Reagent kit for determination of creatinine concentration in serum and urine. Colorimetric, enzymatic test.

Creatinine is released during metabolism of creatine phosphate, and is excreted by the kidneys. Creatinine concentration in blood and in urine represents a primary indicator for renal function, especially for glomerular filtration. Increased levels are associated with acute renal impairment, chronic nephritis, obstruction of the urinary tract, strong physical overloading. Low creatinine concentrations are found in conditions with juvenile diabetes mellitus, pregnancy and muscular dystrophy.

**Reference values**

**Serum creatinine:**
- Male: 53-100 µmol/l (0.6-1.13 mg/dl)  
- Female: 40-88 µmol/l (0.45-1.00 mg/dl)

**Urine:** 7-16 mmol/24 h (0.08-0.18 mg/dl/24h)

It is recommended that each laboratory should assign its own normal range.

**Procedure**

**Discard cloudy reagent.** Avoid contamination by using clean laboratory materials (pipettes, plastic vials, ... for analyzers.

**Serum**

Serum free of haemolysis. Urine diluted in ratio of 1:100 with distilled water.

Mix and read the absorbance (A1) after a 5-minute incubation then add:

- **R1**  
  - Blank: 1 ml  
  - Standard: 1 ml  
  - Sample: 1 ml

- **Distilled water**: 45 µl

- **Standard**: 45 µl

- **Sample**: 45 µl

Mix and read the absorbance (A2) after a 5-minute incubation.

**Calibration:**

- **S1:** Distilled water  
- **S2:** Creatinine standard Cat. No.: 50911 or Roche C.F. A.S. (Calibrator for automated system)  
- **Randomo Calibration Serum Level I** or **Randomo Calibration Serum Level II**  
- **Calibration frequency:** Two point calibration is recommended

**Quality control**

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

**CALCULATION**

\[
\frac{A2 - A1}{A2 - A1}_{\text{standard}} \times C_{\text{standard}} = C_{\text{sample}}
\]

Where:
- \( A \) = Absorbance
- \( C \) = Concentration

**PERFORMANCES DATA**

The following data were obtained using the Olympus 600 analyzer (37 °C).

**Linearity**

The test is linear up to 1770 µmol/l (20 mg/dl)

**Sensitivity**

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs is equivalent to 2.2 µmol/l (0.025mg/dl) creatinine concentration at 546 nm.

**Precision**

**Reproducibility**

<table>
<thead>
<tr>
<th>Average concentration (µmol/l)</th>
<th>SD</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>112</td>
<td>0.94</td>
</tr>
<tr>
<td>Sample II</td>
<td>352</td>
<td>3.48</td>
</tr>
</tbody>
</table>

**Repeatability**

<table>
<thead>
<tr>
<th>Average concentration (µmol/l)</th>
<th>SD</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>99</td>
<td>1.08</td>
</tr>
<tr>
<td>Sample II</td>
<td>157</td>
<td>1.31</td>
</tr>
</tbody>
</table>

**Correlation**

Comparative studies were done to compare our reagent with another commercial Creatinine Jaffe reagent. The results from these studies are detailed below.

**Specificity**

Bilirubin 684 µmol/l (40 mg/dl), ascorbic acid 1136 mg/dl (11,36 mmol/l) and haemoglobin 80 µmol/l (500 mg/dl) don’t interfere with the assay up to the given levels.

**Note**

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

**For in vitro diagnostic use only.**

The following symbols are used on labels:

- **For in vitro diagnostic use**
- **Use by (last day of the month)**
- **Temperature limitation**
- **Batch Code**
- **Code**

**Bibliography**