

Plasma/Serum test for creatine phosphokinase

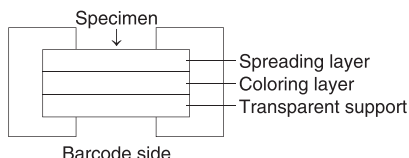
FUJI DRI-CHEM SLIDE CPK-PIII

[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.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

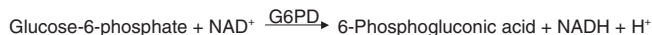
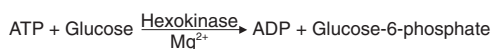
• Creatine phosphate disodium salt	0.28 mg (1.1 µmol)
• Nitrotetrazolium blue	0.12 mg (0.15 µmol)
• Adenosine 5'-diphosphate (ADP)	0.11 mg (0.24 µmol)
• Glucose	0.093 mg (0.52 µmol)
• Hexokinase	0.44 U
• NAD ⁺	0.093 mg (0.14 µmol)
• Glucose-6-phosphate dehydrogenase	0.63 U
• Diaphorase	0.17 U

[Intended use]

Quantitative measurement of creatine phosphokinase activity in plasma or serum. For *in vitro* diagnostic use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE CPK-PIII. The spotted specimen 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 from 2.5 min to 4 min at 540 nm by reflective spectrophotometry and the CPK activity is calculated according to the installed formula.



[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
 Other implements: FUJI DRI-CHEM QC CARD (attached)
 : FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO 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 is recommended to 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.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum.
- 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.

[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 interval]

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)

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.

*JSCC: Japan Society of Clinical Chemistry

[Performance characteristics]

1. **Dynamic range** 10–2000 U/L (0.17–33.4 µkat/L)

2. **Accuracy**

Concentration range	Accuracy
10–100 U/L	Within ± 20 U/L
100–2000 U/L	Within ± 20 %

3. **Precision**

Concentration range	Precision
10–100 U/L	SD ≤ 5 U/L
100–2000 U/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.

	n	Slope	Intercept	Correlation coefficient
Serum	57	0.986	5.38	0.998

5. **Known interfering substances**

- For the specimen which include mitochondrial origin CK (macro CK type 2), the measured value gives minus bias. For the specimen both CPK activity is lower than 20 U/L and the activity of LDH is higher than 1000 U/L, because of the effect of LDH, the measured value give plus bias.
- Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.
- The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	340 µmol/L
Total protein	40–95 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 FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

- Select control level in accordance with your purpose.
- Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
- When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

CPK...ReCCS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

ReCCS: Reference Material Institute for Clinical Chemistry Standards

[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.

[Contents]

: Slide 24
 : QC card 1

<http://www.fujifilm.com/products/medical/>

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