skyla™ Clinical Chemistry Analyzer HB1

Operator's Manual

For In-Vitro Diagnostic Use Only

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Section 1: General Information

1.1 Overview

skyla™
Clinical Chemistry Analyzer

skyla™ Reagent Discs
(Reagent discs must be stored at temperatures between 2 to 8°C)

The **skyla**™ Clinical Chemistry Analyzer, together with its exclusive HB1 reagent disc series, offers a quick, easy and accurate method to measure various biochemical markers in whole blood, plasma, or serum.

CAUTION :

1. If the **skyla**™ Clinical Chemistry Analyzer is operated in any manner different from those described in this manual, the analyzer may produce no or inaccurate results. If used outside safe design limits, the **skyla**™ Clinical Chemistry Analyzer may not function as intended and may be hazardous.

2. The **skyla**™ Clinical Chemistry Analyzer should only be used with **skyla**™ **HB1** series of reagent discs.

1.2 Universal Precautions

As the use of this device involves clinical blood samples, health and safety regulations require that Universal Precautions be observed at all times when handling the samples. Handling of used reagent discs and the parts of the analyzer that may have come into contact with samples must be treated in accordance with relevant legal regulations in the locality or standard operation procedures of affiliated units.

1.3 Introduction

The **skyla**™ Clinical Chemistry Analyzer provides clinical testing laboratories of medical facilities and clinics with an in-vitro clinical chemistry diagnostic tool that is compact, portable, and reports rapid results. The portable design of the clinical chemistry analyzer utilizes precision photometric measurement technology, combined with the use of specific reagent discs. The reagent disc contains a set of dry assay reagents that are used in the quantitative testing of various biomarkers in the blood sample.

Features of the clinical chemistry analyzer include:

- Compatibility with lithium-heparinized whole blood samples without the need for sample dilution.
- Operation by a colored touchscreen panel.
- Fully automated system for simple operation.
- Rapid analysis, reporting test results in approximately 15 minutes.
- Testing a maximum of 15 blood clinical chemistry markers in a single analysis.
- Power-on self-test capability, ensuring instrument stability.
- Internal quality control functionality, ensuring reliable test results.
- Built-in thermal printer for immediate printing of the test results.
- A USB interface for connecting to an external printer, or exporting the test results.
- A RS232 interface for connecting with external instruments or computers.
- A USB interface supporting an externally connected barcode scanner for patient record numbers.
- A RJ45 LAN port for communication with external PC networks.

The reagent disc is a round plastic disc that contains dry assay reagents. The automated operation protocol of the

analyzer includes blood separation, sample dilution, and reagent reaction in the reagent disc. Optical signals are then analyzed by the analyzer to obtain the test results. Use of the **skyla™** Clinical Chemistry Analyzer does not require complex operational training.

Note: The clinical chemistry analyzer screen captures displayed in this manual are for illustration only, and may differ from system displays during actual operations.

Warning:
Please do not attempt to disassemble or repair the **skyla™** Clinical Chemistry Analyzer by yourself. This will void the warranty.

1.4 Technical Support

skyla™ technical support personnel of **skyla™** (or authorized agents) are available to assist users regarding the operation of the **skyla™** Clinical Chemistry Analyzer.

Technical Support &
Customer Service
Contact Tel:
Tel: +886- 3- 6118511
Fax: +886- 3- 5795393
E-mail: support@skyla.com

1.5 Consumables and Supplies

To order consumable supplies or additional accessories, please contact the customer service representatives or authorized distributors.

1.6 Understand the Symbols

The definitions of symbols found on the **skyla™** Clinical Chemistry Analyzer and its peripherals are as follows:

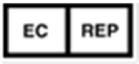
In Vitro Diagnostic Medical Equipment

Caution

Biohazard. Please strictly adhere to laboratory practices when handling blood and body fluid samples; consider all samples to be potentially infectious and handle them

with caution. Please refer to the biological medical waste disposal regulations of the locality.

Do not reuse



EC authorized representative

Date of manufacture

Manufacturer

Temperature limits (2-8°C)

Use by date

Serial number

Lot number

Consult instructions for use

Direct current

RJ45 LAN network connection

IOIOI RS232 serial port

USB port

Power button

Package Checklist

- Clinical chemistry analyzer
- Power adapter & power supply cord
- One roll of thermal printer paper
- 200 µL micropipette
- One box of pipette tips (96 tips)
- Operator's manual
- Quick guide of operation
- Quick guide of error code
- Warranty card
- External barcode scanner and stand (optional)
- USB-to-RS232 connection cord (optional)

Section 2: Setup and Quick Start

2.1 Pre-installation Check

1. Remove the **skyla**™ Clinical Chemistry Analyzer from the shipping box. Place the analyzer on a clean surface off the floor. Do not expose the analyzer to direct sunlight or any heat source.
2. Please refer to the checklist on the left and check that the components and other peripherals received with the analyzer are present.

Checklist		
No.	Item	Picture of Item
1	Clinical Chemistry analyzer	
2	Power adapter & power supply cord	
3	Roll of thermal printer paper	
4	200 µL micropipette	
5	One box of pipette tips (96 tips)	
6	Operator's manual	
7	Quick guide of operation	
8	Quick guide of error code	
9	Warranty card	

10	External barcode scanner and stand (optional)	
11	USB-to-RS232 connection cord (optional)	

3. After the successful setup, fill in the warranty card and mail it to LITE-ON Technology Corp. H.S.P.B. or email to support@skyla.com for receiving periodic mail or email regarding software upgrades and **skyla**^{TM} Clinical Chemistry Analyzer product information.

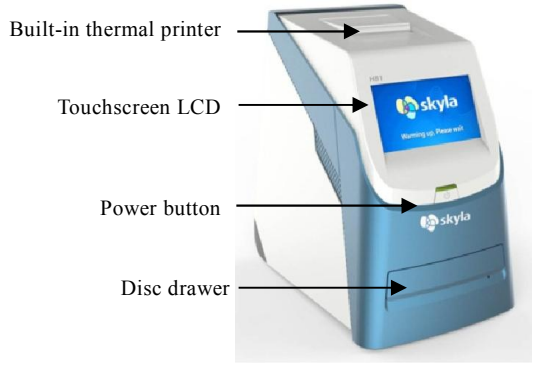
2.2 Specifications and Installation Characteristics

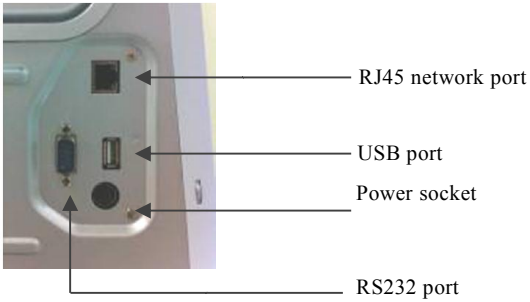
Dimensions:	Height: *300 mm*
	Width: *223 mm*
	Depth: *285mm*
Weight:	Analyzer: *5.5 kg (12.1 pounds)*
Ambient Operating Temperature:	Indoor 10 - 32°C (50 - 89.6°F)
Operating Humidity:	<95% relative humidity (non-condensing)
Device Storage/Transportation Temperature:	<65°C(149 °F)
Device Storage/Transportation Humidity:	<90% relative humidity (non-condensing)
Reaction Temperature:	37°C (98.6 °F)
Thermal Protection Rating:	100°C (212 °F)
Waterproof Class:	Ordinary equipment (IPX0)
Altitude:	2,000 m (6,562 ft)
Power Requirements:	100-240 volts AC; 50-60 Hz; Output 12 Volts DC; 5.0 A
Main Supply Voltage:	Fluctuations must not exceed ± 10% of the nominal voltage
Transient Over voltages:	Installation Category II in accordance with EN610101-1
Pollution:	Degree 2 in accordance with IEC 664
Consumables:	Reagent disc/pipette tip
Quality Control:	Self-calibration function/internal quality control function for each reagent disc
Samples:	Serum and lithium-heparinized whole blood or plasma
Sample Volume:	200 μL ±10 μL
Warm-up Time:	Less than 15 minutes (may exceed this time limit in unique environments)
Test Time:	15 minutes
Touch Panel:	5” TFT color LCD touchscreen
Printer:	Built-in thermal printer; can be connected to compatible external printers
Communication:	USB port: 1x ; RS232 port: 1x ; RJ45 network port: 1x
Memory Capacity:	Capacity for up to 50,000 test results

2.3 Installation and Setup

This section provides important information for the installation and setup of the **skyla**™ Clinical Chemistry Analyzer.

Exterior function diagram





Installation Location

Place the **skyla**™ Clinical Chemistry Analyzer on a level surface off the ground and be sure that the surface is:

- Free from vibration.
- Clean and free of contaminants.
- Indoors at a room temperature of 10–32 °C (50 - 89.6 °F).
- Away from direct sunlight and other heat sources.
- At least 10cm from any wall to ensure proper ventilation around the analyzer and access to the

power connector, RS232 and USB ports at the back of the analyzer. At the same time, there must be at least 15 cm of space to the front of the analyzer to ensure normal operation of the disc drawer.

Power Supply

In addition to the clinical chemistry analyzer and power supply cord, the analyzer comes with a power adapter. Connect the power adapter into the clinical chemistry analyzer on one end and plug the power supply cord into a grounded electrical outlet.

Note:
The clinical chemistry analyzer should not share the same circuit with other high-current devices. A surge protector is recommended to protect the clinical chemistry analyzer.

Printer Paper

Open the top cover of the built-in thermal printer and place the printer paper into the paper slot. Confirm that the heat-sensitive side is facing the correct direction (the arrow sticker on the roll should point downwards).

Connecting an External Printer

If you choose to use an externally connected printer instead of the built-in thermal printer, please plug the external printer into the **skyla**™ Clinical Chemistry Analyzer's USB port and switch the system settings to an external printer. Refer to section 5.1.2 for details.

Note:
The clinical chemistry analyzer supports few USB interfaced external printer models. Please contact your **skyla**™ authorized technical support personnel for the latest information on external printer models.

Connecting an External Barcode Scanner

If you purchase an external barcode scanner (CIPHER 1500H) for patient ID scanning, please connect it to the USB port on the clinical chemistry analyzer's rear panel. The clinical chemistry analyzer's operating system will automatically detect and launch the scanner when it's connected.

Connecting Other External USB Devices

Using a USB flash drive, you can export test results or historical data to the USB drive for data backup.

Connecting an External Device via the RS232 Serial Port

The clinical chemistry analyzer can be connected to external equipment or personal computers via the RS232 serial port. The administrator can set different transfer baud rates for the RS232 serial port according to needs. Connecting to a personal computer via USB is possible by using a RS232-to-USB connection cord (optional purchase).

Connect to LAN Network (RJ45)

If you need to link the clinical chemical analyzer to the laboratory's LAN via RJ45, please contact the authorized technical support personnel.

Icons for touchscreen interface:

 Page Up, Increase

 Page Down, Decrease

 Page Back/Next

2.4 Touchscreen Interface

The clinical chemistry analyzer is equipped with a touchscreen which is easy to operate and facilitates rapid interaction between the user and the system software interface during function selection and test execution. The user can utilize the touchscreen for procedural instructions on completing a test. The interface provides information about function, test progress, system settings, and other messages.

 Backspace

 Back

 Confirm (Next step)

 Home (Home menu)

 Print

 Export to RS232

 Dump to USB

 Show all test results (regular reports)

 Show custom report

 option activated

 option not activated

 Analyte selected

 Selection is being updated

 Show numerical keypad

On-Line help explanation

- Input the password or patient ID using the keypad on touchscreen (up to 12 digits).
- To change typed information, please use the backspace or delete key on the touch screen  to move the cursor on screen backwards in order to delete a typed character.
- Use the up  and down  arrow keys on the touchscreen to browse the displayed list of items or to increase or decrease a displayed value.
- Use the page back  and page next  keys on touchscreen to navigate between pages.
- All clinical chemistry analyzer functions are operated via various icons on touchscreen, as well as specific keys that appear on screen.
- Press the back  key on touchscreen to cancel a choice and return to the previous step, or to move backward through a series of screens/items.
- Press OK  to confirm the step.
- Press HOME  to return to the top layer (Home).
- Press Printer  to print the test results shown on screen. To print results with the built-in thermal printer or external printer, select this option under the **system settings menu.**
- Press Export to RS232  to export the test data shown on screen to an external information device via the RS232 interface.
- Press Dump to USB  to export all of the historical test data in the system via USB.
- Press Show all test results  to display results for all test items on the reagent disc (regular report).
- Press Show custom report  to display the custom report on screen.
-  means an option has been activated.
-  means an option has not been activated.
-  means an analyte has been selected for display in the Custom Report function.

QW English keyboard

SPC Space

A a 1 Uppercase /Lowercase / Number

Warning:
Please do not touch or scratch the touchscreen with sharp, hard objects to avoid damaging the screen.

- 38 yellow frame means that the selected value is currently being updated.
- means to show the numerical keypad for manual key-in when using an external barcode scanner.
- Provides an on-line help explanation.
- QW English keyboard. Press one time to show the left character; press twice to show the right character.
- SPC Enter space.
- A a 1 Switch the keyboard among uppercase, lowercase and number.

2.5 Power-On and Initialization

Power-On:
Press the Power button to turn on the analyzer. Warm-up requires up to 15 minutes (this time may be exceeded in unique environments)

Built-in Self-test:
System self-test and precision calibration.

Power-On and Built-in Self-tests

Turn the clinical chemistry analyzer on and off by pressing the power button on the front panel. The system automatically launches the warming procedure and completes system self-test after power on. It may take up to 15 minutes for the system to be ready (depending upon room temperature).

Warm boot screen after start up

Low temperature warm boot screen after start up

Initialization:
The first time the clinical chemistry analyzer is turned on, you will be prompted to set the “Language”, “Password” , “Date & Time”, and “Analytes Unit” on screen.

Initialization

The first time the clinical chemistry analyzer is turned on, once the warm up and system self-test are complete, the language menu in the operator interface will appear on screen. The manager should tick and click “OK”.

After the language is set, the screen to set the password will appear. Please input a numerical password and then enter the same password again for confirmation. Then press “OK.”

If the administrator presses **“OK”** button without entering any numbers in both **“New Password” & “Confirmation”** boxes, the password will no longer be required by the system.

Once the system password setting is complete, the **“Date & Time”** setup screen will appear. Please select the date edit box and use the up and down arrow keys to adjust to the correct date. Press the “**OK”** icon to save the changes on the system. After confirming the time is correct, select the “**Format**” square and choose the usual date format. Finally, press “**OK**” to save information in the system.

After completing the date and time setting, the all analytes units setting menu will appear on screen. Select and press "**OK**" to complete setting. The system processing will take about 10 seconds, and it will automatic be directed to the system homepage.

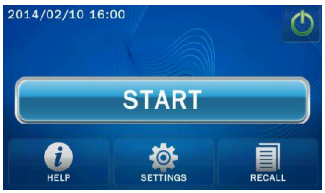
Home Menu:
When the "START" icon appears on screen, sample analysis may begin.

Home Menu

After completing the warm-up and system self-tests, the "**START**" icon will appear on screen for sample analysis to be commenced.

The screen displayed at this time is referred to as the Home (top level) menu. You can return to the home menu from any stage by simply pressing the  icon.

Press the "**START**" icon on screen and the reagent disc drawer at the front of the analyzer will automatically open up. Place the prepared reagent disc inside to start the analysis.



Prior to inserting a reagent disc into the clinical chemistry analyzer, check that the expected reference ranges and specified units have been set up properly. Also check if there is thermal paper in the built-in thermal printer, or, if it applies, whether setup of the external printer and other connected devices are complete.

Power-Off:
Press the power icon on screen and press "YES" to confirm power-off.

Power-Off

Please turn off the clinical chemistry analyzer if it will not be used for a prolonged period. Press the power icon  on screen, and press "YES" to confirm power-off.

2.6 Maintenance and cleaning

LITE-ON suggests the **skyla**™ Clinical Chemistry Analyzer should be cleaned routinely at least once per week.

Use a clean cloth dampened with cleaning solution (ex. 10% commercial bleach solution) to wipe the exterior surface of the analyzer. When using the cleaning solution for the first time gently wipe a small area of the analyzer surface to ensure no obvious damage occurs before cleaning the entire surface.

If the exterior surface of analyzer is stained with blood then clean immediately using a cloth dampened with 10% commercial bleach solution.

When necessary, clean the interior area of disc drawer using the following steps:

1. Press the "START" icon on screen to open the disc drawer.
2. Use a cotton swab dampened with 10% commercial bleach solution to wipe the drawer area.

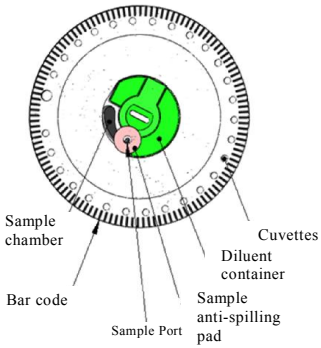
3. Use a dry cotton swab to wipe the same area.
4. Close the disc drawer.

The disc drawer will automatically close in 15 seconds. If the cleaning procedure is not yet finished, please press the “START” icon again to open the drawer.

Section 3: Sample Analysis

3.1 Functions of Reagent Disc

Reagent disc



All the chemical reactions that take place in the **skyla**™ Clinical Chemistry Analyzer are completed inside a circular and transparent plastic reagent disc. A series of automated liquid handling and reaction procedures on the injected whole-blood, plasma, or serum are performed in the reagent disc, enabling accurate and reproducible test results on the clinical chemistry analyzer. Each reagent disc contains one set of dry assay reagents needed for the specified panel of test markers. A number of clinical chemistry markers can be simultaneously tested in a single analysis.

The functions of the reagent disc include:

- Checking if the diluted sample is sufficient and distributed to all reaction cuvettes in the reagent disc.
- Confirming that the amount of the injected sample is sufficient.
- Providing various configurations of assay reagents in the disc.
- The barcode ring on the reagent disc contains the serial number, batch number and valid date of the reagent disc. The barcode ring also protects the optical surface of the reaction cuvettes from finger prints and other debris that may interfere with the optical measurement. The clinical chemistry analyzer can automatically check the above information and exclude expired reagent discs.
- The sample anti-spilling pad prevents overflowing of the sample on the surface of the reagent disc when in excess, reducing the occurrence of analyzer interior contamination by the splashed sample during operation.

- The center of the reagent disc contains a tightly sealed sample diluent container. Prior to use, the aluminum foil strip of the diluent container that covers the sample anti-spilling pad must be removed to ensure the normal operation of the clinical chemistry analyzer.
- During analysis, the clinical chemistry analyzer first performs a centrifugation step, where the plasma and blood cells are separated in the reagent disc if the sample is a whole-blood sample. This step has no effect on plasma or serum samples. Next, accurately quantified sample and diluent are delivered to the mixing chamber for dilution. The fully diluted sample is then distributed to all reaction cuvettes in the disc by centrifugal force, where the chemical reactions with assay reagents occur. Clinical chemistry markers are quantified by photometric measurement of the absorbance changes arising from these chemical reactions.

  The reagent disc features internal quality control functions in order to ensure adequate sample and diluent are properly distributed to every reaction cuvette in the disc. In addition, possible sample interferences that might affect the test results are automatically monitored. If the degree of interference exceeds the specification limit of relevant markers under analysis, the system will display a warning message.

Sample Conditions:

- Use serum or lithium-heparinized whole-blood or plasma samples.

3.2 Sample Preparation

The compatible sample types for the **skyla™** Clinical Chemistry Analyzer include: serum, lithium-heparinized whole blood or plasma.

- Conduct testing within 60 minutes after collecting a whole-blood sample.
- Use the provided micropipette to obtain a 200μL sample and dispense it into the reagent disc.

Warning:

1. Always pay special attention and follow standard precautions to protect the operator's health and follow local regulatory requirements when operating the machine with clinical blood samples.

- The amount of sample required for one panel test is 200 μL.
- Once the whole-blood sample is collected, testing must be conducted within 60 minutes (at room temperature) in order to prevent cellulose precipitation in the blood.
- To prevent hemolysis of the sample, do not refrigerate, freeze, or shake whole-blood sample.
- If the whole-blood sample can't be analyzed within 60 minutes, separate the blood into plasma or serum using a centrifuge. After centrifugation, do not store the plasma or serum at room temperature for more than 5 hours. In case storage for more than 5 hours is needed, store the plasma or serum in a tightly sealed test tube covered with a cap and place it in a refrigerated space at 2-8°C (36-46°F) for no longer than 48 hours, or in a freezer at -20°C (4°F) without automatic defrost for no more than 5 weeks. Please adhere to the above recommended storage conditions in order to ensure that the test results are without serious errors.
- According to the following table, the blood collection tube used should correspond to the sample type. Note that the whole-blood or plasma sample should fill **more than half of the blood collection tube** in order to avoid excessive lithium heparin concentrations in the test tube that may adversely affect the accuracy of the test results.

(Whole blood) (Plasma)		✓ Use lithium heparin blood collection tubes (Green cap). DO NOT use sodium heparin blood collection tubes. ✓ **DO NOT use EDTA blood collection tubes.** ✓ Once the whole-blood sample is collected, it must be tested within 60 minutes

2. Follow local regulations or standard operating procedures for the disposal of reagent discs and the clinical chemistry analyzer that come in contact with the sample.

		(at room temperature). ✓ The blood sample must be at least half the volume of the blood collection tube.
(Serum)		✓ Use the serum clot activator blood collection tube (Gold cap).

Step 1: Reagent Disc Preparation

■ Remove the reagent disc from the refrigerator and tear open the package from the upper right side of the foil pouch.

■ Remove the reagent disc gently with finger and thumb along with tissue paper from the foil pouch.

■ After removal, use the other hand to hold the reagent disc by the edge.

3.3 Preparation Before Testing

Disc Storage and Handling

Before using a reagent disc, carefully check the foil pouch for any damage. After removing the reagent disc, inspect the disc for any damage or abnormality. Do not attempt to tap on the reagent disc. Do not use reagent discs that have been dropped or damaged.

■ Each reagent disc should be stored in accordance with the instructions printed on the disc's foil pouch in order to maintain the stability of the reagent beads within the valid period. The clinical chemistry analyzer will automatically reject expired reagent discs. Reagent discs taken from 2-8°C storage can be used directly without warming. Avoid placing unopened reagent discs in places higher than 25°C (77 °F) for more than 48 hours.

■ Do not expose reagent discs, either in or out of their foil pouches, to direct sunlight or to temperatures above 32°C (90°F).

Disc Preparation

The steps for preparing the reagent disc are as follows:

■ Tear open the package from the notch at the side of the foil pouch.

■ When removing the reagent disc, gently grip it with finger and thumb together with tissue paper.

- Release the fingers that grip the regent disc, unwrap and discard the tissue paper.

- Inspect and do not use any damaged reagent discs.
- Once the pouch is opened, use the disc **within 20 minutes.**
- Before dispensing the sample, remove the aluminum strip covering the sample port on the disc.

- After removal, use the other hand to hold the reagent disc by the edge.
- Release the fingers that grip the regent disc, unwrap and discard the tissue paper.
- Inspect the reagent disc for any damage or abnormality. **Do Not Use Any Damaged Reagent Discs.**
- After opening the pouch, the disc should be used within 20 minutes. Do not place the disc back in the refrigerator for later use.
- **The surface of the reagent disc should be kept clean at all times. Hold the disc by the edge to avoid contact with the reagent disc surface where optical measurement takes place.**

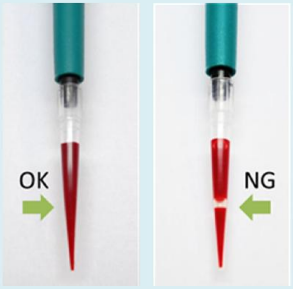
Remove The Aluminum Strip

Before dispensing the sample, remove the aluminum strip of the diluent container to ensure normal operation of the clinical chemistry analyzer. Please follow these steps to remove the aluminum strip:

- Hold the reagent disc by the edge and avoid touching the barcode ring. Meanwhile, avoid contacting the top and bottom sides of the reaction cuvettes that are located on the outer part of the reagent disc (round holes next to the barcode). Remove the aluminum strip of the diluent container, which covers the sample port on the reagent disc, by gently pulling the end of the aluminum strip in an outward direction along the surface of the reagent disc. Please completely remove the aluminum strip from the reagent disc.
- Discard the removed aluminum strip.

Step 2: Dispensing the Sample

- Use the provided micropipette and a new tip to pick up 200 µL of the sample.
- When picking up the sample, avoid drawing in any air. This can cause insufficient volume of the sample pickup.



- Insert the pipette tip into the sample port. The pipette tip only needs to make slight contact with the bottom of the sample chamber. **Do not push down hard** to avoid deforming the pipette tip.

- Keep the pipette **perpendicular**. Gently push the plunger down **in a slow, continuous motion** to dispense the sample into the reagent disc. Do not push down the pipette plunger repeatedly to avoid

3.4 Dispensing the Sample

Use the provided micropipette to dispense 200 µL of the sample into the sample chamber through the sample port of the reagent disc.

- Attach a new tip to the end of the 200 µL pipette. Do not touch the tip.
- Hold the pipette and use your thumb to push down the plunger at the top of the pipette all the way to the end. Hold it down to pick up the sample.
- Immerse the pipette tip below the surface of the sample. Slowly release the plunger to pick up the sample. Remove the pipette from the sample tube.
- Make sure there are no air bubbles or air gaps in the pipette tip.
- Insert the pipette tip into the sample port attached with the sample anti-spilling pad on the top of the reagent disc. The pipette tip only needs to make slight contact with the bottom of the sample chamber; do not push down hard to avoid deforming the pipette tip. When dispensing the sample, ensure that you keep the reagent disc level and keep the pipette **perpendicular** to the surface of the reagent disc. Gently push down the plunger at the top of the pipette all the way to the end to dispense the entire sample to the reagent disc. After the sample is completely dispensed into the reagent disc, keep the pipette plunger held down and remove the pipette from the sample port before releasing the plunger to **avoid withdrawing the sample from the reagent disc.**
- If some of the sample flows out of the sample anti-spilling pad, use a lint-free tissue to clean the disc and make sure that the tissue does not withdraw any sample from the sample port.
- Dispose of the used tissue and pipette tip in a designated biohazard container.

early entry of the sample into the sample measurement area, which may affect the metering of sample volume.

- After the sample is completely dispensed into the reagent disc, keep the pipette plunger down and remove the pipette from the sample port before releasing the plunger to avoid withdrawing the sample from the reagent disc.

- Use a lint-free tissue to clean any sample spilled on the outside of the reagent disc.

- Dispose of the used tissue and pipette tip in a designated biohazard container.

- Hold the reagent disc by its edges and keep it level; gently place it into the analyzer's disc drawer.
- Close the analyzer's disc drawer and begin the analysis. Please refer to section **3.5 Performing a Test** for detailed information.

Notes:

1. Wear powder-free gloves while handling reagent discs or operating the analyzer in order to avoid powder affecting the system's optical measurement properties.
2. Perform the test within 10 minutes of dispensing the sample into the reagent disc.

- Perform the test within 10 minutes after dispensing the sample into the reagent disc.

Step 3: Performing a Test

- Press the **START** icon on the touch screen to open the disc drawer.
- Hold a reagent disc that contains a sample by its edge and keep it level. Avoid touching the surface of the reagent disc. Gently place the disc into the drawer.
- Press **OK** to close the drawer.
- Use the touchscreen or barcode scanner to enter the patient ID.
- If the system requires gender and age information to be entered, please fill them out in sequence.
- The system will begin the analysis. “Analyzing…” will be displayed on screen.

3.5 Performing a Test

When the **skyla**™ Clinical Chemistry Analyzer is turned on and the touchscreen displays the function options, it is ready to perform the test sequence.

Press the **START** icon on the touchscreen to open the reagent disc drawer at the front of the Clinical Chemistry Analyzer.

Hold a reagent disc that contains a sample by its edge, with the barcode side facing up and the disc kept level. Avoid touching the surface of the reagent disc. Gently place the disc into the drawer and press **OK** to close the disc drawer.

Note:

1. The system will automatically perform the test sequence when the drawer contains a reagent disc and is closed.
2. If the clinical chemistry analyzer's system settings include the calculation of **eGFR** values, please answer the questions on the system prompt screen in sequence, including information such as "**gender**" and "**age**".

■ When the **Operator Control** setting is **ON**, the system will require the operator to enter the Operator ID before the test starts.

■ Use the touchscreen to enter the patient ID (up to 12 numbers) or scan the patient ID using the optional external barcode scanner and press **OK**.

If you press OK without entering a patient ID, the system will use the current date and time as the patient ID in the format ddmmyyyyhhmm.

■ If you enable the **eGFR** option, the system will prompt you to enter **Gender** and **Age**. Press **OK** when you finish.

Select Gender

Enter the patient's age

Warning:
A reagent disc cannot be reused if a test has been canceled.

The system will commence automatic test procedures after the patient code is entered.

When the analysis is completed, the system will store the analysis results and display them on the touchscreen. To cancel a test in progress, simply press the **CANCEL** icon on the touchscreen. The system will prompt you to confirm and then stop the analysis.

Step 4: Test Results

- The system will automatically display the test report, which can be printed out.
- You can use the **Recall** and **Printer** functions to search for test records and print reports.
- The system will store the analysis results. They can be exported as a document file.
- Press the **HOME** icon to return to the main menu and press **OK** to open the drawer and remove the reagent disc.
- To perform another test, simply insert a new reagent disc into the drawer.

3.6 Test Results

When the test is completed, the system will store the information produced. You can print out the results using the built-in thermal printer or export them as a document file. Under normal circumstances, the system will automatically display the test report and you can choose whether to print it using the built-in thermal printer or an external printer (configured at the Printer function menu). You can also use the “Search Test Records” and “Print” functions to obtain reports. See Section 4.1.1 “Searching for Test Records” for instructions.

Press the **HOME** icon and then the OK icon to open the drawer and remove the reagent disc.

Notes:
Dispose of used reagent discs according to laboratory regulations and local legislation.

To analyze another sample, insert a new reagent disc sample and repeat the above steps. Press "**OK**" without inserting any disc and the touch screen will return to the main menu. Analysis is now complete.

Step 5: Reviewing the Test Results

■ Printed reports include:

1. Test marker
2. Analyte concentration
3. Reference range
4. Unit

3.7 Reviewing the Test Results

Table 1 shows the format of the analysis report that is automatically displayed on the touchscreen. The report consists of two sections (see Table 1). The heading at the top of the report includes information about the analyzer model, test date and time, sample type, specimen/patient ID, reagent disc serial number, operator ID, gender and age. The results section consists of four columns: test marker, analyte concentration, reference range and unit. The test report also shows the degree of Lipemia (LIP), Hemolysis (HEM), and Icterus (ICT) of the sample analyzed. If the system administrator enables the QC Report function, the report will also include the internal QC results (see Table 2).

Symbols used in test reports:

- (#): Calculated value
- (↑)：Result is higher than referance range.
- (↓)：Result is lower than referance range.
- (>): Result is greater than the highest value of the dynamic range.
- (<)：Result is less than the lowest value of the dynamic range.
- (+): Degree of lipemia, hemolysis, or icterus.

- LIP: Lipemia
  HEM: Hemolysis
  ICT: Icterus
  Severity:
  "0" (Clear)
  "+" (Mild)
  "++" (Moderate)
  "+++" (Severe)
- (L): Lipemia interference effect is outside the permissible range by 10% or more. "L:_:_" is shown.
- (H) Hemolysis interference effect is outside the permissible range by 10% or more. "_:H:_" is shown.

Table 1: Test report generated when the QC Report function is not used

skyla HB1 analyzer
Basic Biochemistry Panel

LITEON Hospital

30-09-2013 17:05:07
Sample Type: Patient
Patient ID: 123456789012
Name: Andy Liu
Gender: Male
Age: 48 Yr
Operator ID: 123456789012
PR Code: 1140109201AM0FAEM0D
QC: OK
LIP: +++ HEM: 0 ICT: +

Item	Result	Range	Unit
ALB	4.12	3.5-5.3	U/L
TP	↓ 2.12	6.0-8.3	U/L
GLU	80	70-100	mg/dL
ALT	↑ >1100	M0-41	U/L
		F0-31	U/L
BUN	12.12	8-20	mg/dL
CREA	L:H:I	M0.7-1.3	mg/dL
		F0.6-1.0	mg/dL
#GLOB	↑ 12.12	2.3-3.5	g/dL
#A/G	1.2	1.0-1.8	
#eGFR	123	≧90	mL/min /1.73m2

3.7.1 Symbols Used in Test Reports

- (#): Calculated value.
- (↑)：Result is higher than referance range.
- (↓)：Result is lower than referance range.
- If the result is outside the dynamic range of the test marker, a "less than" symbol (<) will be displayed next to the lowest value or a "greater than" symbol (>) will be displayed next to the highest value to indicate that the result where the marker is less than the lowest value or greater than the highest value of the dynamic range of the marker. For example, the dynamic range of glucose is 10–600 mg/dL. If the analyte glucose concentration is less than this range, "<10 mg/dL" will be shown; if it is greater than this range, ">600

■(I): Icterus interference effect is outside the permissible range by 10% or more. "_:_:I" is shown.

■(_:_:I): Test marker affected by interference due to icterus (ICT).

■(_:H:_): Test marker affected by interference due to hemolysis (HEM).

■(L:_:_): Test marker affected by interference due to lipemia (LIP).

■(L:H:I): Test marker affected by interference due to lipemia (LIP), hemolysis (HEM), and icterus (ICT).

mg/dL" will be shown.

■(+): Indicates the degree of lipemia (LIP), hemolysis (HEM), and icterus (ICT) of the sample. The more plus symbols (+) are shown, the more severe this interference found in the sample.

■The degree of lipemia (LIP), hemolysis (HEM), icterus (ICT) of the sample is classified as follows:

"0" (Clear or without interference)
"+" (Mild)
"++" (Moderate)
"+++" (Severe)

■(L): Indicates that the marker has been affected by interference due to sample lipemia (LIP) that is outside the permissible range by 10% or more.
"L:_:_" is shown.

■(H): Indicates that the marker has been affected by interference due to sample hemolysis (HEM) that is outside the permissible range by 10% or more.
"_:H:_" is shown.

■(I): Indicates that the marker has been affected by interference due to sample icterus (ICT) that is outside the permissible range by 10% or more.
"_:_:I" is shown.

■(_:_:I): Indicates that the marker has been affected by interference due to sample icterus (ICT).

■(_:H:_): Indicates that the marker has been affected by interference due to sample hemolysis (HEM).

■(L:_:_): Indicates that the marker has been affected by interference due to sample lipemia (LIP).

■(L:H:I): Indicates that the marker has been affected by interference due to sample lipemia (LIP), hemolysis (HEM), and icterus (ICT).

■ Explanations of NA results :

1) N.A. for certain calculated values: for example, if TP or ALB is out of dynamic range, or one of them is N.A., the result of GLOB# will show N.A..
2) Assay equation and FW version does not match. Please upgrade system firmware.
3) The analysis is severely impacted by possible interferences in blood samples. N.A. is shown to avoid incorrect results.
4) N.A. for marker ALT or AST. Please confirm the LIP scores. If LIP scores are over 300, the NA means the analysis is interfered by high lipemia in the sample.
5) N.A. for marker BUN or AMY. Please contact technical support. There might an error with these two markers.
6) AST result shows N.A.： Possibly damaged assay disc due to moisture. Please use a new assay disc. And make sure the disc packaging is intact. Please contact technical support.

Symbols used in test reports:

- SCORE: Indicates the numerical value of sample lipemia (LIP), hemolysis (HEM), and icterus (ICT).
- min：Indicates the minimum acceptable value

Table 2: Test report generated when the QC Report function is activated

```
        skyla HB1 analyzer
          Metabolic Panel

  LITEON                Hospital

  30-09-2013             17:05:07
  Sample Type:            Control
  Patient ID:       123456789012
  Name:                Alice Chen
  Gender:
  Age:                       28 Yr
  Operator ID:      123456789012
  PR Code: 1140109202AM0FAEM0D
- - - - - - - - - - - - - - - - -
  QC Items:      Result      Range
    QC1:            100     min.90
    QC2:            100     min.90
    QC3:            100     min.90
    QC4:            140     min.90
    QC5:            210     min.90
    QC6:            100     min.90
    QC7:            100     90-110
    L340nm:         100     90-110
    L405nm:         100     90-110
    L450nm:         100     90-110
    L510nm:         100     90-110
    L540nm:         100     90-110
    L600nm:         100     90-110
    L650nm:         100     90-110
    L940nm:         100     90-110
  System      QC:   100     min.90
  Chemistry   QC:   123     min.90

  LIP: +     HEM: 0     ICT: +++
SCORE: 123       : 005       : 321
- - - - - - - - - - - - - - - - -
 Item    Result    Range       Unit
- - - - - - - - - - - - - - - - -
 ALB      4.12    3.5-5.3       U/L
 TP     ↑ 9.6     6.0-8.3       U/L
 GLU      80      70-110       mg/dL
```

3.7.2 Symbols Used in internal QC Reports

- QC1: This QC item indicates whether the volume of the diluted sample is sufficient. Normal score range is 90 or over.
- QC2: This QC item indicates whether the diluent has been contaminated. Normal score range is 90 or over.
- QC3: This QC item indicates whether the assay chemical reagents have been degraded due to deliquescence. Normal score range is 90 or over.
- QC4: This QC item indicates whether the dilution is sufficient. Normal score range is 90 or over.
- QC5: This parameter indicates whether the volume of the sample is sufficient. Normal score range is 90 or over.

- QC6: This QC item indicates the degree of sample hemolysis. Normal score range is 90 or over.
- QC7: This QC item indicates temperature control stability of the instrument. Normal score is within the range 90–110.
- L340nm: This QC item indicates the linear stability of the equipment's first optical channel. Normal score is within the range 90–110.
- L405nm: This QC item indicates the linear stability of the instrument's second optical channel. Normal score is within the range 90–110.
- L450nm: This QC item indicates the linear stability of the instrument's third optical channel. Normal score is within the range 90–110.
- L510nm: This QC item indicates the linear stability of the instrument's fourth optical channel. Normal score is within the range 90–110.
- L600nm: This QC item indicates the linear stability of the instrument's fifth optical channel. Normal score is within the range 90–110.
- L650nm: This QC item indicates the linear stability of the instrument's sixth optical channel. Normal score is within the range 90–110.
- L540nm: This QC item indicates the linear stability of the instrument's seventh optical channel. Normal score is within the range 90–110.
- L940nm: This QC item indicates linear stability of the instrument's eighth optical channel. Normal score is within the range 90–110.
- System QC: This QC item indicates the stability and reliability of the instrument's system. Normal score range is 90 or over.
  System QC Acceptable Minimum: 90

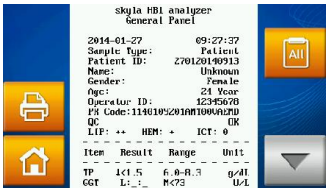
- Chemistry QC: This QC item indicates the activity quality of the chemical reagents. Normal score range is 90 or over.
  Chemistry QC Acceptable Minimum: 90
- SCORE: Shows the numerical value of interference of lipemia (LIP), hemolysis (HEM), and icterus (ICT) of the sample, based on a proprietary calculation method.
- min: Indicates the minimum acceptable value.

3.8 Custom Reports

The **Custom Report** function can be activated in the settings. You can choose which test markers are to be shown or hidden in the reports. After the Clinical Chemistry Analyzer is ready and the patient ID is entered, the system will ask if you want to show custom report details.

If you select **NO**, a standard report will be displayed after the analysis. A standard report shows all test markers of the reagent disc.
If you select **YES**, the system will let you select what test markers are to be included in the analysis report. Choose the ones that you want to show on the report by pressing respective marker icons on the touchscreen, and press **OK** when finished.

The custom report will be displayed after the completion of the analysis. Only those selected test markers will be shown.



Custom report

To temporarily switch to a standard report and show all test markers, simply press the 

icon on the touchscreen.

Standard report

Press the  or 

icons on screen to switch between custom report and standard report.

Performing Quality Control:

- Perform a quality control test on a regular basis.

3.9 Performing Quality Control

Quality control tests should be performed on a regular basis in order to ensure the reliability of the **skyla**™ Clinical Chemistry Analyzer. Quality control can be regularly performed using commercially available controls supplied by manufacturers that ensure a stable

■ Perform a quality control test if you have doubts regarding analysis results.

long-term supply and provide adequate traceability information.

It is recommended that the quality control test be performed:

- ■ At least every 30 days.
- ■ Whenever there is a significant change to the laboratory environment.
- ■ After the analyzer has been used for staff training.
- ■ When test results are inconsistent with patient symptoms or diagnosis.

3.9.1 Selecting an External Control

Select a commercially available control that covers all test markers of the reagent discs selected for the control test and the concentrations thereof.

3.9.2 Using a skyla™ Reagent Disc for the Quality Control Test

Any **skyla™** reagent disc can be used to perform the quality control test. Make sure that the known concentrations of the test markers in the control cover the test markers of the reagent disc.

Note:

1. Contact authorized **skyla™** technical support personnel or agents to inquire about commercially available controls.
2. If you have any questions about the selection of reagent discs, please contact authorized **skyla™** technical support personnel or agents.

3.9.3 Performing a Quality Control Test

Turn on the analyzer by pressing the power button on the front of the analyzer and wait for about 15minutes for the self-test and calibration of the analyzer to be completed. Remove the reagent disc from the refrigerator.

- ■ Follow the procedures as indicated in Section 3.2 ‘Sample Preparation’ and 3.3 ‘Preparation Before Testing’.
- ■ Follow the procedures as indicated in Section 3.4 ‘Dispensing the Sample.’ Use a micropipette to dispense 200μL of the control into the reagent disc via the sample port.

Notes:

1. Perform and record the quality control test according to the laboratory's quality control regulations. Quality control records should be indefinitely documented in the laboratory's records.
2. The quality control tests must be performed using the Control function in the Settings on the **skyla**™ Clinical Chemistry Analyzer to ensure the accuracy of the results.
3. Please refer to the package insert of the selected control for detailed sample preparation and testing information.

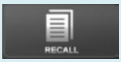
- Press **SETTINGS** on the main menu screen.
- Press the **Control** icon to start the quality control test process. The test process is the same as the one for sample analysis and the system will automatically complete the test. However, there is no need to input any patient related information.

- The quality control test results are stored separately from sample analysis test results. The results can be printed out or exported after the quality control test is completed.
- Quality control test results are stored in the system database. You can search for, review, and print past control test results using the **RECALL** function (see Section 4.1.3 Searching for System Quality Control Test Records'.

3.9.4 Quality Control Test Results

Quality control test results of each test marker should be in agreement with the reference values provided by the control manufacturer.

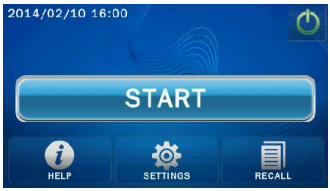
- Recall the historical report information stored in the clinical chemistry analyzer.



Recall historical information

Section 4: Review of Historical Data & Operation Information

When the Home screen appears on the **skyla**™ Clinical Chemistry Analyzer, click "HELP" to display the quick guide or click **"RECALL"** to browse historical report information stored in the clinical chemistry analyzer.



4.1 Review of Historical Data (Recall)

The **skyla**™ Clinical Chemistry Analyzer automatically stores test results in the system for display, printing, or export to USB for later review or further implementation. Please refer to section 5.2.5 "Dump to USB Drive" for detailed information on exporting test results to USB.

In the **Home** screen, press the **"RECALL"** 

icon to recall previous test reports, search past test results, or browse all test records in sequence. You can also export or print selected historical reports.

4.1.1 Searching for Test Records (Search)

Use the Search function to search test records.

- Select the "RECALL" function in the HOME screen.
- In the RECALL screen, select "Search" to see the search function on screen.

■ Enter the administrator password.

■ The administrator can search test records by “Date” or “Patient ID”, or press the “Controls” icon to search quality control test records.

To search for results by “Date”:

■ Press the “Date” icon to access the date and time input panel.

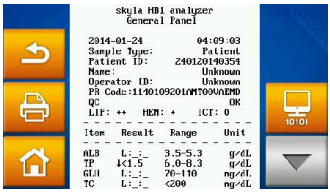
■ When the change date/time option is displayed on screen, press any number to activate the edit mode. Please use the up  and down  arrow keys to adjust the year, month, and day.

■ After selecting the dates, press the “OK” icon to begin the search. Test records which match the search parameters will be displayed and can be identified by their patient ID numbers. The results sorted by the patient ID numbers will be displayed in chronological order.

■ Use the up  and down  arrows to select the desired report.

■ Press the USB  icon to export and save the selected data to USB.

■ Press the print  icon when the report is displayed on screen to print the report.



To search for results by "**Patient ID**":

■ Press the "**Patient ID**" icon to activate the input screen.

■ Use the number pad to enter the patient ID.

■ Press the "OK" icon to begin the search.

■ Test record fit to the ID will be displayed on screen.

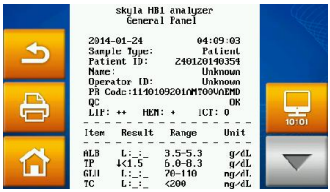
■ Test records that meet the search criteria will appear on screen.

■ Use the up  and down  arrows to select the desired report.

■ Select a patient ID to display the test reports for the patient on screen.

■ Press the USB  icon to export and save the selected data to USB.

■ Press the print  icon when the report is displayed on screen to print the report.



4.1.2 Browsing Test Results (Browse)

■ Select the **"RECALL"** function in the **HOME** screen.

■ In the **RECALL** screen, press the **"Browse"** icon to display all reports.

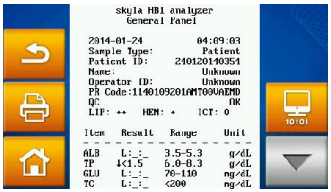
■ Enter the administrator password.

■ All reports will be sorted by patient ID. Please use the up  and down  arrows to search for the desired report.

■ Select a patient ID to display the test reports.

■ Press the USB  icon to export and download data to USB. This option also provides the capability to back up all data.

■ Press the **printer** icon when the report is displayed on screen to print the report.



4.1.3 Searching for System Quality Control Test Records (Controls)

■ Select the **"RECALL"** function in the **HOME** screen.

■ In the **RECALL** screen, select **"Search"** to see the search function on screen.

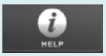
■ Enter the administrator password.

■ Press the **"Controls"** icon to access the quality control test records stored by test dates on screen.

The quality control test results will be permanently retained in the **skyla**™ Clinical Chemistry Analyzer. Quality control test results obtained from use of the **"Controls"** function option will also be stored separately from sample test results. Results may be printed immediately after system quality control is complete. The **RECALL** function can also be used to search and print historical data. Please contact **skyla**™ authorized technical support personnel or distributors for consultations on detailed information regarding quality control testing.

Note:

1. Quality control testing must be performed under the **Controls** function in the Clinical Chemistry Analyzer. Please refer to section 3.9 on system quality control.
2. **"Browse"** in the **RECALL** menu can be utilized to export all data and records saved in the system to USB via text file format.

 Access "**HELP**" information

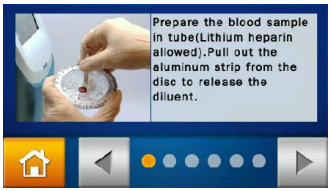
Press the on-line help icon to browse operational information of the system.

4.2 Help Information

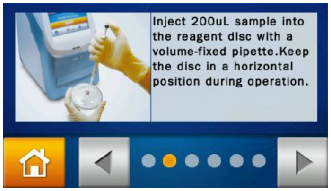
The **skyla**™ Clinical Chemistry Analyzer provides a user interface that is easy to understand and simple to operate. No prior training is required. The system is also equipped with a **"HELP"** function which aids users in understanding all of the system functions.

■ Select the **"HELP"**  icon to refer to the quick guide of the **skyla**™ Clinical Chemistry Analyzer. The important operational information is as follows:

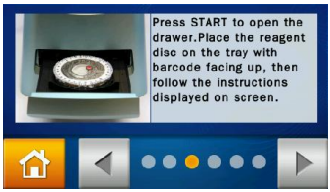
1. Prepare the sample in a tube. Remove the foil strip from the disc for releasing the sample diluent.



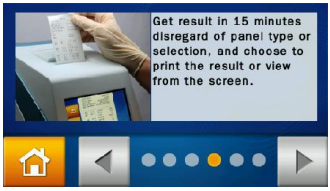
2. Collect 200 µL of the sample and dispense it into the reagent disc with a micropipette. Keep the disc in a flat position.



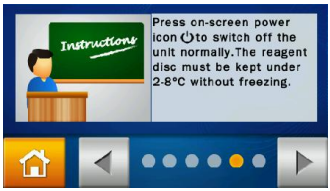
3. Press the **"START"** icon to open the disc drawer. Gently place the reagent disc in the tray with the barcode facing up. Follow the instructions on screen to start the test.



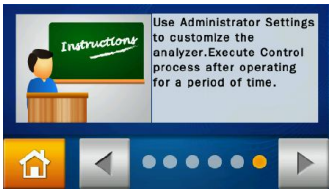
4. All test items on the reagent disc will be completed and report printable results in 15 minutes.



5. Press on-screen power icon to switch off the unit normally. Sealed reagent discs should be stored at temperatures of 2~8°C.



6. Use the **Administrator Settings** to customize **skyla™** Clinical Chemistry Analyzer functions for different needs. Execute quality control processes periodically to ensure test reliability of the clinical chemistry analyzer.



Main Menu option:

Settings

- Settings
- Version
- Printer
- Brightness
- eGFR
- Control
- Custom Report
- Administrator Settings

Note:
The clinical chemistry analyzer only supports few types of external printer model. Please contact **skyla**™ authorized technicians or distributors for more information about supported external printers.

Section 5: System Settings

The **skyla**™ Clinical Chemistry analyzer provides the user with a variety of customization functions to optimize the system operations of the system.

5.1 System Settings

In the main menu, press the "Settings" icon to view the Version, Printer, Brightness, eGFR value calculation function, Control, Custom Report and Administrator Settings options.

5.1.1 System Version

Version contains the system version and system installation date of the **skyla**™ Clinical Chemistry Analyzer.

- Under Setting, press the "Version" icon to access the version information.

5.1.2 Printer Selection

Press the **Printer** icon to select the internal or external printer.

- In the **Setting** screen, press the **"Printer"** icon.
- In the **Printer Setting** screen, select whether to print the results via **"Internal"** or **"External"** printer.

5.1.3 Screen Brightness Adjustment

■ In the **Setting** screen, press **"Brightness"** icon to adjust the brightness of the touchscreen.

■ Use the - / + buttons to adjust the brightness level. There are four possible levels of brightness for the touchscreen.

5.1.4 eGFR value

■ **eGFR** is a calculation value, and therefore, it is generally not included as an essential item in test reports. The operator may launch the **eGFR** calculation function in order for the clinical chemical analyzer system to calculate the **eGFR** value.

■ **skyla**™ clinical chemical analyzer uses Simplified MDRD formula to calculate the eGFR value. The formula is as follows:

eGFR = 186 * Scr-1.154 * Age-0.203 * 0.742

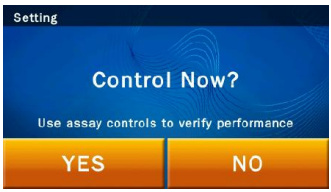
(if female) * 1.212 (if African)

In addition, if the tested patient is African by race, multiply the eGFR data by 1.212.

■ In the Setting option, click the **eGFR** setting **ON**. Before test, the operator should enter the information required by the system according to the prompt screen in order for the eGFR value to be calculated.

5.1.5 Control (Performing Quality Control)

- In the Setting screen, press the **"Control"** icon to enable assay controls.
- Assay control test results will be permanently retained by the system in a separate database from the sample test results.



Note:

The Control function of the clinical chemistry analyzer must be tested in appropriate intervals using traceable external assay samples to guarantee the reliability of routine test results. Please see Chapter 3.9 for more details on Control.

5.1.6 Custom Report

- In the Setting screen, press the **"Custom Report"** icon to enable displaying/hiding of selected test items.

Note:

Only when Custom Report is enabled under Settings will the clinical chemistry analyzer prompt the user to use the custom report layout during testing.

- When the user enters the patient ID, a pop-up window will ask if the user wishes to create a Custom Report or not.

■ If the answer is “NO”, the standard report will be shown after testing. All of the test results from that reagent disc will be shown in the report. If the answer is "Yes", the system will only show the selected content in the custom report.

■ The system will display the analytes on the reagent disc for the user to choose from. The items selected for display in the report will be highlighted in a yellow frame.

■ Next, press the **“OK”** icon to confirm the selection.

5.2 Administrator Settings

Administrator settings options:

- Screen
- Calibration
- Date & Time
- Ref. Range
- Marker Unit
- Backup Records
- System Upgrade

The **skyla**™ Clinical Chemistry Analyzer provides the user with a variety of customization functions to optimize the system operations. On the Home screen, press the **“SETTINGS”** icon then press ***“Administrator Settings.”*** Entering the correct password allows the user to browse the Administrator Settings which allow the user to customize or change the system defaults or enable/show/stop various functions, including: Screen Calibration, Date & Time, Ref. Range, Marker Unit, Backup Records, System Upgrade, Password, System Default, Operator Control, Operator List, Operator Creation, RS232 Baud Rate, Demo Mode, QC Report, Buzzer, Hospital Name, Patient Name, Languages,

- Password
- System Default
- Operator Control
- Operator List
- Operator Creation
- RS232 Baud Rate
- Demo Mode
- QC Report
- Buzzer
- Hospital Name
- Patient Name
- Languages
- Automatic Printing
- Save Log to USB
- Export Database
- Import Database
- Error Log

Automatic Printing, Save Log to USB, Export & Import Database, and Error Log.

In the **Home** screen, press **"SETTINGS"** to browse the system settings. Next, press the **"Administrator Settings"** icon to browse the administrator settings options.

The system will prompt the user to enter the administrator password.

Once the correct password is entered, **Setting** will be shown at the top of the touchscreen. This indicates that the system is now in Administrator Setting mode. There are two Administrator Setting pages. Please use the up  and down  buttons to change pages.

Administrator Settings menu page 1

Note:
Pressing the **Home** icon at any time will return to the home page (top level).

Administrator Settings menu page 2

Administrator Settings menu page 3

5.2.1 Screen Calibration

If the touchscreen is responding incorrectly or poorly to selections, use **Screen Calibration** to adjust it.

The screen calibration procedures are as follows:

- Under **Administrator Settings**, select **"Screen Calibration**."
- The calibration process consists of selecting the cross symbols on screen one by one. You must select the symbols five times (at each of the 4 corners and in the center) to finish the calibration process. You will return to the **Setting** screen once calibration is complete.

5.2.2 Date & Time

Please adjust the system to the local time before testing.

- Under Administrator Settings, select “Date & Time”.
- When the **Date & Time** menu appears, select the edit box (Date, Month, Year, Hour, Minute, Format) and use the up and down arrow keys to adjust the Date & Time.
- There are three options for Date format: Y/M/D, D/M/Y, and M/D/Y.
- Select **“OK”** to save the changed settings.

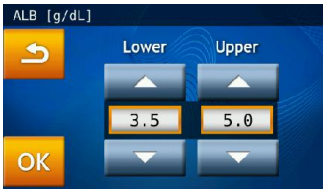
5.2.3 Reference Range

The administrator can change the reference range set by the factory. The administrator can also re-define and adjust the reference range if necessary. Custom reference range can also be cancelled.

- Under **Administrator Settings**, select the **“Ref. Range”** and inspect the analyte list.
- View the analyte list: If the analyte list covers 2 pages, use the Up and down arrow keys to change page. Select any item from the menu and the next step will be shown on screen for the administrator to edit.

■ The procedure for changing the reference range of an analyte is as follows:

1. Use the up  and down  arrow keys to increase or decrease the reference range shown. Select "**OK"** to save the changes.



2. To cancel the changes and return to the old settings, please press the Return  icon.
3. The administrator can also directly select the value to change. The new value can then be entered using the keypad.

4. If the reference values vary due to gender, select gender first before changing the setting values.

5. Press the  icon to return to the previous step or **Home**.

5.2.4 Marker Unit

The system also allows the administrator to select the unit for each analyte. Before testing, the output unit for each analyte can be selected from the menu.

■ Under **Administrator Settings** (see page 5-5), select the **"Marker Unit"** icon.

■ The administrator can set the unit for one analyte with "Single Analyte" or set the unit for "All Analytes."

■ **All Analytes**：

Set **All Analytes Units** to SI Unit or Common Unit.

Choose Common Unit (default) or SI Unit.

Select "**OK"** to save the changed settings.

To cancel the changes and return to the old settings, please press the Return icon.

■ **Single Analyte**：

To set the unit of measurement for a single analyte, please press the "**Single Analyte"** icon at the **Set Unit** page. This will bring up the analyte list.

1. Please select any item from the list.

2. Please select the desired unit.

3. Select **"OK"** to save the changed settings.

5.2.5 Backup Records

Backup the test results of the chemistry analyzer to an USB drive.

- Under Administrator Settings, select the "Backup Records" icon.
- Insert the USB drive into the USB port at the back of the chemistry analyzer then select **"Yes"** to output data.

Note:
USB driver for Backup Records does not support the NTFS format. Please format USB drive to FAT16 or FAT32.

5.2.6 System Upgrade

The authorized technical support department will periodically inform the updated system version. The current system version of the chemistry analyzer can be checked through the Version function. Please contact the authorized technical support unit for information about new versions.

Note:
Please contact **skyla™** authorized technical support personnel or distributors for information about new versions.

Warning:
The clinical chemistry analyzer must remain powered on throughout the system upgrade process.

Note:
We recommend having a **skyla™** authorized technician assist with the clinical chemistry analyzer system upgrades. If the system upgrade software was not correctly installed, the error message "*No Softwarw Found!*" will be shown on screen.

The System Upgrade procedures are as follows:

- Go online (URL: www.skyla.com) and download the system upgrade software. Copy the system upgrade software or system parameter file to the USB drive, then insert the USB drive into the USB port at the back of the chemistry analyzer.
- Under **Administrator Settings** (see page 5-4), select the "**System Upgrade"** icon then select "**YES"** to start system upgrade.
- Once the system software has been updated, the chemistry analyzer will automatically reboot. The chemistry analyzer will not reboot if it is only a system parameter update and the user can continue to use the system normally.

5.2.7 Password Change

A system password should be set when the analyzer is started for the first time. We recommend entering an easy-to-remember password.

The change password procedures are as follows:

- Under **Administrator Settings** (see page 5-4), select the "**Password"** icon.
- Please use the keypad to enter a new password. The system will ask you to re-enter the new password for confirmation. When it's done, select "**OK"** to save the changed setting.

■ If the administrator presses **"OK"** button without entering any numbers in both **"New Password" & "Confirmation"** boxes, the password will no longer be required by the system.

5.2.8 System Default

The **skyla**™ Clinical Chemistry Analyzer comes loaded with default starting values, ref. ranges and units. The above settings can be customized by the administrator if necessary.

If the administrator wishes to restore the custom settings to their default values, select the **"System Default"** icon under **Administrator Settings**. This will reset the system to its original factory settings. All custom settings such as ref. range and units will be restored to their default factory settings as well. However patient test results and control test results will NOT be deleted and will be retained in the system.

Warning:
Once the "**System Default**" function is launched, the system will delete all the customized setting options and ref. ranges. Once this command is executed, the deleted data cannot be restored. Hence, the user should regularly back up saved data (such as outputting all information to USB and then execute System Default). However, all test results of patients and quality control records will not be deleted.

5.2.9 Operator Control

The clinical chemical analyzer provides an operator control function. It also shows the operator ID on the printed report, which is helpful for quality control of the test operation on the clinical chemical analyzer.

■ On the selection screen of **Administrator Settings** (Page 2), click the **"Operator Control"** icon.

■ After setting **Operator Control "ON"**, click **"OK"** to complete the setting change.

When the **Operator Control** setting is **ON**, before the clinical chemical analyzer proceeds to **START**, the system will require the operator to enter the Operator ID before the test starts, and the Operator ID will be stored in the system database.

5.2.10 Operator List

The system manager may check, manage, and delete the operator from the Operator List through the Operator List function.

■ On the Administrator Settings (Page 2) selection screen, click the "Operator List" icon.

■ Use the page up/page down keys to browse the Operator List.

■ After clicking the **Operator ID**, click the Trash  icon and select **"YES"** to complete the deletion.

5.2.11 Operator Creation

The system manager can create an Operator ID through the Operator Creation function.

■ On the Administrator Settings (Page 2) selection screen, click the “Operator Creation” icon.

■ After entering the new **Operator ID**, click **“OK”** to confirm the creation.

■ Use the Operator List function to view the Operator ID created.

5.2.12 RS232 Baud Rate Setting

Changing the RS232 baud rate allows the transfer rate to be optimized. The options for RS232 Baud Rate are 4800, 9600, 19200, 38400, 57600 and 115200.

■ Under **Administrator Settings** (see page 5-5), select the **“RS232 Baud Rate”** icon.

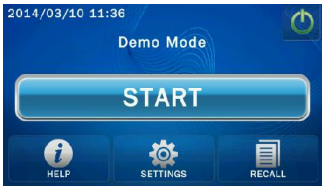
■ Select the baud rate required for connecting to an external instrument or device then select “**OK”** to save the changed settings.

5.2.13 Demo Mode

The **skyla**™ Clinical Chemistry Analyzer has a built-in demo mode that provides a complete simulated testing environment for education and training. The built-in demo mode includes a set of known test results and is stored under the patient ID "demo" in the chemistry analyzer.

■ Under **Administrator Settings** (see page 5-5), select the "**Demo Mode"** icon.
■ Set **Demo Mode** to "**ON"** then select **"OK"** to save the changed settings.

Demo Mode has the following functions:
■ Commercial marketing display
■ Education and training for new operators or administrators
■ Once the **Demo Mode** is enabled, the text **"Demo Mode"** will be shown on the **START** and **Analyzing...** screens as a reminder.



5.2.14 QC Report

The system administrator can use the **QC Report** function to show the QC results in the report file.
■ Under the **Administrator Settings** menu (see page 5-5), select the "**QC Report"** icon to enter the menu.
■ To print the QC results, please set **QC Result Report** to "**ON"** then select **"OK"** to save the changed settings.

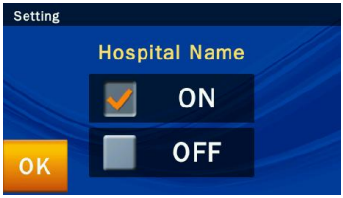
5.2.15 Buzzer

The **skyla**™ Clinical Chemistry Analyzer has a built-in buzzer function that can alert users that the test has been completed, or an error occurred. The administrator can decide whether to enable this function based on the need under the use environment. There are four preset volume levels: Off, High, Medium, and Low.

5.2.16 Hospital Name

If the administrator turns on this feature in the Hospital Name menu, the header will appear when the test report is printed out.

- In the Options screen of the administrator's dedicated system function Administrator Settings (page 2), click the icon "Hospital Name."



Click "ON" to turn on the option.

Enter the name of the hospital and press "OK" to save.

5.2.17 Patient Name

If the manager turns on this function in the Patient Name menu, the input frame will appear on screen during testing, and it will appear at the top of the table when printing test reports.

5.2.18 Language

The **skyla**™ Clinical Chemistry Analyzer provides the user interface in six languages: Deutsch, Espanol, Italiano, English, Francais, and Simplified Chinese. The administrator can click "OK" to select according to the need, and the system can automatically switch.

5.2.19 Automatic Printing

If you turn on the automatic printing option, after the completion of tests, the **skyla**™ Clinical Chemistry Analyzer will automatically print the test report.

5.2.20 Save Log to USB

When there is any error, please use this function to save system log to a USB drive and provide the log file to authorized technical support department.

■Under Administrator Settings, select the "Save Log to USB" icon.

■Insert the USB drive (with FAT 16/32 format) into the USB port at the back of the chemistry analyzer, wait for seconds for device recognize it, then select **"Yes"** to output data.

5.2.21 & 22 Export Databse & Import Databse

This is merely for technical service during the replacement of device malfunction.

■Use "Export Database" to extract the whole user database from existing device.

■Use "Import Database" to reload the whole user database to the new replaced device.

5.2.23 Error Log

When there is any error, user can use this function to recall previous error code log (5 events at most) and contact authorized technical support department for initial troubleshooting.

■Under Administrator Settings, select the "Error Log" to recall the error logs data.

Troubleshooting:

- ■ Power and Function
- ■ Settings and Reports
- ■ Data Export
- ■ Password Setting

Section 6: Troubleshooting & Error Handling

Operation of the **skyla™** Clinical Chemistry Analyzer is simple and almost fully automated. When a user error occurs during operation, the system automatically displays an error message. Most issues which users will encounter can be easily resolved by following the simple steps in the system's suggestions.

6.1 Troubleshooting

The troubleshooting recommendations contained in this section are solutions (S) to resolve common conditions (C) users encounter in a few simple steps.

■ Analyzer Power and Function

C: Touchscreen is black or blue; power light is OFF.

S: Turn the analyzer power off. Check the power cable connections. Disconnect and reconnect on both ends, then turn the power on.

C: Touchscreen is blue or blank; power light is ON.

S: Remove the reagent disc from the drawer. Check that the drawer closes properly, then re-boot the analyzer.

C: Damaged touchscreen

S: Please contact the authorized distributor or technical support department of LITE-ON Technology Corp..

■ Settings and Reports

C: There are no values for some of the results within a printed test report, or the system automatically cancels a reagent disc test without generating a report.

S: The **skyla**™ Clinical Chemistry Analyzer performs automatic system calibrations to maintain high system precision. Thus, when the Analyzer detects a faulty reagent disc, it automatically cancels the test and displays an operational error message. Please insert a new reagent disc to resume operations.

C: The test report exported by the built-in thermal printer is blank.

S: The thermal paper roll may have been installed in the wrong direction within the built-in thermal printer. Please remove the roll of thermal paper and confirm that the heat-sensitive side is facing the correct direction (the arrow sticker on the roll should point downwards) before replacing the roll in the built-in thermal printer.

C: After choosing to initiate the "System Default*"* function, previously customized reference range settings have disappeared.

S: Once the "System Default" function is initiated, the system will delete all custom settings and reference ranges. Once the command is executed, all settings will be reset to the default system settings. The settings that have been deleted cannot be recovered. However, none of the patient test results and calibration records will be deleted.

Warning: Once the *System Default* function is initiated, all custom settings and reference ranges will be irreversibly deleted.

■ Exporting data from the system to other devices

C: Peripheral and media of the exported data.

S: "Dump to USB" function: will export selected historical data to an external USB drive.

"RS232 Export" function: will export selected historical data to an RS232 station.

C: How many options are available for exporting data?

S: Data can be exported in two ways: to a USB drive (Dump to USB), and export through RS232.

■ Password setting

C: Solution for a lost password.

S: Please input universal password 5787722 or contact the authorized distributor or technical support department.

Content of error messages:

- ■ Booting up
- ■ Printing
- ■ Abnormal drawer operation
- ■ Testing and analysis
- ■ Settings
- ■ Recall

6.2 Error Messages & Handling

The **skyla™** Clinical Chemistry Analyzer can display built-in error messages and recommendations to aid users during operation.

Stage	Error Message	Error Handling
Booting up	Password Error	Please enter the correct password.
	Device Abnormal (Error Code1~20, 30, 51~56)	Please reboot the anaylzer. If the error code cannot be resolved, please contact the authorized technical support department.
	Date & Time Error	Please enter the correct date and time.
	Internal Memory Error	Please contact the authorized technical support department.
	Assay Parameter Error	Please restart the device. If the error code cannot be resolved, please contact an authorized technical support.
Printing	Internal Printer Error	Please contact the authorized technical support department.
	No External Printer Found	Please check that the external printer is correctly connected and whether the printer is an analyzer compatible model.
	No Paper	Check if the thermal paper roll in the built-in thermal printer is properly installed, or add a new roll of thermal paper.
Abnormal drawer operation	Drawer Jam	Please remove any objects that prevent the drawer from closing properly. Contact the authorized technical support department if the issue is not resolved.
Testing and analysis	Internal Memory Full	Please contact the authorized technical support department.
	Empty	Please insert a reagent disc.
	Invalid ID	Please enter the correct Operator ID.
	Unrecognized Disc Bar Code (Error Code 101~104)	The reagent disc barcode cannot be recognized. Please insert a new reagent disc.
	Unauthorized Disc (Error Code 105, 106)	This is an unauthorized reagent disc. Please contact the authorized technical support department.
	Disc Expired (Error Code 107)	The reagent disc is expired. Please insert a new reagent disc.

Stage	Error Message	Error Handling
	Assay Parameter Version Mismatch (Error Code 108)	Please contact the authorized technical support department to get the latest version of firmware or assay parameter.
	Used Disc (Error Code 201)	Please remove the used reagent disc and insert a new reagent disc.
	Insufficient Sample (Error Code 204, 213)	The sample volume is insufficient. Please insert a new reagent disc and make sure to inject 200μL of sample.
	Disc Error (Error Code 202, 203, 211, 212,323,355,841,842,843)	Please insert a new reagent disc.
	Device Abnormal (Error Code 1~20, 30, 60~62, 3XX, 800, 801, 802)	Please remove the reagent disc, reboot the anaylzer, and insert a new regent disc. If the situation is not resolved, please contact the authorized technical support department.
Settings	Password Error	Please enter the correct password.
	Date & Time Error	Please enter the correct date and time.
	USB Drive Error (Error Code 411)	Please check that the USB drive is properly plugged into the device. Please check whether the USB drive space is full. If the situation is not resolved, please contact the authorized technical support department.
	No Software Found	There is no Software update file found within the USB drive. Please contact the authorized technical support department for this firmware.
	Upgrade Failure (Error Code 950, 951, 953, 959)	Please contact the authorized technical support department.
	Assay Parameter Upgrade Failure (Error Code 950, 953)	Please contact the authorized technical support department.
	Internal Memory Full	Please contact the authorized technical support department.
	Invalid ID	Please enter the correct Operator ID.

Stage	Error Message	Error Handling
	No Data Matched	There is no Operator ID. Please create Operator ID.
	ID Existed	The Operator ID existed. Please create another Operator ID.
Recall	No Data Matched	There is no historical data within the system. Please conduct a sample analysis first in order to accumulate analysis results within the database.
	RS232 communication failure (Error Code 401)	Please check that the RS232 cable is correctly connected. If the situation is not resolved, please contact the authorized technical support department.
	Test result preparation failure (Error Code 402)	Please contact the authorized technical support department.

If the information and troubleshooting steps provided by the system do not resolve your issue, please record the error message and call a **skyla™** authorized technical support technician or authorized distributor. **skyla™** contact information is as follows:

Telephone: +886-3-611-8511

Fax: +886-3-579-5393

E-mail: support@skyla.com

Website:www.skyla.com

Note: The system parts of the chemistry analyzer require professional handling. Please do not attempt to disassemble or repair the chemistry analyzer by yourself, as this will void the warranty. When the chemistry analyzer requires service, please contact a **skyla™** technical support technician (or authorized distributor).

Appendix I: RS232 Communication Protocol Specifications

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2. COMMUNICATION PROTOCOL AND MESSAGE FORMAT...A-3

2.1 COMMUNICATION PROCEDURES.....A-3

2.2 MESSAGE BODY FORMAT DEFINITION A-4

1. INTRODUCTION

This RS232 Communication Protocol Specification describes the communication format & protocol information for data exchanges between the **skyla**^{TM} Clinical Chemistry Analyzer and external computer (e.g., PC) through the RS232 interface. The baud rate of RS232 data transmissions can be set to 4800, 9600, 19200, 38400, 57600 and 115200 bps and the configuration is N-8-1. (N: no parity, 8: eight data bits, 1: one stop bit). Please operate the **skyla**^{TM} Clinical Chemistry Analyzer's GUI to set the baud rate.

2. COMMUNICATION PROTOCOL AND MESSAGE FORMAT

Section 2.1 describes the communication procedures between the **skyla™** Clinical Chemistry Analyzer and an external computer. Section 2.2 includes detailed information of message bodies sent to the external device.

2.1 COMMUNICATION PROCEDURES

Below are some commands which will be used during communication procedures.

Command (One Byte)	Description
0x01	Connect command. This is a command for creating connections. This command will only be sent out via the HB1 Clinical Chemistry Analyzer side.
0x04	Close command. This is a command for closing connections. This command will only be sent out via the HB1 Clinical Chemistry Analyzer side.
0x06	Acknowledge command. This is a confirmation command that the external computer responds with when it receives commands issued from the HB1 Clinical Chemistry Analyzer to indicate that there is no problem in reception.
0x15	Negative Acknowledge command. This is a negative confirmation command that the external computer responds with when it receives connection or close commands issued from the HB1 Clinical Chemistry Analyzer to indicate that there are issues.

The communication procedures are listed below:

(1) The **skyla™** Clinical Chemistry Analyzer sends the connect command to the external computer. Upon receiving the connect command, the external computer must respond with the acknowledge command. The **skyla™** Clinical Chemistry Analyzer waits one second for the external computer to respond with the acknowledge command. If the external computer does not respond with the acknowledge command, the **skyla™** Clinical Chemistry Analyzer will send the connect command to the external computer again. If the **skyla™** Clinical Chemistry Analyzer still does not receive the acknowledge command from the external computer, the **skyla™** Clinical Chemistry Analyzer will report an error message if the Export to RS232 function was triggered manually from the Recall function. Test results will also be exported to RS232 after analysis completion. In this case, no error message is exported.

(2) The external computer must respond to the acknowledge command.

(3) The **skyla**^{TM} Clinical Chemistry Analyzer sends the message body to the external computer.
(4) The **skyla**^{TM} Clinical Chemistry Analyzer sends the Close Command to external computer.
(5) The external computer must respond with the acknowledge command. The **skyla**^{TM} Clinical Chemistry Analyzer waits one second for the external computer to respond with the acknowledge command. If the external computer does not respond with the acknowledge command, the **skyla**^{TM} Clinical Chemistry Analyzer will send the Close command to the external computer. After timeout, the anaylzer system will go to step (3). But it only retries one time. If the **skyla**^{TM} Clinical Chemistry Analyzer still does not receive the Acknowledge command from the external computer, the **skyla**^{TM} Clinical Chemistry Analyzer will report an error message if the **Export to RS232** function was triggered manually from the **RECALL** function. Test results will also be exported to RS232 after analysis completion. In this case, no error message is exported.

2.2 MESSAGE BODY FORMAT DEFINITION

The messages below will be sent to the external computer in sequence. The contents of empty location are 0x20. Each message is ended by CR: 0x0D and LF: 0x0A.

(1) Model Name

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
M	o	d	e	l		N	a	m	e						X	X	X	X	X	X	X	X	X					CR	LF

Byte 16 to 24: Model name. The output is “Skyla HB1.”

(2) Panel Name

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
P	a	n	e	l		N	a	m	e						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47												
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF												

Byte 16 to 45: Panel Name. E.g. General Biochemistry Panel, Metabolic Panel, Basic Biochemistry Panel, or Liver Panel.

(3) Hospital Name

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
H	o	s	p	i	t	a	l		N	a	m	e			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

31	32	33	34	35	36	37																						
X	X	X	X	X	CR	LF																						

Byte 16 to 35: Hospital Name.

(4) FW Version

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
F	W		V	e	r	s	i	o	n						X	X	X	X	X	X	X	X	X					CR	LF

Byte 16 to 19: Firmware version.

Byte 20 to 24: Assay Parameter version.

(5) Date & Time

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Y	Y	Y	Y	-	M	M	-	D	D						H	H	:	M	M	:	S	S						CR	LF

(6) Sample Type

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
S	a	m	p	l	e		T	y	p	e					X	X	X	X	X	X	X							CR	LF

Byte 16 to 22: Sample Type. There are two types of sample. One is “Patient,” one is “Control”.

(7) Patient ID

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
P	a	t	i	e	n	t	I	D							X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 28: Patient ID.

(8) Patient Name

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
P	a	t	i	e	n	t		N	a	m	e				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

31	32	33	34	35	36	37																							
X	X	X	X	X	CR	LF																							

Bytes 16 to 35: Patient Name.

(9) Gender

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
G	e	n	d	e	r										X	X	X	X	X	X	X							CR	LF

Byte 16 to 22: There are three types of Gender; Male, Female or Unknown.

(10) Age

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
A	g	e													X	X	X	X	X	X	X							CR	LF

Byte 16 to 22: Byte 16 to 18 indicates age, Byte 21 to 22 indicates "Yr". If there is no age information, the value of Byte 16 to 22 will be “Unknown”.

(11) Operator ID

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
O	p	e	r	a	t	o	r		I	D					X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 28: Output Operator ID. “Unknown” will be output if no Operator ID is available.

(12) Production Code

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
P	R		C	o	d	e									X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF

Bytes 16 to 28: PR Code.

(13)Quality control 1 to Quality control 7 (QC1 to QC7)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	1													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 1 (QC1) value.
Byte 21 to 28: Quality control 1 (QC1) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	2													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 2 (QC2) value.
Byte 21 to 28: Quality control 2 (QC2) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	3													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 3 (QC3) value.
Byte 21 to 28: Quality control 3 (QC3) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	4													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 4 (QC4) value.
Byte 21 to 28: Quality control 4 (QC4) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	5													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 5 (QC5) value.
Byte 21 to 28: Quality control 5 (QC5) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	6													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 6 (QC6) value.
Byte 21 to 28: Quality control 6 (QC6) standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Q	C	7													X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Quality control 7 (QC7) value.
Byte 21 to 28: Quality control 7 (QC7) standard range.

(14) LED Quality control (QC)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	3	4	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 340nm value.
Byte 21 to 28: Wavelength 340nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	4	0	5	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 405nm value.
Byte 21 to 28: Wavelength 405nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	4	5	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 450nm value.
Byte 21 to 28: Wavelength 450nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	5	1	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 510nm value.
Byte 21 to 28: Wavelength 510nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	5	4	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 540nm value.
Byte 21 to 28: Wavelength 540nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	6	0	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 600nm value.
Byte 21 to 28: Wavelength 600nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	6	5	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 650nm value.
Byte 21 to 28: Wavelength 650nm standard range.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	9	4	0	n	m										X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Wavelength 940nm value.
Byte 21 to 28: Wavelength 940nm standard range.

(15) System quality control (System QC)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
S	y	s	t	e	m		Q	C							X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: System quality control (System QC) value.
Byte 21 to 28: System quality control (System QC) standard range.

(16) Chemistry quality control (Chemistry QC)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
C	h	e	m	i	s	t	r	y		Q	C				X	X	X			X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 18: Chemistry quality control (Chemistry QC) value.
Byte 21 to 28: Chemistry quality control (Chemistry QC) standard range.

(17) LIP, HEM and ICT indication

First send LIP, HEM and ICT indications (0, +, ++ or +++), then send LIP, HEM and ICT indication values.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
L	I	P		X	X	X				H	E	M		X	X	X				I	C	T		X	X	X		CR	LF

Byte 5 to 7: LIP indications are +, ++ or +++, if there are no issues, Byte 5 will have the value of 0.
Byte 15 to 17: HEM indications are +, ++ or +++, if there are no issues, Byte 15 will have the value of 0.
Byte 25 to 27: ICT indications are +, ++ or +++, if there are no issues, Byte 25 will have the value of 0.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30

L	I	P		X	X	X				H	E	M		X	X	X				I	C	T		X	X	X		CR	LF

Byte 5 to 7: LIP indication value.
Byte 15 to 17: HEM indication value.
Byte 25 to 27: ICT indication value.

(18) Total test result item number

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
T	o	t	a	l		N	u	m	b	e	r				X	X												CR	LF

Byte 16 to 17: Total test result item number.

(19) Test Result

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
X	X	X	X	X	X	X	X	X	X		Y	Y	Z	Z	Z	Z	Z	Z	Z		A	A	A	A	A	A	A

29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53
A	A	A	A	A	A	A		B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	CR	LF

Byte 1 to 10: Marker name, if the first character is "#", this indicates that this marker is a calculated value.
Byte 12: Abnormal mark

Blank byte (0x20） - The analysis result is within the reference range.
l (0x6C) - The analysis result is lower than the reference range.
h (0x68) - The analysis result is higher than the reference range.

Byte 13: Abnormal mark

Blank byte (0x20） - The analysis result is within the dynamic range.
< (0x3C） - The analysis result is less than the lower limit of the dynamic range.

> (0x3E） - The analysis result is greater than the upper limit of the dynamic range.

Byte 14 to 20: Normally filled with the analysis result. If Byte 13 is <, it is below the lower limit of dynamic range. If Byte 13 is >, it is above the upper limit of dynamic range. If “N.A.” is displayed, the analysis result cannot be calculated. If test results are influenced by more than 20% due to LIP, HEM, or ICT, L: _: _, _: H: _, _: _: I, L: H: _, L: _: I, _: H: I, or L: H: I will be displayed. L indicates LIP interference, H indicates HEM interference, and I indicates ICT interference.

Byte 22 to 35: Reference range.
Byte 37 to 51: Unit symbol.

Note: If males and females are distinguished for the normal value range, (19) will be output twice. However, only “Bytes 22-35: Reference range” and “Bytes 37-51: Unit symbols” will be output the second time, while the rest of the byte contents will be left blank.

(20) is as described in (19), but the times sent are “Total item number - 1” times.

Appendix II: Backup Records Data Export Specifications

The **skyla**^{TM} Clinical Chemistry Analyzer provides export of analysis results to a USB drive connected via the USB port. The file is named as DumpToUSB_yyyymmddhhmmss.csv.
(i.e., DumpToUSB_20121107152039.csv)
Sample export is listed below, with each field separated by a comma.

Example of analysis results:

29032012144130, Liver panel, 2013/3/11, 14:41:30, Patient, 5586245, John, 120101000, 1234, Male, 40 Year, 103, min.90, 98,min.90, 101,min.90, 109,min.90, 95,min.90, 131, min.90, 99, 90-110, 103, 90-110, 98, 90-110, 101, 90-110, 109, 90-110, 95, 90-110, 99, 90-110, 101, 90-110, 98, 90-110, 100, min.90, 123, min.90, 0, ++, +, 50, 25, 30, ALB, 5, 4.5, 7.5, 4.5, 7.5, g/dL, 1

Definition of each field:

Field number	Example	Definition
1	29032012144130	Index code: The serial number of this data within the test result database
2	Liver panel	Panel name: E.g. “General”, “Metabolic”, “Basic”, “Liver” or “ER”. If panel name is unknown, “Unknown” will be output.
3	2013/3/11	Date.
4	14:41:30	Time.
5	Patient	Sample type: There are two types of sample, one is clinical samples (“Patient”), and the other is quality control calibration (“Control”).
6	5586245	Patient ID.
7	John	Patient Name.
8	120101000	Serial Number.
9	1234	Operator ID: If the Operator ID function is activated, the column will output the Operator ID. If the Operator ID function is deactivated, “Unknown” will be output.

10	Male	Gender: There are three types of Gender: Male, Female or Unknown.
11	40 Year	Age.
12	103	Quality control 1(QC1) value.
13	min.90	Quality control 1(QC1) standard range.
14	98	Quality control 2(QC2) value.
15	min.90	Quality control 2(QC2) standard range.
16	101	Quality control 3(QC3) value.
17	min.90	Quality control 3(QC3) standard range.
18	109	Quality control 4(QC4) value.
19	min.90	Quality control 4(QC4) standard range.
20	95	Quality control 5(QC5) value.
21	min.90	Quality control 5(QC5) standard range.
22	131	Quality control 6(QC6) value.
23	min.90	Quality control 6(QC6) standard range.
24	99	Quality control 7(QC7) value.
25	90-110	Quality control 7(QC7) standard range.
26	103	Wavelength 340nm value.
27	90-110	Wavelength 340nm standard range.
28	98	Wavelength 405nm value.
29	90-110	Wavelength 405nm standard range.
30	101	Wavelength 450nm value.
31	90-110	Wavelength 450nm standard range.
32	109	Wavelength 510nm value.
33	90-110	Wavelength 510nm standard range.
34	95	Wavelength 540nm value.
35	90-110	Wavelength 540nm standard range.
36	99	Wavelength 600nm value.
37	90-110	Wavelength 600nm standard range.

38	101	Wavelength 650nm value.
39	90-110	Wavelength 650nm standard range.
40	98	Wavelength 940nm value.
41	90-110	Wavelength 940nm standard range.
42	100	System quality control (System QC) value.
43	min.90	System quality control (System QC) minimum acceptable value.
44	123	Chemistry quality control (Chemistry QC) value.
45	min.90	Chemistry quality control (Chemistry QC) minimum acceptable value.
46	0	LIP indication: LIP indications are 0, +, ++ or +++. 0 represents no interference, +, ++, +++ represents degrees of seriousness.
47	++	HEM indication: HEM indications are 0, +, ++ or +++. 0 represents no interference, +, ++, +++ represents degrees of seriousness.
48	+	ICT indication: ICT indications are 0, +, ++ or +++. 0 represents no interference, +, ++, +++ represents degrees of seriousness.
49	50	LIP indication value.
50	25	HEM indication value.
51	30	ICT indication value.
52	ALB	Marker name: If the first character is “#”, this indicates that this marker is calculated from other markers.
53	5	Analysis result. If this cannot be calculated, “N.A.” will be exported.
54	4.5	Lower limit of male normal reference range.
55	7.5	Upper limit of male normal reference range.
56	4.5	Lower limit of female normal reference range.
57	7.5	Upper limit of female normal reference range.
58	g/dL	Analysis result unit.
59	1	0: Close custom field export. 1: Open custom field export.