LiquiMAX CK-NAC

(IFCC Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVNAC - 10	10 ml	1 x 8 / 1 x 2 ml
AVNAC - 20	20 ml	2 x 8 / 2 x 2 ml
AVNAC - 50	50 ml	5 x 8 / 5 x 2 ml

INTENDED USE:

Kit is use for the determination of CKNAC Iso Enzyme in Human Serum and Plasma

PRODUCT FEATURES

1. Liquid Stable, Ready to use Two Reagents (R1= Buffer, R2=Substrate)
2. Kinetic Factor: 3987
3. NADP analogues are used for better stability
4. Linearity 2000 IU/L.
5. 6 Minutes increasing Kinetic Reaction
6. Measuring wavelength 340 nm.
7. Serum and Plasma are the Specimens
8. Available as multipurpose reagents and dedicated system packs

CLINICAL SIGNIFICANCE:

CK is a dimeric enzyme occurring in 4 different forms, a mitochondrial iso-enzyme and 3 cytoplasmic iso-enzymes. CK MM is a muscle enzyme, CK BB is a brain enzyme and CK MB is the heart enzyme. CK activity has elevated many diseases including those involving skeletal muscle, heart, central nervous system and the thyroid. Most determinations of CK in the clinical laboratory are used for the early detection of Myocardial Infarction in which the enzyme is elevated within 3 to 8 hours after the onset .

PRINCIPLE

This procedure for CK MB incorporates a polyclonal antibody to CK M in the Reagent 1. The antibody inhibits 99.6% of the CK M without affecting the CK B units. The remaining CK B activity therefore corresponds to half the CK MB activity and is determined by the method used for total CK.

$$\text{Creatine Phosphate} + \text{ADP} \xrightarrow[\text{HK} + Mg^{2+}]{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow[\text{G6P-DH}]{} \text{ADP} + \text{Glucose-6-phosphate (G-6-P)}$$

$$\text{G-6-P} + \text{NADP Analogue} \longrightarrow \text{6-phosphogluconate} + \text{NADP Analogue (Reduced)} + H^{+}$$

N.B: The CK activity should be determined using the CK-NAC method before performing the CK-MB assay.

STORAGE AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions 2-8°C are maintained.

KIT COMPONENTS

1. Reagent R1
2. Reagent R2

COMPOSITION:

	Ingredients	Concentration in Tests
Reagent 1	Imidazole Buffer pH 6.7	100 mmol/l
	Glucose	20 mmol/l
	Magnesium Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	NADP	2.0 mmol/l
	N-acetylcysteine	20 mmol/l
Reagent 2	**Creatine Phosphate**	**30 mmol/l**
	G6P-DH	> 1.5 U/ml
	Diadenosine pentaphosphate	10 µmol/l

REAGENT RECONSTITUTION & STABILITY

Two Ready to use liquid reagents (R1 and R2) stable till the expiry date mentioned on the labels. Do not contaminate the reagents.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank rgent absorbance exceeds 0.8 at 340 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

Use serum, free from haemolysis, heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/Plasma should be separated from cells immediately after collection and stored in the dark.

Stability of specimen up to 7 days at 2-8°C.

SYSTEM PARAMETERS:

Reaction Type (Mode)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	340nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay time	:	120 seconds
Measuring Time	:	240 Seconds
Reagent Volume	:	0.5 ml (400 µl R1+ 100 µl R2)
Sample Volume	:	25 µl
Factor	**:**	**3987**
Linearity	:	2000
Units	:	IU/L
High Normal	:	190 (Adult Male)
	:	167 (Adult Female)

Test Procedure :

Reagent	Test
Reagent 1	400 µL
Sample	25 µL
Mix and incubate for 5 min at 37 °C	
Reagent 2	100 µL

Mix well and immediately aspirate in to the analyzer. After 120 Seconds incubation, measure the change in optical density per 60 seconds during 240 seconds against distilled water at 340 nm as follows.

Ao - Exactly after 120 Seconds
A1, A2, A3, A4 - Exactly after every 60 seconds for 240 seconds.

CALCULATIONS:

Calculate the average change in absorbance per minute (△ Abs/min).

Activity of Creatine Kinase in iU/L

At 340 nm in iU/L = △Abs / min x 3987

EXPECTED VALUES:

Men up to 190 IU/L (37°C)
Women up to 167 IU/L (37°C)

Each Laboratory should establish its own reference range. Creatine Kinase results should always be reviewed with the patients' medical examination and history

QUALITY CONTROL & CALIBRATION:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed: Prior to reporting patient results. Following any maintenance procedure on the photometer used. At intervals established by the Laboratory Q.C. Programme.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

1. Linearity

Linear up to 2000 IU/L .

2. Sensitivity/ Limit of Detection (LOD)

The Lowest Detectable Level was estimated at 2 U/l

3. Interferences

Bilirubin (mixed isomers): > 10% interference up to 600µmol/l Bilirubin.
Haemolysis: > 10% interference up to 1.25 g/l Haemoglobin.
Lipemia: > 10% interference up to 2.5 g/l Intralipid.

4. Precision:

Intra-Assay (N=20)

Control	Mean (IU/l)	SD (IU/l)	CV%
Level 1	177	2.5	1.41
Level 2	408	3.43	0.84

Inter-Assay (N=20)

Control	Mean (IU/l)	SD (IU/l)	CV%
Level 1	169	1.50	0.89
Level 2	383	1.29	0.34

5. Method Comparison:

Using 50 samples, a comparison, between LiquiMAX CK- NAC test (y) and another commercially available test (x) gave the following results:

y = 0.997x – 5.765 r = 0.986

LIMITATIONS

Linear up to 2000 IU/L . For samples with a higher concentration, dilute 1:1 with Saline (0.9 g/l NaCl) and reassay. Multiply result by 2.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES

1. Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352 390 and 974-975

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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GMP 5th Schedule MDR 2017

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