[Intended use]
Quantitative measurement of albumin 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 ALB-P.
After deposition, the sample spreads uniformly on the spreading layer.
In the process, albumin reacts with bromocresol green (BCG) to form an albumin-BCG complex.
The albumin-BCG complex diffuses onto the underlying 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 625 nm. The optical reflection density is then converted into the albumin concentration using calibration curve preinstalled in the analyzer.
Albumin + Bromocresol green → Blue color dye

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

[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.
CAUTION: Do not use expired slides.

[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 reuse.
4. Handle all patient samples, 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.
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 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 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 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 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.

[Reference intervals]
3.8–5.0 g/dL (38–50 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
(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: 1000 mg/L
(2) When albumin concentration is lower than the reference intervals and the A/G ratio is low, the result may have a plus bias.
(3) Bicarbonate salts give plus bias. Do not use the sample from a patient administered bicarbonate salt, such as sodium bicarbonate.
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 1.0–6.0 g/dL (10–60 g/L)
2. Accuracy

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0–6.0 g/dL (10–60 g/L)</td>
<td>Within ± 15 %</td>
</tr>
</tbody>
</table>

3. Precision

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0–2.0 g/dL (10–20 g/L)</td>
<td>SD ≤ 0.1 g/dL (SD ≤ 1 g/L)</td>
</tr>
<tr>
<td>2.0–6.0 g/dL (20–60 g/L)</td>
<td>CV ≤ 5 %</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>54</td>
<td>0.987</td>
<td>0.02</td>
</tr>
</tbody>
</table>

[Traceability of calibrators and control materials]
Albumin...IRMM (ERM DA470k)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
IRMM: Institute for Reference Materials and Measurement

Date of issue: 1/Jul/2014
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