Cat. No 4-537

DIAGNOSTIC KIT FOR DETERMINATION OF CREATININE CONCENTRATION

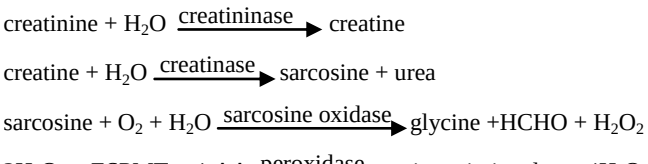
HC – CREA ENZYMATIC

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

Enzymatic, colorimetric method.



The colour intensity measured at 546 nm is proportional to the creatinine concentration.

REAGENTS

Package

1-Reagent	3 x 48 ml
2-Reagent	3 x 15.8 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Components and concentrations

1-Reagent

Good's buffer	≤ 5%
creatinase	≤ 5%
N-ethyl-N-(3-sulfopropyl)-3-methylaniline (ESPMT)	≤ 5%
sarcosine oxidase	≤ 0.01%
ascorbate oxidase	≤ 1%
detergents, stabilizers and preservatives	

2-Reagent

Good's buffer	≤ 5%
creatininase	≤ 1%
peroxidase	≤ 5%
4-ammoantipyrine (4-AA)	≤ 0.01%
stabilizers and preservatives	

Warnings and notes

- Product for in vitro diagnostic use only.
- 2-Reagent contains sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum and urine.
Urine preparation: before analysis urine sample should be diluted with 0.9% NaCl 2-10 times. Multiply the result by dilution factor.
Serum can be stored up to 1 day at 2-8ºC. For longer storage samples should be frozen at -20ºC.
Urine can be stored up to 1 day at 20-25ºC, 4 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 [2, 3]

serum / plasma	**mg/dl**	**µmol/l**
newborns	0.3 – 1.0	26.5 – 88.4
infants	0.2 – 0.4	17.7 – 35.4
children	0.2 – 0.8	17.7 – 70.7
female	0.5 – 1.0	44.2 – 88.4
male	0.7 – 1.2	61.9 – 106.1
urine (morning)	**mg/dl**	**mmol/l**
female	29 – 226	2.56 – 20.0
male	40 – 278	3.54 – 24.6

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) is recommended. **Calibrator and deionised water** should be used for calibration.
The calibration curve should be prepared every 12 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:** 0.08 mg/dl (7.07 µmol/l).
- **Linearity:** up to 24 mg/dl (2122 µmol/l).
- **Specificity / Interferences**
  Haemoglobin up to 5 g/dl, ascorbic acid up to 62 mg/l, bilirubin up to 20 mg/dl, triglycerides up to 1000 mg/dl and creatine up to 20 mg/dl do not interfere with the test both at serum and urine.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.25	0.03	2.36
level 2	5.52	0.07	1.32

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.33	0.03	2.38
level 2	5.52	0.11	2.06

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 38 serum samples gave following results:
y = 0.9678 x + 0.0459 mg/dl;
R = 0.9916 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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