H618 HbA1c Analyzer

Operating/Technical Manual

Shenzhen Xilaiheng Medical Electronics Co., Ltd.

Content

Product information

Product model: H618

Product name: HbA1c Analyzer

Manufacturing site: No. B of 3/F, Xinghua Industry Building 7, Shekou Industry Road, Nanshan District, Shenzhen 518066, China

Version information

This version is subject to change or upgrade without prior notice.

Version:

Issue date:

Declaration:

Shenzhen Xilaiheng Medical Electronics Co., Ltd. reserves the right to change the product described in this Operating Manual.

All information contained in this Operating Manual is subject to change without prior notice.

Manufacturer's Responsibilities

Xilaiheng Medical is responsible for the safety, reliability and performance of the device under the following conditions:

1. Operating this device follows this Manual.
2. Assembling, upgrading, resetting, and repairing are performed by Xilaiheng's authorized personnel.
3. Product storing, operating and electrical environment are described in this manual.
4. Product serial number and labels are intact to verify the product identity as manufactured by Shenzhen Xilaiheng Medical Electronics Co., Ltd.
5. Any damage that is not caused by miss-use or accidental dropping.

Free services apply to those products with applicable items within warranty period. For those beyond the description of warranty conditions, Xilaiheng Medical will charge for service. Any returned goods to Xilaiheng Medical for service, customers should pay for the transportation and any applicable customs fees.

Return Procedures

If return is necessary, take the following steps:

1. Obtain return merchandise authorization from Xilaiheng Customer Service Department.
2. Inform Xilaiheng of the serial number and mark this serial number on the cartons. If the serial number cannot be recognized, the return cannot be accepted.
3. Describe briefly reasons for return.
4. Freight Charge: customer is responsible for freight charges (including customs) for any returns.

Chapter 1 Overview

H618 series of HbA1c analyzer, based on Affinity Chromatography and fluorescence immunoassay technology by control of microcomputer, is a clinical testing equipment which is rapid, accurate, convenient, practical.

Hemoglobin (Hb) is composed by a variety of sub-components and derivatives. Therefore, a variety of glycosylated hemoglobin (GHb) produced after scarification is collectively referred to as HbA1. HbA1 is a mixture with subtypes such as a, b, c and d. HbA1c constitutes the majority and the most stable part of it. HbA1c is formed during non-enzymatic reaction in glucose and adult's Hb (HBA) of amino-N-terminal (B link) through two steps.

The first step is reversible and produces unstable HbA1c, after which it will slowly change into the stable HbA1c during the second-stage reaction. The relative proportion of HbA that changes into stable HbA1c will increase with the average blood glucose concentration in erythrocytes. As erythrocyte's life cycle is about 100-120 days, HbA1c can reflect the average blood glucose levels within the last 2-3 months. Therefore, HbA1c is also suitable for long-term monitoring of blood sugar levels for the patients of diabetes. In case of serious metabolic disorder, the risk of the occurrence of diabetic complications (such as diabetic nephropathy and retinopathy) will be increased accordingly.

As an indicator of average blood sugar levels, HbA1c can predict the risk of diabetes complications. For clinical routine examination, it is sufficient to have HbA1c examination every 3-4 months. In some cases, such as in pregnancy or major change for treatment programs, it is very helpful to have HbA1c examination once every 2-4 weeks.

Chapter 2 Product information

2.1 Working principle

H618 analyzer is based on the principle of affinity chromatography. On the basis of this principle, the blood cells will be rapidly pyrolyzed and release the hemoglobin after mixing the test sample with the hemolysin. When the hemolysis sample is dropped to the detection area, it can adsorb chemically the glycosylated hemoglobin from the sample that has been dissolved with the hemolysin under the condition of the pH value of the eluent B. Through the 430-nm illuminant of the analyzer, quantitative detection of hemoglobin is taken by use of 415 nm absorbance peak. At the same time, the light reflected in the test strip surface can be detected by the photodiode where the reflected light value has a direct and certain proportion with the glycosylated hemoglobin concentration of the sample.

2.2 Main Features

a) Measuring method: Affinity Chromatography

b) Test parameters: HbA1c, eAG

c) Sample type: Whole blood or peripheral blood

d) Measuring range: HbA1c 4.0%-15.0%

e) Test time: 3-5 minutes

f) Display: LCD display

g) Dimension：205×130×70mm，1Kg

h) Power：AC100-240V,50/60Hz，60VA

Internal battery optional 12V, 2600mAh

2.3 Product structure

H618 Series HbA1c analyzer is composed of microprocessor, LCD display, light source, light receiving system, RFID receiving system.

All the operations are applied for man-machine touch communication.

2.4 Reagents application

H618 Series HbA1c analyzer reagents contains hemolytic A and eluent B. The reagents of H618 series is used only as In Vitro Diagnostic reagents. Reagent should be stored at room temperature 18℃ -25℃, can be cold, but not frozen. If out from the fridge, should be placed more than 30 minutes, temperature should up to room temperature before using. All the reagents should be used within the period of validity.

Chapter 3 The equipment installation

3.1 Operating environment requirements

Environment temperature: 10℃-30℃

Power voltage: AC100-240V, 50/60Hz, 60VA, internal battery is optional 12V

Relative humidity range: ≤80％

Keep away from strong electromagnetic interference source.

Avoid direct light exposure.

The equipment must have good grounding.

This equipment should not be put in the same room or with same power supply socket **such as** centrifuge, refrigerator, oven, large power **and** large jamming equipments.

Ventilation requirements:

The instrument should be placed in good ventilation indoors.

Placement should be avoided fan, air conditioning and other direct blowing instrument, so as not to affect the precision of temperature control.

Strong vibration should be avoid during working process.

3.2 Installation Steps

1. Open the instrument package first, please follow the packing list at the end of operation manual to check if listed component is complete and check if there is damage of components due to improper transportation.

2. If there is any damage during transportation, please immediately notify the supplier.

Attention**:** If equipment is damaged, do not use it to ensure safety.

3. If any problems, take out of the equipment carefully; put it in the working table smoothly.

4. Installation of printer: This product uses external printer. Connect interface 1 to the back of the instrument on the 232-2 interface, connect the plug 2 to power supply.

3.3 Installation inspection

1. After turning on the power, equipment will be self-checking, and then to standby.

2. Enter to each menu

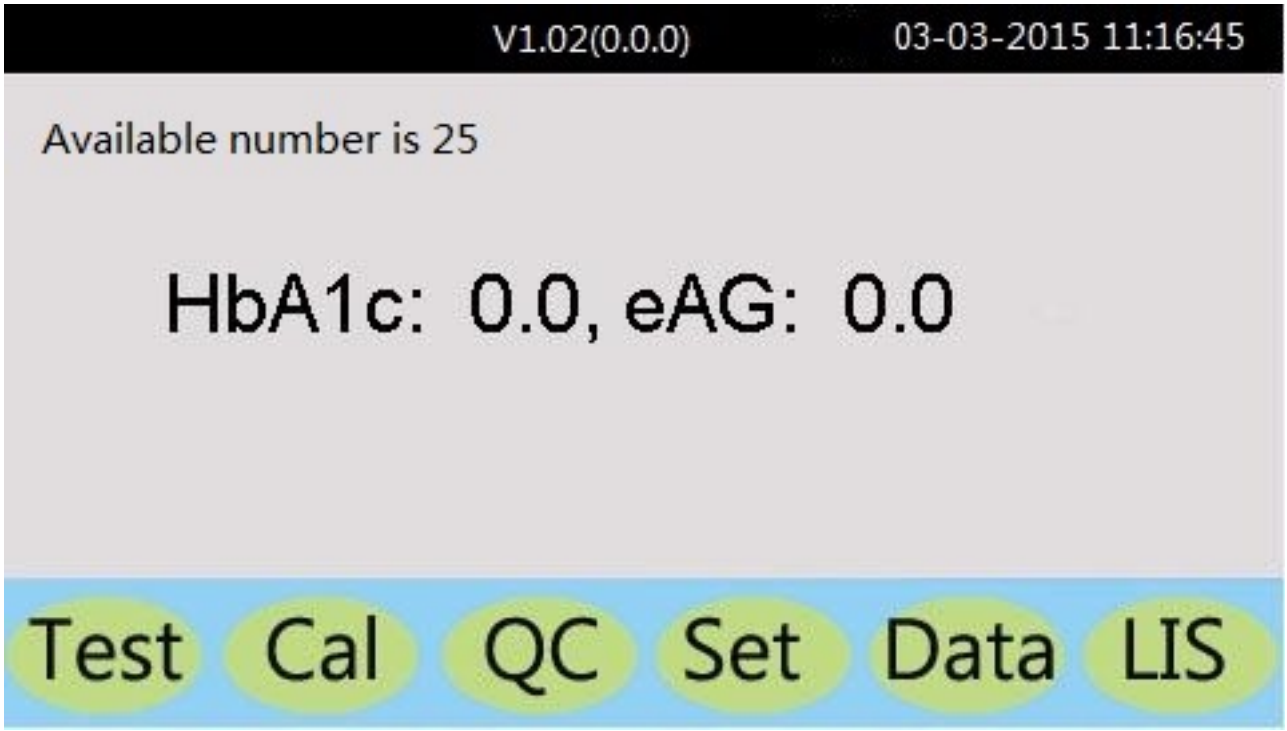
to operate according to the operation steps to make sure every step is works normally.

3. Using QC solution to do the test, if result meets the demand, the equipment is qualified.

Chapter 4 Operation

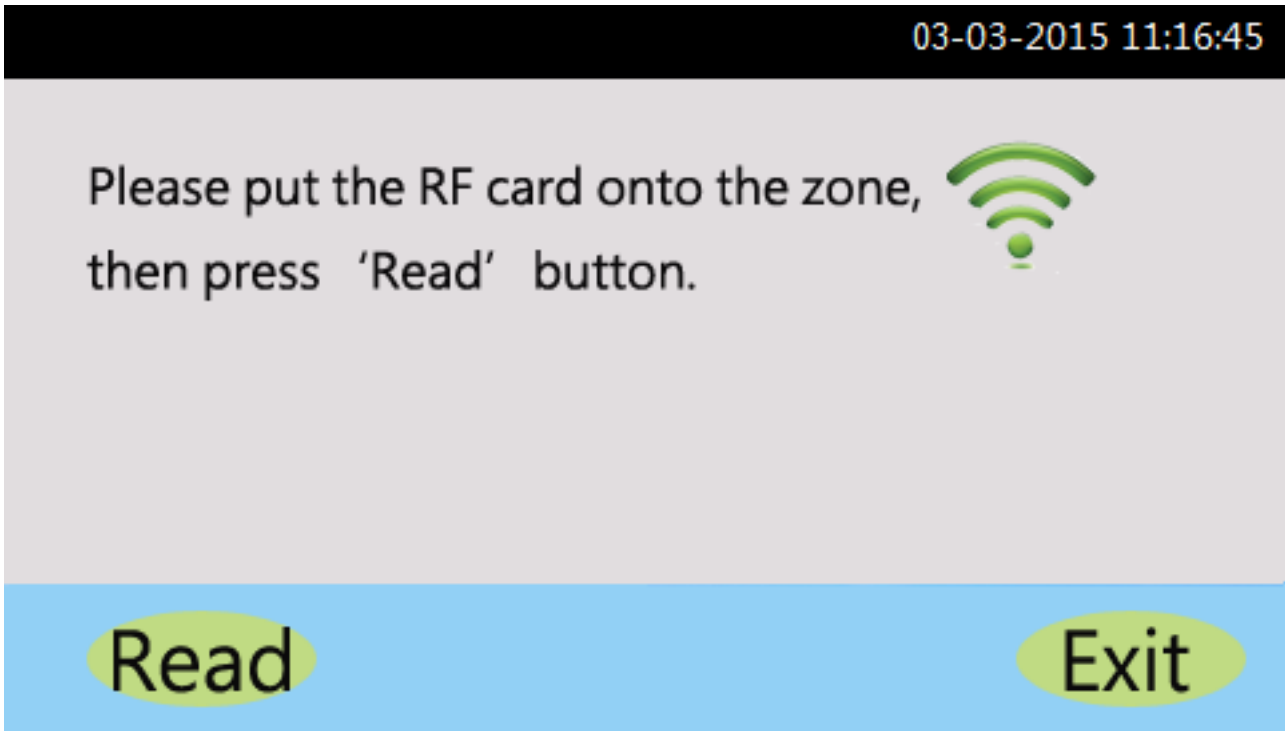
4.1 Power on

Turn on the power switch， system will be preheating. The main menu will be showed as follows.



4.2 Calibration

Press the “Cal” button， system will show as follows:



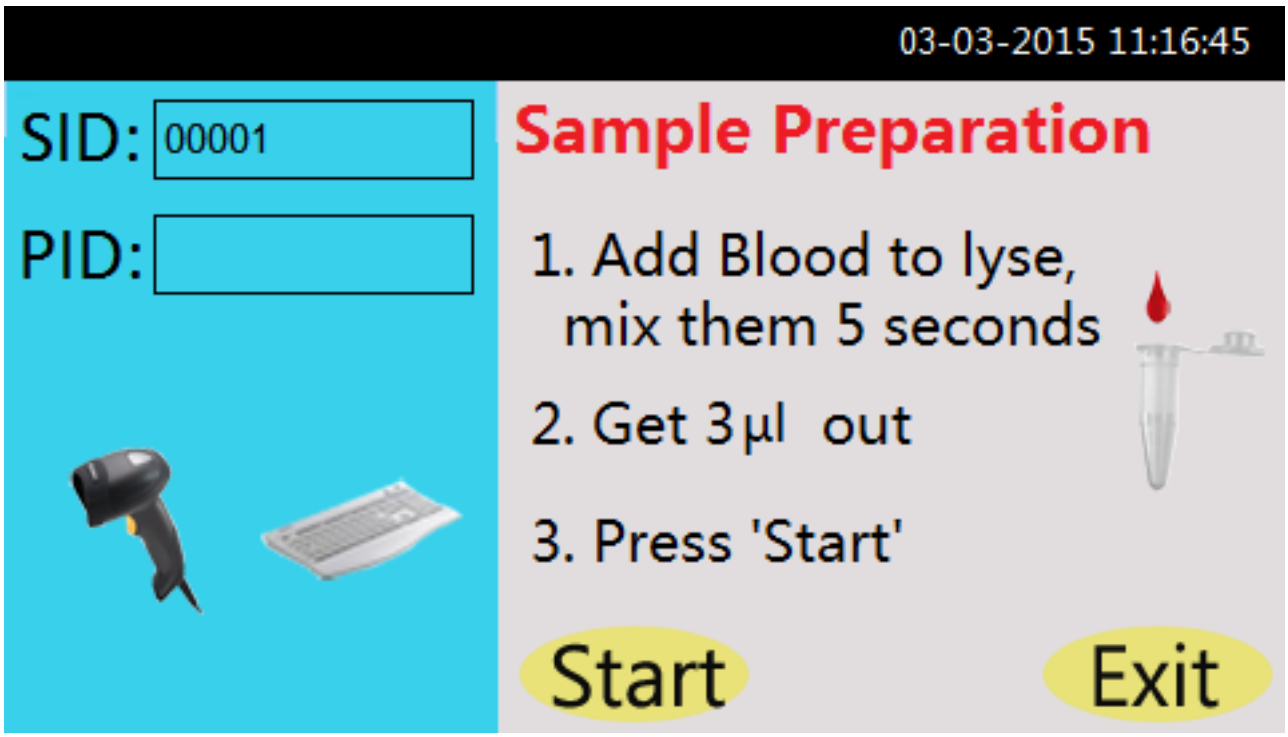
Put the RF card onto the zone， press “Read”. The read position is showed as below：

4.3 Sample testing

Sample tests for H618 Analyzer can be divided into 2 kinds of testing mode--- 'Need not reading blank' & 'Need reading blank'. Compared with 'Need not reading blank', 'Need reading blank' can make sure the stability and precision of results but spend more time. On the contrary, under 'Need not reading blank' mode, testing speed can be faster but the results will be less stable and precise. It depends on the choice of the user.

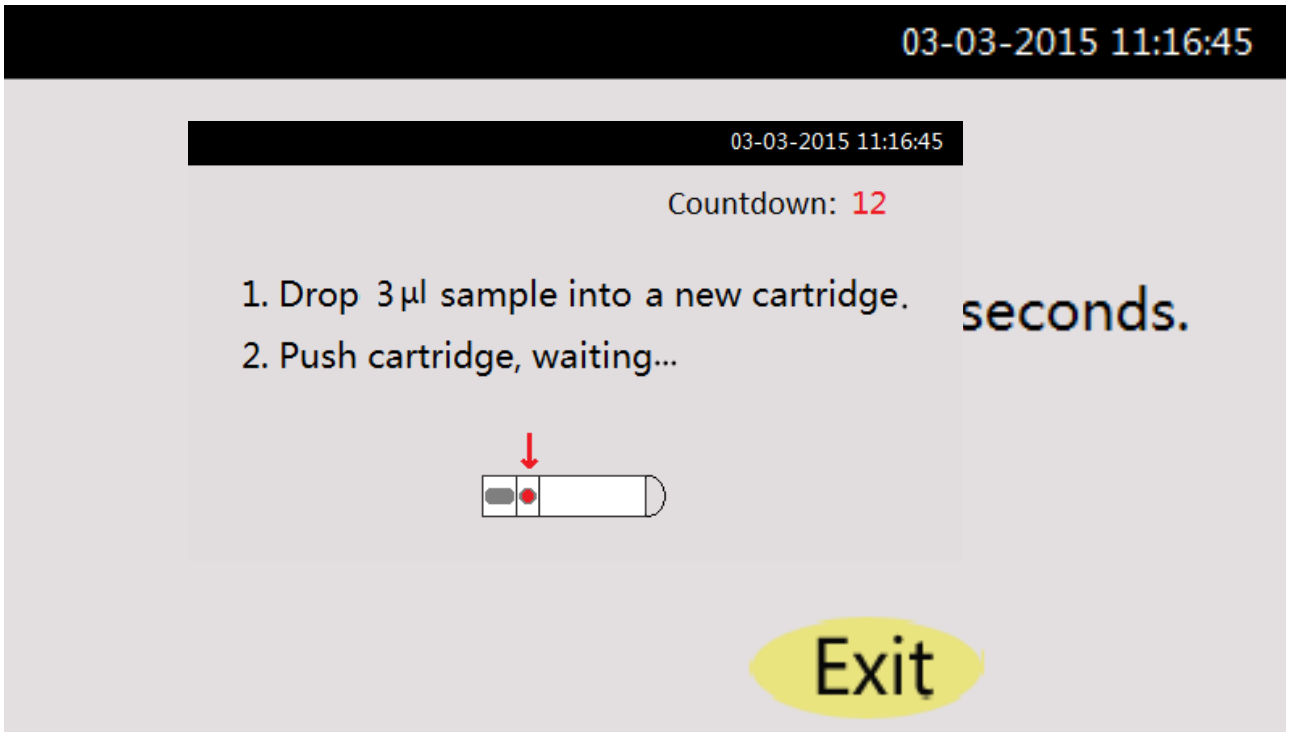
Preparation for 'Need not reading blank' (see 'setting menu')

1) After reading the card, press "Test" button and the screen will show as below.

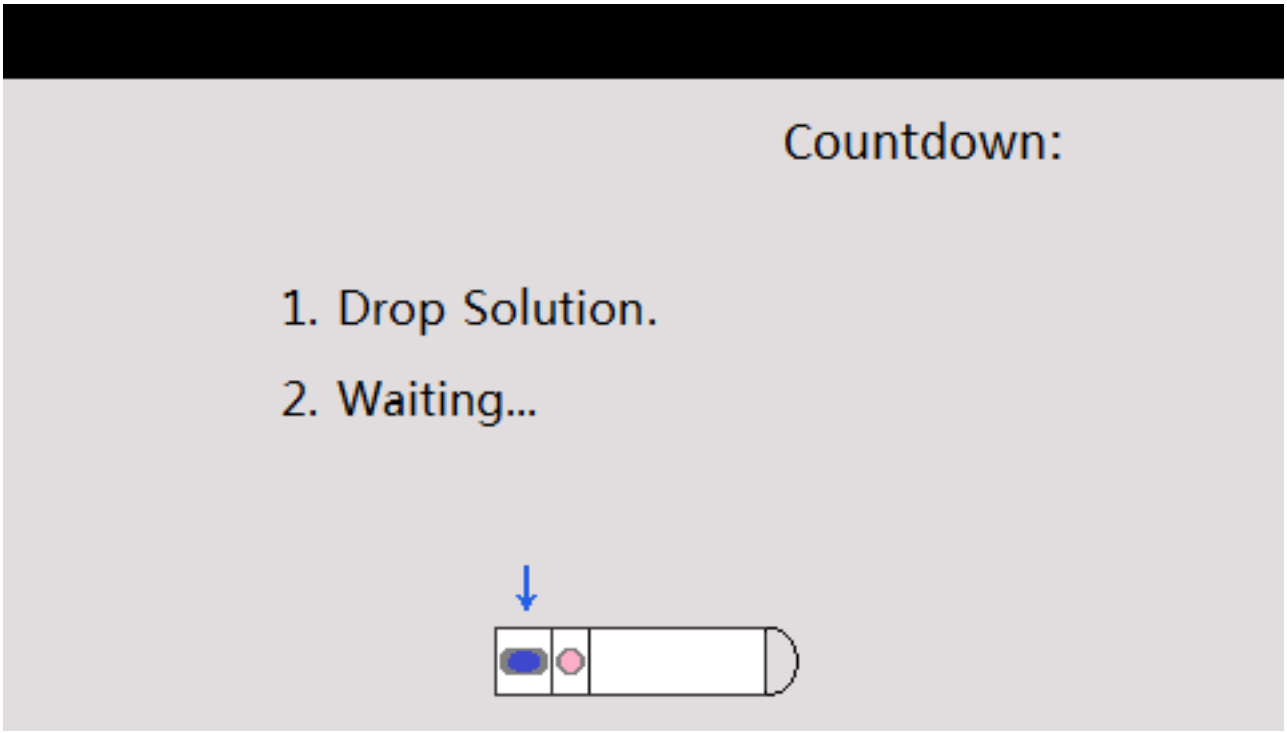


Add sample (**10ul blood**) into the hemolytic (**50ul**) and mix to standby. Get **3ul sample** out and press" Start" button.

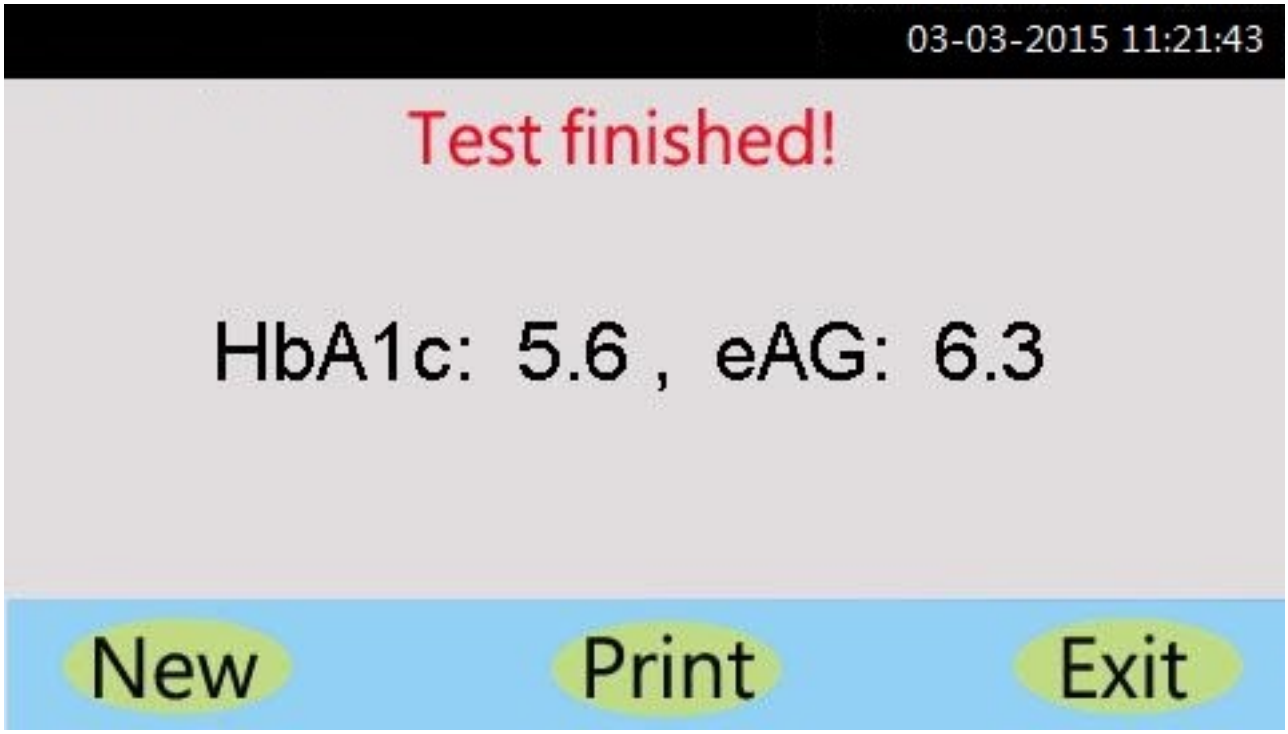
2) Drop **3ul sample** to the right position of cartridge and insert it into the instrument.



3) When the warning tone sounds again, drop the eluent B (35**ul**) to the left position of cartridge and wait.

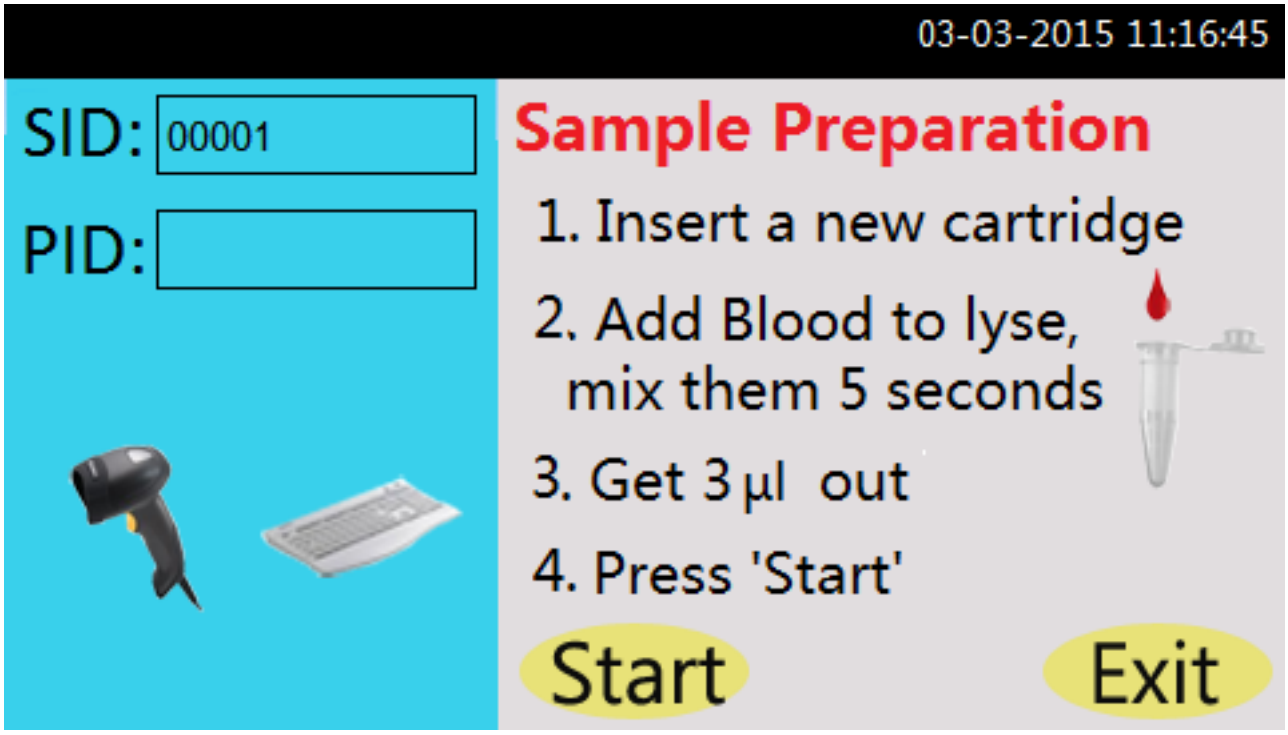


4) Wait for 200 seconds, system calculates the testing result automatically, the value of HbA1c and eAG. The screen displays as follows. Click "New" to start a new sample.



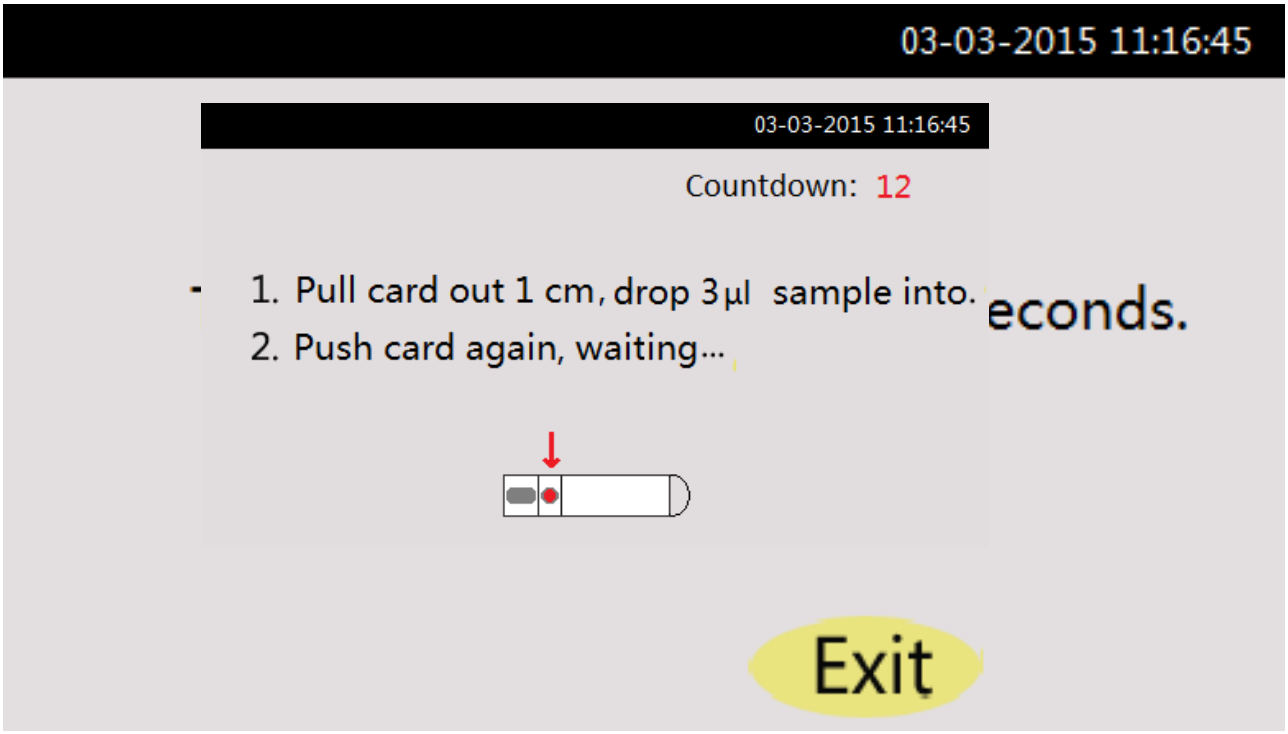
Preparation for 'Need reading blank' (see 'setting menu')

1) After reading the card, press "Test" button and the screen will show as below.

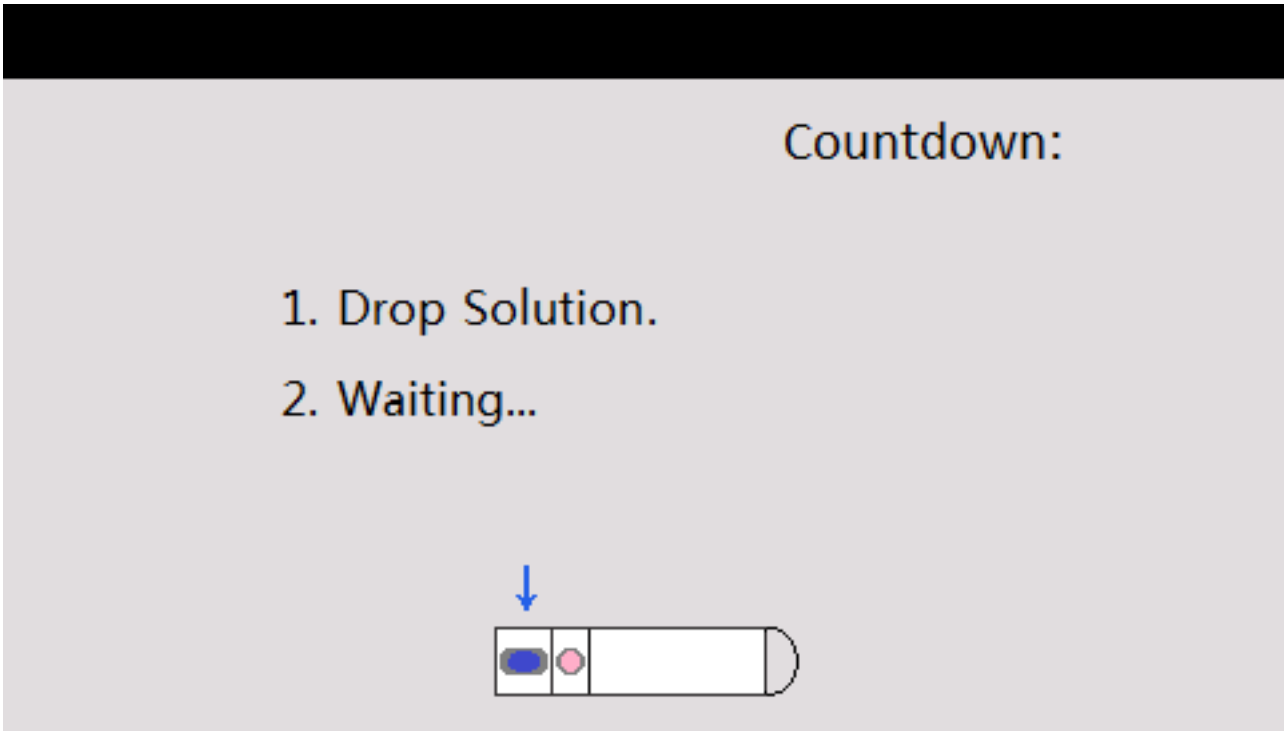


Insert a new cartridge. then add sample (**10ul blood)** into the hemolytic (**50ul**) and mix to standby. Get **3ul sample** and press" Start" button.

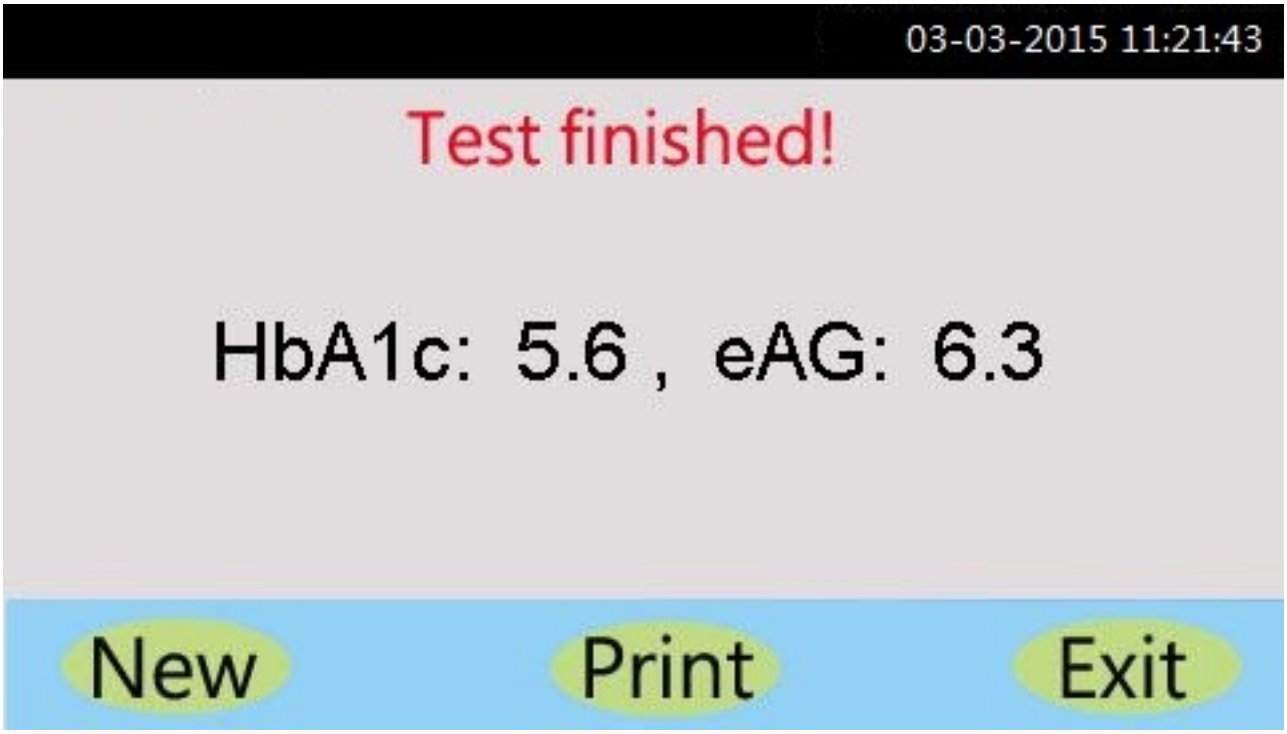
2) Drop **3ul sample** to the right position of cartridge and push it back into the instrument.



3) When the warning tone sounds again, drop the eluent B (35**ul**) to the left position of cartridge and wait.

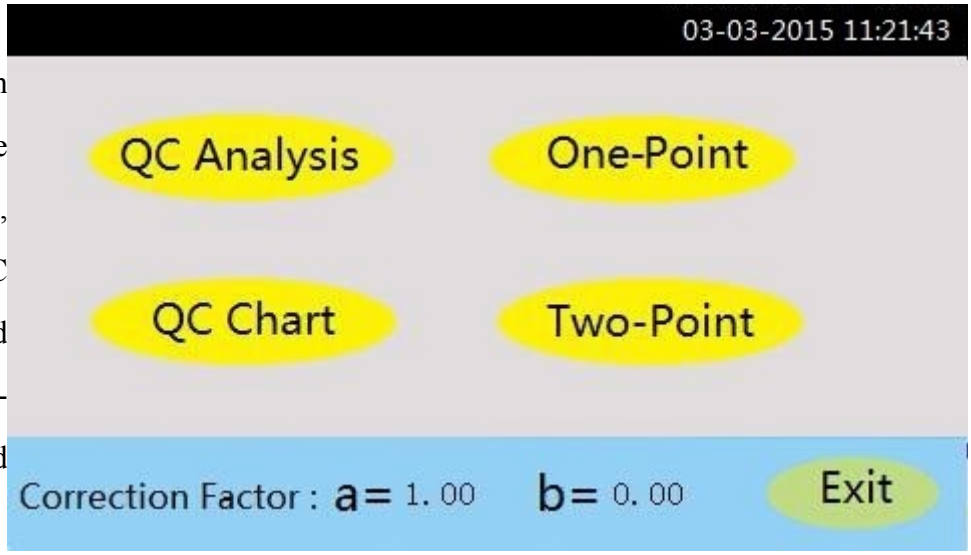


4) Wait for 200 seconds, system calculates the testing result automatically, the value of HbA1c and eAG. The screen displays as follows. Click “New” to start a new sample.



4.4 QC

Click “QC” in the main menu to enter the interface of QC, screen display as follows.

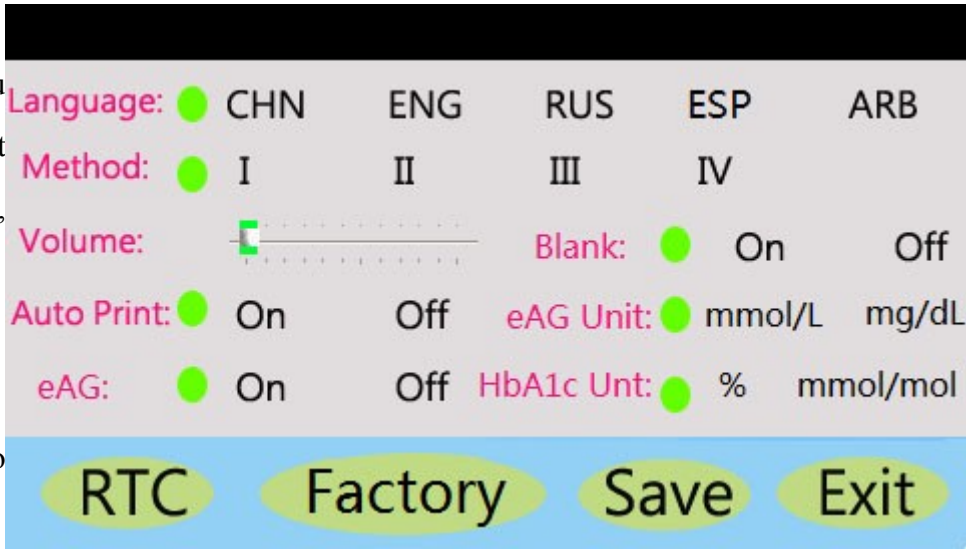


You can modify the QC value, print QC chart, and do One-point and Two-point correction from this page.

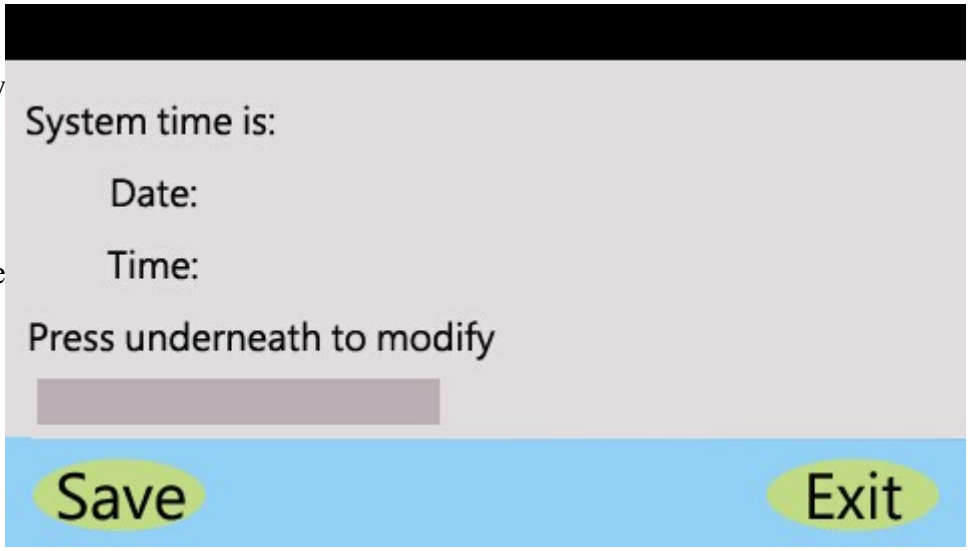
4.5 Setting

Click “Set” in the main menu to enter the interface of Setting

If you need to set the time, click "RTC" button. Click "save" to complete the setting.



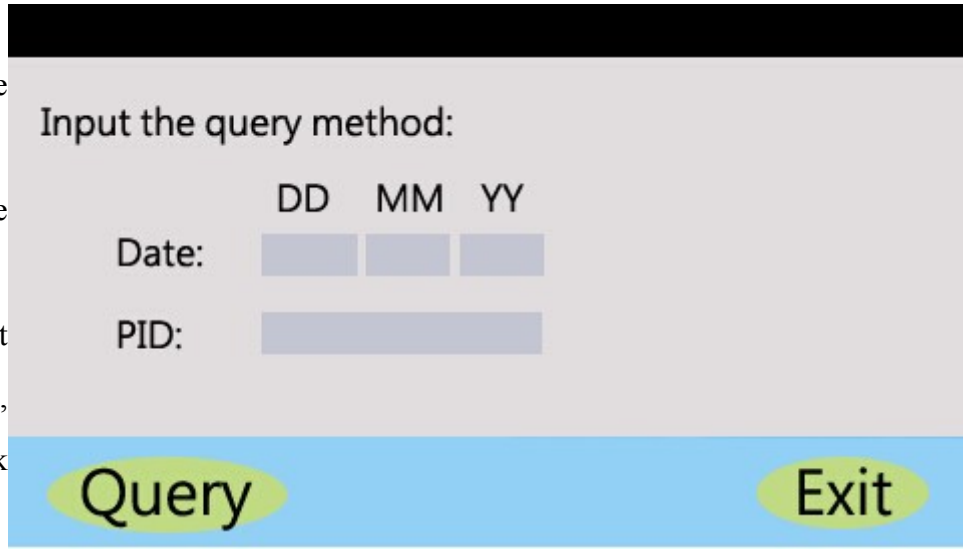
To modify system time please click the part of gray shadow.

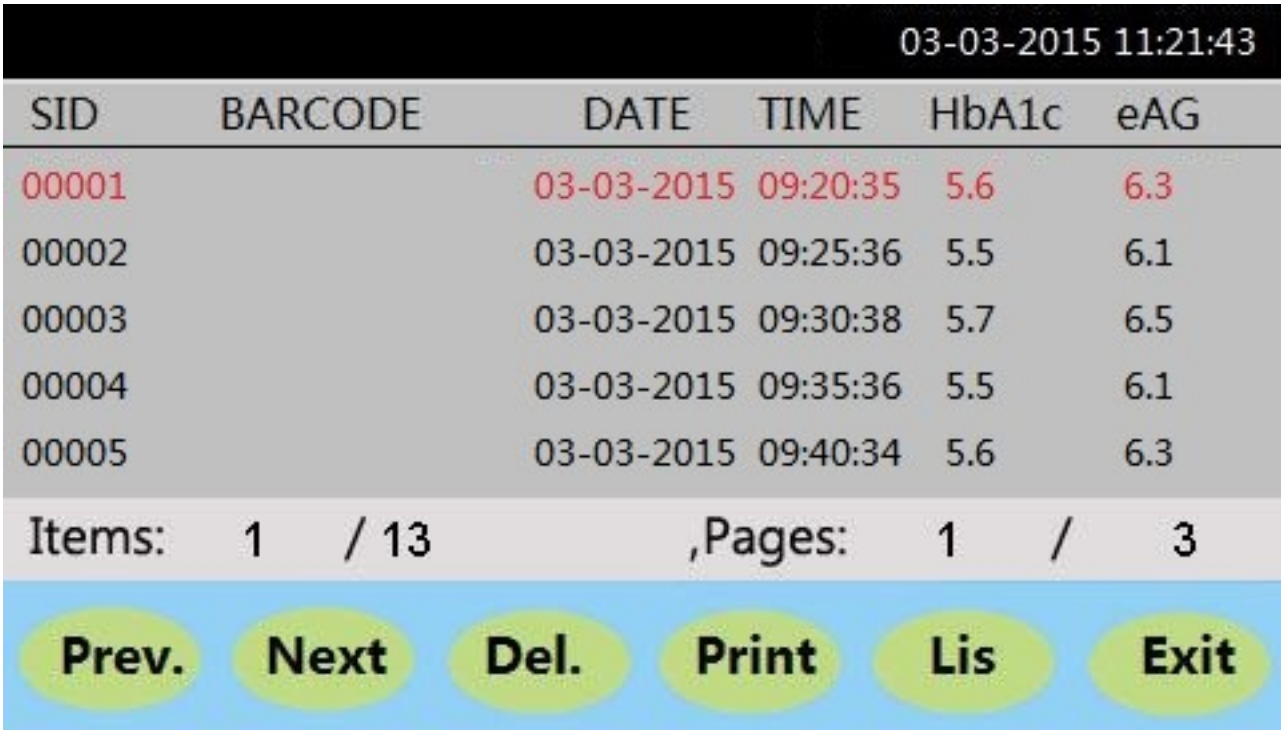


4.6 Review

If users need to view the history test records, click on “Data” in the main menu. The screen displays as followings.

Input the testing time of the sample you want to check, then click “Query” to find the testing result.





Chapter 5 Attention

5.1 Attentions during operation

1.1 Pay attention not to absorb coagulated blood, to prevent blockage of pipeline.

1.2 Do not to absorb bubbles, which may affect the precision of test result.

1.3 Do not use solution with mildew and precipitate, should be abandoned once be found.

1.4 All the reagents should be tightened immediately after taking, avoid long time open placed.

1.6 This instrument do not contain any component capable of self-repair, do not disassemble it when break down.

1.7 Ensure the power supply environment and ground environment are of good stability.

5.2 Attentions while collecting and processing samples

Sample collecting and processing should be done by professional persons, to avoid affect of rest result.

5.3 Attentions for Sample of serum and plasma

1. Serum and plasma refrigerated can be analyzed, but make it back to room temperature before testing.

2. When making the serum sample, some materials which may affect test result can not be added (such as surface active agent, anti-coagulant, ect,) it may disturb the test and even damage the sensor.

Chapter 6 Package, Storage and Transportation

6.1 Transportation

During transportation, the instrument should be kept away from rain, snow and mechanical collision, and should not be mixed with or transported together with corrosive substances.

Simple shockproof facilities should be set up in the packing case, making it suitable for air, rail, highway and sea transports. Rain and snow splash, inversion and collision should be avoided.

6.2 Normal storage conditions

The instrument should be stored in a place or warehouse that satisfies the following conditions.

Ambient temperature: 0-40℃; relative humidity: ≤80%; Clean and ventilated; sunshine, rain and hazardous gases with chemical corrosion can be avoided.

6.3 Special storage conditions and methods

When the device has been stored for more than 6 months, it should be taken out from the packing case and energized for 4h; then put the instrument in the packing case again according to the direction shown on the case and place it in the warehouse. Do not stack up instruments, and do not place them close to the ground, walls and roof.