PERFORMANCE DATA

- **Analytical range**
The reagent is linear from 0.06 to 10 mg/dL.

- **Detection limit**
The detection limit is 0.053 mg/dL.

- **Precision**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 1</td>
<td>1.28</td>
<td>0.006</td>
<td>0.47%</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Control 2</td>
<td>3.67</td>
<td>0.010</td>
<td>0.27%</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Patient</td>
<td>1.45</td>
<td>0.012</td>
<td>0.83%</td>
<td>mg/dl</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 1</td>
<td>1.34</td>
<td>0.012</td>
<td>0.90%</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Control 2</td>
<td>3.66</td>
<td>0.014</td>
<td>0.38%</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Patient</td>
<td>1.47</td>
<td>0.016</td>
<td>1.09%</td>
<td>mg/dl</td>
</tr>
</tbody>
</table>

- **Correlation**
A comparative study has been performed between the Greiner method and another commercial reagent on 34 human serum samples.

The parameters of linear regression are as follows:

\[ y = 0.951 \times + 0.049 \text{ mg/dl} \quad r = 0.999 \]

INTERFERENCES
Interferences are found according to the relevant literature.

BIBLIOGRAPHY


SYMBOLS USED

- **IVD** For in vitro diagnostic medical use
- **LOT** Batch Code
- **Use by** Temperature limitation
CREATININE
Jaffe – Kinetic (1 + 1 Reagent)

<table>
<thead>
<tr>
<th>Cat.No</th>
<th>Package Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>122 100</td>
<td>R1 = 1 x 100 ml / R2 = 1 x 100 ml + Standard (10 ml)</td>
</tr>
</tbody>
</table>

METHOD

PRINCIPLE
The rate of formation of a colored complex compound between creatinine and alkaline picrate is measured. The effects of interfering substances are reduced through the kinetic procedure.

REAGENTS
Composition (concentrations in the testmixture)

<table>
<thead>
<tr>
<th></th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>Sodiumhydroxide 160 mmol/L</td>
</tr>
<tr>
<td>R2</td>
<td>Picric acid 4.0 mmol/L</td>
</tr>
<tr>
<td>Standard</td>
<td>Creatinine 2.0 mg/dL (176.8 µmol/L)</td>
</tr>
</tbody>
</table>

Precautions
- For in vitro diagnostic use only.
- IRRITANT!

R1 contains sodiumhydroxide (160 mmol/L):

R36/38 : Irritating for eyes and skin.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37 : Wear suitable gloves.
S39 : Wear suitable eye/face protection.
S45 : In case of incident or if feeling faint, see a physician.

Stability
When stored at 2-25° C and protected from light, the reagents are stable up to the expiry date printed on the labels.

Preparation and stability of Working Reagent:
Mix 1 volume of R1 with 1 volume of R2.

Stability : 5 hours at 20-25 °C

SAMPLES
Serum. and plasma (EDTA/heparine)
Urine, diluted 1/20 with distilled water.

REFERENCE VALUES
Serum, plasma:

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/dL</td>
<td>0.6 - 1.3</td>
</tr>
<tr>
<td>µmol/L</td>
<td>6 - 13</td>
</tr>
</tbody>
</table>

Urine:

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/L</td>
<td>0.80 - 1.80</td>
</tr>
<tr>
<td>mmol/24 h</td>
<td>7 - 16</td>
</tr>
</tbody>
</table>

Note: It is recommended for each laboratory to establish and maintain its own reference values. The given data here are only an indication.

PROCEDURE
This reagent can be used manually (see method below) and on most analyzers. Applications are available on request.

Wavelength : 492 nm (480-520)
Temperature : 37°C
Cuvette : 1 cm light path
Read against distilled water

<table>
<thead>
<tr>
<th>Working reagent : 1 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard or Sample: 50 µL</td>
</tr>
</tbody>
</table>

Mix and read the optical absorbance (A1) 60 seconds after the sample or standard addition. Exactly 2 minutes after the first reading take second reading (A2).

CALCULATION

\[
\frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{Standard}}} \times C \quad \text{mg/dL} \quad C = 2
\]

\[
\frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{Standard}}} \times C \quad \text{µmol/L} \quad C = 177
\]

C = standard concentration

Take dilution factor into account for calculation of concentration in urine.

CALIBRATION & QUALITY CONTROL
For the calibration of automated analyzers Greiner Multicalibrator is recommended, for quality control use Greiner normal and abnormal controls Unitrol I and Unitrol II.