LACTATE DEHYDROGENASE (LDH)

METHOD – P→L UV-KINETIC
PRODUCT CODE – LL01

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of LDH activity in serum/plasma using P → L UV-Kinetic method.

SUMMARY AND PRINCIPLE

Lactate dehydrogenase is concentrated in heart, kidney, liver, muscle and body tissue. Elevated levels are associated with myocardial infarction, hepatitis, anaemia, malignancies and muscular disease or damage. LDH is a reagent set for determination of Lactate Dehydrogenase activity in human serum and plasma based on the recommendation of IFCC (P → L). LDH is a two-liquid reagent. Lactate dehydrogenase catalysis the conversion of Pyruvate to Lactate

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

KIT COMPONENTS

Reagent 1: LDH Reagent 1
Reagent 2: LDH Reagent 2

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagents. Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired working reagent prior to use. Do not shake vigorously. The working reagent is stable for 30 days at 2-8 ^{0}C. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent goes below 1.000 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	LDH
Reaction Type	Kinetic (↓)
Wavelength Primary	340 nm
Flow Cell Temp.	37 °C
Blank setting	D.W.
Blank Abs Limit	>1.000
Linearity	2000 IU/L

Reagent Volume	1000 µl
Sample Volume	20 µl
Incubation Temp.	37 °C
Delay Time	60 sec.
Read Time	120 sec.
Factor	8109
Standard Conc.	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum is preferred. Plasma with heparin or EDTA can be used. Haemolysed samples should not be used since erythrocytes are rich in LDH activity. LDH in serum or plasma is stable for 4 days at 2-8 ^{0}C and for 1 month at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Tris Buffer, pH 7.5	100 mmol/l
Pyruvate	> 1.2 mmol/l
NADH	0.25 mmol/l
Stabilizers and inactive ingredients.	

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	20 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Record the absorbance at 60th, 90th, 120th and 150th sec.	

CALCULATION

LDH Activity (IU/L) = Δ Abs. per min x 8109.

REFERENCE VALUES FOR NORMAL PEOPLE

Temperature	At 25 ^{0}C	At 30 ^{0}C	At 37 ^{0}C
Activity (IU/L)	120 – 240	160 – 320	225 - 450

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 40 – 2000 IU/L. If the LDH value exceeds linearity limit (above 2000 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct LDH value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL. Haemolysed serum gives false elevated result.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	352.6	4.03	1.1	381.3	4.5	1.2
High Value Serum	691.3	3.47	0.5	703.6	3.1	0.4

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for LDH. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is less than 1.000 at 340 nm against distilled water.

2. If LDH value exceeds 2000 IU/L then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct values.

BIBLIOGRAPHY

1. Tietz NW, ed. Fundamentals of Clinical Chemistry, 3rd ed. Philadelphia, Pa : W.B. Saunders Co., 391 (1987).

2. NCCLS Document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2 nd ed. (1992).

3. Thomas L. Clinical Laboratory Diagnostic.1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998 : 89 - 94.

4. Moss DW; Henderson AR. Clinical Enzymology In : Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia. W.B. Saunders Company; 1999 : 617 - 721.

5. Deutsche Gesellschaft fur Klinische Chemie : Recommendation of the German Society of Clinical Chemistry. Standardization of Methods for the Measurement of Enzymatic activities in biological fluids. J. Clin. Chem. Clin. Biochem. 1972; 10: 182 - 193.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE