Liquid Reagents – ready to use

LDH-P
(Lactate Dehydrogenase - P)
IFCC

2 Reagents

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

Ref.No.	Kit Size	Content
DIA010341	62.5 ml	2x25 ml R1 + 1x12.5 ml R2
DIA010342	5 x 20 ml	4x20 ml R1 + 1x20 ml R2
DIA010343	5 x 25 ml	4x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)

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 (R2) 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
protect from light!

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

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{\text{LDH}} \text{Lactate} + NAD^+$$

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

ABBREVIATIONS

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

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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 Diagnostica 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:

DIA030012	1 x 5 ml	**DIACON N**	Assayed Control Serum Normal
DIA030022	1 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

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

DIA040012	1 x 3 ml	**DIACAL**	Assayed Multi Calibration Serum

AUTOMATION

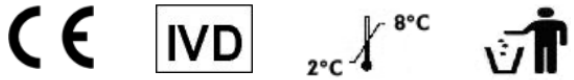
Special adaptations for automated analyzers can be made on request.

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.



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