Spectrum For Diagnostic Industries

Lactate (4+1)
Enzymatic colorimetric (LOX / PAP)

IVD

REF.	Pack size
137 05 020	(5 x 20 ml) 100 tests

Intended Use

Lactate reagent is intended for the in-vitro quantitative and diagnostic determination of lactate in human Plasma and CSF on both automated and manual systems.

Introduction

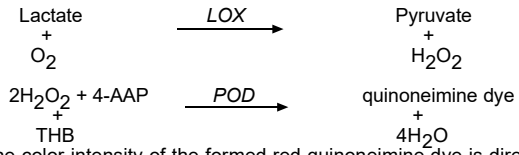
Lactate is an intermediate product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. The blood lactate concentration is affected by its production in muscle cells and erythrocytes and its rate metabolism in the liver. CSF lactate level is increased in bacterial meningitis, epilepsy, and intracranial hemorrhage.

Method

Enzymatic colorimetric method (LOX / PAP)

Principle

Lactate is oxidized to pyruvate and hydrogen peroxide (H_2O_2) by lactate oxidase (LOX). In the presence of peroxidase (POD), hydrogen peroxide reacts with 2,4,6-tribromo-3-hydroxybenzoic acid (THB) and 4-aminoantipyrine (4-AAP) to form a red quinoneimine dye.



The color intensity of the formed red quinoneimine dye is directly proportional to the lactate concentration. It is determined by measuring the increase in absorbance at 546 nm.

Reagents

Reagent 1 (Buffer)

Tris buffer	100 mmol/L
2,4,6-tribromo-3-hydroxybenzoic acid	2.0 mmol/L
4-Amino antipyrine	0.8 mmol/L

Reagent 2 (Enzyme)

Lactate oxidase	>20 U/L
Peroxidase	>15 U/L
Sodium Azide	0.02 %

Standard lactate (ST) 10 mg/dL

Reagents preparation, storage and stability

Prepare the working solution according to the number of tests required by mixing 4 volumes of reagent 1 (R1) and 1 volume of reagent 2 (R2), e.g. 400 µl R1 +100 µl R2. Once opened, the reagent and the standard vial are stable for 3 months at the specified temperature.
The reagents are stable till expiration date stated on label when stored refrigerated at 2 - 8 °C.

Deterioration

The working reagent is normaly clear or pale pink. Do not use lactate reagent if it is turbid or if the absorbance is greater than 0.1 at 546 nm.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent **(R2)** contains sodium azide which may react with copper or lead plumbing.

Specimen collection and preservation

Plasma and CSF. Do not use serum specimens. The only acceptable anticoagulants are fluoride/heparin and iodoacetate/heparin. The patient should be fasting and at complete rest and exercise of the arm or hand should be avoided before or during collection of the specimens. The collected blood should be cooled on ice immediately and separated from the cells within 15 minutes.
Once the plasma is separated from the cells, lactate values are stable.Use the CSF samples with addition of glycolysis inhibitor, e.g. sodium fluoride. Lactate in CSF is stable for 3 hours at 20 - 25°C, for 24 hours at 4 - 8 °C, and for 2 months frozen at -20 °C, stable in plasma for 2 hours at 20 - 25 °C and 2 days at 4 - 8°C.

Procedure

Wavelength	546 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
Temperature	37 °C or 15 - 25 °C
Zero adjustment	Reagent blank
Reagent Blank Limits	Low 0.00 AU High 0.25 AU
Incubation time	5 minutes at 37 °C or 10 minutes at 15 - 25 °C

	Reagent Blank	Standard	Specimen
Working solution	1.0 ml	1.0 ml	1.0 ml
Standard	____	10 µl	____
Specimen	____	____	10 µl

Mix and incubate for 5 minutes at 37 °C or 10 minutes at 15 – 25 °C. Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank .

Calculation

$$\text{Lactate conc. (mg/dL)} = \frac{A_{specimen}}{A_{standard}} \times 10$$

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Interference

Haemolysis
Haemoglobin levels higher than 2.5 g/L (0.16 mmol/L) increase the apparent lactate concentration significantly.

Icterus
Bilirubin levels higher than 4.0 mg/dL (68 mmol/L) decrease apparent lactate concentration significantly.

Lipemia
No significant interference.

Ascorbic acid
Physiological ascorbic acid concentrations do not interfere with the test. Ascorbic Acid levels higher than 5 mg/dL (284 mmol/l) decrease the apparent lactate concentration significantly.

Expected Values

1-Plasma		
a) Venous	4.5 – 19.8 mg/dL	0.5 – 2.2 mmol/L
b) Arterial	4.5 – 14.4 mg/dL	0.5–1.6 mmol/L
2-CSF		
a) Adult	10 – 22 mg/dL	1.1 – 2.4 mmol/L
b) Neonates	10 – 60 mg/dL	1.1 – 6.7 mmol/L

Performance Characteristics

Method Comparison

A comparison between SDI Lactate reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.992 was obtained.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	14.8	33.4
SD	0.12	0.078
CV%	0.82	0.26

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	14.8	33.4
SD	0.12	0.088
CV%	0.79	0.27

Sensitivity

When run as recommended, the minimum detection limit of the assay is 0.3 mg/dL (0.033 mmol/L).

Linearity

The reaction is linear up to lactate concentration of 90 mg/dL (9.99 mmol/L), specimens showing higher concentration should be diluted 1+1 using physiological saline, reassayed and the result multiplied by two.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1.Bailey EM, Domenico P,Cunha BA. Bacterial or viral meningitis Measuring lactate in CSF can help you know quickly. Meningitis.3.Klein TO. Nervensysteme. In:Greiling H, Gressner AM,eds.
2.Lehrbuch der Klinischen Chemie und Pathobiochemie. Stuttgart:Schattauer.
3.Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, eds. Tietz Fundamentals of Clinical Chemistry. 4 th ed. Philadelphia:WB Saunders.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch Code/Lot number
REF	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

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