LACTATE (9+1

Reagent for the in-vitro quantitative determination of lactate in human plasma and CSF on both automated and manual system.

REF: V/LAC02.020	40 test	REF: V/LAC02.025	50 test
REF: V/LAC02.050	100 test		

CLINICAL SIGNIFICANCE

Lactate is the final product of the anaerobic glycolysis and serves as indicator for the oxygen status in cellular tissues. Increased lactate levels in blood occur in anoxia due to shock, congestive heart failure, intoxication and thiamine deficiency. Therefore, lactate is measured in intensive care medicine. As metabolic variable for the capability of the muscles lactate determination is used in evaluation of the training status in athletes.

METHOD PRINCIPLE

$$\text{L-Lactate} + O_2 \xrightarrow{\text{LOX}} \text{Pyruvate} + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{THB} \xrightarrow{\text{POD}} \text{quinoneimine dye} + 4H_2O$$

REAGENT COMPOSITION

R1: Standard	10 mg/dl
R2: Buffer Reagent	
Tris Buffer	100 mmol/L
2,4,6-tribomo-3-hydroxybenzoic acid	2 mmol/L
4-Amino antipyrine	0.8 mmol/L
R3: Enzyme	
Lactate oxidase	> 20 U/L
Peroxidase	> 15 U/L
Sodium Azide	0.02 %

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

For further information, refer to the **Lab.Vie**. lactate reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie.lactate reagent are stable until expiration date stated on label when properly stored refrigerated at 2-8°C.
Prepare the working reagent by adding 9 volumes of R2 + 1 volume of R3 e.g. 900 µl R2 + 100 µl R3.

Deterioration
The **Lab.Vie**. lactate reagent is normally clear, do not use reagent if it is turbid.

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 avoiding before or during collection of the specimens.
Use the CSF samples with addition of glycolysis inhibitor, e.g. Sodium fluoride.
Stability in plasma: 2 hrs. at 20 - 25 °C, 2 days at 2 - 8 °C
Stability in CSF: 3 hrs. at 20 - 25 °C, 24 hrs. at 2 - 8 °C, 2 months at 20 °C.

SYSTEM PARAMETERS

Wavelength	546 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Temperature	37°C or 15-25°C
Zero adjustment	Reagent blank
Sensitivity	0.3 mg/dl
Linearity	90 mg/dl

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

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

Mix carefully, incubate for 5 min at 37°C or 10 min at 15-25°C, read absorbance of specimen and standard against reagent blank.

CALCULATION

$$\text{Lactate (mg/dl)} = \frac{A\ \text{specimen} \times 10}{A\ \text{standard}}$$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact BioScien technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean mg/dl	14.8	33.4	14.8	33.4
SD.	0.12	0.078	0.12	0.088
CV. %	0.82	0.26	0.79	0.27

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from **Lab.Vie**. lactate reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.998.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.3 mg/dl.

Linearity
The reaction is linear up to lipase concentration of 90 mg/dl.

INTERFERING SUBSTANCES

Hemolysis
No significant interference up to 2.5 g/L.

Icterus
No significant interference up to 4 mg/dl.

lipemia
No significant interference up to 1000 mg/dl.

EXPECTED VALUES

Plasma	mg/dl	mmol/l
Venous	4.5-19.8	0.5-2.2
Arterial	4.5-14.4	0.5-1.6
CSF		
Adult	10-22	1.1-2.4
Neonate	10-60	1.1-6.7

It is recommended for each laboratory to establish and maintain its own reference values.

DYNAMIC RANGE

0.3 - 90 mg/dl

REFERENCES

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:Gressner AM,eds.
Sacks DB. Carbohydrates. In, Burtis CA, Ashwood ER, eds. Tietz Fundamentals of Clinical Chemistry. 4 th ed. Philadelphia:WB Saunders.
Lehrbuch der Klinischen Chemie und Pathobiochemie. Stuttgard: Schattauer.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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