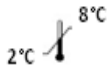
Atlas Medical CE

Creatine kinase

IVD *For in -vitro diagnostic and professional use only*



Store at 2-8°C

INTENDED USE

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

INTRODUCTION

Creatine kinase is a cellular enzyme with wide tissue distribution in the body. Its physiological role is associated with adenosine triphosphate (ATP) generation for contractile or transport systems.

Elevated CK values are observed in diseases of skeletal muscle and after myocardial infarction.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

Creatine kinase (CK) catalyses the reversible transfer of a phosphate group from phosphocreatine to ADP. This reaction is coupled to those catalysed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH):

Phosphocreatine + ADP —CK→ Creatine + ATP

ATP + D-Glucose —HK→ ADP + Glucose-6-phosphate

G6P + $NADP^+$ —G6P-DH→ 6-Phosphogluconate + NADPH + H^+

The rate of NADPH formation, measured photometrically, is proportional to the catalytic concentration of CK present in the sample.

REAGENTS

R 1	Imidazol pH 6.7	125mmol/L
	D-Glucose	25mmol/L
	N-Acetyl-L-Cysteine	25mmol/L
	Magnesium acetate	12.5mmol/L
	NADP	2.52mmol/L
	EDTA	2.02mmol/L
	Hexokinase	≥6 800 U/L
R 2	ADP	15.2mmol/L
	AMP	25 mmol/L
	di-Adenosine-5- pentaphosphate	103 mmol/L
	Glucose-6-phosphate dehydrogenase (G6P-DH)	≥ 8 800U/L
	Creatine phosphate	250mmol/L

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 340 nm.
- Thermostatic bath at 25°C/30°C/ 37°C (± 0.1°C).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- Working reagent (WR)
  Mix: 4 vol. (R1) + 1 vol. (R2)
  Stability: 2 weeks 2-8°C or 48 hours at room temperature (15-25°C).

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
- Do not use reagents over the expiration date.
- **Signs of reagent deterioration:**
  - Presence of particles and turbidity.
  - Blank absorbance (A) at 340 nm ≥1.00.

SAMPLES

Serum or heparin plasma: Stability 7 days at 2-8°C, protected from light.

The creatine kinase activity decreases 10% after 1 day at 2-5°C or after 1 hour at 15-25°C.

PROCEDURE

1. Assay conditions:
   Wavelength:.....340 nm.
   Cuvette :.....1 cm light path.
   Constant temperature:..... 25°C / 30°C / 37°C.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	25 - 30°C	37°C
WR (mL)	1.0	1.0
Sample (µL)	40	20

4. Mix, incubate for 2 minutes.
5. Read initial absorbance (A) of the sample, start the stopwatch and read absorbances at 1 minutes intervals thereafter for 3 minutes.
6. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

25°- 30°C ΔA / min x 4127 = U/L CK

37°C ΔA / min x 8095 = U/L CK

Units:

One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per litre of sample (U/L).

Temperature conversion factors

To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to 25°C	30°C	37°C
25°C	1.00	1.56	2.44
30°C	0.64	1.00	1.56
37°C	0.41	0.63	1.00

QUALITY CONTROL

- Control sera are recommended to monitor the performance of assay procedures.
- If control values are found outside the defined range, check the instrument, reagents and technique for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

	25°C	30°C	37°C
Men, up to	80 U/L	130 U/L	195 U/L
Women, up to	70 U/L	110 U/L	170 U/L

These values are for orientation purpose; each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS

Measuring range:

From detection limit of 2.12 U/L to linearity limit of 2000 U/L. If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.

Precision:

	Intra-assay	
Mean U/L	147	494
CV(%)	0.84	0.73
SD	1.23	3.60

Inter-Assay	
145	485
2.01	1.85
2.91	8.97

Sensitivity:

1 U/L = 0.00012 ΔA/min.

Accuracy:

Results obtained using reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained were the following:

Correlation coefficient $(r)^2$: 0,9995.

Regression equation: y = 1,0846x – 0,3512.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No interferences were observed with glucose until 7g/L, hemoglobin until 5g/dL and triglycerides 7mmol/L. A list of drugs and other interfering substances with CK determination has been reported.

REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry