LDH
(IFCC UV Kinetic method) (Lot LDHXXXX)

DIATEK

CLINICAL SIGNIFICANCE :

The enzyme lactate dehydrogenase (LDH-L) is distributed in tissues particularly heart, liver, muscle, and kidney. The enzyme found in circulation is a mixture of five isoenzymes based on their mobility. Elevated serum levels of LDH-L are found in serum in myocardial infarction, liver disease, renal disease, certain forms of anemia, malignant diseases and progressive muscle dystrophy.

TEST PRINCIPLE :

LDH catalyzes the oxidation of lactate to pyruvate, and NAD is reduced to NADH, which can be measured at 340nm.

$$\text{L-lactate} + \text{NAD+} \xrightarrow{\text{LDH}} \text{Pyruvate} + \text{NADH} + \text{H+}$$

LDH = Lactate Dehydrogenase

The increasing absorbance of NADH is measured photometrically following time and temperature controlled kinetic reaction.

REAGENTS COMPOSITION :

R1: N-Methyl-D-Glucamin 325 mmol/, L-Lactate 50 mmol/l
R2: NAD+ 10 mmol/l

KIT CONTENTS :

	CODE No. LDH02
Pack size :	(6 x 10ml)
Reagent 1	5 x 10 ml
Reagent 2	1 x 10 ml

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8 ºC, and contaminations prevented during their use. Do not use reagents over the expiration date. It is recommended to use the kit within one month after opening.

SAMPLES :

Serum or Heparinised plasma

MATERIALS REQUIRED BUT NOT PROVIDED :

LDH IFCC Control L>P (Use of assayed QC sera is recommended to validate instrument specific Kinetic Factor and test result).

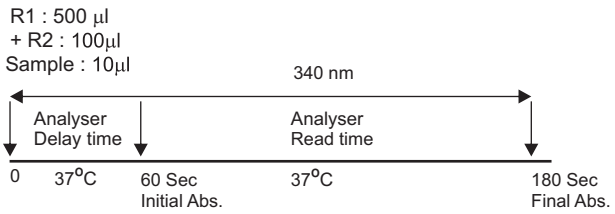
ASSAY CONDITIONS:

Wavelength :	340 nm
Cuvette:	1 cm light path
Constant temperature	37ºC
Reaction (Mode)	Kinetic
Kinetic Factor	Lot specific value
Delay	60 sec
Read time	180 sec
Linearity	1450 U/L
Unit	U/L
Blanking	D. Water
Slope of reaction	Increasing
Instrument sipping Volume	450 - 500 µl

PROCEDURE :

1. Mix 100 µl of R2 into the 500µl R1 to prepare Working Reagent. Mix carefully (do not shake).
2. Programe the Analyser and set Sipping volume 450 - 500 µl.
3. Add 10 µl of sample in the Working Reagent.
4. Mix and start read the change of absorbance (ΔA) with delay time 60 sec and Read time 180 sec at 37ºC.

Assay Procedure summary (Serum/Plasma):



CALCULATIONS :

LDH Activity in U/L = Δ Abs/mint of Test x KF*

**Kinetic Factor (KF) value is Lot specific.*
Kinetic Factor is also dependent upon Instrument specific wavelength, Temperature and Path length.

REFERENCE RANGE :

Serum/plasma : < 248 U/L

The above reference range is guideline and all the laboratories must establish their own specific normal reference range. Final diagnosis should be made with correlation of clinical factors.

PRECAUTIONS :

1. Do not pipette by mouth therefore avoid contact of the reagent with skin.
2. Use fresh microtips while pipetting sample, R1 and R2
3. Avoid contamination of the reagent during the assay process.
4. **Before the assay begins, bring all the reagents to room temperature.**
5. Do not freeze or expose the reagents to high temperature and protect from direct sunlight as it will affect the performance of the kit.
6. Programmes for specific analysers are available on request.
7. For accuracy of results, the assay procedure, reagent preparation and storage has to be meticulously followed.
8. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.
9. **The value of Factor is Lot specific.**

LINEARITY AND DETECTION LIMIT :

The linearity limit of the standard serum procedure is up to the LDH activity of 1450 U/l. At higher activities the sample has to be diluted 1:10 with Normal saline and the final result to be multiplied by 10. The lowest detection limit for serum samples is equal to 15 U/L.

INTERFERENCES

The following analytes were tested up to the levels indicated and found not to interfere with Ascorbic acid upto 30 mg/dl, Bilirubin upto 40 mg/dl, Hemoglobin upto 200 mg/dl and Triglycerides upto 2000 mg/dl

BIBLIOGRAPHY

1. 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.

2. Deutsche Gesellschaft für Klinische Chemie.(German Society for Clinical Chemistry). Recommendation for the determination of the catalytic concentration of lactate dehydrogenase at 37°C.Eur J Clin Chem Clin Biochem 1993;31:897-9.

LDH
(IFCC UV Kinetic method)

MONOTEST (Lot LDHXXXX)

DIATEK

CLINICAL SIGNIFICANCE :

The enzyme lactate dehydrogenase (LDH-L) is distributed in tissues particularly heart, liver, muscle, and kidney. The enzyme found in circulation is a mixture of five isoenzymes based on their mobility. Elevated serum levels of LDH-L are found in serum in myocardial infarction, liver disease, renal disease, certain forms of anemia, malignant diseases and progressive muscle dystrophy.

TEST PRINCIPLE :

LDH catalyzes the oxidation of lactate to pyruvate, and NAD is reduced to NADH, which can be measured at 340nm.

$$\text{L-lactate} + \text{NAD+} \xrightarrow{\text{LDH}} \text{Pyruvate} + \text{NADH} + \text{H+}$$

LDH = Lactate Dehydrogenase

The increasing absorbance of NADH is measured photometrically following time and temperature controlled kinetic reaction.

REAGENTS COMPOSITION :

R1: N-Methyl-D-Glucamin 325 mmol/, L-Lactate 50 mmol/l
R2: NAD+ 10 mmol/l

KIT CONTENTS :

	CODE No. LDH01
Pack size :	(10 Test)
Reagent 1	10 Vials (Prefilled)
Reagent 2	1 x 1.1 ml

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8 ºC, and contaminations prevented during their use. Do not use reagents over the expiration date. It is recommended to use the kit within one month after opening.

SAMPLES :

Serum or Heparinised plasma

MATERIALS REQUIRED BUT NOT PROVIDED :

LDH IFCC Control (Use of assayed QC sera is recommended to validate test result).

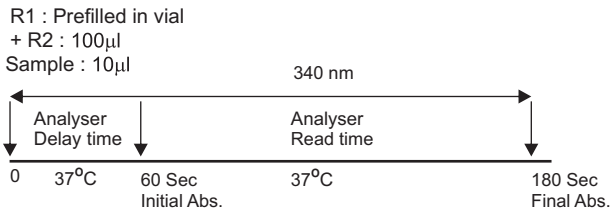
ASSAY CONDITIONS:

Wavelength :	340 nm
Cuvette:	1 cm light path
Constant temperature	37ºC
Reaction (Mode).....	Kinetic
Kinetic Factor.....	Lot specific value
Delay	60 sec
Read time.....	180 sec
Linearity.....	1450 U/L
Unit.....	U/L
Blanking.....	D. Water
Slope of reaction.....	Increasing
Instrument sipping Volume.....	450 - 500 µl

PROCEDURE :

1. Add 100 µl of R2 directly into the prefilled R1 vial to prepare Working Reagent. Mix carefully (do not shake).
2. Programe the Analyser and set Sipping volume 450 - 500 µl.
3. Add 10 µl of sample in the Working Reagent.
4. Mix and start read the change of absorbance (ΔA) with delay time 60 sec and Read time 180 sec at 37ºC.

Assay Procedure summary (Serum/Plasma):



CALCULATIONS :

LDH Activity in U/L = Δ Abs/mint of Test x KF

LDH Calibrator (IFCC L>P) is recommened to use for calculation of Kinetic Factor in LW SERIES and other fully automated Analysers. Kinetic Factor (KF) value is Lot Specific.

REFERENCE RANGE :

Serum/plasma : < 248 U/L

The above reference range is guideline and all the laboratories must establish their own specific normal reference range. Final diagnosis should be made with correlation of clinical factors.

PRECAUTIONS :

1. Do not pipette by mouth therefore avoid contact of the reagent with skin.
2. Use fresh microtips while pipetting sample and R2
3. Avoid contamination of the reagent during the assay process.
4. **Before the assay begins, bring all the reagents to room temperature.**
5. Do not freeze or expose the reagents to high temperature and protect from direct sunlight as it will affect the performance of the kit.
6. Programmes for specific analysers are available on request.
7. For accuracy of results, the assay procedure, reagent preparation and storage has to be meticulously followed.
8. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.
9. **The value of Factor is Lot specific.**

LINEARITY AND DETECTION LIMIT :

The linearity limit of the standard serum procedure is up to the LDH activity of 1450 U/l. At higher activities the sample has to be diluted 1:10 with Normal saline and the final result to be multiplied by 10. The lowest detection limit for serum samples is equal to 4 U/L.

INTERFERENCES

The following analytes were tested up to the levels indicated and found not to interfere with Ascorbic acid upto 30 mg/dl, Bilirubin upto 40 mg/dl, Hemoglobin upto 200 mg/dl and Triglycerides upto 2000 mg/dl

BIBLIOGRAPHY

1. 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.

2. Deutsche Gesellschaft für Klinische Chemie.(German Society for Clinical Chemistry). Recommendation for the determination of the catalytic concentration of lactate dehydrogenase at 37°C.Eur J Clin Chem Clin Biochem 1993;31:897-9.

Manufactured by : **DIATEK Healthcare Pvt. Ltd.**
P-54 , Phase-I , Kalyani Industrial Estate, Kalyani, Dist. : Nadia, Pin : 741235 E-mail : diatek@rediffmail.com
Corporate Office : P-27, Kalindi Housing Scheme, Kalindi, Kolkata- 700089, Help line : 033 - 25223075