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Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus

Purpose

This procedure provides instructions to perform ionized calcium testing on the Diamond Diagnostics SmartLyte Plus analyzer. It includes instructions for processing, storing, and testing specimens, as well as procedures for instrument calibration, quality control, and maintenance.

Principle

The SMARTLYTE® PLUS Electrolyte Analyzer is a sophisticated medical instrument that uses the Ion Selective Electrode (ISE) measurement principle to precisely determine electrolyte values.

Scope

This procedure is intended for Clinical Laboratory Scientists and Medical Laboratory Technicians.

Safety Precautions

All staff members performing these procedures must adhere to regional and local workplace safety policies. These will include but may not be limited to:

- Equipment safety, proper body mechanics, sharps exposure
- Proper use of gloves/personal protective equipment while performing these procedures
- Exposure to body fluids
- Proper handling of regular and biohazardous waste
- Proper cleaning of work area
- Proper handwashing
- Proper storage and disposal of chemical hazardous waste

Policy

The list below states the policies followed by the organization.

- Do not use expired materials.
- Tests must be performed by testing personnel who have been trained and found competent to perform the procedure.
- The laboratory participates in the following CAP proficiency testing survey: C.
- The laboratory director or designee reviews quality control (QC) and instrument maintenance records at least monthly.

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Policy, continued

- The laboratory establishes or verifies acceptable ranges for QC materials prior to use.
- If more than one instrument is in-use, the laboratory checks the instruments against each other at least twice a year for comparability of results.
- The laboratory reports results above or below the AMR as "greater than" or "less than" the limits of the AMR.
- The laboratory verifies the AMR at least every six months.

Specimen Sources

- Serum

Specimen Storage and Stability

See table below for specimen storage temperature and stability.

Specimen Source	Storage Temperature	Stability
Serum	15 - 33°C (tightly capped)	4 hours
	4 - 8°C (tightly capped)	70 hours

Processing Notes:

- Centrifuge tubes within 4 hours of collection
- Prior to analysis, samples must be warmed to room temperature
- Do not open specimen tubes until they are ready to test. Prolonged exposure to air may cause a decrease in ionized calcium.

Specimen Rejection

The following specimens will be rejected:

- Specimens improperly labeled
- Specimens collected in the wrong tube
- Specimens not meeting storage and stability requirements
- Grossly hemolyzed and icteric samples

Equipment

- Diamond Diagnostics SmartLyte Plus Analyzer
  - Operating Temperature: 15 - 32°C
  - Operating Humidity: 20 – 85% (non-condensing)
- Printer Paper (5 pack): Onelink #10877420
- Peristaltic Pump Tubing: Onelink #10877422
- Lint-free, non-ionic paper (Kimwipe)

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Reagents / Materials The following contains the list of reagents/materials required.

Description	Vendor	OneLink	Storage
Ionized Calcium Electrode	Diamond Diagnostics AV-BP0360D	10863934	18-25°C Onboard Stability: up to 1 year or as indicated by QC or calibration
Unassayed Chemistry Control Level 1 and 2 (or equivalent serum control)	Bio-Rad 691/692	L1: 10008873 L2: 10008874	Unopened: -20 to -70°C Thawed: 2-8°C for up to 15 days (follow manufacturer's instructions if alternate QC is used)
Mission Control Level 1, 2, and 3 (10 sets)	Diamond Diagnostics DD-92123	10877424	18-25°C Avoid freezing and exposure to temperatures greater than 30°C. Use immediately after opening.
Verichem Electrolyte Standard Kit	Verichem 9200	10738051	2-8°C
Mission Complete Linearity Control (4 sets)	Diamond Diagnostics DD-92900	10877425	2-8°C until manufacturer expiration date or 8-25°C for up to 6 months Avoid freezing and exposure to temperatures greater than 30°C. Use immediately after opening.
Electrode Conditioning Solution	Diamond Diagnostics AV-BP0380D	10877416	18-25°C
Deproteinizer Solution	Diamond Diagnostics AV-BP0521D	10877417	2-25°C
ISE Cleaning Solution	Diamond Diagnostics AV-BP1025D	10877418	18-25°C

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Reagents / Materials, continued

Description	Vendor	OneLink	Storage
Reference Electrode Housing	Diamond Diagnostics AV-BP5019D	10877419	18-25°C
Reference Electrode	Diamond Diagnostics AV-BP5026D	10877421	18-25°C Onboard Stability: up to 1 year
Fluid Pack	Diamond Diagnostics AV-BP5186D	10877423	18-25°C Onboard Stability: up to 14 weeks

Note: All thawed materials must be labeled with new expiration date.

Quality Control Frequency

Two levels of controls are required to be run:
- Daily

Three levels of controls are required to be run:
- After each electrode change,
- After startup of the analyzer,
- To verify instrument operation

Quality Control Procedure

Follow the steps below to perform quality control:

Step	Action
1	Bring all control solutions to room temperature (as needed)
2	Mix control material before sampling
3	For Mission Controls, gently tap the head of the ampule to remove any liquid and carefully open by breaking off the top.
4	Starting from the Sample Measurement Main Menu, press **[RUN CONTROLS]**.

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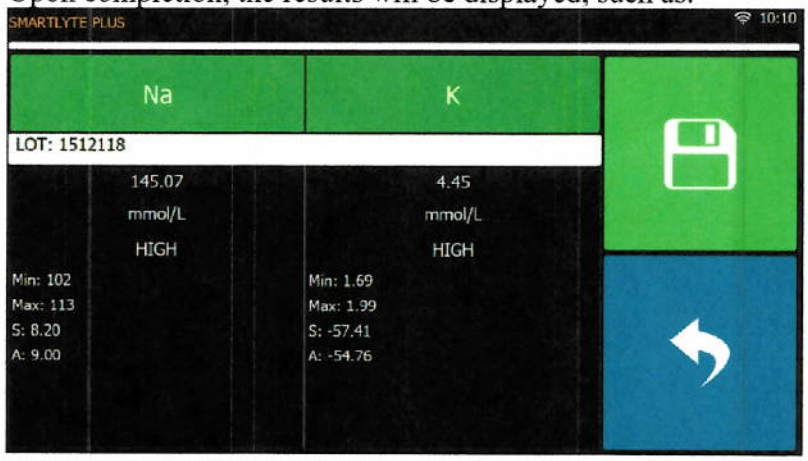
Quality Control Procedure, continued

Step	Action
5	Press the Control to be tested.
6	Upon the prompt [OPEN DOOR], lift the door.
7	When prompt [LOAD SAMPLE] is displayed, place sample probe into the ampule ensuring the probe opening is immersed.
8	Hold the ampule under the probe until [WIPE PROBE SHUT SAMPLE DOOR] is displayed.
9	Use a lint-free tissue to clean the probe, and then close the sample door.
10	The analyzer will display [CONTROL…TESTING…] and a countdown will begin, during which the QC will be analyzed.
11	Upon completion, the results will be displayed, such as:  NOTE: The SMARTLYTE® PLUS Electrolyte Analyzer displays "flags" for values that are above (HIGH) or below (LOW) the programmed target ranges. If the value is outside the measurement range (↑↑↑↑,↓↓↓↓ or ERR), it will automatically be rejected.
12	To discard the values, press to return to QC test menu and repeat the test
13	If values are in range, press to save the values.
14	Document all results on the QC log

Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Quality Control Troubleshooting

Follow the steps below to troubleshoot out-of-range quality control results:

Step	Action
1	• Review previous QC results for shifts/trends. • Verify acceptable control range is correct. • Ensure QC solutions have been brought to room temperature.
2	For Bio-Rad Unassayed QC, repeat test using the same QC bottle
3	Repeat test using a fresh QC bottle or ampule
4	Recalibrate the analyzer
5	• If quality control results are still unacceptable after recalibration, call Diamond Diagnostics Technical Support (508) 429-0450 and notify a Lead/Manager. • Take instrument out of service and do not perform patient testing until the issue is resolved.
6	Document all corrective actions on appropriate log

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Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Quality Control Range Establishment/ Verification

Control ranges for new lots of controls must be established or verified before use.

Follow the steps below to establish or verify SmartLyte Plus ionized calcium quality control ranges:

If the control is...	Then ...
Unassayed	**Establish** an acceptable control range by following the steps below:

Step	Action
1	Run each level of the new QC lot at least every four hours apart in parallel with current lot. Collect at least 20 data points for each level. Note: If the control lot must be placed into service immediately or before sufficient data points can be collected (i.e., due to shipment delays) a temporary range can be established. Run each level in replicate within the same run until at least 20 points are collected and proceed to the following steps. Re-evaluate the temporary range after sufficient data is collected.
2	Calculate 2SD range for each level of control.
3	Using Bio-Rad QCNet, determine 2SD peer QC range for the new lot of control.
4	Verify the experimental 2SD range is within the peer 2SD range.
5	If the experimental range is within the peer range, the experimental 2SD range has been established and can be used as the acceptable control range. Note: If the experimental 2SD range is too narrow, the historical CV can be used with the experimental mean to establish a range.

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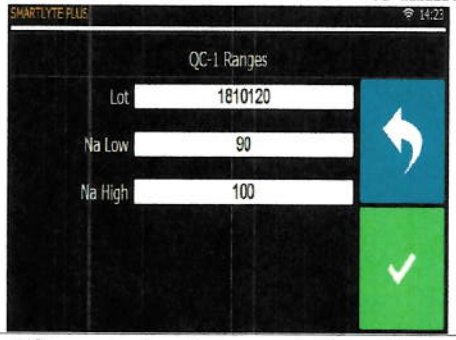
Quality Control Range Establishment/ Verification, continued

If the control is...	Then ...
Assayed	**Verify** the manufacturer control range: **Step** / **Action** 1 — Run new QC lot in replicate at least 5 times. 2 — Calculate 2SD range for each level of control. 3 — Using the manufacturer control insert, determine the acceptable QC range for the new lot of control. 4 — Verify experimental 2SD range is within the control insert range. 5 — If experimental range is within the insert range, the manufacturer control range has been verified and can be used as the acceptable control range. Note: It is also acceptable to **establish** control ranges for assayed controls following the unassayed control procedure above.

Adding a Quality Control Material

Follow the steps below to add a new lot of quality control material.

Step	Action
1	Starting from the Main Menu, Press [INSTRUMENT SETTING] then [SET RANGES] followed by the pressing the QC level to enter lot and limit information.
2	Press the parameter for which changes will be made.
3	Enter lot number and the lower limit and upper limit. 
4	After entering the new information, press ✓ to accept
5	Once "Ranges Updated" is flashed, press ↩ to return to menu to set ranges for remaining parameters or return to Main Menu.

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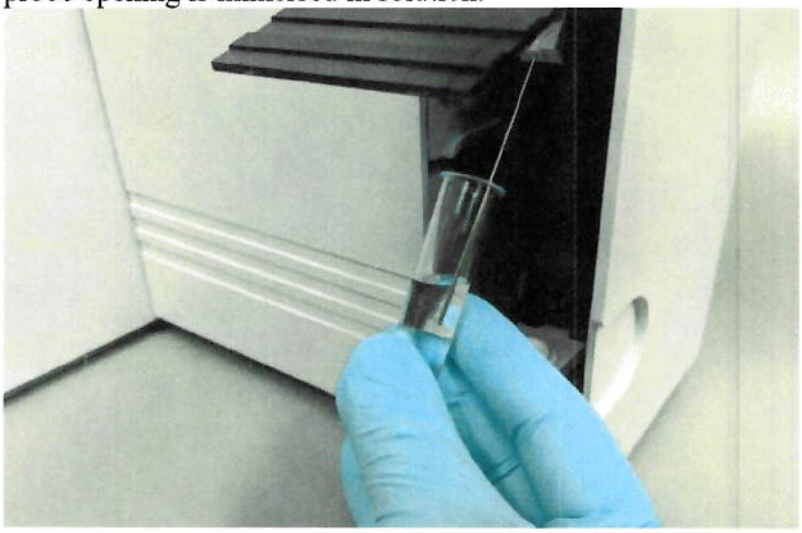
Patient Test Procedure

Follow the steps below to perform a patient test.

Step	Action
1	Don appropriate PPE.
2	Verify the correct order is placed for the sample: • CALCIUM, IONIZED [82330C]
3	Verify calcium electrode calibration was successful (Ca highlighted in green)
4	Press the **Run Serum** button and open the door when the analyzer displays [OPEN DOOR].
5	Once analyzer displays [LOAD SAMPLE], introduce sample by moving the sample container to the sample probe ensuring the probe opening is immersed in solution. 

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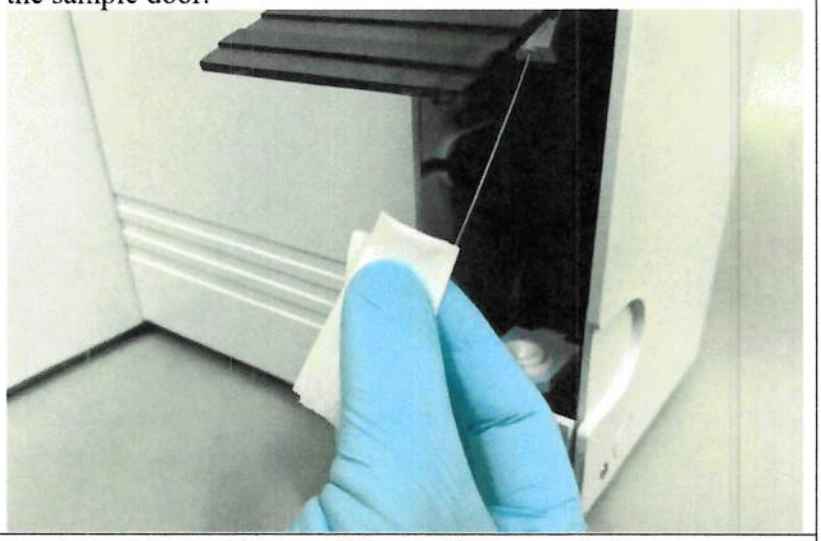
Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Patient Test Procedure, continued

Step	Action
6	Remove sample when [WIPE PROBE & CLOSE DOOR] is displayed. Use a lint-free tissue to wipe the probe. Then close the sample door. 
7	A 30 second countdown will begin if the sample is successfully found.
8	Touch the input field on the screen and enter/scan the sample accession number.
9	At completion of analysis, the test results will be displayed.

Reference Range

See table below for ionized calcium reference ranges:

Source	Age Range	Reference Range	Units
Serum	0 – <18 y	1.100 – 1.500	mmol/L
	≥18 y	1.180 – 1.430	mmol/L

Reportable Range (AMR)

0.300 – 4.500 mmol/L

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Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Troubleshooting

If unexpected/questionable results are obtained, or if an analyzer issue is suspected:

- Refer to Troubleshooting in SmartLyte Plus Operator Manual
- Contact Diamond Diagnostics Technical Support (508) 429-0450
- Notify a Lead/Manager
- Document all issues and corrective actions
- Do not perform patient testing until issue is resolved

Calibration

Calibration is performed automatically:

- Every 4 hours (2-point) if samples have been run
- During each measurement (1-point)
- After power-on or reset
- After fluid pack replacement

Calibration must be performed manually:

- If results for the QC solutions are outside acceptable limits and the system cannot be corrected to bring control values into the acceptable range
- If QC results show an unusual trend or shift
- After major preventive maintenance or change of a critical instrument component

To perform a calibration/recalibration:

Step	Action
1	From the Main Operations Menu screen, tap [CALIBRATE].
2	Upon completion, the analyzer displays parameters in green for successful calibration. The analyzer is now ready for sample analysis.
3	Document and evaluate results on the Calibration Log. Do not perform patient testing until calibration is verified.

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AMR Verification

AMR verification is performed:

- At least every six months,
- When QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range, and
- After major preventive maintenance or change of a critical instrument component

To perform AMR verification:

Step	Action
1	Bring all calibration verification material to room temperature (as needed)
2	Mix material before sampling
3	For Mission Complete Linearity Controls, gently tap the head of the ampule to remove any liquid and carefully open by breaking off the top.
4	Follow Patient Test Procedure and run each sample in duplicate
5	Document and evaluate results. Do not perform patient testing until calibration is verified. Acceptability criteria: • Correlation coefficient (r): ≥ 0.90 • Slope: 0.9 – 1.1 • Error within TAE for each level

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Instrument Comparison (if applicable)

If more than one instrument is in use, an instrument comparison is performed using one of the following methods at least twice per year:

- Split patient sample studies
- Participation in CAP Quality Cross Check program CZQ.

Follow the steps below to perform an instrument comparison:

If ...	Then ...
Performing split patient sample studies	**Step** / **Action** 1 — Gather at least 5 serum patient specimens (if possible, include both results within and outside the reference ranges). Note: Reference materials validated to have the same response as fresh human specimens may be used when availability or pre-analytical stability of patient specimens is a limiting factor. 2 — Follow patient testing procedure to analyze specimens on all analyzers being compared. 3 — Compare results. At least 90% of results must be within total allowable error to be acceptable (see Total Allowable Error below).
Participating in a CAP Quality Cross Check program	**Step** / **Action** 1 — Follow CAP Kit Instructions to analyze Quality Cross Check specimens on the analyzers being compared. Submit results to CAP. 2 — CAP will evaluate results and send a report. 3 — Use CAP acceptability criteria to assess acceptability.

Total Allowable Error (TAE)

± 0.07 mmol/L

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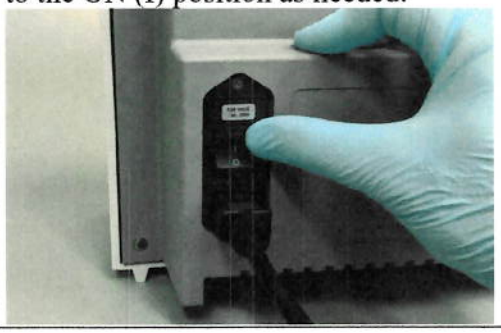
Maintenance / Cleaning

Frequency	Required Maintenance
Daily	Perform cleaning cycle at end of the day
	Perform conditioning cycle at end of the day
	Check printer paper supply
Weekly	Clean sample probe and fill port
	Clean exterior analyzer surfaces
Monthly	Clean reference electrode housing
Quarterly	Change pump tubing
Annually (performed by LTS)	Exchange main tubing harness
	Replace sample probe
As Needed	Ionized Calcium Electrode Replacement
As Needed	Fluid Pack Replacement

Note: Document completion of maintenance tasks on maintenance log. See operator manual for detailed instructions for maintenance steps not listed in this procedure.

Startup / Shutdown of Analyzer

Follow the steps below to start up or shut down the analyzer

Step	Action
	Startup Procedure
1	Power on the SmartLyte analyzer by pushing the power switch to the ON (I) position as needed. 

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Startup / Shutdown of Analyzer, continued

Step	Action
2	The unit will automatically begin initialization. Approximately 2 minutes are needed for this process.
3	When initialization is complete, the Main Menu will be displayed
	Shutdown Procedure
1	NOTE: Never attempt to turn the power off for an extended period of time without performing a complete shutdown of the analyzer. In case the analyzer is not being used for several days only, it is not recommended to perform a complete shutdown, but to leave the analyzer in Standby Mode.
2	Press [INSTRUMENT SETTINGS], then [SYSTEM] to obtain the system menu
3	Select [SHUTDOWN]. Confirm [ARE YOU SURE?] by pressing.
4	Press  to start shutdown process. Follow the step-by-step instructions on the display (see Operator Manual for detailed information).

Performing a Cleaning and Conditioning Cycle

Follow the steps below to perform the cleaning and conditioning cycle.

Step	Action
1	Press [MAINTENANCE] after installing electrodes or in Main Operations Menu. If the Clean and Condition buttons are orange, these tasks are required before calibration.
2	Pour a small amount of Cleaning Solution into a clean container or sample cup. Press [CLEAN].
3	Follow the prompt [OPEN DOOR]. Upon lifting the sample door, the pump will begin to turn.

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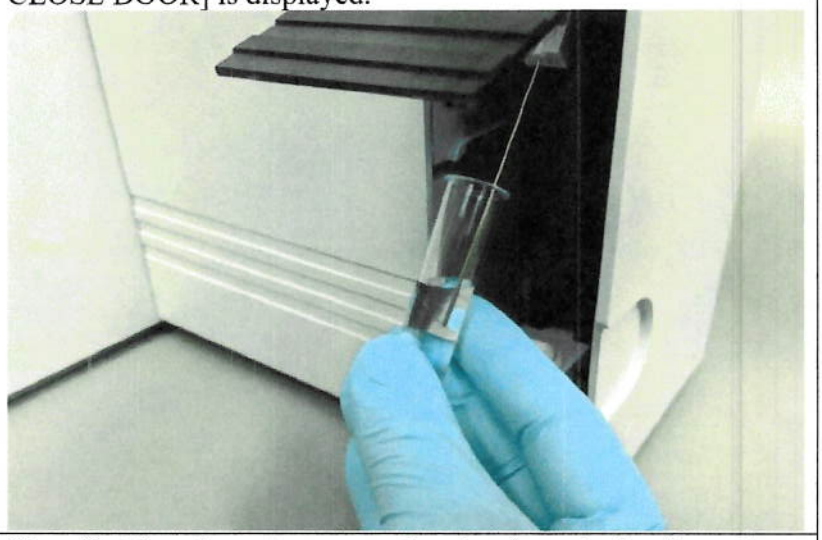
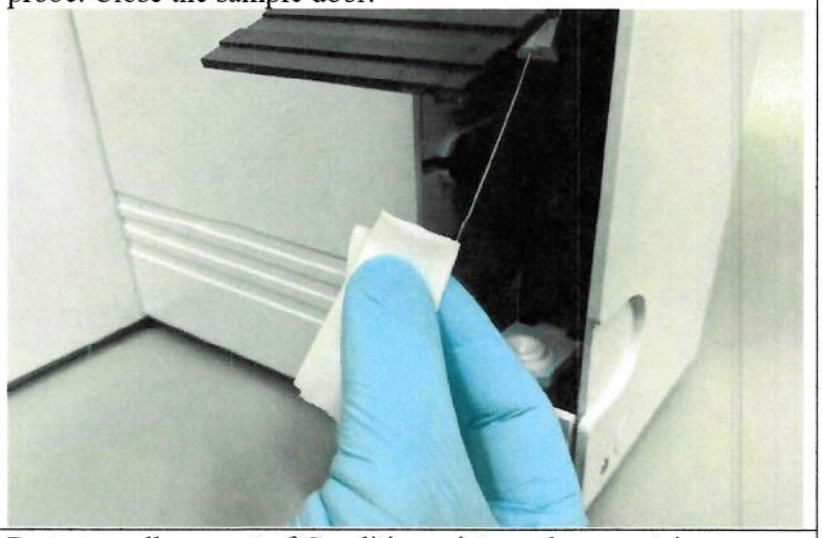
Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Performing a Cleaning and Conditioning Cycle, continued

Step	Action
4	When the prompt, [LOAD SAMPLE], is displayed, dip the probe into the Cleaning Solution until [WIPE PROBE & CLOSE DOOR] is displayed. 
5	Use a lint-free tissue to remove the cleaning solution from the probe. Close the sample door. 
6	Pour a small amount of Conditioner into a clean container or sample cup. Press [CONDITION].

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Performing a Cleaning and Conditioning Cycle, continued

Step	Action
7	Follow the prompt [OPEN DOOR]. Upon lifting the sample door, the pump will begin to turn.
8	When the prompt, [LOAD SAMPLE], is displayed, dip the probe into the Conditioner until [WIPE PROBE & CLOSE DOOR] is displayed. Use a lint-free tissue to remove the Conditioner from the probe. Close the sample door.
9	Press  or  , then [CALIBRATE].
10	Upon completion, the analyzer displays parameters in green for successful calibration. The analyzer is now ready for sample analysis.

Ionized Calcium Electrode Replacement

Follow the steps below to change the ionized calcium electrode.

Step	Action
1	Check that the electrode is ¾ filled with Fill Solution.
2	Check for air bubbles in the fill chamber near sample path. If there are any, tap the electrode body to dislodge air bubbles.
3	Verify that the O-rings are in place on the electrode body.
4	Install electrode in your system.
5	Allow the electrode to equilibrate for at least 15 minutes.
6	Perform a two-point calibration.
7	Perform quality control.

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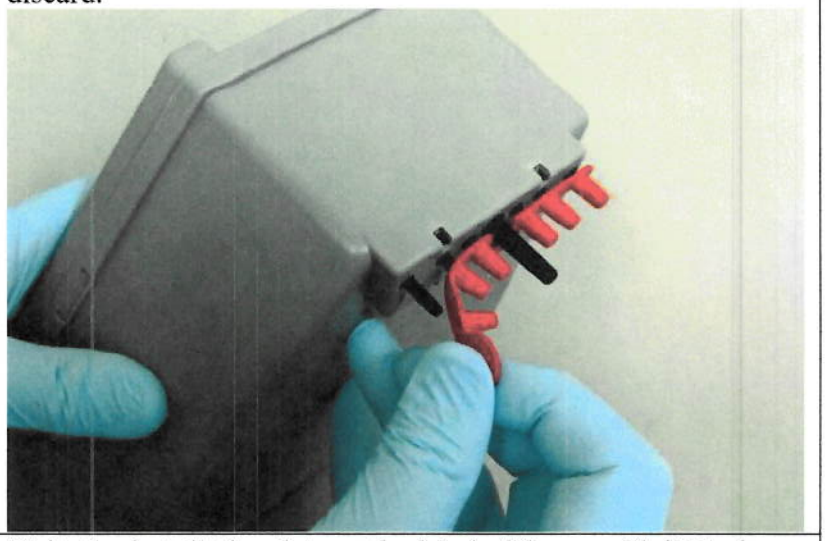
Fluid Pack Replacement

Follow the steps below to change the fluid pack.

Step	Action
1	Remove the protective strip from the new Fluid Pack. Do not discard. 
2	Write the installation date on the label of the new Fluid Pack.
3	Remove the used Fluid Pack from the analyzer by grasping the pack firmly and pull outward. If removal is difficult, press on the end of the Fluid Pack guide pin (protruding through the connector located to the left of the measuring chamber inside the front door). NOTE: The Fluid Pack must be treated as medical waste and disposed of in accordance with local regulations.
4	Place the protective strip on the used Fluid Pack.

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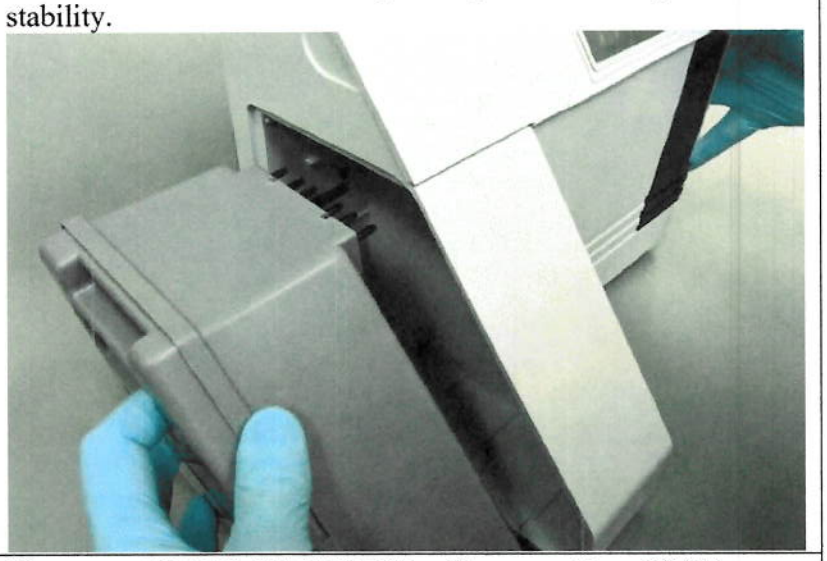
Fluid Pack Replacement, continued

Step	Action
5	Press the new Fluid Pack firmly into the cavity on the left side of the instrument while holding the right side securely for stability. 
6	The prompt PACK CHANGED? will appear. Press YES to indicate that a new Fluid Pack is installed.
7	The analyzer will prompt ARE YOU SURE? Press YES, and the Electrolyte Analyzer will automatically reset the Fluid Pack counter to 100% and commence system calibration.

Limitations

The following list describes known limitations of the SmartLyte ionized calcium test:

- For ionized calcium values, anaerobic conditions must be followed for all sample types. Contact with ambient air will cause a loss of CO2 in the sample and the subsequent rise in pH will cause a reduction in ionized calcium.
- A number of substances have been reported to cause physiological changes in blood, serum and plasma analyte concentrations. Medications and endogenous substances can affect results and clinicians must evaluate results based on the patient's entire clinical situation.

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Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus, Continued

Interfering Substances

The following list describes known interfering substances of the SmartLyte ionized calcium test:

- For dialysis solutions, small organic molecules such as lactate can affect ionized calcium concentrations. At 12 mmol/L Lactate, a 0.1 mmol/L decrease in ionized calcium may be observed.

Note: Grossly hemolyzed and icteric samples should not be used since their interferent effect on the SMARTLYTE® PLUS has not been tested.

Non-Controlled Documents

The following non-controlled documents support this policy:

- Clinical and Laboratory Standards Institute (CLSI), Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling, CLSI guideline C31-A2.
- College of American Pathologists, All Common and Chemistry Testing Checklist
- Diamond Diagnostics Mission Control Package Inserts
- Diamond Diagnostics SmartLyte Plus Electrolyte Analyzer Operator Manual

Author(s)

Chemistry Working Group

Signature Manifest

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Ionized Calcium Using the Diamond Diagnostics SmartLyte Plus

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	17 Oct 2023, 05:30:46 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	17 Oct 2023, 06:19:37 PM	Approved