Lactate FS*

Diagnostic reagent for quantitative in vitro determination of lactate in plasma on DiaSys BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 4001 99 10 964
R1: 6 x 90 tests
R2: 6 x 90 tests

Method

Enzymatic UV test with lactate dehydrogenase (LDH)

Principle

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

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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents.

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 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 or doctor / physician.
2. The reagents contain 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. 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

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Plasma (no serum)
As anticoagulants use glycolytic inhibitors e.g. fluoride/oxalate or fluoride/heparin.
Stability in plasma [1]:
8 hours at 20 – 25°C
14 days at 2 – 8°C
Discard contaminated specimens.

Calibrators and Controls

For calibration the 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 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 lactate (12.8 mmol/L) (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 lactate (0.1 mmol/L)
On-board stability	8 days
Calibration stability	8 days

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 1000 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Dopamin up to 10 mg/L
L-Dopamin up to 20 mg/L
Methyldopamine up to 10 mg/L
Glycolic acid up to 1200 mg/L
For further information on interfering substances refer to Young DS [5].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	15.4	49.7	32.9
Mean [mmol/L]	1.70	5.51	3.65
Coefficient of variation [%]	1.61	1.43	1.23
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	18.6	34.0	54.5
Mean [mmol/L]	2.06	3.77	6.05
Coefficient of variation [%]	1.75	1.82	1.37

Method comparison (n=100)	
Test x	Competitor Lactate
Test y	DiaSys Lactate FS
Slope	0.992
Intercept	–0.108 mg/dL (–0.012 mmol/L)
Coefficient of correlation	0.9973

** 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 [2]

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.

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Literature

1. 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.
2. Section I – General Clinical Tests In: Tietz NW, editor. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: Saunders; 1995. p. 382-3.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 160-166.
4. David B. Sacks, M.B., Ch.B., F.A.C.P. Carbohydrates In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 787-790.
5. 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.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

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BioMajesty

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.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	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