Pariksha Biotech
A game changer in IVD

LDH Estimation Kit

High-Q LDH (L→P)

IFCC Method / NAD Analogue

HIGH®
Command on Quality

Intended Use:
Kit for the quantitative determination of Lactate Dehydrogenase in human Serum and Plasma

Summary and Clinical Significance:
The lactate dehydrogenase (LDH) enzyme is widely distributed in tissue, particularly in the heart, liver, muscles and kidneys. The LDH in serum can be separated into five different isoenzymes based on their electrophoretic mobility. Each isoenzyme is a tetramer composed of two different subunits. These two subunits have been designated heart and muscle, based on their polypeptide chains. There are two homo tetramers, LDH-1 (heart) and LDH- 5 (muscle), and three hybrid isoenzymes. Elevated serum levels of LDH have been observed in a variety of disease states. The highest levels are seen in patients with megaloblastic anemia, disseminated carcinoma and shock. Moderate increase occurs in muscular disorders, nephrotic syndrome and cirrhosis. Mild increase in LDH activity has been reported in cases of myocardial or pulmonary infarction, leukemia, hemolytic anemia and non-viral hepatitis. This method is in accordance with the recommendations of the International Federation of Clinical Chemistry (IFCC).

Principle:
Kinetic determination of LDH activity according to the recommendations of IFCC

$$\text{Lactate} + \text{NAD Analogue} \xrightarrow{\text{LDH}} \text{Pyruvate} + \text{NADH} + H^+$$

Lactate dehydrogenase catalyses the conversion of Lactate to Pyruvate. NAD Analogue is converted into NADH in this process. The rate of increase in NADH formation is directly proportional to the LDH activity.

Reagents:
Components and Concentration

R1	:	Imidazole	pH 8.70	500 mMol/l
	:	Lithium Lactate		100 mMol/l
R2	:	NAD Analogue		19 mMol/l

Storage instructions and stability:
- The reagents are stable up to the end of the indicated month of expiry, if stored at 2-8ºC and contamination is avoided.
- Do not freeze the reagents!
- Reagent 2 must be protected from light.

Specimen:
Fresh Serum is the preferred specimen. Heparin or EDTA Plasma can be used.

LDH activity in the serum sample is stable for 3 days at 2-8ºC and 7 Days at -20ºC.

Precautions:
Working Reagent storage is not recommended in LDH IFCC assays.

Mix R1 and R2 in the ratio mentioned (4 Parts R1 and 1 Part R2) whenever the test is performed.

Assay Procedure:
Pipette the reagents as follows

R1	800 µl
Serum	20 µl
R2	200 µl

Mix well and immediately aspirate in to the analyzer. After 60 Seconds incubation, measure the change of optical density per 60 seconds during 180 seconds against distilled water at 340 nm as follows:

A° - Exactly after 60 Seconds.

A1, A2, A3 - Exactly after every 60 seconds for 180 seconds.

Calculations:
From absorbance readings calculate Δ A/min and multiply by the corresponding factor 8095 at 340 nm

LDH Activity (IU/L) = Δ Abs / Min X 8095 (Kinetic Factor)

System Parameters:

Reaction Type (Mode)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	340nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay time	:	60 seconds
Measuring Time	:	180 seconds
Reagent Volume	:	1ml (800 µl R1+ 200 µl R2)
Sample Volume	:	20µl
Factor	:	8095
Linearity	:	2000
Units	:	IU/L
High Normal	:	250 (Adult Male)
	:	245 (Adult Female)

Reference Values:

Adult Male	:	Up to 250 IU/L
Adult Female	:	Up to 245 IU/L
Children (1-15 Years)	:	Up to 330 IU/L
Neonates (4-20 Days)	:	Up to 620 IU/L

Performance Characterestics:

Measuring Range / Linearity
The test has been developed to determine LDH activities which correspond to a maximal Δ A/min of 0.247 at 340.
(2000 IU/l)

If these values are exceeded the sample should be diluted 1+9 with NaCl solution (9 g/l) and results multiplied by 10.

Specificity /Interference
No interference was observed by Ascorbic acid up to 30 mg/dl,

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Billirubin up to 45 mg/dl and Lipemia up to 2,000 mg/dl Triglycerides. Hemoglobin interferes starting with a concentration of 50 mg/dl.

Sensitivity/Linearity:

The lower limit of detection is 5 IU/L

Linearity up to 2000 IU/L

PRECISION:

Intra-assay precision	mean	SD	CV
N=20	(IU/l)	(IU/l)	(%)
sample1	178	2.00	1.12
sample 2	187	2.12	1.14
sample 3	566	2.27	0.40

Inter-assay precision	mean	SD	CV
N=20	(IU/l)	(IU/l)	(%)
sample1	170	1.62	0.95
sample 2	176	2.48	1.41
sample 3	566	3.61	0.64

Method Comparison:

A comparison between High-Q LDH (IFCC) (y) and the IFCC of reference reagent (x) using 50 samples gave the following results:

y = 0.949 x + 8.451 U/l; r = 0.990.

A comparison with a commercially available test with 32 samples gave following results;

y = 0.992 x + 10.72 U/l; r = 0.997.

References:

1. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt; TH-Books Veriagsgesellschaft; 1998. 89-94

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2. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 3: Reference procedure for the measurement of catalytic concentration of lactate dehydrogenase. Clin Chem Lab Med 2002; 40:643-48.

3. Soldin JS, Hicks JM. Pediatric reference ranges. Washington : AACC Press : 1995-95.

Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-LDH - 10	10 ml	8 ml (R1) + 2 ml (R2)
P-LDH - 20	20 ml	2 x 8 ml (R1) + 2 x 2 ml (R2)
P-LDH - 50	50 ml	5 x 8 ml (R1) + 5 x 2 ml (R2)

Product Features

- **Liquid Stable, Ready to use Two Reagents (4 parts R1 + 1 part R2).**
- **NAD Analogues are used for better stability**
- **4 Minutes increasing Kinetic Reaction (60 Sec Delay+ 180 Sec Measuring)**
- **Linearity 2000 IU/L**
- **Measuring Wavelength 340 nm**
- **Results by Kinetic Factor**
- **Serum/ EDTA Plasma as specimens**
- **Available as multipurpose reagents and dedicated system packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
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AN ISO 13485 Certified Company

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