CK-MB

Kinetic UV Method.

REF. 0083 **40x 10 ml**

CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of CK-MB in serum.

PRINCIPLE

CK-MB consists of the subunits CK-M and CK-B. Specific antibodies against CK-M inhibits completely CK-MM activity (main part of the total CK activity) and CK-M subunit of CK-MB. Therefore only CK-B activity is measured, which is half of the CK-MB activity.

The activity of CK-MB is obtained multiplying the activity of CK-B by 2

SAMPLE

Serum, plasma with heparin. Do not use hemolyzed samples.

CK activity in serum is unstable and is rapidly lost during storage. CK is inactivated both by bright daylight and by increasing specimen pH owing to loss of carbon dioxide; accordingly, specimens should be stored in the dark in tightly closed tubes.The CK is subject to thermal denaturation, rapidly cool the sample at 4°C after collection.

KIT COMPONENTS

Reagent (A) CK-MB Volume = 40 ml	Imidazole buffer, pH 6.7 D-Glucose N-Acetiyl-L-cysteine Magnesium acetate NADP EDTA Hexokinase Anti-CK-M antibody with inhibitory capacity	150 mmol/l 25 mmol/l 25 mmol/l 12.5 mmol/l 2.52 mmol/l 2.02 mmol/l ≥6800 U/l 2000 U/l
Reagent (B)) CK-MB Volume = 10 ml	Creatine phosphate ADP AMP Diadenosine pentaphosphate G-6-PDH	250 mmol/l 15.2 mmol/l 25 mmol/l 10 mmol/l ≥8800 U/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not use over expiry data.

Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1.60.

REAGENT PREPARATION

Add 1 Volune of Reagent (B) to 4 Volumes of Reagent (A). Ratio 4+1.

The working solution (A+B) is stable 1 week at 2-8°C.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	increasing kinetic

pipette:	
Working solution (A+B)	1000 µl
sample	50 µl

Mix, incubate at 37°C for 10 minutes, read the initial absorbance(A)of the sample , start the stopwatch and read again after 5 minutes (A_2).

Calculate the difference between absorbances $\Delta A = A_2 - A_1$.

Reaction volumes can be proportionally varied.

This method describes the manual procedure to use the kit.

For automated procedure, ask for specific applications.

RESULTS CALCULATION

Perform calculation in Units per litre, multiplying the ΔA by the factor as it is indicated:

CK-MB Activity (U/L): ΔA x 4500 (*)

Percentage of CK-MB in the sample:

% CK-MB = CK-MB / Total CK x 100

to calculate **Total CK activity** use the kits CK-NAC SL (Ref. 0018-4054-4052)

(*) Factor calculated in our laboratories. We recommend the use of CK-MB Calibrator (Ref. 6021 - 1x2 ml) to verify that this factor is correct for your test system.

EXPECTED VALUES

CK-MB **< 25 U/l**

% CK-MB **< 6 %**

The probability of myocardial infarction is high under the following conditions:

Total CK

Men **> 171 U/l**

Women **> 145 U/l**

CK-MB **> 25 U/l**

% CK-MB **6 – 25 %**

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control sera: CK-MB Control (Ref. 6020).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 2 U/L.

Linearity: the method is linear up to 600 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2
Mean (U/L)	25	66
CV %	10.3	4.5

Precision inter-assay:

	Level 1	Level 2
Mean (U/L)	25	74
CV %	9.8	2.6

Interferences: No significant interfrence up to 8 mmol/l of triglycerides. Glucose does not interfere up to 7g/l. Hemoglobin does not interfere up to 6g/l. .

Correlation against a reference method: Y = 1.018x +0.308 r = 0.99

REFERENCES

1. Abbot B et al. Creatinine Kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116
2. Gerhardt W et al.Creatine Kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979:(25/7): 1274-1280.
3. Young, D.S.,Effects of drugs on Clinical Lab. Tests, 4th Ed., AACC Press, 1995.
4. Young, D.S., Effects of disease on Clinical Lab. Tests, 4th Ed., AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd Ed. AACC 1999.
6. Tietz N W et al.Clinical Guide to Laboratory Tests, 3rd Ed. AACC 1995.
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration catalytique de la creatinine kinase dans la serum humain. Ann. Biol. Clin., 40, (1482),87.

Giesse Diagnostics srl
V. Enrico Fermi, 3 - Z.I. V. Tiburtina Km 18.300 - 00012 Guidonia Montecelio (RM) - Italia
Tel. +39 0774 051100 - Fax +39 0774 05111
e-mail: info@giessediagnostics.com – web site: www.giessediagnostics.com

008207
Ed. 2015/12 rev. 00