LiquiMAX LDH (L→P)

IFCC Method / NAD Analogue

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVLDH - 10	10 ml	1 x 8 ml (R1) + 1 x 2 ml (R2)
AVLDH - 20	20 ml	2 x 8 ml (R1) + 2 x 2 ml (R2)

INTENDED USE

LiquiMAX LDH is an in-vitro diagnostic kit is use for the quantitative determination of Lactate Dehydrogenase in human Serum and Plasma.

PRODUCT FEATURES:

1. Liquid Stable, Ready to use Two Reagents (4 parts R1 + 1 part R2).
2. NAD Analogues are used for better stability
3. 4 Minutes increasing Kinetic Reaction (60 Sec Delay+ 180 Sec Measuring)
4. Linearity 2000 IU/L
5. Measuring Wavelength 340 nm
6. Results by Kinetic Factor
7. Serum/ EDTA Plasma as specimens
8. Available as multipurpose reagents and dedicated system packs

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 homotetramers, LDH-1 (heart) and LDH- 5 (muscle), and three hybrid isoenzymes. Elevated serum levels of LDH have been observed in a variety of diseasestates. The highest levels are seen in patients with megaloblastic anemia, disseminated carcinoma and shock. Moderate increases occur in muscular disorders, nephritic syndrome and cirrhosis. Mild increases in LDH activity have been reported in cases of myocardial or pulmonary infarction, leukaemia, haemolytic 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.

STORAGE 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.

KIT COMPONENTS

1. Buffer Reagent R1
2. Substrate Reagent R2

COMPOSITION

Components and Concentration

R1	:	Imidazole	pH 9.40	400 mMol/l
	:	Lithium Lactate		60 mMol/l
R2	:	NAD Analogue		17 mMol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.8 at 340 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

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.

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
Kinetic Interval	:	60 seconds
Number of readings	:	4
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)

TEST PROCEDURE:

Pipette the reagents as follows

R1	800 µl
R2	200 µl
Serum	20 µl

Mix well and after 1 minute incubation, measure the change of optical density per 60 seconds during 180 seconds against distilled water at 340 nm as follows:

Aº	-	Exactily after 1 minute.
A1, A2, A3	-	Exactily after every 60 seconds for 180 seconds.

CALCULATION:

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

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

EXPECTED VALUE

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

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

a) When using a new reagent or lot.

b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 2000 IU/l

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 5 IU/L

3. Interferences

No interference was observed by Ascorbic acid up to 25 mg/dl, 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.

4. Precision:

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

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

5. Method Comparison:

A comparison between LiquiMAX 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.

LIMITATIONS

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

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

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES

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

Symbols Used on Pack

REF	Catalogue Number	⚠	Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
Σ	Contains sufficient no. of test		

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