LACT2- LACTIC ACID2

Intended Use

The Lactic Acid2 assay is used for the quantitation of lactic acid in human plasma on the Alinity c system. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Clinical Significance

Lactic acid (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. Normally, there is a small amount of lactate in the blood.1
Type A lactic acidosis is caused by hypoperfusion of tissues resulting from cardiovascular failure, sepsis, trauma, and profound anemia. Type B lactic acidosis is due to overproduction of lactate or inadequate oxygen utilization and is associated with malignancies, diabetes, severe infection and several drugs.

Methodology

The Lactic Acid2 assay is an automated clinical chemistry assay. Lactic acid is converted to pyruvate and hydrogen peroxide (H2O2) by lactate oxidase. Peroxidase catalyzes the oxidative coupling of H2O2 with N,N-bis(4-sulfobutyl)-3-methylaniline,disodium salt (TODB) and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which is quantitated at 604 nm. The increase in absorbance at 604 nm is directly proportional to the lactic acid concentration in the sample. Methodology: Lactic acid to pyruvate

Specimen

Type of Specimen

Specimen Type	Collection Vessel
• Plasma	Potassium oxalate/ sodium fluoride/ disodium EDTA

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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 if possible. Separate the plasma by centrifugation within 30 minutes of sample collection. A delay in separation can lead to an increase in lactic acid values. To ensure accurate results, the plasma specimen tube should be filled with the prescribed minimum volume for an appropriate anticoagulant to specimen ratio.

Specimen Storage and Stability

1. Tubes of blood are kept closed at all times in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.
2. Do not use: heat-inactivated specimens, pooled specimens, grossly hemolyzed specimens, specimens with obvious microbial contamination, and specimens with fungal growth
3. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Ensure centrifugation is adequate to remove platelets. Separate the plasma by centrifugation within 30 minutes of sample collection. A delay in separation can lead to an increase in lactic acid values.
4. If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Type	Temperature	Maximum Storage Time
Serum/ Plasma	20 to 25 °C	72 hours
	2 to 8°C	14 days
	-20°C	38 days

Sample Dilution Procedures

Serum/Plasma

Samples with lactic acid value exceeding 13.32 mmol/L are flagged with the code "> 13.32 mmol/L" and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

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Automated Dilution Protocol

Plasma

The automated dilution factor verified for the Lactic Acid2 assay is 1:7.92. The system performs a dilution of the sample, relative to the standard dilution, and automatically calculates the concentration by multiplying the result by the dilution factor.

Dilution Name	Dilution Name
Standard	1:1.98
1:4	1:7.92

Manual Dilution Procedure

Specimens with a lactic acid value exceeding 13.32 mmol/L can be manually diluted using a 1:4 dilution. Dilute the sample with saline (0.85% to 0.90% NaCl). The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

Reagents

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

Reagent Storage and Stability

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position
Onboard	System Temperature	30 days	

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Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Calibration

Calibration Required

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual. Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary. This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Calibration Preparation

Calibration material is the Alinity c 04V6201 Consolidated Chemistry Calibrator.

1. Reconstitute by pipetting exactly 5.0 mL of purified water (15 to 25°C) into the vial. Replace the rubber stopper.
2. Let stand for 30 minutes away from bright light.
3. Swirl gently several times or use a roller mixer during the reconstitution period to ensure the contents are completely dissolved. Ensure that no lyophilized material remains reconstitute.
4. Prior to use, mix the contents by inverting the vial. Do not shake the vial, as the formation of foam should be avoided.

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Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
ConCC Cal	Unopened (Lyophlized): 2 to 8 (until expiration date)	2 to 8 °C: 7 days -20 °C: 28 days

Calibration Information

1. Calibrator values may be configured using e-files accessed and imported from www.corelaboratory.abbott, or from Abbott Mail.
2. Verify that the correct calibrator values have been entered into the calibration file.
3. Calibration is performed by Alinity c Consolidated Chemistry Calibrator.
4. For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.

Quality Control

See Policy Chemistry Quality Control Policy

Sample Processing

See Policy RIV-PPP-1199

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Reference Range

Test unit=mmol/L for all ages and both sexes

Age Year Low	Age Year High	Ref Low	Ref High
0	250	0.2	13.3

Analytic Range

AMR Low	AMR High	CRR Low	CRR High
0.2	13.3	0.2	53.2

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