# CREATININE 4

## Mod.Jaffe Method

**Intended use:**
Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on photometric systems.

**Summary:**
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.

**Method**
Kinetic test without deproteinization according to the Jaffé method.

**Test principle:**
Creatinine forms a colored orange-red complex in an alkaline picrate solution. The difference in absorbance at fixed times during conversion is proportional to the concentration of creatinine in the sample.
Creatinine + Picric acid ---> Creatinine picrate complex

**Reagent concentration:**
Components and Concentrations
*N.B Concentrations are those in the final test mixture*

| | | |
|---|---|---|
| **R1:** | Sodium hydroxide | 0.16 mol/l |
| **R2:** | Picric acid | 4.0 mmol/l |

**Warnings and Precautions**
1. Reagent 1 contains sodium hydroxide and is a caustic solution. Keep out of the reach of children. Wear suitable gloves and eye / face protection. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Remove contaminated clothing immediately.
2. Reagent 2 contains picric acid. Toxic by inhalation, in contact with skin and when swallowed. Wear suitable gloves and eye / face protection. After contact with skin, wash immediately with polyethylenglycol 400 (DAB 8) or plenty of water. If sickness occurs seek medical advice.

**Storage Instructions and Reagent Stability**
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 25 °C and contamination is avoided. Do not freeze the reagents!

**Waste Management**
Please refer to local legal requirements.

**Reagent Preparation:**
The standard is ready–to-use.
Mix 4 parts of R1 + 1 part of R2 (e.g. 20 ml R1 + 5 ml R2) = monoreagent
Onboard Stability: 2 week.

**Specimen**
Serum, heparin plasma, urine.

**Stability**

| | | | |
|---|---|---|---|
| in serum /plasma: | 7 days | at | 4-25°C |
| | at least 3 months | at | -20°C |
| in urine: | 2 days | at | 20-25°C |
| | 6 days | at | 4-8°C |
| | 6 months | at | -20°C |

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

**Testing procedure:**
Applications for automated systems are available on request.
Materials provided
Working solutions as described above Additional materials required
Calibrators and controls as indicated below
0.9% NaCl

| **Manual procedure:** | |
|---|---|
| Wavelength: | Hg 492 nm, (490 - 510 nm) |
| Temperature: | +37°C |
| Cuvette: | 1 cm light path |
| Zero adjustment: | reagent blank |
| Blank | Sample/ standard |
| Reagent 1 | 800 µl |
| Sample | 160 ul |
| Mix, incubate 1-5 min. Then Add; | |
| Reagent 2 | 200 ul |
| Mix, incubate for 60 seconds and read absorbance A1<br>Then incubate for 120 seconds and read absorbance A2 | |
| **Calculation:**<br>$\frac{\text{A Sample}}{\text{A Calibrator}}$ x calibrator conc. = Creatinine conc. (mg/dl) | |

**Measuring/reportable range:**
Serum/plasma: 0.2 - 15.0 mg/dl
Determine samples with higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2)

**Expected values:**
Serum / Plasma **[1]**

| | | |
|---|---|---|
| Women | 0.6 – 1.1 mg/dl | 53 – 97 µmol/l |
| Men | 0.9 – 1.3 mg/dl | 80 – 115 µmol/l |

Urine **[1]**

| | | |
|---|---|---|
| Women | 11 – 20 mg/kg/24 hours | 97 – 177 µmol/kg/d |
| Men | 14 – 26 mg/kg/24 hours | 124 – 230 µmol/kg/d |

Creatinine clearance **[2]**

| | |
|---|---|
| Women | 95 - 160 ml/min/1.73 $m^2$ |
| Men | 98 - 156 ml/min/1.73 $m^2$ |

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.

**Analytical sensitivity (lower detection limit)**
Detection limit: 0.2 mg/dl
The lower detection limit represents the lowest measurable creatinine concentration that can be distinguished from zero.

**Imprecision:**
Reproducibility was determined using controls. The following results were obtained:

| | Within run | | |
|---|---|---|---|
| Sample | Mean (mg/dl) | SD (mg/dl) | CV % |
| Sample 1 | 1.29 | 0.01 | 0.91 |
| Sample 2 | 2.81 | 0.02 | 0.63 |
| Sample 3 | 4.28 | 0.03 | 0.69 |
| | Between day | | |
| Sample | Mean (mg/dl) | SD (mg/dl) | CV % |
| Sample 1 | 1.27 | 0.03 | 2.35 |
| Sample 2 | 2.73 | 0.02 | 0.80 |
| Sample 3 | 4.24 | 0.03 | 0.72 |

# CREATININE 4

Mod.Jaffe Method

**Quality Control:**

Control Serum:

| | | |
|---|---|---|
| BIOCON N | 5 x 5 ml | #B10814 |
| BIOCON P | 5 x 5 ml | #B10817 |

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

**Calibration:**

| | | |
|---|---|---|
| S1: 0.9% NaCl | | |
| S2: BIOCAL H | 5 x 3 ml | #B11895 |

**Calibration frequency:**

A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

**Literature:**

1. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.

**Order information (Cat No.) :**

| | | | | | |
|---|---|---|---|---|---|
| CC385 | AB385 | B25120 | B30120 | B33121 | B37121 |
| SH385 | BCRE250 | B25121 | B30121 | B34120 | B42120 |
| CR385 | B21120 | B27120 | B31120 | B35120 | B80120 |
| OL385 | B21121 | B27121 | B32120 | B36120 | B80121 |
| KL385 | B22120 | B28120 | B32121 | B36121 | |
| BCRE500 | B24120 | B28121 | B33120 | B37120 | |

**Manufacturer**

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com

## SYMBOLS

| | |
|---|---|
| IVD | for in vitro diagnostic use only |
| LOT | lot of manufacturing |
| REF | code number |
| | storage at temperature interval |
| | expiration date (year/month) |
| | warning, read enclosed documents |
| | Read the directions |

ISO 9001:2015
ISO 13485:2016