

## TRAINING UPDATE

**Lab Location:** SGMC & WAH  
**Department:** Core Lab

**Date Distributed:** 3/21/2017  
**Due Date:** 4/11/2017  
**Implementation:** 4/11/2017

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>	
<b>V-LYTE Integrated Multisensor (Na<sup>+</sup> / K<sup>+</sup> / Cl<sup>-</sup>) by Dimension Vista® System SGAH.C110 v3</b>	
<b>Note:</b> this has been converted to a system SOP	
<b>Description of change(s):</b>	
<i>(note QC change is already in effect)</i>	
Section	Reason
Header	Add WAH
3.2	Remove specimen onboard stability
4,5,6	Remove individual section labeling instructions and add general one
6.1, 6.2	Update QC material and storage
7.2	Change freezer upper limit to -50C
10.5	Move patient review from section 6
14.3	Update list of interferences
15	Update to new standard wording
17	Update QC product and PI dates

**This revised SOP will be implemented on April 11, 2017**

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

Technical SOP

<b>Title</b>	<b>V-LYTE Integrated Multisensor (Na<sup>+</sup> / K<sup>+</sup> / Cl<sup>-</sup>) by Dimension Vista® System</b>	
<b>Prepared by</b>	Ashkan Chini	Date: 6/25/2012
<b>Owner</b>	Robert SanLuis	Date: 10/29/2013

<b>Laboratory Approval</b>		<b>Local Effective Date:</b>
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		

<b>Review</b>		
Print Name	Signature	Date

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**1. TEST INFORMATION**

Assay	Method/Instrument	Local Code
Sodium, Plasma/Serum	Dimension Vista® System	SOD
Urine Sodium, Random		UNAR
Urine Sodium, 24 hour		UNA24
Potassium, Plasma/Serum		K
Urine Potassium, Random		UKR
Urine Potassium, 24 hour		UK24
Chloride, Plasma/Serum		CL

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

Department
Chemistry

**2. ANALYTICAL PRINCIPLE**

Na+ K+ Cl- methods use indirect V-LYTE® Integrated Multisensor Technology (IMT). There are four electrodes used to measure electrolytes on the Dimension Vista® V-LYTE® system. Three of these electrodes are ion selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensor. Diluted sample (1:10 with V-LYTE® Diluent) is positioned in the sensor and Na+, K+ or Cl- ions establish 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
<b>Fasting/Special Diets</b>	N/A
<b>Specimen Collection and/or Timing</b>	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. Random Urine: Clean catch specimen. Deliver to laboratory promptly. 24 Hour Urine: Record duration of collection on requisition <b>and</b> container
<b>Special Collection Procedures</b>	24 Hour Urine: <b>Inpatient:</b> See Laboratory Test Directory (electronic) for details. No preservative should be added. Refrigerate during collection. <b>Outpatient:</b> Provide patient with prepared instruction sheet and container.
<b>Other</b>	N/A

**3.2 Specimen Type & Handling**

Criteria	
<b>Type</b>	Plasma (Lithium Heparin), Urine
<b>-Preferred</b>	
<b>-Other Acceptable</b>	Serum

Form revised 2/02/2007

Criteria			
<b>Collection Container</b>	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST) <b>24 Hour Urine:</b> 24 hour container, no additives or preservatives. <b>Random urine:</b> Urine collection cup.		
<b>Volume</b> - Optimum - Minimum	Plasma/Serum: 1.0 mL 0.5 mL	24 hour urine: Total volume collected in 24 hours	Random Urine: 10 mL 5 mL
<b>Transport Container and Temperature</b>	Serum/Plasma: Collection container or Plastic vial at room temperature. Urine Random: Collection kit or container at room temperature submitted within 2 hour of collection. Urine 24 hour: Collection container at room temperature.		
<b>Stability &amp; Storage Requirements</b>	Room Temperature:		Serum/Plasma: 7 days Urine: Not recommended
	Refrigerated:		Serum/Plasma: 7 days Urine: 24 hours
	Frozen:		Serum/Plasma: 1 year Urine: 1 week
<b>Timing Considerations</b>	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.		
<b>Unacceptable Specimens &amp; Actions to Take</b>	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.		
<b>Compromising Physical Characteristics</b>	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)		
<b>Other Considerations</b>	Allow Red Top or SST 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. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.**

Form revised 2/02/2007

#### 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
Diluent	Siemens Health care Diagnostics, Inc. Cat. No. K835
Dilution Check	Siemens Health care Diagnostics, Inc. Cat. No. K840

##### 4.2 Reagent Preparation and Storage

Reagent	Diluent
Container	Plastic Bottle
Storage	Store at room temperature
Stability	Both unopened and opened reagents are stable until expiration date stamped on the reagent.
Preparation	Reagent is ready for use. No preparation is required.

Reagent	Dilution Check
Container	Plastic Bottle
Storage	Store at room temperature
Stability	Unopened reagent is stable until expiration date stamped on the reagent. Opened reagent is for single use only.
Preparation	Reagent is ready for use. No preparation is required.

#### 5. CALIBRATORS/STANDARDS

##### 5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Integrated Multisensor	Siemens Health care Diagnostics, Inc. Cat. No. K800A
Standard B/Salt Bridge	Siemens Health care Diagnostics, Inc. Cat. No. K825
Standard A	Siemens Health care Diagnostics, Inc. Cat. No. K820

##### 5.2 Calibrator Preparation and Storage

Reagent	Integrated Multisensor
Container	Cartridge
Storage	Store at 2-8° C

<b>Stability</b>	Unopened multisensor is stable until expiration date stamped on the cartridge. Opened multisensor is stable for 14 days.
<b>Preparation</b>	Multisensor is ready for use. No preparation is required.

<b>Reagent</b>	<b>Standard B / Salt Bridge</b>
<b>Container</b>	Plastic Bottle
<b>Storage</b>	Store at room temperature
<b>Stability</b>	Both unopened and opened reagents are stable until expiration date stamped on the reagent.
<b>Preparation</b>	Reagent is ready for use. No preparation is required.

<b>Reagent</b>	<b>Standard A</b>
<b>Container</b>	Plastic Bottle
<b>Storage</b>	Store at room temperature
<b>Stability</b>	Both unopened and open reagents are stable until expiration date stamped on the reagent.
<b>Preparation</b>	Reagent is ready for use. No preparation is required.

### 5.3 Calibration Parameter

Criteria	Special Notations
<b>Reference Material</b>	<b>V-LYTE Integrated Multisensor, Standard A, Standard B and Salt Bridge</b>
<b>Assay Range</b>	See Reagent Package Insert for specific AMR values.
<b>Suggested Calibration Level</b>	See Reagent Package Insert for lot specific assigned values in mmol/L
<b>Frequency</b>	<ul style="list-style-type: none"> <li>• Every new reagent lot.</li> <li>• IMT system performs a two point automatic calibration in duplicate every 4 hours. In addition the system will routinely perform a one point calibration check with each sample measurement.</li> <li>• When major maintenance is performed on the analyzer.</li> <li>• When control data indicates a significant shift in assay.</li> </ul>
<b>Calibration Scheme</b>	2 levels, n = 2

### 5.4 Calibration Procedure

The Dimension Vista® IMT system performs a two point automatic calibration in duplicate every 4 hours. In addition, the system will routinely perform a one point calibration check with each sample measurement. Auto-calibration occurs after power-on, with the changing of standards A, B, or a sensor and when the system software is reset. Calibration can be initiated at any time a sample is not being run.

### 5.5 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
Liquid Assayed Multiquel® Levels 1 and 3	Bio-Rad Laboratories Cat. No. 337 and 339

### 6.2 Control Preparation and Storage

<b>Control</b>	Liquid Assayed Multiquel® Levels 1 and 3
<b>Preparation</b>	Allow the frozen control to stand at room temperature (18-25°C) for 30 minutes or 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.
<b>Storage/Stability</b>	<p>Frozen controls are stable until the expiration date at -20 to -50°C.</p> <p>Thawed and Unopened: When this product is stored at 2-8°C and the stopper is not punctured, it will be stable for 30 days for total protein</p> <p>This product can be used for 7 days when stored on-board the Siemens Dimension Vista at 2- 8°C.</p> <p>Thawed and Opened: Once the product stopper is punctured, all analytes will be stable for 5 days when stored at 2- 8°C.</p> <p>Store away from light.</p>

### 6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).



Refer to the Dimension Vista® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension Vista® 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	<p><b>Run Rejection Criteria</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.</li> </ul>
3	<p><b>Corrective Action:</b></p> <ul style="list-style-type: none"> <li>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 <u>reanalyzed according to the Laboratory QC Program</u>. 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.</li> <li>Corrective action documentation must follow the Laboratory Quality Control Program.</li> </ul>
4	<p><b>Review of QC</b></p> <ul style="list-style-type: none"> <li>QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.</li> <li>If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.</li> </ul>

#### 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 Vista® System

### 7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

### 7.3 Supplies

- Aliquot Plates
- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

## 8. PROCEDURE

V-LYTE is performed on the Dimension Vista® 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.**

<b>8.1</b>	<b>Sample Processing</b>
1.	A sample rack holding tubes or cups is placed on the rack input lane.
2.	The sample shuttle moves the rack to the barcode reader which identifies the rack and samples to the system.
3.	The rack moves into the sample server and to the rack positioner.
4.	At the same time, aliquot plates move from the aliquot loader into position.
5.	The aliquot probe aspirates the sample from the tubes or cups and dispenses it into the wells of the aliquot plates.
6.	After each aspirate-dispense action, the probe is thoroughly rinsed inside and out to prevent sample carryover.
7.	When sample aspiration is completed, the sample server moves the rack back to the sample shuttle, where it is placed on the output lane and can be removed by the operator.

<b>8.2</b>	<b>Specimen Testing</b>
1.	For QC placement and frequency, refer to the Dimension Vista® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension Vista® Operator’s 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 Vista® 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). 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.

<b>Test Conditions</b>	
Sample Volume:	25 µL
Diluent Volume:	225 µL
Reaction Time:	21 seconds
Test Temperature:	37° 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 the concentration of electrolytes 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 as a whole number and reports Potassium up to one decimal point.

### 10.3 Units of Measure

mmol/L

### 10.4 Clinically Reportable Range (CRR)

Analyte	Serum / Plasma	Urine
Sodium	50 – 200 mmol/L	5 – 300 mmol/L
Potassium	1.0 – 10.0 mmol/L	1.0 – 300.0 mmol/L
Chloride	50 – 200 mmol/L	N/A

### 10.5 Review Patient Data

Each result is reviewed for error messages. Refer to the Dimension Vista system manual “Error messages” section for troubleshooting. 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 within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is ...	THEN...
Plasma/serum 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.
Urine results Na >300 mmol/L K >300.0 mmol/L	Repeat the assay using a freshly prepared aliquot from 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

#### Plasma/Serum:

Age	Sodium	Potassium	Chloride
<b>Adult (&gt;18 years):</b>	135 - 145 mmol/L	3.5 - 5.1 mmol/L	98 - 107 mmol/L
<b>Pediatric:</b>			
> 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

#### Random Urine:

Age	Sodium	Potassium
All	40 - 220 mmol/L	25.0 - 125.0 mmol/L

#### 24 hour Urine:

Age	Sodium	Potassium
All	40 - 200 mmol/24hr	25.0 - 125.0 mmol/24hr

### 11.2 Critical Values

#### Plasma/serum:

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**

Sodium, potassium and chloride (Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>), also referred to as electrolytes, are commonly analyzed together in a metabolic panel since their concentrations provide the most relevant information about osmotic, hydration, and pH status of the body. The methods for measurement of electrolytes include flame photometry, spectrophotometry and direct or indirect ion selective electrode potentiometry.

**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 Vista Operator's Guide.

The expected maximum observed standard deviations for repeatability using n = 5 replicates at the following electrolytes concentrations are:

<b>Na Concentration</b>	<b>Acceptable S.D. Maximum</b>
120 mmol/L	5.4 mmol/L
164 mmol/L	4.9 mmol/L
<b>K Concentration</b>	<b>Acceptable S.D. Maximum</b>
4.0 mmol/L	0.17 mmol/L
7.4 mmol/L	0.29 mmol/L
<b>Cl Concentration</b>	<b>Acceptable S.D. Maximum</b>
99 mmol/L	4.2 mmol/L
123 mmol/L	4.9 mmol/L

**14. LIMITATIONS OF METHOD****14.1 Analytical Measurement Range (AMR)**

Analyte	Serum / Plasma	Urine
Sodium	50 – 200 mmol/L	5 – 300 mmol/L
Potassium	1.0 – 10.0 mmol/L	1.0 – 300.0 mmol/L
Chloride	50 – 200 mmol/L	N/A

**14.2 Precision**

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Na, Serum Pool	201	1.3 (0.7)	2.1(1.1)
Na, Multiquel Unassayed L2	140	1.3 (0.9)	1.8 (1.3)
Na, Multiquel Unassayed L3	164	1.2 (0.7)	1.7 (1.0)

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
K, Serum Pool	9.0	0.07 (0.9)	0.10 (1.1)
K, Multiquel Unassayed L2	4.0	0.04 (1.0)	0.06 (1.4)
K, Multiquel Unassayed L3	7.4	0.07 (0.9)	0.10 (1.4)
Cl, Serum Pool	174	1.6 (0.9)	2.0 (1.2)
Cl, Multiquel Unassayed L2	99	1.0 (1.0)	1.5 (1.5)
Cl, Multiquel Unassayed L3	123	1.2 (1.0)	1.6 (1.3)

### 14.3 Interfering Substances

- Hemolyzed samples may give incorrect elevated potassium results. Intracellular potassium concentration is 30-50 fold greater than that of extracellular serum or plasma.
- Samples exposed to Benzalkonium salts present in certain blood catheter devices will cause falsely elevated sodium and potassium measurements.
- Thiopental increases sodium results by as much as 33 mmol/L at 14 mg/dL of thiopental and up to 6 mmol/L at 2.8 mg/dL of thiopental.
- Salicylate has been shown to increase chloride results over the operational life of the chloride electrode.
- Salicylate at 60 mg/dL increases the chloride result at 103 mmol/L by 15%. Salicylate at 20 mg/dL increases the chloride result at 103 mmol/L by 4%.
- Iron at 1 g/dL increases the potassium result at 5 mmol/L by 28.6%.
- Iodine at 50 mg/dL increases the chloride result at 100 mmol/L by 16%.
- Bromide at 200 mg/dL increases the chloride result at 100 mmol/L by 66%.
- Iron at 1 g/dL increases the potassium result at 5 mmol/L by 28.6%.

#### HIL Interference:

The electrolytes method was evaluated for interference according to CLSI/NCCLS EP7-A2. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Substance Concentration	mmol/L	Bias %
Hemoglobin (hemolysate)	750 mg/dL	Na 132 K 3.8 Cl 97	<10
Bilirubin (unconjugated)	60 mg/dL	Na 132 K 3.8 Cl 97	<10
Bilirubin (conjugated)	60 mg/dL	Na 132 K 3.8 Cl 97	<10
Lipemia Intralipid®	3000 mg/dL	Na 132 K 3.8 Cl 97	<10 -16

#### 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.

#### 16. RELATED DOCUMENTS

1. Dimension Vista® Clinical Chemistry System Operator's Manual
2. Dimension Vista® Calibration/Verification Procedure
3. Dimension Vista® Cal Accept Guidelines
4. Dimension Vista® Calibration summary
5. Dimension Vista® Sample Processing, Startup and Maintenance procedure
6. Laboratory Quality Control Program
7. QC Schedule for Siemens Dimension Vista®
8. Laboratory Safety Manual
9. Safety Data Sheets (SDS)
10. Dimension Vista® Limits Chart (AG.F200)
11. Quest Diagnostics Records Management Procedure
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
14. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications  
at [http://questnet1.qdx.com/Business\\_Groups/Medical/qc/docs/qc\\_bpt\\_tea.xls](http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls)
17. Current package insert V-LYTE Flex® Reagent Cartridge K800A

#### 17. REFERENCES

1. Package Insert, V-LYTE Flex® Reagent Cartridge K800A, Siemens Healthcare Diagnostics Inc., 08/30/2013.
2. Package Insert, Liquid Assayed Multiqual® Chemistry Controls, Bio-Rad Laboratories, 09/2015.

#### 18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	10/29/13		Update owner	L Barrett	R SanLuis



Version	Date	Section	Reason	Reviser	Approval
000	10/29/13	11.1	Change ranges for random urine sodium and potassium	L Barrett	R SanLuis
000	10/29/13	16	Update titles	L Barrett	R SanLuis
000	10/29/13	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
1	4/13/15	3.2	Specify lithium heparin anticoagulant	L Barrett	R SanLuis
1	4/13/15	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
1	4/13/15	11.2	Standardize low K+ critical value <3.0	L Barrett	R SanLuis
2	3/6/17	Header	Add WAH	L Barrett	R SanLuis
	3/6/17	3.2	Remove specimen onboard stability	L Barrett	R SanLuis
2	3/6/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	3/6/17	7.2	Change freezer upper limit to -50C	L Barrett	R SanLuis
2	3/6/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
2	3/6/17	14.3	Update list of interferences	L Barrett	R SanLuis
2	3/6/17	15	Update to new standard wording	L Barrett	R SanLuis
2	3/6/17	17	Update QC product and PI dates	L Barrett	R SanLuis

**19. ADDENDA**

None