

BioMed- LACTATE DEHYDROGENASE



Kinetic

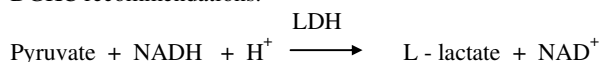
REF: LDH117030 (6x5 ml)
LDH117090 (5x18 ml)

INTENDED FOR USE:

For the quantitative determination of Lactate Dehydrogenase in serum or plasma .

PRINCIPLE :

Kinetic determination of Lactate Dehydrogenase in accordance with DGKC recommendations:



The initial oxidation rate of NADH is proportional to the LDH catalytic activity .
LDH activity in the sample is calculated by measuring the per time absorbance decrease at 340 nm.

SPECIMEN COLLECTION:

Non hemolized serum or plasma(Heparin/EDTA).

Notes: Do not use hemolyzed serum.

Red cells contain high concentration of LDH.

Serum should be separated from the clot as soon as possible

LDH in serum is stable up to 2/3 days at room temperature (+15-25°C). In order not to compromise the LDH fraction thermal transiency, do not freeze , not expose serum to high temperature (+37°C).

Shake and bring the samples at room temperature (+15-25°C) before using

REAGENT COMPOSITION:

R1	Buffer	80mmol/L
	Sodium Chloride	200mmol/L
	Sodium Pyruvate	1.6mmol/L
R2	NADH	2.4mmol/L

PACKAGE : Collection & Storage .

Store at (+2-8°C)

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination

PRECAUTIONS & WARNING:

Avoid pipetting by mouth .

The preparation , according to current regulation . is classified as not dangerous.

The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes
The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPATION & STABILITY :

All reagent are stable until expiration date when stored refrigerated at 2- 8 °C

Mix 5 volumes of R1 with one volume of R2

Working solution is stable for 2 months 2- 8 °C or 1 week at 15-25 °C

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength 340nm (334-365)
Optical path : 1 cm light path
Temperature : +25,30 or 37°C
Reading : Against distilled water
Assay type : Decreasing Kinetic

Macro method		
Pipette into test tubes		
	25°C or 30°C	37°C
Specimen	100 µl	50 µl
Working reagent	3.0 ml	3.0 ml
Semi-micro method		
Pipette into cuvette		
	25°C or 30°C	37°C
Specimen	50 µl	20 µl
Working reagent	1.5 ml	1.0 ml
Mix, read initial absorbance after 30 sec. and start timer simultaneously. Read again after 1,2 and 3 min. determine the mean absorbance change per minute (ΔA/min).		

Volumes can be proportionally modified

This methodology describes the manual procedure to use the kit.

For automated procedure , ask for specific application

CALCULATION :

To calculate the LDH activity use the formula

Macro Method

25°C or 30°C	37°C
U/l = 5016 x ΔA 334 nm/min	U/l = 9871 x ΔA 334 nm/min
U/l = 4921 x ΔA 340 nm/min	U/l = 9683 x ΔA 340 nm/min
U/l = 9118 x ΔA 365 nm/min	U/l = 17941 x ΔA 365 nm/min

Semi-micro Method

25°C or 30°C	37°C
U/l = 5016 x ΔA 334 nm/min	U/l = 8252 x ΔA 334 nm/min
U/l = 4921 x ΔA 340 nm/min	U/l = 8095 x ΔA 340 nm/min
U/l = 9118 x ΔA 365 nm/min	U/l = 15000 x ΔA 365 nm/min

EXPECTED VALUES:

37°C	230-460 U/L
30°C	160-320 U/L
25°C	120-240 U/L

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCES:

Ann.Biol.Clin.,40,123 (1982).

Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986).

PERFORMANCE :

MEASURE INTERVAL INEARTY :	12 -1200 U/L
LOWEST MEASURABLE LIMIT:	12 U/L
SENSITIVITY:	1 U/L = 0.00010ΔE/min

PRECISION WITHIN SERIES: n=20

LOW LEVEL	M= 181 U/L	C.V.=1.15%
MEDIUM LEVEL	M= 308 U/L	C.V.=2.41%

PRECISION AMONG SERIES: n=20

LOW LEVEL	M= 186 U/L	C.V.6.47%
MEDIUM LEVEL	M= 301 U/L	C.V.4.49%
INTER.ANALIZED	r = 0.996	n= 50
CORRELATION	181 – 308 U/L	
LIN. REGRESSION	y = 1.06x – 10.8	n= 50

INTERFERENCE:






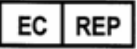

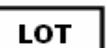

Interferences are negligible up to :			
Bilirubin	20mg/dL	Glucose	500 mg/dL
Triglycerids	1000mg/dL	Ascorbic Acid	160mg/dL

METHOD LIMITATIONS:

For concentration higher than 1200 U/L repeat the measure on a sample diluted 1:5 with physiological solution and multiply the results x 5.

Hemoglobin concentration of 2g/L, in hemolyzed samples will determine a 10 % overvalue.

For a thorough evaluation of the interfering substances , consult : Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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