**INTENDED USE**
Reagent kit for the determination of creatinine concentration in serum and urine. A colorimetric, alkaline picrate method (Jaffé).

**CLINICAL SIGNIFICANCE**
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 that 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.

**METHODOLOGY**
Creatinine forms with alkaline picrate (in ratio of 1:1) a colored creatinine picrate complex containing ionic bounds. The rate of formation of the colored complex is proportional to the creatinine concentration.

**REAGENTS**
- **Contents**: Concentration
  - R1: Picric acid 14 mmol/L
  - R2: Sodium hydroxide 250 mmol/L
- **STD**: Creatinine Standard 2 mg/dL or 177 µmol/L

**STORAGE CONDITIONS**
- Store the kit at 15-25°C.
- The reagent is stable until the expiration date indicated on the box when stored at the recommended conditions.

**SPECIMEN COLLECTION AND HANDLING**
- **Serum**: Use non-haemolysed serum.
- **Urine**: 24 hours urine specimens, diluted 1+49 with double distilled water.

**EXPECTED VALUES**
- **Creatinine**
  - Serum: Male 0.6 – 1.2 mg/dL (53 – 106 µmol/L), Female 0.5 – 1.0 mg/dL (44 – 88 µmol/L)
  - Urine 24h: Male 1.0 – 2.0 g/day, Female 0.8 – 1.8 g/day

**CREATININE CLEARANCE (ENDOGENOUS)**
- Male: 97 – 137 mL/minute
- Female: 88 – 128 mL/minute

**INSTRUCTIONS FOR USE**

**Preparation of reagents**
Mix equal volume of R1 and R2

**Procedure Parameters**
- **Wavelength**: 505 nm (490 – 510) nm
- **Optical path**: 1 cm path length
- **Temperature**: 20-25°C or 37°C
- **Measurement**: against distilled water
- **Reaction slope**: Increasing

**Calculations**

**Creatinine Concentration in Serum**

- (mg/dL) = \( \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{STD}}} \times 2 \)
- (µmol/L) = \( \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{STD}}} \times 177 \)

**Creatinine Concentration in Urine**

- (mg/dL) = \( \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{STD}}} \times 2 \times 50 \) (dilution factor)
- (µmol/L) = \( \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{STD}}} \times 177 \times 50 \) (dilution factor)

**Creatinine concentration in 24 h urine**

- mg creatinine/24 h = \( \frac{\text{mg/dL} \times 100 \times \text{mL Urine/24 hrs}}{1000} \)
- µmol creatinine/24 h = \( \frac{\text{µmol/L} \times \text{mL Urine/24 hrs}}{1440} \)

**Creatinine Clearance**

- \( \frac{\text{mg creatinine/dL urine} \times \text{mL urine 24 hrs}}{\text{mg creatinine/dL serum} \times 1440} \) (mL/min)
LINEARITY

The test is linear up to a creatinine concentration of 10 mg/dL (=884 μmol/L) in serum or 500mg/dL (= 44.2 mmol/L) in urine. Samples above this concentration should be diluted 1 + 4 with normal saline. (Result x 5)

PERFORMANCE DATA

The following data was obtained using the Chemhouse Creatinine Reagent on a well maintained automated clinical chemistry analyzer. Users should establish product performance on their specific analyzer used.

IMPRECISION

Imprecision was evaluated using two levels of commercial control.

<table>
<thead>
<tr>
<th></th>
<th>LEVEL I</th>
<th>LEVEL II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of samples</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Mean (μmol/L / mg/dL)</td>
<td>186 / 2.1</td>
<td>628 / 7.1</td>
</tr>
<tr>
<td>Within run: SD (μmol/L / mg/dL)</td>
<td>4 / 0.05</td>
<td>7 / 0.08</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.8</td>
<td>1.4</td>
</tr>
<tr>
<td>Within run: SD (μmol/L / mg/dL)</td>
<td>4 / 0.05</td>
<td>7 / 0.08</td>
</tr>
<tr>
<td>CV (%)</td>
<td>2.2</td>
<td>1.1</td>
</tr>
<tr>
<td>Between Day: SD (μmol/L / mg/dL)</td>
<td>8 / 0.09</td>
<td>13 / 0.15</td>
</tr>
<tr>
<td>CV (%)</td>
<td>2.2</td>
<td>1.1</td>
</tr>
</tbody>
</table>

METHOD COMPARISON

Comparison studies were carried out using a similar commercially available Creatinine reagent as a reference. Serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Number of sample pairs | 50
Range of sample results | 60 - 1170 μmol/L (0.68 - 13.20 mg/dL)
Mean of reference method results | 210 μmol/L (2.4 mg/dL)
Mean of Chzemhouse Creatinine results | 200 μmol/L (2.3 mg/dL)
Slope | 0.95
Intercept | - 4 μmol/L (-0.04 mg/dL)
Correlation coefficient | 0.998

BIBLIOGRAPHY