skyla™ VB1
Veterinary Clinical Chemistry Analyzer

Operator's Manual (Rev.1A)

For Veterinary In-Vitro Diagnostic Use Only

Manual Text, Rev. 1A

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skyla™ VB1 Veterinary Clinical Chemistry Analyzer

skyla™VB1 Reagent Discs (Reagent discs must be stored at temperatures between 2 to 8°C)

Section 1: General Information

1.1 Overview

The **skyla™ VB1** Veterinary Clinical Chemistry Analyzer, together with its exclusive VB1 reagent disc series, offers a quick, easy and accurate method to measure various biochemical markers in whole blood, plasma, or serum.

CAUTION：If the **skyla™ VB1** Veterinary 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™ VB1** Veterinary Clinical Chemistry Analyzer may not function as intended and may be hazardous.

Note: The **skyla™ VB1**Veterinary Clinical Chemistry Analyzershould should only be used with **skyla™ VB1** 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™ VB1** Veterinary Clinical Chemistry Analyzer provides clinical testing laboratories of medical

facilities and veterinary 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™ VB1** Veterinary 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.

1.4 Technical Support

skyla™ technical support personnel (or authorized agents) are available to assist users regarding the operation of the **skyla™ VB1** Veterinary Clinical Chemistry Analyzer.

Warning: Please do not attempt to disassemble or repair the skyla™ VB1 Veterinary Clinical Chemistry Analyzer by yourself. This will void the warranty.

1.5 Consumables and Supplies

To order consumable supplies or additional accessories, please contact skyla™ customer service or authorized distributors.

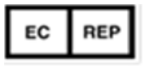
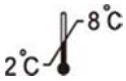
1.6 Understand the Symbols

The definitions of symbols found on the **skyla™ VB1** Veterinary Clinical Chemistry Analyzer and its peripherals are as follows:

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)
- RS232 to USB connection cord package for external device connection (optional)

Section 2: Setup and Quick Start

2.1 Pre-installation Check

1. Remove the **skyla™ VB1** Veterinary 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	Pipette tips	
6	Operator'smanual	
7	Quick guide of operation	
8	Quick guide of error code	
9	Warranty card	

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

3. After the successful setup, fill in the warranty card and mail or email it to skyla™ manufacturer LITE-ON IT Corp. Hsinchu Science Park Branch for receiving periodic mail or email regarding software upgrades and VB1 Veterinary Clinical Chemistry Analyzer product information.

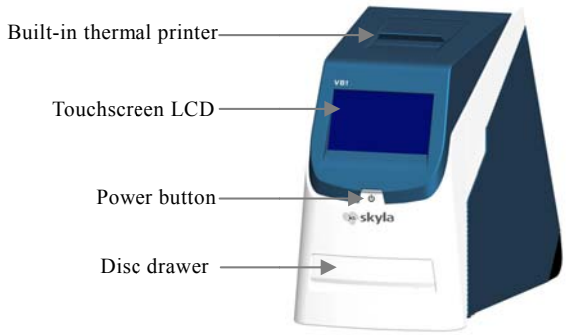
2.2 Specifications and Installation Characteristics

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 Overvoltages:	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:	200μL ±10μL
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™ VB1** Veterinary Clinical Chemistry Analyzer.

- **Exterior function diagram**



- **Installation Location**

Place the skyla™ VB1 Veterinary 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 VB1 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 skyla™ authorized technical support personnel.

- Icons for touchscreen interface:

Page Up, Increase

Page Down, Decrease

Page Back/Next

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

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.

- Input the password or patient ID using the keypad on the 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 the touchscreen to navigate between pages.
- All clinical chemistry analyzer functions are operated via various icons on the touchscreen, as well as specific keys that appear on the screen.
- Press the back key on the touchscreen to cancel a choice and return to the previous step, or to move backward through a series of screens/items.

38 Selection is being updated

Show numerical keypad

On-Line help explanation

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

- Press OK OK to confirm the step.
- Press HOME to return to the top layer (Home).
- Press Print to print the test results shown on the 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 the 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.
- Internal means an option has been activated.
- Internal means an option has not been activated.
- ALT means an analyte has been selected for display in the Custom Report function.
- 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.

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

2.5 Power-On and Initialization

● **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).

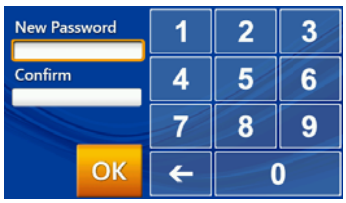
● **Built-in Self-test:**
System self-test and precision calibration.

● **Initialization:**
The first time the clinical chemistry analyzer is turned on, you will be prompted to set the "Password" and "Date & Time" on screen.

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

● **Initialization**

The first time the clinical chemistry analyzer is turned on, once the warm up and system self-test are complete, the clinical chemistry analyzer will prompt to set a password on the screen. Please input a numerical password and 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.

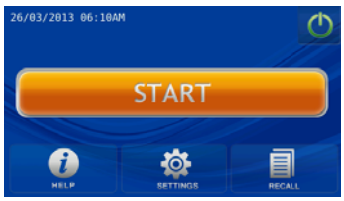
Once the system password setting is complete, the **"Date & Time"** setup screen will appear. Please select the date edit box and use the up and down arrow keys to adjust to the correct date. Press the "**OK"** icon to save the changes on the system.

● **Power-Off:**
Press the power icon on the screen and press “YES” to confirm power-off.
Press the Power button down for 5 seconds to force the analyzer to shut down.

■ **Home (Top Level) Menu**

When the warm-up and system self-tests are complete, and input of the correct password is confirmed, the **“START”** icon will appear on screen for sample analysis. 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 the 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 (refer to section 5.2.4 & 5.2.5 for details). 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**

Please turn off the clinical chemistry analyzer if it will not be used for a prolonged period. Press the power icon on the screen, and press “YES” to confirm power-off. Alternatively press the power button on the front of the analyzer for 5 seconds to force the analyzer to shut down.

Sample Conditions:
- Use serum or lithium-heparinized whole-blood or plasma samples.
- 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.

Section 3: Sample Analysis

3.1 Sample Preparation

The compatible sample types for the skyla™ VB1 Veterinary Clinical Chemistry Analyzer include: serum, lithium-heparinized whole blood or plasma.

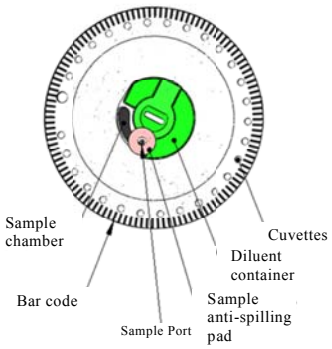
- The amount of sample required for one panel test is 200µL.
- Once the whole-blood sample is collected, testing must be conducted within 60 minutes (at room temperature) in order to prevent cellulose precipitation in the blood.
- To prevent hemolysis of the sample, do not refrigerate, freeze, or shake 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 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.

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

(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 (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).

Reagent disc



3.2 Functions ofReagent Disc

All the chemical reactions that take place in the **skyla**^{TM}**VB1** Veterinary 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.

Note: Do not reintroduce the sample into the reagent disc once it is removed from the reagent disc.

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 ℉) 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℉).

● 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

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.

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

- Use a new pipette tip for each sample.
- Attach a new tip to the end of the 200 µL pipette. Do not touch the tip.
- Use your thumb to push down the plunger at the top of the pipette to the first (1st stop) position; 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 to the lowest (2nd stop) position in a slow, continuous motion 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.
- Hold the reagent disc by its edges and keep it level; gently place it into the analyzer's disc drawer.

- 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.

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

- Close the analyzer's disc drawer and begin the analysis. Please refer to section **3.5 Performing a Test** for detailed information.

Notes:

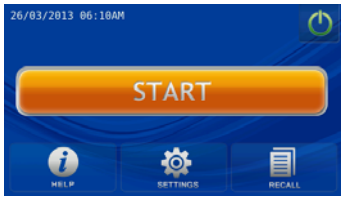
1. Wear powder-free gloves while handling reagent discs or operating the analyzer to avoid powder affecting the analyzer's optical measurement components.
2. Perform the test within 10 minutes after dispensing the sample into the reagent disc.

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.
- Select the species to use the relevant reference ranges.
- If you enable the Report Heading Option, the system will prompt you to enter gender and weight.
- The system will begin the analysis. “Analyzing…” will be displayed on the screen.

3.5 Performing a Test

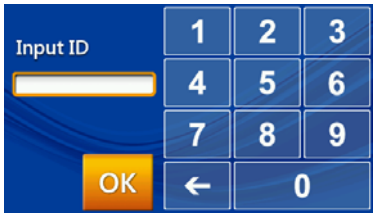
When the **skyla**^{TM}**VB1** Veterinary Clinical Chemistry Analyzer is turned on and the touchscreen displays the function options, it is ready to perform the test sequence.



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

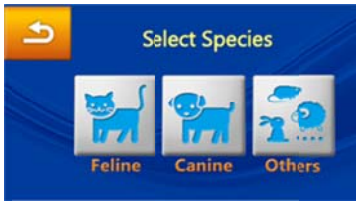
- Use the touchscreen to enter the patient ID (up to 12 numbers) or scan the patient ID using the optional external barcode scanner and press **OK**.



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.

Note:
The system will automatically perform the test sequence when the drawer contains a reagent disc and is closed.

- Select the species (feline, canine, and others).



Select species

- If you enable the **Report Heading Option**, the system will prompt you to enter **Gender** and/or **Weight** and/or **Age**. Press **OK** when you finish.

Select gender

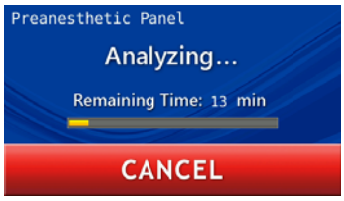
Enter weight

Enter age

The information you entered will appear on the test report heading.

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

- The fully automated analysis sequence will commence once the disc drawer is closed.



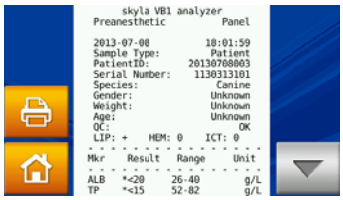
When the analysis is completed, the system will store the analysis results and display them on the touchscreen. To cancel a test in progress, simply press the **CANCEL** icon on the touchscreen. The system will prompt you to confirm and then stop the analysis.

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

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.

reagent disc.

- To perform another test, simply insert a new reagent disc into the drawer.

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.

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

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, patient ID, reagent disc serial number, species, gender and weight. The results section consists of four columns: test marker, analyte concentration, reference range and unit. The test report also shows the degree of ipemia (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 outside the reference 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.
- (%%)：Result is significantly impacted by the interference of LIP, HEM or ICT of the sample that is outside the permissible range by 20% or more.

- LIP: Lipemia
  HEM: Hemolysis
  ICT: Icterus
  Severity:
  “0” (Clear)
  “+” (Mild)
  “++” (Moderate)
  “+++” (Severe)

- N.A.: Indicates that the result cannot be calculated for the test marker.

Table1: Test report generated when the QC Report function is not used

```
        skyla  VB1 analyzer
  Diagnosis                 Panel

  2013-03-08              17:05:07
  Sample Type :            Patient
  Patient ID :        123456789012
  Serial Number:      1234567890
  Species:          User Defined 2
  Gender:                  Unknown
  Weight:                   123 Kg
  Age:                     16 Year
  QC:                           OK
  LIP: +++   HEM: ++   ICT: 0
 - - - - - -  - - - - - - - - - -
 Result severely impacted by LIP
 Result severely impacted by HEM
 %% signals over tolerance limit
 - - - - - -  - - - - - - - - - -
 Mkr    Result   Range      Unit
 - - - - - -  - - - - - - - - - -
 ALB      4.12    3.5-5.0     U/L
 GLU      80      70-100      mg/dL
 BUN  %%  23.0    10-27       mg/dL
 CREA %%<0.2      <1.3        mg/dL
 Ca     *  12.1   2.1-2.6     umol/L
 Cl       103.1   98-106      umol/L
#GLOB   *  12.12  2.3-3.5     g/dL
#A/G       1.2   1.0-1.8
```

3.7.1 Symbols Used in Test Reports

- (#): Calculated value.
- (*): Test result is outside the reference range.
- (%%)：The test results are significantly impacted by the interference of LIP, HEM or ICT of the sample that is outside the permissible range by 20% or more.
- 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 70–600 mg/dL. If the analyte glucose concentration is less than this range, “<70 mg/dL” will be shown; if it is greater than this range, “>600 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)
- Not applicable (N.A.): Indicates that the result cannot be calculated for the marker.

Symbols Used in Analysis 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 VB1 analyzer
  Diagnosis                Panel

  2013-03-08            17:05:07
  Sample Type:           Patient
  Patient ID:      123456789012
  Serial Number:     1234567890
  Species:                Feline
  Gender:                 Female
  Weight:                  12 Lb
  Age:                   16 Year
 - - - - - - - - - - - - - - - -
  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: ++    ICT: 0
SCORE: 321      : 345      : 011
 - - - - - - - - - - - - - - - -
 Result severely impacted by LIP
 Result severely impacted by ICT
 %% signals over tolerance limit
 - - - - - - - - - - - - - - - -
 Mkr     Result   Range      Unit
- - - - - - - - - - - - - - - - --
 ALB      4.12   3.5-5.0       U/L
 TP    %% 12.12  6.8-8.7       U/L
 GLU      80     70-100      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.

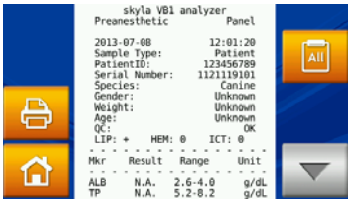
- L650nm: This QC item indicates the linear stability of the instrument's sixth optical channel. Normal score is within the range 90–110.
- L540nm: This QC item indicates the linear stability of the instrument's seventh optical channel. Normal score is within the range 90–110.
- L940nm: This QC item 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 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.

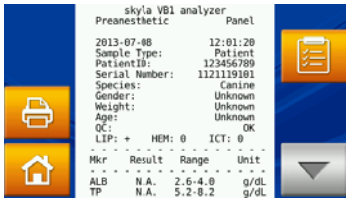
The custom report will be displayed after the completion of the analysis. Only those selected test markers will be shown.



Custom report

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

icon on the touchscreen.



Standardreport

Press the or icons on the screen to switch between custom report and standard report.

3.9 Performing Quality Control

Performing Quality Control:

- Perform a quality control test on a regular basis.
- Perform a quality control test if you have doubts regarding analysis results.
- Perform a quality control test if there is a significant change to the laboratory environment.

Quality control tests should be performed on a regular basis in order to ensure the reliability of the **skyla™VB1** Veterinary Clinical Chemistry Analyzer. Quality control can be regularly performed using commercially available controls supplied by manufacturers that ensure a stable 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.

Note: Contact authorized skyla™ technical support personnel or agents to inquire about commercially available controls.

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

Any **skyla™ VB1** 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: If you have any questions about the selection of reagent discs, please contact authorized skyla™ technical support personnel or agents.

3.9.3 Performinga 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 3.1 '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 200 μL of the control into the reagent disc via the sample port.
- 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. 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'.

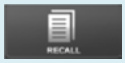
3.9.4 Quality Control Test Results

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

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**™ **VB1**Veterinary 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.

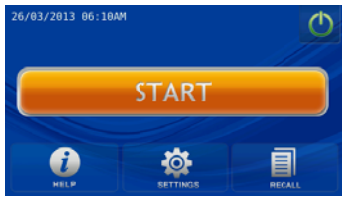
- Recall the historical report information stored in the clinical chemistry analyzer.



Recall historical information

Section 4: Review of Historical Data & Operation Information

When the Home screen appears on the **skyla™ VB1** Veterinary 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™ VB1** Veterinary 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 5.2.6 "Dump to USB Drive" for detailed information on exporting test results to USB.

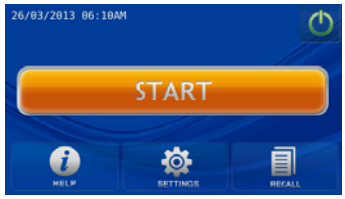
In the **Home** screen, press the **"RECALL"**

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.

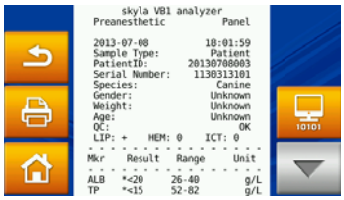
To search for results by “Date”:

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

- When the change date/time option is displayed on the 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.

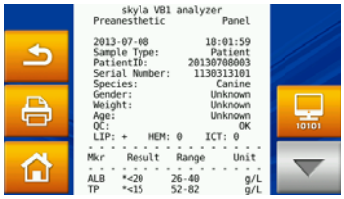


To search for results by “**Patient ID**”:

- 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 records which meet the search parameters will be displayed on screen in sequence of test date.

- 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.

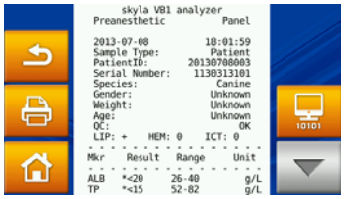


4.1.2 Browsing Test Results (Browse)

- 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 **print** 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 the screen.

The quality control test results will be permanently retained in the **skyla™ VB1** Veterinary 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 **skyla™ VB1** Veterinary 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.

4.2 Help Information

Access "**HELP**" information

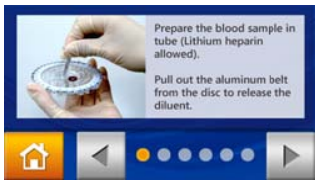
Press the on-line help icon to browse operational information of the system.

The **skyla™ VB1**Veterinary 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"**

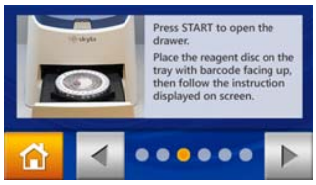
icon to refer to the quick guide of the clinical chemistry analyzer. The important operational information is as follows:

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 the screen to start the test.



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

5. If the power button is pressed continually for more than 5 seconds, the system will turn the power off and cease operations. Sealed reagent discs should be stored at temperatures of 2~8°C.

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

■ If you see a ? icon during system operations, press to get on-line help on function explanations.

Section 5: System Settings

The **skyla™ VB1 Veterinary Chemistry analyzer** provides the user with a variety of customization functions to optimize the system operations of the system.

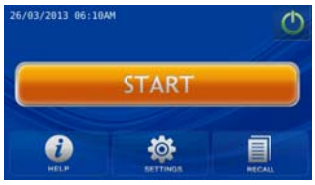
Main Menu option:

Settings

Settings

- Version
- Printer
- Brightness
- Header Option
- Control
- Custom Report
- Administrator Settings

5.1 System Settings



In the main menu, press the "Settings" icon to view the Version, Printer, Brightness, Header Option, Control, Custom Report and Administrator Settings options.

5.1.1 System Version

Version contains the system version and system installation date of the **skyla™ VB1** Veterinary Chemistry Analyzer.

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

5.1.2 Printer Selection

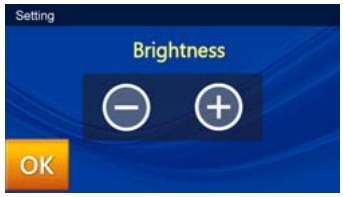
Press the **Printer** icon to select the internal or external printer.

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

Note: The chemistry analyzer only supports the following external printer model:
HP Officejet4610/ HP LaserJet M1132
If you have any other support requirements or questions, please contact skyla™ authorized technicians or distributors for more information about supported external printers.

5.1.3 Screen Brightness Adjustment

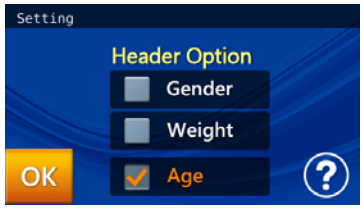
- In the Setting screen, press **"Brightness"** icon to adjust the brightness of the touchscreen.



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

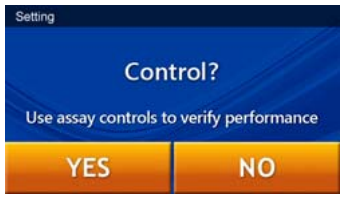
5.1.4 Header Option Selection

- In the Setting screen, press the **"Header Option"** icon to enter patient information such as gender, weight and age
- Once the gender, weight and age options (ON by default) are enabled, the chemistry analyzer will prompt the user to enter the required information at the Start screen. The information provided here does not affect the analysis results and is only used for the report heading.



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 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 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.

- Administrator settings

  Administrator setting options:
- Screen Calibration
- Date & Time
- Pathology Comment
- Ref. Range
- Marker Unit
- Dump to USB
- System Upgrade
- Password
- System Default
- RS232 Baud Rate
- Demo Mode

5.2 Administrator Settings:

The **skyla™VB1 Veterinary Chemistry Analyzer** provides the user with a variety of customization functions to optimize the system operations. In 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, Pathology Comment, Ref. Range, Marker Unit, Dump to USB, System Upgrade, Password, System Default, RS232 Baud Rate, Demo Mode, QC Trport and Buzzer.

.

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

Administrator Settings menu page 2

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

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 the 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) and use the up and down arrow keys to adjust the Date & Time.
- Select "AM/PM".
- Select "OK" to save the changed settings.

Note: If the entered time is invalid, the system will show an error message. Re-enter a valid time then select **OK**.

5.2.3 Pathology Comment

This function is currently not supported on this model.

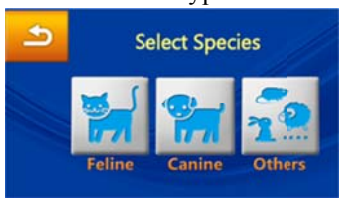
5.2.4 Reference Range

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. First, select the animal type.



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

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

4. The administrator can also directly select the value to change. The new value can then be entered using the keypad.

5. Press the icon to return to the previous step.

Note: The unit used for each reference range item is automatically converted by the chemistry analyzer to the selected analyte.

5.2.5 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 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.

5.2.6 Dump to USB

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

- Under Administrator Settings (see page-5-5), select the "Dump to USB" icon.
- Insert the USB drive into the USB port at the back of the chemistry analyzer then select "**Yes**" to output data.
- When the icon is shown on screen, the Dump to USB function can be used.

Note: Dump to USB does not support the NTFS format. Please format USB drive to FAT16 or FAT32.

5.2.7 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. Contact an authorized **skyla™** technical support unit for information about new versions.

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 5-5), 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.

Note:
Contact an authorized **skyla™** technical support unit for information about new versions.

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

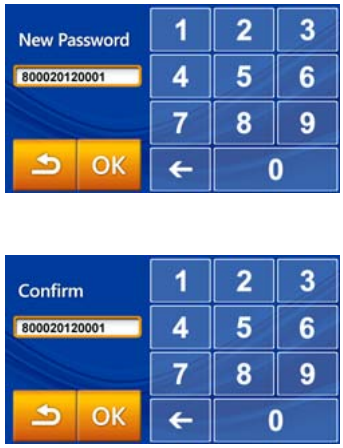
Note: We recommend having an authorized technician assist with **skyla™ VB1 Veterinary Chemistry Analyzer** system upgrades. If the system upgrade software was not correctly installed, the error message "No Firmware Found!" will be shown on screen.

5.2.8 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 5-5), 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.

5.2.9 System Default

The **skyla™ VB1** Veterinary 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 animal test results and control test results will NOT be deleted and will be retained in the system.

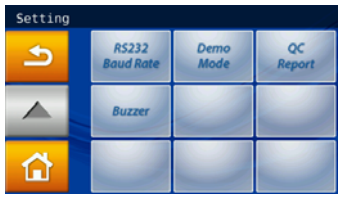
Warning:
Selecting “System Default” will result in the system deleting all custom settings and ref. ranges. The deleted data will not be restorable.
Animal test results and control results will not be deleted.

Note: The System Default function will delete all custom settings permanently.

5.2.10 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.



Administrator Settings menu page 2

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

5.2.11 Demo Mode

The **skyla**™ **VB1** Veterinary Chemistry Analyzer has a built-in demo mode that provides a complete simulated testing environment for education and training. In this mode, any reagent disc (even a used or invalid disc) can be placed inside the analyzer without any samples for practicing all essential touch screen controls. The virtual testing process is also accelerated so that it is completed within 2 minutes. 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.

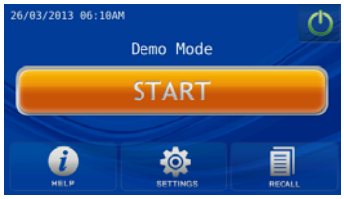
■ Set **Demo Mode** to "**ON**" then select "**OK**" to save the changed settings.

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.



Note: Any changes made to other system settings under "**SETTINGS**" in **Demo Mode** will **still remain valid.** In other words, switching from Demo Mode back to normal mode will keep all the changes made under "**SETTINGS**".

5.2.12 QC Report

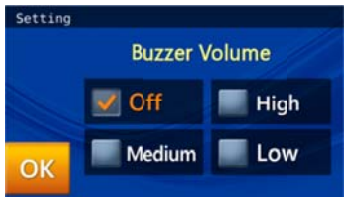
The system administrator can use the **QC Report** function to show the QC results in the report file.

■ 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.

5.2.13 Buzzer

The **skyla™ VB1** Veterinary 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.



Troubleshooting:

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

Section 6: Troubleshooting & Error Handling

Operation of the **skyla™ VB1**Veterinary Clinical Chemistry Analyzer is simple and almost fully automated. When a user error occurs during operation, the system automatically displays an error message, acting as a useful operation guide. 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.

■ 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™ VB1**Veterinary 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 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™ VB1** Veterinary 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.
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.
	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.
	Assay Parameter Version Mismatch (Error Code 108)	Please contact the authorized technical support department to get the latest version of firmware or assay parameter.

Stage	Error Message	Error Handling
	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 200 µL 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 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 Firmware Found	There is no firmware update file found within the USB drive. Please contact the authorized technical support department for this firmware.
	Upgrade Failed (Error Code 951, 953)	Please contact the authorized technical support department.
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, 402)	Please check that the RS232 cable is correctly connected. If the situation is not resolved, 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™ VB1** Veterinary 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™ VB1** Veterinary Chemistry Analyzer's GUI to set the baud rate. This document provides the base-line requirements that firmware/software engineers should fulfill when developing programs.

2. COMMUNICATION PROTOCOL AND MESSAGE FORMAT

Section 2.1 describes the communication procedures between the **skyla™ VB1** Veterinary 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 VB1 Veterinary Chemistry Analyzer side.
0x04	Close command. This is a command for closing connections. This command will only be sent out via the VB1 Veterinary Chemistry Analyzer side.
0x06	Acknowledge command. This is a confirmation command that the external computer responds with when it receives commands issued from the VB1 Veterinary 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 VB1 Veterinary Chemistry Analyzer to indicate that there are issues.

The communication procedures are listed below:

(1) The **skyla™ VB1** Veterinary 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™ VB1** Veterinary 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™ VB1** Veterinary Chemistry Analyzer will send the connect command to the external computer again. If the **skyla™ VB1** Veterinary Chemistry Analyzer still does not receive the acknowledge command from the external computer, the **skyla™ VB1** Veterinary 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™ VB1** Veterinary Chemistry Analyzer sends the message body to the external computer.

(4) The **skyla™ VB1** Veterinary Chemistry Analyzer sends the cClose cCommand to external computer.
The external computer must respond with the acknowledge command. The **skyla™ VB1** Veterinary 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™ VB1** Veterinary 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™ VB1** Veterinary Chemistry Analyzer still does not receive the Acknowledge command from the external computer, the **skyla™ VB1** Veterinary 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.

(1) 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	CR	LF

Byte 16 to 28: Panel Name. There are four types of panel. “Preanesthetic”, “Renal”, “Diagnosis” or “Liver”. If panel name is unknown, “Unknown” will be output.

(2) 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

(3) 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: SampleType. There are two types of sample. One is “Patient,” one is “Control”.

(4) 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.

(5) Serial 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
S	e	r	i	a	l		N	u	m	b	e	r			X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 28: Serial number.

(6) Species

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	p	e	c	i	e	s									X	X	X	X	X	X	X	X	X	X	X	X	X	CR	LF

Byte 16 to 28:
There are five types of species: Canine, Feline, User Defined 1, User Defined 2, or User Defined 3.

(7) 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.

(8) Weight

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
W	e	i	g	h	t										X	X	X	X	X	X	X							CR	LF

Byte 16 to 22: Byte 16 to 18 indicates weight, Byte 21 to 22 indicates weight unit. Weight unit can be indicated in either kilograms (Kg.) or pounds (Lb.). If there is no weight information, the value of Byte 16 to 22 will be “Unknown”.

(9) 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	X	X	X				CR	LF

Byte 16 to 25: Byte 16 to 18 indicates age, Byte 21 to 24 indicates age unit. Age unit can be indicated in either "Year" or “Month”. If there is no age information, the value of Byte 16 to 22 will be “Unknown”.

(10)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.

(11) 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.

(12) 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.

(13) 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.

(14) 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.

(15) 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.

(16) 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.
* (0x2A） - The analysis result is outside the reference range.
%(0x25) – There are LIP, HEM or ICT interference for analysis result.

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.

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

(17) is as described in (16), but the times sent are “Total item number - 1” times.

Appendix II: Dump to USB Data Export Specifications

The **skyla™ VB1** Veterinary 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, 120101000, Canine,Female, 20 Kg, 5 Month, 103, min.90, 98, min.90, 101, min.90, 109, min.90, 95, min.90, 131, min.90, 99, 90-110, 102, 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, 0.5, 3.5, 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: There are four types of panel. "Preanesthetic", "Renal", "Diagnosis" or "Liver" 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	120101000	Serial Number.
8	Canine	Species: There are five types of species: Canine, Feline, User Defined 1, User Defined 2, or User Defined 3.
9	Female	Gender: There are three types of Gender: Male,

		Female or Unknown.
10	20 Kg	Weight and Weight unit: Weight unit can be indicated in either kilograms (Kg.) or pounds (Lb.). If there is no weight information, the value will be “Unknown”.
11	5 Month	Age&Age unit: The unit can be in either "Year" or “Month”. If there is no age information, “Unknown” will be output.
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	0.5	Analysis result. If this cannot be calculated, “N.A.” will be exported.

54	3.5	Lower limit of reference range.
55	5	Upper limit of reference range.
56	g/dL	Analysis result unit.
57	1	0: Close custom field export. 1: Open custom field export.