CREATININE ENZYMATIC
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL286CR	2 x 50 ml	CREATININE – 1	2-8°C
	2 x 25 ml	CREATININE - 2	2-8°C
GL296CR	4 x 50 ml	CREATININE – 1	2-8°C
	4 x 25 ml	CREATININE - 2	2-8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Creatinine in serum, plasma and urine on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [1]

A proportion of free creatine in muscle (1-2%) is with phosphocreatine spontaneously and irreversibly converted to creatinine. The amount of creatinine produced each day is related to muscle mass and dietary intake. Creatinine determination is used primarily in the diagnosis and treatment of acute and chronic renal disease. Urinary creatinine is frequently measured as a reference value with the measurement of microalbumin in suspected diabetic patient.

PRINCIPLE OF THE TEST:

Step 1: Elimination of endogenous creatinine and sarcosine.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Creatine} + H_2O + O_2 \xrightarrow{\text{Sarcosine\_Oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$2H_2O_2 \xrightarrow{\text{Catalase}} O2 + 2H_2O$$

Step 2: Measurement of creatinine. The activity of the catalase is totally inhibited by sodium azide contained in the reagent, which is used in this step.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{\text{Sarcosine\_Oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine} + \text{TOOS}^* \xrightarrow{\text{Peroxidase}} \text{Quinoneimine Dye} + 4H_2O$$

The intensity of the colour of quinoneimine dye formed is directly proportional to the creatinine concentration in the sample.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear pale yellow liquid
Reagent 2: Clear colourless liquid.
Any significant changes could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Goods buffer pH 8.2	20 mmol/l
	TOOS	1 mmol/l
	Ascorbate oxidase	3 U/ml
	Creatinase (C2 AE)	35 U/ml
	Sarcosine oxidase (SOD-TE)	11 U/ml
	Catalase	300 U/ml
	Other chemicals	---
Reagent 2	Goods buffer pH 8.0	20 mmol/l
	4-Aminoantipyrine	4 mmol/l
	Creatininase (C1 E)	370 U/ml
	Peroxidase	15 U/ml
	Sodium azide	0.08 %
	Other chemicals	---

TOOS*: N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.

TYPE OF SPECIMEN: [1]

Serum or heparin plasma is the preferred specimen. Urine can also be used. Dilute urine specimen 1/100 and multiply results by 100 to recover patient's creatinine concentration.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.
- Plasma/serum should be separated from cells within 2 hours after collection.
  Stability: It is essential to store specimens in the dark, at 2-8°C. Only in those conditions, stability is maintained for 3 days.
- Urine should be stored at 2-8°C and analysed no later than 2 hours after collection.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932		

Assay procedure:
Wavelength: λ: 546 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Sample	---	---	0.07ml
Calibrator	---	0.07 ml	---
Blank	0.07 ml	---	---
Reagent 1	2.50 ml	2.50 ml	2.50 ml
Mix and incubate for 5 min at 37°C. Measure absorbance (A1) at 546 nm against distilled water.			
Reagent 2	1.25 ml	1.25 ml	1.25 ml
Mix and incubate for 5 min at 37°C. Measure absorbance (A2) at 546 nm against distilled water.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When installing a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory QC Programme.

CALCULATION:

$$\text{Creatinine (mg/dl)} = \frac{(A2_{sample} - A2_{blank}) - (A1_{sample} - A1_{blank}) xK}{(A2_{calibrator} - A2_{blank}) - (A1_{calibrator} - A1_{blank}) xK} \text{ x Concentration of Calibrator}$$

(Conversion Factor: Qty in µmol/l = 88.4 x Qty in mg/dl.).

EXPECTED VALUES: [1]

	Serum or Plasma µmol/L	*Serum or Plasma* Mg/dl	*Urinary Creatinine Excretion* µmol/kg/day	*Urinary Creatinine Excretion* Mg/kg/day	*Creatinine Clearance* mls/m²
Adult Men	62 - 115	0.70 – 1.30	124 - 230	1.40 – 2.60	0.91 - 1.35
Adult Women	53 - 97	0.60 – 1.10	97 - 177	1.10 – 2.00	0.69 - 1.06

Each laboratory should establish its own reference range. Creatinine results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linear up to 1400µmol/l (15.8 mg/dl).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 5 g/l Intralipid

Precision:

Within Run N = 20	*Mean (µmol/l)*	*SD*	*% CV*	*Between Run N = 20*	*Mean (µmol/l)*	*SD*	*% CV*
Level 1	109	2.35	2.15	Level 1	106	2.77	2.62
Level 2	373	3.05	0.82	Level 2	371	3.79	1.02

Method Comparison:
Using 74 samples, a comparison, between this Creatinine test (y) and another commercially available test (x), gave the following results:

y = 1.026x - 0.829	r = 0.999	Sample range: 46 to 2973 µmol/l

BIBLIOGRAPHY:

1. Burtis CA., Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed.; 30-54, 419-422 and 975.

SYMBOLS:

IVD	In Vitro Diagnostics		Catalogue No
LOT	Batch Code		Content
REAG	Reagent		Calibrator
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature		Consult Instruction for Use
	Expiry Date (Last day of the month)		Manufactured By

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