**Urea CT** FS**

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

**Order Information**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>13115 99 10 021</td>
<td>R1 2 x 25 mL + R2 2 x 25 mL + R3 1 x 0.5 mL</td>
</tr>
<tr>
<td>13115 99 10 026</td>
<td>R1 3 x 100 mL + R2 3 x 100 mL + R3 2 x 1.5 mL</td>
</tr>
<tr>
<td>13115 99 90 305</td>
<td>R1 6 x 25 mL + R2 6 x 25 mL + R3 1 x 1.5 mL</td>
</tr>
<tr>
<td>13100 99 10 030</td>
<td>6 x 3 mL Standard</td>
</tr>
</tbody>
</table>

**Summary** [1,2]

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyperuremia or azotemia. Parallel determination of urea and creatinine is performed to differentiate between pre-renal and post-renal azotemia. Pre-renal azotemia, caused by e.g. dehydration, increased protein catabolism, cortisol treatment or decreased renal perfusion, leads to increased urea levels, while creatinine values remain within the reference range. In post-renal azotemias, for example caused by the obstruction of the urinary tract, both urea and creatinine levels rise, but creatinine in a smaller extent. In renal diseases urea concentrations are elevated when the glomerular filtration rate is markedly reduced and when the protein intake is higher than 200 g/day.

**Method**

Colorimetric test

**Principle**

Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide. Ammonium ions react with hypochlorite and salicylate to give a green dye. The increase in absorbance at 578 nm is proportional to the urea concentration in the sample.

**Reagents**

**Components and Concentrations**

R1: Phosphate buffer 120 mmol/L
Sodium salicylate 60 mmol/L
Sodium nitroprusside 40 mmol/L
EDTA 1.3 mmol/L

R2: Phosphate buffer < 50 mmol/L
Sodium hydroxide 150 mmol/L
Sodium hypochlorite 10 mmol/L

R3: Urea 
≥ 0.5 kU/mL

**Standard:** 50 mg/dL (8.33 mmol/L)

**Storage Instructions and Reagent Stability**

Reagents and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

**Warnings and Precautions**


2. Reagent 3: Danger. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. P261 Avoid breathing vapours. P304+P340 If inhaled: Remove person to fresh air and keep comfortable for breathing. P342+P311 If experiencing respiratory symptoms: Call a poison center or doctor/physician.

3. Stability of R1A:
   - 2 days at 15 – 25°C
   - 2 weeks at 2 – 8°C

4. Dilute urine 1 + 100 with dist. water and multiply results by 101.

5. For professional use only!

**Waste Management**

Please refer to local legal requirements.

**Reagent Preparation**

Mix R1 + R3 in the ratio 100 + 1
e.g. 20 mL R1 + 0.2 mL R3 = R1A

Stability of R1A:
- 2 weeks at 2 – 8°C
- 2 days at 15 – 25°C

R1A and R2 must be protected from light!

Reagent 2 and standard are ready for use.

**Materials required but not provided**

- NaCl solution 9 g/L
- General laboratory equipment

**Specimen**

Serum, EDTA plasma and heparin plasma (no ammonium heparin!), urine

Dilute urine 1 + 100 with dist. water and multiply results by 101.

**Assay Procedure**

**Application sheets for automated systems are available on request.**

**Blank**

Wavelength 578 nm, 560 – 600 nm
Optical path 1 cm
Temperature 20 – 25°C, 37°C
Measurement Against reagent blank

**Sample or standard**

- 10 µL

**Reagent 1A**

- 1000 µL
- 1000 µL

Mix, incubate 10 min. at 20 – 25°C or 5 min. at 37° C, then add:

**Reagent 2**

- 1000 µL
- 1000 µL

Mix, incubate 10 min. at 20 – 25°C or 5 min. at 37° C. In case of 20 – 25°C read the absorbance against reagent blank within 30 min.; in case of 37°C within 5 min.
Calculation

With standard or calibrator

\[
\text{Urea [mg/dL]} = \frac{\Delta A \text{Sample}}{\Delta A \text{Std/Cal}} \times \text{Conc. Std / Cal [mg/dL]}
\]

**Conversion factors**

- Urea [mg/dL] x 0.1665 = Urea [mmol/L]
- Urea [mg/dL] x 0.467 = BUN [mg/dL]
- BUN [mg/dL] x 2.14 = Urea [mg/dL]

(BUN: Blood urea nitrogen = Urea-N in blood)

**Calibrators and Controls**

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrators have been made traceable to NIST SRM®-909 Level 1.

For internal quality control, commercially available controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>TruCal U</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 9100 99 10 063</td>
<td>20 x 3 mL</td>
<td></td>
</tr>
<tr>
<td>5 9100 99 10 064</td>
<td>6 x 3 mL</td>
<td></td>
</tr>
</tbody>
</table>

**Performance Characteristics**

**Measuring range**

The test has been developed to determine urea concentrations within a measuring range from 1 – 400 mg/dL (0.17 – 67 mmol/L) in serum/plasma or 40 g/dL (6.7 mol/L) in urine. When values exceed this range, the samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

**Specificity/Interferences**

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 200 mg/dL and lipemia up to 800 mg/dL triglycerides. Ammonium ions interfere; therefore do not use ammonium heparin as anticoagulant for collection of plasma. For further information on interfering substances refer to Young DS [6].

**Sensitvity/Limit of Detection**

The lower limit of detection is 1 mg/dL.

**Precision (at 20 – 25°C)**

<table>
<thead>
<tr>
<th>Intra-assay n = 20</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>27.3</td>
<td>0.38</td>
<td>1.38</td>
</tr>
<tr>
<td>Sample 2</td>
<td>39.0</td>
<td>0.54</td>
<td>1.39</td>
</tr>
<tr>
<td>Sample 3</td>
<td>149</td>
<td>2.50</td>
<td>1.68</td>
</tr>
</tbody>
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<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>21.1</td>
<td>0.74</td>
<td>3.51</td>
</tr>
<tr>
<td>Sample 2</td>
<td>43.8</td>
<td>1.01</td>
<td>2.31</td>
</tr>
<tr>
<td>Sample 3</td>
<td>145</td>
<td>3.50</td>
<td>2.41</td>
</tr>
</tbody>
</table>

**Method Comparison**

A comparison of DiaSys Urea CT FS (y) with a kinetic test (x) using 64 samples gave following results:

\[
y = 1.03 x - 2.55 \quad r = 0.999
\]

**Reference Range**

**In Serum/Plasma [1]**

<table>
<thead>
<tr>
<th>Adults</th>
<th>[mg/dL]</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>17 – 43</td>
<td>2.8 – 7.2</td>
</tr>
<tr>
<td>Women &lt; 50 years</td>
<td>15 – 40</td>
<td>2.6 – 6.7</td>
</tr>
<tr>
<td>Women &gt; 50 years</td>
<td>21 – 43</td>
<td>3.5 – 7.2</td>
</tr>
<tr>
<td>Men &lt; 50 years</td>
<td>19 – 44</td>
<td>3.2 – 7.3</td>
</tr>
<tr>
<td>Men &gt; 50 years</td>
<td>18 – 55</td>
<td>3.0 – 9.2</td>
</tr>
</tbody>
</table>

**Children**

| 1 – 3 year(s) | 11 – 36 | 1.8 – 6.0|
| 4 – 13 years  | 15 – 36 | 2.5 – 6.0|
| 14 – 19 years | 18 – 45 | 2.9 – 7.5|

**BUN in Serum/plasma [2]**

<table>
<thead>
<tr>
<th>Adults</th>
<th>[mg/dL]</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>7.94 – 20.1</td>
<td>2.8 – 7.2</td>
</tr>
<tr>
<td>Women &lt; 50 years</td>
<td>7.01 – 18.7</td>
<td>2.6 – 6.7</td>
</tr>
<tr>
<td>Women &gt; 50 years</td>
<td>9.81 – 20.1</td>
<td>3.5 – 7.2</td>
</tr>
<tr>
<td>Men &lt; 50 years</td>
<td>8.87 – 20.5</td>
<td>3.2 – 7.3</td>
</tr>
<tr>
<td>Men &gt; 50 years</td>
<td>8.41 – 25.7</td>
<td>3.0 – 9.2</td>
</tr>
</tbody>
</table>

**Urea/Creatinine ratio in serum [1]**

<table>
<thead>
<tr>
<th>25 – 40 [(mmol/L)/(mmol/L)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 – 35 [(mg/dL)/(mg/dL)]</td>
</tr>
</tbody>
</table>

**Urea in Urine [2]**

| 26 – 43 g/24h (0.43 – 0.72 mol/24h) |

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

**Literature**


**Manufacturer**

DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany