BioMed- Creatinine

Colorimetric, Endpoint

REF: CRE105100 (2x50 ml)
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

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

Additional reagent TCA 1.2 mmol/1

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 **2** days at room temperature
Use as much reagent quantity as necessary for the number of analyses to run.
Reagent (R2). is limpid/yellow; Reagent (R3) is limpid/colourless.

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				
	Blank	**Standard**	**Specimen**	**Specimen (Urine 1 +49)**
Dist.water	**0.5** ml			
Standard		**0.5** ml		
TCA	**0.5** ml	**0.5** ml		**0.5ml**
Supernatant			**1.0** ml	
Urine (1+49)				**0.5** ml
Working Regent	**1.0** ml	**1.0** ml	**1.0** ml	**1.0** ml
Mix, Measure the absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against blank after exactly 20 min. at 25°C.				

CALCULATION:

Concentration of Creatinine in serum or plasma.

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

Concentration of Creatinine in urine

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

$$\textbf{Creatinine clearance} = \frac{\text{Creatinine in urine (mg / dl)} \times \text{Vol. urine (ml) / 24 hour}}{\text{Creatinine serum (mg / dl)} \times 1440}$$

EXPECTED VALUES:

Serum	
Men	0.7 - 1.4 mg/dl (0.062 - 0.124 mmol/L)
Women	0.5 - 1.2 mg/dl (0.044 - 0.106 mmol/L)
Children < 2 years old	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.

IQUALITY 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.

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:

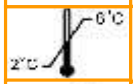
Interferences are negligible up to:			
Glucose	500mg/dL	Bilirubin	> 55mg/dL
Urea	1g/dL	Increase the reading	
Ascorbic Acid	100mg/dL	Hemoglobin	> 100mg/dL
		Increase the reading	

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).

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.

	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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