FUJIFILM

Use after reading this "Instructions for Use"

IVD

Date of issue: 1/May/2012

Plasma/Serum test for uric acid

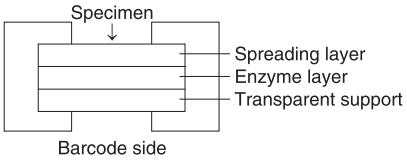
FUJI DRI-CHEM SLIDE UA-PIII

[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 either the center part of the surface or the back of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient specimens, 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.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Uricase 0.092 U
- Diarylimidazole leuco dye 0.049 mg (0.10 µmol)
- Peroxidase 2.4 U

[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 specimen spreads uniformly on the spreading layer and uric acid in the specimen is hydrolyzed in the enzyme layer by uricase. In this process, hydrogen peroxide (H_2O_2) 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.

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + H_2O_2 + CO_2$$

$$\text{Diarylimidazole leuco dye} + H_2O_2 \xrightarrow{\text{POD}} \text{Blue color dye} + 2H_2O$$

[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]

1. After collecting the blood specimen, 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 monoiodoacetic acid.
3. Avoid using plasma 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.

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

[Reference interval]

Male 238–416 µmol/L (4.0–7.0 mg/dL)
Female 178–327 µmol/L (3.0–5.5 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 30–1071 µmol/L (0.5–18.0 mg/dL)

2. Accuracy

Concentration range	Accuracy
30–297 µmol/L	Within ± 45 µmol/L
297–1071 µmol/L	Within ± 15 %

3. Precision

Concentration range	Precision
30–297 µmol/L	SD ≦ 15 µmol/L
297–1071 µmol/L	CV ≦ 5 %

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.

	n	Slope	Intercept	Correlation coefficient
Plasma	59	0.997	1.2	0.999
Serum	59	0.998	1.2	0.999

5. Known interfering substances

(1) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.
(2) 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	5000 mg/L
Total protein	50–95 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.

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 specimens.
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 or QP-H.

[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

[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.
3. Use immediately after opening the individual package.

[Contents]

: Slide 24
: QC card 1

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

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