

Plasma/Serum test for creatine phosphokinase isozyme MB

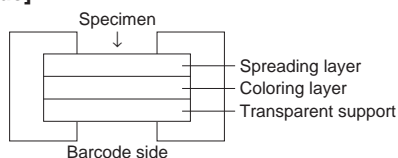
FUJI DRI-CHEM SLIDE CKMB-P

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.
- Because it is highly sensitive to light, as soon as the slide is removed from its package, it should be set in the cartridge and slide weight placed on it.
- One measurement will not be adequate for diagnosis, because CKMB levels peak briefly in patients with myocardial infarction. Repeated sampling every few hours is thus recommended.
- If specimens contain CKBB, the analyzing method using the slide will result in error. If macro-CPK (type1), which is a combination of CPK and immunoglobulin, and macro-CPK (type2), which is a CPK oligomer derived from mitochondria, are present in specimens, the analyzing method will also result in error. Specimens in which CKMB constitutes 25 % or more of the total CPK level should be using further analyzed electrophoresis.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Creatine phosphate disodium salt 0.21 mg (0.64 μ mol)
- Nitroterazolium blue 0.10 mg (0.13 μ mol)
- Adenosine 5'-diphosphate (ADP) 0.05 mg (0.10 μ mol)
- Hexokinase 3.11 U
- β -nicotinamide adenine dinucleotide (β -NAD⁺) 0.10 mg (0.15 μ mol)
- Glucose-6-phosphate dehydrogenase 2.25 U
- Diaphorase 0.24 U

[Intended use]

Quantitative measurement of creatine phosphokinase isozyme MB activity in plasma or serum.

For *in vitro* diagnostic use only.

[Principle of the measurement]

10 μ L of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE CKMB-P. While incubating at 37 °C, the spotted specimen is diffused uniformly in the spreading layer, where CK-M activity is inhibited by the anti-CK-M subunit antibody contained in the layer. The CK-B subunit in the layer is not inhibited by the antibody but activated by N-acetyl cysteine (NAC) to promote the reaction of creatine phosphate with ADP, producing creatine and ATP.

The reaction between ATP and glucose is catalyzed by hexokinase (HK) to produce glucose-6-phosphate and ADP. Glucose-6-phosphate is then oxidized by glucose-6-phosphate dehydrogenase (G6PDH), yielding NADH. NADH reduces nitroterazolium blue (NTB) by the action of diaphorase (DI), finally producing formazan dye. The increase of absorbance by the generated dye is measured from 2.5 min to 5 min at 540 nm by reflective spectrophotometry and the CKMB activity is calculated according to the installed formula.

CKMM, CKMB $\xrightarrow{\text{Anti-CK-M antibody}}$ CK-B

Creatine phosphate + ADP $\xrightarrow[\text{NAC, Mg}^{2+}]{\text{CK-B}}$ Creatine + ATP

ATP + Glucose $\xrightarrow[\text{Mg}^{2+}]{\text{Hexokinase}}$ ADP + Glucose-6-phosphate

Glucose-6-phosphate + NAD⁺ $\xrightarrow{\text{G6PDH}}$ 6-Phosphogluconic acid + NADH + H⁺

NTB + NADH + H⁺ $\xrightarrow{\text{Diaphorase}}$ Formazan dye + NAD⁺

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER

Other implements: FUJI DRI-CHEM QC CARD (attached)

: FUJI CLEAN TIPS

: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- After collecting the blood specimen, immediate measurement is recommended.
- For plasma, heparin can be used as the anticoagulant. The amount of heparin should be used less than 50 units per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum.
- Specimens with glucose content of 30 mg/dL or less should not be used because the measurement reaction requires glucose.

[Procedure]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM analyzer.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing.

For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM analyzer.

[Reference intervals]

Below 25 U/L (Immuno inhibitory method) (Below 0.418 μ kat/L)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]

1. **Dynamic range** 1–300 U/L (0.02–5.01 μ kat/L)

2. Accuracy

Concentration range	Accuracy
1–30 U/L	Within \pm 6 U/L
30–300 U/L	Within \pm 20 %

3. Precision

Concentration range	Precision
1–45 U/L	SD \leq 2.7 U/L
45–300 U/L	CV \leq 6 %

4. Correlation

Correlation was evaluated between immunoinhibition method, 37 °C and FUJI DRI-CHEM system. Immunoinhibition method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Plasma	67	1.018	-2.8	0.994
Serum	81	1.004	-3.1	0.992

5. Known interfering substances

(1) Increase of bilirubin gives minus bias.

(2) No significant effect was observed to the following concentration for each substance.

CKMM	2000 U/L
Ascorbic acid	0.28 mmol/L
LDH	1000 U/L (L \rightarrow P reaction)
Total protein	45–85 g/L

These results are representative;

- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Internal quality control]

- The accuracy and precision of this product can be evaluated with control materials such as pooled human serum. Commercially available control sera may give results which differ between the FUJI DRI-CHEM method and the liquid methods owing to their matrix effect.
- Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
- The control materials should be measured in the same way as patient samples.
- We recommend that control limits be established for assayed analytes so as to enable assessment of the control status. For details, consult "Tietz Fundamentals of Clinical Chemistry" 5th edition, Ed. Carl A. Burtis and Edward R. Ashwood, 285-298, 2001; Saunders ISBN 0-7216-8634-6 or other published references.
- If results are found outside of the control limits, investigate the cause before submitting reports.

[Traceability of calibrators and control materials]

The calibration of this product has already been accomplished in our factory before shipping using internal calibrators which are not commercially available. Calibration data are supplied by a QC card enclosed in this package. Assigned values of the internal calibrators for CKMB are traceable to a CK-M immunoinhibition method with quantitating the residual CK-B subunit activity by Japan Society of Clinical Chemistry (JSCC) standard method at 37 °C.

[Storage and shelf life]

- Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
- Expiry date is printed on the carton.
- Use immediately after opening the individual package.

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