IVD CE

i-Smart 30 PRO
ELECTROLYTE ANALYZER
Operator's Manual

Software version 2.1.0.x

PDNAA-000003 REV0 2021/04

i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea

[Manufacturing facility] i-SENS Songdo Factory
12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon 22014, Korea

EC REP Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert, Germany

Copyright © 2021 i-SENS, Inc. All Rights Reserved

Please take time to read this operator's manual
before setting up and operating the analyzer.

Table of Contents

1 Introduction

Safety 8
Symbols and Terminology 10
Product Description 13

2 Installation

Installation Requirements 16
Power Cable Connection 17
Barcode Scanner Connection 18
Power-on 19
Printer Paper Installation 21
Cartridge Installation 24

3 Instrument Settings

Screen Menu 30
Instrument Setup 38
Parameter Setup 44
Unit Setup 45
Sample Setup 46
QC Setup 52
L-J Chart Setup 55
Interface Setup 57

4 Sample Analysis

Blood Sample 62
Urine Sample 69
QC Sample 76

5 Database

Sample Data 82
QC Data 86
Calibration Data 92
Cartridge Data 93

6 Shutdown

Analyzer Shutdown 96
Power Recovery 98

7 Maintenance

Calibration 100
Cartridge Removal 103
System Information 106
Event Log 107
Analyzer Status 108
Cleaning 109

8 Troubleshooting

Troubleshooting 112
Error Code 117

9 Product Specification

Operation Specifications 120
Instrument Specifications 121
Cartridge Specifications 122
Principles 123
Performance 125

Appendices

Appendix A: Collecting and Handling Samples 147
Appendix B: Order Information 149
Appendix C: Warranty 150

1. Introduction

Safety 8

Symbols and Terminology 10

Product Description 13

Safety

General Warnings

- ❑ Use only the provided power cord and adapter.
- ❑ Do not use damaged power cord, adapter, or loose outlet.
- ❑ Never touch the power supply accessories with wet hands.
- ❑ Keep dust away from the outlet and power cord.
- ❑ Do not use or store any hot equipment or flammable material near the analyzer or power supply accessories.
- ❑ Do not allow water or foreign substances to get into the analyzer or power supply accessories.
- ❑ Do not directly look at the red light emitting from the barcode scanner as direct eye exposure to this light can damage vision.

General Caution

- ❑ Power cord must be plugged into a grounded outlet.
- ❑ The rear vent of the analyzer must be free of obstruction and not covered by cloth or any other material.
- ❑ Do not install or operate the analyzer in an area where ferromagnetic fields are generated (e.g., the MRI room).
- ❑ Before long term storage of the analyzer, remove the cartridge, turn off the power, and clean any contamination from the analyzer.
- ❑ There are no operator seviceable parts inside the product.
  Do not disassemble, repair, or modify the product.
- ❑ If electromechanical problems are suspected, call a service engineer to report the problems.
- ❑ When disposing the analyzer and provided electrical accessories, contact your local distributor where you purchased them.
  You must not discard this electrical/electronic product in domestic household waste.

Safety *continued*

Biohazard Caution

- ❑ All materials used in collecting blood and/or other samples from humans should be treated as biohazardous materials with the potential carrying infectious agents capable of producing disease.
- ❑ All biohazardous materials should be handled and disposed of in accordance with applicable rules and regulations of the hospital, laboratory, or other testing facility.
- ❑ Wear appropriate personal protective clothing (lab coat, gloves, goggles, etc.) before operating the analyzer.
- ❑ Be careful not to let the sample and/or collecting tools directly touch the mouth, eyes, mucus membranes, or any area with broken skin.
- ❑ Wash hands after collecting the sample or using the analyzer.

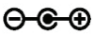
Symbols and Terminology

Symbols

Symbol	Description
	CE mark
	In vitro diagnostics device
	Consult instructions for use
	Authorized representative in the European Community
	Serial number
	Caution: Attention, see operating instructions
	Manufacturer
	Date of manufacture
	Temperature limitation
	Humidity limitation
	Catalogue number
	Batch code
	Contains sufficient for <n> tests
	Use by (Expiration Date)
	Biological risks
	This marking indicates that you must not discard this electrical/electronic product in domestic household waste. Distributors of this product within the EU have taken the necessary step to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive.

Symbols and Terminology *continued*

Symbols,
continued

Symbol	Description
	Printer
	DC Power port
	Power off
	Power on
	This way up: indicates correct upright position of the transport package.
	Keep dry
	Fragile, handle with care
	Stacking limit by number: maximum number of identical packages which may be stacked on one another

Symbols and Terminology *continued*

Terminology

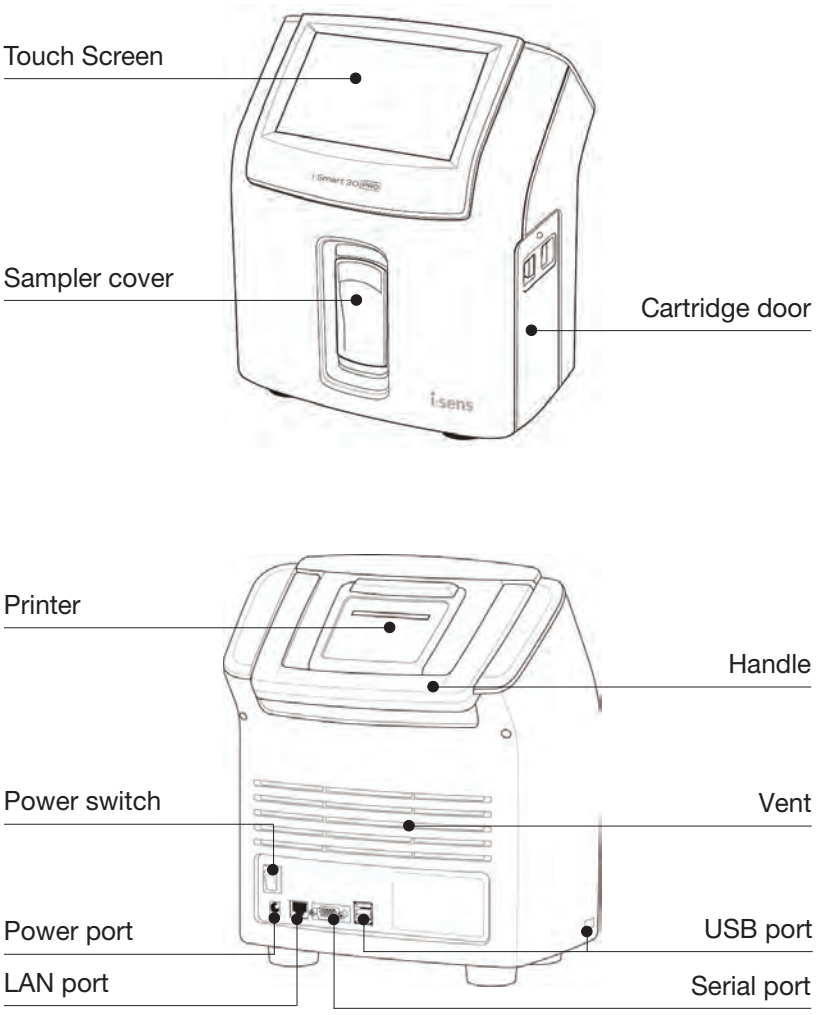
Terminology	Description
Na^+	Sodium ion
K^+	Potassium ion
Cl^-	Chloride ion
Ca^{2+}	Ionized calcium ion
Cal	Calibration
Cal 1	1-Point Calibration
Cal 2	2-Point Calibration
QC	Quality control
Warning	A statement that alerts the operator to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.
Caution	A statement that alerts the operator to the possibility of device malfunction, device failure, damage to the device or damage to other property associated with the use or misuse of the device.

Product Description

Intended Use

The i-Smart 30 PRO Electrolyte Analyzer is intended for use in the quantitative measurements of sodium, potassium, chloride and ionized calcium in whole blood, serum, plasma, or urine. Measurements obtained by this device are used for the diagnosis, monitoring, and treatment of diseases involving electrolyte imbalance.
The i-Smart 30 PRO Electrolyte Analyzer is intended for *in vitro* diagnostic use and for use by healthcare professionals.

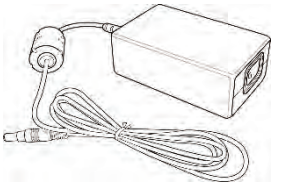
Analyzer



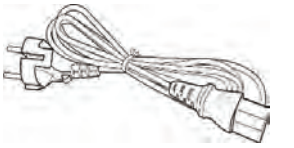
i-Smart 30 PRO Electrolyte Analyzer

Product Description *continued*

Accessories

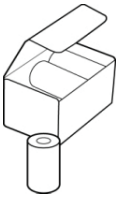


Power adapter



Power cord

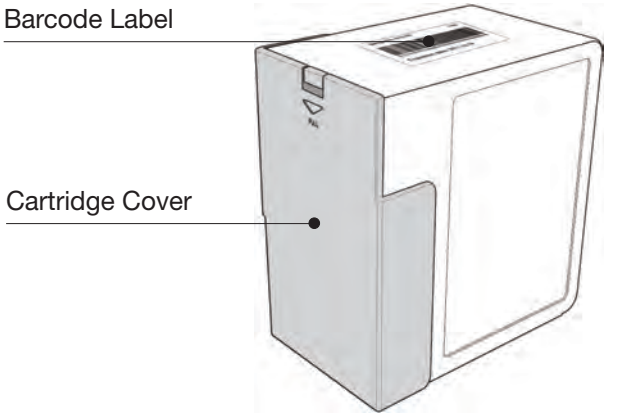
Barcode scanner



Printer papers

Pedestal

Cartridge



i-Smart 30 PRO Cartridge / i-Smart 30 PRO Cartridge E4

2. Installation

Installation requirements 16
Power Cable Connection 17
Barcode Scanner Connection 18
Power-On 19
Printer Paper Installation 21
Cartridge Installation 24

Installation requirements

Unpacking

- ❑ Inspect the shipping package of the product for any signs of damage from shipment.
- ❑ Ensure all listed components are included in the package.

Environment

- ❑ Set up Location : Indoor
- ❑ Operating Temperature : 15 ~ 35 °C
  ※ It has been confirmed that analyzer is safe to operate in an environment of 5 ~ 40 ºC according to IEC 61010-1. However, Please operate the analyzer at 15 ~ 35 ºC to achieve the performance of cartridge.
- ❑ Operating Humidity : 5 ~ 85 %, relative humidity
- ❑ Operating Altitude : Below 3,000 m

Note:

- ✓ Set up the analyzer away from sunlight or heat, but on flat, stable surface with space for good air circulation.
- ✓ Allow enough space to open the cartridge door and insert cartridge into the analyzer.
- ✓ Allow at least 10 cm of space from the back of the analyzer for adequate air circulation.

Electric Power

- ❑ Analyzer Requirements
  - Input Rated Voltage : +24 Vd.c
  - Input Current : Max. 2.7 A
- ❑ Adapter Requirements
  - Input Rated Voltage : 100 ~ 240 Va.c., grounded electrical supply
  - Input Current : Max. 1.5 A
  - Rated Line Frequency : 50/60 Hz
  - Power Cord : 3-wire, approved
  - Output Rated Voltage : +24 Vd.c.
  - Output Rated Current : Max. 2.7 A

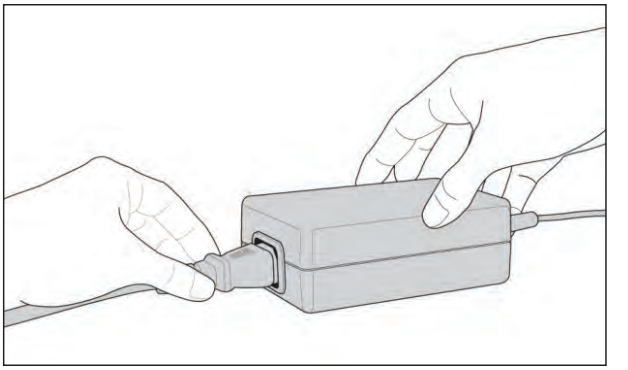
Power Cable Connection

Caution

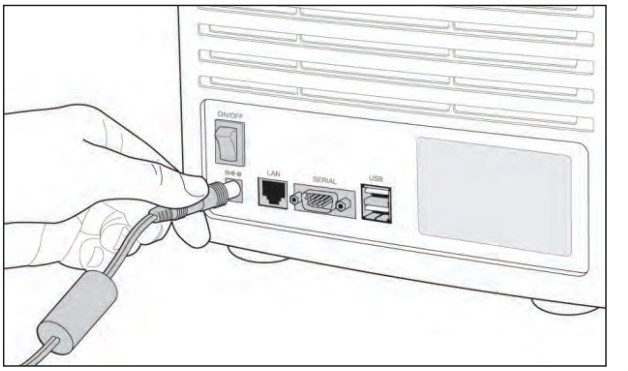
- ❑ Check that the power switch is in " ○ " (OFF) position.
- ❑ Connect to the power following the instructions listed on this manual.
- ❑ Always use a grounded electrical outlet.
- ❑ Use only the power cord and power adapter provided by the manufacturer.
- ❑ Electrical plugs and sockets vary by countries. If necessary, use appropriate power plug or power strips to connect the provided power cord to the outlet.

Connect to power

1. Plug the power cord into power adapter's socket.



2. Connect the power adapter to the power port in the back of the analyzer.

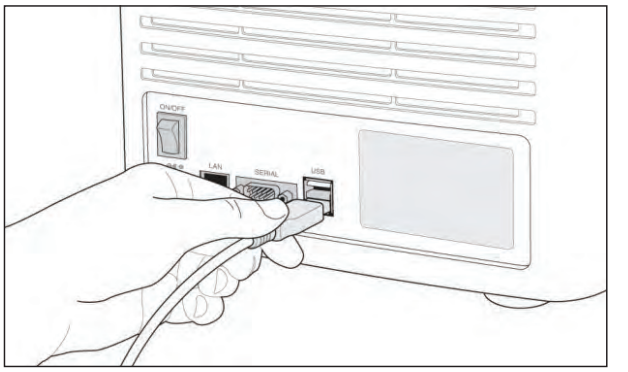


3. Connect the power cord to the electrical power outlet.

Barcode Scanner Connection

Connect Barcode Scanner

1. Insert the USB connector of the barcode scanner into a USB port on the back or side of the analyzer.



Note:

✓ When the analyzer is turned on, the barcode scanner will make a beep sound and the indicator light on the scanner will turn on briefly.

Power-On

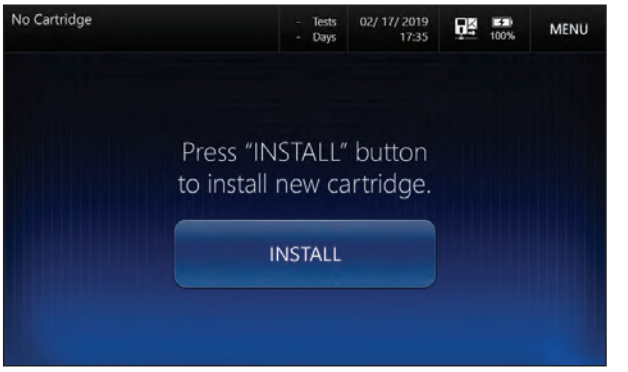
Caution

- ❑ Before turning on the power switch, please remove the USB memory or the network cable from the analyzer.

Turn on the power

1. Turn on the power by pushing the switch so the " | " would be pressed.
2. The screen will turn on and the analyzer will start booting.

3. Once the booting is complete, the main screen will appear.



Note:

- ✓ When the analyzer is booted without a cartridge installed, 'No cartridge' status will appear.
- ✓ If the machine is rebooted with a usable cartridge, Cartridge Restart will be automatically performed.
- ✓ If the machine is rebooted with an unusable cartridge, "Cartridge Expired" status will appear.

Power-On *continued*

Turn on the power, ***continued***

4. Please check 'connect power supply icon' is indicated on the top of the screen.

   Note:

   ✓ If the 'connect power supply icon' does not appear, please check whether the power cable is connected loosely or the electrical outlet has the power.

   ✓ If the 'connect power supply icon' still does not appear when the power cable is plugged into the electrical power outlet, please contact service teams.

5. Please check the analyzer's time and date. If the time and date are incorrect, please update the time and date by referring to ***3. Instrument Settings > Instrument Setup > Date and Time***.

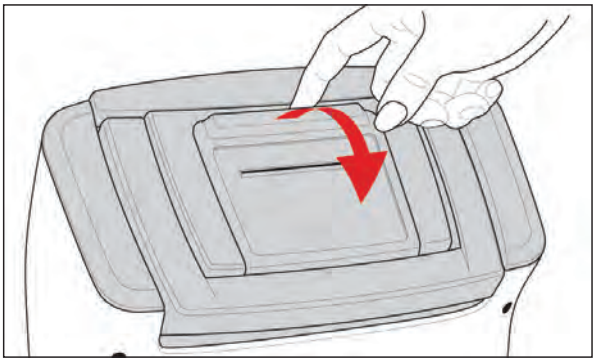
   Note:

   ✓ Changing the analyzer's date and time is only allowed when a cartridge is not installed. Once a cartridge is installed, date and time cannot be changed until the cartridge is removed.

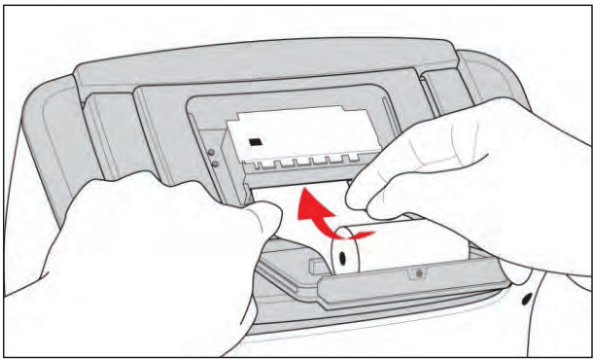
Printer Paper Installation

Install printer paper

1. Facing the back of the analyzer, flip down the printer cover.



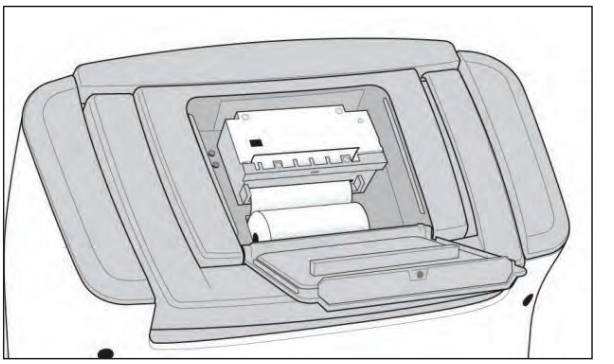
2. Insert the end of the paper in parallel with the printer slot. The printer will begin to feed the paper automatically.



Note:

- ✓ The cut end of the paper should be straight and clean for auto feeding.
- ✓ Paper should be fed from the bottom of the roll.

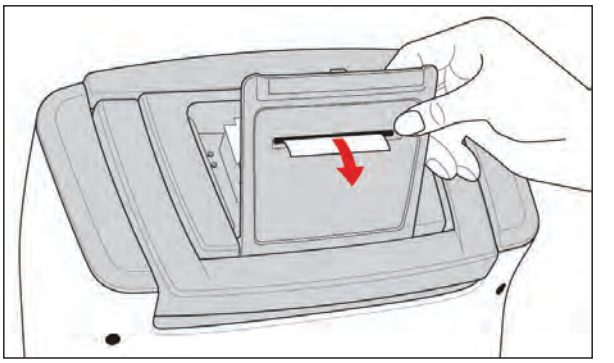
3. Place the paper roll into the paper compartment.



Printer Paper Installation *continued*

Install printer paper, *continued*

4. Insert the end of the paper roll into the paper slot and close the printer cover.



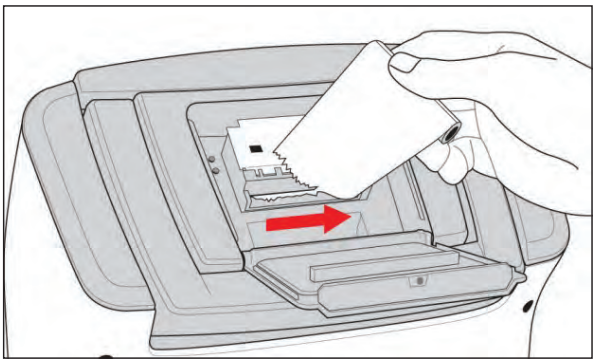
Note:

- ✓ Once the cover is closed, any excess paper out of the printer will cut off automatically.
- ✓ To avoid paper jams, use manufacturer recommended (or supplied) paper.
- ✓ To purchase printer roll paper, contact the reseller.

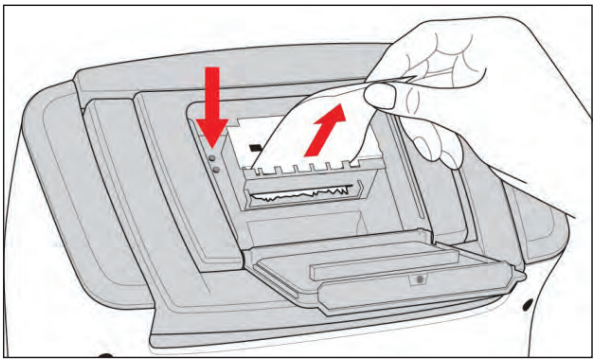
Printer Paper Installation *continued*

Remove Printer Paper

1. Facing the back of the analyzer, flip down the printer cover and remove the remaining paper roll.



2. Hold down the feed switch to advance the remaining paper.



Note:

- ✓ Do not use force to pull out the paper from the printer.
- ✓ Never pull the paper in the reverse direction of printing.

Cartridge Installation

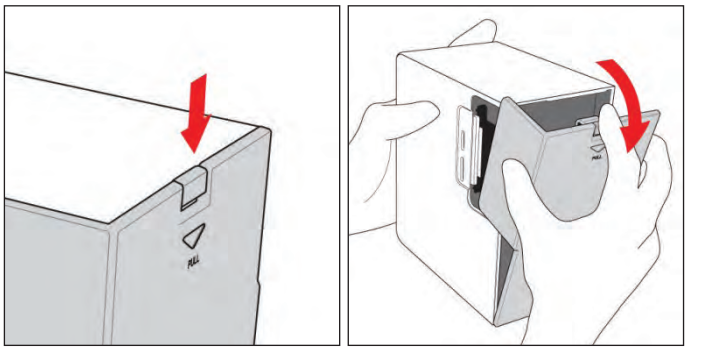
Install Cartridge

Note:

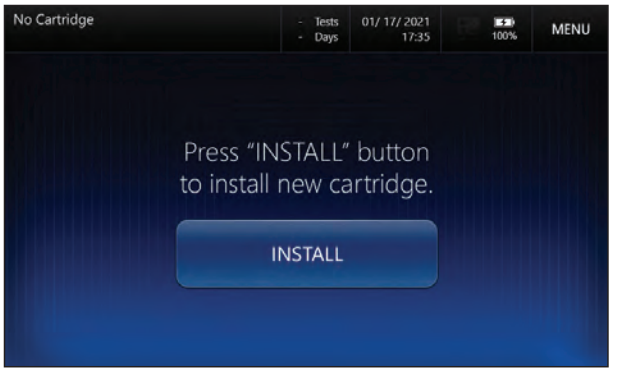
✓ Once the package has been opened, the cartridge should be used immediately. Do not store opened cartridges for later use.

1. Open the cartridge package and remove from the box.

2. Open the cartridge cover by pressing the cover lock button and remove the cover.



3. Following the instruction on the screen, press “INSTALL” button. You will hear the click sound as the cartridge door is unlocked.



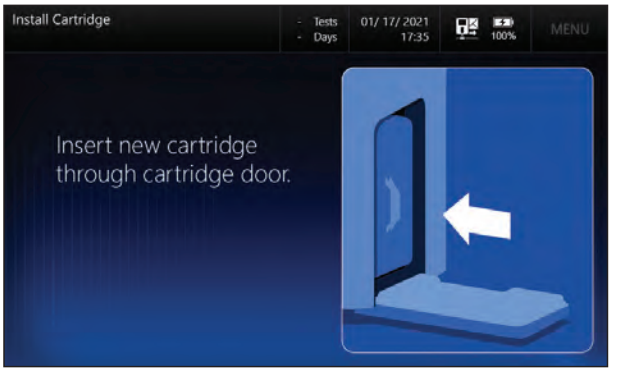
4. Hold the cartridge door lock with two fingers and open the door.

Cartridge Installation *continued*

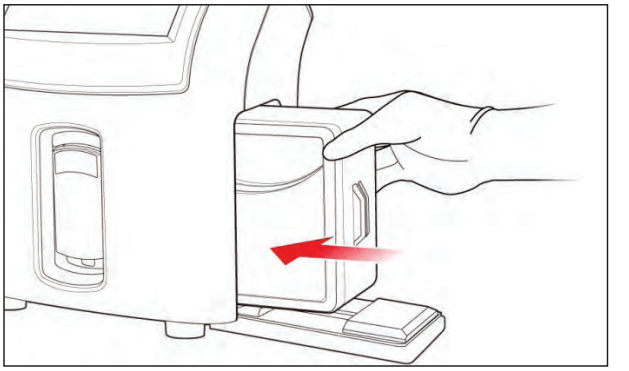
Install Cartridge, *continued*

5. When the "***Scan new cartridge barcode.***" message appears, scan the barcode on the new cartridge using the barcode scanner.

6. If the barcode is valid, "***Insert new cartridge through cartridge door.***" message appears.



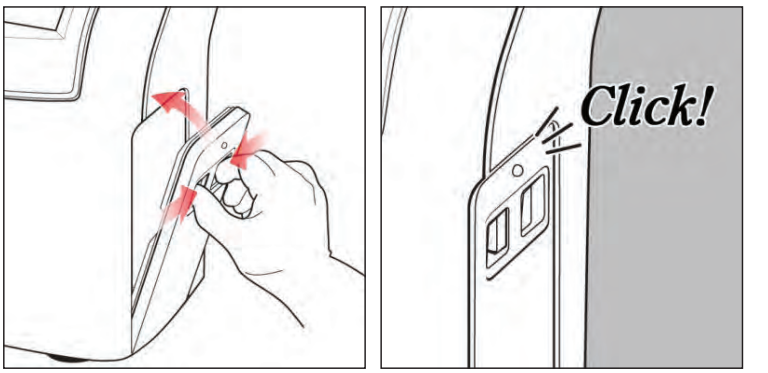
7. Facing the cartridge label, insert the cartridge into the analyzer.



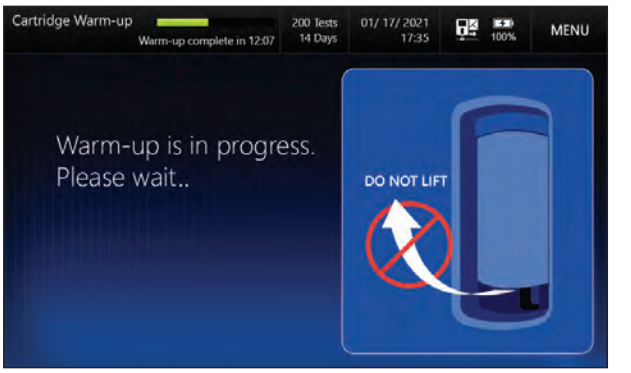
Cartridge Installation *continued*

Install Cartridge, *continued*

8. When "***Close cartridge door and wait for a few seconds***" message appears, close the door. You will hear 'click' locking sound if the door has been closed normally.



9. Cartridge **Warm-Up** will begin.



10. Warming up the new cartridge takes about 21 minutes.

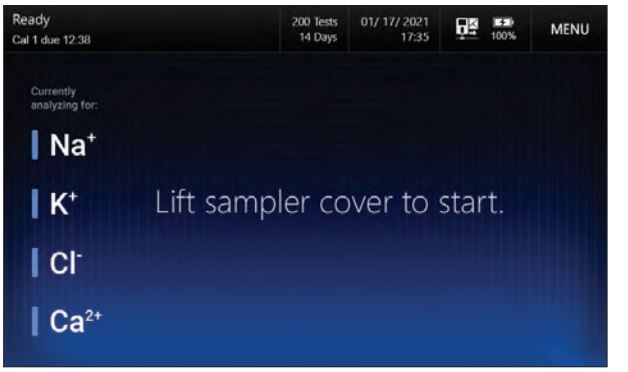
Note:

- ✓ Caution on the sharp edges exposed after the cartridge cover is removed.
- ✓ The sampler cover is locked when it is not **Ready**.

Cartridge Installation *continued*

Install Cartridge, *continued*

11. When **Cartridge Warm-Up** is completed, the following **Ready** screen will appear.



Note:

✓ Depending on the cartridge, the following parameters will appear:

- i-Smart 30 PRO Cartridge: Na^+, K^+, Cl^-
- i-Smart 30 PRO Cartridge E4: Na^+, K^+, Cl^-, Ca^{2+}

✓ Depending on the status of the cartridge sensor, the sensor color may be displayed in **red**. Refer to ***7. Maintenance > Calibration*** for details.

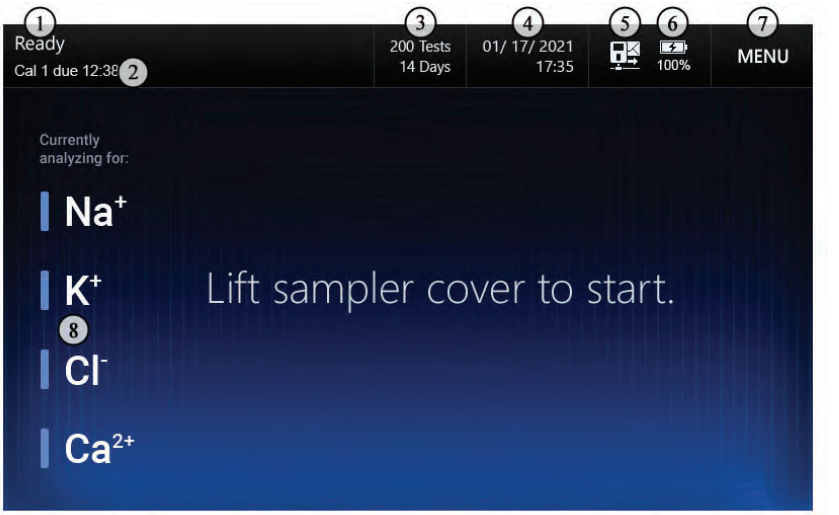
This page is intentionally left blank

3. Instrument Settings

Screen Menu 30
Instrument Setup 38
Parameter Setup 44
Unit Setup 45
Sample Setup 46
QC Setup 52
L-J Chart Setup 55
Interface Setup 57

Screen Menu

Ready Screen



No.	Description
①	Current screen name(Status)
②	Analyzer operation schedule
③	Remaining test number of the installed cartridge / Remaining days until expiration of the installed cartridge
④	Current date and time
⑤	Interface setup status
⑥	Power connect status / Battery status
⑦	Menu button
⑧	Current status of each sensor Pressing each button twice will display the latest slope of the sensor.

Screen Menu, *continued*

Using Menu

1. Touch **MENU** to display the menu options (SAMPLE, QC, CALIBRATION, STATUS and SETUP), and REPLACE CARTRIDGE and SHUTDOWN buttons on the screen.

2. Select a menu option to access more options.

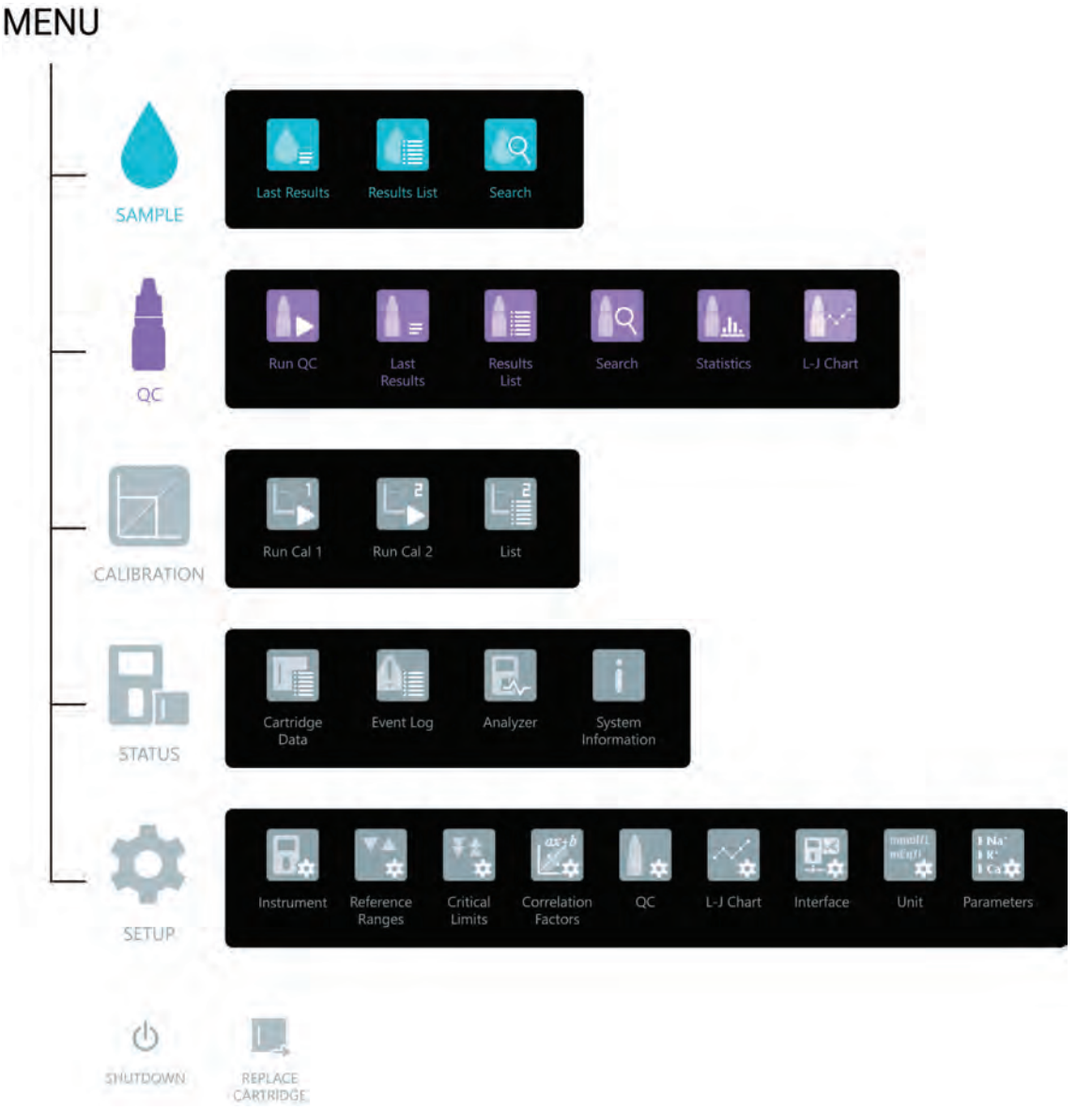
Note:

✓ The **MENU** button is disabled on the following screens:

- Install Cartridge, Remove Cartridge
- Introduce Blood Sample
- Introduce Urine Sample
- Run Sampling
- Sample – Results
- Introduce QC Sample
- QC - Results

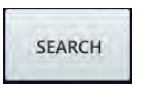
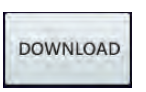
Screen Menu, *continued*

Menu options



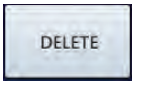
Screen Menu, *continued*

Icons and buttons

Button, Icons	Function
	Print results or settings on screen
	Transmit results to LIS/HIS
	Cancel and return to main screen
	Go to the list screen
	Go to the search screen
	View result screen
	Scroll to previous/next page from the list
	Go to previous/next result screen
	Execute search
	Download data to USB

Screen Menu, *continued*

Icons and buttons, *continued*

Button, Icons	Function
	Run 1-point calibration or 2-point calibration
	Run QC sampling
	Accept or discard QC results
	Delete QC Lot information
	Scan QC barcode
	Delete all information entered in the current tab
	Restore default values
	OK
	Save
	Return to the previous screen
	Copy cartridge data to USB

Screen Menu, *continued*

Icons and buttons, *continued*

Button, Icon	Description
	Deselect an item on the list
	Select an item on the list
	Items sent to LIS/HIS
	Select the items to be sent to LIS/ HIS
	Scan barcode for data entry
	Show keyboard for data entry
	Show number keypad for data entry
	Enable the interface
	Connect to power supply
	Battery level

Screen Menu, *continued*

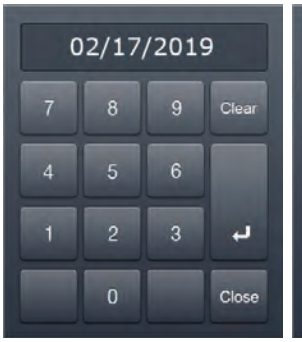
Keyboards

i-Smart 30 PRO Electrolyte Analyzer will display the keyboard as follows on the screen.

Alphabet keyboard

Numbers and special characters keyboard

Date entry keypad



Time entry keypad

Numeric keypad

Screen Menu, *continued*

Screen Saver

When the analyzer is inactive longer than 10 minutes, the screen saver will be turned on and the LCD screen brightness will be adjusted to dim.

Note:

- ✓ Screen Saver is disabled on the **Sample-Results** and **QC-Results** screens.

Message

On analyzer screens, the following messages will appear for the detailed information:

- ✓ Function about to be performed in the analyzer or the current function.
- ✓ Steps the operator needs to follow such as sample collection or cartridge replacement.
- ✓ Error messages.

Voice guide

The analyzer is equipped with a voice guidance feature. The following instructions are available for the voice guidance.

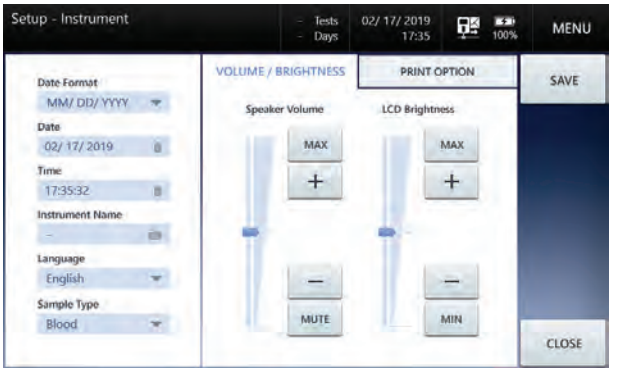
- ✓ Blood sample introduction
- ✓ Urine sample introduction
- ✓ QC sample introduction
- ✓ Cartridge removal
- ✓ Cartridge installation
- ✓ Cartridge data copy
- ✓ Battery status information: "**The battery is low**"
  (When the voice informs, please connect the system to the power supply immediately. The analyzer will shut down automatically unless you reconnect the system to the power supply.)

Instrument Setup

Date and Time

1. Go to **MENU > SETUP > Instrument.**

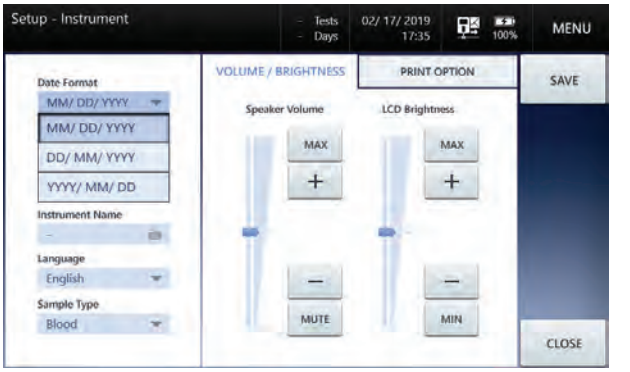
2. Date format, Date, Time, Instrument Name, Language, Sample Type, Speaker volume, LCD brightness and Print Option can be adjusted under the **Setup - Instrument**.



Note:

✓ Date format, Date and Time can be setup only when the cartridge is not installed. Once the cartridge is installed, the set up for these 3 items will be inactive.

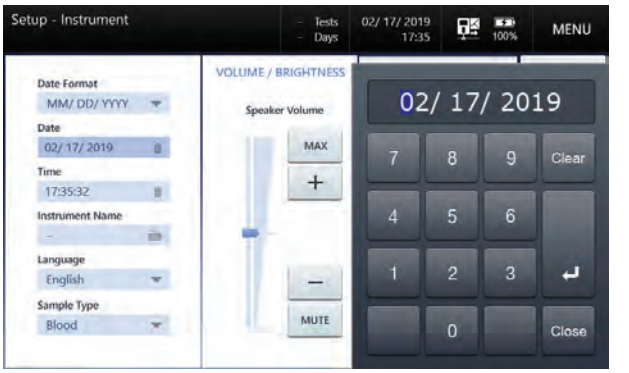
3. Press **Date Format** box and select the desired date format from the drop-down list.



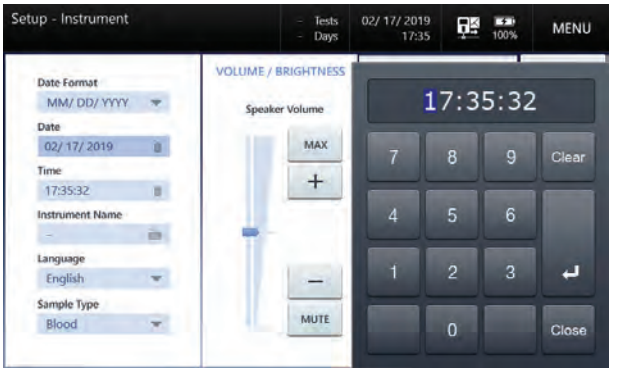
Instrument Setup, *continued*

Date and Time, *continued*

4. Press **Date** box and enter the current date using the keyboard.



5. Press **Time** box and enter the current local time using the keyboard.

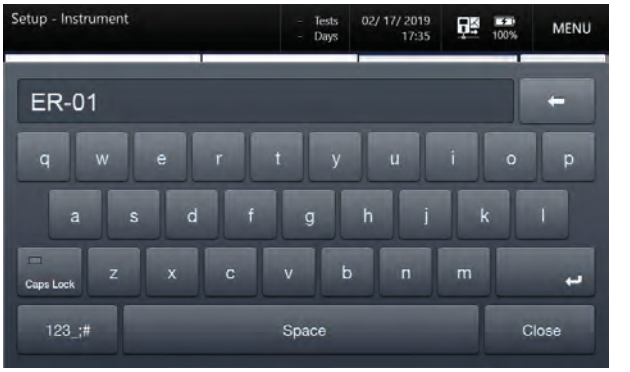


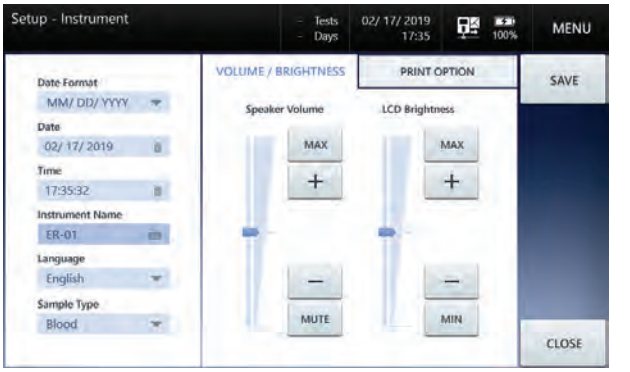
6. Press **SAVE** to save the setup and exit to main screen.

Instrument Setup, *continued*

Instrument Name

1. Press **Instrument Name** box and enter the desired name using the keyboard.





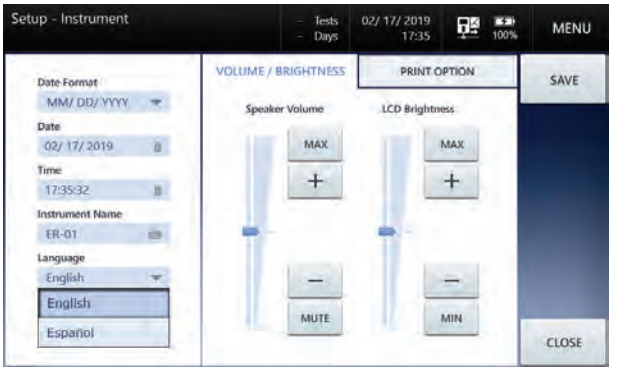
Note:

✓ The entered instrument name will appear on Status- System Information screen, printouts and interface messages.

Instrument Setup, *continued*

Language

1. To change the language, press **Language** box and select the desired language from the drop-down list.

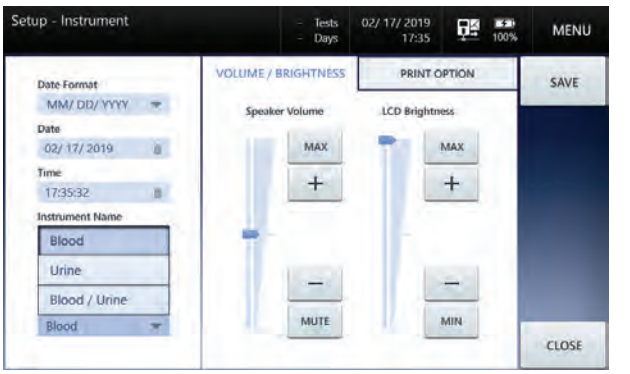


Note:

- ✓ Currently supported languages are **English** and **Spanish**.
- ✓ The selected language applies to the **UI**, **voice** and **print output**.

Sample Type

1. To change the sample type, press **Sample Type** box and select the desired type from the drop-down list.



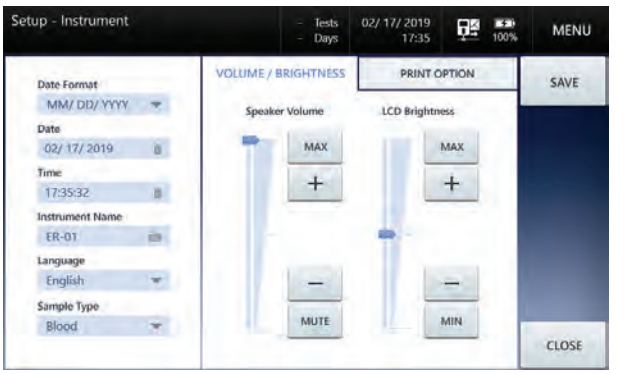
Note:

- ✓ Default is **Blood**.
- ✓ Selecting **Blood** will only allow an examination of blood sample.
- ✓ Selecting **Urine** will only allow an examination of urine sample.
- ✓ By selecting **Blood** / **Urine**, you can select either blood sample or urine sample at the beginning of the test.

Instrument Setup, *continued*

Speaker Volume

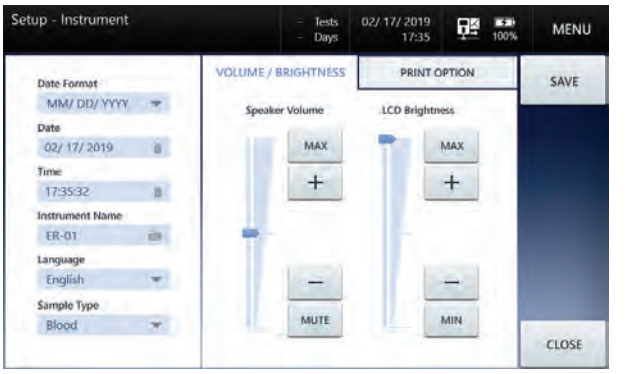
1. To adjust speaker volume, press + or — button under **Speaker Volume**.



2. Using MUTE or MAX button to mute the sound or set to the max volume.

LCD Brightness Setup

1. The LCD screen brightness can be adjusted to 15 different levels using + and — buttons under **LCD Brightness**.



Note:

✓ Use **MIN** or **MAX** button to set the LCD to the brightest and dim setting.

2. Press **SAVE** to save the setup and exit to main screen.

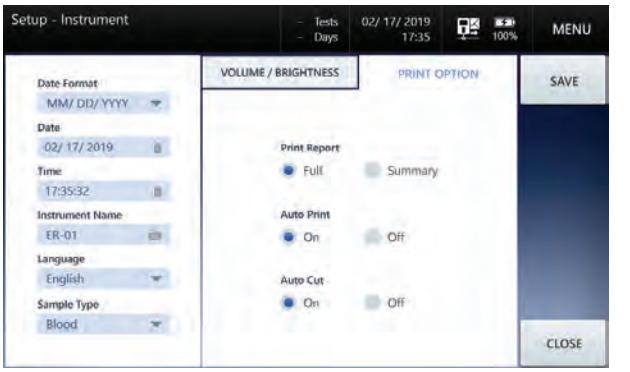
Note:

✓ Press **CLOSE** button to return to the main menu without saving the changed settings.

Instrument Setup, *continued*

Print Setup

1. Select **PRINT OPTION** tab. The following screen will appear.



2. Select **Full** or **Summary** for a report of the sample and QC data results.

   Note:

   ✓ Selecting **Summary** will only print the information entered.

3. Select **On** or **Off** for Auto Print.

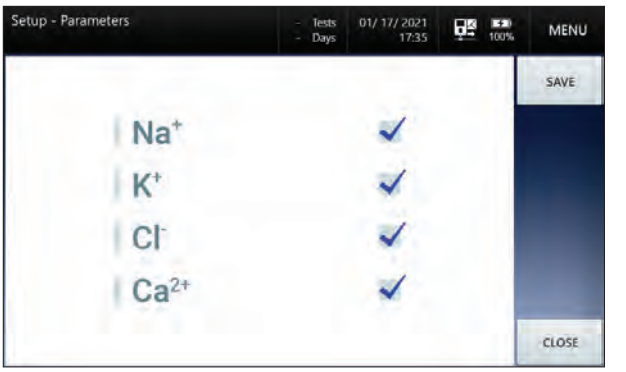
4. Select **On** or **Off** for Auto Cut.

5. Press **SAVE** to save the setup and exit to main screen.

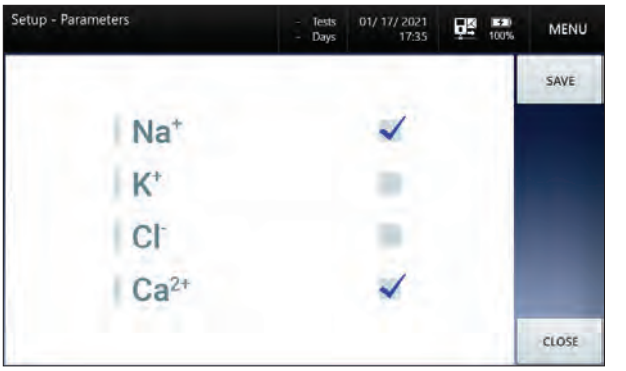
Parameter Setup

Parameter Setup

1. Select **MENU > Setup > Parameters**. The following screen will appear.



2. The parameters to be tested by the analyzer can be entered by selecting desired items from the Measured Parameters shown on the **Setup - Parameters** screen.



3. Press **Save** to save the setup and go back to the **main** screen.

Note:

✓ The selected parameters from the Parameter Setup will impact the followings:

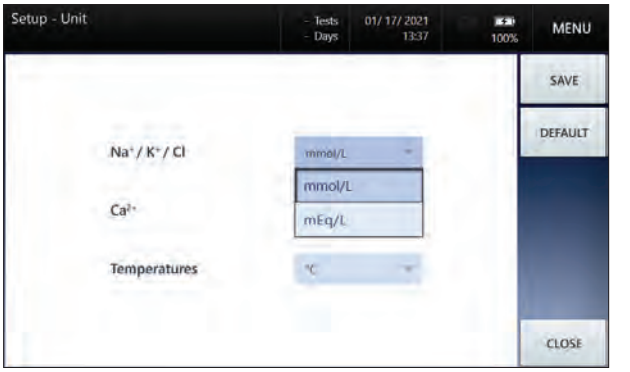
- Main screen and Result screen.
- Parameter setup in sample analysis
- Calibration - List.
- Sample and QC result print.

Unit Setup

Unit Setup

1. Select **MENU > SETUP > Unit**. The following screen will appear.

2. Units of parameters used in the analyzer can be selected from the drop down lists.



Note:

✓ Available options for parameter units are as follows.

Parameter	Default Unit	Optional Unit	
Na^+ / K^+ / Cl^-	mmol/L	mEq/L	
Ca^{2+}	mmol/L	mEq/L	mg/dL
Temperatures	℃	℉	

✓ The selected unit will be applied to all screens, printout and interface messages.

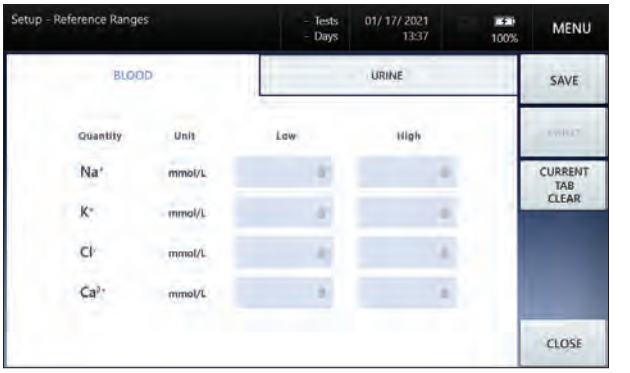
✓ The values in this manual are shown in default units.

3. Press **SAVE** to save the setup and go back to the main screen.

Sample Setup

Reference Range

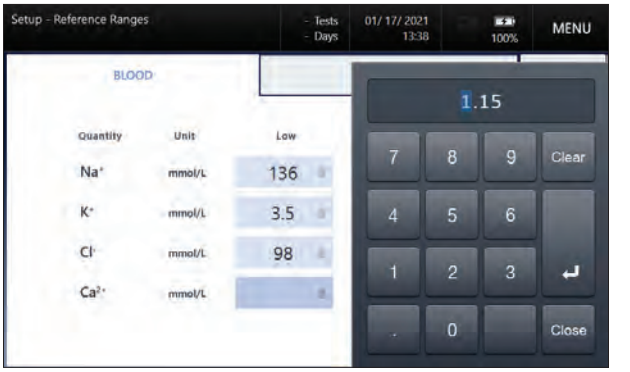
1. Select **MENU > SETUP > Reference Ranges**. The following screen will appear.



Note:

- ✓ The unit selected from **Setup - Unit** will be displayed.
- ✓ The **Reference Ranges** for blood samples and urine samples can be set by selecting the **BLOOD** tap and **URINE** tap, respectively.

2. Using the numeric keypad, enter the low and high range values for each measuring parameters.



Note:

- ✓ Pressing **CURRENT TAB CLEAR** button will erase all values entered in the current tab.
- ✓ Before saving the reference range values, please check if entered values meet the following criteria:
  - − Both low and high values must be entered.
  - − The low value must be lower than the high value.
- ✓ The setup will not save if any value entered is invalid and an error message indicating the cause of the error will appear.

Sample Setup, *continued*

Reference Range, *continued*

3. Press **PRINT** to print out the saved reference ranges.
4. Press **SAVE** to save the setup and go back to the main screen.

Note:

✓ The reference ranges in the table below are shown only as general guidelines for the normal adults. Testing lab or hospital must use their own set values as the reference range.

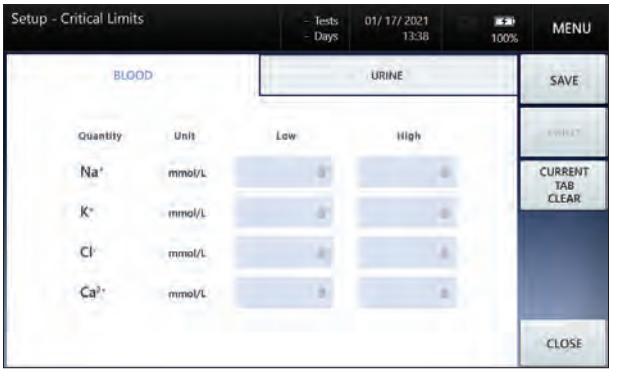
Parameters	Unit	Blood Reference Range	Urine Reference Range
Na^+	mmol/L	136 ~ 145	40 ~ 220
K^+	mmol/L	3.5 ~ 5.1	25.0 ~ 125.0
Cl^-	mmol/L	98 ~ 107	110 ~ 250
Ca^{2+}	mmol/L	1.15 ~ 1.33	-
Reference: TIETZ, Fundamentals of Clinical Chemistry. 6th ed. 2008			

✓ Ca^{2+} results of urine sample are not supported.

Sample Setup, *continued*

Critical Limits

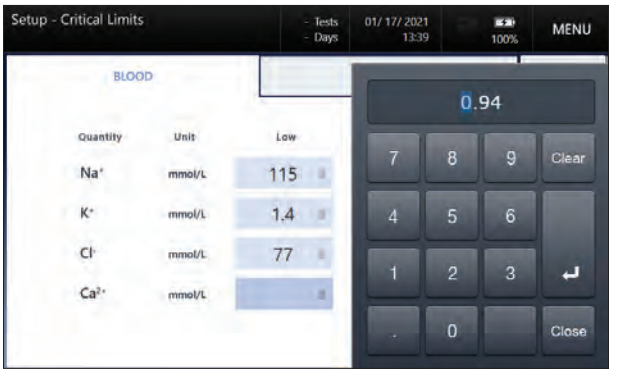
1. Select **MENU > SETUP > Critical Limits**. The following screen will appear.



Note:

- ✓ The unit selected from **Setup - Unit** will be displayed.
- ✓ The **Critical Limits** for blood samples and urine samples can be set by selecting the **BLOOD** tap and **URINE** tap, respectively.

2. Using the numeric keypad, enter low and high values of each parameter's critical limit.



3. Press **Print** to print out the saved critical limits.

4. Press **SAVE** button to apply and save the setup settings and return to the main screen.

Sample Setup, *continued*

Critical Limits, *continued*

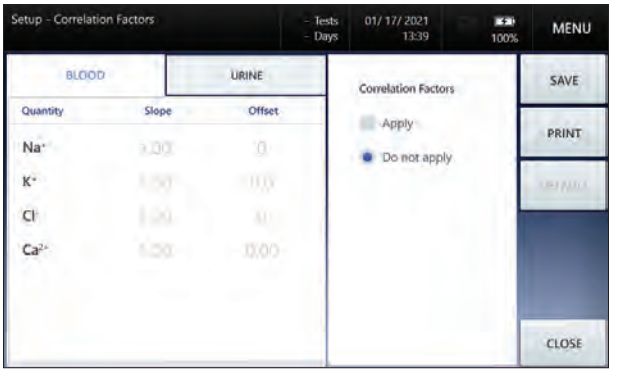
Note:

- ✓ Pressing **CURRENT TAB CLEAR** button will erase all values entered in the current tab.
- ✓ Before saving the reference range values, please check if entered values meet the following criteria:
  - Both low and high values must be entered.
  - The low value must be lower than the high value.
- ✓ The setup will not save if any value entered is invalid and an error message indicating the cause of the error will appear.
- ✓ The high value must be set higher than the high value of the reference range.
- ✓ The low value must be set lower than the low value of the reference range.

Sample Setup, *continued*

Correlation Factors Setup

1. Select **MENU > SETUP > Correlation Factors**. The following screen will appear.



Note:

✓ The **Correlation Factors** for blood samples and urine samples can be set by selecting the **Blood** tap and **Urine** tap, respectively.

2. Select **Apply** on the right and the window with default values will become active.

3. Click each parameters field to enter **Slope** and **Offset** values.

Sample Setup, *continued*

Correlation Factors Setup, *continued*

Note:

✓ Acceptable ranges for slopes and offsets of the correlation factors are as follows:

Parameter	Slope range	Offset range
Na^+	0.80 ~ 1.20	±10
K^+	0.80 ~ 1.20	±1.0
Cl^-	0.80 ~ 1.20	±10
Ca^{2+}	0.80 ~ 1.20	±1.00

4. Press **PRINT** button to print out all saved correlation factor values.

5. Press **SAVE** to save the setup and go back to the main screen.

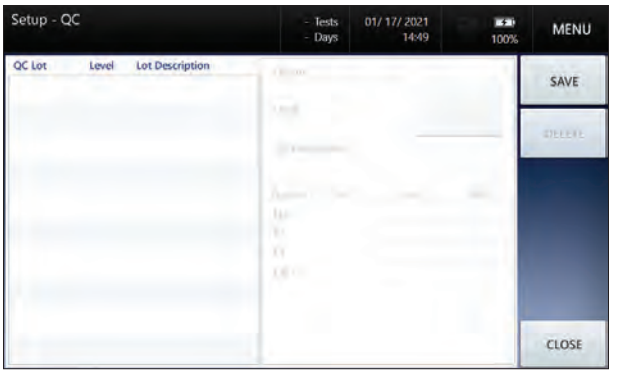
Note:

✓ Pressing **DEFAULT** button will reset all the entered values to default values.

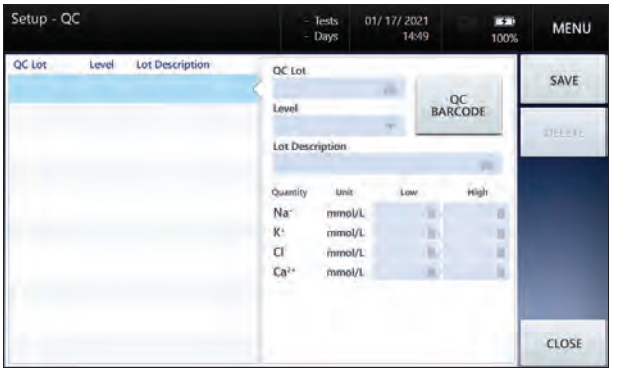
QC Setup

QC Lot Setup

1. Select **MENU > SETUP > QC**. The following screen will appear.



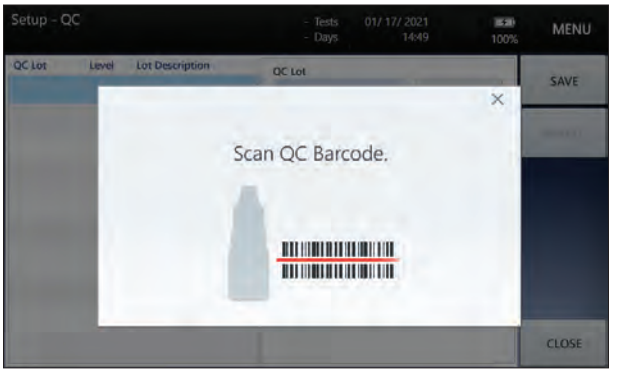
2. Select an empty row on the list located in the left to enable the QC Lot setup window to the right as shown below.



Note:

✓ The unit selected from **Setup - Unit** will be displayed.

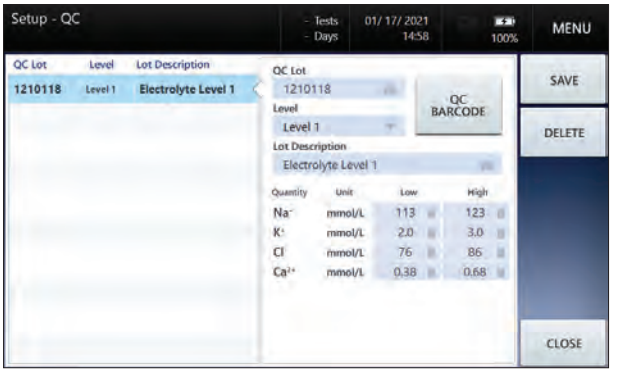
3. When using the QC material with the QC barcode provided by i-SENS, press **QC BARCODE** button. Then, scan the barcode printed on the insert sheet.



QC Setup, *continued*

QC Lot Setup, *continued*

4. QC Lot information will be automatically populated once the QC barcode is recognized.



Note:

✓ When the unit is changed from **Setup - Unit** and the QC Information is manually entered, the QC Range Values are saved automatically in the unit selected from **Setup - Unit**.

5. If it is not QC barcode provided by i-SENS, Enter QC lot information manually.

Note:

✓ When the unit is changed in **Setup - Unit** and the QC Information is manually entered, the QC Range Values must be entered in the changed value.

6. After entering the QC Lot information, choose another row on the list and the entered QC Lot information will be added on the list automatically.

Note:

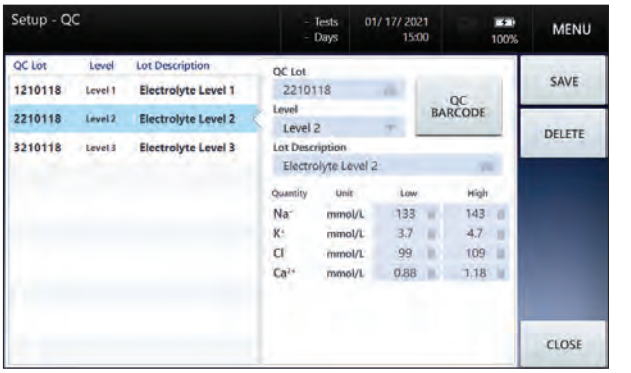
✓ By choosing an empty row on the list to add new QC Lot or select the entered QC Lot information to delete the information.

QC Setup, *continued*

QC Lot Setup, *continued*

7. To delete the entered QC Lot information, select the QC Lot entry to delete and press **DELETE** button.

8. To edit the entered QC Lot information, select the QC Lot from the list and delete the entry using **DELETE** button and reenter with the new QC Lot information.



Note:

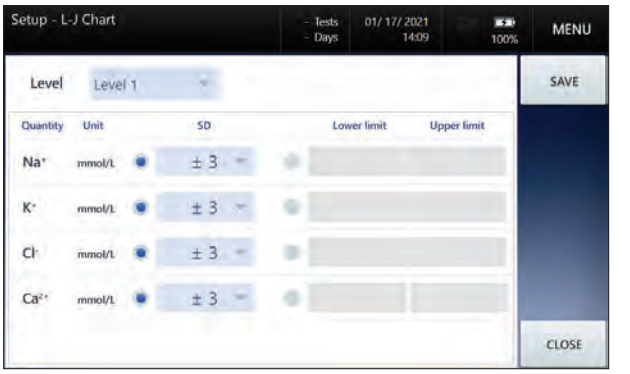
✓ Newly entered or edited QC Lot appears in **bold text**.

9. Press **SAVE** to save all changes and exit to main screen.

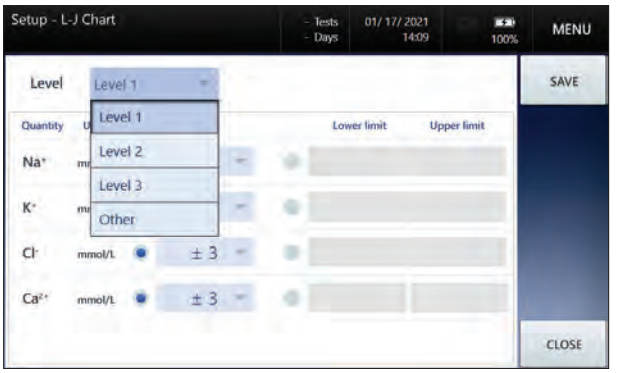
L-J Chart Setup

L-J Chart Setup

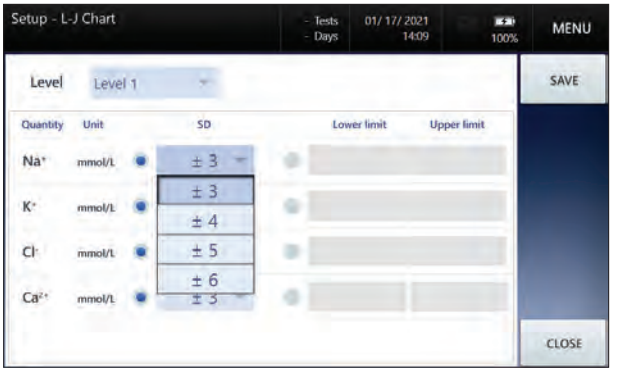
1. Select **MENU > SETUP > L-J Chart**. The following screen will appear.



2. Select QC level on the top of the screen.



3. To setup the SD range, select the SD range in each unit's SD selection field.

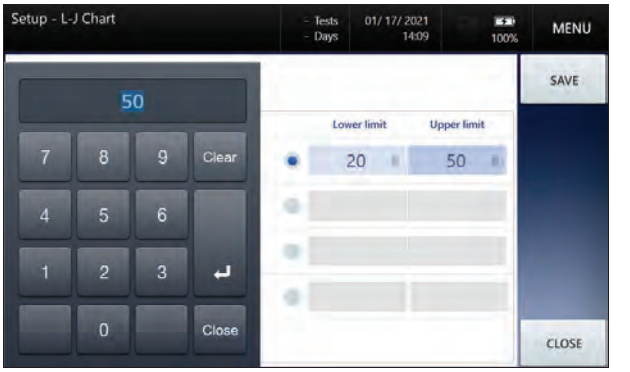


L-J Chart Setup, *continued*

L-J Chart Setup, *continued*

4. To manually setup the lower and high limit, select Lower limit and Upper limit located on the right.

5. Using the numeric keypad, enter low limit and high limit.



6. Press **SAVE** to save the setup and exit to main screen.

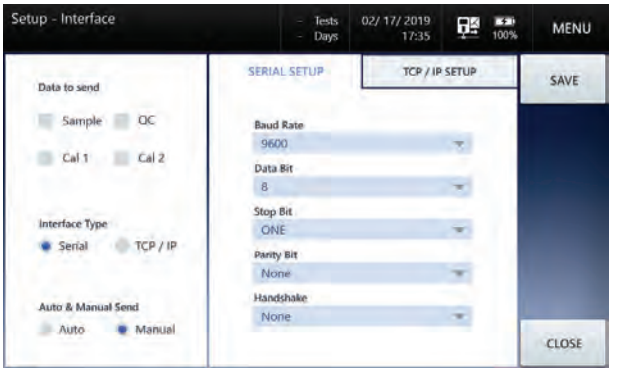
Interface Setup

Option Setup

Note:

✓ Please ensure the serial cable is properly connected to the analyzer before starting the interface set up.

1. Select **MENU > SETUP > Interface**. The following screen will appear.



2. Select the data type to send by checking the box next to the data type (**Sample, QC, Cal 1, Cal 2**).

3. To automatically send the analysis result select **Auto**. To send the selected data by manually pressing SEND button, choose **Manual** option.

4. Set up the **Serial** details.

Serial Setup

1. Press **Baud Rate** box and select the desired option from the drop-down list. Default is 9600.

2. Press **Data Bit** box and select the desired option from the drop-down list. Default is 8.

3. Press **Stop Bit** box and select the desired option from the drop-down list. Default is ONE.

4. Press **Parity box** and select the desired option from the drop-down list. Default is None.

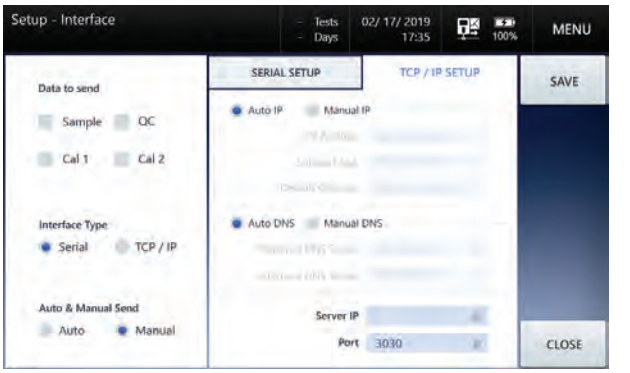
5. Press **Handshake** box and select the desired option from the drop-down list. Default is None.

6. If serial setup is completed, press **SAVE** button. The settings will be saved and return to the main screen.

Interface Setup, *continued*

TCP/IP Setup

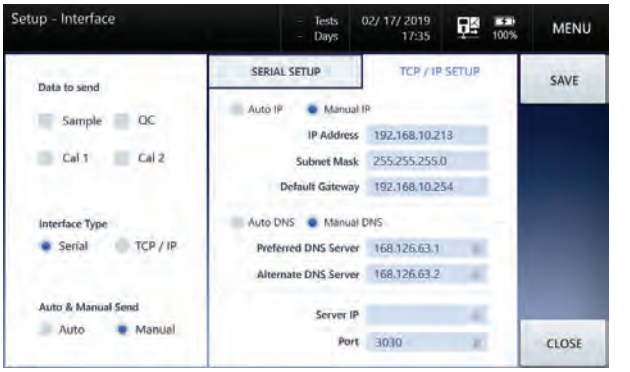
1. Select the **TCP/IP SETUP** tap. The following screen will appear.



Note:

- ✓ If the analyzer is connected to a network. IP information of IP and DNS automatically appears in the TCP/IP SETUP tab.
- ✓ If the analyzer is disconnected from a network. **Disconnected** appears in each item of IP and DNS in the TCP/IP SETUP tab.

2. To manually set up IP and DNS information, select the **Manual IP** and **Manual DNS**.



3. Press **IP entry box** and enter necessary information.

4. Enter other necessary information in order to complete the TCP/IP Setup.

Note:

- ✓ Automatic setup may cause network conflicts. Manual setup is recommended instead of automatic setup.

Interface Setup, *continued*

TCP/IP Setup, *continued*

5. Press **SAVE** to save the settings and return to the main screen.

Note:

✓ If press **CLOSE** button, the changed settings are not saved and return to the main screen.

This page is intentionally left blank

4. Sample Analysis

Blood Sample.....62

Urine Samples.....69

QC Sample.....76

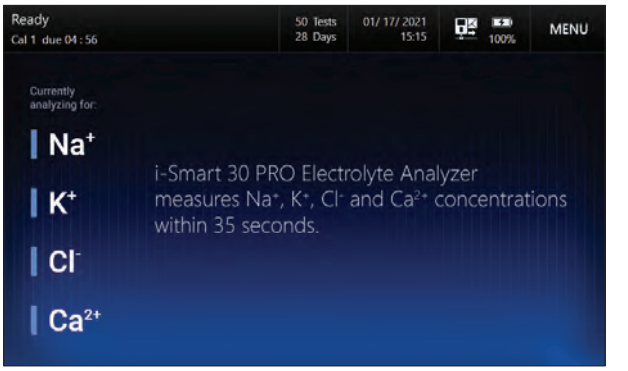
Blood Sample

Introduce Sample

Note:

✓ Sample analysis is available only when the analyzer is in **Ready**. The sampler cover is locked when it is not **Ready**.

1. Check if the analyzer's status is **Ready** on the screen.



2. The introduce sample screen will appear when the sampler cover is lifted.

Note:

✓ To cancel the sample analysis, close the sampler cover to the original position before pressing **START ASPIRATION** button.

Blood Sample, *continued*

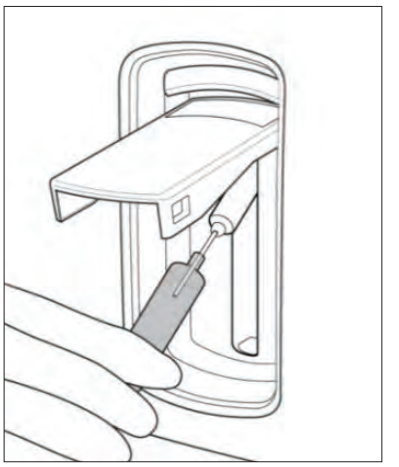
Introduce Sample, *continued*

3. Measured parameters for the sample being analyzed can be changed during the analysis by pressing "**Parameter Setup**" at the bottom of the screen.

Note:

- ✓ Parameter Setup items selected from the Introduce Sample screen apply only to the analysis in progress.
- ✓ The measuring parameters cannot be selected if they had not been selected at the initial Parameter Setup step (***Menu > Setup > Parameters***).
- ✓ To parameter setup, refer to ***3. Instrument Settings > Parameter Setup*** for detailed procedure.

4. Insert the end of the sampler probe into the sample container.



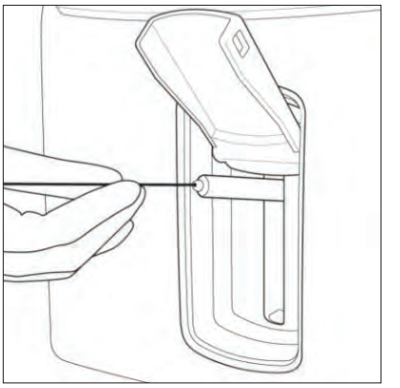
Note:

- ✓ Take precaution and make sure the sample is free of air bubbles, a blood clot or any foreign object and the analyzer is not contaminated.

Blood Sample, *continued*

Introduce Sample, *continued*

5. For a capillary sample, lift the sampler cover all the way up to retract the sample probe until the septum is exposed.



Note:

- ✓ Make sure there is no gap between a capillary tube and a septum so that air bubbles will not be trapped.

6. Once the sampler probe is inserted sample properly, press **START ASPIRATION** button.

Note:

- ✓ For a capillary sample, first remove the capillary end caps, then insert the capillary into the septum, and then press **START ASPIRATION** button.

7. "***Aspirating sample... Please wait***" message will appear as the sample is aspirated into the analyzer.

8. When sample aspiration is complete, the message "***Remove sample now***" will appear. Please remove the sample container from the sampler probe.

9. Please wait until the "***Close sampler cover***" message will appear.

10. Close the sampler cover to the original position.

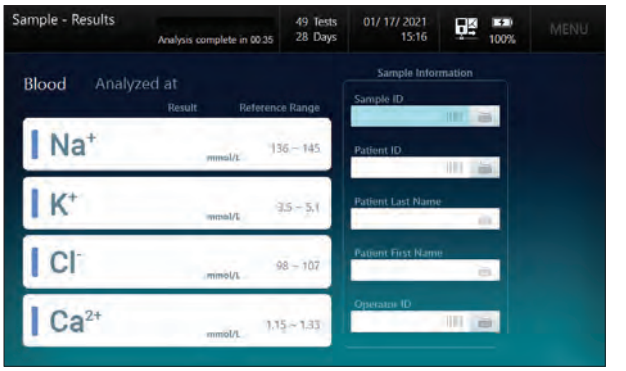
Note:

- ✓ If the sample aspiration process was not done properly or the sample aspiration amount is insufficient, the message "**Insufficient sample error. Sample is being aborted.**" will appear and will not proceed to the **Sample - Results** page.

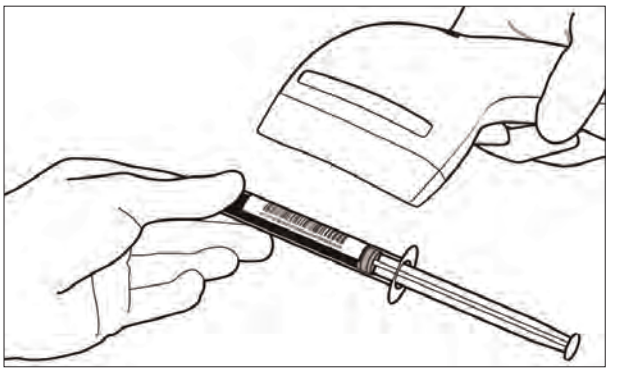
Blood Sample, *continued*

Sample Information

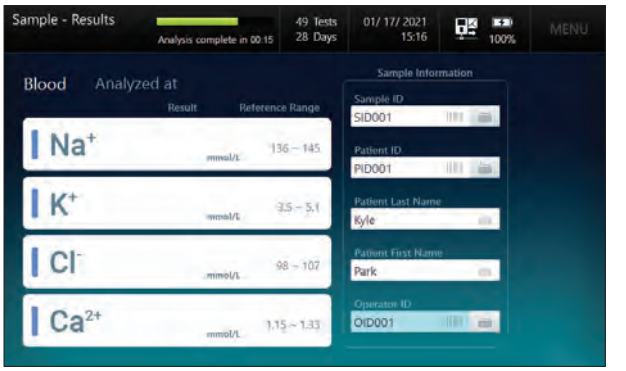
1. Once the sampler cover is closed, the following screen will appear.



2. Scan a barcode to enter information using the barcode scanner.



3. If the barcode scan is difficult, enter information by clicking each item or keyboard button.



Blood Sample, *continued*

Sample Results

Note:

- ✓ Sample - Results Screen, Printouts, and Interface messages will display the units selected from **Setup - Unit**.
- ✓ The Sample Type will be displayed as **Blood** above the result table on the screen.

1. When the sample analysis is complete, the result will appear under the **Sample - Results** screen.

2. If the reference ranges were not set, the result will be indicated in blue.
3. If the reference ranges were set up, the result within the ranges will be indicated in blue.
4. If the result is above the referenced range, the result will be indicated in blue with the ▲ arrow.
5. If the result is below the referenced range, the result will be indicated in blue with the ▼ arrow.

Blood Sample, *continued*

Sample Results, *continued*

6. If the sample result is out of blood critical limit, the result will be indicated in red. If the sample result is above the high limit of the blood critical limit, the result will appear along with a double arrow ⏫, if the result is below the low critical limit, then will be indicated in red along with a double arrow ⏬.

7. When the sample result is out of the measuring range, no result will be shown and the red capital letter **R** will be marked.

   Note:

   ✓ If the result is above the high of the measuring range, will be indicated by red arrow ▲.

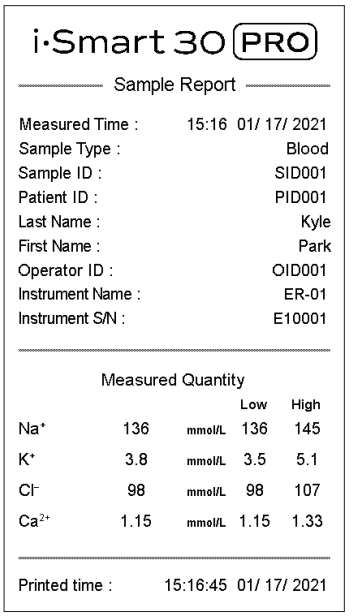
   ✓ If the result is below the low of the measuring range, will be indicated by red arrow ▼.

8. The result with the **Slope Error** will be marked as a red capital letter **S** without value.

Blood Sample, *continued*

Sample Results, *continued*

9. Press **PRINT** to print out the results.
   A printout similar to following will be printed.



i·Smart 30 PRO

Sample Report

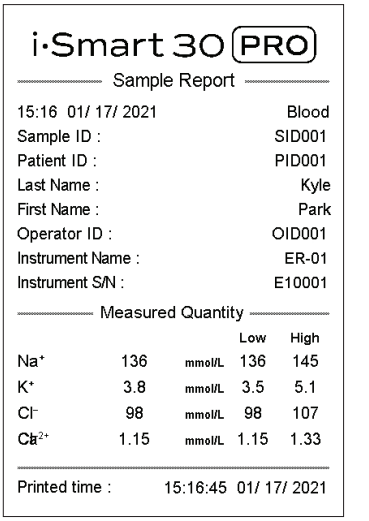
Measured Time :	15:16 01/ 17/ 2021
Sample Type :	Blood
Sample ID :	SID001
Patient ID :	PID001
Last Name :	Kyle
First Name :	Park
Operator ID :	OID001
Instrument Name :	ER-01
Instrument S/N :	E10001

Measured Quantity

			Low	High
Na^+	136	mmol/L	136	145
K^+	3.8	mmol/L	3.5	5.1
Cl^-	98	mmol/L	98	107
Ca^{2+}	1.15	mmol/L	1.15	1.33

Printed time : 15:16:45 01/ 17/ 2021

Full



i·Smart 30 PRO

Sample Report

15:16 01/ 17/ 2021	Blood
Sample ID :	SID001
Patient ID :	PID001
Last Name :	Kyle
First Name :	Park
Operator ID :	OID001
Instrument Name :	ER-01
Instrument S/N :	E10001

Measured Quantity

			Low	High
Na^+	136	mmol/L	136	145
K^+	3.8	mmol/L	3.5	5.1
Cl^-	98	mmol/L	98	107
Ca^{2+}	1.15	mmol/L	1.15	1.33

Printed time : 15:16:45 01/ 17/ 2021

Summary

Note:

- ✓ For blood samples, the Sample Type will be displayed as **Blood** on the printout.
- ✓ When the analyzer is running on a battery, the print function will not be available.
- ✓ When **Summary** is selected in the print option, only the sample information entered will be printed.
- ✓ When the Auto-Print option is set to ON, the sample result will appear on the screen and will be printed in real time.

10. To send the result to LIS/HIS, press **SEND** button.

11. Press **CLOSE** to save the results and exit to main screen.

12. The analyzer will go through **Rinse** and **Cal 1** process before returning to the **Ready** state for a next sample.

Urine Samples

Introduce Urine Sample

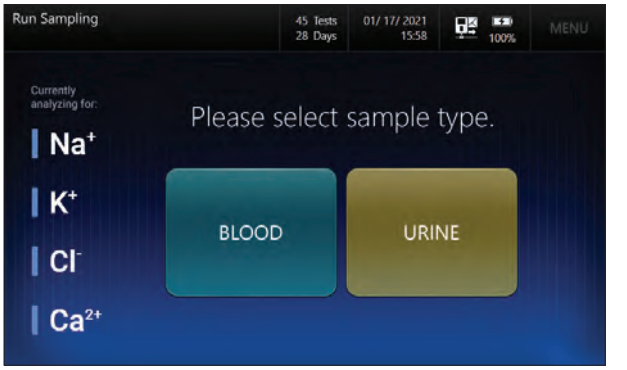
Note:

✓ To analyze the urine sample, select **Urine** or **Blood / Urine** from the **Sample Type** options on the **Setup-Instrument** screen.

✓ Urine samples do not require dilution for analysis.

1. If **Urine** is selected from the **Sample Type** options on the **Setup-Instrument**, the following screen appears when you lift the sampler cover.

2. If **Blood / Urine** is selected from the **Sample Type** options on the **Setup-Instrument**, the following screen appears when you lift the sampler cover.



Note:

✓ Please select BLOOD or URINE according to the sample type.

Urine Samples, *continued*

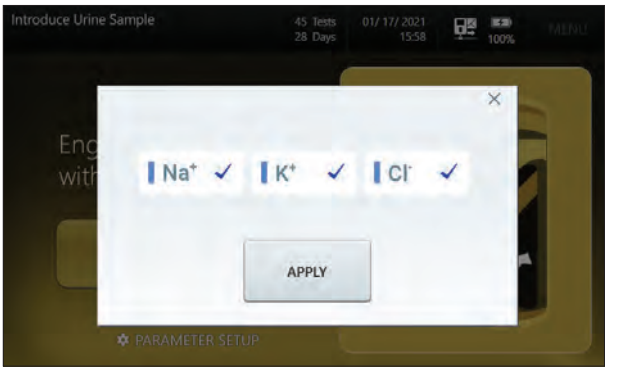
Introduce Urine Sample, *continued*

3. Immerse the end of the sampler probe into the urine sample and press **START ASPIRATION**.

Note:

- ✓ To cancel sample, lower the sampler cover to the original position before pressing **START ASPIRATION**.

4. Measured parameters for the sample being analyzed can be changed during the analysis by pressing "**Parameter Setup**" at the bottom of the screen.



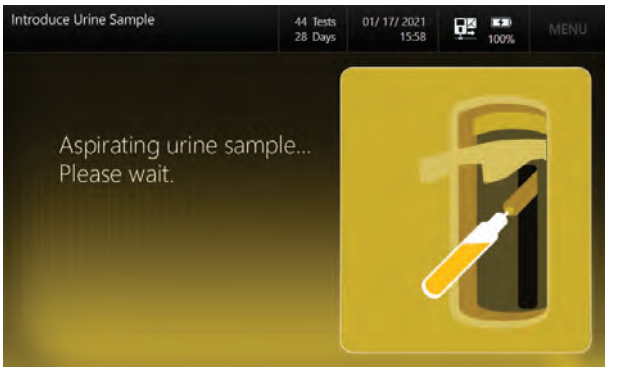
Note:

- ✓ Parameter Setup items selected from the Introduce Sample screen apply only to the analysis in progress.
- ✓ The measuring parameters cannot be selected if they had not been selected at the initial Parameter Setup step (***Menu > Setup > Parameters***).
- ✓ To parameter setup, refer to ***3. Instrument Settings > Parameter Setup*** for detailed procedure.

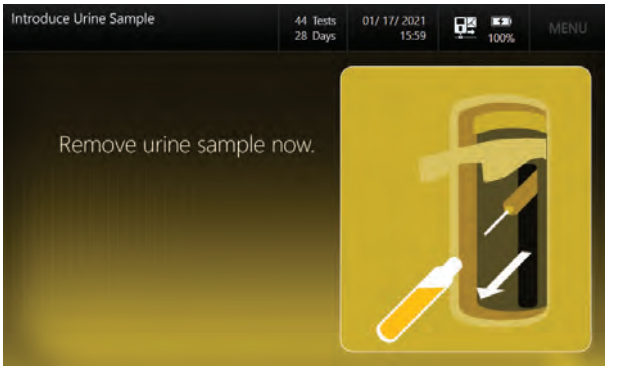
Urine Samples, *continued*

Introduce Urine Sample, *continued*

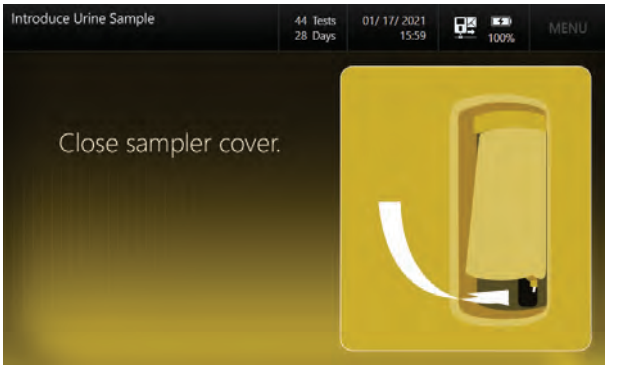
5. The "***Aspirating urine sample... Please wait***" message will appear.



6. If the aspiration is completed, the "***Remove urine sample now***" message will appear. Remove urine sample from the sampler probe.



7. Wait a second until the "***Close sampler cover***" message will appear.

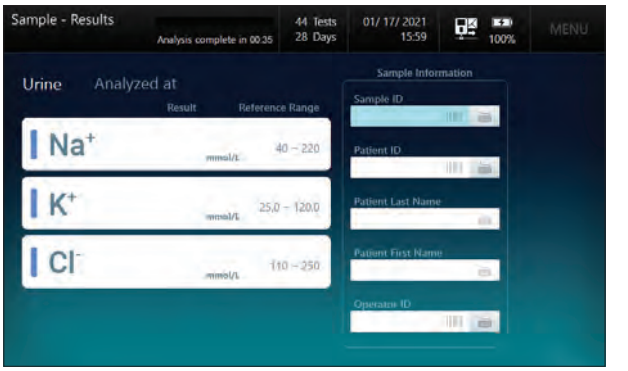


8. Push down the sampler cover to the original position.

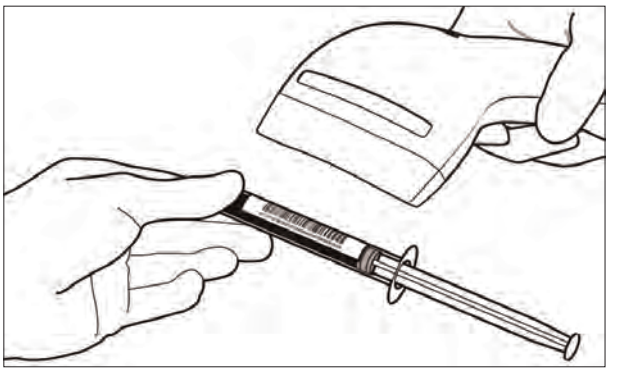
Urine Samples, *continued*

Urine Sample Information

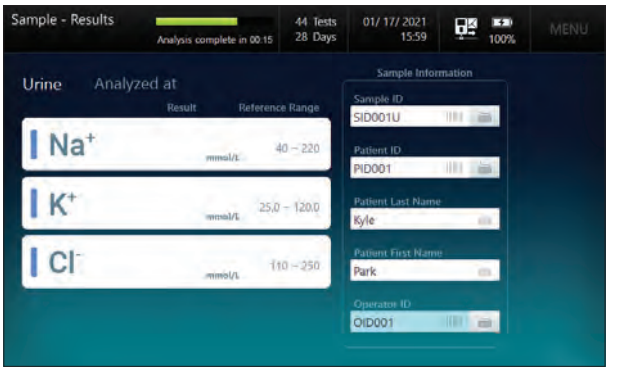
1. Once the sampler cover is closed, the following screen will appear.



2. Scan a barcode to enter information using the barcode scanner.



3. If the barcode scan is difficult, enter information by clicking each item or keyboard button.



Urine Samples, *continued*

Urine Sample Results

Note:

- ✓ Sample - Results Screen, Printouts, and Interface messages will display the units selected from **Setup - Unit**.
- ✓ For urine samples, the Sample Type will be displayed as **Urine** above the result table on the screen.
- ✓ Ca^{2+} results of urine sample are not supported.

1. When the urine sample analysis is complete, the result will appear under the **Sample - Results** screen.

2. If the urine reference ranges were not set, the result will be indicated in blue.

3. If the urine reference ranges were set up, the result within the ranges will be indicated in blue.

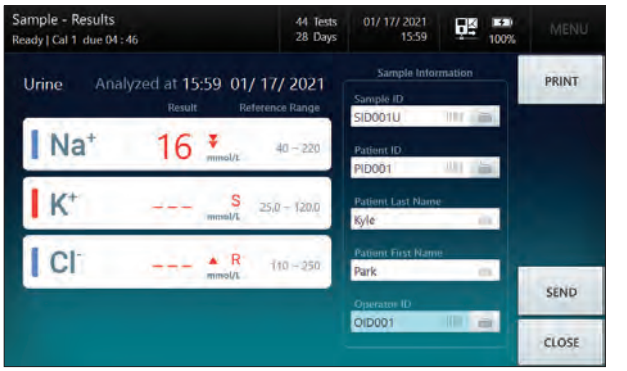
4. If the result is above the urine referenced range, the result will be indicated in blue with the ▲ arrow.

5. If the result is below the urine referenced range, the result will be indicated in blue with the ▼ arrow.

Urine Samples, *continued*

Urine Sample Results, *continued*

6. If the sample result is out of urine critical limit, the result will be indicated in red. If the sample result is above the high limit of the urine critical limit, the result will appear along with a double arrow ⏫, if the result is below the low critical limit, then will be indicated in red along with a double arrow ⏬.



7. When the sample result is out of the measuring range, no result will be shown and the red capital letter **R** will be marked.

   Note:

   ✓ If the result is above the high of the measuring range, will be indicated by red arrow ▲.

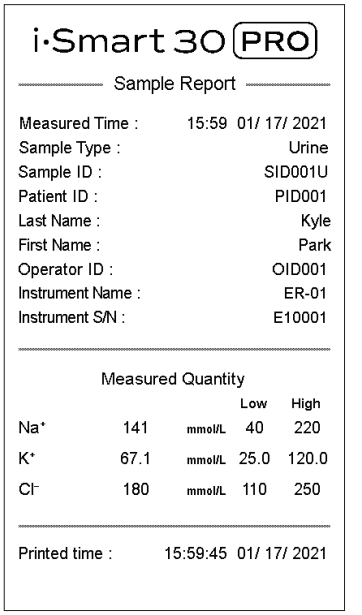
   ✓ If the result is below the low of the measuring range, will be indicated by red arrow ▼.

8. The result with the **Slope Error** will be marked as a red capital letter **S** without value.

Urine Samples, *continued*

Urine Sample Results, *continued*

9. Press **PRINT** to print out the results.
   A printout similar to following will be printed.


i-Smart 30 PRO

Sample Report

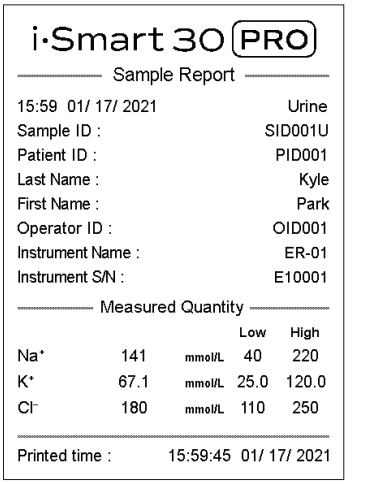
Measured Time :	15:59 01/ 17/ 2021
Sample Type :	Urine
Sample ID :	SID001U
Patient ID :	PID001
Last Name :	Kyle
First Name :	Park
Operator ID :	OID001
Instrument Name :	ER-01
Instrument S/N :	E10001

Measured Quantity

			Low	High
Na^+	141	mmol/L	40	220
K^+	67.1	mmol/L	25.0	120.0
Cl^-	180	mmol/L	110	250

Printed time : 15:59:45 01/ 17/ 2021

Full


i-Smart 30 PRO

Sample Report

15:59 01/ 17/ 2021	Urine
Sample ID :	SID001U
Patient ID :	PID001
Last Name :	Kyle
First Name :	Park
Operator ID :	OID001
Instrument Name :	ER-01
Instrument S/N :	E10001

Measured Quantity

			Low	High
Na^+	141	mmol/L	40	220
K^+	67.1	mmol/L	25.0	120.0
Cl^-	180	mmol/L	110	250

Printed time : 15:59:45 01/ 17/ 2021

Summary

Note:

- ✓ For urine samples, the Sample Type will be displayed as **Urine** on the printout.
- ✓ When the analyzer is running on a battery, the print function will not be available.
- ✓ When **Summary** is selected in the print option, only the sample information entered will be printed.
- ✓ When the Auto-Print option is set to ON, the sample result will appear on the screen and will be printed in real time.

10. To send the result to LIS/HIS, press **SEND** button.

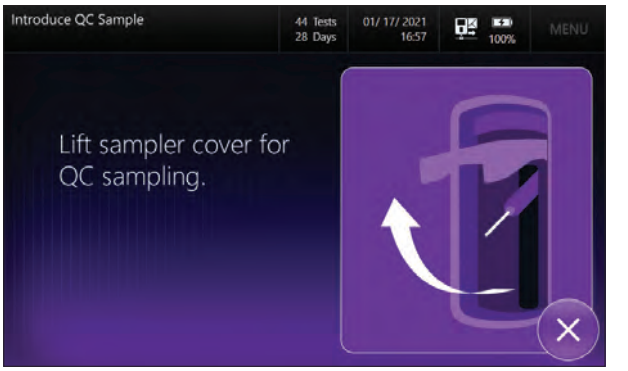
11. Press **CLOSE** to save the results and exit to main screen.

12. The analyzer will go through **Rinse** and **Cal 1** process before returning to the **Ready** state for a next sample.

QC Sample

Introduce QC sample

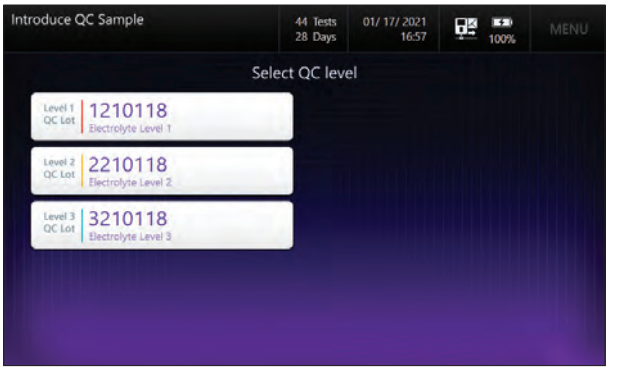
1. Press **MENU > QC > Run QC** to proceed with QC sampling. The following screen will appear.



Note:

- ✓ **Run QC** can be performed under the **Setup - QC** when the **QC Lot** is set up.
- ✓ If idle more than 60 seconds at the "***Lift sampler cover for QC sampling***" screen, it will go back to Ready screen.

2. Lift up the sampler cover and the following screen will appear.



3. Select the level of the QC sample.

QC Sample, *continued*

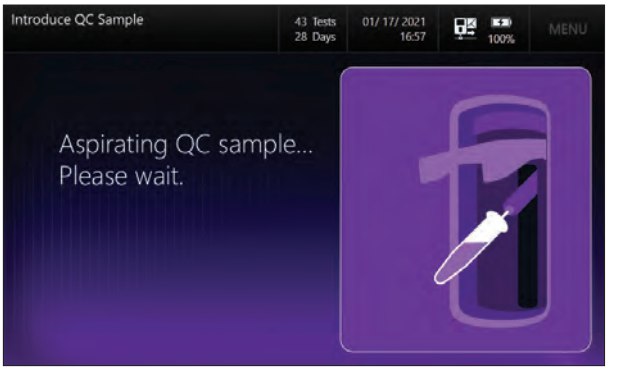
Introduce QC sample, *continued*

4. When the message "***Engage QC sample with the sampler probe***" appears, insert the end of the Sampler probe into the QC sample, and press **START ASPIRATION** button.

Note:

- ✓ To cancel QC sample analysis, close the sampler cover to the original position without pressing the **START ASPIRATION** button.
- ✓ Once **START ASPIRATION** is pressed, the QC sample analysis cannot be cancelled.

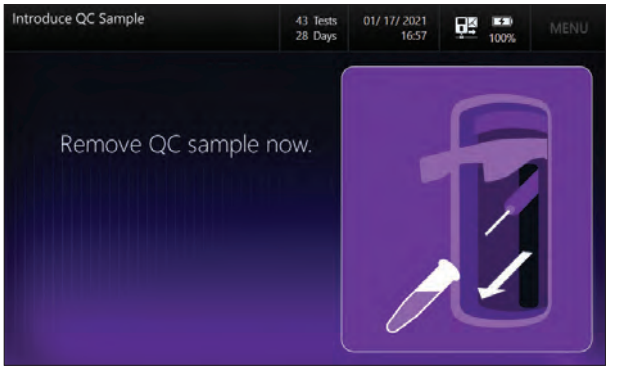
5. The "***Aspirating QC sample... Please wait***" message will appear as the QC Sample is being aspirated.



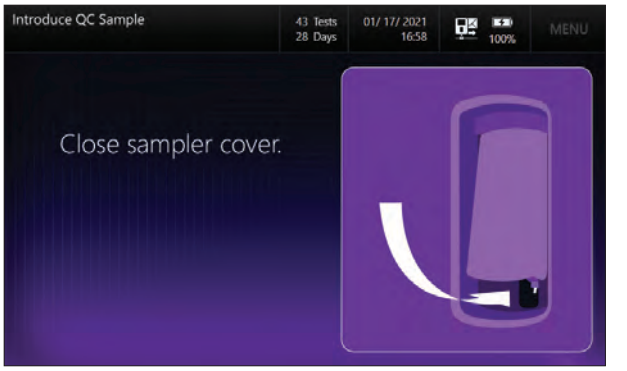
QC Sample, *continued*

Introduce QC sample, *continued*

6. Once the aspiration is complete, "***Remove QC sample now***" message will appear. Please remove the QC sample from the sampler probe.



7. Wait momentarily until the "***Close sampler cover***" message appears.



8. Close the sampler cover to the original position.

QC Sample, *continued*

QC Results

Note:

✓ QC screen results, Printouts, and Interface messages will display the unit selected from **Setup - Unit**.

1. When QC sample analysis is complete, the following screen will appear.

Note:

✓ If the result is within the QC range, the result will display in blue.

✓ If the result is above the QC range, the result will display in red, with the ▲ arrow.

✓ If the result is below the QC range, the result will display in red, with the ▼ arrow.

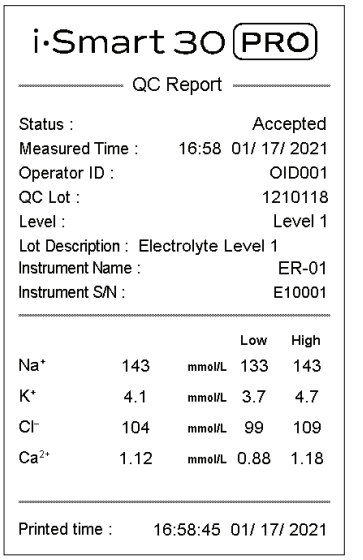
2. If needed, enter the **Operator ID** using the barcode or on- screen keyboard.

3. Depends on the QC results, press either the **ACCEPT** or **DISCARD** button. The result status will change from Pending to **Accepted** or **Discarded**.

QC Sample, *continued*

QC Results, *continued*

4. Press **PRINT** to print out the results. A printout similar to following will be printed.

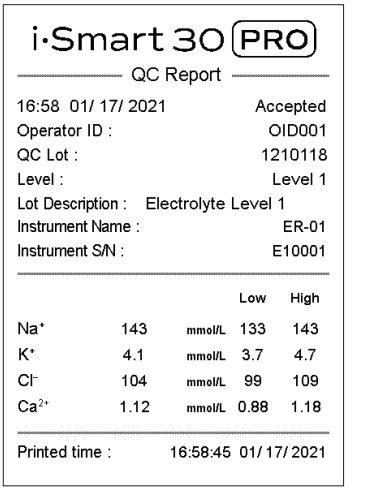


i·Smart 30 PRO

QC Report

Status :				Accepted
Measured Time :				16:58 01/ 17/ 2021
Operator ID :				OID001
QC Lot :				1210118
Level :				Level 1
Lot Description :	Electrolyte Level 1			
Instrument Name :				ER-01
Instrument S/N :				E10001
			Low	High
Na^+	143	mmol/L	133	143
K^+	4.1	mmol/L	3.7	4.7
Cl^-	104	mmol/L	99	109
Ca^{2+}	1.12	mmol/L	0.88	1.18
Printed time :				16:58:45 01/ 17/ 2021

Full



i·Smart 30 PRO

QC Report

16:58 01/ 17/ 2021				Accepted
Operator ID :				OID001
QC Lot :				1210118
Level :				Level 1
Lot Description :	Electrolyte Level 1			
Instrument Name :				ER-01
Instrument S/N :				E10001
			Low	High
Na^+	143	mmol/L	133	143
K^+	4.1	mmol/L	3.7	4.7
Cl^-	104	mmol/L	99	109
Ca^{2+}	1.12	mmol/L	0.88	1.18
Printed time :				16:58:45 01/ 17/ 2021

Summary

Note:

- ✓ When the analyzer is running on a battery, the print function will not be available.
- ✓ When **Summary** is selected in the print option, only the QC information entered will be printed.

5. To send the result to LIS/HIS, press **SEND** button.

6. Press **CLOSE** to save the results and return to main screen.

5. Database

Sample Data.....82

QC Data 86

Calibration Data 92

Cartridge Data.....93

Sample Data

Last Sample Results

Note:

✓ Screen Sample Results, Printouts, and Interface messages will display the unit selected from **Setup - Unit**.

1. Select **MENU > SAMPLE >Last Results**. The following screen will appear.

2. Press **NEXT**, **PREV** to see the next and previous results.
3. Press **LIST** to go to the list of Sample results.
4. Press **SEND** button to send results to LIS/HIS.
5. Press **CLOSE** to exit to main screen.

Sample Data, *continued*

Sample Results List

1. Select **MENU > SAMPLE > Results List**. The following screen will appear.

2. The sample results list will be displayed in descending order (the last result on top). Use **PAGE UP** or **PAGE DOWN** to scroll the results.

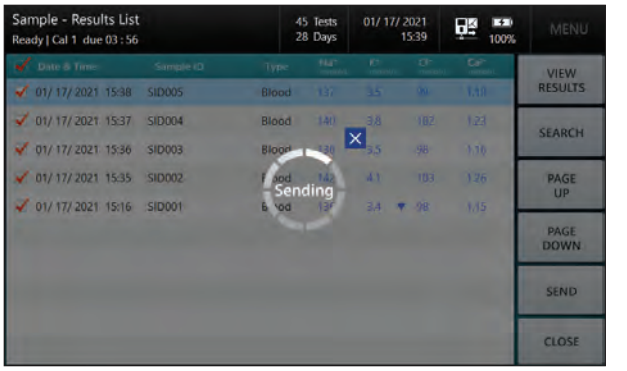
3. To view a patient sample results screen, select a desired row from the list and press **VIEW RESULTS**. The corresponding patient results screen will appear.

4. To search the results, click **SEARCH** button from the **Sample - Results List** screen. The sample result search screen will display.

Sample Data, *continued*

Sample Results List, *continued*

5. To send the sample results to LIS/HIS, select the results to send and press the **SEND** button.



6. Press **CLOSE** to exit to main screen.

Sample Data, *continued*

Sample Results Search

1. Select **MENU > SAMPLE > Search**. The following screen will appear.

Note:

✓ Search criteria are as follows:

- ❑ From and To date of the search date range
- ❑ Sample Type
- ❑ Sample ID
- ❑ Patient ID
- ❑ Patient Last Name
- ❑ Patient First Name
- ❑ Operator ID

2. Enter the desired search criteria into the search box.
3. Press **SEARCH**. The searched patient results will appear.
4. To go to the list of Sample results, press **LIST**.
5. Press **CLOSE** to exit to main screen.

QC Data

Last QC Results

Note:

✓ QC screen results, Printouts, and Interface messages will display the unit selected from **Setup - Unit**.

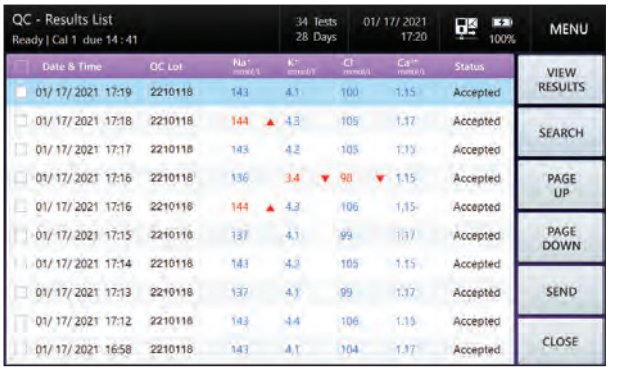
1. Select **MENU > QC > Last Results**. The following screen will appear.

2. Press **LIST** to go to the list of QC results.
3. Use **NEXT**, **PREV** button to browse previous and next results.
4. Press **SEND** button to send results to LIS/HIS.
5. Press **CLOSE** to exit to main screen.

QC Data, *continued*

QC Results List

1. Select **MENU > QC > Results List**. The following screen will appear.



2. The QC Results will display in descending order (the most recent result on top). Use **PAGE UP** or **PAGE DOWN** to scroll the QC results.

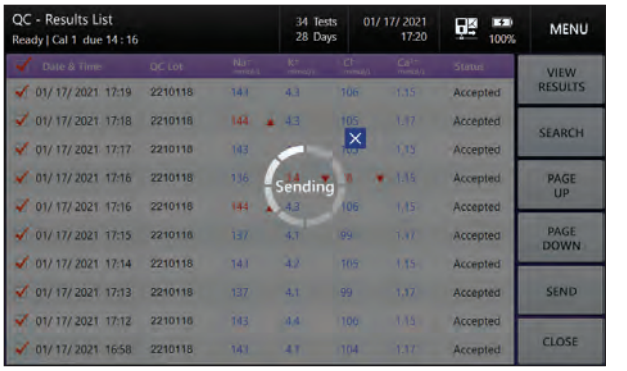
3. To view a QC results screen, select a desired row from the list and press **VIEW RESULTS**. The corresponding QC results screen will appear.

4. To search the results, click **SEARCH** button from the **QC - Results List** screen. The QC result search screen will display. Refer to the next section regarding the QC results search.

QC Data, *continued*

QC Results List, *continued*

5. Press **SEND** button to send QC results to LIS/HIS.

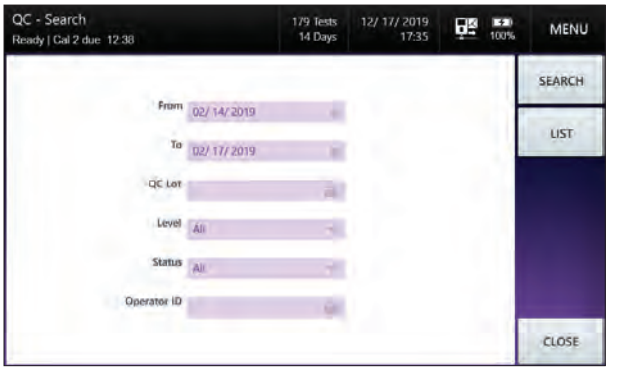


6. Press **CLOSE** to exit to main screen.

QC Data, *continued*

QC Results Search

1. Select **MENU > QC > Search**. The following screen will appear.



Note:

✓ Search criteria are as follows:

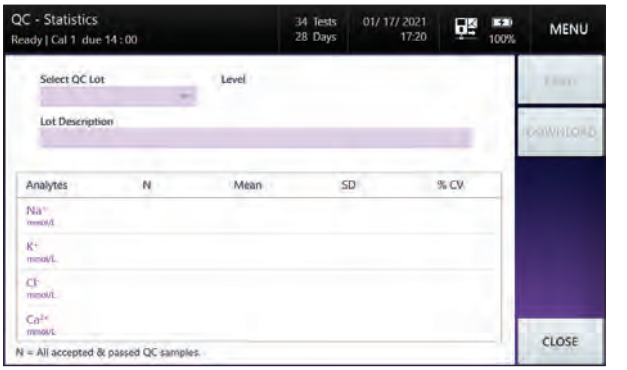
- ❑ From and To date of the search date range
- ❑ QC Lot
- ❑ Level
- ❑ Accepted or Discarted QC or other results
- ❑ Operator ID

2. Click a search box or dropdown menu and enter desired search criteria.
3. Press **SEARCH**. The searched QC results will appear.
4. To go to the list of QC results, press **LIST**.
5. Press **CLOSE** to exit to main screen.

QC Data, *continued*

QC Statistics

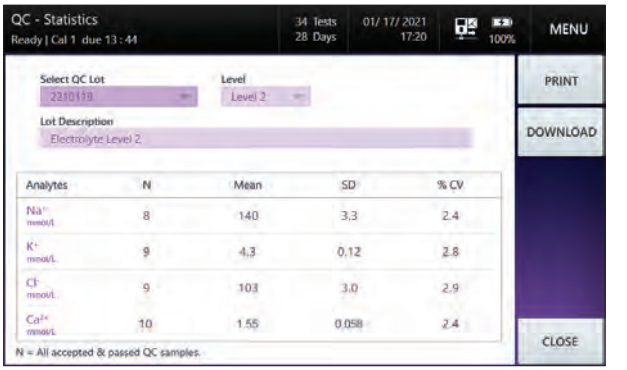
1. Select **MENU > QC > Statistics**. The following screen will appear.



2. Press **Select QC Lot** box and select a desired QC lot number from the drop-down list.

3. Press **Level** box and select a desired QC level from the drop-down list.

4. The statistics of the selected QC lot will appear.



Note:

✓ QC Statistics requires at least five Accepted QC results per QC Lot.

5. Press **PRINT** to print the QC statistics.

Note:

✓ When the analyzer is running on a battery, the print function will not be available.

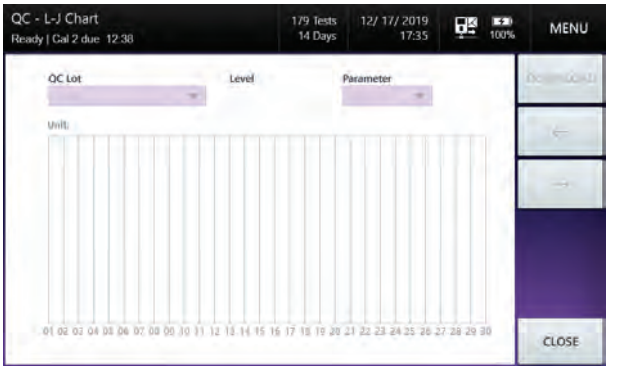
6. To copy the results of QC statistics to a USB drive, insert the USB drive into the USB port and press **DOWNLOAD** button.

7. Press **CLOSE** to exit to main screen.

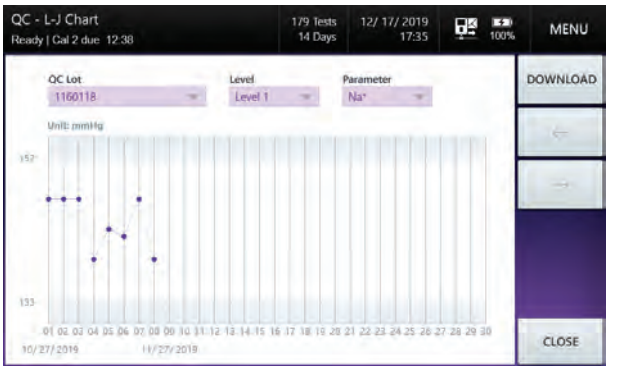
QC Data, *continued*

L-J Chart

1. Select **MENU > QC > L-J Chart**. The following screen will appear.



2. Select QC Lot, Parameter and Level on top of the screen. Following chart will appear for selected parameter.



Note:

- ✓ Most recent data will be marked on the right and maximum of 30 will be displayed in chart screen.
- ✓ The configured SD value from the **Setup - L-J Chart** will be marked with shaded lines and data which are out of SD range will marked as red dot.

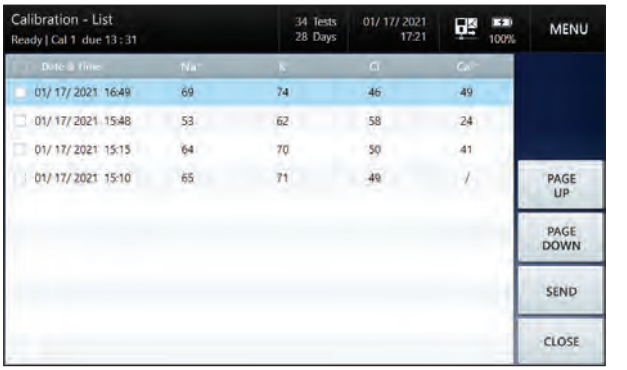
3. To copy the QC chart data to a USB drive, insert the USB drive into the USB port and press **DOWNLOAD** button.

4. Press **CLOSE** to exit to main screen.

Calibration Data

Calibration List

1. Select **MENU > CALIBRATION > List**. The following screen will appear.

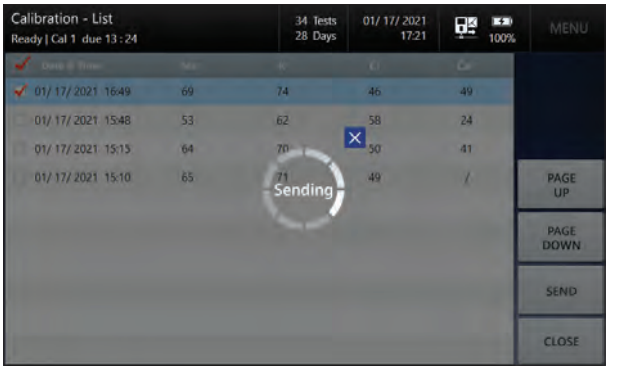


Note:

✓ Calibration List Screen, Printouts, and Interface messages will display the unit selected from **Setup - Unit**.

2. The Cal 2 results will display in descending order (the most recent result on top). Use **PAGE UP** or **PAGE DOWN** to scroll Cal 2 results.

3. Press **SEND** button to send Cal 2 results to LIS/HIS.

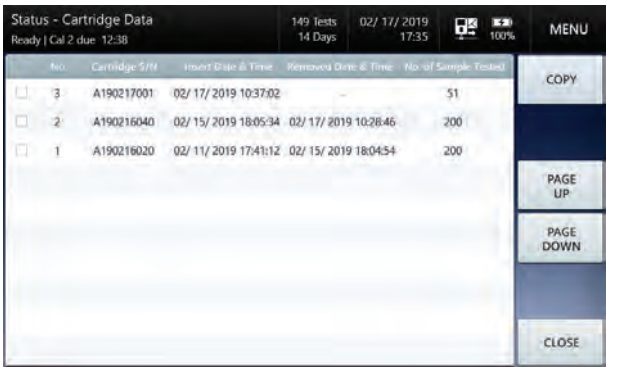


4. Press **CLOSE** to exit to main screen.

Cartridge Data

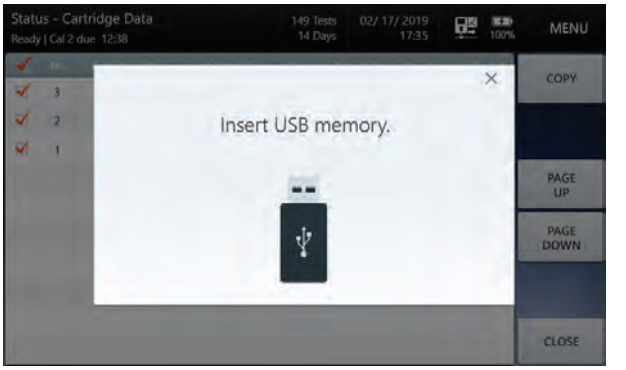
Cartridge Data Copy

1. Select **MENU > STATUS > Cartridge Data**. The following screen will appear.



2. Cartridge Data list will display in descending order (the most recent result on top) Use **PAGE UP** or **PAGE DOWN** to scroll the cartridge log.

3. Check all the cartridge data to copy by pressing the entry, and press **COPY** button. The following screen will appear.



4. Insert USB memory into one of the analyzer's USB ports.

5. "***Data copy in progress. Please wait***" message will appear with the progress bar.

6. Once the data copy is complete, "***Cartridge data copy has completed. Remove USB memory***" message will appear.

7. Remove USB memory from the USB port.

This page is intentionally left blank

6. Shutdown

Analyzer Shutdown 96

Power Recovery 98

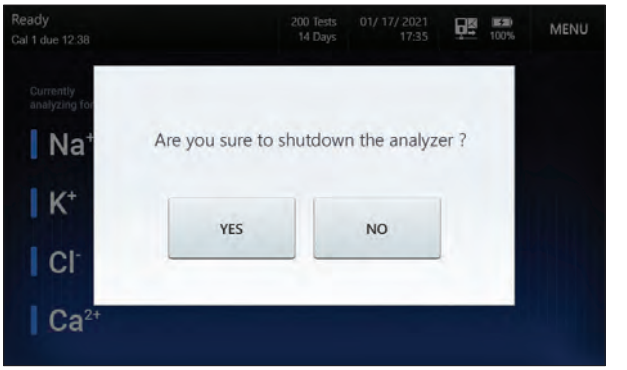
Analyzer Shutdown

Caution

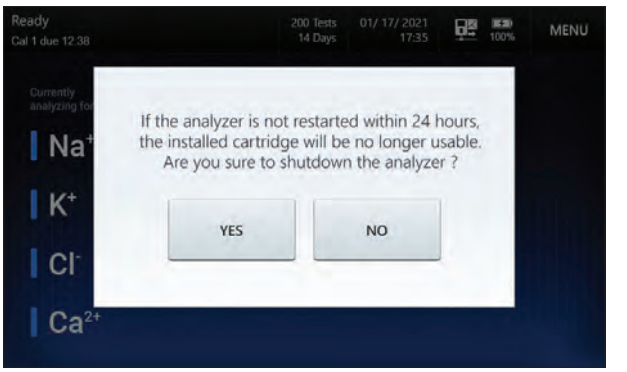
- ❑ Please shutdown the power following the instructions on this manual. Failure to follow the shut down steps may result in data loss or damage in components.
- ❑ The cartridge cannot be removed while the power is turned off or during the shutdown process.

Shutdown Analyzer

1. Select **MENU > SHUTDOWN**. The following screen will appear.



2. Press **YES** and the following message will appear.



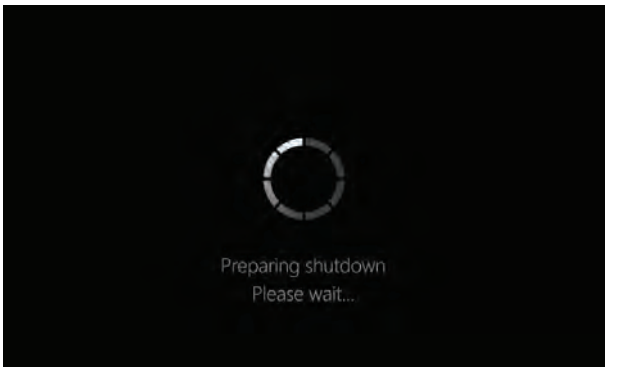
Note:

- ✓ After shutdown, if the analyzer is not restarted within 24 hours, the installed cartridge will be no longer usable.

Analyzer Shutdown, *continued*

Shutdown Analyzer, *continued*

3. Press **YES** and the following screen will appear.



4. When the "***Turn off the analyzer***" message is displayed, Turn off the power by pushing the power button so that ○ mark will be pressed.

Note:

✓ To remove the power cable from the analyzer, unplug the power cord from the outlet first, then remove the power adaptor from the analyzer.

Power Recovery

Restart Cartridge

- ❑ Although the power is turned off while using a cartridge, cartridge can be restarted if the analyzer is rebooted on following cases:
  - ✓ The analyzer was in Ready state or in process of calibration when the power was interrupted and the power returns within 24 hours.
  - ✓ The analyzer was analyzing a sample when the power was interrupted and the power returns within 20 minutes.
  - ✓ Less than 24 hours from the power turned off during the QC measurement
- ❑ If the analyzer is turned off for longer than the allowed time to restart cartridge, the cartridge will expire.

1. **Cartridge Restart** screen will appear once the Cartridge restart is in progress.

2. **Cartridge Restart** normally takes about 7 minutes.
3. After the warm up, the analyzer will return to the **Ready** status.

7. Maintenance

Calibration 100

Cartridge Removal 103

System Information 106

Event Log 107

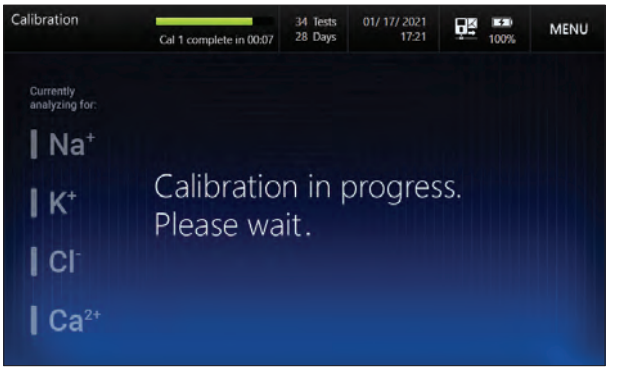
Analyzer Status 108

Cleaning 109

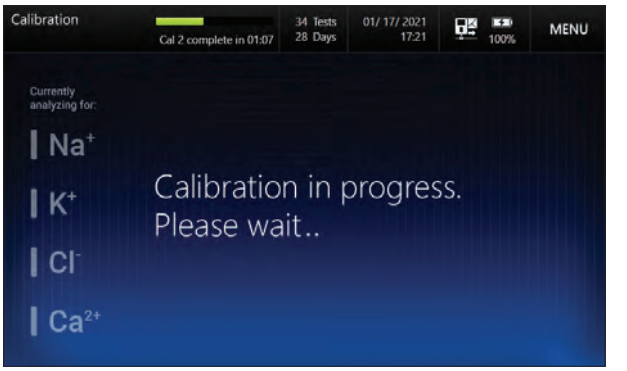
Calibration

Run Cal

1. Select **MENU > CALIBRATION > Run Cal 1** to display the following screen and Perform **Cal 1**.



2. Select **MENU > CALIBRATION > Run Cal 2** to display the following screen and Perform **Cal 2**.



Note:

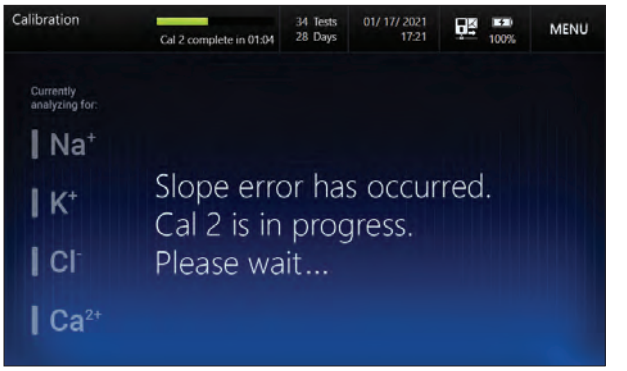
- ✓ Network Sending popup will not appear after performing Calibration in other pages except Calibration - List page.
- ✓ Sent calibration results data can be confirmed from the Calibration - List page.

Calibration, *continued*

Repeat Auto Cal 2

1. When the slope error appears after the completion of Cal 2, the analyzer will automatically repeat Cal 2 process twice.

2. While the auto Cal 2 loop is in progress, "***Slope error has occurred. Cal 2 is in progress. Please wait...***" message will appear.

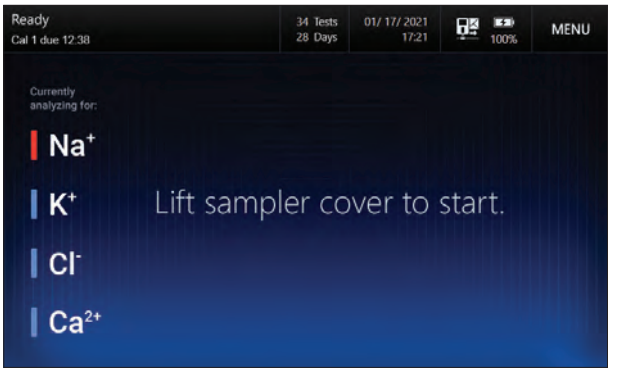


3. In case a slope error occurs on 2 consecutive occasions during Cal 2, the sensor status in the main screen will turn red.

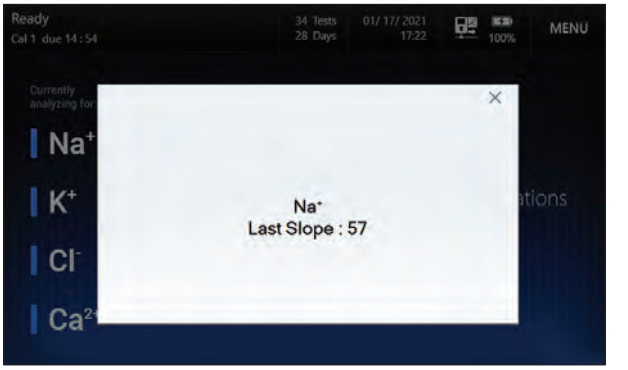
Calibration, *continued*

Sensor status

1. The status of each sensor from the last calibration performed will appear as blue or red (Slope Error) depending on the status.



2. When pressing a sensor status icon twice, the slope of the corresponding sensor obtained from the last calibration will display.



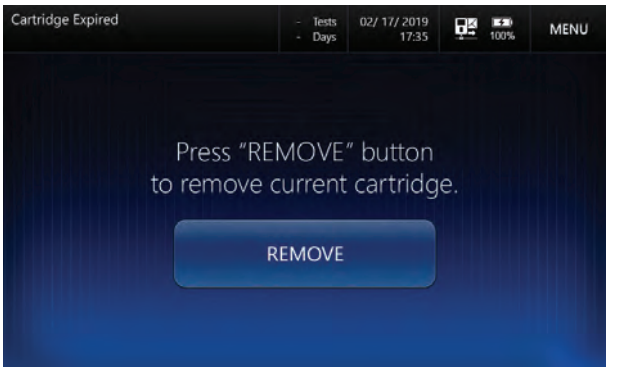
Cartridge Removal

Caution

- ❑ Handle any used cartridge as a biological hazard.
- ❑ The used cartridge must be disposed according to the laboratory's biohazard waste disposal guidelines and procedures.
- ❑ Before disposing of the used cartridge, please wear protective gear and gloves for protection from any biological hazard.
- ❑ If the analyzer has not been used and in storage for a long time, take out the cartridge and turn off the power.

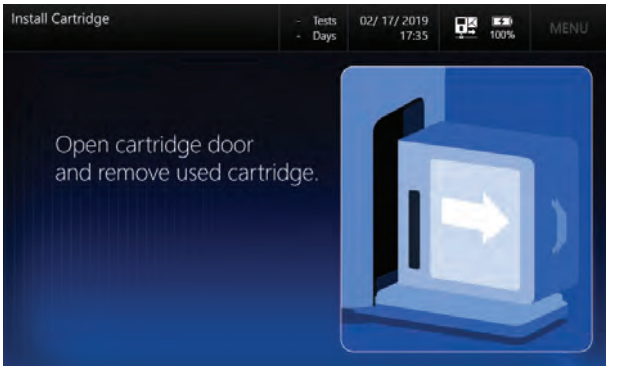
Expired Cartridge

1. When a cartridge is expired for any of the below reason, it will change to **Cartridge Expired** status automatically.



   - ✓ The uselife of the cartridge has expired
   - ✓ Cartridge's remaining test is 0
   - ✓ Analyzer has been turned off for longer than the allowed time to restart cartridge

2. Press **REMOVE** button from the **Cartridge Expired** screen and the following screen will appear.



Cartridge Removal, *continued*

continued

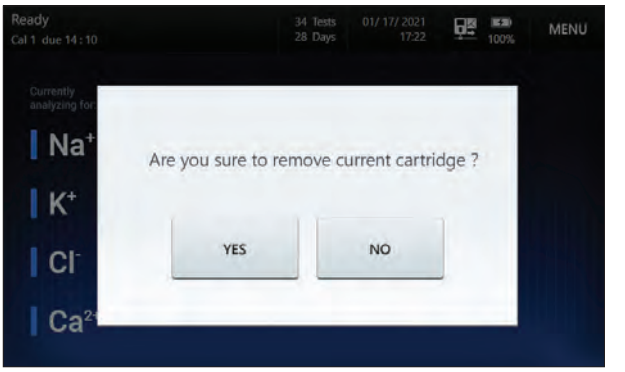
3. Proceed with the cartridge removal following the instructions on the screen.

4. To install a new cartridge, refer to ***2. Installation > Cartridge*** for detailed procedure.

Cartridge Removal, *continued*

Remove cartridge in use

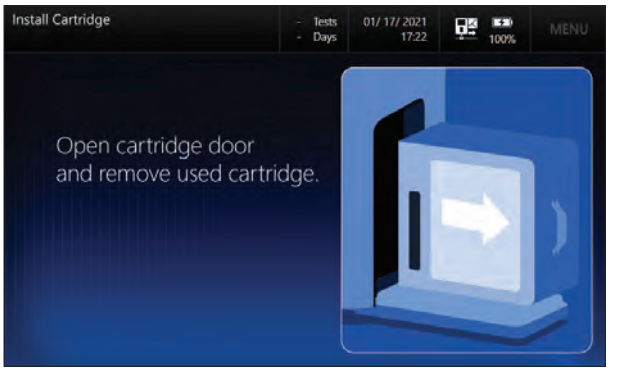
1. To remove a cartridge currently in use, select **MENU > REPLACE CARTRIDGE** and the following pop-up will appear.



Note:

- ✓ To cancel cartridge removal, press **NO**.
- ✓ Removed cartridge cannot be reused even if the expiration date and the number of tests are still available.

2. Press **YES**, and the following screen will display.



3. Proceed with cartridge removal following the instructions on the screen.

4. To install a new cartridge, refer to ***2. Installation > Installation*** for detailed procedure.

System Information

System Information

1. Select **MENU > STATUS > System Information**. The following screen will appear.

2. System Information screen includes the following:

   - ❑ Instrument information:
     software version, firmware version, serial number, instrument name
   - ❑ Cartridge information currently installed:
     serial number, installation date & time, expiration date & time
   - ❑ Calibration information:
     concentration of Cal 1 and Cal 2 solutions

   Note:

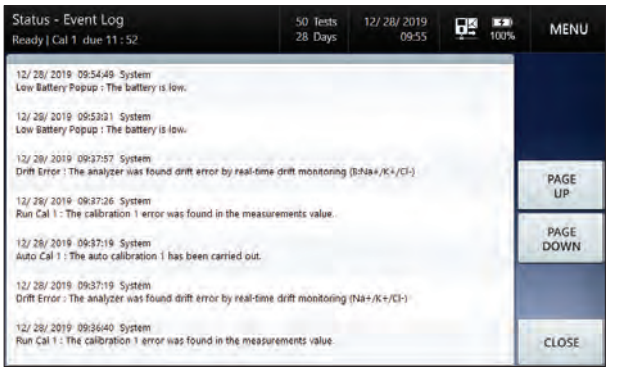
   - ✓ Cartridge information will not be available if a cartridge has been removed.
   - ✓ Cal 1 and Cal2 values from Cartridge information will display the unit selected from **Setup - Unit**.

3. Press **CLOSE** to exit to main screen.

Event Log

Event Log

1. Select **MENU > STATUS > Event Log**. The following screen will appear.



Note:

✓ The Event Log is displayed in the language that was set when the log was recorded.

2. The following events occurred during the analyzer operation will be recorded in the **Event Log**:

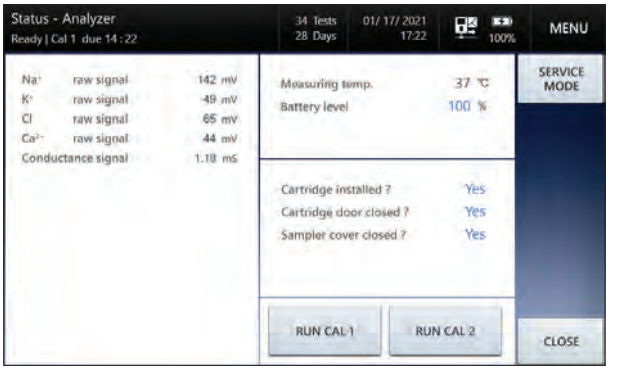
   - ❑ Power related events (Shutdown, Low Battery, Power Recovery)
   - ❑ Interface transmission related errors
   - ❑ Operating software related events & DB errors
   - ❑ Calibration related events (Calibration Error, Auto Cal)
   - ❑ Saving procedure errors
   - ❑ Cartridge installation and replacement records
   - ❑ Reference, Critical Range, Correlation Factor records
   - ❑ QC Setup records
   - ❑ L-J Setup records
   - ❑ Interface Setup records
   - ❑ No Solution Errors
   - ❑ QC Errors
   - ❑ Unit Setup records

3. Press **CLOSE** to exit to main screen.

Analyzer Status

Analyzer Status

1. Select **MENU > STATUS > Analyzer**. The following screen will appear.



2. **Status - Analyzer** screen will include the following information:
   - ❑ Sensors' raw signals
   - ❑ Measuring temperature
   - ❑ Battery level
   - ❑ Cartridge installation information, Cartridge door status (open/closed) Sampler cover status (open/closed)
3. Press **RUN CAL 1** or **RUN CAL 2** to perform Cal 1 or Cal 2 at the current screen.
4. Press **CLOSE** to exit to main screen.

Note:

- ✓ When the cartridge is correctly installed, the **Cartridge**, **Cartridge Door** and **Sampler Cover** status will be all indicated as **Yes**.
- ✓ Temperature unit will be the one selected from **Setup - Unit**.
- ✓ The **SERVICE MODE** is for service engineers ONLY and protected by password.

Cleaning

Caution

- ❑ Wear appropriate personal protective clothing to prevent infection when cleaning.
- ❑ Clean the analyzer after use or periodically.
- ❑ Do not spray cleaning solution directly onto the analyzer.
- ❑ Do not allow cleaning solution to enter the analyzer.
- ❑ Do not use force to wipe the screen.
- ❑ Prepare 0.5% hypochlorite cleaning solution immediately before use.
- ❑ Dispose of all waste after cleaning in accordance with the laboratory's established procedures for disposing of biohazardous materials.

Cleaning procedure

1. Use 0.5% hypochlorite cleaning solution.

   Note:

   - ✓ Commercial Clorox contains approximately 5% sodium hypochlorite.
   - ✓ To prepare 0.5% hypochlorite solution, mix 1 part of Clorox and 9 parts of water.

2. Dampen a soft cloth with the cleaning solution.
3. Using a dampened soft cloth, wipe sampler cover, screen, and other contaminated areas on the analyzer.
4. Allow to air-dry for about 10 minutes.
5. Using a soft cloth dampened with water, wipe the analyzer.
6. Using a dry cloth, dry the surface of the analyzer.

This page is intentionally left blank

8. Troubleshooting

Troubleshooting.....112

Error Code.....117

Troubleshooting

Guidelines

- ❑ If the problems described below are encountered during installation and/or operation of the analyzer, try the suggested solutions as described in this manual.
- ❑ If the problem persists, please call a service engineer for further assistance.

Barcode Scanner

❑ *When scanning barcode, the scanner does not emit the red light:*

1. Remove the USB connector of the barcode scanner from the analyzer.
2. Insert the USB connector into the same USB port of the analyzer. The barcode scanner will make a beep sound and the indicator light on the scanner will turn on briefly
3. Wait 5 seconds for the analyzer to recognize the barcode scanner.
4. If the same problem occurs, repeat the procedure from step 1 with a different USB port of the analyzer.

❑ *When scanning barcode, the scanner emits red light, but does not take barcode (no beep sound and no indicator light on):*

1. Position the barcode scanner close to and in parallel with the barcode.
2. Check the cartridge barcode for any damage. If damage is found, try again with another new cartridge. Report the damaged cartridge to a service engineer.

Screen

If one of following situations applies:

- ❑ *The screen does not respond.*
- ❑ *The screen is frozen.*
- ❑ *Abnormal screen appears.*

1. Turn off the power switch of the analyzer.
2. Wait 10 seconds.
3. Turn on the power switch of the analyzer.

Troubleshooting, *continued*

Battery

If one of following situations applies:

- ❑ *The analyzer was turned off immediately upon disconnection from the outlet.*
- ❑ *The analyzer was turned off during brief power outages.*
- ❑ *The battery does not recharge.*

1. If not already done, turn off the power switch of the analyzer.
2. Check for loose power connections between the analyzer and the outlet.
3. Tighten any loose power connections.
4. Turn on the power switch of the analyzer.
5. The analyzer will turn on and the battery will begin to recharge.
6. If the analyzer does not turn on, turn off the power switch of the analyzer.
7. Recharge the battery for 10 minutes.
8. Turn on the power switch of the analyzer again.
9. While the analyzer is turned, if the battery level stays low and does not increase at all over the time, call a service engineer for help.
10. Until the battery is replaced, the analyzer will operate normally as long as the power is supplied from the outlet.

- ❑ *If the "**Battery is low**" appears,*

1. Check for loose power connections between the analyzer and the outlet.
2. Tighten any loose power connections.

Note:

- ✓ When the power of the analyzer goes out because of low battery, turn off the power switch of the analyzer, in order to allow the battery to recharge from the main power when it is restored.

Troubleshooting, *continued*

Calibration

❑ *If the sensor state appears as **red**,*

1. Run Cal 2.
2. If needed, repeat additional Cal 2 a few times more.

Cartridge Data Copy

❑ *The analyzer does not recognize USB memory.*

1. Remove USB memory from the USB port.
2. Insert USB memory into a different USB port.
3. If it still does not work, try a different USB memory.

❑ *"**Cartridge data copy has failed**" message appears while the data copy is in progress.*

1. Close the message popup and try again from the beginning.
2. Select desired cartridge data and press **COPY**.

Cartridge Installation

❑ *If the barcode scanner does not emit red light,*

1. Check the connection between the barcode scanner and the analyzer (refer to barcode scanner in Troubleshooting).

❑ *If the analyzer rejects the cartridge barcode,*

1. Check that the cartridge is an i-Smart 30 PRO cartridge.
2. Check that the cartridge is not past its expiration date.
3. Check that the cartridge has not been previously used.

❑ *If the analyzer does not change to the warming-up screen after the cartridge is inserted into the analyzer,*

1. Open and close the cartridge door.
2. Gently press the cartridge door toward the analyzer until a clicking sound is heard.

Troubleshooting, *continued*

Power

❑ *Power icon* *is not indicated while power cable is plugged into the analyzer.*

1. Check if the connection between the analyzer and the power cable is loose.
2. Fix the loose power connection.

In case you experience one of the following issues:

❑ *The analyzer is turned off.*

❑ *The analyzer is not turning on.*

1. If the analyzer's power switch is on, turn it off.
2. Check the connection between the analyzer and the power outlet. If it is loose, fix the loose power connection.
3. Turn on the analyzer's power switch.
4. In case the analyzer is not turning on, turn off the power switch again.
5. Charge the battery for approximately 10 minutes.
6. Turn on the power switch of the analyzer again.

Troubleshooting, *continued*

Printer

If one of following situations applies:

- ❑ *The printer does not print.*
- ❑ *The printer does not feed paper.*

1. Open the printer cover.
2. Replace a roll of print paper if the paper has run out.
3. Lift up the printer head and check for paper jam. If jammed, remove the jam and close the printer head. Then, press the **RESET** switch on the left side of the printer.
4. Connect the power adapter.
   When the analyzer is running on a battery, the print function will not be available.

Sample Analysis

If one of following situations applies:

- ❑ *The "**Insufficient sample error**" appears on the result screen.*
- ❑ *The result is out of the measurement range.*
- ❑ *A result is suspicious.*

1. Try sample analysis again with the same sample.
2. If the same error is repeated, run Cal 2.
3. Try sample analysis again.
4. Repeat Cal 2 a few times if the same problem occurs.
5. Try QC solutions for analysis.
   If the QC results are within the QC range, the analyzer is okay for sample analysis.
6. Check Appendix A for sample collection and handling procedure.

Error Code

Error code

1. If the analyzer encounters an error during operation, the following error code will appear on the screen.

Error Code	Description
ESYS001 ~ ESYS010	Hardware error
EDB001 ~ EDB010	Database error
ESW001 ~ ESW045	Software error
T000000 ~ T000012	Data transfer error

2. Memo the error code.
3. Turn off the power switch of the analyzer.
4. Wait 10 seconds.
5. Turn on the power switch of the analyzer.

This page is intentionally left blank

9. Product Specifications

Operation Specifications....120
Instrument Specifications....121
Cartridge Specifications....122
Principles....123
Performance....125

Operation Specifications

Measuring Parameters

❑ Measured Parameters and Ranges

For Whole blood/Serum/Plasma

Parameter	Unit	Measurement Range	Resolution
Na^+	mmol/L	20 ~ 250	1
K^+	mmol/L	0.5 ~ 20.0	0.1
Cl^-	mmol/L	20 ~ 250	1
Ca^{2+}	mmol/L	0.25 ~ 5.00	0.01

For Urine

Parameter	Unit	Measurement Range	Resolution
Na^+	mmol/L	10 ~ 400	1
K^+	mmol/L	1.0 ~ 120.0	0.1
Cl^-	mmol/L	10 ~ 400	1

❑ Sample Type : whole blood, serum, plasma, urine

❑ Anticoagulant : Appropriate amount of heparin salts

❑ Sample volume : 60 µL

❑ Sample introduction method : Aspiration

❑ Sample analysis time : 35 seconds

❑ Sample analysis temperature : 37.0 ± 0.2 °C

❑ Measuring principle : electrochemistry (ion-selective electrodes)

❑ Calibration : Automatic or manual

Environmental requirements

❑ Operating location : Indoor, flat surface

❑ Operating temperature : 15 ~ 35 °C
※ It has been confirmed that analyzer is safe to operate in an environment of 5~40 °C according to IEC 61010-1. However, Please operate the analyzer at 15~35 °C to achieve the performance of cartridge.

❑ Operating humidity : 5 ~ 85 % (relative humidity)

❑ Operating altitude : under 3,000 m

❑ Power supply : 100 ~ 240 Va.c., 50/60 Hz

Instrument Specifications

Instrument Specifications

- ❑ Internal PC: Intel Celeron N3350 1.1GHz dual Core PC/4GB RAM/32GB SSD
- ❑ Operating System: Microsoft® Windows® 10 IoT Enterprise
- ❑ Display: 7" TFT-LCD, touchscreen
- ❑ Printer: 2" thermal printer (internal printer)
- ❑ Printer paper: thermal (width: 57 mm, diameter: 30 mm)
- ❑ Port: USB (3 ports), Serial (RS-232), LAN (RJ45 Ethernet)
  - − USB Port Output : 5 Vd.c, Max. 300 mA
  - − Use the STP cable for Ethernet communication.
- ❑ Analyzer Input power: + 24 Vd.c., Max. 2.7 A
- ❑ Power adapter:
  - − Input: 100 ~ 240 Va.c., 1.5 A, 50/60 Hz, Max. 1.5 A
  - − Output: +24 Vd.c., Max. 2.7 A
- ❑ Internal fuse: 125 V (AC/DC combo), 4 A (slow blow) , 3 A (slow blow)
- ❑ Internal battery: 14.52 V, 5200 mAh (Lithium-ion cells: 4S2P)
  - − Discharge time: maximum two hours
  - − Charging time: maximum two hours
- ❑ Battery life:
  - − 20% reduced capacity for charging/discharging for 300 times.
  - − Replace when the capacity drops below 50% (discharging time is less than one hour).
  - − The life and replacement cycle of the battery can vary depending on operating conditions.
- ❑ Storage temperature: -20 ~ 50 °C
- ❑ Storage humidity: 0 ~ 90% (relative humidity)
- ❑ Size (HxWxD): 292 mm x 256 mm x 177 mm
- ❑ Weight: 5.5 kg

Cartridge Specifications

Cartridge

- ❑ Packing unit: 1 cartridge
- ❑ Uselife: maximum 4 weeks
- ❑ Available sample numbers: 50, 100, 200, or 300
- ❑ Shelf life
  - − i-Smart 30 PRO Cartridge: 18 months from manufactured date
  - − i-Smart 30 PRO Cartridge E4: 12 months from manufactured date
- ❑ Storage temperature: 10 ~ 30 °C
- ❑ Components:
  - − Sensors
  - − Sampler
  - − Waste bag
  - − Valve and tubing
  - − Cal 1solution, approx. 410 mL
  - − Cal 2 solution, approx. 55 mL
  - − Reference solution, approx. 40 mL
- ❑ Composition of calibration solutions

	Cal 1	Cal 2
Na^+	145 mmol/L	101 mmol/L
K^+	4.3 mmol/L	7.4 mmol/L
Cl^-	124 mmol/L	84 mmol/L
Ca^{2+}	1.10 mmol/L	0.30 mmol/L
Other substances	Aqueous solution containing biological buffers, salts, preservative and surfactant	Aqueous solution containing biological buffers, salts, preservative and surfactant

The nominal concentrations are provided and the exact values are included in the cartridge barcode.

- ❑ Size (HxWxD): 138 mm x 139 mm x 80 mm
- ❑ Weight: 0.8 kg

Principles

Measuring Principle

The measurement of sodium, potassium, chloride and ionized calcium by the i-Smart 30 PRO Electrolyte Analyzer is based on the principle of ion-selective electrode (ISE).

In an ion-selective electrode, an electrical potential is established across a membrane that is selective to a specific ion. Such electric potential of the ion-selective electrode is measured against a reference electrode and it is used to determine the activity (a) or *effective* concentration (c) of the ion of interest in a sample.

The electrical potential (E) of the ion-selective electrode measured against the reference electrode can be described by the following Nernst equation.

$$E = E^{o} \pm \frac{RT}{nF} \ln(a)$$

where, (+) for cation, (-) for anion

E: monitored potential
E^{o}: potential at a = 1
R: gas constant
T: temperature in Kelvin scale
n: valence of ion
F: Faraday constant
a: activity of the target ion

The Nernst equation above can be simplified as follows:

$$E = E' + S \cdot \log(c)$$

The standard electrical potential (E') and slope (S) are determined by measuring the electrical potentials of the ion-selective electrode in two calibration solutions that have known concentrations of the measuring ions at different levels. This process is called two-point calibration. Once the E' and S are determined, the unknown concentration of a sample can be determined by measuring the electric potential of the electrode in a sample.

Principles, *continued*

Measurement Principle, *continued*

The i-Smart 30 PRO analyzer employs miniaturized sensors where the ion-selective electrodes were applied in planar type as shown in Figure 1 below. Each sensor is composed of polymeric sensing membranes dispensed over internal hydrogel layers on a thin plastic substrate. For a reference electrode, the Ag/AgCl reference electrode is used. A liquid junction between the sensors and the reference electrode is formed where the reference solution flowing over the reference electrode meets the sample or calibration solution flowing over the sensors.

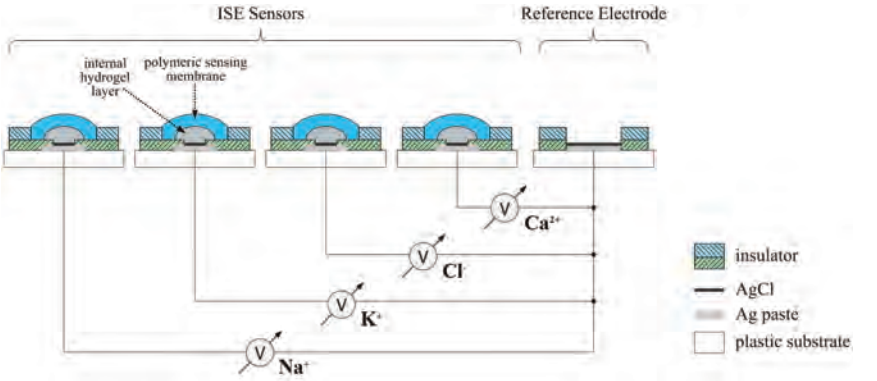


Figure 1. A cross-sectional view of the sensors for i-Smart 30 PRO

The i-Smart 30 PRO analyzer calibrates the sensors using Cal 1 and Cal 2 solutions according to the pre-determined two-point calibration schedule during the lifetime of the cartridge. In addition, the analyzer performs one-point calibrations using Cal 1 solution between two-point calibration intervals to correct the baseline drift of the sensors.

Performance

Introduction

The results obtained during evaluation of i-Smart 30 PRO Electrolyte Analyzers at i-SENS' research laboratories are shown below to demonstrate the typical performance characteristics of the analyzer.

The evaluation protocols were derived from CLSI guidelines such as EP5-A3(Precision), EP6-A(Linearity), EP7- A2(Interference), and EP9-A2(Method Comparison).

QC Materials Precision

i-Smart QC materials were measured during 4 weeks running period. Na^+, K^+, Cl^- and Ca^{2+} parameters were measured using 3 levels of i-Smart QC for 4 weeks. (N per level=240).

Na^+ QC Materials Precision

Level	Average (mmol/L)	Standard Deviation (SD)	Coefficient of Variation (%CV)	Acceptance Criteria (SD ≤ 1/2 TEa)	Pass/ Fail
1	111.2	0.65	0.6%	2.5	Pass
2	130.8	0.54	0.4%	2.0	Pass
3	151.5	0.65	0.4%	2.0	Pass

K^+ QC Materials Precision

Level	Average (mmol/L)	Standard Deviation (SD)	Coefficient of Variation (%CV)	Acceptance Criteria (SD ≤ 1/2 TEa)	Pass/ Fail
1	2.20	0.077	3.5%	0.25	Pass
2	4.51	0.058	1.3%	0.25	Pass
3	6.15	0.060	1.0%	0.25	Pass

Cl^- QC Materials Precision

Level	Average (mmol/L)	Standard Deviation (SD)	Coefficient of Variation (%CV)	Acceptance Criteria (SD ≤ 1/2 TEa)	Pass/ Fail
1	76	0.8	1.1%	2.0	Pass
2	96	0.4	0.4%	2.0	Pass
3	120	0.3	0.3%	3.0	Pass

Ca^{2+} QC Materials Precision

Level	Average (mmol/L)	Standard Deviation (SD)	Coefficient of Variation (%CV)	Acceptance Criteria (SD ≤ 1/2 TEa)	Pass/ Fail
1	1.367	0.0188	1.4%	0.068	Pass
2	1.124	0.0078	0.7%	0.056	Pass
3	0.552	0.0139	2.5%	0.050	Pass

Performance, *continued*

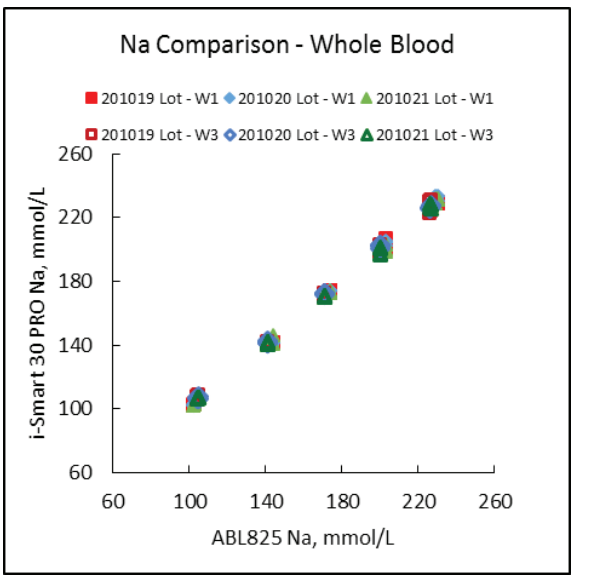
Blood Method Comparison

The method comparison test was conducted in a manner that measures the blood samples alternately with the reference analyzer and i-Smart 30 PRO Analyzer, and compare and analyze the results generated therefrom. Na^+, K^+, Cl^- and Ca^{2+} Samples were produced by adding deionized water or high concentrated ionic solutions to whole blood, plasma and serum samples. The test was conducted using the method that measures 5 levels of samples of whole blood, plasma and serum with different concentrations produced in the above manner alternately with the reference analyzer and i-Smart 30 PRO Analyzer 2 times repetitively.

Whole Blood Sample Method comparison Test Results

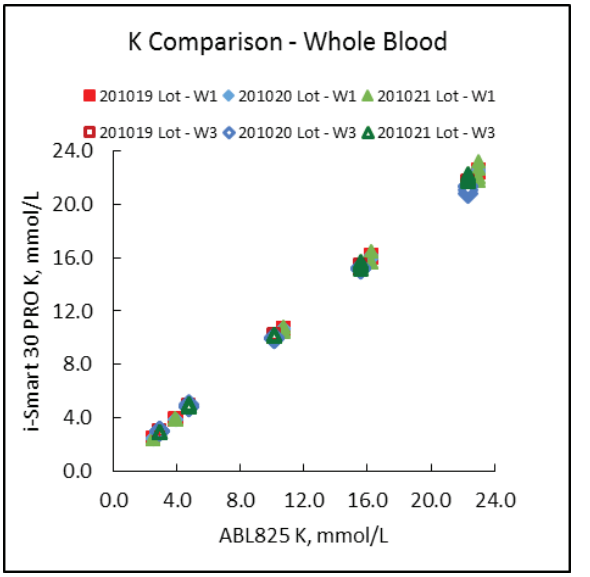
Parameter	Slope	Offset	Coefficient of determination (R^2)	Scope of Test	Acceptance Criteria	Pass/ Fail
Na^+	0.998	0.801	0.998	102 - 234	0.85 ≤ Slope ≤ 1.15, & $R^2 \geq 0.95$	Pass
K^+	0.972	0.159	0.999	2.4 - 23.2		Pass
Cl-	0.999	-1.158	0.999	29 - 229		Pass
Ca^{2+}	1.052	-0.051	0.998	0.27 - 5.00		Pass

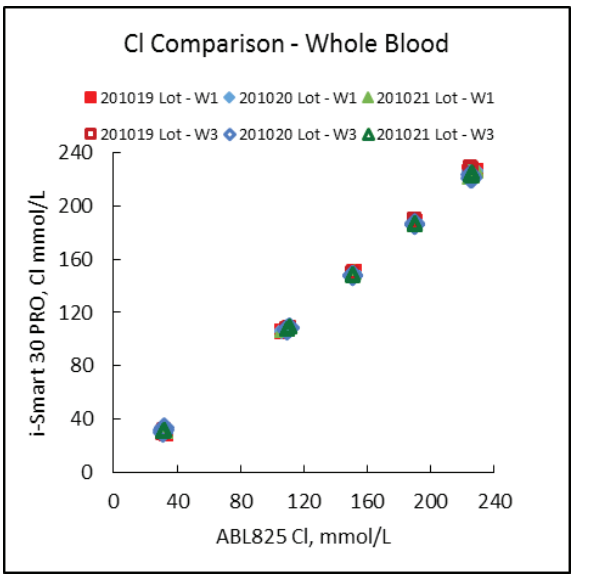
Scatter Plot Graph of Whole Blood Sample



Performance, *continued*

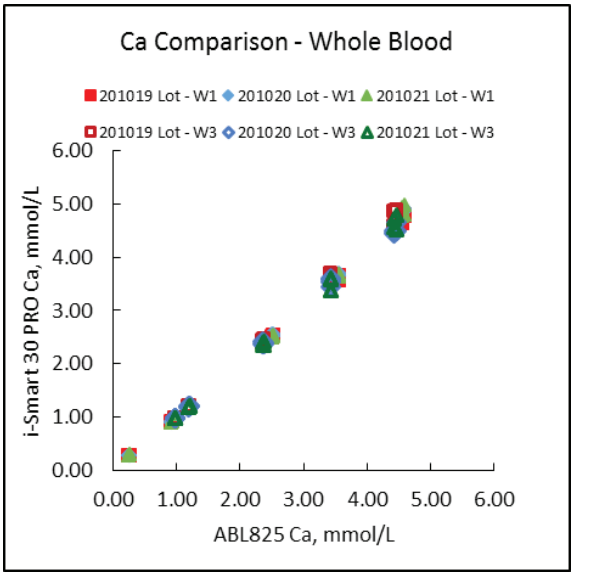
Blood Method Comparison, *continued*



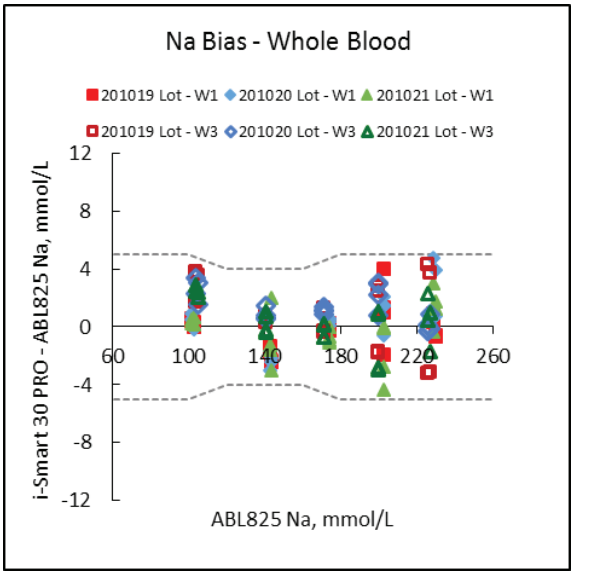


Performance, *continued*

Blood Method Comparison, *continued*

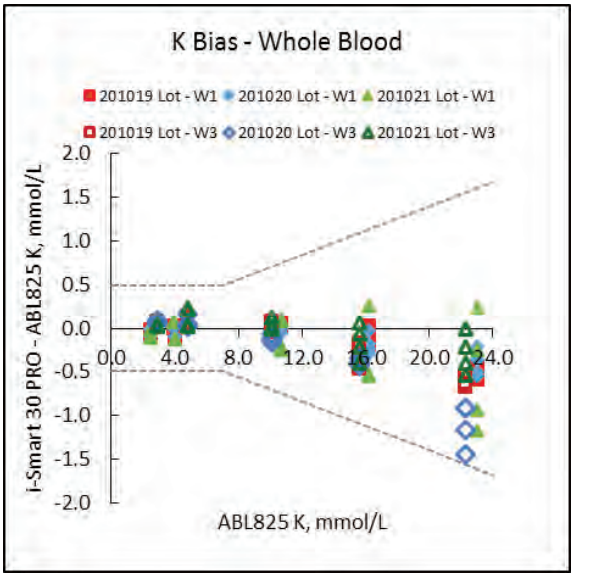


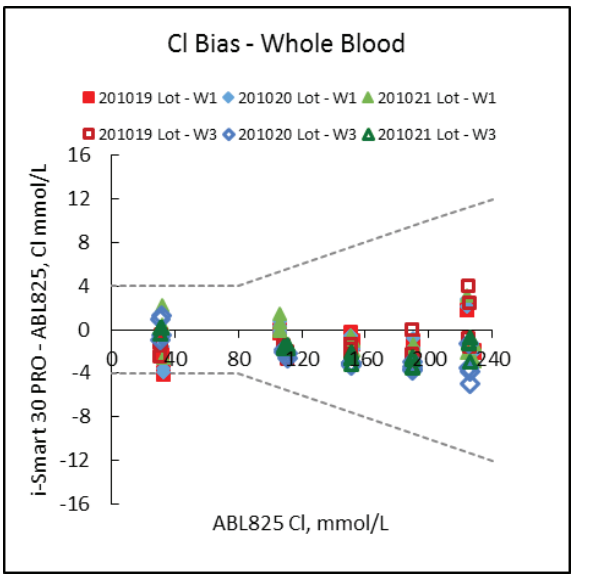
Bias Plot Graph of Whole Sample Blood



Performance, *continued*

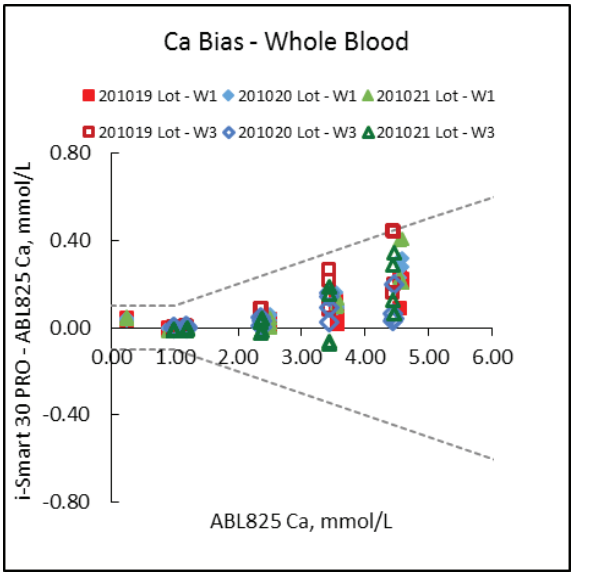
Blood Method Comparison, *continued*





Performance, *continued*

Blood Method Comparison, *continued*



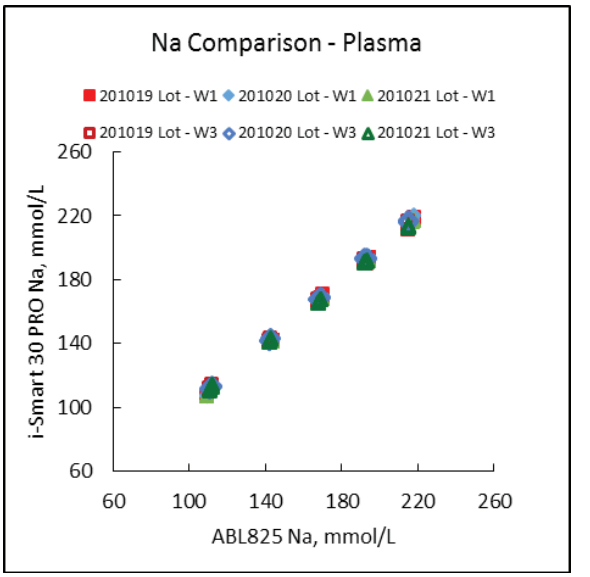
Performance, *continued*

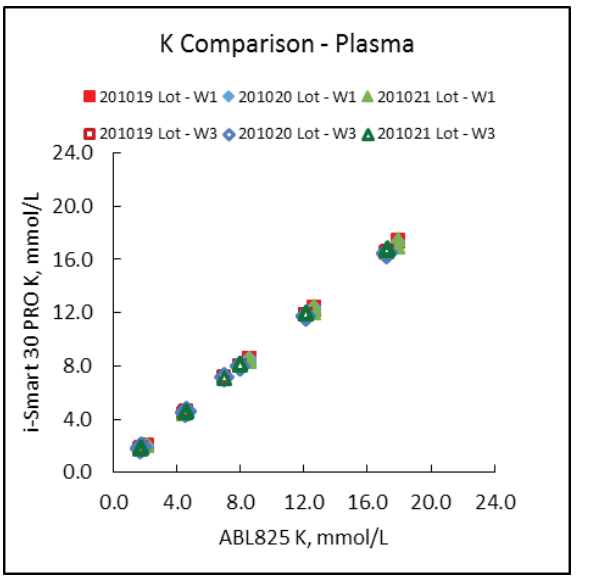
Blood Method Comparison, *continued*

Plasma Sample Method comparison Test Results

Parameter	Slope	Offset	Coefficient of determination (R^2)	Scope of Test	Acceptance Criteria	Pass/ Fail
Na^+	1.004	-1.221	0.999	107 - 220	0.85 ≤ Slope ≤ 1.15, & $R^2 \geq 0.95$	Pass
K^+	0.958	0.187	0.999	1.8 - 17.6		Pass
Cl-	1.002	-0.424	1.000	58 - 206		Pass
Ca^{2+}	1.020	-0.022	0.998	0.56 - 4.81		Pass

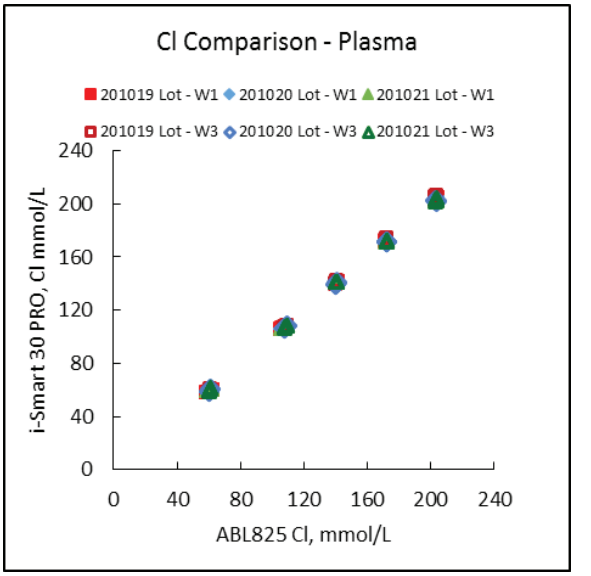
Scatter Plot Graph of Plasma Sample

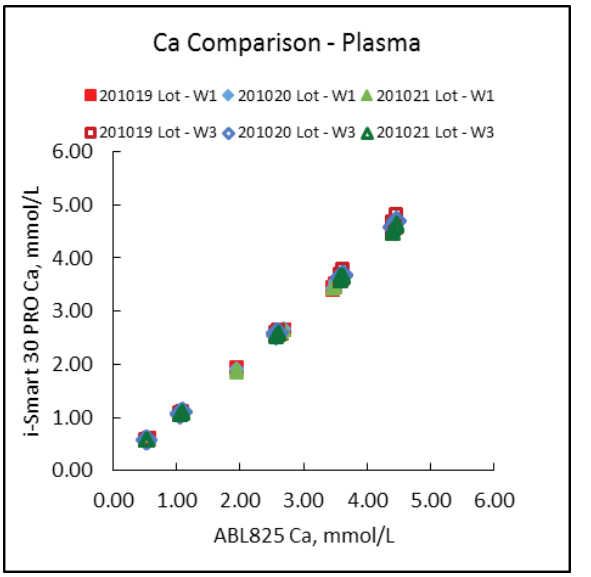




Performance, *continued*

Blood Method Comparison, *continued*

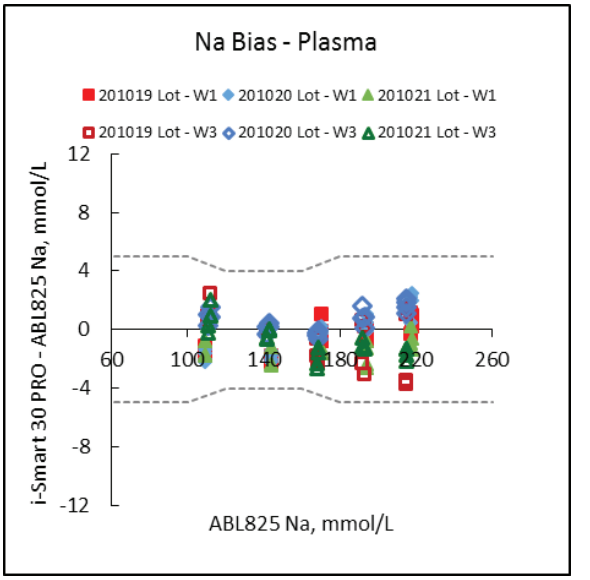


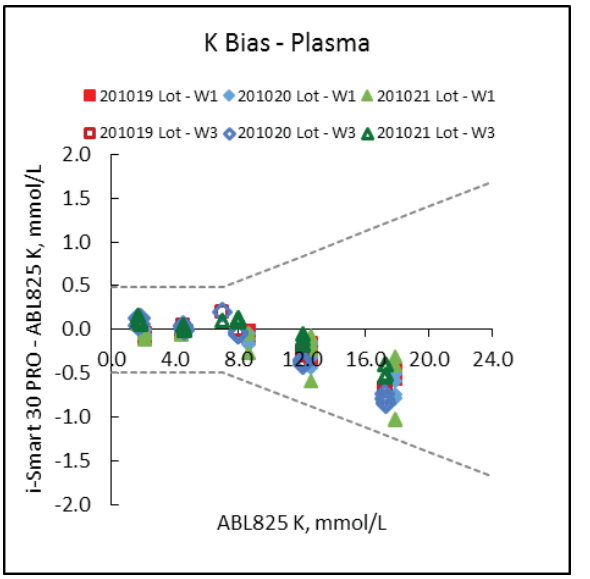


Performance, *continued*

Blood Method Comparison, *continued*

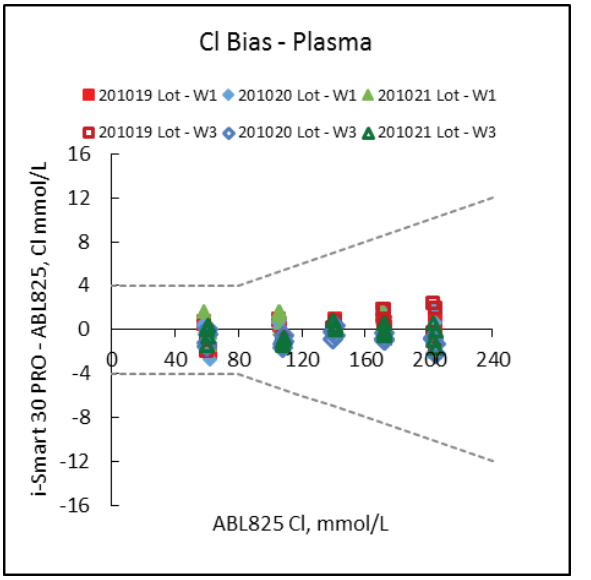
Bias Plot Graph of Plasma Sample

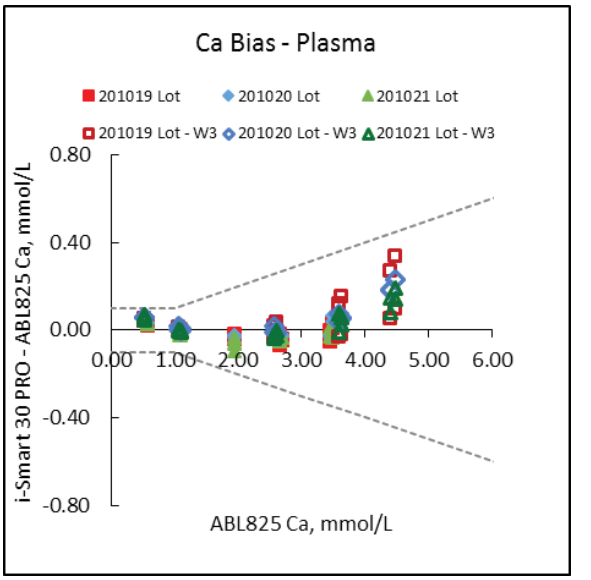




Performance, *continued*

Blood Method Comparison, *continued*





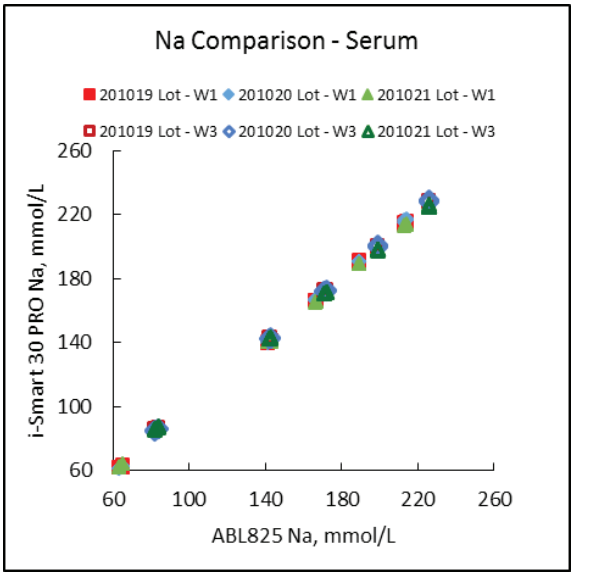
Performance, *continued*

Blood Method Comparison, *continued*

Serum Sample Method comparison Test Results

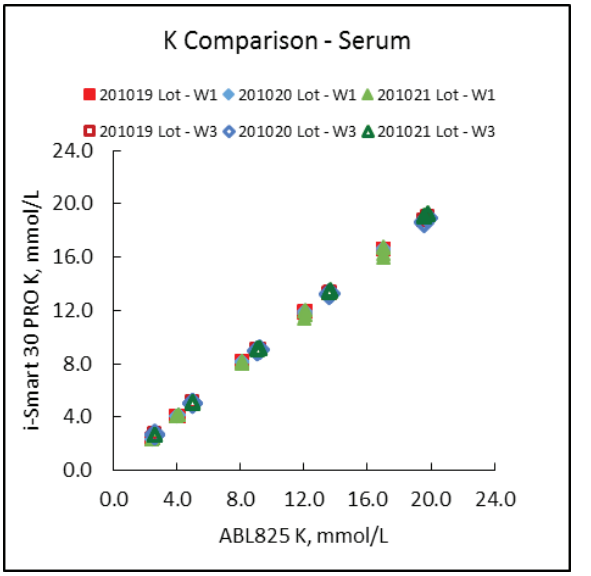
Parameter	Slope	Offset	Coefficient of determination (R^2)	Scope of Test	Acceptance Criteria	Pass/ Fail
Na^+	1.006	-0.441	0.999	61 - 229	0.85 ≤ Slope ≤ 1.15, & R^2 ≥ 0.95	Pass
K^+	0.959	0.215	0.999	2.3 - 19.3		Pass
Cl-	0.999	-0.176	0.999	58 - 221		Pass
Ca^{2+}	1.021	-0.030	0.999	0.63 - 5.23		Pass

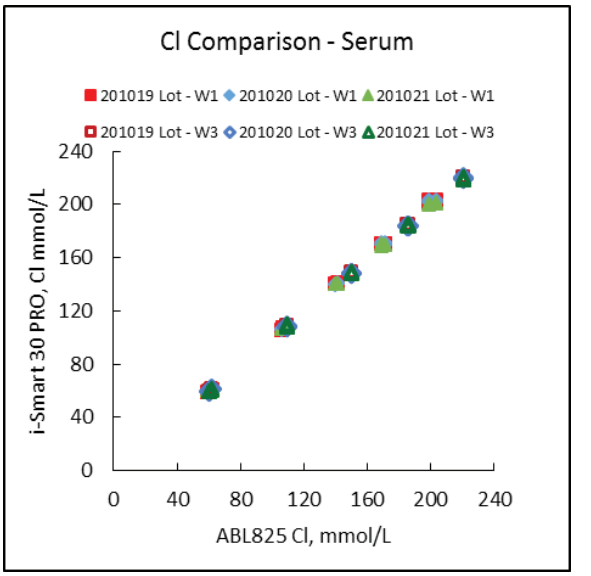
Scatter Plot Graph of Serum Sample



Performance, *continued*

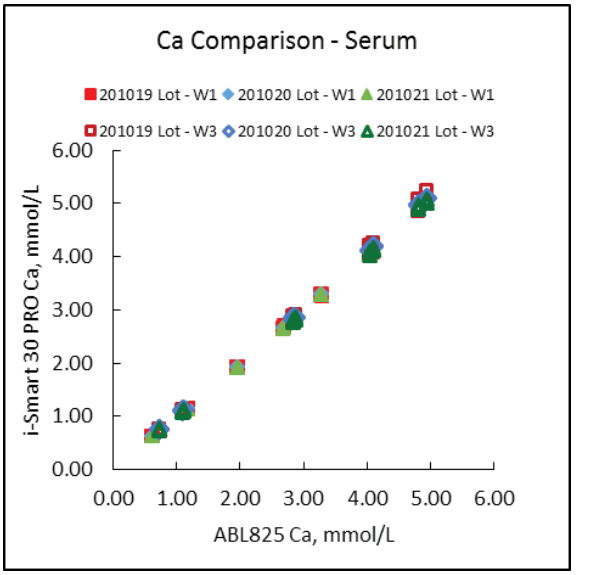
Blood Method Comparison, *continued*



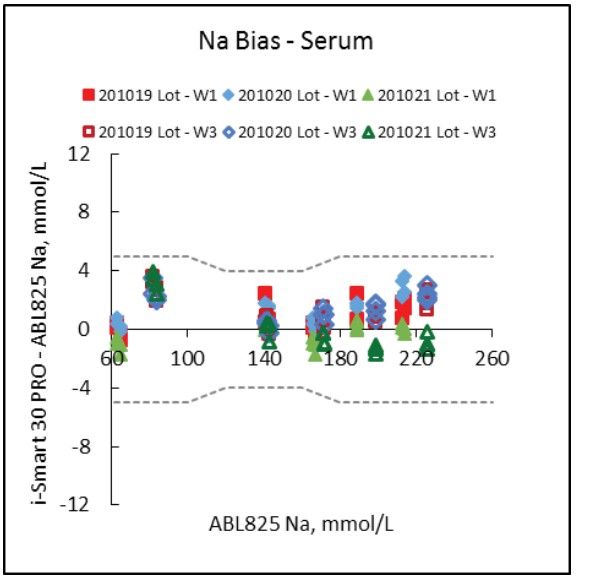


Performance, *continued*

Blood Method Comparison, *continued*

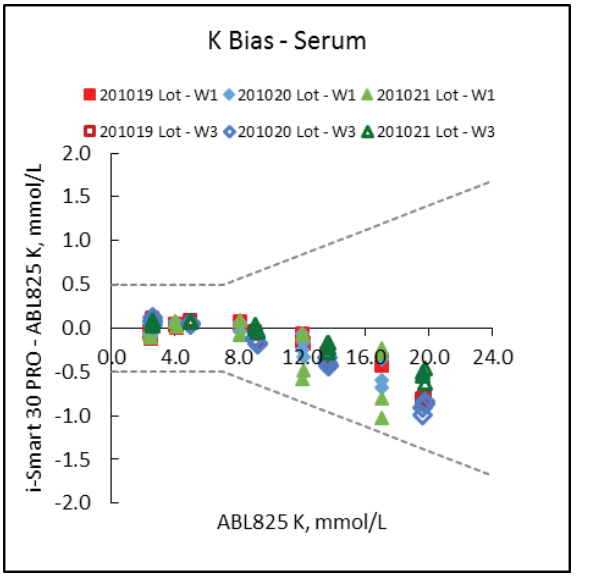


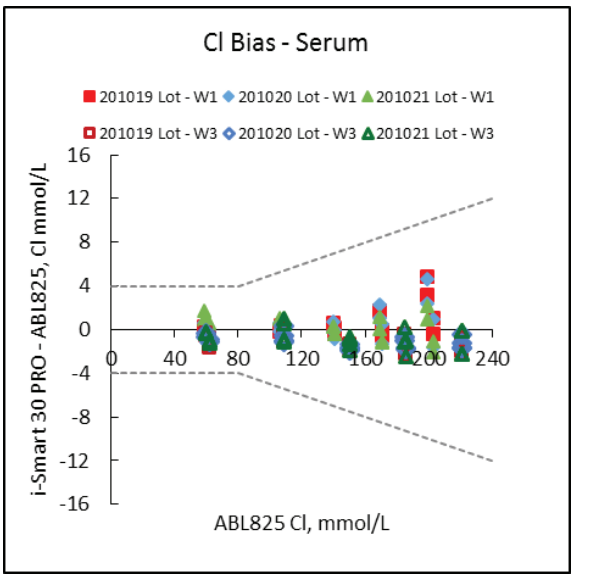
Bias Plot Graph of Serum Sample



Performance, *continued*

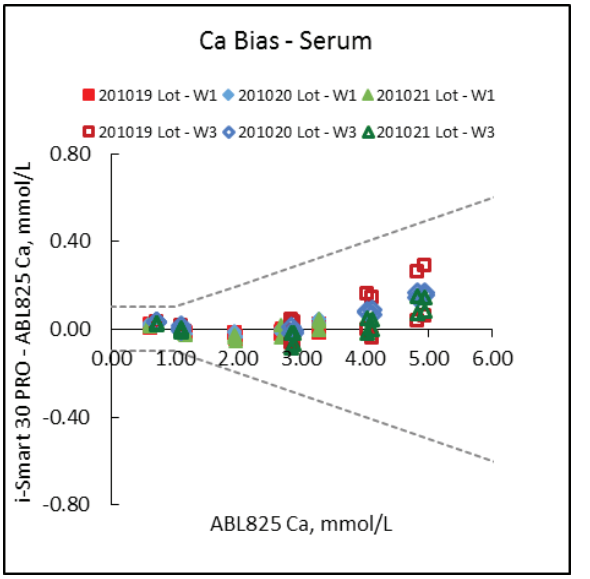
Blood Method Comparison, *continued*





Performance, *continued*

Blood Method Comparison, *continued*



Performance, *continued*

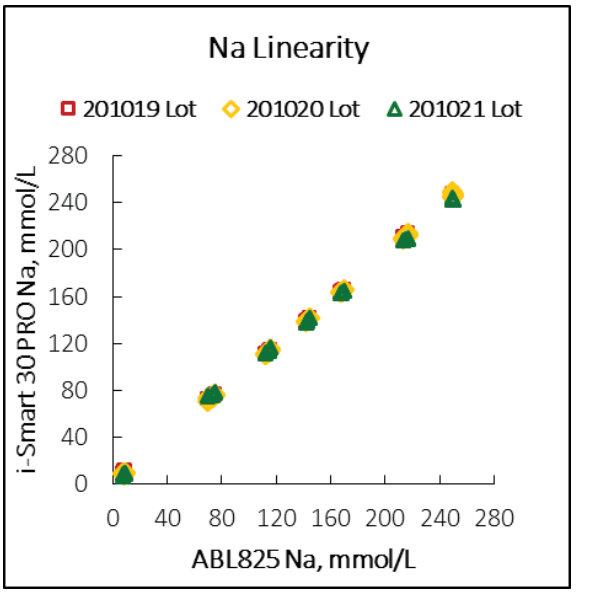
Aqueous Solutions Linearity

For the linearity test, 7 levels of aqueous solution samples that include all the reportable ranges of i-Smart 30 PRO were produced for each measurement parameter. Samples were produced by adding deionized water and high concentrated ionic solutions. The test was conducted using the method that measures the aqueous solution samples produced in the above manner alternately with the reference analyzer and i-Smart 30 PRO Analyzer 3 times repetitively.

A Summary of i-Smart 30 PRO Linearity Test Results

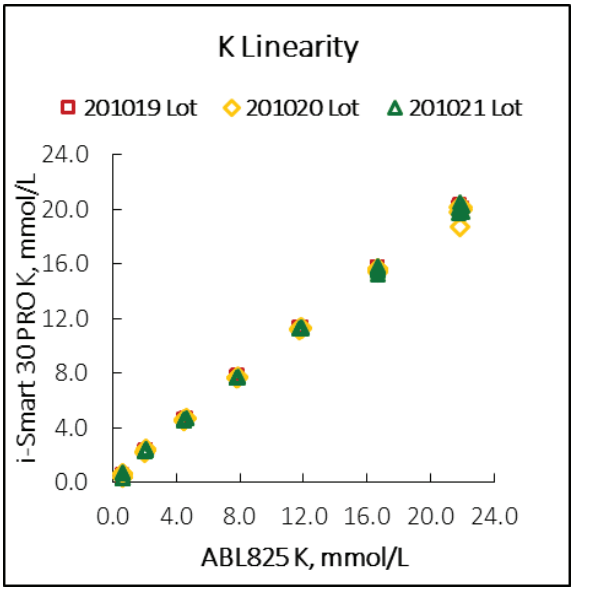
Parameter	Slope	Offset	Coefficient of Determination (R^2)	Scope of Test	Acceptance Criteria	Pass/ Fail
Na^+	0.972	1.952	0.999	6 - 250	$R^2 \geq 0.975$	Pass
K^+	0.909	0.349	0.998	0.3 - 20.5		Pass
Cl-	0.997	0.377	0.999	9 - 253		Pass
Ca^{2+}	1.028	-0.056	0.999	0.20 - 5.53		Pass

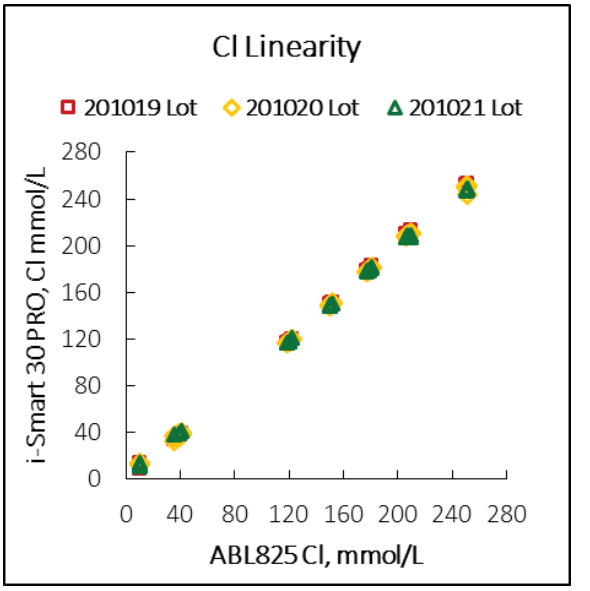
Linearity Test Linear Regression Line



Performance, *continued*

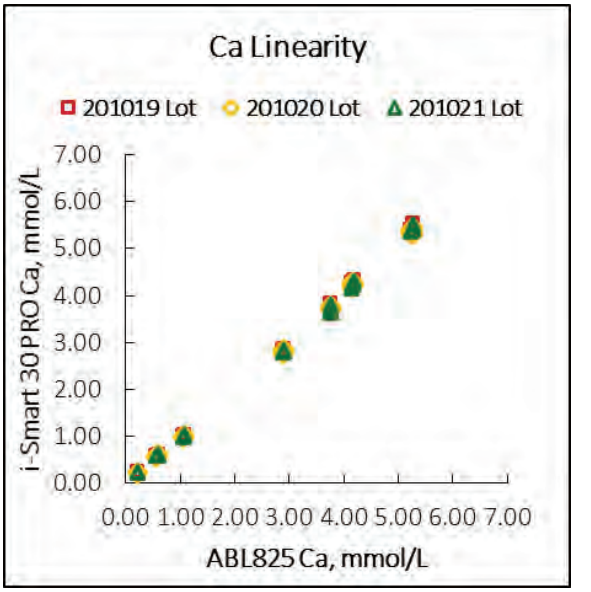
Aqueous Solutions Linearity, *continued*





Performance, *continued*

Aqueous Solutions Linearity, *continued*



Performance, *continued*

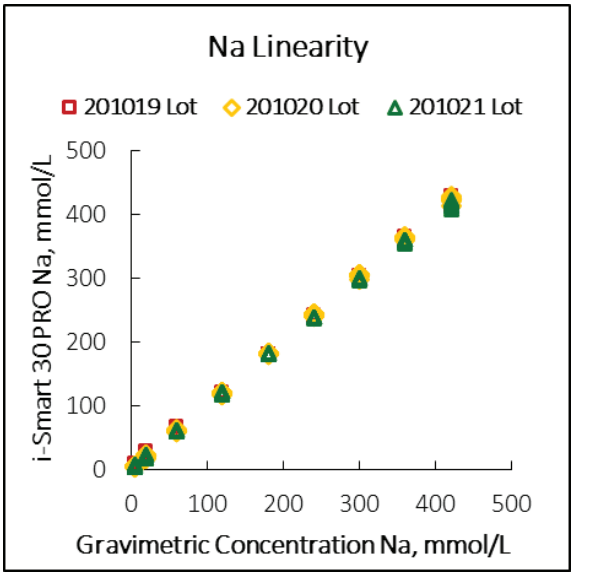
Urine Linearity

For the linearity test, 9 levels of aqueous solution samples that include all the reportable ranges of i-Smart 30 PRO in Urine Mode were produced for each measurement parameter. Samples were produced by adding NaCl and KCl reagents to deionized water. The test was conducted using the method which measures the aqueous solution samples produced in the above manner with i-Smart 30 PRO Analyzer 5 times repetitively.

A Summary of i-Smart 30 PRO Urine Mode Linearity Test Results

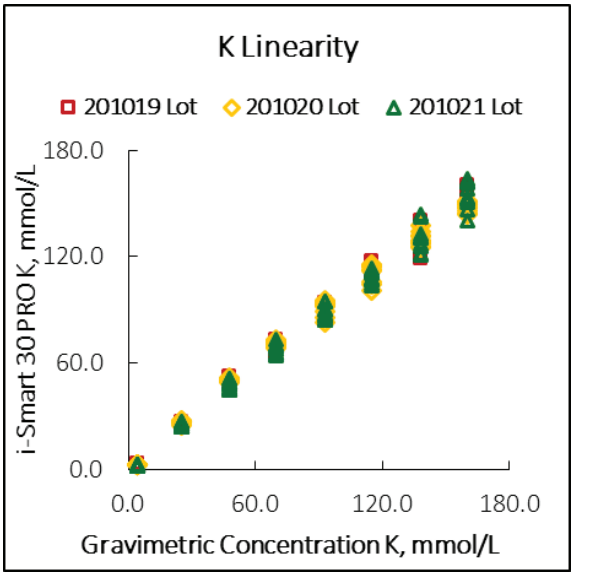
Parameter	Slope	Offset	Coefficient of Determination (R^2)	Scope of Test	Acceptance Criteria	Pass/ Fail
Na^+	1.001	0.341	1.000	1 - 429	$R^2 \geq 0.975$	Pass
K^+	0.957	0.586	0.994	-2.2 - 163.7		Pass
Cl-	0.991	-1.575	0.998	-6 - 419		Pass

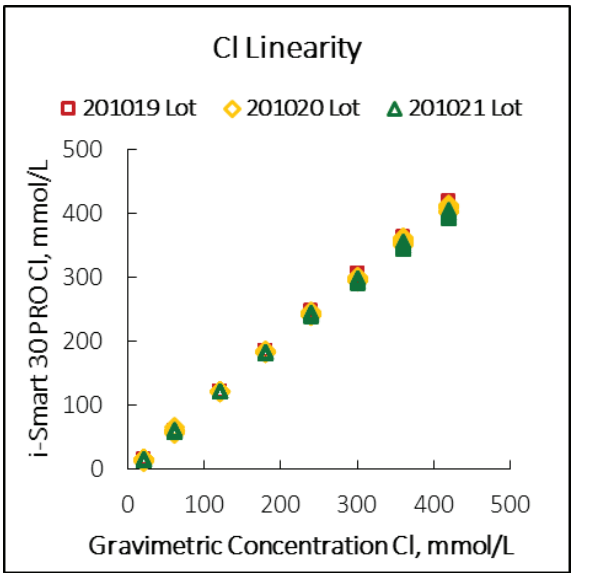
Urine Mode Linearity Test Linear Regression Line



Performance, *continued*

Urine Linearity, *continued*





Performance, *continued*

Interference Test

In order to check whether measurement values are interfered by interfering substances to be tested and the degree thereof, Specimens inclusive of the interfering substances were produced by adding the adequate amount of stock solutions of the interfering substances to Cal 1 solutions, so that it could have the targeted concentration level for the test, and then specimens exclusive of the interfering substances were produced by adding the same amount of deionized water instead of stock solutions of the interfering substances to Cal 1 solutions. The two types of specimens (specimens inclusive of interfering substances and specimens exclusive of interfering substances) were measured 2 times each repetitively using 3 units of i-Smart 30 PRO Analyzers.

It was confirmed that the influences of the interfering substances tested on Na^+, K^+ and Ca^{2+} sensors were ignorable. It was confirmed that Br^- and I^- acted as interfering substances in respect of Cl^- sensor, and that the influences of 5 interfering substances except these two were ignorable.

Interference Test Results on Na^+ Parameter

Interfering Substance	Test Concentration Level (mmol/L)	Na^+ (at about 140 mmol/L)		
		(A)	(B)	| (B) - (A) |
Li^+	4	138.0	138.5	0.5
K^+	12	139.3	140.3	1.0
NH^{4+}	1	139.0	139.7	0.7
Ca^{2+}	5	139.0	141.0	2.0
Mg^{2+}	5	139.0	139.5	0.5

Interference Test Results on K^+ Parameter

Interfering Substance	Test Concentration Level (mmol/L)	K^+ (at about 4.0 mmol/L)		
		(A)	(B)	| (B) - (A) |
Li^+	4	4.07	4.10	0.03
NH^{4+}	1	4.10	4.10	0.00
Ca^{2+}	5	4.10	4.10	0.00
Mg^{2+}	5	4.10	4.10	0.00

Performance, *continued*

Interference Test, *continued*

Interference Test Results on Cl^- parameter

Interfering Substance	Test Concentration Level (mmol/L)	Cl^- (at about 110 mmol/L)		
		(A)	(B)	| (B) - (A) |
Br^-	10	114.8	137.0	22.2
F^-	1	112.7	114.8	2.1
I^-	3	113.0	120.7	7.7
HCO_3^-	25-50	109.5	112.3	2.8
Lactate	10	114.7	115.2	0.5
Acetylsalicylic acid	3	115.0	119.5	4.5
Ascorbic acid	1	113.7	113.5	-0.2

Interference Test Results on Ca^{2+} Parameter

Interfering Substance	Test Concentration Level (mmol/L)	Ca^{2+} (at about 1.00 mmol/L)		
		(A)	(B)	| (B) - (A) |
Li^+	4	0.995	1.002	0.007
NH^{4+}	1	1.000	1.025	0.025
K^+	12	0.997	1.002	0.005
Mg^{2+}	5	1.005	1.012	0.007

Appendix A: Collecting and Handling Samples

Caution

- ❑ Make sure there are no small air bubbles trapped in the collected sample. Small bubbles in the sample can affect the results.
- ❑ Do not use liquid anticoagulants as they can dilute the sample and affect the results.
- ❑ Hemolysis at any stage of sample preparation may cause erroneously high potassium results.
- ❑ If blood is not mixed completely with anticoagulant, blood clots can be partially formed in the sample. Samples containing clots must not be used as clots will cause sampling failure in the cartridge.
- ❑ Samples in which hemolysis is present or suspected and samples collected more than one hour before analysis must not be used.

Whole Blood

- ❑ Use heparinized vacuum blood collection tubes for whole blood.
- ❑ Whole blood samples should be analyzed within 15 minutes.
- ❑ Collect blood up to the fill indicator on the tube label.
- ❑ Immediately after collecting blood, roll the tube between palms or gently shake it slowly up and down 8 to 10 times to thoroughly mix the blood and anticoagulant.
- ❑ If a storage is required for a brief period, the sample should be stored under ice baths in a tightly capped container up to 30 minutes. The cooled sample needs to be allowed to return to room temperature prior to analysis.

Serum

- ❑ Use non-heparinized, plain vacuum blood collection tubes for serum separation.
- ❑ Collect blood up to the fill indicator on the tube label.
- ❑ After collection, gently shake the tube slowly up and down five times.
- ❑ Allow the blood collection tube to stand vertically for about 30 minutes to fully clot before centrifugation.
- ❑ Centrifuge the blood sample, then collect and transfer the serum (liquid component separated from solid components of blood) to another clean container.

Appendix A: Collecting and Handling Samples

Plasma

- ❑ Use heparinized vacuum blood collection tubes for plasma separation.
- ❑ Collect blood up to the fill indicator on the label.
- ❑ Roll the tube between palms or gently shake the tube slowly up and down 8 to 10 times.
- ❑ Centrifuge the tube immediately after collection.
- ❑ Collect and transfer the plasma (liquid component separated from solid components of blood) to another clean container.

Urine

- ❑ For the preparation and storage of urine samples, the standard clinical chemistry precdures guided by CLSI regulations must be followed.
- ❑ For the colletion and handling of urine samples, institutinal regulations given by hospitals must be followed.
- ❑ Urine samples can be analyzed without dilution.
  Pure urine samples should be used.
- ❑ Occasionally some contamination particulates including urine crystals can be present in samples, and those need to be removed by centrifuging, prior to the analysis.
- ❑ When the urine sample cannot be analyzed right after the collection, the sample must be kept under refrigeration.
  The sample must be brought back to a room temperature for the analysis.

Appendix B: Order Information

1. i-Smart 30 PRO Cartridge

Available Test number and Uselife	Part No.	Order Unit
50 Test / 4 weeks	6410	1
100 Test / 4 weeks	6411	1
200 Test / 4 weeks	6413	1
300 Test / 4 weeks	6414	1

2. i-Smart 30 PRO Cartridge E4

Available Test number and Uselife	Part No.	Order Unit
50 Test / 4 weeks	6420	1
100 Test / 4 weeks	6421	1
200 Test / 4 weeks	6422	1
300 Test / 4 weeks	6423	1

3. Quality Control

Analyzer Accessories	REF	Order unit
i-Smart Electrolyte Quality Control (10 ml x 3 levels)	6206	1

4. Analyzer Accessories

Product Description	Part No.	Order Unit
Power adapter	3152	1
Power cord (220 V for Europe)	3153	1
Power cord (110 V for America)	3154	1
Barcode scanner	3155	1
Printer paper	3087	1
Pedestal	5099	1

Appendix C: Warranty

The warranty period for the analyzer and its components except cartridge is **one year** from the date the product was purchased.

The product quality is assured only when the analyzer was operated under the normal condition in accordance with the operator's manual and properly maintained.

Liability for a paid service. (Customer's expense):

- ❑ Any failure occurred due to the customer's negligence
- ❑ Any damage from the external force or drop
- ❑ Any malfunction caused by using unapproved consumables or parts sold separately
- ❑ The failure caused by not following cautions listed in the operator's manual or failing to observe cautions or following installation and operation instructions of the product
- ❑ Any damage caused during the disassemble, repair or the remodel of the analyzer by a person not authorized from © i-SENS, Inc.
- ❑ Breakdown caused by using wrong electrical power
- ❑ Failure from the user's negligence or lack of care
- ❑ Damage by a natural disaster (thunder lightening, fire, storm, flood, etc.)
- ❑ Life of the consumable parts exhausted (i.e. battery)

Please call a service engineer responsible for the product if you have any questions.