TRAINING UPDATE

Lab Location:	SGMC	**Date Assigned:**	10/20/23
Department:	Core Lab	**Due Date:**	11/6/23

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Title: Lactic Acid testing changes for the Atellica
Description of change(s):
Sample stability at room temperature and refrigerated temperature has been changed to "not recommended". Criteria for repeat testing has been tightened due to limited stability for this test. When results are <0.1 mmol/L, QC acceptability confirmation and repeat testing added to procedure. This revised SOP will be implemented November 1, 2023.

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

SGMC.C 3053 Lactic Acid (Lac-2) by Atellica CH Analyzer

Copy of version 2.0 (in review)

Effective Date 11/6/2023

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Lab Service director	4/11/2023	1.0	Robert SanLuis Robert SanLuis	
Approval	Lab Director	5/6/2021	1.0	Nicolas Cacciabeve	
Approval	Core lab approvals	5/6/2021	1.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	5/5/2021	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	5/5/2021	5/17/2021	Indefinite

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Technical SOP

Title	**Lactic Acid (Lac-2) by Atellica CH Analyzer**	
Prepared by	Ashkan Chini	Date: 4/21/2021
Owner	Robert SanLuis	Date: 4/21/2021

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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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Lactic Acid	Atellica CH Analyzer	LACT

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Synonyms/Abbreviations
Lactate, LA, Lac-2

Department
Chemistry

2. ANALYTICAL PRINCIPLE

Lactate is oxidized by lactate oxidase to pyruvate and hydrogen peroxide. Lactate is measured by the formation of dye from hydrogen peroxide and a chromogen in the presence of a peroxidase. The corresponding change in absorbance at 545/694 nm is proportional to the plasma lactate concentration.

3. SPECIMEN REQUIREMENTS

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3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	The patient should be fasting and at complete rest.
Specimen Collection and/or Timing	Collect blood from a stasis-free vein and store it in an ice bath. Separate the plasma by centrifugation within 30 minutes.
Special Collection Procedures	A delay in separation can lead to an increase in lactate values.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	Plasma – Gray Top (Sodium Fluoride)	
-Other Acceptable	Non	
Collection Container	Gray Top Tube	
Volume - Optimum	1.0 mL	
- Minimum	0.5 mL	
Transport Container and Temperature	Plastic vial or spun barrier tube on ice	
Stability & Storage Requirements	Room Temperature:	Not Recommended
	Refrigerated:	Not Recommended
	Frozen:	30 days
Timing Considerations	Separate the plasma by centrifugation within 30 minutes. **Assay the sample immediately.**	

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Criteria	
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	Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter • Do not repeat assay unless done so immediately. • Lactic acid not stable- Not appropriate for add-ons.

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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
Lactate-2 (Lac-2)	Siemens, Atellica CH, Cat. No. 11532568

4.2 Reagent Preparation and Storage

Reagent	Lactate-2 (Lac-2)
Storage	• Store at 2-8°C • Store in upright position, away from light and heat.
Stability	Onboard per pack: 30 days
Preparation	Prepare Reagent 1: 1. Add a portion of the contents of well 1 of the P1 pack to the contents of the Lac-2 R1 vial. 2. Mix well to ensure homogeneity. 3. Pour the solution back into well 1 of the P1 pack and mix well.

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Preparation	4. Carefully rinse the Lac-2 R1 vial several times with the contents of well 1 and empty the contents back into well 1 of the P1 pack. **Note:** Do not use reagents that are cloudy, discolored, or contain precipitates.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Special Chemistry Calibrator (SPCL CHEM CAL)	Siemens Atellica CH, Cat. No. 11099438

5.2 Calibrator Preparation and Storage

Calibrator	Special Chemistry Calibrator (SPCL CHEM CAL)
Preparation	1. Open each vial carefully. 2. Add 5.0 mL of reagent grade water into each vial using a calibrated pipette. Replace rubber stopper. 3. Let the vials stand for 30 minutes at room temperature to allow the lyophilized material to dissolve. 4. Prior to use, to ensure homogeneity and to avoid foam formation, mix the contents by gently inverting the vials.
Storage/Stability	• Store at 2-8°C • **Unopened:** until expiration date stamped on the box • **Reconstituted:** stable for 7 days

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5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Special Chemistry Calibrator (SPCL CHEM CAL)
Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mmol/L
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (62 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (30 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service. At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack.

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	Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.
Procedure	Refer to the Atellica Solution Operating, QC, Calibration and Maintenance 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

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6.1 Controls Used

Controls	Supplier and Catalog Number
InteliQ Assayed Multiqual Control Levels 1 & 3	Bio-Rad Laboratories Cat. No. 12008256, 12008258

6.2 Control Preparation and Storage

Control	InteliQ Assayed Multiqual Control Levels 1 & 3
Preparation	Allow to stand at room temperature (18-25C) until completely thawed but not more than one (1) hour. Once thawed, gently invert several times to ensure homogeneity.
Storage/Stability	**Frozen**: until the expiration date if unopened at -20 to -70C **Thawed and Unopened**: 30 days at 2-8C for lactic acid **Thawed and Opened**: 14 days at 2-8C for lactic acid Note: stability varies by assay

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 Siemens Atellica QC Schedule and the Siemens Atellica Quick Reference Guide.

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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.

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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.

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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

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7.1 Assay Platform

Siemens Atellica CH 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

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

8. PROCEDURE

Atellica CH Lactate-2 (Lac-2) is required to perform this test.

Lactic Acid is performed on the Atellica CH Analyzer after the method is calibrated 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.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

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8.2	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.
4.	Follow protocol in section 10.6 “Repeat Criteria and Resulting” for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as 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.

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.

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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 – 122.1 mmol/L

10.5 Review Patient Data

Each result is reviewed for error messages. 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.

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Values that within the AMR or CRR may be reported without repeat. Values that exceed the upper or lower 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 (sample issues that could interfere with testing or sampling). If the sample is acceptable, repeat the sample immediately with QC if within 30 minutes of sample receipt. If QC is within acceptable range, report as: < 0.1 mmol/L.
≥ 12.2 mmol/L	**On Board Automated Dilution:** Results ≥ 12.2 mmol/L will automatically have repeat testing performed into the instrument using dilution factor of 10. No multiplication is necessary.
> 122.1 mmol/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 122.1 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.

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11. EXPECTED VALUES

11.1 Reference Ranges

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

11.2 Critical Values

> 4.0 mmol/L

For Sepsis Protocol: call values > 1.9 mmol/L 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)

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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 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.

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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.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.1 – 12.2 mmol/L
Note: manufacturer insert has 2 decimals, rounded to one decimal to match practice)

14.2 Precision

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Control	12.5	0.24	4.9
Plasma Pool 1	48.7	0.46	4.8
Plasma Pool 2	99.0	0.75	4.6

14.3 Interfering Substances

HIL Interference:
Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2.

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Substance tested	Substance Concentration	mmol/L	Bias %
Hemoglobin	300 mg/dL	6.6	-8
Bilirubin (unconjugated)	3.75 mg/dL	6.6	-8
Bilirubin (conjugated)	5.18 mg/dL	6.3	-1
Lipemia Intralipid®	1000 mg/dL	6.1	2

14.4 Clinical Sensitivity/Specificity/Predictive Values

Detection Capability
The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ limit of detection (LoD). The Limit of Detection (LoD) corresponds to the lowest concentration of lactate that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ 0.1 mmol/L for plasma.

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15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Atellica Solution Operating, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of Lactate-2 Reagent

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, Lactate-2 Reagent, Siemens Healthcare Diagnostics Inc., 09/2020.
3. Package Insert, Special Chemistry Calibrator (SPCL CHEM CAL), Siemens Healthcare Diagnostics Inc., 10/2019.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020

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18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	10/20/23	3.2 10.6	Revised Stability for refrigerated. Added immediate repeats only, no add-ons. Updated to repeat if <0.1 with QC	M Belay H Genser D Collier	R SanLuis

19. ADDENDA

None

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