

Quantitative determination of Creatinine in serum & urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

| REF | Cont. |
|----------|------------|
| CRE 100 | 2 X 50 ML |
| CRE 200 | 2 X 100 ML |
| CRE 500 | 2 X 250 ML |
| CRE 1000 | 2 X 500 ML |

CLINICAL SIGNIFICANCE

Creatinine is the catabolic product of high energy storage compound, Creatinine Phosphate formed in muscle. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is excreted out of body entirely by the kidneys. Elevated levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure) diabetes acromegaly. Decreased levels are found in muscular dystrophy

PRINCIPLE

Creatinine reacts with alkaline picrate to produce orange coloured complex. Intensity of the colour formed during the fixed time is directly proportional to the amount of creatinine present in the sample.

REAGENT COMPOSITION

Reagent I : NaOH Reagent
Reagent II : Picrate reagent
Creatinine Standard : 2 mg/dl (0.16 mmol/L)

SAMPLE COLLECTION AND PRESERVATION

Serum, heparinized plasma or urine collected by standard procedures. Anticoagulants other than heparin should not be used. Creatinine in serum or plasma is stable for 1 day at 2-8°C. Urine (24 hr) : Dilute sample 1/20 with distilled water. Mix. Multiply results by 20 (dilution factor); Creatinine stability: 7 days at 2-8°C.

REAGENT PREPARATION

Mix equal volumes of the two reagents prior to use. A measuring cylinder may be used for this as the exact volumes are not critical, eg: to 5 mL of Picric Acid reagent add 5 mL of NaOH reagent.

REAGENT STORAGE AND STABILITY

Prior to use:

When stored at 15-30°C and protected from direct sunlight, the reagents are stable until the expiry date stated on the bottle and kit box labels.

Working Reagent:

The working reagent is stable for 3 days when stored capped at 2-8°C

REFERENCE VALUES

| | MEN | WOMEN |
|-----------|-----------|-----------------|
| SERUM | 0.8 - 1.4 | 0.7 - 1.2 mg/dl |
| 24h URINE | 1.0 - 2.0 | 0.8 - 1.8 G/24h |

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

| AUTOMATED PARAMETERS | |
|----------------------|-------------------|
| Wavelength | 500 nm |
| Measurement | Against D/W blank |
| Cuvette | 1 cm light path |
| Reaction Temperature | Room Temperature |
| Reaction Type | Fixed Time |
| Reaction Direction | Increasing |
| Sample Volume | 100 µl |
| Reagent Volume | 1000 µl |
| Delay/Lag/Time | 30 sec. |
| Interval Time | 60 sec. |
| No. of Readings | 01 |
| Low Normal at 37°C | 0.8 mg/dl |
| High Normal at 37°C | 1.4 mg/dl |
| Linearity at 37°C | 25 mg/dl |

MANUAL ASSAY PROCEDURE

PIPETTE INTO TEST TUBES

| | BLANK | STD | SAMPLE |
|-----------------|---------|---------|---------|
| Sample | - | - | 100 µl |
| Standard | - | 100 µl | - |
| Working Reagent | 1000 µl | 1000 µl | 1000 µl |

Mix and after 30 secs at R.T., read initial absorbance and start timer simultaneously. Read again after 1 min. determines ΔAbs/min. of standard (As) and sample (Ac) against reagent blank.

CALCULATION

| | |
|---------------------------|--|
| Creatinine mg /dl Serum | $\Delta A / \Delta A_s \times C$ |
| Creatinine mg /dl Urine | $\Delta A / \Delta A_s \times C \times 20$ |
| Urine Creatinine g/24 Hrs | Urine Creatinine in g/L x Vol. of urine in 24 Hrs. |

C = Concentration Standard

LINEARITY

The method is linear to a concentration of 25 Mg/dl

QUALITY CONTROL

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

REFERENCES

Henry, J.B, Young D.S. teitz N.W, Vasilades, J, Can. Chem (1972), 18.