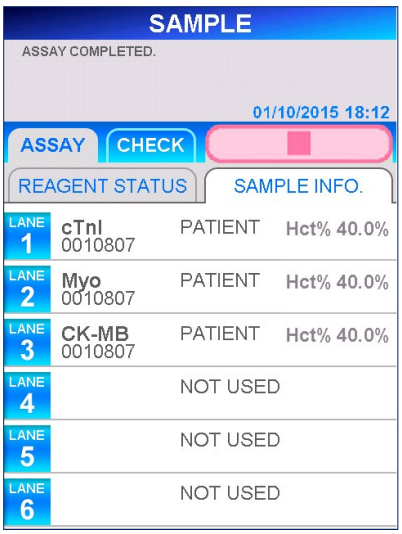


SAMPLE INFORMATION 2

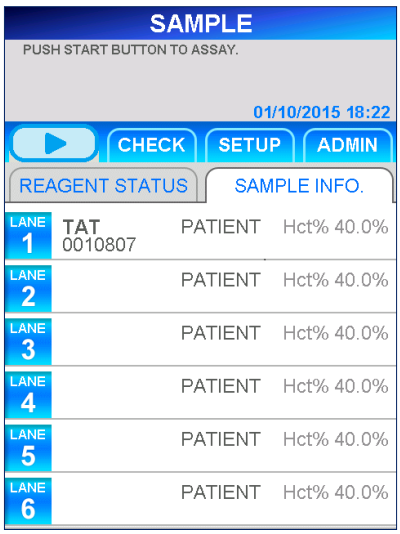


10. The assays that were not selected are stored in the internal memory as the reserved assays to be performed next, and after the completion of the selected assays, these stored assays are displayed on the lanes of the [SAMPLE INFORMATION 3] screen.

COMPLETION OF FIRST ASSAYS



SAMPLE INFORMATION 3



■ If the memory contains more than one group of assays, the [SELECT ITEM 1] screen will be displayed again, and you can select the group for next assay.

11. If there is an unused lane on the [SAMPLE INFORMATION 2] screen, you can receive an order for another sample from host computer.
Select [REAGENT STATUS] to go to the [ASSAY/HOME] screen and repeat steps 1 through 9 above.

■ If there is a combination of assays that cannot be performed simultaneously, the empty lanes for the number of assays in the previously selected protocol group will be added. Other assays will be stored in the internal memory by protocol.

12. If no order information is received or too many orders are received from the host computer, the following messages are displayed on the screen.

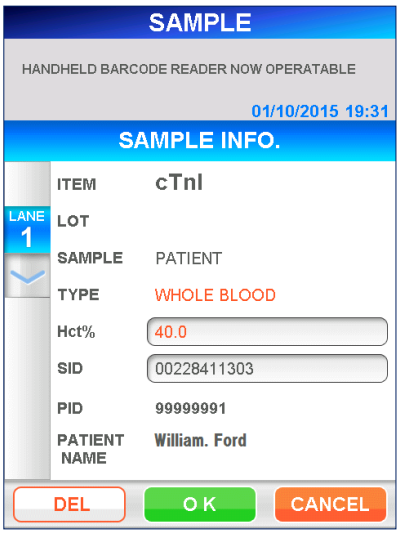
- If no order information is received
  [NO ORDERS RECEIVED. CHECK SID.]
- If too many orders are received
  [EXCEED CAPABLE TEST NUMBERS. ASSAY THIS SAMPLE IN NEXT]

■ Exceeding tests will be stored in the internal memory.

In addition, if an error is detected in host communication, corresponding error messages and error codes are shown on the screen. Refer to Section **14.4 Error Messages** for further information.

13. When you are finished receiving orders from the host computer, check each sample's order information on the [SAMPLE INFORMATION] screen. To check the details of each lane, select [LANE NO.] to show the [EDIT INFORMATION] screen.

EDIT INFORMATION



14. Select [DEL] to delete the sample information. You will receive the following confirmation message. "DELETE LANE INFORMATION?"
Select [OK] to delete the patient sample information. You can verify that the information has been deleted on the [SAMPLE INFORMATION] screen.

- If the internal memory contains the reservations for the same assays as the group in deleted order, the reserved assay items will be assigned to the same lanes automatically.

15. To edit the hematocrit value for the sample, select the display box of Hct% to input the value on the numeric keypad.
    - **Range : 0.000 – 60.0 (initial value: 40.0)**
    - When the sample is not recognized as whole blood, the Hct% value is hidden.

Caution : You don't have to edit SID of lane by the host computer.

16. Perform the same procedure for any other whole blood samples.

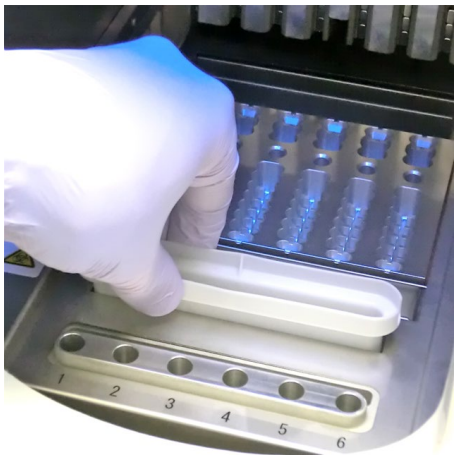
17. After verifying all information, go back to the [SAMPLE INFORMATION] screen for preparation to begin the assay run.

12.3 Preparation of Instrument and Samples

12.3.1 Setting Tip Waste Box (PATHFAST WASTE BOX)

Before preparing samples and reagent, check if there are any used tips left in the tip waste box. If necessary, remove the box and discard the used tips. Reset the waste box.

Note: Replace the tip waste box every 20 batch runs or weekly.



[Setting Tip Waste Box]

12.3.2 Sample Preparation

Sample types (whole blood, plasma, or serum), anti-coagulants, and sample volume are assay dependent. Refer to the package insert of the appropriate reagent for details.

Follow the universal precaution instructions when collecting and handling samples.

12.3.3 Preparing Reagent Cartridges and Setting to PATHFAST

In preparing reagent cartridges for assay runs, follow the precaution instructions below.

- Wear appropriate personal protective equipment to prevent exposure from reagents or sample.
- Run assays soon after taking the reagent cartridges from refrigerator, Do not leave reagent cartridges unrefrigerated for extended period of time.
- Follow the precaution instructions described in the applicable package inserts.

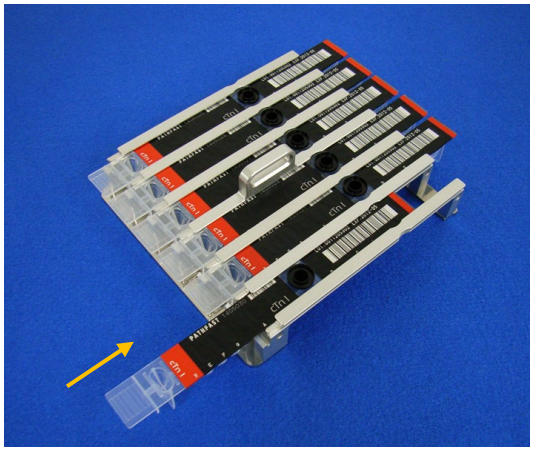
1. Take reagent cartridges out of the refrigerator. Insert reagent cartridges needed in the slots of reagent cartridge rack and push them firmly into place.

The following precaution should be taken in the procedure to avoid erroneous results:

- When handling reagent cartridge, hold it by the cartridge edge. Avoid touching

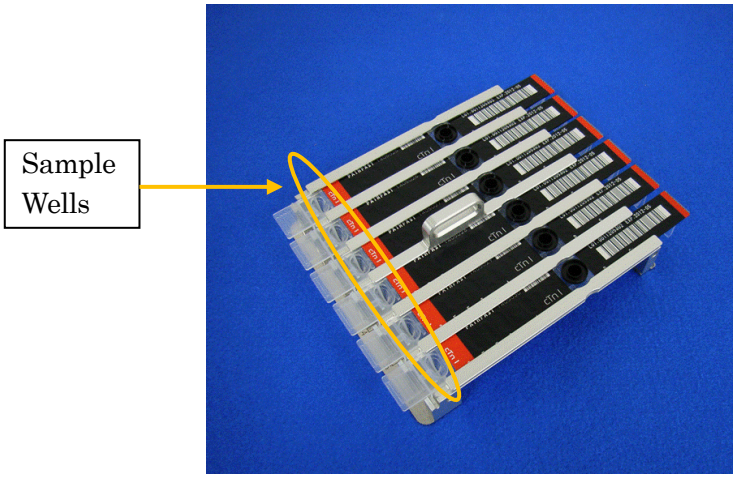
the aluminum seal and detection well.

- Be careful not to introduce saliva into the detection well by blowing into the well.
- Do not use reagent cartridges that have been dropped on the floor.
- Before testing, remove any bubbles in wells of reagent cartridge or liquid on the aluminum seal inside, by softly tapping the cartridge on a flat surface.



[Inserting Reagent Cartridge in Reagent Cartridge Rack]

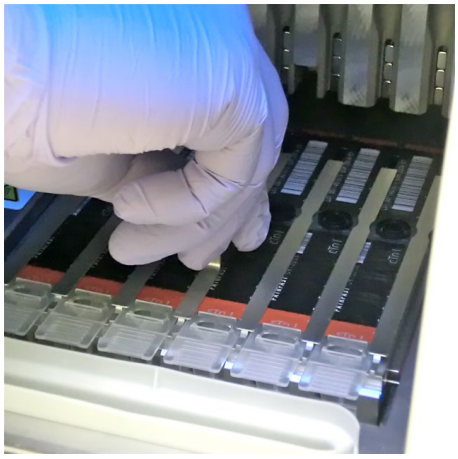
2. Dispense sample into sample well of reagent cartridge up to the line inside the well using pipette or dropper. Remove any bubbles before running the assay.



[Dispense samples in Sample Wells]

Caution : When orders are received from a host computer, each assay item is assigned to a lane as shown in the above screen. The reagent cartridges and patient samples must be set to correspond to the designated lane.

3. Open the front cover of the instrument and set the reagent cartridge rack properly into place.



[Set Reagent Cartridge Rack]

12.3.4 Setting Disposable Tips (PATHFAST TIP)

Use the designated disposable tips with PATHFAST.

[PATHFAST TIP]

1. Remove new disposable tips from the tip box and set them into the tip holder holes of PATHFAST for lanes in which reagent cartridges are set. Be careful that the tip ends are not dirty or damaged.

[Setting PATHFAST TIPs]

2. When finished setting disposable tips on tip holder, close the front cover completely.

[Close Front Cover]

12.4 Starting Assay Run and Assay Completion

12.4.1 Starting Assay Run

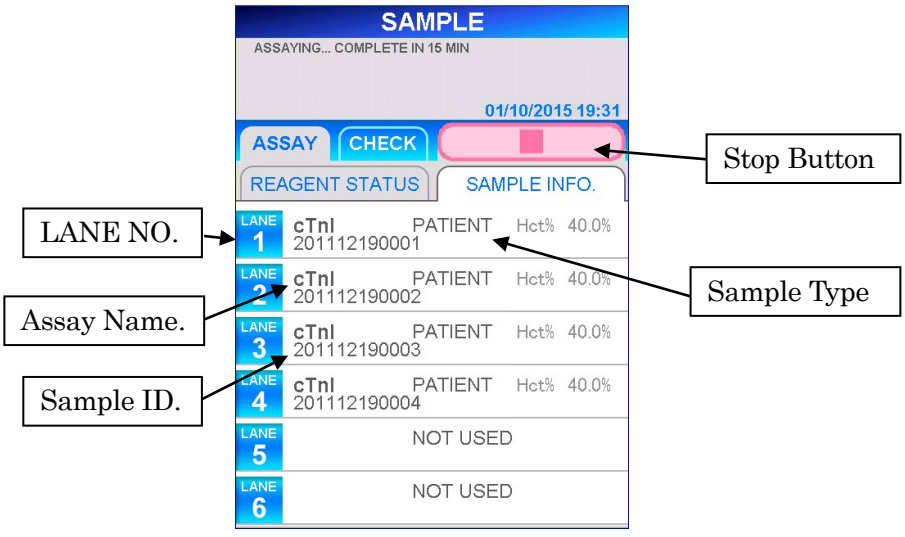
1. Push " ▶ " button in the Subtitle Area of the screen to begin the assay run.

> *Note:*
> - *Start the assay run promptly when assay preparation is completed.*
> - *Precipitation of blood cells in a whole blood sample or sample evaporation may affect the result obtained.*

Before starting the actual assay, PATHFAST completes various checks.
An error message will be displayed if any abnormal condition is found.
Stay near the instrument so that, if necessary, you may take the appropriate actions according to the message displayed. Refer to Chapter **14 Troubleshooting** for further information on error messages.

2. The following screen is shown during assay operation.

ASSAYING SAMPLE



- After the assay is started, PATHFAST checks Reagent Cartridges, Assay Item and Type of Sample (whole blood or other) for each lane in order to display the information on the screen above. If the sample is not recognized as whole blood, Hct% is not shown for that sample.

- When canceling QC assay after starting, select " ■ " button in the Menu area of the screen. A confirmation message is displayed.

3. Sample information can be edited after you start an assay run.
Select [LANE NO.] on the [SAMPLE INFORMATION] screen and follow steps 2 to 6 of Section **6.2 Editing Sample Information**.

Caution : You don't have to edit SID of lane by the host computer.

Note: Finish editing sample information before the assay run completes.
If you keep the [EDIT INFORMATION] screen displayed, the measured results are not printed. The instrument gives you a message asking if you want to continue editing information or not. Follow the instructions displayed.

12.4.2 Result Output

When the assay run is completed the measured results are printed on the built-in printer and the [ASSAY/HOME] screen is displayed.

Note: If the instrument is set to send the results to external computer, the results are sent to the external computer before printing.

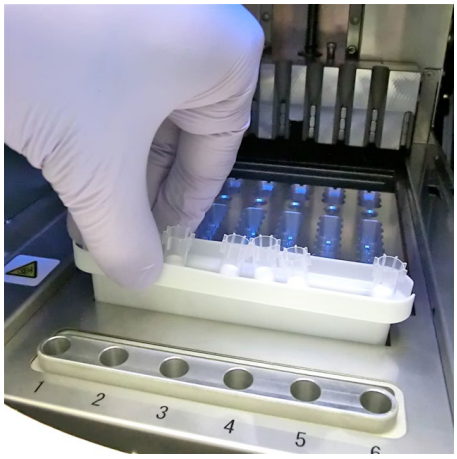
The following is a sample print out.

Printed Data	Description

DATE: 10/01/2022 14:55	←Time Assay Started
SAMPLE ID: 202201100011	←ID of Sample
LANE: 1	←Lane No
cTnI	←Assay Item
0.058 ng/mL	←Result with Unit
REMARK: DF	←Remarks Separated by comma*
TYPE: WB (40.0%)	←Sample Type
SAMPLE: PATIENT	←Sample (Patient)
PATIENT ID: A1300901	←ID of Patient
PATIENT NAME: John K. Washington	Patient Information (Name, Birthday, Sex) from Host Computer
BIRTH DATE: 12/12/1965	
PATIENT SEX: M	
INSTRUMENT SERIAL: 1511D2600	←Instrument Serial Number
PROGRAM VERSION: 4.1.1	←Program Version
OPERATOR ID:USER1	←User ID
REAGENT LOT: 1012210243	←Reagent Lot No.
CALIBRATED ON: 04/01/2022	←Date of Calibration

12.4.3 Discarding Used Reagent Cartridges and Tips

1. Discarding used tips:
   Remove the tip waste box from the instrument and discard the used tips.
   Follow regional guidelines for handling when discarding used tips.
   After discarding tips return the tip waste box back to its position.
   Note: Replace the tip waste box every 20 batch runs or weekly.



[Tip Waste Box]

2. Discarding used reagent cartridges:
   Take the reagent cartridge rack out of the instrument and remove the used cartridges. Be careful not to drop or splash liquid from the cartridges. Refer to the regional guidelines when discarding the reagent cartridges.

13 Maintenance

In this chapter, periodic maintenance and the replacement of consumables procedures are described. Perform maintenance with the instrument powered off and wearing the appropriate personal protective equipment (gloves, glasses, lab coat, etc.).
Keep the instrument, accessories and disposable clean. Use the "**IV. Records of Maintenance**" page of this manual to keep a record of any maintenance performed.

Clean your PATHFAST instrument (ex: stage surface) by the procedure in "**13.1.1 Weekly Maintenance**" and "**13.1.2 Monthly Maintenance**".

For cleaning of your PATHFAST instrument, please use only cleaning agents listed at "**13 Maintenance**". When using cleaning agents which is not listed at "**13 Maintenance**", ask your PATHFAST representative.

If your PATHFAST instrument requires repair or disposal, please contact your PATHFAST representative. Before repair or disposal, clean your PATHFAST instrument by the procedure in " **13.1 User Maintenance** ".

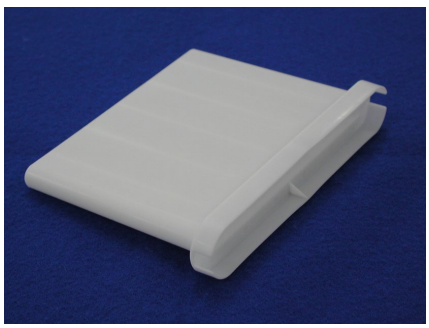
13.1 User Maintenance

13.1.1 Weekly Maintenance

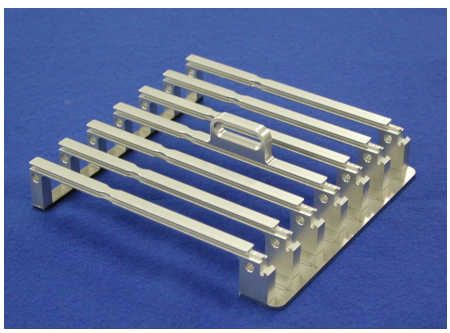
1) Replacing the Tip Waste Box
Replace it every 20 batch runs or once a week, whichever comes first.

2) Cleaning the Reagent Cartridge Rack
Wipe the rack using gauze soaked with antiseptic ethanol.

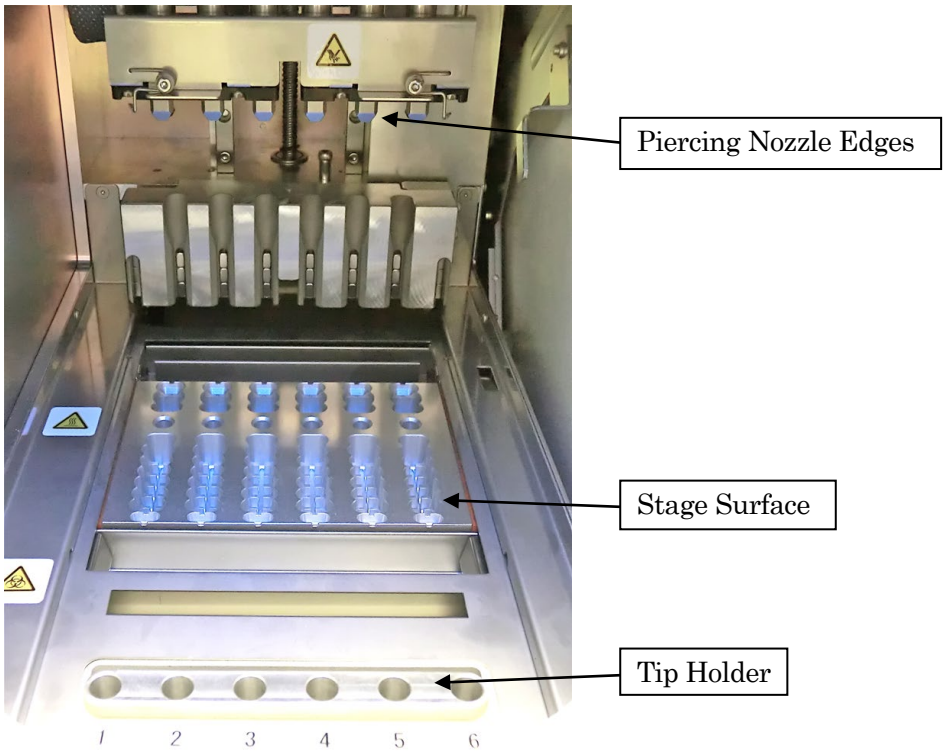
3) Cleaning the stage surface
Wipe the surface using gauze soaked with antiseptic ethanol.



[Tip Waste Box]



[Reagent Cartridge Rack]



13.1.2 Monthly Maintenance

Perform the following monthly.

1) Clean the outside of the instrument

Wipe the outside of the instrument using gauze moistened (not dripping) with a neutral detergent.

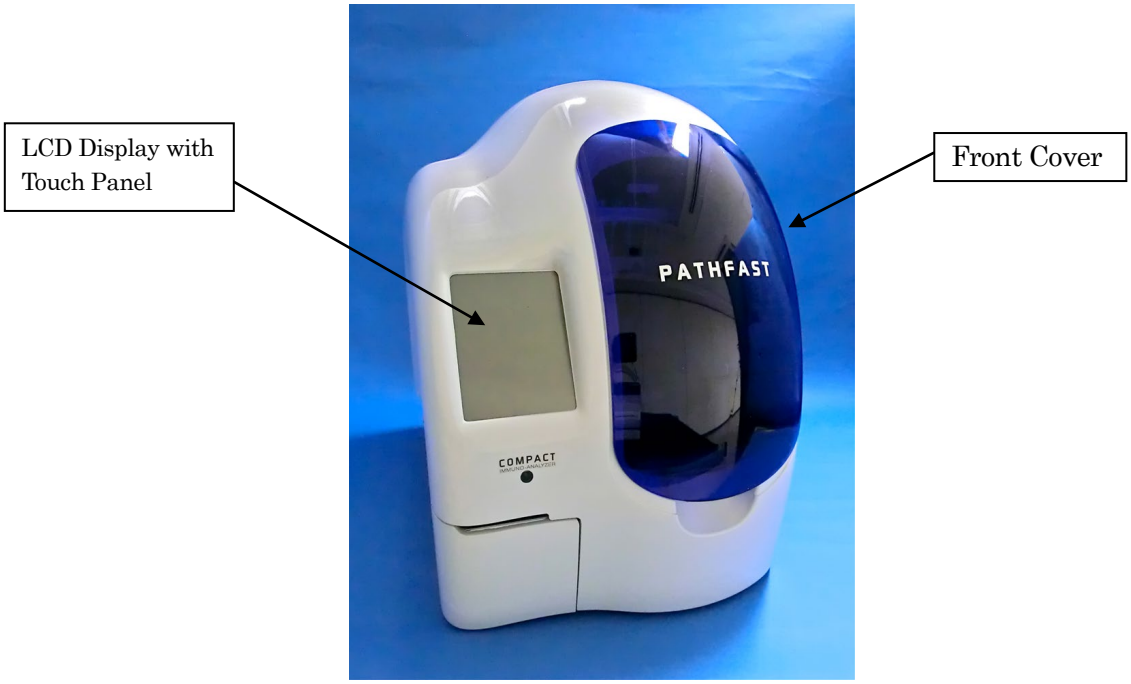
Note: Be sure that the detergent does not get into the instrument.

2) Cleaning the piercing nozzle edges

Using gauze moistened (not dripping) with antiseptic ethanol, lightly wipe the piercing nozzle edges one by one. The nozzle edge is very sharp, use extra care. To avoid contamination of the nozzle edge, do not touch with an ungloved hand.

3) Cleaning the Tip Holder

Wipe the surface of the tip holder using gauze moistened (not dripping) with antiseptic ethanol. To clean inside the hole, use a cotton swab wrapped with gauze moistened with antiseptic ethanol. To avoid cross-contamination, use new gauze for each hole.



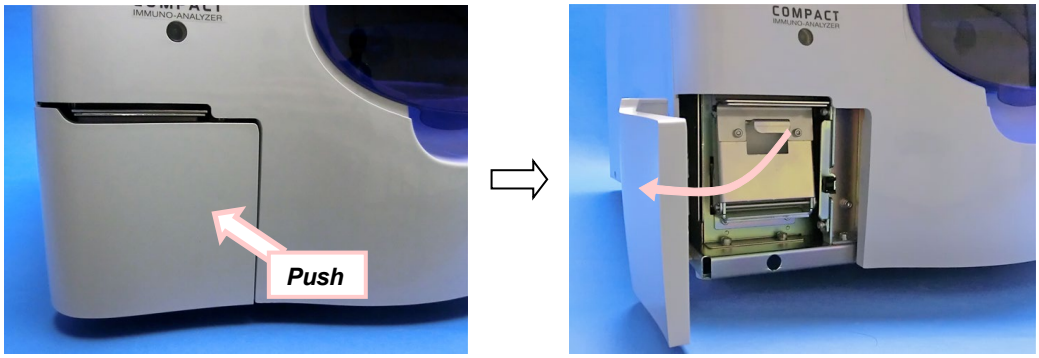
13.2 Miscellaneous

13.2.1 Replacing Printer Paper

Follow the procedure below to replace the printer paper.

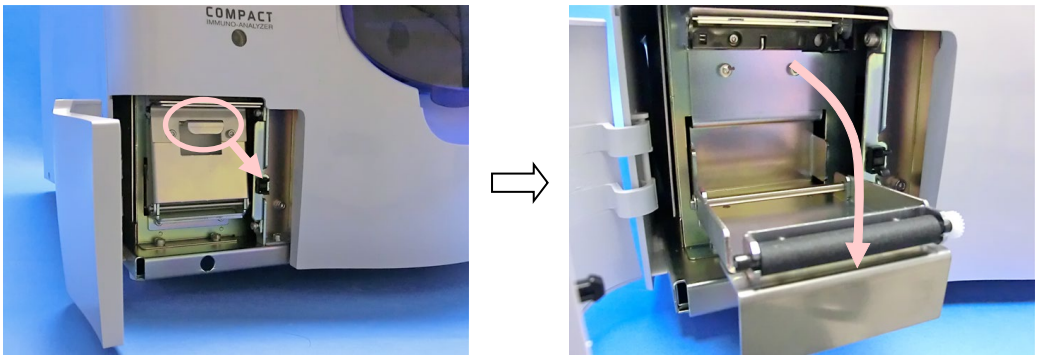
<Procedure for replacing printer paper>

1. Open the printer cover located at lower front left of the instrument by pushing the right upper center of it.

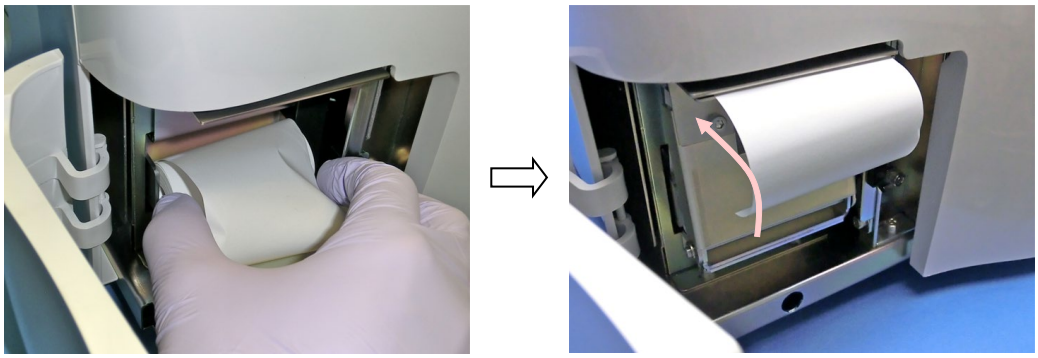


2. Pull the knob in the center to open the printer paper holder plate as shown in the picture below.

> ⚠ *Caution : Take care not to be hurt by the paper cutter teeth.*



3. Remove the used printer paper roll and set the new paper so that the paper rolls out from the top. Then push the holder plate back in place. Cut the excessive paper by using the cutter teeth.



4. Close the printer cover.

13.3 Recommended Periodic Maintenance

To ensure optimal performance of your PATHFAST instrument we recommend periodic maintenance be done by an authorized PATHFAST technical service representative. Please contact your PATHFAST representative for complete details and scheduling.

1) Periodically we will
- Check the overall mechanical movements
- Check the teaching positions
- Check the optical unit
- Check the fans
- Perform an overall cleanup
- Other maintenance as needed

2) Recommended Part Replacement
- Air Filter
  Once a year with average use
- Timing Belts for P-Axis and Z-Axis motors
  Once every two years or sooner depending on usage
- Syringe Unit
  Once every three years or sooner depending on usage

13.4 SELFCHECK

PATHFAST has the self-check function executed automatically at regular intervals or manually as needed . Refer to **11.4.4 SELFCHECK** for details.

In the event that some failure has been detected during self-check, no further assay run will be allowed. When this happens, please contact our representatives.

14 Troubleshooting

This chapter provides information about remarks and error message. If you experience a problem, look here first. If the problem persists, or is not addressed in this manual, contact your PATHFAST representative for additional assistance.

14.1 Introduction

PATHFAST responds to detected error conditions with remarks and error Messages. Remarks are added to the printed results and are shown on the screen. Remarks consist of one or two alphabetic characters.

14.2 Remarks

The table below lists remark codes, the code description and the recommended user action.

Table 14-1 Remark Codes

Remark Code	Description	Data Handling	User Action
S	No sample found	The remark code is added to the result. Asterisks are printed instead of data.	Re-assay
NT	No tip found	The remark code is added to the result. Asterisks are printed instead of data.	Re-assay
NC	No valid calibration available on assay completion.	The remark code is added to the result. Asterisks are printed instead of data.	Recalibrate
ED	Secondary count is lower than predefined value.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
H1	Temperature of Heat Block L is too high.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
H3	Temperature of Heat Block T is too high.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
L1	Temperature of Heat Block L is too low.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
L3	Temperature of Heat Block T is too low.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
UK	Error reported by sample recognition sensor	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative

ER	LED light signal of sample recognition sensor too low.	The remark code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
DF	Assay result was calculated with hematocrit correction using the default hematocrit value.	Data will print with remark added.	None
OR	Measured QC is out of control range.	Data will print with remark added.	Re-assay
RS	Remark added for recalculated data using new Hct% value when transmitted to the host computer.	None	None
AE	Abnormal luminescent count	The remark code is added to the result. Asterisks are printed instead of data	Re-assay
HC	Hct% calculation error	The remark code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative
CI	Calculation error other than HC above	The remark code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative
BE	PMT position error	The remark code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative

14.3 Error Codes for Calibration Fail

When calibration assay fails, error codes are added in the printout of the result. The error codes consist of two digit numeric number.
The table below is the list of error codes with meanings and countermeasures.

Table 14-2 Error Codes for Calibration Fail

Code	Description	Data Handling	User Action
01	CV% of CAL1 counts is greater than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
02	CV% of CAL2 counts is greater than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
03	In two point calibration, average of CAL1 counts is greater than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
04	In one point calibration, average of CAL1 counts is smaller than a preset limit. Or in two point calibration, average of CAL2 counts is smaller than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
05	In one point calibration, average of CAL1 counts is greater than a preset limit. Or in two point calibration, average of CAL2 counts is greater than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
06	Absolute value of "Cal F b" in two point calibration is greater than the specified value.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
07	Secondary count is greater than a preset limit and counts ratio to primary count is smaller than a preset limit.	Calibration is failed. The failed data are stored with error code.	Re-calibrate
08	Calculation Error	Calibration is failed. The failed data are discarded.	Re-calibrate
09	At least one remark is added for the calibrators.	Calibration is failed. The failed data are stored with error code.	Re-calibrate

10	Similarity error to the master calibration curve	Calibration is failed. The failed data are stored with error code.	Re-calibrate

14.4 Error Messages

If an operational error and/or an instrument malfunction is detected, error messages are displayed on the screen.
Error messages may contain instructions for the next action to be taken.
In the following list, possible error messages are listed, along with the reason for the message and any user action to be taken.

Table 14-3 Error Messages

When observed	Message	Possible causes	User Action
Assay processing	ABNORMAL DARK CURRENT	Abnormal dark current obtained in the detection well	Replace reagent cartridge
Assay processing	LUMINESCENCE ERROR	Abnormally large counts obtained in the detection well	Replace reagent cartridge
Assay processing	PMT FITTING ERROR	PMT did not fit on the detection well correctly	Replace reagent cartridge
Host communication	RECEIVED ASSAY ITEM DOES NOT EXIST	The assay item received from host computer is not registered in PATHFAST	Perform MC Entry operation for the assay item
Host communication	COMMUNICATION ERROR	Communication with host computer could not established	Check communication cable and PC ready status
System initialization	SYSTEM ERROR I0011, I0013,I0020	Error detected during system initialization	Record the Error Code and contact your PATHFAST representative
File operation	SYSTEM ERROR F0051, F0054	Error detected in file operation	Record the Error Code and contact your PATHFAST representative
Motor control	SYSTEM ERROR M0101 – M0103 M0105, M0107	Error detected for motors or position sensors	Record the Error Code and contact your PATHFAST representative
PMT control	SYSTEM ERROR P0200 – P0202	Error detected in PMT Operation	Record the error code and contact your PATHFAST representative

Host communication	SYSTEM ERROR H0351	No response from host computer	Check if Host PC is ready
New item registration	Barcode Type Error	The "ITEM PARAMETER DATA SHEET" for Type-A / B / C is used.	Please use the "ITEM PARAMETER DATA SHEET" for Type D

FOR TECHNICAL SERVICE CONTACT
YOUR AUTHORIZED PATHFAST REPRESENTATIVE.

Contact for technical assistance

www.pathfast.eu/contact

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EC REP

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