**INTENDED USE**
Reagent for quantitative in vitro determination of creatinine in biological fluids.

**SUMMARY OF TEST**
Between 1 and 2% of muscle creatine is converted to creatinine daily. Because the amount of endogenous creatinine produced is proportional to muscle mass, the production varies with age and sex. Because creatinine is endogenously produced and released into body fluids at a constant rate and its plasma levels maintained within narrow limits, its clearance may be measured as an indicator of glomerular filtration rate (GFR).

**PRINCIPLE OF THE METHOD**
Creatinine reacts with picric acid in alkaline environment to form a color complex. Developing of this red color may be followed photometrically at 500-520 nm. The association constant as A₄. After exactly 60 seconds, the absorbance as A₄.

**KIT COMPONENTS**
For in vitro diagnostic use only. The components of the kit are stable until expiration date on the label. Keep away from direct light sources.

- **CREA R1**
  - 0500: 2 x 125 ml (liquid) blue cap
  - 1000: 2 x 250 ml (liquid) blue cap

- **CREA R2**
  - 0500: 2 x 125 ml (liquid) red cap
  - 1000: 2 x 250 ml (liquid) red cap

Composition in the test: picric acid 14 mM, NaOH 0.18 M, sodium tetraborate 10 mM, surfactant.

**STORAGE**
Store all components at 15-25°C.

**MATERIALS REQUIRED BUT NOT SUPPLIED**
Current laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

**PRECAUTIONS**

**Crea R1:** Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). IF IN EYES: Rinse cautiously with water for several minutes. IF INHALED: Remove to fresh air. IF INGESTED: Do not induce vomiting. If vomiting occurs, contact a physician immediately. Store away from direct light sources.

**Crea R2:** It is not classified as hazardous.

**EXPECTED VALUES**

- Serum/plasma samples:
  - Men: 0.7 - 1.2 mg/dl (62 - 105 μmol/l)
  - Women: 0.6 - 1.1 mg/dl (53 - 97 μmol/l)

- 24h urine:
  - Men: 1000 - 2000 mg/24h (8.85 - 17.70 mmol/24h)
  - Women: 800 - 1800 mg/24h (7.08 - 15.93 mmol/24h)

Each laboratory should establish appropriate reference intervals related to its population.

**QUALITY CONTROL AND CALIBRATION**
It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

- QUANTINORM CHEMA with normal or close to normal control values
- QUANTIPATH CHEMA with pathological control values,

If required, a multiparametric, human based calibrator is available:

- AUTOCAL H

Please consult Customer Care for further information.

**TEST PERFORMANCE**

**Linearity**
The method is linear up to 20 mg/dl.

- If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

**Sensitivity/limit of detection (LOD)**
The limit of detection is 0.2 mg/dl.

**Interferences**

<table>
<thead>
<tr>
<th>Interference</th>
<th>Observation</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>≤ 500 mg/dl</td>
<td></td>
</tr>
<tr>
<td>Lipids</td>
<td>≤ 1250 mg/dl</td>
<td></td>
</tr>
<tr>
<td>Bilirubin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Precision**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sample 1</td>
<td>1.25</td>
<td>0.03</td>
<td>2.60</td>
</tr>
<tr>
<td>sample 2</td>
<td>3.87</td>
<td>0.07</td>
<td>1.90</td>
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<tr>
<td>Inter-assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sample 1</td>
<td>1.31</td>
<td>0.04</td>
<td>2.90</td>
</tr>
<tr>
<td>sample 2</td>
<td>3.80</td>
<td>0.14</td>
<td>3.80</td>
</tr>
</tbody>
</table>

**Methods comparison**
A comparison between Chema and a commercially available product gave the following results:

Creatinine Chema = x
Creatinine competitor = y
n = 104

\[ y = 0.982x - 0.081 \text{ mg/dl} \quad r^2 = 0.94 \]

**REFERENCES**

**WASTE DISPOSAL**
This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

**CONTACT**
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**SYMBOLS**
- in vitro diagnostic medical device
- batch code
- catalogue number
- temperature limit
- use by date
- caution
- consult instructions for use