FUJIFILM

Use after reading this "Instructions for Use"

IVD

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Plasma/Serum test for blood urea nitrogen

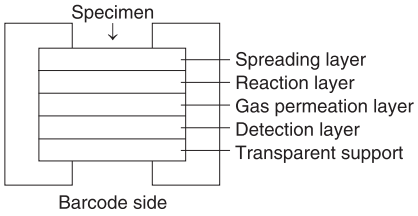
FUJI DRI-CHEM SLIDE BUN-PIII

[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

• Urease	4.86 U
• Bromcresol green	0.028 mg (0.040 μmol)

[Intended use]

Quantitative measurement of urea nitrogen 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 BUN-PIII. After depositing, the specimen spreads uniformly on the spreading layer which filtrates large molecular components (protein and dye), and penetrates into the reaction layer. Urea is decomposed to ammonia and carbon dioxide by the reaction with urease. By alkalizing pH of the layer, ammonia gas is generated. The gas permeated through the gas permeation layer (porous layer) attains to the detection layer. Bromcresol green contained in the detection layer is changed from yellow to green by the ammonia gas. The color change is proportional to the urea nitrogen concentration. 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 625 nm. The optical reflection density is then converted into the urea nitrogen concentration using a calibration curve preinstalled in the analyzer.

$$H_2NCONH_2 + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$\text{Bromcresol green} + NH_3 \longrightarrow \text{Green dye}$$

[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. For plasma, heparin and EDTA salt can be used as the anticoagulant. Heparin and EDTA salt should be used less than 50 units or 5 mg per 1 mL of whole blood, respectively. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. 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. Set slides on FUJI DRI-CHEM ANALYZER.
2. Set a sample tube in the specified sample rack.
3. Input a sequence No. and a sample ID if appropriate.
4. Press the "START" key to initiate testing.
   For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

2.9–8.2 mmol/L (8–23 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 1.79–49.98 mmol/L (5.0–140.0 mg/dL)

2. Accuracy

Concentration range	Accuracy
1.79–49.98 mmol/L	Within ±15 %

3. Precision

Concentration range	Precision
1.79–49.98 mmol/L	CV ≦ 6 %

4. Correlation

Correlation was evaluated between Urease-GLD* method and FUJI DRI-CHEM system. Urease-GLD* method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.
*GLD: Glutamate dehydrogenase

	n	Slope	Intercept	Correlation coefficient
Plasma	61	1.005	0.05	1.000
Serum	61	0.999	0.05	1.000

5. Known interfering substances

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	50–90 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]

BUN...ReCCS (GN3-6)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
ReCCS: Refference Material Institute for Clinical Chemistry Standards

[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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BUN-P III