Lactate FS*

Order Information

Cat. No.	Kit size		
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

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of lactate in human heparin plasma or cerebrospinal fluid (CSF) on automated photometric systems.

Summary

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 [1]. Therefore, lactate is measured in intensive care medicine. Lactate measurement is recommended in patients with sepsis. An elevated lactate level is part of the Sepsis 3 definition of septic shock [2]. As metabolic variable for the capability of the muscles, lactate determination is used in evaluation of the training status in athletes [3].

Method

Enzymatic UV test with lactate dehydrogenase (LDH)

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

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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 15 months until expiry date.

Warnings and Precautions

1. Components contained in Lactate FS are classified according to EC regulation 1272/2008 (CLP) as follows:

⚠ Reagent 1: Danger. Contains 1,3-Diaminopropan-2-ol. 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. 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/doctor.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [4].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human heparin plasma or CSF

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

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

Stability in plasma [5]:

6 days	at	20 – 25°C
14 days	at	2 – 8°C
1 month	at	-20°C

Stability in CSF [6]:

30 minutes	at	20 – 25°C
1 hour	at	4 – 8°C
1 month	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340/805 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With Calibrator

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

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to a primary standard. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 115 mg/dL, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	1 mg/dL

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	25.7
Bilirubin (conjugated)	60 mg/dL	25.8
Bilirubin (unconjugated)	60 mg/dL	25.7
Dopamine	10 mg/L	21.6
Glycolic acid	1200 mg/L	21.3
Hemolysis	1000 mg/dL	25.7
L-Dopamine	20 mg/L	21.3
Lipemia (triglycerides)	2000 mg/dL	25.7
Methyldopamine	10 mg/L	21.6

For further information on interfering substances, refer to the literature [7,8].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	15.4	49.7	32.9
CV [%]	1.61	1.43	1.23
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	18.6	34.0	54.5
CV [%]	1.75	1.82	1.37

Method comparison (n=100)	
Test x	Competitor Lactate (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Lactate FS (BioMajesty® JCA-BM6010/C)
Slope	0.992
Intercept	-0.108 mg/dL
Coefficient of correlation	0.997

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [9]

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 the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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IVD CE

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* Fluid Stable