CK-MB Kit

CliniQuant – FSR

IFCC Method, Kinetic

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 CK-MB Reagent	R2 CK-MB Reagent
CKMFSR-01	2 x 8 / 2 x 2ml	2 x 8ml	2 x 2ml

INTENDED USE

This reagent is intended for quantitative determination of creatine kinase level in human serum.

CLINICAL SIGNIFICANCE

Creatine kinase (CK) is an enzyme which is contained in heart, brain and skeletal muscles. Thus, an increase of circulating level of CK may be associated to myocardial infarction, acute cerebrovascular disease, trauma or diseases of skeletal muscles. After a myocardial infarction, CK level begin rising between 4th and 6th hour after first acute symptoms, reaching the peak between 18th and 30th hour and coming back to normal values during the 3rd day. CK exists in serum in dimeric forms as CK-MM, CK-MB, CK-BB and as macro-enzymes. Measurement of CK-MB is a specific test for detection of cardiac muscle damage and is therefore used for diagnosis and monitoring of myocardial infarction.

PRINCIPLE OF THE METHOD

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

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

$$\text{G6P} + \text{NAD} \xrightarrow{\text{G6PDH}} \text{6-PG} + \text{NADH}$$

KIT COMPONENTS

Composition

R1 - CK-MB Reagent : Anti CK-MM serum, AMP 5 mmol/l, A2p5 10 µmol/l, Magnesium acetate 10 mmol/l, ADP 50 mmol/l, NAD 1 mmol/l, NAC 20 mmol/l, Hexokinase 16 KU/l, G6PDH > 11 KU/l, Immidazole buffer 100 mmol/l pH 6.7

R2 - CK-MB Reagent : Creatine phosphate 263 mmol/l, Bicine buffer 20 mmol/l pH 9.3

MATERIALS REQUIRED BUT NOT PROVIDED

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

REAGENT PREPARATION, STORAGE & STABILITY

Mix reagent 1 & reagent 2 in ratio 4:1.
Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability of working reagent: 5 days at 2-8 °C.

REAGENT DETERIORATION

1. Discard the reagent if absorbance exceeds 0.4 at 340 nm against distilled water.
2. Discard the working reagent if it fails to achieve assigned assay values of fresh control sera.

WARNINGS AND PRECAUTIONS

1. Do not ingest. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use unhemolysed serum. Avoid use of plasma containing heparin, EDTA, citrate or flouride as it inhibits CK activity. CK activity in serum is unstable and is rapidly lost during storage. Samples are stable for 1 day at 2-8 °C and for longer when frozen at -20°C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Rate
Factor	8360
Filter - 1 (nm)	340
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	300
Test Time (Sec)	180
Unit	U/l
Reaction Direction	Increase
Reference Low	0
Reference High	25
Linearity Limit	1000

CE
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TEST PROCEDURE

Dispense in tube, the working reagent	1000 µl
Sample	40 µl
Mix, execute a first reading of absorbance after 300 seconds, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

RESULT CALCULATION

Perform calculations in units per litre, multiplying the ΔA/min by the factor.

Activity in U/l = ΔA/min x 8360

SI conversion factor: 1 U/l x 0.017 = 1 µkat/l

EXPECTED VALUES

< 25 U/l OR < 0.4 µkat/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal control, to confirm the validity of the test and assure the accuracy of patient result.

When using a known Calibrator, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 1000 U/l or 17 µkat/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 4.7U/l.

The limit of quantification is 14.4 U/l.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 50 mg/dl; Bilirubin up to 40 mg/dl

Triglycerides up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	32.0	1.58	4.94
sample 2	6.86	0.26	3.8

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	34.84	2.68	7.70
sample 2	6.9	2.2	2.5

5. Methods Comparison

Comparison was done between reference CK-MB Reagent and CliniQuant - FSR CK-MB Reagent (test)

N = 20 y = 0.976x – 0.260

r^2 = 0.976

LIMITATIONS

1. Samples with values above 1000 U/l, or ΔA/min exceeds 0.250 it should be diluted with 0.9% saline 1:1, re-run and results multiplied by 2.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 798 - 809.

2. Data on file: Meril Diagnostics.

IFU/CKMFSR01/00

06-11-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community