Nr kat. 4-566

DIAGNOSTIC KIT FOR DETERMINATION OF LACTATE CONCENTRATION

HC – 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	1 x 57 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 12 weeks on board the analyser at 2-10°C. Do not freeze the reagent. Protect from light and contamination!

Concentrations in the test

Tris buffer (pH 7.5)	50 mmol/l
lactate oxidase	0.2 kU/l
peroxidase	3 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 purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [2]

plasma (venous)	4.5 – 19.8 mg/dl	0.5 – 2.2 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) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 6 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 Hitachi 912 and Olympus AU600. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.5 mg/dl (0.056 mmol/l).

- **Linearity:** up to 113 mg/dl (12.5 mmol/l).
  For higher concentration dilute the sample 1:1 with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.22 g/dl, bilirubin up to 10 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	14.78	0.07	0.50
level 2	49.97	0.13	0.26

Reproducibility (day to day) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	14.3	0.40	2.79
level 2	46.8	0.38	0.82

- **Method comparison**

A comparison between lactate values determined at Hitachi 912 (y) and at Biolis 24i Premium (x) using 25 samples gave following results:
y = 0.9444 x + 1.5895 mg/dl
R = 0.9996 (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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