CREATININE JAFFE
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL266CR	3 x 50 ml 3 x 50 ml 1 x 10 ml	CREATININE - 1 CREATININE - 2 CREATININE - Standard	15 - 25°C
GL276CR	2 x 250 ml 2 x 250 ml 1 x 10 ml	CREATININE - 1 CREATININE - 2 CREATININE - Standard	15 - 25°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative 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: [2, 3]

In an alkaline solution, creatinine reacts with picric acid to form a coloured complex. The rate of formation of the complex is measured and is directly proportional to the amount of creatinine in the sample.

Creatinine + picric acid $\xrightarrow{\text{Alkaline\_Solution}}$ Creatinine-picric acid complex

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: Colourless liquid.
Reagent 2: Clear yellow 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:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Label Elements:

DANGER

H314 - Causes severe skin burns and eye damage.

Precautionary Statements:
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor/physician.

Handling precautions:
- 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.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	Alkaline Buffer	200 mmol/l
Reagent 2	Picric Acid	25.0 mmol/l
Standard	Creatinine	177 µmol/l

INSTRUMENTS:

Instrument applications are available upon request.

REAGENT PREPARATION AND STABILITY:

Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, unopened components are stable until the expiry date stated on the label
Monoreagent procedure: Add 1 volume of Reagent 2 to 1 Volume of Reagent 1.
Working reagent is stable 1 day at 15-25°C.
Bireagent procedure: Liquid reagent 1 and 2 are ready for use.
Once open, components are stable until expiry date on label if store and handle properly.

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 dilution factor.
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 [1]: 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: 500 nm (Hg 480 – Hg 520)
Temperature: 37°C
Optical path: 1 cm light path.

MONOREAGENT PROCEDURE:	Blank	Calibrator	Sample
Working reagent	1000 µl	1000 µl	1000 µl
Sample	----	----	50 µl
Calibrator	----	50 µl	----
Gently mix and Incubate at 37°C for 30 seconds. Measure the Optical Density (OD1) after sample/standard addition. *Exactly* 3 minutes after first reading measure the Optical Density (OD2).			

BIREAGENT PROCEDURE:	Blank	Calibrator	Sample
Reagent 1	500 µl	500 µl	500 µl
Sample	----	----	50 µl
Calibrator	----	50 µl	----
Reagent 2	500 µl	500 µl	500 µl
Gently mix and Incubate at 37°C for 1 minute Measure the Optical Density per minute (ΔOD/min) over the next 2 minutes			

Calibration:
Using recommended Calibrator, calibrate the assay:
- Daily.
- 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:

Concentration of Creatinine = $\frac{\text{Sample}_{OD2} - \text{Sample}_{OD1}}{\text{Calibrator}_{OD2} - \text{Calibrator}_{OD1}}$ 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:
This assay is linear up to 1516 µmol/l (17 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): 25% interference up to 200 µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 15.6 µmol/l (0.176 mg/dl).

Precision:

Within Run N = 20	Mean (µmol/l)	SD	% CV	Between Run N = 20	Mean (µmol/l)	SD	% CV
Level 1	117.6	5.59	4.76	Level 1	117.6	5.55	4.72
Level 2	387.0	9.33	2.41	Level 2	374.9	9.01	2.40

Method Comparison:
Using 50 samples, a comparison, between this Creatinine test (y) and another commercially available test (x), gave the following results:

y = 1.010x – 2.150	r = 1.00	Sample range: 72 to 905 µmol/l

BIBLIOGRAPHY:

1. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 419-422 and 975.
2. Jaffe M et al Physiol. Chem. 10, (1886) 391.
3. Hienegard D, Diderstrom G., Clin. Chem. Acta 43, (1973) 305.
4. Voit R. Plasma-Serum-Unterschiede und Lagerungs stabilitat klinisch-chemischer Meβgroβen bei Verwendung von Plasma-trennrohrchen [Dissertation]. Munich: Ludwig-Maximilian-University, 1993.
5. Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa: WB Saunders Company 1995:186-188.

SYMBOLS:

The following symbols are used in the labelling Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	STD	Aqueous Standard

CE Mark - Device complies with the Directives 98/79/EC
Storage temperature
Consult Instruction for Use
Expiry Date (Last day of the month)
Manufactured By

GLENBIO LTD
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