

LACTATE DEHYDROGENASE (DGKC)

INTENDED USE

Bioline LDH is intended for the quantitative *in vitro* diagnostic determination of Lactate Dehydrogenase (LDH) in human serum.

CLINICAL SIGNIFICANCE

Lactate dehydrogenase (LDH) can be found in nearly all cells of the body with highest activities in myocardium, liver, kidney and skeletal muscle. Consequently, elevations of LDH in the serum have been considered non specific (for any disease or disorder). LDH increases in case of acute myocardial infarction, hepatic disorders (viral hepatitis, cirrhosis), muscular dystrophy, cancer, metastasis, anemia (hemolytic, megaloblastic), kidney diseases and in numerous other diseases involving tissue damage.

METHOD AND PRINCIPLE

Lactate dehydrogenase (LDH) catalyses the reduction of pyruvate by NADH, according the following reaction:



The rate of decrease in concentration of NADPH, measured photometrically, is proportional to the catalytic concentration of LDH present in the sample .

REAGENT COMPOSITION

Tris Buffer	100mmol/L
Sodium pyruvate	1.2mmol/L
NADH	0.18 mmol/L

WARNINGS AND PRECAUTIONS

The reagents contain less than 0.1 % sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If discharged in the plumbing system, rinse with plenty of water. Use clean and disposable accessories to avoid contamination. For more information, Material Safety Data Sheet (MSDS) is available on request for the professional users.

WORKING REAGENT PREPARATION

The working reagent is prepared by mixing 4 volumes of R1 with 1 volume of R2.

REAGENT STORAGE AND STABILITY

Store at 2-8 °C and protect from light.

The reagent is stable until the expiry date stated on the label.

REAGENT DETERIORATION

The reagent should be discarded if:

1. Turbidity has occurred; turbidity may be a sign of contamination.
2. The working reagent has an absorbance against water less than 1.0 at 340 nm.

SPECIMEN COLLECTION AND STABILITY

Serum or Lithium heparinized plasma.

Do not use other specimens

Samples are stable for 7 days at 2-8 °C and at least 2 months at -20 °C. For longer storage, freeze samples at -70 °C

Samples must be free from haemolysis and lipemia.

INTERFERENCE

No Significance interference upto

Triglycerides	: 3146 mg/dl
Unconjugated bilirubin	: 30 mg/dl
Conjugated bilirubin	: 29.5 mg/dl
Ascorbic Acid	: 20 mg/dl
Acetylsalicylic acid and Acetaminophen	: 30 mg/dl

ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.

Wavelength	: 340 nm
Temperature	: 37°C

	Sample
Reagent R1	800 µL
Reagent R2	200 µL
Sample	20 µL

Mix and aspirate in the analyzer , after a 1 minute of delay, measure the change of optical density per minute ($\Delta\text{OD}/\text{min}$) during next two minutes.

CALCULATION

LDH Activity (IU/L) at 340 nm = $\Delta\text{OD}/\text{min}$. X 8109

LIMITATIONS

Samples that exceed the linearity limit 1600 IU/L should be diluted with an equal volume of saline and re-assayed and the final results multiplied by two.

QUALITY CONTROL

To ensure adequate quality, control sera normal and abnormal control should be used. These controls must be performed & validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control material should be used in accordance with local guidelines.

EXPECTED VALUES

230-460 U/L

PERFORMANCE CHARACTERISTICS

1. Linearity: 1600 IU/L. Samples that exceed 1600 IU/L should be diluted with an equal volume of saline and re-assayed. Multiply the result by 2.

2. Comparison: A comparative study has been performed between competitor and our reagent on human serum samples.

The parameters of linear regression are as follows:

Correlation coefficient : $r^2 = 0.997$

Linear regression : $y = 1.010x + 3$

3. Precision

	Within-run reproducibility			Between-run reproducibility		
	n	Mean (IU/L)	CV (%)	n	Mean (IU/L)	CV (%)
Level 1	20	149	1.2	20	150	4.3
Level 2	20	291	0.8	20	289	1.9
Level 3	20	908	1.2	20	894	2.4

GENERAL TECHNICAL PARAMETER

Mode	Kinetic
Wavelength (Filter)	340 nm
Reaction Direction / Type	Decreasing
Reagent Blank	No
Sample Vol.	20 µL
Reagent Vol.	1000 µL
Delay Time	60 Sec
Interval Time	60 Sec
No. of reading	2
Measuring Time	120 Sec
Factor	8109
Reagent Blank Abs.(Max)	NLT 1.0 Abs
Calibration Method	Fix Factor
Linearity	1600 IU/L
Decimal Places	1
Temp.	37°C
Unit	IU/L
Ref. Low (Male / Female)	230 IU/L
Ref. High (Male / Female)	460 IU/L

REFERENCES

1. Tietz, N.W., editor, Fundamentals of Clinical Chemistry, 3rd Ed., W.B.Saunders Co., 391 (1987).
2. Young DS et al. Clin Chem, 21: ID432D(1975)
3. Burtis CA, Ashwood ER, eds. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WBSaunders, 1994:8138