CREATININE LS KINETIC MONO

IVD

Quantitative determination of Creatinine in Serum, Plasma or Urine. Colorimetric kinetic MODIFIED method according to Jaffé.

REF CC1195 R1: 4x100 mL R2: 1x3 mL (standard)

METHOD AND PRINCIPLE

Kinetic test without deproteinization according to the Jaffé method.
Creatinine forms with alkaline picrate a coloured creatinine picrate complex. The rate of formation of the complex, measured fotometrically, is proportional to the Creatinine concentration in the sample.

Creatinine + Picric acid ⟶ Creatinine picrate complex

CLINICAL SIGNIFICANCE

Creatinine 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 trough 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 conjugation with the plasma urea level since there is an increase in both levels in postrenalazotemia, while the CC, or urine levels, are diminished.

REAGENT COMPOSITION

Reagent (R1)

Phosphate buffer, pH 12,7	300 mmol/L
Picric acid	25 mmol/L

Reagent (R2)

Creatinine Standard	value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use reagents, stable until the expiry date shown on the label, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents.
Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera.
After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation.

SPECIMEN

Serum, heparin plasma, urine.
Dilute urine 1:50 (1 + 49) with distilled water. Avoid hemolysate or lipemic samples. Separate the serum from the clot quickly.
Discard contaminated specimens.
Stability in serum/plasma: 7 days at 4°- 25°C, at least 3 months at -20°C.
Stability in urine: 2 days at 20°- 25 °C, 6 days at 4° - 8°C, 6 months at -20°C
.

PROCEDURE

Wavelength:	510 nm (500 – 530)
Temperature:	37°C
Measurement:	against distilled water

Pipette as follow:

Reagent (R1)	1000 µL
Sample, Std / Cal	100 µL

Mix and after 60 seconds read Absorbance Abs1. After further 120 seconds read Absorbance Abs2. Calculate ΔAbs ($Abs_2 – Abs_1$).

CALCULATION

Serum/Plasma:

$$\text{Creatinine} = \frac{\Delta \text{ Abs Sample}}{\Delta \text{ Abs Std/Cal}} \times \text{Std/Cal Concentration}$$

Urine:
Calculate as for the serum and multiply the result by 50 (initial sample dilution).

Creatinine Clearance

$$\text{Clearance (mL/min)} = \frac{\text{Creatinine Urine (mg/dL) x Vol. Urine 24h (mL) x 1.73}}{\text{Creatinine Serum (mg/dL) x 1440 x Body Surface mq}}$$

To calculate the Body Surface it is possible to use the nomogram of Du Bois (weight / height) or to take 1.73 a standard value for the body surface of subjects of standard height and weight.

Conversion Factor:Creatinine [mg/dL] x 88.4 = Creatinine [µmol/L]

CALIBRATION

The results depend on the accuracy of the calibration, on the correct setting of the test on the instrument, on the correct volumetric ratio of reagent / sample and on the correct analysis temperature.
As an alternative to the standard included in the package, it is possible to use **MTD Diagnostics Calibrator**:

Chemistry Multicalibrator - REF CAL1010 (10x3 mL)

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Chemistry Control N - REF CNN1010 10x5 mL (Level 1)
Chemistry Control P - REF CNP1020 10x5 mL (Level 2)

EXPECTED VALUES

Serum/plasma:

Men	0.7 – 1.2 mg/dL
Women	0.5 – 1.0 mg/dL

Urine:

Men	40 – 278 mg/dL
Women	29 – 226 mg/dL

Creatinine Clearance:

Adults:	66.3 – 143 mL/min

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:

Low Level: Samples= 20; Average = 0.79; S.D. = 0.01; CV = 1.26%

High Level: Samples = 20; Average = 5.74; S.D. = 0.05; CV = 0.87%

ACCURACY (CORRELATION): A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y=1.031x - 0.03 ; r=1.0

SENSITIVITY: 0.2 mg/dL

LINEARITY: 0.2 - 10 mg/dL

SPECIFICITY / INTERFERENCES

No interference was observed by Ascorbic Acid up to 30 mg/dL, Hemoglobin up to 500 mg/dL, Bilirubin up to 4,0 mg/dL and lipemia up to 500 mg/dL Triglycerides.

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.

PRECAUTIONS

R1 contains SODIUM HYDROXIDE, 300 mmol/L – pH 12.7 - CAS N.: 1310-73-2 - C R35 (H314).

PICRIC ACID 25 mmol/L - CAS N. 88-89-1 - E T R2 () R23/24/25 (H331 – H311 - H301).

R2 (): Risk of explosion by shock, friction, fire or other sources of ignition

R23/24/25 (H331 – H311 - H301): Toxic by inhalation and if swallowed

R35 (H314): Causes severe burns.

The product contains dangerous substances or mixtures according to the EC regulation n ° 1272/2008 (CLP), therefore it needs the special labeling required by the aforementioned regulation. The product is labeled according to the directive for CE marking (98/79 / CE).

Sodium Azide less than 0.1%.

However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:

S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.

S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.

S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.

S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.

S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis.

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

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