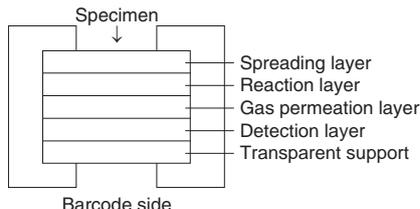


FUJI DRI-CHEM SLIDE CRE-PIII

[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**

- Creatinine deiminase 0.28 U
- Bromphenol blue 0.018 mg (0.026 µmol)

3. Other ingredients

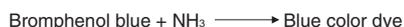
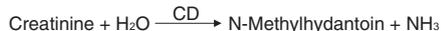
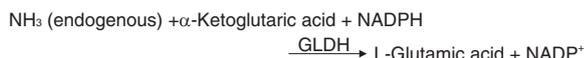
- α-Ketoglutaric acid disodium salt
- Glutamate dehydrogenase
- NADPH

[Intended use]

Quantitative measurement of creatinine concentration 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 CRE-PIII. The spotted specimen diffuses into the underlying layers after spreading uniformly in the spreading layer. The specimen diffuses and penetrates into the reaction layer. Endogenous ammonia is removed by the action of α-ketoglutaric acid, glutamate dehydrogenase (GLDH) and NADPH. Creatinine is decomposed by the action of creatinine deiminase (CD) in the reaction layer and ammonia gas is generated. The ammonia gas passes through the gas permeation layer and reaches detection layer. The color of bromphenol blue contained in the detection layer changes from yellow to blue. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 600 nm. The optical reflection density is then converted into the creatinine concentration using a calibration curve preinstalled in the analyzer.

**[Additional special equipment]**

Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
: FUJI CLEAN TIPS or FUJI AUTO TIPS
: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- For plasma, heparin and EDTA salt can be used as the anticoagulant. The amount of heparin and EDTA salt should be used less than 100 units and 5 mg per 1 mL of whole blood, respectively. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- Positive bias may occur by increasing ammonia if the specimen is left for a long time at room temperature after sampling. Perform measurement soon after sampling. Note that specimens containing high concentration of ammonia such as control serums give positive bias.
- When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[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.

5. Press the "START" key to initiate testing.

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

[Reference interval]

Male 53–97 µmol/L (0.6–1.1 mg/dL)
Female 35–71 µmol/L (0.4–0.8 mg/dL)

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 18–2122 µmol/L (0.2–24.0 mg/dL)

2. Accuracy

Concentration range	Accuracy
18–118 µmol/L	Within ±18 µmol/L
118–2122 µmol/L	Within ±15 %

3. Precision

Concentration range	Precision
18–354 µmol/L	SD ≤ 18 µmol/L
354–2122 µmol/L	CV ≤ 5 %

4. Correlation

Correlation was evaluated between enzymatic method and FUJI DRI-CHEM system. Enzymatic 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	74	1.011	-1.8	0.999

5. Known interfering substances

- When isopropyl amine is present in the blood, owing to pesticide poisoning, plus bias may occur.
- When the low molecular weight amines, such as dimethylamine, are present in the blood, owing to renal failure, plus bias may occur.
- 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
Hemoglobin	3000 mg/L
Total protein	50–95 g/L
Ammonia (N amount)	428 µmol/L (600 µg/dL)

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 and/or QP-H.

[Traceability of calibrators and control materials]

Creatinine...NIST (SRM 914)

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

NIST: National Institute of Standards & Technology

[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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