[Intended use]
Quantitative measurement of ammonia concentration in whole blood. For in vitro diagnostic use only.

[Principle of the measurement]
10 μL of whole blood is deposited on a FUJI DRI-CHEM SLIDE NH3-WII. After depositing, the sample spreads uniformly on the 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 + NH₃ → Blue color dye

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

2. Ingredients per slide
   - Bromphenol blue: 0.018 mg (0.026 μmol)

[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
   - 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.
[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 re-use.
4. Handle all patient samples, control serum and used tips carefully as biohazardous substances. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them according to legal regulations, such as incineration, melting, sterilization or disinfection.
6. Ammonia gas from human sweat may affect the measurement value. Be sure to handle the slides carefully after opening the individual packages.
7. Keep QC card away from magnetic material.
8. Do not use the slide if the individual package is damaged.
9. Do not measure in an environment in the presence of ammonia. It may be affected in the measured value.

[Sample requirements]
1. NH₃ concentration is known to increase with time, especially when kept as whole blood. Measure immediately after the blood collection. When the sample cannot be measured immediately, keep the sample on ice.
2. Heparin·Na/heparin·Li 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 10 mg should be used per 1 mL of whole blood. Do not use heparin ammonium, sodium fluoride, citric acid, oxalic acid and monooiodoacetic acid. Do not use kanamycin added blood collection tubes.
3. Do not use kanamycin added blood collection tube.

[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.
   CAUTION: Use immediately after opening the individual package.
For further details of operation procedure, consult “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

[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 samples.
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 ANALYZER.

[Reference intervals]
12–66 μg/dL (9–47 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: 5000 mg/L
   - Corticrom: 20–60 μg
(2) When isopropanol is present in the blood, owing to herbicide 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.
• Interferences from other substances are not predictable.
   *At the normal range of ammonia concentration.

[Performance characteristics]
1. Dynamic range
   - 10–600 μg/dL (7–357 μmol/L as NH₃-N)
2. Accuracy
   - Concentration range: 10–150 μg/dL (7–107 μmol/L), 150–500 μg/dL (107–357 μmol/L)
   - Accuracy: Within ± 15 %
3. Precision
   - Concentration range: 10–150 μg/dL (7–107 μmol/L), 150–500 μg/dL (107–357 μmol/L)
   - Precision: Within ± 3 %

4. Correlation
Correlation was evaluated between NADS* method run on HITACHI automated analyzer and the FUJI DRI-CHEM system. Whole blood measured by FUJI DRI-CHEM system was then centrifuged and the obtained plasma was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.
* NADS: Nicotinamide adenine dinucleotide synthetase

<table>
<thead>
<tr>
<th>Whole blood and plasma</th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>77</td>
<td>1.044</td>
<td>-4.1</td>
<td>0.999</td>
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</tr>
</tbody>
</table>
[Traceability of calibrators and control materials]

NH₃...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

[Contents]

Slide : 24
QC card : 1

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

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(Symbol)

Do not touch the center part of the slide.

Sample 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