CREATININE

COD 12502 10 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

CREATININE
JAFFÉ COMPENSATED

INTENDED USE

Reagent for the measurement of creatinine concentration in human serum, plasma or urine. The obtained values are useful as an aid in diagnosis and treatment of renal diseases.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Creatinine is a catabolic end product of creatine (or phosphocreatine). The amount produced each day is related to the muscle mass. Creatinine is freely filtered by the glomerulus (small amounts are reabsorbed and are also secreted by the renal tubules).

Creatinine measurement is used almost exclusively in the assessment of kidney function (impaired renal perfusion, loss of functioning nephrons) and in the monitoring renal dialysis[1,2].

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

PRINCIPLE OF THE METHOD

Creatinine in the sample reacts with picrate in alkaline medium forming a coloured complex (Jaffé method). The complex formation rate is measured in a short period to avoid interferences[3,4]. Serum and plasma samples contain proteins that react in a non specific way; nevertheless, the results can be corrected subtracting a fixed value. The use of this correction is known as the Jaffé method compensated[5,6].

CONTENTS AND COMPOSITION

A. Reagent. 5 x 50 mL. Sodium hydroxide 0.4 mol/L, detergent.

WARNING: H315: Causes skin irritation. H319: Causes serious eye irritation. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313: If skin irritation occurs: Get medical advice/attention.

B. Reagent. 5 x 50 mL. Picric acid 25 mmol/L.

For further warnings and precautions, see the product safety data sheet (SDS).

STORAGE AND STABILITY

Store at 2-30ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer at 2-8°C are stable 2 weeks.

Indications of deterioration: Reagents: RA is a NaOH solution with high concentration. In some storage conditions (i.e. storage at a lower temperature than indicated) a precipitate may appear in the vial that will not affect the reagent performance and will disappear with a slight rotation of the vial before carrying out the analysis. RB, presence of particulate material, turbidity. Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Working Reagent: Mix equal volumes of Reagent A and Reagent B. Mix thoroughly. Stable for 1 month at 2-8ºC.

SAMPLES

Serum, plasma or urine collected by standard procedures. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

Creatinine in samples is stable for 1 day at 2-8ºC.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 3 days, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, cod. 18009 and cod. 18042) and II (cod. 18007, cod. 18010 and cod. 18043) and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[7]:

Men: 0.7 - 1.2 mg/dL = 62 - 106 μmol/L
Women: 0.5 - 0.9 mg/dL = 44 - 80 μmol/L

Urine[1]:

Men: 14 - 26 mg/kg/24-h = 124 - 230 μmol/kg/24-h
Women: 11 - 20 mg/kg/24-h = 97 - 177 μmol/kg/24-h

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 0.04 mg/dL = 3.5 μmol/L.
- Linearity limit: 20 mg/dL = 1768 μmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
1.67 mg/dL = 148 μmol/L	3.2 %	3.5 %
4.63 mg/dL = 409 μmol/L	1.7 %	2.2 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 10 mg/dL), hemolysis (hemoglobin up to 1000 mg/dL), lipemia (triglycerides up to 200 mg/dL) and protein and ketonic bodies do not interfere. High concentration of reducing compounds may interfere. Other drugs and substances may interfere[8].

NOTE

1. For measurement in serum or plasma, introduce corrective value for the reaction of nonspecific proteins as a factor in the equation of the instrument y = ax + b, where a = 1.0 and b = -0.37 (mg/dL), or a = 1.0 and b = -33 (μmol/L)[5,6].

BIBLIOGRAPHY

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3. Bartels H, Böhmer M. Eine mikromethode zur kreatininbestimmung. *Clin Chim Acta* 1971; 32: 81-85.
4. Fabiny DL, Ertingshausen G. Automated reaction-rate method for determination of serum creatinine with CentrifiChem. *Clin Chem* 1971; 17: 696-700.
5. Weber JA, Van Zanten AP. Interferences in current methods for measurements of creatinine. *Clin Chem* 1991; 37: 695-700.
6. Peake M, Whiting M. Measurement of serum creatinine-current status and future goals. *Clin Biochem* 2006;27:173-184.
7. Mazzachi BC, Peake MJ, Ehrhardt V. Reference range and method comparison studies for enzymatic and Jaffé creatinine assays in plasma and serum and early morning urine. *Clin Lab* 2000;46:53-55.
8. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS (Note 1)

R1: use Reagent A.

R2: use Reagent B.

	A25	A15
GENERAL		
Name	**CREATININE**	**CREATININE**
Sample type	SER / URI	SER / URI
Analysis mode	fixed-time mon.	fixed-time mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	No
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	505	505
Reference filter	-	-
Sample	30	30
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	4	3
Reading 2 (cycle)	8	6
Reagent 2 (cycle)	-	-
Predilution factor	- / 50	- / 50
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.350	0.350
Kinetic blank limit	-	-
Linearity limit	20 / 1000	20 / 1000
Substrate depletion	-	-

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