Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	8/30/2012
Department:	Core	**Due Date:**	9/30/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:	
Magnesium by Dimension® Xpand Chemistry Analyzer	**GEC.C13.002**
Lipase by Dimension® Xpand Chemistry Analyzer	**GEC.C05.002**
Lactic Acid by Dimension® Xpand Chemistry Analyzer	**GEC.C31.001**

Description of change(s):

Magnesium

section	description
1	Add analyzer name
4.2	Add well numbers
5.3	Refer to PI for calibration levels
6.4	Delete QC ranges stored in instrument
6.7	Add use of TEA for lot to lot runs
10.5	Add below CRR instructions, clarify manual dilution

Lipase

section	description
1	Add analyzer name
3.2	Change frozen storage to 12 months
5.2	Revise Calibration preparation
5.3	Refer to PI for calibration levels
5.5	Correct second entry of ‘and’ to ‘or’
6.2	Reformat section, no change to content
6.4	Delete QC ranges stored in instrument
6.7	Add use of TEA for lot to lot runs
7.2	Add Centrifuge
7.3	Remove volumetric pipettes
10.5	Edit section, correct manual dilution. Add message code
14.2	Revise to match PI
14.3	Update Siemens method code
15	Update to standard wording
16	Update document list titles

Lactic Acid

section	description
1	Add analyzer name
4.2	Add well numbers
10.5	Add decimal and clarified Repeat Criteria, remove QNSR code
14.1	Add decimal point to the AMR
17	Update QC P. I.

Changes on SOPs are in highlighted in yellow

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

Technical SOP

Title	**Magnesium by Dimension® Xpand Chemistry Analyzer**
Prepared by	Leslie Barrett Date: 4/16/2010
Owner	Robert SanLuis Date: 8/8/2012

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

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

Form revised 2/02/2007

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Magnesium	Dimension® Xpand Chemistry Analyzer	MG

Synonyms/Abbreviations
MG

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The magnesium method is a modification of the methylthymol blue (MTB) complexometric procedure described by Connery, Lau, and Briggs. The barium salt of ethylenebis (oxyethylenitrilo) tetraacetic acid (Ba-EGTA) is used to reduce interference due to calcium which also reacts with MTB.

MTB forms a blue complex with magnesium. Calcium interference is minimized by forming a complex between calcium and BA-EGTA (chelating agent). The amount of MG-MTB complex formed is proportional to the magnesium concentration and is measured using a bichromatic (600 and 510 nm) endpoint technique. For Dimension AR (software version 4.4 and above), ES (software 2.7. or 4.3 and above) and XL/RxL (software version 5.0 and above), a sample blank is used to minimize bilirubin interference.

Mg^{++} + MTB ----------→ Mg-MTB Complex
(absorbs at 600 nm)

Ca^{++} + Ba-EGTA----------→Complex
(nonabsorbing at 600 nm)

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method. Avoid prolonged contact of the serum and plasma with separated red cells.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Plasma (Heparin)
-Other Acceptable	Serum
Collection Container	Plasma: Green top tube Serum: Red top tube, Serum separator tube (SST)

Criteria	
Volume - Optimum	1.0 mL
- Minimum	0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 7 days if separated
	Refrigerated: (2-8°C) 7 days if separated
	Frozen: (-20°C or colder) 1 year
Timing Considerations	N/A
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	Allow to clot completely prior to centrifugation.

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	Supplier & Catalog Number
Magnesium	Siemens, Flex® reagent cartridge, Cat. No. DF57

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.

Reagent	**Magnesium**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. • Once wells 1 - 8 have been entered by the instrument, they are stable for 2 days.
Preparation	Reagents are supplied ready for use. No additional preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM II Calibrator	Siemens Dimension®, Cat. No. DC20

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 II Calibrator
Preparation	• Wrap the ampule with towel to avoid the potential of hand injury. • Remove ampule top by applying pressure above the scored line. • Transfer contents of the ampule to the sample cup.
Storage/Stability	• Store at 2-8° C. • The unopened calibrators are stable until the expiration date printed on the label • Opened ampules should be used immediately and any portion not used should be discarded.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHEM II Calibrator
Assay Range	0.0-20.0 mg/dL

Calibration levels	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 3 months for any one 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 - 0.200 C_1 0.100

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
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 & 2	Bio-Rad Laboratories Catalog # 691 & 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 Controls, Level 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® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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 Review Patient Data

Technologist must review each result print-out for error messages. Refer to the Dimension® 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 the LIS. The LIS 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.

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- 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® Chemistry Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- Millipore® water
- Calibrated pipettes and disposable tips

8. PROCEDURE

MG Flex® reagent cartridge Cat. No. DF57 is required to perform this test.

Magnesium is performed on the Dimension® clinical chemistry 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® procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	For sites with StreamLab (Lynx): **Qualifying** samples are loaded via the Dimension® Lynx System which automatically routes specimens to the instruments. Refer to the Dimension® Streamlab® Analytical Workcell (Lynx) System manual for instructions.
3.	Alternatively, specimens are placed in color-coded Dimension® segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® 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® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® 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® 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:	100 µL
Reagent 2 Volume:	200 µL
Diluent Volume:	696 µL
Test Temperature:	37° C
Wavelength:	600 and 510 nm
Type of measurement:	bichromatic endpoint

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of magnesium in mg/dL.

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

mg/dL

10.4 Clinically Reportable Range (CRR)

0.0 – 60.0 mg/dL

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…
< 0.0 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.0 mg/dL
≥ 20.0 mg/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 3 **DILUENT**: Water Enter dilution factor as a whole number on the "Enter Sample Data" screen. Reassay. Resulting readout is corrected for dilution.
> 60.0 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 60.0 mg/dL-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>18 years):	1.8 – 2.4 mg/dL	1.8 – 2.4 mg/dL
Pediatric:		
0– 90 days	1.5-2.1	1.5-2.2
3 – 12 months	1.6-2.2	1.6-2.5
13 months – 3 years	1.5-2.2	1.6-2.2
4 – 10 years	1.6-2.5	1.5-2.2
11 – 17 years	1.6-2.1	1.4-2.1
18 years	1.5-1.9	1.6-2.1

11.2 Critical Values

All ages, male and female

Low ≤ 1.0 mg/dL
High ≥ 7.0 mg/dL

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Magnesium is involved in many enzymatic reactions of metabolism as an activating ion. Decreased levels of magnesium lead to muscle irritability, and possibly tetany, if not corrected. Elevated levels reduce muscle and nerve irritability, and at extremely high levels result in an anesthetic effect that could ultimately cause cardiac arrest. Magnesium may be increased in patients with kidney failure. Some conditions in which magnesium may be decreased include: 1) prolonged intravenous feeding, 2) chronic alcohol intoxication and alcoholic cirrhosis, 3) primary hyperaldosteronism 4) malabsorption syndromes 5) diabetic coma, and 6) hyperparathyroidism.

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 you Dimension Operator's Guide.

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

Concentration	S.D.
1.0 mg/dL [0.41 mmol/L]	>0.11mg/dL [0.05mmol/L]
9.0 mg/dL [3.7 mmol/L]	>0.56 mg/dL [0.23 mmol/L]

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.0 – 20.0 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Within-run	Total
QCS™ Control Serum Assayed			
Normal	2.2 [0.91]	0.07 [0.03][3.2]	0.11[0.04][5.0]
Abnormal	3.9 [1.60]	0.18 [0.07][4.6]	0.09[0.98][4.9]
Fisher Urine Chemistry Control			
Level 1	20.1 [8.27]	0.4 [0.16][2.0]	0.6[0.25][3.0]
Level 2	4.2 [1.73]	0.1 [0.04][2.4]	0.1[0.04][2.4]
Urine Pool	9.8 [4.03]	0.1 [0.04][1.0]	0.2[0.08][2.0]

14.3 Interfering Substances

- Bilirubin (unconjugated) of 60 mg/dL [1026 µmol/L] increases a magnesium concentration of 0.97 mg/dL [0.40 mmol/L] by 14%.
- Lipemia (Intralipid®) of 3000 mg/dL (33.9 mmol/L) increases a magnesium concentration of 0.92 mg/dL [0.38 mmol/L] by 14%.
- Hemoglobin (hemolysate) of 300 mg/dL [0.19 mmol/L] (monomer) increases a magnesium concentration of 0.94 mg/dL [0.39 mmol/L] by 18%.

HIL Interference:
The MG 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	MG Concentration mg/dL	Bias %
Hemoglobin (hemolysate)	200 mg/dL (monomer)	0.94	<10
Bilirubin (unconjugated)	40 mg/dL	0.97	<10
Lipemia (Intralipid®)	1000 mg/dL	0.92	<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® Clinical Chemistry System Operator's Manual
2. Dimension® Calibration/Verification Procedure
3. Dimension® Cal Accept Guidelines
4. Dimension® Calibration summary
5. Sample Processing, Siemens Dimension® procedure
6. Start up and Maintenance, Siemens Dimension® procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension® Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension® Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirement (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 MG Flex® Reagent Cartridge DF57

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, MG Flex® Reagent Cartridge DF57, Siemens Healthcare Diagnostics Inc., 02/2010.
3. Package insert, CHEM II Calibrator DC20, Siemens Healthcare Diagnostics Inc., 02/2010.
4. Package insert, Liquichek™ Unassayed Chemistry Controls, Bio-Rad Laboratories, 8/2008.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C097.000		
000	6/17/11		Update owner	L Barrett	J Buss
000	6/17/11	3.2	Add documentation for hemolysis rejection	L Barrett	J Buss
000	6/17/11	5.5	Correct second entry of 'and' to 'or'	L Barrett	J Buss
000	6/17/11	6.2	Simplified storage/stability by removing redundant instructions.	L Barrett	J Buss
000	6/17/11	7.3	Remove volumetric pipettes	L Barrett	J Buss
000	6/17/11	11.2	Revise upper critical value	L Barrett	Dr Cacciabeve
000	6/17/11	16	Update related documents	L Barrett	J Buss
000	6/17/11	17	Update references	L Barrett	J Buss
001	8/8/12		Update owner	L Barrett	J Buss, RSL
001	8/8/12	1	Add analyzer name	L Barrett	J Buss, RSL
001	8/8/12	4.2	Add well numbers	A Chini	J Buss, RSL
001	8/8/12	5.3	Refer to PI for calibration levels	A Chini	J Buss, RSL
001	8/8/12	6.4	Delete QC ranges stored in instrument	A Chini	J Buss, RSL
001	8/8/12	6.7	Add use of TEA for lot to lot runs	A Chini	J Buss, RSL
001	8/8/12	10.5	Add below CRR instructions, clarify manual dilution	A Chini	J Buss, RSL

19. ADDENDA

None

Technical SOP

Title	**Lipase by Dimension® Xpand Chemistry Analyzer**
Prepared by	Leslie Barrett Date: 7/24/2009
Owner	Robert SanLuis Date: 8/8/2012

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

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

Quest Diagnostics Nichols Institute
Site: Germantown Emergency Center
Title: **Lipase by Dimension® Xpand Chemistry Analyzer**

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Lipase	Dimension® Xpand Chemistry Analyzer	LIPA

Synonyms/Abbreviations
LIPL

Department
Chemistry

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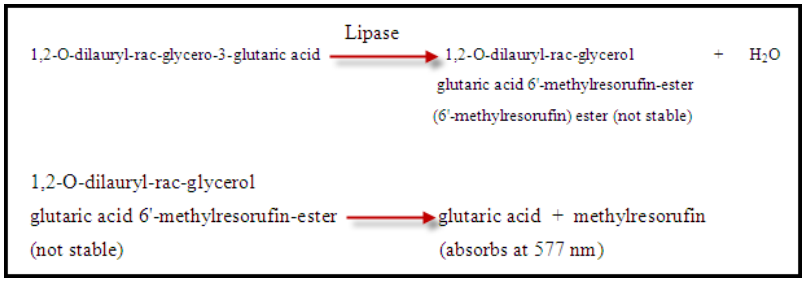
2. ANALYTICAL PRINCIPLE

Lipase catalyzes the hydrolysis of the lipase substrate, 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester in the presence of colipase, bile salt, and $CaCl_2$, (reaction outlined below). The unstable intermediate glutaric acid-6'-methylresorufin ester is produced by this hydrolysis. This intermediate is then hydrolyzed by H_2O to yield free methylresorufin which absorbs at 577 nm. Lipase activity is measured by a biochromatic rate reaction at 577/700 nm. The rate of the reaction is proportional to the amount of lipase in the sample.



3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Heparin) Serum
Collection Container	Plasma: Green top tube Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Serum/ Plasma: Plastic vial or spun barrier tube at room temperature within 2 hours of collection.
Stability & Storage Requirements	Room Temperature: 24 hours, separated or barrier Refrigerated: (2-8°C) 7 Days, separated or barrier Frozen: (-20°C or colder) 12 months
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Any anticoagulants other than heparin. 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	Bacterial contamination of the specimen may cause increased lipase values. Gross hemolysis. Reject sample and request redraw.
Other Considerations	Allow to clot completely prior to centrifugation.

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	Supplier & Catalog Number
Lipase	Siemens, Flex® reagent cartridge, Cat. No. DF56

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagent boxes upon receipt and enter in reagent log. Each container is be labeled with (1) substance name, (2) lot number, (3) expiration date, and (5) checked 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.

Corrosive. Contains sodium hydroxide.
Causes burns. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

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Site: Germantown Emergency Center
Title: **Lipase by Dimension® Xpand Chemistry Analyzer**

Form revised 2/02/2007

Reagent	**Lipase**
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 1-6 have been entered by the instrument, they are stable for 7 days.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Lipase Calibrator	Siemens Dimension®, Cat. No. DC56

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container *is* 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	Lipase Calibrator
Preparation	Calibrator is ready for use. No preparation is required.
Storage/Stability	• Store at 2 – 8° C. • The unopened reagents are stable until the expiration date printed on the label. • Once opened assigned values are stable for 24 hours when vials are tightly stoppered and stored at 2–8°C.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Lipase Calibrator
Assay Range	10 – 1500 U/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L
Frequency	• Every new reagent cartridge lot. • Every 45 days for any one 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 0.6103 C_1 0.0529

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
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 & 2	Bio-Rad Laboratories Catalog # 691 & 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® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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

Step	Action
	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 print-out for error messages. Refer to the Dimension® 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 the LIS. The LIS 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® Chemistry Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- Calibrated pipettes and disposable tips

8. PROCEDURE

LIPL Flex® reagent cartridge Cat. No. DF56 is required to perform this test.

Lipase is performed on the Dimension® clinical chemistry 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 (*when appropriate to negate risk of splash*) 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® procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	For sites with StreamLab (Lynx): **Do Not Use, place specimens directly on the instrument and program STAT.**

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8.2	Specimen/Reagent Preparation
3.	Alternatively, specimens are placed in color-coded Dimension® segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® 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® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® 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® 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:	3 µL
Reagent 1 Volume:	186 µL
Reagent 2 Volume:	115 µL
Test Temperature:	37° C +/- 0.1
Reaction time:	5.5 minutes
Wavelength:	577 and 700 nm
Type of measurement:	bichromatic rate

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of lipase in U/L.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. The instrument reports lipase as a whole number.

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10.3 Units of Measure

U/L

10.4 Clinically Reportable Range (CRR)

10 – 15,000 U/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…
< 10 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 10 U/L
≥ 1500 U/L	**On Board Automated Dilution:** Results ≥ 1500 U/L will automatically have repeat testing performed into the instrument using dilution factor of 1.5. No multiplication is necessary.
> 2,250 U/L	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 10 **DILUENT**: Water Enter dilution factor as a whole number on the "Enter Sample Data" screen. Reassay. Resulting readout is corrected for dilution.
> 15,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 15,000 U/L-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

Lipase	Male and Female
Adult (>19 years):	63-286 U/L
Pediatric:	
0 - 2 months	44-174 U/L
3 - 11 months	43-190 U/L
1 year	44-199 U/L
2 - 6 years	44-199 U/L
7 - 10 years	44-199 U/L
11 - 16 years	46-211 U/L
17 - 18 years	58-260 U/L

11.2 Critical Values

None established.

11.3 Priority 3 Limit(s)

None established.

12. CLINICAL SIGNIFICANCE

Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas, such as acute pancreatitis and obstruction of the pancreatic duct.

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 you Dimension Operator's Guide.

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

Activity	S.D.
187 U/L	>6 U/L
581 U/L	>14 U/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

10 – 1500 U/L

14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Within-run	Total
Level 1	109.2	1.4 (1.3)	3.0 (2.8)
Level 2	227.4	3.3 (1.4)	5.1 (2.3)
Level 3	716.3	7.8 (1.1)	15.1 (2.1)

14.3 Interfering Substances

HIL Interference:
The LIPL method was evaluated for interference according to CLSI EP7-A2. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance tested	Test Concentration SI Units	LIP Activity U/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL (monomer)	200	<10
Bilirubin (unconjugated)	80 mg/dL	200	<10
Lipemia (Intralipid®)	3000 mg/dL	200	<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® Clinical Chemistry System Operator's Manual
2. Dimension® Calibration/Verification Procedure
3. Dimension® Cal Accept Guidelines
4. Dimension® Calibration summary
5. Sample Processing, Siemens Dimension® procedure
6. Start up and Maintenance, Siemens Dimension® procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension® Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension® Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirement (Lab policy)
17. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
18. Current package insert LIPL Flex® Reagent Cartridge DF56

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, LIPL Flex® Reagent Cartridge DF56, Siemens Healthcare Diagnostics Inc. Revised 07/2008.
3. Package insert, LIP CAL DC56, Siemens Healthcare Diagnostics Inc., Revised 03/2008.
4. Package insert, Liquichek™ Unassayed Chemistry Control, Bio-Rad Laboratories, Revised 8/2008.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C095.001		
000	7/26/2010	Title pg	Update owner	R.SanLuis	Dr Cacciabeve
		4.1	Reagent change		
		4.2	Reagent Preparation and Storage		
		5.1	Calibrator change		
		5.2	Calibrator Preparation and Storage		
		5.3	Calibration Parameters		
		6.2	Control and Storage		
		8.0	Change to test conditions		

		10.4 10.5 11.1 11.2 14.1 16 19	CRR 10-15,000 U/L Change to repeat criteria Reference Ranges Update terminology AMR 10-1,500 U/L Add current package insert Delete package insert		
001	8/8/2012		Update owner	L Barrett	J Buss, RSL
001	8/8/2012	1	Add analyzer name	L Barrett	J Buss, RSL
001	8/8/2012	3.2	Change frozen storage to 12 months	A Chini	J Buss, RSL
001	8/8/2012	5.2	Revise Calibration preparation	A Chini	J Buss, RSL
001	8/8/2012	5.3	Refer to PI for calibration levels	A Chini	J Buss, RSL
001	8/8/2012	5.5	Correct second entry of ‘and’ to ‘or’	A Chini	J Buss, RSL
001	8/8/2012	6.2	Reformat section, no change to content	A Chini	J Buss, RSL
001	8/8/2012	6.4	Delete QC ranges stored in instrument	A Chini	J Buss, RSL
001	8/8/2012	6.7	Add use of TEA for lot to lot runs	A Chini	J Buss, RSL
001	8/8/2012	7.2	Add Centrifuge	A Chini	J Buss, RSL
001	8/8/2012	7.3	Remove volumetric pipettes	L Barrett	J Buss, RSL
001	8/8/2012	10.5	Edit section, correct manual dilution. Add message code	A Chini	J Buss, RSL
001	8/8/2012	14.2	Revise to match PI	A Chini	J Buss, RSL
001	8/8/2012	14.3	Update Siemens method code	A Chini	J Buss, RSL
001	8/8/2012	15	Update to standard wording	A Chini	J Buss, RSL
001	8/8/2012	16	Update document list titles	L Barrett	J Buss, RSL

19. ADDENDA

None

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.		

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

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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 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 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

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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.

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. • Sealed cartridge wells on the instrument are stable for 30 days.

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	• Once wells 1 - 8 have been entered by the instrument, they are stable for 5 days
Preparation	The instrument automatically performs mixing and diluting.

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 ± 0.01 ml Purified Water Diluent or Millipore 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 mmol/L
Suggested calibration level	0,8,15 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.
Procedure	Refer to calibration section on this SOP
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
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

Quest Diagnostics Nichols Institute
Site: Germantown Emergency Center
Title: **Lactic Acid Dimension® Xpand Chemistry Analyzer**

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6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Controls Levels 1 & 2	Bio-Rad Laboratories Catalog # 691 & 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 Controls, Level 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 (notated on the QC frequency sheets posted on the instruments).
Refer to the QC Schedule for Dimension®" in the Laboratory Quality Control Program and in the Dimension® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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

Technologist must review each result print-out for error messages. Refer to the Dimension® 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 the LIS. The LIS 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® Chemistry Analyzer

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
- Purified Water (NERL, Cat#C435-1)
- Millipore® water

8. PROCEDURE

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

Lactic Acid is performed on the Dimension® clinical chemistry 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® procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of the automated parameters, see below under “Test conditions.”

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	For sites with StreamLab (Lynx): **Do Not Use, place specimens directly on the instrument and program STAT.**
3.	Alternatively, specimens are placed in color-coded Dimension® segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® 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® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® 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® 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

None

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.

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)

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 you 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

		Standard Deviation (% CV)	
Material	**Mean (mmol/L)**	**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® Clinical Chemistry System Operator's Manual
2. Dimension® Calibration/Verification Procedure
3. Dimension® Cal Accept Guidelines
4. Dimension® Calibration summary
5. Sample Processing, Siemens Dimension® procedure
6. Start up and Maintenance, Siemens Dimension® procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension® Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension® 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., 02/20/2008.
3. Package insert, CHEM I Calibrator DC18A, Siemens Healthcare Diagnostics Inc., 05/2008.
4. Package insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 12/2011.

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

19. ADDENDA

None