Instructions For Use

GENESIS

Creatinine (Jaffé method)

Cat no.	size
1104 101	2*100
1104 102	4*100

INTENDED USE

The creatinine Reagent is intended for in vitro Quantitative diagnostic determination of Creatinine in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Creatinine is a catabolic end product of Creatinine (or phosphocreatine). The amount produced each day is related to the muscle mass. Creatinine is freely filtered by the glomerulus (small amounts are reabsorbed and are also secreted by the renal tubules). Creatinine measurement is used almost exclusively in the assessment of kidney function (impaired renal perfusion, loss of functioning nephrons) and in the monitoring renal dialysis. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Creatinine in the sample reacts with picrate in alkaline medium forming a coloured complex (Jaffé method).

The complex formation rate is measured in a short period to avoid interferences serum and plasma samples contain proteins that react in a non-specific way; nevertheless, the results can be corrected subtracting a fixed value.

The use of this correction is known as the Jaffé method compensated.

COMPOSITION

Picric Acid (R1)	25 mmol/L
Sodium Hydroxide (R2)	0.4 mol/L
Standard(S)	2.0 mg/dL

STORAGE.

Store at 20-25ºC.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Working Reagent:

Mix equal volumes of picric acid (R1) and sod hydroxide (R2).

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC
- Analyzer, spectrophotometer or photometer able to read at 492 nm

SPECIMEN

1.Serum, plasma or urine collected by standard procedures.
2.Dilute fresh urine 1/50 with distilled water before measurement.
3.Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.
4.Creatinine in samples is stable for 24 hours at 2-8ºC.

Precautions and Warnings

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.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

PROCEDURE

1.Assay Parameters:
Mode……Fixed time
Wavelength……492 nm
Cuvette……1 cm
Delay Time……30 sec
Measuring time……90 sec
2.Pipette into labeled test tubes:

	Standard	Sample
Working reagent	1.0 mL	1.0 mL
Standard (S)	100 µL	-
Sample	-	100 µL

3.Mix and read the absorbance (A1) of the standard or specimen after **30 sec** . Exactly **90 sec Later ,** read the absorbance (A2) of the standard or specimen at 492 nm.

CALCULATIONS

The Creatinine concentration in the sample is calculated using the following general formula:

A2-A1= A specimen or A standard

$$\text{Conc of sample} = \frac{\text{A Sample}}{\text{A Standard}} \times \text{conc. of standard (2 mg/dL)}$$

Creatinine conc in urine (dilute 1:50)

$$\text{Conc of sample} = \frac{\text{A Sample}}{\text{A Standard}} \times \text{conc. of st (2)} \times \text{Dilution factor (50)}$$

$$\text{Clearance Creatinine (ml/min)} = \frac{\text{Creat. urine (mg/dl)} \times \text{Vol. urine/24h in ml}}{\text{Creatinine serum (mg/dl) x 1440}}$$

REFERENCE VALUES

Serum and plasma	Urine24-h
Male: 0.6 – 1.4 mg/dL	10 – 20 mg/kg/24-h
Female: 0.5 – 1.2 mg/dL	8 –18 mg/kg/24-h
Children: 0.3 – 0.9 mg/dL	
Creatinine clearance	
Male	85 – 125 ml/min
Female	75 – 115 ml/min

METROLOGICAL CHARACTERISTICS

Detection limit 0.04 mg/dL = 3.5 umol/L
Linearity limit: 20.0 mg/dL = 1768 umol/L
For higher values dilute sample **1/3** with physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	cv	n
1.67 mg/dL	3.2 %	20
4.63 g/dL	1.7 %	20

− Reproducibility (run to run):

Mean Concentration	cv	n
1.67 g/dL	3.5 %	25
4.63 g/dL	2.2 %	25

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (10 mg/dL), protein and ketonic bodies do not interfere. Lipemia (triglycerides > 2 g/L) may interfere.

BIBLIOGRAPHY

1. Allain CC, Poon LS, Chan CSG, Richmond W and Fu PC. Enzymatic determination of totalserum cholesterol. ClinChem 1974; 20: 470-475.
2. Meiattini F, Prencipe L, Bardelli F, Giannini G and Tarli P. The 4-hydroxybenzoate/4-aminophenazone chromogenic system used in the enzymic determination of serumcholesterol. ClinChem 1978; 24: 2161-2165.

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-CR-05
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain