Manual - Automation

CREATININE

IVD

Test without deproteinizzation.

REF	Σ	Reagenti	
1000136100	Content :6x100 ml Manual :300 test Autom :2400 test	R1(liquid)3x100 ml R2(liquid)3x100 ml R3 (standard)1x4ml	+30 +15

1.0 SUMMARY

Creatinine is a de-composition by product of the energy producing compound, creatine phosphate. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is removed from the plasma by glomerular fi ltration and then excreted in the urine without any appreciable re-absorption by the tubules. Typically 7-10 % of creatinine in the urine is derived from tubular secretion but this is increased in the presence of renal insuffi ciency. Because creatinine is endogenous and is freely fi ltered at the glomerulus, it is widely used to assess kidney function (Glomerular Filtration Rate or GFR) and is expressed either as a plasma concentration or renal clearance. Elevated levels of plasma creatinine are associated with impaired renal function. However, as serum creatinine is affected by factors independent of GFR including tubular secretion, age, sex, body size, diet, certain drugs and methodology, a normal plasma creatinine does not necessarily equate with normal kidney function. Therefore, serum creatinine alone should not be used to estimate GFR or detect the presence of impaired renal function. More accurate and precise estimations of GFR can be obtained with equations that are designed to average the effects of factors that affect serum creatinine other than GFR. One such equation was developed as a result of the Modifi cation of Diet in Renal Disease (MDRD) study, however, these formulas too have there limitations, especially in patients with acute renal failure and children, and do not take into account variations in assay specifi city and calibration. Nevertheless, the use of an equation such as the MDRD study equation is recommended above the use of serum creatinine alone.

2.0 PRINCIPLE

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.

3.0 SPECIMEN

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

4.0 MATERIALS REQUIRED BUT NOT PROVIDED

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

5.0 REFERENCE VALUES

Serum/plasma samples:
Men ..... 0.7 - 1.2 mg/dl (62 - 105 ⎡mol/l)
Women ..... 0.6 - 1.1 mg/dl (53 - 97 ⎡mol/l)
24h urine ..... 250 - 750 mg/24h (2.21 - 6.63 mmol/24h)

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

6.0 REAGENTS

R1 Liquid ready to use	NaOH 0.18 M, sodium tetraborate 10 mM, surfactant
R2 Liquid ready to use	picric acid 14 mM, NaOH 0.18 M,
R3 Liquid ready to use	Standard: creatinine - 4 ml

7.0 PREPARATION AND STABILITY OF REAGENTS

Mix 1 part of reagent 1 with 1 part of reagent 2. Stability of working reagent: ε 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 fi rst opening of vials of unmixed reagents: ε 60 days at 15-25°C.

8.0 PRECAUTIONS

Labelling reagent 2: Xi
R36/38 Irritating to eyes and skin.
S20/21 When using do not eat, drink or smoke.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 After contact with skin wash immediately with plenty of water.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

9.0 PROCEDURE

Wavelenght: 510 (500-520) nm
Temperature: 37°C
Reading: against water
Reaction: fixed time

	BLANK	STANDARD	SAMPLE
Reagent	2000 uL	2000 uL	2000 uL
Incubate at 37° C for 5 min.			
Dist.water	200 uL	-	-
Standard	-	200 uL	-
Sample	-	-	200 uL

Mix, incubate 60 seconds at 37°C, then record absorbance absorbance as A2.

10.0 QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available :
101265 PRECISE NORMAL with normal or close to normal control values.
101267 PRECISE PATH with pathological control values.
If required, a multiparametric, human based calibratori s available :
101031 BIOCAL HUMAN

11.0 CALCULATION OF RESULTS

11.1 Serum/plasma. creatinine mg/dl = $\frac{\text{A2-A1 (sample)}}{\text{A2-A1 (standard)}}$ x 2 (standard value)

11.2 Random urine sample.creatinine mg/dl = $\frac{\text{A2-A1 (sample)}}{\text{A2-A1 (standard)}}$ x 2 x 100 (standard value and diluition)

11.3 24 hours urine sample (creatinine mg/24 hours):
[A2-A1 (sample)] / [A2-A1 (standard)] x 2 x 100 x urine volme (standard value, dilution factor and diuresis in decilitres)

11.4 Clearance. $\frac{U}{S}$ x V x $\frac{1,73}{A}$ (medium value of physical surface of m^2 1,73)

U = mg/dl urine creatinin
S = mg/dl serum creatinin
V = urine volume ml/min.
A = patient physical surface in m^2

12.0 TEST PERFORMANCES

12.1 Linearity. Reaction is linear up to 20 mg/dL
12.2 Sensitivity/limit of detection (LOD) the limit of detection is 0.1 mg/dl.
12.3 Interferences. no interference was observed by the presence of:
hemoglobin ..... ≤ 200 mg/dl
bilirubin ..... ≤ 14 mg/dl
lipids .....≤ 600 mg/dl

12.1 Precision :

intra-assay (n=10)	Mean (U/L)	SD (U/L)	CV%
Sample 1	1.25	0.03	2.60
Sample 2	3.87	0.07	1.90

Inter-assay (n=10)	Mean (U/L)	SD (U/L)	CV%
Sample 1	1.31	0.04	2.90
Sample 2	3.80	0.14	3.80

12.2 Methods comparison. A comparison between MEDIA and a commercially available product gave the following results:
Cretinine MEDIA = x, Creatinine competitor = y, n = 104,
y = 0.982x - 0.081 mg/dl r = 0.94

13.0 WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal. S56:dispose of this material and its container at hazardous or special waste collection point. S57:use appropriate container to avoid environmental contamination. S61:avoid release in environment. Refer to special instructions/safety data sheet.

14.0 REFERENCES

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

SYMBOLS – 98/79/EC DIRECTIVE

Attenzione, consultare le istruzioni per l'uso	N°determinazioni per kit	Fabbricante	
IVD Solo per uso diagnostico *in vitro*	Usare entro	Non riutilizzare	
Conservare a 2-30°C	LOT Numero del lotto	REF Codice #	

MEDIA DIAGNOSTICI s.r.l.

Via Costiera 31 D/E
47100 FORLI (FC)
Telefono 0543 782.786
Fax 0543 782.787
e-mail info@mediagnostics.com
web http://www.mediagnostics.com

CREAT_100013-6100-CE_ UK_1_04112013 Rev. 1 4 november 2013

MeDia diagnostici

If You need to be sure !