Plasma/Serum test for creatine phosphokinase isozyme MB

FUJI DRI-CHEM SLIDE CKMB-P

[Warnings and precautions]
1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the center part of the surface or the back of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. 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.
6. Because the color 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.
7. 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 for clinical practice.
8. 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 used for further analysis or electron microscopy.

[Principle of the measurement]
For in vitro diagnostic use only.

[Composition of the slide]
1. Multi-layered structure

2. Ingredients per slide
   • Creatine phosphate disodium salt: 0.21 mg (0.64 μmol)
   • Nitrotetrazolium blue: 0.10 mg (0.13 μmol)
   • Adenosine 5'-diphosphate (ADP) sodium salt: 0.05 mg (0.10 μmol)
   • Hexokinase: 11.1 U
   • p-nicotinamide adenine dinucleotide (p-NAD+): 0.10 mg (0.15 μmol)
   • 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.

[Procedure]
1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the “START” key to initiate testing.

[Performance characteristics]
1. Dynamic range
   1–300 U/L (0.02–5.01 μkat/L)
2. Accuracy
   Concentration range: Within ± 6 U/L
   30–300 U/L: Within ± 20 %
3. Precision
   Concentration range: Precision ± 2.3 U/L
   45–300 U/L: CV ± 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.

[Notice for instructing the doctor]
1. 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.
2. Concentration levels of the control materials should be adjusted in accordance with each laboratory's own calibrator for CKMB.
3. The control materials should be measured in the same way as patient samples.
5. If results are found outside of the control limits, investigate the cause before submitting reports.

5. Known interfering substances
   (1) Increase of bilirubin gives minus bias
   (2) No significant effect was observed to the following for each substance

6. 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 100% accuracy and within ± 6% accuracy, which is 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.

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

8. Contents
   - Slide: 24
   - QC card: 1
   - FUJIFILM Europe GmbH
   - Heesestraße 31, 40549 Düsseldorf, GERMANY
   - FIIJIFILM Corporation
   - 26-30, Nishiazabu 2-Chome, Minato-ku, Tokyo 106-8620, JAPAN