

LiNEAR

AURA

Chemiluminescence Immunoassay Analyzer

Operator's Manual



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CE

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If the manual needs to be modified due to technical development, no prior notice will be given.

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Renewal History

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1.0.0.0	1.0.0.0	2019-9-29	New formulation

Edition notice

Operator's Manual of AURA Analyzer.

This document is for users of the AURA analyzer.

Every effort has been made to ensure that all the information contained in this document is correct at the time of printing. However, Linear Chemicals, S.L.U. reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Software updates are done by the Linear Diagnostics service representative.

Linear Chemicals, S.L.U. has confirmed the provided operational guidelines for use of the system, reagents, analyzers, software, and confirmed the characteristics of which can be defined by the user, to ensure the optimization of product performance and meets the requirement of product specifications. Linear Chemicals, S.L.U. does not recommend user-defined changes that maybe affect system performance and test results. Users are responsible for confirming any changes to these guidelines, analyzers, reagents or software provided by the company.

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Contents

1 About Operator's Manual	5
2 Before You Begin.....	6
2.1 Scope of application.....	6
2.2 Features	6
2.3 Specifications	7
2.4 Performance	7
2.5 Electromagnetic compatibility EMC.....	8
2.6 Hazardous substances requirements.....	10
3 Overview	11
3.1 Principle of test	11
3.2 Components.....	11
3.3 Accessory list.....	17
3.4 Disposable materials.....	18
3.5 Reagent kit composition	19
4 Safety Instructions for Installation and Operation	21
4.1 Installation	21
4.2 Sample disposal	22
4.3 Warning symbols.....	22
4.4 Safety instructions	23
4.5 Disclaim clause	26
5 Preparation Procedure.....	27
5.1 Introduction	27
5.2 Operations and expressions.....	27
5.3 Before power on	28
5.4 Power on	28
5.5 Sample Assay/Home	29
5.6 Registering new assay.....	32
5.7 QC Setting	34
5.8 Shut down	36
6 Sample Assay.....	38
6.1 Check validity of calibration and QC.....	38
6.2 Edit sample info	38
6.3 Preparation of analyzer and samples	41
6.4 Start and End Sample Assay.....	44
7 Calibration.....	49
7.1 Introduction	49
7.2 Calibration purposes	49
7.3 About calibration	49
7.4 Preparation for calibration	50
7.5 Preparation of analyzer and calibrators	52

7.6 Start and End Calibration Assay	55
8 QC Test	60
8.1 Introduction	60
8.2 Purpose of QC test	60
8.3 About QC test.....	60
8.4 Preparation for QC test.....	60
8.5 Preparation of analyzer and QC samples.....	62
8.6 Start and End QC Assay.....	66
9 Check.....	70
9.1 Introduction	70
9.2 Sample result check	70
9.3 QC result check	72
9.4 Calibration result check	74
9.5 Real-time temperature check	76
10 Setting	78
10.1 Introduction	78
10.2 System Setting	79
10.3 Assay parameter setting	79
10.4 QC Setting	83
11 Maintenance	87
11.1 User Maintenance.....	87
11.2 Others	88
11.3 Recommended regular maintenance	89
12 Troubleshooting	90
12.1 Introduction	90
12.2 Remark definition	90
12.3 Error codes of failed calibration	92
12.4 Error messages.....	93
Appendix	97



1 About Operator's Manual

This manual contains the necessary information for correct, safe and effective operation of the AURA. Please read and understand this manual before operating the AURA.

2 Before You Begin

This chapter includes the AURA test principle, scope of application, features, specifications, components, accessories, disposable materials & reagent kit compositions.

2.1 Scope of application

This product is designed to quantitate analytes in human specimens by counting and analyzing photons generated by enzymatic chemiluminescence immunoreactivity of human samples.

The reagents are manufactured by Linear Chemicals, S.L.U. The test principle used in the reagent system is CLEIA (chemiluminescent enzyme immunoassay).

2.2 Features

Compact design	Space-saving.
Automation	Automatic sampling, reagent reaction and test.
Sample	Whole blood, plasma, serum.
Multiple assays processing	Up to six different assays can be completed simultaneously.
Short test time	Min. 15 minutes (it depends on the assay).
Easy to use	Independent quantitative disposable cartridges, no washing liquid or waste liquid container(s) required.
High sensitivity / precision / repeatability	High precision and repeatable operation of the photon counter can detect micro scale analytes.
Minimum cross contamination	The possibility of cross contamination between samples is minimized by the use of the separate cartridge.
Barcode management	Barcode includes assay name, manufacturer calibration data, and product expiration date. Sample ID and user ID can also be acquired by scanning barcode.

2.3 Specifications

Instrument type	Benchtop
Throughput	Samples: up to 6 samples/batch Throughput: Min 15 minutes /6 tests (*Depends on the IFU of each assay)
Sample type	Whole blood, plasma, and serum
Temperature control	Constant temperature 37 °C Preheating 35 °C
Sample volume	20-700 micro liter
Pipetting precision	50 µL; CV is up to 2% Note: use distilled water, RT20-25 deg.c
Wave length	300-650 nm (PMT sensitive peak 450 ± 50 nm)
Data memory:	
Patient data	Up to 3 days, up to 600 per day
QC data	Up to 4 batches, the latest 200 per batch
Calibration data	Up to 4 batches, the latest 200 per batch Note: first-in, first-out
Power	100-240 VAC, 50/60 Hz
Power consumption	150 VA
Dimensions	55 cm*36 cm*55 cm (length * width* height)
Weight	40.6 Kg (net weight)
Product life	10 Years
Date of manufacture	See label

2.4 Performance

2.4.1 Accuracy and volatility of temperature control in reaction environment

The environment temperature accuracy should be within plus or minus 0.5 °C of set value, and volatility should be not more than 1.0 °C.

2.4.2 Stability of the analyzer

The relative deviation among the test results at 4th hour and 8th hour in the steady working state of the analyzer and the test results at the beginning of the stable working state is not more than 10%.

2.4.3 Repeatability in batches

Repeatability in batches: (CV, %) ≤ 8%.

2.4.4 Linear correlation

The linear correlation coefficient (r) ≥ 0.99 in the concentration range of not less than 2 orders of magnitude.

2.4.5 Main function of the analyzer

The analyzer should have the following main functions:

- The user can use the man-machine dialogue command to enable the instrument to automatically complete the analysis tasks of different samples and assays;
- The instrument should be able to indicate the status of consumables and wastes such as reagents;
- The instrument has a self-test function;
- Fault prompt: The instrument should have corresponding prompts for operational errors, mechanical and circuit faults.

2.5 Electromagnetic compatibility EMC



Note:

The AURA chemiluminescence immunoassay analyzer meets the emission and immunity requirements specified in this part of GB/T 18268.26, see table below.

It is the responsibility of the user to ensure that the equipment is in an electromagnetic compatibility environment so that the equipment can work properly. It is recommended to evaluate the electromagnetic environment before the equipment is used.

Table 2-1:

Electromagnetic emission	
Emission test	Compliance
GB 4824 RF transmission	Group 1
GB 4824 RF transmission	Class A
GB 17625.1 Harmonic emission	N/A
GB 17625.2 Voltage fluctuation / flicker emission	N/A

Table 2-2:

Electromagnetic immunity			
Item	Basic standard	Test value	Compliance criteria
Electrostatic discharge (ESD)	GB/T 17626.2	Contact discharge: $\pm 2\text{kV}$, $\pm 4\text{kV}$ Air discharge: $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$	B
Radio frequency electromagnetic field	GB/T 17626.3	3V/m, 80MHz ~ 2.0GHz, 80%AM	A
Pulse group	GB/T 17626.4	Power line: $\pm 1\text{kV}$ (5/50ns, 5kHz) I/O signal line: $\pm 0.5\text{kV}$ (5/50ns, 5kHz)	B
surge	GB/T 17626.5	Wire to ground: $\pm 2\text{kV}$ Wire to wire: $\pm 1\text{kV}$	B
Radio frequency conduction	GB/T 17626.6	Power cord: 3V/m, 150kHz to 80MHz, 80% AM I/O signal line: 3V/m, 150kHz~80MHz, 80%AM	A
Power frequency magnetic field	GB/T 17626.8	3A/m, 50/60Hz	A
Voltage dip, interruption	GB/T 17626.11	1 cycle 0%; 5/6 cycle 40%; 25/30 cycle 70%; 250/300 cycles 5%	B C C C
Performance judgment:			
During the test, the performance is normal within the specification limits.			
During the test, the function or performance is temporarily reduced or lost, but it can be recovered by itself.			
During the test, the function or performance is temporarily reduced or lost, but requires operator's intervention or system resetting.			

**Warning**

- The AURA Chemiluminescence Immunoassay Analyzer is designed and tested in accordance with Class A equipment in GB 4824. In a domestic environment, this analyzer may cause radio interference and protective measures may be required.
- Do not use this analyzer near strong radiation sources (such as unshielded RF sources) as this may interfere with proper operation of the analyzer.

Disposing equipment

For information on how to dispose the instrument or equipment components, please contact your Linear Diagnostics representative.

2.6 Hazardous substances requirements

According to SJ-T11363 "Limited Requirements for Toxic and Hazardous Substances in Electronic Information Products", the toxic and hazardous substances in this product (lead, mercury, septa, hexavalent chromium, polybrominated biphenyl (PBB), polybrominated diphenyl ether (PBDE); excluding decabromodiphenyl ether) are not exceeded.

3 Overview

The AURA is a fully automated medical analyzer designed for quantitation of analytes in whole blood, plasma, and serum samples.

In this chapter, we will discuss the test principle, equipment construction, accessories, and the required tips and reagents used on the AURA.

3.1 Principle of test

The principle of test adopted by the AURA is CLEIA (chemiluminescent enzyme immunoassay).

The reagents used in each test are stored in a special 15-hole cartridge and sealed with aluminum foil.

The following uses the quantitation of cardiac myoglobin as an example to introduce the principle of detection.

Composition of Reagents:

- Magnetic particle labeled antibody reagent
- Enzyme labeled antibody reagent
- Washing solution
- Luminescent substrate

Test Process:

1. The samples (whole blood, plasma, serum) were mixed with magnetic particle reagent and enzyme marker reagent solution for 5 minutes. In this step, immune sandwich compounds are formed: antibody labeled by a magnetic particle—the material that detected by the machine -- antibody compound labeled by a specific enzyme.
2. Use magnetic separation technology to wash and remove excess reagents or other substances remained in step 1.
3. The added luminescent substrate is catalyzed by the enzyme marker reagent and emits photons. The photons emitted are counted by the PMT (photocell) of the AURA detection system.
4. The number of photons obtained through PMT is calculated automatically according to the calibration curve stored in the AURA.

3.2 Components

This section describes the components of the AURA and their features.

3.2.1 Structure and composition

The product consists of control system, detection system, mechanical device, input and output part, power supply and application software.

The materials constituting the product are mainly aluminum alloy, stainless steel and ABS materials.

3.2.2 Front view

The AURA's front view, their name and function descriptions are as follows:

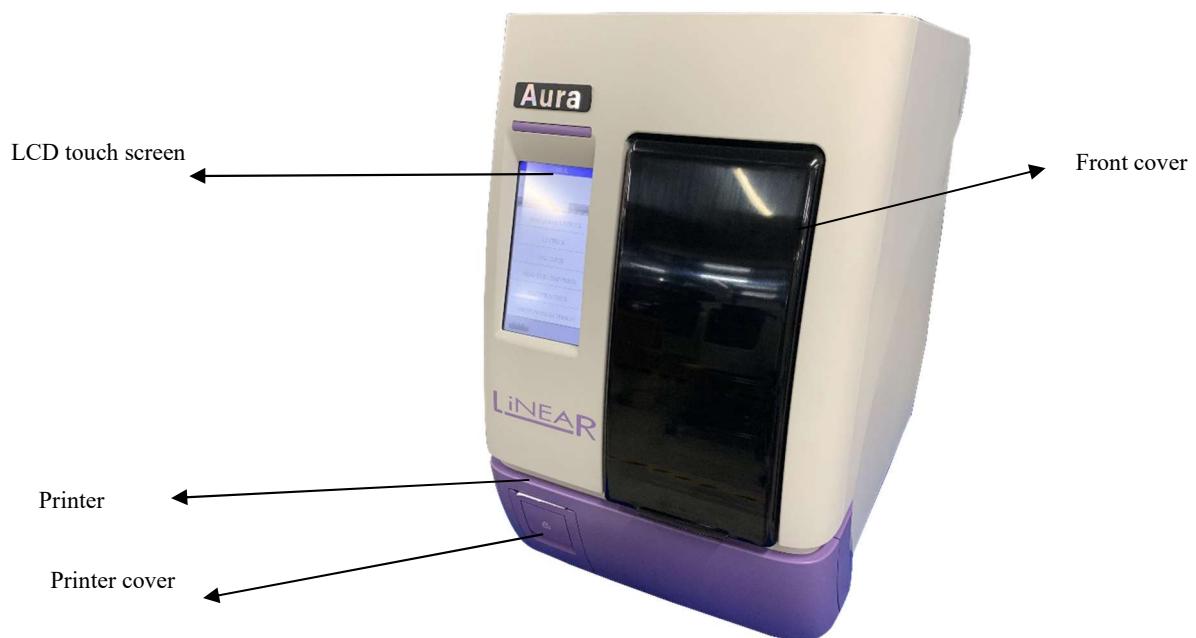


Figure 3-1 the AURA's front view

LCD touch screen	Displays the AURA's various information and accepts input from operator operating analyzer.
Front cover	Slide up and open, then place the cartridge rack, sample, or tips for test, cleaning, or maintenance.
Printer	Print test results or other information.
Printer cover	Open the lid and replace the printing paper.



Figure 3-2 Printer cover opened view

3.2.3 Rear view

There are vents and fan at the rear panel of the analyzer, and the vent is used to ventilate and control the temperature of the heating unit. Keep at least 10 cm distances between these vents and walls. The fan is used for cooling the power supply / source.

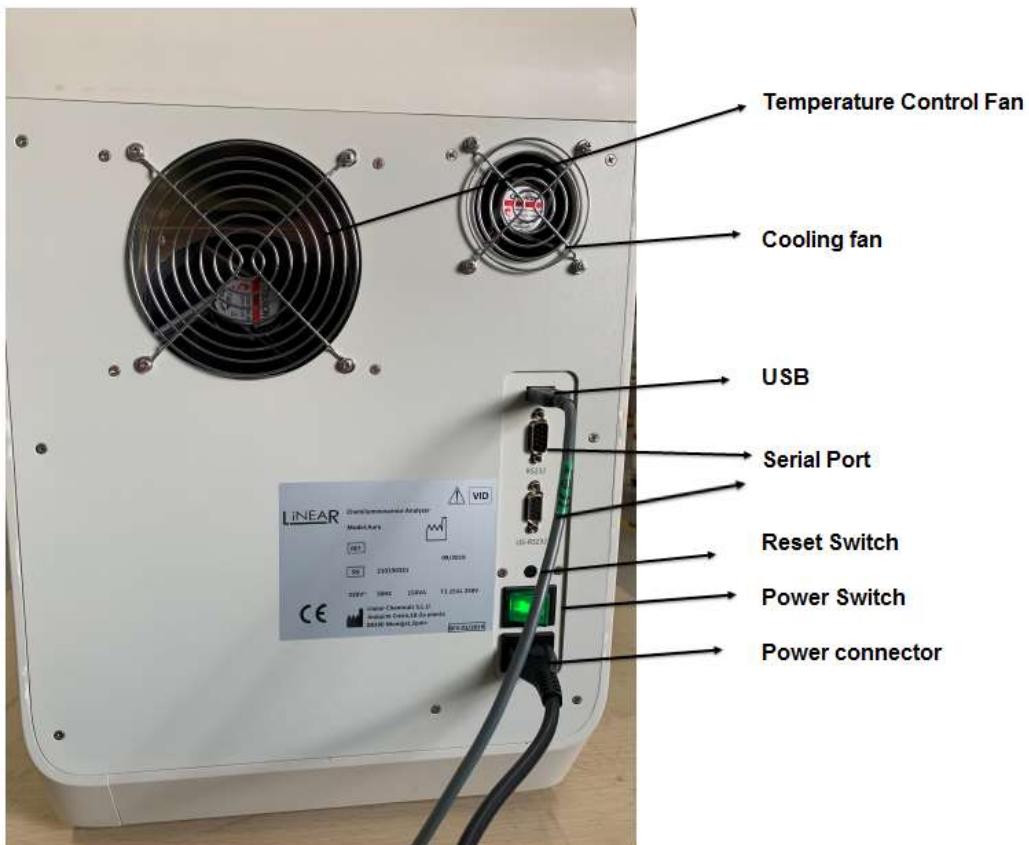


Figure 3-3 Rear view

Temperature Control Fan	The air inside is ventilated to control the temperature through exhaust vent.
Cooling Fan	Power source heat dissipation.
USB port	Connected to external portable barcode reader or upgrade software in USB memory disk
Serial port	A serial port connected to an external computer.
Power switch	The main power switch of the instrument.
Power connector	Power cable connection.

3.2.4 Internal components

Open the AURA's front cover and you can see the internal components of the analyzer. This part of the manual is mainly about the internal components and their functions. With the protective cover, the piecing unit, spraying unit and syringe unit cannot be seen in the picture below.



Figure 3-4 Interior view

Syringe unit	A device containing six syringes for aspirating and dispensing samples or reagents loaded in the rear of the AURA and connected to the spraying unit.
Table-board	To place cartridge rack, tips and waste tip box, and run the program here.

Pre-heating zone	Heat the liquid in the tips, which is needed to keep temperature in maximum of 35 °C for the reaction.
Piecing unit	Piece holes in the reagent cartridge aluminum foil seal so that the tip can enter the reagent hole.
Magnet unit	Place magnetic particles on the inner wall of the tips and utilize magnetic field for magnetic separation
Constant temperature zone	Guarantee the reagent in the reagent cartridge's temperature close to the sample slot's temperature --37 °C.
Tip slot	To load new disposable tips.

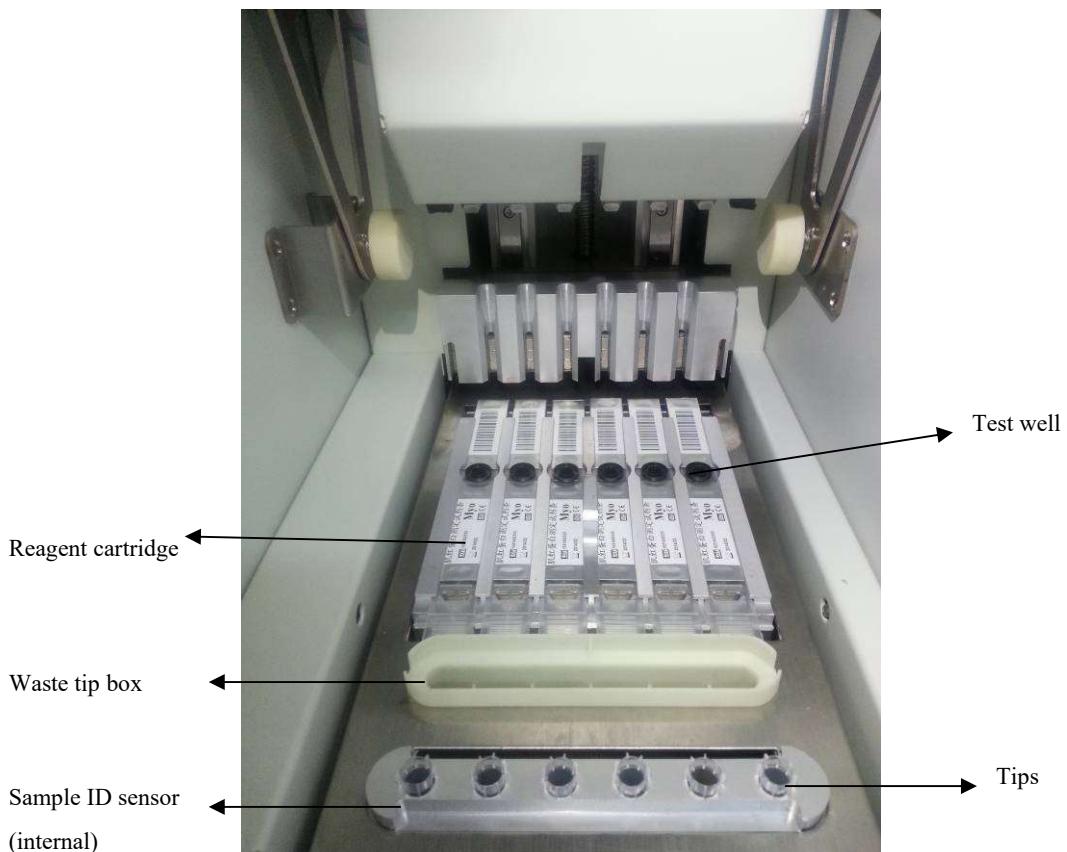


Figure 3-5 Interior view of the tray of reagent cartridges and consumables

Reagent cartridges	Specially designed plastic cartridge with 15 wells, all reagents that needed to be used are preloaded in the special well and sealed with aluminum foil. There are barcodes on the aluminum foil that provide reagent information for the analyzer to identify.
Inspection well	In the final step of the test, the intensity of the light produced by chemiluminescence can be detected in this well.
AURA tips	Used for dispensing & pipetting samples or reagents, also

	used for magnetic separation by magnetic separation technology.
Waste tip box	Replaceable plastic box contains used the AURA tips.
Sample identification sensor	To identify whether the sample is whole blood or not by testing the substance in the disposable tips. AURA automatically corrects the test results according to Hct%.

3.3 Accessory list

The analyzer's accessories are listed below:

Description	Qty.	Remark
Power cable, 220-240 VAC	1	
Reagent cartridge frame	1	
Hand-held barcode reader	1	

- 1) Power cable, 220-240 VAC



Figure 3-6 Cable

- 2) Reagent cartridge rack

The following figure shows the reagent cartridge rack. After the reagent cartridges are loaded in the six slots, the cartridge rack can be placed into the AURA. The reagent cartridge rack featuring high pressure resistance is shipped with the AURA analyzer.



Figure 3-7 Reagent cartridge rack

3) Hand-held barcode reader

Hand-held barcode readers are applicable to:

- Obtain barcode information from new assay registration card.
- Obtain barcode information of the sample ID and the user ID.
- When the AURA is powered off, connect or disconnect the handheld barcode reader. The USB port for connecting the handheld barcode reader is located at the rear panel of the AURA as shown below.



Figure 3-8 Hand-held barcode reader

The readable barcode defaults to the following standards:

- CODABAR(NW7)
- CODE128

3.4 Disposable materials

The following disposable materials are required for the analyzer's test.

Product name	Quantity	Package quantity
AURA tips	-	70 pcs/box
AURA printing paper	1	1 pc/box

1) AURA tips (disposable)

The disposable tips are used to dispense and aspirate sample and liquid reagent, or prevent magnetic particles from loss with liquid outflow during the magnetic separation by fixing magnetic particles on the wall of magnetic unit.



Figure 3-9 disposable tips

2) Printer paper roll

The AURA printer paper is a thermal paper used for printing.



Figure 3-10 Thermal printing paper

3.5 Reagent kit composition

The AURA reagent kit contains reagent cartridges (6*10), calibrator, calibration solution, calibration data card and IFU.

Caution: Different reagents with different components.

Note: please use the relevant reagents designated by Linear Chemicals, S.L.U. and to use the reagents not designated by the company may cause serious analyzer damage or error result.

a) Reagent kit

The reagent kit (as shown below) contains six reagent cartridges, which are sealed with aluminum foil and have a barcode for each package. The barcode contains reagent assays name, lot numbers, expiration dates, and other identification

information. Please check assays, lot numbers and expiration date of each assay before use.



Figure 3-11 Reagent kit

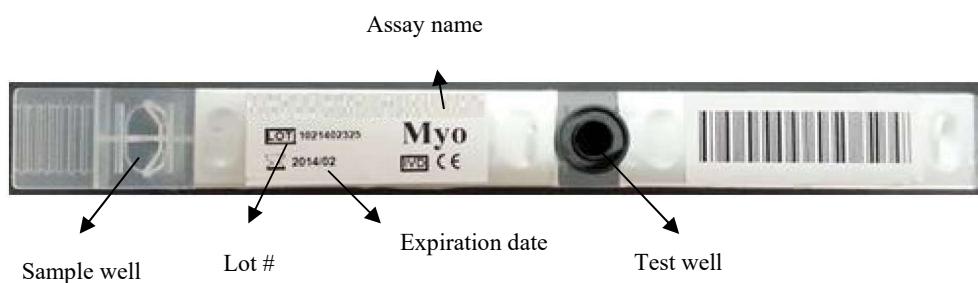


Figure 3-12 Reagent cartridge

b) Calibrator and its solution

If the calibrator is lyophilized powder, reconstitute it by the solution and follow the IFU for use.

c) Reagent registration barcode

Each kit is supplied with the reagent registration card. Acquiring the barcode is required when you perform the first test or use the reagent with different lot number for the first time. Use the handheld barcode reader to obtain barcode data from the reagent registration card. For additional information, refer to Chapter 7 Calibration.

4 Safety Instructions for Installation and Operation

In order to operate the analyzer safely and effectively, please read and understand this safety instruction. The effective analyzer protection may be reduced if it is not used as required by the manufacturer.

4.1 Installation

The unpacking and installation of the analyzer shall be arranged by the trained personnel. The following environmental factors shall be taken into account when selecting the installation site.

4.1.1 Power supply

The analyzer requires power supply of AC100 ~ 240 V, +/-10%, 50/60 hz, 150 VA. Make sure the power supply is properly grounded to avoid a shared power supply with other equipment or instruments.

4.1.2 Environmental conditions

The AURA is equipped with a temperature control unit. Please keep the environment temperature and humidity in the following area:

- Temperature: 10°C to 30 °C
- Relative humidity: 70% or less
- Keep the AURA in flat sturdy surface.
- Keep the AURA in a place where there is enough space
- Do not place the AURA in a position where it is difficult to operate the analyzer.
- Avoid placing the AURA near high-power consumption electric appliances or where voltage changes or electromagnetic radiation may occur.
- Keep the AURA away from direct exposure to sunlight, air conditioning or other interfering devices.
- Do not block the vent at the bottom of the machine and the vent at the top of the back. Make sure there is no paper or other objects in the area that will affect air flow.
- Don't block the analyzer.
- The analyzer is only for indoor use. (Pollution index is II)
- Place the analyzer at altitude of maximum 2000m.

4.1.3 Storage and transportation conditions

Storage condition	Temperature +5 ~ +40 °C
	Relative humidity ≤ 70%
Transportation conditions	Temperature - 20 ~ + 70 °C
Relative humidity	70% or less

4.2 Sample disposal



BIOHAZARD

Specimen disposal should follow the laboratory contamination safety procedures, such as in microbiological and biomedical laboratory, and follow Biosafety in microbiological and biomedical laboratories safety procedures * (Micro-biological and Biomedical laboratory Biosafety) and the relevant regulation in CLSI Document M29 - t. **, after finishing sample disposal, clean hands thoroughly.

[* *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 (CLSI), Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline, M29 - T, Villanova, PA: CLSI, 1989*]

4.3 Warning symbols

The warning labels are attached to the analyzer, indicating assays that need special attention during operation and maintenance.

Symbols	Meaning
	High temperature There are heaters in the thermostat and preheating parts. When the analyzer is abnormal, there may be a lot of heat. Please be careful not to touch these areas and avoid accidental burns.
	Biohazard Samples used in the AURA, such as whole blood, plasma and serum, and other QC materials and reagents should be treated as potentially infectious. Please take appropriate protective measures during operation and maintenance of analyzer. Please follow all local guidelines and general blood disease precautions regulations.
	Laceration The sharp piercers used to open the reagent aluminum seal is placed in the syringe unit. In order to avoid damage, please pay special attention when loading reagent cartridge and cleaning piercers

4.4 Safety instructions

Please read this section carefully to understand the possible danger.

Symbols	Meaning
	Danger Failure to follow instructions can lead to "Serious injury" *1 or even death, a high level of warning.
	Warning Failure to follow instructions can lead to "Serious injury" *1 or even death, a low level of warning.
	Caution Failure to follow instructions can lead to "Wound pain" *2 or other "Physical injury" *3.

[*1 "Severe injury" means blindness, injury, burns (high or low temperature), electric shocks, or bone fractures that cause the operator to be hospitalized for a long period of time after the injury]

[*2 "Wound pain" means not requiring long hospital stay]

[*3 "Physical injury" means possible physical harm caused by incorrect diagnosis from wrong test result.]

[General warning symbols]

	Danger! Contacting with internal electronic components may lead to power failure. Do not perform operations or maintenance which is not described in this manual.
	Danger! Do not make any modification to the analyzer, do not use other devices other than the device designed for the analyzer.
	Danger! Turn off the power immediately in emergency, unplug the socket, remove the cable, and contact your AURA distributor.
	Warning! The AURA abides by EMC rules, but we cannot block radiation from external high-power appliances. Do not place mobile phones and high-power radio etc. close to the AURA.
	Caution! The AURA can only be operated after the operators trained by the AURA representatives.



Caution! Turn off the power when not in use.



Caution! If there are any problems, please refer to Chapter 12: Troubleshooting and Take Necessary Precautions. If problems still exist, please contact your Linear Diagnostics representative.



Caution! If you want to move the AURA to another location, please contact your representative first for help. For your safety, at least two people are needed to move the analyzer.



Caution! Perform the regular maintenance as described in the manual. Higher levels of maintenance should be performed by an authorized representative.



Caution! When operating the AURA, follow the procedures described in this manual.



Caution! If the test assays are different, then the operation of the analyzer is different. Please refer to each package label for information of specific operation.



Caution! For QC, please use the QC recommended by Linear Chemicals, S.L.U.



Caution! Do not try to replace the CF card, follow the specified procedure or follow the instructions of the AURA representative. Incorrect operation will result in data loss and analyzer operation breakdown.



Caution! Do not press more than one button at a time, or press the button continuously, which will lead to system failure.

(Note --- related to reagents)



Warning! Please use reagents and instruments designated by Linear Chemicals, S.L.U.



Caution! Strictly follow rules about the usage, storage, operation and other rules, which are written in package instructions



Caution! Do not use expired reagent cartridge.



Caution! Please pay attention to samples that contain no specific decomposition of the reaction material.



Caution! Diagnosis of diseases based on test results requires doctors to consider other test results and patients' clinical conditions comprehensively.



Caution! Please keep reagents cartridge in strict accordance with the actual packaging requirements.



Caution! When operating the reagent cartridge, do not touch the aluminum seal and the black test well. Hold the reagent cartridge only in the designated holding position.



Caution! Saliva spill into the black test well will result in an test error.



Caution! Reagent cartridges which have fallen on the ground may lead to test error.



Before test, gently remove the reagent on a flat surface. Excessive shock, turbulence, and even falling down and so forth will result in the reagent under the aluminum seal creates a large number of air bubbles, which may lead to test error.



Caution! Samples with high turbidity, including those with high lipid concentration, may be mistaken by the sample identification sensor as the whole blood sample. This result can be adjusted by correcting blood value.



Caution! Blood cells or other substances in the body may be wrongly identified as whole blood by the sample identification sensor when the sample is added to the sample slot. This result can be adjusted by correcting blood value.

(Other matters needing attention)



Warning! Sample Assayed by the AURA is potentially infectious, during operation and maintenance of the analyzer, please wear appropriate protective equipment (gloves, safety glasses, lab coat, laboratory cap), if stained with reagents or waste liquid on the skin, please rinse and sterilize, and consult with a doctor.



Warning! Waste disposal shall comply with local safety instructions and relevant rules.



Warnings! Used reagent cartridges and other disposals should be considered potentially infectious and handled in accordance with relevant regulations.



Caution! The AURA is a medical analyzer for measuring whole blood, plasma, and serum. Do not use it for other purposes.



Caution! Carefully place the reagent cartridge on the rack to avoid damage.



Be careful not to get stabbed by the sharp tearing paper when replacing the paper.



Please pay attention to the notes for chemicals contained in the tips and in the test tube.



Caution! The alcohol used to clean the AURA is flammable and needs careful treatment.

4.5 Disclaim clause

It is important to follow the precautionary instructions mentioned in previous sections when operating and maintaining the AURA. But even if you follow all the precautions, there is still the possibility of an accident.

Under the following circumstances, Linear Diagnositcs Inc. shall be exempted from liability for accidents, problems and damages:

- Damage to analyzer or users caused by uncontrollable events such as earthquake or fire.
- The result of damage or error to the analyzer caused by the intentional negligence or misoperation of the user.
- Incidental loss due to the use or non-use of analyzer, such as reduction in operating income, interruption of medical examination, patient impact, etc.
- Damage caused by failure to comply with safety instructions in the operations manual.
- Damage caused by failure to integrate external computers/equipment or software unrelated to Linear Chemicals, S.L.U.
- Damage caused by acceptance of maintenance or repair by personnel not authorized by Linear Diagnositcs Inc.

5 Preparation Procedure

This chapter describes the preparation procedure before test with the AURA.

5.1 Introduction

The AURA operates through a liquid crystal display (LCD) screen with a touchable panel. In the manual, the expression "Press the button" refers to "Touch the button with your finger on the screen".

5.2 Operations and expressions

In this section, the meaning of the button function symbol or instrument operation symbol is explained.

1) Display area name:

Title area: the commonly selected screen title (screen name) is displayed in this area.

Message and start area: this area displays operating instructions or matters need attention.

Subtitle area: this area displays the subtitle of the pressed screen or the optional buttons on the screen.

Display area: in this area, various information of a specific screen is displayed, and the display of information varies according to the screen.

Shift area: in this area, display "Press button, confirm button, cancel button, other screen shift button"

2) Screen description

The following is an example of a description screen:

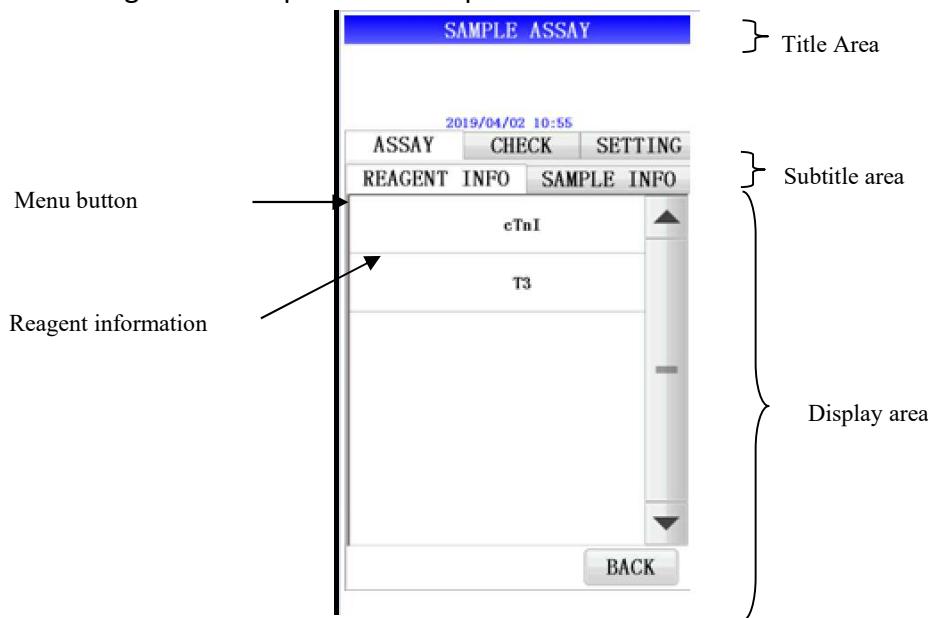


Figure 5-1 Screen

The start screen shows the operation instructions and notes. The "Start" button is always displayed on the right side of the screen.

The buttons under "Assay" are the reagent information and sample info.

The reagent information: list recently registered assays

Sample info: list each sample's information.

5.3 Before power on

Please confirm the following before turning on the power switch:

- The power cable is connected to the appropriate socket.
- There is no packaging material or used disposable materials in the analyzer (for example, the remaining used tips from the last test) and other nuisance.
- When using the analyzer, do not block the rear exhaust vent or obstruct the operation of the front cover.

5.4 Power on

Make sure the front cover is closed.

Turn on the power switch. When the power is on, the screen is shown as follows.

Start up: when the operating system starts to initialize, the analyzer begins to upload the AURA software for various mechanical inspection. This process is called system initialization. The screen shows as follows:

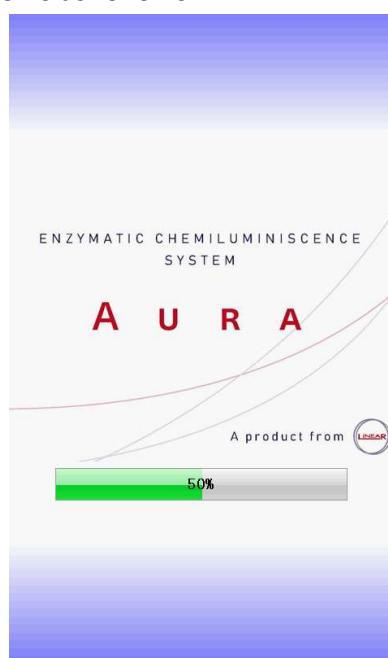


Figure 5-2 System initializing

Below are the checking procedures during system initialization:

- Check assays
- PMT power, on/off

- The syringe unit boots automatically
- PMT unit boots automatically
- Magnetic unit boots automatically
- The table-board unit boots automatically
- The piston unit boots automatically
- Printer paper

If any abnormality is found during the initialization, the screen will display the corresponding error message. Please follow the troubleshooting instructions in Chapter 12 for information of the error messages.

Note: before starting, please make sure there are no used tips (sharp looks like bullet) in the waste tip box.

5.5 Sample Assay/Home

The “Sample Assay/Home” screen is the default screen after start-up. A 25-minute warm-up preparation is required after the initialization is completed.

Note: please wait for the instrument to warm up for 25 minutes before the test, otherwise the test result may be incorrect.

In the “Sample Assay/Home” screen, in the message area, it displays: “Press the <Start> button to start the test”. Other messages such as reagents, calibration, and the validity period of the QC are also displayed if any. Refer to 6 Sample Assay, 7 Calibration test and 8 QC test.

The “Sample Assay/Home” screen is the same as “Sample Assay” in the “Assay” screen. Using the "Sample Assay" in the main screen, it is easier to start the test, because, without the instrument description, you can prepare for the test.

To display the Sample Assay/Home screen, on the Test screen, click “Sample Assay”, or click the Home button.

The “Sample Assay/Home” screen displays the menu list as shown below:

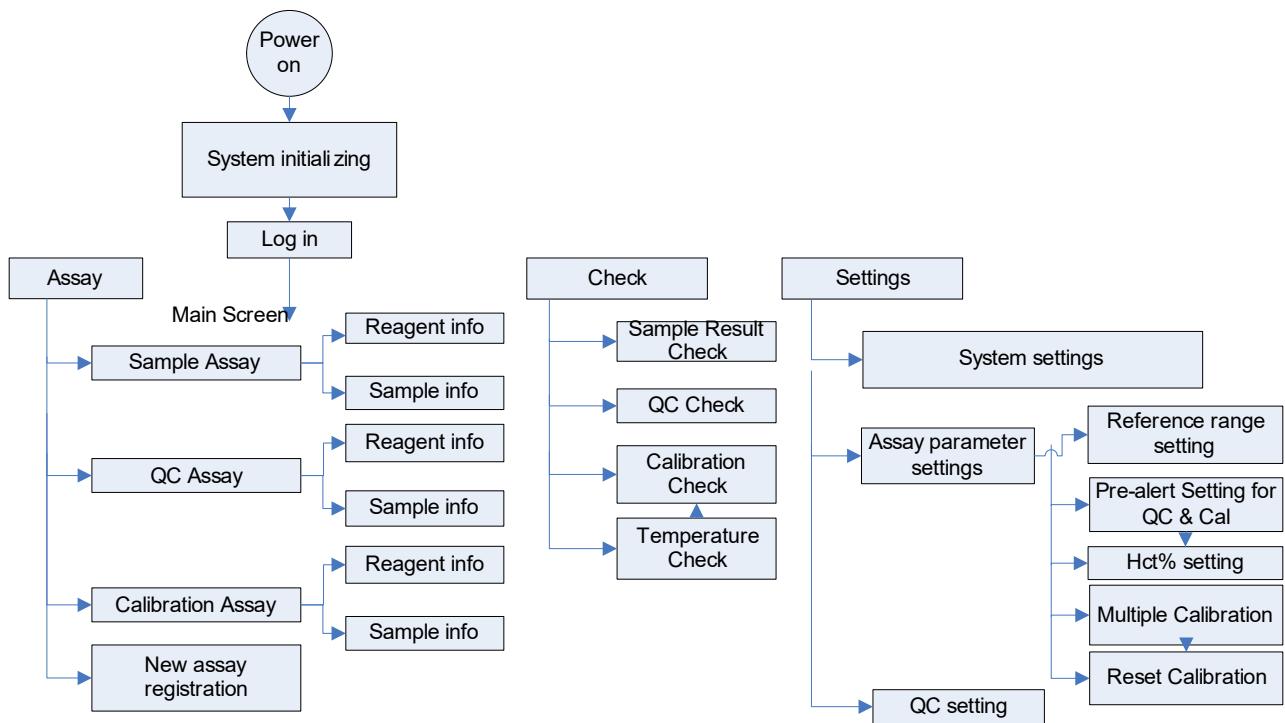


Figure 5-3 Menu list

Reagent information

In the reagent information display screen, the registered assay name is displayed with a button, and the button display is different depending on whether the calibration and QC within the validity period, as shown in the following figure:

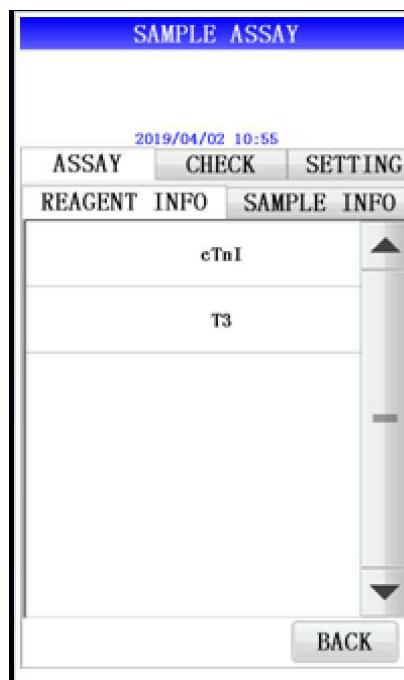


Figure 5-4 Reagent info

cTnI Normal: can be tested, calibration and QC are within the validity period.

Hidden: Cannot be tested, the test is not calibrated or the reagent is expired.

- The displayed status of the assay name button will be updated based on the status of the latest lot number (except for hidden one).
- During calibration, the validity period of the calibrator can be set automatically. The user can set the validity period of the QC material according to each assay. See section 5.7 QC Setting for details.

Click on the selected assay on the above screen, you can see the validity period of the assay and the remaining days of the calibration and QC validity period.

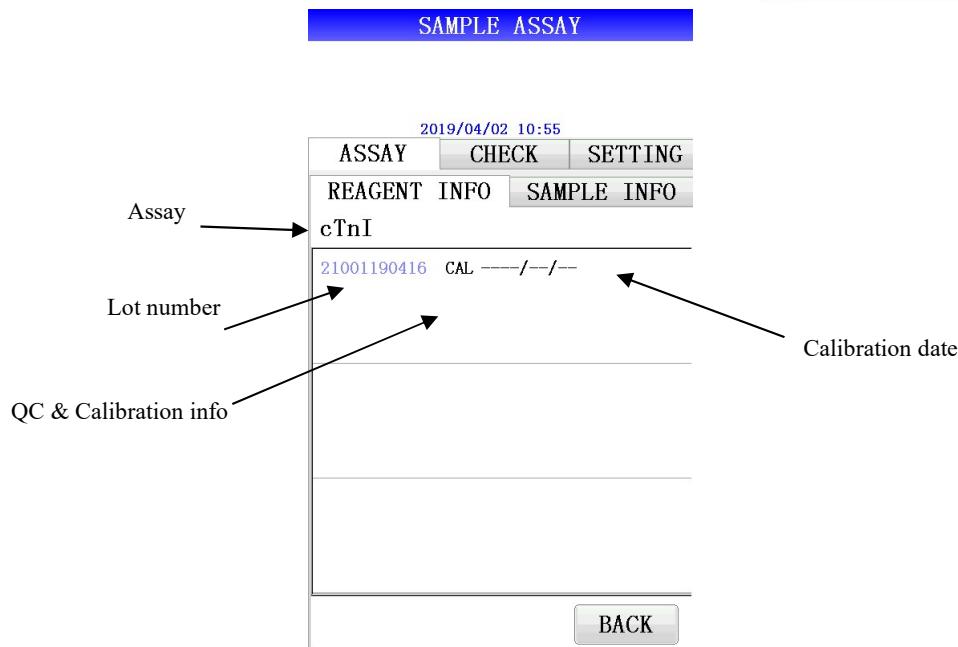


Figure 5-5 Sample Assay screen

- The validity period of three recent reagent lot numbers will be displayed.
- For the same lot number of reagents, the most recent information on calibration and QC is displayed.
- Expired reagent information is not displayed.
- The expiration date or calibration expiration date of the reagent lot number is shown in the display.

5.6 Registering new assay

When a new assay or a new lot of reagents is to be used, register the calibration data of reagents in the analyzer as follows:

1. Press the "ASSAY" menu in the subtitle area to enter the following screen:

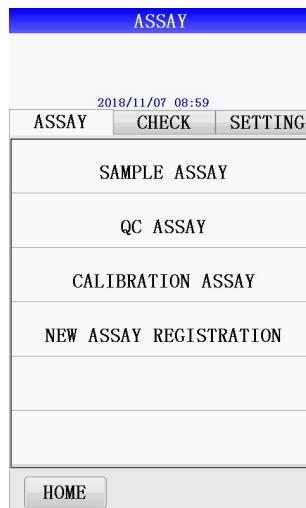


Figure 5-6 Assay screen

2. Press "New assay registration" to display the following "New Assay Registration" Screen.

NEW ASSAY REGISTRATION

Use barcode scanner to input data

2018/11/07 09:04

NEW ASSAY REGISTRATION

Scan assay barcode
one by one

Assay
Lot No.
Lot A
Lot B
Lot C

BACK

Figure 5-7 New assay registration

3. Use a handheld barcode reader to scan the barcode of the calibration card and store the data in the AURA. When scanning, the reader should be 10 to 15 centimeters away from the barcode.
4. After reading the information, the AURA displays: lot no. registered. Data will be stored.

NEW ASSAY REGISTRATION

Use barcode scanner to input data

2019/05/24 15:42

NEW ASSAY REGISTRATION

Scan assay barcode
one by one

Lot no. registered!

Assay cTnI
Lot No. 21001191212
Lot A
Lot B
Lot C

BACK

Figure 5-8 New assay registration screen

5. If the information has been registered, the analyzer will show "Parameters are input"

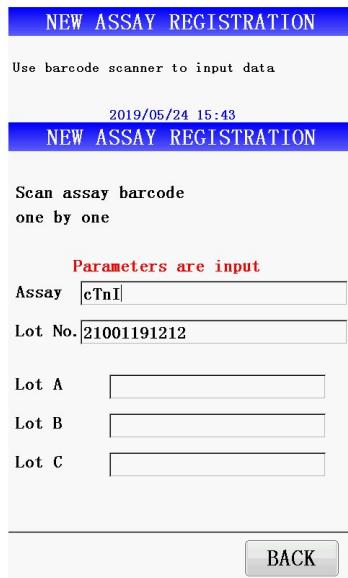


Figure 5-9 Screen after assay is successfully registered

6. After registration, press "Back" and return to the "ASSAY" screen.

Run calibration test after assay registration. Please refer to Chapter 7 Calibration.

5.7 QC Setting

Set the program for the QC Setting function.

The new instrument has no information in the QC Setting, and cannot be used for any setting or correction. The assay can only be set or corrected after entering the new assay registration card information.

1. Click the "Setting" menu in the subtitle area and the following screen appears:

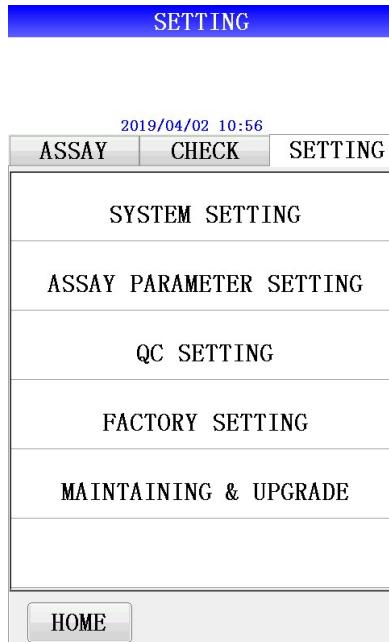


Figure 5-10 Setting menu

2. On the Setting screen, click QC Setting.

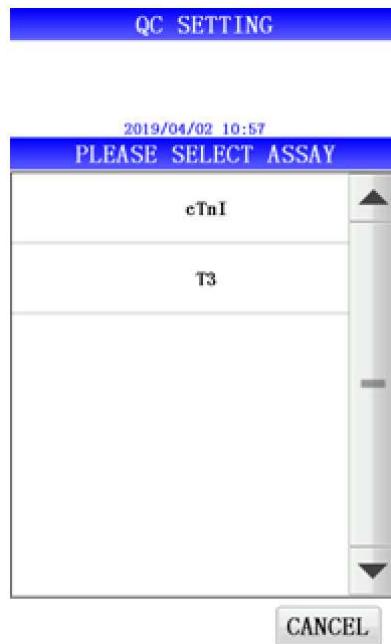


Figure 5-11 QC Setting - select assay

3. Select the assay, and click "OK" to enter the QC Setting screen.

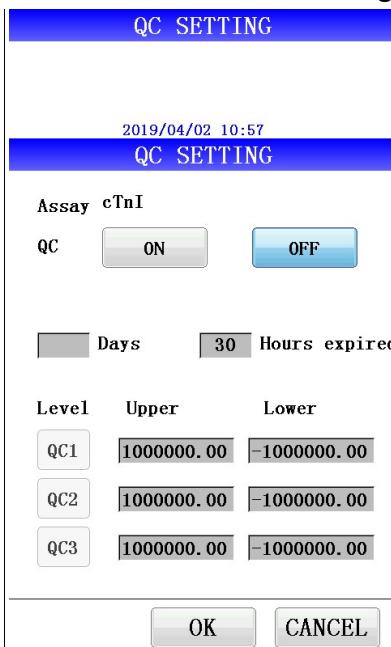


Figure 5-12 cTnI QC Setting

Assay

Display the currently set assay.

QC

Click "On" to enable the QC setting function, or click "Off" to disable it.

Days/hour

Setting the validity period of the QC in the form of days or hours can only be done in one way.

Range: Days 1-999 days (999 days means no activation)

Hour: 1-30 hours

Note: One day and hour cannot be set at the same time. The one displayed is valid.

QC Level

Click the QC level to check during the validity period, and the selected button will be highlighted.

Upper / Lower Limit

Click each box to display the numeric keypad and enter the limit number.

Figure 5-13 QC setting numeric keypad

Range: -1000000.00 to 1000000.00.

Note: Confirm that the upper limit is equal to or greater than the lower limit. These values will be used to create the scale of the QC chart.

4. Click "OK" to store the entered data and return to the "Setting" screen.

5.8 Shut down

Make sure the followings before shutting off the analyzer. Otherwise it will result in data loss or instrument failure.

- No test is running, and the analyzer is in standby mode.
- Print completed.

After the above status is confirmed, press the switch to turn off the analyzer.

After the analyzer is shut down, the reagent cartridge rack in the analyzer needs to be taken out; the reagent cartridge shall be taken out from the reagent cartridge rack.



Then the reagent cartridge rack shall be placed back into rack slot, and the used tips in the waste tip box shall be disposed.

Re-place the waste tip box to keep the analyzer clean, prepare for the next test, and finally close the front cover.

6 Sample Assay

This chapter will describe the procedure for the determination of sample assay.

6.1 Check validity of calibration and QC

Check the validity period of the assay name, lot number and reagent cartridge to be used, and the lot number and validity period of reagent cartridge can be found on reagent cartridge, kit box or reagent registration card. If the reagent cartridge expires, the AURA will not continue the test.

Press the “Reagent info” on the “Sample Assay/Home” screen to check the validity of calibration and QC:

1. Assay name and registered lot numbers are in accordance with reagent cartridges
2. Display calibration data and it is not expired.

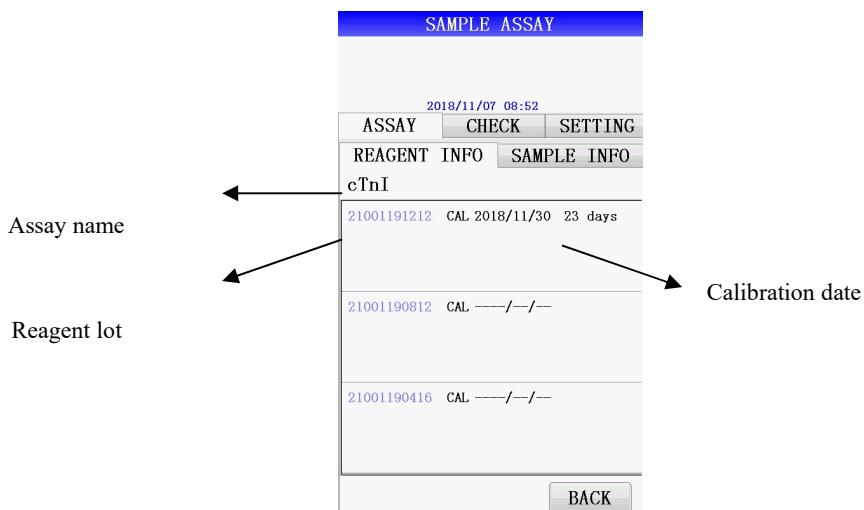


Figure 6-1 Reagent details

6.2 Edit sample info

Please follow these steps to edit the sample info:

1. In the "Sample Assay/Home" screen, press "Sample Info" to display the following screen:

SAMPLE ASSAY/HOME

Click < START > to start Assay

START

2018/11/07 08:52

ASSAY	CHECK	SETTING
REAGENT INFO	SAMPLE INFO	
LINE 1	Common sample Hct% 40.0% Whole Blood	
LINE 2	Common sample Hct% 40.0% Whole Blood	
LINE 3	Common sample Hct% 40.0% Whole Blood	
LINE 4	Common sample Hct% 40.0% Whole Blood	
LINE 5	Common sample Hct% 40.0% Whole Blood	
LINE 6	Common sample Hct% 40.0% Whole Blood	

Figure 6-2 Sample info

2. Press the column number to enter the “Sample Info” editing screen, and the display is as follows:

SAMPLE ASSAY

Use barcode scanner to input data

2019/04/02 10:58

1ST LINE

Type Whole Blood Plasma Serum

Hct% %

Sample ID

7	8	9
4	5	6
1	2	3
0	.	<-

Figure 6-3 Sample editing screen

Note:

- Need to select sample type. The sample types include whole blood, plasma and serum.
- The assay and lot numbers will be read automatically through the reagent cartridge after the test begins.
- Hct% is used to calibrate each test result of the whole blood sample. The default Hct% value is adopted if there is no special setting. The default Hct% value is 40.0 (range 0.0-60.0). To change the value of Hct%, go to the Setting

menu (see 10.3.3 for details). If the sample is not whole blood sample, the Hct% value will not be adopted to the result calculation.

3. Edit the sample ID. Press the display box and the input keyboard appears as shown below.

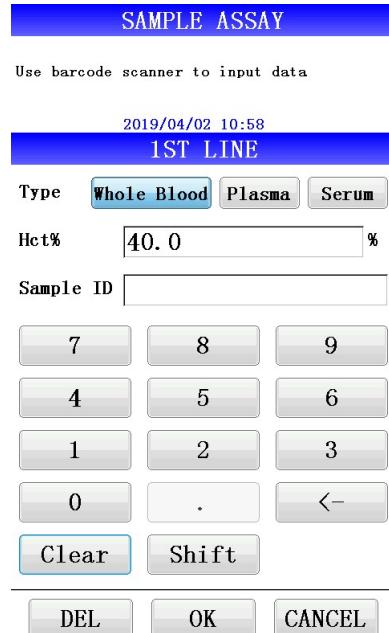


Figure 6-4 Sample editing keyboard

Enter the sample ID with soft keyboard. The ID length is 0-20 characters of the full-screen keyboard. Or enter the barcode data automatically with the handheld barcode reader.

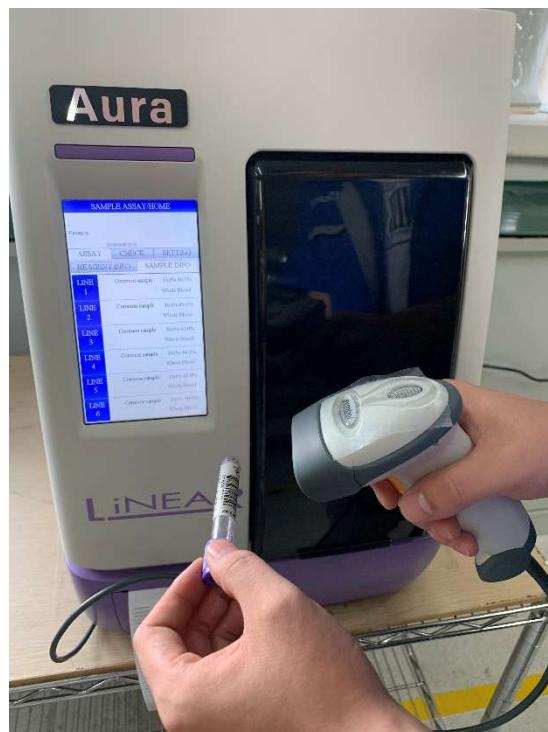


Figure 6-5 Read the barcode data automatically

4. After entering the sample ID, press “OK” to store the data and return to the “Sample Info” editing screen, and then press “OK” to return to the “Sample Info” screen.

5. Repeat Steps 2-4 to add other samples.

6. After all sample info is entered; check the information on the “Sample Info” screen.

SAMPLE ASSAY/HOME		
Click < START > to start Assay		
2018/11/07 08:52		
ASSAY	CHECK	SETTING
REAGENT INFO	SAMPLE INFO	
LINE 1	Common sample Hct% 40.0% Whole Blood	
LINE 2	Common sample Hct% 40.0% Whole Blood	
LINE 3	Common sample Hct% 40.0% Whole Blood	
LINE 4	Common sample Hct% 40.0% Whole Blood	
LINE 5	Common sample Hct% 40.0% Whole Blood	
LINE 6	Common sample Hct% 40.0% Whole Blood	

Figure 6-6 Input the sample

6.3 Preparation of analyzer and samples

6.3.1 Load the waste tip box to the AURA

Before preparing the sample and reagent, check if there is any used tips in the waste tip box. If necessary, dispose of the used tips, clean the waste tip box and load the waste tip box.

Note: clean the waste tip box after every 20 tests.



Figure 6-7 Loading waste tip box

6.3.2 Sample preparation

The type and volume of sample are determined by test requirements. Please refer to the IFU of assay. Also refer to the general prevention instructions when collecting and handling samples.

6.3.3 Prepare and load the reagent cartridge in the AURA

When preparing the reagent cartridge, follow the following precautions:

- Wear gloves and masks to avoid contamination with other reagents or samples.
- Test the cartridges in time after taking them out from the fridge. Do not leave them in a non-refrigerated state for long period of time.
- Please follow the instructions on the package.

1. Take the reagent cartridge out from the fridge, load the reagent cartridge to the cartridge rack, and push it into slot smoothly. Please pay attention:

- Hold the edge of the reagent cartridges to avoid contacting with the aluminum seal and the detection slot; otherwise it will lead to error results.
- Be careful not to spill saliva into the detection slot, which can lead to errors.
- Do not use cartridges that have dropped onto the ground, which can lead to error.
- Before test, gently shake the reagent cartridge upside down to remove bubbles on the walls of the reagent cartridge or the liquid inside the aluminum seal.

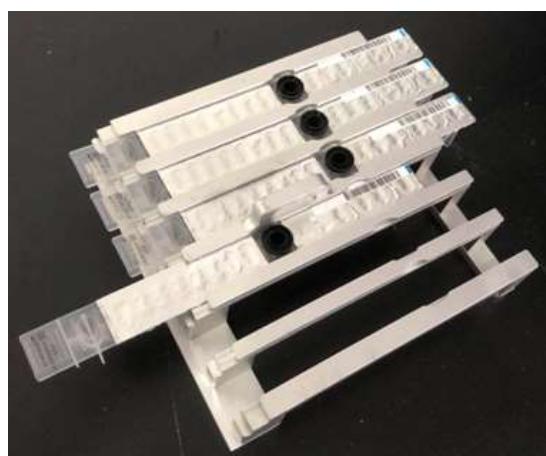


Figure 6-8 Load the reagent cartridge into the reagent rack

2. Add appropriate sample volume (volume as per IFU; do not overflow the sample well) to the sample well of cartridge by pipette. Remove bubble formation (if any) before test.

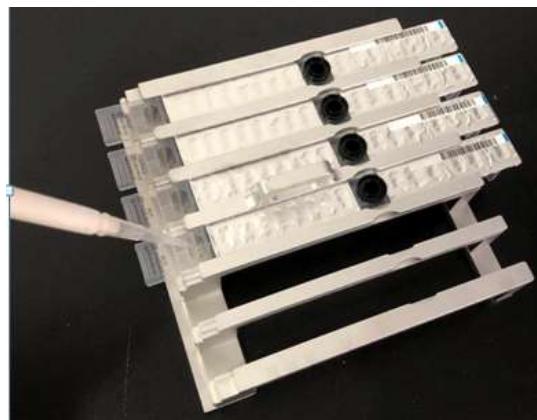


Figure 6-9 Pipette the sample into the sample well

3. Open the front cover and load the cartridge rack properly.



Figure 6-10 Load cartridge rack

6.3.4 Load disposable tips

Disposable tips are specially designed for the AURA.



Figure 6-11 Disposable tips

1. Take out the new tips from the tip box and load them in the tip slot (shown as picture 6-12 below). Align with the line of the reagent cartridges loaded. Note that the end of the tip should not be contaminated or damaged.

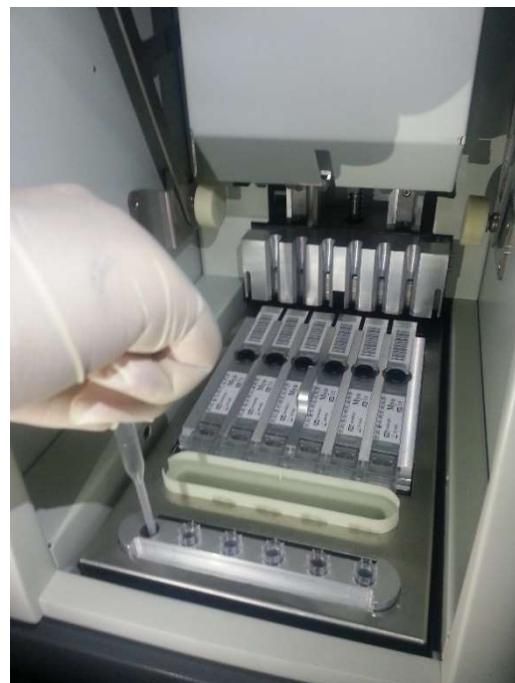


Figure 6-12 Load the disposable tips

2. After loading the tips in the tip slot, close the front cover.



Figure 6-13 Close front cover

6.4 Start and End Sample Assay

6.4.1 Start Sample Assay

Press the "Start" button on the sample info screen of "Sample Assay/Home".

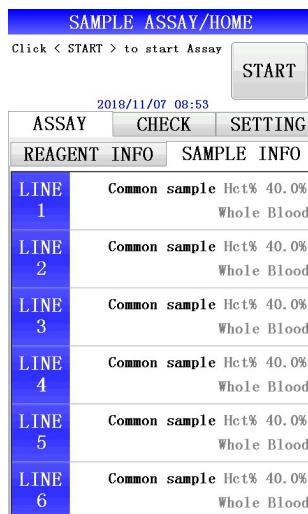


Figure 6-14 Press the “Start” button

Note: Perform the test soon after the preparation is complete. The evaporation of sample and blood cells subsided in the whole blood sample may affect test results. The analyzer will run the relevant checks before test. If there is any abnormality, it will prompt error message. Take necessary action according to the message. See Chapter 12 Troubleshooting for error information details.

2. The following screen will be displayed when the test is in progress.

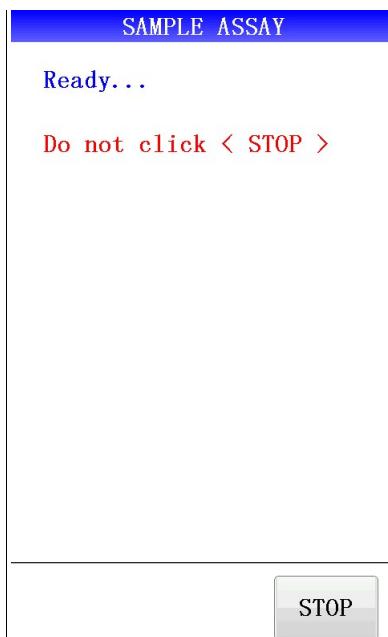


Figure 6-15 the screen in progress of test

After the test is started, the AURA checks the reagent cartridge, assays and sample in each column, which are not displayed on the screen. The progressing screen will be displayed throughout the whole test process until the test is completed.

In case of emergency, press “Stop” button, and it will show the following screen.

Notes: please do not press “Stop” if there is no special situation during the test. Once stopped, it might need to re-calibrate with the new reagent cartridge and

calibrator. After stopping, the test with the reagent cartridge and sample in the analyzer may not be able to continue.

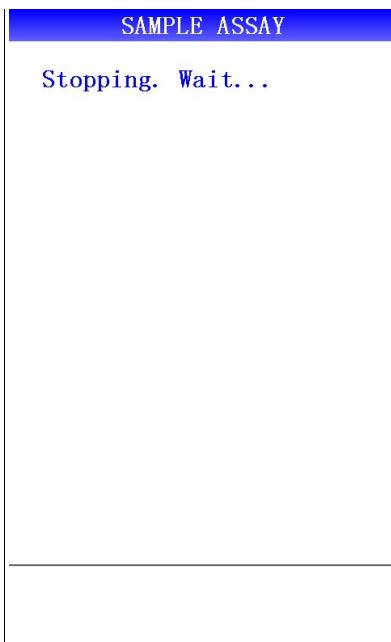


Figure 6-16 Screen after pressing "Stop"

3. After test, the results will be automatically printed out instead of being shown on the screen. The analyzer screen will return to the "Sample Assay" screen after printing. If you want to check the result, you can find it in "Check" -- "Sample Result Check".

SAMPLE ASSAY/HOME	
Click < START > to start Assay	
2019/04/02 10:58	
ASSAY	CHECK
REAGENT INFO	SAMPLE INFO
LINE 1	Common sample Hct% 40.0% Whole Blood
LINE 2	Common sample Hct% 40.0% Whole Blood
LINE 3	Common sample Hct% 40.0% Whole Blood
LINE 4	Common sample Hct% 40.0% Whole Blood
LINE 5	Common sample Hct% 40.0% Whole Blood
LINE 6	Common sample Hct% 40.0% Whole Blood

Figure 6-17 Screen after the test is finished

6.4.2 Sample Assay results

When the test is completed, the results are automatically printed out. Result will not be displayed on the screen. The screen will go back to sample test.

If you want to check the result, you can find it in "CHECK" -- "Sample result check".

The following is a sample of the printed results:

REPRINT DATE:2014/11/26 10:08	← Date and time of printing
DATE:2014/11/25 15:00	← Sample test starting time
SAMPLE ID:X029948	← Sample ID
LINE:5	← Line number
cTnI	← Assay name
25.123 ng/ml	← Test result
REMARK:DF	← Remark: default
TYPE:WB(50%)	← Whole blood, Hct%
SAMPLE:PATIENT	← Sample (patient information)
INSTRUMENT SERIAL:040140216	← Equipment serial number
OPERATOR ID:	← Product ID
REAGENT LOT:1011408210	← Reagent lot No.
CALIBRATED ON:2014/08/29	← Calibration date

Figure 6-18 Print report of Sample Assay results

6.4.3 Dispose used cartridges and tips

1. Dispose used tips

Take the waste tip box out of the analyzer, and dispose the used tips according to the local regulation and rules. Place the waste tip box back to the AURA.

Note: Please clean the waste tip box after every 20 tests.



Figure 6-9 Take out the waste tip box



2. Dispose used reagent cartridges

Take out the cartridge rack from the analyzer and remove the used reagent cartridges. Be careful not to drop or splash the reagent cartridge from the rack. Refer to local rules when disposing reagent cartridges.

7 Calibration

This chapter will describe the procedure for the assay calibration.

7.1 Introduction

After completing the test preparation with reference to Chapter 5, perform the calibration test according to the following procedure.

7.2 Calibration purposes

In order to get reliable results, obtain the validated calibration curve before testing patient samples.

The validity date of calibration for each assay has been predetermined.

Note: Patient's Sample Assay or QC tests are not allowed if calibration is expired.

7.3 About calibration

1. Calibrator

Please use the recommended calibrator (usually packed with the cartridge), and if it is lyophilized powder, the calibrator must first be treated with a diluent (which must be supplied with the calibrator).

2. Calibration level

The calibration level may vary depending on the reagents.

3. Repeat calibration

Re-calibrate (N=2), (or N=3)

4. Start calibration

- 1) New assays.
- 2) New lot of reagent.
- 3) The calibration expires.
- 4) The QC result is out of range.
- 5) Use the newly arrived reagent even if the lot number is the same.
- 6) After maintenance of the optical system.

Note: for the above 4, 5 and 6, the Sample Assay or QC assay will not be suspended without the calibration, but the calibration is recommended to ensure the reliability of the test results.

5. Validity of the calibration

The validity period of the calibration varies according to the assay. For details, refer to the package instructions for the kit.

6. Valid lot number

Three valid calibration lot numbers can be recorded for each analyte.

7. Attention:

- Calibration should use the same calibrator with the same lot of reagents.
- Set the repeated times for calibration (Multiple Calibration, n=2 or n=3). Place the cartridge with calibrator according to the instructions on the screen.
- Scan the barcode information on the reagent registration card in the reagent kit when you are going to run a new assay or a new lot of reagent. See section 5.6 for information on new assay registration.

8. Calibration validation

Calibration validity is automatically detected by the system

7.4 Preparation for calibration

7.4.1 Check the validity of the calibration

Prior to performing the calibration assay, check and make sure that the reagent with specific lot number has been registered in the AURA.

1. On the “SAMPLE ASSAY/HOME” screen, click “Reagent Info”, click the assay to be calibrated, and enter the following screen.

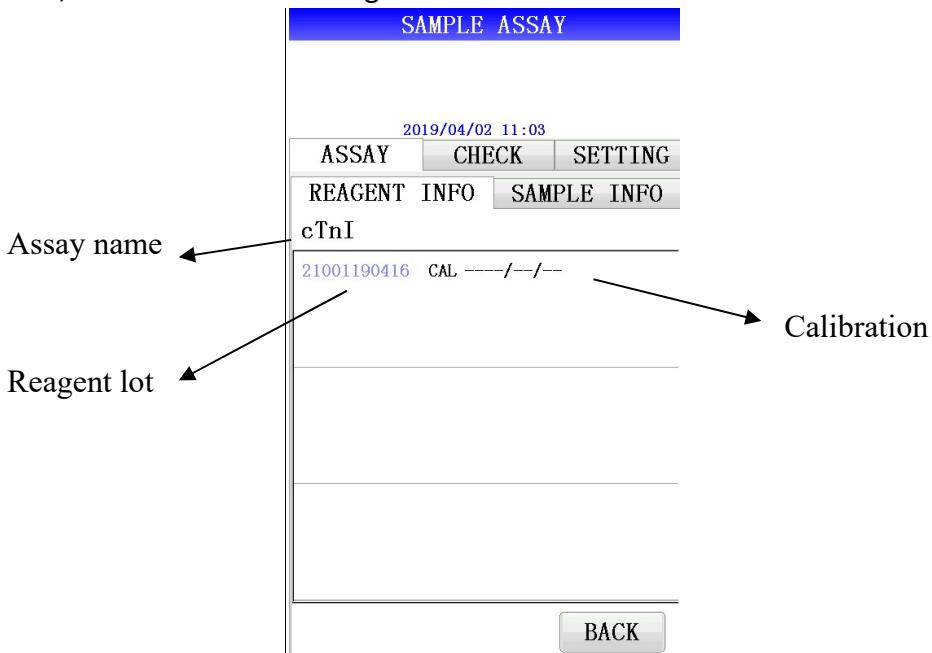


Figure 7-1 Reagent info.

1. Check that the reagent registration data is registered on the AURA.

If the lot has been registered, the lot number will be displayed on the screen.

If the lot number is not displayed, register the new assay data before starting the calibration test. Refer to 5.6 *Registering new assay* for more information.

7.4.2 Edit calibration information

1. Click “ASSAY” - “Calibration ASSAY”, the following screen appears; click the assay to be calibrated from the list. Note: there is no information in the “Please select assays” screen for default factory setting. The assay name is displayed only after registering the reagent.

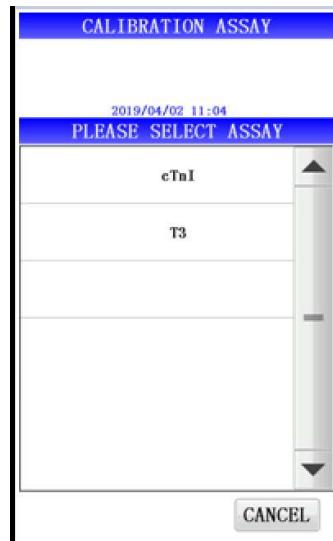


Figure 7-2 assay selected for calibration test

2. After selecting the assay to be calibrated, click “START”, the sample info screen for calibration test is displayed (Multiple Calibration N=2).

CALIBRATION ASSAY		
Click < START > to start Assay		
2019/04/02 11:06		
ASSAY	CHECK	SETTING
REAGENT INFO		SAMPLE INFO
LINE 1	cTnI	CAL1
LINE 2	cTnI	CAL1
LINE 3	cTnI	CAL2
LINE 4	cTnI	CAL2
LINE 5		/
LINE 6		/

Figure 7-3 Sample info for calibration

Note: Please place the reagent cartridge and calibrator in the order shown in the screen. Otherwise, the calibration will fail.

7.5 Preparation of analyzer and calibrators

7.5.1 Loading the AURA waste tip box

Remove the used tip from the tip box and reload the tip box.

Note: clean the waste tip box after every 20 tests.



Figure 7-4 Load tip box

7.5.2 Prepare calibrator

Calibrators are packed together with reagent kit. Please refer to IFU of the kit for the use of calibrators.

7.5.3 Prepare and load the reagent cartridge in the AURA

When preparing the reagent cartridge, follow the following precautions:

- Wear gloves and masks to avoid contamination with other reagents or samples.
- Test the cartridges in time after taking them out the fridge. Do not leave them in a non-refrigerated state for long period of time.
- Please follow the instructions on the package.

1. Take the reagent cartridge out from the fridge, place the reagent cartridge to the cartridge rack, and push it into slot smoothly. Please pay attention to:

- Hold the edge of the reagent cartridges to avoid contacting with the aluminum seal and the detection slot; otherwise it will lead to error results.
- Be careful not to spill saliva into the detection slot, which can lead to errors.
- Do not use cartridges that have dropped onto the ground, which can lead to error.

- Before test, gently shake the reagent cartridge upside down to remove bubbles on the walls of the reagent cartridge or the liquid inside the aluminum seal.
2. On the “sample info” screen of calibration test, the calibrator is required to be tested twice.

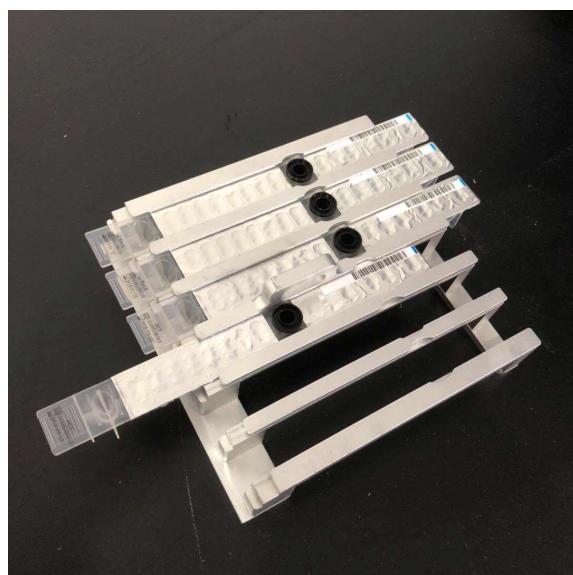


Figure 7-5 Load the reagent cartridge into the reagent rack

3. Add appropriate volume of sample (volume as per IFU; do not overflow the sample well) to the sample well of cartridge by pipette. Remove bubble formation, if any, before test.

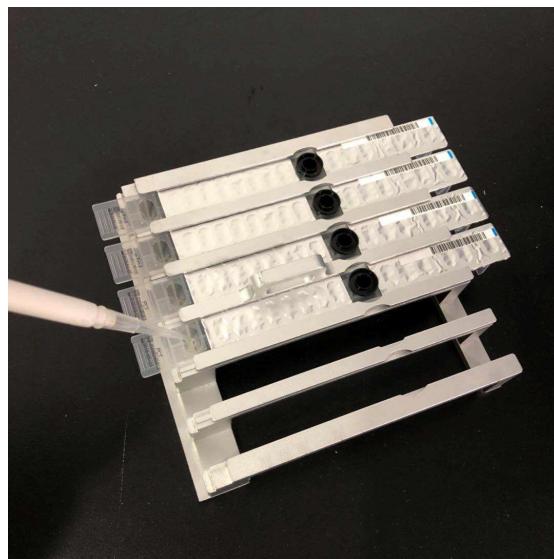


Figure 7-6 Pipette the sample into the sample well

4. Open the front cover and load the cartridge rack properly.



Figure 7-7 load the reagent cartridge rack

7.5.4 Load disposable tips

Please use disposable tips specially designed for the AURA.



Figure 7-8 Disposable tips

1. Take out the new tips from the tip box and load them in the tip slot on AURA. Align with the line of the reagent cartridges loaded. Note that the end of the tips should not be contaminated or damaged.

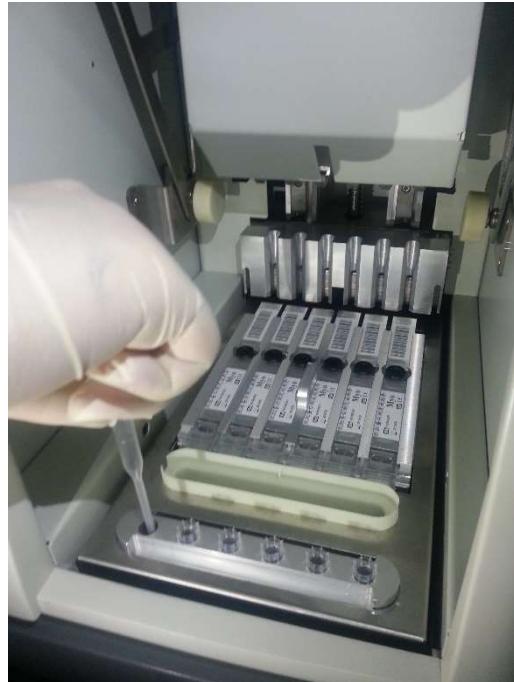


Figure 7-9 Load the disposable tips

2. Close the front cover.



Figure 7-10 Close the front cover

7.6 Start and End Calibration Assay

7.6.1 Start

1. Press the “Start” button on the “Calibration Assay” screen to start calibration.

CALIBRATION ASSAY		
Click < START > to start Assay		
2018/11/07 08:58		
ASSAY	CHECK	SETTING
REAGENT INFO	SAMPLE INFO	
LINE 1	cTnI	CAL1
LINE 2	cTnI	CAL1
LINE 3	cTnI	CAL1
LINE 4	cTnI	CAL2
LINE 5	cTnI	CAL2
LINE 6	cTnI	CAL2

Figure 7-11 Press "Start" to calibrate

Note: Run the calibration as soon as the preparation is completed. Sample precipitation and evaporation in the well might affect the test results.

Do not leave the instrument so that if necessary, take appropriate action based on the information displayed. Refer to Chapter 12 Troubleshooting for details on error information.

2. When the calibration started, the following screen will show:

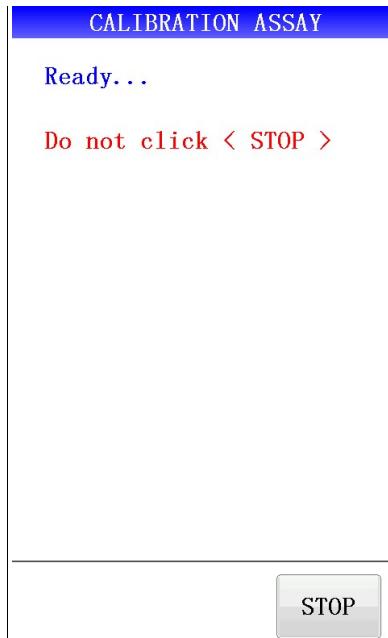


Figure 7-12 The screen of the calibration test in progress

In case of emergency press the "Stop" button, and the following screen shows.

Note: Please do not press "Stop" if there is no special situation during the test.

Note: Once stopped, it might need to re-calibrate with new reagent and calibrator.

After stopping, the test with the reagent cartridge and sample in the analyzer may not be able to continue.

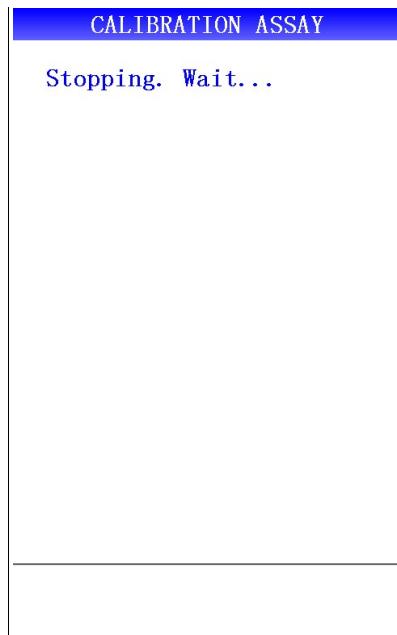


Figure 7-13 Calibration stop screen during test

2. When the calibration test is completed, the result will be automatically printed out, and the system will automatically come back to sample info screen of the calibration test. The results are not shown on the screen. If the calibration fails, the results will be printed out and relevant information will be displayed. Refer to Chapter 12 for rules to know the appropriate solutions.

7.6.2 Output calibration results

When completed the test, the results will be printed out but no showing on the screen. If you need to check the results, you can find it in the "CHECK" -- "Calibration Results CHECK" and you can also choose "Print". Following is a printed result of calibration.

Note: Calibration is done in pairs.

REPRINT DATE:2014/11/26 10:08	Date and time of printing
DATE:2014/11/25 15:00	Calibration start time of test
INSTRUMENT SERIAL:040140216	Equipment serial number
OPERATOR ID:	Product ID
cTnI	Calibration and test items
REAGENT LOT:1011410317	Reagent lot.
CALINRATION PASSED	Calibration status
CAL F:a(1.120)	Calibration factor a/b
CAL F:b(0.960)	
ERROR CODE:	Error code
TYPE: COUNT:REMARK	
CAL1: 352	3 CAL1 values
CAL1: 358	
CAL1: 349	
CAL2: 1500010	3 CAL2 values
CAL2: 1500050	
CAL2: 1500090	

Figure 7-14 Print report on calibration test

7.6.3 Dispose used reagent cartridges and tips

1. Dispose used tips

Take the waste tip box out of the analyzer, and dispose the used tips according to the local regulation and rules. Place the waste tip box back to the AURA.

Note: Please clean the waste tip box after every 20 tests.



Figure 7-15 Take out the waste tip box

2. Dispose used reagent cartridges

Take out the cartridge rack from the analyzer and remove the used reagent cartridges. Be careful not to drop or splash the reagent cartridge from the rack. Refer to local rules when disposing reagent cartridges.

8 QC Test

This chapter will describe the procedure for QC test.

8.1 Introduction

Refer to the preparation and basic operations of the test in Section 5. After the calibration is completed, perform the QC test according to the following procedure.

8.2 Purpose of QC test

QC test is to inspect the calibration curve and data to control quality. It is essential to the validity of sample results.

8.3 About QC test

A QC sample is a sample specially prepared for quality purposes. Please consult your representative for recommended QC materials.

1. QC level

We recommend at least two levels for control.

2. Situations requiring QC test:

- The QC validity expires (when the QC Setting function is set to be enabled).
- After calibration.
- After frequent user setting to analyzer.
- When an error in the sample result is suspected.
- After maintenance of the optical/dispensing system
- The requirements for QC.

3. Validity of QC data

Validity period of the QC data can be defined manually. The QC Setting function is useful for checking whether the validity period is expired. Please refer to 5.7 for details about QC Setting.

8.4 Preparation for QC test

8.4.1 Check the validity of the calibration

Check the test assay name, lot number and validity period of the reagent cartridge. The lot number and validity period of reagent cartridge can be found on cartridge label, kit label or reagent registration card. If the reagent cartridge expires, the AURA will not run the test.

Press "Reagent Info" on the "Sample Assay/Home" screen to check the validity of calibration and QC:

- The assay and lot number are the same as the reagent.
- It shows that the calibration is valid and does not expire.

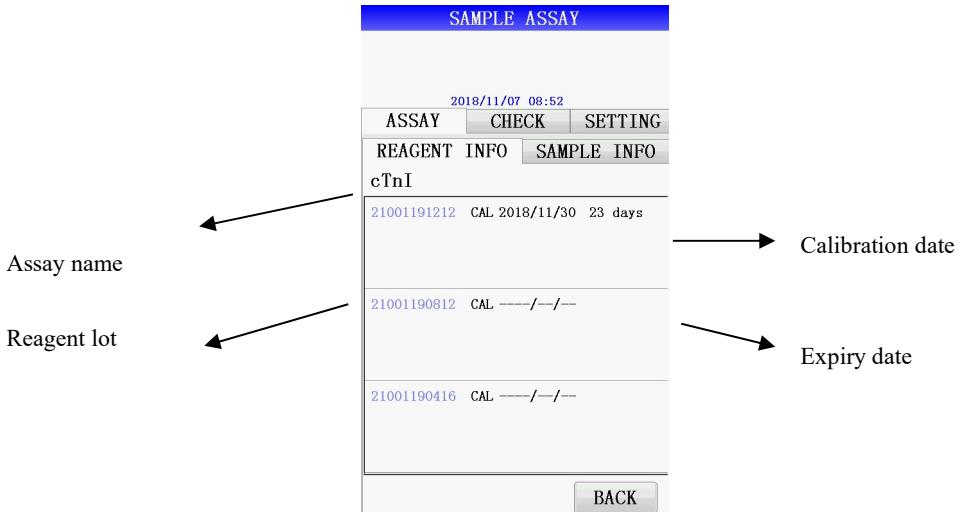


Figure 8-1 reagent information

Note: when the QC Setting is "Disabled", the QC data will not be displayed.

8.4.2 Edit QC information

1. Press the "ASSAY" button on the "Sample ASSAY" screen to enter the following test screen:

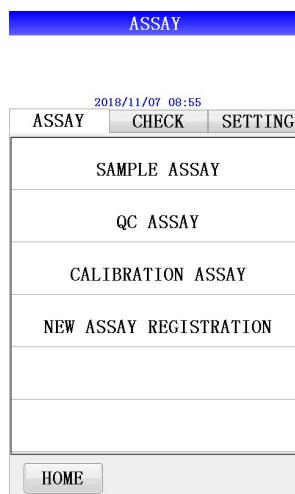


Figure 8-2 Test menu screen

2. Press "QC ASSAY" on the "ASSAY" screen to enter the following screen:

QC ASSAY	
Click < START > to start Assay	
2018/11/07 08:56	
ASSAY	CHECK
REAGENT INFO	SAMPLE INFO
LINE 1	QC1
LINE 2	QC2
LINE 3	QC3
LINE 4	QC1
LINE 5	QC2
LINE 6	QC3

Figure 8-3 QC "Sample Info" screen

3. In the "Sample Info" screen of QC, the position of each QC sample is shown as the above chart. Each column of information can be edited as required. When editing, press the column number and then the following screen shows:

QC ASSAY	
Click < START > to start Assay	
2018/11/07 08:56	
ASSAY	CHECK
REAGENT INFO	SAMPLE INFO
LINE 1	QC1
LINE 2	QC2
LINE 3	QC3
LINE 4	QC1
LINE 5	QC2
LINE 6	QC3

Figure 8-4: QC "Sample Info" editing screen

QC sample type

Press the QC sample type selection frame. Select one from the general sample, QC1, QC2, and QC3.

8.5 Preparation of analyzer and QC samples

8.5.1 Load the AURA waste tip box

Before preparing the sample and reagent, check if there is any used tips in the waste tip box. If necessary, remove the used tips from the box and load the waste tip box.

Note: clean the waste tip box after every 20 tests.



Figure 8-5 Load waste tip box

8.5.2 Preparing QC Samples

When preparing the QC sample, follow the precautionary instructions.

8.5.3 Prepare and load the reagent cartridge in the AURA

When preparing the reagent cartridge, follow the following precautions:

- Wear gloves and masks to avoid contamination with other reagents or samples.
- Test the cartridges in time after taking them out from the fridge. Do not leave them in a non-refrigerated state for long period of time.
- Please follow the instructions on the package.

1. Take the reagent cartridge out from the fridge, load the reagent cartridge to the cartridge rack, and push it into slot smoothly. Please pay attention to:

- Hold the edge of the reagent cartridges to avoid contacting with the aluminum seal and the detection slot; otherwise it will lead to error results.
- Be careful not to spill saliva into the detection slot, which can lead to errors.
- Do not use cartridges that have dropped onto the ground, which can lead to error.
- Before test, gently shake the reagent cartridge upside down on the surface to remove bubbles on the walls of the reagent cartridge or the liquid inside the aluminum seal.

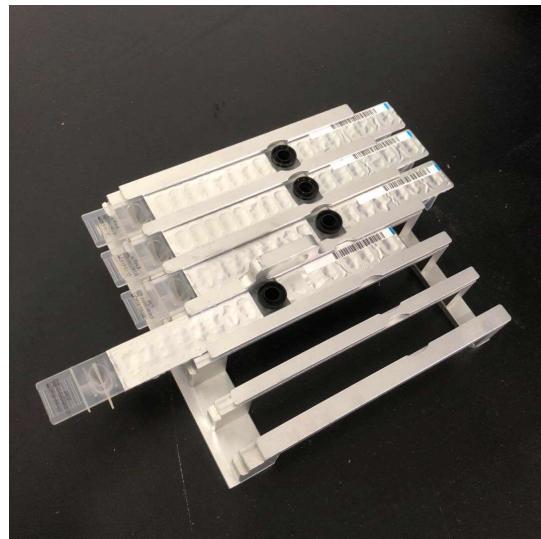


Figure 8-6 Load the reagent cartridge into the cartridge rack

2. Add appropriate sample volume (volume as per IFU; do not overflow the sample well) to the sample well of cartridge by pipette. Remove bubble formation (if any), before test.

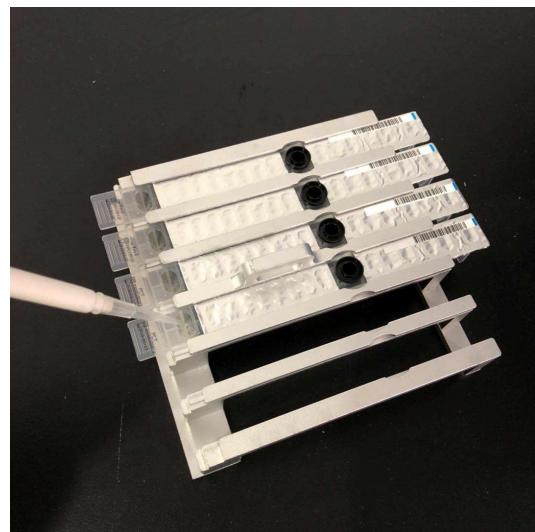


Figure 8-7 Pipette the sample into the sample well

3. Open the front cover and load the cartridge rack properly.



Figure 8-8 Load the cartridge rack

8.5.4 Load disposable tips

Use disposable tips specially designed for the AURA.



Figure 8-9 Disposable tips

1. Take the new tips out from the tip box and load them in the AURA. Align with the line of the cartridges loaded. Note that the end of the tips should not be contaminated or damaged.

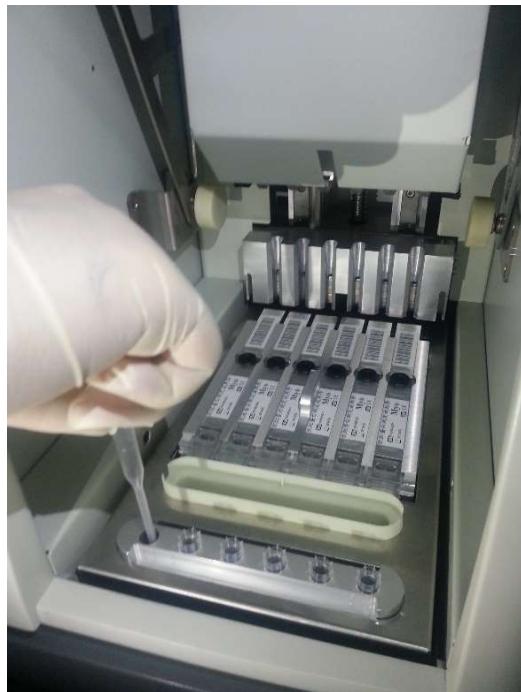


Figure 8-10 Place disposable tips

2. After loading the disposable tips, close the front cover.

Figure 8-13 Close the front cover

8.6 Start and End QC Assay

8.6.1 Start test

1. Press the "Start" button on the "Sample Info" screen of "QC ASSAY".

The screenshot shows a software interface titled "QC ASSAY". At the top, a blue bar contains the text "QC ASSAY" and "Click < START > to start Assay". Below this is a grey button labeled "START". The main area has a white background with a date and time stamp "2018/11/07 08:56". There are three tabs at the top: "ASSAY" (which is selected), "CHECK", and "SETTING". Below these tabs are two more tabs: "REAGENT INFO" (selected) and "SAMPLE INFO". A table follows, with columns for "LINE" and "INFO". The table rows are as follows:

LINE	INFO
1	QC1
2	QC2
3	QC3
4	QC1
5	QC2
6	QC3

Figure 8-12 The "Sample Info" screen of "QC ASSAY".

Note: Run the test as soon as the preparation is completed. Sample precipitation and evaporation in the well might affect the test results.

The analyzer will run the relevant checks before test. If there is any abnormality, it will prompt error message. Do not leave the analyzer so that you can take necessary action according to the message. See Chapter 12 Troubleshooting for error information details.

2. The following screen will be shown during test:

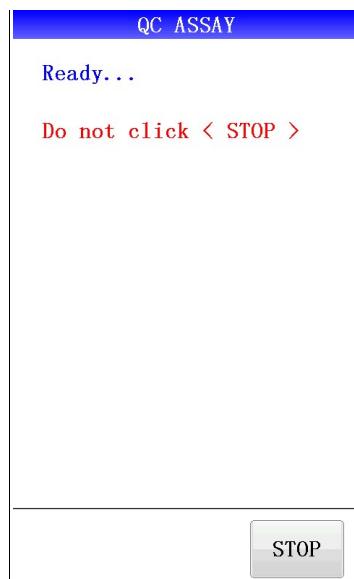


Figure 8-13 Display screen during QC test

If you press the "Stop" button in case of emergency, the following screen will be shown:

Note: Please do not press "Stop" if there is no special situation during the test.

Note: Once stopped, the test may not be able to continue and it may be necessary to run the test again with the new reagent cartridge and new QC material.

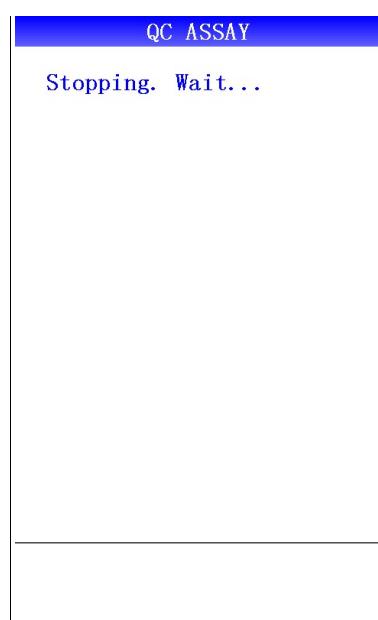


Figure 8-14 "Stop" screen during QC test

3. After QC test is finished, the result of QC sample will be automatically printed out instead of showing on the screen. After printing, the system will return to the "QC ASSAY" screen. To view the test results, you need to press "CHECK" -- "QC Result Check".

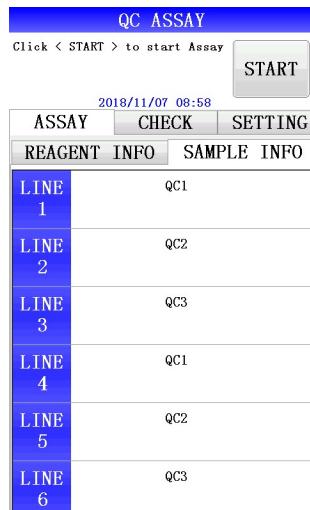


Figure 8-15 "Sample Info" screen after QC test

8.6.2 QC results

When the test is completed, the results will be printed out automatically. Check result in the "CHECK"--"QC Results" screen and reprint is available.

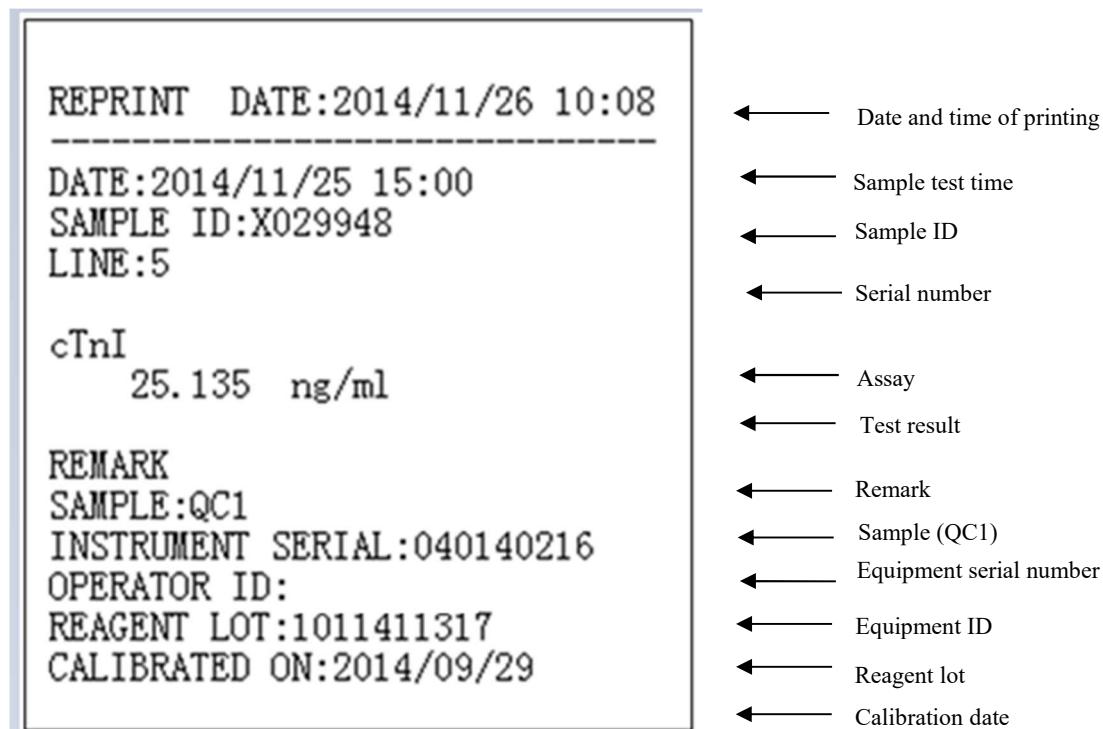


Figure 8-16 Printing report of QC result

8.6.3 Dispose used reagent cartridges and tips

1. Dispose used tips

Take the waste tip box out of the analyzer, and dispose the used tips according to the local regulation and rules. Place the waste tip box back to the AURA.

Note: Please clean the waste tip box after every 20 tests.



Figure 8-17 Take out the waste box

2. Dispose used reagent cartridges

Take out the cartridge rack from the analyzer and remove the used reagent cartridges. Be careful not to drop or splash the reagent cartridge from the rack. Refer to local rules when disposing reagent cartridges.

9 Check

In this chapter, sample result check, QC result check, calibration result check, temperature real-time check functions and reprint program are described.

9.1 Introduction

Press “CHECK” in the subtitle area of the home screen to enter the following “CHECK” screen.

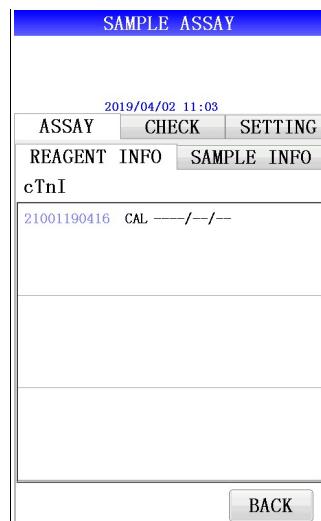


Figure 9-1 CHECK screen

In the CHECK screen, the following operations can be done by pressing each sub-menu on the screen:

Sample Result Check: to check and print sample data.

QC Result Check: to check and print QC data.

Calibration Result Check: to check and print calibration data.

Real-time Temperature Check: to display the temperature of the pre-heating zone and the constant zone.

9.2 Sample result check

You can check or print the stored sample result or QC data. The sample result information for the last 3 days can be queried, and up to 600 records per day can be displayed.

1. Press the “Sample Result Check”, and the following assay selection screen shows.

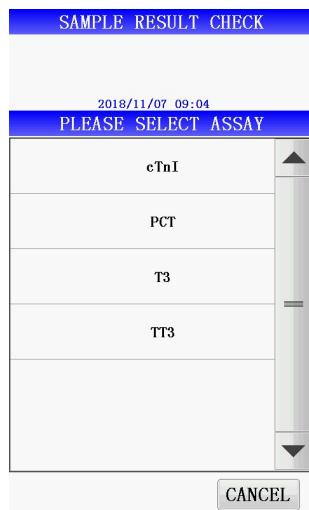


Figure 9-2: The assay selection screen of Sample Result Check

2. Select the item you want to check and press "OK". The following screen shows for date selection, and only the last 3 days' records are displayed on the screen.



Figure 9-3 Date selection screen for sample results

3. After selecting the date, press "OK" to check the sample results of that date. The results will be displayed in chronological order. As shown below:

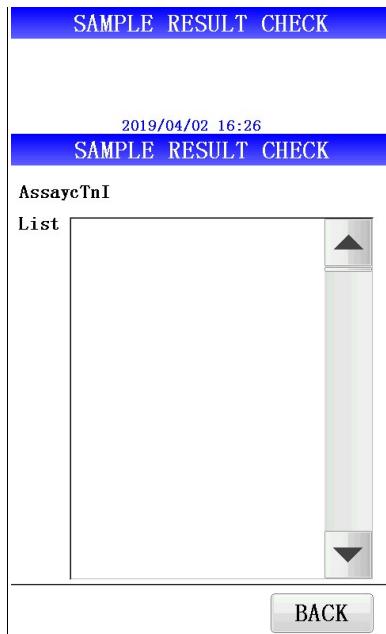


Figure 9-4 Sample results list

4. Press on a sample record and press “CHECK” button. Detailed sample test result information then shows.

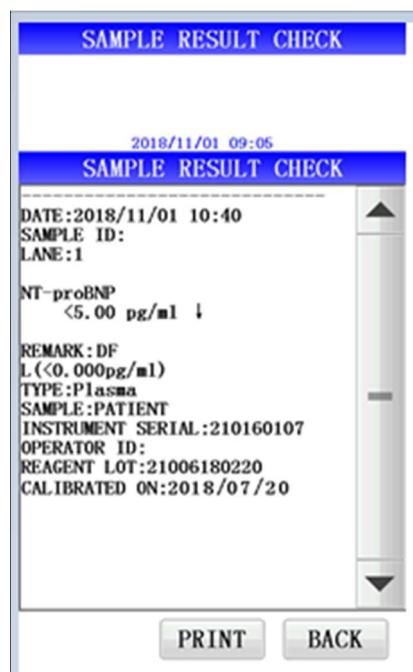


Figure 9-5 Sample result

5. Press “Print” on the above screen and the printer will print the result.
 6. Repeat steps 1-5 according to the assays and dates, and check the sample results you need for the last three days.

9.3 QC result check

From this menu, you can see the stored QC data which can be printed out.

1. Press "QC Check", and the following assay selection screen shows:



Figure 9-6 QC CHECK

2. Select the assay which needs inquiry and press "OK", and the analyzer will show four lots of the reagent which have been recently tested for QC. As shown below:

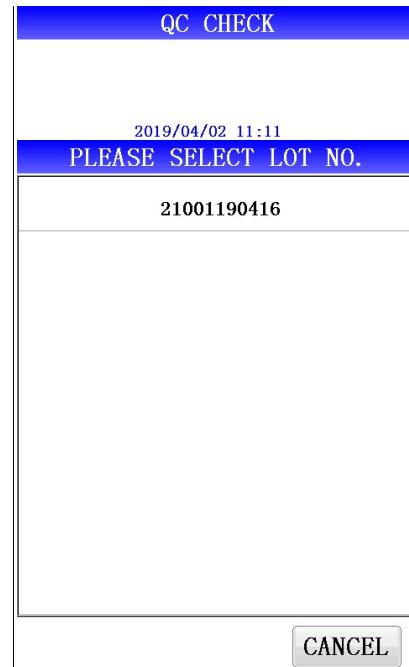


Figure 9-7 QC CHECK

3. Select the reagent lot number and press "OK" to display a list of QC data containing the reagent lot number in chronological order. A maximum of 200 QC records can be displayed.

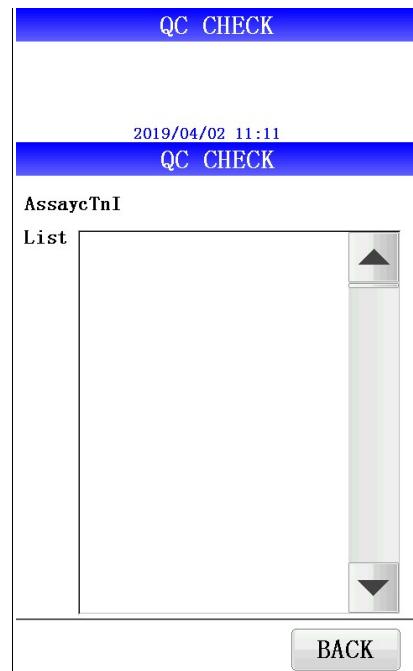


Figure 9-8 QC result list

4. Select the QC record and press "CHECK" to display the following detailed QC results.



Figure 9-9 Detailed QC result information

5. In the above screen, you can choose to print QC result. Press "Print", and the printer will print the QC result.
6. Repeat step 1-5 and check the QC results you need.

9.4 Calibration result check

From this menu, you can view the stored data and print it again on the printer.

1. Press "CAL Check" to enter the following assay selection screen:

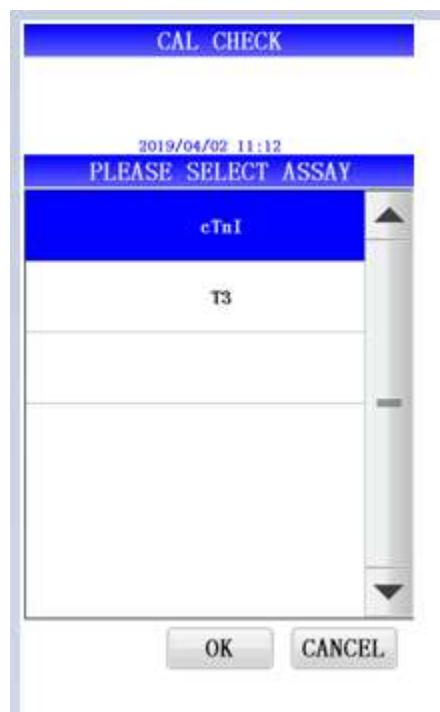


Figure 9-10 The assay selection screen of calibration check

2. Select the assay and press "OK" to display four lots of reagent which have been recently calibrated. As shown in the chart below:

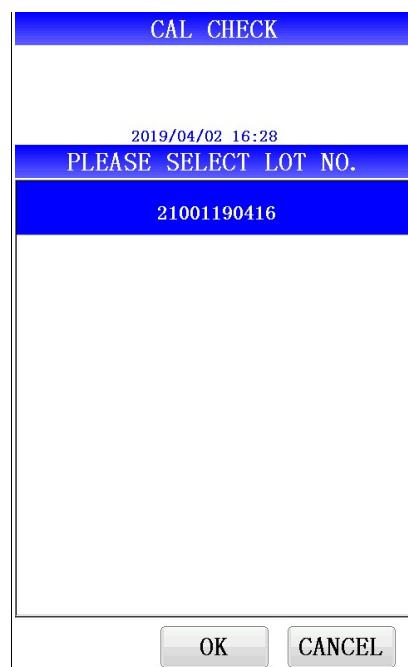


Figure 9-11 Reagent lot number selection screen of calibration results check

3. Select the reagent lot number and press "OK" to display the list of calibration data containing the reagent lot number in chronological order. A maximum of 200 calibration records can be displayed.

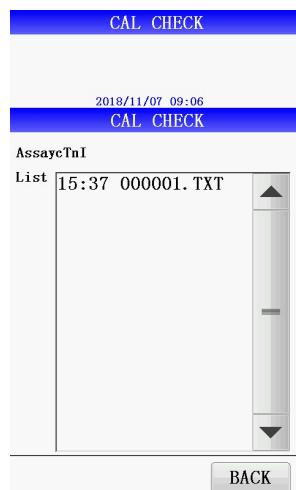


Figure 9-12 Calibration result list

4. Select the calibration record and press "CHECK", and it will display the following detailed calibration results.



Figure 9-13 Calibration result information screen

5. On the above screen, you can choose to print. Press "Print", and the printer will print the selected calibration result.
6. Repeat step 1-5 and check the calibration results you need.

9.5 Real-time temperature check

In this menu, you can check the temperature of the pre-heating zone and the constant temperature zone.

Press "Real-time Temp CHECK" on the "CHECK" screen and the following screen shows. The current temperature of the pre-heating zone and constant zone are shown.

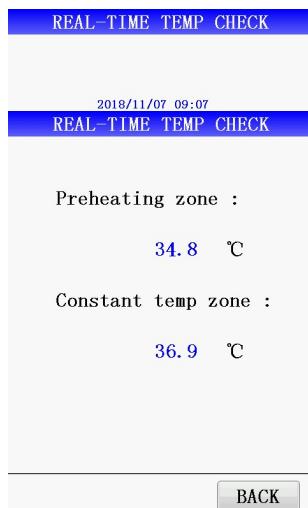


Figure 9-14 Real-time temperature check

10 Setting

This chapter describes setting process of the AURA parameters.

10.1 Introduction

Press "Setting" in the subtitle area and start setting, then the following "Setting" screen is displayed:

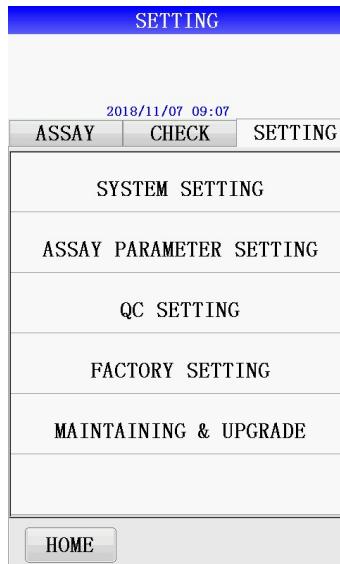


Figure 10-1 Setting screen

On the "Setting" screen, you can set or edit the followings:

System Setting

- Date
- Time
- Language
- Key tone
- LIS
- Print
- Sample ID

Assay Parameter Setting

- Reference range setting
- Pre-alert setting for QC & CAL
- Hct% Setting
- Multiple Calibration
- Reset Calibration

QC Setting

- QC is carried out/not carried out and upper/lower limits

10.2 System Setting

Press “System Setting” on the “Setting” screen to display the following screen to set the system date, time and key tone etc.



Figure 10-2 System Setting screen

Date

Edit the system date; press each display box to enter the date through the digital keyboard.

Time

To edit the system time, you can select the 24-hour display mode or the 12-hour display mode. Press each display box to enter the time through the digital keyboard. When selecting the 12-hour mode, the morning/afternoon button is displayed. You can press the button to select. When setting is completed, press “OK”.

Key Tone

Press the “Setting” button for the key tone: turn on or turn off tone. When the button shows "Yes", indicating tone is enabled; when the button shows "No", it indicates no sound.

10.3 Assay parameter setting

Press on "Setting" screen “Assay Parameter Setting”, and it will show the following screen, in which we can set the assay reference range, pre-alert setting for QC & Calibration, Hct % default setting, multiple calibration and reset calibration.

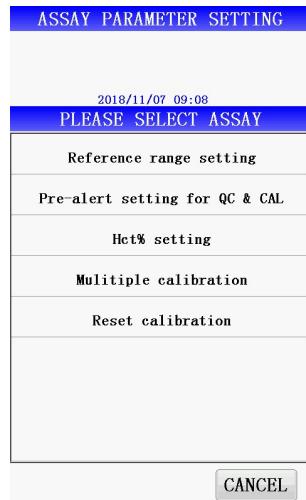


Figure 10-3 Assay Parameter Setting screen

10.3.1 Reference range Setting

There is no information for reference range in this screen for the new analyzer. Reference range can be set after registering the assay in the system.

1. Select "Reference range Setting" on the screen of "Assay Parameter Setting", and the following screen shows:

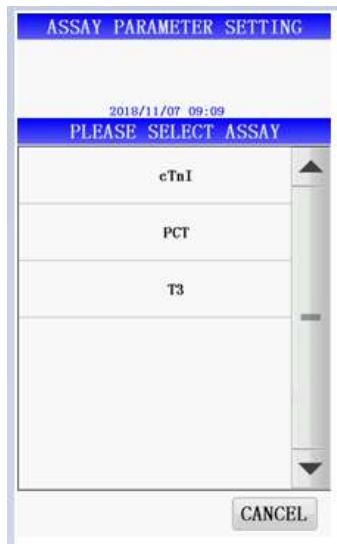


Figure 10-4 Assay selection screen for range setting

2. Select the assay that needs to set reference range, and press "OK" to enter the setting screen of the assay:

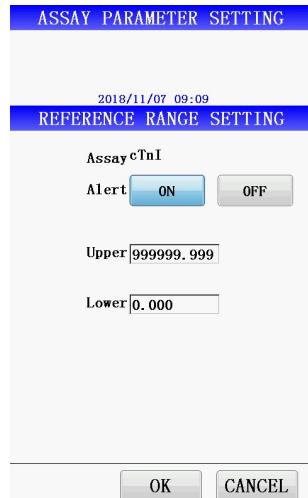


Figure 10-5 Reference range Setting

Assay

Displays the name of the assay

Alert

Press "Yes" to enable the function, or press "No" to disable it.

Upper/Lower Limit

Press each box to display the numeric keypad and enter the numbers.

Upper/ lower limit range: 0.000 to 999999.999.



Figure 10-6 Numeric keypad

3. After Setting, press "OK" to return to the screen of "Assay Parameter Setting"
4. Repeating steps 1-3 for the other assays.

10.3.2 Pre-alert setting for QC & Cal

In "Pre-alert Setting for QC & Cal" screen, you can set the time to inform users of the remaining days of validity of calibration or QC. When the recent calibration or QC valid

date is close to the Setting date, the system will prompt an alert on the reagent status screen when starting the system.

1. Select "Pre-alert Setting for QC & Cal" on the screen of "Assay Parameter Setting" and press "OK". The following screen "Pre-alert Setting for QC & Cal" will show:

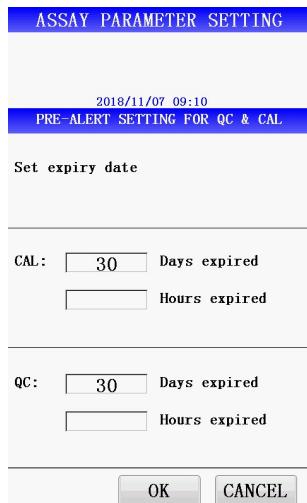


Figure 10-7 QC Pre-alert setting for QC & Cal

2. Calibration and QC can be set separately. Select the day or hour input box and enter the number of days or hours through the numeric keyboard. You can set it to hours or days. When one box is selected, the other display box is empty.

The range can be 0-999 days or 0-30 hours.

Note: the number of days and hours cannot be set at the same time.

3. Press "OK" to save the Setting and go back to the "Assay Parameter Setting" screen.

10.3.3 Hct% Setting

When the patient's sample Hct% is not available, a default Hct% valuation should be set for the whole blood sample for revising calculation.

1. Press the "Hct% Setting" on the "Assay Parameter Setting" screen, and the following default Hct% screen shows.

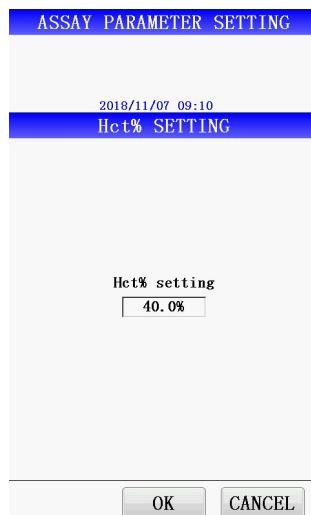


Figure 10-8 Hct% Setting screen

2. Select the edit box to enter the new default value through the numeric keypad.
Range: 0.0-6 0.0 (initial Setting 40.0).
3. Press “OK” to save the Setting and go back to the “Assay Parameter Setting” screen.

10.3.4 Multiple Calibration

On the “Multiple Calibration” screen, you can set the default number of calibration times used in calibration test. The Setting procedure of the calibrator determines the process of calibration test.

1. On the “Assay Parameter Setting” Screen, press "Multiple Calibration", and press "OK" to display the number of calibration repeat times.

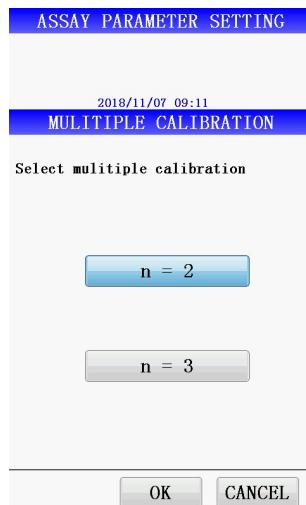


Figure 10-9 Multiple Calibration Setting screen

2. Choose N=2 or N=3
3. Press “OK” to save the changes and return to the “Assay Parameter Setting” screen.

10.3.5 Reset Calibration: This function is not open to common users. It is only accessible to authorized engineers with password.

10.4 QC Setting

In this menu you can activate or disable the QC Setting function and set the control range for each QC level.

The new analyzer has no information in the QC Setting screen, which cannot be set or modified. Only after registering the new assay information, QC data can be set or modified.

1. Press the "Setting" menu in the subtitle area, and the following screen shows:

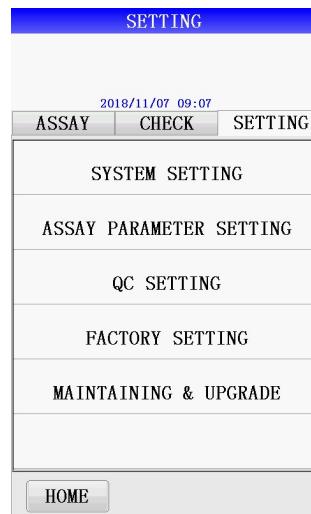


Figure 10-10 Setting menu screen

2. On the Setting screen, press "QC Setting". Enter the following screen:

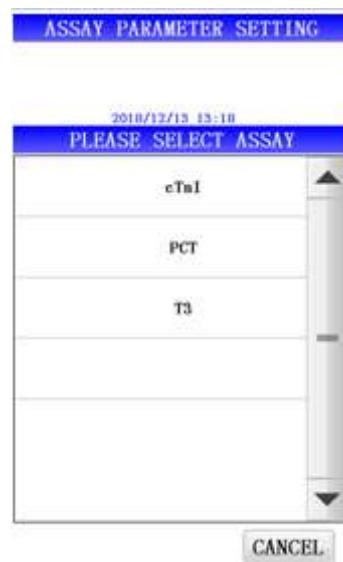


Figure 10-11 Assay selection screen for QC Setting

3. Select the assay that needs to be set up and press "OK" to enter the screen of QC Setting of the assay.

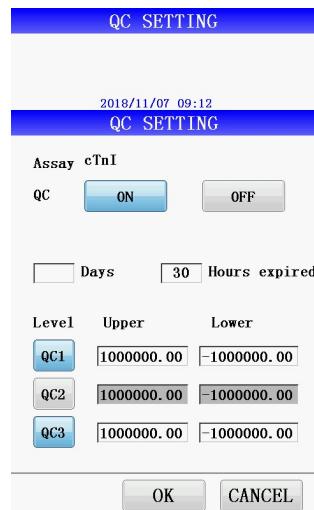


Figure 10-12 cTnI assay QC Setting

Assay

To display QC assay to be set

QC

Press "ON" to activate the QC setup function, or press "OFF" to disable.

Day/hour

The QC period can only be set in the form of days or hours.

Scope: number 1-999 days (999 days means inactivation)

Hour: 1-30 hours

Note: day and hour cannot be set at the same time, and the displayed one is valid.

Quality level

Within the validity period, click the QC level to check, and the selected level is highlighted.

Upper/lower limit

To key in threshold numbers with the numeric keypad.



Figure 10-13 Numeric keyboard

Range: -9999.999 to 999999.999

Note: Check that the upper limit is equal or greater than the lower limit. These values will be used to make the scale of the QC curve.

11 Maintenance

This chapter describes the regular maintenance of AURA and replacement of the consumables. Please disconnect power and wear appropriate safety gears (gloves, experimental coat, goggles, etc.) while maintaining the analyzer.

Keep analyzer accessories and disposable components clean. Use the maintenance record pages in this manual to record each maintenance. Follow 11.1.1 weekly maintenance procedures and 11.1.2 monthly maintenance procedures to clean the AURA (including analyzer surfaces and operating tables).

When cleaning the AURA, please only use the detergents listed in the manual. If you need to use other detergent, please contact your Linear Diagnostics representative to confirm.

If the AURA needs to be repaired or disposed, please contact your Linear Diagnostics representative. Follow the instructions in the manual (11.1 user maintenance) to clean the analyzer before maintenance.

11.1 User Maintenance

11.1.1 Weekly Maintenance

1. Clean the waste tip box

Clean the waste tip box after every 20 test or once a week.

2. Clean the cartridge rack

Clean the cartridge rack with a piece of gauze soaked with alcohol.

3. Cleaning surface

Clean the surface with gauze soaked with alcohol.

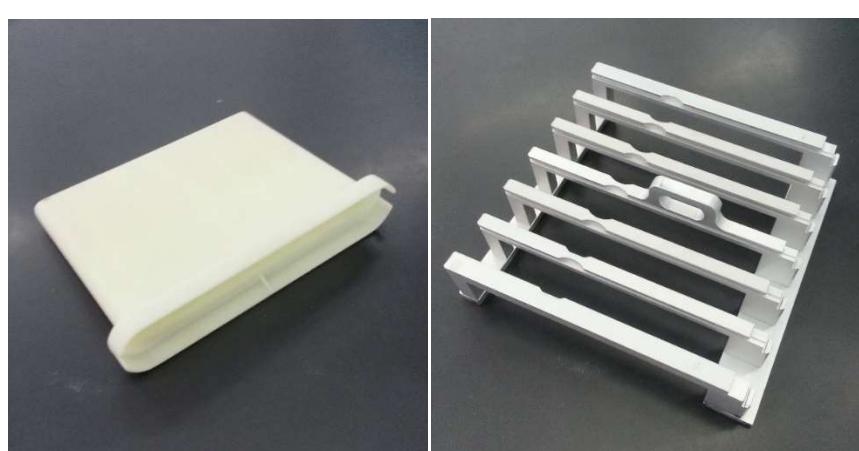


Figure 12-1 Waste tip box and cartridge rack

11.1.2 Monthly maintenance

1. Clean analyzer surface

Note: Do not let detergent flow into the analyzer.

2. Clean the edge of the cap piercer

Gently clean the edges of the cap piercer one by one with gauze soaked with alcohol. Be careful that the edges are sharp. Gloves must be worn to avoid contaminating the edges of the cap piercer.

3. Clean the tip slot

Gently clean the surface of the tips with gauze soaked with alcohol. To clean the inside, use a cotton swab wrapped with gauze which has soaked with alcohol. To avoid contamination, change cotton for each slot.

11.2 Others

11.2.1 Load the printer paper

Follow the procedures below to load the printer paper.

1. Open the printer cover at the bottom left side of the analyzer.



Figure 11-2 Open printer cover

2. Remove the used printer paper shaft and load new paper to roll the paper down. Push the retaining plate back into place. Cut off excess paper with paper cutting knife. Close the printer cover.

Note: be careful to the sharp edge of the paper



Figure 11-3 Load the thermal paper and close the printer cover

11.3 Recommended regular maintenance

In order to ensure the best condition of your AURA analyzer, we recommend that the authorized technical service representative of the AURA be responsible for regular maintenance. Please contact our AURA representative for details.

1. Check the following regularly:

- Check all mechanical movements
- Check training of the new users
- Inspect optical unit
- Check the fan
- Make thorough cleaning
- Other necessary maintenance

2. Recommended spare parts:

- Syringe unit: replace every three years or earlier, depending on usage.

12 Troubleshooting

This chapter describes remarks and error messages. Check this chapter if you have a problem with the AURA. If the problem is not solved, or is not included in this manual, then contact your Linear Diagnostics representative for help.

12.1 Introduction

AURA uses memories and error messages to respond the detected errors, and remarks are added to the printed results. Messages codes consist of 1-2 characters.

12.2 Remark definition

The following index lists remark codes, code descriptions, and suggested solution to be taken.

Tabel 12-1 Code with remarks

Code	Description	Data Processing	Suggested Solution
S	No samples found	Add remark code to the result and print with an * instead of data.	Re-test
NT	No tips found	Add remark code to the result and print with an * instead of data.	Re-test
NC	No valid calibration is available upon completion of the test	Add remark code to the result and print with an * instead of data.	Re-calibrate
ED	Secondary data is lower than that preset	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
H1	The temperature of constant zone is too high	Add remark code to the result and print with an * instead of data.	Contact your AURA representative

H3	The temperature of pre-heat zone is too high	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
L1	The temperature of constant zone is too low	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
L3	The temperature of pre-heat zone is too low	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
UK	Error from the sample identification sensor	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
ER	The LED signal used to identify the sample is too weak.	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
DF	The test results were adjusted by Hct%	Add remark code to the result	None
OR	The QC value is out of range	Add remark code to the result	Re-test
RS	When sending information to host, add remark with new Hct % to recalculate.	None	None
AE	Abnormal luminescence value	Add remark code to the result and print with an * instead of data.	Re-test
HC	Hct% miscalculation	Add remark code to the	Contact your AURA representative

		result and print with an * instead of data.	
CI	The calculation error is different from above HC	Add remark code to the result and print with an * instead of data.	Contact your AURA representative
BE	PMT positional failure	Add remark code to the result and print with an * instead of data.	Contact your AURA representative

12.3 Error codes of failed calibration

When the calibration test fails, the error code is added to the printout. The error message contains two digits.

Table 12-2 Error codes for failed calibration

Code	Description	Data Processing	Action suggested
01	CAL-1 CV% is greater than the current limit	Calibration failed. The failed data was stored by error code	Re-calibrate
02	CAL-2 is greater than the current limit	Calibration failed. The failed data was stored by error code	Re-calibrate
03	When 2-point calibration method is used, the average value of CAL1 is greater than the limit	Calibration failed. The failed data was stored by error code	Re-calibrate
04	When 1- point calibration method is used, the average value of CAL1 is less than the limit, or the average value of CAL2 is less than the limit range	Calibration failed. The failed data was stored by error code	Re-calibrate

	when 2-point calibration is used.		
05	When 1- point calibration method is used, the average value of CAL1 is more than the limit, or the average value of CAL2 is more than the limit range when 2-point calibration is used.	Calibration failed. The failed data was stored by error code	Re-calibrate
06	With 2- point calibration method, the absolute value of CALFb is greater than the given value.	Calibration failed. The failed data was stored by error code	Re-calibrate
07	Secondary data is greater than the current limit, and the ratio of data to primary data is less than the current limit	Calibration failed. The failed data was stored by error code	Re-calibrate
08	Calibration error	Calibration failed. The failed data was stored by error code	Re-calibrate
09	At least add a remark to one of the calibrator solutions	Calibration failed. The failed data was stored by error code	Re-calibrate
10	Inconsistent with the main calibration curve	Calibration failed. The failed data was stored by error code	Re-calibrate

12.4 Error messages

If an operation error or analyzer failure is detected, the error message will be displayed on the screen.

Error messages may contain a description of the next action to be taken. The following table lists the error message, possible reasons, and suggested solutions.

Table 12-3 Error messages

Term	Error Message	Possible Cause	Suggested Solution

The test process	Anomalous concealed current	Abnormal hidden water flow was found in the detection slot.	Replace reagent cartridge
The test process	Luminous error	Abnormal large values are obtained in the detection slot	Replace reagent cartridge
The test process	PMT Setting error	PMT failed to load the detection slot properly	Replace reagent cartridge
Connecting to the host	The assay does not exist	The assay is not registered in the AURA	Registering new assays
Connecting to the host	Connection error	Cannot establish connection with the host	Check the connection between cable and PC
System initialization	System error 10001-10020	Error detected during system initialization	Record error codes and contact your AURA representative
File operations	System error F005 0-F005 3	Error detected in file operation	Record error codes and contact your AURA representative
Motor control	System error M0100-M0107	Motor or position monitor detects error	Record error codes and contact your AURA representative
Tip control	System error D015 0-D015 1	Detection error of tips management device (Aspirate & dispense)	Record error codes and contact your AURA representative
PMT control	System error P0200-P0203	Error detected in PMT operation	Record error codes and contact your

			AURA representative
Heater control	System error P025 0-P025 1	The temperature controller detected an error	Record error codes and contact your AURA representative
Host Connection	System error H035 0	The host connection cannot be established	Check cables and wiring
Host Connection	System error H035 1	The host is not responding	Check host is ready
Relevant protocol command	System error S0400-S0412	Execution protocol error	Record error codes and contact your AURA representative



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Appendix

Aura Device Maintenance Records

Record No.:



Aura Device Maintenance Records

Record No.: _____