respons®910

Lactate FS*

Order Information

Cat. No.	Kit size
1 4001 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of lactate in human heparin plasma on automated respons®910.

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)

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

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. 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 from 0.61 mg/dL up to 120 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**	0.61 mg/dL
Limit of quantitation**	0.61 mg/dL
Onboard stability	1 week
Calibration stability	1 week

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	21.5
Bilirubin (conjugated)	65 mg/dL	6.86
	65 mg/dL	21.9
Bilirubin (unconjugated)	70 mg/dL	6.03
	70 mg/dL	22.1
Dopamine	10 mg/L	21.6
Glycolic acid	1200 mg/L	21.3
Hemolysis	1200 mg/dL	6.31
	1200 mg/dL	21.8
L-Dopamine	20 mg/L	21.3
Lipemia (triglycerides)	1500 mg/dL	5.85
	1800 mg/dL	20.9
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]	5.60	12.9	24.0
CV [%]	2.92	1.69	1.65
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	7.33	13.0	29.6
CV [%]	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 CLSI document EP17-A, Vol. 24, No. 34

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

1. 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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4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.
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7. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in November 2023. Published by AACC Press and John Wiley and Sons, Inc.
8. Section I – General Clinical Tests In: Tietz NW, editor. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: Saunders; 1995. p. 382-3.

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.

IVD CE

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* Fluid Stable

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