TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	1/24/2020
Department:	Core Lab	**Due Date:**	2/24/2020
		Implementation:	**1/27/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

QuikLYTE Na+ / K+ / Cl- by Dimension® Xpand Chemistry Analyzer GEC.C30 v5

Description of change(s):

Updated the expiration of sample diluent once it is opened, other changes to SOP are minor

Section	Reason
4.2	Add open expiration for sample diluent
5.3	Corrected coefficient for Cl
7.3	Specified water type
16	Updated SOP titles
17	Updated insert dates

This revised SOP will be implemented on January 27, 2020

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**QuikLYTE Na^+ / K^+ / Cl^- by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 5/11/2011
Owner	Robert SanLuis Date: 4/13/2015

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Sodium, Plasma/Serum	Dimension® Xpand Chemistry Analyzer	SOD
Potassium, Plasma/Serum		K
Chloride, Plasma/Serum		CL

Synonyms/Abbreviations
Sodium / Na^+, Potassium/ K^+, Chloride/ Cl^-, Lytes Sodium, Potassium, and Chloride are part of batteries BMP, COMP, LYTE, AND RENP

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The sodium, potassium and chloride (Na/K/Cl) methods use indirect sample sensing with the QuikLYTE® Integrated Multisensor Technology (IMT) to develop an electrical potential proportional to the activity of each specific ion in the sample.
There are five electrodes used to measure electrolytes on the Dimension® system. Three of these electrodes are incorporated into the QuikLYTE® Integrated Multisensor and are ion selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensor. After a diluted sample is positioned in the sensor, Na^+, K^+ or Cl^- ions establish an equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method. For potassium measurements, avoid having the patient make a fist during collection.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Serum/ Plasma: Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 1 week
	Refrigerated: (2-8°C) 1 week
	Frozen: (-20°C or colder) 1 month
Timing Considerations	Plasma/serum should be separated from the cells within one hour.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code.
Other Considerations	Allow to clot completely prior to centrifugation.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Sample Diluent	Dimension® clinical chemistry system, REF791092901
Dilution Check	Dimension® clinical chemistry system, REF S640
QuikLYTE® Integrated Multisensor	Dimension® clinical chemistry system, REF S600
Flush Solution	Dimension® clinical chemistry system, REF S630

4.2 Reagent Preparation and Storage

Reagent	**Sample Diluent**
Container	Manufacturer supplied vial
Storage	Store at 2-8°C
Stability	**Unopened:** stable until expiration date on the vial. **Opened**: stable for 30 days when recapped and stored at 2-8°C
Preparation	Ready for use. No preparation is required.

Reagent	**Dilution Check**
Container	Manufacturer supplied bottle
Storage	Store at 2-8°C
Stability	• **Unopened:** stable until expiration date on the bottle. • **Opened:** stable for 6 months after first use.
Preparation	Ready for use. No additional preparation is required.

Reagent	**Flush Solution**
Container	Manufacturer supplied reagent bag
Storage	Store at 2-30°C
Stability	• **Unopened:** stable until expiration date on the label. • **Opened:** stable for 21 days after first use.
Preparation	Ready for use. No additional preparation is required.

Sensor	**QuikLYTE® Integrated Multisensor**
Container	Manufacturer sensor
Storage	Store at 2-8°C
Stability	Sensor is stable for 5 days or 1000 samples after first use.
Preparation	Ready for use. No additional preparation is required.

Reagent	**Salt Bridge Solution**
Container	Manufacturer supplied bottle
Storage	Store at 2-30°C
Stability	• **Unopened:** stable until expiration date on the bottle. • **Opened:** stable for 21 days after first use.
Preparation	Ready for use. No preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
QuikLYTE® Standard A solution	Siemens Dimension®, REF S620
QuikLYTE® Standard B solution	Siemens Dimension®, REF S625

5.2 Calibrator Preparation and Storage

Calibrator	QuikLYTE® Standard A & B solutions
Preparation	Calibrators are supplied ready for use. No additional preparation is required.
Storage/Stability	Store at 2-30°C **Unopened:** stable until expiration date on the label. **Opened:** stable for 21 days after first use.

5.3 Calibration Parameter

Criteria	**Special Notations**		
Reference Material	QuikLYTE® Standard A & B solutions		
Frequency	The IMT system will routinely perform a one point calibration with each sample measurement. In addition, the system performs a two point automatic calibration in duplicate every 2 hours. If no analysis is in progress. Auto-calibration also occurs shortly after turn-on, with the changing of standards A, B, or a sensor and when reset.		
Assay Range	Sodium	50 - 200 mmol/L	
	Potassium	1 - 10 mmol/L	
	Chloride	50 - 200 mmol/L	
Assigned Coefficients		Sodium	Potassium	Chloride
	C_0	1.5	- 0.2	- 10.0
	C_1	1.01	1.05	1.09
Procedure	Refer to Calibration / Verification Siemens Dimension® Xpand procedure for specific instructions.		

5.4 Tolerance Limits

IF……	**THEN……**
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	**Supplier and Catalog Number**
Liquichek™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

Control	Liquichek™ Unassayed Chemistry Control, Levels 1 and 2
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	**Opened:** stable for 15 days at 2-8°C. **Unopened:** stable until the expiration date at -20 to -70°C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension X-pand® Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.

Step	Action
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.

- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- ~~Purified~~ Reagent grade water (Millipore® or equivalent)
- Calibrated pipettes and disposable tips

8. PROCEDURE

QuikLYTE® is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® Xpand system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Repeat critical values and document according to Critical Values procedure.

8.3	Specimen Testing
	Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

Test Conditions	
Sample Size: Na^+, K^+, Cl^-	45 µL
Temperature:	18-29°C
Type of Measurement:	Indirect Potentiometric

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of Na^+, K^+, Cl^- in mmol/L.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports sodium and chloride results as a whole number and potassium results to one decimal place.

10.3 Units of Measure

mmol/L

10.4 Clinically Reportable Range (CRR)

Sodium	50 - 200 mmol/L
Potassium	1.0 - 10.0 mmol/L
Chloride	50 - 200 mmol/L

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high

percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
Na >200 mmol/L K >10.0 mmol/L Cl >200 mmol/L	Repeat the assay using the primary sample. If results are still greater than the CRR, consult supervisor before releasing results

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Sodium	Potassium	Cloride
Adult (>18 years):	135 - 145 mmol/L	3.5 - 5.1 mmol/L	98 - 107 mmol/L
Pediatric:			
> 2 years	135 - 145	3.5 - 5.1	98 - 107
13 – 24 months	132 - 141	3.3 - 4.7	97 - 107
6 – 12 months	131 - 140	3.5 - 6.1	97 - 106
1 – 5 months	132 - 140	3.5 - 5.8	97 - 108
7 – 30 days	132 - 142	3.4 - 6.1	97 - 108
0 – 6 days	131 - 144	3.5 - 5.7	97 - 108

11.2 Critical Values

Analyte	Low Critical Values	High Critical Values
Na	< 120 mmol/L	> 160 mmol/L
K	< 3.0 mmol/L	> 6.1 mmol/L
Cl	< 75 mmol/L	> 126 mmol/L

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Chloride may be decreased in the following cases: Hypoventilation, Protracted Vomiting, Chronic Diarrhea, Diabetic Ketoacidosis, Lactic Acidosis, Adrenal Disease, and/or Renal Failure. Increased Chloride may occur in the following: **Hyperventilation:** Excess breathing results in the reduction of carbonic acid content of plasma and therefore a fall in bicarbonate ion concentration. There are many causes of excess ventilation: they include many diverse diseases, drugs which stimulate the respiratory center, anxiety, fear, and decreased oxygen tension or increased CO2 tension in the blood. **Drugs:** Large doses of ammonium or potassium chloride may produce hyperchloremia. **Dehydration:** A decrease in plasma water will necessarily result in an increase in the chloride concentration.

Some causes of increased potassium may include anuria, tissue damage (crush injuries, with damage to large volumes of muscle tissue, and massive hemolysis, are examples), violent muscle contraction (vigorous exercise may cause a temporary elevation in plasma potassium), certain seizures, Addison's disease (Primary Adrenal Insufficiency), and Diabetes mellitus.
Decreased potassium levels may occur in prolonged diarrhea or vomiting, diuretic administration, and mineralocorticoid excess.

Increased Sodium may occur in simple dehydration, diabetes insipidus, hypothalamic disease, osmotic loading, excessive sodium intake, steroid therapy, excessive sweating, or Cushing's disease. Decreased sodium levels are more common and may be due to diuretics, sweating, kidney disease, congestive heart failure, severe diarrhea and vomiting, primary adrenal insufficiency, hepatic cirrhosis, diabetes mellitus, or inappropriate antidiuretic hormone secretion.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

	Concentration	**S.D.**
Sodium	120-160 mmol/L	> 2.0 mmol/L
Potassium	2-6 mmol/L	> 0.15 mmol/L
Chloride	95-128 mmol/L	> 2.0 mmol/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Sodium 50 - 200 mmol/L
Potassium 1.0 – 10.0 mmol/L
Chloride 50 - 200 mmol/L

14.2 Precision

Material	Mean mmol/L	Standard Deviation (%CV)	
		Within-run	Total
Sodium Normal QC	130	0.7	2
Sodium Elevated QC	148	0.9	1.5
Potassium Normal QC	4.2	0.02	0.05
Potassium Elevated QC	5.8	0.05	0.07
Chloride Normal QC	96	0.6	1.4
Chloride Elevated QC	110	0.6	1.1

14.3 Interfering Substances

Samples exposed to Benzalkonium salts present in certain blood catheter devices will cause falsely elevated sodium and potassium measurements.
Citrate at a test concentration of 52.9 mmol/L decreases sodium by 38 mmol/L, decreases potassium by 0.6 mmol/L and increases chloride by 57 mmol/L.
Thiopental increases sodium results by as much as 8 mmol/L at 14 mg/dL of thiopental and up to 4 mmol/L at 2.8 mg/dL of tipental.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Sample Diluent may cause an allergic skin reaction. Contains: 2-Chloracetamide. Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure

6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Siemens Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Specimen Acceptability Requirements (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Critical Values (Lab policy)
18. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert QuikLYTE® Integrated Multisensor REF S600

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144
2. Package Insert, QuikLYTE® Integrated Multisensor REF S600, Siemens Healthcare Diagnostics Inc., 08/25/2011.
3. Package Insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 04/2016.
4. Package Insert, Sample diluent REF791092901, 09/2019.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C106.001		
000	7/30/2012	1	Add analyzer name	L Barrett	J Buss, RSL
000	7/30/2012	3.1	Add electronic directory	L Barrett	J Buss, RSL
000	7/30/2012	6.7	Add use of TEA for lot to lot runs	L Barrett	J Buss, RSL
000	7/30/2012	9	Add manual calculation for 24hr urine	J Buss	J Buss, RSL
000	7/30/2012	10.5	Remove code QNSR	L Barrett	J Buss, RSL
000	7/30/2012	11.3	Removed SGAH specific preop value	L Barrett	J Buss, RSL
000	7/30/2012	15	Update to standard wording	L Barrett	J Buss, RSL
001	4/13/2015		Update owner	L Barrett	R SanLuis
001	4/13/2015	3.2	Specify lithium heparin anticoagulant	L Barrett	R SanLuis
001	4/13/2015	7.1	Add analyzer name	L Barrett	R SanLuis
001	4/13/2015	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
001	4/13/2015	11.2	Standardize low K+ critical value <3.0	L Barrett	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
001	4/13/2015	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
2	7/1/2015	1, 3, 5, 9, 10,11,14	Remove testing criteria for urine specimens (not performed at this site)	L Barrett	R SanLuis
2	7/1/2015	10.2	Add reporting potassium to one decimal	L Barrett	R SanLuis
3	3/1/18	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
3	3/1/18	5.3	Remove specific calibration steps and reference separate SOP	L Barrett	R SanLuis
3	3/1/18	10.5	Move patient review from section 6	L Barrett	R SanLuis
3	3/1/18	10.6	Remove repeat value below AMR/CRR	L Barrett	R SanLuis
3	3/1/18	15	Update to new standard wording, move hazard statement from 4.2	L Barrett	R SanLuis
3	3/1/18	17	Update PI dates	L Barrett	R SanLuis
4	1/10/20	4.2	Add open expiration for sample diluent	L Barrett	R SanLuis
4	1/10/20	5.3	Corrected coefficient for Cl	L Barrett	R SanLuis
4	1/10/20	7.3	Specified water type	L Barrett	R SanLuis
4	1/10/20	16	Update policy title	L Barrett	R SanLuis
4	1/10/20	17	Update PI date	L Barrett	R SanLuis

19. ADDENDA

None