Nr kat. 7-466

DIAGNOSTIC KIT FOR DETERMINATION OF LACTATE CONCENTRATION

A-400 LACTATE

INTRODUCTION
Lactate is produced in Cori cycle, by anaerobic conversion of glucose, mainly in skeletal muscle. Its determination, frequently done together with pyruvate, is useful in discovering lactic acidosis due to i.a. reduced tissue oxygenation, enzymatic deficiencies, diabetes mellitus, liver and kidneys diseases.

METHOD PRINCIPLE
Lactate is oxidized by lactate oxidase to pyruvate and hydrogen peroxide, which, in presence of peroxidase (POD), reacts with 4-aminoantipirine and phenol forming a compound, which colour intensity is proportional to the concentration of lactate in the examined sample.

REAGENTS
Package

1-Reagent	2 x 20 ml

Unopened reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagents are stable for 11 weeks on board the analyser at 2-10°C.

Concentrations in the test

Tris buffer (pH 7.5)	≥ 50 mmol/l
lactate oxidase	≥ 0.2 kU/l
peroxidase	≥ 2 kU/l
4-aminoantipyrine	≥ 0.4 mmol/l

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not freeze the reagent!
- Protect from light and contamination!
- Do not use after expiry date.
- The appearance of turbidity or control sera values outside the manufacturer's acceptable range may indicate of the reagents instability.
- Lactate concentration rapidly increases during physical activities. Normal levels are reached again after usually 30 minutes but it may vary according to individuals.
- Draw blood with lowest venous stasis as possible (max. 30 seconds) from fasting and completely resting patient and avoid using a tourniquet.

SPECIMEN
Plasma. Avoid haemolysis.
Collect samples in tubes containing sodium fluoride and potassium oxalate. Keep samples on ice. Centrifuge within 15 minutes after collection and separate from cells. Analyze promptly. Note whether sample is venous or arterial.
It is recommended to follow NCCLS procedures regarding specimen collecting and handling.
Lactate in plasma is stable up to 8 hours at room temperature or up to 14 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
This reagent may be used in automatic analysers BS-400 and BS-480.
1-Reagent is ready to use.
For reagent blank deionized water is recommended.

REFERENCE VALUES [2]

plasma (venous)	4.5 – 19.8 mg/dl	0.5 – 2.2 mmol/l
plasma (arterial)	4.5 – 14.4 mg/dl	0.5 – 1.6 mmol/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) are recommended. Deionized water should be used as a calibrator 0.
The calibration curve should be prepared every 11 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using automatic analysers BS-400 and BS-480. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:**

1.8 mg/dl (0.20 mmol/l) – BS-400
1.51 mg/dl (0.17 mmol/l) – BS-480

- **Linearity:**

up to 87 mg/dl (9.66 mmol/l) – BS-400
up to 83.75 mg/dl (9.30 mmol/l) – BS-480
For higher concentration dilute the sample 1:1 with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**

a) In plasma samples containing approximately 12 mg lactate/dl, there is no interference up to: 0.23 g/dl haemoglobin, 8 mg/dl bilirubin, 330 mg/dl triglycerides, 15.5 mg/l ascorbic acid.
b) In plasma samples containing approximately 40 mg lactate/dl, there is no interference up to: 1.25 g/dl haemoglobin, 10 mg/dl bilirubin, 1000 mg/dl triglycerides, 62 mg/l ascorbic acid.

- **Precision**

Repeatability (run to run)		Mean [mg/dl]	SD [mg/dl]	CV [%]
BS-400 (n = 10)	level 1	12.55	0.05	0.40
	level 2	28.20	0.10	0.36
BS-480 (n = 10)	level 1	9.61	0.08	0.79
	level 2	40.96	0.17	0.40
Reproducibility (day to day)		**Mean [mg/dl]**	**SD [mg/dl]**	**CV [%]**
BS-400 (n = 10)	level 1	9.02	0.06	0.63
	level 2	42.24	0.33	0.78
BS-480 (n = 10)	level 1	9.67	0.12	1.23
	level 2	41.66	0.27	0.65

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 55 samples at BS-400, gave following results:
y = 0.9816 x – 0.1303 mg/dl;
R = 0.999 (R – correlation coefficient)

A comparison between lactate values determined at BS-480 (y) and at Advia 1650 (x) using 52 samples gave following results:
y = 1.0258 x + 0.5445 mg/dl;
R = 0.999 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Tietz Textbook of Clinical Chemistry (Edited by Burtis CA and Ashwood ER Eds): Third Edition WB Saunders Company 787-8, (1999).
2. Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 650-652, (2006).

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MANUFACTURER

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