CREATININE CE

CONTENTS			
REF	1123005	Creatinine	2 x 50 mL
	1123010	Creatinine	4 x 100 mL
	1123020	Creatinine	4 x 250 mL
For *in vitro* diagnostic use only			

CREATININE

Kinetic colorimetric method

FIXED TIME

PRINCIPLE

This procedure is based upon a modification of the original picrate reaction (Jaffe)[1]. Creatinine under alkaline conditions reacts with picrate ions forming a reddish complex. The formation rate of the complex measured through the increase of absorbance in a prefixed interval of time is proportional to the concentration of creatinine in the sample.[2-4]

$$\text{Creatinine + Picric acid} \xrightarrow[37^{o}C]{pH > 12} \text{Red addition complex}$$

REAGENT COMPOSITION

R1 **Picric acid**. Picric acid 25 mmol/L

R2 **Alkaline buffer**. Phosphate buffer 300 mmol/L pH 12.7, SDS 2.0 g/L (w/v). **X_i R:36/37/38**

CAL **Creatinine standard**. Creatinine 2 mg/dL (177 µmol/L). Organic matrix based primary standard.

STORAGE AND STABILITY

Store at 15-30ºC.
The reagents are stable until the expiry date stated on the label, stored **tightly closed and protected from light.**

REAGENT PREPARATION

Working reagent. Mix 1 volume of **R1 +** 1 volume of **R2**. Stable for 1 week at room temperature, stored **tightly closed and protected from light.**

SAMPLES

Serum or heparinized plasma, and urine (see Notes).
Creatinine in serum or plasma is stable up to 24 hours at 2-8ºC. Freeze for longer storage.
Creatinine from random samples of urine is stable for 4 days at 2-8ºC. Freeze for longer storage. The 24-hour urine samples for the Clearance Test should be collected on a preservative (fluoride-thymol) and immediatelly refrigerated.

INTERFERENCES

- The non-specific color formation from proteins and carbohydrates are suppressed by the alkaline SDS-borate buffer.
- The oxidant prevents against the negative bilirubin interference.
- Triglycerides up to 2 g/L do not interfere.
- A number of drugs are known to affect creatinine levels.[5]

MATERIALS REQUIRED

- Photometer or colorimeter with a thermostatted cell compartment, able of reading at 500 ± 10 nm.
- Constant temperature incubator set at 37ºC.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm pathlength.
- Pipettes to measure reagent and samples.

PROCEDURE

1. Preincubate working reagent, samples and standard to reaction temperature (37ºC).
2. Set the photometer to 0 absorbance with distilled water.
3. Pipette into a cuvette.

Working reagent	1.0 mL
Sample or Standard	100 µL

4. Mix gently. Insert cuvette into the temperature-controlled instrument and start stopwatch.
5. Record absorbance at 500 nm after 30 seconds (A_1) and after 90 seconds (A_2) of the sample or standard addition.

CALCULATIONS

Serum, plasma

$$\frac{(A_2 - A_1)_{Sample}}{(A_2 - A_1)_{Standard}} \times C_{Standard} = \text{mg/dL creatinine}$$

Samples with concentrations higher than 20 mg/dL should be diluted 1:4 with saline and assayed again. Multiply the results by 4.

If results are to be expressed as SI units apply:
mg/dL x 88.4 = µmol/L

Clearance Test

$$\text{mL/min} = \frac{\text{mg creatinine/ dL URINE x mL 24-h}}{\text{mg creatinine/ dL SERUM x 1440 min}}$$

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REFERENCE VALUES[6]

Serum, plasma

Men	0.70-1.20 mg/dL (62-106 μmol/L)
Women	0.50-0.90 mg/dL (44-80 μmol/L)

Urine

Men	14-26 mg/Kg/24-h (124-230 μmol/Kg/24-h)
Women	11-20 mg/Kg/24-h (97-117 μmol/Kg/24-h)

Clearance Test

Men	97-137 mL/min
Women	88-128 mL/min

It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **1980005** HUMAN MULTISERA NORMAL
Borderline level of creatinine. Assayed.

REF **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of creatinine. Assayed.

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 postrenal azotemia, while the CC, or urine levels, are diminished.

NOTES

- Creatinine in urine may be assayed on fresh random samples. No special preparation of the patient is needed. Dilute specimen 1:50 with distilled water before the assay. Multiply the result by 50.

ANALYTICAL PERFORMANCE

- ***Linearity.*** Up to 20 mg/dL
- ***Precision***

mg/dL	Intraserial		Interserial	
Media	0.8	4.9	0.8	4.9
DE	0.05	0.1	0.06	0.15
CV%	6.25	2.04	7.5	3.06
N	10	10	5	5

Replicates: 5 for each level. Replicates: 5 for each level
Instrument: CECIL CE 2021 for 8 days.

- ***Sensitivity.*** Using this reagent and method an ΔA/min of 0.020 read at 500 nm is equivalent to 1 mg of creatinine/dL.
- ***Correlation.*** This assay (y) was compared with a similar commercial method (x). The results were:
  N = 25 r = 0.997 y = 1.025x + 0.012

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