[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 sample diffuses into the underlying layers after spreading uniformly in the spreading layer. The sample 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.

N\textsubscript{2}H\textsubscript{4} (endogenous) \rightarrow α-Ketoglutaric acid + NADPH
GLDH \rightarrow L-Glutamic acid + NADPH
Creatinine + H\textsubscript{2}O → N-Methylhydantoin + NH\textsubscript{3}
Bromphenol blue + N\textsubscript{2}H\textsubscript{4} \rightarrow Blue color dye

[Composition of the slide]
1. Multi-layered structure
   - Sample layer
   - Spreading layer
   - Reaction layer
   - Gas permeation layer
   - Detection layer
   - Transparent support
   - Barcode side

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

[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 DRI-CHEM SLIDE CRE-PIII

[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.

[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 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 monooiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. If the sample is left for a long time at room temperature after sampling, positive bias may occur by increasing ammonia. Perform measurement soon after sampling. Note that samples containing high concentration of ammonia such as control sera give positive bias.
5. 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]
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 QP-L and/or QP-H.
1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-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 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.

[Reference intervals]
Male: 0.6–1.1 mg/dL (53–97 μmol/L)
Female: 0.4–0.8 mg/dL (35–71 μmol/L)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

[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.

Known interfering substances
1. No significant effect was observed to the following concentration for each substance.
   - Ascorbic acid: 10 mg/dL (0.57 mmol/L)
   - Bilirubin: 20 mg/dL (340 μmol/L)
   - Hemoglobin: 3000 mg/L
   - Total protein: 50–95 g/L
   - Ammonia (N amount): 600 μg/dL (428 μmol/L)

2. In the case of isopropyl amine is present in the blood, owing to pesticide poisoning, plus bias may occur.
3. When the low molecular weight amines, such as dimethylamine, are present in the blood, owing to renal failure, plus bias may occur.

These results are representative; Test condition may have some influence on your results.

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.

[Performance characteristics]
1. Dynamic range: 0.2–24.0 mg/dL (18–2122 μmol/L)
2. Accuracy
<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2–1.33 mg/dL (18–118 μmol/L)</td>
<td>Within ± 15 %</td>
</tr>
<tr>
<td>1.33–24.0 mg/dL (118–2122 μmol/L)</td>
<td>Within ± 5 %</td>
</tr>
</tbody>
</table>

3. Precision
<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2–4.0 mg/dL (18–354 μmol/L)</td>
<td>SD ≤ 0.2 mg/dL (SD ≤ 18 μmol/L)</td>
</tr>
<tr>
<td>4.0–24.0 mg/dL (354–2122 μmol/L)</td>
<td>CV ≤ 5 %</td>
</tr>
</tbody>
</table>

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.
[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

[Contents]
Slide : 24
QC card : 1

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

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[Symbols]

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