Creatine kinase Assay Kit (CK-NAC)

Method: Phosphocreatine Method

Cat .No.	Size	Analyzer
EGS201X	R1: 2×70 ml R2: 1×35 ml	For Hitachi917 & OlympusAU640/400/600
EGB200X	R1: 2×80 ml R2: 1×40 ml	For Hitachi 717 & ShimadzuCL7200/8000
EGH201X	R1: 2×50 ml R2: 1×25 ml	For Hitachi902
EGD201X	R1: 24×4.3 ml R2: 6×4.3 ml	For Siemens Dupont/Siemens Behring Series
EGCK460BS	R1: 6×20 ml R2: 3×10 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGCK	R1: 6×20 ml R2: 3×10 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of creatine kinase in human serum or plasma.

CLINICAL SIGNIFICANCE[1]

CK begins to rise at 4-8h after myocardial infarction, reaches a peak at 16-36h, and returns to normal within 2-4 days. It is one of the early diagnostic indicators of acute myocardial infarction, and its increase is consistent with the degree of myocardial damage.

Various muscle diseases, such as progressive muscular dystrophy, polymyositis, CK is also significantly increased; systemic convulsions, myocarditis, pericarditis, CK can also be increased.

CK increases in acute brain injury and epilepsy.

After surgery, cardiac catheterization, coronary angiography, exercise test, repeated intramuscular injection, and strenuous exercise, CK increased transiently.

ASSAY PRINCIPLE[2,3]

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{Creatine kinase}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{Hexokinase}} \text{ADP} + \text{Glucose-6-phosphate}$$

$$\text{Glucose-6-phosphate} + \text{NAD} \xrightarrow{\text{G-6-P-D-H}} \text{6-phosphogluconate} + \text{NADH} + \text{H}^+$$

CK specifically catalyzes thetransphosphorylati-on of ADP to ATP. Through a series of coupled enzymatic reactions, NADH is produced at a rate directly proportional to the CK activity and is measured at 340 nm.

REAGENT COMPOSITION

Contents	Concentration
Imidazole buffer pH6.7	100 mmol/L
Creatine phosphate	30 mmol/L
Glucose	20 mmol/L
N-Acetylcysteine (NAC)	20 mmol/L
MgAC	10 mmol/L
EDTA	2 mmol/L
ADP	2 mmol/L
AMP	5 mmol/L
Diadenosine pentaphosphate	10 μmol/L
G6PDH	>1.5 KU/L
HK	>2.5 KU/L
$NADP^+$	2mmol/L

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. The production date and expiry date are shown on the label.
3. Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
4. Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340nm.

It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Serum, plasma (EDTA anticoagulation or heparin anticoagulation).

The samples are stable for 8 hours when stored at 2-8℃, and for 7 days when stored at (-15)-(-25)℃.

ASSAY PROCEDURE

Test Condition (Hitachi 917)

Main wavelength	340 nm	Sample (S)	10μl
Secondary wavelength	405 nm	Reagent 1 (R1)	200μl
Reaction temperature	37℃	Reagent 2 (R2)	50μl
Cuvette diameter	1cm	Reaction type	Rate method

Operate procedure

Add into cuvette：	
Sample (S)	10μl
Reagent 1 (R1)	200μl
Mix well and incubate for 5 minutes at 37℃	
Reagent 2 (R2)	50μl
Mix well and incubate for 2 minutes at 37℃, continuously measure the absorbance within 180 seconds and calculate the absorbance change rate Calculate (△A/min)	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell calibrator.

Calibrator traces to the IFCC reference method (ultraviolet spectrophotometry).

1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2. Treatment of the calibrator: the calibrator is lyophilized, the zero-point calibrator is ultrapure water, and the lyophilized needs to be reconstituted with ultrapure water.
3. Calibration mode: two-point linear calibration.
4. Requirements for calibration and frequency: It is recommended to calibrate every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry

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analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell quality control . The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check that the cuvette and sipper are clean.
5. Check that the water is not contaminated and that bacterial growth can lead to incorrect results.

CALCULATION RESULT

1. Using calibrator

$$\text{Concentration} = \frac{A_{sample}\ /\text{min}}{A_{calibrator}\ /\text{min}} \times \text{Calibrator value}$$

2. Using K factor

CK (U/L) =ΔA/min × K factor

Wavelength	340 nm	334 nm	365 nm
Factor	4127	4207	7429

REFERENCE RANGE

	25℃	30℃	37℃
female	< 70 U/L	< 110 U/L	< 167 U/L
male	< 80 U/L	< 130 U/L	< 190 U/L
newborn	< 136 U/L	< 210 U/L	< 325 U/L
Children and old	< 94 U/L	< 150 U/L	< 225 U/L

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of Intralipid ≤ 250 mg/dL, bilirubin ≤ 40 mg/dL, VitC ≤ 50mg/dL, Hb ≤ 500mg/dL, is less than 10%.

ACCURACY

The kit is tested with ERM-AD455 international reference material. The deviation of the results should ≤10%.

SENSITIVITY

When the sample concentration is 500 U/L, the change of absorbance should ≥ 0.06.

LINEARITY

In the range of [4,1032] U/L, the linearity correlation coefficient r≥0.990. In the range of [4,150] U/L, the absolute deviation should ≥ ±15 U/L; In the range of [150,1032] U/L, the relative deviation should ≤10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 5 days, and each batch was measured for 5 times.The results are as follows:

a) Repeatability precision (N=20)

	Mean (U/L)	CV(%)
Control 1	194.865	0.62
Control 2	501.490	0.4

b) Intermediate precision (N=25)

	Mean (U/L)	CV(%)
Control 1	194.32	3.4
Control 2	437.89	3.3

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations. The following treatment methods can be selected:

Autoclave at 121°C for 15 minutes (but do not use autoclave to treat waste containing hypochlorous acid solution), or soak in hypochlorous acid solution (effective concentration greater than 1000ppm) for one hour the above.

REFERENCES

1. Rec. GSCC (DGKC); J. Clin. Chem. Clin. Biochem 1977; 15: 255.
2. Stein, W. (1985), Med. Welt 36: 572.
3. Szasz, G., et al. Clin. Chem 1976; 22: 650.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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