LDH Kinetic-IFCC Tablet

IVD *For In Vitro Diagnostic and professional 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 required during the process of turning sugar into energy for your cells. LDH is present in many kinds of organs and tissues throughout the body, including the liver, heart, pancreas, kidneys, skeletal muscles, lymph tissue, and blood cells. When illness or injury damages your cells, LDH may be released into the bloodstream, causing the level of LDH in your blood to rise. High levels of LDH in the blood point to acute or chronic cell damage, but additional tests are necessary to discover its cause. Abnormally low LDH levels only rarely occur and usually aren't considered harmful.

PRINCIPLE

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

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

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

MATERIALS

REAGENTS

R 1 Buffer	Imidazol	65 mmol/L
	Pyruvate	0.6 mmol/L
R 2 Substrat (Tablets)	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):

- Dissolve 1 tablet of R 2 in 3 mL of R 1. Cap and mix gently to dissolve contents.
- Stability: 2 days at 2-8°C or 12 hours at room temperature (15-25°C).

PRECAUTIONS

- R1: May damage fertility or the unborn child.
- Follow the precautionary statements given in MSDS.

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 the tablets if appears broken.
- 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:……..1cm 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 absorbances at 1 min intervals thereafter for 3 min.
6. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

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 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter 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	30°C	37°C
120-240 U/L	160-320 U/L	230-460 U/L

NOTE

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

QUALITY CONTROL

- Control sera are recommended to monitor the performance of assay procedures.
- 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

1. Measuring range:

From *detection limit* of 2 U/L to *linearity limit* of 1500 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.

2. Precision:

	Intra-assay (n= 20)		Inter-assay (n= 20)	
Mean (U/L)	388	731	402	757
SD	7.44	12.49	12.45	16.96
CV %	1.92	1.71	3.10	2.24

3. Sensitivity:

1 U/L = 0,00010 ΔA/min.

4. 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 $(r)^2$: 0,987.

Regression equation: y= 1,6383x - 57,4835.

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
Σ	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