DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Liquid Reagents – ready to use

Lactate

Enzymatic, UV

2 Reagents

Diagnostic reagent for quantitative in vitro determination of lactate in human plasma or CSF on photometric systems

REF	Kit Size	Content
D08130	**5 x 50 mL**	4 x 50 mL R1 + 1 x 50 mL R2
D08140	**5 x 25 mL**	4 x 25 mL R1 + 1 x 25 mL R2
D14150	**5 x 10 mL**	4 x 10 mL R1 + 1 x 10 mL R2
D75911	**5 x 50 mL**	4 x 50 mL R1 + 2 x 25 mL R2
D0445917	**5 x 50 mL**	4 x 50 mL R1 + 1 x 50 mL R2
DA0834	**5 x 20 mL**	4 x 20 mL R1 + 1 x 20 mL R2
DT1034	**5 x 20 mL**	4 x 20 mL R1 + 1 x 20 mL R2
DK1431	**5 x 50 mL**	4 x 50 mL R1 + 1 x 50 mL R2
DE1834	**2 x 62.5 mL**	2 x 50 mL R1 + 2 x 12.5 mL R2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98485SV	1 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D14481	5 x 5 ml	Control normal	Diacon N
D98481SV	1 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P
D14482	5 x 5 ml	Control abnormal	Diacon P
D98482SV	1 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Enzymatic, UV Increasing Reaction, Endpoint
Wavelength:	340 nm
Temperature:	37 °C
Sample:	Plasma, CSF
Linearity:	up to 120 mg/dl (13.3 mmol/L)
Sensitivity:	The lower limit of detection is 1 mg/dl (0.1 mmol/L)

SUMMARY [1,2]

Lactate is the final product of the anaerobic glycolysis and serves as indicator for the oxygen status in cellular tissues. Increased lactate levels in blood occur in anoxia due to shock, congestive heart failure, intoxication and thiamine deficiency. Therefore, lactate is measured in intensive care medicine. As metabolic variable for the capability of the muscles lactate determination is used in evaluation of the training status in athletes.

TEST PRINCIPLE

In the presence of NAD, lactate is converted to pyruvate by lactate dehydrogenase. In this procedure NADH is formed which is measured at 340 nm. The absorbance of the produced NADH is proportional to the lactate concentration in the sample.

$$\text{L-Lactate} + NAD^+ \xleftarrow{LDH} \text{Pyruvate} + NADH + H^+$$

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Buffer, pH 9.0	500 mmol/L
LDH	≥ 25 kU/L
Reagent 2:	
NAD^+	20 mmol/L

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.
Sample Start:
Mix 4 parts of R1 + 1 part of R2 (= working reagent)
Do not use icteric or haemolytic samples with sample start.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light
Close immediately after use
Do not freeze the reagents!
Avoid contamination

Substrate Start:
Storage: at 2 – 8 °C
Stability: up to the expiration date
Sample Start (Working Reagent):
Stability: at 2 – 8 °C 2 weeks

SAMPLE STABILITY AND STORAGE

plasma [3]: at 20 – 25 °C 8 hours
at 2 – 8 °C 14 days
Discard contaminated specimens.
Do not use serum!
Use glycolytic inhibitors e.g. fluoride/oxalate or fluoride/heparin as anticoagulants.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.
Substrate start

Pipette into test tubes	Blank	Calibrator	Sample
Reagent 1	1000 µL	1000 µL	1000 µL
Sample	-	-	15 µL
Calibrator	-	15 µL	-
Distilled water	15 µL	-	-
Mix. Incubate 5 min. at 37 °C. Read absorbance A1 against reagent blank, then add:			
Reagent 2	250 µL	250 µL	250 µL
Mix. Incubate 5 min. at 37 °C and read absorbance A2 against reagent blank within 30 minutes. ΔA = (A2 – A2)			

Sample start
Do not use icteric or haemolytic samples!

Pipette into test tubes	Blank	Calibrator	Sample
Sample	-	-	10 µL
Calibrator	-	10 µL	-
Dist. water	10 µL	-	-
Reagent	1000 µL	1000 µL	1000 µL
Mix, incubate for 5 min. at 37°C Read absorbance against reagent blank within 30 min.			

CALCULATION

With calibrator:

$$\text{Lactate [mg/dl]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Calibrator}} \times \text{Conc. Cal [mg/dl]}$$

With factor (light path 1 cm):
From absorbance readings calculate ΔA and multiply by the corresponding factor:
Lactate [mg/dL] = ΔA x factor

	Substrate Start	Sample Start
Factors at 340 nm:	120.6	144.4

UNIT CONVERSION

mg/dL x 0.1109 = mmol/L

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REFERENCE RANGE [5] *

Plasma:		
Venous	4.5 – 19.8 mg/dL	0.5 – 2.2 mmol/L
Arterial	4.5 – 14.4 mg/dL	0.5 – 1.6 mmol/L
CSF:		
Adults	10 – 22 mg/dL	1.1 – 2.4 mmol/L
Newborn	10 – 60 mg/dL	1.1 – 6.7 mmol/L
3 – 10 days	10 – 40 mg/dL	1.1 – 4.4 mmol/L
> 10 days	10 – 25 mg/dL	1.1 – 2.8 mmol/L

* Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine lactate concentrations up to 120 mg/dL (13.3 mmol/L). When values exceed this range, samples should be diluted 1+1 with NaCl solution (9 g/L) and the results multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The limit of detection is 1 mg/dL (0.1 mmol/L).

PRECISION

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	11.9	0.26	2.22
Sample 2	19.0	0.31	1.62
Sample 3	26.5	0.31	1.15

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	12.0	0.23	1.91
Sample 2	19.0	0.28	1.45
Sample 3	26.7	0.31	1.16

SPECIFICITY/INTERFERENCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	60 mg/dL
Triglyceride	2000 mg/dL
Hemoglobin	1000 mg/dL
Dopamine	10 mg/L
L-Dopamine	20 mg/L
Methyldopamine	10 mg/L
Glycolic acid	1200 mg/L

For further information on interfering substances refer to Young DS [4]:

METHOD COMPARISON

A comparison between Dialab Lactate (y) and a commercially available test (x) using 117 samples gave following results: y = 0.984 x – 0.742 mg/dl; r= 0.999.

CALIBRATION

We recommend the Dialab multi calibration serum **Diacal Auto**. The assigned values of the calibrator are traceable to a primary standard.

QUALITY CONTROL

All control sera with lactate values determined by this method can be used.
We recommend the Dialab controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

Special applications for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent 1: Danger.
   H315: Causes skin irritation.
   H318: Causes serious eye damage.
   P264: Wash hands and face thoroughly after handling.
   P280: Wear protective gloves/protective cothing/eye protection.
   P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
   P310: Immediately call a poison center or doctor/physician.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [6].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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