CREATININE LR liquid reagent

REF E2706100 6x100 ml
E2700650 6x50 ml
E2700450 4x50 ml

CE IVD For in vitro medical device

Use
Kit for measurement of creatinine in serum, plasma and urine Colorimetric method Jaffé without deproteinization

Summary
Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

Principle
Fixed time analysis. Creatinine reacts in alkaline environment with picrate to give a coloured compound whose intensity is proportional to the creatinine concentration in the sample.

Reagents

R1	Litium hydroxide	120.0 mmol/l
	Boric acid	80.0 mmol/l
R2	Picric acid	67.0 mmol/l

Reagent Preparation
Reagents are liquid and ready to use. About using as monoreagent ("sample starter" procedure) pour the content of **R2** vial into the **R1** vial. For minor use mix the reagents **R1** and **R2** in equal parts.

Storage and Stability
- Store the kit at 15-25°C
- After opening, the vials R1, R2 are stable 90 day if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 7 days at 15-25°C.

Precaution In Use
The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.
However the reagent should be handled with caution, according to good laboratory practice.

Waste Management
Please refer to the local legal requirements.

Specimen Collection and Preparation
- Serum or plasma. Urine. Diluted 1: 10 (multiply the result by the dilution factor).
- Do not use hemolyzed samples.
- Creatinine in the samples is stable for 7 days when stored at +4 ° C.

Note
- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedure

Wavelength	λ: 510 (500-550) nm
Working Temperature	37°C
Optical Path	1 cm
Reaction	"fixed time"

Monoreagent Procedure "sample starter"

	Blank	STD	Sample
Working Reagent	1000µl	1000µl	1000µl
Distilled Water	100 µl	–	–
Sample	–	–	100 µl
Standard	–	100 µl	–

Mix and after 30" at 37°C measure the absorbance of sample (E1C) and standard (E1STD) against the reagent blank . After other 2' make the second reading (E2C), (E2STD).

- Bireagents Procedure "substrate starter"

	Blank	STD	Sample
Reagent R1	500µl	500µl	500µl
Distilled Water	100 µl	–	–
Sample	–	–	100 µl
Standard	–	100 µl	–

Mix, incubate at 37°C for 1', then add :

Reagent R2	500 µl	500 µl	500 µl

Mix and after 30'' at 37°C measure the absorbance of sample (E1C) and standard (E1STD). After other 2' make the second reading (E2C), (E2STD).

Calculation

$$\text{Creatinine [mg/dl] o [µmol/l]} = \frac{(E2C - E1C)}{(E2STD - E1STD)} \times \text{Conc. STD}$$

The reagent performances are related to 37°C,1 cm and 510 nm.

Conversion Factor
Creatinine [mg/dl] x 88.4 = Creatinine [µmol/l]

Reference Values
Serum – plasma
Man 0.9 - 1.3 mg/dl (80 -115 µmol/l)
Man Urine 800 – 2000 mg/24h (7.1 -17.7 mmol/24h)
Woman 0.6 - 1.1 mg/dl (53 - 97 µmol/l)
Woman Urine 600 - 1800 mg/24h (7.1 -15.9 mmol/24h)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES
The factor and the analytical performance are reported at 510 nm and 37 ° C

Linearity
The reaction is linear for values between 03 to 25 mg/dl (27-2210 mmol / l). Samples with values exceeding 25 mg / dl must be diluted with saline solution. Multiply, then, the result for diluting factor.

Analytical sensitivity
The test sensitivity in terms of detection limit is 0.3 mg/dl (27 µmol/l).

"Intra-Assay" precision (within-Run)
Determined on 20 samples for each control (N-H) (Normal-High).
Results:

MEAN [mg/dl]	N =1.15	H = 3.87
S.D.	N =0.05	H = 0.13
C.V.%	N = 4.6	H = 3.4

"Inter-Assay" precision (between-Run)
Determined on 20 samples for each control (H-N).Results:

MEAN [mg/dl]	N = 1.15	H = 3.86
S.D.	N = 0.05	H = 0.08
C.V.%	N = 4.19	H = 2.02

Correlation
A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.98**

y=0.98 x + 0.0775

Interferences
No interference was observed by the presence of :

Bilirubin	≤ 15mg/dl.
Triglycerides	≤ 1500 mg/dl
Hemoglobin	≤ 150mg/dl

Quality Controls
It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should estabilish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Henry, R.J.: Clinical Chemistry: Principles and Techniques, Harper & Row.N.Y., p. 287, (1964).
Young et al., Clinical Chemistry, 18, (1972).
Newman, D.J., Price, C.P.: Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B. Saunders Company; p. 1204, (1999). Kaplan, L.A., Pesce, A..J.: "Clinical Chemistry", Mosby Ed. (1996).

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl