BIOBASE

# Creatinine (CREA) Test Kit

## (Trinitrophenol)

### 【NAME】

Creatinine (CREA) Test Kit (Trinitrophenol)

### 【INTEND USE】

The reagent is intended for the in vitro quantitative determination of Creatinine (CREA) in human serumor plasma. Plasma creatinine concentration reflects renal impairment, the glomerular filtration rate and other urinary tract patency.

### 【METHODOLOGY】

Bile acid is oxidation by 3-α-hydroxysteroid dehydrogenase and Thio - Creatinine and picric acid orange form into red complexes under alkaline condition, within the fixed time absorbance increase rate is proportional to creatinine concentrations in the sample. CREA is a more specific renal function index than urea and uric acid. Creatinine increased: Early kidney creatinine values often are not high, until renal parenchymal damage, serum creatinine value was increased. Its value increased three to five times suggesting the possibility of uremia, increased by 10 times, common in uremia. If the creatinine and urea nitrogen increased at the same time, suggesting that severe kidney damage. If blood urea nitrogen elevated, but creatinine is often not high due to factors outside. Reduced creatinine: renal failure late, muscle atrophy, anemia, leukemia, diabetes insipidus and so on.

### 【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;

Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 week.

Reagent is not allowed frozen.

### 【SPECIMEN COLLECTION AND HANDLING】

Serum or Heparin plasma or plasma.

Application of distilled water to dilute urine, the detection value multiplied by the dilution report results

Stability of sample: Serum or plasma stability: 4 ~ 25℃ preservation stability in 7 days, - 20℃ preservation can be stable for 3 months.

Urine stability: 20~ 25℃keep stable 2 days; 4 ~ 8℃ keep stable 6 days; - 20℃ can be stable for 6 months.

### 【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

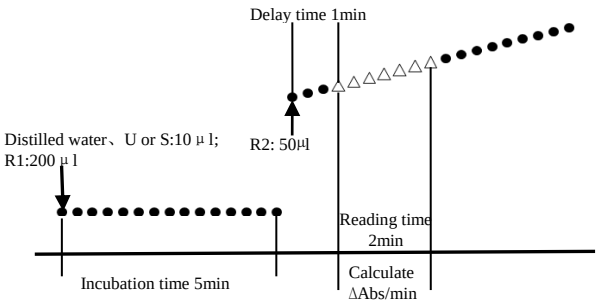
### 【SYSTEM PARAMETERS】

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

| | |
|---|---|
| Temperature | 37° C |
| Cuvette light path | 1.0cm |
| Primary Wavelength | 505 nm |
| Secondary Wavelength | 600nm |
| Assay Type | Fixed time method |
| Direction | Increase |
| Sample : Reagent Ratio | 10:200:50 |
| eg : Sample Vol | 10 μL |
| Reagent1 Vol | 200 μL |
| Reagent2 Vol | 50 μL |
| Linearity | 0～880μmol/L |
| Testing | Deducting the reagent blank |

### 【OPERATION STEPS】

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample




### 【CALCULATION】

$$\text{CREA（u mol/L）} = \frac{\text{Sample } \Delta A/\text{min}}{\text{Calibrator } \Delta A/\text{min}} \times \text{Calibrator concentration}$$

### 【REFERENCE RANGE】

Serum/Plasma:female:53～97 μmol/L male:80～115 μmol/L

Urine: female:97～177 μmol/24h male:124～230 μmol/24h

By clinical trials, choose no less than 100 women or men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

Recommendation: The laboratory set up its own reference range!

### 【THE LIMITATION OF TEST RESULTS】

CREA testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

### 【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

### 【PERFORMANCE INDEX】

1. Reagent blank absorbance≤0.5,（ 505nm,lcm optical path).
2. Precision : repeatability CV≤5%;batch variations R≤8%.
3. Accuracy: relative deviation ≤10%.
4. Linearity range: 0～880μmol/L, r≥0.990.
5. Stability: All package reagent, unopened and avoid light, preservation in 2~8 ℃, stable 12 months, once opened, avoid light, preservation in 2~8 ℃,stable 1 week.

### 【ATTENTION】

1.The maximum linearity is 880 μmol/L.If testing results is upper limit,dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

2.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane. Some necessary preventive measures should be taken during use of reagents. If reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.

3.Liquid waste disposal: Suggest follow local regulations.

**Biobase Biodustry(Shandong)Co.,Ltd**

Add: Biobase Biological Industrial Park, Mingshui Economic Development Zone, Jinan, China, 250200

Tel: 0086-531-91219801/03 Fax: 0086-531-81219804