

## Lactate FS\*

# Diagnostic reagent for quantitative in vitro determination of lactate in plasma and CSF on photometric systems

#### **Order information**

Cat. No.	Kit s	ize				
1 4001 99 10 021	R1	5 x	20 mL +	R2	1 x	25 mL
1 4001 99 10 023	R1	1 x	800 mL +	R2	1 x	200 mL
1 4001 99 10 930	R1	4 x	20 mL +	R2	2 x	10 mL

#### **Summary** [1, 2]

Lactate is the final product of the anaerobic glycolysis and serves as indicator for the oxgen 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.

#### Method

Enzymatic UV test with lactate dehydrogenase (LDH)

#### **Principle**

L-Lactate + NAD<sup>+</sup> < LDH > Pyruvate + NADH + H<sup>+</sup>

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

## Reagents

## **Components and Concentrations**

R1:	Buffer	pH 9.0	500 mmol/L
	LDH		≥ 25 kU/L
R2:	NAD		20 mmol/L

## Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at  $2-8\,^{\circ}\text{C}$ , protected from light and contamination is avoided. Do not freeze the reagents!

#### **Warnings and Precautions**

- 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 clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of water/soap. P332+P313 If skin irritation occurs: Get medical advice/attention. 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.
- Reagent 1 contains sodium azide (0.95 g/L) as preservative.
  Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- 6. For professional use only!

#### **Waste Management**

Please refer to local legal requirements.

#### **Reagent Preparation**

#### Substrate Start

The reagents are ready to use.

#### Sample Start

Mix 4 parts of R1 + 1 part of R2

(e.g. 20 mL R1 + 5 mL R2) = monoreagent

The stability of the mono-reagent is 14 days at  $2-8\,^{\circ}$ C. Do not use icteric or hemolytic samples with sample start.

#### Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

#### **Specimen**

Plasma and CSF (no serum)

Use glycolytic inhibitors e.g. fluoride/oxalate or fluoride/heparin as

anticoagulants.

Stability in plasma [3]: 8 hours at 20 – 25 °C

14 days at 2 – 8 °C.

Discard contaminated specimens!

#### **Assay Procedure**

## Application sheets for automated systems are available on request.

Wavelength 340 nm Optical path 1 cm Temperature 37 °C

Measurement Against reagent blank

#### Substrate Start

	Reagent blan	k Sample/ Calibrator
Sample/Calibrator	-	15 µL
Dist. water	15 µL	<u>-</u>
Reagent 1	1000 µL	1000 μL
Mix and incubate 5 min. at 3	°C. Read absort	bance A1 then add:
Reagent 2	250 µL	250 µL
Mix and incubate 5 min. at	37 °C. Read a	absorbance A2 within
30 min.		

 $\Delta A = (A2 - A1)$  sample/calibrator

#### Sample Start

(Do not use icteric or hemolytic samples)

(Do not use ictenc of hemolytic samples)					
	Reagent blank	Sample/ Calibrator			
Sample/Calibrator	-	10 µL			
Dist. water	10 μL	-			
Mono-reagent	1000 µL	1000 μL			
Mix and incubate 5 min.	at 37 °C. Read	absorbance A within			
30 min.					

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#### Calculation

#### With calibrator

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

#### With factor

From absorbance readings calculate  $\Delta A$  and multiply by the corresponding factor from table below:

#### $\Delta A \times factor = Lactate concentration [mg/dL]$

	Substrate start	Sample start
340 nm	120.6	144.4

#### **Conversion factor**

Lactate [mg/dL] x 0.1109 = Lactate [mmol/L]

#### **Calibrators and Controls**

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator are traceable to a primary standard. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.		Kit	size	
TruCal U	5 9100 99 10 063	20	Х	3 mL	
	5 9100 99 10 064	6	Х	3 mL	
TruLab N	5 9000 99 10 062	20	Х	5 mL	
	5 9000 99 10 061	6	Х	5 mL	
TruLab P	5 9050 99 10 062	20	Х	5 mL	
	5 9050 99 10 061	6	Х	5 mL	

## **Performance characteristics**

#### 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 result multiplied by 2.

### Specifity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, conjugated and unconjugated bilirubin up to 60 mg/dL, lipemia up to 2000 mg/dL triglycerides, hemoglobin up to 1000 mg/dL, dopamine up to 10 mg/L, L-dopamine up to 20 mg/L, methyldopamine up to 10 mg/L and glycolic acid up to 1200 mg/L. For further information on interfering substances refer to Young DS [4].

#### Sensitivity/Limit of Detection

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

#### Precision

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

#### **Method Comparison**

A comparison of DiaSys Lactate FS (y) with a commercially available assay (x) using 117 samples gave following results: y = 0.984 x - 0.742 mg/dL; r = 0.999

#### 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:

10 – 22 mg/dL (1.1 – 2.4 mmol/L) 10 – 60 mg/dL (1.1 – 6.7 mmol/L) Adults Newborn 3 - 10 days10 - 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 the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

#### Literature

- David B. Sacks, M.B., Ch.B., F.A.C.P. Carbohydrates In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 787-790.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 160-166.
- Westgard JO, Lahmeyer BL, Birnbaum ML. Use of the Du Pont "Automatic Clinical Analyzer" in Direct Determination of Lactic Acid in Plasma Stabilized with Sodium Fluoride. Clin Chem 1972; 18: 1334-8.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
- Section I General Clinical Tests In: Tietz NW, editor. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: Saunders; 1995. p. 382-3.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.

## Manufacturer



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