**Quantitative determination of Creatinine in serum & Urine**
**Only for *In Vitro* Diagnostic use**

## ORDER INFORMATION

| REF | Cont. |
|---|---|
| CRZ 125 | 5 X 25 ML |
| CRZ 375 | 15 X 25 ML |
| CRZ 600 | 10 X 60 ML |
| CRZ 40 | 1 X 40 ML |
| CRZ 80 | 1 X 80 ML |

## CLINICAL SIGNIFICANCE

Creatinine is the catabolic product of high energy storage compound, Creatinine Phosphate formed in muscle. The amount of creatinine produced is fairly constant and is primarily a function of muscle mass. Creatinine is excreted out of body entirely by the kidneys.
Elevated levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure) diabetes acromegaly. Decreased levels are found in muscular dystrophy.

## Method

Photometric Enzymatic Test method

## PRINCIPLE

Through a series of enzymatic reactions, creatinine is converted in to glycine, whilst endogenous components such as creatine and sarcosine are eliminated in the first step of the sequence. The formed hydrogen peroxide reacts with TOPS in the presence of peroxidase, to give a quinoneimine dye. The intensity of color, measured at 546 nm, is proportional to creatinine concentration in the sample.

## REAGENT

Reagent I : Buffer Reagent
Reagent II : Enzyme Reagent
Creatinine Standard : 2 mg/dl (0.16 mmol/L)

## REAGENT PREPARATION

Use separate reagents ready to use.

## REAGENT STORAGE AND STABILITY

Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: use preferably within 60 days at 2-8°C.
**Prior to use:** When stored at 2-8°C and protected from direct sunlight, the reagents are stable until the expiry date stated on the bottle and kit box labels.

## WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

## WASTE MANAGEMENT

Please refer to local legal requirements.

## MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

## SAMPLE COLLECTION AND PRESERVATION

**Serum or Urine**
It is very important to store the sample protected from light!
Stability: 1 day at 20 – 25°C
7 days at 4 – 8°C
6 months at –20°C in case of immediate freezing.
in Urine: 1 day at 20 – 25°C
4 days at 4 – 8°C
3 weeks at –20°C
Freeze only once! Discard contaminated specimens!

## ASSAY PROCEDURE

### Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28 ºC, prior to analysis.

| AUTOMATED PARAMETERS | |
|---|---|
| Wavelength | 650nm (620 – 650nm) |
| Cuvette Light Path | 1 cm |
| Reaction Type | End Point |
| Reaction Temperature | 37°C |
| Measurement | Against Reagent blank |
| Sample Volume | 10 µl |
| Reagent 1 Volume | 300 µl |
| Reagent 2 Volume | 100 µl |
| Incubation | 5 mins. + 5 mins. |
| Low Normal | 0.80 mg/dl |
| High Normal | 1.40 mg/dl |
| Linearity | 25 mg/dl |

## MANUAL ASSAY PROCEDURE

### Pipette into Test Tubes

| Dispense: | Blank | Standard | Sample |
|---|---|---|---|
| Reagent R1 | 300 µl | 300 µl | 300 µl |
| Water | 10 µl | - | - |
| Calibrator | - | 10 µl | - |
| Sample | - | - | 10 µl |
| **Mix, incubate at 37°C for 5 minutes.** | | | |
| **Dispense:** | **Blank** | **Standard** | **Sample** |
| Reagent R2 | 100 µl | 100 µl | 100 µl |
| **Mix, incubate at 37°C for 5 minutes.** Read absorbance at 546 nm of Standard (AS) and samples (AT) againstreagent blank. | | | |

### SAMPLE DILUTIONS

- This method is linear upto a concentration of 25 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

## CALCULATION

**Serum/plasma sample:**
Creatinine mg/dl = AT/AS x Conc of Standard

**Random urine sample:**
Creatinine mg/dl = AT/AS x Conc of Standard x 20

**24 hours urine sample (Creatinine mg/24h):**
Creatinine mg/24h = AT/AS x Conc of Standard x 20 x diuresis
(dilution, diuresis in dL)

## CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

## PERFORMANCE CHARACTERISTICS

### WITHIN RUN

| Sample | Mean Concentration | SD | CV % |
|---|---|---|---|
| Norm | 1.03 | 0.02 | 2.34% |
| Path | 3.35 | 0.09 | 2.60% |

### RUN TO RUN

| Sample | Mean Concentration | SD | CV % |
|---|---|---|---|
| Norm | 1.00 | 0.03 | 1.67% |
| Path | 3.44 | 0.06 | 1.66% |

## LINEARITY

The method is linear upto a concentration of 25mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

**Limit of detection**: The limit of detection for Creatinine Total is 0.04 mg/dL.

## METHOD COMPARISON

A comparison of Accucare Bilirubin Total with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

## REFERENCE VALUES

| SPECIMEN | MEN | WOMEN |
|---|---|---|
| **SERUM** | 0.8 - 1.4 | 0.7 - 1.2 mg/dl |
| **24h URINE** | 1.0 - 2.0 | 0.8 - 1.8 G/24h |

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

## LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

## INTERFERENCE

- Hemoglobin: No interference found upto 1000 mg/dL.
- Lipemia: No Interference found upto 1400mg/dL.
- Bilirubin: No Interference found upto 28mg/dL.
- Ascorbic Acid: No Interference found upto 50mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

## BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 797-801
2. Clin. Chem. 2012, 58(2), 391-401

## GLOSSARY OF SYMBOL

| | | | |
|---|---|---|---|
| | Consult Instruction for Use | LOT | Lot Number |
| REF | Catalog Number | | Date of Manufacturing |
| | Store between | | Use By or Expiration Date |
| | Manufacturer | IVD | For *in vitro* Diagnostic use only |
| | Keep away from sunlight | CONT | Content of the kit |

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