LIQUIZYME

CREATININE

(Alkaline Picrate Method)

BEACON

Code	Product Name	Pack Size
LS016D	Liquizyme Creatinine	240 ml

Intended Use

Diagnostic reagent for quantitative in vitro determination of Creatinine in human serum, plasma and urine.

Clinical Significance

Creatnine is a waste product formed in muscle from the high energy storage compound, creatine phosphate. The amount of creatinine produced is fairly constant (unlike Urea) and is primarily a function of muscle mass. It is not greatly affected by diet, age, sex or exercise. Creatinine is removed from plasma by glomerular filteration and then excreted in urine without any appreciable resorption by the tubules.
Creatinine is used to assess renal function, however, serum creatinine levels do not start to rise until renal function has decreased by at least 50%.

Principle

Creatinine reacts with alkaline picrate to produce a reddish color. This is a non-specific reaction and is given by many other substances. Speciaficity of the assay has been improved by the introduction of a kinetic method 1, however the cephalosporin antibiotics are still major interferents.

Reaction

Creatinine + Alkaline Picrate → Orange Coloured Complex

Reagent Composition

Reagent 1 : Creatinine Buffer Reagent

Sodium Hydroxide : >200 mmol/L

Reagent 2 : Creatinine Picrate Reagent

Picric Acid : >15 mmol/L

Reagent 3 : Creatinine Standard : 2 mg/dl

Working Reagent Preparation

Working Reagent is prepared by combining equal volume of Reagent 1 and reagent 2. Mix by gently swirling. Allow the reagent mixture to stand at RT For 5 minutes for equilibrium. The working Reagent is ready for use.

Materials Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pipettes or Micropipettes & Tips - Colorimeter or Bio-Chemistry Analyzer.

Stability And Storage

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2–+8°C.
After first opening, reagents are stable for 30 days at +2–+8°C if stored at appropriate conditions, closed carefully and without any contamination.

Specimen Collection And Handling

Use serum, plasma, urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

In Serum / Plasma :

7 days : at +4 – +25°C

In Urine :

2 days : at+20 – +25°C
6 days : at +4 – +8°C

For the determination in urine use 24 hours specimen. It is important to exactly measure the volume of collected urine. Dilute urine samples in 1+19 ratio with distilled water and multiply results by 20.
Discard contaminated specimens.

Calibration

Calibration with Creatinine standard provided in the kit is recommended.

Quality Control

It's recommended to run normal and abnormal control sera to validate reagent performance.

Expected Values

Serum	Male	:	0.9 - 1.4 mg/dl
	Female	:	0.8 - 1.2 mg/dl
Urine	Male	:	0.4 - 1.8 gm/24h
	Female	:	0.35 - 1.6 gm/24h

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

Performance Data

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 0.06 mg/dl
Linearity : 20 mg/dl
Measuring range : 0.06 – 20 mg/dl

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	1.36	0.04	2.90
Sample 2	3.34	0.06	1.79

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	7.782	0.35	4.46

Comparison

A comparison between Beacon Creatinine (y) and a commercially available test (x) using 20 samples gave following results :

y = 0.9803 x - 0.0218 mg/dl

r = 0.999

Interferences

Following substances do not interfere :

haemoglobin upto 10 g/l, bilirubin up to 15 mg/dl, triglycerides up to 1000 mg/dl.

Warning And Precautions

For in vitro diagnostic use. To be handles by entitled and professionally educated person.

Reagent 1 contains 1.0% sodium hydroxide.

Waste Management

Please refer to local legal requirements.

Assay Procedure

Wavelength : 505 nm

Cuvette : 1 cm

Addition Sequence	Standard	Sample
Working Reagent	1000 µl	1000 µl
Standard	50 µl	-
Sample	-	50 µl

Mix and measure the initial abosorbance after 30 sec (A_1), start timer simultaneously and read again exactly after 120 sec (A2). Measure against reagent blank.

Calculate absorbance change $\Delta AT = (A_2 - A_1) / min$

Calculation

$$\text{Creatinine Concentration (mg/dl)} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 2$$

Applications for automatic analysers are available on request.

Assay Parameters For Photometers

Mode	Fixed Time
Wavelength 1 (nm)	505
Sample Volume (µl)	50
Working Reagent Volume (µl)	1000
Lag time (sec.)	30
Read Time (sec.).	120
Reaction temp. (°C)	37
Reaction Direction	Increasing
Normal Low (mg/dl)	0.9
Normal High (mg/dl)	1.4
Linearity Low (mg/dl)	0.06
Linearity High (mg/dl)	20
Standard Concentration	2 mg/dl
Blank with	Water
Unit	mg/dl

References

1. Myers, G.L., Greg Miller, W., Coresh, J., Fleming, J., Greenberg, N. et al.: Recommendations for Improving Serum Creatinine Measurement, Clin. Chem.52,5 18,2006.
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3. Bowers, L.D., Wong, E. T.: Cliln. Chem. 26, 555, 1980.
4. Tietz, N. W.: Textbook of Clin. Chem., 1245-1250, W. B. Saunders, Co., Philadelphia, 1999.
5. Fischer Jifl: Laboratorni Zprava c. 525, Lachema a.s., 1981.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/CR2/LS/IFU Ver-03
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JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016