ANA BIO ISP Creatinine

(Jaffe without deproteinization rate blanked method)

For Miura Instruments

Intended Use
Creatinine is a reagent kit used for the determination of Creatinine in serum/plasma or in urine based on initial rate method using alkaline picrate.

Principle
Creatinine in alkaline medium reacts with picrate to produce orange colour. The intensity of the colour formed is directly proportional to the concentration in the specimen and is measured kinetically.

Creatinine + Picrate $\xrightarrow{\text{Alkaline medium}}$ Creatininepicrat (Orange Colour)

Components & Concentration of Reagents

Reagent	Component	Concentration
R1	NaOH	≥200 mmol/L
	Stabilizers, exipients & surface active agents	
R2	Picric acid	≥25 mmol/L
	Stabilizers, exipients & surface active agents	

Reagent storage and stability
The reagents are stable till the expiry date stated on the bottle label, when stored at 15 - 25°C).
After opening the solution is stable for 30 days at 2° - 8°C. Protect the reagent from light and contamination.
Do not freeze the reagent.

DETERMINATION OF SERUM/PLASMA CREATININE
Specimen collection and preservation
Blood should be collected in a clean and dry container. Avoid use of plastic or siliconized container which may prolong clotting time. Samples should not be collected during PSP/BSP clearance test. For plasma separation HEPARIN (200 IU/ml of blood) may be used as anticoagulant.
Creatinine in serum and plasma is stable for 2 days when stored at 2° - 8°C.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration
For Calibration use the "Multicalibrator"

Calibration Stability
For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit
Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Creatinine	
Method Code	CRE	
Type	Fixed Time Substrate start	
Unit	Mg/dl	
Filter F1	505 nm	
Blank in	Not Use	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	12	µl
Incubation R1,S ⟶ R2	36	Sec
Volume reagent R2	40	µl
Final Incubation	36	Sec.
Fixed Time Second read	96	Sec

DETERMINATION OF URINE CREATININE
Specimen collection
Creatinine determination in urine is usually carried out on 24 hrs. urine sample. Thymol as preservative should be used for collection. The urine specimen should be thoroughly mixed and then diluted 1:25 with distilled water.
Urine samples containing Thymol as preservative are stable for one week at 2° - 8°C.

Procedure
Follow the same procedure as given before.

Calculation for urine sample
Urine Creatinine (mg/dl) = Obtained Value x 25 ml/dl

Creatinine Clearance

$$mL/dl = \frac{\text{Urinary Creatinine in mg/dl x Urinary volume in ml/24hours}}{\text{Serum/Plasmatics Creatinine in mg/dl x 1440}}$$

Note: for children is necessary to account the body surface(m2) and to multiply the data of creatinine clearance for 1.73/m2.

Normal Range

Guidance Value for Male	Serum	0.7 - 1.2 mg/dl
	Urine	21 - 26 mg/kg. Body weight / 24 hrs.
Guidance Value for Female	Serum	0.5 - 1.0 mg/dl
	Urine	16 - 22 mg/kg. Body weight / 24 hrs.

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation
Reaction is linear up to 20 mg/dl. For higher values, dilute the sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control
To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery
Cratinine added to a serum matrix containing known amounts of creatinine gave an average recovery of 96%.

Interference
The following substances showed no interference up to the concentrations reported:
Glucose 600 mg/dl, fructose 200 mg/dl, Acetone 20 mg/dl and Ascorbic Acid 20 mg/dl.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V. (%)	No. run
Low	mg/dl	1.32	0.02	1.74	20
High	mg/dl	7.17	0.10	1.34	20
Between run					
Range	U.M	Mean	S.D.	C.V. (%)	No. run
Low	mg/dl	1.32	0.02	1.70	60
High	mg/dl	7.17	0.10	1.35	60

Sensitivity
At 505 nm a concentration of 0.055 mg/dl of Creatinine can estimate.

References

1. Hendry R.J., et al. "Clinical Chemistry- Principles and Technics" Harper & Row, II Ed (1974).
2. Larson K., Clin. Chem Acta. 41, 209, (1972).

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

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