## Storage and Stability

Reagents are ready to use.

### Substrate Start:
- Concentration of creatinine in the sample.
- Difference in absorbance at fixed times during conversion is proportional to the creatinine.
- Creatinine forms a coloured orange-red complex in an alkaline picrate solution. The reaction is measured photometrically, using a colorimetric method (mod. Jaffé).

### Test Principle

Creatinine in serum, plasma or urine on photometric systems

### Specimen Collection and Storage

Sample preparation (Urine): Dilute urine 1+9 with dist. water. Multiply result by 50. (The urine controls Diacon Urine must be prediluted in the same way as patient samples).

### Interpreting Results

2. Colorimetric, "mod. Jaffé", 2 point kinetic, increasing reaction
3. Hg 492 nm (490 nm - 510 nm)
4. 2 – 25 °C
5. 24 months

### Substrate Start

#### Storage
- Stability: up to the expiration date
- Sample Start (Working Reagent):
  - Stability: at 15 – 25 °C
  - 5 hours

### Warnings and Precautions

1. Reagent 1: Warning
   - H280: May be corrosive to metals.
   - H315: Causes skin irritation.
   - H319: Causes serious eye irritation.
   - P234: Keep only in original container.
   - P264: Wash hands and face thoroughly after handling.
   - P280: Wear protective gloves/protective clothing/eye protection.
   - P382+P370: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
   - P333+P313: If eye irritation persists: Get medical advice/attention.
   - P335: Absorb spillage to prevent material damage.

2. Reagent 2: Warning
   - H280: May be corrosive to metals.
   - P234: Keep only in original container.

### General Information

- Temperature: 2 – 25 °C
- Shelf life: 24 months
- Sample: Serum, heparin plasma, urine

### Intended Use

Diagnostic reagent for quantitative in vitro determination of creatinine in human serum, plasma or urine on photometric systems.

### Diagnostic Significance

1. Creatinine is a waste product excreted by the kidneys mainly by glomerular filtration. The concentration of creatinine in plasma of a healthy individual is fairly constant, independent from water intake, exercise and rate of urine production. Therefore, increased plasma creatinine values always indicate decreased excretion, i.e. impaired kidney function. The creatinine clearance enables a quite good estimation of the glomerular filtration rate (GFR) which allows better detection of kidney diseases and monitoring of renal function. For this purpose creatinine is measured simultaneously in serum and urine collected over a defined time period.

### Test Procedure

1. Pipette into test tubes
   - Blank
   - Std/Cal
   - Sample
2. Reagent 1
   - 1000 µL
   - 1000 µL
   - 1000 µL
3. Reagent 2
   - 250 µL
   - 250 µL
   - 250 µL
4. Mix Incubate 0 - 5 min, then add:
   - Reagent 2
   - 1000 µL
   - 1000 µL
   - 1000 µL
5. Calculation:
   - Creatinine [mg/dL] = \( \frac{A \times \text{Conc. Std/Cal} \times 50}{A \text{ Std/Cal}} \)
   - Creatinine [mg/dL] = \( \frac{A \times \text{Conc. Std/Cal} \times 50}{A \text{ Std/Cal}} \)

### Automation

Special adaptations for automated analysers can be made on request.

### Interpretation of Results

#### Calculation

- Serum/Plasma:
  - Creatinine [mg/dL] = \( \frac{A \times \text{Conc. Std/Cal} \times 50}{A \text{ Std/Cal}} \)
- Urine:
  - Creatinine [mg/dL] = \( \frac{A \times \text{Conc. Std/Cal} \times 50}{A \text{ Std/Cal}} \)
Creatinine Clearance [7]

\[ \text{[mL/min/1.73 m²]} = \frac{\text{mg Creatinine/100 mL Urine} \times \text{mL Urine}}{\text{mg Creatinine/100 mL Serum} \times \text{min Urine collection time}} \]

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m²).

Unit Conversion

Creatinine [mg/dL] x 88.4 = Creatinine [µmol/L]

COMPENSATED METHOD [3, 4]

Picric acid which forms the colored complex reacts unspecifically with interfering serum components, so-called pseudo-creatinines. This leads to falsely elevated creatinine values in serum and plasma samples especially in the low measuring range.

To compensate these interferences the calibration factor for the compensated method indicated in the value sheet of Dialac Auto has to be used for calculation. Additionally 0.3 mg/dL (27 µmol/L) has to be subtracted from the calculated creatinine value. For use of the compensated method calibration with the calibrator Diacal Auto is strictly recommended. The method is applicable only for serum and plasma samples.

QUALITY CONTROL AND CALIBRATION

All controls with Creatinine values determined by this method can be used. We recommend the Dialab serum controls Diasoc N (control serum with values in the normal range) and Diasoc P (control serum with values in the abnormal range) as well as the Dialab urine controls Diacur H20 Level 1 (urine control normal) and Level 2 (control urine abnormal). Each laboratory should establish corrective action in case of deviations in control recovery.

Calibration

The assay requires the use of a creatinine standard or calibrator. We recommend the Dialab Creatinine Standard and the Dialab multi calibration serum Diacal Auto

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine creatinine concentrations with a measuring range from 0.2 – 15 mg/dL (18 – 1330 µmol/L). When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.2 mg/dL (17.7 µmol/L).

PRECISION (at 37 °C)

<table>
<thead>
<tr>
<th></th>
<th>n = 20</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample 1</td>
<td>1.05</td>
<td>0.01</td>
<td>1.30</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>1.24</td>
<td>0.01</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>Sample 3</td>
<td>6.73</td>
<td>0.06</td>
<td>0.93</td>
<td></td>
</tr>
<tr>
<td>Inter-assay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample 1</td>
<td>0.81</td>
<td>0.03</td>
<td>3.63</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>1.00</td>
<td>0.01</td>
<td>0.87</td>
<td></td>
</tr>
<tr>
<td>Sample 3</td>
<td>5.73</td>
<td>0.05</td>
<td>0.85</td>
<td></td>
</tr>
</tbody>
</table>

SPECIFICITY/INTERFERENCES

no interference up to:

- Ascorbic acid 30 mg/dL
- Bilirubin 4 mg/dL
- Hemoglobin 500 mg/dL
- Triglycerides 2000 mg/dL

For further information on interfering substances refer to Young DS [10].

METHOD COMPARISON

A comparison of Dialab Creatinine (y) with a commercially available Jaffé method (x) using 68 human sera samples within a range of 0.6 – 10 mg/dL (53.0 – 884 µmol/L) gave following results:

\[ y = 1.014x - 0.031 \text{mg/dL}; r = 1.000 \]

A comparison of Dialab Creatinine compensated (y) with an enzymatic method (x) using 65 human sera samples within a range of 0.5 – 4.3 mg/dL (44.2 – 380 µmol/L) gave following results:

\[ y = 0.986x + 0.043 \text{mg/dL}; r = 0.996 \]

TRACEABILITY

The values of Creatinine Jaffé-method compensated and not compensated in the calibrator Dialac Auto have been made traceable to NIST (National Institute for Standardization) Standard Reference Material SRM 967 using level 1 and 2 and therefore to GC-IDMS (gas chromatography – isotope dilution mass spectrometry).

EXPECTED VALUES

Serum/plasma, Jaffé-method not compensated:

<table>
<thead>
<tr>
<th></th>
<th>[mg/dL]</th>
<th>[µmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults [1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>0.6 – 1.1</td>
<td>53 – 97</td>
</tr>
<tr>
<td>Men</td>
<td>0.7 – 1.3</td>
<td>62 – 115</td>
</tr>
<tr>
<td>Children [2,8]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonate</td>
<td>0.5 – 1.2</td>
<td>44 – 106</td>
</tr>
<tr>
<td>Infant</td>
<td>0.4 – 0.7</td>
<td>35 – 62</td>
</tr>
<tr>
<td>Child</td>
<td>0.5 – 1.2</td>
<td>44 – 106</td>
</tr>
</tbody>
</table>

Serum/plasma, Jaffé-method compensated:

<table>
<thead>
<tr>
<th></th>
<th>[mg/dL]</th>
<th>[µmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults [3]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>0.5 – 0.9</td>
<td>44 – 85</td>
</tr>
<tr>
<td>Men</td>
<td>0.7 – 1.2</td>
<td>62 – 106</td>
</tr>
<tr>
<td>Children [9]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonate</td>
<td>0.24 – 1.04</td>
<td>21 – 92</td>
</tr>
<tr>
<td>Infant</td>
<td>0.17 – 0.41</td>
<td>15 – 37</td>
</tr>
<tr>
<td>Child</td>
<td>0.24 – 0.87</td>
<td>21 – 77</td>
</tr>
</tbody>
</table>

Creatinine clearance [2]:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>95 – 160 mL/min/1.73 m²</td>
</tr>
<tr>
<td>Men</td>
<td>98 – 156 mL/min/1.73 m²</td>
</tr>
</tbody>
</table>

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

LIMITATIONS

- Potential interference with Jaffé reagents Phosphoric Inorganic (Molybdate), Iron (Ferene), LDH-L (IFCC) and LDH-P (opt. DGKC). The actual carry-over depends on the analyser.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE