

LiquiMAX Lactate

LOX-PAP Method

ORDER INFORMATION:

Ref. No. Pack Size Presentation

AVLAC - 25 25 ml Two Liquid Reagents with Calibrator

AVLAC - 50 2 x 25 ml

INTENDED USE:

LiquiMAX Lactate is an in-vitro diagnostic kit is use for the quantitative determination of lactate in human Plasma or CSF on photometric systems.

PRODUCT FEATURES

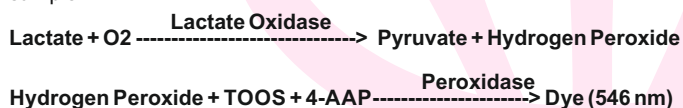
- Two Liquid Reagents with Calibrator.
- Linearity : 60 mg/dl.
- Measuring wavelength 546 nm.
- Two Point Kinetic (Fixed Time) Assay : 5 Sec Delay+ 120 Sec Measuring

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.

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.



STORAGE & STABILITY:

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

KIT COMPONENTS

- Buffer Reagent R1
- Substrate Reagent R2

COMPOSITION

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

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

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at RT & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.2 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

- Plasma collected in sodium fluoride/potassium oxalate is the recommended specimen.
- The specimen should be immediately placed on ice and the cells must be separated within 15 minutes.
- The sample should be drawn from a stasis-free vein.
- If not analyzed promptly, specimens may be stored at 2-8°C for up to 2 days.
- 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

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 Label)
Linearity	:	60 mg/dl
High Normal	:	19.8 mg/dl

TEST PROCEDURE:

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.

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

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

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

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

- When using a new reagent or lot.
- When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 60 mg/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.3 mg/dL

3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl, Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. 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

5. Method Comparison:

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

LIMITATIONS

Measuring range: 0.3 – 60 mg/dL. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).














WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES:

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

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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