

# CK - NAC

## (IFCC - KINETIC)



ISO 9001:2008  
ISO 13485:2003

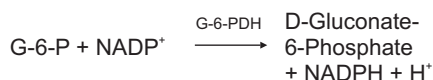
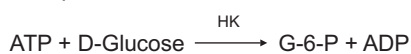
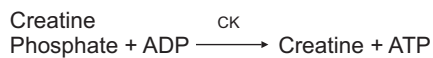
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### CLINICAL SIGNIFICANCE

Creatine kinase (CK) is primarily found in skeletal muscle, cardiac muscle and brain tissue. Damage to any of these tissues may result in increased levels of CK activity in serum. Following myocardial infarction usually within 18 to 30 hours CK values increase by 7-12 times the normal level. Elevated CK activity is indicated in hypothyroidism, various types of muscular dystrophy, viral myositis and similar types of skeletal muscle disease.

### PRINCIPLE

Kinetic determination of the creatine kinase based upon IFCC recommendations (and optimized according to ECCLS standard method):



CK = Creatine kinase  
HK = Hexokinase  
G-6-P = D-Glucose-6-phosphate  
G-6-PDH = Glucose-6-phosphate dehydrogenase

### REAGENTS COMPOSITION

#### Reagent 1: R1 (Enzyme)

Imidazole, pH 6.7	125 mMol/L
D-Glucose	25 mMol/L
N-Acetyl-L-Cystein	25 mMol/L
Magnesium acetate	12.5 mMol/L
NADP	2.52 mMol/L
Hexokinase	≥ 6800 U/L
EDTA	2.02 mMol/L

#### Reagent 2: R2 (Buffer)

Creatine phosphate	250 mMol/L
ADP	15.2 mMol/L
AMP	25 mMol/L
Diadenosine-5-phosphate	103 mMol/L
G-6-PDH	≥ 8 800 U/L

### Working Reagent Preparation

Reconstitute Enzyme (R1) with the volume of Buffer (R2) indicated on R1 Label. Mix gently and the working reagent is ready after 10 minutes.

### STORAGE AND STABILITY

Unopened reagent when storage at 2-8°C is stable until the expiry date marked on each labels. Reconstituted reagents stable at 2-8°C for 2 weeks at 20-24°C for 12 Hrs.

### PROCEDURE

Pipette in to a clean test tube :-

Working Reagent 1	500 µL
Sample	20 µL

Mix and after 2 minute incubation, measure the variation of absorbance per minute ( $\Delta A/\text{min.}$ ) for 3 minutes and multiply the average  $\Delta A/\text{min}$  X Factor.

### SAMPLES

Serum or plasma which has no sign of haemolysis. Specimen should be stored in dark till the test is being performed. No Prior patient preparation is needed. (All samples should be handled as potential infective agents as no laboratory methods make conclusive finding for its safety. Therefore, adequate protective laboratory measures should be taken while handling such materials).

### SYSTEM PARAMETERS

Reaction	Kinetic/Increasing
Temperature	37° C
Wavelength	340 nm
Factor	4127
Std Concentration	NA
Absorbance Range	0-2 A
Cuvette Path Length	1 cm
Reagent Volume	500 µL
Sample Volume	20 µL
Delay time	120 secs
Interval Time	30 secs
No. of Readings	4
Linearity	1000 IU/L
Max. limit of Blank Reagent	0.5 A
Final Colour Stability	NA
Zero setting with	Distilled Water

### RESULTS CALCULATION

CK Activity (IU/L) =  $4127 \times \Delta A/\text{minute}$   
Where F = 4127 (based on the millimolar absorption of NADPH at 340 nM).

### EXPECTED VALUES

	30° C	37° C
Women	: 15-110 IU/L	24-170 IU/L
Men	: 15-130 IU/L	24-200 IU/L

**Note** : It is recommended for each laboratory to establish and maintain its own reference values. The values are only an indication.

### LINEARITY

The method is linear upto 1000 IU/L For the sample values higher than 1000 IU/L, dilute the sample suitably with 0.9% saline and repeat the assay. Obtain test result by applying proper dilution factor.

### WARNING

This reagent system is for in vitro use Only. This reagent system is containing preservatives and components that have not established for safety if contacted on broken skin or eye or taken orally. In case of such incidents wash off with plenty of water, or consult a physician.

### QUALITY CONTROL

To ensure adequate quality control, each kit should be tested against standard control sera. It should be realized that the use of quality control material checks both instrument and reagent function together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glass wares and accuracy of pipetting. It is appropriate to establish each laboratory's accuracy constant and interpret values accordingly. Similarly, laboratory findings should be established by clinical manifestations.

### BIBLIOGRAPHY

- Henderson, A. R., Donald W. M., *Enzymes*, Tietz Fundamentals of Clinical Chemistry, 5<sup>th</sup> Ed., Burtis, C.A & Ashwood, E.R (W.B Saunders eds. Philadelphia USA), (2001), 352.
- Sanhai, W.R., Christenson, R.H., Cardiac and muscle disease. Clinical Chemistry: Theory, Analysis, Correlation, 4<sup>th</sup> Ed., Kaplan, L.A, Pesce, A.J., Kazmierczak, S.C., (Mosby Inc. eds St. Louis USA), (2003), 566 and appendix.
- Schumann, G., *et al.*, Clin Chem Lab Med., (2002), 40, 635.
- Tietz, N.W., Clinical guide to laboratory tests, 3<sup>rd</sup> Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 180.
- Vassault, A., *et al.*, Ann. Biol. Clin. (1986), 44, 686.
- Vassault, A., *et al.*, Ann. Biol. Clin. (1999), 57, 685.
- Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2<sup>nd</sup> Ed., AACCPress, (1997).
- Young, D.S., Effects of drugs on clinical laboratory tests, 4<sup>th</sup> Ed., AACCPress, (1995).

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