CREATININE-E FL

CE F125 CH	5 x 25 ml
CE F375 CH	15 x 25 ml
CE F600 CH	10 x 60 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

Through a series of enzymatic reactions, creatinine is converted in glycine, whilst endogenous components such as creatine and sarcosine are eliminated in the first step of the sequence. The formed hydrogen peroxide reacts with TOPS in the presence of peroxidase, to give a quinoneimine dye. The intensity of color, measured at 546 nm, is proportional to creatinine concentration in the sample.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label at 2-8°C.
Keep away from direct light sources.

CREA-E R1	**F125:**	**4 x 25 ml (liquid) blue cap**
	F375:	**12 x 25 ml (liquid) blue cap**
	F600:	**8 x 60 ml (liquid) blue cap**
CREA-E R2	**F125:**	**1 x 25 ml (liquid) red cap**
	F375:	**3 x 25 ml (liquid) red cap**
	F600:	**2 x 60 ml (liquid) red cap**

Composition in the test: Creatinase ≥ 10 kU/l, Creatininase ≥ 10 kU/l, Sarcosine Oxidase ≥ 1 kU/l, Peroxidase ≥ 5 kU/l, TOPS ≥ 3 mM, 4-aminoantipyrine ≥ 20 mg/l.

Store all components at 2-8°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

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: use preferably within 60 days at 2-8°C

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
N-acetylcysteine (NAC), metamizole and acetaminophen may cause interference in the Trinder reaction.[1,2]
To avoid interference, the blood withdrawal should be performed before drug administration.

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.

TEST PROCEDURE

Wavelenght: 546 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	20 µl	-	-
calibrator	-	20 µl	-
sample	-	-	20 µl

Mix, incubate at 37°C for 5 minutes.
Read absorbances of calibrator (Ac_1) and samples (Ax_1) against reagent blank.

dispense:	blank	calibrator	sample
reagent R2	250 µl	250 µl	250 µl

Mix, incubate at 37°C for 5 minutes.
Read absorbances of calibrator (Ac_2) and samples (Ax_2) against reagent blank.

RESULTS CALCULATION

Serum/plasma sample:
creatinine mg/dl = $(Ax_2-Ax_1)/(Ac_2-Ac_1)$ x calibrator value

Random urine sample:

creatinine mg/dl = $(Ax_2-Ax_1)/(Ac_2-Ac_1)$ x calibrator value x 10 (dilution)

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

creatinine mg/24h = $(Ax_2-Ax_1)/(Ac_2-Ac_1)$ x calibrator value x 10 x diuresis (dilution, diuresis in dl)

EXPECTED VALUES

Serum/plasma:

Men:	0.67 - 1.17 mg/dl	(59 - 104 µmol/l)
Women:	0.51 - 0.95 mg/dl	(45 - 84 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 50 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 0.04 mg/dl.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 28 mg/dl
lipids	≤ 1400 mg/dl
ascorbic acid	≤ 50 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	0.98	0.01	1.10
sample 2	3.98	0.02	0.56

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	0.97	0.03	3.28
sample 2	3.97	0.11	2.90

Methods comparison
A comparison between Chema and a commercially available product gave the following results with 99 samples:

Creatinine competitor = x
Creatinine Chema = y

$y = 1.004 x + 0.037$ mg/dl $r^2 = 0.998$

WASTE DISPOSAL

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

REFERENCES

1) N-acetylcysteine interference of Trinder-based assays. Genzen JR, Hunsaker JJ, Nelson LS, Faine BA, Krasowski MD. Clin Biochem. 2016 Jan;49(1-2):100-4
2) Drug interference in Trinder reaction. Wiewiorka O, Čermáková Z, Dastych M. Euromedlab 2017. ISSN 1437-4431
3) Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 797-801
Clin. Chem. 2012, 58(2), 391-401

MANUFACTURER

Chema Diagnostica
Via Campania 2/4
60030 Monsano (AN) - ITALY - EU
phone +39 0731 605064
fax +39 0731 605672
e-mail: mail@chema.com
website: http://www.chema.com

SYMBOLS

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

CE