CREATININE LS KINETIC Mono

CREATININE KINETIC  Colorimetric method Jaffé. Quantitative determination of Creatinine in Serum, Plasma or Urine.

REF CC1195  R1: 4x100 mL  R2: 1x5 mL (standard)

METHOD AND PRINCIPLE
Kinetic test without deproteinization according to the Jaffé method. Creatinine forms with alkaline picrate a coloured creatinine picrate complex containing ionic bounds. The rate of formation of the coloured complex is proportional to the creatinine concentration.

Creatinine + Picric acid -> Creatinine picrate complex

SPECIMEN
Serum, heparin plasma, urine

Sample Start
Dilute urine 1 + 49 with dist. water.
Discard contaminated specimens.

REAGENT COMPOSITION
Reagent (R1)
Phosphate buffer, pH 12.7
300 mmol/L
Picric acid
25 mmol/L
Reagent (R2)
Standard
2 mg/dL (177 µmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY
The reagent is stable up to the end of the indicated month of expiry, if stored at +2 to +8°C, protected from light and contamination is avoided. Do not freeze the reagent!

PRECAUTIONS / DANGER SYMBOLS
1. Reagent R1 is irritating. R36/38: Imitating to eyes and skin.
3. R38: In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

Sample Start procedure:
Working Reagent 1000 µL
Sample, Std / Cal 100 µL
Mix and read absorbance (A1) after 60 sec, read absorbance (A2) after further 120 sec.

CALCULATION WITH STANDARD OF CALIBRATOR

CONVERSION FACTOR
Creatinine [mg/dL] x 8.4 = Creatinine [µmol/L]

EXPECTED VALUES

Serum/plasma, Jaffé-method not compensated
Women 0.6 – 1.1 mg/dL 53 – 97 µmol/L
Men 0.9 – 1.3 mg/dL 80 – 115 µmol/L

Serum/plasma, Jaffé-method compensated
Women 0.5 – 0.9 mg/dL 44 – 80 µmol/L
Men 0.7 – 1.2 mg/dL 62 – 106 µmol/L

Urine
Women 11 – 20 mg/kg/24h 97 – 177 µmol/kg/24h
Men 14 – 26 mg/kg/24h 124 – 230 µmol/kg/24h
Creatinine clearance [2]
Women 95 – 160 mL/min/1.73 m2
Men 98 – 156 mL/min/1.73 m2

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the Creatinine results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

WASTE DISPOSAL
The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL
Normal and abnormal control sera of known Creatinine activities should be analysed routinely with each group of unknown samples utilizing MTD Diagnostics Quality Control Material:

Chemistry Control N (Normal)  REF: CNN1010 (10 x 5 mL)
Chemistry Control P (Pathologic)  REF: CNP1020 (10 x 5 mL)
CALIBRATION WITH STANDARD OR CALIBRATOR

Results will depend on the accuracy of the instrument calibration, assay settings, the reagent/specimen ratio and the temperature control.

- Use MTD Diagnostics Clinical Chemistry Calibrator (calibration value determined with validated statistical technics and metrological controlled instrument):

  Chemistry Multicalibrator: REF CAL1010 (10 x 3 mL)

PERFORMANCE

Precision (at 37 °C)

<table>
<thead>
<tr>
<th>Mg/dL</th>
<th>Within-run</th>
<th>Between-run</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>1.43 - 4.00</td>
<td>1.43 - 4.00</td>
</tr>
<tr>
<td>SD</td>
<td>0.04 - 0.07</td>
<td>0.05 - 0.12</td>
</tr>
<tr>
<td>CV%</td>
<td>2.68 - 1.64</td>
<td>3.34 - 3.11</td>
</tr>
<tr>
<td>N</td>
<td>10 - 10</td>
<td>10 - 10</td>
</tr>
</tbody>
</table>

Method Comparison

The MTD Diagnostics Creatinine LS (y) was compared with a similar commercial method (x). The results were: N = 62 r = 0.98 y = 1.00x - 0.12

The analytical performances have been generated using an automatic instrument. Results may vary depending on the instrument.

SPECIFICITY / INTERFERENCES

No interference was observed by ascorbic acid up to 30 mg/dL, haemoglobin up to 500 mg/dL and lipemia up to 2,000 mg/dL triglycerides. Bilirubin interferes starting with a bilirubin concentration of 4 mg/dL.

PERFORMANCE CHARACTERISTICS

The test has been developed to determine Creatinine concentrations within a measuring range from 0.2 – 15 mg/dL (18 – 1330 mol/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.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact your distributor for any question on the application method.

2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

CLINICAL SIGNIFICANCE

Creatine is synthesized in the body at a fairly constant rate from creatine, which is produced during muscle contractions from creatine phosphate. Creatinine in the blood is then removed by filtration through the glomeruli of the kidney for excretion in the urine. Since the excretion of creatinine in healthy individuals is independent of diet and thus relatively constant, the creatinine clearance (CC) test is one of the most sensitive tests to diagnose renal function especially the glomerular filtration rate (GFR) the concentration of creatinine in serum being dependent almost entirely upon its rate of excretion by the kidney. Elevated levels of creatinine in serum are usually associated with renal diseases, especially those related to GFR such as glomerular nephritis. Therefore, the clinical significance of the creatinine level in plasma or serum is usually determined in conjunction with the plasma urea level since there is an increase in both levels in postrenalazotemia, while the CC, or urine levels, are diminished.

BIBLIOGRAPHY


Proteins together with copper ions form a violet blue colour complex in alkaline solution. The absorbance of the colour is directly proportional to the concentration.