NEO CHEM

CREATININE (Kin.)

(Mod. Jaffe's Kinetic method)

KIT NAME	Pack Size
NEO CHEM - CREATININE (KIN.)	2X100 ML

Intended Use:
Creatinine Test reagent/kit is a medical device intended for estimation of Creatinine in serum or plasma or urine.

Clinical Significance
Creatinine is the catabolic product of creatinine phosphate, which is used by the skeletal muscle. The daily production depends on muscular mass and it is excreted out of the body entirely by the kidneys.

Principle
Creatinine + Sodium Picrate $\xrightarrow{\text{Alkali}}$ CreatininePicrate Complex (yellow to orange)
Intensity of the colour formed is directly proportional to the amount of creatinine present in the sample.

Reagent Composition

R1 Buffer Reagent R2 Picric acid Reagent	Picric Acid- 20 mmol/L Sodium Hydroxide – 15mmol/L EDTA – 30 mmol/L Surfactants
Std conc.	2mg/dl

Working Reagent Preparation
Mix one volume of Reagent (R1) with one volume of Reagent (R2) (according to the requirement).The Working Reagent (WR) is stable for one week when stored in dark at RT.

Stability and Storage
Store below 30ºC.
All the kit contents are stable until the expiry date stated on thelabel. Do not use reagents beyond the expiration date.
Store the vials tightly closed protected from light and preventcontaminations during the use.

Discard if signs of deterioration appear:
- Presence of particles and turbidity.

Materials required

- Photometer or spectrophotometer with a thermostat cell compartment set at 25/30/37ºC, capable of reading at 520nm.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm path length
- Pipettes to measure reagent and samples.

Sample and Stability
Serum or plasma or urine
Serum or heparinized plasma free of hemolysis or urine.
Creatinine is reported to be stable in the sample for 1 day when stored at 2-8^{0}C.
Urine of 24 hours collection is preferred. Dilute the Specimen 1:50 with distilled or deionised water before the assay.

Assay Procedure

KINETIC METHOD:
Pipette into clean dry test tubes labeled as Standard (S) and Test (T)

Addition Sequence	Std	Test
Working Reagent	1000µl	1000µl
Standard (S)	50µl	-
Sample		50µl

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Mix well and read absorbance A0 exactly after 30 seconds. Final absorbance A1 exactly after 60 seconds of Standard (S) & Test (T) against distilled at 520 nm (505-570nm)
Determine ΔA for Standard (S) & Test (T):
ΔAS = AS1 - AS0
ΔAT = AT1 - AT0

Calculation

a) Serum Creatinine (mg/dl) = $\frac{(\Delta AT)}{(\Delta AS)} \times 2$

b) Urine Creatine (gm/L) = $\frac{(\Delta AT)}{(\Delta AS)} \times 2$

c) Urine Creatinine (gm/24 hrs) = (b) x 24 Hrs Urine vol.collectedin Ltrs.

Quality Control
To ensure adequate quality control (QC), each run should include aset of controls (normal and abnormal) with assayed values handledas unknowns.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable results.

Linearity
This procedure is linear upto 30 mg/dl of creatinine. If values exceed this limit, dilute the serum with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Reference Values

	Serum	Urine (24hrs collection)
Males	0.6 – 1.2 mg/dl	1.1 – 3.0 gms
Females	0.5 – 1.1 mg/dl	1.0 – 1.8 gms

It is recommended that each laboratory establish its own normal range representing its patient population.

General System Parameters

Method	Fixed Time(2-Point)
Reaction	Increasing
Wavelength	520 nm (505-570nm)
Blank with	Distilled water
Sample Volume	50 µl
Reagent Volume	1000 µl
Std Conc.	2mg/dl
Incubation Temp.	37°C
Delay Time	30sec
Read Time	60 sec
Linearity	30 mg/dl
Unit	mg/dl

Notes

1. Maintain the reaction time of 20 min as closely as possible since as a longer incubation causes an increase in the values due to the reaction or pseudo chromogen and the determination is not specific and may be affected by the presence of large quantities of reducing substance in the sample. The reaction is temperature sensitive and all the tubes should be maintained at a uniform temperature.

2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Reference

1. Bones, R.W. etal .(1945) J.Bio. Chem 158,581.
2. Toro,G. etal. (1975) practical clinical chem..P : 154

For *in vitro* Diagnostic use only.