

# Bioway Chemistry Reagent Series

## The Serum Creatine Kinase Reagent Kit

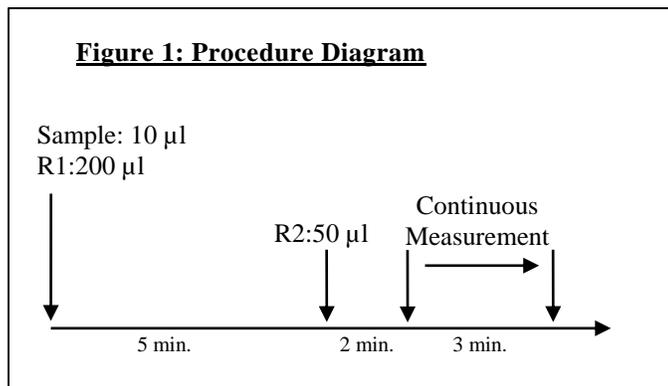
Detection of Creatine Kinase in Human Serum or Plasma on Chemistry Analyzers



Cat. No. R019K11

The Serum CK Reagent Kit

### SUMMARY OF TEST PROCEDURE



**Table 1: Instrument Parameters\***

F factor	4180	Slope of reaction	Increase
Testing wavelength	Dλ : 340 nm Sλ : 405 nm	Sample volume	10 µl
Test method	Rate Method	R1 volume	200 µl
Reaction temperature	37°C	R2 volume	50 µl

\*Refer to Figure 1 and the package insert for detail

### INTENDED USE

**Bioway Chemistry Reagent Series CK Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Creatine Kinase in human serum or plasma on automated clinical chemistry analyzers.

### SUMMARY AND EXPLANATION

Creatine kinase is also known as creatine phosphokinase or phosphocreatine kinase because it catalyzes the reaction of creatine and adenosine triphosphate to form phosphocreatine. Creatine kinase can be found in various tissues like skeletal muscle, smooth muscle and brain. Creatine kinase is often measured in patients with chest pain for diagnosing heart attack and other muscle diseases because of the studies which point out the correlation between increased serum CK concentration and the possibility of muscle injury, rhabdomyolysis, myositis, myocardial infarction and myocarditis.

### TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the CK activity (U/L) in human serum or plasma.



Creatine kinase catalyzed the phosphorylation of ADP to form ATP in the presence of creatine phosphate. Then a phosphate group is transferred from ATP to glucose and produces glucose-6-phosphate which is oxidized to 6-phosphogluconate accompanying with the production of NADPH. The process is quantified by measuring the absorbances at 340 nm in a kinetic fashion.

The rate of increase in absorbance at 340 nm is directly proportional to the amount of CK in the sample.

### MATERIALS PROVIDED

#### Reagents:

<b>R1</b>	Creatine phosphate N-Aetyl Cysteine Glucose-6-phosphate dehydrogenase	100 mmol/L 20 mmol/L 2000 U/L
<b>R2</b>	Magnesium acetate AMP	100 mmol/L 5 mmol/L

### MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer
- CK control and calibrator 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. The 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 preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2-8°C for 10 days.

### TEST PROCEDURE (see Figure 1)

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

**Calibration:** Recommend using commercially available calibrator set for optimal results.

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

- Add 10 µl of sample and 200 µl of R1; mix well and incubate at 37°C for 5 minutes.
- Add 50 µl of R2; mix well and incubate at 37°C for 2 minutes.
- Take continuous optical density measurement for 3 minutes.
- Calculate average  $\Delta A / \text{min}$

### RESULT

The CK activity in U/L can be obtained by the following calculation:

$$\text{CK (U/L)} = (\Delta A_{\text{test}} / \text{min} - \Delta A_{\text{blank}} / \text{min}) \times \text{factor (F)}$$

The calculation factor for UV spectrophotometer is 4180 when the optical path is 10 mm. It is recommended for each laboratory to

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establish its own F factor. Please refer to instrument application if testing under different conditions.

### EXPECTED VALUES

Male : 38~174 U/L (37°C)

Female : 26~140 U/L (37°C)

It is recommended for each laboratory to establish its own expected values.

### 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. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with CK exceeding the maximum measurement range should be diluted with saline and retested.

### PERFORMANCE CHARACTERISTICS

**Linearity:** 0 - 1500 U/L ( $R \geq 0.990$ )

**Accuracy:** Bias proportion 90%~110%

**Precision:** Within Run:  $CV \leq 5\%$ ;  
Run-to-Run:  $CV \leq 6\%$

**Interference:** no interference detected for: Conjugated bilirubin ( $\leq 684 \mu\text{mol/L}$ ), heparin ( $\leq 6000 \text{U/dl}$ ), and lipid ( $\leq 3000 \text{NTU}$ )

**Reagent Blank Absorbance:** At 340nm wavelength and 10mm optical diameter, O.D.  $\leq 0.70$ .

### REFERENCES

1. Engle W. K. *et al.*, Science, 168:273 (1970)
2. Young D. S. *et al.*, Clin. Chem., 21: 1D (1976).
3. Ziegenhorn J. *et al.*, Clin. Chem., 22:151 (1976)
4. McComb R. B. *et al.*, Clin. Chem., 22:141 (1976)

Not Intended for Sale in the United States.

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