skyla Solution

Veterinary Biochemical Immunoassay Analyzer

For Veterinary In-Vitro Diagnostic Use Only

Operator's Manual

SKYLA CORPORATION H.S.P.B

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For Veterinary In-Vitro Diagnostic Use Only

Model: VC-P11/21/31/41/51

skyla Corporation Hsinchu Science Park Branch

Manufacturer: skyla Corporation Hsinchu Science Park Branch
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Section 1: General Information

1.1 Overview

The **skyla Solution** Veterinary Biochemical Immunoassay Analyzer (hereinafter as the **Analyzer**), together with its exclusive reagent kits including disc (hereinafter as **Disc**) and cartridge (hereinafter as **Cartridge**), offers a quick, easy and accurate method to measure various biochemical markers in whole blood, plasma, or serum.

CAUTION：

If the **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 **Analyzer** may not function as intended and may be hazardous.

As the use of this **Analyzer** 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 **Cartridge**s 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.

1.2 Accessory Checklist

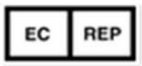
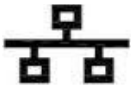
#	Item	#	Item
1	The Analyzer	2	AC Power adapter & power cord
3	Thermal printer paper	4	RS232-to-USB connection cord
5	Pipette tips box	6	Dust Cover
7	Micropipette (220μL) for Panel test	8	Micropipette (50uL) for Single Assay Cartridge test
9	Micropipette (35uL) for Cartridge-E test	10	Metal Carrier for Single Assay Cartridge test
11	Metal Carrier for Cartridge-T test	12	Metal Carrier for Cartridge-E test
13	Pipette holder	14	Two carrier boxes in different color
15	Operator’s Manual	16	Quick Manuals of different Cartridge/Disc operation

1.3 Technical Support

skyla authorized distributor technical service are available to assist users regarding the installation and operation of the **Analyzer**.
Please do not attempt to disassemble or repair the **Analyzer** by yourself.
This will void the warranty if the warranty stickers is broken after disassembled.

1.4 Understand the Symbols

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

	Caution		Serial number
	Manufacturer		Lot number
	Do not reuse		EC authorized representative
	Temperature limits (2-8°C)		Power button
	Use by date		RJ45 LAN network connection
	USB port	**IOIOI**	RS232 serial port
	Direct current		Consult instructions for use
	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.		
	WEEE		

Section 2: Installation and Quick Start

2.1 Analyzer Specifications and Installation Characteristics

Analyzer Dimensions:	490 mm (Height) * 230 mm (Width) * 358 mm (Depth)
Analyzer Weight:	12 kg (26.5 pounds)
Ambient Operating Temperature & Humidity:	Indoor 5 - 35°C (41 - 95°F), <90% relative humidity (non-condensing)
Storage/Transportation Temperature & Humidity:	<65°C(149 °F), <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:	Input 100-240 volts AC/50-60 Hz/1.8~0.9A; Output 12 Volts/ DC 12.5 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, Single Assay Cartridge, SA Dilution Tube (110-940), Cartridge-T, Cartridge-E and Pipette tip
Quality Control:	Self-calibration function/internal QC (quality control) function for each test
Sample Types:	Reagent Disc : Serum or lithium-heparinized whole blood or plasma Single Assay Cartridge : 13x ratio diluted Serum or lithium-heparinized plasma Cartridge-T and Cartridge-E : Serum or lithium-heparinized plasma
Warm-up Time:	About 15 minutes (may exceed this time limit in unique environments)
Touch Panel:	8’ TFT color LCD touchscreen
Printer:	Built-in thermal printer; can be connected to compatible external printers
Communication:	USB 2.0 port: x 5 (for connecting printer, USB drive , scanner and WiFi dongle) RS232 port: x 1 (in Female Connector) RJ45 network port: x 1 PS2 port : x 3 (for engineering use only)
Memory Capacity:	Capacity for up to 50,000 test results

2.2 Description of Reagent Kit

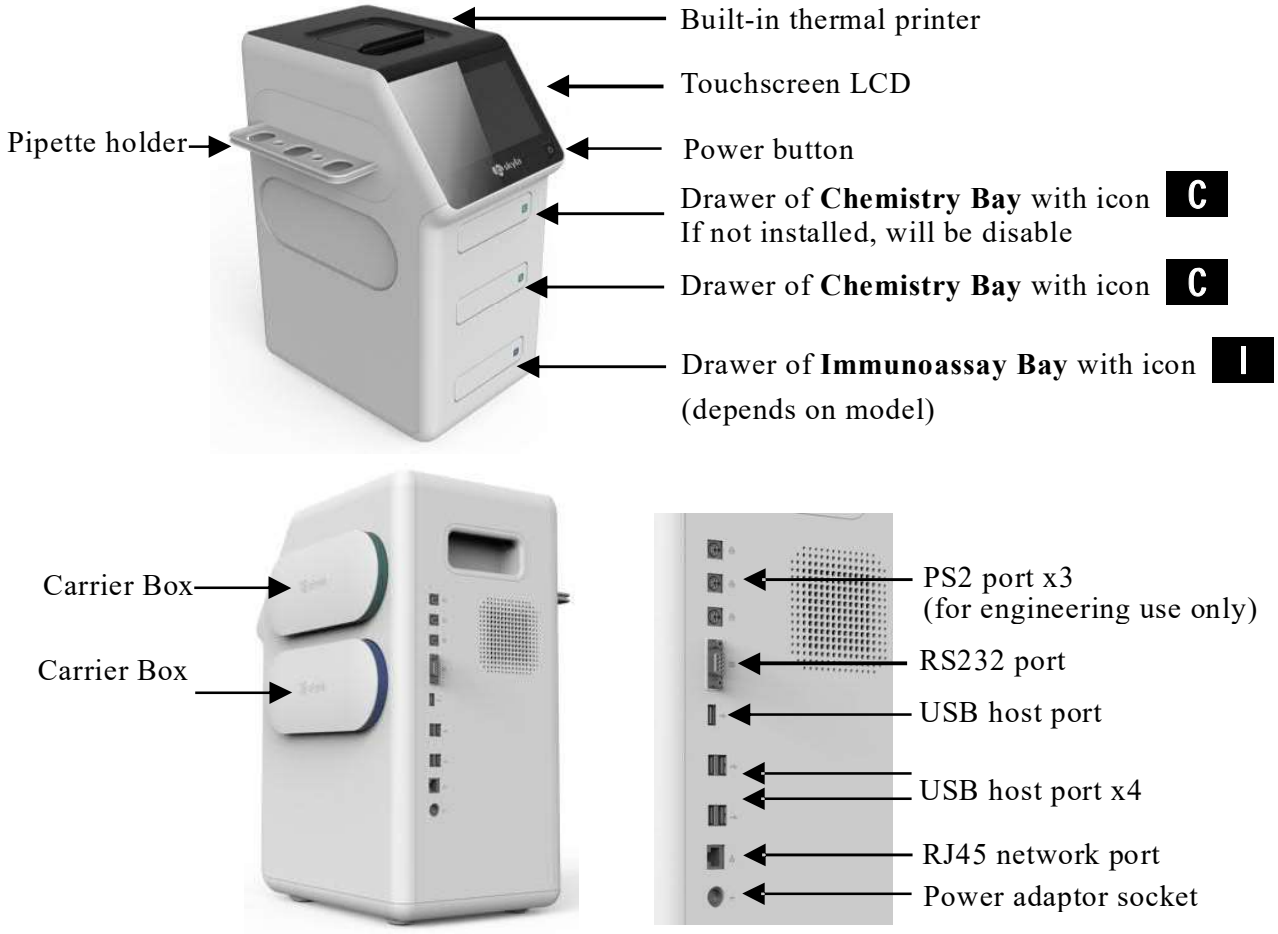
Bay	Reagent Kit		Sample	Test Time
Chemistry	Disc		220µL (190~300µL is acceptable range)	15 minutes (for whole blood sample in a reagent disc) 12 minutes (when the plasma/serum sample type is selected)
	Single Assay Cartridge	 Carrier-SA required	100µL (13x ratio diluted lithium heparin plasma or serum)	12 minutes (please use product code: 110-940 to do 13x ratio dilution)
Immunoassay	Cartridge-T	 Carrier-T required	5~10µL (lithium heparin plasma or serum)	5~8 minutes (refer to each reagent kit package insert)
	Cartridge-E	 Carrier-E required	35µL (lithium heparin plasma or serum)	≦30 minutes (refer to each reagent kit package insert)

Reagent Handling Note :

- Make sure reagent **Disc/Cartridge** is kept at 2~8°C.
- No need to rewarm before use.
- Before use, the unopened reagent **Disc/Cartridge** should not stay at >25°C (77°F) for more than 48 hours.
- Do not expose reagent **Disc/Cartridge** , either in or out of the foil pouches, to direct sunlight or to temperatures above 32°C (89.6℉).
- After opening the pouch, the Disc should be used within 20 minutes.
- Perform the test within 10 minutes after sample injected to the reagent **Disc/Cartridge**.
- This product is for in vitro diagnostic use only
- The product must not be used individually for diagnostic purpose.
- Please wear the gloves when performing the test.
- Do not re-use any part of the test kit.
- Dispose all waste in accordance with applicable national and/or local regulations.

2.3 Installation and Setup

Exterior function diagram



Installation Location

Place the **Analyzer** at the location of :

- On a level surface off the ground and surface free from vibration.
- Clean and free of contaminants, indoors with room temperature 5–35 °C (41–95 °F).
- Away from direct sunlight and other heat sources.
- At least 10 cm 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 drawers.

Power Supply

Connect the **Analyzer** to the grounded electrical AC outlet with supplied AC power adapter and power cord.

NOTE :

The **Analyzer** should not share the same circuit with other high-current devices.

A surge protector is recommended to protect the **Analyzer**.
If necessary, use the UPS or power regulator to prevent unstable AC supply.
Not to position the equipment so that it is difficult to operate the disconnecting **Analyzer**.
Not to replace detachable MAINS supply cords by inadequately RATED cords.

Install Thermal Printer Paper

It can be chosen to use built-in thermal printer or external USB printer connected.
If using built-in thermal printer, open the top cover of it 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 new roll should point downwards).

Connecting an External USB Printer if necessary

If user choose to use an externally USB connected printer instead of the built-in thermal printer, please plug the printer to the **Analyzer**'s USB port at rear panel and switch the system settings to an external printer. Refer to **Section 10.1.6.**

NOTE :
The **Analyzer** can support USB printers with spec of PCL 3GUI, PCL6, PCL 5e.
Contact the authorized technical service to inquire printer models.

Connecting an USB flash drive

Using an USB flash drive, has to be formatted in FAT 16/32. User can:
1. Perform "System Upgrade".
2. Save the troubleshooting log file for technical service. ("Save Log to USB")
3. Export historical results for troubleshooting or backup(csv format, "Backup Records")

Connecting a Personal Computer (PC) via the RS232 Serial Port

Get authorized technical service to help to setup the link with computer.
Use the accessory of RS232-to-USB connection cord to connect the **Analyzer** to the USB port of external personal computer via the RS232 serial port of **Analyzer**.

Connect to LAN Network in hospital (RJ45)

Only available on selected model, if user need to link the **Analyzer** to the laboratory's LAN to a Computer (PC) via RJ45 cable connection, Contact the authorized technical service.

Use skyla LIS software "skyla Data Manager" to manage the test results on PC

It can achieve the test report/task transfer between the Analyzer and the computer once the Analyzer and the computer are well connected and work properly.
Others compatible of ASTM protocol LIS/HIS software connection is achievable.

2.4 Touchscreen Interface

The symbols on the touchscreen of the **Analyzer**.

	Ready for start test (in Light gray color)
	Disable Bay (If not installed)
	Editing (in Blue color)
	Analyzing (in Orange color)
	Report is done (in Green color)
	Bay with error code (in Red color)
	Page Up (Increase)
	Page Down (Decrease)
	Backspace
	Back
	Confirm (Next step)
	Cancel
	Home (Home menu)
	Merge report (Chem+Immuno)

	Print
	Export the test report to PC (if the report is missed to be sent automatically)
	Open Drawer
	Run a Control test
	Import from USB
	Export to USB
	Switch numerical and letter keypad
	Space
	Switch keypad type: Uppercase / Lowercase / Number
	Information
	Help information
	Error
	WiFi signal strength
	Demo mode is turned ON
	Search
	While Custom Report function is ON Show all test items (regular reports)
	While Custom Report function is ON Show Custom Report (selected items)

2.5 Power-On, Initialization, Performing a Test and Power-OFF

Power-On and Built-in Self-tests

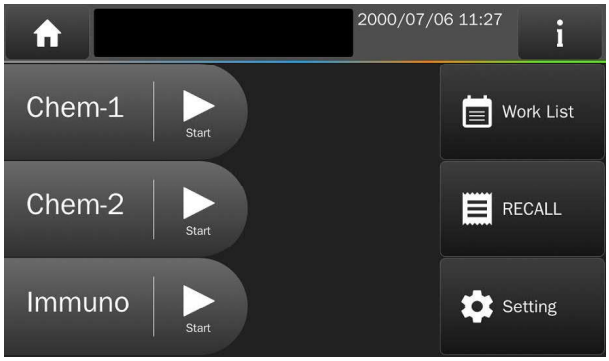
Press power button to turn ON the **Analyzer,** the system will perform the warming procedure to complete system self-test after a period. It takes about 15 minutes for the system to be ready (depending upon room temperature).

Initialization settings

The first time the **Analyzer** is turned on, once the warm up and system self-test are completed, it is required to set up the **Analyzer** configuration of

1. **Language** for operating interface and test report.
2. System Administrator **Password.** (if it is not required, press "OK" directly.)
3. Setup the **"Date & Time".**
4. Set **Unit** System, choose from Common or SI units.

Home (Top Level) Menu



After the initialization settings completed, the available bays for analysis will appear on the left side of screen with **"Start"**  icon.

The screen displayed at this time is referred to as the Home (top level) menu.

User can return to the Home menu from any stage with the Home  icon.

Performing a test

Get Reagent Disc/Cartridge ready with sample (according to **Section 2.2** if required carrier), choose a proper bay, press its **"Start"** icon to launch a test.

The Patient ID and Species must be identified (Edit patient information) before you can open the drawer to place **Disc/Cartridge** on drawer for analysis.

Power-Off

At any menu screen, **pressing the Power Button for 2 seconds** to turn off the **Analyzer.**

NOTE: If the **Analyzer** is no response, it can be forced to shut-down by pressing the power button for **5 seconds.**

It is recommended to turn off the **Analyzer** if it will not be used for a long period.

Section 3: Perform a Chemistry Reagent Disc Test

Bay of Chem

3.1 Functions of Reagent Disc

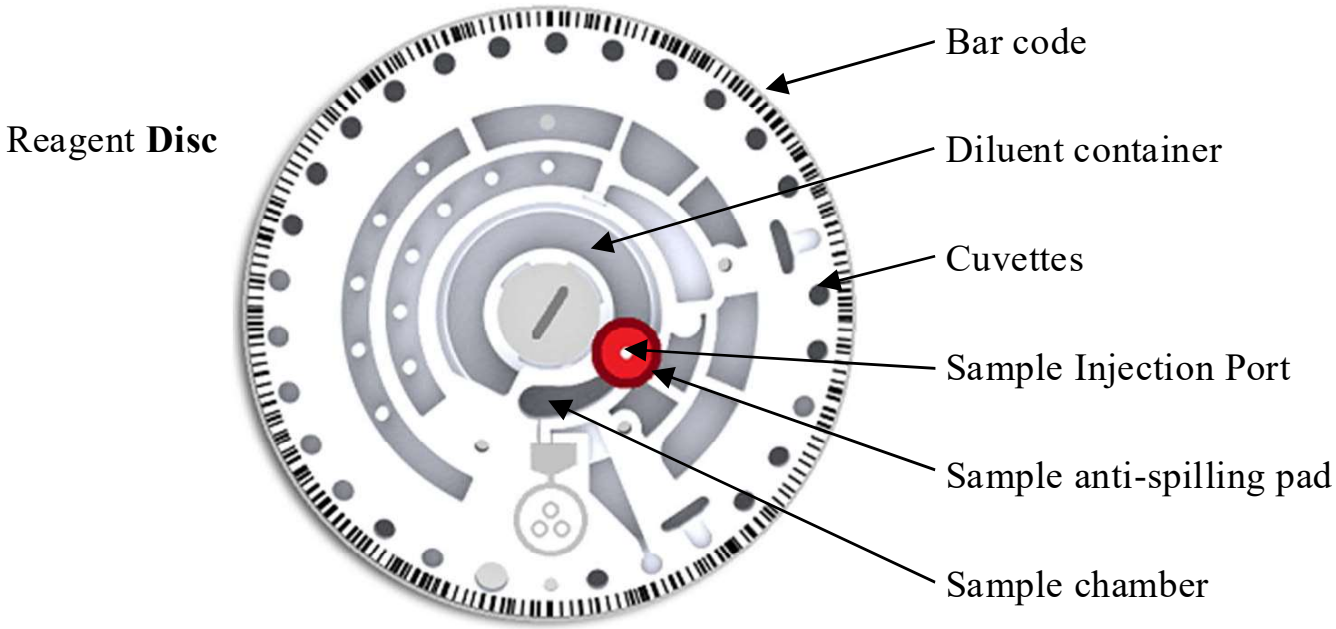
The **Analyzer** will perform the test on the reagent **Disc** with sample automatically including:

- Sample volume check and sample volume quantitate.
- Centrifuge the whole blood to get plasma/serum and do the quantitation.
- Automatic plasma/serum dilution with build-in diluent quantitation.
- Automatic mixing and reaction with all chemicals build-in the **Disc** for analysis.
- Check bar code information of the **Disc** with correct shelf-life and batch version.
- Perform Internal QC upon the **Disc** for

  Sample interference situation of HEM, LIP & ICT to do the necessary compensation.

  Reagent **Disc** contamination and degradation situation.

  Calibrate the optical system to match the performance requirement.



3.2 Sample Preparation

The compatible sample types for reagent **Disc** test include:
Lithium-heparinized whole blood/plasma or serum.

- Using blood lancets of 23G (I.D. ≥ 0.337 mm) or larger gauge is recommended with slow and gentle operating to avoid hemolysis during blood collection.
- Patient Animal must be fasting for 6 hours to avoid severe lipemia sample.
  The amount of sample required for one reagent **Disc** is 200μL. however, to avoid human error of insufficient sample injection, the **Analyzer** accessory is with a 220μL two-step pipette to ensure the sample volume.
- Once the whole-blood sample is collected, testing must be conducted within 2 hours (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 to be plasma or serum using a centrifuge.
- 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.
- Suggest to move the separated plasma/serum to another tube.

NOTE :

- Please adhere to the above recommended sample storage conditions in order to ensure that the test results are without serious errors.
- The blood collection tube used should correspond to the sample type as below table. Colors of the cap might be various due to different countries.

Whole blood	✓ Use **lithium heparin** blood collection tubes (**Green** cap). DO NOT use sodium heparin blood collection tubes. ✓ DO NOT use EDTA blood collection tubes.
Plasma	✓ The sample should fill **more than half of the collection tube** to avoid excessive lithium heparin concentrations in the tube that may adversely affect the accuracy of the test results.
Serum	✓ Use the serum **clot activator** blood collection tube (**Gold** cap).

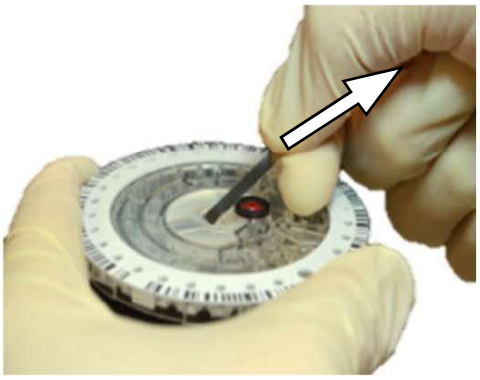
3.3 Preparation Before Reagent Disc Testing

Disc Preparation

1. Please wear powder-free glove to handle the reagent **Disc**.
2. When removing the reagent **Disc** after tore the foil pouch, gently grip it together with tissue paper.
3. After opening the pouch, the **Disc** should be used within 20 minutes.
4. Do not place the **Disc** back in the refrigerator for later use.
5. The surface of the reagent **Disc** should be kept clean at all times.

Remove The Aluminum Strip to release build-in diluent

1. Hold the reagent **Disc** by the edge and avoid touching the barcode ring and the optical measurement area.
2. Remove the aluminum strip of the diluent container by gently pulling the end of the strip in an outward direction along the surface of the reagent **Disc**.
3. Please inspect to ensure the aluminum strip is not broken and completely removed from the reagent **Disc**. Then Discard the removed aluminum strip.



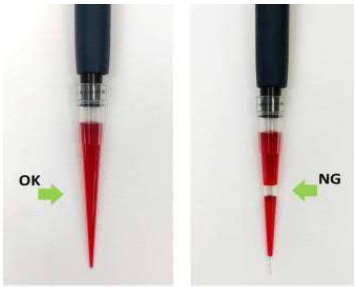
3.4 Applying Sample to the Reagent Disc

Use the provided **skyla** micropipette (220µL) to dispense at least 200µL of the sample into the sample chamber through the sample injection port of the reagent **Disc**.

Take Sample by pipette

1. Use a new pipette tip for each sample.
2. **skyla** 220µL pipette is a 2-steps pipette. Push down the pipette plunger the 1st stop and hold it.
3. Draw about 220uL sample from the tube.
4. **SLOWLY** release the plunger to pick up sample.

   Avoid taking the lipemia (if any) in milk color at upper level in the tube.



5. Avoid taking at the bottom with too much red cells deposited.
6. Make sure there is no air bubble or air gap in the pipette tip.
7. HCT or PCV % of sample should not >60%.

NOTE: Sample volume will be automatically quantitated in the reagent disc again.

Dispense the sample to reagent Disc

1. Place the **Disc** on a flat desk.
2. Insert the pipette tip into the sample injection port, keep the pipette **perpendicular** to the **Disc**. The pipette tip only needs to make "slight contact" with the bottom of chamber.
3. When dispensing the sample, **VERY SLOWLY** and gently push down the plunger.
4. If using a 2-steps pipette, push the plunger continuously and slowly to the 1st stop, then push the plunger continuously and slowly to the 2nd stop.
5. Make sure all sample in pipette tip had been injected into the reagent **Disc**.
6. Remove the pipette tip from the sample port before releasing the plunger.
7. Avoid withdrawing the sample from the reagent **Disc**.
8. If any sample spilled on the **Disc** surface, use a lint-free tissue to clean.
9. Dispose of the used tissue and pipette tip in a designated biohazard container.
10. Perform the test within 10 minutes for the reagent **Disc** with sample.

3.5 Performing a Test

1. Following sequence of patient information will be required to be input/selected.

   (A) Patient ID (Must),

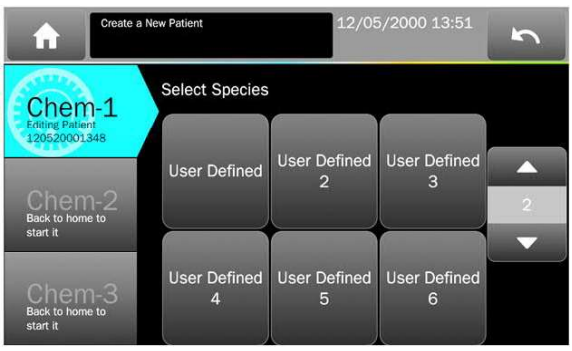
   Up to 16 numbers or scan the patient ID using an optional external barcode scanner. If user press OK without entering, the system will use the current date and time as the patient ID in the format "ddmmyyyyhhmm"

   (B) Species (Must) : Canine, Feline, "Equine Panel" or user-defined.

   User can also press  to select other user-defined species up to 9 kinds when Large Animal Panel or Avian & Reptile Panel is used, the species and reference range could be customized.

   The User-Defined species can be renamed in the Administration Settings menu.

   For Canine and Feline can use all kinds of panel



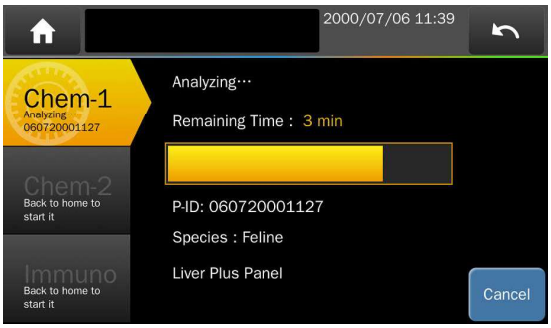
to test.

For Equine sample test, only Equine Panel (900-150) can be used with build-in reference range.

Below input information are optional, depends on the “Header Option” settings.
Users can choose which information could be included in the test report.
The patient information can be changed before the analysis completed.

Press “OK” directly if you don’t want to input any item of below information.

(C) Patient Name (Optional)
(D) Pet Owner (Optional)
(E) Breed (Optional)
(F) Gender (Optional)
(G) Weight (Optional)
(H) Age (Optional)



2. Press “**Open Drawer**”  icon to open the drawer.
3. Hold the **Disc** that contains a sample by its edge, with the barcode side facing up and the **Disc** kept level.
   Gently place the **Disc** on the drawer to proceed the test.
4. Reagent **Disc** Panel test take 15 minutes.

   For **Disc** Panel test, if the plasma/serum sample type option turned on and chose the sample type selected as plasma/serum, it can skip the centrifuge stage to save 3 minutes to have 12minutes analysis time.

   Single Assay **Cartridge** test is taking 12 minutes. (Identify automatically)

   User can turn on the sample type option function in Administrator Settings menu.
   Please refer to **section 10.2.20.**
5. To cancel a test in progress, press the **CANCEL** icon on touchscreen and confirm.

   NOTE: The ejected **Disc** cannot be re-used.
6. Test results

   When the test is completed, the system will store the information produced.
   User can print out the results, link to export to the LIS/HIS software (such as **skyla** Data Manager) of a Personal Computer (PC). (Send automatically if setup well)

3.6 Reviewing the Test Results

3.6.1 The Format of Test Report

Report Heading :

The heading at the top of the report with information :

- Test Panel.
- Hospital Name.
- Test Date & Time.
- Sample Type.
- Patient ID.
- Species.

Header Option of Patient Information :

- Pet Owner.
- Patient Name.
- Breed.
- Gender.
- Weight.
- Age.

- PR Code : include Reagent LOT number and system configuration for the test.
- System QC result. If a suspected used **Disc** been analyzed will be reported.
- Sample QC result. To know the sample quality.
- Sample Interference Index. (4 levels indication)

  The degree of Lipemia (LIP), Hemolysis (HEM), and Icterus (ICT) of the sample.

  "0" (Clear or without interference)

  "+" (Mild)

  "++" (Moderate)

  "+++" (Severe)
- Sample Interference score. (0 ~ 999)

  It will be only shown if the severe interference and some items with % as warning.

Analysis Results include :

- Test Items, Analyte Concentration Result, Reference Range & Unit.

You can **slide the LCD screen** up or down to review the results.

Press "**OK**" icon to eject the used reagent **Disc**.

3.6.2 Symbols Used in Test Report

- (#): Calculated item.
- (↑): Result is higher than referance range.
- (↓): Result is lower than referance range.
- (<): The result is lower and outside the measurable range of the test marker.

Item	Result	Range	Unit
ALB	<1.0	2.6-4.6	g/dL
TP	↓ 4.5	5.2-8.2	g/dL
BUN	8.7	6.0-26.0	mg/dL
CREA	0.6	0.4-1.6	mg/dL
Ca	↑%>12.0	7.9-12.0	mg/dL
PHOS	5.8	2.5-6.8	mg/dL
#GLOB	~	2.2-4.6	g/dL

- (>): The result is higher and outside the measurable range of the test marker.
- (**%**): The test results are significantly impacted by the interference of the sample that is possible outside the permissible tolerant range.
  Check the comment of Sample QC in the report header if % symbol displayed.
- (**N.A.**): Not Available for an analyte.
- (~): Not Available for a calculated item.

Explanations of result as Not Available :

1) For calculated analyte : for example, if TP or ALB is out of measurable range, or one of them is N.A., the result of #GLOB (= TP-ALB) will show "~".
2) Check the sample QC should indicate the analysis is severely impacted by possible interferences in blood samples. Or any abnormal optical signal captured and result had been blocked by internal QC. So N.A. is shown to avoid incorrect results.
3) For analyte: AST result shows N.A., possibly damaged assay **Disc** due to moisture. Please use a new assay **Disc**. And make sure the **Disc** packaging is intact.

NOTE: As with all diagnostic tests, do not make a definitive diagnosis base on the result of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.

3.6.3 Symbols Used in internal QC Reports (if turn-ON)

- QC1: Check the volume of the diluted sample, score should be ≧90.
- QC2: Check the diluent is contaminated or not, score should be ≧90.
- QC3: Check assay reagents have been degraded or not, score should be ≧90.
- QC4: Check the dilution is sufficient, score should be ≧90.
- QC5: Check volume of the sample, score should be ≧90.
- QC6: Check the degree of sample hemolysis, score should be ≧90.
- QC7: Check the temperature control stability of the **Analyzer**, score should be 90–110.
- L340nm~L940nm:
  Check the linear stability of the optical channel, score should be 90-110.
- System QC: Indicates overall QC summary, score should be ≧90.
- Chemistry QC: Indicates overall reagent quality, score should be ≧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.

3.7 Custom Report

To use the **Custom Report** function, it has to be turn "**ON**" in " **Settings**".
Custom Report function allow user to choose which test markers are shown or hidden in the test reports.

If the function is activated in Settings, during the test, the system will ask if user want to create the Custom Report or not after complete patient information.

If choose **NO**, a standard report will be displayed after the test completed. A standard report shows all test markers of the reagent **Disc**.

If choose **YES**, the system will let user select what test markers are to be included in the test report. Choose the items which user want to show and press **OK** when finished.

Custom report

Standard report

To temporarily switch back to the standard report and show all test markers of the panel, simply press the 

icon.

Press the  or 

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

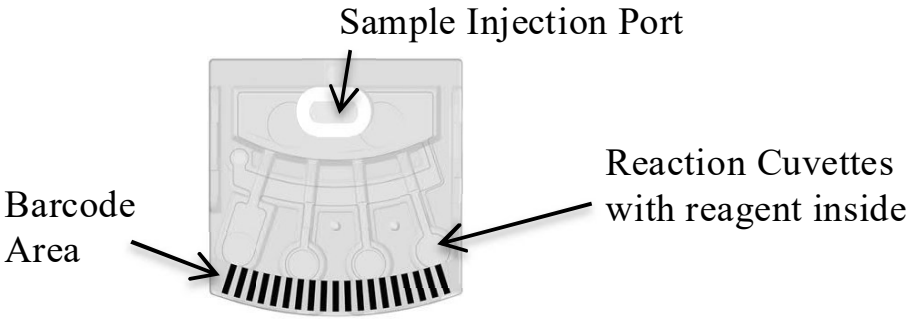
Section 4: Perform a Chemistry Single Assay Cartridge Test

Bay of Chem

4.1 Function of the Single Assay Cartridge

Each single assay cartridge can be included one or two chemistry markers to be tested simultaneously. The combination of the markers is factory designed.

The barcode on top of the reagent cartridge records the reagent cartridge lot number, type, and expiration date.



- The only two internal QC of Single assay cartridges are :

1. The reagent shelf life check.
2. Measuring the interference of samples about the Hemolysis, Lipemia and Icterus. Compensate the interference by using multi-wavelength LEDs measuring. The system will display a warning message if the interference level is higher than the specified limit.

NOTE: Sample volume will NOT be quantitated in the Single assay cartridge.

The sample volume needs to be 100µL precisely.

4.2 Preparing the Specimen

- Available sample type is **diluted plasma or serum** for the Single Assay Cartridge test.
- Refer to **section 3.2** for patient sample preparation.
- Whole blood centrifugation at least 150µL is recommended in order to obtain enough amount (more than 50µL) of plasma or serum specimen.

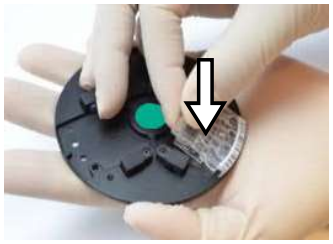
4.3 Preparing the Single Assay Cartridge

- Use the Single Assay metal Carrier-SA (110-950) to carry the cartridges to be test.

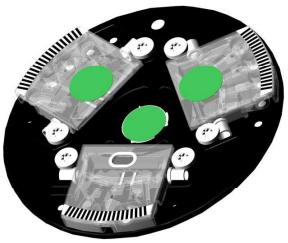
NOTE: The metal Carrier-SA can be **repeatly used**, please keep it properly after test.

- It has to be 3 cartridges on the metal Carrier-SA to be tested.
- Dummy cartridge(s) with green dot should be placed in the empty slots as the balancer.
- Never use the used cartridge(s) to be the dummy cartridge(s) as the balancer.
  It will confuse your reading of result.

Raised bump



Press the cartridge on Carrier-SA



3 cartridges on Carrier-SA

- To place the single assay cartridge on the Carrier-SA, align the groove below the barcode on the cartridge to the **raised bump** on the outer edge of the Carrier-SA. When aligned, press the cartridge into the test **Disc**.

4.4 Preparing the Diluted Specimen

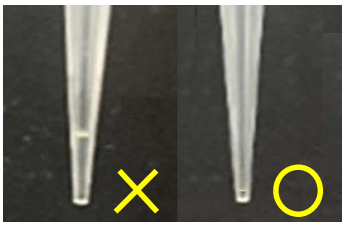
	**One-step 50µL pipette** **exclusively used for Single Assay Cartridge test.**
	Dilution Tube Contains 600µL±1% of diluent (110-940) for the plasma/serum specimen **13X** dilution.

Please use the 50µL pipette which comes in the accessory box and the single assay cartridge dilution tube (110-940) to complete the specimen solution (total in 650µL).

NOTE: Each Single Assay test should conduct for the **same patient**'s specimen.

- To avoid diluent maybe chilled to attach inside of cap or inner wall of tube,
  Centrifuge the diluent tube (110-940) 10 seconds before use.
- With a new pipette tip,
  Use the 50µL pipette to extract 50µL of plasma/serum.
- Open the cap of diluent tube (110-940) carefully.

- Lean the tip on inner wall of tube without touching the diluent.
- Inject **VERY SLOWLY 50µL** plasma/serum.
  Inject too fast will result more remaining specimen in tip.
- Make sure all specimen in tip had been **drawn by inner wall** as possible. (very few remaining is acceptable)
- Tip should **NEVER SINK** into the diluent (fluid) in the tube.
  Because tip could attach few plasma outside.



- After specimen injected, close the cap tightly and
  invert it 10 times to thoroughly mix the solution.
  The 13X Diluted specimen solution in 650µL is prepared.
- **Change for a new pipette tip.**
- **Each Single Assay Cartridge require 100µL of specimen.**
  Use the 50µL pipette to inject **2 shots** specimen as **100µL for each cartridge.**
- To avoid incorrect volume of specimen, **slowly** inject the specimen to the single assay cartridge to avoid bubble or overflow from the cartridge.

4.5 Performing a Test and Read the Report

Please refer to **Section 3.5** as the similar way of reagent **Disc** test for the Single Assay cartridge testing procedure and reviewing the test results.

When using a single assay cartridge for testing, "Location" (1~3) information will be added in the test report.
Information displays in each Location with following order:

The production serial number of the cartridges.
The situation of interferences, and test results.

If dummy cartridge is placed in a/some location(s), the result(s) will indicate as "Empty".

- After reading the report, Press "OK" to eject the disc.
- Please keep the dummy cartridge(s) on the carrier after used for next test.
- Please detach the used cartridge from the carrier after used.
- Please **keep the Carrier-SA** in the **Green** color carrier box.
  (the same color)

Section 5: Perform an Immuno Cartridge-T Test

(Turbidimetry items, such as cCRP, fSAA, PHBR & cA1C)

Bay of Immuno

5.1 Function of Reagent Cartridge-T

The **Analyzer** will perform the test on the reagent **Cartridge** automatically including :

- Automatic mixing and reaction with all chemicals build-in the **Cartridge** for analysis.
- Check bar code information of the **Cartridge** with correct shelf-life and batch version.
- Perform Internal QC upon the **Cartridge.**

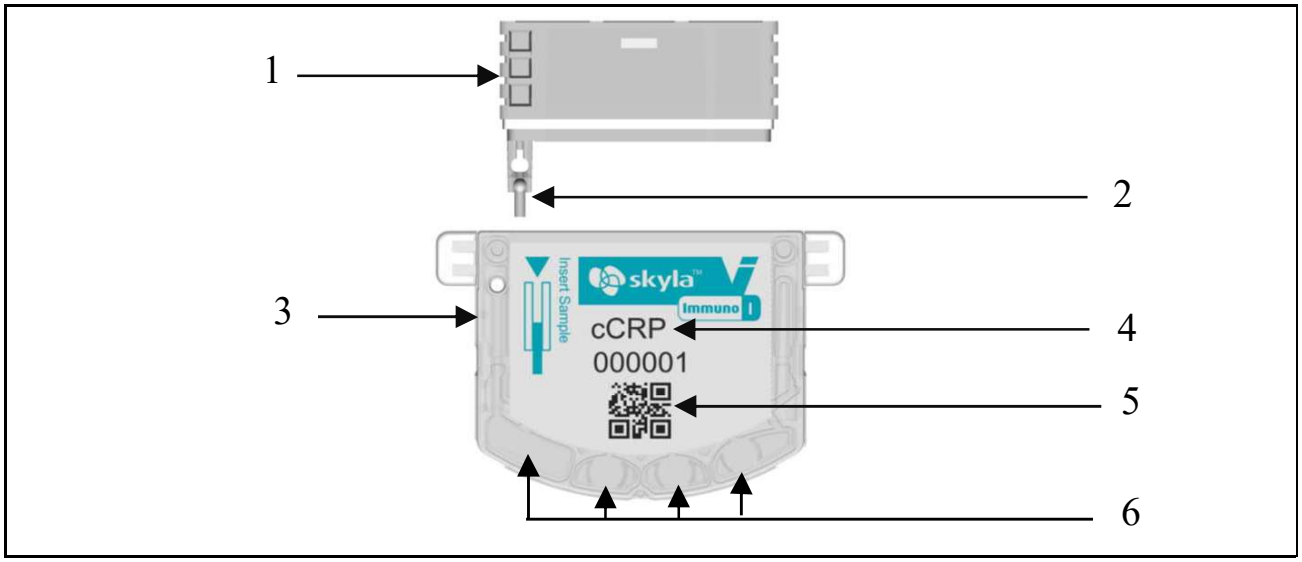


Illustration a skyla Reagent **Cartridge-T** Kit

1. Reagent Pack	Contains pre-packed reagents.
2. Capillary tube	To collect sample.
3. Cartridge body	Cartridge-T main body.
4. Analyte name	Analyte name of this Cartridge-T.
5. QR code	Contains assay and lot-specific information.
6. Reaction wells	Optical reading area, Do NOT touch here while handling

5.2 Sample preparation

- Available sample type is plasma or serum for Cartridge-T test.
- Refer to **section 3.2** for patient sample preparation.
- Recommend obtaining about 10μL of plasma or serum specimen.
- Please refer to the package insert of each skyla Cartridge-T reagent kit for the detailed information.

5.3 Analyzing a Sample

Reagent Cartridge & Carrier Preparation

- Get the reagent cartridge from the refrige storage, no need to rewarm.
- Get the Carrier-T (201-900) ready.

NOTE: The analyzer performs one test at a time, it is recommended that only one reagent cartridge is prepared for each test.

- Remove the Cartridge-T from the foil pouch.

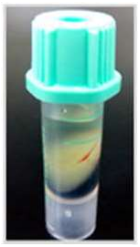
Carrier-T

NOTE: Please retain the **paper** for sample collection purpose.

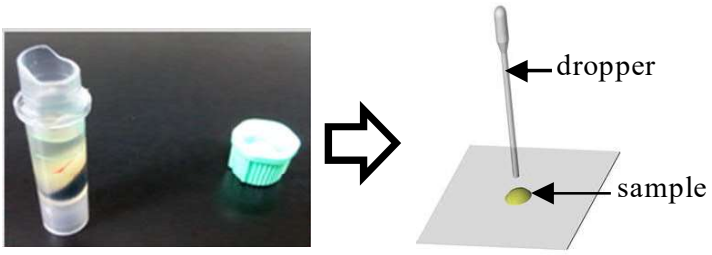
Apply Sample to the Cartridge-T

- Get the centrifugal plasma or serum sample.
- Using a dropper or Pipette take 1 drop of sample (>10μL) from the tube, transfer the droplet onto the paper.

NOTE: Sample should be taken from the clear portion of the centrifuged sample.

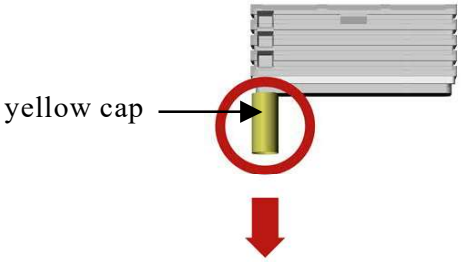


centrifugal sample

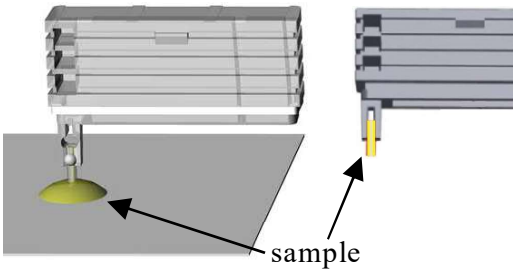


sample transfer onto to paper

- Within 3 minutes, Remove the yellow cap on the capillary tube, use the capillary to collect the sample.
- Touch the sample with the capillary tube for about **3 seconds**, Ensure that the capillary tube is fully-filled with the sample.



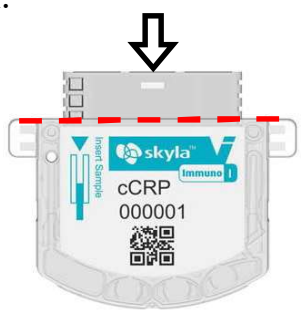
remove the yellow cap



sample collection

Perform a Test

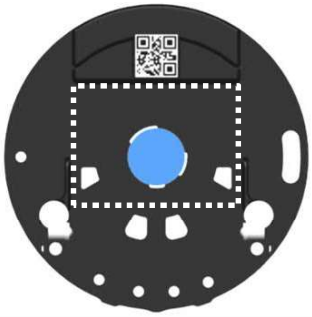
- Insert the reagent pack into the cartridge body until the reagent pack cannot be pushed in further.



Insert reagent pack

Put the cartridge onto the Carrier-T

- Place the Cartridge-T onto the Carrier-T in the correct way as below flow :

		
1. Place the cartridge on the Carrier-T at the highlighted position as shown in above picture. (The label on the cartridge should face up).	2. Slide the cartridge into the slot, along the arrow indicated direction. Until the “click” sound is produced.	3. Ensure that the front part of cartridge has been inserted in the slot and cannot be pushed in further.

Start to Analyze

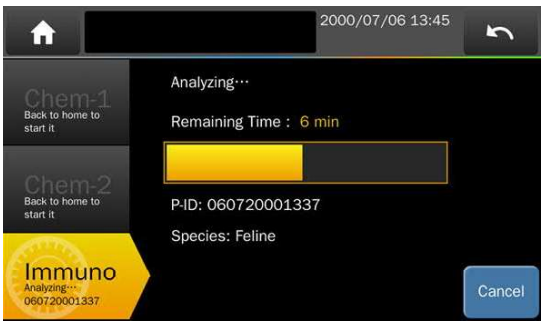
- Choose the Immuno bay and press **“Start”**  icon to launch a test.

- The Patient ID and Species must be identified before you can open the drawer to place **Cartridge** with the carrier on drawer for analysis.

launch an Immunoassay test

- Put the carrier on the tray then press “OK” to begin the analysis.

Performing a Test



Analyzing page

Test Result

- The results will be shown on the screen while analysis is completed.
- Press “OK” to eject the cartridge.
- Please detach the used cartridge from the Carrier-T after used.

NOTE: Please **keep the Carrier-T** in the **Blue** color carrier box. (the same color)

Section 6: Perform an Immuno Cartridge-E Test

(ELISA items, such as cTSH, cCOR, cPROG & cTT4)

Bay of Immuno I

6.1 Function of Reagent Cartridge-E

The **Analyzer** will perform the test on the reagent **Cartridge** with sample automatically including:

- Automatic mixing and reaction with all chemicals build-in the **Cartridge** for analysis.
- Check bar code information of the **Cartridge** with correct shelf-life and batch version.
- Perform Internal QC upon the **Cartridge.**

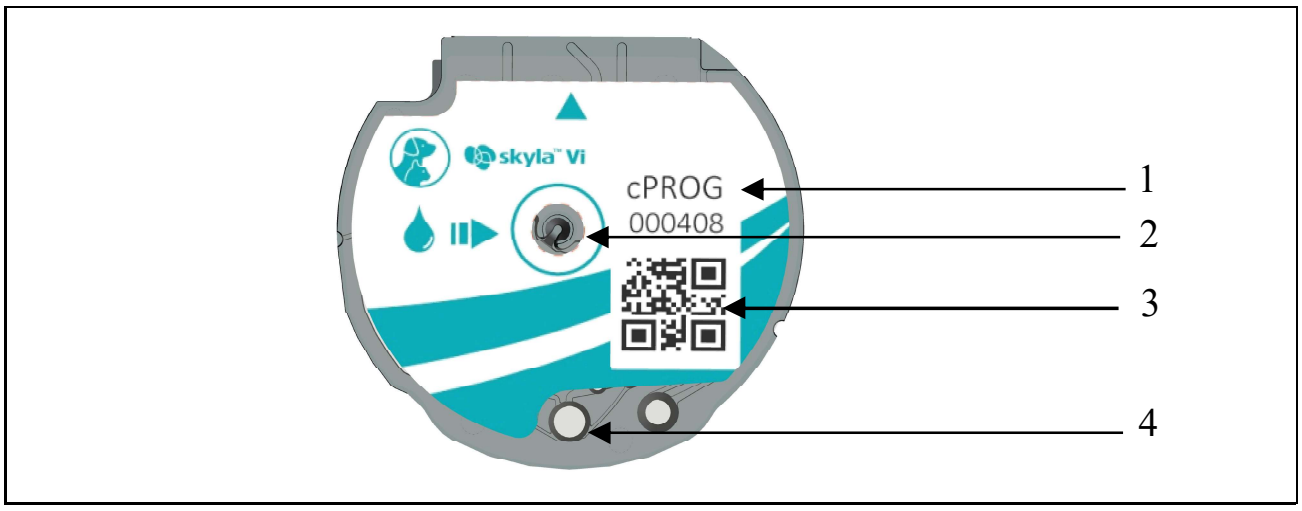


Illustration a skyla Reagent **Cartridge-E** Kit

1. Analyte name	Analyte name of the Cartridge-E.
2. Sample injection Port	Insert sample into cartridge
3. QR code	Contains assay and lot-specific information for the Analyzer.
4. Reaction well	Optical reading area, Do NOT touch here while handling.

6.2 Sample preparation

- Available sample type is plasma or serum for 35uL volume at least for Cartridge-E test.
- Refer to **section 3.2** for patient sample preparation.
- Please refer to the package insert of each skyla Cartridge-E reagent kit for the detailed information.

6.3 Analyzing a Sample

Reagent Cartridge Preparation

Carrier-E

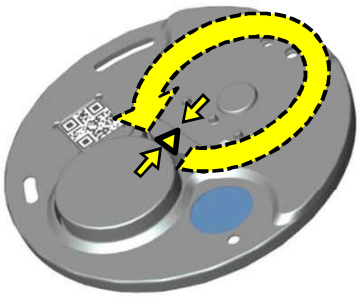
- Get the reagent cartridge from the refrige storage, no need to rewarm.
- Get the Carrier-E (201-910) ready.

NOTE: The analyzer performs one test at a time, it is recommended that only one reagent cartridge is prepared for each test.

- Remove the **Cartridge-E** from the foil pouch.

Perform a Test

- Place the Cartridge-E onto the carrier in the correct way as below flow :

		
1. Rotate the round slot of the carrier to the position to aim the blue mark to the carrier center.	2. Align the blue mark of the Cartridge-E to the blue mark of the slot to insert the cartridge into the slot along the indicated direction. (Label of the cartridge face up).	3. Press down the cartridge until the "click" sound is produced.

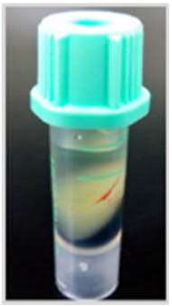
Apply Sample to the Cartridge-E :

- Get the centrifugal sample.
- Use the 35uL Pipette to draw 35uL sample from the tube.

	**One-step 35µL pipette exclusively used for Cartridge-E test.**

NOTE: Sample should be taken from the clear portion of the centrifuged sample.

- Inject 35uL sample into the **Cartridge-E** .



centrifugal sample

sample collection

sample injection

Analyze to get results :

- Please refer to **<u>Section 5.3</u>** the paragraph after "**Start to Analyze"** as the similar way for the cartridge testing procedure and reviewing the test results.
- The results will be shown on the screen while analysis is completed.

- Press "OK" to eject the cartridge.
- Please detach the used cartridge from the Carrier-E after used.

NOTE: Please **keep the Carrier-E** in the **Blue** color carrier box. (the same color).

Section 7: Perform Quality Control Test

Use Assay Control solution as sample to verify the performance of the **Analyzer** and reagent.

Any reagent **Disc** can be used to perform the quality control test for **Chemistry Bay**.

Any reagent **Cartridge-T and Cartridge-E** can be used to perform the quality control test for **Immunoassay Bay**.

Make sure to use **skyla** specified Control solution with the correct items of reagent **Disc/Cartridge** covered by the control.

Use the correct control solution as the sample to be injected into the reagent **Disc/Cartridge**.

Choose a proper Bay, Press the **Control** 

icon to launch the test process.

There are 4 sets of Control Reference Ranges can be imported for quick reference.

Control results can be separately reviewed in the Control Search function in RECALL.

Consult the authorized technical service for the Control test.

NOTE :

- Consult the authorized technical service to get proper assay control solution and assigned value sheet.
- Recommended Quality Control Test timing is as follows:
  - ✓ Every half year.
  - ✓ When the laboratory environment is subject to major changes.
  - ✓ After using the analyzer as an educational training tool.
  - ✓ When test results and the patient's symptoms or diagnosis are not consistent.

Section 8: Merge Reports

The test reports of the same patient can be merged if the test time is close.
On Home menu, press the "**Recall**" icon to merge previous test reports.

Press "Merge"  icon to select reports to be merged with

- within ±12 hours
- the same Patient-ID
- the same Species
- the same Patient Name (Optional)

How to process conflict values ?

- Always Use Latest One (Default)
- Decide One by One

Section 9: Review the Historical Reports

On Home menu, press the "**Recall**" icon to recall previous test reports.
Administrator password required if the password was set.

Recall function

Search function

List of matched results

9.1 Browse the Test Reports

- All previous test reports are listed to be reviewed. List by Test date and Time, latest is on the top.
- Patient Sample test results and Control test results are listed separately.

9.2 Searching for Test Reports (Search)

- To use Search function, press  icon.
  The reports can be searched by :

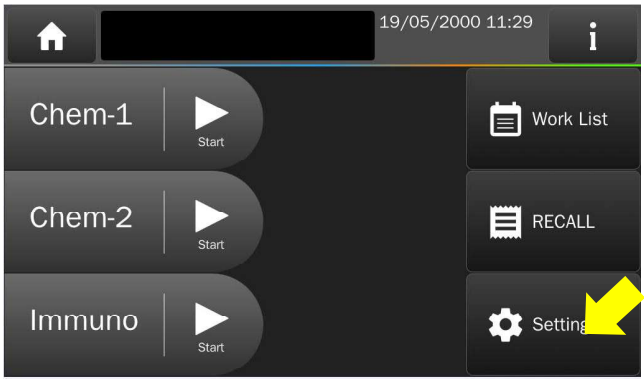
  "Date" (a period) , user need to input the Start date and End date of the period.
  "Patient ID" , all the reports of the same patient ID will be listed.
- All reports will be sorted by the order of test, latest is on the top of list.
- Press the USB  icon to export and save the selected reports to USB.

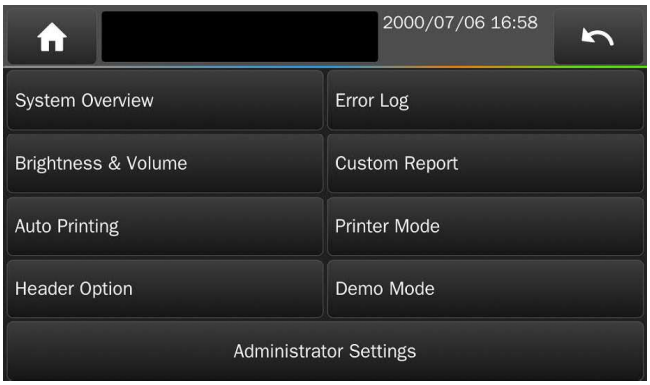
Section 10:System Settings

The **Analyzer** provides variety of customization functions to optimize the operations.

10.1 General Settings

At HOME menu, press the "Settings" icon to access the generic settings of Analyzer.





10.1.1 System Overview

(1) Model Name.

(2) Software Version : The main version of the **Analyzer** operation.
Always keep it as up-to-date version to have the best performance of the **Analyzer**.

(3) Device SN : The Serial Number of the Analyzer.
Chem-1 SN : The Serial Number of individual bay at CHEM-1.
Chem-2 SN : The Serial Number of individual bay at CHEM-2.
Chem-3/Immuno SN : The Serial Number of individual bay at CHEM-3/Immuno.

(4) Installation Date.

(5) Assay Parameter Version : The reagent assays calibration version of the **Analyzer**.
Always keep the Software Version up-to-date will also update the Assay Parameter Version.

(6) Network connection : MAC Address, IP Address and Wi-Fi Dongle IP Address.

10.1.2 Error Log

The latest 5 error codes could be recalled.
Orally report to technical service for initial troubleshooting.

10.1.3 Brightness and Volume Adjustment

Adjust the brightness of the touchscreen with four possible levels.
Adjust the volume of the buzzer in three levels or Off. (Default: Medium).
The built-in buzzer to alert users for the test has been completed or an error occurred.

10.1.4 Custom Report (Default: OFF)

Turn on the **"Custom Report"** function to display/hide the selected test items of chemistry panel test.
Please refer to **Chapter 3.7** for more details of the Custom Report function.

10.1.5 Auto Printing (Default: ON)

After the test is completed, the **Analyzer** will automatically print the test report.

10.1.6 Printer Mode (Default: Internal)

Choose to use the internal thermal printer or a connected external USB printer.
Choose an external USB printer model with the spec conforms to either PCL 3GUI, PCL6 or PCL 5e.

NOTE: Contact the authorized technical service to inquire printer models.

10.1.7 Header Option Selection (Default: OFF)

There is addition patient information such as "Patient Name", "Pet Owner", "Breed", "Gender", "Weight" and "Age" can be added in the header of test report. So user need to enter the required information during analysis. The information provided here does not affect the analysis results and is only used for the displaying/printing of report.

10.1.8 Demo Mode (Default: OFF)

The **Analyzer** has a built-in demonstration mode that provides a complete simulated testing environment for training or demonstration.
In this mode, any **Disc/Cartridge** (even an used one) can be used without any sample applied. This allow user to practice all essential touch screen operations. The virtual testing process will be completed in 2 minutes to have a pre-loaded result for demonstration.

- The patient ID of the Report will be noted as "Demo".
- Once the Demo Mode is enabled, the "Demo" DEMO icon will be shown on the upper side of screen.

NOTE:

- Any changes made on System settings under **Demo Mode** will remain valid still**.**
- Remember to change back to normal mode after you finished demonstration.

10.2 Administrator Settings

More detail settings for administrator under the option of **"*Administrator Settings*"**.
The password (if presented) need to be entered.
There are four Administrator Setting pages.

10.2.1 Save Log to USB

To save the system log file to an USB drive (FAT) then provide to technical support.
This is for authorized technical service troubleshooting upon error.

10.2.2 System Upgrade

skyla will release new System Upgrade periodically to improve the functions of the **Analyzer**. Contact authorized technical service about the new version information.

There are two ways to do System Upgrade:

By USB Drive

- Get the System Upgrade file (xxxxx.bin) from technical service.
- Copy the file to an **USB drive** (FAT) then plug on the USB port of the **Analyzer**.
- Press the **"System Upgrade"** icon then choose "**USB**", it will take about 20min for the System Upgrade.
- The **Analyzer** will automatically reboot after the system software has been updated.

By FTP server (internet and skyla server connected)

- If the **Analyzer** is internet linked, choose "**FTP**" option to let the **Analyzer** get the System Upgrade file through network to do System Upgrade automatically.

NOTE:

To have authorized technical service to perform the system upgrade or setup.
The **Analyzer** must remain powered on throughout the system upgrade process.

10.2.3 Reference Range

Administrator can adjust the build-in reference range if necessary.

- The reference range of each analyte will be set separately by Species of Canine, Feline, Equine Panel and 9 kinds of User Defined Species.
- Custom reference range can be cancelled by "System Default" to the build-in values.
- Reference Ranges can be loaded from an USB drive with preloaded file(csv format).

Press the 

icon to load the reference range of User Defined Species.

10.2.4 Marker Unit

Administrator can select the unit for each analyte.

- User can set **All Analytes** to "SI" or "Common" unit system.
- User can select the unit of a single analyte by pressing the **"Single Analyte"** icon.
- Press "OK" to save the changed settings.

NOTE: The Reference Range will be automatically **Converted** if the unit is changed.

10.2.5 Pathology Comment (Default: OFF)

The function is only supported in certain languages.

The factory build-in pathology comment will be prompted (displayed/printed) after the test report while some items are out of reference range.

10.2.6 Edit Patient

Use this function to edit or create patient information.

10.2.7 Password

Password can be set to protect the accessing of Administrator's Settings functions.

- Input a password and re-enter again for confirmation.
- Disable Administrator Password : Press **"OK"** without entering any numbers while setting the password.
- Enable Administrator Password : Set a password again.

10.2.8 Backup Records

Backup ALL the test reports to an USB drive (FAT), save a file in csv format.

10.2.9 Date & Time

Press the Day/Month/Year/Hour/Minute/Format icon then use  to adjust.

NOTE: Date of Analyzer should align to local date correctly to avoid the inaccuracy of analysis.

10.2.10 Language

The **Analyzer** provides the user interface and test report in different languages, such as: Deutsch, English, Espanol, Francais, Italiano, Polish and Simplified Chinese.

10.2.11 Hospital Name (Default: OFF)

The Hospital Name can be displayed and printed at the top of test report.
The name can be up to **24** characters.

10.2.12 Rename Species

The **Analyzer** provides **9** kinds of User Defined Species other than “Canine”, “Feline” & “Equine Panel”
User can change the name (max: **16** characters) of them in the report.
User need to define the reference ranges for different kinds of species.

10.2.13 RS232 Baud Rate Setting (Default: 115200)

The baud rate should be the same as the setting on the connected computer (PC).

10.2.14 Print Direct Data (Default: OFF)

When this function is enabled, there will be two copies printed for the test report if there is a “N.A.”, “>” or “<“ symbol in the result of any test item.
First printed copy will be the usual results with all these symbols. And then
Second printed copy (called: “Direct Data” copy) will be obtained from the actual measurement data without any error correction.

NOTE :

- Direct Data includes information beyond the measuring range of the **Analyzer**.
- Results of the Direct Data copy is only for troubleshooting.
- Do not change your treatment base on a single result that beyond reference range or if you believe the test results could be incorrect.

10.2.15 Connectivity

User can select RS232 or Ethernet(LAN) to connect the **Analyzer** with computer (PC).

10.2.16 Remote Computer

To set the IP/Name and Port number of the connected computer (PC).

10.2.17 Local IP Setting

User can select DHCP or Static for IP setting of the **Analyzer**.

10.2.18 Wireless

The wireless function of the **Analyzer** can be supported by **skyla** specified WiFi dongle.

NOTE: Contact the authorized technical service to inquire the USB WiFi dongle.

10.2.19 Export Database & Import Database

This is for technical service during the replacement of a malfunctional analyzer.

- Use “Export Database” to extract the test report database from existing analyzer.
- Use “Import Database” to reload the test report database to the new replaced analyzer.

10.2.20 Sample Type Option (Default: OFF)

The **Analyzer** could skip centrifuging function when the plasma/serum sample is used. This can save the test time for 3 minutes.

WARNING: Use with whole blood sample but choose plasma/serum sample type could result the severe hemolysis interference.

10.2.21 Carrier Calibration (for Immunoassay carriers ONLY)

- Only upon the advice from authorized technical service to perform the calibration.
- Place the new carrier (without any cartridge) in drawer to perform the calibration.

10.2.22 System Default

The **Analyzer** comes loaded with default values of system settings which can be customized by administrator if necessary.

After System Default had been executed completed, except Language, Date & Time and history test reports, all customized settings such as reference range, units, hospital name, user defined species, header option… will be restored to the default factory settings.

WARNING :

“System Default” will **Erase most settings** and cannot be restorable.

“System Default” will **NOT** erase the historical test reports.

10.2.23 Delete All Reports (for authorized technical service only)

WARNING :

The function will erase all historical test/control reports in the **Analyzer** without changing any system Settings. After deleted that cannot be recovered.

10.2.24 QC Report (Default: OFF)

The **Analyzer** will always do the Internal QC (IQC) for each test upon the optical system of the **Analyzer** and reagent **Disc/Cartridge**. A completed IQC report is included but hidden in each test report.

- To include the IQC results for each test report, please turns the function ON.

10.2.25 Service Q

For authorized technical service check only.

10.2.26 Save Settings to USB / Restore Setting

This is for technical service during the replacement a malfunctional analyzer.

- Use “Save Settings to USB” to extract all the user’s settings from existing analyzer.
- Use “Restore Settings” to reload all the user’s settings to the new replaced analyzer.

10.2.27 Curve Calibration / Curve Calibration Info

- For reagent LOTs calibration if necessary.
- Calibration file will be offered by authorized technical service.

Copy the file to an USB drive (FAT) then plug on the USB port of the Analyzer.

10.2.28 Reset Filter Timer

Filter timer will remind user to clean the air filter at bottom side of Analyzer.
Press “Reset Filter Timer” icon after cleaned the filter.

10.2.29 Sleep Mode

User can use this function to set when the analyzer should enter the “Sleep mode”.
There are 5 levels of time can be selected.

10.2.30 BarCode Scanner Test

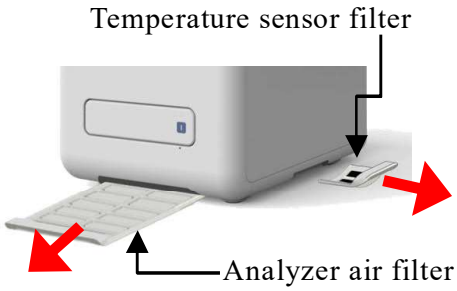
To check the external barcode scanner function is avaliable or not.
NOTE: Contact the authorized technical service to inquire the external barcode scanner.

Section 11:Maintenance

Suggested maintenance by users :

If the Analyzer won't be used for a period, please use dust cover to protect the **Analyzer.** It is suggested the **Analyzer** should be cleaned routinely once per week including ,

- **Analyzer air filter**
- **Ambient temperature sensor filter**



Take out the filters in the direction of the arrows, use a vacuum to clean the surface of filters.
A timer can remind you to clean it periodically.
The filter timer can be reset in Administration Settings menu.

- **Exterior surface of the Analyzer**

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

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

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

1. Press the "Open Drawer"  icon on screen to open the drawer.
2. Use a cotton swab dampened with 10% commercial bleach solution to wipe the drawer area.
3. Use a dry cotton swab to wipe the same area.
4. Close the drawer.

If the cleaning procedure is not yet finished, press "Open Drawer" again to open the drawer.

- **Suggested maintenance by authorized technical service :**

It is suggested to clean inside the Analyzer every 6~12 months depends on the environment and frequency of use.

Section 12: Troubleshooting & Error Handling

12.1 Troubleshooting

There are solutions (S) to resolve common Conditions (C) while user encounter problem. Contact the **skyla** authorized technical service if the problem is not resolved.

C: Touchscreen LCD is dark or in blue color.

S: Press power button for 5 seconds to force the **Analyzer** power off. Check the power cable connections. Disconnect and reconnect on both ends, then turn the power on.

C: If **Analyzer** stays on booting screen (not HOME screen) for more than 30minutes.

S: Press Power button for 5seconds to force the **Analyzer** power off.
Power on again the **Analyzer**.

C: At HOME screen, but some Bay is stock at warming up stage with START icon in gray color for more than 30minutes.

S: You can use available bay (with START icon is normal) to perform analysis, or turn off the **Analyzer** if the touch screen is still workable.
The environment temperature is too low. Please turn on the heater in the room. Make sure the room temperature is between 5~35°C before turning on the **Analyzer**..

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

S: The **Analyzer** performs automatic system calibrations and Internal QC to maintain high system precision. Thus, when the **Analyzer** detects a faulty reagent **Disc/Cartridge**, it automatically cancels the test and displays an operational error message. Please use a new reagent **Disc/Cartridge** to resume operations.

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

S: The thermal paper roll may have been installed in wrong direction. Please install the paper roll in correct direction and recall the last report to be printed.

C: To test result was not sent to the LIS/HIS software of the connected computer(PC).

S: Recall the last report that missed to be sent, press the resend  icon to resend to LIS/HIS software again.

C: Forget the Administrator password you set.

S: Use the universal password 5787722 to reset the desired password again.

12.2 Error Messages Handling

While	LCD Error Message	Error Handling
Anytime	Internal Memory Full Internal Memory Error Device Abnormal	Restart the analyzer. Contact the authorized technical service if the issue cannot be resolved.
	Password Error	Please enter the correct password. Or use the universal password to reset password.
Warming up	Device Abnormal (Error Code 1~20, 30, 51~56, 1000~1099)	Check the room temperature is within 5~35°C. Restart the analyzer. Contact the authorized technical service if the issue cannot be resolved.
Printing Report	Internal Printer Error	Contact the authorized technical service.
	No External Printer Found	Please check the external printer is correctly connected and whether the external printer is an **Analyzer** compatible model.
	The content is not printed	Check if the thermal paper roll is properly installed in correct direction.
Drawer operation	Drawer Jam	Please remove any objects that prevent the drawer from closing properly. Contact the authorized technical service if the issue cannot be resolved.
Sample Analyzing	Unrecognized **Disc/Cartridge** Bar Code (Error Code 101~104, 111, 112, 114, 1111)	Check if the barcode of the **Disc** is dirty or with defective printing. Use a new reagent **Disc** to test. Contact the authorized technical service if the issue cannot be resolved.
	Unauthorized **Disc/Cartridge** (Error Code 105, 106, 115, 116, 1115, 1116)	This is an unauthorized reagent **Disc/Cartridge**. Please use a new and correct reagent **Disc/Cartridge** to test. Contact the authorized technical service.
	Disc/Cartridge Expired (Error Code 107, 117, 1117)	The reagent **Disc/Cartridge** is expired. Please use a new reagent **Disc/Cartridge** within shelf life to test.
	Assay Parameter Version Mismatch (Error Code 108)	Please Do **System Upgrade**. Contact the authorized technical service to get the latest version of system upgrade file.

	Unbalanced (Error Code 118, 1118)	Unbalanced while doing test. Please put the balancer cartridge in the empty location of carrier before doing the analysis.
	Insufficient Sample (Error Code 204, 1908)	The sample volume is insufficient. Please use a new reagent **Disc/Cartridge** to test, refer to **section 2.2** and make sure to inject sample slowly with enough volume according to the reagent kit.
	Disc Error (Error Code 202)	The **Disc** build-in diluent is not enough. Please use a new reagent **Disc** to test
	Disc Error (Error Code 203, 212)	The **Disc** maybe in poor storage environment. Please use a new reagent **Disc** to test.
	Disc Error (Error Code 213, 355)	Possible inject too rush or too much sample. Please use a new reagent **Disc** to test. Contact the authorized technical service if the issue cannot be resolved.
	Disc/Cartridge Error (Error Code 323, 541, 841, 842, 843, 1907)	Please use a new reagent **Disc/Cartridge**. Contact the authorized technical service if the issue cannot be resolved.
	Disc/Cartridge Error (Error Code 1902~ 1909)	Please contact the authorized technical support department.
	Carrier Error (Error Code 1121)	Please contact the authorized technical support department.
	Carrier Calibration Error (Error Code 1122)	Please remove the reagent kit and put carrier only.
	Used **Disc/Cartridge** (Error Code 1901)	Please remove the used reagent kit and insert a new reagent kit.
	Device Abnormal (Error Code 1~20, 30, 60~62, 3XX , 5XX, 800, 801, 802, 1102, XX70, 1151~1899, 7000~7999)	Please reboot the analyzer after remove the reagent **Disc/Cartridge** to use a new reagent **Disc/Cartridge**. Contact the authorized technical service if the issue cannot be resolved.
Settings	USB Drive Error (Error Code 411)	Please check the USB drive is properly plugged on the device or in correct format of FAT 16/32. Please check whether the USB drive space is full. Contact the authorized technical service if the issue cannot be resolved.

	Password Error	Please enter the correct password.
	No Software Found (doing System Upgrade)	There is no new System Upgrade file found within the USB drive. Please contact the authorized technical service for the file.
	Upgrade Failure (Error Code 951, 957, 959, 2000, 2001~ 2099)	The system upgrade file is wrong. Contact the authorized technical service.
	Assay Parameter Upgrade Failure (Error Code 950, 953)	The System upgrade file is incomplete or damaged. Contact the authorized technical service.
Recall	No Data Matched	No history reports. Please start the analysis to increase the database.
	RS232 communication failure (Error Code 401, 402, 3001)	Please check that the RS232 cable is correctly connected, and the settings is proper. Contact the authorized technical service if the issue cannot be resolved.
	Network communication failure (Error Code 3003)	Check the Network connection is correct first. If yes, please contact the authorized technical support department.

If the information and troubleshooting steps provided do not resolve your issue, please record the error message and error code on LCD screen and call the **skyla** authorized distributor technical service.

If distributor technical service does not response properly, contact **skyla** by information as follows:

Telephone: +886-3-611-8511 (Taiwan)

Fax: +886-3-579-5393

E-mail: support@**skyla**.com

Website: www.**skyla**.com

NOTE :

The system parts of the **Analyzer** require professional handling.
Please do not attempt to disassemble or repair the **Analyzer** by yourself, as this will void the warranty.
Always contact the **skyla** authorized technical service while the **Analyzer** requires service.

LIMITED WARRANTY

How long does the coverage last? **skyla** warrants to the original purchaser that the **skyla Analyzer** (as in the section-1 **Analyzer**, hereinafter to as "**Analyzer**") and accompanying power supply will be free from defects in materials and workmanship for a period of at least two years from the date of purchase or initial installation whichever comes first.

What does skyla Limited Warranty cover? Only the original purchaser of the **Analyzer** purchased from an authorized distributor/representative may obtain coverage under this limited warranty. **skyla** is not responsible for any additional representations or warranties, with the sole exception of representations made in writing and signed by an authorized officer of **skyla**.

This limited warranty does not cover (a) any problem that is caused by neglect, accident, abuse, shock, electrostatic **Disc**harge, heat or humidity beyond product specifications, improper installation, operation, maintenance, modification or alteration; (b) any misuse contrary to the instructions in the operator's manual; (c) malfunctions caused by other equipment. This limited warranty is voided if the **Analyzer** (a) is repaired or serviced by anyone not authorized by **skyla** to render such service; (b) is returned with removed, damaged or tampered labels of any alterations. This limited warranty does not cover loss of time, loss of revenues or profits, property damage, inconvenience, or data loss – back-up the contents of your test results on a regular basis, and consequential damages; incidental damages whether or not caused by a failure to a **skyla** product; and costs related to data recovery, removal and installation are not recoverable under this warranty.

What will skyla do? Under this warranty, **skyla** will, at its option, refurbish or replace, any **Analyzer** which is not as warranted, given the conditions of that the purchased the **Analyzer** is within the warranty period with a valid proof of purchase, and follows **skyla**'s instructions regarding warranty or may replace an **Analyzer** with a new or reconditioned unit. The new or refurbished unit will receive this same limited warranty for the balance of the original warranty period. The foregoing in **skyla**'s sole obligation and the purchaser's exclusive remedy under this limited warranty.

skyla makes no warranty other than the limited warranty set forth above and Disclaims all other warranties including all implied warranties of fitness for a particular purpose or merchantability. Under no circumstances will **skyla**'s liability exceed the price paid by the purchaser for the **Analyzer**.

Hospital/Clinic Name _____

Address _____

Telephone _____ E-mail _____

Distributor's Name _____

Date of purchase or initial installation: date/month/year _____

Serial Number(S/N) (Please refer to the label on the back of the device)_____

To preserve your right to the **skyla** Limited Warranty, email above information and a copy of your purchase receipt to **skyla** Support at support@**skyla**.com or Fax to : +886-3-579-5393.