Pariksha Biotech
A game changer in IVD

Lactate Estimation Kit

High-Q Lactate

LOX-PAP Method

HIGH®
Command on Quality

Intented Use:
Kit for the quantitative in vitro determination of lactate in human Plasma or CSF on photometric systems

Clinical Significance:

Lactic acid, present in blood entirely as lactate is an intermediary 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. During exercise, blood lactate can increase up to ten times of normal levels. Under normal conditions, the ratio between lactate and pyruvate is constant(10:1).The liver can normally metabolize more lactate than is produced.In the case of decreased perfusion of the liver , however, removal of lactate by the liver may be significantly reduced.The amount of lactate in cerebrospinal fluid normally parallels blood levels. CSF lactate level is increased in bacterial meningitis, epilepsy, and intracranial hemorrhage. CSF lactate level may be an aid to distinguish between bacterial from viral meningitis.

Diagnostic Implications:

Normal lactate acid levels are 4.5-19.8 mg/dL. Elevate lactate acid levels can result from severe tissue oxygen deprivation leading to 'lactic acidosis' characterised by weakness, stupor, fatigue and coma. Lactate measurement can also be useful clinically in the diagnosis of angina pectoris or in liver function testing where reduced liver function is suspected.

Principle

Lactate oxidase catalyzes the oxidation of lactic acid to pyruvate and hydrogen peroxide. Peroxidase then catalyzes the reaction of hydrogen peroxide with a hydrogen donor, in the presence of 4-aminophenazone, to form a dye. Color intensity, measured at 546nm is proportional to the lactate concentration in the sample.

$$\text{Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + \text{Hydrogen Peroxide}$$

$$\text{Hydrogen Peroxide} + \text{TOOS} + \text{4-AAP} \xrightarrow{\text{Peroxidase}} \text{Dye (546 nm)}$$

Reagents:

Lactate Reagent (R1): TRIS Buffer 100mM, 4-aminoantipyrene 1.7mM, Peroxidase (Horseradish) > 10,000 U/L, Surfactant, Stabilizer, Sodium Azide (0.09%) as preservative.

Lactate Reagent (R2): TRIS Buffer 100mM, Lactate Oxidase (Microbial) > 1,000 U/L, TOOS 1.5mM, Surfactant, Stabilizer, Sodium Azide (0.09%) as preservative.

Reagent Preparation :

Lactate reagents R1 and R2 are ready to use for instruments suitable for two reagent analysis.

Reagent Storage:

All reagents are stable until the expiration date on the label when stored at 2-8°C.

Specimen Collection and Storage:

1. Plasma collected in sodium fluoride/potassium oxalate is the recommended specimen.
2. The specimen should be immediately placed on ice and the cells must be separated within 15 minutes.
3. The sample should be drawn from a stasis-free vein.
4. If not analyzed promptly, specimens may be stored at 2-8oC for up to 2 days.
5. If specimens need to be stored for more than 2 days, they may be stored for one month frozen at –20°C.

DO NOT USE SERUM

Expected Values:

Freshly Isolated Plasma	Venous	4.5 – 19.8 mg/dL
	Arterial	4.5 – 14.4 mg/dL
CSF	Adult	10.0 – 22.0 mg/dL
	Neonates	10.0 – 60.0 mg/dL

Analytical Range/ Linearity

0.3 – 60 mg/dL

System Parameters:

Reaction Type (Mode)	:	Fixed Time
Reaction Direction	:	Increasing
Wave Length	:	546 nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay Time	:	5 Seconds (A1)
Measuring Time	:	120 Seconds (A2)
Reagent Volume	:	375 µl (R1) + 125 µl (R2)
Calibrator / Sample Volume	:	10 µl
Calibrator Concentration	:	Lot Specific (On the Calibrator Lebel)
Linearity	:	60 mg/dl
High Normal	:	19.8 mg/dl

Test Procedure:

1) Pipette R1 375 µL in to each tube labelled Calibrator and Sample
2) Add Calibrator 10 µL to the tube containing R1
3) Add R2 125 µL and immediately aspirate in to the analyzer which is pre programmed.
4) Instrument automatically calculates the absorbance and factor
5) Add Plasma /CSF sample 10 µL to the another tube containing R1
6) Add R2 125 µL and immediately aspirate in to the analyzer and calculate the concentration of Lactate

Note: After adding R2, the reaction mixture needs to be aspirated immediately in to the analyzer as there is instant colour development

Reagent	Calibrator / Plasma / CSF
Reagent 1	375 µL
Calibrator/ Plasma/CSF	10 µL
Reagent 2	125 µL

After the addition of R2 immediately aspirate the reaction mixture in to the Analyzer.

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Record the first absorbance (A1) after 5 seconds. Exactly 120 Seconds after the first reading record the absorbance (A2) at 37 °C.

Calculate the change in absorbance for the Calibrator and Samples.

Calculations with calibrator:

$$\text{Lactate (mg/dl)} = \frac{A2-A1\ (\text{Sample})}{A2-A1\ (\text{Calibrator})} \times \text{Conc. Calibrator in mg/dl}$$

Precision:

Intra-assay
n = 20

	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	11.9	0.26	2.22
Sample 2	19.0	0.31	1.62
Sample 3	26.5	0.31	1.15

Inter-assay
n = 20

	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	12.0	0.23	1.91
Sample 2	19.0	0.28	1.45
Sample 3	26.7	0.31	1.16

Accuracy:

Comparison studies were carried out using another similar commercially available Lactate reagent. Plasma samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Number of sample pairs	:	42
Range of sample results	:	(3 -120 mg/dl)
Mean of reference method results	:	(13 mg/dl)
Mean of High-Q Lacate results	:	(12.8 mg/dl)
Slope	:	1.002
Correlation coefficient	:	0.9974

Method Comparison:

A comparison between High-Q Lactate (y) and a commercially available test (x) using 117 samples gave following results: y = 0.984 x – 0.742 mg/dl; r= 0.999.

Quality Control:

All control sera with lactate values determined by this method can be used.

References:

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p 160.166

2. David B. Sacks, M.B., Ch.B., F.A.C.P. Carbohydrates. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of ClinicalChemistry. 3rd ed. Philadelphia: W.B. Saunders Company; 1999. p. 787-790.

3. Westgard JO, Lahmeyer BL, Birnbaum ML. Use of the Du Pont „Automatic Clinical Analyzer“ in Direct Determination ofLactic Acid in Plasma Stabilized with Sodium Fluoride. Clin Chem 1972;18:1334-8.

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-LAC - 25	25 ml	Two Liquid Reagents with Calibrator
P-LAC - 50	2 x 25 ml	

Product Features

- **Two Liquid Reagents with Calibrator.**
- **Linearity : 60 mg/dl.**
- **Measuring wavelength 546 nm.**
- **Two Point Kinetic (Fixed Time) Assay : (5 Sec Delay+ 120 Sec Measuring)**
- **Available as multi purpose reagents and dedicated system packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
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