CK-MB
(Creatine Kinase - MB)
Op. DGKC / Mod. IFCC

Test for the quantitative determination of CK-MB in human serum and plasma.
Liquid, Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2150	5X100 ML	R2150	2885 Tests	K2151	4000 Tests	S2150	3077 Tests
A2151	5X50 ML	R2151	962 Tests	BY2150	6136 Tests	S2151	1477 Tests
A2152	5X25 ML	N2150	880 Tests	BY2151	4091 Tests	L2150	3750 Tests
T2150	3474 Tests	N2151	440 Tests	M2150	2512 Tests	L2151	2000 Tests
T2151	1795 Tests	K2150	6000 Tests	M2150	1675 Tests		

INTENDED USE

Test for the quantitative determination of CK-MB in human serum and plasma.

TEST PRINCIPLE

The sample is incubated in the CK-MB reagent which includes the anti-CK-M antibody. The activity of the noninhibited CK-B is then determined using the following series of reactions:

$$\text{ADP} + \text{Creatine Phosphate} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-Phosphate}$$

$$\xrightarrow{\text{G6PDH}} \text{G-6-P} + \text{NAD}^+ \quad \text{6-Phosphogluconate} + \text{NADH} + \text{H}^+$$

CK-B catalyses the reversible phosphorylation of ADP in the presence of creatine phosphate, to form ATP and creatine. The auxiliary enzyme hexokinase (HK) catalyzes the phosphorylation of glucose by the ATP format, to produce ADP and glucose-6-phosphate (G-6-P) is oxidized to 6-phosphogluconate with the concomitant production of NADH. The rate of NADH formation, measured at 340 nm, is directly proportional to serum CK-B activity.

TEST PARAMETERS

Method	: Colorimetric
Wavelength	: 340-460
Temperature	: 2 – 8°C
Sample	: Serum, Plasma
Linearity	: 20 UI/mL – 800 UI/mL

REAGENT COMPOSITION

Components	Concentration
Reagent 1	
Imidazole pH 6.7	≤ 132 mmol/L
Glucose	≤ 24 mmol/L
N-Acetylcystein	≤ 27.6 mmol/L
Magnesiumacetate	≤ 12 mmol/L
EDTA	≤ 2,52 mmol/L
ADP	≤ 3 mmol/L
NADP	≤ 2,76 mmol/L
AMP	≤ 6 mmol/L
Diadenosinpentaphosphate	≤ 13.2 µmol/L
Glucose-6-Phosphate-Dehydrogenase	≥ 1.5 kU/L
Hexokinase	≥ 2.5 kU/L
CK-M (human) inhibiting polyclonal antibodies (sheep) inhibiting capacity	≥ 33.3 µkat/L
Reagent 2	
Creatinephosphate	≤ 223 mmol/L
Imidazole pH 6.7	≤ 132 mmol/L
Glucose	≤ 24 mmol/L
Magnesiumacetate	≤ 12 mmol/L
EDTA	≤ 2,52 mmol/L

REAGENT PREPARATION

Working Reagents: The working reagent is stable for 10 days 2°C - 8°C (On board stability of working reagent may differ from analyzer to analyzer in accordance with cooling, evaporation degree) and for 24 hours at room temperature.

Sample start:
Mix 4 parts of Reagent 1 with 1 part of Reagent 2. For example: 4 ml Reagent 1 and 1 ml Reagent 2.

Substrate Start:
Reagent 1 is liquid, Reagent 2 is liquid.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Store unopened and opened reagents at 2°C - 8°C. Protect from light. Note expiration date on the label. Close immediately after use. Avoid contamination of the opened reagents. Incompetent handling will release ARCHEM from any responsibility.
Collect serum using standard sampling tubes. Stability: 2 days at 20-25°C, 7 days at 4-8°C and 4 weeks at -20°C .
On board Stability: Reagent 1 and Reagent 2: 3 Weeks.
On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum and plasma are collected by standard procedures.
CK-MB in serum is stable for 3 days at 2-8ºC.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

ΔA/min x factor = U/L CK-MB in sample.
Factor for: 340 nm = 5600

Unit Conversion
CKMB µkat/L *60= CKMB U/L

REFERENCE INTERVALS (NORMAL VALUES) (Based On CLSI C28-P Document)*

		+25°C	+30°C	+37°C
1)	CK Men	>80 U/L (1.33 µkat/L)	>130 U/L (2.17 µkat/l)	>174 U/L* (2.90 µkat/L)
	CK Women	>70 U/L (1.17 µkat/L)	>110 U/L (1.83 µkat/L)	>140 U/L* (2.33 µkat/L)
2)	CK-MB	>10 U/L (0.17 µkat/L)	>15 U/L (0.25 µkat/L)	>24 U/L* (0.40 µkat/L)
3)	The CK-MB-activity accounts for 6-25% of the total CK activity.			

If MI is suspected but the values obtained are below the specified limits, a fresh infarct may have occurred. In this case, tests should be repeated after 4 hours.

The following factors were used for converting the reference values from 25°C : 1.53 (+30°C) and 2.38 (+37°C).

CK varies with physical activity level and race in healthy individuals.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the CK results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

QUALITY CONTROL AND CALIBRATION

A laboratory may establish its own Control Serum by assaying the sera a sufficient number of times to generate a valid mean and acceptable range. All control sera with CK-MB values determined by this method can be used. Archem ready controls are;

ACK3930	CK-MB Control Level I	2	mL
ACK3940	CK-MB Control Level II	2	mL

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

Calibrator:
The use of a CK - MB Calibrator (for automated Systems) is optional.
ACK3950 Archem CK-MB Calibrator 2 ML is used to calibration. Calibration frequency: Two point calibration is recommended (First point is BLANK)
• after reagent lot change
• as required following quality control procedures disposal.

All calibrators with CK - MB values determined by this method may be used.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Low Linearity / High Linearity: That is approximately 2-1000 U/L. (0.08-16.67µkat/L) If Δ Absorbance/min is greater than 0.22 dilute the sample with physiological NaCl (150 mmol/L) and rerun multiplying the result by the dilution factor.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (intra-assay):

Mean conc.	SD	CV%
34	2.8	8.2
132	9.9	7.5

Reproducibility (run to run) (inter-assay):

Mean conc.	SD	CV%
32	3.1	9.8
122.8	9.2	7.4

Sensitivity (LOD) (Based on CLSI EP17 document):
Based on an instrument resolution of A = 0.001, this procedure has a sensitivity of 4 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

Prior to the CK-MB assay, the total CK activity should be determined CK NAc method. The antibody is capable of inhibiting up to 2000U/l CK-M subunit (37°C). Accordingly, CK-MM activities up to 1000 U/L (37°C) are completely inhibited. Therefore, samples with total CK activities above 1000U/l (37°C) require dilution because complete inhibition is no longer assured.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CK-MB : Creatine Kinase MB
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for in vitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
SN	Serial Number
INGRED	Reagent Ingredients
REF	References
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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