BECKMAN COULTER

SYNCHRON® System(s)
Chemistry Information Sheet

LD
Lactate Dehydrogenase

REF 442655 (200 tests/cartridge)
REF 476841 (300 tests/cartridge)

For *In Vitro* Diagnostic Use

ANNUAL REVIEW

Reviewed by:	Date	Reviewed by:	Date

PRINCIPLE

INTENDED USE

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

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.[1,2] 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.

CHEMICAL REACTION SCHEME

E015239L.EPS

SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[3] Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are 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.[4]
2. Refrigerated or frozen samples are not recommended.[3]

Additional specimen storage and stability conditions as designated by this laboratory:

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.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:

Two LD Reagent Cartridges (2 x 200 tests) or (2 x 300 tests)

VOLUMES 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

REAGENT CONSTITUENTS

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).**

Avoid skin contact with reagent. Use water to wash reagent from skin.

EUROPEAN HAZARD CLASSIFICATION

LD-L Substrate (Compartment A)	Xn;R22	Harmful if swallowed.
	S28	After contact with skin, wash immediately with plenty of water.
Lactate Dehydrogenase Reagent, Lactate→Pyruvate (Compartment A)	Xn;R22	Harmful if swallowed.
	S28	After contact with skin, wash immediately with plenty of water.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

At least two levels of control material
Saline

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.

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 FREEZE.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

Calibration is not required.

TRACEABILITY

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

QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new reagent cartridge and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and 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.

REPORTING RESULTS

Equivalency between the SYNCHRON CX, SYNCHRON LX, and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.[5]

Table 2.0 Reference intervals

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Serum or Plasma	100 – 190 IU/L	1.6 – 3.1 µkat/L
SYNCHRON	Serum or Plasma	98 – 192 IU/L	1.6 – 3.2 µkat/L

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Laboratory			

Refer to References (6, 7, 8) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

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:

Table 3.0 Compatible Anticoagulants

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

a NSI = No Significant Interference (within ±10.0 IU/L or 7%).

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

Table 4.0 Incompatible Anticoagulants

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	PLASMA-SERUM BIAS (IU/L)[a]
EDTA	1.5 mg/mL	-27
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	-140

a Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

LIMITATIONS

None identified.

INTERFERENCES

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

Table 5.0 Interferences

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI[a]
Lipemia	Intralipid[b]	500 mg/dL	NSI

a NSI = No Significant Interference (within ±10.0 IU/L or 7%).
b Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

2. Samples showing evidence of hemolysis should not be used. Hemolysis may cause falsely elevated results.
3. Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

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

Table 6.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	5 – 750 IU/L	0.1 – 12.5 µkat/L
Serum or Plasma ORDAC[a]	600 – 2700 IU/L	10.0 – 45.0 µkat/L

a Overrange Detection and Correction. Refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for more details on this function.

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

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 7.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

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 (0.08 µkat/L).

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or plasma (in the range of 5 to 787 IU/L):

Y (SYNCHRON LX Systems)	= 1.018X + 0.17
N	= 80
MEAN (SYNCHRON LX Systems)	= 171.8
MEAN (SYNCHRON CX® 7 DELTA)	= 168.5
CORRELATION COEFFICIENT (r)	= 0.9993

Refer to References (12) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON® System(s) should exhibit precision values less than or equal to the following:

Table 8.0 Maximum Performance Limits

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[a]		% CV
		IU/L	µkat/L	IU/L	µkat/L	
Within-run	Serum/Plasma	5.0	0.08	143	2.3	3.5
	Serum/Plasma (ORDAC)	NA[b]	NA	NA	NA	10.0
Total	Serum/Plasma	7.5	0.12	143	2.3	5.3
	Serum/Plasma (ORDAC)	NA	NA	NA	NA	15.0

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

b NA = Not applicable.

Comparative performance data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.[13] Each laboratory should characterize their own instrument performance for comparison purposes.

Table 9.0 NCCLS EP5-T2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (IU/L)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	49.9	1.6	3.2
	Serum	Control 2	1	80	363.5	3.4	1.0
Total	Serum	Control 1	1	80	49.9	2.0	4.0
	Serum	Control 2	1	80	363.5	5.3	1.5

a The point estimate is based on the data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX® System and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

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

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

REFERENCES

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9. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).
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13. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).

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