CE IVD DIALAB

Liquid Reagents – ready to use

LDH-P

(Lactate Dehydrogenase - P)

Optimized DGKC
2 Reagents

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in human serum or plasma on photometric systems

REF Cont.

D94651	**5 x 50 ml**	4 x 50 ml	Reagent 1
		1 x 50 ml	Reagent 2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	UV,Kinetic, Decreasing Reaction
	Optimized DGKC
Wavelength:	Hg 334 nm, Hg 365 nm, 340 nm
Temperature:	25°C, 30°C, 37°C
Sample:	Serum, heparin- or EDTA-plasma,
Linearity:	up to 3059 U/L
Sensitivity:	The lower limit of detection is 5 U/L

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1:	
Pyruvate	0.60 mmol/L
Phosphate	50 mmol/L
Reagent 2:	
NADH	0.18 mmol/L
Good´s buffer, pH 9.6	

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.

Sample Start:
Mix 4 parts of Reagent 1 with 1 part of Reagent 2.
(= Working Reagent)

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use

Substrate Start:
Storage: at 2 – 8°C
Stability: up to the expiration date

Sample Start (Working Reagent):
Stability: at 15 –25°C 8 hours
at 2 – 8°C 5 days
Minimum allowable absorbance of the Working Reagent measured at 340 nm against water as reference is 1.1.

SAMPLE STABILITY AND STORAGE

Loss of activity:	at 15 - 25°C	< 2% within 24 hours
	at 2 - 8°C	< 8 % within 3 days
Stability:	at –20 °C	at least 6 weeks

Discard contaminated specimens

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	30 mg/dl
bilirubin	40 mg/dl
triglycerides	2000 mg/dl

hemoglobin interferes because LDH is released by erythrocytes.

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start

Pipette into test tubes	25°C, 30°C	37°C
Reagent 1	1000 µl	1000 µl
Sample	20 µl	10 µl
Mix. Incubate for approximately 1- 5 min. Then add		
Reagent 2	250 µl	250 µl
Mix. Read initial absorbance against air after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 min. Determine ΔA/min. during the linear part of the assay.		

Sample Start

Pipette into test tubes	25°C, 30°C	37°C
Working reagent	1000 µl	1000 µl
Sample	20 µl	10 µl
Mix. Read initial absorbance against air after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 min. Determine ΔA/min. during the linear part of the assay.		

CALCULATION (light path 1 cm)

LDH [U/L] = ΔA/min x Factor

Factors:
Substrate Start

	25°C or 30 °C	37°C
Factor at 340 nm	10080	20000
Factor at 334 nm	10275	20390
Factor at 365 nm	18675	37060

Sample Start

	25°C or 30 °C	37°C
Factor at 340 nm	8095	16030
Factor at 334 nm	8250	16345
Factor at 365 nm	15000	29705

UNIT CONVERSION

U/L x 0.01667 = µkatal/L

REFERENCE RANGE * (U/L)

	25°C	30°C	37°C
Adults	< 240	< 346	< 480

* It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

Pyruvate + NADH + H^+ < LDH > Lactate + NAD^+

Reaction is buffered at physiological pH to favor equilibrium to lactate.

ABBREVIATIONS

LDH = Lactate Dehydrogenase
NAD^+ = Nicotinamide Adenine Dinucleotide
NADH = Reduced NAD

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine LDH activities which correspond to a maximal ΔA/min of 0.15 at 340 and 334nm or 0.08 at 365nm.
If these values are exceeded the sample should be diluted 1 + 10 with NaCl (9 g/L sodium chloride in water) and results multiplied by 11.

PRECISION (at 25 °C)

Intra-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	142	5.50	3.86
Sample 2	245	4.95	2.01
Sample 3	497	8.39	1.69

Inter-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	144	3.09	2.13
Sample 2	248	4.53	1.82
Sample 3	492	6.23	1.26

METHOD COMPARISON

A comparison between Dialab LDH-P (y) and a commercially available test (x) using 78 samples gave following results: y = 1.03 x + 2.13 U/L; r= 0.999.

QUALITY CONTROL

All control sera with LDH values determined by this method can be used.
We recommend:

REF	Cont.		
D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The use of a LDH Calibrator is optional.
We recommend:

REF	Cont.		
D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

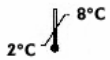
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Tietz, N. (Ed.), **Fundam. of Clin. Chem.**, W. B. Saunders Co., Philadelphia, PA 1986.



IVD

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