

Lactate Dehydrogenase (P→L DGKC-KINETIC METHOD)

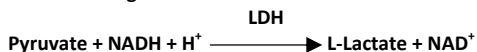
Invitro Diagnostic reagent kit for quantitative determination of Lactate Dehydrogenase (LDH) activity in serum/plasma sample on Photometric System.

Reagent

Reagent 1: Enzyme Solution
Reagent 2: Substrate Solution

Principle

Lactate dehydrogenase (LDH) catalyses the reduction of pyruvate by NADH forming NAD.



Summary

Lactate dehydrogenase (LDH) is an enzyme found in many tissues in the body. The main organs include are liver, heart, kidney, skeletal muscle and RBC's. Increased levels of the enzyme are found in serum during liver disease, anemia, myocardial infarction, muscular dystrophy and renal disease.

Storage Instructions and Reagent Stability

Reagents are stable up to the end of the indicated month of expiry, if stored at 2° - 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Components and Concentrations

TRIS buffer 80mmol/L, Pyruvate – 1.6 mmol/L, Sodium Chloride – 200 mmol/L, NADH 240 mmol/L.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent. The stability of the working reagent is 21 days at 2° - 8°C. Protect the reaction solution from light.

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days at 2° -8°C
30 days at -20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength 340nm
Optical Path 10mm
Temperature 37°C

Sample Start

Sample	20 µL
Working reagent	1000 µL
Mix immediately and read absorbance after every 1 min. for 3 min.	

Calculation

ΔA/min and multiply by the corresponding factor from table below:
LDH activity U/L = ΔA/min x factor (8095)

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Performance Characteristics and Measuring Range

The test has been developed to determine the activity of Lactate dehydrogenase (LDH) within a measuring range from 5-2000 U/L. When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Linearity/Limit of Maximum Detection

The higher limit of detection is 2000 U/L.

Sensitivity/Limit of Detection

The lower limit of detection is 5 U/L.

Interferences

No interference was observed by, Ascorbic Acid up to 30 mg/dL, Bilirubin upto 40 mg/dL and triglycerides up to 1000 mg/dL.

Precision

Intra-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	115.50	1.26	1.09
Sample 2	246.64	1.47	0.60
Sample 3	502.47	2.46	0.49

Inter-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	146.21	1.27	0.87
Sample 2	213.82	1.79	0.84
Sample 3	426.78	2.04	0.48

Method Comparison

A comparison of Precision Biomed Lactate dehydrogenase (LDH) (y) with a commercially available test (x) using 15 samples gave following results:

$$y = 0.990x + 3.023; r^2 = 0.998$$

Reference Range

Normal Range:
120-240 U/L at 25°C
160-320 U/L at 30°C
230-470 U/L at 37°C

Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	LDH (P→L)
Mode	Kinetic
Reaction slope	Decreasing
Wavelength	340 nm
Path length	10 mm
Temperature	37°C
Working reagent	4 part Reagent 1 1 Part Reagent 2
Working reagent Volume	1000 µL
Sample volume	20 µL
Delay	60 sec.
Rate	60 sec.
No. of readings	3
Factor	8095
Normal range	230 – 470 U/L
Linearity	2000 U/L
Sensitivity	5 U/L









Pack Size

Cat No.	Configuration	Pack Size
LDH00025	Reagent R1 - 1 x 20mL Reagent R2 - 1 x 5mL	25mL
LDH00500	Reagent R1 - 1 x 400mL Reagent R2 - 1 x 100mL	500mL

Literature

1. Pesce A. Lactate dehydrogenase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Princeton 1984; 1124-117, 438.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

Version : LDH/00

IVD In Vitro Diagnostic Use	 See Pack Insert For Procedure	 Single Use only	
 Temperature Limit	 Manufacturer's Address	 Manufacturing Date	 Expiry Date
			 LOT Lot Number



Manufactured in India by :

Precision Biomed Pvt. Ltd.

Plot No. – 193, “Silver Soil Industrial Park”, Village – Anantpura-Chimanpura,

Teh.- Chomu, District- Jaipur – 303702 (Rajasthan) India.

Ph.: +91-9982806050 Customer Care : +91-7820806050

E-mail: info@precisionbiomed.in, Website: www.precisionbiomed.in

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