PARAMCARE LIFE SCIENCES PVT. LTD.
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PARAMCARE™

LDH (L-P) Test Kit

Kinetic Method

Quantitative determination of Lactate Dehydrogenase (LDH) in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
LDH 10	1 X 10 mL
LDH 25	1 X 25 mL

CLINICAL SIGNIFICANCE

Lactate dehydrogenase (LDH) is an enzyme with wide tissue distribution in the body. Increased levels of the enzyme are found in serum in liver disease, myocardial infarction, renal disease, muscular dystrophy and anemia.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry)

PRINCIPLE

Lactate is oxidised to Pyruvate in the presence of NAD by the action of lactate dehydrogenase. The rate of formation of NADH is directly proportional to LDH concentration.

REAGENT

Reagent 1 : Buffer reagent
Reagent 2 : Substrate reagent

REAGENT PREPARATION

Mix 4 Part of Buffer reagent with 1 Part of Substrate reagent.

REAGENT STORAGE AND STABILITY

Prior to use:
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Reconstituted Reagent:
When stored capped at 2-8°C, the reagent is stable for at least 7 days.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or heparin plasma or EDTA plasma
Separate at the latest 1h after blood collection from cellular contents.
1 month at 4 – 8°C
Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	340nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled water
Reaction Type	Kinetic test
Reaction direction	Increasing
Sample Volume	25 µl
Reagent Volume	1000 µl
Delay/lag/time	60 Secs
Interval Time	30 Secs
No. of Readings	04
Blank Absorbance limit	≤ 0.6
Factor	6592
Low Normal at 37°C	80 U/l
High Normal at 37°C	285 U/l
Linearity	1200 U/l

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

Working Reagent	1000 µl
Sample	25 µl

Mix well and after 1 min incubation, measure the change in absorbance per min. (Δ A/min.) for next 2 minutes.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 1200 U/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

LDH Activity (U/L) = Δ A/min x 6592

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

This method has been standardized against the original IFCC formulation.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	196.23	0.11	0.05
Randox 3	377.09	0.06	0.02

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	196.24	0.08	0.03
Randox 3	377.08	0.03	0.01

LINEARITY

The method is linear upto a concentration of 1200 U/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for LDH is 5 U/L.

METHOD COMPARISON

A comparison of Paramcare LDH with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9800$

REFERENCE VALUES

Males	30°C	50 - 166 U/L
	37°C	80 - 285 U/L
Females	30°C	60 - 132 U/L
	37°C	103 - 227 U/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Ascorbic Acid: No interference found upto 30 mg/dL.
- Bilirubin: No interference found upto 40mg /dL.
- Lipemia: No interference found upto 1500 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

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GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

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