**CREATININE ENZYMATIC**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Pack Name</th>
<th>Packaging (Content)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XSYS0085</td>
<td>CREA ENZ 200</td>
<td>R1: 5 x 30 ml, R2: 5 x 10 ml</td>
</tr>
</tbody>
</table>

**INTENDED USE**
Diagnostic reagent for quantitative in vitro determination of Creatinine in human serum, plasma and urine.

**CLINICAL SIGNIFICANCE**
Creatinine is a waste product formed in muscle from the high energy storage compound, creatine phosphate. The amount of creatinine produced is fairly constant (unlike Urea) and is primarily a function of muscle mass. It is not greatly affected by diet, age, sex or exercise. Creatinine is removed from plasma by glomerular filtration and then excreted in urine without any appreciable resorption by the tubules.

Creatinine is used to assess renal function, however, serum creatinine levels do not start to rise until renal function has decreased by at least 50%.

**PRINCIPLE**
In the first reaction, creatinase and sarcosine oxidase are used in the enzymatic hydrolysis of endogenous creatine to produce hydrogen peroxide, which is eliminated by catalase.

Creatinase and 4-aminoantipyrine are added, and only the creatine generated from creatinine by creatinase is hydrolysed sequentially by creatinase and sarcosine oxidase to produce hydrogen peroxide. This newly formed hydrogen peroxide is measured in a coupled reaction catalysed by peroxidase, with N-ethyl-N-sulphopropyl-m-toluidine (ESPMT) as a chromogen.

**SPECIMEN COLLECTION & HANDLING**
Use serum, plasma (heparin, EDTA), urine. It is recommended to follow NCCLS procedures (or similar standardized conditions).

**Stability**
- In serum / plasma: 7 days at 4–25°C
- In urine: 2 days at 20–25°C

For the determination in urine use 24 hours specimen. It is important to exactly measure the volume of collected urine. Dilute urine samples in 1+19 ratio with distilled water and multiply results by 20.

**QUALITY CONTROL**
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

**CALCULATION**
Results are calculated automatically by the instrument.

**UNIT CONVERSION**
mg/dl x 88.4 = μmol/l

**EXPECTED VALUES**

<table>
<thead>
<tr>
<th></th>
<th>Serum</th>
<th>Urine</th>
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</thead>
<tbody>
<tr>
<td>Male:</td>
<td>0.7 - 1.3 mg/dl</td>
<td>14 - 26 mg/kg/day</td>
</tr>
<tr>
<td>Females:</td>
<td>0.6 - 1.1 mg/dl</td>
<td>11 - 20 mg/kg/day</td>
</tr>
<tr>
<td>Newborn:</td>
<td>0.3 - 1.0 mg/dl</td>
<td>8 - 20 mg/kg/day</td>
</tr>
<tr>
<td>Infant:</td>
<td>0.2 - 0.4 mg/dl</td>
<td>8 - 20 mg/kg/day</td>
</tr>
<tr>
<td>Child:</td>
<td>0.3 - 0.7 mg/dl</td>
<td>8 - 22 mg/kg/day</td>
</tr>
<tr>
<td>Adolescent:</td>
<td>0.5 - 1.0 mg/dl</td>
<td>8 - 30 mg/kg/day</td>
</tr>
</tbody>
</table>

**INTERFERENCES**
Following substances do not interfere: haemoglobin up to 5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 1000 mg/dl.

**WARNING AND PRECAUTIONS**
For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but Reagent R2 contains less than 0.1% sodium nitrite – classified as toxic and dangerous substance for the environment.

**WASTE MANAGEMENT**
Please refer to local legal requirements.
REFERENCES

SYMBOLS USED ON LABELS

1. REF Catalogue Number
2. Manufacturer
3. See Instruction for Use
4. LOT Lot Number
5. CE Mark - Device comply with the Directive 98/79/EC
6. Storage Temperature
7. Expiry Date
8. IVD In Vitro Diagnostics
9. CONT Content