**Intended use**
Quantitative measurement of creatine phosphokinase activity in plasma or serum.

**Principle of the measurement**
10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE CPK-PIII. The spotted sample is incubated at 37 °C and catalyses the reaction of creatine phosphate and ADP while spreading uniformly in the spreading layer. ATP reduces nitrotetrazolium blue (NTB) by the action of coexisting enzymes such as hexokinase, glucose-6-phosphate dehydrogenase (G6PD) and diaphorase to form diformazan dye (purple). Increase in absorption by the generated dye is measured at 540 nm by reflective spectrophotometry and the CPK activity is calculated according to the installed formula.

**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.

**Internal quality control**
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL OP-L and/or OP-H.
1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL OP-L and/or OP-H in the same way as patient samples.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL OP-L or OP-H, investigate the cause.

**Limitation of the examination procedure**
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
   - CPK
     - 0.17–100 μkat/L
     - Within ± 20%
     - SD ± 5 μkat/L
   - 100–2000 μkat/L
     - Within ± 20%
     - SD ± 5 μkat/L

2. Accuracy
   - Concentration range: 0.17–100 μkat/L
   - Accuracy range: Within ± 20 μkat/L

3. Precision
   - Concentration range: 0.17–100 μkat/L
   - CV: ± 5%

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

**Reference intervals**
| Male | 40–200 U/L (JSCC Standard Method, 37 °C) (0.67–3.34 μkat/L) |
| Female | 30–150 U/L (JSCC Standard Method, 37 °C) (0.50–2.51 μkat/L) |

**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 membrane in the center of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient samples, 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. Keep QC card away from magnetic material.
7. Do not use the slide if the individual package is damaged.

**Sample requirements**
1. After collecting blood sample immediate measurement is recommended.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with inactivated serum. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation. Dilution by distilled water or saline may cause large plus bias.
Do not touch the center part of the slide.

Warmed up to room temperature before opening the individual packages.

SLIDE CODE

Do not reuse

Lot number

Use by

Contains sufficient for <n> tests

Temperature limitation

Consult instructions for use

In vitro diagnostic medical devices

Manufacturer

Authorized representative in the European Community