Creatine Kinase (CK) Diagnostic Reagent Kit (DGKC Method)
Product Instruction

Product name
Creatine Kinase (CK) Diagnostic Reagent Kit (DGKC Method)
Abbreviation: CK

Package Specifications

R1	R2
80ml×2	20ml×1

Calibrator (lyophilized):

Specification 1 (1.0mL×1; 1 level).

Intended use
Creatine kinase (CK) diagnostic reagent is used for quantitative in vitro determination of creatine kinase in human serum on photometric systems.

Clinical significance
The determination of CK and CK-isoenzyme activities is utilized in the diagnosis and monitoring of myocardial infarction such as the progressive Duchnne muscular dystrophy. Following injury to the myocardium, such as occurs with acute myocardial infarction, CK is released from the damaged myocardial cells. In early cases, a rise in the CK-activity can be found just 4 hour after an infarction. The CK-activity reaches a maximum after 12-24 hours and then falls back to the normal range after 3-4 days.

Principle
The assay consists of three reaction steps:

1. $\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$
2. $\text{ATP} + \text{Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-P}$
3. $\text{Glucose-6-P} + \text{NADP}^+ \xrightarrow{\text{G6P-DH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^+$

The NADPH formed is measured by determining its absorbance at 340 nm and this is directly proportional to the amount of CK activity in the sample.

Main ingredient

Composition	Concentration
Imidazole buffer	100mmol/L
N-acetyl cysteine	20mmol/L
EDTA	2mmol/L
NADP	2mmol/L
G6P-DH	>1500U/L
Hexokinase (HK)	>2500U/L
Glucose	20mmol/L
Creatine phosphate	30mmol/L
Di(adenosine-5') pentaphosphate	10μmol/L
ADP	2mmol/L

Storage and stability
This kit stays stable for 12 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Serum.
Stability:
2 days at 15-25°C
7 days at 2-8°C
4 weeks at (-15)-(-25)°C.

Assay procedure

	Blank	Sample
Reagent 1	200μl	200μl
Dist. water	10μl	-
Sample	-	10μl
Mix. Incubate for 5 minutes at 37°C. Then add:		
Reagent 2	50μl	50μl
Mix. Incubate for 2 minutes at 37°C. Read absorbance within 2 minutes and calculate the average rate of the absorbance change ΔA/min.		
Main wavelength	340 nm	
Sub wavelength	405 nm	
Method	Rate	
Reaction direction	+	

Procedure (Manual):
1. Zero spectrophotometer at 340nm with distilled water.
2. Appropriately label cuvettes: reagent blank, sample, etc.
3. Pipette 1.0ml (1000μl) of reagent 1 into all cuvettes.
4. Add 0.50ml (50μl) of sample to respective cuvettes. Mix.
5. Incubate for 5 minutes at 37°C.
6. Then add 0.25ml (250μl) of reagent 2 to respective cuvettes. Mix gently.
7. Incubate for 2 minutes at 37°C. Read absorbance within 2 minutes and calculate the average rate of the absorbance change ΔA/min.

Determine the average absorbance per minute (ΔA/min), multiply by factor 4180 for results in U/L.

Calculations

$$\text{Conc. of CK} = \frac{\text{A(sample)- A(blank)}}{\text{A(Cal.) - A(blank)}} \times \text{conc. of Cal.}$$

Reference interval

Males: < 190 U/L
Females: < 170 U/L
It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

Measuring range
The method is linear up to 1000 U/L.
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Direct Bilirubin	40mg/dl
Total Bilirubin	40mg/dl
Haemoglobin	200mg/dl
Intralipid	0.50 %
VC	50mg/dl

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

Paramters

HITACHI Parameters	
Model	7180
Assay Code	Rate-A
Reaction Time	10
Assay Point	22-32
Wave Length Sec	405
Wave Length Prim	340
ABS. Limit	32000
Sample Volume（uL）	10
R1 Volume（uL）	200
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	Linear
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	10
Sample DIL. VOL.	/
R1 Volume（uL）	200
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	405
METHOD	RATE
SLOPE	-
Method Point	15--25
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5

LAST	-2.0-+2.5
Dynamic Range L	15
Dynamic Range H	600
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	liner
STD(1) Conc.#	*
Unit	U/L

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