Creatine kinase Assay Kit (CK-NAC)

Method: DGKC

Cat .No.	Size	Instrument
GB200X	R1: 2×80 ml R2: 1×40 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS201X	R1: 2×70 ml R2: 1×35 ml	For Hitachi917 & OlympusAU640/400/600
GH201X	R1: 2×50 ml R2: 1×25 ml	For Hitachi902
GX201X	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT201X	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA

INTENDED USE

This reagent is intended for the *in vitro* quantita-tive determination of creatine kinase in human serum. This product is suitable for manual use, and is also suitable for all automatic analyzer.

CLINICAL SIGNIFICANCE[1]

Serum creatine kinase (CK) levels have proven valuable in the assessment of cardiac and skeletal muscle diseases, including myocardial infarction and muscular dystrophy. There may also be an increase in CK values associated with diseases of the central nervous system. Diseases of the thyroid show an inverse relationship to CK values. A combined analysis of creatine kinase and lactate dehydrogenase isoenzymes provides a definitive diagnosis of acute myocardial infarction.

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.

SAMPLE COLLECTION AND PREPARATION

Samples are stable for 4 hours at temperature, for 8 hours at 2-8°C, for 2 days at -20°C.

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

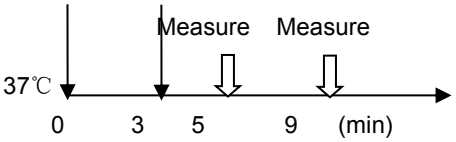
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent after opening is stable for 28 days month on-board the analyser .

ASSAY PROCEDURE

Test Procedure for Analyzers

Assay Mode: Rate
Wave Length (main/sub): 340 nm/410 nm

Sample:10 μl
R1: 200 μl R2: 50 μl



1. Mix 10 μl sample with 200 μl R1 and incubate at 37℃ for 3 minutes.
2. Add 50 μl R2 into cuvette, mix and incubate at 37℃ for 2 minutes.
3. Read initial absorbance and start timer simultaneously, read again after 1, 2 and 3 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALCULATION

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 (K = 4180)

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall

within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

	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

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

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SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The assay is linear up to 1000 U/L. If the sample above this concentration should be diluted 1+1 with distilled water and repeat assay. Multiply the result by 2.

PRECISION
The CV of the test should be less than 10%

Intra assay precision		
N=15	Level1	Level 2
Mean (U/L)	204.5	446.3
SD(U/L)	0.64	2.8
CV	0.31%	0.62%
Inter assay precision		
N=5	Level1	Level 2
Mean (U/L)	200.3	459.6
SD(U/L)	1.03	1.96
CV	0.52%	0.43%

SENSITIVITY
The minimum detectable level that can be distinguished from zero has been determined as 3.0 U/L.

INTERFERENCE
The following analyze were tested up to the levels indicated and found not to interfere:
Hemoglobin: 500 mg/dl
Intralipid: 500 mg/dl
Direct bilirubin: 40 mg/dl
Ascorbic Acid: 50 mg/dl

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y=1.0026X-0.2193 , R^2=0.9995; 50 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Tietz, N. W, Textbook of Clinical Chemistry, W.B. Saunders Co.,Philadelphia, 1986, p. 678-6863.
2. Szasz, G., et al. Clin. Chem 1976; 22: 650.
3. Recommendations of the German Society for Clinical Chemistry.Standardization of methods for the estimation of enzyme activities in biological fluids: Standard method for the determination of creatine kinase activi-ty. J Clin Chem Clin Biochem 1977; 15:255-60.

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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