

Ana-Chek® CREATINE KINASE - MB

METHOD – IMMUNOINHIBITION / UV KINETIC
PRODUCT CODE – LC06

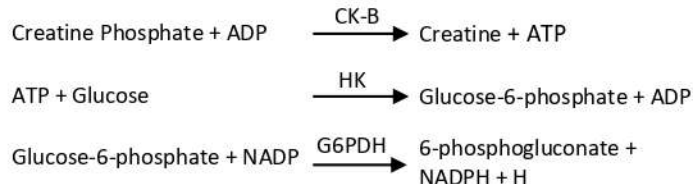


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of CK - MB in serum / plasma using Immunoinhibition / UV Kinetic method.

SUMMARY AND PRINCIPLE

Ana-Chek® CK-MB is a reagent set for determination of Creatine Kinase activity in human serum/plasma based on Immunoinhibition / UV kinetic method. Ana-Chek® CK-MB is a two liquid reagent system.



KIT COMPONENTS

Reagent 1: CK-MB Reagent 1
Reagent 2: CK-MB Reagent 2

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagents. Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent prior to use. Do not shake vigorously. The working reagent is stable for 14 days at 2-8 °C. The reagent kit should be stored at 2 - 8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.700 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	CK-MB	Reagent Volume	1000 µl
Reaction Type	UV Kinetic (↑)	Sample Volume	50 µl
Wavelength Primary	340 nm	Incubation Temperature	37 °C
Flow Cell Temp.	37 °C	Delay Time	300 sec
Instrument Blank setting	D.W.	Read Time	120 sec
Reagent Blank Abs Limit	<0.700	Factor	6752
Linearity	2000 IU/L		

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. The assay should

be carried on the same day as far as possible. Serum or plasma are stable for 1 week at 4 °C and 1 month at -10 °C. Avoid use of haemolysed and grossly contaminated samples.

COMPONENTS OF REAGENT

Component	Concentration
Imidazole Buffer, pH 6.7	100 mmol/l
NAC	20 mmol/l
Glucose	20 mmol/l
Magnesium Acetate	10 mmol/l
Hexokinase	>4500 IU/L
ADP	2 mmol/l
AMP	5 mmol/l
Di (adenosine -5) - pentaphosphate	10 mol/l
NADP	2 mmol/l
EDTA	2 mmol/l
Anti CKMM antibody sufficient amount to inhibit upto 2000 IU/L.	
Stabilizers and inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	50 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Aspirate reaction mixture into flow cell and record the absorbance at 300, 330, 360, 390 sec.	

CALCULATION

Absorbance/min = Absorbance per 30 sec. x 2
CK – MB Activity (IU/L) = Δ Absorbance / min x 6752

REFERENCE VALUES FOR NORMAL PEOPLE

CK – MB < 24 IU/L at 37 °C.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 10 – 2000 IU/L. If the CK-MB value exceeds linearity limit (above 2000 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct CK-MB value of the specimen.

Interference: There is no significant interference in samples containing upto 20 mg/dl of bilirubin and 200 mg/dl of haemoglobin.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	13.01	0.58	4.5	14.96	0.65	4.4
High Value Serum	40.65	0.96	2.4	42.6	0.27	0.6

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for CK-MB. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. The working reagent is considered unsatisfactory and should not be used if its absorbance exceeds 0.700 at 340 nm against distilled water.
2. If CK-MB value exceeds 2000 IU/L then dilute the specimen suitably with normal saline & repeat the assay.
3. Avoid using haemolysed serum since red blood cells may release enzymes and intermediates such as ATP and G6P which may interfere.
4. CK-MB Activity in serum may be elevated in patients receiving intramuscular injection upto one week prior to sample collection. Strenuous or unusual physical exercise may also cause elevated CK-MB activity.

BIBLIOGRAPHY

1. Rozemann Y, Gotsman MS. The earliest diagnosis of acute myocardial infarction. Annu.Rev.Med.1994; 45:31-44.
2. Adams JE, Abendschein DR, Jaffe AS. Biochemical markers of myocardial injury; Is MB creatine kinase the choice for the 1990s? circulation 1993;88:750-763
3. Apple FS. Diagnostic markers for detection of acute myocardial infarction and reperfusion, Laboratory Medicine 1992;23:297-322
4. Nuemeir D *et al*: Activity kinetics and diagnostic Significance in myocardial Infarction. Clinica chemica acta 73:445-451,1976
5. Melathini F, *et al*: Clin.chem. 24/3 : 498-501, 1978.
6. Wicks R, *et al*: Immuno chemical determination of CK-MB isoenzyme in Human serum, II.an Enzyme approach Clin chem; 28/1:54-58, 1982.
7. Tietz NW, Fundamentals of Clin Chem,(iii) 377,383(1981).
8. Faulkner, Willard R., selected Methods of clin. chem.(9) 185 (1982)

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE