TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	11/20/2015
Department:	Core	**Due Date:**	12/14/2015
		Implementation:	**12/15/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Lipase by Dimension® Xpand Chemistry Analyzer	**GEC.C05 v3**
Magnesium by Dimension® Xpand Chemistry Analyzer	**GEC.C13 v3**
Protein, Cerebrospinal Fluid by Dimension® Xpand Chemistry Analyzer	**GEC.C25 v2**
Lactic Acid by Dimension® Xpand Chemistry Analyzer	**GEC.C31 v2**

Description of change(s):

Most changes are minor and the following apply to all of them

Section	Reason
6.4, 6.6	Replace LIS with Unity Real Time
6.5	Remove print out
8.2	Remove Lynx
16	Update titles

Lipase and Magnesium

Section	Reason
3.2	Specify anticoagulant, add separation within 2 hours

Protein, CSF only

Section	Reason
1,3,11,12	Remove urine test information
9	Remove 24 hour urine calculation

Lactic Acid only

Section	Reason
4.2	Add chemical safety information
11.3	Add sepsis protocol value

A copy of the Lactic Acid SOP is attached with changes highlighted

These revised SOPs will be implemented on December 15 , 2015

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

Approved draft for training

Technical SOP

Title	**Lactic Acid by Dimension® Xpand Chemistry Analyzer**
Prepared by	Leslie Barrett Date: 7/27/2009
Owner	Robert SanLuis Date: 06/29/2011

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**

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Lactic Acid	Dimension® Xpand Chemistry Analyzer	LACT

Synonyms/Abbreviations
Lactate, LA

Department
Chemistry

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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.	

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Criteria	
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

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) 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 / Kits	Supplier & Catalog Number
Lactic Acid	Siemens, Flex® reagent cartridge, Cat. No. DF16

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) 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.

Contains Hydrazine sulfate; Benzalkonium chloride.
Harmful if swallowed, in contact with skin or if inhalded.
Wear protective clothing, gloves and eye/face protection.

Reagent	**Lactic Acid**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• The unopened reagents are stable until the expiration date printed on the label when stored at 2-8°C.

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	• Sealed cartridge 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	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. DC18A

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) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	CHEM I Calibrator
Preparation	• Remove vials from refrigerator and proceed directly to next step. • Remove stopper and add 2.00 mL 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. • The 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
Suggested calibration level	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

5.4 Calibration Procedure

1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated - if lot number is incorrect Press F1: Other Lot
3. Enter all information on screen
4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.
6. Press F7: Load/run
7. Load cups into assigned position
8. Press F4: RUN

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis

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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

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	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 controls are stable for 15 days at 2-8°C. Unopened controls are 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

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.

Step	Action
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 Review Patient Data

Technologist must review each result for 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.

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 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.

6.7 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 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

- 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 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.

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	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. 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

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 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…
< 0.3 mmol/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.3 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 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" 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:	
0–3 months	1.0 -3.5
3 months – 2 years	1.0 - 3.3
2 – 18 years	1.0 -2.4

11.2 Critical Values

> 4.0 mmol/L

11.3 Priority 3 Limit(s)

> 1.9 mmol/L are flagged to be called per Sepsis protocol

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] 40 mg/dL [684 µmol/L]	2.88 2.88	<10 14
Lipemia Intralipid®)	1000 mg/dL [11.3 mmol/L]	1.66	<10

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 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. Material Safety Data Sheets (MSDS)
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. Hemolysis, Icteria and Lipemia Interference (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., 01/30/2015.
3. Package insert, CHEM I Calibrator DC18A, Siemens Healthcare Diagnostics Inc., 02/2014.
4. Package insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 08/2014.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	8/8/2012	1	Add analyzer name	L Barrett	J Buss, RSL
000	8/8/2012	4.2	Add well numbers	A Chini	J Buss, RSL
000	8/8/2012	10.5	Add decimal and clarified Repeat Criteria, remove QNSR code	A Chini L.Barrett	J Buss, RSL
000	8/8/2012	14.1	Add decimal point to the AMR	A Chini	J Buss, RSL
000	8/8/2012	17	Update QC P. I.	A Chini	J Buss, RSL
001	10/14/15	4.2	Add chemical safety information	A Chini	R SanLuis
001	10/14/15	6.4, 6.6	Replace LIS with Unity Real Time	A Chini	R SanLuis
001	10/14/15	6.5	Remove print out	A Chini	R SanLuis
001	10/14/15	8.2	Remove Lynx	A Chini	R SanLuis
001	10/14/15	9	Add statement	A Chini	R SanLuis
001	10/14/15	11.3	Add sepsis protocol value	L Barrett	R SanLuis
001	10/14/15	16	Update document titles	L Barrett	R SanLuis
001	10/14/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None