CK–NAC (2–8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCKN3	10x5ml / 2x5ml
MPRCKN4	10x10ml / 2x10ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of Creatine Kinase in human serum.

Clinical Significance:
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, pulmonary infarction, electrical shock, strenuous exercise and recent surgery. Early pregnancy may induce decreased levels.

Test Principle:
Creatine Phosphate + ADP $\xrightarrow{CK}$ Creatine + ATP

Glucose + ATP $\xrightarrow{HK}$ ADP + Glucose-6-Phosphate

G-6-P + NADP $\xrightarrow{G6PDH}$ 6-Phosphogluconate + NADPH + H^+

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
CK Reagent R1	Imidazole Buffer pH6.6	100 mmol/l
	Glucose	20 mmol/l
	Mg Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	NADP	2 mmol/l
	G6PDH	2000 U/l
	HK	2500 U/l
CK Reagent R2	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	Creatine Phosphate	30 mmol/l
	Adenosine	10 µmol/l

Reagent Preparation and Stability:
R1: Liquid, ready to use.
R2: Liquid, ready to use.
Kit components R1 and R2 are stable till the expiry date when stored at 2 - 8°C.

Sample Collection, Preparation and Stability:
Collect serum by separation after standard venepuncture technique. CK will be stable in the sample for up to 3 days when stored at 2 – 8°C.
Do not use haemolysed samples.

Assay Procedure: Sample Start:
Prepare a suitable volume of Working Reagent by mixing 5 volumes of Reagent 1 with 1 volume of Reagent 2 (5 R1 + 1 R2). This mixture will be stable for up to 10 days at 2 - 8°C if stored sealed and free from contamination.

WAVELENGTH	340nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length

Description	Volume
Working Reagent	1000 µl
Incubate the Working Reagent at assay temperature for two minutes to equilibrate.	
Sample	20 µl
Mix and incubate for 1 minute at assay temperature. Start a timer and read the absorbance of the sample after exactly 1, 2 & 3 minutes. Calculate the mean absorbance/min (Δ Abs)	

Calculation:
Concentration (U/l) = ΔAbs Sample x 8095

Performance Characteristics:
Measuring range:
8 - 2000 U/l
Dilute samples with higher concentrations using Normal saline 1+9 and rerun the assay. Multiply the result by the dilution factor (10).

Analytical Sensitivity: (Lowest detection limit):
8 U/l

Imprecision

Intra-Assay Precision:

Sample	Mean (U/l))	SD (U/l)	CV %
Pool 1	172.5	8.80	5.10
Pool 2	476.8	14.6	3.06

Inter-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	168.4	4.23	2.51
Pool 3	479.0	5.32	1.11

Reference Range:

	37°C
Male	24 – 195 U/l
Female	24 – 170 U/l

Each laboratory should establish its own mean reference range according to the population.

Limitations:
The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:
Contact AMS Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. IFCC methods for the measurement of catalytic concentrations of enzymes, JIFCC, 1989; 1: 130.
2. Szasz G and Busch EW. Paper presented at 3rd Eur. Congr. Clin. Chem. Brighton, England. June 1979; 3-8 (abstract).

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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