Instructions For Use

GENESIS

LDH (DGKC Method (4+1))

Cat no.	size
1206 101	2*25
1206 102	5*20

INTENDED USE

LDH Reagent is intended for the in vitro Quantitative diagnostic determination of lactate dehydrogenase (LDH) in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Lactate dehydrogenase is present in all cells of the body but its higher concentrations are found in liver, heart, kidney, skeletal muscle and erythrocytes.Total LDH concentration in serum or plasma is increased in patients with liver disease, renal disease, myocardial infarction, many malignant diseases, progresive muscular dystrophy and almost any cause of hemolysis

PRINCIPLE OF THE METHOD

Lactate dehydrogenase (LD or LDH) catalyzes the reduction of pyruvate by NADH, to form lactate and NAD+. The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm

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

COMPOSITION

Reagent (R1)	Tris	121 mmol/L
	pyruvate	100 mmol/L
	Sodium chloride	50 mmol/L
Reagent (R2)	NADH	2.0 mmol/L
	SodiumAzide	9.5 g/L

STORAGE

The Reagent is stable until the expiry date shown on the Vial label when stored at 2-8 ° C .

REAGENT PREPARATION

Working reagent: (4) Parts of (R1) are mixed with one part of (R2).

Working reagent : stable for 1 month when Stored at 2-8 ° C

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC
- Analyzer, spectrophotometer able to read at 340 nm

SPECIMEN

1. Serum or plasma collected by standard procedures.
2. Serum or plasma must be separated from the clot as soon as possible.
3. Do not use hemolysed samples.
4. Lactate dehydrogenase in serum or plasma is stable for 2 days at room temperature and for 24 hours at 2-8ºC.
5. Use heparin as anticoagulant.

Precautions and Warnings

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Reaction…….Kinetic
Wavelength……..340nm
Cuvette: ……..1cm light path Constant temperature ……..37ºC
Delay time……..…30sec
Measuring time……..180sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working reagent	1.0 ml
sample	20 µL

5. Mix and incubate for one 30 sec.
6. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minutes.
7. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

LDH (U/l) = ΔA/min x8095

REFERENCE VALUES

Adult	240 - 480 U/L

QUALITY CONTROL

It is recommended to use the Control Serum level Iand II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

- Detection limit: 40.5 U/L = 0.67 µkat/L
- Linearity limit: 1250 U/L =20.92 µkat/L.

For higher values dilute sample **1/5** with physiological saline and repeat measurement.

- **Repeatability (within run):**

Mean Concentration	CV	n
420 U/L = 7.0 µkat/L	1.3 %	20
852 U/L = 14.20 µkat/L	1.2%	20

- **Reproducibility (run to run):**

Mean Concentration	CV	n
420 U/L = 7.0 µkat/L	2.0 %	25
852 U/L = 14.20µkat/L	2.7%	25

- **INTERFERENCES:**

Bilirubin (20 mg/dL) does not interfere. Lipemia (triglycerides 2 g/L) and hemolysis may affect the results.

Other drugs and substances may interfere.

BIBLIOGRAPHY

1. Sociedad Española de Química Clínica, Comité Científico, Comisión de Enzimas. Métodorecomendado para la determinación en rutina de la concentración catalítica de lactate deshidrogenasa en suero sanguíneo humano. Quim Clin 1989; 8: 57-61.

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CE

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