CK NAC-activated (CK- NAC)

Creatine Kinase
RX DAYTONA PLUS

INTENDED USE

For the quantitative *in vitro* determination of Creatine Kinase in serum. This product is suitable for use on the RX **daytona plus** RX **series** analyser.

Cat. No.			
CK 8313	R1	Buffer	4 x 20 mL
	R2	Substrate	4 x 7 mL

GTIN: 05055273208535

CLINICAL SIGNIFICANCE

Measurements of Creatine Kinase (CK) and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

UV METHOD

This method is an optimized standard method according to the concentrations recommended by the IFCC.

PRINCIPLE

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

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

$$\text{Glucose-6-P} + \text{NADP}^{+} \xrightarrow{\text{G-6-PDH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^{+}$$

SAMPLE COLLECTION AND PREPARATION

Non-haemolysed serum, non-haemolysed EDTA or heparinized plasma. CK is stable in serum for 24 hours at +25°C or for 7 days at +2 to +8°C.

REAGENT COMPOSITION

Contents		Concentration in the Test
R1.	**Buffer**	
	Buffer	123 mmol/L, pH 6.5
	EDTA	2.46 mmol/L
	ADP	2.46 mmol/L
	AMP	6.14 mmol/L
	Diadenosine Pentaphosphate	19 µmol/L
	NADP	2.46 mmol/L
	HK	≥ 4000 U/L
	G-6-PDH	≥ 2800 U/L
	N-Acetylcysteine	24.6 mmol/L
	Mg^{2+}	12.3mmol/L
	Sodium Azide	0.09% (w/v)
R2.	**Substrate**	
	Buffer	20 mmol/L, pH 8.8
	Glucose	120 mmol/L
	Creatine Phosphate	184 mmol/L
	EDTA	2.46 mmol/L
	Sodium Azide	0.09% (w/v)

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Safety Data Sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1 Buffer
Stable up to the expiry date when stored at +2 to +8°C. The reagent is stable on board the analyser for approximately 28 days at +10°C.

R2 Substrate
Stable up to the expiry date when stored at +2 to +8°C. The reagent is stable on board the analyser for approximately 28 days at +10°C.

MATERIALS PROVIDED

R1 Buffer
R2 Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multi-sera Level 2, (Cat. No. HN 1530) and Level 3, (Cat. No. HE 1532).
Randox Calibration Serum Level 3, (Cat. No. CAL 2351).
RX **series** Saline, (Cat. No. SA 8396).

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **daytona plus** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

RX DAYTONA PLUS CALIBRATION

0.9% NaCl as zero calibrator and Randox Calibration sera Level 3 are recommended for calibration. A 2 point calibration is recommended every 28 days, with change of reagent lot/bottle or as indicated by quality control procedures.

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 cleanliness of all equipment in use.
3. Check water. Contaminants, i.e. bacterial growth, may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

NORMAL VALUES IN SERUM [3]

	+25°C	+30°C	+37°C
Men	10-80 U/L	15-125 U/L	24-195 U/L
Women	10-70 U/L	15-110 U/L	24-170 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance data was obtained using an RX **daytona plus** analyser at +37°C.

INTERFERENCE

The following analytes were tested up to the levels indicated at CK-NAC concentrations of 65.0 U/L and 475 U/L and found not to interfere:

	65.0 U/L	**475 U/L**
Haemoglobin	500 mg/dL	1000 mg/dL
Total Bilirubin	30 mg/dL	60 mg/dL
Conjugate Bilirubin	60 mg/dL	60 mg/dL
Triglycerides	2000 mg/dL	2000 mg/dL
Intralipid®	1000 mg/dL	2000 mg/dL

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [4]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for CK-NAC on the RX **daytona plus** is 7 to 2379U/L**.**

SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with ≤40% Total Error. LoD is the lowest concentration that can be detected to determine the presence or absence of CK-NAC. LoB is the highest concentration that is likely to be observed in a blank sample.

RX daytona plus

Limit of Blank (U/L)	0.33
Limit of Detection (U/L)	2.24
Limit of Quantitation (U/L)	7.00

PRECISION

Within Run Precision

	Level 1	Level 2	Level 3
Mean (U/L)	53.6	98.2	222
SD	2.05	2.43	7.09
CV (%)	3.83	2.48	3.19
n	80	80	79

Total Precision

	Level 1	Level 2	Level 3
Mean (U/L)	53.6	98.2	222
SD	3.20	4.40	10.5
CV (%)	5.98	4.48	4.73
n	80	80	79

CORRELATION

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

Y = 0.99X +10.17
and a correlation coefficient of r = 1.00

40 patient samples were analysed spanning the range 33.34 to 2336.18 U/L.

REFERENCES

1. GSCC (DGKC); J. Clin. Chem. Clin. Biochem 1977; **15**: 255.
2. Szasz, G., *et al.* Clin. Chem 1976; **22:** 650.
3. Lothar Thomas. Clinical Laboratory Diagnostics. 1st edition. 1998. p73.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

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