Reactivos GPL

Barcelona, España

CE

- Creatinine-J -

CREATININE
Jaffe Colorimetric - Kinetic

Store at: +2+25ºC.

Presentatión:
Cod. SU015-SP CONT: *R 2 x 50 mL.+ CAL 1 x 5 mL.*
Cod. SU015 CONT: *R 2 x 125 mL.+ CAL 1 x 5 mL.*
Cod. SU016 CONT: *R 8 x 125 mL.+ CAL 1 x 5 mL.*

Procedure

Quantitative determination of Creatinine.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY
The assay is based on the reaction of creatinine with sodium picrate as described by Jaffé. Creatinine reacts with alkaline picrate forming a red complex. The time interval chosen for measurements avoids interferences from other serum constituents.
The intensity of the color formed is proportional to the creatinine concentration in the sample[1].

REAGENTS COMPOSITION

R.1 (Picric Reagent)	Picric Acid	17.5 mmol/L.
R.2 (Alkaline Reagent)	Sodium hydroxide	0.29 mol/L.
Creatinine Cal	Creatinine aqueous primary calibrator	2 mg/dL.

PRECAUTIONS
R1/ R2: H314-Causes severe skin burns and eye damage.
CAL: H290-May be corrosive to metals.
Follow the precautionary statements given in MSDS and label of the product.

REAGENT PREPARATION AND STABILITY
Working reagent (WR): Mix equal volumes of R.1 (Picric Reagent) and R.2 (Alkaline reagent). The (WR) is stable for 10 days at 2-25º C.
Creatinine Cal: Proceed carefully with this product because due its nature it can get contaminated easily.
Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 492 nm. ≥ 1.80

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-25ºC, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

SPECIMEN
- Serum or heparinized plasma[1].
  Creatinine stability: 24 hours at 2-8º C
- Urine[1]: Dilute sample 1/50 with distilled water. Mix. Multiply results by 50 (dilution factor).
  Creatinine stability: 7 days at 2-8º C.

MATERIAL REQUIRED BUT NOT PROVIDED
- Spectrophotometer or colorimeter measuring at 492nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE
1. Assay Conditions
   - Wavelength: ..... 492 nm. (490-510)
   - Cuvette: ..... 1 cm light path.
   - Temperature ..... 37º C. 15-25º C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
WR (mL.)	1.0	1.0	1.0
Calibrator (µL.) (note1-2)	--	100	--
Sample (µL.)	--	--	100

4. Mix and start stopwatch.
5. Read the absorbance (A_1) after 30 seconds and after 90 seconds (A_2) of the sample addition.
6. Calculate: $\Delta A = A_2 - A_1$.

CALCULATIONS
Creatinine (mg/dL.) = $\frac{(\Delta A)\,Sample - (\Delta A)\,Blank}{(\Delta A)\,Calibrator - (\Delta A)\,Blank}$ x 2 (Calibrator conc.)

Conversion Factor. mg/dL. x 88.4 = µmol/L.

QUALITY CONTROL
Control sera are recommended to monitor the performance of the procedure, Control H Normal Ref. QC003 and Control H Pathological Ref. QC004. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES[1]
Serum or plasma:
Male 0.7 – 1.4 mg/dL ≅ 61.8 – 123.7 µmol/L
Female 0.6 – 1.1 mg/dL ≅ 53.0 – 97.2 µmol/L
Urine: 15-25 mg/Kg/24h
Male 10 - 20 mg/Kg/24 h ≅ 88– 177 µmol/Kg/24 h
Female 8 - 18 mg/Kg/24 h ≅ 71– 177 µmol/Kg/24 h
*(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE
Creatinine is the result of the degradation of the creatine, component of muscles, it can be transformed into ATP, that is a source of high energy for the cells. The creatinine production depends on the modification of the muscular mass, and it varies little and the levels usually are very stable. Is excreted by the kidneys. With progressive renal insufficiency there is retention in blood of urea, creatinine and uric acid.
Elevate creatinine level may be indicative of renal insufficiency[1,4,5].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
– *Measuring Range*:
From detection limit of 0.09 mg/dL. to linearity limit of 15 mg/dL., under the described assay conditions.
If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.
– *Precision*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (mg/dL)	1.06	3.58	1.03	3.314
SD	0.22	0.06	0.04	0.06
CV	2.07	1.54	3.97	1.75

- Sensitivity: 1 mg/dL. = 0.03 A/min.
- Accuracy: Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
  The results obtained using 50 samples were the following:
  Correlation coefficient (r)[2]: 0.986
  Regression Equation: y = 0.975x + 0.047
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES
- Hemoglobin (1 g/L), Bilirrubin (55 mg/dL), interfere[1].
- Lipids < 4 g/L do not interfere.
- A list of drugs and other interfering substances with creatinine determination has been reported by Young et. al[2,3].

NOTES
1. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

BIBLIOGRAPHY

1. Murray R.L. Creatinine. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1261-1266 and 418.
2. Young DS. Effects of drugs on Clin Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nave J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75

GPLBSDTT13-I
Rev. 10 – 15/05/19