Creatinine – Jaffè

Intended Use
Spectrum Diagnostics creatinine reagent is intended for the in-vitro quantitative diagnostic determination of creatinine in human serum or urine on both automated and manual systems.

Background
Creatine is synthesized in kidney, liver and pancreas. It is transported in blood to other organs such as muscle and brain where it is phosphorylated to phosphocreatine. Some free creatine in muscle is converted to creatinine daily and the amount of creatine produced is proportional to muscle mass. In the absence of renal disease, excretion rate of creatinine in an individual is relatively constant. Therefore, measurement of creatinine clearance is useful in detecting renal disease and estimating the extent of impairment of renal function. Both serum creatinine and urea levels are elevated in patients with renal malfunction, especially decreased glomerular filtration. In the early stage of kidney damage, increase in serum urea level usually precedes the increase in serum creatinine. However, serum urea levels may be affected by dehydration, diet and protein metabolism. On the other hand, serum creatinine levels tend to be constant and unaffected by such factors. Thus serum creatinine is a significantly more reliable renal function screening test than serum urea.

Method
Buffered Kinetic jaffé reaction without deproteinization.

Assay Principle
Creatine reacts with picric acid under alkaline condition to form a yellow-red complex. The absorbance of the color produced, measured at a wavelength of 492 nm, is directly proportional to creatinine concentration in the sample.

Reagents
Standard (ST) 2 mg/dL 177 µmol/L

Reagent 1 (R1) Picric acid 25 mmol/L

Reagent 2 (R2) Sodium hydroxide 0.4 mol/L Irritant (x) R36/38: Irritating to eyes and skin. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection.

Precautions and Warnings
Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation
Prepare working solution as following: Combine one volume of R1 with one volume of R2 e.g. 1.0 ml R1 + 1.0 ml R2.

Calculation
A2 – A1 = Aspecimen or Astandard.

Concentration of creatinine in serum:
Creatinine (mg/dL) = \frac{Aspecimen}{Astandard} \times 2

Concentration of creatinine in urine:
Creatinine (mg/dL) = \frac{Aspecimen}{Astandard} \times 2 \times 50
Creatinine clearance (ml/minutes):

\[
\text{mg creatinine / dl urine x ml urine / 24 hours} \\
\text{mg creatinine / dl serum x 1440}
\]

Correction for body surface area can be done using the following formula for creatinine clearance:

\[
\frac{UCr \times V}{PCr \times A} \times 1.73
\]

Where:
- UCr = Concentration of creatinine in urine (mg/dl)
- PCr = Concentration of creatinine in plasma (mg/dl)
- V = Volume of urine flow in mL/min.
- A = Body surface area in square meter.
- 1.73/A = Factor normalizes clearance for average body surface.

Note: Body surface area can be determined from height weight via normograms in Tietz (6).

Quality Control

Normal & abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>20</td>
</tr>
<tr>
<td>Mean (mg/dL)</td>
<td>1.55</td>
</tr>
<tr>
<td>SD</td>
<td>0.069</td>
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<tr>
<td>CV%</td>
<td>4.45</td>
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</table>

Run to run (Repeatability)

Methods Comparison

A comparison between Spectrum Diagnostics Creatinine Jaffé reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.991 was obtained.

Sensitivity

When run as recommended, the minimum detection of this assay is 0.31 mg/dL creatinine (0.027 mmol/L).

Linearity

The reaction is linear up to serum creatinine concentration of 20mg/dL (1.77 mmol/L). Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Interfering Substances

Serum, plasma

Haemolysis

Erythrocyte contamination doesn’t elevate results.

Icterus

Serum bilirubin levels higher than 5 mg/dL (85 µmol/L) decrease serum creatinine.

Lipemia

Lipemic specimens may cause high absorbance flagging. Diluted sample treatment may be recommended.

Expected Values

<table>
<thead>
<tr>
<th></th>
<th>Serum, plasma</th>
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<tbody>
<tr>
<td></td>
<td>Females</td>
</tr>
<tr>
<td></td>
<td>0.7-1.3 mg/dL</td>
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<tr>
<td></td>
<td>62-115 µmol/L</td>
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<table>
<thead>
<tr>
<th>Urine(24 hrs)</th>
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<tbody>
<tr>
<td></td>
<td>Females</td>
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<tr>
<td></td>
<td>0.9 – 1.6 g/24 hrs</td>
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<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>Females</th>
<th>Males</th>
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<tr>
<td></td>
<td>75 – 115 ml / min.</td>
<td>85 – 125 ml / min.</td>
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Analytical Range

0.31 – 20 mg/dL (0.027-1.77 mmol/L).

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

References


ORDERING INFORMATION

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<thead>
<tr>
<th>CATALOG NO.</th>
<th>QUANTITY</th>
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<tbody>
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<td>2 x 50 ml</td>
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<tr>
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</tr>
<tr>
<td>234 002</td>
<td>4 x 100 ml</td>
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<tr>
<td>234 003</td>
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<tr>
<td>234 006</td>
<td>4 x 250 ml</td>
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</table>

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