TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	7/20/2016
Department:	Core	**Due Date:**	8/8/2016
		Implementation:	**8/9/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Lactic Acid by Dimension Vista® System SGAH.C80 v2

Note: this has been converted to a system SOP

Description of change(s):

Section	Reason
Header	Add WAH
4.2	Add safety instructions
5.1	Update Catalog number
6.1, 6.2	Update QC product – *new QC is already in use*
6.4, 6.6	Replace LIS with Unity Real Time
7.2	Change freezer range to -50C
11.2	Add sepsis protocol value
17	Update QC, PI revision dates

This revised SOP will be implemented on August 9, 2016

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

Technical SOP

Title	**Lactic Acid by Dimension Vista® System**		
Prepared by	Ashkan Chini	Date:	6/22/2012
Owner	Robert SanLuis	Date:	6/12/2014

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

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Lactic Acid	Dimension Vista® System	LACT

Synonyms/Abbreviations
Lactate, LA

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Lactic Acid method is a modification of the Marbach and Weil method which employs the oxidation of lactate to pyruvate.
Rabbit muscle lactic dehydrogenase (LDH) catalyzes the oxidation of L-lactate to pyruvate with simultaneous reduction of nicotinamide adenine dinucleotide (NAD). One mole of NAD is converted to one mole of NADH for each mole (equivalent) of lactate present. The absorbance due to NADH is directly proportional to the lactate concentration and is measured using a two-filter (340 – 383 nm) end point technique.

$$\text{L-lactate} + NAD^{+} \xrightarrow{\text{LDH}} \text{Pyruvate} + NADH + H^{+}$$

Hydrazine is used to trap the pyruvate (as a Hydrazone) as it is formed, thus driving the reaction to completion.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	The patient should be fasting and at complete rest.
Specimen Collection and/or Timing	Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes.
Special Collection Procedures	Keep sample on ice and analyze promptly.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type	**-Preferred**	Plasma – Gray Top (sodium fluoride/potassium oxalate)
	-Other Acceptable	None
Collection Container		Gray Top Tube
Volume	**- Optimum**	1.0 mL
	- Minimum	0.5 mL
Transport Container and Temperature		Plastic vial or spun barrier tube on ice
Stability & Storage Requirements	Room Temperature:	Unacceptable
	Refrigerated:	1 day
	Frozen:	1 month

Criteria	
	Instrument on board aliquot stability 2 hours
Timing Considerations	Separate from cells within 15 minutes, test immediately.
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 explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	None.

4. REAGENTS

Refer to the Safety Data Sheet (SDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Lactic Acid	Siemens, Flex® reagent cartridge, Cat. No. K3016

4.2 Reagent Preparation and Storage

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. Refer to the Safety Data Sheet (SDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Harmful if swallowed, in contact with skin or if inhaled. May cause an allergic skin reaction May cause cancer.
Wear protective clothing, gloves and eye/face protection.

Reagent	**Lactic Acid**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent

	cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 8 have been entered by the instrument, they are stable for 5 days.
Preparation	Hydration, mixing and diluting are automatically performed by the instrument.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM 1 CAL	Siemens Dimension Vista®, Cat. No. KC110B

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

Calibrator	CHEM 1 CAL
Preparation	Allow CHEM 1 Calibrator to thaw and equilibrate to room temperature (22 – 28° C) for 1 hour. Before use, **gently** invert the calibrator vials at least 10 times to ensure that the contents are thoroughly mixed. **Do not vortex.**
Storage/Stability	• Store at -25 to -15° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHEM 1 CAL
Assay Range	0.1 – 15.0 mmol/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mmol/L

Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

1. Place the required calibrator vials in a carrier. Make sure the barcode labels are entirely visible through the slots.
2. Place the carrier in the loading area.
3. Position the carrier with the labels facing away from the user.
4. Press the **Load** button.
5. Automatic calibration requires that calibrators be on the instrument. As the time for processing approaches, the instrument reviews onboard inventory for the appropriate calibrators.

Manual Calibration:

1. Verify that calibrators and reagents are in inventory on the instrument.
2. Press **System > Method Summary > Calibration**.
3. Select a method from the sidebar menu. Press the **Order Calibration** button on the screen.
4. Verify that the information on the screen is correct. Verify that the calibrator lot is correct using the drop-down menu.
   a. When calibrating using Vials press **OK**.
   b. When calibrating using Cups, check the Use Cups box. This displays the rack and cup position fields. For additional cups use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU. Scan the rack barcode and place calibrator cups in an adapter in position 1 on a rack. Press **OK** and load the rack on the instrument.
5. The status field in the calibration screen changes sequentially to Awaiting Scheduling, Preparing Calibrators and Processing.

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 Multiqual Levels 1 & 3	Bio-Rad Laboratories Cat. No. 337 & 339

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquid Assayed Multiqual, Levels 1 and 3
Preparation	Allow the frozen control to stand at room temperature (18-25°C) for 30 minutes or until completely thawed. A precipitate may be present that dissolves upon mixing. Before loading vials, gently swirl the contents to ensure homogeneous with no visible sign of precipitate. (Do not use a mechanical mixer)
Storage/Stability	Unthawed controls are stable until the expiration date at -20 to -50°C. Once the product stopper is punctured, all analytes will be stable for 5 days when stored at 2 - 8° C.

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

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.

Step	Action
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.
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 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.

6.6 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
- 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.

6.7 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

LA Flex® reagent cartridge Cat. No. K3016 is required to perform this test.

Lactic Acid 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.

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.

8.1	Sample Processing
1.	A sample rack holding tubes or cups is placed on the rack input lane.

8.1	Sample Processing
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.

8.2	Specimen Testing
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.

Test Conditions	
Sample Volume:	1.8 µL
Buffer Volume:	71.1 µL
Dihydrazine Sulfate:	9 µL
NAD Volume:	33.8 µL
LDH solution Volume:	9 µL
Test Temperature:	37° C
Reaction Time:	8.9 minutes
Wavelength:	340 & 383 nm
Type of measurement:	Bichromatic endpoint

9. CALCULATIONS

The instrument automatically calculates the concentration of Lactic Acid 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 results up to one decimal point.

10.3 Units of Measure

mmol/L

10.4 Clinically Reportable Range (CRR)

0.1 – 60.0 mmol/L

10.5 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…
< 0.1 mmol/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.1 mmol/L
≥ 15.0 mmol/L	**On Board Automated Dilution:** Results ≥ 15.0 mmol/L will automatically have repeat testing performed into the instrument using dilution factor of 4. No multiplication is necessary.
> 60.0 mmol/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 60.0 mmol/L-REP" Bring to the attention of your supervisor prior to releasing result.

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

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11. EXPECTED VALUES

11.1 Reference Ranges

Age	Male/Female
Adult:	0.4 - 2.0 mmol/L
Pediatric:	
2 – 18 years	1.0 - 2.4
3 months – 2 years	1.0 - 3.3
0–3 months	1.0 - 3.5

11.2 Critical Values

> 4.0 mmol/L

For Sepsis Protocol: call values > 1.9 mmol/L

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Lactate is a product of carbohydrate metabolism. Lactic acid is produced during periods of anaerobic metabolism when cells do not receive adequate oxygen to allow conversion of fuel sources to carbon dioxide and water. Lactic acid will accumulate because of excess production of lactate and decreased removal of lactic acid from blood by liver

This measurement contributes to the knowledge of acid-base volume in the body and is used to detect lactic acidosis in persons with underlying risk factors that predispose them to this imbalance, such as cardiovascular and renal disease. Lactate will be elevated in a variety of conditions in which hypoxia is present and in liver disease. Lactic acidosis can occur both in diabetics and nondiabetics, and it is an often-fatal form of metabolic acidosis. The presence of an unexplained fall in pH associated with a hypoxia producing condition is reason to suspect lactic acidosis.

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 analyte concentrations are:

LA Concentration	Acceptable S.D. Maximum
2.7 mmol/L	0.1 mmol/L
13.5 mmol/L	0.6 mmol/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.1 – 15.0 mmol/L

14.2 Precision

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	1.5	0.03 (2.3)	0.04 (2.7)
Level 2	15.0	0.1 (0.9)	0.2 (1.1)

14.3 Interfering Substances

Cholesterol at 500 mg/dL increased LA results by 14.9 % at LA concentration of 6 mmol/L.

HIL Interference:
The LA 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	LA mmol/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	6	<10
Bilirubin (unconjugated)	40 mg/dL 60 mg/dL	6	<10 11.3
Bilirubin (conjugated)	60 mg/dL	6	<10
Lipemia Intralipid®	800 mg/dL 1000 mg/dL 3000 mg/dL	6	<10 13.4 12.2

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14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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
17. Current package insert LA Flex® Reagent Cartridge K3016

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, LA Flex® Reagent Cartridge K3016, Siemens Healthcare Diagnostics Inc., 04/27/2015.
3. Package Insert, CHEM I CAL, Siemens Healthcare Diagnostics Inc., 03/2015.
4. Package Insert, Liquid Assayed Multiqual, Bio-Rad Laboratories, 09/2015.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/12/14		Update owner	L Barrett	R SanLuis
000	6/12/14	5.2	Update open calibrator stability	A Chini	R SanLuis
000	6/12/14	16	Update titles	L Barrett	R SanLuis
000	6/12/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
1	7/10/16	Header	Add WAH	L Barrett	R SanLuis
1	7/10/16	4.2	Add safety instructions	A Chini	R SanLuis
1	7/10/16	5.1	Update Catalog number	A Chini	R SanLuis
1	7/10/16	6.1, 6.2	Update QC product	A Chini	R SanLuis
1	7/10/16	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
1	7/10/16	7.2	Change freezer range to -50C	L Barrett	R SanLuis
1	7/10/16	11.2	Add sepsis protocol value	L Barrett	R SanLuis
1	7/10/16	17	Update QC, PI revision dates	A Chini	R SanLuis

19. ADDENDA

None