Atlas Medical CE

LDH Pyruvate Kinetic
UV DGKC Liquid

IVD *For in -vitro diagnostic use only.*

Store at 2-8°C

INTENDED USE

For the quantitative determination of lactate dehydrogenase (LDH) in human serum.

INTRODUCTION

Lactate dehydrogenase (LDH) is an enzyme with wide tissue distribution in the body. The higher concentrations of LDH are found in liver, heart, kidney, skeletal muscle and erythrocytes. Increased levels of the enzyme are found in serum in liver disease, myocardial infraction , 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.

PRINCIPLE

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

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

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

MATERIALS

REAGENTS

Reagent 1 Buffer	Imidazol Pyruvate	65 mmol/L 0.6 mmol/L
Reagent 2 Substrate	NADH	0.18 mmol/L

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 340 nm.
- Water bath at 25°C, 30°C ,37°C (± 0.1°C)
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- Working reagent (WR) :

  Mix: 4 vol. (R1) Buffer + 1 vol. (R2) Substrate
- Stability: 15 days at 2-8°C or 5 days at 15-25°C.

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
  - Presence of particles and turbidity.
  - Blank absorbance (A) at 340 nm <1.00.

SAMPLES

- Serum. Separated from cells as rapidly as possible. Do not use oxalates as anticoagulants since they inhibit the enzyme.
- Do not use haemolysed samples.
- Stability: 2 days at 2-8°C.

PROCEDURE

1. Assay conditions:
   Wavelength:.....340 nm
   Cuvette:.....1 cm light path
   Constant temperature :.....25°C /30°C / 37°C
2. Adjust the instrument to zero with distilled water or air.
3. Pipette into a cuvette:

	25- 30°C	37°C
WR (mL)	3.0	3.0
Sample (µL)	100	50

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

CALCULATION

25- 30°C	ΔA/min x 4925 = U/L LDH
37°C	ΔA/min x 9690 = U/L LDH

Units: One international unit (IU) is the amount of enzyme that transforms 1µmol of substrate per minute, in standard conditions. The concentration is expressed in units per llitre of sample (U/L).

Temperature conversion factors

To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to 25°C	30°C	37°C
25°C	1.00	1.33	1.92
30°C	0.75	1.00	1.43
37°C	0.52	0.70	1.00

REFERENCE VALUES

25°C	120-240 U/L
30°C	160-320 U/L
37°C	230-460 U/L

NOTE

These values are for orientation purpose; each laboratory should establish its own reference range.

QUALITY CONTROL

- If control values are found outside the defined range, check the instrument, reagents and technique for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Measuring range:

From detection limit of 3.42U/L to linearity limit of 1600 U/L.

If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	400	785	392	773
SD	3.15	10.97	6.23	9.93
CV (%)	0.79	1.40	1.59	1.28

Sensitivity:

1 U/L = 0.00009 ΔA /min.

Accuracy:

Results obtained using ATLAS reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 50 samples were the following:

Correlation coefficient $(r)^2$: 0.98382.

Regression equation: y= 0.8988x+2.583.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Haemolysis interferes with the assay.

Some anticoagulants such as oxalates interfere with the reaction.

A list of drugs and other interfering substances with LDH determination has been reported by Young.

REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry