

# BioMed- Creatinine

## Colorimetric, Endpoint



REF: CRE105120 ( 2x60 ml )  
CRE105240 (2x120 ml )

### INTENDED FOR USE

For the quantitative determination of creatinine in serum, plasma and urine

### PRINCIPLE:

Creatinine reacts with picric acid in alkaline conditions to form a yellow- orange color complex.

The rate of formation of color is proportional to the creatinine quantity in the sample.

### SPECIMEN COLLECTION :

Serum, heparinized plasma and 24 hours urine.

Urine must be diluted 1:50 with physiological saline.

Do not use hemolyzed samples.

Creatinine in serum or plasma is stable for 1 day at room temperature (+15-25°C) and up to 7 days if in refrigerator at (+2-8°C).

Shake and bring the samples at room temperature (+15-25°C) before using

### REAGENT COMPOSITIONS

<b>R1</b>	Creatinine standard	2.0 mg/dl
<b>R2</b>	Picric acid	38 mmol/l
<b>R3</b>	Sodium hydroxide	1.2 mmol/l

Additional reagent TCA 1.2 mmol/l

### PACKAGE: Collection & storage.

Store at room temperature (+15-25°C).

Stable until the expiration date indicated on the label.

After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacteric contamination.

### PRECAUTIONS & WARNING

#### AVOID PIPETTING WITH MOUTH

The Reagent (B) contains **sodium hydroxide** and , according to current regulation, is classified as: **C – Corrosive**

**R34** - Causes burns.

**S26** - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**S45** - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**S36/37/39** - Wear suitable protective clothing, gloves and eye/face protection.

A safety and precaution form is available on request.

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.

Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis

### REAGENT PREPARATION & STABILITY :

Mix Reagents (R2) and (R3) in the ratio 1+1

Stable 7 days at room temperature

Use as much reagent quantity as necessary for the number of analyses to run. Stable 7 days at room temperature.

Reagent (R2) is limp/yellow; Reagent (R3) is limp/courless.

### REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

### PROCEDURE:

Wavelength 546 nm (500-550)  
Optical path 1 cm  
Incubation temperature 20 - 25°C  
Measurement Against blank

#### Deproteinization

Pipette into centrifuge tube	
Trichloro acetic acid	1.0 ml
Serum or heparinized plasma	1.0 ml
Mix well, centrifuge for 10 min, then carefully pour clear supernatant into dry test tube.	

Pipette into test tubes				
	<b>Blank</b>	<b>Standard</b>	<b>Specimen</b>	<b>Specimen (Urine 1 +49)</b>
Dist.water	<b>0.5 ml</b>	—	—	—
Standard	—	<b>0.5 ml</b>	—	—
TCA	<b>0.5 ml</b>	<b>0.5 ml</b>	—	—
Supernatant	—	—	<b>1.0 ml</b>	—
Urine (1+49)	—	—	—	<b>0.5 ml</b>
Working Reagent	<b>1.0 ml</b>	<b>1.0 ml</b>	<b>1.0 ml</b>	<b>1.0 ml</b>
Mix, Measure the absorbance of specimen ( $A_{\text{specimen}}$ ) and standard ( $A_{\text{standard}}$ ) against blank after exactly 20 min. at 25°C.				

### CALCULATION:

$$A_2 - A_1 = A_{\text{specimen}} \text{ or } A_{\text{standard}}$$

**Concentration of Creatinine in serum or plasma.**

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

**Concentration of Creatinine in urine**

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

$$\text{Creatinine clearance} = \frac{\text{mg creatinine / dl urine} \times \text{ml urine / 24 hour}}{\text{mg Creatinine / dl serum} \times 1440}$$

### EXPECTED VALUES:

<b>Serum : Men</b>	0.7 - 1.4 mg/dl (0.062 - 0.124 mmol/l)
<b>Women</b>	0.5 - 1.2 mg/dl (0.044 - 0.106 mmol/l)
<b>Children &lt; 2 years old</b>	0.3 - 0.6 mg/dl (0.027 - 0.053 mmol/l)

**Urine:** up to 13.3 mmol/24h (1.5 g/24h)

Clearance Creatinine

**Men:** 98 -160 ml/min

**Women :** 95 -150 ml/min

The above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol.

### WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal .

### QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

### REFERENCES:

1. Jaffè, M. Zischr Physiol Chem . 10 (391), 1886.
2. Henry, R.J. Ed., Clinical Chemistry: Principles and Technics (2°Ed). Harper and Row, 1974.
3. Young D.S., et al.Clin Chem. 21(286), 1975.

### PERFORMANCE :

MEASURE INTERVAL\LINEARITY:	0.1-20 mg/dl
DETECTION LIMIT(2 DS):	0.09 mg/d
SENSITIVITY:	1.0 mg/dl = Δ0.046A

#### INTRA-ASSAY PRECISION: n=30

MEDIUM LEVEL	M=1.2mg/dL	C.V.=1.6%
HIGH LEVEL	M=3.6mg/dL	C.V.=1.07%

#### INTER-ASSAY PRECISION: n=30

MEDIUM LEVEL	M=1.8mg/dL	C.V.=2.15%
HIGH LEVEL	M=8.1mg/dL	C.V.=2.55%
INTER. ANALYZED	0.16-32mg/dL	
CORRELATION	r = 0.9879	n= 60
LIN.REGRESSION	y = 0.9999x - 0.1028	n= 60






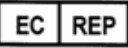

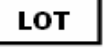

#### INTERFERENCES:



Interferences are negligible up to:	
Glucose 500mg/dL	Bilirubin > 55mg/dL
Urea 1g/dL	Increase the reading
Ascorbic Acid 100mg/dL	Hemoglobin > 100mg/dL
	Increase the reading

### METHOD LIMITATIONS:

For concentration higher than 20 mg/dl, repeat the measure on a sample diluted 1:2 with saline solution and multiply the results by 2.

For a thorough evaluation of the interfering substances , consult : Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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