



Spectrum For Diagnostic Industries

IVD

## Creatinine – colorimetric

REF.	Pack size
125 04 100	( 4 x 100 ml ) 400 tests
125 04 125	( 4 x 125 ml ) 500 tests

### Intended Use

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

### Introduction

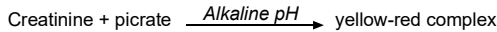
Creatine is synthesized in kidney, liver and pancreas. It is transported in blood to other organs such as muscle and brain where it is phosphorylated to phosphocreatine. Some free creatine in muscle is converted to creatinine daily and the amount of creatinine produced is proportional to muscle mass. In the absence of renal disease, excretion rate of creatinine in an individual is relatively constant.

### Method

Colorimetric method with deproteinization.

### Principle

Creatinine reacts with picric acid in alkaline solution to form a coloured complex.



### Reagents

**Reagent 1** **Irritant (Xi)**  
Picric acid 38 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 1.6 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

#### Additional Reagent not supplied

Trichloroacetic acid 1.2 mol/l

### Reagents preparation, storage and stability

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

### Deterioration

The creatinine reagents are not suitable for use if working solution have an absorbance greater than 0.6 at 492 nm measured in a 1-cm light path or if the reagents develop a hazy appearance.

### Precautions and Warnings

For invitro diagnostics use only . Do not ingest or inhale. 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

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 °C ; > 1 year at -20 °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 °C ; 6 days at 2 - 8 °C  
6 months at -20°C away from light

### Procedure

Wavelength	546 nm
Optical path	1 cm
Assay type	End point
Direction	increase
Sample : Reagent Ratio	1 : 1
Temperature	25 °C
Zero adjustment	Against Air
Reagent Blank Limits	Low 0.3 AU High 0.6 AU

#### Deproteinization Procedure

Pipette into centrifuge tubes	
Trichloroacetic acid (TCA)	1.0 ml
Serum or heparinized plasma	1.0 ml
(TCA reagent is available upon request)	

Mix well using glass rod to disperse the precipitate. Centrifuge at 3000 rpm for 10 minutes, then pour off the supernatant into clean tube. **Stability:** the supernatant is stable for 7 days at 2 - 4 °C.

	Blank	Standard	Sample	Urine
Distilled Water	0.5 ml	.....	.....	.....
Standard	.....	0.5 ml	.....	.....
TCA	0.5 ml	0.5 ml	.....	0.5 ml
Supernatant	.....	.....	1.0 ml	.....
Urine (1+ 49)	.....	.....	.....	0.5 ml
Working solution	1.0 ml	1.0 ml	1.0 ml	1.0 ml

Mix and let stand for 20 minutes, at 20–25 °C. Measure the absorbance of specimen and standard against reagent blank at 546 nm.

#### Calculation

Concentration of creatinine in serum:

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

Concentration of creatinine in urine:

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

### Creatinine clearance:

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

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

Serum creatinine / min. per standard surface area =

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

**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 nomograms in Tietz .

### Quality control

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

### Interference

#### Haemolysis

Erythrocyte contamination doesn't elevate results.

#### Icterus

Serum bilirubin levels higher than 5 mg/dL (85 µmol/L) decrease serum creatinine correlation of 0.991 was obtained.

#### Lipemia

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

### 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.
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### Performance characteristics

#### Mehod Comparison

A comparison between SDI Creatinine colorimetric reagent and a commercial reagent of the same methodology was performed on 40 human sera. A correlation (R) of 0.996 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

### Sensetivity

When run as recommended, the minimum detection limit of the assay is 0.4 mg/dL (0.035 mmol/L).

### Linearity

The reaction is linear up to a creatinine concentration of 15 mg/dL; 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 clearance,1962.

### SYMBOLS IN PRODUCT LABELLING

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

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**IFUF125 Rev.(2), 26/7/2020**

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