LDH-P SL

Kinetic UV Method (DGKC)

Liquid Reagents ready to use

REF. 4161	**2x 50 ml**	CE
REF. 4162	**2x100 ml**	IVD
REF. 0008	**5x 10 ml**	

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of lactate dehydrogenase enzyme (LDH) in serum and plasma, according to DGKC recommendations.

PRINCIPLE

In presence of NADH, LDH transforms pyruvate in lactate and NAD^+. NADH oxidation in unit time, measured at 340 nm, is proportional to the LDH concentration in the sample.

SAMPLE

Serum, EDTA or heparinized plasma. Do not use oxalate as anticoagulant. Avoid hemolyzed samples. Quickly separatethe serum from the clot.
LDH activity is stable 3 days in sample stored at 2-8°C.

KIT COMPONENTS

Reagent (A) LDH Volume = 40/80 ml	Buffer Sodium chloride Sodium pyruvate	80 mmol/l 200 mmol/l 1.6 mmol/l
Reagent (B) LDH Volume = 10/20 ml	NADH	2.4 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not freeze. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.
Keep bottles closed when not in use.

REAGENTS PREPARATION

Liquid Reagents, bring to room temperature (15-25°C) before use.
For **use as monoreagent**: add a part of Reagent (B) to 4 parts of Reagent (A).
The working solution (A+B) is stable 2 days at 15-25°C and 1 week at 2-8°C.

PRECAUTIONS AND WARNINGS

Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm (334-365)
Lightpath:	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	decreasing kinetic
Sample/Reagent	1/50

Use as monoreagent:

pipette:	
Working solution (A+B)	1000 µl
sample	20 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

Use as bireagent:

pipette:	
Reagent (A)	800 µl
sample	20 µl
Mix and after 1 minute add:	
Reagent (B)	200 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

This method describes the manual procedure to use the kit.
For automated procedure, ask for specific applications.

RESULTS CALCULATION

Perform calculation in Units per litre, multiplying the ΔA/min by the factor as it is indicated:

Activity in U/L: ΔA/min x 7100 **(*)** **340 nm**

(*) Factor calculated in our laboratories. We recommend the use of Clinical Chemistry Calibrator (Ref. 6002/8 - 8x3 ml) to verify that this factor is correct for your test system.

EXPECTED VALUES

225 – 450 U/L

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control sera: PRECISENORM (REF.6000) and PRECISEPATH (REF.6001).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 15 U/L
Linearity: the method is linear up to 1800 U/L. For higher values, dilute the sample 1:5 and multiply the result by 5.
Precision intra-assay:

	Level 1	Level 2
Mean (U/L)	302	486
DS	3.2	7.6
CV %	1.1	1.6

Precision inter-assay:

	Level 1	Level 2
Mean (U/L)	311	522
DS	16	24
CV %	5.15	4.6

Interferences: bilirubin does not interfere up to 20 mg/dl. Triglycerides do not interfere up to 1000 mg/dl.
Hemolysis presence in the sample causes falsely positive results.
Correlation against a reference method: Y = 1.0803x - 5.3694 r = 0.9987

REFERENCES

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