DXC (LD) LACTATE DEHYDROGENASE

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PURPOSE

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

PRINCIPLE

LD reagent, when used in conjunction with UniCel® DxC 600/800 System(s), is intended for the quantitative determination of Lactate Dehydrogenase activity in human serum or plasma.

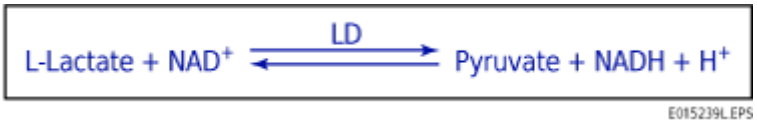
BACKGROUND

Clinical Significance

Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

Methodology

LD reagent is used to measure lactate dehydrogenase activity by an enzymatic rate method. In the reaction, LD catalyzes the reversible oxidation of L-lactate to pyruvate with the concurrent reduction of β-nicotinamide adenine dinucleotide (NAD) to reduced β-nicotinamide adenine dinucleotide (NADH).
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 20 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of lactate dehydrogenase in the sample and is used by the System to calculate and express the lactate dehydrogenase activity.



RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators
J-F-CH1940	DXC 800 Analytical Measurement Range
M-F-CH0820	Chemistry Controls
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 Analytical Measurement Range
R-W-CH0815	DXC Reagent Lot to Lot Correlations
R-F-CH0814	Lot-to-Lot Correlation

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma is the preferred specimen. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine is not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and 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. Refrigerated or frozen samples are not recommended.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours. • Refrigerated or frozen samples are not recommended.

Criteria 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 LD Reagent Cartridges, Kit number 442655, (2 x 200 tests) or (2 x 300 tests)

Volume per Test	
Sample Volume	13 µL
Ordac Sample Volume	3 µL
Total Reagent Volume	260 µL
Cartridge Volumes	A 251 µL B – – C 9 µL

Reactive Ingredients	
L-Lactate Acid	50 mmol/L
NAD	11 mmol/L

Also non-reactive chemicals necessary for optimal system performance

⚠ 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 ensuring that quality control results are within your facility`s acceptance criteria.

NOTE: New lots of reagent require lot to lot correlation studies. Refer to Related Documents section for related work instructions/forms.

Reagent Storage and Stability

LD 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 cartridge is stable for 30 days unless the expiration date is exceeded. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

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CALIBRATION

Calibrator Required

Calibration is not required.

Traceability

This analyte is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. Program controls for analysis.

3. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform 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

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (IU/L)
Ammonium Heparin	14 Units/mL	NSI[a]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

2. The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (IU/L)[b]
EDTA	1.5 mg/mL	-27
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/mL	-140

PERFORMANCE CHARACTERISTICS

Reference Range

Age	Range
0 – 3 Days	290 - 816 U/L
4 to 9 Days	545 to 2105 U/L
10 Days to 2 yrs	180 to 453 U/L
2 to 12 yrs	110 to 311 U/L
12 to 60 yrs	115 to 225 U/L
60 to 90 yrs	110 to 221 U/L
>90 yrs	99 to 299 U/L

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	5 – 750 U/L
Serum or Plasma ORDAC[e]	600 – 2700 U/L

Samples with activities exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of range	5 U/L	Results below 5, report as < 5 U/L
Upper limit of range	2700 U/L	Results >2700 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X5. Results >13,500 are reported as >13,500 U/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LD determination is 5 IU/L.

LIMITATIONS

None identified.

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 20	NSI[c]
Lipemia	Intralipid[d]	500 mg/dL INDEX of 10	NSI
Hemolysis		INDEX 1	Samples showing evidence of hemolysis **should not be used**. Hemolysis can cause falsely elevated results.

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3. Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

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

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