Spectrum For Diagnostic Industries

Creatinine – Jaffè

IVD

REF.	Pack size
123 02 125	(2 x 125 ml) 250 tests
123 04 250	(4 x 250 ml)1000 tests

Intended Use

Creatinine reagent is intended for the in-vitro quantitative and diagnostic determination of creatinine in human serum or urine on both automated and manual systems.

Introduction

Creatine is synthesized in kidney, liver and pancreas. It is transported in blood to other organs such as muscle and brain where it is phosphorylated to phosphocreatine. Some free creatine in muscle is converted to creatinine daily and the amount of creatinine produced is proportional to muscle mass. In the absence of renal disease, excretion rate of creatinine in an individual is relatively constant. Therefore, measurement of creatinine clearance is useful in detecting renal disease and estimating the extent of impairment of renal function.Both serum creatinine and urea levels are elevated in patients with renal malfunction, especially decreased glomerular filtration.

Method

Buffered Kinetic jaffé reaction without deproteinization.

Principle

Creatinine reacts with picric acid under alkaline condition to form a yellow-red complex. The absorbance of the color produced, measured at a wavelength 492 nm, is directly proportional to creatinine concentration in the sample.

Creatinine + picrate $\xrightarrow{\textit{Alkaline pH}}$ yellow-red complex

Reagents

Reagent 1 **Irritant (Xi)**
Picric acid 25 mmol/L

The reagent contains a low concentration of picric acid, a chemical which, in its dry form, is flammable and potentially explosive. For this reason, it is recommended that drains be well flushed with water when discarding the reagent, spills be cleaned up at once, and dried material not be allowed to build up around the reagent bottle opening.

Reagent 2 ***Corrosive (C)***
Sodium hydroxide 0.4 mol/L

R35 cause severe burns.
R41 Risk of serious damage to eyes.
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 soap and water.

Standard
2 mg/dL 177 µmol/L

Reagents preparation, storage and stability

All reagents are stable till the expiration date stated on label when stored at 15 - 25 ^{o}C.Once opened, the reagent is stable for 6 months and the standard is stable for 3 months at the specified temperature if contamination is avoided.
Working solution is prepared by adding equal volumes from R1 and R2. Working solution is stable for 5 hours at 15 – 25^{o}C away from light .

Deterioration

The creatinine reagents are not suitable for use if working solution have an absorbance greater than 0.8 at 492 nm measured in a 1cm lightpath or if the reagents develop a hazy appearance.

Precautions and Warnings

For in-vitro diagnostic use only . Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

Serum or Plasma
Both serum and plasma are suitable for analysis. The only acceptable anticoagulants are heparin and EDTA. Specimen should be promptly separated from cells after blood collection. The biological half-life of creatinine in blood is few minutes.
Stability: 7 days 2 - 8 ^{o}C ; > 1 year at -20 ^{o}C.

Urine
Thymol or toluene may be used for urine preservation. To determine creatinine concentration in urine, dilute 1 part sample with 49 parts isotonic saline prior to assay. Multiply result by 50 to compensate for dilution.
Stability: 2 days at 15 - 25 ^{o}C ; 6 days at 2 - 8 ^{o}C
6 months at -20^{o}C away from light

Procedure

Wavelength	492 nm
Optical path	1 cm
Assay type	Fixed Rate
Direction	increase
Sample : Reagent Ratio	1 : 10
First read time	30 seconds
delay time	120 seconds
last read time	150 seconds
Temperature	30 ^{o}C
Zero adjustment	Against Air
Reagent Blank Limits	Low 0.3 AU
	High 0.8 AU

Reagent	1.0 ml
Standard or Specimen	100 µl

Mix, and after 30 seconds. Read the absorbance A1 of the standard or specimen. After exactly 2 minutes later, read absorbance A2 of standard or specimen.

Calculation

A2 – A1 = Aspecimen or Astandard.

Concentration of creatinine in serum:

$$\text{Creatinine (mg/dL)} = \frac{A_{specimen}}{A_{standard}} \times 2$$

Concentration of creatinine in urine:

$$\text{Creatinine (mg/dL)} = \frac{A_{specimen}}{A_{standard}} \times 2 \times 50$$

Creatinine clearance:

$$\frac{\text{mg creatinine / dL urine x mL urine / 24 hours}}{\text{mg creatinine / dL serum x 1440}}$$

Correction for body surface area can be done using the following formula for creatinine clearance:

Serum creatinine / min. per standard surface area =

$$\frac{UCr \times V}{PCr} \times \frac{1.73}{A}$$

Where: UCr = Concentration of creatinine in urine (mg/dL)
PCr = Concentration of creatinine in plasma (mg/dL)
V = Volume of urine flow in mL/min.
A = Body surface area in square meter .
1.73/A = Factor normalizes clearance for average body surface.

Note : Body surface area can be determined from height and weight via normograms in Tietz .

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Expected Values

Serum/Plasma

Females	0.7-1.3 mg/dL	62-115 µmol/L
Males	0.9-1.5 mg/dL	80-133µmol/L

Urine(24 hrs)

Females	0.9 – 1.6 g/24 hrs
Males	1.1 – 2.8 g/24 hrs

Creatinine clearance

Females	75 – 115 ml / min.
Males	85 – 125 ml / min.

Performance Characterstics

Method Comparison

A comparison between Creatinine Jaffè reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.991 was obtained.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	1.55	4.58
SD	0.069	0.1
CV%	4.45	2.2

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	1.67	4.63
SD	0.081	0.19
CV%	4.58	2.7

Interference

Haemolysis
Erythrocyte contamination doesn't elevate results.

Icterus
Serum bilirubin levels higher than 5 mg/dL (85 µmol/L) decrease serum creatinine.

Lipemia
Lipemic specimens may cause high absorbance flagging. Diluted sample treatment may be recommended.

Sensitivity

When run as recommended, the minimum detection of this assay is 0.31 mg/dL creatinine (0.027 mmol/L).L).

Linearity

The reaction is linear up to serum creatinine concentration of 20 mg/dL (1.77 mmol/L). Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

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 sheets.

References

1.Tietz NW: Textbook of clinical chemistry. WB saunders, philadelphia, 1986.
2.. Spencer K, Price CP: A review of Non-enzyme mediated reaction and their application to centrifugal analyzers. IN centerfugal analyzers in clinical chemistry.
3.Tobias GJ, Mclaughlin RF, Hopper J: Endogenous creatine clearence,1962.

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

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