BIOBASE

Creatine Kinase (CK) Test Kit
(IFCC Method)

【NAME】

Creatine Kinase (CK) Test Kit(IFCC Method)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Creatine Kinase (CK) in human serum or plasma. Increased activity common to all types of progressive muscular atrophy, Duchenne muscular dystrophy, etc.

Creatine kinase increased: mainly used for the diagnosis of myocardial infarction and various types of progressive muscular atrophy, skeletal muscle injury, muscular dystrophy, acute myocarditis, cerebrovascular accident, meningitis, thyroid dysfunction, strenuous exercise, the use of chlorpromazine , penicillin and other drugs. Determination of creatine kinase activity has an important value in the diagnosis of these diseases.

【METHODOLOGY】

$$\text{ADP + Phosphocreatine} \xrightarrow{\text{CK}} \text{Creatine + ATP}$$

$$\text{ATP + GLU} \xrightarrow{\text{Hexokinase}} \text{ADP + H2O}$$

$$\text{GLU-6-Phosphoric acid} + NAD^+ \xrightarrow{\text{G6P-DH}} \text{6-Phosphogluconate + NADH} + H^+$$

【STABILITY AND STORAGE】

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

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

Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh Serum. Do not use hemolysis.

Stability of sample: 2~8℃ preservation stability in 8 hours.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

【SYSTEM PARAMETERS】

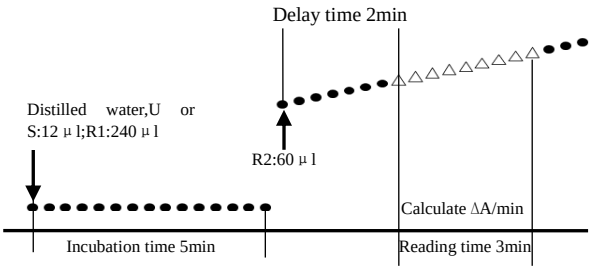
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	340nm
Secondary Wavelength	405nm
Assay Type	Rate Method
Direction	Increase
Sample : Reagent1 : Reagent2Ratio	1:20:5
eg : Sample Vol.	12 μL
Reagent1 Vol.	240 μL
Reagent2 Vol.	60 μL
Linearity	0～1000U/L
Testing	Deducting the reagent blank

【OPERATIONG STEPS】

Double reagent operation:

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



【CALCULATION】

Use the Calibrator

$$\text{Sample Concentration} = \frac{\text{Sample } \Delta\text{Abs/min}}{\text{Calibrator } \Delta\text{Abs/min}} \times \text{Calibrator Concentration}$$

【REFERENCE RANGE】

Female :24～170U/L Male: 0～190U/L

Newborn(2-12months) :0～325 U/L

Children and the elderly:0～225 U/L

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】

CK 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≤0.4,（340nm,lcm optical path).

2.Precision: repeatability CV≤5%;batch variations R≤5%.

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～1000U/L, r≥0.990.

【ATTENTION】

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

2.The maximum linearity is 1000U/L.If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

3.Liquid waste disposal: Suggest follow local regulations

4.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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