Lactic Acid using Abbott Architect ci4100

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Department:	STAT Lab	**Effective Date:**	8/24/18
Policy, Procedure, or Both:	Procedure	**Revision Date(s):**	
Author:	Kim Clark, MT (ASCP)	**Version:**	1

Applicable Standards	
Standard	Organization
COM.10000	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
1	08/24/2018	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
8/22/18	1	**New Policy/Procedure**	System Laboratory Medical Director, Joe A. Lewis. M.D.. F.C.A.P.

Distribution
Christus Spohn Shoreline STAT Lab

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Lactic Acid on the Abbott Architect ci4100
Proc. #: HSL0200.01

Intended Use
The Lactic Acid assay is used for the quantitation of lactic acid in human plasma.

Clinical Significance
Lactic acid and lactate are often used interchangeably, though it is understood that lactate is the deprotonated form (or conjugate base) of lactic acid. In the neutral pH of healthy persons, lactate is generally found. Lactate is a byproduct of glucose metabolism. The intermediary step in this pathway is the conversion of pyruvate to lactate by lactate dehydrogenase. Lactate is generated in red blood cells, muscle, the brain and the gut. Under normal circumstances, there is a small amount of lactate in the blood. Type A lactic acidosis is caused by insufficient oxygenation of tissues. In the decreased oxygen environment, anaerobic metabolism results. Causes include circulatory failure, trauma, and profound anemia. Type B lactic acidosis is due to overproduction of lactate or inadequate oxygen utilization. The former is most commonly associated with strenuous exertion while causes of the latter include malignancies, diabetes, severe infection and several drugs. It is worth noting that while the L isomer is generally measured in clinical practice, the D isomer which is produced by bacteria, may also be associated with clinical disease. Most clinical laboratory analyzers do not measure D-lactate.

Principle

Lactic acid is converted to pyruvate and hydrogen peroxide (H2O2) by lactate oxidase. Peroxidase catalyzes the oxidation of chromogen precursor by H2O2 to produce a colored dye. The increase in absorbance at 572 nm is directly proportional to the lactic acid concentration in the sample.

Methodology: Lactic Acid to Pyruvate

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

Specimen Collection and Handling

Plasma: Glass or plastic tubes without gel barriers. Acceptable anticoagulant is: Potassium oxalate/sodium fluoride

Special Conditions: Patients should not clench and unclench hands before or during phlebotomy. Ideally, a tourniquet should not be used. If a tourniquet is used but the draw is unsuccessful, remove the tourniquet and allow two minutes to elapse before trying again. Transport sample on wet ice. To ensure accurate results, the plasma specimen tube should be filled with the prescribed minimum volume for an appropriate anticoagulant to specimen ratio.

Suitable Specimens

Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens. For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.

Separated plasma may be analyzed immediately, stored at 2 to 8°C, or frozen. Store up to 3 days at 2 to 8°C or -20°C, if not analyzing immediately.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

Materials and Equipment Required

TEST INSTRUMENT: Abbott ARCHITECT System

MATERIALS PROVIDED

9P18 Lactic Acid Reagent Kit

MATERIALS REQUIRED BUT NOT PROVIDED

- 1E65 Multiconstituent Calibrator
- Saline (0.85% to 0.90% NaCl) for specimen dilution

Reagent Handling and Storage:

***CAUTION*:**

1. For in vitro diagnostic use.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

The following warnings and precautions apply to: R1	
	
WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Reagent Handling

- Do not use reagents beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- When the R1 reagent cartridge becomes empty, replace the cartridge and validate the system by analyzing controls.
- Do not invert reagent cartridges prior to use. Reagents are susceptible to the formation of foam and bubbles.
- Remove any air bubbles present in the reagents with a new applicator stick, or allow the reagents to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove bubbles.

CAUTION: Bubbles may interfere with proper detection of reagent level in the cartridge and cause insufficient reagent aspiration which could impact results.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

Unopened reagents are stable until the expiration date when stored and handled as direct.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage.
On board	System temperature	30 days	Stable for 30 days if uncapped and on board. Discard after 30 days.

Reagent Preparation:

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9P18 Lactic Acid Reagent Kit is supplied as a liquid, ready-to-use, single reagent kit

Reactive Ingredients	Concentration
R1	
Lactate oxidase	900 U/L
Peroxidase (horseradish)	18000 U/L
Chromogen precursors	As required

Inactive Ingredients: Contains buffer, fillers and stabilizers.

Calibrator: 1E65 Multiconstituent Calibrator
Quality Control: Biorad Multiqual Controls level 1-2-3 (697/698/699)

Calibration

Frequency:
Calibration is stable for 30 days (720 hours) for any one lot.

A new calibration is required:

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Calibrator Required: 1E65 Multiconstituent Calibrator
Multiconstituent Calibrator requires no preparation prior to use.

Reagents:

REF 1E65-05 Multiconstituent Calibrator
CAL 1-2 3 x 5 mL
CAL VALUE MEDIA 1

Calibrator Preparation:
None required
Store unopened Multiconstituent Calibrator upright at 2 to 8°C.
Unopened calibrator is stable until the expiration date when stored at 2 to 8°C.
Opened calibrator is stable for 7 days at 2 to 8°C or for 24 hours at 15 to 30°C if kept tightly capped.

Calibration Procedure:
Calibration is performed by running a water blank and the Multiconstituent Calibrator set. Water for the blank is provided by the instrument.

1. Verify that the correct calibrator values have been entered into the calibration file.
2. Allow calibrator to come to room temperature.
3. Mix bottle five times by gentle inversion.
4. Open bottle, place an appropriate amount of each calibrator in a separate sample cup, and place in the assigned positions.
5. Cap bottle tightly and return to refrigerated storage immediately after use.
6. Perform calibration as indicated in the **ARCHITECT System Operations Manual**.

Troubleshooting and Overall Acceptance Criteria Failure

See ARCHITECT Operations Manual for further calibration troubleshooting.

Quality Control:

Controls are tested according to each location/site Quality Control Procedure.

- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Procedure
For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

Calculations
Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Reporting Results
ARCHITECT Lactic Acid can be reported in mg/dL or mmol/L

Specific Performance Characteristics
Reference Ranges
It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Serum/Plasma (Abbott Package Insert)
Plasma

	Range (mg/dL)	Range (mmol/L)
Venous	4.5 – 19.8	0.50 – 2.20

Serum/Plasma (this facility)

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Critical Values ***(Refer to Critical value policy)***

Performance Characteristics

Measuring Interval (Abbott Package Insert)
The measuring interval of Lactic Acid assay is 1.5 to 120.0 mg/dL (0.17 to 13.32 mmol/L).
The measuring interval is defined as the range of values across which the limits of acceptable performance for imprecision and bias are met.

Dilution:
Specimens with lactic acid values exceeding 120.0 mg/dL (13.32 mmol/L) are flagged.

No dilutions on this assay.

Results outside the AMR will be reported with a < or > result.

Limit of Quantitation (LOQ):
The LOQ for Lactic Acid is ≤ 1.5 mg/dL (0.17 mmol/L).

Precision:
The imprecision of the Lactic Acid assay is ≤ 4.0% Total CV or ≤ 0.36 mg/dL SD.

Control		Level 1	Level 2	Level 3
N		80	80	80
Mean (mg/dL)		14.1	54.1	114.6
Mean (mmol/L)		1.57	6.01	12.72
Within Run	%CV	1.3	0.5	1.3
Total	%CV	1.7	0.7	1.5

Limitations of Procedure

Do not use hemolyzed samples.
Samples containing elevated levels of bilirubin displayed significant interference and should not be used.
Samples containing glycolic acid displayed significant interference and should not be used. Samples containing high levels of N-acetyl- L-cysteine displayed significant interference and should not be used.

Interfering Substances
Interference studies were conducted using some acceptance criteria of +/-10% deviation or 0.9 mg/dL (0.10 mmol/L) from the target value. Results are provided below in separate tables per conventional and SI units.

Interfering Substance	Interferent Concentration (Conventional Units)	N	Target (mg/dL)	Observed % of Target	Observed Difference (mg/dL)
Acetaminophen	204 µg/mL	5	8.2		-0.1
	204 µg/mL	5	15.7	-1	
N-acetyl-L-cysteine	424 mg/L	5	8.2		-0.5
	424 mg/L	5	15.7	-5	
L-ascorbic Acid	1.5 mg/dL	5	7.5		-0.7
	1.5 mg/dL	5	14.1	-6	
Bilirubin (conjugated)	3.5 mg/dL	5	7.8		-0.9
	3.4 mg/dL	5	16.7	-8	
Bilirubin (unconjugated)	12.3 mg/dL	5	6.9		-0.7
	12.7 mg/dL	5	16.8	-9	
Intralipid	525 mg/dL	5	6.4		0.0
	525 mg/dL	5	15.7	1	
D-Lactic Acid	105 mg/dL	5	5.1		0.1
	105 mg/dL	5	15.7	1	
Phenobarbital	102 mg/L	5	7.5		0.0
	102 mg/L	5	14.1	-1	
Salicylic Acid	691 mg/L	5	7.5		0.0
	691 mg/L	5	14.1	0	
Total Protein	13.3 g/dL	5	7.8		-0.3
	13.1 g/dL	5	14.8	-10	

Interfering Substance	Interferent Concentration (SI Units)	N	Target (mmol/L)	Observed % of Target	Observed Difference (mmol/L)
Acetaminophen	1350 µmol/L	5	0.91		-0.01
	1350 µmol/L	5	1.74	-1	
N-acetyl-L-cysteine	2.6 mmol/L	5	0.91		-0.06
	2.6 mmol/L	5	1.74	-5	
L-ascorbic Acid	85 µmol/L	5	0.83		-0.08
	85 µmol/L	5	1.57	-6	
Bilirubin (conjugated)	60 µmol/L	5	0.87		-0.10
	58 µmol/L	5	1.85	-8	
Bilirubin (unconjugated)	210 µmol/L	5	0.77		-0.08
	217 µmol/L	5	1.86	-9	
Intralipid	5.25 g/L	5	0.71		0.00
	5.25 g/L	5	1.74	1	
D-Lactic Acid	11.7 mmol/L	5	0.57		0.01
	11.7 mmol/L	5	1.74	1	
Phenobarbital	440 µmol/L	5	0.83		0.00
	440 µmol/L	5	1.57	-1	
Salicylic Acid	5.0 mmol/L	5	0.83		0.00
	5.0 mmol/L	5	1.57	0	
Total Protein	133 g/L	5	0.87		-0.03
	131 g/L	5	1.64	-10	

References:

1. ABBOTT ARCHITECT Lactic Acid package insert
   Abbott Laboratories
   Diagnostics Division
   Abbott Park, IL 60064

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2. ABBOTT ARCHITECT Multiconstituent Calibrator package insert
   Abbott Laboratories
   Diagnostics Division
   Abbott Park, IL 60064
   June 2013 306297/R04
3. Abbott ARCHITECT Operator's Guide

Alternative Method:

Send to sister facility if unable to perform at this site.

Effective date of this Procedure:

Revised by: Rebecca Olog, MT(ASCP)
Revised by: Kimberlee J. Clark, MT(ASCP)