FUJIFILM

Use after reading this "Instructions for Use"

IVD

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Plasma test for ammonia

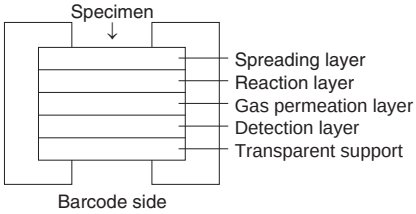
FUJI DRI-CHEM SLIDE NH_3-PII

[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

• Bromphenol blue 0.018 mg (0.026 µmol)

[Intended use]

Quantitative measurement of ammonia concentration in plasma.
For *in vitro* diagnostic use only.

[Principle of the measurement]

10 µL of plasma is deposited on a FUJI DRI-CHEM SLIDE NH_3-PII. After depositing, the specimen spreads uniformly on the special spreading layer and diffuses into the underlying reaction layer, in which solubilized ammonium ion reacts to generate ammonia gas. The color of bromphenol blue in the detection layer is changed from yellow to green or blue by the ammonia gas penetrated from the porous gas permeation layer. 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 ammonia concentration using a calibration curve preinstalled in the analyzer.

Bromphenol blue + NH_3 ⟶ Blue color dye

[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]

1. For plasma, heparin·Na/heparin·Li and EDTA salt can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 10 mg should be used per 1 mL of whole blood. Do not use heparin ammonium, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Do not use serum especially by a tube with separator.
3. Avoid using plasma with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. NH_3 concentration is known to increase with time, especially when kept as whole blood. Centrifugation and measurement of plasma should be done as soon as possible after blood collection.

[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]

9–47 µmol/L (12–66 µg/dL as NH_3-N)
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 7–357 µmol/L (10–500 µg/dL as NH_3-N)

2. Accuracy

Concentration range	Accuracy
7–107 µmol/L	Within ± 16 µmol/L
107–357 µmol/L	Within ± 15 %

3. Precision

Concentration range	Precision
7–107 µmol/L	SD ≦ 6.4 µmol/L
107–357 µmol/L	CV ≦ 6 %

4. Correlation

Correlation was evaluated between NADS* method and FUJI DRI-CHEM system. NADS* method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.
*NADS: Nicotinamide adenine dinucleotide synthetase

	n	Slope	Intercept	Correlation coefficient
Plasma	78	1.040	-2.9	0.999

5. Known interfering substances

(1) Isopropylamine gives plus 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	40–95 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 QN.

1. Measure FUJI DRI-CHEM CONTROL QN in the same way as patient specimens.
2. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QN, investigate the cause.
   For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QN.

[Traceability of calibrators and control materials]

NH_3…CERI (Ammonium ion standard)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
CERI: Chemicals Evaluation and Research Institute, Japan

[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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NH_3-PII