LACTATE

LACI
LACI-0250
R1 : 2 x 8 mL
R2 : 1 x 5 mL

PIMAC-LACI-EN-V3 (05/2022)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of lactate in human plasma samples on Selectra Mach Series analyzers.

This *in vitro* diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE [1-2]

Lactate is the basic form of lactic acid at blood physiological pH. It is a byproduct resulting from the transformation of Pyruvate by Lactate dehydrogenase in cellular cytoplasm during anaerobic glycolysis. This synthesis occurs in all organs but specifically in skeletal muscles or red blood cells. The blood lactate concentration depends on the rate of production in these tissues and the rate of metabolism in the liver. An increase of lactate in blood associated with pH < 7.35 (lactic acidosis) occurs in 2 clinical settings:
-type A, lactic acidosis associated with tissue hypoxia, and
-type B, hyperlactatemia without tissue hypoxia, associated with systemic disease, drug or toxin poisoning, or in-born metabolic failure.
In sports, a lactate test can be used to evaluate the capacity of exercise of athletes (recovery after transient lactic acidosis).
In clinical practice, lactate measurement is an aid to diagnostic in the presence of acidosis.

LIMITATION OF USE

The quantitative assay of lactate alone cannot be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE [3]

Enzymatic / PAP – End Point

$$\text{Lactate} + O_2 \xrightarrow{\textit{Lactate oxidase}} \text{Pyruvate} + H_2O_2$$

$$2\ H_2O_2 + \text{4-AAP} + \text{EHSPT} \xrightarrow{\textit{Peroxidase}} \text{Quinoneimine} + 4\ H_2O$$

4-AAP: Amino-4-antipyrine
EHSPT=N-Ethyl-*N*-(2-Hydroxy-3-Sulfopropyl)-*m*-Toluidine

COMPOSITION

Reagent: R1
Good's buffer, pH 7.5

EHSPT		1.78	mmol/L
Sodium azide	<	0.1	% (w/w)

Reagent: R2
Good's buffer, pH 7.5

Amino-4-antipyrine		2.46	mmol/L
Peroxidase	≥	10 000	U/L
Lactate oxidase	≥	2 000	U/L
Sodium azide	<	0.1	% (w/w)

MATERIALS REQUIRED BUT NOT PROVIDED

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- Consult Safety Data Sheet (SDS) for a proper handling.
- The reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not interchange reagent vials from different kits.

STABILITY

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 8 weeks.

PREPARATION

The device is ready to use.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimen required [1,4,5]
- Plasma (sodium fluoride/potassium oxalate).
☛- CSF (Cerebrospinal Fluid) samples are compatible with this device based on data obtained by ELITechGroup Clinical Systems. It is recommended the use of CSF be validated by the laboratory.
- Using any other specimen type must be validated by the laboratory prior to use.

Warnings and precautions
- The patient should avoid exercise of the hand and arm before and during procedure.[1]
- Venous sample must be collected without use of a tourniquet or immediately after it has been applied. Alternatively, an arterial sample can be withdrawn. [1]
- Cool the sample at 4°C immediately after collection. Separate from cells within 15 minutes. If the sample is not preserved as directed, lactate rapidly increases in blood as a result of glycolysis. [1,5]
- Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.

Storage and stability [6]
Plasma:
- 8 hours at room temperature.
- 3 days at 2-8°C.

REFERENCE VALUES [5]

Plasma	mg/dL	mmol/L
Venous sampling	4.5 – 19.8	0.5 – 2.2
Arterial sampling	4.5 – 14.4	0.5 – 1.6

Lactate concentrations in plasma may increase 20-50% after meals. They also increase rapidly during exercise and hyperventilation.

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE

Consult Selectra Mach operator manual.
Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer. Refer to Instructions For Use of WASH SOLUTION A & WASH SOLUTION B for adequate programming (See PIMAC-WASH).

PROCEDURE

The application is included in the 2D barcode on this insert.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

ELICAL 2 is traceable to a primary reference material (weighed in purified material).
Calibration frequency : 8 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as ELITROL I and ELITROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

☛PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

3.0 – 120.0 mg/dL (0.33 – 13.32 mmol/L)
Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 600.0 mg/dL (66.61 mmol/L).
Do not report results outside this extended range.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD : 0.3 mg/dL (0.03 mmol/L)
LoQ : 3.0 mg/dL (0.33 mmol/L)

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented below:

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	11.4	1.27	1.2	2.1
Level 2	80	24.7	2.74	0.8	1.6
Level 3	80	80.6	8.95	0.7	1.2

- Correlation

A comparative study has been performed between LACTATE reagent on a Selectra Mach5 analyzer and a similar commercially available system on 109 human plasma-samples.
The sample concentrations ranged from 3.5 to 132.3 mg/dL. (0.39 - 14.69 mmol/L).
The results are as follows :
Correlation coefficient : (r) = 1.000
Linear regression: y = 1.083 x – 1.2 mg/dL (0.13 mmol/L).

- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following lactate levels were tested: 10.0 mg/dL and 70.0 mg/dL.
No significant interference is defined by a recovery ≤ ±20% of the initial value at lactate concentration of 10.0 mg/dL and ≤±10% of the initial value at lactate concentration of 70.0 mg/dL.

Triglycerides: No significant interference up to 3 000 mg/dL (33.9 mmol/L).
Hemoglobin: No significant interference up to 500 mg/dL.
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin: No significant interference up to 22.1 mg/dL (378 µmol/L).
Acid uric: No significant interference up to 20.0 mg/dL (1190 µmol/L).
Methyl Dopa: No significant interference up to 1.6 mg/dL.
L-Dopa: No significant interference up to 1.50 mg/dL.
Pyruvate: No significant interference up to 3.0 mg/dL.
Ascorbic acid: No significant interference up to 3.0 mg/dL.
Acetaminophen: No significant interference up to 30 mg/dL.
Acetylsalicylic acid: No significant interference up to 200 mg/dL.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[7]

- Results can be falsely lowered by significant levels in the sample of NAC (*N*-Acetyl-Cysteine), NAPQI (metabolite of acetaminophene (paracetamol)) or metamizole.

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[8-9]

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member state of the European union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

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SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent 1
R2	Reagent 2
☛	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE

Contact your local distributor or ELITech Clinical Systems SAS (ccsupport@elitechgroup.com).

LACI

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