respons®910

Lactate FS*

Diagnostic reagent for quantitative in vitro determination of lactate in plasma on DiaSys respons®910

Order Information

Cat. No. 1 4001 99 10 921
4 twin containers for 120 tests each

Method

Enzymatic UV test with lactate dehydrogenase (LDH)

Principle

L-Lactate + NAD^+ $\xleftarrow{LDH}$ 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. DiaSys respons containers provide protection from light. 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. 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. 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 rotor.

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, 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 120 mg/dL lactate (13.3 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	1 week
Calibration stability	1 week

Interfering substance	**Interferences < 10%**	**Lactate [mg/dL]**
Ascorbate	up to 30 mg/dL	21.5
Hemoglobin	up to 1200 mg/dL	6.31
	up to 1200 mg/dL	21.8
Bilirubin, conjugated	up to 65 mg/dL	6.86
	up to 65 mg/dL	21.9
Bilirubin, unconjugated	up to 70 mg/dL	6.03
	up to 70 mg/dL	22.1
Lipemia (triglycerides)	up to 1500 mg/dL	5.85
	up to 1800 mg/dL	20.9
Dopamine	up to 10 mg/L	21.6
L-Dopamine	up to 20 mg/L	21.3
Methyldopamine	up to 10 mg/L	21.6
Glycolic acid	up to 1200 mg/L	21.3
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	5.60	12.9	24.0
Coefficient of variation [%]	2.92	1.69	1.65
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	7.33	13.0	29.6
Coefficient of variation [%]	2.62	2.93	1.51

Method comparison (n=108)	
Test x	DiaSys Lactate FS (Hitachi 917)
Test y	DiaSys Lactate FS (respons®910)
Slope	0.980
Intercept	–0.560 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [3]

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

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. 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.
3. Section I – General Clinical Tests In: Tietz NW, editor. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: Saunders; 1995. p. 382-3.
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. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 160-166.
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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respons®910

Lactate

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	LACT
Shortcut:	
Reagent barcode reference:	043
Host reference:	043

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	800
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	1.0000
Concentration technical limits-Upper	120.0000
SERUM	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Venous
Age	
SERUM	
URINE	
PLASMA	>=4.50 <=19.80
CSF	
Whole blood	
Gender	Arterial
Age	
SERUM	
URINE	
PLASMA	>=4.50 <=14.40
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.015
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value