[Intended use]
Quantitative measurement of uric acid concentration in plasma or serum. For in vitro diagnostic use only.

[Principle of the measurement]
10 μL of plasma is deposited on a FUJI DRI-CHEM SLIDE UA-PIII. After depositing, the sample spreads uniformly on the spreading layer and uric acid in the sample is hydrolyzed in the enzyme layer by uricase. In this process, hydrogen peroxide (H₂O₂) is generated, which oxidizes diarylimidazole leuco dye by the action of peroxidase (POD) to form blue color dye. 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 650 nm. The optical reflection density is then converted into the uric acid concentration using a calibration curve preinstalled in the analyzer.

Uric acid + O₂ +2H₂O → Allantoin + H₂O₂ + CO₂

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

   Sample
   Spreading layer
   Enzyme layer
   Transparent support
   Barcode side

2. Ingredients per slide
   • Uricase
   • Diarylimidazole leuco dye
   • Peroxidase

   Concentrations: 0.092 U, 0.049 mg (0.10 μmol), 2.4 U

[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

[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.

CAUTION: Do not use expired slides.

[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, in accordance with the proper method of disposal, such as incineration, melting, sterilization or disinfection.
6. Because it is highly sensitive to light, as soon as the slide is taken out of its package, it should be set in the cartridge with the slide weight placed on the top of it.
7. Keep QC card away from magnetic material.
8. 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.
   When using heparin, less than 50 unit of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and monooiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. 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.
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[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 initia testing.
CAUTION: Use immediately after opening the individual package.

[Reference intervals]
Male 4.0–7.0 mg/dL (238–416 μmol/L)
Female 3.0–5.5 mg/dL (178–327 μmol/L)

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

[Performance characteristics]
1. Dynamic range
   Concentration range: 0.5–18.0 mg/dL (30–1071 μmol/L)
2. Accuracy
   Concentration range: 0.5–5.0 mg/dL (30–297 μmol/L), 5.0–18.0 mg/dL (297–1071 μmol/L)
   Accuracy: Within ± 45 %
3. Precision
   Concentration range: 0.5–5.0 mg/dL (30–297 μmol/L), 5.0–18.0 mg/dL (297–1071 μmol/L)
   Precision: SD ≤ 0.25 mg/dL (SD ≤ 15 μmol/L)
4. Correlation
   Correlation was evaluated between uricase-POD method and FUJI DRI-CHEM system. Uricase-POD method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>59</td>
<td>0.997</td>
<td>0.02</td>
<td>0.999</td>
</tr>
<tr>
<td>Serum</td>
<td>59</td>
<td>0.998</td>
<td>0.02</td>
<td>0.999</td>
</tr>
</tbody>
</table>

[Traceability of calibrators and control materials]
Uric acid...NIST (SRM913)
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

[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