

Bioway Chemistry Reagent Series

The Creatinine Reagent Kit

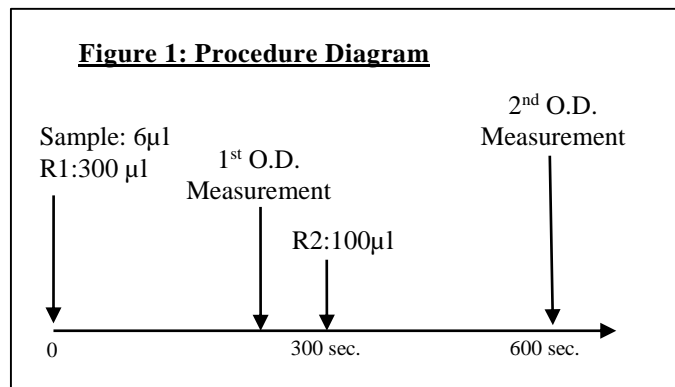
Detection of Creatinine in Human Serum on Chemistry Analyzers



Cat. No. R022K11

The CRE Reagent Kit

SUMMARY OF TEST PROCEDURE



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

Calibration method	2-point linear	Slope of reaction	Increase
Wavelength	Dλ : 546nm Sλ : 660nm	Sample volume	6 µl
Test method	2-point end	R1 volume	300 µl
Reaction temperature	37°C	R2 volume	100 µl

INTENDED USE

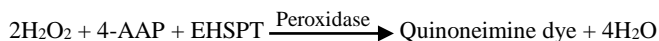
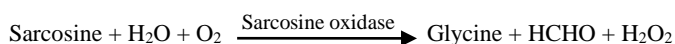
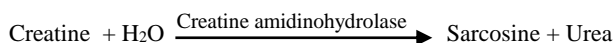
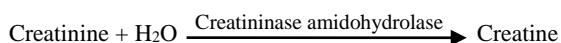
Bioway Chemistry Reagent Series CRE Reagent Kit (the Kit) is an enzymatic assay intended for *in vitro* quantitative detection of creatinine in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Creatinine is one of the decomposition products of muscle metabolism, and then filtered and excreted by kidney in urine. High concentration creatinine is in every urine samples of health human beings. It is commonly used to be a marker of undiluted urine in case of samples being replaced for avoiding drug test. A rise of creatinine level in blood also indicates renal function deficiency by reflecting the glomerular filtration rate decreased. Be careful that the test result of creatinine concentration detection is easy to be affected by gender, age, weight or even daily intake.

TEST PRINCIPLES

The detecting method adopted in this kit is enzymatic colorimetric determination which is developed for overcoming the chromogenic interferences in Jaffe method.



*4-AAP = 4-Aminoantipyrine

*EHSPT = N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl)-m-Toluidine

The addition of quinoneimine dye results in an increase in absorbance at 546nm which is directly proportional to the amount of creatinine in the sample.

MATERIALS PROVIDED

Reagent:

R1	Creatine amidinohydrolase Sarcosine oxidase EHSPT	2000U/L 6000U/L >0.4mmol/L
R2	Peroxidase Creatinine amidohydrolase 4-AAP	1mmol/L >2500000U/L 1mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.

- Creatinine control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. Reagent is stable for 1 month at 2-8°C after opening.

PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum, heparinized, trisodium citrate or EDTA treated plasma or distilled deionized water diluted 1% urine samples.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using included Bioway calibrators for optimal results. Use 2-point linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 6 µl of sample and 300 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Take optical density measurement OD 1 just before addition of R2.
- Add 100 µl of R2, mix well and incubate at 37°C.
- Take optical density measurement OD 2 at 600 seconds.
- Calculate $\Delta\text{OD} = \text{OD 2} - \text{OD 1}$

RESULT

$$\frac{\text{Abs. sample}}{\text{Abs. standard}} \times \text{Standard Conc. } (\mu\text{mol/L}) = \text{Creatinine Conc. } (\mu\text{mol/L})$$

EXPECTED VALUES

Serum/Plasma

Health adult male: 59 - 104 µmol/L

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Health adult female: 45 - 84 $\mu\text{mol/L}$

Urine

4.42-16.8mmol/24hr or 0.5-1.9g/24hr

It is recommended for each laboratory to establish its own reference range.

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Bilirubin, Dopamine and Hemoglobin may affect the result of creatinine concentration detection. A sample blank control is necessary for hemolyzed samples or with high level bilirubin.
3. Samples exceeding 1000 $\mu\text{mol/L}$ should be diluted with saline and retested.
4. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 1000 $\mu\text{mol/L}$ ($R \geq 0.99$)

Accuracy: control recovery relative deviation $\leq 10\%$

Precision: Within Run: $CV \leq 3\%$;
Run-to-Run: $CV \leq 5\%$

Interference: no interference detected for: ascorbic acid($\leq 40\text{mg/dl}$), chylomicrons($\leq 2500\text{U/dl}$), bilirubin($\leq 20\text{mg/dl}$), heparin($\leq 5000\text{U/dl}$) and trisodium citrate($\leq 1000\text{mg/dl}$).

Reagent Blank Absorbance: at 546nm wavelength and 10 mm optical diameter, O.D. ≤ 0.1

REFERENCES

1. H. Crocker *et al.*, J Clin Pathol 41:576-581 (1988)
2. Sheshadri Narayanan *et al.*, Clin. Chem. 26(8):1119-1126 (1980)
3. Amy Earley *et al.*, Ann Intern Med. 156:785-795 (2012)

Not Intended for Sale in the United States.

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