Getein Biotech, Inc.

CE

CM-400

Biochemistry Analyzer

User Manual

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Getein Biotech, Inc.

Contents

Warnings, Precautions, and Limitations

- Read this manual carefully to ensure optimum performance of your instrument.
- The instrument can only be used for *in vitro* diagnostic analysis of human whole blood, plasma, serum and urine.
- Only the dedicated kits mentioned in this manual are allowed. Otherwise, the accuracy of measurement cannot be guaranteed.
- Use only specified replacement parts on the instrument.
- To avoid fire, electric shock or personnel injuries, cut off the power immediately and disconnect the power plug when liquid seeps into the instrument, or the instrument leaks, emits smoke or a smell. Contact us for after-sales support when this happens.
- Take proper safeguard measures following health and safety standards in the local country.
- Specimens and reagents may be biologically infectious, operators should wear laboratory protective clothing and gloves required by the operation regulations of laboratory safety to avoid potential biological infection or contamination.
- All the test kits and consumables should be disposed of after a single use. Proper handling and disposal methods should be established by the laboratory director under local and national regulations.
- Operators or person in charge shall be trained on cautions and operation instructions before operating the analyzer.
- If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

1. Safety Instructions and Precautions

1.1 Safety Symbols

This manual is intended to help users and operators operate the instrument safely and properly. Before using this analyzer, operators must be familiar with safety points in the manual and operate the analyzer according to the manual. Users must pay attention to the information in this manual. Only technicians trained by the manufacturer can operate the analyzer properly.

To draw your attention to important information, operation instruction and safety information, this manual includes **Notes**, **Caution**, **Warning** and **Danger**. Before reading this manual, you must understand these safety prompts.

Prompt	Description
Note	Highlight or provide additional information.
Caution	The occurrence **may** cause malfunction, loss of data and damages to the instrument.
Warning	The occurrence **may** cause personal injuries to operators, patients or people around.
Danger	The occurrence **will** cause personal injuries to operators, patients or people around.

1.2 Intended Use

The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal liquid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and operators shall use and operate the analyzer according to relevant laws or legally binding regulations.

The analyzer is limited to its intended use.

Note:

All authorizations will be automatically void if the use of this analyzer exceeds the manufacturer's requirements, specifications and agreements. The manufacturer reserves the right to protect own interests by legal means.

1.3 EMC Performance

Definition: EMC (Electromagnetic Compatibility) is defined as the ability of an instrument to withstand or suppress electromagnetic interference of other instruments without causing similar electromagnetic radiation interference with other instruments.

Note:

- Assess the electromagnetic environment before using the instrument.
- The analyzer may not function stably when in proximity to devices capable of emitting radio waves, such as cellular phones, transceivers, mobile radio-controlled toys, etc. The power supply of these devices should be cut off with the presence of the analyzer.
- During the installation, the analyzer should be kept away from other electronic devices as far as possible.
- Use cables provided or designed by Getein for connection according to installation procedures.
- Connect the designated peripheral equipment to this analyzer. The connection with non-designated

equipment may decrease the EMC of the analyzer.

- Do not make any changes to this analyzer without permissions as they may decrease its EMC. Changes include cable changes, system installation/layout changes, system configuration/components change, fixed system/part method changes, etc.
- Make sure all screws are tightened after repair. Loose screws will affect EMC performance.

Possible solutions:

- The electromagnetic interference can be reduced by keeping other equipment away from the analyzer.
- The electromagnetic interference can be reduced by adjusting the relative position/installation angle between the analyzer and other equipment.
- Electromagnetic interference can be reduced by changing the wiring position of power/signal cables of other equipment.
- Electromagnetic interference can be reduced by changing the power path of other equipment.

1.4 Note for Use

- Installing other software except for the operating software of this analyzer to the system may cause malfunction of the system.
- The configuration of the instrument purchased by the user may differ from what is described in this manual. Refer to the purchase contract if you have any questions.
- Observe the working procedures in the user manual all the time. Make sure that patients' information entered is correct before testing. Wrong operations or patients' information may lead to the incorrect interpretation of test results.
- Any changes and modifications done by the users to the analyzer or software systems are forbidden. Any unapproved changes or modifications and maintenance against rules and regulations will not be covered by the warranty.
- Software can only meet the needs for routine tests. For some special tests, users must edit and verify by themselves.
- Any modification to the existing test process must be re-validated.

1.5 Safety Instructions

Users should pay attention to the contents and regulations of safety precautions in this section.
Class of analyzer: Anti-shock Class I, Overvoltage Class II, Pollution Class 2.

1.5.1 Safety Notes for Daily Operation

- Users should ensure that the upper cover of the analyzer is closed when the analyzer is running.
- Only personnel designated by the manufacturer or local distributors can replace the instrument components. Any removed components from the analyzer must be disposed of as potential pollutants.
- Any tools and devices used in the test must be disinfected after they are used (wipe with cotton dampening 75% ethanol).
- All operations related to installation, inspection and maintenance are performed by technical personnel.
- Stop using the instrument if any damages or malfunction of the analyzer are found. Do not use the instrument until the qualified maintenance personnel solves the problem.
- Avoid spilling liquid on or inside the instrument.
- When placing samples and reagents, ensure that sample and reagent containers are placed on the analyzer as stably as possible.
- Confirm the reliability of stuff used for testing (including pipette, reaction cup, reagent and sample containers, etc.).

Note:

Pay attention to electrical safety, grounding safety, operation safety, personnel safety, peripheral equipment safety, data backup safety and disposal safety. Obey all preventive and protective operation rules used in the laboratory.

1.5.2 Electrical Safety and Grounding

- There are high-power electric circuits and various electrical devices in this instrument. To avoid any personal injuries, untrained personnel shall not open the outer cover or repair it.
- The power supply of the analyzer must be turned off before cleaning the laboratory. Do not use organic solvents or any flammable liquids to wipe the surface of the instrument or wash the floor. Be careful not to let liquid seep into the instrument.
- 3000VA is required during the working period of the system. It is not allowed to start the system when there is a power shortage. To avoid any damages to computers or other electrical devices, it is not allowed to use generators with an unstable power supply to generate electricity.
- Before starting the system, it is necessary to check whether the external wires and cables are connected securely.
- Before cutting off the computer's power supply, users shall exit the system software first to avoid any damages to the system software, files or data.
- The instrument should be used with a power outlet with the grounding wire (the electric resistance of the grounding wire is less than 10 Ω).

1.5.3 Maintenance

Users must operate the analyzer according to the maintenance procedures. With proper use and maintenance, the degradation of the performance of the medical instrument will not affect its safety during its service life.

Caution

Users must carry out the daily maintenance to ensure that the analyzer can work properly.

Maintenance operations should follow the requirements below:

- Read 14 Maintenance carefully before maintenance.
- Wipe instrument with a soft cloth.
- Remove spills or stains from instrument surface timely.
- Corrosive solvents should not be used.

1.5.4 Potential Risks

- There is no guarantee that the analyzer will not pose risks to users, so the users must treat the analyzer as a potentially hazardous instrument.

Warning

All components dismantled from the instrument may be directly exposed to contaminants and must be wiped with cotton in absolute ethanol before leaving the laboratory.

- Only well-trained personnel can operate the instrument after reading the manual carefully. Only approved personnel from Getein can replace spare parts.
- The operator in the laboratory should take preventive measures.
- If the instrument is not used in the manner specified by Getein, the protection provided by the instrument may be impaired. We will not be responsible for any damages caused by the user's improper operations against the specified guidelines.

1.5.5 Personnel Risks

To avoid personal risks, obey the safety requirements as follows:

- Do not eat, drink or smoke in the laboratory.
- Wear lab coats especially near the instrument.

It is not guaranteed that there is no harm to the exposed parts of the human body when the instrument is in use. The instrument must be treated as a potentially infectious device because it may contact with blood directly.

> **Warning**
> The instrument must be treated as a potentially infectious device.

When dealing with potentially contaminated substances, operators should take protective measures as follows:

- Wear lab gowns.
- Wear disposable gloves.

And be careful when handling the following components.

- Metal probe.
- Waste liquid bottle.

Note:

If any emergency and unusual circumstances happen, press the left button to switch off the instrument.

1.5.6 Peripheral Equipment

- Peripheral equipment such as computers and printers must pass CCC (China Compulsory Certification). Unqualified peripheral equipment may cause system malfunction or personal injuries.
- Only personnel designated by the manufacturer or local distributors can install computers, printers, inlet and outlet water pipelines and other peripheral equipment.
- Computer viruses may destroy software and data. Do not use the computer for other purposes or link it to the Internet. Install anti-virus software if any computer virus is identified.
- Extension cords should not be placed on the ground.
- Do not connect other power cords and USB cables to the system.

1.5.7 Data Backup

The system can save data automatically in computer hard disk, but the data will not be restored if the data is deleted from the hard disk or the disk is damaged. Back up data and measurement parameters regularly to other mobile storage devices.

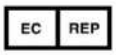
1.5.8 Waste Disposal

Dispose of all wastes, including liquids and solids according to laws and local regulations.
Disassemble the instrument according to the national regulations and the requirements of local environmental organizations.

1.6 Instrument Symbols

Symbols on the instrument are to draw your attention to safety and important information. If you do not follow the safety information and operation instructions, the analyzer may cause personal injury and damage to the instrument. This manual introduces the symbols and their meanings, as shown in the table below.

Table 1.1 Analyzer Symbols

	Manufacturer		Serial number
	Authorized representative in the European Community/European Union		Catalogue number
	CE Mark		Consult instructions for use or consult electronic instructions for use
	*In Vitro* diagnostic medical device		This way up
	Warning; Sharp element		Fragile, handle with care
	Warning; Laser beam		Keep dry
	Protective earth		Keep away from sunlight
	Warning		Do not stack
	Warning; Biological hazard		Do not roll
	Warning; Electricity		Atmospheric pressure limitation
	Warning; Hot surface		Humidity limitation
	“ON” (power)		Temperature limit
	“OFF” (power)	~	Alternating Current

Note:
Refer to the manual whenever your encounter “Caution”, “Warning”, “Danger” to identify potential hazards and take protective measures.

1.7 Environmental Protection Requirements

The waste liquid generated after the use of the instrument should be treated before being discharged following the national regulations and standards of the local environmental organizations.
The remaining samples and other appendant objects after testing should be treated before being disposed of properly according to the national regulations and standards of the local environmental organizations.

1.8 Laser Description

The laser scanner used in our products belongs to class I of laser products.

The laser scanner is in the reagent tray and sample tray. The product is labeled 'Beware of Laser' and 'Class I Laser Product'.

Warning

Improper operations or adjustments of the instrument may cause radiation exposure. Do not try to disassemble the cover without permission because there is a built-in radiation module. Take relevant measures to prevent laser radiation during maintenance.

2. Transportation and Installation

2.1 Transportation and Storage Requirements

- Avoid inversion and violent vibration during the transportation.
- Keep away from humidity, sunlight and avoid collision during transportation.
- Fix the instrument in the rear and front with a belt during the transportation.
- Move the instrument through doors and elevators of appropriate size (width: 100 cm).
- Discharge water thoroughly with the air compressor after emptying the pipeline of the liquid system.
- Empty the pure water tank.
- Fix the movable structures, such as arms and probes.
- Pack the outer cover to prevent dust.
- Storage temperature: 1 ~ 45℃.
- Storage humidity: 5% ~ 95%.
- Atmospheric pressure: 86.0 kPa ~ 106.0 kPa.
- Store the instrument in a well-ventilated indoor warehouse without strong light. There should be no corrosive gas in the warehouse.

2.2 Instrument Installation

Note:
Only trained and qualified after-sale engineers can install the instrument. If you need to reposition the instrument, contact the Getein customer service centre or your local dealer for help.

2.2.1 Installation Requirements

1. Space Requirements

Analyzer Dimension: 1160 mm(L)×790 mm(W)×1140 mm(H)
Ground space requirements: 2160 mm×1790 mm

- The analyzer should be close to the power supply with a space of at least 0.5 meters. Do not place the analyzer in a position where it is difficult to operate and switch on/off the power supply.
- The distance between the computer desk and the analyzer should not exceed 3 meters.

2. Environment Requirements

To ensure the proper operation of the analyzer, obey the below environmental conditions:

- Avoid direct sunlight.
- Place the instrument in a dust-free environment.
- Place it on a smooth and flat surface (inclination is less than 1/200).
- The ground should be able to support more than 300 kg of weight.
- The room temperature should be between 15 and 30 ℃.
- The relative humidity should be between 40%-85% (no condensation).
- If the temperature and humidity are not within the permitted range, the test results may be unreliable.
- Place the instrument in a well-ventilated environment and avoid direct airflow of the air conditioner.
- Place the instrument in a position without tremendous vibration.
- Place the instrument away from strong electromagnetic power and electrical interference.

3. Electricity Requirements

CM-400 should meet the electricity requirements in the following table.

Table 2.1 Electricity Requirements

Voltage and Frequency	Single direction continuous and stable voltage: 220 V
Frequency	50 Hz
Power	3.0 kVA
Grounding	The analyzer should be properly grounded.
Power Cord	The analyzer is equipped with a three-core power cord.

Warning

Use appropriate power cords and ensure the instrument is properly grounded. The incorrect grounding may damage the analyzer.

4. Water Supply and Drainage Requirements

- Water quality: resistivity is not less than 1 M.cm@25 ℃ (conductivity is not less than 1 S/cm@25 ℃).
- Hydraulic pressure: 100 ~ 392 kPa. If the hydraulic pressure of the water filter cannot meet the requirements, the optional water supply module should be equipped.
- Flow: The water yield should not be less than 20 L/H.
- Temperature: water supply temperature is 15 ~ 32 ℃;
- The length of the pipe connecting the outlet of the water filter to the water inlet of the instrument is not more than 5 m.
- The water filter needs to be equipped with a pure water tank with cover. The pure water tank capacity is ≥20 L, and the height of the pure water tank from the ground is not less than 1 m.
- Water supply method: pressure water supply/non-pressure water supply;
- The standard water pipe of the instrument is ID7.9 mm OD11.1 mm, which is used to connect the water filter and the analyzer by the water filter supplier.
- The analyzer supplies water via the water supply module (optional).
- The water supply module is placed between the water supply device and the analyzer.
- The length of the waterpipe from the outlet of the water supply device to the inlet of the analyzer shall not exceed 5 m.
- The analyzer directly discharges low concentration waste liquid to sewer, and the discharge outlet is not higher than 200 mm from the ground.
- The diameter of the discharge outlet for low-concentration waste liquid is not less than 50 mm.
- The length of the discharge pipe of low-concentration waste liquid is not more than 5 m. The pipe should be not bent, connecting instrument waste liquid outlet with the floor drain. When the pipe length is relatively long, the middle pipeline should be properly erected to form a smooth discharge line from high to low. The Pipeline should not be bent like U-shaped or V-shaped forms, otherwise, waste liquid may be poured back into the analyzer, as shown in Fig 2.1.

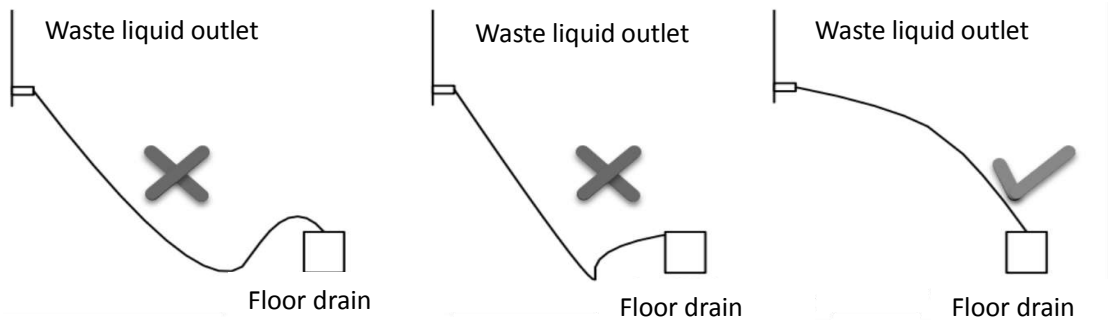


Figure 2.1 Waste Liquid Discharge

2.2.2 Checking Accessories List

- Upon receiving the instrument, check the appearance of the packing boxes. If the packing box is damaged, take photos and contact the agent immediately.
- Check if all the packing boxes listed in the invoice have arrived.

2.2.3 Unpacking the Analyzer

Open the analyzer box carefully; otherwise, the precisely calibrated optical and electronic components might be damaged.

The analyzer should be unpacked under the supervision of the agent engineer.

Caution

- At least four people are needed to move and unpack the analyzer because the analyzer is heavy.
- To avoid damages to the instrument, when pushing the analyzer off the wooden tray, grip the bottom instead of instrument side to lift it.
- Push the side cover instead of the upper cover of the instrument when you are moving the instrument.

Unpack the analyzer according to the following steps:

1. Remove all clamps with a screwdriver or other tools as shown in Fig 2.2 and 2.3, and then remove the side cover of the packing box.

Figure 2.2

Figure 2.3

Note:

When disassembling the fixing panel, do not push the instrument to avoid it falling from the tray.

2. Remove the panel fixing the feet with a wrench as shown in Fig. 2.4.

Figure 2.4

3. Rotate the four feet to the highest position with a wrench as shown in Fig 2.5.

Figure 2.5

4. Push the instrument down the ramp from the tray, as shown in Fig 2.6.

Figure 2.6

5. Place the instrument in the installation position before removing the inner plastic packaging.

Note:

After unpacking, check the appearance of the instrument and the packing list. If any missing parts or damages during the handling, inform our customer service department or local distributors immediately.

2.2.4 Unpacking the Accessories Box

After-sale engineers check the accessories according to the accessories list with customers.

2.2.5 Installing CM-400

Make sure the installation environment is qualified before installation, and see **2.2.1 Installation Requirements** for more information.

2.2.5.1 Moving Instrument Indoors

The instrument is equipped with wheels. You can push the instrument on the floor and transport it by elevator (elevator door should be over 90cm wide).

Note:

Do not tilt the instrument when moving it. Avoid slipping away and scraping when carrying the instrument on the slope.

2.2.5.2 Relocating System

When the instrument needs to be relocated, contact our customer service department or local distributors.

3. Product Description

3.1 Introduction and Intended Use

CM-400 is a fully automated analyzer intended for the quantitative analysis of human bodily fluids in clinical diagnosis. It is characterized by open reagents, discrete system, emergency priority, random access and an external computer. Operators should read the manual and be familiar with its functions before operating the instrument.

The analyzer consists of the main instrument and the computer. The main instrument is composed of an optical system, reaction system, sample adding system, reagent adding system, cleaning system and mixing system, and the electrolyte module is optional.

This analyzer is intended for the quantitative analysis of chemical components in human serum, plasma, whole blood, urine, and cerebrospinal liquid samples.

3.2 Testing Principle

According to the absorbance spectra of substances in the ultraviolet and visible light areas and the principle of Lambert-Beer law, compare the samples with the unknown concentration with those with the known concentration or conduct quantitative analysis with the molar absorptivity coefficient. The working principle is to inject a monochrome light/white light into the detected liquid and the transmitted light is converted into electrical signals. The signal is then translated into the concentration of the solution after calculations by reference to the standard curve. Lambert-Beer's Law is defined as when a parallel monochromatic light passes vertically through a uniform, non-scattering absorbing solution, its absorbance (A) is proportional to the thickness (b) and concentration (c) of the solution.

Mathematical Formula: A=lg(1/T)=Kbc

Among them, A: absorbance, T: transmittance, K: Molar absorptivity coefficient, b: thickness, c: concentration.

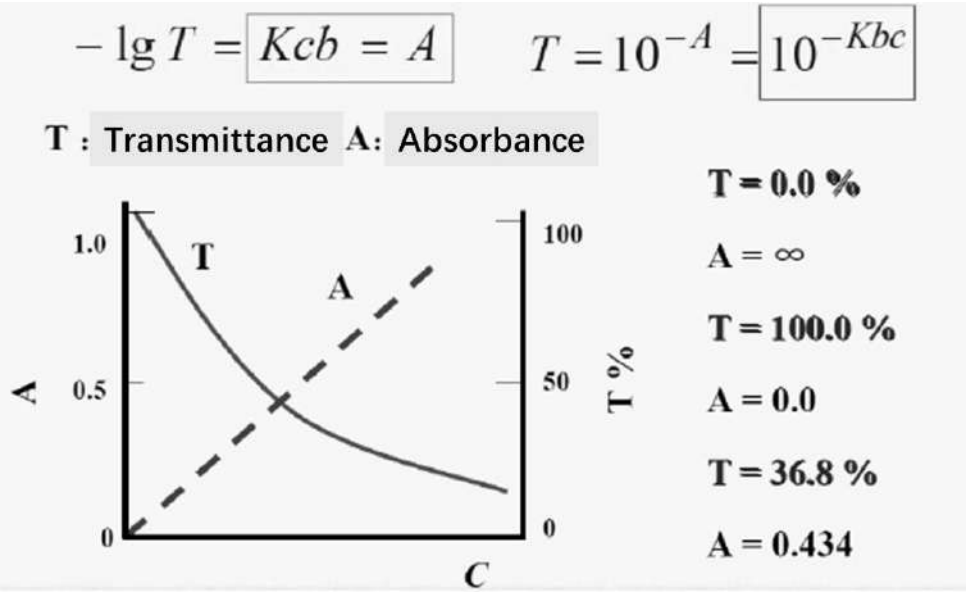


Figure 3.1 Theory of Lambert-Beer law

3.3 Functions

CM-400 Biochemistry Analyzer has the following main functions:

1. Software functions:
   a) schedule tests for samples and other test items;

b) display reagent and the other consumables status;
c) self-detect
d) prompt error message of operation, mechanical parts, circuits and so on;
e) transfer data between LIS and hospital;
f) test request, reagent management, QC management, result query, item setup, maintenance, system log displaying, and system setup.

2. Analyzer functions:
   a) fulfill the tasks from the software and upload the test results to the software;
   b) carry out the command from the software, such as scanning barcode and uploading the relevant information to the software;
   c) self-monitor status and prompt the message of:
      i. obstacles blocking the way of sample probe to aspirate;
      ii. no reagent detected (no reagent);
      iii. no sample detected (no sample);
      iv. incubator inside temperature out of the range;
      v. insufficient pure water;
      vi. cup blank value lower than the set range;
   d) set time and date;
   e) calibrate with specific calibrator;
   f) calculate electrode slope value (for instrument with ISE module);
   g) save and print the test results and data;
   h) check if the sample probe is clogged (for instrument with probe clogging module);
   i) judge the water quality based on water conductivity (for instrument with water quality detect module);
   j) refrigerate the control and calibrator in the sample tray (for instrument with sample tray refrigeration module).

3.4 Technical Parameter

Table 3.1 Functional Parameters

Main function	**Description**
Testing mode	• Allows for batch testing and random tests. • Allows for routine, calibration and QC test.
Suitable disease syndrome	Liver function, renal function, myocardial enzymes, carbohydrates, blood lipids, pancreas series, infectious diseases, endocrine system, tumors, etc.
Reagent management	• Reagent refrigeration • Barcode recognition • Track and record calibration validity • Track and record remaining volume of on-board reagents • Monitor reagent expiry date
STAT	Emergency sample test
Sample type	• Serum • Plasma • Whole blood • Urine • Cerebrospinal fluid

Main function	Description
Sample probe	• Sample aspiration • Blockage detection • Vertical anti-collision • Liquid level detection • Volume monitoring
Reagent probe	• Reagent aspiration • Vertical anti-collision • Liquid level detection • Volume monitoring
Barcode scanning	Allows for barcode scanning of reagents and samples.
Automation	• Automatic cleaning and maintenance • Auto-loading of sample • Auto-dilution • Automatically monitor system status • Automatically store data and free access to data
LIS	LIS online connection 2-way online data transmision
Electrolyte	Allows for K+, Na+, cl-, Li+ electrolyte detection (optional).

Table 3.2 Performance Parameters

Performance	Descriptions
Test principles	• Latex particle-enhanced turbidimetric immunoassay • Immunoturbidimetry • Colorimetry
Analysis assay	• Rate method • End point method • Fixed time method
Test Speed	• Constant speed 400 T/H • ISE (optional): 400 T/H at most
Throughput	78 test items at the same time
Reagent module	Single/ two/ three/ four-reagent test
Spectroscopic method	Holographic concave flat field grating splitting
Optical source	12 V/20 W halogen lamp
Accuracy of wavelength	± 2 nm
Spectral width (FWHM)	<10 nm

Performance	Descriptions
Reaction tray	90 positions
Reaction time	About 12.3 minutes
Temperature control method	Constant temperature (37.0 ± 0.2) ℃; fluctuation ± 0.1℃
Pre-heating time	About 20 minutes
Minimum reaction volume	100 μL
Reaction cup	Standard plastic reaction cup, or quartz glass reaction cup Optical path: 5 mm Internal dimensions: 5mm × 5mm × 29mm
Sample type	Five types (serum, plasma, whole blood, urine, cerebrospinal fluid)
Sample volume	1.5 μL - 50 μL (an increment of 0.1 μL)
Specification of sample container	Allows for sample cup with a diameter of 11.5mm – 13mm.
Sample position	90 positions, including 30 calibrator positions
Reagent position	80 positions, including 40 positions of 20 mL and 40 positions of 70 mL
Refrigeration of reagents	2℃ - 8℃
Refrigeration method	Cooling with peltier
Reagent volume	R1:10.0 μL-450.0 μL; R2/R3/R4: 0 or 10.0 μL-450.0 μL (an increment of 0.1 μL)
Specification of reagent container	20 mL or 70 mL reagent container
Calibration method	11 types
Water consumption	Less than 20 L/H
Stray light	Absorbance is not less than 3.0
Stability of absorbance	The variability of absorbance should not be more than 0.01.
Accuracy of absorbance	Absorbance is 0.5 and permitted error is ± 0.025; Absorbance is 1 and permitted error: ± 0.07
Repeatability of Absorbance	CV is not more than 1.5%
Carry-over Rate	The sample carry-over rate should be not more than 0.01%.

optional quartz glass rection cup; reaction cup can be reusable;

1- 35 μL （an increment of 0.1 μL)

Absorbance: 0 - not less than 4.0 Abs

<table>
<tr><td>Performance</td><td colspan="8">Descriptions</td></tr>
<tr><td>Accuracy and repeatability of sample and reagent adding:</td><td colspan="8">• Checking the specified minimum & maximum sample adding volume and the volume around 5uL. The volume error should not exceed ±5% and CV should not exceed 2%.
• Check the specified minimum and maximum reagent adding volume. The volume error should not exceed (±5%) and CV should not exceed 2%.</td></tr>
<tr><td rowspan="4">Within-run Precision of clinical Items</td><td>Item</td><td colspan="3">Concentration Range</td><td colspan="4">CV</td></tr>
<tr><td>ALT</td><td colspan="3">30 U/L ～ 50 U/L</td><td colspan="4">⩽ 5%</td></tr>
<tr><td>UREA</td><td colspan="3">9.0 mmol/L ～ 11.0 mmol/L</td><td colspan="4">⩽ 2.5%</td></tr>
<tr><td>TP</td><td colspan="3">50.0 g/L ～ 70.0 g/L</td><td colspan="4">⩽ 2.5%</td></tr>
<tr><td rowspan="5">Electrolyte module performance requirements</td><td>Parameter</td><td>Accuracy</td><td>Precision (CV)</td><td colspan="3">Linearity</td><td>Stability (R)</td><td>Carryover (C)</td></tr>
<tr><td></td><td></td><td></td><td>Range/ (mmol/L)</td><td>Deviation</td><td>Correlation (r)</td><td></td><td></td></tr>
<tr><td>K+</td><td>⩽ ± 3.0%</td><td>⩽ 1.5%</td><td>1.5 ~ 7.5</td><td>⩽ 3.0%</td><td rowspan="4">⩾ 0.995</td><td>⩽ 2.0%</td><td>⩽ 1.5%</td></tr>
<tr><td>Na+</td><td>⩽ ± 3.0%</td><td>⩽ 1.5%</td><td>100.0 ~180.0</td><td>⩽ 3.0%</td><td>⩽ 2.0%</td><td>⩽ 1.5%</td></tr>
<tr><td>Cl-</td><td>⩽ ± 3.0%</td><td>⩽ 1.5%</td><td>80.0 ~ 160.0</td><td>⩽ 3.0%</td><td>⩽ 2.0%</td><td>⩽ 1.5%</td></tr>
<tr><td>Li+</td><td>⩽ ± 5.0% or ± 0.05 mmol/L</td><td>⩽ 1.5%</td><td>0.40 ~2.00</td><td>⩽ ± 5.0% or ± 0.05 mmol/L</td><td>⩽ 3.0%</td><td>⩽ 2.0%</td></tr>
<tr><td>Power supply</td><td colspan="8">AC 220 V 50 Hz</td></tr>
<tr><td>Operating humidity</td><td colspan="8">40% ~ 85% (no condensation)</td></tr>
<tr><td>Operating temperature</td><td colspan="8">15 ℃ ~ 30 ℃</td></tr>
<tr><td>Atmospheric pressure</td><td colspan="8">86.0 kPa～106.0 kPa</td></tr>
</table>

4. System Overview

CM-400 is an automated analyzer designed for in vitro quantitative testing of chemical components in human serum, plasma, whole blood, urine, and cerebrospinal liquid samples.
It consists of an operating computer, and an analyzer consisting of an optical system, reaction and detection system, sample adding system, reagent adding system, cleaning system and mixing system, and the optional electrolyte module.

Figure 4.1 Front view of system

4.1 System Components

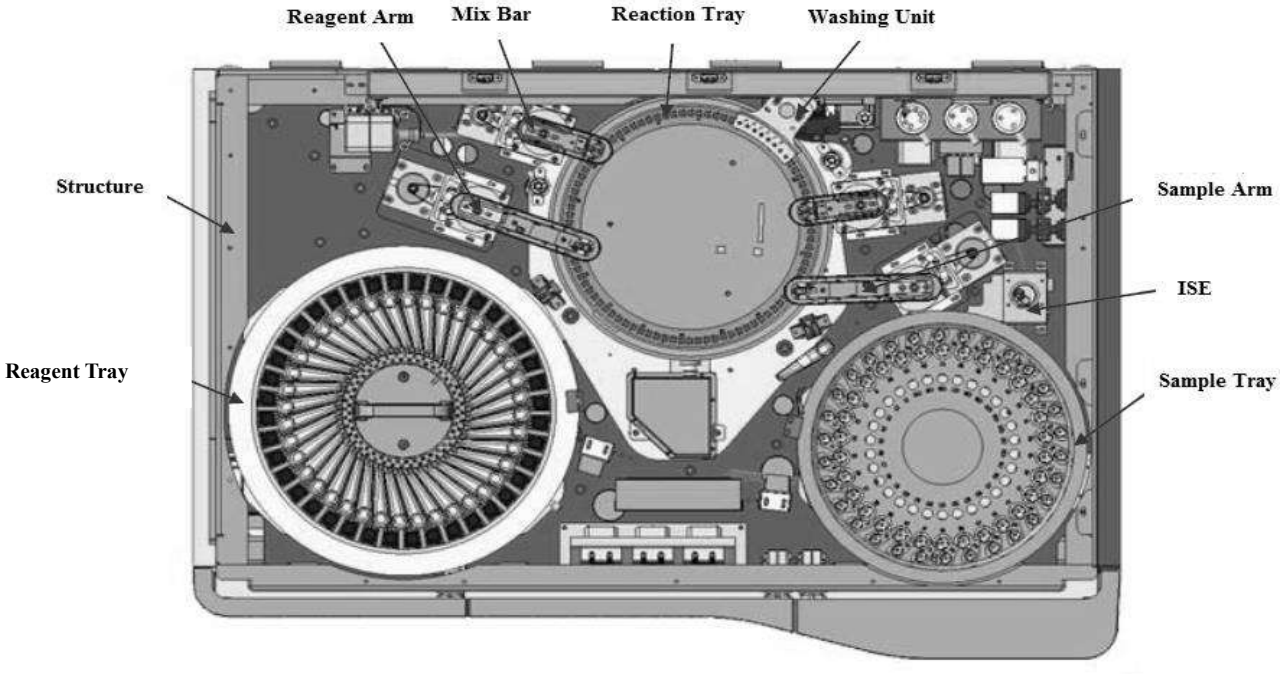


Figure 4.2 Top view of system

Functions of each component are as follows:

Table 4.1 Components Description

Component	Descriptions
Sample Tray	Hold samples, QC materials, calibrators
Sample Arm	Equipped with sample probe to aspirate and dispense samples.
Mix Bar	Mix reagents and samples in the reaction cup.
Reagent Tray	Hold reagents.
Reaction Tray	Driving the reaction cup to rotate counterclockwise and run to the expected position for reagent and sample adding, reacting, mixing and cleaning.
Reagent Arm	Equipped with reagent probe to aspirate and dispense reagent into reaction cup.
Optical Unit	Measure absorbance of each reaction cup at the optical path of the photometer.

2 indipendent mixing bars : mix reagents and samples in the reaction cup.

4.2 System Performance and Specifications

4.2.1 Sample Adding System

Sample adding system consists of sample adding module and sample tray.

4.2.1.1 Sample Adding Module

Function: Aspirate sample from sample tray and dispense it into the reaction cup.

Composition: sample arm, sample syringe and mix bar as shown by the Fig 4.3.

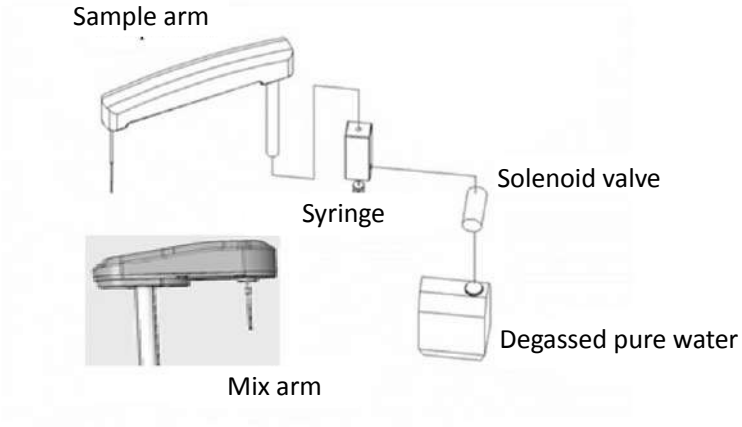


Figure 4.3 Sample Adding Module

The performance of sample module is shown in the following table.

Table 4.2 Performance of Sample Adding Module

Sample probe	• Aspirate and dispense sample (volume: 1.50 ~ 50.0 L). • Calculate automatically according to the test items and automatic re-checking.

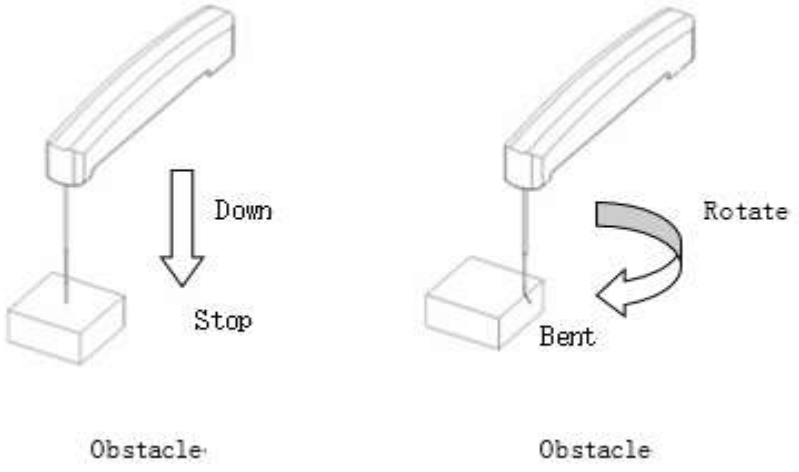
	• The electrostatic-sensitive probe features a liquid level sensor, collision sensor and clogging checking function.
Mix bar	Mix with mix bar

The general running procedure of the sample module is as follows:

1. The sample arm moves to the sample aspiration position and goes down.
2. The probe detects the liquid level and aspirates the sample.
3. The probe rises and moves to the expected reaction cup.
4. The probe goes down and stops above the liquid level of reagent in the reaction cup.
5. Dispense the sample into the reaction cup.
6. Clean the exterior and interior of the probe with pure water.
7. The reaction tray rotates and moves the reaction cup to the mixing position.
8. The mix bar 1 mixes the solution in the cup.

Caution

- Make sure there are no obstacles in the movement path of the sample arm before the instrument is running. Do not place your hands or other objects near the sample arm when the instrument is working.
- If your hands are close to the sample arm when it moves down to the sample, errors may occur during the liquid level detection, which may lead to incorrect measurement results.
- Equipped with VOD sensors, the sample arm will stop automatically when detecting obstacles vertically. Collisions during the vertical movement may result in the deformation or bending of the probe. Note that the arm cannot detect obstacles in the horizontal direction.



4.2.1.2 Sample Tray

Function: The sample tray holds routine samples, emergency samples, calibration solution (calibrator), and control. The sample tray is divided into inner, middle and outer sections, totaling 90 positions. It rotates to move the samples to the aspiration position.

Composition: sample tray and its driver unit.

Figure 4.4 Sample Tray

The specification of sample tray is shown in the following table.

Table 4.3 Specifications of Sample Tray

Outer Section	Positions: No.1~30 Hold routine samples and emergency samples in blood tubes or sample cups.
Middle Section	Positions: No.31~60 Hold routine samples and emergency samples in blood tubes or sample cups.
Inner Section	Calibrator positions (C1~C30)
Blood Tube	Suitable for 5 mL or 7 mL blood tube (external diameter is 13 mm). Refer to **4.2.6 Sample Containers** for more information.
Sample Cup	Standard sample cup and micro sample cup can be used. Refer to **4.2.6 Sample Containers** for more information.

Movement: it rotates the needed sample towards the aspiration position.

Caution

- If the sample has been placed in the sample tray, do not take out the tested sample or open the sample cover. Frequent opening of the cover may result in abnormal test results because of liquid evaporation.
- Do not touch the running sample tray. Otherwise, your hands may be pinched or even fractured.
- Do not open/close the cover when the tray is running. Or, the sample probe may be damaged.
- When taking out the sample tray, grab the handle firmly and lift the tray vertically. To install the tray, align the mounting holes on the sample tray with the fixing bolts and gently lower it until it locks securely.
- Insert the blood tube vertically into the sample tray and push it gently to its bottom. If the tube is tilted or not fully inserted into the tray, it may bend the sample probe, damage sample arm and affect test results.

4.2.2 Reagent Adding System

The reagent adding system consists of reagent tray and reagent adding module.

4.2.2.1 Reagent Adding Module

Function: Aspirate specified volume from the reagent tray and dispense it to the reaction cup.
Composition: The reagent probe consists of reagent arm, syringe and mix bar.
The performance of reagent adding module is shown in the following table.

Table 4.4 Performance of Reagent Adding Module

Reagent Volume	R1:10.0 μL ~450.0 μL R2/R3/R4: 0 μL or 10.0μL ~ 450.0 μL (an increment of 1 μL)
Reagent Probe	• Aspirate and dispense reagent • Liquid level detection and VOD anti-collision
Mix bar	Mix reaction liquid

Working procedure:

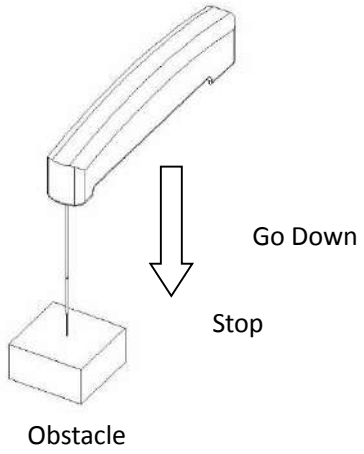
1. The reagent arm moves to the reagent aspiration position and goes down.
2. The probe detects the liquid level and aspirates the reagent via reagent syringe.
3. The reagent arm rises, moves to the expected reaction cup and goes down.
4. Dispense reagent.
5. Wash the probe.

Warning

- Do not place your hands near the reagent arm when the instrument is running, and otherwise, the probe may prick your fingers.

Caution

- When the instrument is running, make sure there are no obstacles in the movement path of the reagent arm and do not put your hands or other objects near the reagent tray.
- If your hands are close to the reagent arm when it moves down to aspirate the reagent, the sensor may fail to detect the liquid level, which may lead to incorrect measurement results.
- Equipped with VOD sensors, the reagent arm can stop automatically when detecting obstacles vertically.



4.2.2.2 Reagent Tray

Function: The reagent inner and outer section have 40 reagent positions respectively, and the reagent tray can store and refrigerate the reagent with the cooling system. The reagent tray can rotate the reagent to the aspiration position during the reagent adding process.
The specification of reagent tray is shown in the following table.

Table 4.5 Specifications of Reagent Tray

Applicable reagent container	Suitable for containers of 70 mL or 20 mL. Fix the bottle in the proper adapter. Refer to **4.2.7 Reagent Containers** for more information.
Refrigeration storage	Control the liquid temperature by cycle refrigeration system.

Working procedure:
The reagent tray will rotate the reagent to the expected aspiration position.

Warning

- Do not touch the reagent tray when the instrument is running. Otherwise, your hands may be pinched or even fractured.
- Do not place your hands near the reagent arm when the instrument is running, otherwise, the probe may prick your fingers.

Caution

- When reagents are loaded in the reagent tray, do not open/close the cover of the reagent tray frequently during the reagent replacement. Otherwise, it will adversely affect the cooling of the reagent and lead to inaccurate measuring results.
- Do not open the cover of the reagent tray when the instrument is running; otherwise, the moving reagent probe may be damaged.
- Fit the reagent bottle into proper adapter in the reagent tray and push it gently to the bottom when loading reagents. If the reagent bottle is not firmly inserted into the bottom, the collision between the reagent bottle mouth and the tray cover may occur, thus causing damages to the reagent tray.
- Do not put any other items on the reagent tray when the instrument is running. Otherwise, the items may scratch the reagent tray or even damage the instrument when the tray is rotating.

4.2.3 Washing System

Function: wash the reaction cups after testing and dispense pure water into the cups for blank cup tests.
Composition: eight nozzles moving up and down to clean the cups

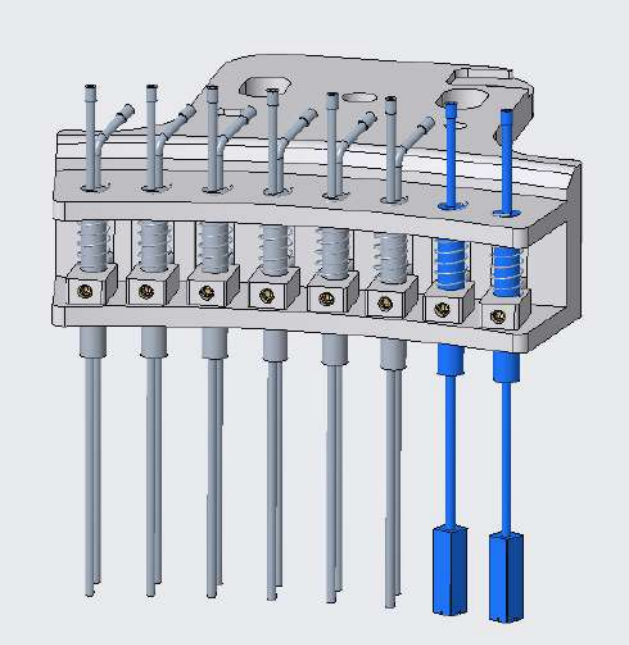


Figure 4.5 Nozzles

The general workflow of the reaction cup washing unit is as follows:

Nozzle	Function
1	Aspirate waste liquid and dispense wash solution
2	Aspirate waste liquid and dispense wash solution
3	Aspirate residual liquid and dispense pure water
4	Aspirate residual liquid and dispense pure water
5	Aspirate residual liquid and dispense pure water
6	Aspirate residual liquid and dispense pure water

7	Aspirate residual liquid
8	Drain the pure water in the reaction cup and dry it

Working procedure:

(1) When reaction tray stops, each nozzle goes down and aspirates in sequence.

(2) The wash arm rises and the wash nozzle dispenses wash solution or pure water. After that, the reaction tray continues its rotation.

Caution
When the instrument is running, do not put your hands and other objects near the wash station. The wash station is driven by a high-power motor. Hands near the wash nozzles is prone to be pricked.

4.2.4 Mix System

Function: fully mix the reagent and sample to enable a full reaction.

Composition: the three mix bars is driven by a vertical, a horizontal and a mixing motor to mix the reaction solution and after mixing, the bars are washed by deionized water.

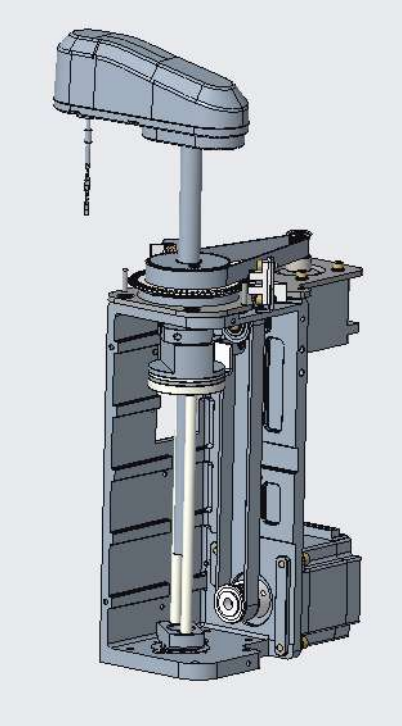


Figure 4.6 Mixing Device

4.2.5 Optical System

Function: When the reaction tray rotates, the absorbance of the reaction solution will be measured in sequence.

Light Source	20 W halogen light. The life span is about 2,000 hours.
Light Splitter	Flat-field concave diffraction grating
Detector	Photodiode array

Detection Wavelength	12 wavelengths: 340, 380, 405, 450, 505, 546, 578, 600, 660, 700, 750 and 800 nm

Working procedure:

When the reaction tray is in rotation, the transmittance of each wavelength of the reaction solution will be measured when the light source projects light into the reaction cup vertically.

Caution

- The temperature of the lamp is still high when the instrument is just turned off. When replacing the halogen lamp, be careful not to be scalded.
- Do not touch the lamp directly with your hands. Fingerprints on the lamp will affect its optical properties. If the surface of the lamp is stained, wipe it clean with lens cleaning paper dampening 75% ethanol.
- The photometry unit has been precisely calibrated. Do not touch it directly with your hands except the lamp replacement. Avoid collision and any outside forces.

4.2.6 Sample Containers

Users should use sample containers with specified specifications. Other containers can damage the system and affect the test results.

4.2.6.1 Blood Collection Tube

CM-400 fits with 5 mL and 7 mL blood collection tube.

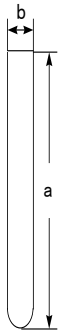


Figure 4.7 Blood Collection Tube

The specification of blood collection tube is as follows:

Table 4.6 Blood Container Specification

Volume	5 mL and 7 mL
Size	a: 75~100 mm b: 11.5~13 mm
Barcode label type	• CODABAR (NW-7) • CODE 39 • 2 of 5 interleaved (ITF)

Attaching barcode labels:

To ensure the internal barcode reader can correctly read the sample information, use the following procedure to label the barcode on the sample container.

1. Label the barcode on the sample container to make sure that the label is at least 8 mm from the top and the scan range is 56 mm as shown by Fig 4.8**.**

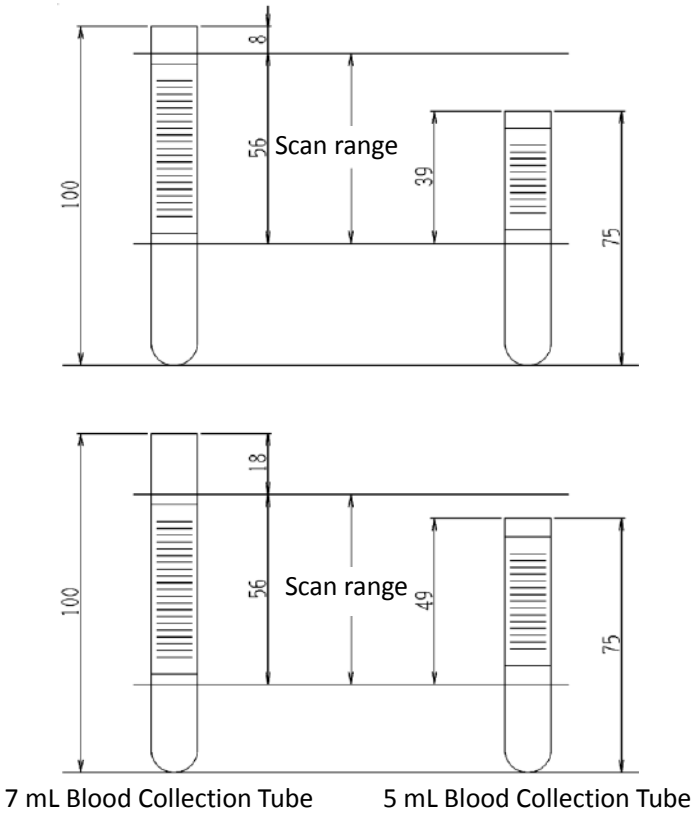


Figure 4.8 Sample Barcode Placement

2. Add the sample container to the sample tray, and make sure the sample barcode label facing the slot opening for accurate scanning.

4.2.6.2 Sample Cup

CM-400 fits with the standard sample cup and micro sample cup as shown below.

Standard sample cup:

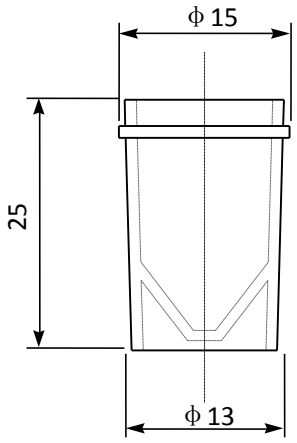
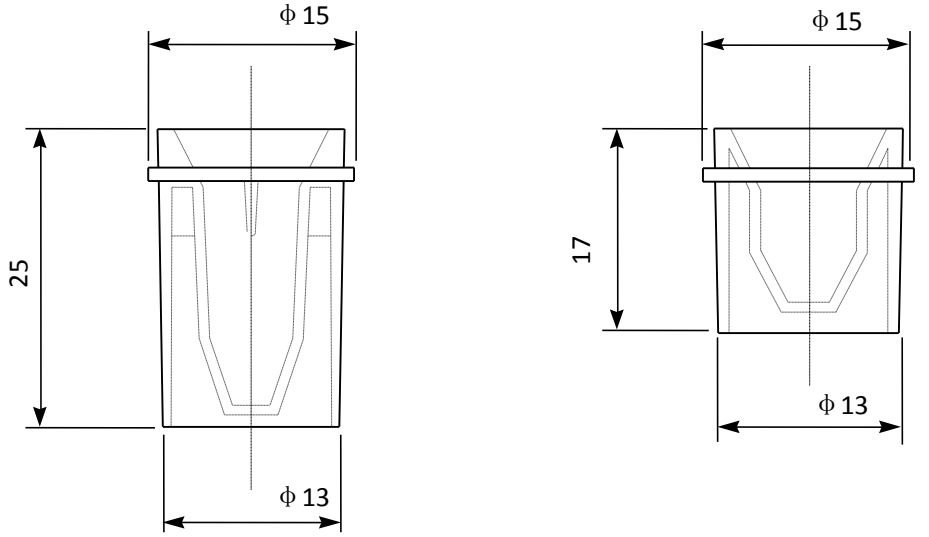


Figure 4.9 2 mL Standard Sample Cup

Micro sample cup：



500 µL Sample Cup　　200 µL Sample Cup

Figure 4.10 Micro Sample Cup

The specification of sample cup is as follows:

Table 4.7 Sample Cup Specification

Standard sample cup	ϕ 13×25 mm (2 mL)
Micro sample cup	ϕ 13×25 mm (500 µL) ϕ 13×17mm (200 µL)

4.2.7 Reagent Containers

This analyzer supports 20 mL and 70 mL reagent containers.

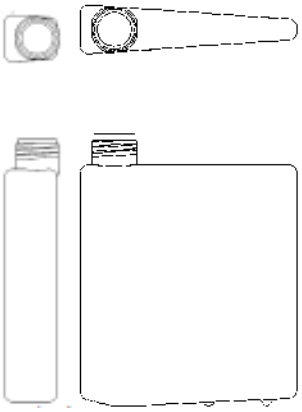


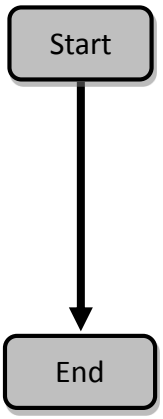
Figure 4.11 Reagent Containers

The general working procedure of a test:

1. Schedule a test.
2. The reagent probe dispenses reagent 1 into the reaction cup.
3. The sample probe aspirates the sample from the sample tray into the reaction cup.
4. The mix bar mixes the reaction liquid and it is incubated in the incubator at a specified temperature.

5. For the double-reagent test, reagent 2 will be added to the reaction cup and mixed by the mix bar.
6. The incubator maintains a constant temperature of 37 ℃ and the photometric unit measures the absorbance.
7. The system calculates the concentration based on the obtained absorbance, and then perform auto-rerun based on the analysis results.
8. The wash unit cleans the reaction cup after the test completes.

5. Basic Operation Process



5.1 Checking before Startup

5.2 Checking after Startup

5.3 Preparing Reagent

5.4 Calibration Test

5.5 QC Test

5.6 Routine Sample Test

5.7 Result Query

5.8 Shutdown

5.1 Checking before Startup

Check and prepare before starting the instrument. Follow the below startup procedures.

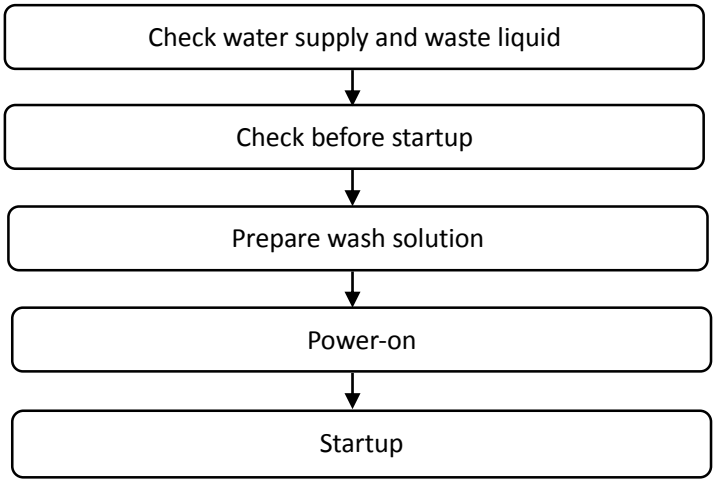


Fig 5. 1 Start-up Process

5.1.1 Checking the Analyzer and Supplies

To make sure the analyzer can function well, operators should check the analyzer and supplies before startup.

- Check the water filter switch, status, and the water reserve to ensure enough water supply when the instrument is working.
- Check whether the waste liquid pipe is securely connected with the waste liquid outlet. Make sure that waste liquid containers have been emptied before being used to hold waste liquid.

Caution
Please dispose of infectious waste liquid properly.

- Check whether the sample probe, reagent probe and mix bar are bent or stained. If any, wipe it gently with 75% ethanol cotton swab.
- Open the front door of the analyzer and make sure there is no leakage of the syringe.

5.1.2 Preparing Wash Solution

Wash solution is required during the washing process. Prepare enough wash solution before you turn on the instrument. Insufficient wash solution will trigger the warning message to remind you to replenish or replace it.

5.1.3 Starting the Instrument

Start the instrument and operating software with the following steps:

1. Switch on the main power on the right-side panel of the instrument.
2. Start up the analyzer system. The software will connect with the analyzer automatically and come into preheating status.
3. Wait for 20 minutes until the system shows standby status.

5.2 Checking after Startup

5.2.1 Checking Instrument Status

After the operating software is started, view the status icon in the upper left corner to check the system status. There are 9 kinds of status as follows. See **6.3 Menu Interface** for more information.

- Initialization
- Preheating
- Standby
- Testing
- Running
- Pause
- Test completed
- Unconnected
- Stopped

5.2.2 Checking Reaction Cup Blank

In the menu list, click **Maintenance→ Daily Maintenance→ Cup Blank Test→ Auto Execution**.

If…	**It means…**
a reaction cup highlighted in red	the reaction cup is not clean.
many reaction cups highlighted in red	• the lamp is aging. • the incubator has impurities or bacteria in the water.

Note

The blank value of a reaction cup will not be updated until the reaction cup is cleaned.

5.2.3 Checking Printer

Check the following items before printing:

- Check if the printer driver is installed.
- Check if the printer is connected to the computer correctly.
- Make sure there are no paper jams or other obstacles in the printer.
- Insert papers into the printer and turn on the printer.

- Print to test whether the printer functions well.

5.3 Prepare Reagent

Take the following steps to prepare reagent:

1. Place the reagent in the reagent tray correctly.

Note

Use specified reagent containers. See for **4.2.7 Reagent Containers** for more information.

2. In the main menu interface, select **Reagent** → **Load Reagent** to check the reagent name and remaining reagent volume.
3. If the reagent is insufficient, replace the reagent.
4. Optional: If you want to change the reagent position, perform **Load/Unload**. See **9 Reagent Management** for more information.
5. Perform **Auto Detection**. According to the current remaining reagent volume, the system calculates the number of tests that the remaining reagent can be used for.

If the remaining tests are not more than…	The system will…
the preset alarm value	send the alarm.
the preset minimum value	display a prompt and stop the test.

After replacing the reagent, you should re-schedule the test.

5.4 Calibration Test

Select **Test Manager** → **Test Request** → **Calibration Test** → select the calibration item → click **OK** → **Start**.

See **7.2 Requesting Calibration** for details.

5.5 QC Test

Select **Test Manager** → **Test Request** → select the sample position → click **QC Test** → select the QC item → click **OK** → **Start**.
See **7.3 Requesting QC** for details.

5.6 Routine Sample Test

Select **Test Manager** →**Test Request** → select the sample position → click **Routine Test** → select the sample type, sample volume, cup type, item or profile → click **OK** → **Start**.
See **7.1 Requesting Routine Test** for details.

5.7 Results Query

If you want to view the sample test results by sample ID, the specific steps are as follows:
Click **Result Query** →**Sample Results** to review, print, delete and edit routine sample test results. If you need to view the previous test results, click **Request Date** to select the date, or use the **Advanced Query**. See **8.1 Sample Results** for more information.
If you want to view the results by items, the specific steps are as follows:
Click **Result Query**→ **Item Results** → the item needed→ **Test Date** to set a specific time period. See **8.2 Item**

Results for more information.

5.8 Shutdown

This section describes a series of operations including the shutdown of the analyzer and checking after shutdown.

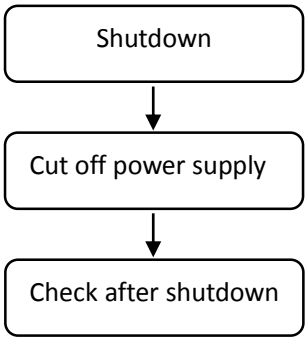


Fig 5. 2 Shutdown Process

5.8.1 Shutdown Step

1. Select **Exit** to shut down the analyzer.
2. Turn off the switch on the right side of the analyzer.
3. Turn off the main power switch of the analyzer if you do not need to keep the reagent refrigerated in the reagent tray.

5.8.2 Operations after Shutdown

After shutdown, please check:

- Whether the main switch of the waterway is turned off;
- Whether the probe is bent or stained;
- Whether the wash solution is enough;
- Whether there is any leak around the syringe;
- Whether the waste liquid should be treated properly as required;
- Whether the instrument surface is clean.

6. Software Overview

CM-400 system software consists of a real-time operating system in the instrument and a PC-based user interface (UI) software. This interface has available function buttons to perform routine sample tests, calibration, quality control and maintenance. You can navigate everywhere by interacting with the interface to perform the desired functions.

6.1 Network Connection

Figure 6.1 Network Connection

RS232 serial port: help transfer data via self-defined transferring protocol

RJ45 network port: test if the main controller program works properly by sending PING command under TCP/IP protocol.

6.2 Log in

After the instrument is started, a login window will pop up. Enter username and password and then click Login to enter the operating software. Then, the instrument will start initialization.

Figure 6.2 Login Window

6.3 Menu Interface

The main menu interface is the first screen you see after you log in. It consists of main menu, system status, system command button and function buttons, date/time display and information field.

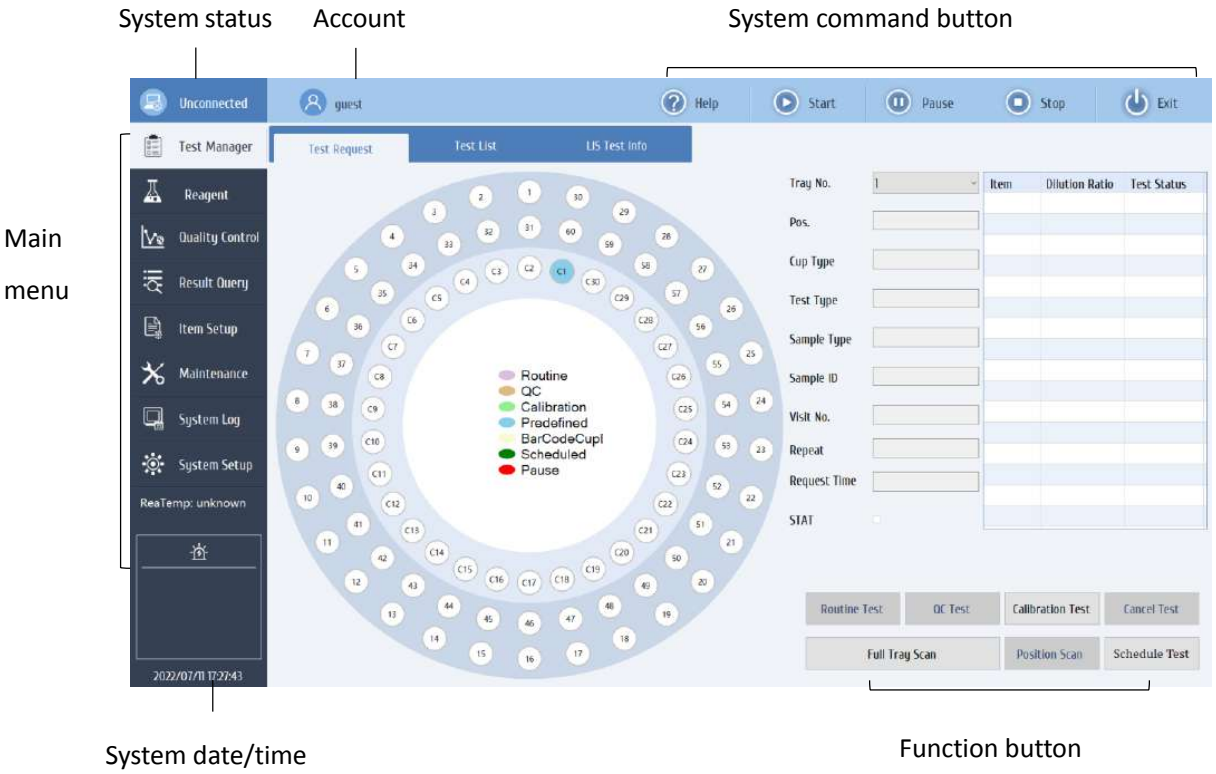


Figure 6.3 The main interface of software

Main Menu

The main menu is an integrated function list on the left side of the interface, which allows you to go to expected sub-windows and perform desired functions.

Main Menu List	Description
Test Manager	Select to: • add sample to, or remove it from the tray • request routine test, calibration and qc • cancel or schedule tests • scan barcode • manage test list and monitor test progress See **7. Test Manager** for more information
Reagent	Select to: • detect liquid level and reagent volume • load or unload reagents • scan reagent barcode • add or delete calibrators • edit calibration information See **9 Reagent Management** for more information.
Quality Control	Select to:

	• add or delete controls • edit controls information • review qc results See **11 Quality Control** for more information.
Result Query	Select to : • manage and review sample test results • manage and review qc results • manage and review calibration results • manage and review item results See **8 Result Query** for more information.
Item Setup	Select to: • add or delete test item • set item parameters • set carryover parameters • set printer parameters See **12 Item Setup** for more information.
Maintenance	Select to: • perform instrument maintenance • review maintenance log • monitor liquid inventory • review cup blank data See **14 Maintenance** for more information.
System Log	Select to: • review and filter system alarm logs • refresh and print system logs See **13.7 System Log** for more information.
System Setup	Select to: • perform remote control • upgrade firmware • modify hospital setting • set up user accounts • set up printing See **13 System Setup** for more information.

System Status

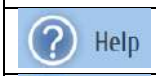
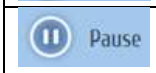
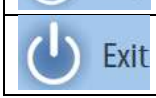
The system status area is in the upper left corner of the main menu interface. It displays the current status of the instrument.

Status	**Description**
Initialization	The system is initializing.
Preheating	The system is preheating.
Standby	The system is in standby mode and you can start testing.
Testing	The system is the process of a testing.
Running	The system is performing an action, such as maintenance and resetting.
Pause	The test is paused.
Test completed	The test is completed.
Unconnected	The analyzer is not connected.

Stopped	The analyzer stops

System Command Buttons

They are located at the top of the main menu interface. You can use them to switch accounts, view online user manual, start, pause, stop or exit the CM-400 system.

Button	Description
	User name icon. Click the icon to switch users.
	Select to view online user manual.
	Select to start testing.
	Select to pause testing.
	Select to stop testing immediately.
	Select to log out or exit the system.

Function Buttons

Different interfaces display different function buttons. You can select a function button to perform a desired operation. See **7 Test Manager** for more information.

Information Fields

Information field is the area where you should enter information or select from available options.

System Date/Time

It displays the current date and time.

6.4 Main Menu Workflow

You can select one from the menu list to display associated sub-windows and more specific functions. The following chart outlines the main workflow of CM-400 system.

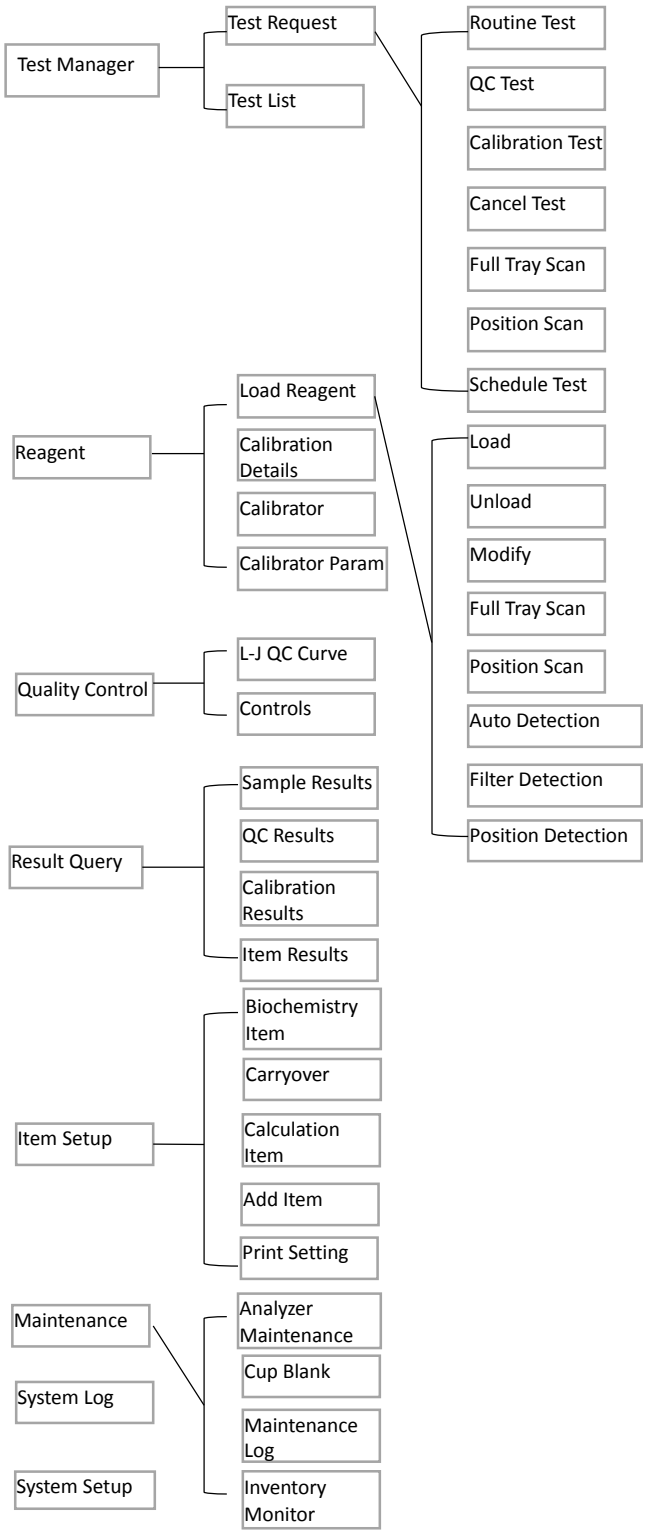


Figure 6.4 Menu Tree of Software Interface

7. Test Manager

Users can request, change or cancel tests, including routine test, QC test and calibration test.

7.1 Requesting Routine Test

1. In the menu list, click **Test Manager** → **Test Request**, the system displays **Test Request** window below.

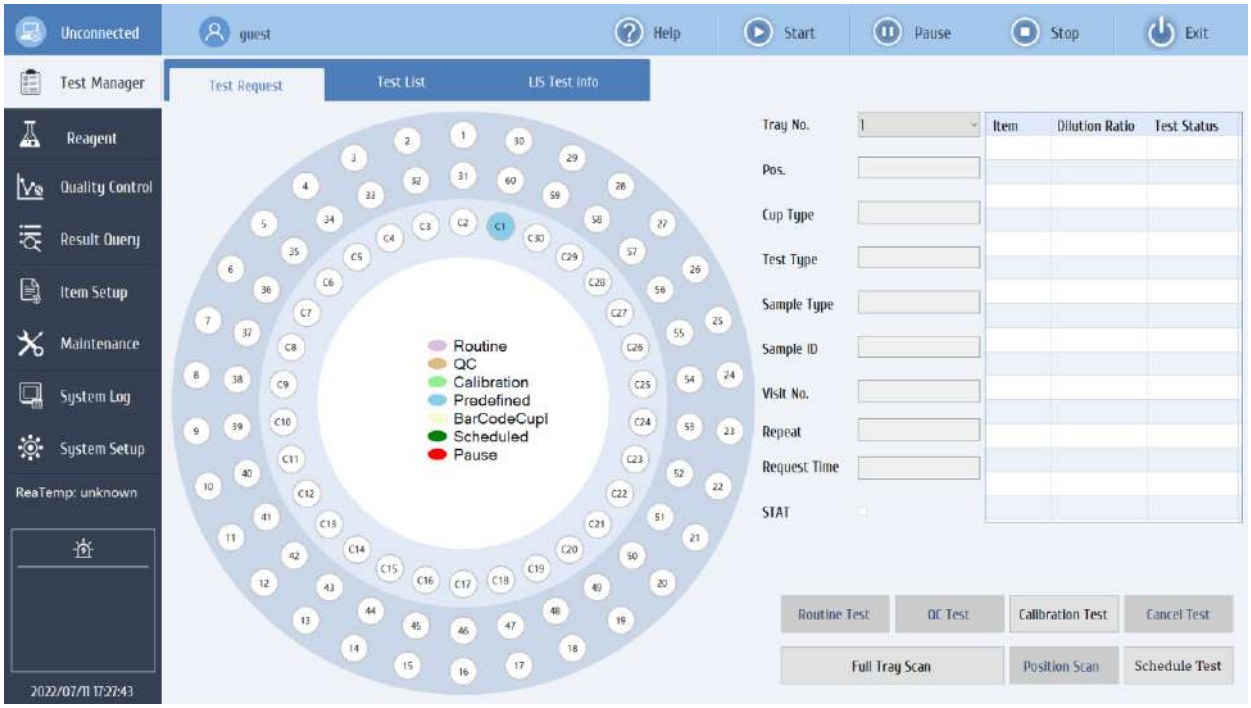


Figure 7.1 Test Request Window

2. Select the expected sample cup position and click **Routine Test**, the system displays the **Routine Request** window below.

Figure 7.2 Routine Test Request Window

Sample ID	Mark different samples and cannot be repeated within the same date. Sample ID is automatically numbered from 1 by default.
Sample Type	Sample type includes： • Serum (by default) • Plasma • Whole blood • Urine • Cerebrospinal liquid Parameters settings specific to these sample types can be found in the analysis method.
Sample Vol	Sample volume includes： • Normal (by default) • Increase • Decrease
Cup Type	Cup type includes: • Test Tube: 5 mL, 7 mL • Serum Cup: 2 mL, 500 µL, 200 µL The decrease degree of sample probe varies according to different cup type.
Tray No./Pos.	Tray No. is from 1 to 10. Each sample tray can only hold 60 routine sample positions. If requested samples are more than 60, the virtual Tray No will be used. The formula is as follows: Sample ID= (Tray No. -1) *60 + Cup Position. **Example**: If sample ID=71, Tray No.= 2, Then, Cup Position = 11. The Pos means the cup position in the tray.
Repeat	Enter the test repeat times.
Bulk Add	Select to edit multiple samples with the same test item.
STAT	Select to prioritize emergency sample.
Visit No.	Visit No. can be entered manually or read by the barcode scanner.
Profile	Display item combinations.
Patient Info	Select to manage patient information.
Dilution	Select the set dilution ratio.
OK	Save the current sample request.
Cancel	Cancel the current operation.

3. Enter the following information:
   - Sample Type
   - Sample Vol
   - Cup Type
4. Optional: Select **STAT** to prioritize emergency samples.
5. Optional: Select **Bulk Adding** to request multiple samples with the same test items.
6. Select the single test item or profile.
7. Click **OK.**

Bulk Adding:

For multiple samples with the same test item, you can request sample in bulk as follows:

1. Select the initial sample ID and the test item.
2. Select **Bulk Adding** and enter the number of samples you want to request in the **Bulk Adding** field.
   If you enter the number **N**, the total samples (including the initial sample) you want to request are **N**.
   Example: if the initial sample ID is 1 and **N** is 10, it means that the sample ID from 1-10 are requested at once.

Deleting Test Request:

You can delete a sample test request with the following two methods:

- On the **Test Request** window, select the sample position you want to delete and select **Cancel Test.**
- On the **Test List** window, select the sample you want to delete and select **Clear Test**.

Note

Tests for which the sample has been aspirated or that is being run cannot be deleted.

Caution

Sample cup type selection must be correct; otherwise, sample aspiration failure may occur.

7.2 Requesting Calibration

Calibration can ensure the accuracy of test results. There are 11 kinds of calibration methods available to select from. Refer to **10.3 Calibration Parameter** for details.

Use this procedure to request calibration:

1. In the main menu interface, select **Test Manager→ Test Request→ Calibration Test**, the system displays the **Calibration Request** window.

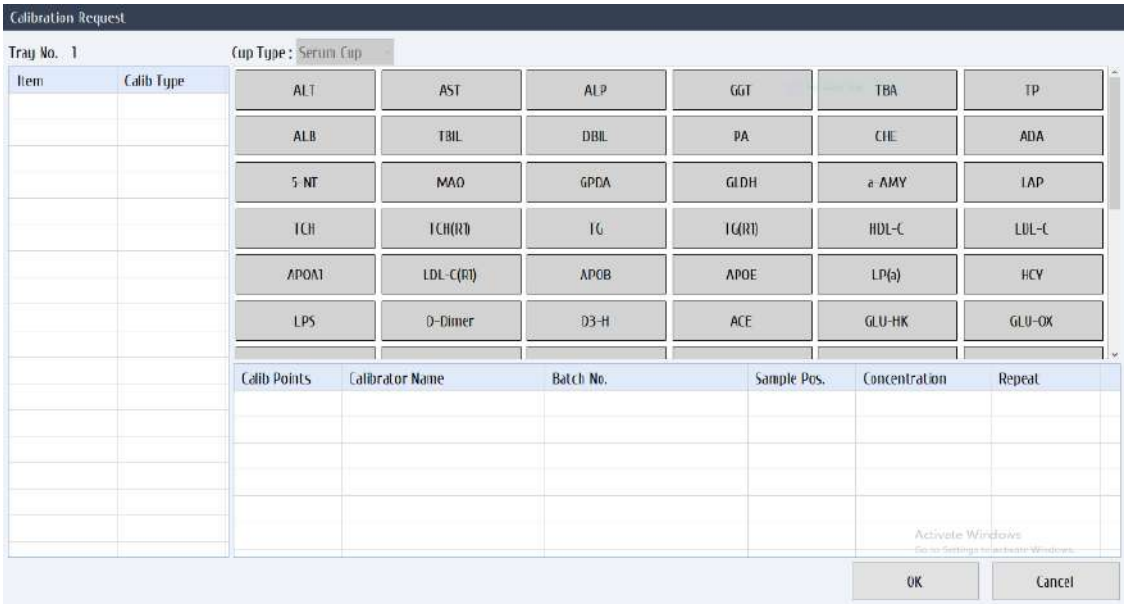


Figure 7.3 Calibration Request Window

Calibration Information Field	Display calibrator parameters. • Calib Points: display calibration points. • Calibrator name: display calibrator name. • Batch No.: display the calibrator batch No.

	• Sample Pos.: display calibrator position on the sample tray. • Concentration: display calibrator concentration value. • Repeat: display the test repeat times.
Button Area	• OK: save the calibration request of the current calibrators. • Cancel: cancel the operation.

2. Select test item you want to request.

Note

Item in grey cannot be selected as they have not been added into the system.

3. Select **OK→ Start**.

Note

Tests for which the sample has been aspirated or that is being run cannot be deleted.

Deleting Calibration Request:

1. On the **Test List** window, select the calibrator you want to delete.
2. Select the test item of the calibrator you want to delete.
3. Select **Clear Test**.

7.3 Requesting QC

1. In the main menu interface, select **Test Manager→ Test Request.**
2. Select the control, the sample tray and select **QC Test**, the system displays the **QC Request** window.

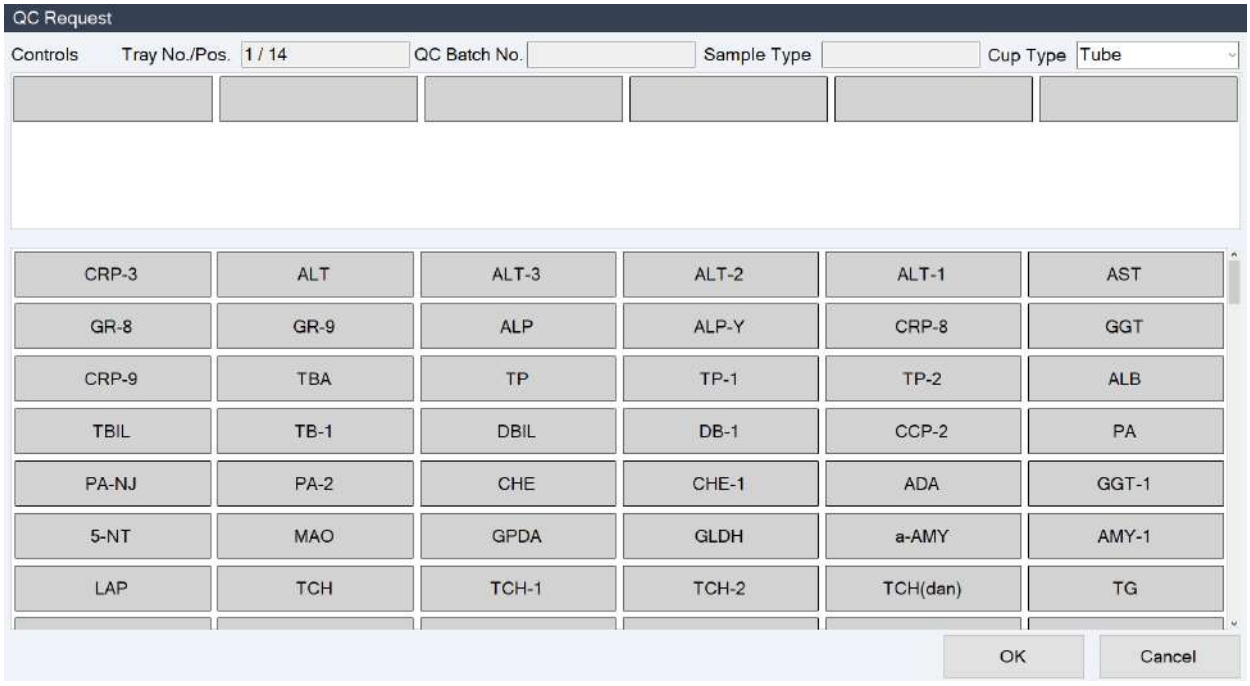


Figure 7.4 QC Request Window

Controls	Display control name.
Tray No./Pos.	Display the tray No. and position of the control.
QC Batch No.	Display the batch No. of the control.
Sample Type	Display the sample type of the control (serum by default).
Cup Type	Display the cup type of control.
OK	(Button) Select to confirm.

Cancel	(Button) Select to cancel.

3. Select QC test item and select **OK**.
4. Select **Start** to start testing.

Deleting QC Request:

You can delete a QC request with the following two methods:

- On the **Test Request** window, select the control sample position you want to delete and select **Cancel Test.**
- On the **Test List** window, select the QC test you want to delete and select **Clear Test**.

7.4 Test List

Select **Test Manager** →**Test List** to review requested tests or clear tests.

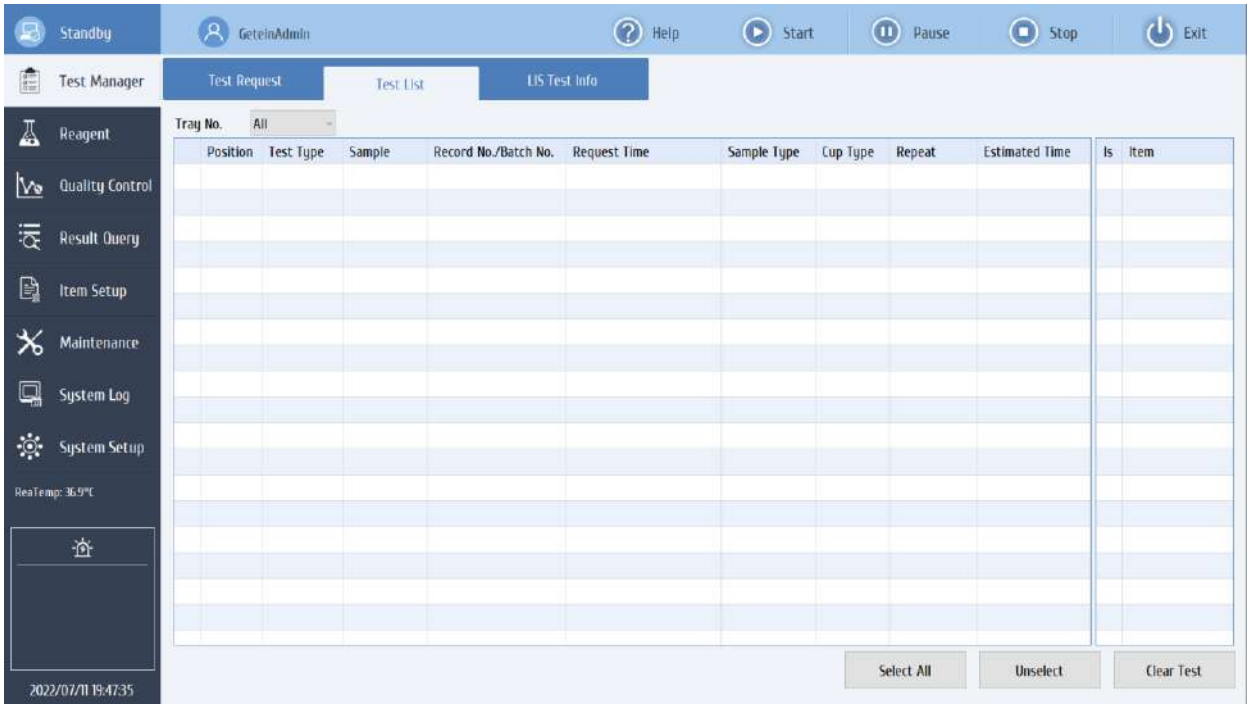


Figure 7.5 Test List Window

Tray No.	(Box) Click to select tray number.
Position	(Column) Display the position of the sample.
Test Type	(Column) Display the test type.
Sample	(Column) Display the sample name.
Record No./Batch No.	(Column) Display the patient visit No. or sample/control/calibrator batch No.
Request Time	(Column) Display the test request time.
Sample Type	(Column) Display the sample type.
Cup Type	(Column) Display the cup type.
Repeat	(Column) Display test repeat times.
Estimated Time	(Column) Display estimated completion time.
Is	(Column) Means the checkbox
Item	(Column) Display test items.
Select All	(Button) Select all tests.
Unselect	(Button) Unselect tests.
Clear Test	(Button) Clear tests.

7.5 LIS Test Information

Select **Test Manager** →**LIS Test Info** to review test information on the LIS server.

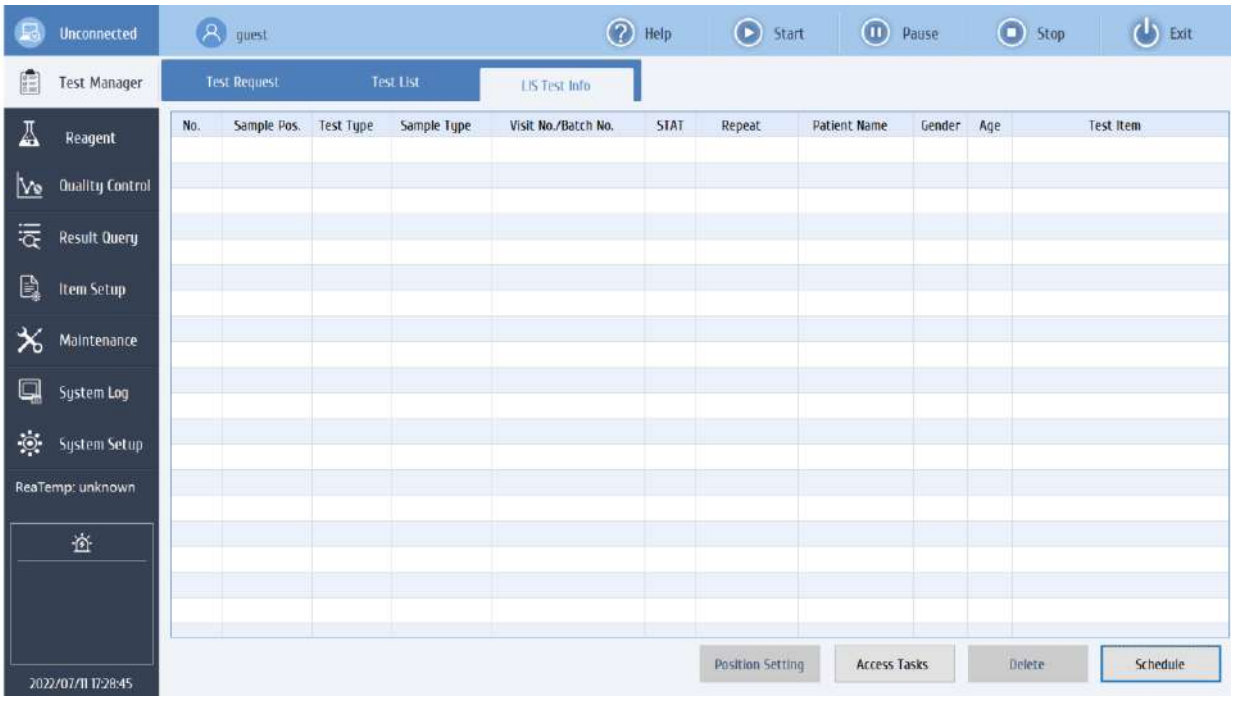


Figure 7.6 LIS Test Info Window

No.	(Column) Display the sequence.
Sample Pos.	(Column) Display the sample position.
Test Type	(Column) Display the test type.
Sample Type	(Column) Display the sample type.
Visit No./Batch No.	(Column) Display the patient visit number or batch number.
STAT	(Column) Display if the sample is emergent or not.
Repeat	(Column) Display the test repeat times.
Patient Name	(Column) Display the patient name.
Gender	(Column) Display the patient gender.
Age	(Column) Display the patient age.
Test Item	(Column) Display the test item name.
Position Setting	(Button) Select to set position.
Access Tasks	(Button) Select to access test tasks from LIS server.
Delete	(Button) Select to delete the chosen test information.
Schedule	(Button) Select to schedule the test.

8. Result Query

In the main menu interface, select **Result Query** to view and manage test results, including:

- Sample results
- QC results
- Calibration results
- Item results

8.1 Sample Results

In the main menu interface, select **Result Query** → **Sample Results**, the system displays **Sample Results** window as below.

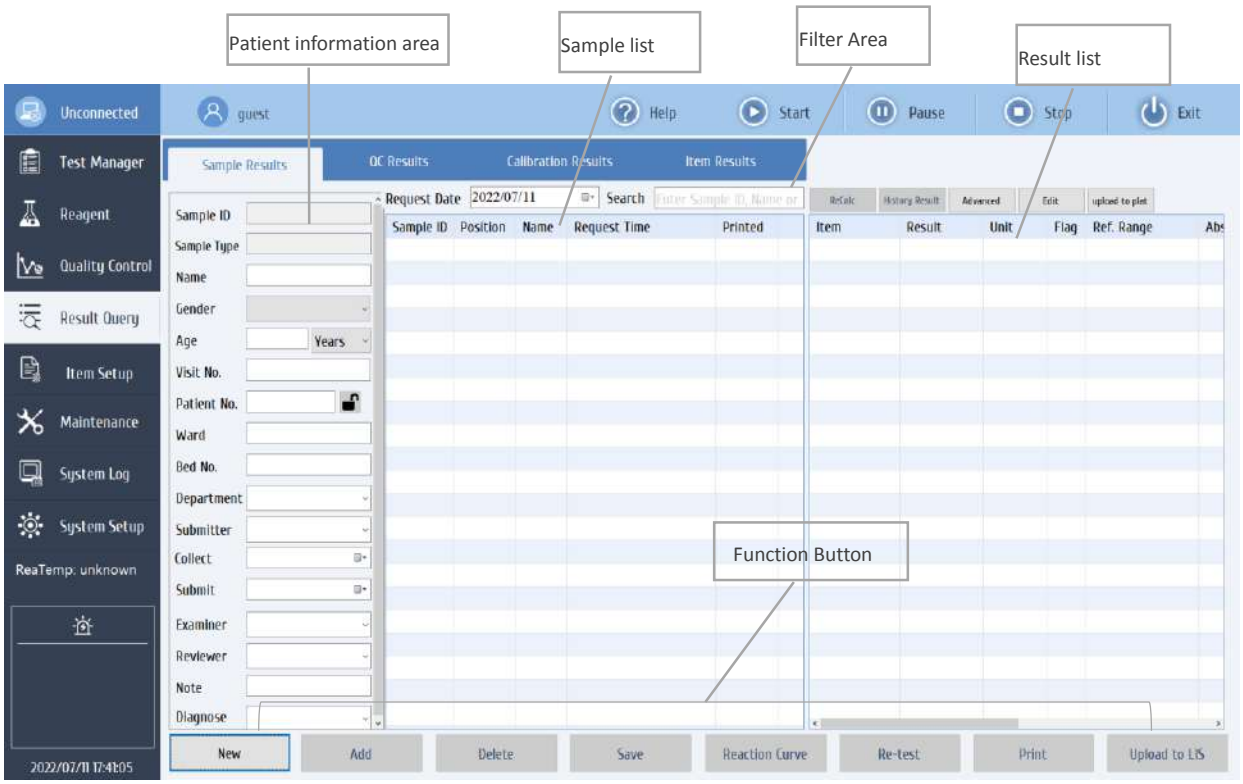


Figure 8.1 Sample Results Window

Patient Information Area

Enter patient information on the left side of the interface. Patient information entries are only required in report printing not in LIS connecting.

Sample ID	(Field) Display sample ID.
Sample Type	(Field) Display sample type.
Name	(Field) Enter the patient name.
Gender	(List) Select the patient gender : • Male • Female

	• Other
Age	(Field and List) Enter the patient age and select the age unit: • Year • Month • Day
Visit No.	(Field) Enter the visit No. of the patient according to the medical examination request form.
Patient No.	(Field) Enter the patient No. according to the medical examination request form.
Ward	(Field) Enter the ward.
Bed No.	(Field) Enter the bed No. according to the medical examination request form.
Department	(List) Select the clinical department. Refer to **13.4 Hospital Setting** for details.
Submitter	(List) Select the one who sends the sample. Refer to **13.4 Hospital Setting** for details.
Collect	Select the sample collection time.
Submit	Select the sample submitted time.
Examiner	(List) Select the examiner.
Reviewer	(List) Select the one who reviews the test.
Note	(Field) Enter notes.
Diagnose	(Field) Enter diagnosis.

Filter Area

If you use the system-defined filters, and the system will display the sample results you want to view. See the available filters in the following table. You can select one or more filters to search.

Request Date	Filter test results based on the test request date.
Search	(Field) Enter Sample ID, Name or Cup Position to filter test results.
ReCac	(Button) Select to re-calculate the sample test results.
History Result	(Button) Select to view the history sample results.
Advanced	(Button) Select to filter test results with the advanced query. See **Advanced Query** for more information.
Edit	(Button) Select to edit test results.
Upload to platform	(Button) Select to upload test results.

Sample List

Sample ID	(Column) Display sample ID.
Position	(Column) Display sample position.
Name	(Column) Patient name
Request Time	(Column) Display the time when you request the test.
Printed	(Box) Display whether the report has been printed.

Result List

Item	(Column) Display the name of the test item.
Result	(Column) Display the concentration value.
Unit	(Column) Display the concentration unit.
Flag	(Column) Display ‘↑’ or ‘↓’ to flag abnormal results: • Flag ‘↑’ means the result is above the upper limit of the reference range.

	• Flag ‘↓’ means the result is below the lower limit of the reference range.
Ref. Range:	(Column) Display the reference range.
Abs.	(Column) Display measured absorbance.
Dilution Ratio	(Column) The pre-set dilution ratio.
Test Time	(Column) Display the test completion time.
Mark	(Column) Mark the test results. See **A.7 Mark List** for more information.

Function Buttons

New	(Button) Create new patient sample information.
Add	(Button) Add patient sample information.
Delete	(Button) Delete patient sample information.
Save	(Button) Save the patient sample information.
Reaction Curve	(Button) View the response curve of the selected sample. See **Reviewing Reaction Curve** for more information.
Re-test	(Button) Re-run test of the selected sample.
Print	(Button) Print test results. Make sure the printer is correctly connected to the analyzer.
Upload to LIS	(Button) Transmit test results to LIS.

Advanced Query:

1. On the Sample Results window, select Advanced, the system displays the Advanced Query window as shown below.

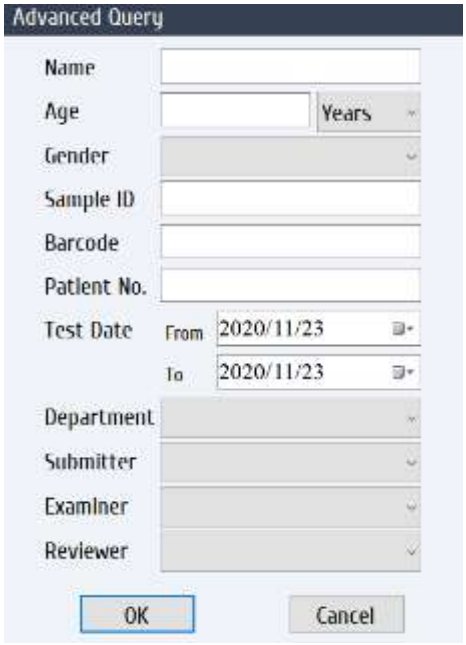


Figure 8.2 Advanced Query Window

2. Enter the information as filter(you can select more than more filters):
   - Name
   - Age
   - Gender

- Sample ID
- Barcode
- Patient No.
- Test Date
- Department
- Submitter
- Examiner
- Reviewer

3. Click **OK**. The system displays results you want.

Reviewing Reaction Curve:

1. On the **Sample Results** window, select the expected sample and test item.
2. Select **Reaction Curve**, and the system displays the **Reaction Curve** window as below.

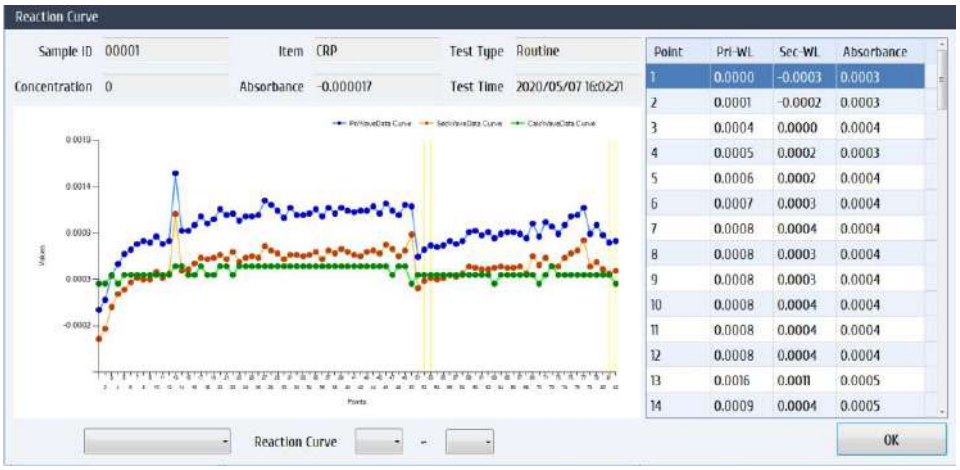


Figure 8.3 Reaction Curve Window

Sample ID	(Field) Display sample ID.
Item	(Field) Display the Test item.
Test Type	(Field) Display the test type, including: • Routine • Calibration • QC
Concentration	(Field) Display the concentration value.
Absorbance	(Field) Display the absorbance value.
Test Time	(Field) Display the test time.
Point	(Column) Display the measuring point.
Pri-WL	(Column) Display the primary wavelength.
Sec-WL	(Column) Display the secondary wavelength.
Absorbance	(Column) Display the absorbance value.

8.2 Item Results

Go to the main menu interface, click **Result Query** → **Item Results** to review and search test item results.

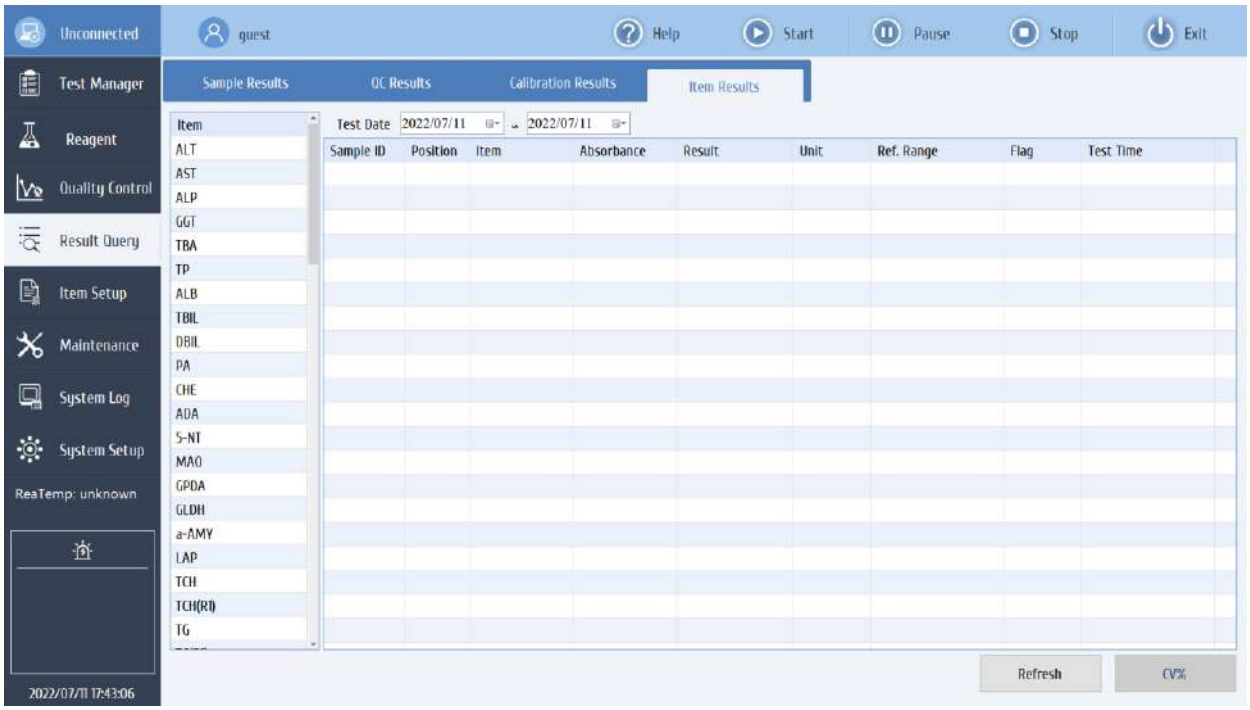


Figure 8.4 Item Results Window

Item	(Column) Select the test item.
Test Date	(Box) Select the test time range (year/month/day).
Sample ID	(Column) Display the sample ID.
Position	(Column) Display the item position.
Item	(Column) Display the test item name.
Absorbance	(Column) Display the absorbance value.
Result	(Column) Display test item results.
Unit	(Column) Display the unit of test results.
Ref. Range	(Column) Display the reference range of the test item.
Flag	(Column) Display the abnormal results with flags: • ↑ indicates the value is above the reference range. • ↓ indicates the value is below the reference range.
Test Time	(Column) Display the time when the test completes.
Refresh	(Button) Select to refresh item results.
CV%	(Button) Select to calculate CV% of item results.

9. Reagent Management

Users can manage reagents in the Reagent interface, including:

- Loading/unloading reagents.
- Editing reagent parameters.
- Monitoring reagent reserve.
- Scanning reagent tray.

Loading Reagent:

You can load reagent with the following steps:

In the menu list, select **Reagent→Load Reagent,** and the system displays the **Load Reagent** window as below.

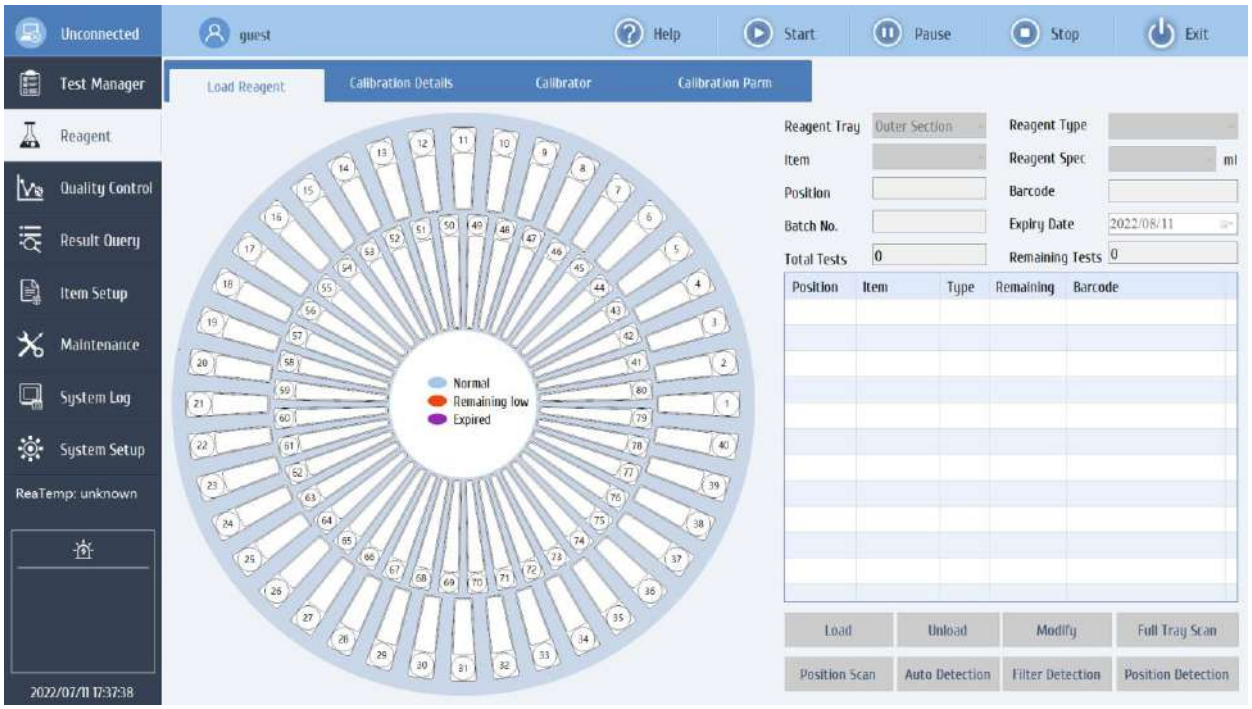


Figure 9.1 Load Reagent Window

Graphic Reagent Tray

The graphic reagent tray displays the position of reagent containers. It indicates the reagent status with the following highlight colors after they are loaded:

Indicator	Description
Normal	The reagent is loaded successfully.
Remaining low	The number of tests left is insufficient.
Expired	The reagent is expired.

Reagent Parameter Area

Reagent Tray	(List) Display the tray section of the selected reagent, including: • Outer Section • Inner Section
Item	(List) Select the test item of reagent.
Reagent Type	(List) Select the reagent type, including: • R1 • R2 • R3 • R4
Reagent Spec	(List) Select the reagent container type.
Position	(Field) Display the reagent position on the tray.
Barcode	Reagent barcode can be entered manually or read by barcode scanner.
Batch No.	Reagent batch number.
Expiry Date	The shelf life of the reagent.
Total Tests	The number of tests can be performed with the total reagent.
Remaining Tests	The number of tests can be performed with the remaining reagent.

Reagent List

It displays the information of each reagent on the tray.

Position	(Column) Display the reagent position on the tray.
Item	(Column) Display the test item of the reagent.
Type	(Column) Display the reagent type, including: • R1 • R2 • R3 • R4
Remaining	(Column) Display the remaining test times of the reagent.
Barcode	(Column) Display the reagent barcode.

Button Area

Load	(Button) Select to load the selected reagent. See **Loading Reagent** for more information.
Unload	(Button) Select to unload the selected reagent.
Modify	(Button) Select to modify the reagent information of the selected reagent.
Full Tray Scan	(Button) Select to read the barcode information of all reagents in the tray.
Position scan	(Button) Select to read the barcode information to the selected reagent in the tray.
Auto Detection	(Button) Select to detect the remaining volume of all loaded reagents in the tray, and then update the remaining volume and the remaining tests after the detection.
Filter Detection	(Button) Select to detect the remaining volume of the loaded reagents which have not been detected before and calculate the remaining tests.
Position Detection	(Button) Select to detect the remaining volume of the selected reagent and calculate the remaining tests.

Loading Reagent:

1. Place the specified reagent container into the reagent tray correctly.
2. On the main menu interface, select **Reagent→Load Reagent**, and then select the expected reagent position in the graphic reagent tray.
3. Enter the following information in the **Reagent Parameter Area.**
   - Test item
   - Reagent type
   - Barcode
   - Batch No.
   - Expiry date
   - Total tests
   - Remaining tests
4. Select **Load** to load the reagent.

10. Calibration

Calibration is a key factor to ensure the accuracy of the test results. You should perform calibration if the following situations occur：

- Reagent type or reagent lot number changes.
- Calibration is out of validity period.
- The instrument or the system has performed large-scale preventive maintenance.
- Important parts have been replaced.
- The QC shows an abnormal trend or deviation, or exceeds the specified acceptance limit.

10.1 Calibrator

In the main menu list, select **Reagent→Calibrator** to display **Calibrator** window as below.

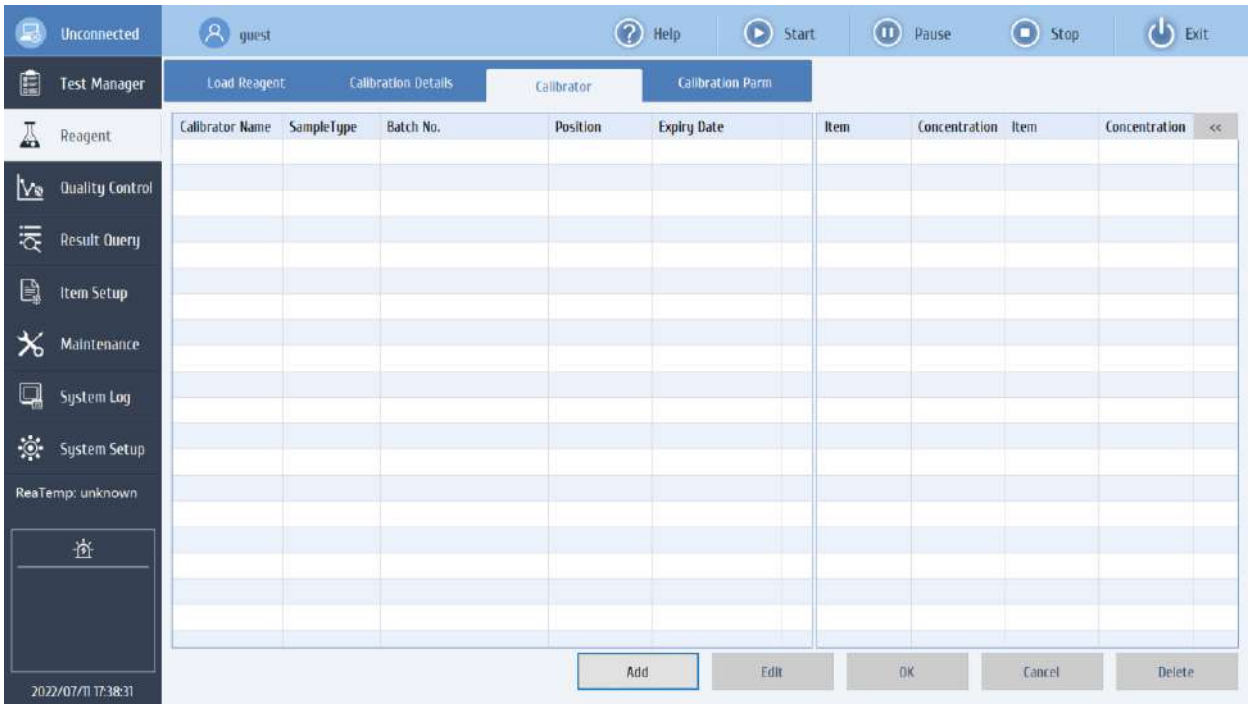


Figure 10.1 Calibrator Window

Calibrator Name	(Column) Display the calibrator name.
Sample Type	(Column) Display the sample type.
Batch No.	(Column) Display the batch No.
Position	(Column) Display the calibrator position.
Expiry Date	(Column) Display the expiry date of the calibrator.
Item	(Column) Display the test item of the calibrator.
Concentration	(Column) Display the concentration value.
<<	(Icon) Select to display all test items.
Add	(Button) Select to add calibrator information.
Edit	(Button) Select to edit the selected calibrator information.
OK	(Button) Select to save current calibrator information.
Cancel	(Button) Select to cancel the operation.
Delete	(Button) Select to delete the selected calibrator information.

Adding Calibrators：

1. Select **Reagent→ Calibrator**.
2. Select **Add** and enter calibrator information.
3. Select the test item for the calibrator.
   - If it is a multi-calibrator, click << to add more test items.
4. Select **OK** to save changes

10.2 Calibration Details

Go to the main menu interface, select **Reagent → Calibration Details**. The system displays the Calibration Details window as shown below.

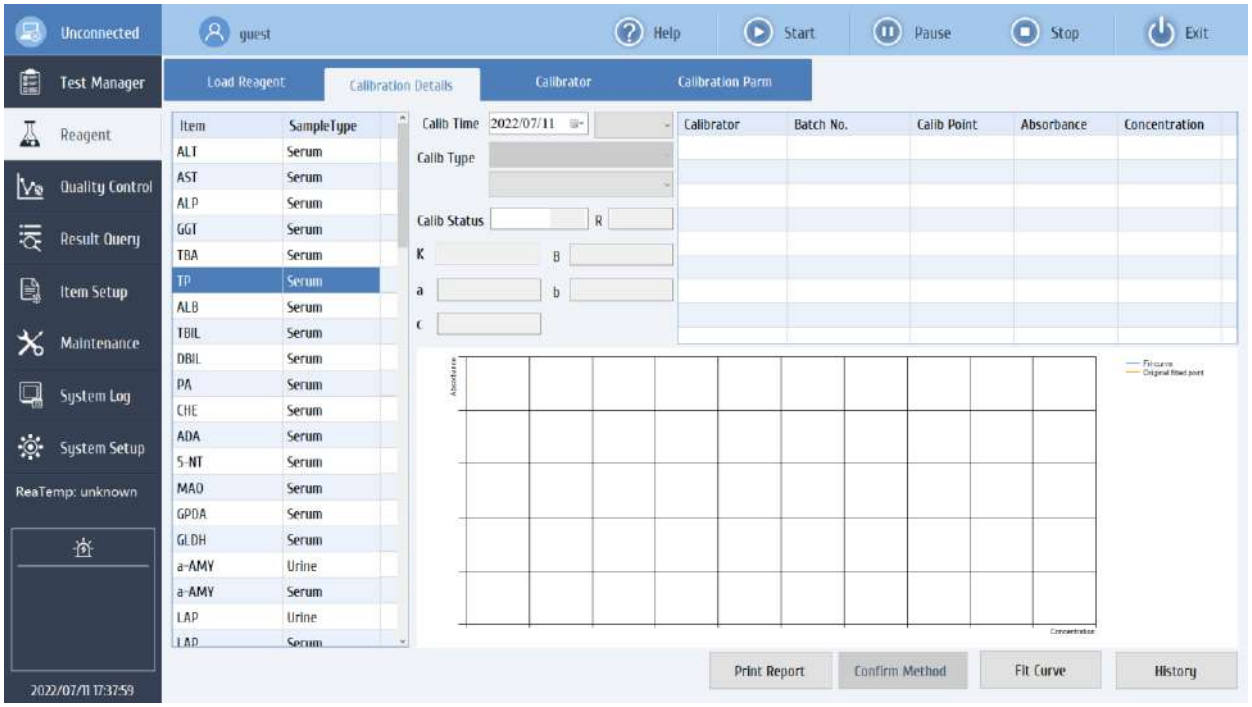


Figure 10.2 Calibration Details Window

Item	(Column) Display the calibration item.
Sample Type	(Column) Display the sample type.
Calib Time	Display the calibration time.
Calib Type	(List) Display the calibration type.
Calib Status	(Field) Display the calibration status.
Calibrator	(Column) Display the calibrator name.
Batch No.	(Column) Display the calibrator batch No.
Calib Point	(Column) Display the calibration point.
Absorbance	(Column) Display the absorbance value.
Concentration	(Column) Display the calibrator concentration.
Print Report	(Button) Select to print calibration report.
Confirm Method	(Button) Select to confirm calibration method.

Fit Curve	(Button) Select to fit calibration curve.
History	(Button) Select to review calibration history.

Setting calibration parameters:

1. On the **Calibration Details** window, select the calibration item from the item column.
2. Enter the following calibration parameters:
   - Time (year/month/day/hour/minute),
   - Calibration type
   - Calibration status
   - Calibration factor R/K/B/a/b/c

10.3 Calibration Parameter

Go to main menu interface, select **Reagent** → **Calibration Parm** to set the calibration parameters. The system displays the **Calibration Parameters** window as below. There are 11 calibration methods can be chosen.

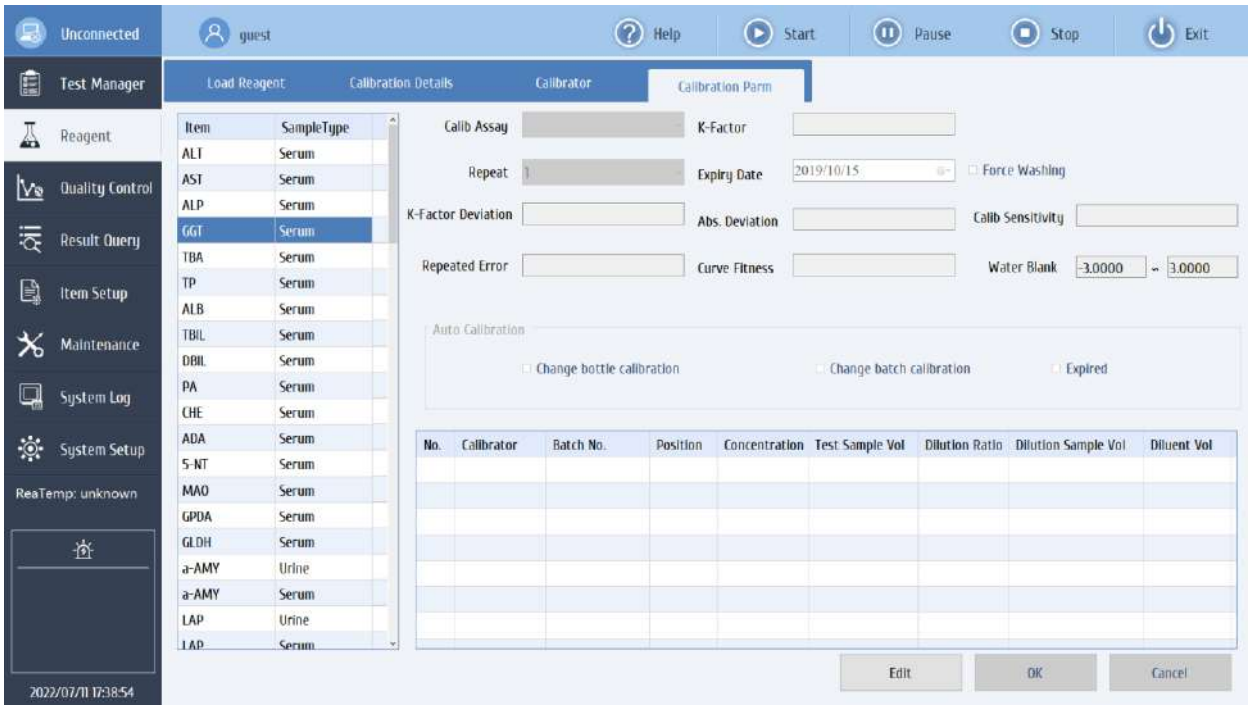


Figure 10.3 Calibration Parameter Window

1. 1-point Linearity (K-factor Method)

The working curve is obtained with measured absorbance of calibrator 1 (reagent blank) and the K factor as shown below.

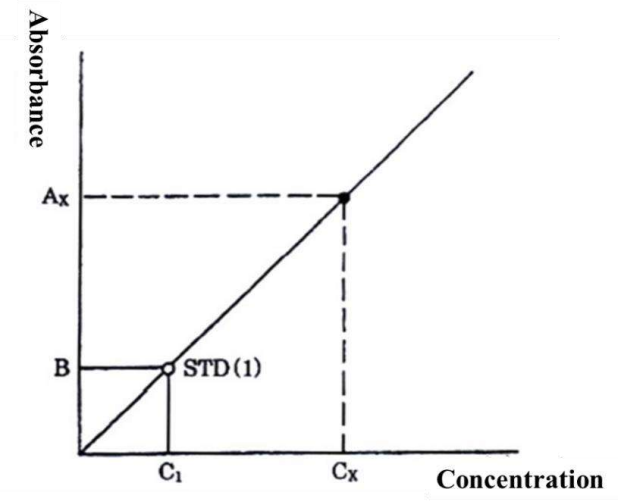


Figure 10.4 1-point Linearity (K-factor Method)

a. Enter calibration parameters.
   - Calibration type: 1-point linearity.
   - Calibration Point: [1] (Number of Calibrator).
   - Span Point: [0].

b. Enter K factor.

c. Calculate concentration with formula.

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

   - B (S1ABS): The absorbance of calibrator 1 (reagent blank) or the absorbance change rate per minute.
   - K: K factor
   - C_1: The concentration of calibrator 1 (reagent blank).
   - C_x : The concentration of the sample.
   - A_x : The absorbance of the sample or the absorbance change rate of the sample per minute.
   - IFA and IFB are constants to represent slope and intercept respectively.

d. Applicable analysis methods:
   - 1 point end-point method
   - 2 point end-point method
   - Rate method

2. 2-point Linearity Method

The working curve is obtained by measuring absorbance of the calibrator 1 (reagent blank) and the calibrator 2 as shown below.

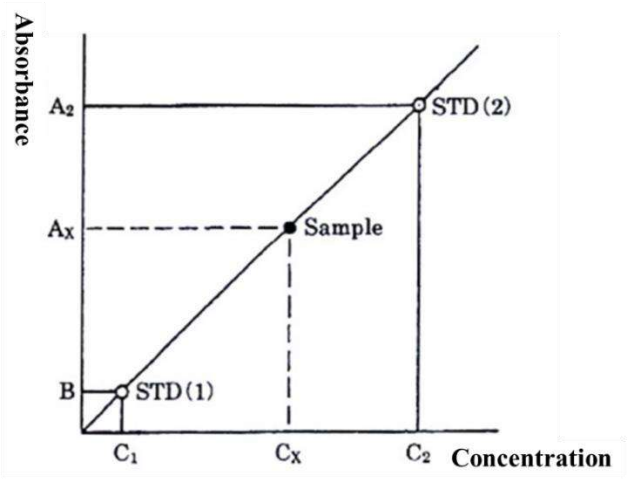


Figure 10.5 2-point Linearity

a. Enter calibration parameters.
- Calibration Type: 2-point linearity
- Calibration Point: [2] (Number of Calibrators)
- Span Point: [2-6]

b. Calculate K factor with the formula below.

$$K = \frac{C_2 - C_1}{A_2 - B}$$

- K: The constant of the calibration curve.
- B (S1ABS): The absorbance of calibrator 1 (reagent blank) or the absorbance change rate per minute.
- C_1: The concentration of calibrator 1 (reagent blank).
- C_2: The concentration of calibrator 2.
- A_2: The absorbance of calibration 2 or its absorbance change rate per minute.

c. Calculate concentration.

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

- C_x : Concentration of the sample.
- A_x : The absorbance of the sample or its absorbance change per minute.
- IFA and IFB: Constants to represent slope and intercept.

d. Applicable analysis methods:
- 1 point end-point method
- 2 point end-point method
- Rate method

3. Multi-point Linearity

The working curve is obtained by linear regression through the measurement of blank (or calibrator 1) and calibrators (calibrator 2 to calibrator 6). The calibration curve is shown below.

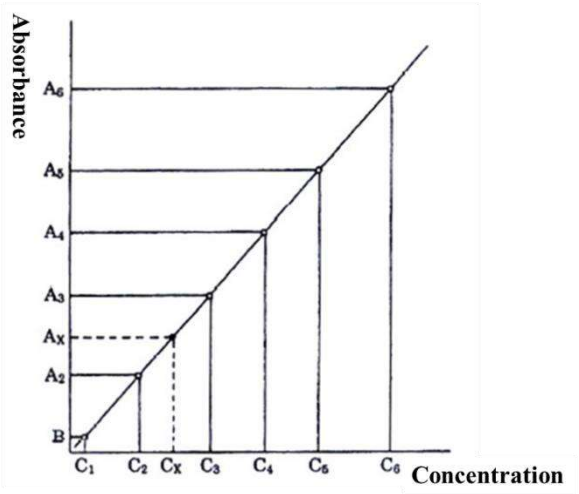


Figure 10.6 Multi-point Linearity

a. Enter calibration parameters.
   - Calibration Type: multi-point linearity
   - Calibration Point: [3-6] (Number of calibrators).
   - Span Point: [3-6]

b. Calculate calibration parameters.
   - B (S1ABS): The absorbance of calibrator 1 (reagent blank) or the absorbance change rate per minute, which represents the intercept of linear regression equation.
   - K: The reciprocal of slope of calibration curve in the linear regression.

$$S1ABS(B) = \bar{A} - \frac{X \times \overline{Cr}}{Y}$$

$$K = \frac{Y}{X}$$

$$X: \sum_{i=1}^{n}\left(Cri - \bar{Cr}\right)\times\left(Ai - \bar{A}\right)$$

$$Y: \sum_{i=1}^{n}\left(Cri - \bar{Cr}\right)^2$$

$$\bar{A}: \left(\sum_{i=1}^{n} Ai\right)/n$$

$$\bar{Cr}: \left(\sum_{i=1}^{n} Cri\right)/n$$

   - B (S1ABS): The absorbance of calibrator 1 (reagent blank) or the absorbance change rate per minute, which represents the intercept of linear regression equation.
   - K: The reciprocal of slope of calibration curve in the linear regression.
   - A_1 and A_2: two measured values of calibrator 1, n is the number of calibrator N * 2, and Cri is the concentration of calibrator (i).

c. Calculate concentration.

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

- C_x : Concentration of the sample.
- A_x : The absorbance of the sample or its absorbance change per minute.
- IFA and IFB: Constants to represent slope and intercept.

d. Applicable analysis methods

- 1 point end-point method
- 2 point end-point method
- Rate method

4. Polyline Method (Non-linearity)

The curve is obtained by measuring and drawing a line from the absorbance of calibrator (1) to that of calibrator (5) or (6). The calibration curve is shown below.

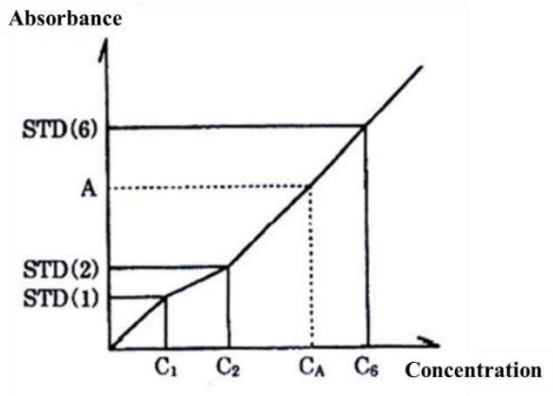


Figure 10.7 Polyline Method (Non-linearity)

a. Enter calibration parameters.

- Calibration type: [polyline].
- Calibration point: [5-6] (number of calibrators).
- Span Point: [0] span calibration is invalid.

b. Calculate calibration parameters

S1ABS is the average value of absorbance or absorbance change of calibrator 1 which is measured twice.

$$K = \frac{C_2 - C_1}{A_2 - B}$$

- B: Absorbance or absorbance change of calibrator 1
- A_2: Absorbance or absorbance change of calibrator 2
- C1: Concentration of calibrator 1
- C2: Concentration of calibrator 2

K_2, K_3, K_4 and K_5 are calculated with the same way.

c. Calculate concentration

$$C_X = \{K_N \times (A_X - A_N) + C_N\} \times IFA + IFB$$

d. Applicable analysis methods

- 1 point end-point method
- 2 point end-point method
- Rate method

5. Logit-log3P (Non-linearity)

Fit for the curve whose absorbance achieves convergence as the concentration increases. The calibration curve of Logit-log3P (non-linearity) is shown below.

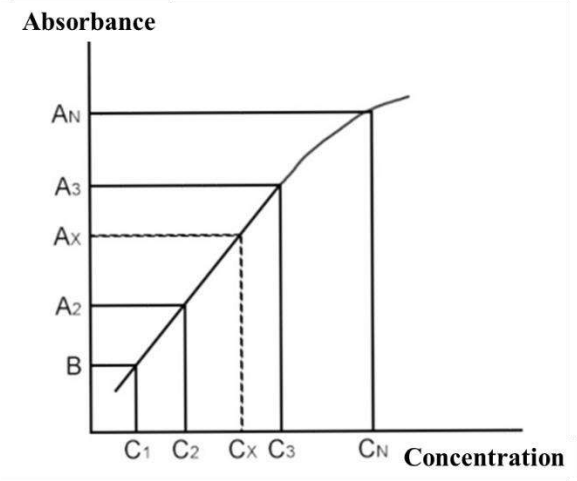


Figure 10.8 Logit-log3P (Non-linearity)

a. Enter calibration parameters.
- Calibration type: [Logit-log3P].
- Calibration point: [3-6] (number of calibrators).
- Span point: [0] span calibration is invalid.

b. Calculate calibration parameters.

$$C_X = (C + C_1) \times IFA + IFB$$

$$A_X = B + \frac{K}{1 + aC}$$

$$C = \frac{1}{a} \times \left\{ \frac{K - (A_X - B)}{A_X - B} \right\}$$

- B: The approximate value of the absorbance or the absorbance change per minute when C_x approaches ∞.
- K: The difference between B and the approximate value of the absorbance or the absorbance change per minute of reagent blank (calibrator 1).
- a: The constant of the approximate formula, which will be calculated automatically.

c. Calculate concentration
- C_X : the concentration of the sample
- C_1 : the concentration of reagent blank
- A_X : the absorbance of the sample or its absorbance change per minute.
- K : the constant of the formula.
- IFA and IFB: constants to indicate the slope and intercept respectively.

The closer C_X approaches ∞, the more similar to B AX will be. If K＜0, AX≤B+K or K＞0, AX≥B+K, C=C1.

d. Calculate SD

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(Aij - A_i'\right)^2}{2N-3}}$$

(N=3～6、j=1 or 2)

A_{ij}-A_i': the difference between Ai' calculated by the curve-fit equation and the measured value A_{ij} or A_{12}. Each calibrator is measured twice, so the maximum number of A_{ij} is 12.

e. Applicable analysis methods
- 1 point end-point method
- 2 point end-point method
- Rate method

6. Logit-log4P (Non-linearity)

Fit for the curve whose absorbance achieves convergence as the concentration increases. The calibration curve of Logit-log3P (non-linearity) is shown below.

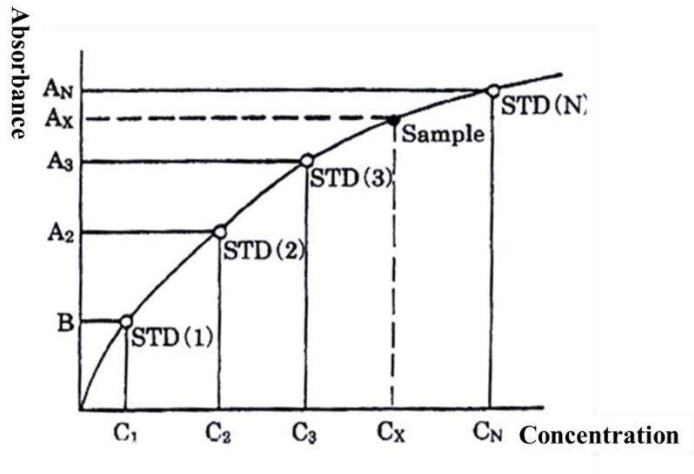


Figure 10.9 Logit-log4P (Non-linearity)

a. Enter calibration parameters
- Calibration type: Logit-log4P.
- Calibration point: 4-6 (number of calibrators).
- Span Point: [0] span calibration is invalid.

b. Calculate parameters of working curve
- B: The approximate value of the absorbance or the absorbance change per minute when C_x approaches ∞.
- K: The difference between the approximate value of absorbance or absorbance change per minute of B and reagent blank (calibrator 1).
- a, b: Constants of the formula, which will be calculated automatically.

c. Calculate concentration

$$C_X = (C + C_1) \times IFA + IFB$$

$$A_X = B + \frac{K}{1 + aC^b}$$

$$C = b\sqrt{\frac{1}{a} \times \left\{ \frac{K - (A_X - B)}{A_X - B} \right\}}$$

- C_X :The concentration of the sample.
- C_1 : The concentration of the reagent blank.
- A_X : The absorbance of the sample or its absorbance change per minute.
- K : The constant of the formula.

- IFA and IFB: Constants indicating the slope and intercept respectively.

The closer C_X approaches ∞, the closer A_X approximates B. If K＜0, $A_X \leqslant B+K$ or K＞0, $A_X \geqslant B+K$, $C_1=0$.

d. Calculate SD

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij}-A_{i}'\right)^{2}}{2N-4}}$$

(N=4～6, j=1 or 2)

A_{ij}-A_i' : the difference between the calculated absorbance A_i' by the curve fit equation and the measured A_{ij} or A_{12}. Each calibrator is measured twice and the maximum number of A_{ij} is12.

e. Applicable analysis methods
   - 1 point end-point method
   - 2 point end-point method
   - Rate method

7. Logit-log5P (Non-linearity)

It has the same characteristics as Logit-log4P. As one more calculation parameter is involved in the method, the test result is more accurate in some cases.

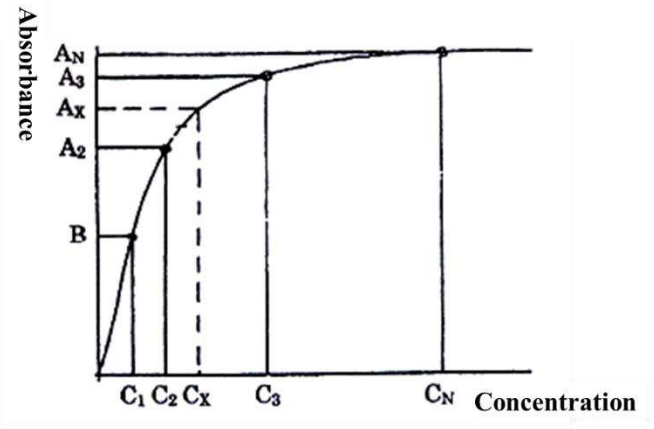


Figure 10.10 Logit-log5P (Non-linearity)

a. Enter calibration parameters
   - Calibration type: Logit-log5P
   - Calibration point: 5-6 (numbers of calibrators).
   - Span point: [0] span calibration is invalid.

b. Calculate parameters of the working curve
   - B: The approximate value of the absorbance or the absorbance change per minute when C_x approaches ∞.
   - K, a, b, c: Constants of the formula, which will be calculated automatically.

B: It is the approximate value of the absorbance or the change rate of absorbance per minute when C_x approaches ∞.

K, a, b, c: are constants of approximate formula, which will be calculated automatically.

c. Calculate concentration

$$a+b\times lnC+c\times C-ln\left\{\frac{A_X-B}{K-(A_X-B)}\right\}=0$$

Calculate C according to Newton Method.

$$C_X=(C+C_1)\times IFA+IFB$$

$$A_X=B+\frac{K}{1+\exp(-a-b\times l\,\mathrm{n}\,C-c\times C)}$$

- C_X : The concentration of the sample.
- C_1 : The concentration of the reagent blank.
- A_X : The absorbance or absorbance change per minute of the sample.
- K: The constant of the formula.
- IFA and IFB: Constants representing the slope and intercept.

The closer C_X approaches ∞, the more A_X approximates B. If K<0, AX<B or K>0, AX>B, then C=0.

d. Calculate SD

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij}-A_{i'}\right)^2}{2N-5}}$$

(N=5～6、 j=1 or 2)

A_{ij}-A_i' : the difference between the calculated absorbance A_i' by the curve fit equation and the measured A_{ij} or A_{12}. Each calibrator is measured twice and the maximum number of A_{ij} is12.

e. Applicable analysis methods
   - 1 point end-point method
   - 2 point end-point method
   - Rate method

8. Exponential Method

The curve shows a discrete distribution of the absorbance as the concentration increases. The calibration curve is shown below.

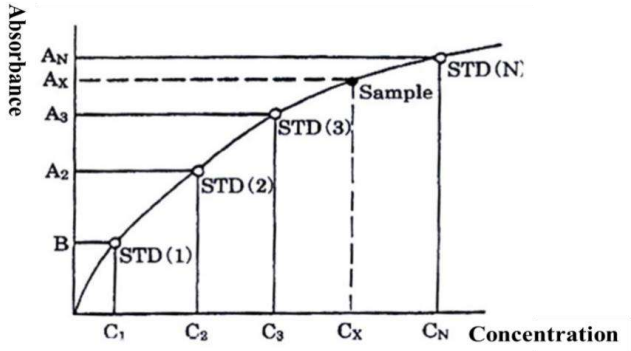


Figure 10.11 Exponential Method (Non-linearity)

a. Enter calibration parameters.
   - Calibration type: Exponential method
   - Calibration point: [5-6] (number of calibrators).
   - Span point: [0] span calibration is invalid.

b. Calculate parameters of the working curve.
- B: The approximate value of absorbance or absorbance change per minute of the reagent blank (calibrator 1).
- K, a, b, c: Constants of the formula and will be calculated automatically.

c. Calculate concentration.

$$A_X = B + K \times \exp\left\{a \times (l\,n\,C) + b \times (l\,n\,C)^2 + c \times (l\,n\,C)^3\right\}$$

$$a \times (l\,n\,C) + b \times (l\,n\,C)^2 + c \times (l\,n\,C)^3 - l\,n\left(\frac{A_X - B}{K}\right) = 0$$

Calculate C according to Newton Method.

$$C_X = (C + C_1) \times IFA + IFB$$

- C_X : The concentration of the sample.
- C_1 and C_2-C_N: the concentration of the reagent blank and calibrators.
- A_X :The absorbance or absorbance change per minute of the sample.
- IFA and IFB: Constants representing the slope and intercept.

If K>0, A_X<B, or K<0, A_X>B, C=0.

d. Calculate SD

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_{i'}\right)^2}{2N-5}}$$

(N=5～6、j=1 or 2)

A_{ij}-A_i' : The difference between the calculated absorbance A_i' by the curve fit equation and the measured A_{ij} or A_{12}. Each calibrator is measured twice and the maximum number of A_{ij} is12.

e. Applicable analysis methods
- 1 point end-point method
- 2 point end-point method
- Rate method

9. Polynomial Method

The polynomial method uses calibrators with at least three concentrations (including reagent blank).

If there are n points (x_1, y_1), (x_2, y_2) ... (x_n, y_n), the following formula will be able to define a curve connecting all n points, which is called Lagrange polynomial equation:

$$x = \sum_{i=1}^{n} x_i \prod_{j \neq i}\left(\frac{y - y_j}{y_i - y_j}\right)$$

The relationship between concentration and absorbance can be fitted by the above Lagrange polynomial equation, and the concentration can be calculated by using the following formula:

$$C_{sample} = \sum_{i=1}^{n} C_i \prod_{j \neq i}\left(\frac{A_{sample} - A_j}{A_i - A_j}\right)$$

C_{sample} = sample concentration, A_{sample} = sample absorbance, A_i = absorbance of the Calibrator i, C_i = concentration of Calibrator i.

10. Spline Method

Connect all measured absorbance of calibrator (point to point) to construct a complete curve. The measurement error is also fitted to the curve, so the fitting curve is better than the polyline. The calibration curve is shown below.

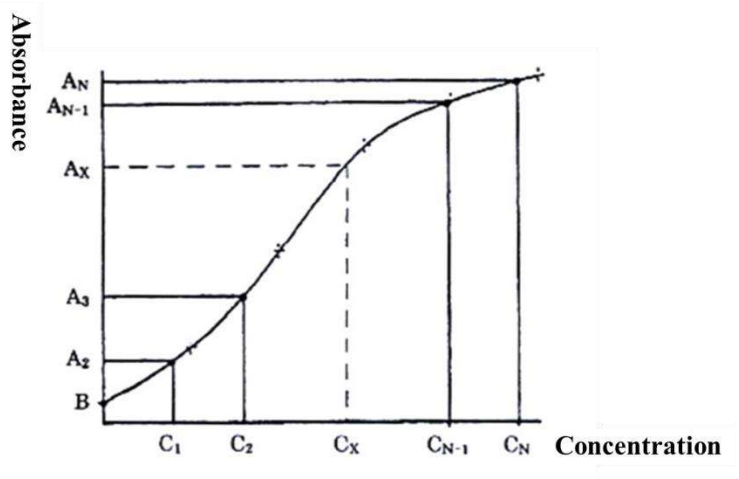


Figure 10.12 Spline (Non-linearity)

a. Enter calibration parameters.
- Calibration type: Spline.
- Calibration point: [5-6] (quantity of calibrators).
- Span Point: [0] span calibration is invalid.

b. Calculate parameters of the working curve.
- A (I), b (I), c (I), d (I): Constants of approximation formula, I = 1 - N.
- S1ABS represents a (I) (the intercept of the absorbance axis).

c. Calculate concentration

$$A_X = a(I) + b(I) \times \left(C_X - C(I) + c(\mathrm{I})\right) \times \left(C_X - C(I)^2\right) + d(\mathrm{I}) \times \left(\mathrm{C_X\text{-}C(I)}\right)^3$$

$$f \times (C_X - C(I)) = a \times (I) + b \times (I) \times (C_X - C(I)) + d \times (I) \times (C_X - C(I))^2 + d(I) \times (C_X - C(I))^3 - A_X$$

Calculate C according to Newton Methods.

$$C_X = (C + C_1) \times IFA + IFB$$

- C_X : The concentration of the sample.
- C_1-C_N : The concentration of the reagent blank and calibrators.
- A_X and A_2-A_N : The absorbance or absorbance change per minute of sample and calibrators.
- IFA and IFB: Constants representing slope and intercept respectively.

d. Calculation SD.

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_{i'}\right)^2}{2N-4}}$$

(N=5～6、 j=1 or 2)

A_{ij}-A_i' : The difference between the calculated absorbance A_i' by the curve fit equation and the measured A_{ij} or A_{12}. Each calibrator is measured twice and the maximum number of A_{ij} is12.

e. Applicable analysis methods
- 1 point end-point method
- 2 point end-point method
- Rate method

11. Parabola Method

The calibration curve is a parabola. Minimum number of required calibrators: Poly1 requires at least two calibrators (including reagent blank); Poly2, Poly3, Poly4 calibration curves require at least 3-5 calibrators (including reagent blank).

Calculation formula:

Calibration Curve	Fitting Equation
Poly2	$Cs=a+bAs+cAs^2$

where C_s = sample concentration, A_s = sample absorbance, a, b, c are coefficients obtained by matrix method.

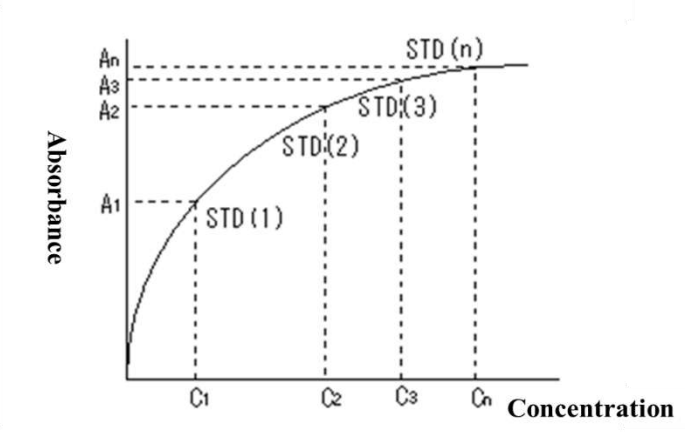


Figure 10.13 Poly2 Curve

10.4 Calibration Results

Select **Result Query** →**Calibration Results**, and the system displays **Calibration Results** window as shown below. You can view and manage the calibration results.

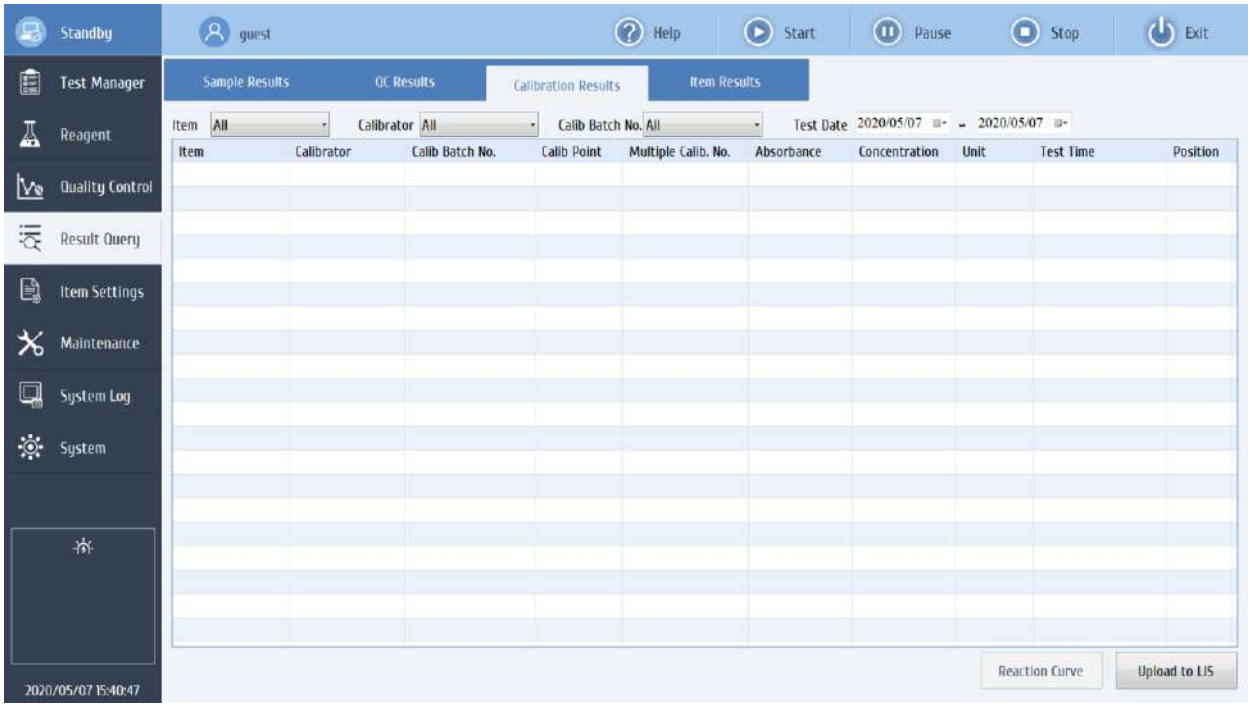


Figure 10.14 Calibration Results Window

Filter Area

Use the system-defined filters to display the calibration results you want to view. See the available filters in the following table. You can select one or more filters to search results.

Item	(List) Select the test item to filter results.
Calibrator	(List) Select calibrator name to filter results.
Calib Batch No.	(List) Select the calibrator batch No. to filter results.
Test Date	(List) Select calibration time period to filter results.

Result List

Item	(Column) Display the name of the test item.
Calibrator	(Column) Display the calibrator name.
Calib Batch No.	(Column) Display the batch number of the calibrator.
Calib Point	(Column) Display the calibration points.
Multiple Calib No.	(Column) Display sequence No. of multiple calibrations.
Absorbance	(Column) Display the calibrator absorbance.
Concentration	(Column) Display the calibrator concentration.
Unit	(Column) Display the concentration unit.
Test Time	(Column) Display calibration time (year/month/day: min: sec)
Position	(Column) Display the calibrator position on the tray.

Function Buttons

Reaction Curve	(Button) Select to view calibration curve.
Upload to LIS	(Button) Select to transmit calibration results to LIS.

11. Quality Control

Select **Quality Control** on the main menu list to manage controls and review L-J chart.

11.1 Controls

Select **Quality Control** →**Controls**, and the system displays the **Controls** window as shown in below.

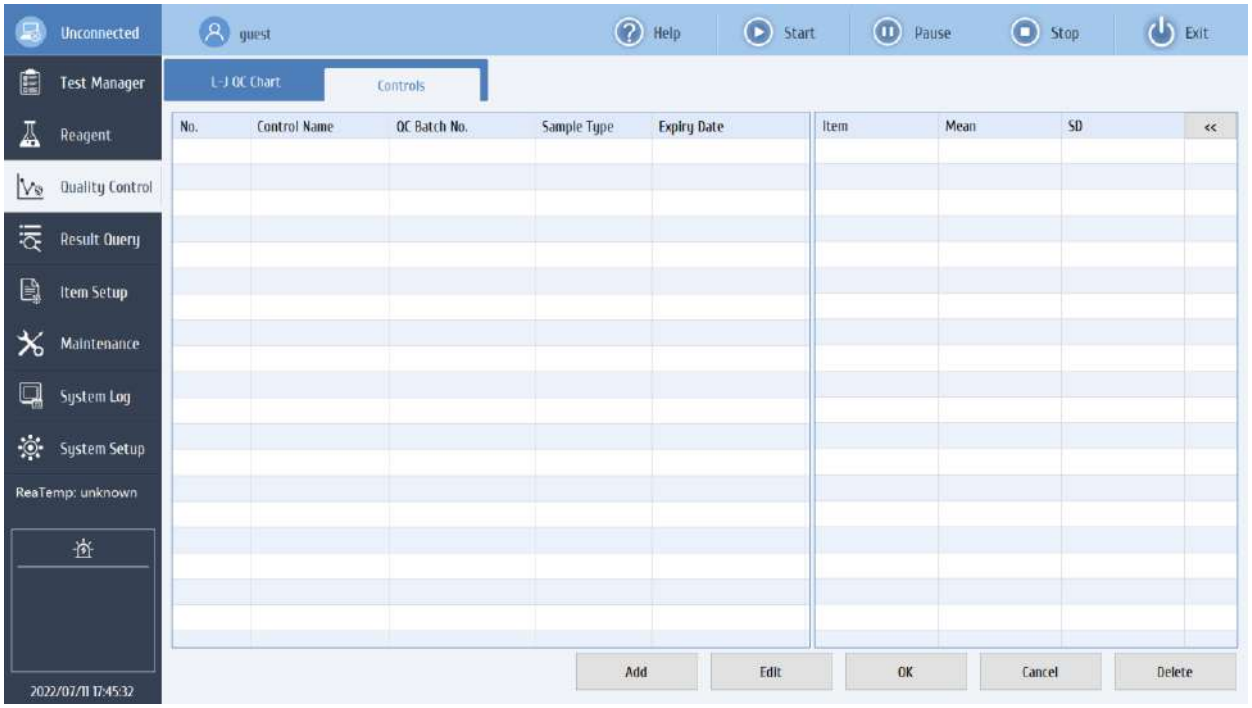


Figure 11.1 Controls Window

No.	(Column) Display the sequence No.
Control Name	(Column) Display the control name.
QC Batch No.	(Column) Display the QC batch No.
Sample Type	(Column) Display the calibrator type.
Expiry Date	(Column) Display the time when the calibrator expires.
Item	(Column) Display the test item of the calibrator.
Mean	(Column) Display the mean of the test item.
SD	(Column) Display the SD of the test item.
<<	(Icon) Select to display more test items.
Add	(Button) Add new control.
Edit	(Button) Edit the selected control information.
OK	(Button) Save the current control information.
Cancel	(Button) Cancel the operation.
Delete	(Button) Delete the selected control information.

Adding Controls:

1. Select **Quality Control**→ **Controls**.
2. Select **Add** and enter control information.
3. Select the test item for the control and enter the **Mean** and **SD**.

- If it is a multi-control, click << to add more test items.

4. Select **OK** to save changes.

11.2 QC Results

Select **Result Query** → **QC Results**, and the system displays **QC Results** window as below.

You can review QC results, view QC curve and upload QC results to LIS.

Select Result Query → QC Results, and the system displays QC Results windows as below. You can view QC charts with Westgard multi-rule, Levy-Jennings, twin plot and cumulative sum check.

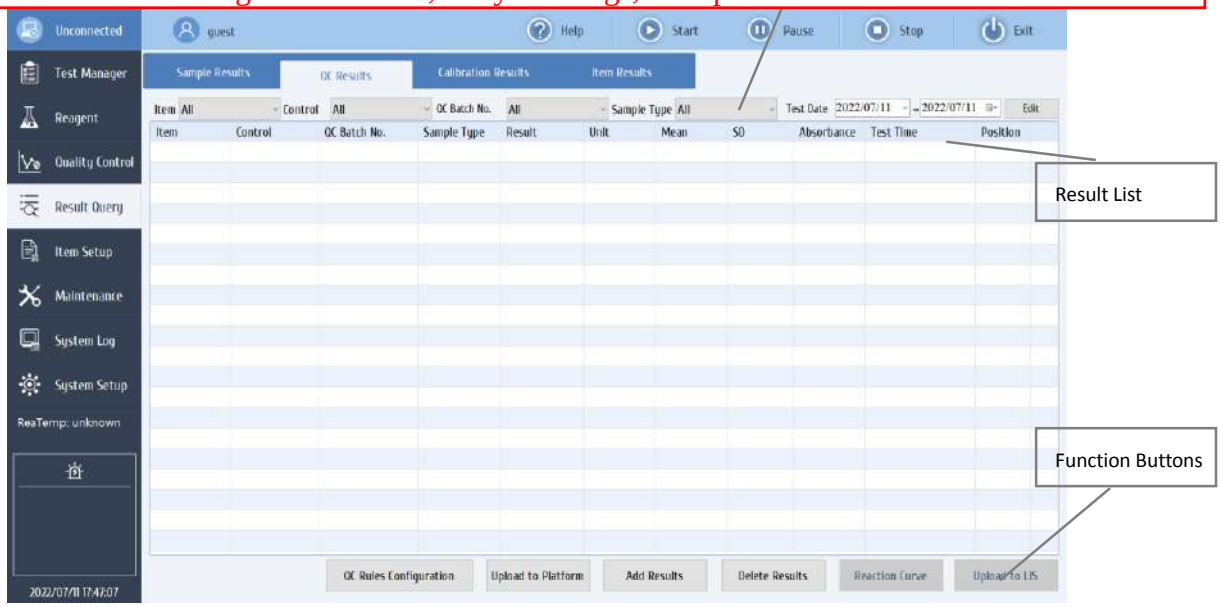


Figure 11.2 QC Results Window

Filter Area

Use the system-defined filters to display the QC results you want to view. See the available filters in the following table. You can select one or more filters to search results.

Item	(List) Select the test item to filter results.
Control	(List) Select control name to filter results.
QC Batch No.	(List) Select the control batch No. to filter results.
Sample Type	(List) Select the sample type to filter results.
Test Date	(List) Select QC time period to filter results.

Result List

Item	(Column) Display the name of the test item.
Controls	(Column) Display the control name.
QC Batch No.	(Column) Display the batch number of the control.
Sample Type	(Column) Display the sample type.
Result	(Column) Display the measured concentration.
Unit	(Column) Display the concentration unit.
Mean	(Column) Display the mean value.

SD	(Column) Display the standard deviation.
Absorbance	(Column) Display the measured absorbance.
Test Time	(Column) Display the QC time.
Position	(Column) Display the control position on the tray.

Function Buttons

QC Rules Configuration	Select to set QC rules.
Upload to Platform	Select to upload the chosen results to the platform.
Add Results	Select to add new QC results.
Delete Results	Select to delete the chosen QC results.
Reaction Curve	Select to view QC curve.
Upload to LIS	Select to transmit QC results to LIS.
Edit	Select to edit QC results.

11.3 L-J QC Chart

Select **Quality Control** → **L-J QC Chart**, and the system displays **L-J QC Chart** window as below.
You can review Levey-Jennings QC chart of a period of time.

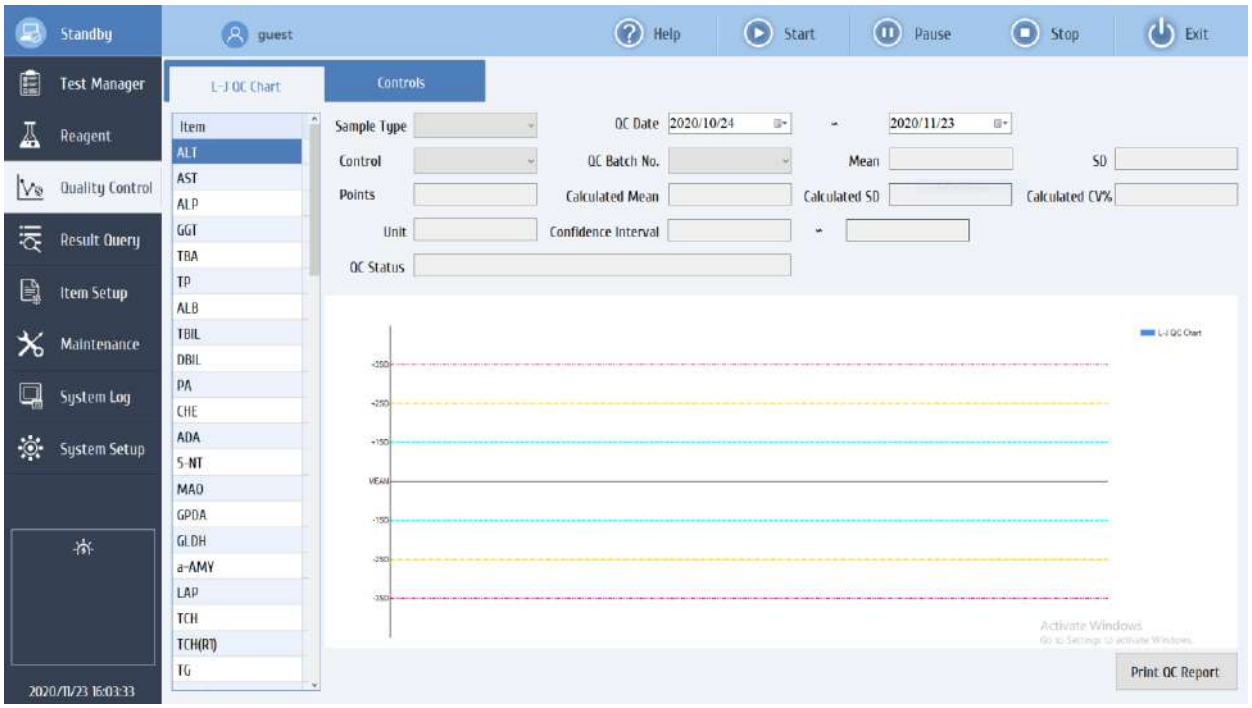


Figure 11.3 L-J QC Chart Window

Item	(Column) Select the test item.
Sample Type	(List) Select the sample type.
QC Date	(Field) Select a time period to see QC chart.
Control	(List) Select the control name.
QC Batch No.	(List) Select the control batch No.
Mean	(List) Display the stated mean of the control.
SD	(Field) Display the stated SD standard deviation (SD) of the control.
Points	(Field) Display the number of points within the chosen time period.

(Field) Select and customize a time period to see QC chart and QC alert.

Calculated Mean	(Field) Display the calculated mean of the points within the chosen time period.
Calculated SD	(Field) Display the calculated standard deviation (SD) of the points within the chosen time period.
Calculated CV%	(Field) Display the calculated coefficient of variation (CV%) of the points within the date range.
Unit	(Field) Display the concentration unit.
Confidence Interval	(Field) Display the value range under control.
QC Status	(Field) Display QC status.
L-J QC Chart	(Chart) Display a graphic representation of QC results. The X-axis displays the number of QC points, and the Y-axis displays the 7 y-axis coordinates to mark the mean, 1, 2, and 3 SDs above and below the mean.

12. Item Setup

On the **Item Setup** window, you can:

- Setup test items.
- Edit calculation item.
- Add profile.
- Set carry-over parameters.

12.1 Biochemistry Item

Select **Item Setup** → **Biochemistry Item**, and the system displays **Biochemistry Item** Window as below.

On this window, you can:

- Add/delete test items.
- Set and modify item parameters.

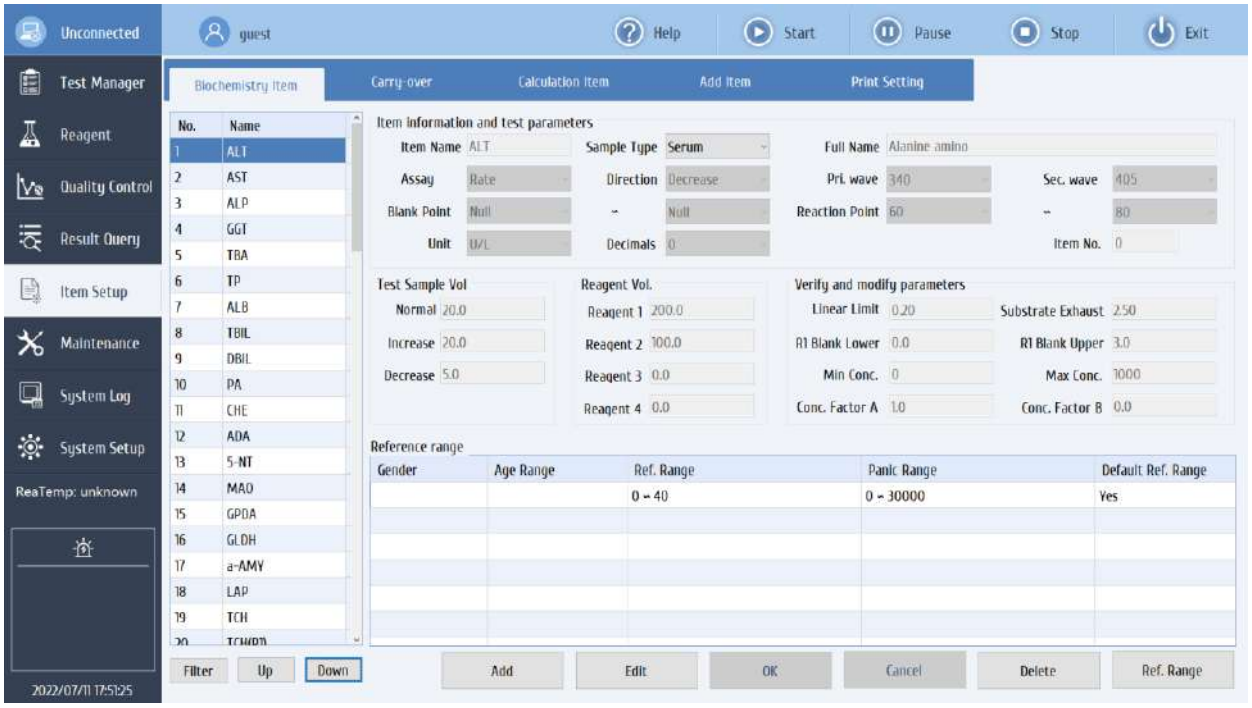


Figure 12.1 Biochemistry Item Window

Note

Refer to reagent package insert to setup reagent parameters.

Item information and test parameters:

Item Name	(Field) Display test item name.
Sample Type	(List) Display sample type.
Full Name	(Field) Display the full name of the test item.
Assay	(List) Select the test assay from the followings: • End-point method • Rate method • Fixed time See **Reaction Assay** for more information.

Direction	(List) Select the response direction: • Positive: the absorbance increases by time. • Negative: the absorbance decreases by time.
Pri-wave / Sec-wave	(List) Select from 12 wavelengths (340, 380, 405, 450, 505, 546, 578, 600, 660, 700, 750 and 800 nm). • For dual-wavelength test, the final absorbance is the absorbance of the primary wavelength minus the absorbance of the secondary wavelength. • For single-wavelength test, enter '0' in the **Sec-wave** field.
Blank Point	(List) Select blank points.
Reaction Point	(List) Select reaction points. The absorbance is measured every 9 seconds. There are 82 measuring points with the 12.3 minutes total reaction time. The 1st point is the R1 blank point, and the 50th point is the first measuring point after R 2 is added.
Unit	(List) Select the concentration unit.
Decimals	(List) Select the decimal places.
Item No.	(Field) Enter the Item No.
Test Sample Vol	(Field) Enter sample volume: • Normal • Increase • Decrease
Reagent Vol	(Field) Enter reagent volume according to the reagent package insert: • Reagent 1 • Reagent 2 • Reagent 3 • Reagent 4 The volume of reagent 1 is set between 10 µL and 450 µL while the volume of the reagent 2 is set at 0 or 10-450 µL (for single reagent tests, the volume of reagent 2 is '0').
Verify and Modify Parameters	(Field) Enter the liner limit, substrate exhaust, R1 blank lower and upper limit, min and max concentration and concentration factor A and B.
Linear Limit	(Field) Enter the value limit of the test item according to the reagent package insert and the instrument performance. If the test result is out of the limit, it will be flagged with Lin.H or Lin.L. If an automatic re-test is set, the system will repeat test with **Increase** volume or **Decrease** volume.
Substrate Exhaust	(Field) Enter the absorbance limit in the rate method. It refers to the upper limit in the positive response direction and refers to the lower limit in the negative direction. High activity of enzyme in the reaction process may lead to substrate depletion, thus causing the abnormally low even negative value. If the absorbance is beyond the limit, the result will be flagged with **AbsLim**. If automatic res-test is set, the system will repeat test with **Decrease** volume.
R1 Blank Lower/ R1 Blank Upper	(Field) Enter the R1 blank lower limit and upper limit according to the reagent instruction. If the reagent blank value exceeds the limit, it indicates that the reagent is out of validity.
Min Conc./ Max Conc.	(Field) Enter the maximum concentration and minimum concentration of the test

	item.
Conc. Factor A/ Conc. Factor B	(Field) Enter concentration factor A and concentration factor B.

Reference Range

Gender	(Field) Display patient gender.
Age Range	(Field) Display patient age range.
Ref. Range	(Field) Display reference range.
Panic Range	(Field) Display the panic range.
Default Ref. Range	(Field) Display whether it is the default reference range.

Function Buttons

Up	(Button) Select to move up to view the test item.
Down	(Button) Select to move down to view the test item.
Filter	(Button) Select to filter the test items.
Add	(Button) Select to add a new item.
Edit	(Button) Select to edit the selected item.
OK	(Button) Select to save the changes you have made.
Cancel	(Button) Select to cancel changes you have made.
Delete	(Button) Select to delete the selected item.
Ref. Range	(Button) Select to edit the reference range of the selected test item.

Reaction Assay

1. End point method

After adding sample and reagents, the absorbance is measured at a specified point to obtain the concentration of the sample (when the absorbance increases until it reaches a stable value). The endpoint method includes one-point endpoint method and two-point endpoint method.

One-point endpoint method: Reaction measuring point L = M, and reaction absorbance formula is:

$$\text{ReactionOD} = \frac{OD_L + OD_{L-1}}{2}$$

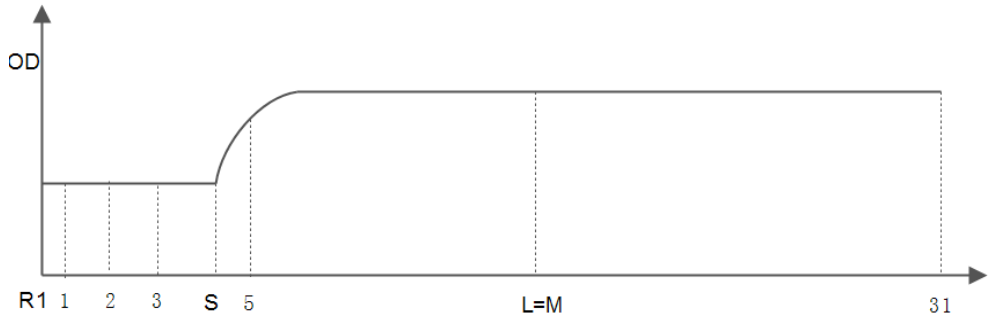


Figure 12.2 Reaction Curve of One-point Endpoint Method

2-point endpoint method: Reaction measuring point L < M, and reaction absorbance formula is:

$$\text{ReactionOD} = \frac{OD_M + OD_{M-1}}{2} - K \times \frac{OD_L + OD_{L-1}}{2}$$

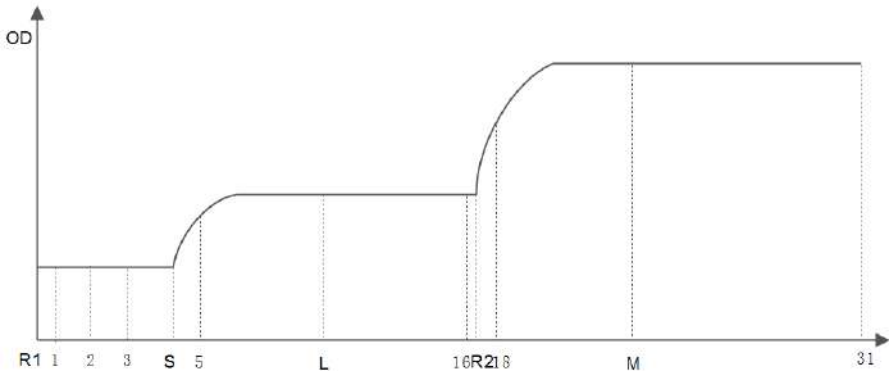


Figure 12.3 Reaction Curve of Two-point Endpoint Method

K is the volume calibrate coefficient. The specific calculation is as follows:

$$K_1 = \frac{V_{R1}}{V_{R1} + V_s}$$

$$K_2 = \frac{V_{R1} + V_s}{V_{R1} + V_s + V_{R2}}$$

$$K_3 = \frac{V_{R1} + V_s + V_{R2}}{V_{R1} + V_s + V_{R2} + V_{R3}}$$

$$K_4 = \frac{V_{R1} + V_s + V_{R2} + V_{R3}}{V_{R1} + V_s + V_{R2} + V_{R3} + V_{R4}}$$

Table 12.1 K Value of End point Method

Reagent Number	Blank Measuring Point	Reaction Measuring Point	K
No Blank Measuring Point			
1 Reagent	$5 \le L = M$	$L = M \le 31$	0
2 Reagents	$18 \le L = M$	$L = M \le 31$	0
3 Reagents	$36 \le L = M$	$L = M \le 62$	0
4 Reagents	$49 \le L = M$	$L = M \le 62$	0
Blank Measuring Point is after Reaction			
1 Reagent	$5 \le L < M$	$L < M \le 31$	1
2 Reagents	$18 \le L < M$	$L < M \le 31$	1
3 Reagents	$36 \le L < M$	$L < M \le 62$	1
4 Reagents	$49 \le L < M$	$L < M \le 62$	1
Blank Measuring Point is before Reaction			
1 Reagent	$1 \le L < 5$	$5 \le M \le 31$	K_1
2 Reagents	$5 \le L \le 16$	$18 \le M \le 31$	K_2
3 Reagents	$18 \le L \le 31$	$36 \le M \le 62$	K_3
4 Reagents	$36 \le L \le 47$	$49 \le M \le 62$	K_4

2. Rate Method

Calculate the concentration or activity by measuring the absorbance change between points over period of specified time during the progress of the reaction.

The calculation formula is as follows:

$\text{ReactionOD} = \Delta\text{OD}(\text{M} - \text{L}) - \text{K} \times \Delta\text{OD}(\text{P} - \text{N})$

$\Delta\text{OD}(\text{M} - \text{L})$ is the absorbance change per minute between L and M with least square method.

$\Delta\text{OD}(\text{N} - \text{P})$ is the absorbance change between N and P with least square method.

K is the volume calibration coefficient and it is calculated in the same way as the end point method.

Table 12.2 K Value of Rate Method

Reagent Number	Blank Measuring Point	Reaction Measuring Point	K
Blank Measuring Point is before Reaction			
1 Reagent	$1 \le N < P < 5$	$5 \le L < M \le 31$	K_1
2 Reagents	$5 \le N < P \le 16$	$18 \le L < M \le 31$	K_2
3 Reagents	$18 \le N < P \le 31$	$36 \le L < M \le 62$	K_3
4 Reagents	$36 \le N < P \le 47$	$49 \le L < M \le 62$	K_4
No Blank Measuring Point			
1 Reagent	$N = P = 0$	$5 \le L < M \le 31$	0
2 Reagents	$N = P = 0$	$18 \le L < M \le 31$	0
3 Reagents	$N = P = 0$	$36 \le L < M \le 62$	0
4 Reagents	$N = P = 0$	$49 \le L < M \le 62$	0

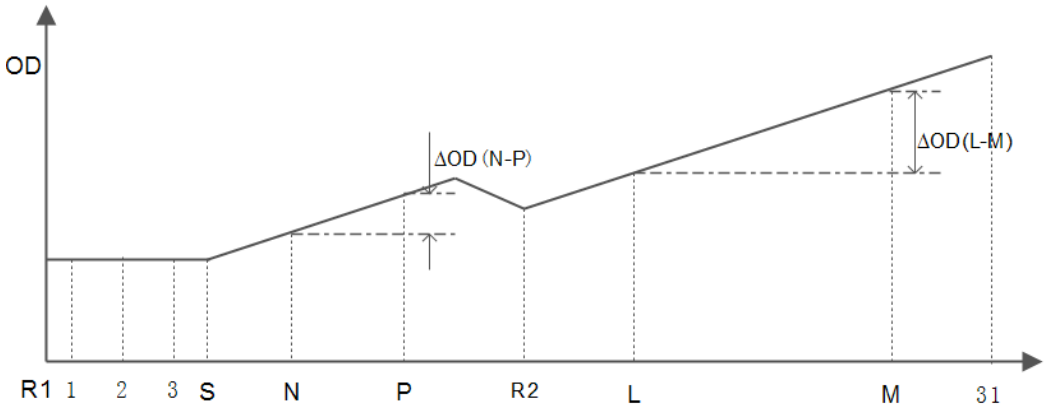


Figure 12.4 Reaction Curve of Rate Method

3. Fixed-time Method

Fixed-time method is a method for calculating the absorbance change between two points.

The formula for calculating OD is as follows:

$$\text{ReactionOD} = \left(\frac{OD_M - OD_L}{t_M - t_L} - K \times \frac{OD_P - OD_N}{t_P - t_N}\right) * 60$$

The K value in the fixed time method is calculated in the same way as in the rate method.

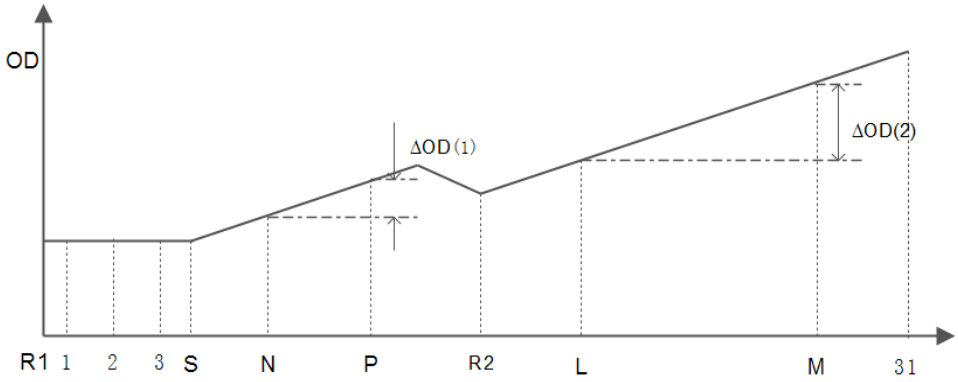


Figure 12.5 Reaction Curve of Fixed-time Method

12.2 Calculation Item

Select **Item Setup** → **Calculation Item**, and the system displays the **Calculation Item** window as below. You can select test items and set up calculation formulas.

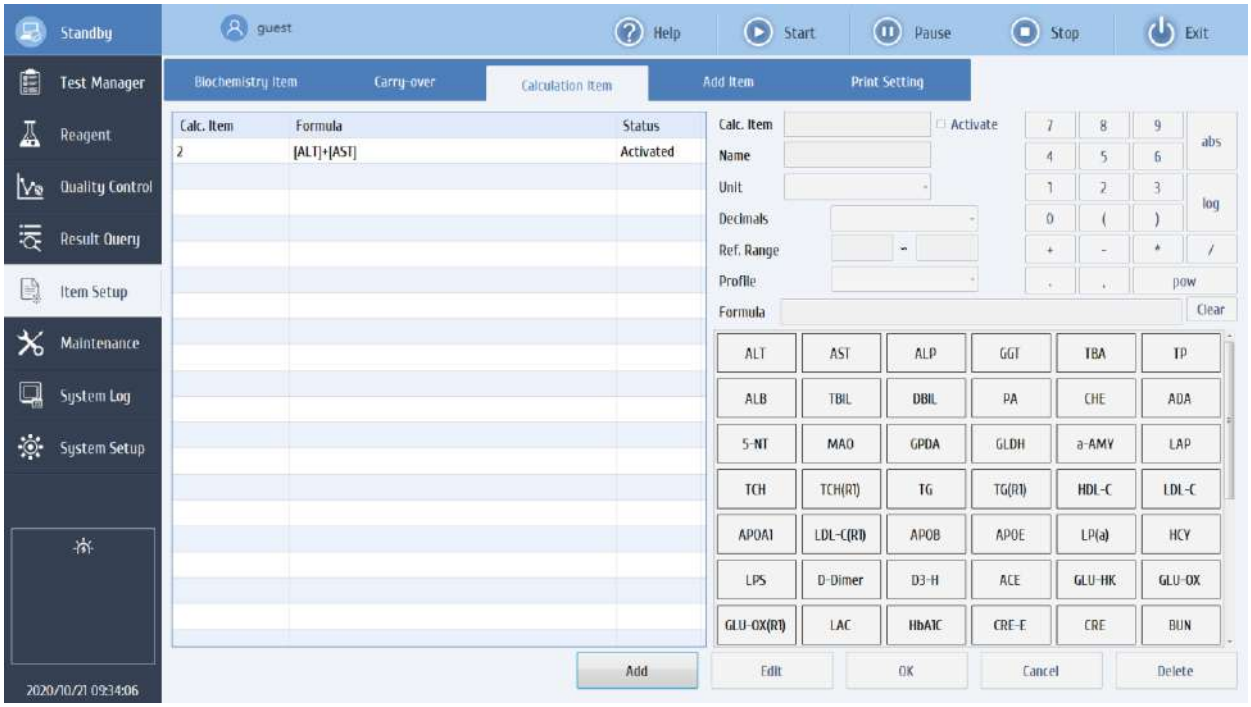


Figure 12.6 Calculation Item Window

Calc. Item	(Column) Display the name of the calculation item.
Formula	(Column) Display the calculation formula.
Status	(Column) Display the status of the calculation item.

Calc. Item	(Field) Enter English abbreviations of the calculation item and check “activate” on the right.
Name	(Field) Enter the full name of the calculation item.
Unit	(List) Select the unit of measurement for a test.
Decimals	(List) Select decimal places for results.
Ref. Range	(Field) Reference range of values of test results
Profile	(List) Select the test profile.
Formula	(Field) Enter the calculation formula.

Function Buttons

Add	(Button) Add a new calculation item.
Edit	(Button) Edit the chosen calculation item.
OK	(Button) Save changes.
Cancel	(Button) Cancel the current changes.
Delete	(Button) Delete to remove the selected calculation item.

Add a Calculation Item:

1. Select **Add.**
2. Enter the following information:
   - Calc. Item
   - Name
   - Unit
   - Decimal
   - Ref. Range
   - Profile
3. Set the test item involved in the calculation, and set the constant and formula in the **Formula** filed.
4. Click **OK** to save changes.

12.3 Carry-over

To avoid carry-over, the system provides a carry-over prevention program. You can set carry-over parameters for test items, and then an extra washing cycle will be added between two test items.

Select **Item Setup** → **Carryover**, the system displays the **Carryover** window as below. You can set up carry -over prevention for the following parts:

- Sample probe
- Reagent probe
- Reaction cup

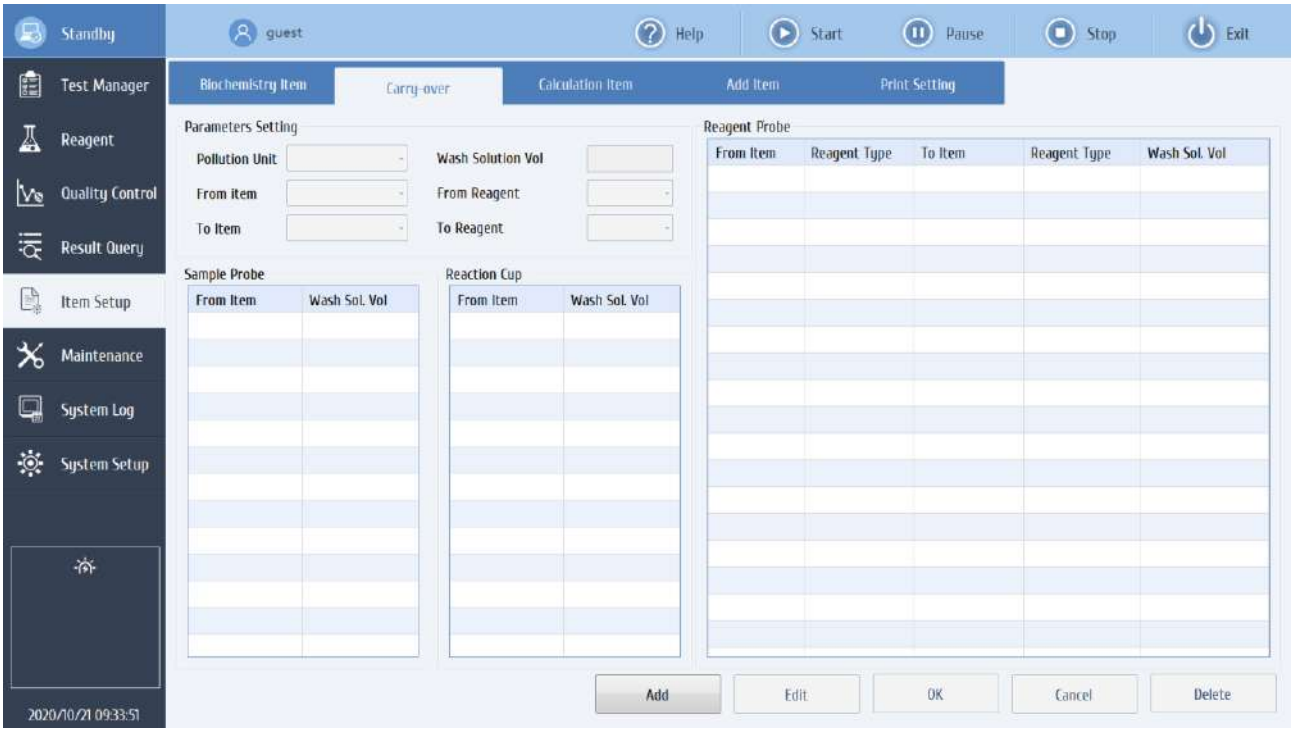


Figure 12.7 Carry-over Window

Pollution Unit	(List) Select the component to set carry-over parameters: • Reagent probe • Sample probe • Reaction cup
Wash Solution Vol:	(Field) Enter wash solution volume.
From Item	(List) Select the source contamination.
To Item	(List) Select the contaminated item.
From Reagent	(List) Select the source contamination.
To Reagent	(List) Select the contaminated reagents.
Reagent Type	(Colum) Display the reagent type.
Add	(Button) Set up carry-over prevention parameters.
Edit	(Button) Edit carry-over parameters.
OK	(Button) Save changes.
Cancel	(Button) Cancel changes.
Delete	(Button) Delete the selected carry-over item.

12.4 Adding Test Item

Select **Item Setup** → **Add Item**, and the system displays the **Add Item** window as below. You can add new test items.

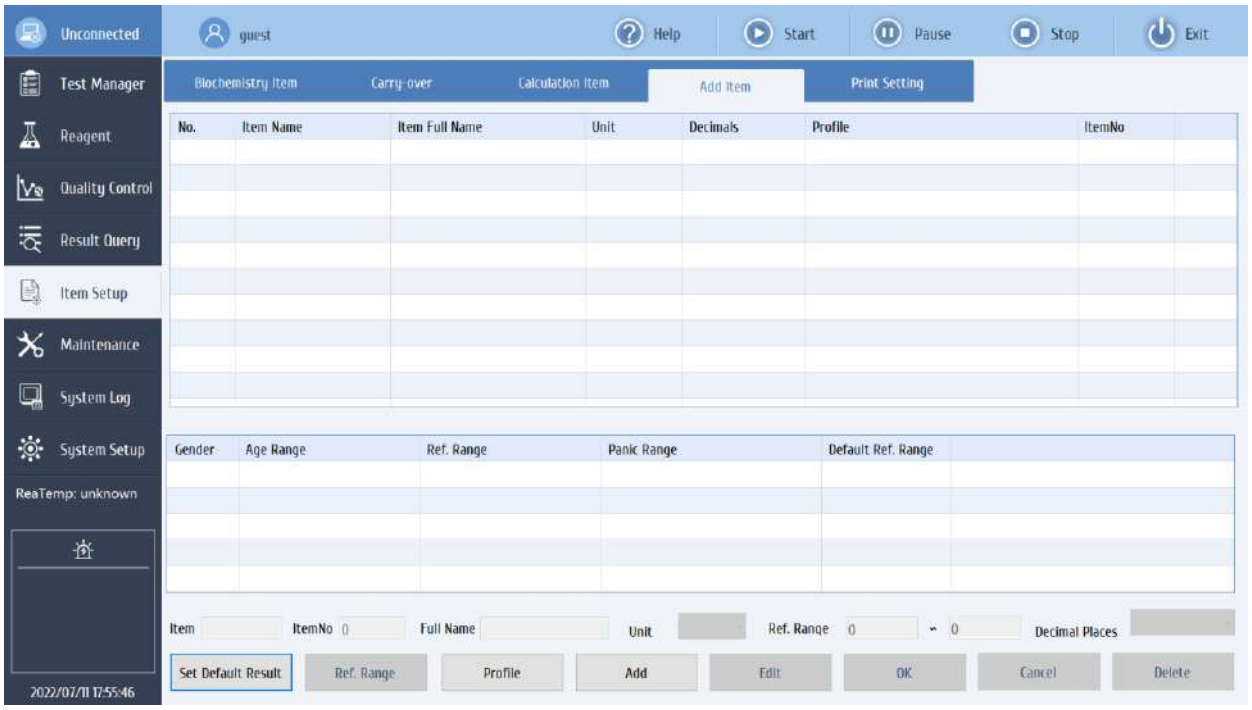


Figure 12.8 Add Item Window

No.	(List) Display the sequence No. of the test item.
Item Name	(List) Display the item name.
Item Full Name	(List) Display the full name of the test item.
Unit	(List) Display the unit of measurement for a test.
Decimals	(List) Display decimal places for results.
Profile	(Colum) Display the profile which the test item is included in.
ItemNo	(Colum) Display the item number.
Gender	(Colum) Display the patient gender.
Age Range	(Colum) Display the age range.
Ref. Range	(List) Display the reference range.
Panic Range	(Colum) Display the critical range.
Default Ref. Range	(Colum) Display the default reference range.
Set Default Range	(Button) Click to set default reference range.
Ref. Range	(Button) Click to set the reference range.
Profile	(Button) Create a new profile.
Add	(Button) Add a new item.
Edit	(Button) Edit the selected test item.
OK	(Button) Save the current added/edited item information.
Cancel	(Button) Cancel the operation.
Delete	(Button) Delete the selected item.

12.5 Print Settings

Select **Item Setup** → **Print Setting**, and the system displays the **Print Setting** window as below.

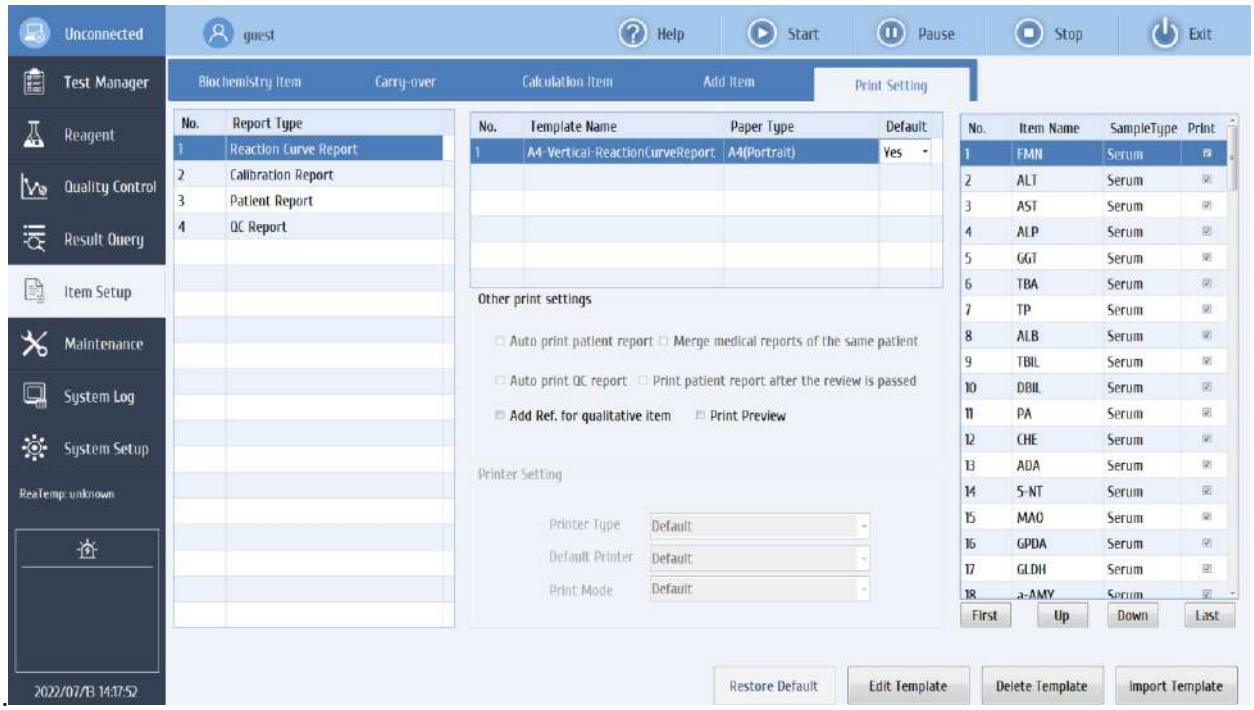


Figure 12.9 Print Setting Window

Report Type List

No.	(Column) Display the sequence No. of the report type.
Report Type	(Column) Display the report type, including: • Calibration report • Patient report • QC report • Reaction curve report

Template List

No.	(Column) Display the sequence No. of the template.
Template Name	(Column) Display the template type.
Paper Type	(Column) Display the paper size.
Default	(Column) Select to set default setting.

Item List

No.	(Column) Display the sequence No. of the test item.
Item Name	(Column) Display the name of the test item.
Sample Type	(Column) Display the sample type.
Print	(Box) Select to print the test item.
First	(Button) Select to move the chosen item to the top.
Last	(Button) Select to move the selected item to the bottom.
Up	(Button) Select to move up the chosen item.
Down	(Button) Select to move down the chosen item.

Other Print Settings

Auto print patient report	(Box) Select to print the patient report automatically.
Auto print QC report	(Box) Select to print the QC report automatically.
Add Ref. for qualitative item	(Box) Select to add reference range for qualitative items.
Merge medical reports of the same patient	(Box) Select to merge medical reports of the same patient automatically.
Print patient report after the review is passed.	(Box) Select to print the patient report automatically after the report is approved.
Print Preview	(Box) Select to preview the report to be printed.

Printer Setting

Printer Type	Select the printer type.
Default Printer	Select the default printer.
Printer Mode	Select the printer mode.

Function Buttons

Restore Default	(Button) Select to restore the selected template to default setting.
Edit Template	(Button) Edit the selected template.
Delete Template	(Button) Delete the selected template.
Import Template	(Button) Import template.

12.6 ISE Settings (Optional)

The system can also perform ISE test to detect concentration of K+, Na+, Ca+, Cl- in body fluids.

The sample types in ISE test include serum and urine and the sample type is serum by default.

Sample type	Select the sample type: • Serum (by default) • Urine If the sample type is neither serum or urine, then the item parameters of serum will be used in the ISE test. Parameters of ISE test can be edited re-configured.
Item	Test item of ISE.
Decimal places	Display the decimal places of the test value.
Item unit	Display the unit of item.
Age range	Set the age range with the unit of year/month.
Reference range	Set the reference value range of the test results.
Critical range	The critical range of the item.

13. System Setup

Select **System Setup** in the main menu list, the system displays the **System Setup** window as below.
With this window, you can:

- Perform remote control.
- Upgrade firmware.
- View version information
- Set up hospital information.
- Set up user accounts.
- Set profile.
- View system log.

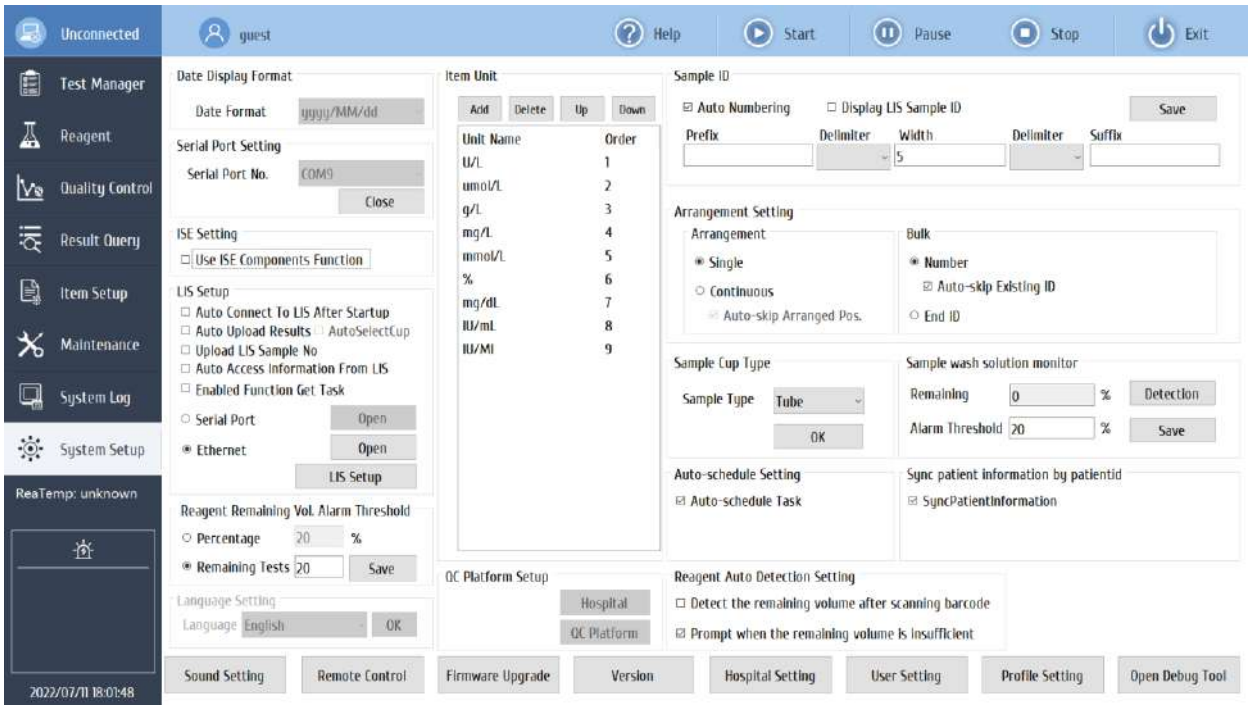


Figure 13.1 System Setup Window

13.1 Remote Control

On the **System Setup** window, select **Remote Control** to enter the IP address and perform remote control.

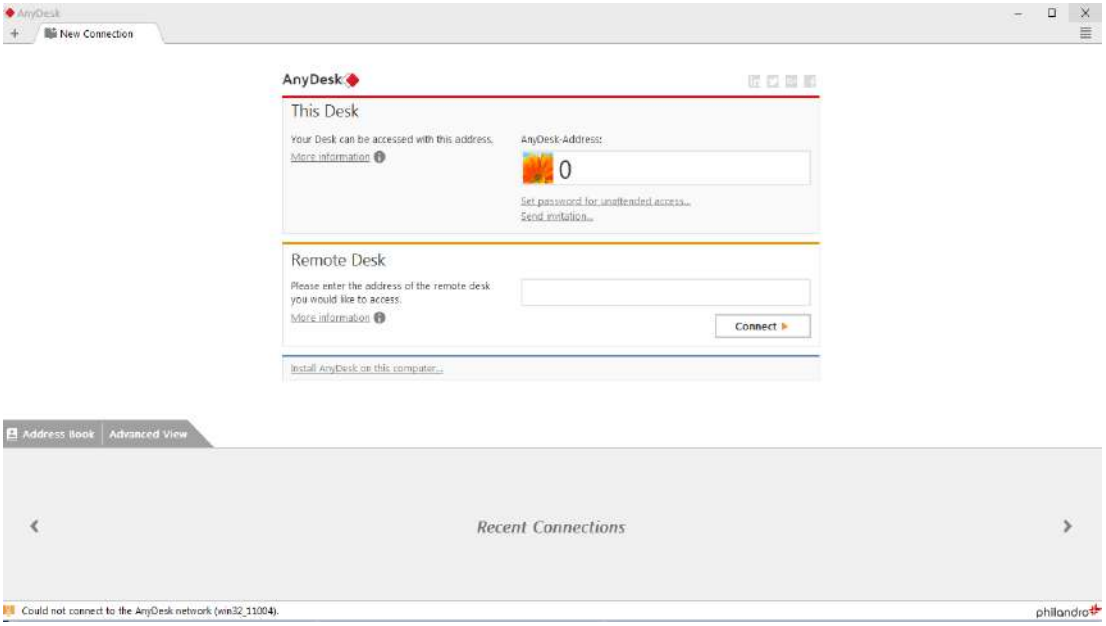


Figure 13.2 Remote Control Window

13.2 Firmware Upgrade

On the **System Setup** window, select **Firmware Upgrade** to upload the upgrade package.

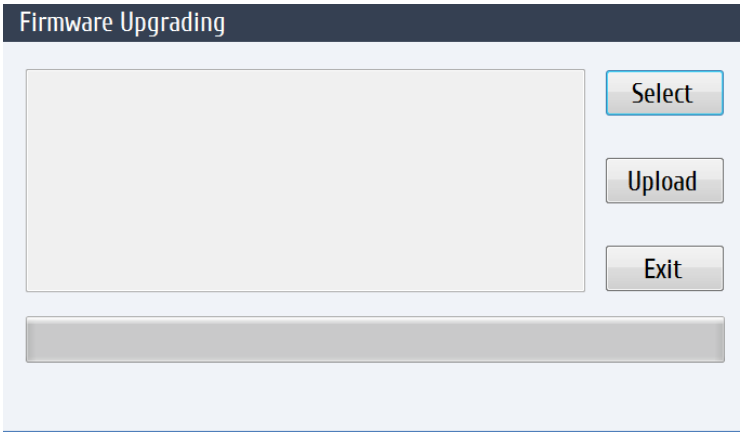


Figure 13.3 Firmware Upgrade Window

13.3 Version Information

On the **System Setup** window, Select **Version Info** to view the version information of each component of the analyzer.

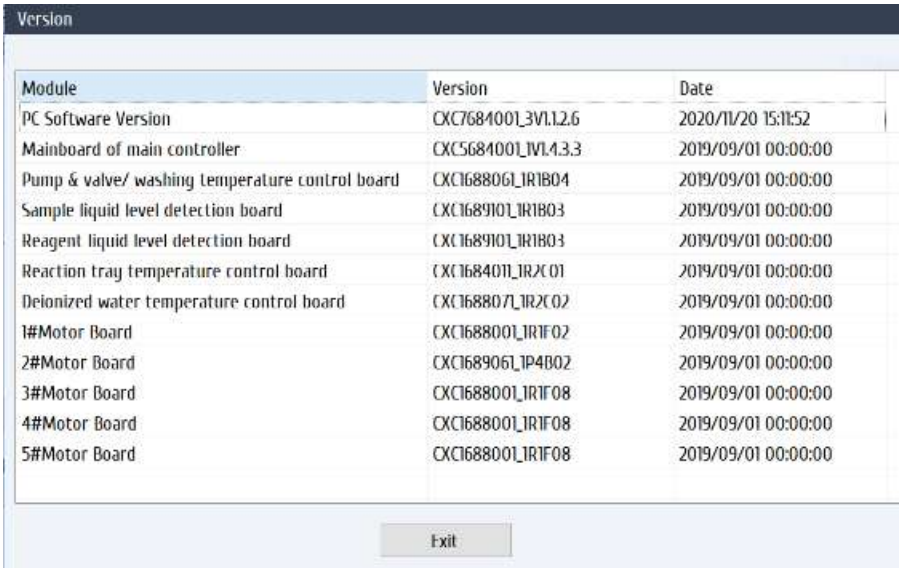


Figure 13.4 Version Info Window

13.4 Hospital Setting

On the **System Setup** window, select **Hospital Setting**, the system displays **Hospital Setting** as below. You can use this window to manage hospital information.

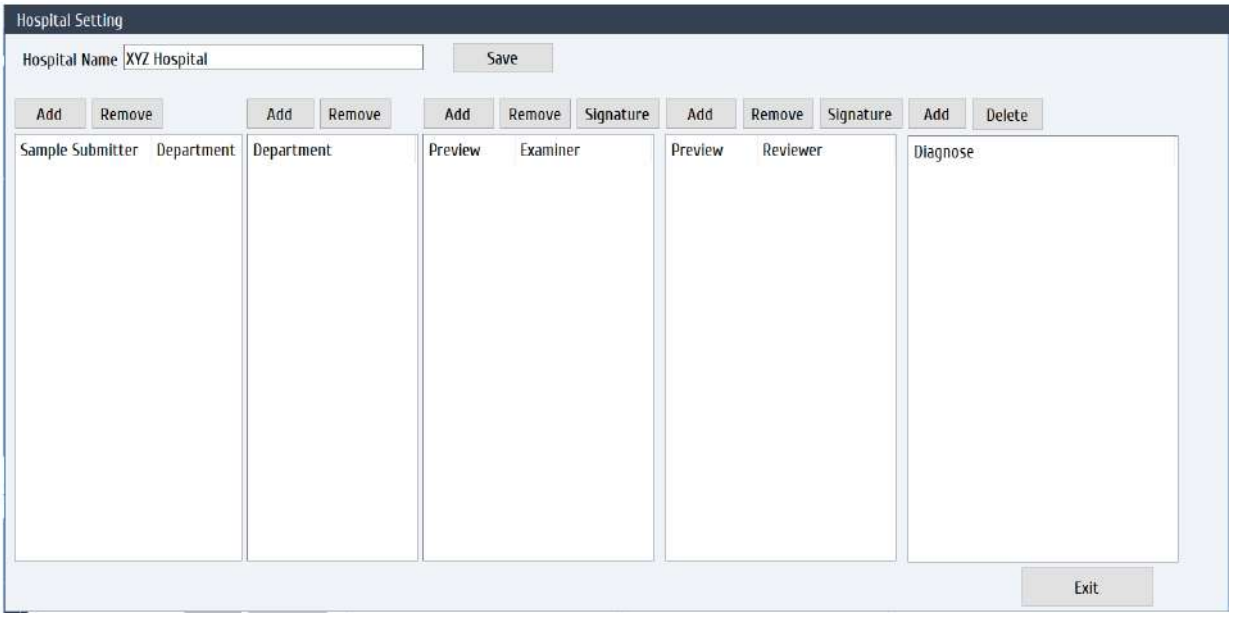


Figure 13.5 Hospital Setting Window

Add	(Button) Select to enter the name in the text field and press **Enter** key to save the change.
Delete	(Button) Select to delete the selected name.
Remove	(Button) Select to remove the selected name.
Signature	(Button) Select to insert electronic signatures of the selected examiner/reviewer.

13.5 User Setting

On the **System Setup** window, select **User Setting** to display the **User Setting** window as below.

Figure 13.6 User Setting Window

Add	(Button) Select to add a new user account.
Edit	(Button) Select to edit the selected user account.
OK	(Button) Select to save changes.
Cancel	(Button) Select to cancel changes.
Delete	(Button) Select to delete the selected user account.
Exit	(Button) Select to exit the current window.

13.6 Profile Setting

On the **System Setup** window, select **Profile Setting** to display the **Profile Setting** window.
You can add, edit or delete profiles with this window.

Figure 13.7 Profile Setting Window

Profile	(Field) Display the profile name.
Save	(Button) Save changes to the profile
Delete	(Button) Delete the selected profile.
Exit	(Button) Exit the current window.

Adding a New Profile

1. Select a blank item box.
2. Enter the profile name in the name filed.
3. Click the existing individual test items below to add them into the profile.
4. Click **Save** to save changes.

13.7 System Log

Select **System Log**, the system displays the **System Log** Window as below. With this window, you can:

- Review and filter system alarm logs.
- Refresh and print system logs.

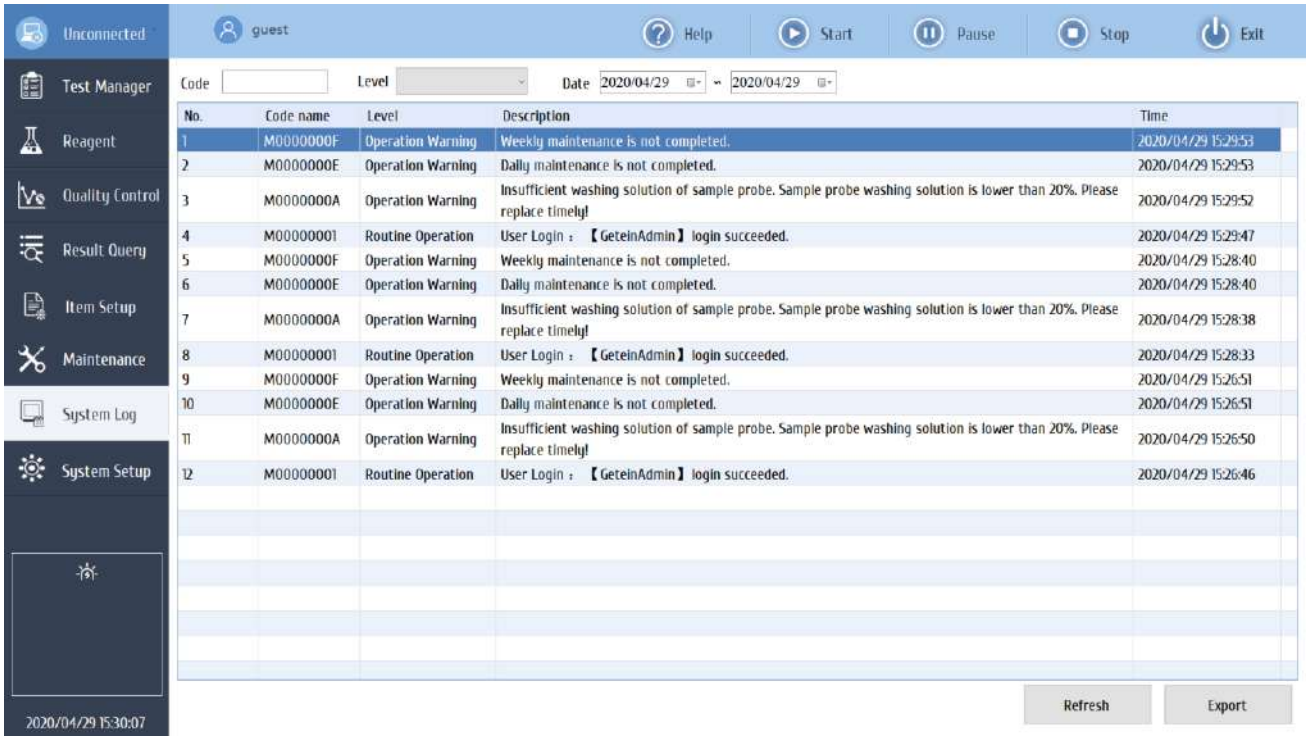


Figure 13.8 System Log Window

Filter Area

If you use the system-defined filters, and the system will display the system alarms you want to view. See the available filters in the following table. You can select one or more filters to search.

Code	(Field) Filter system alarms based on the code name.
Level	(Field) Select the alarm level to filter results.
Date	(Field) Select time period to select alarms.

Function Buttons

Refresh	(Button) Select to refresh the system log.
Export	(Button) Select the system log in tabular format.

14.Maintenance

14.1 Overview

To ensure the optimal performance of the system, users should operate and maintain the analyzer in strict accordance with the requirements in this manual.

For problems you can't solve during operation and maintenance issues not covered in this chapter, contact the customer service department of Getein Biotech Co., Ltd. or your local distributors timely.

Note

The instrument should be maintained at least once after being used for five hours every day of 25 days (5*400*25=50,000 tests) within a month.

Warning

- To avoid personal injuries and any damages to the system, do not perform maintenance procedures that are not stated in this chapter.
- Do not touch any parts, otherwise stated that they can be operated and maintained by the user.
- Unauthorized maintenance of the system may cause system damages and personal injuries, or even invalidate terms and conditions in the maintenance contract.
- Make sure that the system works properly after the completion of maintenance.
- Do not spill water, reagents and other liquids on the mechanical or electrical parts of the system.
- If you need to move the analyzer or do not use it for a period of time (more than a week), contact the customer service department of Getein Biotech Co., Ltd. or local distributors to ensure good performance of the instrument after reboot.
- To ensure personal safety and best system performance, only use the accessories manufactured or recommended by Getein. If you need any help, feel free to contact our customer service department or local distributors.

14.2 Maintenance Requirements

To ensure the good performance of the system and prolong the service life of the instrument, perform regular maintenances according to the manual.

Danger

- If you want to clean and disinfect the surface of the instrument with cloth dampening 75% ethanol, remember that it is only for general disinfection and bacterial spores and viruses cannot be killed.
- Wear disposable latex gloves during operation to avoid biohazard.

Select **Maintenance** →**Analyzer Maintenance**, and the system displays the **Analyzer Maintenance** window.

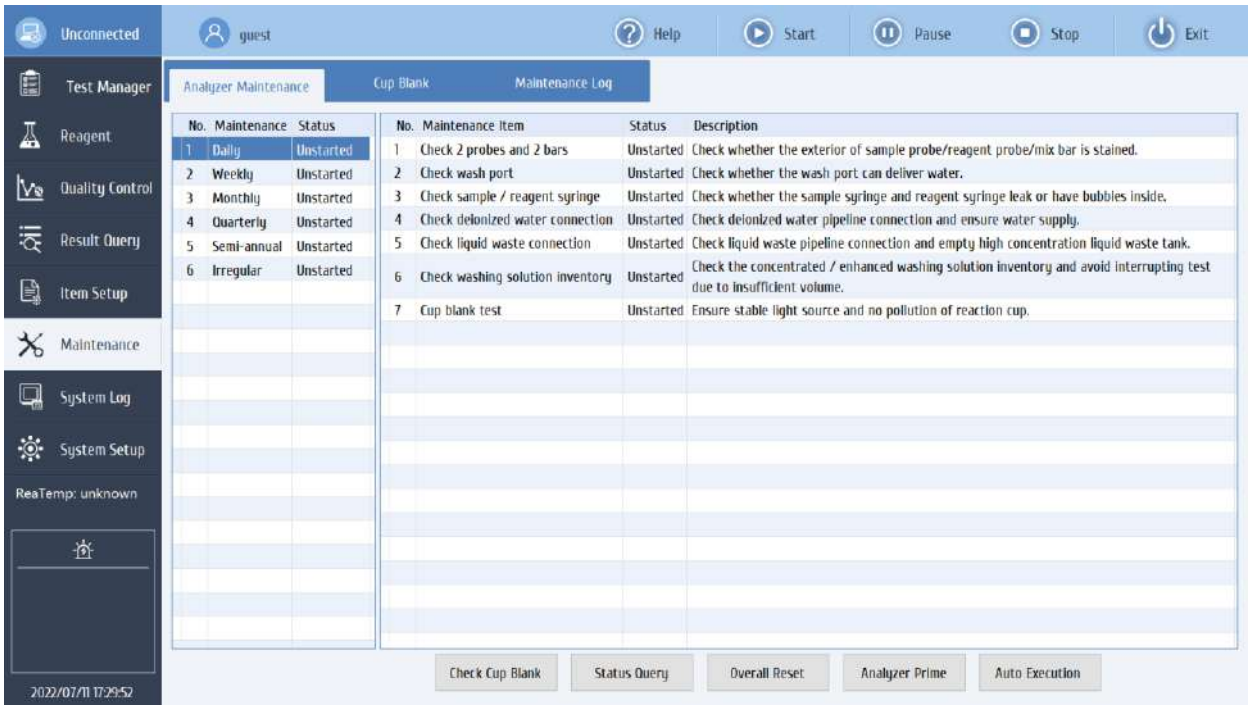


Figure 14.1 Analyzer Maintenance window

Maintenance Item	**Description**
No.	(Column) Display the sequence No. of the maintenance item.
Maintenance	(Column) Display the maintenance type based on maintenance frequency; • Daily • Weekly • Monthly • Quarterly • Semi-annual • Irregular
Status	(Column) Display the maintenance status: • Incomplete • Completed
Maintenance Item	(Column) Display the maintenance items.
Description	(Column) Display the maintenance details.
Check Cup Blank	(Button) View cup blank information.
Status Query	(Button) You can view the current temperature and liquid level of wash solution.
Overall Reset	(Button) Reset all parts of the instrument.
Analyzer Prime	(Button) Prime the liquid system of the instrument and discharge the air in the pipeline.
Auto Execution	(Button) Select to perform the selected maintenance item.

14.2.1 Daily Maintenance

On the **Analyzer Maintenance** window, select **Daily**, and the system displays the **Daily Maintenance Item**.

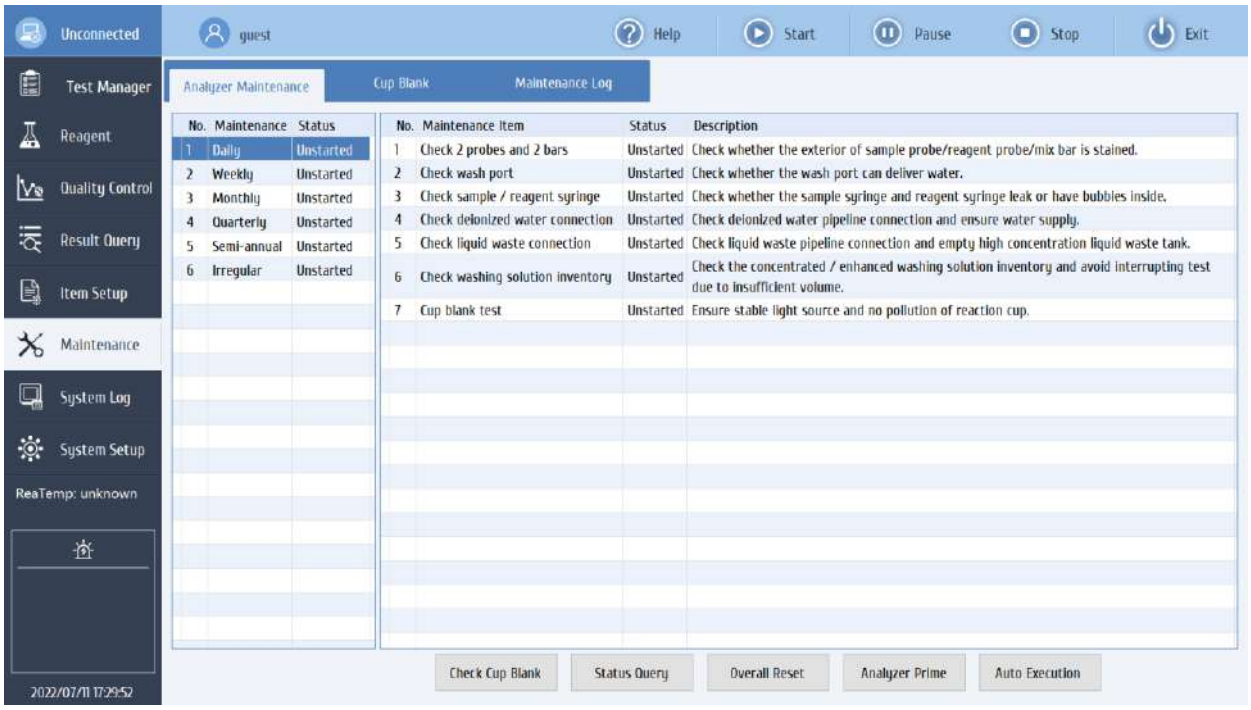


Figure 14.2 Daily Maintenance

Maintenance Item	Description
Check 2 probes and 2 bars	The end and the interior of the probe may be attached with blood and water drop, thus decreasing the precision and accuracy of sample/reagent adding. In severe cases, the sample probe may even be clogged by fibrin filament. Therefore, the sample probe and reagent probe must be checked every day and washed timely. The sample probe and reagent probe should be wiped with cotton swab dampening 75% ethanol after the completion of testing.
Check wash port	Check the wash port to ensure free waterflow. Clean the wash port regularly to keep it clean and unclogged.
Check sample/reagent syringe	Check whether the syringe is leaking and whether there are bubbles inside.
Check deionized water connection	Check the pure water connection to ensure normal water supply.
Check liquid waste connection	Check the connection of waste liquid pipelines and whether high concentration waste liquid tank is emptied to avoid the overflow of waste liquid.
Check Wash solution Inventory	Check the remaining volume of concentrated wash solution and enhanced wash solution to avoid interrupted tests because of insufficient volume.
Cup blank test	Check the cup blank value to ensure the stability of the optical source and the non-pollution of the reaction cup.

14.2.2 Weekly Maintenance

On the **Analyzer Maintenance** window, select **Weekly**, and system displays the **Weekly Maintenance Item**.

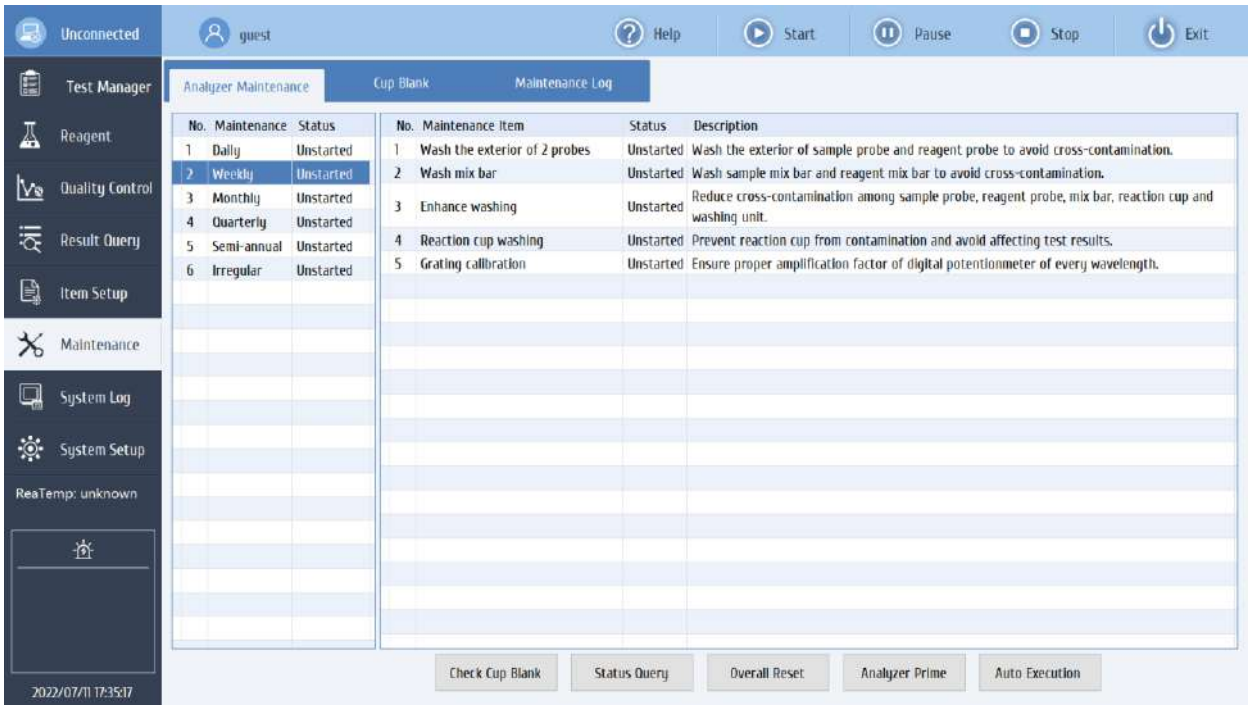


Figure 14.3 Weekly Maintenance Window

Maintenance Item	Description
Wash the exterior of 2 probes	The end and the interior of the probe may be attached with blood and water drop, thus decreasing the precision and accuracy of sample/reagent adding. In severe cases, the sample probe may even be clogged by fibrin filament. Therefore, the sample probe and reagent probe must be checked every day and washed timely. The sample probe and reagent probe should be wiped with cotton swab dampening 75% ethanol after the completion of testing.
Wash mix bar	Carryover may occur once the mix bar is stained. Wipe it clean with a cotton swab dipped in 75% ethanol and then wipe it with clean water.
Enhance washing	To reduce cross-contamination between sample probe, reagent probe, mix bar, reaction cup and wash unit and avoid the silting-up of waste liquid in liquid pipeline. Select the maintenance item and click [Auto Execution] after power-on.
Reaction cup washing	Reaction cup washing is automatically executed to avoid cross-contamination and inaccurate test results.
Grating calibration	Ensure that the amplification factor of the digital potentiometer of each wavelength is appropriate.

14.2.3 Monthly Maintenance

On the **Analyzer Maintenance** window, select **Monthly**, and the system displays the monthly **Maintenance Item**.

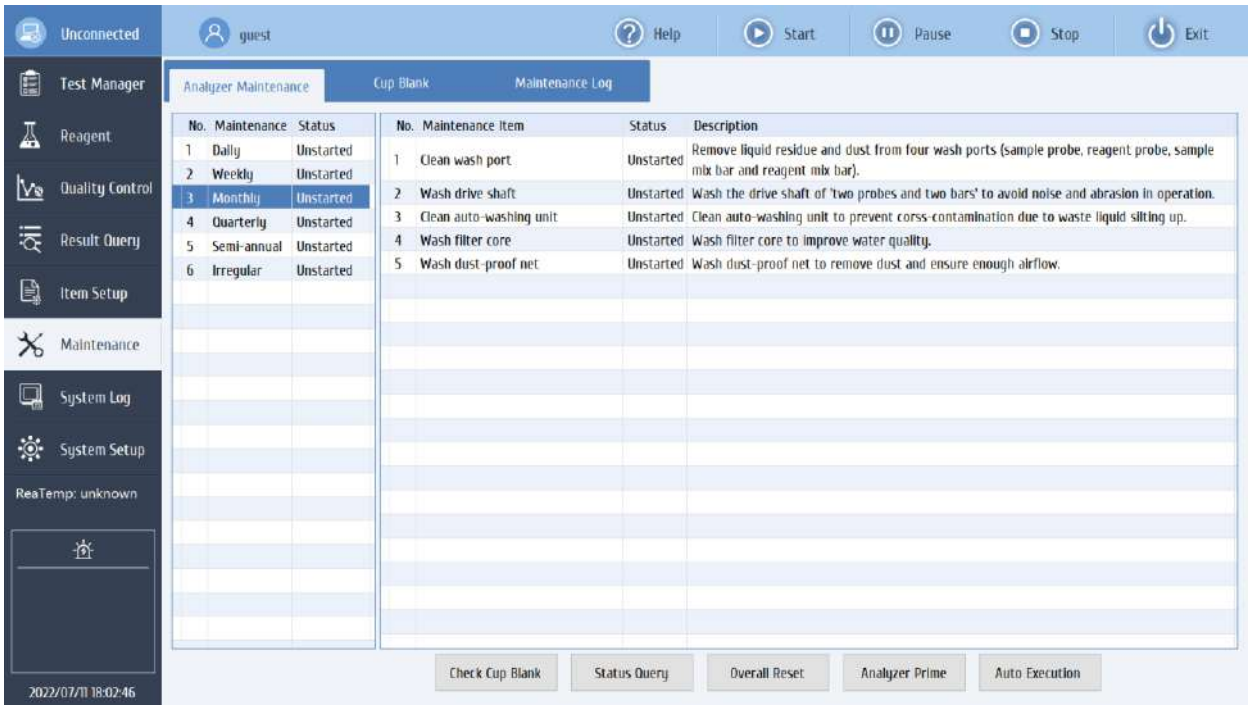


Figure 14.4 Monthly Maintenance Window

Maintenance Item	Description
Clean wash port	Remove waste liquid and dust of four wash ports (sample probe, reagent probe, sample mix bar and reagent mix bar) to prevent blockage.
Wash drive shaft	Wash the drive shafts of two probes and two bars to reduce noise and wear during movement.
Clean auto-washing unit	Clean automatic washing unit to avoid waste liquid silting up and cross-contamination.
Wash filter core	Wash the filter core to avoid the deposition of impurities in the filter and improve the water quality.
Wash dust-proof net	Wash the dustproof net to remove the dust and ensure adequate airflow.

14.2.4 Quarterly Maintenance

On the **Analyzer Maintenance** window, select **Quarterly**, and the system displays the quarterly **Maintenance Item**.

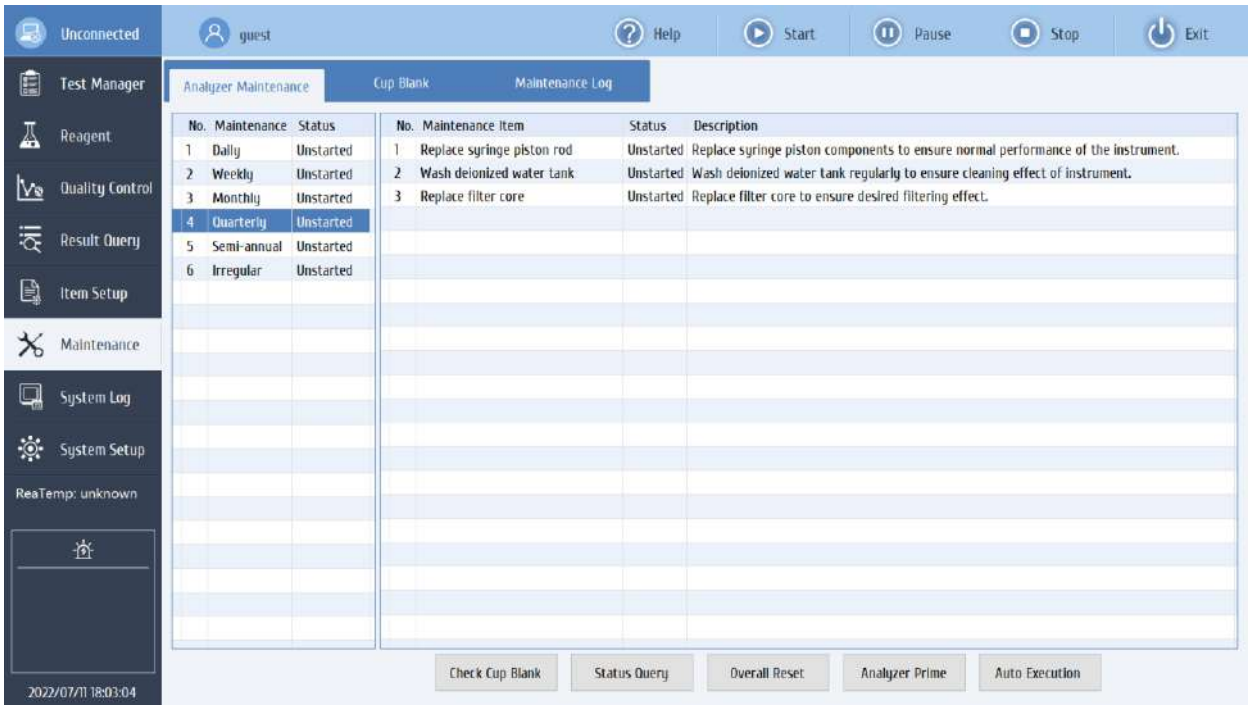


Figure 14.5 Quarterly Maintenance Window

Maintenance Item	Description
Replace syringe piston rod	Replace the piston components of the syringe to ensure the proper function of the instrument.
Wash deionized water tank	Clean the pure water tank regularly to ensure effective washing performance.
Replace filter core	Replace the filter core to ensure the optimum filtering effect.

14.2.5 Semi-annual Maintenance

On the **Analyzer Maintenance** window, select **Semi-annual**, and the system displays the semi-annual **Maintenance Item**.

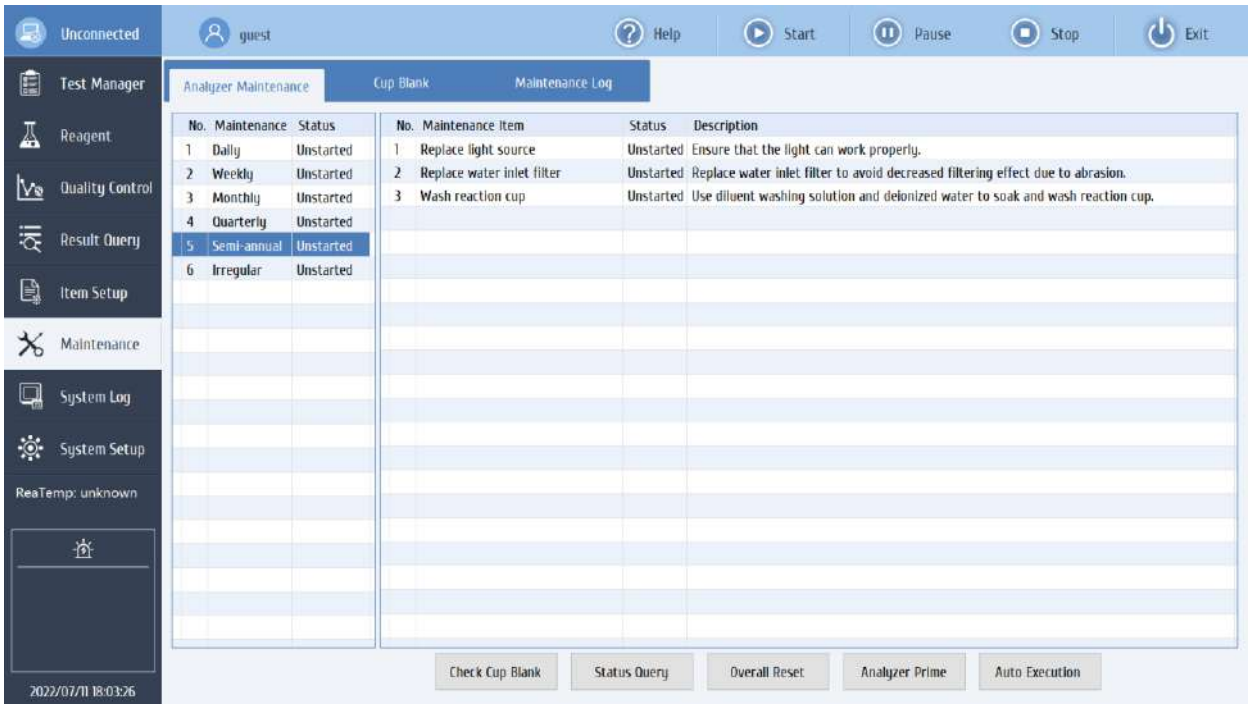


Figure 14.6 Semi-annual Maintenance Window

Maintenance Item	Description
Replace light source	After turn on the analyzer, check the intensity of the optical source of the photometer after preheating. If the automatic gain coefficient value of the photometer keeps decreasing for a long time, it represents a decreasing light intensity of the optical source. If the value fluctuates greatly, it indicates that the optical source is aging and the light intensity is unstable and optical source replacement is required.
Replace water inlet filter	Replace the filter of water inlet to avoid inadequate filtration due to filter wear.
Wash reaction cup	Immerse all reaction cups and clean their inner and outer walls with diluted wash solution and pure water.

Note

The average life of halogen lamp is 2000 hours. The time to replace the halogen lamp depends on the usage frequency and its working time. The service life of filter in the incubator depends on the water quality.

14.2.6 Irregular Maintenance

On the **Analyzer Maintenance** window, select **Irregular**, and the system displays the irregular **Maintenance item**.

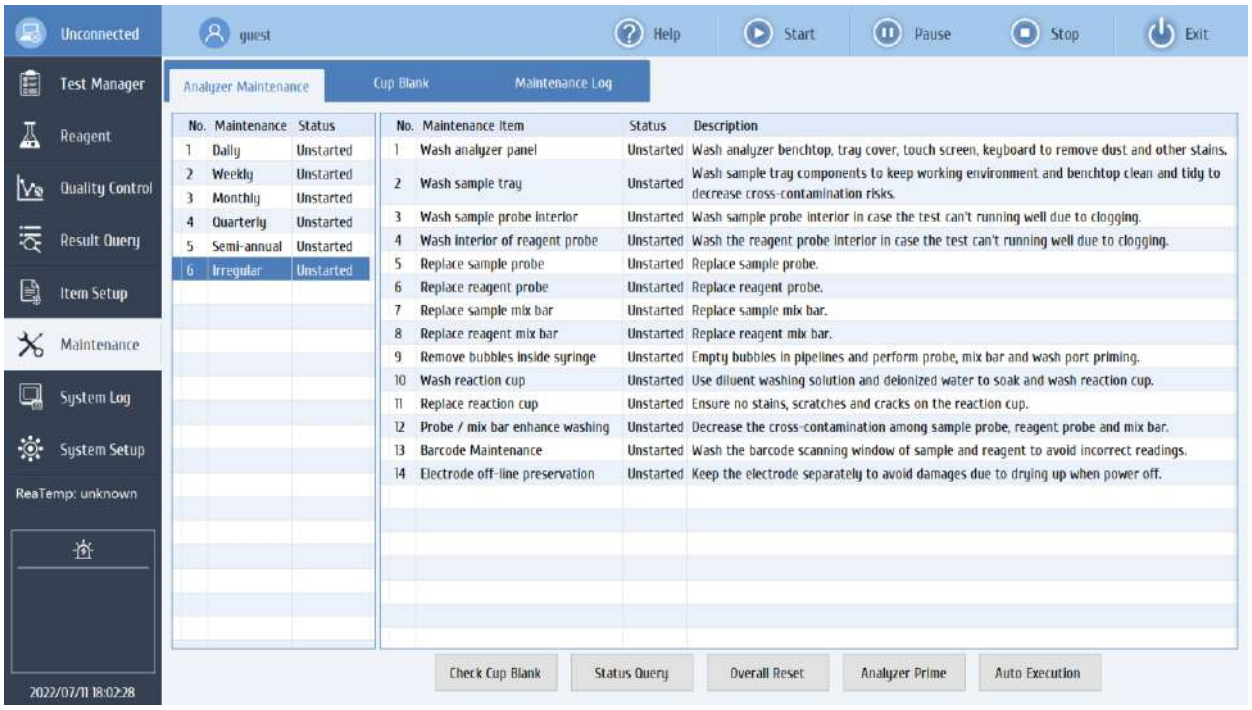


Figure 14.7 Irregular Maintenance Window

Maintenance Item	Description
Wash analyzer panel	Clean the instrument surface, tray cover, touch screen and keyboard.
Wash sample tray	Clean the sample tray assembly; keep the working environment and instrument surface clean to reduce the risk of carry-over.
Wash sample probe interior	Clean the interior of the sample probe in case the test cannot run properly due to probe clogging.
Wash interior of reagent probe	Clean the interior of the reagent probe in case the test cannot run properly due to probe clogging.
Replace sample probe	Replace the sample probe.
Replace reagent probe	Replace the reagent probe.
Replace sample mix bar	Replace the sample mix bar.
Replace reagent mix bar	Replace the reagent mix bar.
Remove bubbles inside syringe	Empty the bubbles in the pipeline, and perform probe, mix bar and wash port priming.
Wash reaction cup	Soak and clean the reaction cup with diluted wash solution and deionized water.
Replace reaction cup	Ensure that the reaction cup is free of contamination, scratches or cracks.
Probe / mix bar enhance washing	Reduce carry-over between sample probe, reagent probe and mix bar.
Barcode maintenance	Clean the barcode scanning window to ensure the accuracy of barcode reading.
Electrode off-line preservation	When the instrument is power-off, the electrodes shall be stored separately to prevent damages due to drying up.

14.3 Cup blank

Select **Maintenance** → **Cup Blank,** the system displays the **Cup Blank** window as below**.**

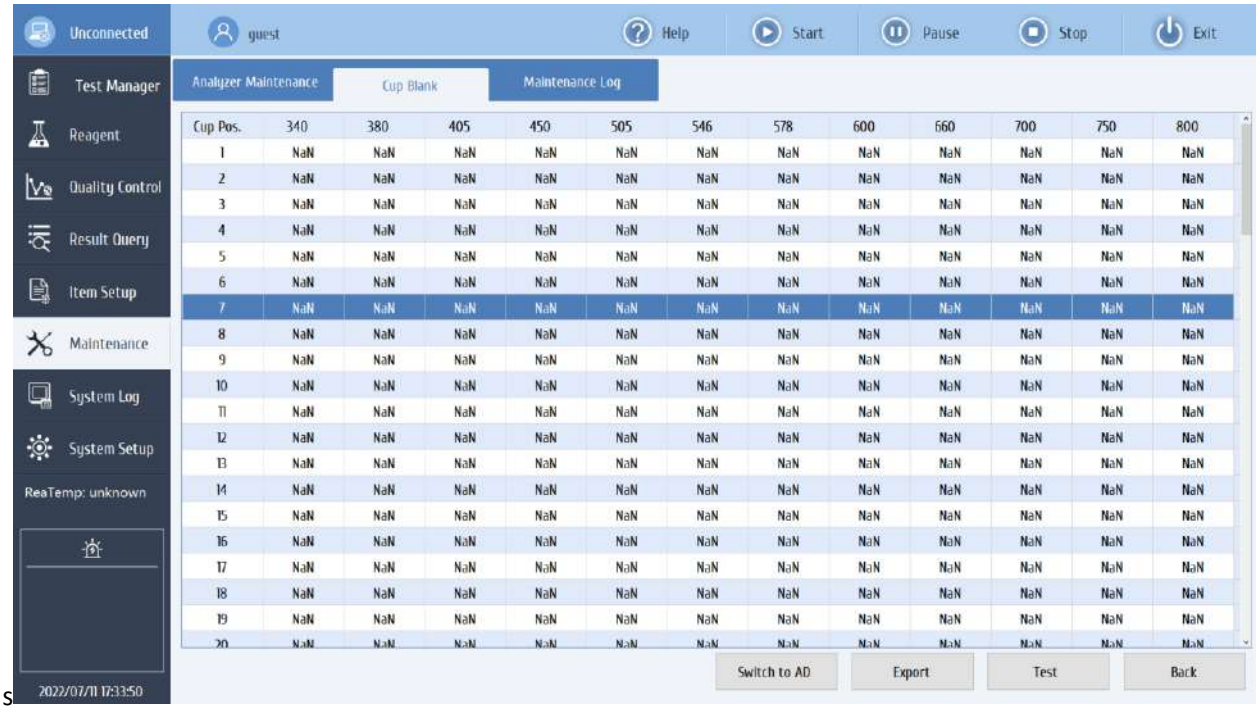


Figure 14.8 Cup Blank Window

Cup Pos.	(Column) Display the cup position.
Switch to AD/Abs.	(Button) Switch the absorbance to AD value or switch the AD value to absorbance.
Export	(Button) Export cup blank data.
Test	(Button) Perform cup blank tests.
Back	(Button) Click to return to the **Analyzer Maintenance** window.

14.4 Maintenance Log

Select **Maintenance** → **Maintenance Log,** the system displays the **Maintenance Log** window as below**.**

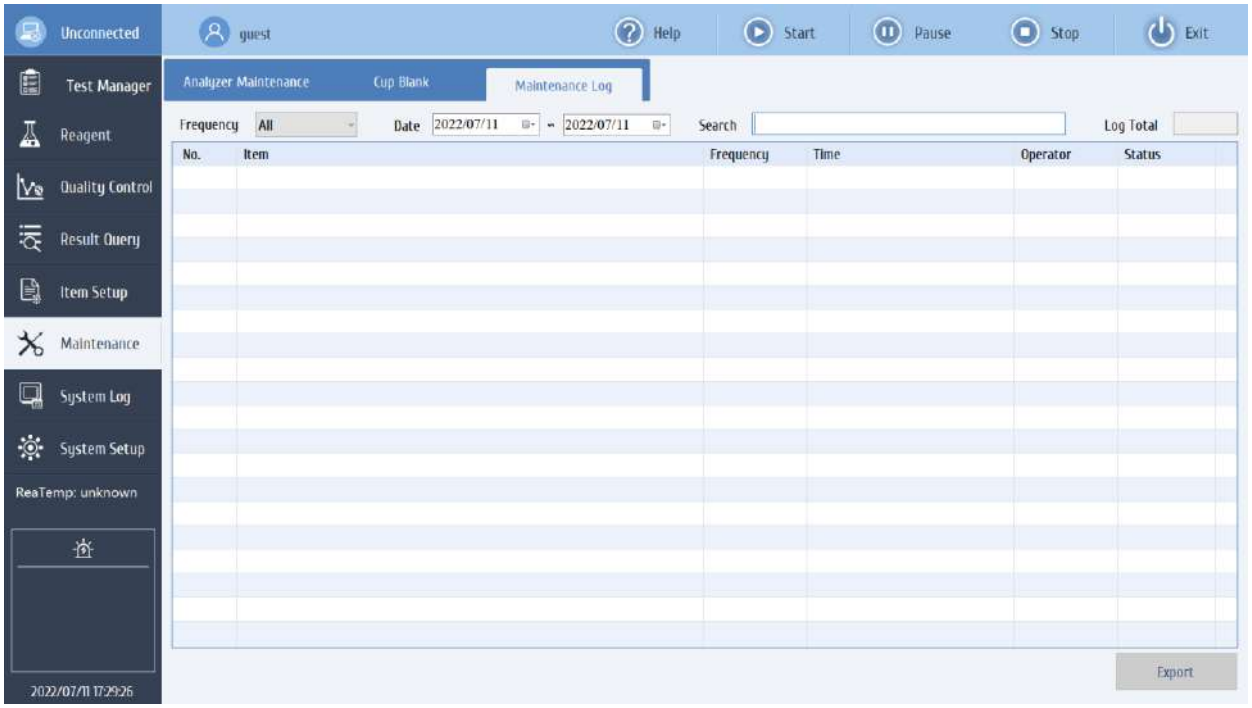


Figure 14.9 Maintenance Log Window

14.5 ISE Maintenance (optional)

Select **Maintenance** → **ISE Maintenance,** and the system displays the **ISE Maintenance** window.

Installation Process

1. Connect the wiring and place the electrode properly.
2. Click the **Installation Process**.
3. Automatic checking the communication of ISE module.
4. Automatic filling up the pipeline with A solution.
5. Automatic filling up the pipeline with B solution.
6. Wait 15 minutes until the electrode is fully infiltrated.

Bubble Calibration

1. Click the **Bubble Calibration** Button.
2. Automatic dispense A solution into the reaction cup.
3. Discharge A solution slowly, and the bubble calibration sensor detects the liquid status change in the pipeline.
4. ISE produces the calibration results.

Disassembly Process

1. Click the **Washing Process** button.
2. Fill the pipeline with A solution of ISE module.
3. Stop relevant operations of ISE module.
4. Disassemble manually.

Pump Calibration

1. Click **Pump Calibration**.
2. ISE module dispenses 150 uL B solution into the reaction cup.
3. The sample probe aspirates 100 uL B solution from the cup.
4. ISE module discharges the remaining B solution.
5. The sample probe dispenses the100 uL B solution to the cup of ISE.
6. ISE module executes pump calibration automatically. Calculate the pump running steps of 100 uL solution.
7. ISE module produces the calibration results.

Pipeline Washing

ISE residue liquid cleaning: dispense 100 uL wash solution into the reaction cup and ISE will perform the automatic cleaning process.

Note: To prevent accumulated protein in the electrode and liquid pipelines, cleaning is required one time per day. If the frequency of using is more than 50 times per day, the cleaning frequency should increase accordingly. The wash solution volume is 100 uL.

AB solution calibration

1. ISE module removes A solution in liquid line via W pump and then injects 100 uL B solution into liquid line via B pump. After that, ISE injects 80 uL B solution to reaction cup and delivers B solution to electrode via W pump. Read electromotive force of electrode after 9s.
2. ISE module removes B solution in liquid line and injects 100uL A solution into liquid line via A pump. After that, ISE injects 80uL A solution and delivers it to electrode. Read electromotive force of electrode after 9s.
3. Repeat the above process once again.
4. Output calibration results.

Clear Display

Clear all the display data on the interface

14.6 Regular Maintenance List

Table 14.1 Regular Maintenance List

No.	Maintenance Item	Maintenance Cycle and Methods						
		Daily	Weekly	Monthly	Quarterly	Half-yearly	Yearly	As Needed
1	Instrument Surface Cleaning	☆						
2	Sample Probe (Exterior)	☆						
3	Reagent Probe (Exterior)	☆						
4	Mix Bar	☆						
5	Sample Tray Cleaning		☆					
6	Reagent Tray Cleaning		☆					
7	Sample Probe (Interior and exterior)		☆					☆
8	Reagent Probe (Interior and exterior)			☆				☆

9	Wash Nozzle Cleaning			☆				
10	Reaction Cup Drying Block			☆				
11	Wash Port Cleaning			☆				
12	Wash Probe Pipelines (Aspirate)					☆		
13	Halogen Lamp					☆		
14	Thermal Insulating Filter					☆		
15	Wash Probe Pipelines (Dispense)						☆	
16	Waste Liquid Pump · Diaphragm, Valve							☆
17	Vacuum Pump · Diaphragm, Valve							☆
18	Degassing Tank							☆
19	Arm Unit							☆
20	Solenoid Valve							☆
21	Mix Bar Motor							☆
22	Analyzer Cleaning							☆
23	ISE Module (Optional)	☆						

Note

- Clean reagent probe (No. 8) every day if latex reagents are frequently used.
- The maintenance should be carried out after every 500 tests per day. When the number of tests exceeds 500 tests, users need to increase the maintenance frequency.

14.7 Maintenance Method

14.7.1 Washing and Replacing Probe

Washing Probe

1. Turn off the instrument, move the arm and the probe to the position where it is easy to operate.
2. Wash the probe gently and carefully to avoid deforming the probe. Wipe the tip of the probe clean with a cotton swab dampening 75% ethanol.
3. Make sure each probe is in the center of its home position after starting the analyzer.

Replacing Probe

1. Turn off the instrument, move the mechanical arm and the probe to an easy-to-operate position.
2. Remove the upper cover of the arm, then unscrew and remove the probe from the arm with a cross screwdriver. Do not let screws fall down.
3. Unplug the conduit inserted into the probe. Do not bend the conduit.

Caution

The liquid in the probe and the conduit may flow out when you plug out the conduit. Wipe off the overflowing liquid with a paper towel timely in case the liquid flows into the instrument accidentally.

4. Insert the new conduit and fix it with a screw, and ensure that the probe is vertical.
5. After startup, select **System Setup→ Open Debug→ Operating Parameter**. Confirm the probe is at the home position.
6. Install the upper cover of the arm. Do not damage the wiring and conduit during the installation.

Caution

- When installing the cover, be gentle and do not rotate the arm hard to avoid mispositioning the arm or damaging the probe.
- During the installation of the upper cover, perform initialization if the mechanical arm is mispositioned due to improper operations.

14.7.2 Cleaning and Replacing Mix Bar

Cleaning Mix Bar

If the mix bar is stained with samples or reagents, wipe clean the front end of the mix bar with a cotton swab dampening 75% ethanol. Wipe very gently to avoid deforming it and replace it timely if it is deformed.

Replacing Mix Bar

1. Shut down the instrument and rotate the mix arm to a position where it is easy for disassembly.
2. Remove the top cover and lower cover of the mix bar.
3. Hold the upper end of the mix bar and rotate upwards to unscrew the mix bar. Do not let the mix bar fall off**.**
4. Hold the upper end of the new mix bar, align it to the mounting hole and insert it into the bottom and then rotate downwards to tighten it.
5. After the replacement, start the instrument, select **System Setup→ Open Debug→ Operating Parameter** to confirm that mix bar is at the center of reaction cup.

Caution

Make sure the mix bar is in the center of the reaction cup. Any misposition may damage the mix bar during operation. If necessary, loosen the screws of the mixing motor and adjust the motor base position to tune the position of mix bar.

14.7.3 Reaction Unit

Washing reaction cup

1. After power off, remove the cover of the reaction tray and take out the reaction cup.
2. Use a cotton swab dampening a 50-fold diluted wash solution to wipe clean the inner and outer walls of the cup, and then rinse it with pure water.

Replacing Reaction Cup

1. After power off, remove the cover of the reaction tray and take out the reaction cup.
2. Place the new reaction cup on the reaction tray.
3. Select **Maintenance→ Analyzer Maintenance → Daily Maintenance→ Cup Blank Test** to test cup blank.

Note: Replace plastic reaction cup as needed.

Cleaning the Washing Unit

1. Switch off the instrument.
2. Loosen the fixing screw of the washing unit; lift the washing arm and remove it.
3. Wipe clean the probe with gauze dipped in 75% ethanol.
4. Install the washing arm to its home position and tighten the screws.

Replacing Halogen Lamp

1. Turn off the analyzer.
2. Loosen the lamp nut with hands and take the lamp from the holder.
3. Do not to touch the lamp surface with hand when installing the new lamp. Align the lamp with guiding block of the lamp base .
4. Tighten the nut.
5. Plug in the instrument.
6. Press the power button on the top left of the instrument to start the analyzer.
7. Check if the lamp is functioning well.
8. Select **Maintenance→ Daily Maintenance→ Cup Blank Test** to test the cup blank.

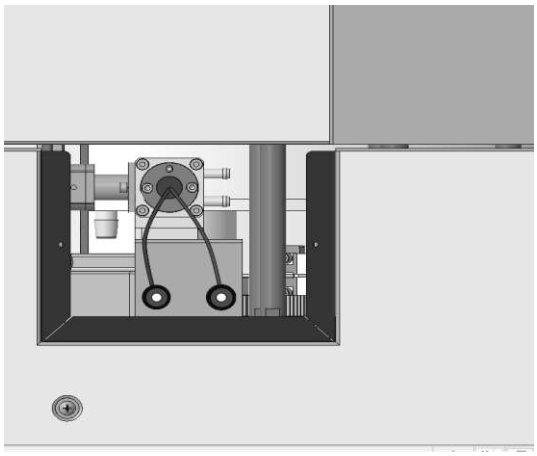


Figure 14.10 Replacement of Optical Source

Caution

- Wait 5 minutes before replacing the lamp after the shutdown of the analyzer as the lamp may be very hot.
- If you touch the surface of the light bulb accidentally, wipe it clean with a gauze dampening 75% ethanol to prolong the service life of the bulb.
- If the lens surface is not clean enough, it will affect the test results. If you accidentally touch the lens surface, wipe it with a gauze dampening 75% ethanol, etc.

14.8 Error Code

Table 14.2 Error Code

Code	Level	Description
D00000000	Stop Error	Reset Failed. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00000001	Stop Error	Communication timeout of sample probe interior valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00000002	Stop Error	Communication timeout of rotation motor of sample tray. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00000003	Stop Error	Parameters error of rotation motor of sample tray. Solution: Contact after-sale engineers.
D00000004	Stop Error	Home position optocoupler error of rotation motor of sample tray. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00000006	Stop Error	Losing steps of rotation motor of sample tray. Solution: Check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00000007	Stop Error	Barcode scanning error of sample tray. Solution: 1. check the alignment of barcode; 2. manual scanning; contact after-sale engineers if the problem remains unsolved.
D00000008	Stop Error	Rotation motor of sample tray is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after 3 failed tries.
D0000000A	Stop Error	Connection timeout of motor driver board 1. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0000000C	Stop Error	Failed to set liquid level detection panel of sample probe. Solution: Check the wiring and liquid level panel. Contact after-sale engineers if the problem remains unsolved.
D0000000D	Stop Error	Failed to connect liquid level detection panel of sample probe. Solution: check the wiring and liquid level panel. Contact after-sale engineers if the problem remains unsolved.
D0000000E	Stop Error	Response timeout error of rotation motor of sample tray. Contact after-sale engineers.
D0000000F	Stop Error	Sample liquid level detection panel pass-thorough is disabled. Contact after-sale engineers.
D00000010	Stop Error	Process timeout of washing sample probe. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.

D000000F0	Stop Error	Updating firmware of motor driver board 1 failed. Solution: check upgrading program and contact after-sale engineers if the problem remains unsolved.
D000000F1	Stop Error	Firmware updating of motor driver board 1 is forbidden. Solution: Check if the upgrading program is the same to the original version No.
D00001800	Stop Error	Communication failed.
D00001801	Runtime Warning	Empty sample.
D00001802	Runtime Warning	There is air in calibrator A pipeline.
D00001803	Runtime Warning	There is air in calibrator B pipeline.
D00001804	Runtime Warning	There is air in the washing pipeline.
D00001805	Runtime Warning	There is air in the electrode end.
D00001806	Runtime Warning	Pump calibration failed.
D00001807	Runtime Warning	No liquid flow.
D00001808	Runtime Warning	Bubble calibration failed.
D00001809	Runtime Warning	Chip reading parameters failed. Contact after-sale engineers.
D0000180A	Runtime Warning	Chip writing parameters failed. Contact after-sale engineers.
D0000180B	Runtime Warning	Invalid command. Contact after-sale engineers.
D00001810	Runtime Warning	Measuring error-Li^+ electric potential timeout (Calibrator B \ Sample).
D00001811	Runtime Warning	Measuring error-Na^+ electric potential timeout (Calibrator B \ Sample).
D00001812	Runtime Warning	Measuring error-Li^+, Na^+ electric potential timeout (Calibrator B \ Sample).
D00001813	Runtime Warning	Measuring error-K^+ electric potential timeout (Calibrator B \ Sample).
D00001814	Runtime Warning	Measuring error-Li^+, K^+ electric potential timeout (Calibrator B \ Sample).
D00001815	Runtime Warning	Measuring error-K^+, Na+ electric potential timeout (Calibrator B \ Sample).
D00001816	Runtime Warning	Measuring error-K^+, Na^+, Li^+ electric potential timeout (Calibrator B \ Sample).
D00001817	Runtime Warning	Measuring error-Cl^- electric potential timeout (Calibrator B \ Sample).
D00001818	Runtime Warning	Measuring error-Cl^-, Li^+ electric potential timeout (Calibrator B \ Sample).
D00001819	Runtime	Measuring error-Na^+, Cl^- electric potential timeout (Calibrator B \ Sample).

	Warning	
D0000181A	Runtime Warning	Measuring error-Cl^-, Na^+, Li^+ electric potential timeout (Calibrator B \ Sample).
D0000181B	Runtime Warning	Measuring error-Cl^-, K^+ electric potential timeout (Calibrator B \ Sample).
D0000181C	Runtime Warning	Measuring error-Cl^-, K^+, Li^+ electric potential timeout (Calibrator B \ Sample).
D0000181D	Runtime Warning	Measuring error-Cl^-, K^+, Na^+ electric potential timeout (Calibrator B \ Sample).
D0000181E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ electric potential timeout (Calibrator B \ Sample).
D00001820	Runtime Warning	Measuring error-Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001821	Runtime Warning	Measuring error-Na^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001822	Runtime Warning	Measuring error-Li^+, Na^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001823	Runtime Warning	Measuring error-K^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001824	Runtime Warning	Measuring error-Li^+, K^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001825	Runtime Warning	Measuring error-K^+, Na^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001826	Runtime Warning	Measuring error-K^+, Na^+, Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001827	Runtime Warning	Measuring error-Cl^- electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001828	Runtime Warning	Measuring error-Cl^-, Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001829	Runtime Warning	Measuring error- Na^+,Cl^- electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000182A	Runtime Warning	Measuring error-Cl^-, Na^+, Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000182B	Runtime Warning	Measuring error-Cl^-, K^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000182C	Runtime Warning	Measuring error-Cl^-, K^+, Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000182D	Runtime Warning	Measuring error-Cl^-, K^+, Na^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000182E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ electric potential timeout (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001830	Runtime Warning	Measuring error-Li^+ electric potential interference (Calibrator B \ Sample).
D00001831	Runtime Warning	Measuring error-Na^+ electric potential interference (Calibrator B \ Sample).

D00001832	Runtime Warning	Measuring error-Li^+, Na^+ electric potential interference (Calibrator B \ Sample).
D00001833	Runtime Warning	Measuring error-K^+ electric potential interference (Calibrator B \ Sample).
D00001834	Runtime Warning	Measuring error-Li^+, K^+ electric potential interference (Calibrator B \ Sample).
D00001835	Runtime Warning	Measuring error-K^+, Na^+ electric potential interference (Calibrator B \ Sample).
D00001836	Runtime Warning	Measuring error-K^+, Na^+, Li^+ electric potential interference (Calibrator B \ Sample).
D00001837	Runtime Warning	Measuring error-Cl^- electric potential interference (Calibrator B \ Sample).
D00001838	Runtime Warning	Measuring error-Cl^-, Li^+ electric potential interference (Calibrator B \ Sample).
D00001839	Runtime Warning	Measuring error-Na^+, Cl^- electric potential interference (Calibrator B \ Sample).
D0000183A	Runtime Warning	Measuring error-Cl^-, Na^+, Li^+ electric potential interference (Calibrator B \ Sample).
D0000183B	Runtime Warning	Measuring error-Cl^-, K^+ electric potential interference (Calibrator B \ Sample).
D0000183C	Runtime Warning	Measuring error-Cl^-, K^+, Li^+ electric potential interference (Calibrator B \ Sample).
D0000183D	Runtime Warning	Measuring error-Cl^-, K^+, Na^+ electric potential interference (Calibrator B \ Sample).
D0000183E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ electric potential interference (Calibrator B \ Sample).
D00001840	Runtime Warning	Measuring error-Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001841	Runtime Warning	Measuring error-Na^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001842	Runtime Warning	Measuring error-Li^+, Na^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001843	Runtime Warning	Measuring error-K^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001844	Runtime Warning	Measuring error-Li^+, K^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001845	Runtime Warning	Measuring error-K^+, Na^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001846	Runtime Warning	Measuring error-K^+, Na^+, Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001847	Runtime Warning	Measuring error-Cl^- electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001848	Runtime Warning	Measuring error-Cl^-, Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).

D00001849	Runtime Warning	Measuring error-Na^+, Cl- electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000184A	Runtime Warning	Measuring error-Cl^-, Na^+, Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000184B	Runtime Warning	Measuring error-Cl^-, K^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000184C	Runtime Warning	Measuring error-Cl^-, K^+, Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000184D	Runtime Warning	Measuring error-Cl^-, K^+, Na^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D0000184E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ electric potential interference (Solution A in Calibration \ Sample mode; Solution B of Urine mode).
D00001850	Runtime Warning	Measuring error-Li^+ slope drift.
D00001851	Runtime Warning	Measuring error-Na+ slope drift.
D00001852	Runtime Warning	Measuring error-Li^+, Na^+ slope drift.
D00001853	Runtime Warning	Measuring error-K^+ slope drift.
D00001854	Runtime Warning	Measuring error-Li^+, K^+ slope drift.
D00001855	Runtime Warning	Measuring error-K^+, Na^+ slope drift.
D00001856	Runtime Warning	Measuring error-K^+, Na^+, Li^+ slope drift.
D00001857	Runtime Warning	Measuring error-Cl^- slope drift.
D00001858	Runtime Warning	Measuring error-Cl^-, Li^+ slope drift.
D00001859	Runtime Warning	Measuring error-Na^+, Cl- slope drift.
D0000185A	Runtime Warning	Measuring error-Cl^-, Na^+, Li^+ slope drift.
D0000185B	Runtime Warning	Measuring error-Cl^-, K^+ slope drift.
D0000185C	Runtime Warning	Measuring error-Cl^-, K^+, Li^+ slope drift.
D0000185D	Runtime Warning	Measuring error-Cl^-, K^+, Na^+ slope drift.
D0000185E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ slope drift.
D00001860	Runtime Warning	Measuring error-Li^+ slope is out of measurement range.
D00001861	Runtime Warning	Measuring error-K^+ slope is out of measurement range.

D00001862	Runtime Warning	Measuring error-Cl^- slope is out of measurement range.
D00001863	Runtime Warning	Measuring error-Na^+ slope is out of measurement range.
D00001864	Runtime Warning	Measuring error-Li^+, K^+ slope is out of measurement range.
D00001865	Runtime Warning	Measuring error-Li^+, Cl^- slope is out of measurement range.
D00001866	Runtime Warning	Measuring error-Li^+, Na^+ slope is out of measurement range.
D00001867	Runtime Warning	Measuring error-K^+, Cl^- slope is out of measurement range.
D00001868	Runtime Warning	Measuring error-K^+, Na^+ slope is out of measurement range.
D00001869	Runtime Warning	Measuring error-Cl^-, Na+ slope is out of measurement range.
D0000186A	Runtime Warning	Measuring error-Li^+, Na^+, K^+ slope is out of measurement range.
D0000186B	Runtime Warning	Measuring error-Li^+, Na^+, Cl^- slope is out of measurement range.
D0000186C	Runtime Warning	Measuring error-Li^+, Cl^-, K^+ slope is out of measurement range.
D0000186D	Runtime Warning	Measuring error-Cl^-, Na^+, K^+ slope is out of measurement range.
D0000186E	Runtime Warning	Measuring error-Cl^-, K^+, Na^+, Li^+ slope is out of measurement range.
D00010001	Stop Error	Communication time out of sample probe exterior valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00010002	Stop Error	Communication timeout of rotation motor of sample arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00010003	Stop Error	Parameters error of rotation motor of sample arm. Solution: contact after-sale engineers.
D00010004	Stop Error	Home position optocoupler error of rotation motor of Sample arm. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D00010006	Stop Error	Losing steps error of rotation motor of sample arm. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00010008	Stop Error	Rotation motor of sample arm is busy. Solution: Cut off the power supply of the instrument and perform system reset. Contact after-sale engineers if the problem remains unsolved after three failed tries.

D00010009	Stop Error	Rotation motor of sample arm doesn't move; optocoupler is triggered by mistake. Solution: Contact after-sale engineers to check the motor wiring and optocoupler.
D0001000E	Stop Error	Response timeout error of rotation motor of sample arm.
D00010010	Stop Error	Process timeout of sample tray rotating to sample position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00020001	Stop Error	Washing stage 1 liquid injection valve timeout. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00020002	Stop Error	Communication timeout of vertical motor of sample arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00020003	Stop Error	Parameters error of vertical motor of sample arm. Solution: contact after-sale engineers.
D00020004	Stop Error	Home position optocoupler error of vertical motor of sample arm. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D00020005	Stop Error	Vertical probe collision of sample arm. Solution: contact after-sale engineers.
D00020006	Stop Error	Losing steps of vertical motor of sample arm. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00020008	Stop Error	Vertical motor of sample arm is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D00020009	Stop Error	Vertical motor of sample arm doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0002000E	Stop Error	Response timeout of vertical motor of sample arm. Solution: contact after-sale engineers.
D00020010	Stop Error	Process timeout of detecting liquid level of sample probe. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00030001	Stop Error	Communication timeout of washing stage 2 liquid injection valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00030002	Stop Error	Communication timeout of sample syringe motor. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00030003	Stop Error	Parameters error of sample syringe motor. Solution: contact after-sale engineers.

D00030004	Stop Error	Home position optocoupler error of sample syringe motor. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00030006	Stop Error	Losing steps of sample syringe motor. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00030008	Stop Error	Sample syringe motor is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D00030009	Stop Error	Sample syringe motor doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0003000E	Stop Error	Response timeout error of sample syringe motor.
D00030010	Stop Error	Process timeout of sample aspiration of sample syringe. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00040001	Stop Error	Communication timeout of washing stage 3 liquid injection valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00040002	Stop Error	Communication timeout of vertical motor of washing unit. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00040003	Stop Error	Parameters error of vertical motor of washing unit. Solution: contact after-sale engineers.
D00040004	Stop Error	Home position optocoupler error of vertical motor of washing unit. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D00040006	Stop Error	Losing steps of vertical motor of washing unit. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D00040008	Stop Error	Vertical motor of washing unit is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D00040009	Stop Error	Vertical motor of washing unit doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0004000E	Stop Error	Response timeout of vertical motor of washing unit. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00040010	Stop Error	Process timeout of sample arm rotating to sample adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three

		failed tries.
D00050001	Stop Error	Communication timeout of stage 4 liquid injection valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00050010	Stop Error	Process timeout of sample arm descending to sample adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D00060010	Stop Error	Process timeout of sample adding of sample arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01000001	Stop Error	Communication timeout of washing valve of sample mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01000002	Stop Error	Communication timeout of rotation motor of sample mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01000003	Stop Error	Rotation motor of sample mix bar error. Solution: contact after-sale engineers.
D01000004	Stop Error	Home position optocoupler error of rotation motor of sample mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D01000006	Stop Error	Losing steps error of rotation motor of sample mix br. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D01000008	Stop Error	Rotation motor of sample mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D01000009	Stop Error	Rotation motor of sample mix bar doesn’t move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0100000A	Stop Error	Connection timeout of motor driver 2. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0100000E	Stop Error	Response timeout error of rotation motor of reagent mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01000010	Stop Error	Process timeout of washing reagent probe. Solution: Perform system reset. cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.

D010000F0	Stop Error	Updating firmware of motor driver 2 failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.
D010000F1	Stop Error	Updating firmware of motor driver 2 is forbidden. Solution: check if the upgrading program is same to the original version.
D01010002	Stop Error	Communication timeout of vertical motor of sample mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01010003	Stop Error	Parameters error of vertical motor of sample mix bar. Solution: contact after-sale engineers.
D01010004	Stop Error	Home position optocoupler error of vertical motor of sample mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D01010006	Stop Error	Losing steps error of vertical motor of sample mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D01010008	Stop Error	Vertical motor of sample mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D01010009	Stop Error	Vertical motor of sample mix bar doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0101000E	Stop Error	Response timeout error of vertical motor of sample mix bar.
D01010010	Stop Error	Process timeout of reagent probe detecting reagent1 or reagent 3. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01020002	Stop Error	Communication timeout of motor of sample mix bar. Solution: Perform system reset. cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01020003	Stop Error	Parameters error of motor of sample mix bar. Solution: contact after-sale engineers.
D01020008	Stop Error	Motor of sample mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D0102000E	Stop Error	Response timeout error of motor of sample mix bar. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D01020010	Stop Error	Process timeout of reagent aspiration of reagent syringe. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.

D01030010	Stop Error	Process timeout of reagent arm rotating to reagent adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01040010	Stop Error	Process timeout of reagent arm descending to reagent adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01050010	Stop Error	Process timeout of reagent adding of reagent arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01060010	Stop Error	Process timeout of washing after the addition of R1 or R3. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01070010	Stop Error	Process timeout of reagent probe detecting R2 or R4. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01080010	Stop Error	Process timeout of reagent aspiration of reagent syringe. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D01090010	Stop Error	Process timeout of reagent arm rotating to reagent adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D010A0010	Stop Error	Process timeout of reagent arm descending to reagent adding position. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D010B0010	Stop Error	Process timeout of reagent adding of reagent arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02000001	Stop Error	Communication timeout of anti-spill injection valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02000002	Stop Error	Communication timeout of rotation motor of reagent tray. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02000003	Stop Error	Parameters error of rotation motor of reagent tray. Solution: contact after-sale engineers.

D02000004	Stop Error	Home position optocoupler error of rotation motor of reagent tray. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D02000006	Stop Error	Losing steps error of rotation motor of reagent tray. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D02000007	Stop Error	Reagent barcode scanning error. Solution: 1, check the alignment of barcode; 2, manual scanning; contact after-sale engineers if the problem remains unsolved.
D02000008	Stop Error	Rotation motor of reagent tray is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D0200000A	Stop Error	Connection timeout of motor driver board 3. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0200000C	Stop Error	Failed to set liquid level detection panel of reagent probe. Solution: check wiring and liquid level detection panel. Contact after-sale engineers if the problem remains unsolved.
D0200000D	Stop Error	Failed to connect liquid level detection panel of reagent probe. Solution: check wiring and liquid level detection panel. Contact after-sale engineers if the problem remains unsolved.
D0200000E	Stop Error	Response timeout error of rotation motor of reagent tray. Contact after-sale engineers.
D0200000F	Stop Error	Reagent liquid level detection panel pass-thorough failed. Contact after-sale engineers.
D02000010	Stop Error	Rising process timeout of washing unit. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D020000F0	Stop Error	Updating firmware of motor driver board 3 failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.
D020000F1	Stop Error	Updating firmware of motor driver board 3 is forbidden. Solution: Check if the upgrading program is the same to the original version No.
D02010002	Stop Error	Communication timeout of rotation motor of reagent arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02010003	Stop Error	Parameters error of rotation motor of reagent arm. Solution: contact after-sale engineers.
D02010004	Stop Error	Home position optocoupler error of rotation motor of reagent arm. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D02010006	Stop Error	Losing steps error of rotation motor of reagent arm. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.

D02010008	Stop Error	Rotation motor of reagent arm is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D02010009	Stop Error	Rotation motor of reagent arm doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0201000E	Stop Error	Response timeout error of rotation motor of reagent arm. Solution: contact after-sale engineers.
D02010010	Stop Error	Process timeout of rotation of reaction tray large section. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02020002	Stop Error	Communication timeout of vertical motor of reagent arm. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02020003	Stop Error	Parameters error of vertical motor of reagent arm. Solution: contact after-sale engineers.
D02020004	Stop Error	Home position optocoupler error of vertical motor of reagent arm. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D02020005	Stop Error	Vertical probe collision of reagent arm. Solution: contact after-sale engineers.
D02020006	Stop Error	Losing steps error of vertical motor of reagent arm. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D02020008	Stop Error	Vertical motor of reagent arm is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D02020009	Stop Error	Vertical motor of reagent arm doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0202000E	Stop Error	Response timeout error of vertical motor of reagent arm. Solution: contact after-sale engineers.
D02020010	Stop Error	Process timeout of mixing of mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02030001	Stop Error	Communication timeout of anti-spill pressure relief valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02030002	Stop Error	Communication timeout of reagent syringe motor. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02030003	Stop Error	Parameters error of reagent syringe motor. Solution: contact after-sale engineers.

D02030004	Stop Error	Home position optocoupler error of reagent syringe motor. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D02030006	Stop Error	Losing steps error of reagent syringe motor. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D02030008	Stop Error	Reagent syringe motor is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D02030009	Stop Error	Reagent syringe motor doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0203000E	Stop Error	Response timeout error of Reagent syringe motor. Solution: contact after-sale engineers.
D02030010	Stop Error	Process timeout of rotation of reaction tray small section. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02040010	Stop Error	Descending process timeout of washing unit. Solution: Perform system reset. cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D02050010	Stop Error	Washing process timeout of washing unit. Solution: Perform system reset. cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D03000001	Stop Error	Communication timeout of vacuum release valve. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D03000002	Stop Error	Communication timeout of rotation motor of reagent mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D03000003	Stop Error	Parameters error of rotation motor of reagent mix bar. Solution: contact after-sale engineers.
D03000004	Stop Error	Home position optocoupler error of rotation motor of reagent mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D03000006	Stop Error	Losing steps error of rotation motor of reagent mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D03000008	Stop Error	Rotation motor of reagent mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D03000009	Stop Error	Rotation motor of reagent mix bar doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.

D0300000A	Stop Error	Connection timeout of motor driver board 4. Solution: Perform system reset. cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0300000E	Stop Error	Response timeout error of rotation motor of reagent mix bar. Contact after-sale engineers.
D030000F0	Stop Error	Updating firmware of motor driver board 4 failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.
D030000F1	Stop Error	Updating firmware of motor driver board 4 is forbidden. Solution: Check if the upgrading program is the same to the original version No.
D03010002	Stop Error	Communication timeout of vertical motor of reagent mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D03010003	Stop Error	Parameters error of vertical motor of reagent mix bar. Solution: contact after-sale engineers.
D03010004	Stop Error	Home position optocoupler error of vertical motor of reagent mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D03010006	Stop Error	Losing steps error of vertical motor of reagent mix bar. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D03010008	Stop Error	Vertical motor of reagent mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D03010009	Stop Error	Vertical motor of reagent mix bar doesn't move; optocoupler is triggered by mistake. Solution: contact after-sale engineers to check the motor wiring and optocoupler.
D0301000E	Stop Error	Response timeout error of vertical motor of reagent mix bar. Solution: contact after-sale engineers.
D03020002	Stop Error	Communication timeout of motor of reagent mix bar. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D03020003	Stop Error	Parameters error of motor of reagent mix bar. Solution: contact after-sale engineers.
D03020006	Stop Error	Motor of reagent mix bar running exception. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D03020008	Stop Error	Motor of reagent mix bar is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D0302000E	Stop Error	Response timeout error of motor of reagent mix bar. Contact after-sale engineers.

D04000002	Stop Error	Communication timeout of rotation motor of reaction tray. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D04000003	Stop Error	Parameters error of rotation motor of reaction tray. Solution: contact after-sale engineers.
D04000005	Stop Error	Home position optocoupler error of rotation motor of reaction tray. Solution: check if there is any blocking and remove it and then perform system reset. contact after-sale engineers if the problem remains unsolved.
D04000006	Stop Error	Losing steps error of rotation motor of reaction tray. Solution: check if there is any blocking and remove it and then perform system reset. Contact after-sale engineers if the problem remains unsolved.
D04000008	Stop Error	Rotation motor of reaction tray is busy. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved after three failed tries.
D0400000A	Stop Error	Connection timeout of motor driver 5. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0400000B	Stop Error	Connection error of grating channel 1. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0400000E	Stop Error	Rotating error of reaction tray. Solution: contact after-sale engineers.
D040000F0	Stop Error	Updating firmware of motor driver board 5 failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.
D040000F1	Stop Error	Updating firmware of motor driver board 5 is forbidden. Solution: check if the upgrading program is same to the original version.
D0401000B	Stop Error	Connection error of grating channel 2. Solution: cut off the power supply of the instrument and restart. contact after-sale engineers if the problem remains unsolved.
D0402000B	Stop Error	Connection error of grating channel 3. Solution: cut off the power supply of the instrument and restart. contact after-sale engineers if the problem remains unsolved.
D0403000B	Stop Error	Connection error of grating channel 4. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0404000B	Stop Error	Connection error of grating channel 5. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0405000B	Stop Error	Connection error of grating channel 6. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0406000B	Stop Error	Connection error of grating channel 7. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.

D0407000B	Stop Error	Connection error of grating channel 8. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0408000B	Stop Error	Connection error of grating channel 9. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D0409000B	Stop Error	Connection error of grating channel 10. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D040A000B	Stop Error	Connection error of grating channel 11. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D040B000B	Stop Error	Connection error of grating channel 12. Solution: cut off the power supply of the instrument and restart. Contact after-sale engineers if the problem remains unsolved.
D05000002	Stop Error	Communication timeout of temperature-control board of reaction tray. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries
D05000003	Stop Error	Failed to set parameters of temperature-control board of reaction tray. Solution: contact after-sale engineers.
D0500000A	Stop Error	Connection timeout of temperature-control board of reaction tray. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D050000F0	Stop Error	Updating firmware of temperature-control board of reaction tray failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.
D050000F1	Stop Error	Updating firmware of temperature-control board of reaction tray is forbidden. Solution: check if the upgrading program is same to the original version.
D06000001	Stop Error	Running timeout of valve. Solution: contact after-sale engineers.
D0600000A	Stop Error	Communication timeout of valve. Solution: contact after-sale engineers.
D060000F0	Stop Error	Updating firmware of pump and valve board failed.
D060000F1	Stop Error	Updating firmware of pump and valve board is forbidden.
D07000002	Stop Error	Communication timeout of heating bar control board. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D0700000A	Stop Error	Connection timeout of heating bar 2 control board. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
D070000F0	Stop Error	Updating firmware of heating bar 2 control board failed. Solution: check upgrading program and re-upgrade. Contact after-sale engineers if the problem remains unsolved.

D070000F1	Stop Error	Updating firmware of heating bar 2 control board failed. Solution: check if the upgrading program is same to the original version.
D07010002	Stop Error	Communication timeout of heating bar 2 control board. Solution: Perform system reset. Cut off the power supply of the instrument and restart if the problem remains unsolved. Contact after-sale engineers after three failed tries.
DFFFF1901	Stop Error	The instrument is disconnected. Solution: Connect first and then synchronize parameters. Contact after-sale engineers if the problem remains unsolved after three failed tries.
DFFFF1902	Stop Error	Parameters is not synchronized. Solution: reset the instrument and contact after-sale engineers if the problem remains unsolved.
DFFFF1903	Stop Error	Overall reset is not performed. Solution: reset the instrument and contact after-sale engineers if the problem remains unsolved.
DFFFF1904	Stop Error	Invalid parameters. Solution: check software version No. or contact after-sale engineers.
DFFFF1905	Stop Error	Compressor communication error. Solution: check connection and contact after-sale engineers if the problem remains unsolved.
DFFFF1906	Stop Error	Updating firmware failed. Solution: check upgrading program and re-upgrade. contact after-sale engineers if the problem remains unsolved.
DFFFF1907	Stop Error	Grating calibration failed. Solution: contact after-sale engineers.
DFFFF1910	Stop Error	FLASH reading failed. Solution: contact after-sale engineers.
DFFFF1950	Stop Error	Abnormal temperature of reaction tray. Solution: check the temperature of reaction tray and contact after-sale engineers if the problem remains unsolved.
DFFFF1951	Stop Error	Abnormal temperature of heating bar. Solution: check the temperature of heating bar and contact after-sale engineers if the problem remains unsolved.
DFFFF1952	Stop Error	Insufficient supply of pure water. Solution: check liquid line of water supply. contact after-sale engineers if the problem remains unsolved.
DFFFF1953	Stop Error	Insufficient supply of diluted wash solution. Solution: check liquid line of water supply.
DFFFF1954	Stop Error	Insufficient supply of concentrated wash solution. Solution: check concentrated wash solution tank.
DFFFF1955	Runtime Warning	Open reagent cover.
DFFFF1956	Runtime Warning	Open sample cover.
DFFFF1957	Runtime Warning	Open upper cover panel.
DFFFF1958	Stop Error	Too much waste liquid in the liquid deposit tank. Solution: check the waste liquid discharge lines.
M00000001	Runtime Operation	User Login.
M00000002	Stop Error	Liquid level abnormal.
M00000003	Stop Error	Can't detect liquid level.
M00000004	Stop Error	Cup blank abnormal.

M00000005	Stop Error	Insufficient reagent.
M00000006	Stop Error	Parameter synchronization error. Solution: contact after-sale engineers.
M00000007	Runtime Warning	LIS auto-connection failed.
M00000008	Runtime Warning	Calibration coefficient K value is changed.
M00000009	Runtime Warning	Instrument initialization error.
M0000000A	Runtime Warning	Insufficient wash solution of sample probe.
M0000000B	Runtime Warning	Calculation parameters error. Solution: contact after-sale engineers.
M0000000C	Runtime Warning	Light source service life.
M0000000D	Stop Error	Calculation item.
M0000000E	Runtime Warning	Daily maintenance is not completed.
M0000000F	Runtime Warning	Weekly maintenance is not completed.
M00000010	Runtime Warning	Out of linearity range or measuring range.
M00000011	Runtime Warning	Incorrect calibration parameters of reagent remaining volume.

Appendix-A More Information

A.1 Copyright

Getein Biotech, Inc.

Copyright No.: V2.0

Issue Date:7/15/2022

Instrument Name: CM-400 Biochemistry Analyzer

A.2 Service Life

The lifespan of CM-400 is 8 years under proper operation and maintenance (continuous working time should be no more than eight hours every day).

A.3 Warranty Period

Getein Biotech, Inc. guarantees that all the products have no defects in materials and processes and meet the product standards.

This warranty only applies to the covered product (provided to users at the time of purchase) in normal use, operation, maintenance conditions during the warranty period. Modifications, adaptations, alterations and repairs of the product without authorization by Getein Biotech, Inc. are not covered by this warranty. The warranty does not cover damages due to improper operation or maintenance, including accidents, abuse, misuse, carelessness, water quality and other non-instrument problems. Consumables such as hoses, absorbers, light source lamps and reaction cups are not covered by the warranty. The warranty period shall be subject to the sales contract.

A.4 Ordering Information

Consult Getein Biotech. Inc. or local authorized distributors.

A.5 Technical Support

Technical supports are provided by Getein Biotech, Inc. or authorized institutions.

A.6 Abbreviation

ABS./abs.	Absorbance
CV	Coefficient of Variation
O.D.	Optical Density
QC	Quality Control
R1, R2, R3, R4	Reagent 1, Reagent 2, Reagent 3, Reagent 4
SD	Standard Deviation
VOD	Vertical Obstacle Detection
Conc.	Concentration

A.7 Mark List

R	Flag on the patient's results to indicate the results of re-test.
+/-1SD	Flag on the QC serum results to indicate that the results are below or above the 1SD limit.
+/-2SD	Flag on the QC serum results to indicate that the results are below or above the 2SD limit.
+/-3SD	Flag on the QC serum results to indicate that the results are below or above the 3SD limit.
AbsLim	Flag on patients, calibrators and QC results: For positive response direction, this flag indicates that the absorbance of the reaction solution is higher than the specified absorbance limit. For test items of negative response direction, this flag indicates that the absorbance of the reaction solution is lower than the specified reaction absorbance limit. If the automatic re-test is set, the system will perform re-test with the decrease volume.
D	Flag on the patient's results to indicate a decrease volume test.
D*	Flag on patients, calibrators and QC results to indicate that the sample is not diluted.
H	Flag on patient's results, indicates that the results are higher than the specified maximum reference value.
I	Flag on patient's results to indicate an increase volume test.
L	Flag on the patient's results to indicate that the test results are below the specified minimum reference value.
Lin.H	Flag on patients, calibrators and QC results to indicate that it exceeds the specified upper limit of reagent linearity. In rate method, it indicates that the reaction rate (△Abs/min) exceeds the specified upper limit of reaction rate. In endpoint method, it indicates the sample concentration exceeds the specified upper limit of concentration. If the automatic re-test is selected, the system will perform re-test with the decrease volume.

Lin.L	Flag on patients, calibrators and QC results to indicate that the results are below the specified lower limit of reagents linearity. For rate method, it indicates that the reaction rate (△Abs/min) is below the lower limit of the reaction rate. For the endpoint method, it indicates that the sample concentration is below the lower limit of concentration. If the automatic re-test is selected, the system will perform re-test with the increase volume.
P*	Flag on patient and QC serum results to indicate that the prozone (substrate depletion) has occurred. If the automatic retest is selected, the system will perform re-test with the decrease volume.
Panic.H	Flag on the serum samples results to indicate that the results exceed the specified upper limit of the serum value. If the automatic re-test is selected, the system will perform re-test with the same volume type, and the sample results after the re-test will be flagged with a '#'.
Panic.L	Flag on the results of serum samples to indicate that the results are below the lower limit of the serum value. If the automatic re-test is selected, the system will perform retest with the same volume, and the sample results after the re-test will be flagged with a '#'.
PD	Flag on patients, calibrators and QC results to indicate that the sample has been pre-diluted.
R1*	Flag on patients, calibrators and QC results to indicate that R1 is not added properly.
R2*	Flag on patients, calibrators and QC results to indicate that R2 was not added properly.
RgtAbsMax	Flag on patients, calibrators and QC results to indicate that the absorbance of the reagent is higher than the specified upper limit of absorbance.
RgtAbsMin	Flag on patients, calibrators and QC results to indicate that the absorbance of the reagent is lower than the specified lower limit of absorbance.
S*	Flag on patient, calibration and QC results to indicate that the sample is not added properly.

A.8 Name and Content of Poisonous and Harmful Substances or Elements

ID	Component Name	Poisonous and Harmful Substances or Elements					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
1	Upper Cover Assembly	×	○	○	○	○	○
2	Operation Panel	×	○	○	○	○	○
3	Frame Assembly	×	○	○	○	○	○
4	Electrical Frame	×	○	○	○	○	○
5	Reaction Tray	×	○	○	○	○	○
6	Reagent Tray	×	○	○	○	○	○
7	Liquid Circuit Assembly	×	○	○	○	○	○
8	Mix Arm	×	○	○	○	○	○
9	Wash Arm	×	○	○	○	○	○
10	Spectrophotometer	×	○	○	○	○	○
11	Sample arm	×	○	○	○	○	○
12	Sample Probe Washing Port	×	○	○	○	○	○
13	Reagent Probe Washing Port	×	○	○	○	○	○
14	Mix Bar Washing Port	×	○	○	○	○	○
15	Reagent Arm	×	○	○	○	○	○
16	Printed Circuit Board Assembly	×	○	○	○	○	○
17	Sample Tray	×	○	○	○	○	○
○: It indicates that the amounts of the toxic and harmful substance in all homogeneous materials of the component is below the limit stipulated in China's SJ/T11363-2006 *Marking for Control of Pollution Caused by Electronic Information Products* .							
×: It indicates that the amounts of the toxic and harmful substance in at least one homogeneous material of the component exceeds the limit stipulated in SJ/T11363-2006 *Marking for Control of Pollution Caused by Electronic Information Products*.							
Printed Circuit Board Assembly*： It includes printed circuit boards and the components, capacitors and connectors.							

Appendix-B Accessories List

Name	Location	Notes
Halogen lamp module	Spectroscopic module	Replace parts regularly. Replace it when it has been used for more than 2000 hours or when the system indicates low light intensity. It is recommended not to use lamp for more than 6 months.
Spiral-shaped mix bar	Mixing mechanical arm,	Replace parts from time to time. Replace it when the bar is damaged.
Reagent probe assembly	Reagent long mechanical arm	Replace parts from time to time. Replace it when it is damaged or bent.
Sample probe assembly	Sampling mechanical arm	Replace parts from time to time. Replace it when it is damaged or bent.
CHP capsule filter	The analyzer water inlet	Replace it every 6 months
Biochemical wash solution	/	Consumable
Acidic wash solution	Reagent Tray	Consumable
Alkaline wash solution	Reagent Tray	Consumable
Electrolyte serum calibrator	ISE module (optional)	Consumable
Electrolyte urine calibrator	ISE module (optional)	Consumable
Electrolyte buffer	ISE module (optional)	Consumable
Electrolyte wash solution	ISE module (optional)	Consumable
Sodium electrode	ISE module (optional)	Consumable
Potassium electrode	ISE module (optional)	Consumable
Chloride electrode	ISE module (optional)	Consumable
Lithium electrode	ISE module (optional)	Consumable
Reference electrode	ISE module (optional)	Consumable
Sodium and potassium electrode	ISE module (optional)	Consumable
Urine controls	ISE module (optional)	Consumable

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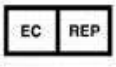

Lotus NL B.V.
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Diagnostic de laborator și dispozitive medicale de uz personal

Adresa: mun. Chișinău, str. Petricani 88/1, etaj 3, of.10
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Website: www.sanmedico.md

Către grupul de lucru

IMSP Institutul de Medicina Urgenta

Licitație deschisă nr. ocds-b3wdp1-MD-1770366366365 din 20.03.2026

Data: 20.03.2026

DECLARAȚIE

Prin prezenta, compania SRL Sanmedico, în calitate de ofertant la Licitație deschisă nr. ocds-b3wdp1-MD-1770366366365 din 20.03.2026, confirmă, că cantitatea testelor determinate per set pentru fiecare tipul de reagenți este:

CC1014 – 826 teste
CC1026 – 730 teste
CC1079 – 846 teste
CC1004 – 1269 teste
CC1041 – 858 teste
CC1007 – 562 teste
CC1006 – 943 teste
CC1012 – 943 teste
CC1037 – 562 teste
CC1005 – 826 teste
CC1074 – 674 teste
CC1032 – 826 teste
CC1021 – 337 teste
CC1028 – 690 teste
CC1027 – 439 teste

Cu respect,

Goreacii Vitalie

Administrator SRL „SANMEDICO”

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: 86-25-68568508 Email: overseas@getein.com.cn Web: www.getein.com

Letter of Declaration

Declaration of Calibration Frequency and Stability

We hereby confirm that for the diagnostic kits manufactured by Getein Biotech:

Calibration is not required at fixed intervals, but is recommended under the following conditions:
- when reagent lots are changed
- when quality control results indicate significant deviation

The calibration frequency is therefore flexible, depending on laboratory quality control performance. For quality assurance purposes, even in the absence of reagent lot changes or deviations, a routine calibration every 30 days may be performed, in accordance with good laboratory practice.

The stability of the calibration curve is up to 30 days, provided that:
- reagents are stored and used according to the manufacturer's instructions
- quality control results remain within acceptable limits

This information is consistent with the manufacturer's instructions for use (IFU) / kit insert documentation.

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein Biotech, Inc.

Reference Code：GP-DT-018-07-19 Issued by 07/26/2019

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

Completion of Getein Products Technical and Operational Training
& Qualification of After-sales Service

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.

EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/746, on in vitro diagnostic medical devices

Ref. No.: 20251022-A01

Manufacturer (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
SRN	CN-MF-000017986
Authorized Representative (Name, Address)	**CMC Medical Devices & Drugs S.L.** Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
SRN	ES-AR-000000293
Medical Devices	Refer to Annex
Classification	Class A (ANNEX VIII Classification rule 5(b) of Regulation EU 2017/746)
Conformity assessment route	CHAPTER V Section 2- Article 48 (10) of Regulation EU 2017/746
Reference to CS	Not available

Signatory representative declares herein the following mentioned devices meet the provisions of the Regulation EU 2017/746.

This declaration of conformity is based on European Parliament and the Council's Regulation EU 2017/746 CHAPTER V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing, 22nd October 2025

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

CE

Annex List of Medical Devices

No.	Medical device name	Basic UDI-DI	Intended use
1	Clinical Chemistry Analyzer	695441479572KV	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal liquid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and operators shall use and operate the analyzer according to relevant laws or legally binding regulations. The analyzer is limited to its intended use.
2	Immunofluorescence Quantitative Analyzer	695441479547KW	Immunofluorescence Quantitative Analyzer is an analyzer for processing Getein test kits and analysis of markers for cardiovascular diseases, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid. This manual contains instructions for the use of immunofluorescence Quantitative Analyzer and general instructions for testing specimens and quality control materials.
3	Quantitative Immunoassay Analyzer	695441479548KY	Quantitative Immunoassay Analyzer is an analyzer for the processing and analysis of Getein test kits including markers for cardiovascular disease, renal disease, inflammation, fertility, diabetes control and thyroid.
4	Hand-held Integrated System	695441479573KX	Hand-held Integrated System should work with dedicated test kits made by Getein Biotech Inc.. It is intended to detect and quantify specific chemical components in human blood serum, plasma, whole blood, capillary blood and urine samples through Dry Chemistry and Fluorescence Immunoassay.
5	Hematology Analyzer	695441479544KQ	This system uses electrical impedance to count red blood cells, white blood cells and platelets, and uses colorimetry to measure the hemoglobin, and relevant parameters will be enumerated. For professional use only.
6	Coagulation Analyzer	695441479549L2	The Coagulation Analyzer is designed to conduct functionality analyses on coagulation vs anticoagulation, and fibrinolysis vs antiplasmin by coagulation method, whose measurable indexes include the prothrombin time (PT), the activated partial thromboplastin time (APTT), the fibrinogen (FIB) content and the thrombin time (TT) of plasma.

7	Nucleic Acid Extraction Kit	695441479518KP	This product is intended use for the extraction and purification of viral nucleic acids (DNA and RNA) in samples. The extraction is intended use for clinical in vitro diagnosis.
8	Sample Extraction Solution	695441471332HF	This solution can be used to dilute human blood, nasal swab, nasopharyngeal swab, oropharyngeal swab and saliva samples. It does not directly participate in the detection.
9	A1c Diluent	695441471338HT	It is used for the pretreatment of blood samples during the detection of glycosylated hemoglobin.
10	Sample Diluent	695441471330HB	This diluent can be used to dilute human blood or urine samples when it is measured by the Immunofluorescence Quantitative Analyzer, Quantitative Immunoassay Analyzer, Chemiluminescence Immunoassay Analyzer of Getein, and it does not directly participate in the detection. It can replace the detection buffer and whole blood buffer in the colloidal gold method or dry immunofluorescence method."
11	Hematology Diluent	695441479514KF	Hematology Diluent can detect parameters such as red blood cells, white blood cells, hemoglobin, platelets, etc. as a supporting reagent for the hematology analyzer. Various diseases can be diagnosed by detecting the number of blood cells in the human body. It can monitor the physical condition of the human body in time, reduce the incidence or control the disease. For professional use only.
12	Hematology Lyser	695441479515KH	Hematology Lyser is used to break lysed cells, release hemoglobin, and maintain cell morphology before blood cell analysis, thereby facilitating white blood cell counting and hemoglobin determination. For professional use only.
13	Hematology Shutdown Solution	695441479516KK	Shutdown Solution can be used as a supporting reagent for the hematology analyzer which can clean sample aspiration probe to prevent blockage, clean the pipeline and valve group to prevent blockage of the hole, maintain the tubing and sample aspiration probe components, and prevent the effects of blood sample sedimentation. It plays a vital role in the accuracy and service life of hematology analyzer. For professional use only.

14	Activator	695441479510K7	Activator is intended to provide luminous reaction environment on chemiluminescence immunoassay analyzer. For professional use only.
15	Hemolyzing Buffer	695441479517KM	Hemolyzing buffer is used for sample pre-processing during the whole blood sample testing. For professional use only.
16	Test Cup	695441479519KR	The test cup is mainly used to provide immunoassay reaction chamber for MAGICL 6000 chemiluminescence immunoassay analyzer. For professional use only.
17	Whole Blood Buffer	695441471331HD	It is used for the pretreatment of blood samples during the detection of glycosylated hemoglobin. For professional use only.
18	CM-400 Clinical Chemistry Analyzer	695441479509KN	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal liquid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and operators shall use and operate the analyzer according to relevant laws or legally binding regulations. The analyzer is limited to its intended use.
19	CM-800 Clinical Chemistry Analyzer	695441479526KN	CM-800 is a fully automated analyzer intended for the quantitative analysis of human bodily fluids in clinical diagnosis. It is characterized by open reagents, discrete system, emergency priority, random access and an external computer. The analyzer introduces Windows operating system with user-friendly designs. Nevertheless, the analyzer is a very complex system, so operators are supposed to read the manual and be familiar with its functions before operating the instrument. This analyzer is intended for the quantitative analysis of chemical components in human serum, plasma, whole blood, urine, and cerebrospinal liquid samples.
20	CM-1000 Clinical Chemistry Analyzer	695441479552KP	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal fluid samples in laboratory use. The use of this analyzer is limited to its design purpose.
21	BBA-300 Clinical Chemistry Analyzer	695441479546KU	The analyzer can test many clinical items involving myocardial enzyme spectrum, blood sugar, blood lipid, liver function, renal function, immunoglobulin,

			etc., by analyzing the chemical component in human fluids such as blood, urine, pleural fluid and cerebrospinal fluid. For professional use only.
22	BBA-300 Automatic Biochemical Analyzer	695441479543KN	The analyzer can test many clinical items involving myocardial enzyme spectrum, blood sugar, blood lipid, liver function, renal function, immunoglobulin, etc., by analyzing the chemical component in human fluids such as blood, urine, pleural fluid and cerebrospinal fluid. For professional use only
23	Cleaning solution	695441479511K9	It is used to clean the reaction system and some pipes of the instrument during the detection process, so as to facilitate the in vitro detection of the substance to be tested.
24	Disposable virus sampling tube	695441479512KB	For the collection, transportation and storage of human nasopharyngeal virus and rash fluid samples.
25	MAGICL 6000 Chemiluminescence Immunoassay Analyzer	695441479506KG	MAGICL 6000 Chemiluminescence Immunoassay Analyzer automates the detection and quantification of markers for thyroid disease, inflammation, cardiac diseases, fertility, diabetes mellitus, bone metabolism, tumor, infectious disease, anemia, and immune globulin by analyzing human serum, plasma, whole blood and urine samples.
26	MAGICL 6800 Chemiluminescence Immunoassay Analyzer	695441479530KD	MAGICL 6800 Chemiluminescence Immunoassay Analyzer automates the detection and quantification of markers for thyroid disease, inflammation, cardiac diseases, fertility, diabetes mellitus, bone metabolism, tumor, infectious disease, anemia, and immune globulin in human serum, plasma and urine samples.
27	Getein 1100 Immunofluorescence Quantitative Analyzer	695441471311H7	Getein 1100 Immunofluorescence Quantitative Analyzer (hereinafter called Getein 1100) is an analyzer for processing Getein test kits and analysis of markers for cardiovascular diseases, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid. This manual contains instructions for the use of Getein 1100 and general instructions for testing specimens and quality control materials.
28	Getein 1160 Immunofluorescence Quantitative Analyzer	695441471337HR	In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases,

			inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.
29	Getein 1180 Immunofluorescence Quantitative Analyzer	695441471336HP	In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.
30	Getein 1200 Immunofluorescence Quantitative Analyzer	695441471335HM	In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.
31	Getein 1600 Immunofluorescence Quantitative Analyzer	695441471310H5	In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.
32	Getein 208 Hand-held Integrated System	695441471309HL	Getein 208 Hand-held Integrated System should work with dedicated test kits made by Getein Biotech Inc. It is intended to detect and quantify specific chemical components in human blood serum, plasma, whole blood, capillary blood and urine samples through Dry Chemistry and Fluorescence Immunoassay. Dry Chemistry: triglyceride, cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, uric acid, glucose, alanine aminotransferase, aspartate aminotransferase, muscle coordination, urea, homocysteine. Dry Fluorescence Immunoassay: Glycosylated hemoglobin, kinase isoenzyme, cardiac troponin I, myoglobin, microalbumin.
33	FIA 8600 Quantitative Immunoassay Analyzer	695441471334HK	FIA 8600 Quantitative Immunoassay Analyzer (hereinafter caled FIA8600) is an analyzer for the processing and analysis of Getein test kits including markers for cardiovascular disease, renal disease, inflammation, fertility, diabetes

			mellitus, bone metabolism, tumor and thyroid. This manual contains instructions for the use of FIA 8600 and general instructions for testing specimens and quality control materials.
34	FIA 8000 Quantitative Immunoassay Analyzer	695441471333HH	FIA 8000 Quantitative Immunoassay Analyzer (hereinafter called FIA8000) is an analyzer for the processing and analysis of Getein test kits including markers for cardiovascular disease, renal disease, inflammation, fertility, diabetes control and thyroid. This manual contains instructions for the use of FIA8000 and general instructions for testing specimens and quality control materials.
35	GN 7120 Akso PCR System	695441479541KJ	Akso PCR System works with dedicated test kits for real-time quantitative PCR technique to automatically execute an integrated nucleic acid detection procedure, including reagent preparation, nucleic acid extraction, PCR amplification, real-time detection and result processing, etc. and quantitatively detect the content of target nucleic acid in biological samples in vitro. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing. For professionals use only.
36	MAGICL 6000i Chemiluminescence Immunoassay Analyzer	695441479554KT	MAGICL 6000i Chemiluminescence Immunoassay Analyzer (hereinafter called MAGICL 6000i) automates the detection and quantification of markers for thyroid disease, inflammation, cardiac diseases, fertility, diabetes mellitus, bone metabolism, tumor, infectious disease, anemia, and immune globulin by analyzing human serum, plasma, and urine samples.
37	MAGICL 6200 Chemiluminescence Immunoassay Analyzer	695441479529KU	MAGICL 6200 works in conjunction with the dedicated reagents produced by Getein, and is used clinically for the qualitative or quantitative detection of analytes in human-derived serum, plasma, whole blood, capillary blood, and urine samples. These analytes include protein markers, hormone markers, enzyme markers, vitamin markers, autoantibody markers, other physiological/biochemical or immunological function markers, pathogenic antigen/antibody markers, tumor markers, and allergen (hypersensitivity) markers.
38	BHA-3000 Automatic Hematology Analyzer	695441479502K8	This system uses electrical impedance to count red blood cells, white blood cells and platelets, and

			uses colorimetry to measure the hemoglobin, and relevant parameters will be enumerated.
39	BHA-5000 Automatic Hematology Analyzer	695441479527KQ	This system uses Laser-based flow cytometry to count white blood cells in blood sample, uses electrical impedance to count red blood cells and platelets, and colorimetry to measure the hemoglobin, and relevant parameters will be enumerated.
40	BHA-5100 Automatic Hematology Analyzer	695441479545KS	This system uses Laser-based flow cytometry to count white blood cells in blood sample, uses electrical impedance to count red blood cells and platelets, and colorimetry to measure the hemoglobin, and relevant parameters will be enumerated. For professional use only.
41	BCS-600 Semi-automated Blood Coagulation Analyzer	695441479534KM	With its reliable performance, and simple and fast operation, the BCS-600 semi-automatic coagulometer is designed to conduct functionality analyses on coagulation vs anticoagulation, and fibrinolysis vs antiplasmin by coagulation method, whose measurable indexes include the prothrombin time (PT), the activated partial thromboplastin time (APTT), the fibrinogen (FIB) content and the thrombin time (TT) of plasma.
42	XN06-II Semi-automated Blood Coagulation Analyzer	695441479532KH	With its reliable performance, and simple and fast operation, the XN-06 semi-automatic coagulometer is designed to conduct functionality analyses on coagulation vs anticoagulation, and fibrinolysis vs antiplasmin by coagulation method, whose measurable indexes include the prothrombin time (PT), the activated partial thromboplastin time (APTT), the fibrinogen (FIB) content and the thrombin time (TT) of plasma.
43	GN-Pure 96 Automatic Nucleic Acid Purification System	6954414797114	GN-Pure 96 Automatic Nucleic Acid Purification System is a fully automatic extraction and purification system for DNA/RNA, proteins and cells. The automatic extraction and purification process is completed by the adsorption, transfer and release of magnetic beads by magnetic rod and magnetic rod sleeve. The operation is automated, fast and easy. Using 1ml nucleic acid purification kit, up to 96 samples can be processed simultaneously. The system works with different types of magnetic bead nucleic acid extraction kits for the

			extraction and purification of nucleic acids in samples of animal and plant tissues, blood and body fluids.
44	Integrated System	695441479528KS	In conjunction with dedicated test kits, this instrument automates the quantitative analysis of clinical chemistry in serum, plasma, whole blood and urine sample. Dry Chemistry: triglyceride, cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, glucose, creatinine. Fluorescence Immunoassay: glycosylated hemoglobin, kinase isoenzyme, cardiac troponin I, myoglobin and microalbumin.
45	SH80 Sample Processing System	695441479562KS	SH 80 is intended for automatic transfer of laboratory samples among the connected biochemistry analyzers and chemiluminescence analyzers.
46	SHC 200 Pre-analytical Module	695441479555KV	SHC 200 is intended to be used for pre-analytical sample handling, including sample delivery, centrifugation and decapping. The instrument works with other modules provided by Getein, such as the biochemistry analysis module, chemiluminescence analysis module, sample supply unit, etc.
47	CM-1000 Clinical Chemistry Analyzer	695441479552KP	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal fluid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and operators shall use and operate the analyzer according to relevant laws or legally binding regulations.
48	CM-400 biochemistry analyzer	695441479524KJ	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal liquid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and operators shall use and operate the analyzer according to relevant laws or legally binding regulations.
49	CM-800 biochemistry analyzer	695441479525KL	The analyzer is intended for the quantitative chemical analysis of serum, plasma, whole blood, urine and cerebrospinal liquid samples in laboratory use. The analyzer should be used in compliance with local laws and regulations. Users and

			operators shall use and operate the analyzer according to relevant laws or legally binding regulations.
50	SH80 sample supply unit	695441479570KR	SH 80 is intended for automatic transfer of laboratory samples among the connected biochemistry analyzers and chemiluminescence analyzers. For professional use only.
51	Integrated system	695441479528KS	In conjunction with dedicated test kits, this instrument automates the quantitative analysis of clinical chemistry in serum, plasma, whole blood and urine sample. Dry Chemistry: triglyceride, cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, glucose, creatinine. Fluorescence Immunoassay: glycosylated hemoglobin, kinase isoenzyme, cardiac troponin I, myoglobin and microalbumin.
52	A1c diluent	695441471338HT	It is used for the pretreatment of blood samples during the detection of glycosylated hemoglobin. For professional use only.
53	Hemolyzing buffer	695441479517KM	Hemolyzing buffer is used for sample pre-processing during the whole blood sample testing.
54	Activator 1	695441479559L5	Activator 1 is intended to provide luminous reaction environment on chemiluminescence immunoassay analyzer. FOR PROFESSIONAL USE ONLY
55	Activator 2	695441479560KN	Activator 2 is intended to provide luminous reaction environment on chemiluminescence immunoassay analyzer.
56	ISE Module	695441479574KZ	The ISE Module is used as a component of other diagnostic test systems, including chemistry analyzers. It measures lithium, sodium, potassium, and chloride and transmits the results of these measurements to the host analyzer for integration into other reported test results. FOR PROFESSIONAL USE ONLY.
57	ISE cleaning solution	695441479566L2	For in vitro diagnostic use.
58	Cyclic ProDX 400	695441479563KU	In conjunction with dedicated test kits for Immunofluorescence, the instrument automates the detection and quantification of markers for cardiovascular disease, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid in a biological sample.

59	Chemiluminescence Immunoassay Analyzer	695441479567L4	MAGICL 6200 works in conjunction with the dedicated reagents produced by Getein, and is used clinically for the qualitative or quantitative detection of analytes in human-derived serum, plasma, whole blood, capillary blood, and urine samples. These analytes include protein markers, hormone markers, enzyme markers, vitamin markers, autoantibody markers, other physiological/biochemical or immunological function markers, pathogenic antigen/antibody markers, tumor markers, and allergen (hypersensitivity) markers. For professional use only.
60	Sample Supply Unit	695441479571KT	SH 80 is intended for automatic transfer of laboratory samples among the connected biochemistry analyzers and chemiluminescence analyzers. For professional use only.
61	Pre-analytical Module	695441479568L6	SHC 200 is intended to be used for pre-analytical sample handling, including sample delivery, centrifugation and decapping. The instrument works with other modules provided by Getein, such as the biochemistry analysis module, chemiluminescence analysis module, sample supply unit, etc.
62	Acid Cleaning Solution	695441479561KQ	It is used to clean the reaction system and some pipes of the instrument during the detection process, so as to facilitate the in vitro detection of the substance to be tested.
63	Alkaline Cleaning Solution	695441479565KY	It is used to clean the reaction system and some pipes of the instrument during the detection process, so as to facilitate the in vitro detection of the substance to be tested.
64	Automated Coagulation Analyzer	695441479549L2	In Vitro Diagnostic medical device.
65	Getein 1150 Immunofluorescence Quantitative Analyzer	695441479553KR	In conjunction with dedicated test kits for Immunofluorescence, the analyzer is used for the qualitative or quantitative analysis of biomarkers in human whole blood, serum, plasma, capillary blood or urine samples. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.
66	GN 7000 Akso PCR System	695441479539KX	This instrument is based on the principle of real-time fluorescence polymerase chain reaction and works in conjunction with the

			specialized test kits. It is used clinically for the extraction and qualitative detection of analytes, including pathogens, from cervical swab and throat swab specimens. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing. For professionals use only.
67	CA 5500 Automated Coagulation Analyzer	695441479549L2	CA 5500 Automated Coagulation Analyzer is used for analyzing the coagulation and anticoagulation, fibrinolysis, and antifibrinolysis functions of human blood samples. For professional use only.
68	CA 5700 Automated Coagulation Analyzer	695441479549L2	CA 5700 Automated Coagulation Analyzer is used for analyzing the coagulation and anticoagulation, fibrinolysis, and antifibrinolysis functions of human blood samples. For professional use only.

EC Declaration of Conformity

According to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.: 220512-jilin02

Maker (Name, Address)	**Jilin Getein Biotech Co., Ltd** No.1399, Ya'an Road, Beihu Science and Technology Development Zone, Changchun, Jilin, China
Authorized Representative (Name, Address)	**CMC Medical Devices & Drugs S.L.** Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

No.	Product Name
1	ADA Control
2	5'-NT Control
3	HbAlc Control
4	D-Dimer Control
5	Cl Control
6	GLDH Control
7	GPDA Control
8	K Control
9	LAP Control
10	LDH1 Control
11	LPS Control
12	NAG Control
13	Na Control
14	CO2 Control
15	CK-MB Control
16	FMN Control
17	Lp(a) Control
18	ACE Control
19	CSF Control
20	MAO Control
21	mAlb Control

22	ADA calibrator
23	5'-NT calibrator
24	HbAlc calibrator
25	D-Dimer calibrator
26	Cl calibrator
27	GLDH calibrator
28	GPDA calibrator
29	K calibrator
30	LAP calibrator
31	LDH1 calibrator
32	LPS calibrator
33	NAG calibrator
34	Na calibrator
35	mAlb calibrator
36	CK-MB calibrator
37	AFU Control
38	AFU calibrator
39	TBA calibrator
40	TP calibrator
41	ALB calibrator
42	PA calibrator
43	CG Control
44	CG calibrator
45	AMM Control
46	AMM calibrator
47	GR Control
48	GR calibrator
49	CK-MBmass Control
50	CK-MBmass calibrator
51	CRE calibrator

52	CRE-E calibrator
53	UREA calibrator
54	UA calibrator
55	CYS-C calibrator
56	β2-MG calibrator
57	GLU-HK calibrator
58	GLU-OX calibrator
59	FMN calibrator
60	D3-H calibrator
61	GA Control
62	GA calibrator
63	SA Control
64	SA calibrator
65	NEFA Control
66	NEFA calibrator
67	TCH calibrator
68	ApoA1 calibrator
69	ApoB calibrator
70	ApoE calibrator
71	Lp(a) calibrator
72	HCY calibrator
73	HCY Control
74	Lp-PLA2 Control
75	Lp-PLA2 calibrator
76	ACE calibrator
77	Myo Control
78	Myo calibrator
79	Ca calibrator
80	P calibrator
81	CO2 calibrator

82	Fe calibrator
83	ASO calibrator
84	RF calibrator
85	CRP calibrator
86	MALB calibrator
87	CSF calibrator
88	RBP calibrator
89	C3 calibrator
90	C4 calibrator
91	IgA calibrator
92	IgM calibrator
93	IgG calibrator
94	PGI Control
95	PGI calibrator
96	PGII Control
97	PGII calibrator
98	CCP Control
99	CCP calibrator
100	Fer Control
101	Fer calibrator
102	TRF Control
103	TRF calibrator
104	hs-CRP Control
105	hs-CRP calibrator
106	Composite Calibrator serum
107	Composite quality control serum
108	Lipid Compound Calibrator
109	Lipid Compound Control
110	Special Protein Control

Classification	Others		
Applicable coordination standards	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015
	EN 61326-2-6:2006	IEC 61326-1:2013	
	EN 61010-2-101:2002	IEC 61010-1:2010	

Signatory representative declares herein the above-mentioned devices meet the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Lipeng Xu

CE

Chang chun, May 12, 2022

(place and date of issue)

(name and signature or equivalent marking of authorized person)

EC Declaration of Conformity

According to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.: 220324-IC

Maker
(Name, Address)

Getein Biotech, Inc.
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

Product Name

1. 5'-NT Reagent Kit (POD Method)
2. ACE Reagent Kit (FAPGG Substrate Method)
3. ADA Reagent Kit (POD Method)
4. ALB Reagent Kit (BCG Colorimetric Method)
5. ALP Reagent Kit (NPP Substrate-AMP Buffer Method)
6. ALT Reagent Kit (Alanine Substrate Method)
7. AMY Reagent Kit (EPS Substrate Method)
8. ApoA1 Reagent Kit (Immunoturbidimetric Method)
9. ApoB Reagent Kit (Immunoturbidimetric Method)
10. ApoE Reagent Kit (Immunoturbidimetric Method)
11. ASO Reagent Kit (Immunoturbidimetric Method)
12. AST Reagent Kit (Asparaginic Acid Substrate Method)
13. Urea Reagent Kit-1(Urease-GLDH Kinetic method)
14. Urea Reagent Kit-2(Urease-GLDH Kinetic method)
15. C3 Reagent Kit (Immunoturbidimetric Method)
16. C4 Reagent Kit (Immunoturbidimetric Method)
17. Ca Reagent Kit (Arsenazo III Colorimetric Method)
18. CCP Reagent Kit (Immunoturbidimetric Method)
19. CG Reagent Kit (Immunoturbidimetric Method)
20. CHE Reagent Kit (Butylthiocholine Kinetic method)
21. CK-MB Reagent Kit (immunoinhibition method)
22. CK Reagent Kit (Phosphocreatine Substrate method)
23. Cl Reagent Kit (Thiocyanate Colorimetric Method)
24. CO2 Reagent Kit (PEPC Method)
25. CRE-E Reagent Kit (Enzymatic Method)
26. CRP Reagent Kit (Immunoturbidimetric Method)
27. CSF Reagent Kit (Pyrogallol red Colorimetric Method)
28. CYS-C Reagent Kit (Latex-enhanced Immunoturbidimetric Method)

29. CRP Reagent Kit (Latex-enhanced Immunoturbidimetric Method)
30. D3-H Reagent Kit (Kinetic Method)
31. DB Reagent Kit (Chemical Oxidation Method)
32. D-Dimer Reagent Kit (Immunoturbidimetric Method)
33. Fe Reagent Kit (Ferrozine Chromogenic Method)
34. FMN Reagent Kit (NBT Reductive Method)
35. GA Reagent Kit (POD Method)
36. GGT Reagent Kit (GCANA substrate Method)
37. GLDH Reagent Kit (Kinetic Method)
38. GLU-HK Reagent Kit (Hexokinase Enzymatic Method)
39. GLU-OX Reagent Kit-2 (GOD-POD Method)
40. GLU-OX Reagent Kit-1 (GOD-POD Method)
41. GPDA Reagent Kit (Enzyme Kinetic Method)
42. HbA1c Reagent Kit (Immunoturbidimetric Method)
43. HBDH Reagent Kit (Kinetic Method)
44. HCY Reagent Kit (Enzymatic Cycling Method)
45. HDL-C Reagent Kit (Direct Colorimetric Method)
46. IgA Reagent Kit (Immunoturbidimetric Method)
47. IgG Reagent Kit (Immunoturbidimetric Method)
48. IgM Reagent Kit (Immunoturbidimetric Method)
49. K Reagent Kit (Enzymatic Method)
50. LAC Reagent Kit (LO - POD Enzymatic-Colorimetric Method)
51. LAP Reagent Kit (L-leucyl-nitroaniline substrate Method)
52. LDH1 Reagent Kit (L-P Method)
53. LDH Reagent Kit (Lactate Substrate Method)
54. LDL-C Reagent Kit-1(Direct Method)
55. LDL-C Reagent Kit-2(Direct Method)
56. Lp(a) Reagent Kit(Immunoturbidimetric Method)
57. LPS Reagent Kit (Enzyme Colorimetric Method)
58. MALB Reagent Kit (Immunoturbidimetric Method)
59. MAO Reagent Kit (Colorimetric method)
60. Mg Reagent Kit (Colorimetric Method)
61. NAG Reagent Kit (MNP-GLcNAc Substrate Method)
62. NA Reagent Kit (Enzymatic Method)
63. NEFA Reagent Kit (Enzymatic Colorimetric Method)
64. PA Reagent Kit (Immunoturbidimetric Method)
65. PG I Reagent Kit (Immunoturbidimetric Method)
66. PG II Reagent Kit (Immunoturbidimetric Method)
67. P Reagent Kit (Phosphomolybdate Method)
68. RBP Reagent Kit (Immunoturbidimetric Method)
69. RF Reagent Kit (Immunoturbidimetric Method)
70. SA Reagent Kit (Enzymatic Method)

71. TBA Reagent Kit (Enzymatic Cycling Method)
72. TB Reagent Kit (Chemical Oxidation Method)
73. TCH Reagent Kit-1 (CHOD-PAP Enzymatic-Colorimetric Method)
74. TCH Reagent Kit-2 (CHOD-PAP Enzymatic-Colorimetric Method)
75. TG Reagent Kit-1 (GPO-PAP Enzymatic-Colorimetric Method)
76. TG Reagent Kit-2 (GPO-PAP Enzymatic-Colorimetric Method)
77. TP Reagent Kit (Biuret Colorimetric Method)
78. UA Reagent Kit-1 (Uricase Method)
79. UA Reagent Kit-2 (Uricase Method)
80. UIBC Reagent Kit (Ferrozine Chromogenic Method)
81. β2-MG Reagent Kit (Immunoturbidimetric Method)
82. Compound Calibrator serum
83. Compound quality control serum
84. Lipid compound calibrator
85. Lipid compound quality control
86. hs-CRP Reagent Kit (Immunoturbidimetric Method)
87. AFU Reagent Kit (CNPF Substrate Method)
88. Lp-PLA2 Reagent Kit (14-NPC Substrate Method)
89. TRF Reagent kit (Immunoturbidimetric Method)
90. AMM Reagent kit (glutamate dehydrogenase method)
91. CK-MB Reagent kit (Immunoturbidimetric Method)
92. Myo Reagent kit (Immunoturbidimetric Method)
93. GR Reagent Kit (Glutathione Substrate Method)
94. Fer Reagent kit (Immunoturbidimetric Method)
95. Special Protein Control
96. Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay)
97. H. pylori Antibody Fast Test Kit (Immunofluorescence Assay)
98. FluA/FluB/SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay)
99. TNT Control
100. Cyclic ProDX 400 Immunofluorescence Quantitative Analyser
101. Malaria P.f/Pv Ag Rapid Test (Colloidal Gold Assay)
102. Malaria P.fPan Ag Rapid Test (Colloidal Gold Assay)
103. Malaria P.f Ag Rapid Test (Colloidal Gold Assay)

Classification	Others		
Applicable	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
coordination	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
standards	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015

Signatory representative declares herein the above-mentioned devices meet the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V.. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

CE

Nanjing, March 16, 2022

(place and date of issue)

(name and signature or equivalent marking of authorized person)

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编：211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-29
Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26
Expiry Date: 2026-07-25

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.
研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29
Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26
Expiry Date: 2026-07-25

Certificate No: **MD 728432**

Location	Registered Activities
Getein Biotech, Inc. No.9 Bofu Road Luhe District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京市 六合区 沿江工业开发区 博富路9号 邮编：211505	Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。
Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编：211505	Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 生产化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

TECHNICAL SPECIFICATIONS

Item	Technical Parameter	Item	Technical Parameter
Test Principle	Latex Immunoturbidimetry, Immunoturbidimetry, Colorimetry	Test Methods	Rate method, end point method, fixed-time method
Test Items	Up to 78 items at the same time	Test Throughput	Constant speed: 400 T/H Optional ISE module 400 T/H
Reaction Time	About 12.3 min	Sample Volume	1.50-50.0μL (0.1 μL increment)
Sample Tray	90 positions (including sample, calibrator and control) Outer: 30 sample positions Median: 30 sample positions Inner: 30 calibrator and control positions	Reagent	Up to 4 reagents per test item
Reagent Volume	R1: 10.0-450.0 μL R2/R3/R4: 0 or 10.0-450.0 μL (1 μL increment)	Reagent Tray	Reagent positions: 40 reagent positions for outer tray 40 reagent positions for inner tray Refrigeration: Peltier system
Reaction Volume	100.0-360.0 μL	Cuvette	Quartz cuvette: 5*5 mm; 90 plastic or quartz cuvettes
Photometry	Direct photometry with multiple wavelengths Light Source: 20 W halogen lamp, over 2000 hours Spectrometer: grating Detector: photodiode array Wavelengths: support single/double wavelength among 16 selected wavelengths 340, 380, 405, 450, 480, 505, 546, 578, 600, 630, 660, 680, 700, 720, 750, 800 nm Points: 82 (every 9 seconds) +2 points for reaction cup blank	Stirring	High speed stirring, more evenly
Reaction Temperature	Constant temperature: (37.0±0.2)°C	Preheat Time	20 min
Application	Calibration: multi-point calibration curve with up to 7 points Dilution: automatic pre-dilution Data Check: basic range check, qualitative judgement	Dimensions	1160 mm (L)*790 mm (W)*1140 mm (H)
Max Noise	58 dB	Gross Weight	300 kg
Water Consumption	No more than 20 L purified water per hour		

CM-400

Clinical Chemistry Analyzer

TEST ITEMS

Liver Function

TBA, ALT, AST, ALP, GGT, TP, AMM, GPDA, GLDH, CG, ALB, TB, DB, PA, CHE, ADA, 5' -NT, LAP, MAO, GR

Specific Protein and Rheumatism

CCP, ASO, RF, CRP, hs-CRP+CRP, C3, C4, IgA, hs-CRP, IgM, IgG, TRF, Fer

Blood Lipids and Cardiovascular

TG, TCH, HDL-C, LDL-C, ApoB, ApoE, Lp(a), HCY, ACE, Myo, Lp-PLA2, ApoA1, NEFA, IMA

Trace Elements and Electrolytes

Ca, Mg, P, CO_2, Fe, UIBC, Na, Cl, K

Venous Thromboembolism and Coagulation

D-Dimer

Tumor

SA, AFU

Renal Function

CRE-E, Urea, UA, β_2-MG, CSF, CysC, mAlb, NAG, RBP, NGAL

Glycometabolism

GLU-HK, GLU-OX, FMN, D3-H, HbA1c, GA, LAC

Pancreatitis

LPS, AMY

Myocardial Enzyme

CK, CK-MB, CK-MB mass, LDH, HBDH, LDH1

Gastric Function

PG I, PG II

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel.: +86-25-68568508/68568594
Fax: +86-25-68568500
E-mail: overseas@getein.com.cn; marketing@getein.com.cn
Web.: www.getein.com

ISO 9001:2015 ISO 13485 FSC CE NMPA MDSAP IVD

WCM3-400-06

Getein Biotech, Inc.

STOCK CODE 603387

CM-400

Clinical Chemistry Analyzer

Your Reliable Laboratory Choice, Smart and Compact

Getein Biotech, Inc.

3 Accurate Sampling System

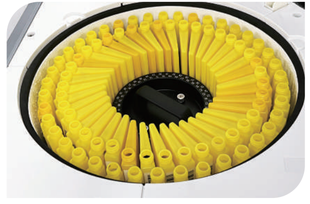
100 µL Minimum Reaction Volume

1.5 µL Minimum Sampling Volume

- High-precision injector
- Internally and externally polished sampling probes
- Liquid volume tracking and level detection
- Minimum reaction volume: 100 µL
- Minimum sampling volume: 1.5 µL
- CV≤2%

4 Intelligent Online Loading System

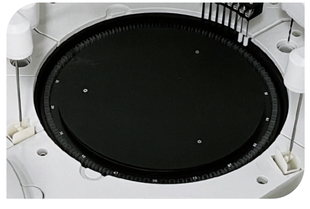
- Reagents can be loaded on-board during test.
- Peltier system provides a longer maintenance period to reduce repair probability.



1 High-efficiency Sample Processing, Constant Speed 400 T/H

400 T/H 90 Sample Positions 80 Reagent Positions

- Constant throughput: 400 T/H, optional ISE module with 400 T/H
- 90 sample positions, 80 reagent positions
- 90 plastic or quartz cuvettes



2 Dry Heating Thermostatic System

——Rapid heating, maintenance free

- Directly heating system enables faster heating and decreases pre-heating time.
- Thermostatic system by dry heating keeps reaction solution in cuvettes at (37.0±0.2)℃.

5 8-step Warm Liquid Washing

——More thorough cleaning

- Whole probe stereo cleaning technology with cross-contamination rate＜0.05%.
- Pure water washing in step 1, cleaning solution washing in step 2-3, pure water washing in step 4-6, then wiping module washing in step 7-8.
- Anti-overflow function prevents liquid spillage.

CE IVD

ALB Reagent Kit (BCG Colorimetric Method)

Instructions for Use REF CC1004

PRODUCT NAME

ALB Reagent Kit (BCG Colorimetric Method)

PACKAGE SPECIFICATION

R:1×10 mL	R:1×20 mL	R:1×50 mL	R:2×30 mL
R:2×35 mL	R:2×40 mL	R:2×45 mL	R:2×50 mL
R:2×55 mL	R:2×60 mL	R:4×20 mL	R:4×30 mL
R:4×35 mL	R:4×40 mL	R:4×45 mL	R:4×50 mL
R:4×55 mL	R:4×60 mL	R:5×20 mL	R:5×120 mL
R:6×20 mL	R:6×30 mL	R:6×35 mL	R:6×40 mL
R:6×45 mL	R:6×50 mL	R:6×55 mL	R:6×60 mL
R:6×100 mL	R:8×20 mL	R:10×20 mL	R:4×1000 mL
R:2×2000 mL	R:2×300T (2×100 mL)		
R:12×72 T (12×25 mL)		Calibrator (optional):1×1 mL	

INTENDED USE

Used for the *in vitro* quantitative determination of Albumin (ALB) in human serum and plasma.
Mainly used clinically to assist in the evaluation of liver function and nutritional assessment.
For professional and laboratory use only.

TEST PRINCIPLE

This reagent is prepared according to the Bromocresol Green (BCG) method recommended by the World Health Organization (WHO).
The principle is as follows: in acidic solution (pH4.15), albumin and BCG form a green complex, of which absorbance at 600 nm is proportional to the concentration of albumin, and its content can be measured against the standard.

MAIN COMPONENTS

Kit content	Reagent components	Concentration
Reagent	Succinate Buffer (pH 4.15)	10 g/L
	Polyoxyethylene (23) Lauryl Ether	2.5 g/L
	Bromocresol green	0.3 g/L
Calibrator (optional)	Albumin, aqueous matrix	30-50 g/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: traceable to National Reference Material GBW (E) 090619.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and heparin anti-coagulated plasma should be separated promptly after blood collection to avoid Hemolysis, and serum and plasma could be stabilised at 15-25°C for 7 days, at 2-8°C for 1 month and at −20°C for 4 months.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	600nm/700 nm	**Calibration type**	Linearity
Sample/Reagent	2/300 μL	**Time of mixture of serum + R1**	1 min
Method	One-point end point assay	**Total reaction time**	1 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

(Absorbance (A) read by the instrument=$A_{\text{Primary wavelength}}$-$A_{\text{Secondary wavelength}}$)
Operating procedures:
Single-reagent operation

Substances added	Test tubes	Standard tubes	Blank tubes
Reagent	300 μL	300 μL	300 μL
Sample	2 μL	-	-
Standard solution	-	2 μL	-
Distilled water	-	-	2 μL
Mix well, incubate at 37°C for 1 min, and then calibrate the with a blank and read the absorbance A of each tube.			

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:
   ALB concentration (g/L)=Concentration of ALB Standard Reference Material (SRM) ×$\triangle A_{\text{test sample}}/\triangle A_{\text{SRM}}$

REFERENCE RANGE

Appropriate level: 40-55 g/L
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Hemolysis interferes with the assay and should be avoided as much as possible during the procedure. The time the sample is left in place also has an effect on the assay.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 400 mg/dL, ascorbic acid ≤ 30 mg/dL, bilirubin ≤ 40 mg/dL, and triglycerides ≤ 500 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent in the kit is a slightly yellowish green clear liquid, which may contain a small number of subvisible particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance $|A_{600nm}| \leq 0.500$.
3. Accuracy
   The relative deviation should not fall outside the range of ± 6.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [3, 60.0] g/L:
   a) The linear correlation coefficient (r) should not be less than 0.990;
   b) The deviation from linearity should not fall outside the range of ± 2.5 g/L for testing within the linear range of [3, 8] g/L; the deviation from linearity should not fall outside the range of ± 10.0% for testing within the linear range of (8, 60] g/L.
5. Analytical sensitivity
   When a sample has a concentration of 40 g/L, its absorbance difference should be ≤ 0.800.
6. Precision
   6.1 Repeatability
   The repeatability (coefficient of variation, CV) of repeat test results for serum at a concentration of (40 ± 5) g/L should not exceed 2.0%.
   6.2 Between-run precision
   Inter-assay variation of serum at a concentration of (40 ± 5) g/L should not be more than 5.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
   3.6 Serum, heparin anti-coagulated plasma, should be separated promptly after blood collection to avoid haemolysis, do not use haemolysed samples.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 203-206

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ALB Reagent Kit (BCG Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

ALP Reagent Kit (NPP Substrate-AMP Buffer Method)

Instructions for Use REF CC1005

PRODUCT NAME

ALP Reagent Kit (NPP Substrate-AMP Buffer Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×5 mL	R1:1×30 mL	R2:1×8 mL
R1:1×40 mL	R2:1×10 mL	R1:1×60 mL	R2:1×15 mL
R1:2×30 mL	R2:1×15 mL	R1:2×35 mL	R2:1×20 mL
R1:2×40 mL	R2:1×20 mL	R1:2×60 mL	R2:2×15 mL
R1:2×60 mL	R2:1×30 mL	R1:2×60 mL	R2:1×35 mL
R1:2×80 mL	R2:1×40 mL	R1:2×80 mL	R2:2×20 mL
R1:4×35 mL	R2:2×20 mL	R1:4×40 mL	R2:2×20 mL
R1:4×50 mL	R2:2×25 mL	R1:4×50 mL	R2:3×20 mL
R1:4×60 mL	R2:2×30 mL	R1:4×60 mL	R2:2×35 mL
R1:4×60 mL	R2:4×15 mL	R1:4×100 mL	R2:2×50 mL
R1:4×120 mL	R2:2×60 mL	R1:4×653 mL	R2:4×146 mL
R1:6×66 mL	R2:6×16 mL		
12×60 T (R1: 12×16.8 mL + R2: 12×4.2 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of alkaline phosphatase activity in human serum and plasma. Alkaline phosphatase is mainly used in the examination of obstructive jaundice, hepatobiliary diseases and bone tissue diseases. Physiologic elevation: in children during physiologic bone development, alkaline phosphatase activity can be 1 to 2 times higher than normal; pathologic elevation: (1) Bone diseases such as rickets, achondroplasia, etc; (2) Hepatobiliary diseases such as extrahepatic bile duct obstruction, cirrhosis, capillary hepatitis, etc; (3) Other diseases such as hyperparathyroidism, pathological lowering: seen in severe chronic nephritis, thyroid insufficiency in children, anemia, etc.
For professional and laboratory use only.

TEST PRINCIPLE

4-NPP + 2A2M1P $\xrightarrow{ALP}$ 4-Nitrophenol + 2A2M1P-phosphate
4-NPP + H_2O $\xrightarrow{ALP}$ 4-Nitrophenol + Phosphate
The rate of generation measured at specific wavelengths was used to calculate ALP viability.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	2-amino-2-methyl-propanol	1.0 g/L
	Magnesium acetate	2.0 g/L
	Ethylene diamine tetraacetic Acid	0.5 g/L
	Zinc sulfate	0.2 g/L
Reagent 2	Disodium 4-nitrophenyl phosphate	0.5 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Serum and plasma anticoagulated with heparin should be separated in time after blood collection to avoid hemolysis.
2. The test results for serum and plasma will not change within 7 days at 15-25°C, 7 days at 4-8°C and 2 months at −20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	415nm/505 nm	**Calibration type**	Linearity
Sample/R1/R2	5/200/50 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

Operating procedures:
Dual Reagent Operation

Substances added	Blank tubes	Test tubes
Reagent 1	200 μL	200 μL
Distilled water	5 μL	-
Sample	-	5 μL
Mix well, incubate at 37°C for 3 min		
Reagent 2	50 μL	50 μL
Mix well, incubate at 37°C for 60s, continuously monitor the absorbance change at the measurement wavelength for 1-3min, and calculate △A/min.		

3. Calibration procedure: Randox calibration serum is recommended.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:

$$\text{ALP viability (U/L)} = \frac{\triangle A/\text{min} \times K\ (2757)}{\text{Total reaction volume (mL)} \times 1000}$$

$$K = \frac{}{\text{Sample volume (mL)} \times \text{millimolar extinction coefficient} \times 1.0}$$

Note: 1000 = conversion factor from U/mL to U/L; 1.0 = cuvette optical diameter

REFERENCE RANGE

The reference range for adults is 15-150 U/L;
The reference range is for reference only. Because there are differences in respect of factors including geography, race, gender and age, it is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 1000 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤50 mg/dL and triglycerides ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
   2.1 Reagent blank absorbance $A_{415\ nm} \leq 1.000$.
   2.2 Rate of change in absorbance of reagent blanks
   Reagent blank absorbance change rate $\left|\Delta A_{415nm}\right|$ /min ≤ 0.004.
3. Accuracy
   The relative deviation should not fall outside the range of ± 10.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [5, 750] U/L (37°C):
   a) The linear correlation coefficient (r) should not be less than 0.9900;
   b) The deviation from linearity should not fall outside the range of ± 10 U/L for testing within the linear range of [5, 50] U/L;
   the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (50, 750] U/L;
5. Analytical sensitivity
   When a sample has a concentration of 120 U/L, its absorbance difference should be ≤0.084.
6. Precision
   6.1 Within-run precision
   Within-run precision should not be more than 5.0%.
   6.2 Between-run precision
   Between-run precision should not be more than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The results of the kit are only used as a basis for clinical diagnosis of various diseases, and should be considered in conjunction with the patient's symptoms/signs, medical history, other laboratory tests and response to treatment.
   1.5 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Avoid direct sunlight during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
   3.6 Serum and plasma anticoagulated with heparin should be separated in time after blood collection to avoid hemolysis.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 309-312.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ALP Reagent Kit (NPP Substrate-AMP Buffer Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

ALT Reagent Kit (Alanine Substrate Method)

Instructions for Use

REF CC1006

PRODUCT NAME

ALT Reagent Kit (Alanine Substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×10 mL	R1:1×40 mL	R2:1×20 mL
R1:1×60 mL	R2:1×30 mL	R1:2×60 mL	R2:2×30 mL
R1:2×30 mL	R2:2×15 mL	R1:2×40 mL	R2:2×20 mL
R1:2×50 mL	R2:1×50 mL	R1:2×60 mL	R2:1×60 mL
R1:2×60 mL	R2:3×20 mL	R1:2×65 mL	R2:1×70 mL
R1:2×80 mL	R2:1×80 mL	R1:2×120 mL	R2:2×60 mL
R1:3×20 mL	R2:3×10 mL	R1:3×40 mL	R2:3×20 mL
R1:4×40 mL	R2:4×20 mL	R1:4×50 mL	R2:2×50 mL
R1:4×55 mL	R2:2×55 mL	R1:4×60 mL	R2:2×60 mL
R1:4×60 mL	R2:4×30 mL	R1:4×60 mL	R2:6×20 mL
R1:4×65 mL	R2:2×65 mL	R1:4×65 mL	R2:2×70 mL
R1:4×100 mL	R2:2×100 mL	R1:4×653 mL	R2:4×283 mL
R1:2×65 mL	R2:1×65 mL	R1:4×65 mL	R2:2×65 mL
12×72T (R1: 12×16.8 mL R2:12×8.4 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of alanine aminotransferase activity in human serum and plasma.
Mainly used to assist in the evaluation of liver function. ALT is a sensitive indicator to reflect liver injury, various acute liver injuries (such as acute infectious hepatitis and drug or alcohol poisoning). Serum ALT can be in the clinical symptoms (such as jaundice) before the emergence of a sharp rise and so on, and is generally parallel with the severity of the disease and the recovery; serum ALT may also be elevated in chronic hepatitis, fatty liver, cirrhosis, hepatic stasis, etc. In addition, cholecystitis, cholelithiasis, pancreatitis, myocardial infarction and taking certain drugs (such as chlorpromazine, quinine, salicylic acid preparations, etc.) can be seen in the serum ALT rise. For professional and laboratory use only.

TEST PRINCIPLE

L-alanine + α-ketoglutarate $\xrightarrow{\text{ALT}}$ Glutamic acid + pyruvic acid
Pyruvate + NADH + H $\xrightarrow{\text{LDH}}$ Lactate + NAD
The rate of NADH reduction was measured at 340 nm and ALT viability was calculated.

MAIN COMPONENTS

Kit contetnt	Components in reagents	Concentration
Reagent 1	Tris(Hydroxymethyl)aminomethane Buffer (pH 7.4)	1.2114 g/L
	NADH	0.55 g/L
	Lactate Dehydrogenase	3000 U/L
	Sodium Azide	2 g/L
Reagent 2	L-Alanine	25 g/L
	α-Ketoglutaric Acid	5 g/L
	Sodium Azide	2 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. This test can be used for human serum and plasma samples.
2. Serum and heparin anticoagulant plasma should be separated in time after blood collection to avoid hemolysis.
3. The test results for serum and plasma will not change within 3 days at 15-25°C, 7 days at 2-8°C and 30 days at -20°C.

TEST PROCEDURE

1. Dual reagents are ready for use and no preparation is required.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/Secondary Wavelength	340nm/415 nm	**Calibration Type**	Linearity
Sample/R1/R2	15-30/200/100 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration Method	Two-point calibration	**Direction of reaction**	Downward

Operating procedures:
Dual Reagent Operation

Substances Added	Blank tubes	Test tubes
Reagent R1	200 μL	200 μL
Distilled water	15-30 μL	-
Sample	-	15-30 μL
Mix and incubate at 37°C for 3 min.		
Reagent R2	100 μL	100 μL
Mix well, incubate at 37°C for 60-90 s, continuously monitor the absorbance change of each tube at the measurement wavelength for 1-3 min, and calculate △A/min for each tube.		

3. Calibration procedure: Randox calibration serum can also be used.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:

4.1 Check whether the parameter settings and light source are correct.
4.2 Check whether the cuvettes and sampling probes are clean.
4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
4.4 Check reaction temperature.
4.5 Check the expiration date of the kit.

5. Result calculation:

$$\text{ALT viability (U/L)} = \frac{(\Delta A_{assay}/\text{min} - \Delta A_{blank}/\text{min}) \times K}{\text{Total reaction volume (mL)} \times 1000}$$

$$K = \frac{}{\text{Sample volume (mL)} \times \text{millimolar extinction coefficient} \times 1.0}$$

Note: 1000 = conversion factor from U/mL to U/L; 1.0 = cuvette optical diameter; millimolar extinction coefficient = 6.22

REFERENCE RANGE

Reference range for adults is 0-40 U/L
The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 500 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 40 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
2.1 Reagent blank absorbance A_{340nm} should be not less than 1.0.
2.2 Rate of change in absorbance of reagent blanks
The reagent blank absorbance change: $|\Delta A_{340nm}|$ /min should not be greater than 0.004.
3. Accuracy
The relative deviation should not fall outside the range of ± 15.0%.
4. Linear range
For serum sample testing within the reagent linear range of [5, 1000] U/L (37°C):
a) The linear correlation coefficient (r) should not be less than 0.9900;
b) The deviation from linearity should not fall outside the range of ± 15 U/L for testing within the linear range of [5, 100] U/L;
the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (100, 1000] U/L;
5. Analytical sensitivity
When a sample has a concentration of 97.4 U/L, its absorbance difference should be ≥ -0.050.
6. Precision
6.1 Within-run precision
Within-run precision should not be more than 5.0%.
6.2 Between-run precision
Between-run precision should not be more than 10.0%.

PRECAUTIONS

1. General precautions
1.1 This product is for *in vitro* diagnostic use only.
1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
1.3 Please use this product according to the IFU.
1.4 The results of the kit are only used as a basis for clinical aid in the diagnosis of various diseases. The clinical diagnosis and management of the patient should take into account his/her signs/symptoms, medical history, other laboratory tests and response to treatment, etc. are considered together.
1.5 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
2.3 Avoid direct sunlight during operation.
3. Precautions for use
3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
3.2 Please do not use expired reagents whose test results may be inaccurate.
3.3 Please avoid adding reagents halfway during a test.
3.4 Please avoid direct sunlight during operation.
3.5 Do not use the reagents with visible signs of turbidity or if the absorbance of the reagent blank is less than 1.000.
3.6 Serum and heparin-anticoagulated plasma should be separated promptly after blood collection to avoid hemolysis; do not use hemolyzed samples.
4. Precautions for waste disposal
Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
5.3 Please do not use the reagent bottles for other purposes.
5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong et al. National clinical testing operation procedures (4th ed.). People's Health Publishing House.2015:279-280.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ALT Reagent Kit (Alanine Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

AMY Reagent Kit (EPS Substrate Method)

Instructions for Use REF CC1007

PRODUCT NAME

AMY Reagent Kit (EPS Substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×5 mL	R1:1×30 mL	R2:1×8 mL
R1:1×40 mL	R2:1×10 mL	R1:1×60 mL	R2:1×15 mL
R1:2×30 mL	R2:1×15 mL	R1:2×35 mL	R2:1×20 mL
R1:2×40 mL	R2:1×20 mL	R1:2×60 mL	R2:2×15 mL
R1:2×60 mL	R2:1×30 mL	R1:2×60 mL	R2:1×35 mL
R1:2×80 mL	R2:1×40 mL	R1:2×80 mL	R2:2×20 mL
R1:4×35 mL	R2:2×20 mL	R1:4×40 mL	R2:2×20 mL
R1:4×50 mL	R2:2×25 mL	R1:4×50 mL	R2:3×20 mL
R1:4×60 mL	R2:2×30 mL	R1:4×60 mL	R2:2×35 mL
R1:4×60 mL	R2:4×15 mL	R1:4×100 mL	R2:2×50 mL
R1:4×120 mL	R2:2×60 mL	R1:6×66 mL	R2:6×16 mL
750 T (R1:1 x 80 mL R2:1 x 18 mL)		300 T (R1: 1 x 33 mL R2: 1 x 9 mL)	
2 x 160 T (R1: 2 x 44 mL R2: 2 x 11 mL)		6 x 60 T (R1: 6 x 16.8 mL R2: 6 x 4.2 mL)	

INTENDED USE

Used for the *in vitro* quantitative determination of amylase activity in human serum, plasma or urine.
It is mainly used clinically as an aid in the diagnosis of pancreatic diseases. For professional and laboratory use only.

TEST PRINCIPLE

The rate of pNP production was measured at specific wavelengths and AMY viability was calculated.

$$5EPS + 5H_2O \xrightarrow{\alpha\text{-Amylase}} \text{ethyliden-}G_3 + \text{pNP-}G_4^+$$

$$\text{2ethyliden-}G_2 + \text{2pNP-}G_3 + \text{2ethyliden-}G_5 + \text{2pNP-}G_2$$
$$\text{pNP-}G_4 + \text{2pNP-}G_3 + \text{2pNP-}G_2 + 14H_2O \xrightarrow{\alpha\text{-Glucosidase}} 5pNP+14G$$

MAIN COMPONENTS

Kit composition	Reagent Components	Concentration
Reagent 1	4-(2-Hydroxyethyl)-1-piperazine-ethanesulfonic acid	2 mol/L
	α-Glucosidase	8 KU/L
	sodium chloride	1.5 g/L
	calcium chloride	1.0 g/L
Reagent 2	4,6-Ethylidene-p-nitrophenyl-alpha-D-malt heptoside	6 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Serum and plasma anticoagulated with heparin should be separated in time after blood collection to avoid hemolysis.
2. The test results for serum and plasma will not change within 7 days at 15-25°C, 1 month at 2-8°C and 12 months at −20°C. The test results for urine will not change within 2 days at 15-25 °C and 10 days at 2-8°C.

TEST PROCEDURE

1. Reagents preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary / secondary wavelength	415nm/505 nm	**Calibration type**	Linearity
Sample/R1/R2	6/240/60 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

Operating Procedure:
Dual Reagent Operation

Substances added	Blank tubes	Test tubes
Reagent R1	240 μL	240 μL
Distilled water	6 μL	-
the root cause and symptoms of a disease	-	6 μL
Mix well, incubate at 37°C for 3 min		
Reagent R2	60 μL	60 μL
Mix well, incubate at 37°C for 60-90s, continuously monitor the absorbance change of each tube at the measurement wavelength for 1-3min, and calculate △A/min of each tube.		

3. Calibration procedure: A Randox calibration serum is recommended.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:
   AMY viability (U/L) = $(\Delta A_{assay}/\text{min}-\Delta A_{blank}/\text{min}) \times 8100$

REFERENCE RANGE

Serum/plasma: ≤220 U/L
Urine: ≤1200 U/L
The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation. The time period between sample collection and tests may also affect the measurement results.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 100 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blanks
   2.1 Reagent blank absorbance
   Reagent blank absorbance A_{415nm} ≤ 0.350.
   2.2 Rate of change in absorbance of reagent blanks
   Reagent blank absorbance change rate $|\Delta A_{415nm}|$/min≤0.002.
3. Accuracy
   The relative deviation should not fall outside the range of ± 10.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [5, 1500] U/L (37°C):
   a) The linear correlation coefficient (r) should not be less than 0.990;
   b) The deviation from linearity should not fall outside the range of ± 5 U/L for testing within the linear range of [5, 50] U/L;
   the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (50, 1500] U/L.
5. Analytical sensitivity
   When a sample has a concentration of 1 U/L, its absorbance difference should be ≤ 0.00056.
6. Precision
   6.1 Repeatability
   The repeatability (coefficient of variation, CV) should be ≤ 5.0%.
   6.2 Between-run precision
   The between-run precision should be ≤ 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Do not use the reagents with visible signs of turbidity or the absorbance of the reagent blank is higher than 0.500.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong et al. National clinical testing operation procedures (4th ed.). People's Health Publishing House.2015:289-290.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AMY Reagent Kit (EPS Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

AST Reagent Kit (Asparaginic Acid Substrate Method)

Instructions for Use

REF CC1012

PRODUCT NAME

AST Reagent Kit (Asparaginic Acid Substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×10 mL	R1:1×40 mL	R2:1×20 mL
R1:1×60 mL	R2:1×30 mL	R1:2×60 mL	R2:2×30 mL
R1:2×30 mL	R2:2×15 mL	R1:2×40 mL	R2:2×20 mL
R1:2×50 mL	R2:1×50 mL	R1:2×60 mL	R2:1×60 mL
R1:2×60 mL	R2:3×20 mL	R1:2×65 mL	R2:1×70 mL
R1:2×80 mL	R2:1×80 mL	R1:2×120 mL	R2:2×60 mL
R1:3×20 mL	R2:3×10 mL	R1:3×40 mL	R2:3×20 mL
R1:4×40 mL	R2:4×20 mL	R1:4×50 mL	R2:2×50 mL
R1:4×55 mL	R2:2×55 mL	R1:4×60 mL	R2:2×60 mL
R1:4×60 mL	R2:4×30 mL	R1:4×60 mL	R2:6×20 mL
R1:4×65 mL	R2:2×65 mL	R1:4×65 mL	R2:2×70 mL
R1:4×100 mL	R2:2×100 mL	R1:4×653 mL	R2:4×283 mL
R1:2×65 mL	R2:1×65 mL	R1:4×65 mL	R2:2×65 mL
12×72 T (R1:12×16.8 mL R2:12×8.4 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of aspartate aminotransferase in human serum and plasma. Mainly used clinically to assist in the auxiliary diagnosis of viral hepatitis, obstructive jaundice and myocardial infarction.
For professional and laboratory use only.

TEST PRINCIPLE

Aspartic acid + α-ketoglutaric acid $\xrightarrow{\text{AST}}$ Glutamic acid + Oxaloacetic acid
Oxaloacetic acid + NADH + H $\xrightarrow{\text{AST}}$ Malic acid + NAD
The rate of NADH reduction was measured at a wavelength of 340 nm and was used to calculate AST viability.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tris(hydroxymethyl)aminomethane buffer (pH 7.6)	12.114 g/L
	α-ketoglutaric	6 g/L
	Reduced Coenzyme I	1 g/L
	Sodium azide	2 g/L
	Lactate dehydrogenase	1500 U/L
	Malate dehydrogenase	2000 U/L
Reagent 2	L-aspartic acid	50 g/L
	Sodium azide	2 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480.
If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and heparinized plasma samples should be separated promptly after collection to avoid hemolysis. Serum and plasma samples can maintain stable enzyme activity for 4 days at 15-25 °C, for 7 days at 2-8 °C and for 3 months at -20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	340 nm/415 nm	**Calibration type**	Linearity
Sample/R1/R2	15-30/200/100 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration method	Two-point calibration	**Direction of reaction**	Downward

Operating procedures:
Dual Reagent Operation

Substances added	Blank tubes	Test tubes
Reagent 1	200 μL	200 μL
Distilled water	15-30 μL	-
Sample	-	15-30 μL
Mix well, incubate at 37°C for 3 min		
Reagent 2	100 μL	100 μL
Mix well, incubate at 37°C for 60-90s, continuously monitor the absorbance change at the measurement wavelength for 1-3min, and calculate △A/min.		

3. Calibration procedure: Randox calibration serum is recommended.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.

5. Result calculation:

$$K = \frac{\text{AST viability (U/L)} = (\triangle A \text{ test/min} - \triangle A \text{ blank/min}) \times K}{\text{Total reaction volume (mL)} \times 1000}$$

$$\text{Sample volume (mL)} \times \text{millimolar extinction coefficient} \times 1.0$$

Note: 1000 = conversion factor from U/mL to U/L; 1.0 = cuvette optical diameter; Millimolar extinction coefficient = 6.22

REFERENCE RANGE

The reference range for adults is 0-45 U/L;
The reference range is for reference only, it is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 500 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 40 mg/dL, and triglycerides ≤1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of subvisible particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect determination.
2. Reagent blank absorbance
   2.1 Reagent blank absorbance
   Reagent blank absorbance $A_{340nm} \geq 1.000$.
   2.2 Rate of change in absorbance of reagent blanks
   Reagent blank absorbance change rate $|\Delta A_{340nm}|$ /min≤0.004.
3. Accuracy
   The relative deviation should not fall outside the range of ± 15.0%.
4. Linear range
   For serum sample testing within the reagent linear range of [5, 1000] (37°C) :
   a)The linear correlation coefficient (r) should not be less than 0.9900;
   b)The deviation from linearity should not fall outside the range of ±10U/L for testing within the linear range of [5, 100] U/L;
   the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (100, 1000] U/L;
5. Analytical sensitivity
   When a sample has a concentration of 95.1U/L, its absorbance difference should be ≥ -0.050.
6. Precision
   6.1 Within-run precision
   Within-run precision should not be more than 5.0%.
   6.2 Between-run precision
   Between-run precision should not be more than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The results of the kit are only used as a basis for clinical diagnosis of various diseases, and should be considered in conjunction with the patient's symptoms/signs, medical history, other laboratory tests and response to treatment.
   1.5 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Avoid direct sunlight during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Reagents should not be used if they are turbid or if the absorbance of the reagent blank is less than 1.000.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 281.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AST Reagent Kit (Asparaginic Acid Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

CRP Reagent Kit (Immunoturbidimetric Method)

Instructions for Use REF CC1027

PRODUCT NAME

CRP Reagent Kit (Immunoturbidimetric Method)

PACKAGE SPECIFICATION

R1: 1×10 mL	R2: 1×10 mL	R1: 1×20 mL	R2: 1×20 mL
R1: 1×25 mL	R2: 1×25 mL	R1: 1×30 mL	R2: 1×30 mL
R1: 1×35 mL	R2: 1×35 mL	R1: 1×40 mL	R2: 1×40 mL
R1: 1×45 mL	R2: 1×45 mL	R1: 1×50 mL	R2: 1×50 mL
R1: 1×55 mL	R2: 1×55 mL	R1: 1×60 mL	R2: 1×60 mL
R1: 2×20 mL	R2: 2×20 mL	R1: 2×30 mL	R2: 2×30 mL
R1: 2×35 mL	R2: 2×35 mL	R1: 2×40 mL	R2: 2×40 mL
R1: 2×45 mL	R2: 2×45 mL	R1: 2×50 mL	R2: 2×50 mL
R1: 2×55 mL	R2: 2×55 mL	R1: 2×60 mL	R2: 2×60 mL
R1: 3×20 mL	R2: 3×20 mL	R1: 3×30 mL	R2: 3×30 mL
R1: 3×35 mL	R2: 3×35 mL	R1: 3×40 mL	R2: 3×40 mL
R1: 3×45 mL	R2: 3×45 mL	R1: 3×50 mL	R2: 3×50 mL
R1: 3×55 mL	R2: 3×55 mL	R1: 3×60 mL	R2: 3×60 mL
250 T (R1: 1×43 mL R2: 1×15 mL)		Calibrator (optional): 5×0.5 mL	
12×72 T (R1: 12×12.9 mL R2: 12×12.9 mL)			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of C-reactive protein in human serum or plasma. C-reactive protein is primarily used as a nonspecific marker of inflammation.
For professional and laboratory use only.

TEST PRINCIPLE

The anti-human C-reactive protein antibodies, coated on latex particles, can agglutinate with the C-reactive protein in the serum to form antigen-antibody complexes. The turbidity level is proportional to the CRP concentration in the serum when a certain amount of antibodies are present. By measuring the absorbance value at a specific wavelength, the concentration of CRP in the serum can be calculated using the multi-point calibration curve.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Ammonium chloride buffer	50 mmol/L
Reagent 2	Anti-human CRP antibody latex particles	20 mL/L
Calibrator (optional)	C-reactive protein	2.0-165.0 mg/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: Traceable to national Standard Reference Material.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480.
If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Fasting is required prior to sample collection. Draw venous blood from the veins in the elbow and preserve the serum.
2. Separate the serum as soon as possible after sample collection. If the test cannot be conducted on the same day of sample collection, the sample can be stored at 2-8°C for a maximum of 3 days.
3. Hemolysis or lipemia should be avoided.
4. Samples can be stable for 11 days at 15-25°C , for 2 months at 2-8°C, and for 3 years at -20°C. Take care when thawing frozen samples, and ensure they are thoroughly mixed before testing. The samples can only be used once after they are thawed.

TEST PROCEDURE

1. The dual reagent is ready for use directly.
2. Test conditions:

Primary/Secondary Wavelength	570nm/700 nm	**Calibration Type**	Nonlinearity
Sample/R1/R2	2/140/140 μL	**Time of Mixture of Serum and R1**	1-5 min
Method	Two-point endpoint method	**Reaction time after addition of R2**	5 min
Calibration Method	Six-point calibration	**Direction**	Upward

(Absorbance (A) read by the instrument=$A_{\text{Primary Wavelength}}$-$A_{\text{Secondary Wavelength}}$)
Operating procedures:

Sample	2 μL
Reagent 1	140 μL
Mix well, incubate at 37°C for 1-5 min	
Reagent 2	140 μL
Mix well, incubate for 10s, perform zero adjustment with the blank tube, and read the absorbance (A_1). Read the absorbance (A_2) after 5 min, and calculate $\triangle A = A_2 - A_1$.	

3.Calibration procedure: A calibrator from Getein is recommended.
4.Quality control procedure: Use the quality control product from Getein, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sample probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5.Result calculation
   The multi-point calibration method, and nonlinear calibration are employed. The concentration of CRP is calculated by determining the ΔA of the test tube.

REFERENCE RANGE

0-6 mg/L
The reference range is established based on the 95% distribution interval of healthy individuals and is for reference purpose only. It is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

1. If the concentration of the sample exceeds the linear range, it should be diluted with physiological saline and retested. The test result should be multiplied by the dilution factor.
2. The test results are for clinical reference only. The diagnosis and treatment of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory tests, and treatment responses.

LIMITATIONS

1. The linear range can reach 150 mg/L when operated according to the instructions.
2. The linear range depends on the sample to reagent ratio and the analyzer used.
3. Reducing the sample volume can increase the linear range, but it also decreases the sensitivity.
4. If the concentration is less than 3 mg/L, the test results will not be stable.
5. There is no interference with the measurement when hemoglobin ≤ 500 mg/dL, bilirubin ≤ 40 mg/dL, and ascorbic acid ≤ 150 mg/dL.
6. Read the instructions for use carefully before using the reagent. Careful handling is required to obtain accurate results. Any modification to the operation procedures may affect the test results.
7. False-negative results can be caused by unknown components shielding the antigenic determinants from antibody binding; degradation of C-reactive protein antigens with prolonged storage and temperature increase; improper sample collection, transport, and handling; and low concentrations of the analyte in the sample.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is an emulsion. The kit components are complete, the inner and outer packaging is complete, the label is legible, and there is no leakage of the liquid reagent.
2. Reagent content
   The net content of the reagent should not be less than the labeled value.
3. Reagent blank absorbance
   Reagent blank absorbance $A_{570nm} \leq 1.500$.
4. Accuracy
   The relative deviation should be within ±15%.
5. Linear range
   5.1 Linear correlation coefficient
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [0.3,150] mg/L.
   5.2 Linear deviation
   Within the range of [0.3, 50] mg/L, the linear absolute deviation should not exceed ±5 mg/L;
   Within the range of (50, 150] mg/L, the linear relative deviation should not exceed ±10%.
6. Analytical sensitivity
   At the wavelength of 570 nm (optical diameter of 1 cm), the absolute value of the change in absorbance (ΔA) caused by CRP at a concentration of 40 mg/L should be in the range of 0.05-0.50.
7. Precision
   7.1 Repeatability
   Within the linear range, select samples with 2 concentration levels, and the concentration selection can refer to the medical decision level, representing normal and outlier levels. Repeat the test 10 times for each level, and the coefficient of variation (CV) should not exceed 10%.
   7.2 Between-run precision
   Between-run precision should not be greater than 15%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Treat the specimens and wastes as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Hemolysis should be avoided during the operation procedure.
   2.4 Although the control product and calibrator in the reagent kit have passed the tests for HBs-Ag, HIV1/2-Ab, HCV-Ab, etc., no test can guarantee absolute safety. Therefore, these components should be treated as potential sources of infection.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Mix the latex reagent thoroughly before adding it to the diluent, and use a small amount of buffer solution to rinse the latex reagent to avoid any reagent loss.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 Linearity is closely related to the sample/reagent ratio. Reducing the sample volume can increase linearity, but the sensitivity of the test will decrease proportionally.
   5.5 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.6 Please do not mix reagents in different batches.

REFERENCE

1. Ultra-rapid, Ultra-sensitive Single-step Kinetic Immunoassay for C-reactive Protein (CRP) in Whole Blood Samples: Determination of CRP Concentration using Sample Dilution Method. Clinical Chemistry, February 2002; 48: 269 - 277.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CRP Reagent Kit (Immunoturbidimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

GGT Reagent Kit (GCANA substrate Method)

Instructions for Use

REF CC1037

PRODUCT NAME

GGT Reagent Kit (GCANA substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2× 30mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 2×80 mL	R2: 2×20 mL
R1: 4×35 mL	R2: 2×20 mL	R1: 4×40 mL	R2: 2×20 mL
R1: 4×50 mL	R2: 2×25 mL	R1: 4×50 mL	R2: 3×20 mL
R1: 4×60 mL	R2: 2×30 mL	R1: 4×60 mL	R2: 2×35 mL
R1: 4×60 mL	R2: 4×15 mL	R1: 4×100 mL	R2: 2×50 mL
R1: 4×120 mL	R2: 2×60 mL	R1: 4×653 mL	R2: 4×146 mL
R1: 6×66 mL	R2: 6×16 mL		
12×60 T(R1: 12×16.8 mL R2: 12×4.2 mL)			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of gamma-glutamyl transferase activity in human serum and plasma.
Clinically, it is mainly used for the auxiliary diagnosis of diseases related to the hepatobiliary system.
For professional and laboratory use only.

TEST PRINCIPLE

GluCANA + Gly-Gly $\xrightarrow{\gamma\text{-GT}}$ Glu-Gly-Gly+ 5-Amino-2-nitrobenzoic acid
The 5-amino-2-nitrobenzoic acid has a maximum absorption at a specific wavelength, and the rate at which it forms is directly proportional to the activity of γ-GT in sample. Therefore, the activity of γ-GT in sample can be determined by measuring the rate of increase in absorbance.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Gly-Gly	11.0 g/L
Reagent 2	γ-glutamyl-3-carboxy-4-nitroaniline	4.0 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and heparin anticoagulated plasma should be separated as soon as possible after sample collection to avoid hemolysis.
Once separated, the sample is stable for 7 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C.

TEST PROCEDURE

1. The dual reagent is ready for use directly.
2. Test conditions:

Primary/Secondary Wavelength	405 nm/505 nm	**Calibration Type**	Linearity
Sample/R1/R2	15/240/60 μL	**Time of Mixture of Serum and R1**	3-5 min
Method	Rate assay	**Reaction time after addition of R2**	3 min
Calibration Method	Two-point calibration	**Direction**	Upward

Operating procedures:
Operation using two reagents

Substances Added	Blank Tube	Test Tube
Reagent 1	240 μL	240 μL
Distilled Water	15 μL	-
Sample	-	15 μL
Mix well, incubate at 37°C for 3-5 min		
Reagent 2	60 μL	60 μL
Mix well, incubate at 37°C for 60 s, continuously monitor the change of the absorbance for 1-3 min, and calculate △A/min		

3.Calibration procedure: A calibrator from Randox is recommended.
4.Quality control procedure: Use the quality control product from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
  4.1 Check whether the parameter settings and light source are correct.
  4.2 Check whether the cuvettes and sample probes are clean.
  4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
  4.4 Check reaction temperature.
  4.5 Check the expiration date of the kit.
5.Result calculation

$$GGT\ (U/L) = (\Delta A_{Measured}/min - \Delta_{ABlank}/min) \times K\ (2213)$$

$$K = \frac{\text{Total Reaction Volume (mL)} \times 1000}{\text{Sample Volume (mL)} \times \text{Molar Extinction Coefficient} \times 1.0}$$

Note: 1000 is the conversion factor from U/mL to U/L; 1.0 refers to the optical path of the colorimetric cell.
The molar extinction coefficient of 5-amino-2-nitrobenzoic acid at a wavelength of 405 nm is 9.49.
The molar extinction coefficient of 5-amino-2-nitrobenzoic acid at a wavelength of 410 nm is 7.96.

REFERENCE RANGE

	Male	Female
37°C	11-50 U/L	7-32 U/L
30°C	3-38 U/L	5-25 U/L

The results measured at 37°C can be multiplied by the coefficient 0.77 if converted to the results at 30°C.
The provided reference range is for reference only, and it is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

Hemolysis can interfere with the measurement, and it should be avoided during the operation.
The storage duration of the sample can also affect the measurement results.

LIMITATIONS

There is no interference with the measurement when hemoglobin is ≤ 200 mg/dL, ascorbic acid is ≤ 50 mg/dL, bilirubin is ≤ 40 mg/dL, and triglycerides is ≤ 500 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank
   2.1 Reagent blank absorbance
   Reagent blank absorbance A_{405nm} ≤ 1.000.
   2.2 Rate of change in reagent blank absorbance
   At 37°C, a 405 nm wavelength, and the 1 cm optical path, when physiological saline is used as the sample added to the reagent test, the rate of change in reagent blank absorbance (△A/min) should not exceed 0.005.
3. Accuracy
   The relative deviation should be within ±15%.
4. Linear range
   When testing serum samples, the linearity is within the range of [5,1200] U/L:
   a) The correlation coefficient (r) should not be less than 0.990.
   b) Within the range of [5,30] U/L, the linear deviation should not exceed ±4 U/L;
   Within the range of (30,1200] U/L, the linear deviation should not exceed ±10%.
5. Analytical sensitivity
   When testing 50 U/L GGT, the difference in the rate of absorbance change should be ≤ 0.03.
6. Precision
   6.1 Repeatability
   The coefficient of variation (CV) should not be greater than 5.0%.
   6.2 Between-run precision
   The relative range between batches should not be greater than 10%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the user manual.
2. Precautions for operation
   2.1 Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Avoid using the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 Phenobarbital, phenytoin, pentobarbital, dichloroantipyrine, antipyrine, etc., may increase GGT levels. Heavy alcohol consumption can also lead to increased GGT levels.
   5.5 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.6 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 286-287.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on GGT Reagent Kit (GCANA substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

TB Reagent Kit (Chemical Oxidation Method)

Instructions for Use

REF CC1074

PRODUCT NAME

TB Reagent Kit (Chemical Oxidation Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2×30 mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 4×35 mL	R2: 2×20 mL
R1: 4×40 mL	R2: 2×20 mL	R1: 4×50 mL	R2: 2×25 mL
R1: 4×50 mL	R2: 3×20 mL	R1: 4×60 mL	R2: 4×15 mL
R1: 4×60 mL	R2: 2×35 mL	R1: 4×60 mL	R2: 2×30 mL
R1: 4×100 mL	R2: 2×50 mL	R1: 4×120 mL	R2: 2×60 mL
R1: 6×62 mL	R2: 6×19 mL		
2×300 T (R1: 2×80 mL+R2: 2×20 mL)			
12×52 T (R1: 12×17.2 mL+R2: 12×4.3 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of Total Bilirubin in human serum and plasma.
Mainly used clinically for the auxiliary diagnosis of bilirubin metabolism disorder. For professional and laboratory use.

TEST PRINCIPLE

Total bilirubin is oxidized by chemical oxidants in the presence of surfactants to form biliverdin, and the decrease in absorbance at 450 nm measured is proportional to the concentration of total bilirubin.

$$\text{Total bilirubin} \xrightarrow[\text{Surfactant}]{\text{Chemical oxidant pH8.2}} \text{Biliverdi}$$

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tris (hydroxymethyl) aminomethane hydrochloride buffer (pH8.2)	100 mmol/L
	Triton X-100	10 mL/L
Reagent 2	Sodium nitrite	1.3 g/L
	Phosphate buffer(pH7.0)	50 mmol/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The reagent should be stored at 2˚C - 8˚C in the dark and unopened state, and the validity period is 18 months. After opening, the reagent should be stored at 2˚C - 8˚C and valid for 42 days.
Production date and expiry date to see the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Use morning fresh serum and heparin anticoagulant plasma; keep the sample out of light. The test results for serum and plasma will not change within 1 day of storage at 15-25°C, 7 days of storage at 4-8°C and 1 year of storage at -20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelengths	450 nm/546 nm	**Calibration type**	Linearity
Sample/R1/R2	8/240/60 μL	**Time of mixture of serum + R1**	1-5 min
Method	Two-point end point assay	**Reaction time after addition of R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Downward

(Absorbance (A) read by the instrument=$A_{\text{Primary wavelength}}$-$A_{\text{Secondary wavelength}}$)
Operating procedures:

Substances added	Blank tubes	Test tubes
Reagent 1	240 μL	240 μL
Sample	-	8 μL
Distilled water	8 μL	-
Mix well, incubate at 37°C for 3-5 min, and read the absorbance (A_0);		
Reagent 2	60 μL	60 μL
Mix well, incubate at 37°C for 5 min, and read the absorbance (A_1); then calculate the change in absorbance (ΔA) according to the formula $\Delta A=A_1-A_0$		

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:
   Concentration of T-BIL (μmol/L) =
   Concentration of T-BIL Standard Reference Material (SRM) × $\triangle A_{\text{test sample}} / \triangle A_{\text{standard}}$

REFERENCE RANGE

Male (aged 20-79) ≤ 26.0 μmol/L, Female, (aged 20-79) ≤ 21.0 μmol/L.
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 300 mg/dL, ascorbic acid ≤ 30 mg/dL, and

triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   R1 and R2 are colorless and clear solution. There are possibly some undissolved small particulates that does not interfere the test result.
2. Reagent blank absorbance
   Reagent blank absorbance A_{450nm}≤0.100.
3. Accuracy
   The relative deviation should be within ±20.0%.
4. Linear range
   4.1 Linear correlation coefficient (r) should be ≥ 0.990 in the range of [2.5, 684] μmol/L.
   4.2 Linear deviation:
   When test a sample with concentration of [2.5, 10] μmol/L, the deviation should be within ±2 μmol/L.
   When test a sample with concentration of (10, 684] μmol/L, the deviation should be within ±10%.
5. Analytical sensitivity
   When a sample has a concentration of 79.9 μmol/L, its absorbance difference should be ≥-0.170.
6. Precision
   Repeatability: The repeatability should not be greater than 4.0%.
   Between-run precision: Between-run precision should not be greater than 5.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, *et al*. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015：296-302.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TB Reagent Kit (Chemical Oxidation Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

TP Reagent Kit (Biuret Colorimetric Method)

Instructions for Use

REF CC1079

PRODUCT NAME

TP Reagent Kit (Biuret Colorimetric Method)

PACKAGE SPECIFICATION

R: 1×10 mL	R: 1×20 mL	R: 1×50 mL	R: 2×30 mL
R: 2×35 mL	R: 2×40 mL	R: 2×45 mL	R: 2×50 mL
R: 2×55 mL	R: 2×60 mL	R: 4×20 mL	R: 4×30 mL
R: 4×35 mL	R: 4×40 mL	R: 4×45 mL	R: 4×50 mL
R: 4×55 mL	R: 4×60 mL	R: 5×20 mL	R: 6×20 mL
R: 6×30 mL	R: 6×35 mL	R: 6×40 mL	R: 6×45 mL
R: 6×50 mL	R: 6×55 mL	R: 6×60 mL	R: 8×20 mL
R: 10×20 mL	R: 2×100 mL	R: 6×100 mL	R: 12×25 mL
R: 2×2000 mL	R: 4×1000 mL	R: 5×120 mL	
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is designed for *in vitro* quantitative measurement of serum or plasma total protein in human. The total protein concentration is mainly used for complementary evaluation of liver hepatic function clinically. For professional and laboratory use only.

PRINCIPLE

The reagent is designed according to the candidate reference method recommended by the American Academy of Clinical Chemistry (AACC). The principle of the kit is that the peptide bonds (-CONH-) in proteins would form purple orchid complex with divalent copper ions (Ca^{2+}) in alkaline solution. Moreover, the absorbance (△A) of the reaction mixture is positively proportional to the protein concentration of the sample.

COMPONENTS

Kit contents	Reagent components	Concentration
Reagent	$NaKC_4H_4O_4$	22 g/L
	$CuSO_4$	3.5 g/L
	KI	3.5 g/L
	NaOH	20 g/L
Calibrator (Optional)	Albumin (aqueous matrix)	65-75 g/L

As for multi-component kit, the components are not exchangeable.
Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND VALIDITY

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE DEVICES

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and plasma with heparin anticoagulant are recommended. Sample should be separated in time after collection to avoid hemolysis. Serum are stable for 6 days at 20-25°C, for 4 weeks at 4-8°C and for 1 year at -20°C.

TEST PROCEDURE

1. Preparation: Use directly;
2. Conditions: (different parameters to be set on the machine can be obtained according to different testing instruments)

Primary/secondary wavelength	546nm/700nm	**Calibration type**	linear
Sample/R1	6/300 μL	**Time of Mixture of Serum and R1**	10min
Method	One point end assay	**Reaction time**	10min
Calibration Method	Two-point calibration	**Direction**	Upward

(The absorbance A read by the device = $A_{\text{Primary wavelength}} - A_{\text{Secondary wavelength}}$)
Operation steps:

Substance Added	Blank tube	Test tube
R1	300 μL	300 μL
Sample	-	6 μL
ddH_2O	6 μL	-
Mixed, incubated at 37˚C for 10 min, then zero calibration and read the absorbance A of each tube.		

3. Calibration: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control: Randox QC serum are recommended. QC value should be within the range of the preset value. If not, please follow the below steps to check:
   4.1 Check whether the parameter setting and light source are correct;
   4.2 Check whether the cuvettes and the sample probe are contaminated;
   4.3 Check whether the ddH_2O are polluted, because bacterial growth cause incorrect results;
   4.4 Check the reaction temperature;
   4.5 Check the expiration date of the kit.
5. Calculation of results:
   $C_{sample} = C_{standard} \times A_{sample} / A_{standard}$

REFERENCE RANGE

65-85 g/L
The reference range is for reference purposes only. It is recommended to set its own reference range in each laboratory.

EXPLANATION OF TEST RESULTS

Hemolysis interferes the assay and should be avoided as much as possible during the operation.

LIMITATIONS

When hemoglobin ≤ 500 mg/dL, vitamin C ≤ 30 mg/dL, bilirubin ≤ 40 mg/dL, triglyceride ≤ 1000 mg/dL, there is no interference to the assay.

PERFORMANCE CHARACTERISTICS

1. Appearance
   The reagent is blue and clear liquid. There are possibly small amount of undissolved particles in the solution that will not affect the test.
2. Blank Absorbance

The blank absorbance of reagent A_{546nm} ≤ 0.200.

3.Accuracy

The relative deviation should not exceed ±5%

4.Linear Range

Serum linearity: [30.0, 120.0] g/L:

a) Linear correlation coefficient r should not be less than 0.995;

b) Comparative linear deviation should not exceed ±6.0%.

5. Analytical sensitivity

The absorbance difference (△A) of the 70 g/L sample should not be less than 0.150.

6. Precision

6.1 Repeatability (within-run precision)

When repeat test sample with concentration of (70.0 ±10.0) g/L using same kit, the CV should not exceed 2%.

6.2 Between-run precision

When repeat test sample with concentration of (70.0 ±10.0) g/L using different batches of kits, the CV should not exceed 5%.

PRECAUTIONS

1. General Precautions

1.1 For *in vitro* diagnosis only.

1.2 When used for clinical diagnosis, please make comprehensive judgment based on the assay results, clinical symptoms and other examination results, etc.

1.3 Please use this product according to the IFU.

2. Precautions for operation

2.1 Please dispose of the specimen as if it were a hazardous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, please use disposable gloves.

2.2 In case of accidental contact with the eyes or mouth, or with the skin, rinse immediately and thoroughly with water and seek medical advice if necessary.

3. Precautions for use

3.1 Please store the reagents according to the storage method and avoid freezing. The quality of reagents may change after freezing, please do not use them.

3.2 Please do not use reagents that have expired. The results of expired reagents may be inaccurate.

3.3 Please avoid adding reagents halfway through the test.

3.4 Please avoid direct sunlight during operation.

3.5 Do not use if the reagent is turbid.

4. Precautions for waste disposal

Samples and waste fluids are potentially biologically infectious. Operators should comply with laboratory safety regulations and dispose of waste fluids according to local regulations for medical waste, infectious waste, and industrial waste.

5. Other precautions

5.1 On automatic biochemistry analyzers, the linearity range is related to the ratio of sample volume used to reagent volume and the time of measurement.

5.2 The volume of reagents and samples can be changed proportionally according to the requirements of different instruments.

5.3 Do not use the reagent bottles for other purposes.

5.4 Hemoglobin and bilirubin can cause interference. The former at 1.0 g/L can cause a positive interference of 1.8 g/L. The latter 300 mg/L can cause a positive interference of 2.0 g/L. Serum blank elimination can be carried out by replacing it with biuret reagent without copper sulfate.

5.5 Cyclic anhydride would bind to copper ions in the reagent and precipitate, the supernatant can be removed by centrifugation and measured without affecting the results.

5.6 The result of calculation with k-value is not as reliable as that using the calibration measurement value of standard substance.

5.7 Do not mix reagents of different batches.

REFERENCE

H. Shang., *et. al.*: National Clinical Test Operation Procedures (4th ed.). People's Health Publishing House. 2015: 200-203.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found onTP Reagent Kit (Biuret Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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EU REP CMC Medical Devices & Drugs S.L.
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Tel: +34951214054

CE IVD

Urea Reagent Kit-2 (Urease-GLDH Kinetic method)

Instructions for Use REF CC1014

PRODUCT NAME

Urea Reagent Kit-2 (Urease-GLDH Kinetic method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2×30 mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 2×80 mL	R2: 2×20 mL
R1: 4×35 mL	R2: 2×20 mL	R1: 4×40 mL	R2: 2×20 mL
R1: 4×50 mL	R2: 2×25 mL	R1: 4×50 mL	R2: 3×20 mL
R1: 4×60 mL	R2: 2×30 mL	R1: 4×60 mL	R2: 2×35 mL
R1: 4×60 mL	R2: 4×15 mL	R1: 4×100 mL	R2: 2×50 mL
R1: 4×120 mL	R2: 2×60 mL	R1: 6×66 mL	R2: 6×16 mL
2×300 T (R1: 2×72 mL R2: 2×18 mL)			
12×60 T (R1: 12×16.8 mL R2: 12×4.2 mL)			
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is designed for *in vitro* quantitative determination of urea in human serum, plasma or urine. The urea concentration is widely used for complementary evaluation of renal function. For professional and laboratory use only.

TEST PRINCIPLE

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$2NH_3 + \alpha\text{-Ketoglutaric acid} + NADH + H^+ \xrightarrow{\text{GLDH}} \text{Glutamate} + NAD^+ + H_2O$$

340nm laser is used to measure the decrease rate of NADH and calculate the urea concentration according to standard equation.

MAIN COMPONENTS

Kit contents	Reagent components	Conc.
Reagent 1	Urease	10 KU/L
	Glutamate dehydrogenase	10 KU/L
	ADP	1.4 g/L
	Tris (pH7.8)	50 mmol/L
Reagent 2	NADH (l)	0.13 g/L
	α-Ketoglutaric acid	1.7 g/L
Calibrator (Optional)	Urea, Aqueous Matrix	6-8 mmol/L

As for multi-component kit, the components are not exchangeable.
Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND SHELF LIFE

The validity period of sealed reagents and calibrators is 18 months at 2-8°C light-proof. Once opened, reagents are stable for 42 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE DEVICES

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Sample type: fresh non-hemolyzed serum, heparin anticoagulated plasma, fresh urine.
2. Sample collection: Routine venous blood collection of about 3 mL, placed in a test tube, after sample collection, immediately sealed and sent to the test. Routine urine should be 10 mL, placed in a test tube and immediately sealed for testing.
3. Blood should be separated in time after collection to avoid hemolysis; after urine collection, strictly avoid contamination. The test results for serum and plasma will not change for 7 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C. The urine is stable for 2 days at 15-25°C, for 7 days at 2-8 °C and for 1 month at -20°C.

TEST PROCEDURE

1. Preparation: Use directly (duo reagents);
2. Conditions: (different parameters to be set on the machine can be obtained according to different testing instruments)

Main/sub wavelength	340 nm/415 nm	**Calibration type**	Linear
Sample/R1/R2	6/240/60 μL	**Time of Mixture of Serum and R1**	3-5 min
Method	Kinetic rate	**Reaction time after addition of R2**	3 min
Calibration Method	Two-point calibration	**Direction**	Downward

Test steps:

Substance Added	Blank tube	Test tube
R1	240 μL	240 μL
Sampel	-	6 μL
ddH_2O	6 μL	-
Mixed, incubated at 37℃ for 3-5min,		
R2	60 μL	60 μL
Mixed, incubated at 37℃ for 90 s and keep monitoring for 180s calculate ΔA/min		

3. Calibration: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control: Randox QC serum are recommended. QC value should be within the range of the preset value. If not, please follow the below steps to check:
   4.1 Check whether the parameter setting and light source are correct;
   4.2 Check whether the cuvettes and the sample probe are contaminated;

4.3 Check whether the ddH_2O are polluted, because bacterial growth cause incorrect results;
4.4 Check the reaction temperature;
4.5 Check the expiration date of the kit.

5. Calculation of results:

C_{urea}(mmol/L) = ($\triangle A_{measurement}$ / min) / ($\triangle A_{standard}$ / min) × standard urea concentration

REFERENCE RANGE

Serum, plasma: 1.43–7.14 mmol/L (5–20 mg/dL).
Urine: 1st morning urine 141–494 mmol/L (847–2967 mg/dL) ; 24 h urine 170–580 mmol/24 h (10000–35000 mg/24 h), equivalent to 110–390 mmol/L (670–2300m g/dL) (assuming the 24-hour urine volume is 1.5 L) .
The reference range is for reference purposes only. The uric acid concentration may change due to geography, race, gender and age. It is recommended to set its own reference range in each laboratory.

EXPLANATION OF TEST RESULTS

Hemolysis interferes the assay and should be avoided as much as possible during the operation. The duration of sample storage also affects the assay results.

LIMITATIONS

When hemoglobin ≤ 500 mg/dL, vitamin C ≤ 200 mg/dL, bilirubin ≤ 40 mg/dL, there is no interference to the assay.

PERFORMANCE CHARACTERISTICS

1. Appearance
Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or light-yellow liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Blank Test
2.1 Reagent blank absorbance
Then blank absorbance of reagent A_{340nm}≥1.000.
2.2 The change rate of the blank absorbance
The change rate of reagent blank absorbance $|A_{340nm}|$ /min ≤ 0.04.
3. Accuracy
The relative deviation should not exceed ±15.0%。
4. Linear range
a）Linear correlation coefficient (r) should be ≥ 0.990 in the range of [0.9, 35.7] mmol/L;
b) In the range of [0.9, 3.0] mmol/L, the linear deviation should less than ±1.5 mmol/L;
In the range of (3.0, 35.7] mmol/L Comparative linear deviation should less than 10%.
5. Analytical sensitivity
The rate of change of absorbance per unit concentration should be ≥ -0.350.
6. Precision
6.1 Repeatability (with-in run precision)
When repeat test sample using same kit，the CV should not be greater than 5%
6.2 Between-run precision
When repeat test sample using same kit，the CV should not be greater than 10%.

PRECAUTIONS

1. General Precautions
1.1 For *in vitro* diagnosis only.
1.2 When used for clinical diagnosis, please make comprehensive judgment based on the assay results, clinical symptoms and other examination results, etc.
1.3 Please use this product according to the IFU.
1.4 The assay results of the kit are only used as a clinical aid for the diagnosis of various diseases. The clinical diagnosis and treatment of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory examinations and their response to treatment.
2. Precautions for operation
2.1 Please dispose of the specimen as if it were a hazardous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, please use disposable gloves.
2.2 In case of accidental contact with the eyes or mouth, or with the skin, rinse immediately and thoroughly with water and seek medical advice if necessary.
3. Precautions for use
3.1 Please store the reagents according to the storage method and avoid freezing. The quality of reagents may change after freezing, please do not use them.
3.2 Please do not use reagents that have expired. The results of expired reagents may be inaccurate.
3.3 Please avoid adding reagents halfway through the test.
3.4 Please avoid direct sunlight during operation.
3.5 Do not use if the reagent is turbid.
4. Precautions for waste disposal
Samples and waste fluids are potentially biologically infectious. Operators should comply with laboratory safety regulations and dispose of waste fluids according to local regulations for medical waste, infectious waste, and industrial waste.
5. Other precautions
5.1 On automated biochemistry analyzers, the linearity range is related to the ratio of sample volume used to reagent volume and the time of measurement.
5.2 The volume of reagents and samples can be changed proportionally according to the requirements of different instruments.
5.3 Do not use the reagent bottles for other purposes.
5.4 The result of calculation with k-value is not as reliable as that using the calibration measurement value of standard substance.
5.5 Do not mix reagents of different batches.

REFERENCE

H. Shang., *et. al.*: National Clinical Test Operation Procedures (4th ed.). People's Health Publishing House. 2015: 307-309.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Urea Reagent Kit-2 (Urease-GLDH Kinetic method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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EU REP CMC Medical Devices & Drugs S.L.
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Tel: +34951214054

CE IVD

Composite Calibrator serum

Instructions for Use REF CC1084

PRODUCT NAME

Composite Calibrator serum

PACKAGE SPECIFICATION

Specification					
Level 1	1×1mL	3×1mL	5×1mL	10×1mL	20×1mL
	1×2mL	3×2mL	5×2mL	10×2mL	20×2mL
	1×3mL	3×3mL	5×3mL	10×3mL	20×3mL
	1×5mL	3×5mL	5×5mL	10×5mL	20×5mL

INTENDED USE

Composite Calibrator serum is used for IVD analyzer or system calibration.
Composite Calibrator serum is used for calibration detection. For professional and laboratory use only.

MAIN COMPONENTS

The product uses human serum as the substrate. Its major components are listed in the following table.

Table 1 Major components of Composite Calibrator serum

Main Component	Concentration
ALT	30-150 U/L
AST	30-150 U/L
ALB	20-55 g/L
TB	10.00-80.00 μmol/L
ALP	40-400 U/L
CHE	2000-8000 U/L
GGT	30-170 U/L
UREA	3.80-15.00 mmol/L
CRE-E	80-300 μmol/L
UA	80-400 μmol/L
$CaCl_2$	1.4-2.5 mmol/L
NaCl	130.0-160.0 mmol/L
KH_2PO_4	0.9-2.0 mmol/L
$MgCl_2$	0.70-1.60 mmol/L
$FeSO_4 \cdot 7H_2O$	15-40 μmol/L
LDH	100-500 U/L
CK	120-800 U/L
HBDH	100-600 U/L
TG	0.8-2.5 mmol/L
TC	2.10-6.50 mmol/L
GLU	4.00-15.00 mmol/L
Amylase	60-300 U/L
$NaHCO_3$	10-30 mmol/L
Sodium cholate	12-50 μmol/L
LAP	10-80 U/L
$C_3H_5O_3 \cdot Li$	1.00-3.00 mmol/L
Preservative PC300	0.05%

Calibrators are lot-specific. For the target values of each lot, please refer to the target values table.

STORAGE AND SHELF LIFE

Unopened calibrators should be stored at 2°C-8°C away from light, with a shelf life of 24 months. Dissolved calibrators are stable for 30 days when stored at -20°C.
Please refer to the label on the kit for the production date and expiration date.

APPLICABLE INSTRUMENT

The calibrator is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Method of reconstitution
Open the bottle carefully, remove the rubber stopper gently, and add distilled or deionized water accurately according to packing specification. Put on the rubber stopper gently, and place the bottle at room temperature for 30 minutes, protected against direct sunlight. Rotate gently to sufficiently dissolve the lyophilized substance and avoid formation of bubble. Then, sample the composite calibrator serum and routine specimen simultaneously for testing. After pipetting each time, put the cap back on the bottle, seal, and store the bottle at -20℃ in dark place.
Calibration procedure
Operate according to the calibration procedure described in operation manual of biochemical analyzer.
Re-calibration is recommended in any of the following cases: change of reagent batch number; significant deviation of quality control value; major maintenance of biochemical analyzer.
Self-prepared materials
Distilled or deionized water; 5mL pipettor; biochemical analyzer; general laboratory instrument

RESULT INTERPRETATION

Change of experiment method or storage condition may lead to variation of concentration of the product.

LIMITATIONS OF TEST METHOD

1. Definite value of the product is batch-specific. Definite value may vary between different batches of calibrator.
2. The CO_2 in the calibrator serum must be used immediately after complete thawing, and the usage time must not exceed 1 hour after thawing.
3. The bilirubin in the calibrator serum is light-sensitive. It is recommended to store the serum protected from light. After reconstitution, it can remain stable for one day when stored at 2-8°C in the dark. Do not store at 15-25°C. Do not freeze.
4. If the reconstituted serum is contaminated by bacteria, it will reduce the stability of many components.
5. Calibrator serum of different lot numbers cannot be cross-used, as the assigned values differ between lot numbers.

PERFORMANCE CHARACTERISTICS

1. Appearance
   The composite calibrator serum prior to reconstitution shall appear as a pale yellow lyophilized powder. After reconstitution, it should present as a colorless or pale yellow liquid, clear or slightly turbid, with no undissolved particles.
2. Moisture Content
   Moisture content must not exceed 10%.
3. Trueness
   The trueness of value transfer shall meet $|E_n| \leq 1$.
4. Homogeneity
   The within-bottle coefficient of variation (CV) should be no greater than 10%, and the between-bottle coefficient of variation (CV) should be no greater than 10%.

PRECAUTIONS

The calibrator serum is prepared from human matrix-based serum. For serum from all donors, testing of HIV (HIV1, HIV2) antibody, hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV) antibody is performed and all results are negative. The used method has been approved by FDA. The test method is highly accurate, but it is impossible to ensure all infected donors can be detected. Therefore, the calibration serum shall be treated as infectious specimen. The calibrator is for *in vitro* diagnosis only.

REFERENCE

ISO18153 *In vitro* diagnostic medical devices-measurement of quantities in biological samples-metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
ISO17511 *In vitro* diagnostic medical devices-measurement of quantities in biological samples-metrological traceability of values assigned to calibrators and control materials

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Composite Calibrator serum are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

Composite quality control serum

Instructions for Use

REF CC1085

PRODUCT NAME

Composite quality control serum

PACKAGE SPECIFICATION

Specification					
Level 1	1×1mL	3×1mL	5×1mL	10×1mL	20×1mL
	1×2mL	3×2mL	5×2mL	10×2mL	20×2mL
	1×3mL	3×3mL	5×3mL	10×3mL	20×3mL
	1×5mL	3×5mL	5×5mL	10×5mL	20×5mL
Level 2	1×1mL	3×1mL	5×1mL	10×1mL	20×1mL
	1×2mL	3×2mL	5×2mL	10×2mL	20×2mL
	1×3mL	3×3mL	5×3mL	10×3mL	20×3mL
	1×5mL	3×5mL	5×5mL	10×5mL	20×5mL

INTENDED USE

Composite quality control serum is used for quality control during clinical lipid item test. For professional and laboratory use only.

MAIN COMPONENTS

The product uses human serum as the substrate. Its major components are listed in the following table.
Table 1 Major components of Composite quality control serum

Main Component	Concentration
ALT	30-150 U/L
AST	30-150 U/L
ALB	20-55 g/L
TB	10.00-80.00 μmol/L
ALP	40-400 U/L
CHE	2000-8000 U/L
GGT	30-170 U/L
UREA	3.80-15.00 mmol/L
CRE-E	80-300 μmol/L
UA	80-400 μmol/L
$CaCl_2$	1.4-2.5 mmol/L
NaCl	130.0-160.0 mmol/L
KH_2PO_4	0.9-2.0 mmol/L
$MgCl_2$	0.70-1.60 mmol/L
$FeSO_4·7H_2O$	15-40 μmol/L
LDH	100-500 U/L
CK	120-800 U/L
HBDH	100-600 U/L
TG	0.8-2.5 mmol/L
TC	2.10-6.50 mmol/L
GLU	4.00-15.00 mmol/L
Amylase	60-300 U/L
$NaHCO_3$	10-30 mmol/L
Sodium cholate	12-50 μmol/L
LAP	10-80 U/L
$C_3H_5O_3·Li$	1.00-3.00 mmol/L
GDH	10.0-80.0 U/L
ApoA1	0.80-2.00 g/L
ApoB	0.50-1.80 g/L
D-3-hydroxybutyrate	0.10-3.50 mmol/L
Ig A	1.00-4.00 g/L
Ig M	3.00-15.00 g/L
Ig G	0.30-2.00 g/L
UIBC	10-40 umol/L
Preservative PC300	0.05%

Quality control are lot-specific. For the target values of each lot, please refer to the target values table.

STORAGE AND SHELF LIFE

Unopened controls should be stored at 2°C-8°C away from light, with a shelf life of 24 months. Dissolved controls are stable for 30 days when stored at -20°C.
Please refer to the label on the kit for the production date and expiration date.

APPLICABLE INSTRUMENT

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Method of reconstitution
Open the bottle carefully, remove the rubber stopper gently, and add distilled or deionized water accurately according to packing specification. Put on the rubber stopper gently, and place the bottle at room temperature for 30 minutes, protected against direct sunlight. Rotate gently to sufficiently dissolve the lyophilized substance and avoid formation of bubble. Then, sample quality control serum and routine specimen simultaneously for testing. After pipetting each time, put the cap back on the bottle, seal, and store the bottle at -20℃ in dark place.
Calibration procedure
Operate according to the calibration procedure described in user manual of biochemical analyzer.
Re-calibration is recommended in any of the following cases: change of reagent batch number; significant deviation of quality control value; major maintenance of biochemical analyzer.

Self-prepared materials
Distilled or deionized water; 5 mL pipettor; biochemical analyzer; general laboratory instrument

RESULT INTERPRETATION

Change of experiment method or storage condition may lead to variation of concentration of the product.

LIMITATIONS OF TEST METHOD

1. Repeated freeze-thaw cycles may compromise the stability of quality control materials.
2. The CO_2 in quality control serum must be used immediately after complete thawing, and the usage time must not exceed 1 hour after thawing.
3. The bilirubin in quality control serum is light-sensitive. It is recommended to store the serum protected from light. After reconstitution, it can remain stable for one day when stored at 2-8°C in the dark. Do not store at 15-25°C. Do not freeze.
4. If the reconstituted serum is contaminated by bacteria, it will reduce the stability of many components.
5. Different lots of quality control serum cannot be used interchangeably due to variations in assigned values between batches.

PERFORMANCE CHARACTERISTICS

1. Appearance
   The composite quality control serum prior to reconstitution shall appear as a pale yellow lyophilized powder. After reconstitution, it should present as a colorless or pale yellow liquid, clear or slightly turbid, with no undissolved particles.
2. Acceptable Range/Value
   Acceptable range/value determination procedures shall be established. Measurement results obtained using the claimed measurement procedure shall fall within their respective acceptable ranges.
3. Between-run precision
   The uniformity of the characteristic values between bottles is good, the CV should not exceed 10%.

PRECAUTIONS

Composite quality control serum is prepared from human matrix-based serum. For serum from all donors, testing of HIV (HIV1, HIV2) antibody, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV) antibody is performed and all results are negative. The used method has been approved by FDA. The test method is highly accurate, but it is impossible to ensure all infected donors can be detected. Therefore, the control serum shall be treated as infectious specimen. The control is for *in vitro* diagnosis only.

REFERENCE

ISO18153 *In vitro* diagnostic medical devices-measurement of quantities in biological samples-metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
ISO17511 *In vitro* diagnostic medical devices-measurement of quantities in biological samples-metrological traceability of values assigned to calibrators and control materials

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Composite quality control serum are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

CK-MB Reagent Kit (Immunoinhibition method)

Instructions for Use

REF CC1021

PRODUCT NAME

CK-MB Reagent Kit (Immunoinhibition method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 1×80 mL	R2: 1×20 mL	R1: 2×30 mL	R2: 1×15 mL
R1: 2×35 mL	R2: 1×20 mL	R1: 2×40 mL	R2: 1×20 mL
R1: 2×48 mL	R2: 2×12 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 2×20 mL	R1: 2×80 mL	R2: 1×40 mL
R1: 4×20 mL	R2: 1×20 mL	R1: 4×20 mL	R2: 4×5 mL
R1: 4×30 mL	R2: 2×15 mL	R1: 4×35 mL	R2: 2×20 mL
R1: 4×40 mL	R2: 2×20 mL	R1: 4×50 mL	R2: 2×25 mL
R1: 4×50 mL	R2: 3×20 mL	R1: 4×60 mL	R2: 2×30 mL
R1: 4×60 mL	R2: 2×35 mL	R1: 4×100 mL	R2: 2×50 mL
600 T (R1: 1×65 mL R2: 1×15 mL)		6×60 T (R1: 6×16.8 mL R2: 6×4.2 mL)	

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of CK-MB activity in human serum or plasma.
CK-MB activity is one of the most valuable biomarkers for the clinical diagnosis of Acute Myocardial Infarction (AMI).
For professional and laboratory use only.

TEST PRINCIPLE

Creatine Kinase (CK) forms three isoenzyme dimers - CK1 (BB), CK2(MB), and CK3(MM) - through the combination of two subunits, M and B, which are mainly located in the cytoplasm. In addition, a small amount of mitochondrial isoenzyme (CKm) is also present in serum. CK activity is high in the myocardium, second only to that found in skeletal muscle. In the myocardium, CK-MB constitutes approximately 13-22% of the total CK activity (less than 1% in skeletal muscle), thereby providing specificity as a biomarker for myocardial injury. This reagent kit employs the immunoinhibition method, using anti-human M serum to inhibit the M subunit, and subsequently measures the B subunit activity. The CK-MB activity is then determined by multiplying the B subunit activity by two.

Phosphate creatine + ADP $\xrightarrow{CK}$ Creatine + ATP

ATP + Glucose $\xrightarrow{HK}$ Glucose 6-phosphate +ADP

Glucose 6-phosphate + $NADP^+$ $\xrightarrow{GPO}$ 6-phosphateglucose + NADPH

The rate of NADPH production was measured at a wavelength of 340 nm and was used to calculate CK-MB activity.

MAIN COMPONENTS

Kit composition	Reagent components	Content
R1	Imidazole buffer (pH6.6)	50 mM/L
	Glucose	1.5 g/L
	Magnesium acetate	0.6 g/L
	EDTA	0.93 g/L
	Hexokinase (HK)	10 KU/L
	ADP	0.61 g/L
	AMP	1.5 g/L
	Adenosine 5'-monophosphate	1.83 g/L
	N-Acetylcysteine	2.1 g/L
	$NADP^+$	0.8 g/L
	Anti-CK-M Antibody	0.84 mL/L
	G6PD	6 KU/L
R2	Phosphate creatine	12 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Reagents should be stored in tightly closed containers at 2°C-8°C, protected from light for a shelf life of 18 months. Once opened, they should be stored at 2°C to 8°C, and the reagents remain valid for 42 days. Production date and expiration date: see details on the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and heparinised plasma are the recommended specimen. Lipaemic, haemolysed and strongly icteric samples should be avoided. Allow specimen to clot and remove serum from cells promptly to minimise haemolysis and contamination by adenylate kinase from the red cells. CK-MB is stable in serum or heparinised plasma, protected from light, for 2 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C.

TEST PROCEDURE

1. Both R1 and R2 can be used directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	340 nm/415 nm	**Calibration type**	Linearity
Sample/R1/R2	10/200/50	**Time of mixing of sample + R1**	5 min
Method	Rate	**Reaction time after addition of R2**	5 min
Calibration method	Blank calibration	**Direction of reaction**	Upward

Operating procedures:
Dual reagent operation:

Sample	10 μL
R1	200 μL
Mix well, incubate at 37°C for 5 min.	
R2	50 μL
Mix well, incubate at 37°C for 2 min, keep monitoring the rate of absorbance change for 1-3 min and calculate ΔA/min.	

3. Calibration procedure: blank calibration is recommended.
4. Quality control procedure: use the quality control product from Getein or Roche, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.

4.4 Check reaction temperature.
4.5 Check the expiration date of the kit.

5. Calculation:

CK-MB activity (U/L) = ΔA/min × K (8360)

$$K = \frac{\text{Total reaction volume (mL)} \times 1000}{\text{Sample volume (mL)} \times \varepsilon \times 1.0} \times 2$$

Note: 1000 = conversion factor from U/mL to U/L; 1.0 = light path of cuvette
ε (NADH absorbance at 340 nm) = 6.22

REFERENCE RANGE

CK activity	CK-MB activity
Male: 35-200 U/L	0-25 U/L
Female: 30-170 U/L	

laboratory should establish its own reference range.

RESULT INTERPRETATION

The major interfering substance is adenosine kinase (AK), which is rich in red blood cells and catalyzes the conversion of ADP to ATP. This reaction can result in an elevated CK measurement. The activity of 10 U/L of AK is equivalent to 1 U/L of CK.

LIMITATIONS

There is no interference with the measurement when ascorbic acid ≤ 30 mg/dL, bilirubin ≤ 40 mg/dL and triglyceride ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Net content
   Should not be less than the indicated content.
3. Reagent Blank
   3.1 Reagent blank absorbance
   Reagent blank absorbance: A_{340nm}≤0.500.
   3.2 Reagent blank absorbance change rate
   Reagent blank absorbance change rate:ΔA_{340nm}/min≤0.002.
4. Accuracy
   When compared with systems with traceability, for samples with concentrations in the range of [5, 200] U/L, the correlation coefficient should be no less than 0.99 and the slope should be within [0.9, 1.1]. When testing samples with concentrations in the range of [5, 50] U/L, the absolute difference should be within ±2.5 U/L. When testing samples with concentrations in the range of (50, 600] U/L, the relative difference should be within ±5%.
5. Linear range
   5.1 linear correlation coefficient
   In the range of [5, 600] U/L , the linear correlation coefficient between the theoretical concentration and measured concentration should be no less than 0.990.
   5.2 linear difference
   When testing samples with concentrations in the range of [5, 50] U/L, the absolute difference should be within ±2.5 U/L. When testing samples with concentrations in the range of (50, 600] U/L, the relative difference should be within ±5%.
6. Analytical sensitivity
   When measuring a sample with a CK concentration of 100 U/L, the absorbance change rate should be no less than 0.008.
7. Precision
   7.1 Repeatability
   When repeatedly testing a sample with a concentration of (25 ± 5) U/L, the coefficient of variation (CV) should be no higher than 6%.
   7.2 Between-run precision
   When testing a sample with a concentration of (25 ± 5) U/L, the relative measures of variation should be no higher than 15%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Hemolysis should be avoided during the operation procedure.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
   3.6 Anticoagulants other than heparin may have an inhibitory effect on CK activity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. Horde M, et al: Scand, J Clin Lab Invest 1979,39:1
2. Gerhardt W et al: Clin Chem 1979,25:1274
3. Delahunty JJ et al: Clin Chem 1980,26:568.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB Reagent Kit (Immunoinhibition method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

CRE-E Reagent Kit (Enzymatic Method)

Instructions for Use

REF CC1026

PRODUCT NAME

CRE-E Reagent Kit (Enzymatic Method)

PACKAGE SPECIFICATION

R1: 1×15 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×10 mL
R1: 1×45 mL	R2: 1×15 mL	R1: 1×60 mL	R2: 1×20 mL
R1: 2×30 mL	R2: 2×10 mL	R1: 2×45 mL	R2: 2×20 mL
R1: 2×55 mL	R2: 2×20 mL	R1: 2×60 mL	R2: 1×40 mL
R1: 2×60 mL	R2: 1×45 mL	R1: 2×60 mL	R2: 2×20 mL
R1: 2×90 mL	R2: 1×60 mL	R1: 3×40 mL	R2: 3×15 mL
R1: 3×60 mL	R2: 1×60 mL	R1: 4×30 mL	R2: 2×20 mL
R1: 4×45 mL	R2: 4×15 mL	R1: 4×45 mL	R2: 2×30 mL
R1: 4×55 mL	R2: 4×20 mL	R1: 4×60 mL	R2: 2×40 mL
R1: 4×60 mL	R2: 2×45 mL	R1: 4×90 mL	R2: 2×60 mL
600 T (R1: 1×51 mL R2: 1×26 mL)			
6×52 T (R1: 6×16.8 mL R2: 6×5.8 mL)			
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is intended for the *in vitro* quantitative determination of CRE-E concentration in human serum, plasma or urine, and is mainly used clinically for the auxiliary diagnosis of renal function. For professional and laboratory use only.

TEST PRINCIPLE

$$\text{Creatinine}+H_2O \xrightarrow{\text{Creatinase}} \text{Creatine}$$

$$\text{Creatine}+H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine}+O_2+H_2O \xrightarrow{\text{Sarcosine oxidase}} \text{Glycine}+HCHO+H_2O_2$$

$$H_2O_2+4\text{-AAP}+\text{TOOS} \xrightarrow{\text{POD}} \text{Quinoneimine dye}+H_2O$$

The absorbance (△A) is directly proportional to the concentration of Cr at a certain wavelength.

MAIN COMPONENTS

Kit Components	Reagent Components	Content
Reagent 1	Creatinase	30 KU/L
	Sarcosine oxidase	40 KU/L
	Peroxidase	50 KU/L
	N-ethyl-n -(2-hydroxy-3-propyl sulfonyl) -3-methylaniline	0.8 g/L
	Creatinase	220 KU/L
Reagent 2	4-aminotipyrine	0.5 g/L
	Creatinase	30 KU/L
Calibrator (Optional)	Creatinine, water matrix	100-300 μmol/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: Traceable to standard reference material 909c.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum, heparin anticoagulant plasma can be used for the test. Serum samples can be stable for 7 days at 15-25°C, for 7 days at 2-8°C and for 3 months at -20°C.
Urine is diluted 100 times with distilled water and the result is multiplied by 100.Urine specimens may be stored for 2 days at 15-25°C, for 6 days at 2-8°C and for 6 months at -20°C.

TEST PROCEDURE

1. Reagents preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	546 nm/700 nm	**Calibration type**	Linearity
Sample/R1/R2	6/225/75 μL	**Serum+R1 time**	5 min
Method	Two-point endpoint method	**Reaction time after adding R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

Operating procedures: Double reagent procedure

Temperature	37°C
Sample	6 μL
R1	225 μL
Mix well, incubate at 37°C for 5 min and measure the absorbance (A_0)	
R2	75 μL
Mix well, incubate at 37°C for 5 min, measure the absorbance (A_1) and calculate the change in absorbance ($\triangle A=A_1-A_0$)	

3. Calibration procedures: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Select the quality control serum of Randox, and the quality control measurement value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:

$$\text{CRE-E Concentration (μmol/L)} = \text{Concentration of CRE-E Standard Reference Material (SRM)} \times \frac{\triangle A_{\text{test sample}}}{\triangle A_{\text{SRM}}}$$

REFERENCE RANGE

Serum: Male adult 44-97 μmol/L (5-11 mg/L)
Female adult 35-80 μmol/L (4-9 mg/L)
Urine（24 hours） 4.42-16.8 mmol/24 h (0.50-1.9 g/24 h)
The reference range is for reference only. It is recommended that each laboratory establish its own reference range for the difference between areas, nationalities, sexes and ages.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation. The placement time of sample also has an effect on the determination.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 16 mg/dL and triglyceride ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 is a slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. R2 is a colorless or slightly yellow clear liquid which may have a small number of insoluble particles that do not affect the determination.
2. Reagent blank absorbance
   Reagent blank absorbance $A_{546nm} \leq 0.20$.
3. Accuracy
   The relative deviation should be within ±10%.
4. Linear range
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [10, 1760] μmol/L.
   Within the range of [10, 50] μmol/L, the linear deviation should not be greater than ±7 μmol/L;
   Within the range of (50, 1760] μmol/L, the linear deviation should not be greater than ±10%.
5. Analytical sensitivity
   When a sample has a concentration of 100 μmol/L, its absorbance difference should be no more than 0.05.
6. Precision
   6.1. Repeatability
   CV should not be greater than 5.0%.
   6.2. Between-run precision
   Between-run precision should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The test results of the kit are only used as clinical auxiliary diagnostic basis for various diseases, and the clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
   1.5 There may be differences in the use of reagents from different manufacturers for testing the same sample, which should be comprehensively considered in the context of clinical practice.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. Xu Guobin, Zhu Lihua, Xia Tie'an. Determination by creatinase method of glutamate dehydrogenase coupled with creatinine iminohydrolytic enzyme. Journal of Clinical Laboratory, 2001,19 (3): 149
2. Yang Changguo, Lu Bangtai, Xu Ye, et al. Two point method for the enzymatic determination of creatinine. Journal of Clinical Laboratory, 1999,17 (2): 71

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CRE-E Reagent Kit (Enzymatic Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

CSF Reagent Kit (Pyrogallol red Colorimetric Method)

Instructions for Use

REF CC1028

PRODUCT NAME

CSF Reagent Kit (Pyrogallol red Colorimetric Method)

PACKAGE SPECIFICATION

R: 1×10 mL	R: 1×20 mL	R: 1×50 mL	R: 1×60 mL
R: 2×30 mL	R: 2×35 mL	R: 2×40 mL	R: 2×45 mL
R: 2×50 mL	R: 2×55 mL	R: 2×60 mL	R: 4×20 mL
R: 4×30 mL	R: 4×35 mL	R: 4×40 mL	R: 4×45 mL
R: 4×50 mL	R: 4×55 mL	R: 4×60 mL	R: 5×20 mL
R: 6×20 mL	R: 6×30 mL	R: 6×35 mL	R: 6×40 mL
R: 6×45 mL	R: 6×50 mL	R: 6×55 mL	R: 6×60 mL
R: 8×20 mL	R: 10×20 mL	R: 6×100 mL	R: 5×120 mL
R: 2×300 T (2×100 mL) R: 12×72 T (12×25 mL)			
Calibrator (optional): 1×1 mL			

INTENDED USE

This reagent kit is used for the *in vitro* quantitative determination of total protein concentration in human cerebrospinal fluid and urine.
Clinically, it is mainly used for auxiliary diagnosis of central nervous system and renal diseases. For professional and laboratory use only.

TEST PRINCIPLE

Pyrogallol red binds to molybdic acid to form a red complex with a maximum absorption peak at 467 nm, and this complex binds to protein to form a blue-purple complex under acidic conditions with a maximum absorption peak at 598 nm.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent	Pyrogallol red buffer	100 mmol/L
	Sodium molybdate	0.1 mmol/L
	Triton X-305	4 mL/L
Calibrator (Optional)	Cerebrospinal fluid and total urine protein	80 mg/dL-110 mg/dL

The components in different batches of a multi-component kit are not interchangeable.
Calibration traceability: Traceability to the enterprise's working calibration.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Urine samples were collected randomly and stored for 1 day at 15-25°C, for 7 days at 2-8°C and for 1 month at -20°C. Centrifuge the supernatant before testing.
Cerebrospinal fluid samples must not contain hemolysis and stored for 1 day at 15-25°C, for 6 days at 2-8°C and for 1 year at -20°C. Centrifuge the supernatant before testing.

TEST PROCEDURE

1. The dual reagent is ready for use directly.
2. Test conditions:

Primary/Secondary wavelength	600 nm/700 nm	**Calibration type**	Linearity
Sample/Reagent	5/300 μL	**Sample + R1 time**	10 min
Methods	One-point endpoint method	**Total reaction time**	10 min
Calibration method	Two-point calibration	**Reaction direction**	Upward

Operating Procedure:

	Sample	Standard	Blank
Reagent 1	300 μL	300 μL	300 μL
Sample	5 μL	/	/
Standard	/	5 μL	/
Blank(water)	/	/	5 μL
Mix well, incubate at 37°C until 600 s, measure absorbance A. (Zero with blank)			

3. Calibration procedure: Recommended to use calibrators come with the kit.
4. Quality control procedure: A quality control from BIO-RAD or Getein is recommended, and quality control measurements should be within the range of labeled values. If the result is out of range, the following steps can be taken to find out the reason:
   4.1 Check that the parameter settings and light source are correct.
   4.2 Check if the colorimetric cup and pipette needle are clean.
   4.3 Check that the water is not contaminated; bacterial growth can lead to incorrect results.
   4.4 Check the reaction temperature.
   4.5 Check kit validity.
5. Calculation:
   Cerebrospinal fluid protein (mg/dL) = standard concentration× ($A_{standard}/A_{sample}$)
   Total urine protein (mg) = total urine volume× standard concentration× ($A_{standard}/A_{sample}$)

REFERENCE RANGE

Cerebrospinal fluid protein: 8-43 mg/dL
Urine protein: 28-141 mg/day
Random urine normal values range from: 1-14 mg/dL
Determined based on the 95% distribution interval for normal subjects.
The reference ranges quoted are for reference only and it is recommended that each laboratory establish its own reference range.

INTERPRETATION OF RESULTS

Hemolysis interferes with the assay.

LIMITATIONS

Hemoglobin ≤ 500 mg/dL, ascorbic acid ≤ 60 mg/dL, bilirubin ≤ 3 mg/dL, and triglycerides ≤ 15 mg/dL do not interfere with the measurement.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent in the kit is a red clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Net Content
   The volume of liquid reagents shall not be less than the labeled value.
3. Reagent blank
   3.1 Reagent blank absorbance
   Reagent blank absorbance $A_{600m} \leq 0.500$.
4. Accuracy
   Use the comparison method and linear regression method to calculate the correlation coefficient (r), r is not less than 0.990. The relative deviation of each concentration point should not be more than ±20%.
5. Linear Range
   5.1 Linear correlation coefficient
   In the range of [2, 200] mg/dL, the linear correlation coefficient r between the theoretical concentration and the measured concentration shall be not less than 0.990.
   5.2 Linear deviation
   Within the range of [2, 25] mg/dL, the absolute deviation of linearity shall not exceed ±10 mg/dL; within the range of (25, 200] mg/dL, the relative deviation of linearity shall not exceed ±10%.
6. Analytical sensitivity
   When testing 100 mg/dL of the measured substance, the difference in absorbance should be ≤ 0.720.
7. Precision
   7.1 Repeatability
   Repeatability (coefficient of variation, CV) should be no more than 6.0%.
   7.2 Between-run Precision
   Between-run Precision should be no more than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Treat the samples as dangerous materials that may cause infection with HV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Hemolysis should be avoided during the operation procedure.
3. Precautions for use
   3.1 Please store the reagents according to the storage method and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Avoid using the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. An improved method for the determination of total urinary protein by molybdenum pyrochrome red. Clinical Chemistry 1989;35:2233-6.
2. Laboratory diagnosis of neurologic diseases. Clinical Laboratory Diagnostics, No. 1, Frankfurt: TH-Book Publishing; 1998. p. 1308-26.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CSF Reagent Kit (Pyrogallol red Colorimetric Method) are the most common ones appearing on medical devices and their packaging.They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CE IVD

DB Reagent Kit (Chemical Oxidation Method)

Instructions for Use

REF CC1032

PRODUCT NAME

DB Reagent Kit (Chemical Oxidation Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2×30 mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 2×80 mL	R2: 2×20 mL
R1: 4×35 mL	R2: 2×20 mL	R1: 4×40 mL	R2: 2×20 mL
R1: 4×50 mL	R2: 2×25 mL	R1: 4×50 mL	R2: 3×20 mL
R1: 4×60 mL	R2: 2×30 mL	R1: 4×60 mL	R2: 2×35 mL
R1: 4×60 mL	R2: 4×15 mL	R1: 4×100 mL	R2: 2×50 mL
R1: 4×120 mL	R2: 2×60 mL	R1: 6×62 mL	R2: 6×19 mL
2×300 T (R1: 2×80 mL R2: 2×20 mL)			
12×52 T (R1: 12×17.2 mL R2: 12×4.3 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of direct bilirubin concentration in human serum and plasma. Mainly used clinically as one of the evaluation indicators of bilirubin metabolism disorders.
For professional and laboratory use only.

TEST PRINCIPLE

In the presence of indirect bilirubin inhibitors and surfactants, direct bilirubin is oxidized by chemical oxidants to produce biliverdin. The decrease in absorbance at 450 nm is proportional to the concentration of direct bilirubin.

$$\text{DB} \xrightarrow[\text{Indirect bilirubin inhibitors}]{\text{Chemical oxidizing agent pH3.0}} \text{Biliverdin}$$

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tartaric acid buffer (pH3.0)	10 g/L
	Thiourea	5 g/L
Reagent 2	Phosphate buffer (pH7.0)	0.7 g/L
	Sodium nitrite	0.3 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Reagents should be stored in tightly closed containers at 2°C-8°C, protected from light for a shelf life of 18 months. Once opened, they should be stored at 2°C to 8°C, and the reagents remain valid for 42 days.
Production date and expiration date: see details on the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Use serum and heparin-anticoagulated plasma sample. Even slight haemolysis can cause a reduction in value and such samples should be avoided. Lipemic samples should also be avoided. Stable in serum and plasma, protected from light, for 2 days at 15-25°C, for 7 days at 2-8°C and for 6 months at -20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different loading parameters can be requested based on different testing instruments)

Primary/secondary wavelength	450 nm/570 nm	**Calibration type**	Linearity
Sample/R1/R2	8/240/60 μL	**Time of mixture of serum + R1**	5 min
Method	Two-point endpoint assay	**Reaction time after addition of R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Downward

Operating procedures:
Dual Reagent Operation

Sample (Standard)	8 μL
Reagent 1 (R1)	240 μL
Mix well, incubate at 37°C for 3-5 min, and read the absorbance A_0.	
Reagent 2 (R2)	60 μL
Mix well, incubate at 37°C for 5 min, and then read the absorbance A_1. $\Delta A = A_1 - A_0$	

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: use the serum control from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:

D-BiL concentration (μmol/L)=Concentration of D-BiL Standard Reference Material (SRM) × $\triangle A_{\text{test sample}} / \triangle A_{\text{SRM}}$

REFERENCE RANGE

Reference range: 2-6.84 μmol/L ;
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Hemolyzed samples interfere with the measurement of the assay and should be avoided as much as possible during the procedure. The sample storage time also influences the assay results.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 200 mg/dL, ascorbic acid ≤ 20 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of subvisible particles that do not affect the determination. Reagent 2 is a colorless clear liquid, which may contain a small number of subvisible particles that do not affect the determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{450nm}≤ 0.100.
3. Accuracy
   By comparison test, the correlation coefficient (r) should not be less than 0.950. In the range of [2, 6] μmol/L, the absolute deviation should not exceed ±1.2 μmol/L; in the range of (6, 342] μmol/L, the relative deviation should not exceed ±20%.
4. Linear range
   4.1 linear correlation coefficient
   The linear correlation coefficient (r) should not be less than 0.990 within the linear range of [2, 342] μmol/L.
   4.2 Linear difference
   The absolute deviation from linearity should not exceed ±2 μmol/L for testing within the linear range of [2, 10] μmol/L;
   The relative deviation from linearity should not exceed ±10% for testing within the linear range of (10, 342] μmol/L.
5. Analytical sensitivity
   When a sample has a concentration of 46.2 μmol/L, its absorbance difference should be ≥ -0.100.
6. Precision
   6.1 Repeatability
   Coefficient of variation (CV) should not be more than 4.0%.
   6.2 Between-run precision
   Between-run precision should not be more than 5.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Avoid direct sunlight during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Clinical Laboratory Procedures (4th Edition). People's Medical Publishing House, 2015: 296-302.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on DB Reagent Kit (Chemical Oxidation Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

CE IVD

GLU-OX Reagent Kit-1 (GOD-POD Method)

Instructions for Use

REF CC1041

PRODUCT NAME

GLU-OX Reagent Kit-1 (GOD-POD Method)

PACKAGE SPECIFICATION

R:1×10mL	R:1×15mL	R:1×20mL	R:1×25mL
R:1×50mL	R:1×60mL	R:1×70mL	R:1×75mL
R:1×1000mL	R:1×2000mL	R:2×25mL	R:2×30mL
R:2×35mL	R:2×40mL	R:2×45mL	R:2×50mL
R:2×55mL	R:2×60mL	R:2×70mL	R:2×75mL
R:2×80mL	R:2×100mL	R:2×2000mL	R:3×50mL
R:3×70mL	R:3×75mL	R:3×100mL	R:4×20mL
R:4×25mL	R:4×30mL	R:4×35mL	R:4×40mL
R:4×45mL	R:4×50mL	R:4×55mL	R:4×60mL
R:4×70mL	R:4×75mL	R:4×100mL	R:4×1000mL
R:5×20mL	R:5×40mL	R:5×60mL	R:5×80mL
R:5×120mL	R:6×20mL	R:6×30mL	R:6×35mL
R:6×40mL	R:6×45mL	R:6×50mL	R:6×55mL
R:6×60mL	R:6×70mL	R:6×100mL	R:7×60mL
R:8×20mL	R:8×25mL	R:10×10mL	R:10×20mL
R:36×3.8mL	R:36×4.3mL	R:12×72T (12×25.8mL)	

INTENDED USE

This reagent is intended for the *in vitro* quantitative determination of glucose content in human serum. Clinically, it is mainly used to monitor blood glucose levels. For professional and laboratory use only.

TEST PRINCIPLE

$Glucose + O_2 + H_2O \xrightarrow{GOD} Gluconic\ acid + H_2O_2$

$H_2O_2 + 4\text{-}AAP + Phenol \xrightarrow{POD} Quinone\ imide + 4H_2O$

By colorimetry at 520 nm, GLU concentration was calculated.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent	KOH	80 mmol/L
	Piperazin-1,4-bis (2-ethylsulfonic acid)	40 mmol/L
	$C_7H_6O_3$	15 mmol/L
	NaCl	140 mmol/L
	Na_2HPO_4	50 mmol/L
	PEG-6000	5 mmol/L
	$C_{10}H_{13}N_2Na_2O_8$	2 mmol/L
	NaN_3	15 mmol/L
	4-Aminoantipyrine	1 mmol/L
	Glucose oxidase	25 KU/L
	Peroxidase	0.6 KU/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Reagents should be stored in tightly closed containers at 2°C - 8°C, protected from light for a shelf life of 18 months. Once opened, it should be stored at 2°C - 8°C, protected from light for a shelf life of 42 days. Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Sample type: Fresh non hemolytic serum.
2. Sample collection: Approximately 3 mL of routine venous blood is collected and placed in a test tube. After sample collection, it is immediately sealed and sent for testing.
3. Serum should be separated promptly after blood collection to strictly avoid hemolysis.
4. Sample interference: Samples that interfere with the absorbance of the reaction, including hemolytic and lipophilic samples, may affect the detection results. In such cases, it is recommended to collect them again. When hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 5 mg/dL, bilirubin ≤ 20 mg/dL, and triglycerides ≤ 500mg/dL in the sample, there is no interference in the measurement.
5. The serum is stored at 2-8°C and the results will not change within 3 days.

TEST PROCEDURE

1. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	520 nm/600 nm	**Calibration type**	Linearity
Sample/R	3/300	**Time of serum + R**	10 min
Method	End point assay	**Direction of reaction**	Upward
Calibration method	Two-point calibration		

2. Operating procedures:

Sample	3 μL
Reagent	300 μL
Mix well, incubate at 37°C for 10min	

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: select quality control serum from Getein or from Randox, and its measured value should be within the range of its label claimed.
5. Result calculation:
   GLU concentration (mmol/L) = Concentration of GLU Standard Reference Material (SRM) × $\triangle A_{test\ sample} / \triangle A_{SRM}$

REFERENCE RANGE

Reference range: 3.89-6.11 mmol/L
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Sample with hemolysis interferes the measurement of this assay and should be avoided as much as possible during the procedure. The time the sample is left in place also has an effect on the assay.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 5 mg/dL, bilirubin ≤ 20mg/dL, and triglycerides ≤ 500 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent in the kit is a light pink clear liquid, which may contain a small number of subvisible particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{520nm} ≤ 0.200。
3. Accuracy
   When the concentration ≤ 4.16 mmol/L, the deviation between the actual value and the indicated value should not exceed ± 0.833 mmol/L.When the concentration > 4.16 mmol/L, the relative deviation should not fall outside the range of ± 20%.
4. Linear range
   For serum sample testing within the reagent linear range of [0, 27.8] mmol/L:
   a) The linear correlation coefficient (r) should not be less than 0.9900;
   b) The deviation from linearity should not fall outside the range of ± 1 mmol/L for testing within the linear range of[0, 10.0] mmol/L; the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (10.0, 27.8] mmol/L.
5. Analytical sensitivity
   When a sample has a concentration of 0.5 mmol/L, its absorbance difference should be ≤ 0.037.
6. Precision
   6.1 Within-run precision
   Within-run precision should not be more than 3.0%.
   6.2 Between-run precision
   Between-run precision should not be more than 5.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The results of the kit are only used as a basis for clinical aid in the diagnosis of various diseases. The clinical diagnosis and management of the patient should take into account his/her signs/symptoms, medical history, other laboratory tests and response to treatment, etc. are considered together.
   1.5 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Avoid direct sunlight during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Do not use the reagents with visible signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP forlaboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. LL Bajema, W Lee, AM Zebelman, and MA Kenny Detergent containing glucose oxidase reagent for use with the Beckman glucose analyzer Clin Chem 1979 25: 127-129.
2. GV Purcell, DB Behenna, and PR Walsh Evaluation of the BMC glucose oxidase peroxidase 4-aminophenazone phenol procedure for glucose as adapted to the Technicon SMAC Clin Chem 1979 25: 1844-1846.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on GLU-OX Reagent Kit-1 (GOD-POD Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054

GP

CE IVD

CRP Calibrator

Instructions for Use REF CA2015

PRODUCT NAME

CRP Calibrator

PACKAGE SPECIFICATION

5×0.5 mL

INTENDED USE

To establish or adjust the correlation (calibration curve) between the concentration and the assay signal on a designated detection system, thereby ensuring the accuracy of quantitative results for patient samples tested by that system. For professional and laboratory use only.

CONTENTS

The kit contains:

1. CRP Calibrator-Level 1
   CRP Calibrator-Level 2
   CRP Calibrator-Level 3
   CRP Calibrator-Level 4
   CRP Calibrator-Level 5
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

STORAGE AND SHELF LIFE

The calibrator can be stable for 18 months when stored at 2–8°C away from light, stable for 30 days at 2–8°C after opening.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Calibration procedure

Follow the calibration procedure in the user manual of the biochemical analyzer. It is recommended to recalibrate when the reagent lot number is changed, the QC value is significantly offset, or the analyzer undergoes major maintenance.

Materials Required But Not Provided

1 mL pipette; Biochemical analyzer.

INTERPRETATION OF TEST RESULTS

Changes in experimental methods or storage conditions may alter the concentration of this product.

LIMITATIONS

The assigned value of this calibrator is batch-specific. Values may vary between different production lots.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Colourless liquid or yellow liquid.
2. Content
   It should not be less than the indicated value.
3. Measurement value traceability
   Traceable to the national standard reference material.
4. Accuracy
   The accuracy of the transmission of the measurement value shall be in accordance with $|En| \leq 1$.
5. Homogeneity
   Intra-bottle CV should not exceed 10% and inter-bottle CV should not exceed 10%.

PRECAUTIONS

The raw materials for this calibrator were tested for HIV (HIV1, HIV2) antibodies, hepatitis B surface antigen (HbsAg), and hepatitis C virus (HCV) antibodies, with all results returning negative. All testing methods employed are FDA-approved. Although the testing methods are highly accurate, it cannot be guaranteed that all infected donors can be detected. Therefore, the calibrator should still be handled as potentially infectious material. For in vitro diagnostic use only.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols appear on medical devices and its packaging.
They are explained in more details in the European Standard EN ISO 15223-1: 2021.

Key to symbols used			
	Manufacturer		Use-by date
	Date of manufacture	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Keep away from sunlight
	Consult instructions for use or consult electronic *instructions for use*	EU REP	Authorized representative
CE	CE mark		Temperature limit
REF	Catalogue number		Biological risks

Jilin Getein Biotechnology Co., Ltd.
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Tel.: +86-4008-603387
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website:www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel.: +34951214054

GP

CE IVD

CK-MB mass Calibrator

Instructions for Use REF CA2052

PRODUCT NAME

CK-MB mass Calibrator

PACKAGE SPECIFICATION

6×1 mL

INTENDED USE

To establish or adjust the correlation (calibration curve) between the concentration and the assay signal on a designated detection system, thereby ensuring the accuracy of quantitative results for patient samples tested by that system. For professional and laboratory use only.

CONTENTS

The kit contains:

1. CK-MB mass Calibrator-Level 1
   CK-MB mass Calibrator-Level 2
   CK-MB mass Calibrator-Level 3
   CK-MB mass Calibrator-Level 4
   CK-MB mass Calibrator-Level 5
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

STORAGE AND SHELF LIFE

The unopened calibrator can be stable for 18 months when stored at 2–8°C away from light. After re-dissolution of the calibrator, it can be stable for 30 days when sealed and stored at -20°C away from light, and 3 days when stored at 2–8°C away from light.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Method of re-dissolution

To use, carefully remove the bottle cap and the rubber stopper and add the volume of distilled or deionized water specified on the product packaging. Gently cover the rubber stopper and leave it at room temperature (15–25°C) for 30 minutes while avoiding direct sunlight. Swirl gently to fully dissolve the lyophilized product and avoid foam formation. The sample can then be taken at the same time as the regular sample for determination. Cap the bottle promptly after each aspiration and store in a sealed container at -20°C away from light.

Calibration procedure

Follow the calibration procedure in the user manual of the biochemical analyzer. It is recommended to recalibrate when the reagent lot number is changed, the QC value is significantly offset, or the analyzer undergoes major maintenance.

Materials Required But Not Provided

1 mL pipette; Distilled water or deionized water; Biochemical analyzer.

INTERPRETATION OF TEST RESULTS

Changes in experimental methods or storage conditions may alter the concentration of this product.

LIMITATIONS

The assigned value of this calibrator is batch-specific. Values may vary between different production lots.

PERFORMANCE CHARACTERISTICS

1. Appearance
   It should be white or light yellow lyophilized powder before re-dissolution; after re-dissolution, it should be colourless or light yellow liquid, transparent or slightly turbid, without undissolved matter.
2. Moisture content
   Moisture content should be ≤10%.
3. Measurement value traceability
   Traceable to the national standard reference material.
4. Accuracy
   The accuracy of the transmission of the measurement value shall be in accordance with |En|≤1.
5. Homogeneity
   Intra-bottle CV should not exceed 10% and inter-bottle CV should not exceed 10%.

PRECAUTIONS

The raw materials for this calibrator were tested for HIV (HIV1, HIV2) antibodies, hepatitis B surface antigen (HbsAg), and hepatitis C virus (HCV) antibodies, with all results returning negative. All testing methods employed are FDA-approved. Although the testing methods are highly accurate, it cannot be guaranteed that all infected donors can be detected. Therefore, the calibrator should still be handled as potentially infectious material. For in vitro diagnostic use only.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols appear on medical devices and its packaging.
They are explained in more details in the European Standard EN ISO 15223-1: 2021.

Key to symbols used			
	Manufacturer		Use-by date
	Date of manufacture	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Keep away from sunlight
	Consult *instructions for use* or consult electronic *instructions for use*	EU REP	Authorized representative
CE	CE mark		Temperature limit
REF	Catalogue number		Biological risks

Jilin Getein Biotechnology Co., Ltd.
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E-mail: tech@getein.com.cn
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Website:www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel.: +34951214054

GP

CE IVD

CK-MB mass Control

Instructions for Use REF QC1034

PRODUCT NAME

CK-MB mass Control

PACKAGE SPECIFICATION

2×1 mL

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CK-MB Reagent Kit (Immunoturbidimetric Method). For professional and laboratory use only.

CONTENTS

The kit contains:

1. CK-MB mass Control-Level 1
   CK-MB mass Control-Level 2
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

STORAGE AND SHELF LIFE

The unopened control can be stable for 18 months when stored at 2–8°C away from light. After re-dissolution of the quality control product, it can be stable for 30 days when sealed and stored at -20°C away from light, and 3 days when stored at 2–8°C away from light.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Method of re-dissolution

To use, carefully remove the bottle cap and the rubber stopper and add the volume of distilled or deionized water specified on the product packaging. Gently cover the rubber stopper and leave it at room temperature (15–25°C) for 30 minutes while avoiding direct sunlight. Swirl gently to fully dissolve the lyophilized product and avoid foam formation. The sample can then be taken at the same time as the regular sample for determination. Cap the bottle promptly after each aspiration and store in a sealed container at -20°C away from light.

Calibration Procedure

Follow the calibration procedure in the user manual of the biochemical analyzer. It is recommended to recalibrate when the reagent lot number is changed, the QC value is significantly offset, or the analyzer undergoes major maintenance.

Materials Required But Not Provided

1 mL pipette; Distilled water or deionized water; Biochemical analyzer.

Test Procedure

1. Transfer the control into a Hitachi cuvette.
2. Place the control onto the sample rack.
3. Load the sample rack into the sample chamber.
4. Edit the test task and start the test.
5. During operation, the instrument will automatically aspirate and process the control, then output the measured value.

INTERPRETATION OF TEST RESULTS

Changes in experimental methods or storage conditions may alter the concentration of this product.

LIMITATIONS

The assigned value of this control is batch-specific. Values may vary between different production lots.

PERFORMANCE CHARACTERISTICS

1. Appearance
   It should be white or light-yellow lyophilized powder before re-dissolution; after re-dissolution, it should be colourless or light yellow liquid, transparent or slightly turbid, without undissolved matter.
2. Acceptable Range/Value
   Acceptable range/value determination procedures shall be established. Measurement results obtained using the claimed measurement procedure shall fall within their respective acceptable ranges.
3. Precision
   The between-bottle homogeneity is good, and the CV should not exceed 10%.

PRECAUTIONS

The raw materials for this calibrator were tested for HIV (HIV1, HIV2) antibodies, hepatitis B surface antigen (HbsAg), and hepatitis C virus (HCV) antibodies, with all results returning negative. All testing methods employed are FDA-approved. Although the testing methods are highly accurate, it cannot be guaranteed that all infected donors can be detected. Therefore, the calibrator should still be handled as potentially infectious material. For in vitro diagnostic use only.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols appear on medical devices and its packaging.
They are explained in more details in the European Standard EN ISO 15223-1: 2021.

Key to symbols used			
	Manufacturer		Use-by date
	Date of manufacture	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Keep away from sunlight
	Consult *instructions for use* or consult electronic *instructions for use*	EU REP	Authorized representative
CE	CE mark		Temperature limit
REF	Catalogue number		Biological risks

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Tel.: +34951214054

GP

CE IVD

CSF Calibrator

Instructions for Use REF CA2049

PRODUCT NAME

CSF Calibrator

PACKAGE SPECIFICATION

1×1 mL

INTENDED USE

To establish or adjust the correlation (calibration curve) between the concentration and the assay signal on a designated detection system, thereby ensuring the accuracy of quantitative results for patient samples tested by that system. For professional and laboratory use only.

CONTENTS

The kit contains:
1. CSF Calibrator
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

STORAGE AND SHELF LIFE

The unopened calibrator can be stable for 18 months when stored at 2–8°C away from light, stable for 30 days at 2–8°C after opening.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

TEST METHOD

Calibration procedure

Follow the calibration procedure in the user manual of the biochemical analyzer. It is recommended to recalibrate when the reagent lot number is changed, the QC value is significantly offset, or the analyzer undergoes major maintenance.

Materials Required But Not Provided

1 mL pipette;Biochemical analyzer.

INTERPRETATION OF TEST RESULTS

Changes in experimental methods or storage conditions may alter the concentration of this product.

LIMITATIONS

The assigned value of this calibrator is batch-specific. Values may vary between different production lots.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Colourless liquid or yellow liquid.
2. Content
   It should not be less than the indicated value.
3. Measurement value traceability
   Traceable to the national standard reference material.
4. Accuracy
   The accuracy of the transmission of the measurement value shall be in accordance with $|En| \leq 1$.
5. Homogeneity
   Intra-bottle CV should not exceed 10% and inter-bottle CV should not exceed 10%.

PRECAUTIONS

The raw materials for this calibrator were tested for HIV (HIV1, HIV2) antibodies, hepatitis B surface antigen (HbsAg), and hepatitis C virus (HCV) antibodies, with all results returning negative. All testing methods employed are FDA-approved. Although the testing methods are highly accurate, it cannot be guaranteed that all infected donors can be detected. Therefore, the calibrator should still be handled as potentially infectious material. For in vitro diagnostic use only.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols appear on medical devices and its packaging.
They are explained in more details in the European Standard EN ISO 15223-1: 2021.

Key to symbols used			
	Manufacturer		Use-by date
	Date of manufacture	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Keep away from sunlight
	Consult *instructions for use* or consult electronic *instructions for use*	EC REP	Authorized representative
CE	CE mark		Temperature limit
REF	Catalogue number		Biological risks

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EU REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel.: +34951214054

GP

CE IVD

CSF Control

Instructions for Use REF QC1031

PRODUCT NAME

CSF Control

PACKAGE SPECIFICATION

2×1 mL

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CSF Reagent Kit (Pyrogallol red Colorimetric Method). For professional and laboratory use only.

CONTENTS

The kit contains:

1. CSF Control-Level 1
   CSF Control-Level 2
2. Instructions for use: 1 piece/kit
3. Target value sheet: 1 piece/kit

STORAGE AND SHELF LIFE

The unopened control can be stable for 18 months when stored at 2–8°C away from light, stable for 30 days at 2–8°C after opening.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

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Calibration Procedure

Follow the calibration procedure in the user manual of the biochemical analyzer. It is recommended to recalibrate when the reagent lot number is changed, the QC value is significantly offset, or the analyzer undergoes major maintenance.

Materials Required But Not Provided

1 mL pipette; Biochemical analyzer.

Test Procedure

1. Transfer the control into a Hitachi cuvette.
2. Place the control onto the sample rack.
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4. Edit the test task and start the test.
5. During operation, the instrument will automatically aspirate and process the control, then output the measured value.

INTERPRETATION OF TEST RESULTS

Changes in experimental methods or storage conditions may alter the concentration of this product.

LIMITATIONS

The assigned value of this control is batch-specific. Values may vary between different production lots.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Colorless or light yellow liquid.
2. Content
   It should not be less than the indicated value.
3. Acceptable Range/Value
   Acceptable range/value determination procedures shall be established. Measurement results obtained using the claimed measurement procedure shall fall within their respective acceptable ranges.
4. Precision
   The between-bottle homogeneity is good, and the CV should not exceed 10%.

PRECAUTIONS

The raw materials for this calibrator were tested for HIV (HIV1, HIV2) antibodies, hepatitis B surface antigen (HbsAg), and hepatitis C virus (HCV) antibodies, with all results returning negative. All testing methods employed are FDA-approved. Although the testing methods are highly accurate, it cannot be guaranteed that all infected donors can be detected. Therefore, the calibrator should still be handled as potentially infectious material. For in vitro diagnostic use only.

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