

Lactate FS*

Order Information

Cat. No.

1 4001 99 10 964

Kit size



540 (R1: 6 x 90, R2: 6 x 90)

Intended Use

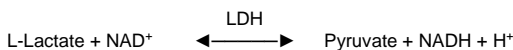
Diagnostic reagent for quantitative in vitro determination of lactate in human heparin plasma on automated BioMajesty® JCA-BM6010/C.

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)



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

- 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.

- Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.

- 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. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human heparin plasma

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 [5]:

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

Only freeze once. Discard contaminated specimens.

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

Measuring range up to 115 mg/dL, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1 mg/dL
Onboard stability	8 days
Calibration stability	8 days

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 [6,7].

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.

Conversion Factor

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

Reference Range [8]

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

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.R.C.Path. Carbohydrates In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 787–789.
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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

Lactate FS

Chemistry code 10 400

Application for plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	LACT
Digits	2
M-wave L.	340
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999