CREATININE

CR 0500 CH	4 x 125 ml
CR 1000 CH	4 x 250 ml

INTENDED USE

Reagent for quantitative in vitro determination of creatinine in biological fluids.

SUMMARY OF TEST

Between 1 and 2% of muscle creatine is converted to creatinine daily. Because the amount of endogenous creatinine produced is proportional to muscle mass, the production varies with age and sex. Because creatinine is endogenously produced and released into body fluids at a constant rate and its plasma levels maintained within narrow limits, its clearance may be measured as an indicator of glomerular filtration rate (GFR).

PRINCIPLE OF THE METHOD

Creatinine reacts with picric acid in alkaline environment to form a color complex. Developing of this red color may be follow photometrically at 500-520 nm. The association on surfactant and sodium tetraborate keeps interferences at minimum.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

CREA R1 **0500:** **2 x 125 ml (liquid) blue cap**
1000: **2 x 250 ml (liquid) blue cap**

CREA R2 **0500:** **2 x 125 ml (liquid) red cap**
1000: **2 x 250 ml (liquid) red cap**

Composition in the test: picric acid 14 mM, NaOH 0.18 M, sodium tetraborate 10 mM, surfactant.

Standard: **creatinine 2 mg/dl - 5 ml**

Store all components at 15-25°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Mix 1 part of reagent R1 with 1 part of reagent R2.
Stability of working reagent: preferably within 30 days at 15-25°C, well capped and away from light sources.
Stability of unmixed reagents: up to expiration date on labels at 15-25°C;
Stability since first opening of vials of unmixed reagents: preferably within 60 days at 15-25°C.

PRECAUTIONS

CREA R1: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

CREA R2: It is not classified as hazardous.

Standard: It is not classified as hazardous

SPECIMEN

Serum, plasma. Urine.
Creatinine is stable 24 hours at 2-8°C. Freeze samples for prolonged storage.
Dilute urine sample 1:100 with deionized water. It could be convenient a slight acidification of urine with HCl.

TEST PROCEDURE

Wavelenght: 510 nm (allowed 500 ÷ 520 nm)
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	standard	sample
working reagent	1 ml	1 ml	1 ml
incubate at 37°C for 5 minutes			
water	100 µl	-	-
standard	-	100 µl	-
sample	-	-	100 µl

Mix, incubate 60 seconds at 37°C, then record absorbance as A_1. After exactly 60 seconds, record again absorbance as A_2.

RESULTS CALCULATION

Serum/plasma sample:

$$\text{creatinine mg/dl} = \frac{A_2\text{-}A_1 \text{ (sample)}}{A_2\text{-}A_1 \text{ (standard)}} \times 2 \text{ (standard value)}$$

Random urine sample:

$$\text{creatinine mg/dl} = \frac{A_2\text{-}A_1 \text{ (sample)}}{A_2\text{-}A_1 \text{ (standard)}} \times 2 \times 100$$

(standard value and dilution)

24 hours urine sample (creatinine mg/24h):

$[A_2\text{-}A_1 \text{ (sample)}] / [A_2\text{-}A_1 \text{ (standard)}] \times 2 \times 100 \times$ urine volume

(standard value, dilution factor and diuresis in decilitres)

EXPECTED VALUES

Serum/plasma samples:

Men:	0.7 - 1.2 mg/dl	(62 - 105 µmol/l)
Women:	0.6 - 1.1 mg/dl	(53 - 97 µmol/l)

24h urine:

Men:	1000 - 2000 mg/24h	(8.85 - 17.70 mmol/24h)
Women:	800 - 1800 mg/24h	(7.08 - 15.93 mmol/24h)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 20 mg/dl.
If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 0.2 mg/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
lipids	≤ 1250 mg/dl

Bilirubins give interference at low levels.

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	1.25	0.03	2.60
sample 2	3.87	0.07	1.90

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	1.31	0.04	2.90
sample 2	3.80	0.14	3.80

Methods comparison
a comparison between Chema and a commercially available product gave the following results:

Cretinine Chema = x
Creatinine competitor = y
n = 104

$y = 0.982x - 0.081$ mg/dl $r^2 = 0.94$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
HU Bergmeyer - Methods of enzymatic analysis, (1987).

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE