

Lactate FS*

Diagnostic reagent for quantitative in vitro determination of lactate in plasma on DiaSys respons[®]920

Order Information

Cat. No. 1 4001 99 10 921

4 twin containers for 120 determinations each

Method

Enzymatic UV test with lactate dehydrogenase (LDH)

Principle



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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. In very rare cases, samples of patients with gammopathy might give falsified results [6].
6. 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.
7. 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: 8 hours at 20 – 25°C and 14 days at 2 – 8°C. [1]

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. 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	5 days
Calibration stability	5 days

Interferences < 10% by	
Ascorbate up to 30 mg/dL	
Hemoglobin up to 1000 mg/dL	
Bilirubin 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 [2].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	13.0	21.4	32.2
Coefficient of variation [%]	1.72	1.22	1.11
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	13.8	20.6	31.8
Coefficient of variation [%]	2.98	1.18	1.28

Method comparison (n=131)	
Test x	DiaSys Lactate FS (Hitachi 917)
Test y	DiaSys Lactate FS (respons [®] 920)
Slope	1.011
Intercept	0.398 mg/dL
Coefficient of correlation	0.999

** 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 [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. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 160–166.
5. 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.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Lactate FS

Application for plasma

Test Details		Test Volumes		Reference Ranges	
Test	: LACT			Auto Rerun	<input type="checkbox"/>
Report Name	: Lactate			Online Calibration	<input type="checkbox"/>
Unit	: mg/dL	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 340	Secondary	: 700	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1	: LACT R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: LACT R2
M2 Start	: 33	M2 End	: 33	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank/Level 0	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator 1	: *
Reaction Direction	: Increasing	React. Abs. Limit	: 0.0000		
Prozone Limit %	: 0	Prozone Check	: Lower		
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000		
Technical Minimum	: 1.0	Technical Maximum	: 120.0		
Y = aX + b	a = 1.0000	b =	0.0000		

* Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: LACT				
Sample Type	: Plasma				
Sample Volumes				Sample Types	
Normal	: 3.00 μ L	Dilution Ratio	: 1 X		
Increase	: 6.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 μ L	Dilution Ratio	: 1 X		
Standard Volume	: 3.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 180 μ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 45 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: LACT				
Sample Type	: Plasma				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit		
	(mg/dL)		(mg/dL)		
Normal	: 4.50		19.80		
Panic	: 0.00		0.00		