LACTATE

Enzymatic Method

5 x 25 ml CL56-125S

INTENDED USE

Enzymatic determination of lactate in plasma and cerebrospinal liquid.

CLINICAL MEANING

Lactic acid is a product of carbohydrate metabolism under anaerobic conditions. It is produced by cells when they don't receive an adequate supply of oxygen to allow them to metabolize glucose into carbon dioxide and water. Lactic acid in blood increases for excess production of lactate and for reduced removal by the liver. Under normal conditions, lactic acid increases after a strenuous exercise, for the imbalance between the energy needs of the muscles and the provision of oxygen through blood circulation. The test contributes to the interpretation of the acid-base alterations that occur in different conditions such as: tissue hypoxia caused by metabolic or circulatory alterations, coma, poisoning, perinatal asphyxia, type 2 diabetes, metabolic hereditary diseases. Lactate levels in cerebrospinal fluid come out increased in case of bacterial meningitis, in case of hypocapnia, hydrocephalus, brain abscess, brain ischemia, and any other pathological condition associated with reduced oxygenation of the brain and/or increased intracranial pressure.

PRINCIPLE

Lactate oxidase promotes the oxidation of lactic acid to pyruvate and hydrogen peroxide. Then peroxidase catalyzes the reaction of hydrogen peroxide with a hydrogen donor, in the presence of 4-aminophenazone, to form a colored adduct. Color intensity, measured at 550 nm, is proportional to the lactate concentration in the sample.
This method is fast, accurate and considerably more stable than previous measurements in the UV enzymatic methods involving the formation of NADH.

SAMPLE

Don't use serum. Use plasma from blood collected by standard venipuncture technique in sodium fluoride or potassium oxalate tubes. Specimens should be immediately placed on ice and the cells must be separated within 15 minutes of collection. Cerebrospinal fluid (CSF) may be used as obtained.
STABILITY:
Plasma: 2 hours at 20-25°C, 2 days at 2-8°C, 1 month a -20°C
CSF: 3 hours at 20-25°C, 24 hours a 2-8°C, 1 month a -20°C

REAGENTS

Only for in Vitro diagnostics. Liquid reagent ready to use.

Package contents:	**CL70-150**
REAGENT Buffer ph 7.6 TOPS 1mmol/L, 4-aminoantipyrine 0.25 mmol/L, Lactate oxidase (LOX) > 100U/L, Peroxidase (POD) > 100 U/L, Activators, stabilizers, surfactants and preservatives	**5 x 25 ml**
STANDARD Standard (values shown on the label)	**1 x 3 ml**

STABILITY': reagents are stable up on the expiration date shown on the label if stored at 2-8°C, avoiding contamination. Don't freeze..

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wavelength:	550 nm
Optical path:	1 cm
Reading:	against blank reagent
Temperature:	37°C
Reaction time:	5 minutes
Linearity:	up to 150 mg/dl
Sample/Reagent:	100/1

Let reagents and samples reach room temperature before use.

Pipette in tubes or marked cuvettes:

	Standard	Sample
Reagent	1000 µl	1000 µl
Standard	10 µl	
Sample		10 µl

Mix carefully and incubate at 37°C. Read the absorbance within 30 minutes.

CALCULATION

Lactate [mg/dL] = (Ac / Ast) x standard conc. [mg/dL]

Use for calibration the lactate aqueous standard included in the kit, or an appropriate serum calibrator.

REFERENCE VALUES

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)

CSF:

Adults	10 - 22 mg/dL (1.1 – 2.4 mmol/L)
Newborns	10 - 60 mg/dL (1.1 – 6.7 mmol/L)
3 – 10 age	10 - 40 mg/dL (1.1 – 4.4 mmol/L)
> 10 age	10 - 25 mg/dL (1.1 – 2.8 mmol/L)

Each laboratory should check if reference ranges can be extended to its own patient population and determine its own reference values if necessary.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should check whether the reference values can be extended to their patients and determine their own reference values if necessary.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is about 1 mg/dL (0.1 mmol/L).

Linearity: up to 150 mg/dl (15 mmol/L).
For higher values, dilute the samples with saline solution fisiologica and multiply the result obtained by the dilution factor.
Precision

Within run (n=10)	Average (mg/dL)	SD	CV %
Sample 1	20,8	0,31	1,48
Sample 2	45,5	0,53	1,16

Between run (n=20)	Average (mg/dL)	SD	CV %
Sample 1	12,4	0,42	3,11
Sample 2	38,2	2,05	5,52

Interferences:
No interference was observed by bilirubin up to 20 mg/dl and by hemoglobin up to 500 mg/dl. Ascorbic acid may interfere, but it is released almost completely through urine within 4 hours after taking. At saturation level in tissues ascorbic acid in the plasma as a concentration of 1-1.5 mg/dl, which does not interfere with the test.

Correlation against a reference method: the correlation of the FAR method against a method currently on the market (Diasys) gives a correlation of 0.997.

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1. Norris K.A. R.H. et al., Clin. Chem. (1975) 21:1093-1101
2. Forrester R.L. et al., Clin. Chem. (1976) 22 : 243-245

MANUFACTURER

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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