DXC (LACT) LACTATE

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☒ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of lactate on the DXC 600/800.

PRINCIPLE

LACT reagent, when used in conjunction with Synchron LX® System(s), UniCel® DxC 600/800 System(s) and Synchron® Systems Multi Calibrator, is intended for the quantitative determination of Lactate concentration in human plasma and cerebrospinal fluid (CSF).

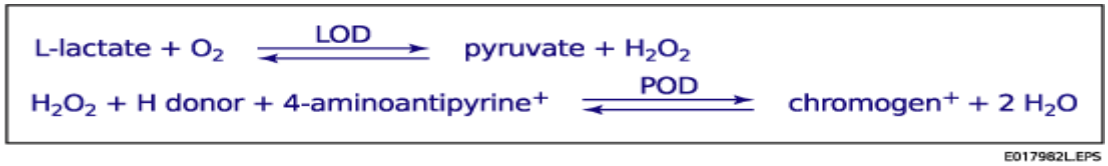
BACKGROUND

Clinical Significance

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).

Methodology

In the assay reaction, lactate oxidase (LOD) converts lactate to pyruvate with the concomitant generation of hydrogen peroxide (H_2O_2). The H_2O_2 formed reacts with a hydrogen donor and 4-aminoantipyrine (4-AAP) in a reaction catalyzed by peroxidase (POD) to form a chromophore. The lactic acid concentration is determined by measuring the absorbance due to the chromophore using an endpoint technique.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of lactic acid in the sample and is used by the system to calculate and express the lactate concentration.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
M-F-CH-0820	Chemistry Controls
J-F-CH-0826	DXC 800 Calibrators
M-F-CH-0826	Chemistry Calibrators
M-F-CH-1940	DXC 600 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn plasma or cerebrospinal fluids are the preferred specimens. Chill the specimen immediately. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood, serum and urine are not recommended for use as a sample. Blood should be drawn without stasis because venous stasis may cause lactate elevation. Samples should remain on ice prior to analysis.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical, stopper-up position. Keep samples on ice. Plasma should be physically separated from contact with cells within 15 minutes of sample collection, and analyzed without delay.

2. CSF samples are stable stored at:+15°C to +25°C up to 4 hours, +2°C to +8°C up to 3 days, -20°C up to 6 months.

Sample Type	Volume	Sample Stability

Plasma
 	
Anticoagulant: **(SODIUM FLUORIDE/POTASSIUM OXALATE)**
	0.5mL	• Separate plasma from cells within 15 minutes and analyze without delay
		• Room Temp:
		  ○ Spun/separated 2 hours
		  ○ Unspun 15 minutes
		• Refrigerated or on ice 2 hours
		• Frozen 3 months

NOTE: This procedure is for plasma/CSF specimens only. See separate procedure “GEM Premier Whole Blood Sample Analysis” R-W-CH-05040 for specimen requirements on whole blood testing.

Critieria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two Lactate Reagent Cartridges (each contains a minimum of 50 tests), Kit # A95550

Volume per Test	
Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	A – – B 250 µL

	C 50 µL

Reactive Ingredients	
Reaction Buffer	15.7 mL
Lactate Oxidase	3.7 mL
Sodium Azide (used as a preservative)	≤ 0.1 (w/w)

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

Reagent Storage and Stability

LACT reagent, when stored unopened at +2°C to +8°C will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent is stable for 30 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. Do not expose reagent to temperatures above +35°C or to direct sunlight. DO NOT FREEZE.

CALIBRATION

Calibrator Required

Synchron® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the Synchron® Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days. Do not use beyond the manufacturer's expiration date.

Calibrator Information

1. The system must have a valid calibration in memory before controls or patient samples can be run.

2. Under typical operating conditions the LACT reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON LX *Maintenance Manual and Instrument Log*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the SYNCHRON LX *Diagnostics and Troubleshooting Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents DXC 800 Controls & Chemistry Controls

STEPS

1. Load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operations. For detailed testing procedures, refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

The SYNCHRON® System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

Only plasma obtained using sodium fluoride/potassium oxalate collection tubes are suitable for use with the Lactate Reagent.

PERFORMANCE CHARACTERISTICS

Reference Range

	Reference Range	Critical Low	Critical High
Male/Female	0.5 – 2.0 mmol/L	N/A	>4.0 mmol/L

For Critical Value reporting protocol, refer to FHS Critical Policy

Analytic Range

Sample Type	Conventional Units
Plasma or CSF	0.4 – 11.0 mmol/L

Reporting results outside of analytical range

Lower limit of detection	0.4 mmol/L	Results below 0.4, report as <0.4 mmol/L
Upper limit of detection	11.0 mmol/L	Results >11.0 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. *Results >16.0 are reported as >16.0 mmol/L.

***Note:** The DXC analytic range is 0.4-11.0 mmol/L but the maximum reportable range for FHS labs is 16.0 mmol/L for all methods. Results >16.0 mmol/L obtained with dilution will only be reported as ">16.0".

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LACT determination is 0.3 mmol/L (2.7 mg/dL).

LIMITATIONS

Samples with very high lactic acid could report as RX RATE LO or INIT RATE HI.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX OF 17	No significant interference ≤ 0.21+ mmol/L or <± 4.8%
Bilirubin (Total)	Porcine	7.9 mg/dL DBIL 25 mg/dL TBIL	≤ -0.44 mmol/L or 10%
Hemoglobin	Human	500 mg/dL INDEX OF 10	No significant interference ≤ 0.21+ mmol/L or <± 4.8%
Lipemia	Intralipid[c]	500 mg/dL INDEX of 10	No significant interference ≤ 0.21+ mmol/L or <± 4.8%
Ascorbic Acid	Sigma	6 mg/dL	No significant interference ≤ 0.21+ mmol/L or <± 4.8%
Lactate Dehydrogenase	Chicken hearts	4000 U/L	No significant interference ≤ 0.21+ mmol/L or <± 4.8%
Pyruvate	Sigma	12 mg/dL	No significant interference ≤ 0.21+ mmol/L or <± 4.8%

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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