LACTATE

For discrete analyzers
Method: Enzymatic colorimetric
Product Code: **1418-1092**
Packaging: **4 x 6 mL (R1) + 4 x 6 mL (R2)**
Store at 2 – 8°C
For *in vitro* use

INTENDED USE

MEDICON Lactate is a set of reagents for the quantitative determination of Lactate in human plasma, with BECKMAN COULTER AU400/480/600/600-IVD/640/680/2700/5400 and other discrete analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE

L-Lactate is produced from pyruvate by the enzymatic action of lactate dehydrogenase (LDH). Lactate is constantly produced during normal metabolism and exercise but doesn't increase in concentration until the rate of lactate production exceeds the rate of lactate removal. There are two major clinical settings in which lactate acidosis occurs (1) conditions associated with hypoxia e.g. shock, congestive heart failure, myocardial infarction, blood loss and primary edema, and (2) metabolic or drug/toxin related disorders. Examples of metabolic disorders include diabetes mellitus, hepatic disease, and neoplasia. Congenital metabolic disorders include type I glycogen storage disease. Examples of drug/toxins which give rise to elevated lactate are methanol, ethanol, acetaminophen, epinephrine. Recent report indicates that the measurement of CSF lactate may be a useful screening test for CNS disease and in aid in distinguishing bacterial from viral meningitis. Moreover increased lactate levels at CSF are observed at reduced cerebral blood flow of oxygenation, increased intracranial pressure, seizures, intracranial hemorrhage, brain abscess, multiple sclerosis, primary or metastatic CNS carcinoma etc.

METHOD PRINCIPLE

Lactate oxidase oxidizes lactate to pyruvate and H_2O_2. Peroxidase catalyses the reaction between H_2O_2, 4-aminoantipyrine and ADPS, leading to the formation of quinoneimine, a colored complex which absorbs light at 540 nm. The increase of the absorbance at 540 nm is proportional to Lactate concentration in the sample.

LIMITATIONS

The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratories practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION

For *in vitro* diagnostic use only.

Reagent 1 (R1)

HEPES buffer (pH 7.8):	50 mM
ADPS :	4 mM

Non reactant components and preservatives

Αντιδραστήριο 2 (R2)

HEPES buffer (pH 7.8):	50 mM
4-Aminoantipyrine:	0.5 mM
Peroxidase:	< 13000 U/L
Lactate Oxidase:	< 3000 U/L

Non reactant components and preservatives

WARNINGS – PRECAUTIONS

- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN_3 < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION

Reagents are ready to use. Vials bear bar code for recognition by BECKMAN COULTER AU series analyzers.

REAGENT DETERIORATION

The reagent should not be used:

- When it does not exhibit the specified linearity or recovery of control values lies outside acceptable range after recalibration.
- After prolonged exposure to high temperature.

SHELF LIFE

Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, reagents are stored refrigerated on the instrument for 2 months.

SAMPLE

Use oxalate-, fluoride-plasma as specimen. The patient should be at complete rest before sampling. Separate blood cells within 15 min. Mark if the sample is arterial or venous.

CALIBRATION

MEDICON MEDICAL (1578-0891) or Lactate Calibrator (1478-1092) can be used for calibration. Calibrate the assay every 1 week. Recalibration is necessary following preventive maintenance or replacement of a critical part of the analyser. Also recalibrate when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.
The operator should follow guidelines for use of calibrator as stated by the manufacturer.

QUALITY CONTROL

MEDICON provides the following products for quality control: MEDICON Clinical Chemistry Control levels 1 and 2 (1578-0901-12, 1578-0902-12).
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls should be tested each date patient samples are tested and each time calibration is performed. Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Lactate should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDEDWITH THE KIT

Lactate calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS

Arterial plasma: 4.5 – 14.5 mg/dL
Venous plasma: 4.5 – 19.8 mg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

WASTE DISPOSAL

This product contains sodium azide (NaN3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity
The assay is linear within measuring range 0 – 1200 mg/L. When values exceed this range samples should be diluted accordingly.
Sensitivity
The lowest detectable level of Lactate is estimated at 0 mg/L.
The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision

Level	Within Run		Total	
(mg/dL)	SD	CV	SD	CV
15.6	0.26	1.69	0.37	2.35
40.6	0.39	0.97	0.77	1.91

Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).
Interference

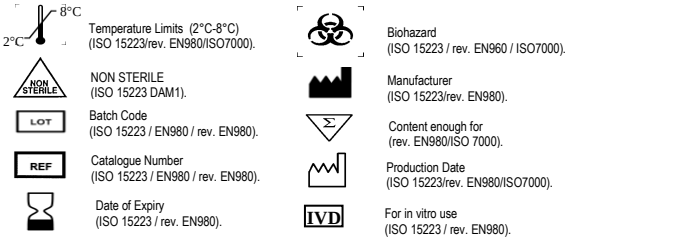
Lipemic:	insignificant up to 1000 mg/dL Intralipid®
Hemoglobin:	insignificant up to 500 mg/dL
Non Conj. Bilirubin:	insignificant up to 20 mg/dL
Conj. Bilirubin:	insignificant up to 20 mg/dL
Ascorbic acid:	insignificant up to 3 mg/dL

Refer to Young[4] for further information on interfering substances.
Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows, on a BECKMAN COULTER AU series analyzer:
Y = 1.0092X + 2.4971 R=0.9978 N=80 Sample range: 13.1 – 101.6 mg/dL

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed. Philadelphia WB Saunders Company, 1995
2. Burtis CA,Ashwood ER, ed. Tietz textbook of clinical chemistry 2nd ed. Philadelphia WB Saunders Company, 1994
3. Jacobs DJ, Demott WR, Grady HJ, Horvat RJ, Huestis DW and Kasten BL, eds. Laboratory test handbook 4th ed. Ohio, Hudson:Lexi-Comp Inc,1996
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

SYMBOLS



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