

IN VITRO DIAGNOSTIC USE



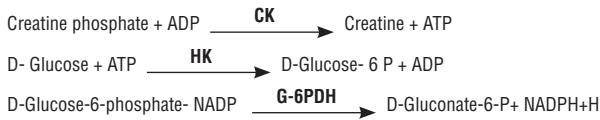
REF 08015	(60 T)	R1 : 2 x 24 ml	R2 : 2 x 6 ml
REF 08022	(150 T)	R1 : 5 x 24 ml	R2 : 5 x 6 ml
REF 08039	(30 T)	R1 : 1 x 24 ml	R2 : 1 x 6 ml

CINICAL SIGNIFICANCE

Creatine kinase (CK) is an enzyme which consists of isoenzymes mainly of the muscle (CK-M) and the brain (CK-B). CK exists in serum in dimeric form as CK-MM, CK-MB, CK-BB and as macro enzyme. Elevated CK values are observed in cardiac muscle damages and in skeletal muscle diseases. Measurement of CK is used especially in conjunction with CK-MB for diagnosis and monitoring of myocardial infarction.

PRINCIPLE

Kinetic determination of creatine kinase reactivated by N-acetylcysteine according to the following reactions:



CK = creatine kinase
HK = Hexokinase

G-6-PDH = Glucose-6-phosphate dehydrogenase. The catalytic activity of CK is determined by measuring the rate of appearance of NADPH+H+ at 340 nm.

REAGENT COMPOSITION

Reagent 1	Buffer imidazole Acetate pH: 6.7 Glucose	100mmol/l 20 mmol/l
Reagent 2	N-Acetyl cysteine Creatine phosphate ADP AMP NADP Diadenosine pentaphosphate Hexokinase Glucose-6-phosphate dehydrogenase	20 mmol/l 30 mmol/l 5 mmol/l 5 mmol/l 2 mmol/l 10 µmol/l 2500 U/l 1500 U/l

REAGENT PREPARATION

Collect sample using standard sampling tubes.
heparinized, or EDTA plasma
Stability: 7 days at +4 °C to 8°C
2 days at +20°C to 25°C

Centrifuge samples containing precipitate before performing assay.

PREPARATION AND STABILITY OF THE WORKING SOLUTION

1) Serum start :

Mix 4 volumes of R1 with 1 volume of R2,
Stability : 10 days at 2 - 8°C
1 day at 20 - 25°C

Unopened kit components, and at 2 - 8°C: Up to the expiry date.

2) Substrate (R2) start:

R1: ready to use
R2: ready to use

Onboard stability: R1 21 days.
R2 21 days.

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- Refer to the current SDS available on request or at www.biomaghreb.com;
- Verify the integrity of the reagents before use; and
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious.
Respect the legislation in force

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory;
- Spectrophotometer or Clinical Biochemistry Analyzer

LINEARITY

Linearity up to 900 U/l at 37° C.

If the ΔDO/min is greater than 0,200 (340 or 334 nm) repeat the test using a sample diluted 1:10 with saline solution. Multiply result by 10.

PROCEDURE

1) Manual procedure : Serum start

Wavelength	340nm. Hg 334 or Hg 365 nm		
Temperature	+25 / +30 / +37°C		
cuvette	1 cm light path		
Zero adjustment	air or distilled water		
	Macro	Semi-Micro	Micro
Working Solution	2500µl	1000µl	500µl
Sample	100µl	40µl	20µl
Mix and incubate for 2 minutes, measure the absorbance increase per minutes for 3 min			
Calculation			
	Macro	Semi-Micro	Micro
340nm ΔA/min.x	4130	4130	4130
Hg 334nm ΔA/min.x	4207	4207	4207
Hg 365nm ΔA/min.x	7429	7429	7429

2) Manual procedure : Substrate (R2) start

Wavelength	340nm. Hg 334 or Hg 365 nm		
Temperature	+25 / +30 / +37°C		
cuvette	1 cm light path		
Zero adjustment	air or distilled water		
	Macro	Semi-Micro	Micro
R1	2000µl	800µl	400µl
Sample	100µl	40µl	20µl
R2	500µl	200µl	100µl
Mix and incubate for 2 minutes, measure the absorbance increase per minutes for 3 min.			
Calculation			
	Macro	Semi-Micro	Micro
340nm ΔA/min.x	4130	4130	4130
Hg 334nm ΔA/min.x	4207	4207	4207
Hg 365nm ΔA/min.x	7429	7429	7429

REFERENCE VALUES

In all cases, each laboratory should establish its own reference values.

T °C	25°C	30°C	37°C
Men	10-80 U/l	15-130 U/l	25-195 U/l
Women	10-70 U/l	15-110 U/l	25-170 U/l

REFERENCES

- Bablok W. et al. A general Regression Procedure for Method transformation;
- J Clin Chem Clin Biochem 1988 ; 26 : 78-790
- Black H.R. Quallich H gareleck CB. Racial differences in serum Creatine kinase levels Am J Med 7986 ; 81 : 479-487;
- Glick M.R, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation Clin Chem 1986 ; 32 ; 470-474 Passing;
- H. Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods J Clin Chem Clin Biochem 1983; 21: 707-720 ;
- Guder W. G., Narayanan S., Wisser H., Zawta B. List of Analytes Preanalytical Variables, Brochure in Samples : From The Patient to the Laboratory Darnstadt GIT Veriag 1996.



Manufacturer



Use by



In Vitro Diagnostic



Temperature
Limitation



Catalogue number



See insert



Store away from light



Sufficient
for < n > essais



Batch number