Cat. No 4-533

DIAGNOSTIC KIT FOR DETERMINATION OF CREATININE CONCENTRATION

HC – CREATININE

INTRODUCTION

Creatinine is a product of creatine nonenzymatic dehydration in skeletal muscle. The amount of creatinine generated and excreted by kidney is proportional to muscle mass and usually is higher in men than women. Daily creatinine generation remains fairly constant, with the exception of crushing injury or degenerative diseases that cause massive damage to muscle. Creatinine blood and urine level depends on glomelural filtration so creatinine clearance is excellent index of renal function.

METHOD PRINCIPLE

Modificated Jaffe's method, without deproteinization. In alkaline solution picrate reacts with creatinine to form a yellow-red 2,4,6-trinitrocyclohexadienate. The colour intensity is proportional to the creatinine concentration.

REAGENTS

Package

1-Reagent	6 x 76 ml
2-Reagent	6 x 19.5 ml

The reagents when stored at 15-25°C are stable up to expiry date printed on the package. The reagents are stable for 10 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

sodium hydroxide	300 mmol/l
carbonate buffer	100 mmol/l
picric acid	6.5 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- 1-Reagent is classified as an irritant!

Ingredients: sodium hydroxide;
Xi – Irritant.
R 36/38: Irritating to eyes and skin.
S 26-28-37/39-45: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

SPECIMEN

Serum, EDTA or heparinized plasma free from hemolysis, 24-hours urine.
Urine preparation: Before analysis urine sample should be diluted 100-fold with 0.9% NaCl and the results multiplied by 100. Mix well probes before measurement.
Specimen can be stored up to 7 days at 2-8ºC. For longer storage samples should be frozen at -20ºC.
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 [7]

serum / plasma	mg/dl	µmol/l
female	0.6 – 1.1	53 – 97
male	0.7 – 1.3	62 – 115
24-hours urine	mg/kg/24h	µmol/kg/24h
female	11 – 20	97 – 177
male	14 – 26	124 – 230

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) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) or LEVEL 2 (Cat. No 5-162) for determination in urine 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) is recommended.
The calibration curve should be prepared every 10 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 the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.69 mg/dl (61.0 µmol/l).

- **Linearity:** up to 22.8 mg/dl (2016 µmol/l).
  If creatinine concentration exceeds 22.8 mg/dl, dilute the sample with 0.9% NaCl in the ratio of 1 to 2 and repeat the assay. Multiply the result by 3.

- **Specificity / Interferences**
  Haemoglobin up to 2.5 g/dl, triglycerides up to 500 mg/dl, ascorbate up to 62 mg/l and bilirubin up to 20 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.04	0.01	0.94
level 2	5.26	0.02	0.29

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.65	0.04	2.61
level 2	5.45	0.31	5.59

- **Method comparison**

A comparison between creatinine values determined at Hitachi 912 (y) and at Cobas Integra 400 (x) using 95 samples gave following results:
y = 1.0353 x - 0.0553 mg/dl;
R = 0.9931 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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