TRAINING UPDATE

Lab Location:	GEC, SGMC & WOMC	**Date Distributed:**	11/4/2020
Department:	Core Lab	**Due Date:**	11/30/2020
		Implementation:	**11/4/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Lactic Acid by Dimension Vista® System SGAH.C80 v4

Lactic Acid by Dimension® EXL Chemistry Analyzer GEC.C262 v2

Description of change(s):

Both SOPs:

Section	Reason
11.2	Updated sepsis protocol **Note**: *DI will add the comment of LACTC to the test comment when the current critical result is less than the previous result and the date/time of the previous result is less than or equal to 24hrs.* *LACTC expands to "Laboratory value indicates a critical value previously reported" in SQ*

The revised SOPs were implemented on November 4, 2020

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.		

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Adventist HealthCare
Site: Shady Grove Medical Center, White Oak Medical Center
Title: **Lactic Acid by Dimension Vista® System**

1. TEST INFORMATION

Assay	Method/Instrument	Test 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 **-Other Acceptable**	Plasma – Gray Top (sodium fluoride/potassium oxalate) None
Collection Container	Gray Top Tube
Volume - Optimum **- Minimum**	1.0 mL 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
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

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.

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
Lactic Acid	Siemens, Flex® reagent cartridge, Cat. No. K3016

4.2 Reagent Preparation and Storage

Reagent	**Lactic Acid**
Container	Reagent cartridge
Storage	Store at 2-8°C

Stability	• Stable until expiration date stamped on reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Open wells: 5 days for wells 1 - 8
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

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:** until expiration date on the box. • **Opened:** once the stopper is punctured, 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

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. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately.
Storage/Stability	**Frozen**: stable until the expiration date at -20 to -50°C. **Thawed and Opened**: Once the stopper is punctured, all analytes will be stable for 5 days when stored at 2-8°C. Store away from light.

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.
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.

Adventist HealthCare
Site: Shady Grove Medical Center, White Oak Medical Center
Title: **Lactic Acid by Dimension Vista® System**

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
- 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 -15 to -25°C for calibrator
- Freezer capable of sustaining range not to exceed -20 to -50°C for QC product
- 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.

8.1	Sample Processing
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.

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 10.6 "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

Test Conditions	
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 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 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…
< 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.

IF the result is …	THEN…
> 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 Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

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

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 only when results are increasing

Example:

First value	1.8	= no call required
Second value	2.8	= call result
Third value	2.2	= no call required (result decreased)
Fourth value	3.0	= call result (result increased)

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

Substance tested	Substance Concentration	LA mmol/L	Bias %
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

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.

LA Flex reagent is harmful if swallowed, in contact with skin or if inhaled. May cause an allergic skin reaction. May cause cancer. Very toxic to aquatic life with long lasting effects. Contains Hydrazine sulfate; Ammonium hydrogen sulfate. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

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. Specimen Acceptability Requirements (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., 05/06/2019.
3. Package Insert, CHEM I CAL, Siemens Healthcare Diagnostics Inc., 06/2019.
4. Package Insert, Liquid Assayed Multiqual® Chemistry Controls, Bio-Rad Laboratories, 08/2019.

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
2	6/16/20	Header	Change WAH to WOMC	L Barrett	R SanLuis
2	6/16/20	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	6/16/20	7.3	Add reagent grade water	L Barrett	R SanLuis
2	6/16/20	8.2	Correct section reference in step 4	L Barrett	R SanLuis
2	6/16/20	10.5	Move patient review from section 6	L Barrett	R SanLuis
2	6/16/20	10.6	Remove repeat value below AMR/CRR	L Barrett	R SanLuis
2	6/16/20	15	Update to new standard wording, add hazard statements	L Barrett	R SanLuis
2	6/16/20	16	Update policy title	L Barrett	R SanLuis
2	6/16/20	17	Update package insert dates	L Barrett	R SanLuis
3	10/23/20	11.2	Updated sepsis protocol	L Barrett	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Lactic Acid by Dimension® EXL Chemistry Analyzer**
Prepared by	Demetra Collier Date: 9/8/2020
Owner	Robert SanLuis Date: 9/8/2020

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
Lactic Acid	Dimension® EXL Chemistry Analyzer	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, 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 Only
-Other Acceptable	None
Collection Container	Gray top
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: (2-8°C) 1 day
	Frozen: (-20°C or colder) 1 month
Timing Considerations	Separate from cells within 15 minutes, test immediately.
Unacceptable Specimens & Actions to Take	Anticoagulants other than fluoride and specimen without ice. Reject sample and request redraw. 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 redraw. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	N/A

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 / Kits	Supplier & Catalog Number
Lactic Acid	Siemens, Flex® reagent cartridge, Cat. No. DF16

4.2 Reagent Preparation and Storage

Reagent	**Lactic Acid**
Container	Reagent cartridge
Storage	Store at 2-8°C
Stability	• Stable until expiration date stamped on reagent cartridges. • Sealed cartridge wells on the instrument are stable for 30 days. • Open well stability: 5 days for wells 1 - 8
Preparation	Hydrating, diluting and mixing are automatically performed by the instrument.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM I Calibrator	Siemens Dimension®, Cat. No. DC18C

5.2 Calibrator Preparation and Storage

Calibrator	CHEM I Calibrator
Preparation	• Remove vials from refrigerator and proceed directly to next step. • Remove stopper and add 2.00 ± 0.01 mL Purified Water Diluent or reagent grade water. The water should be at room temperature. • Replace stopper, and let stand for 5 minutes. Do not invert. • Swirl vials gently for 30 seconds, and then gently invert 10 times. • Let vials stand for 10 minutes, and then gently invert 10 times. • Let vial stand for 15 minutes. Then invert 10 times and swirl gently. • Use immediately or refrigerate at 2-8°C for future use. Prior to use, invert 10 times and swirl gently.
Storage/Stability	• Store at 2-8°C. • Unopened calibrators are stable until the expiration date printed on the label. • Assigned values are stable for 24 hours after reconstitution when stored at 2-8°C.

5.3 Calibration Parameters

Criteria	Special Notations
Reference Material	CHEM I Calibrator
Assay Range	0.3 – 15.0 mmol/L
Calibration levels	See Reagent Package Insert for lot specific assigned values in mmol/L.
Frequency	• Every new reagent cartridge lot. • Every 3 months for any lot. • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate.
Assigned Coefficients	C_0 –1.156 C_1 0.0451
Procedure	Refer to Calibration / Verification Siemens Dimension® EXL 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 Controls 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	**Open thawed controls**: stable for 15 days at 2-8°C. **Frozen**: 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 EXL® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension 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.
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 EXL® 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

- Calibrated pipettes and disposable tips
- Plastic serum tubes and serum cups
- Reagent Grade Water

8. PROCEDURE

LA Flex® reagent cartridge Cat. No. DF16 is required to perform this test.

Lactic Acid is performed on the Dimension EXL® 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® EXL procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® EXL 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® EXL segments for analysis by the instrument. Refer to the Sample Processing, Dimension® EXL 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® EXL QC Schedule.
2.	Follow the instructions, outlined in the Dimension® EXL 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® EXL system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.6 "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. 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:	4 µL
Reagent 1 Volume:	158 µL
Reagent 2 Volume:	20 µL
Reagent 3 Volume:	75 µL
Reagent 4 Volume:	20 µL
Diluent Volume:	197 µL
Temperature:	37°C
Wavelength:	340 and 383 nm
Type of Measurement:	bichromatic end point

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 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 to one decimal point.

10.3 Units of Measure

mmol/L

10.4 Clinically Reportable Range (CRR)

0.3 – 30.0 mmol/L

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension EXL® 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…
< 0.3 mmol/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.3 mmol/L

IF the result is …	THEN…
≥ 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 2. No multiplication is necessary.
> 30.0 mmol/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 30.0 mmol/L-REP" Check for integrity issues prior to releasing result.

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

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 only when results are increasing

Example:

First value	1.8	= no call required
Second value	2.8	= call result
Third value	2.2	= no call required (result decreased)
Fourth value	3.0	= call result (result increased)

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 Operator's Guide.

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

Concentration	S.D.
2.0 mmol/L	> 0.15 mmol/L
8.0 mmol/L	> 0.40 mmol/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.3 – 15.0 mmol/L

14.2 Precision

Material	Mean mmol/L	Standard Deviation (% CV)	
		Within-run	Total
Plasma Pool	3.2	0.09 (2.8)	0.10 (3.2)
Plasma Pool	10.4	0.16 (1.6)	0.20 (1.9)
CSF Pool	2.7	0.08 (3.1)	0.09 (3.5)
CSF Pool	5.5	0.17 (3.2)	0.22 (4.0)

14.3 Interfering Substances

- Intravenous injection of epinephrine, glucose, bicarbonate, or other infusions that modify the acid-base balance causes elevation of lactate (and also pyruvate) levels not necessarily related to hypoxia.
- Lipemia (Intralipid®) of 3000 mg/dL (33.9 mmol/L) tripped a test report message; therefore the magnitude of interference could not be determined.

HIL Interference:
The LA method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NCCLS EP7-P. 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	Test Concentration [SI Units]	LA Conc mmol/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL [0.62 mmol/L] (momomer)	2.97	<10
Bilirubin (unconjugated)	20 mg/dL [342 µmol/L]	2.88	<10
	40 mg/dL [684 µmol/L]	2.88	14
Lipemia Intralipid®)	1000 mg/dL [11.3 mmol/L]	3.99	<10

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.

LA Flex® reagent cartridge may cause an allergic skin reaction. May cause cancer. Harmful if swallowed, in contact with skin or if inhaled. Contains: Hydrazine sulfate; Benzalkonium chloride. Wear protective gloves/protective clothing/eye protection/face protection.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

16. RELATED DOCUMENTS

1. Dimension EXL® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® EXL procedure
3. Dimension EXL® Cal Accept Guidelines
4. Dimension EXL® Calibration summary
5. Sample Processing, Dimension® EXL procedure
6. Maintenance, Siemens Dimension® EXL procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension EXL®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Dimension EXL Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension EXL® 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 LA Flex® Reagent Cartridge DF16

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, Lactic Acid Flex® Reagent Cartridge DF16, Siemens Healthcare Diagnostics Inc., 4/1/2019
3. Package insert, CHEM I Calibrator DC18C, Siemens Healthcare Diagnostics Inc., 5/23/20
4. Package insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 3/2019

18. REVISION HISTORY

Date	Section	Reason	Reviser	Approval
10/23/20	11.2	Updated sepsis protocol	L Barrett	R SanLuis

19. ADDENDA

None