CREATININE liquicolor

Jaffé-Reaction
Photometric Colorimetric Test for Kinetic Measurements. Method without Deproteinisation

Package size

<table>
<thead>
<tr>
<th>REF</th>
<th>10051</th>
<th>200 ml</th>
<th>Complete kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td></td>
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</table>

Method
Creatinine forms in alkaline solution an orange-red coloured complex with picric acid. The absorbance of this complex is proportional to the creatinine concentration in the sample.

Principle
Creatinine + Picric acid $\rightarrow$ Creatinine-picrate complex

Contents, Reagent Composition

<table>
<thead>
<tr>
<th>PIC</th>
<th>1 x 100 ml Picric Acid</th>
<th>26 mmol/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAOH</td>
<td>1 x 100 ml Sodium Hydroxide</td>
<td>1.6 mol/l</td>
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</table>

STD
1 x 25 ml Standard
Creatinine 2 mg/dl or 176.8 µmol/l

Reagent Preparation
Dilute NAOH with dist. water in the ratio 1 + 4. Store the solution in a plastic bottle.
Mix PIC and diluted NAOH for the working reagent in the ratio 1 + 1. The STD is ready for use.

Reagent Stability
The reagents / diluted sodium hydroxide are stable, even after opening, up to the stated expiry date when stored at 15...25°C. Contamination must be avoided. The working reagent, protected from light, is stable for 4 weeks at 15...25°C.

Specimen
Serum, heparinised plasma or urine.
Avoid haemolysis!
Stability: 24 hours at 2...8°C
Dilute urine 1 + 49 with dist. water.

Assay
Wavelength: Hg 492 nm (490 - 510 nm)
Optical path: 1 cm
Temperature: 25°C, (for 37°C procedure ask Human GmbH)
Measurement: against air (increasing absorbance)
Warm the reagents and cuvettes to the desired temperature and keep constant (± 0.5°C) for the duration of the test.

Pipetting Scheme

<table>
<thead>
<tr>
<th>Pipette into cuvettes</th>
<th>Semi-micro</th>
<th>Macro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample / STD</td>
<td>100 µl</td>
<td>200 µl</td>
</tr>
<tr>
<td>Working reagent</td>
<td>1000 µl</td>
<td>2000 µl</td>
</tr>
</tbody>
</table>

Mix and start the stopwatch. After 30 sec. read the absorbance A1.
Read the absorbance A2 exactly after 2 min. A2 - A1 = $\Delta A_{\text{sample}}$ or $\Delta A_{\text{STD}}$

Calculation

1. Serum / Plasma
Please use only the standard supplied with the kit.

$$ C = 2.0 \times \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{STD}}} \quad \text{[mg/dl]} $$

$$ C = 176.8 \times \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{STD}}} \quad \text{[µmol/l]} $$

2. Urine

$$ C = 100 \times \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{STD}}} \quad \text{[mg/dl]} $$

Creatinine concentration in 24 h urine:

$$ C = \frac{\text{mg creatinine/dl urine} \times \text{ml urine/24 h}}{1440} \quad \text{[mg/dl]} $$

$$ C = \frac{\text{mg creatinine/dl urine} \times 0.00884 \times \text{mmol/24 h}}{1440} \quad \text{[mg/dl]} $$

Conversion of [mg/dl] into [µmol/l] and vice versa:

$$ \text{[µmol/l]} = \frac{\text{[mg/dl]} \times 88.402}{\text{[µmol/l]} \times 0.0113} $$

Performance Characteristics

Linearity
The test is linear up to a creatinine concentration in serum of 13 mg/dl or 1,150 µmol/l, in urine of 500 mg/dl or 44,200 µmol/l.
Dilute samples with a higher concentration in serum, plasma or diluted urine 1 + 5 with physiological saline (0.9%) and repeat the assay. Multiply the result by 6.

Typical performance date can be found in the Verification Report, accessible via www.human.de/data/gb/vr/su-crea1.pdf or www.human.de/data/gb/vr/su-crea1.pdf

Reference Values

<table>
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<tr>
<th>Serum</th>
<th>[mg/dl]</th>
<th>[µmol/l]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>0.6 - 1.1</td>
<td>53 - 97</td>
</tr>
<tr>
<td>Women</td>
<td>0.5 - 0.9</td>
<td>44 - 80</td>
</tr>
</tbody>
</table>

Quality Control
All control sera with creatinine values determined by this method can be employed. We recommend the use of our animal serum based HUMATROL or our human serum based SERODOS quality control sera.

Automation
Proposals to apply the reagents on analysers are available on request. Each laboratory has to validate the application in its own responsibility.

Notes
1. The reaction is highly sensitive to temperature. The reaction temperature must be kept constant at 25°C.
2. PIC is harmful when inhaled, swallowed or in contact with the skin. If PIC comes into contact with the skin or mucous membranes wash with plenty of water. In case of sickness, contact a doctor.
3. The assay can be affected by the presence of reducing compounds. The interference can be partially eliminated by boiling the urine for a short time.
4. A slight precipitate in the sodium hydroxide solution is insignificant.

References

3. Schirmeister, J. et al., Dtsch. med. Wschr. 89, 1018 and 1640 (1964)
5. ISO 15223 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.

SU-CREA1
INF 105102 GB
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