ANA BIO ISP LDH

(Kinetic Method)

For Miura Instruments

Intended Use

LDH is a reagent set for determination of lactate dehydrogenase activity in serum and plasma based on Kinetic method.

Principle

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.

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

Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent 1	TRIS buffer pH 7.4	50 mmol/L
	Pyruvate	1.20 mmol/L
	Stabilizers, excipients & surface active agents	
Reagent 2	TRIS buffer pH 9.8	20 mmol/L
	NADH	2.60 mmol/L
	Stabilizers, excipients & surface active agents	

Reagent storage and stability

The reagent kit should be stored at 2° - 8°C and is stable till the expiry date indicated on the label.
A sligt variation in the composition of the components may occur between batches, but this has no effect on the test results.
After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protect from contamination, evaporation, direct light and stored at correct temperature.

Specimen collection and preservation

Collect the specimen in a clean dry container. Although serum is preferred, plasma with Heparin or EDTA can be used. Hemolyzed samples should not be used since LDH activity in erythrocytes is 160 fold higher than in serum. The serum should be separated from the clot promptly. Samples should be assayed soon after collection. LDH is stable in serum or plasma for four days at 2 - 8°C. Do not freeze or expose the serum to high temperature as this may inactivate thermolabile LDH isoenzymes.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	LDH
Method Code	LDH
Type	Kinetic
Unit	IU/L
Filter F1	340 nm
Blank in	Not Use
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Volume reagent R2	50	µl
Sample Volume	5	µl
First Incubation	60	Sec
Final Incubation	240	Sec.

Normal Range

		25°C	**30°C**	**37°C**
IU/L	Adults	120-240	161-322	240-480
µkat/l	Adults	2.00-4.00	2.68-5.37	4.00-8.00

The following factors are used for conversion:
From 25°C to 30°C: 1.34
From 25°C to 37°C: 2.00

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitations

This method is linear up to 1600 IU / L. If the activity exceeds 1600 IU/L, dilute the sample suitably with normal saline and repeat the assay. Apply proper dilution factor to calculate the final results.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

LDH added to a serum matrix containing known amounts of LDH gave an average recovery of 99.8%.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	236.87	6.71	2.83	20
High	IU/L	839.55	22.43	2.67	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	236.87	6.60	2.79	20
High	IU/L	839.55	43.89	5.23	20

Sensitivity

At 340 nm, the activity of LDH of 20 IU/L can estimate.

References

1. Thomas L. Clinical laboratory Diagnostics. 1st ed.Frankfurt: TH-Books verlagsegellschaft; 1998:89-94.
2. NCCLS Document "Evaluation of precisión performance of clinical chemistry Devices",2nd ed. (1992).
3. 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.

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

KEE DIAGNOSTICS PVT LTD
(Formerly known as Kee GAD Biogen Pvt. Ltd.) .
CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2 . NEW DELHI 110028.
W. www.keediagnostics.in.
E. info@keediagnostics.in, T. 011 43136000.

Kee Diagnostics
because life matters