[Intended use]
Quantitative measurement of total protein 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 TP-PIII. After depositing, the sample spreads uniformly on the special spreading layer and reacts with the reactive reagent that was released from the reagent layer to form color. 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 540 nm. The optical reflection density is then converted into the total protein concentration using a calibration curve preinstalled in the analyzer.

Protein + Cu²⁺ → Alkaline, Red purple color

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

Sample

Spreading layer

Reagent layer

Transparent support

Barcode side

2. Ingredients per slide
- Cupric sulfate pentahydrate: 1.7 mg (6.9 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
- 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.

[Warnings and precautions]
CAUTION:
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. Sample requirements
4. Do not use hemolytic plasma or serum.
5. Used slides are categorized as infectious waste. Make sure to dispose them according to the proper method of disposal, such as incineration, melting, sterilization or disinfection.
6. Keep QC card away from magnetic material.
7. 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 can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample 2 times 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.

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 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 samples.
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.

[Reference intervals]
6.7–8.3 g/dL (67–83 g/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
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: 1000 mg/L

These results are representative;
- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Performance characteristics]
1. Dynamic range
- 2.0–11.0 g/dL (20–110 g/L)

2. Accuracy
- Concentration range: Within ± 0.75 g/dL (Within ± 7.5 g/L)
- Within ± 15 %

3. Precision
- Concentration range: SD ≤ 0.25 g/dL (SD ≤ 2.5 g/L)
- CV ≤ 5 %

4. Correlation
Correlation was evaluated between Biuret method and FUJI DRI-CHEM system.
Biuret method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

5. Press the “START” key to initiate testing.

[Traceability of calibrators and control materials]
For additional information, consult "Instructions for Use" for FUJI DRI-CHEM TP-PIII.

[Contents]
Slide: 24
QC card: 1

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